THE TRIPS AGREEMENT AND ACCESS TO ARVs

THE TRIPS AGREEMENT AND ACCESS TO ARVs

Tenu Avafia

and

Savita Mullapudi Narasimhan
*United Nations Development Programme 2006**

* Updated from the original Background Paper prepared by Chandrika Bahadur for the Resident Representatives Meeting on Country Level Responses to HIV/AIDS of November 2001, Johannesburg, South Africa

ACKNOWLEDGMENTS

The original paper by Chandrika Bahadur was prepared for internal circulation only. Acknowledgements for the initial paper are due in particular, to Kamal Malhotra (Trade and Sustainable Human Development Project) and Monica Sharma (HIV/AIDS Special Initiative), UNDP, as well as to Håkan Bjorkman and Mumtaz Keklik, UNDP.

Acknowledgements for the updated paper are due in particular to David Luke (UNDP), Francisco Rossi (UNDP) and Sisule Musungu (South Center) for their comments and inputs. The authors also wish to thank Caitlin Wiesen and Kamal Malhotra (Focal points- Intellectual Property and Access to Drugs Capacity Building project- Cross practice initiative – HIV/AIDS & Poverty Reduction Groups)

EXECUTIVE SUMMARY

The TRIPS Agreement extends product and process patents to the pharmaceutical sector, increasing the cost of patented drugs, and thereby restricting access in low-income countries. However, there are safeguards and flexibilities in the TRIPS Agreement which enable developing countries to pursue their development objectives while remaining in compliance with their TRIPS obligations. This paper highlights two possible areas of intervention for developing countries: a reassessment of policy space created within the TRIPS Agreement created negotiations at the WTO in 2005 and exploring options outside TRIPS to increase access to treatment. As part of the reassessment of TRIPS, the paper proposes three measures. The first pertains to the utilization of TRIPS flexibilities, including compulsory licensing and parallel imports. The paper points out that the TRIPS Agreement doesn't require a country to declare a national emergency before invoking a compulsory license or government use order Developing countries. must be enabled to take full advantage of the flexibilities contained in the TRIPS Agreement as well as the Doha Declaration on TRIPS and Public Health of 2001, the WTO General Council 30 August Agreement of 2003 and the December 2005 decision to amend Article 31. It also recommends that experimental use and early working provisions contained in TRIPS be built into national legislation The other key points the paper makes is that flexibilities contained in the TRIPS Agreement as well as the Doha Declaration on TRIPS and Public Health of 2001, the WTO General Council 30 August Agreement of 2003 and the December 2005 decision to amend Article 31 must be taken advantage of by developing countries. Other flexibilities contained in TRIPS such as experimental use and early working provisions should also be built into national legislation. Second, the implementation of TRIPS (as well as any amendments that take place) should keep in mind the requirements and goals of developing countries. Third, there is a need to build capacity to re-evaluate certain aspects of TRIPS to make it more development-friendly and to improve technology transfer which is yet to be taken advantage of on a large scale. Developing countries may also explore options outside TRIPS which can be utilized in a legal environment that makes full use of TRIPS flexibilities. Such measures may include establishing an aggressive generics policy by not awarding frivolous patents and limiting provisions that create barriers for generic companies to enter and operate in markets. Lastly, existing Technical Cooperation Networks need to be strengthened and more needs to be done to understand the impact of patent monopolies on innovation and access to drugs most needed by developing and underdeveloped countries.

ABBREVIATIONS AND ACRONYMS

ACP	African, Caribbean and Pacific
AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-Retroviral Therapy
ARV	Anti-Retroviral
BI	Boehringer Ingelheim
BMS	Bristol-Meyers Squibb
CSOs	Civil Society Organizations
EDL	Essential Drugs List
EFTA	European Free Trade Area
EPA	Economic Partnership Agreement
ESA	Eastern and Southern Africa
EU	European Union
FDA	Food and Drug Administration (United States)
FDC	Fixed Dose Combination
FTA	Free Trade Agreement
FTAA	Free Trade Agreement of the Americas
HIV	Human Immunodeficiency Virus
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GSK	GlaxoSmithKline
IP	Intellectual Property
LDC	Least Developed Country
MFN	Most Favored Nation
MSF	Médecins sans Frontières
NGO	Non-Governmental Organization
O**API**	African Intellectual Property Organization
PLWHAs	People Living With HIV/AIDS
PMTCT	Prevention of Mother to Child Transmission
R&D	Research and Development
SSA	Sub-Saharan Africa
TRIPs	Agreement on Trade Related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
US	United States
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

TABLE OF CONTENTS

1 INTRODUCTION

The Human Development Report (HDR) of 2005 states that intellectual property policy and rules should strike a balance between creating incentives for innovation through patents and other measures, on one hand and spreading the benefits of innovation as widely as possible on the other. While the Agreement on Trade related Aspects of Intellectual Property Rights (TRIPS) attempts to strike this balance , "TRIPS plus" variants in regional and bilateral agreements, creates tensions between the interests of technology holders and the wider public interest.[1]

The regime of intellectual property law as exists under the TRIPS Agreement is much more structured and standardized than ever before, raising a number of questions about its impact on developing countries. In its current form, the TRIPS Agreement can potentially impact developing countries in a number of important areas such as:

i) **access to drugs and essential medicines;**

ii) **traditional knowledge and benefit sharing of biological resources;**

iii) **copyright and the implications on educational and learning materials; and**

iv) **technology transfer, technical co-operation and capacity building around intellectual property.**

The TRIPS Agreement establishes a global regime for intellectual property rights based on the level of protection provided in the world's most developed countries, including a minimum 20 year patent protection period. Reduced to its essentials, the new regime will increase the price of patented technologies, creating gains for patent holders and raising the cost of technology transfer. If developing countries do not more aggressively make use of favorable provisions contained in the TRIPS Agreement, the technological divide between developed and developing countries could widen. The ability to copy technologies developed in economically advanced countries has historically been an important element enabling developing countries to bridge technology divide. In the nineteenth century the United States made use of British patents without according the necessary compensation. In Asia, Bangladesh, China, India, Japan, the Republic of Korea and Taiwan have all upgraded technologies through reverse engineering and copying of technology and inventions that are otherwise still under patent.[2] Today, the TRIPS Agreement rigidly regulates the instances where technology transfer takes place, thus restricting the policy space for countries attempting to industrialize and build research and development (R&D) competencies.

As a co-sponsor of the Joint United Nations Programme on HIV/AIDS (UNAIDS) UNDP has been designated the lead organization for addressing HIV and development issues. TRIPS and access to essential drugs is a critical aspect of this work for several reasons. AIDS has reversed valuable development gains, and resulted in illness and death among the most productive age group of societies. While low-cost antiretroviral medicines are now more commonly available, only a small portion of the people who need them in developing countries have access. Furthermore, the issue of access to ARVs is a critical aspect of ensuring universal access to affordable health care which is fundamental to human rights-based development. People living with HIV and AIDS (PLWHA), irrespective of where they are from are entitled to receive the best available medical treatment. In this context, TRIPS has profound implications for the escalation of AIDS from a public health challenge into an unparalleled development crisis across Africa, Asia, the Caribbean and Latin America. With offices on the ground in 166 countries UNDP is strategically positioned

[1] Human Development Report 2005, UNDP p 135.

[2] Ibid.

to help developing countries meet this challenge by working to develop the capacity of governments to incorporate best practice intellectual property provisions through south-based exchange, and assisting in the review of national patent laws to improve access to ARVs.

The TRIPS Agreement aims at harmonizing patent laws across countries, bringing them up to a 'minimum standard' and extending them across sectors. At the same time, the Agreement does recognize that exceptions need to be made in cases where development and public health goals are hampered by a stringent intellectual property protection regime. While a strong case has been made by developing countries at the TRIPS Council of the WTO for reviewing TRIPS to make it development-friendly, it is also important to examine the Agreement in its current form more carefully and to use the existing Agreement to maximum advantage.

This paper examines the impact of TRIPS on access to HIV/AIDS drugs in several ways. First, from the point of view of formulating national legislation, it identifies appropriate ways to interpret the flexibilities available in the TRIPS Agreement that can be used to facilitate or increase access to essential medicines including ARVs. It examines the challenges developing countries face in implementing the TRIPS Agreement and ways to minimize them. The paper also identifies key features of TRIPS that warrant further consideration in efforts to ensure a more sustainable supply of ARVs for developing countries. It discusses options for developing countries outside of the TRIPS Agreement, in terms of pricing policy and production capacity to better balance access to drugs within an international patent regime. Lastly, the paper analyzes some of the reasons why TRIPS flexibilities have not been widely used by developing countries to date, as well as some of the challenges posed by the emergence of "TRIPS Plus" provisions.

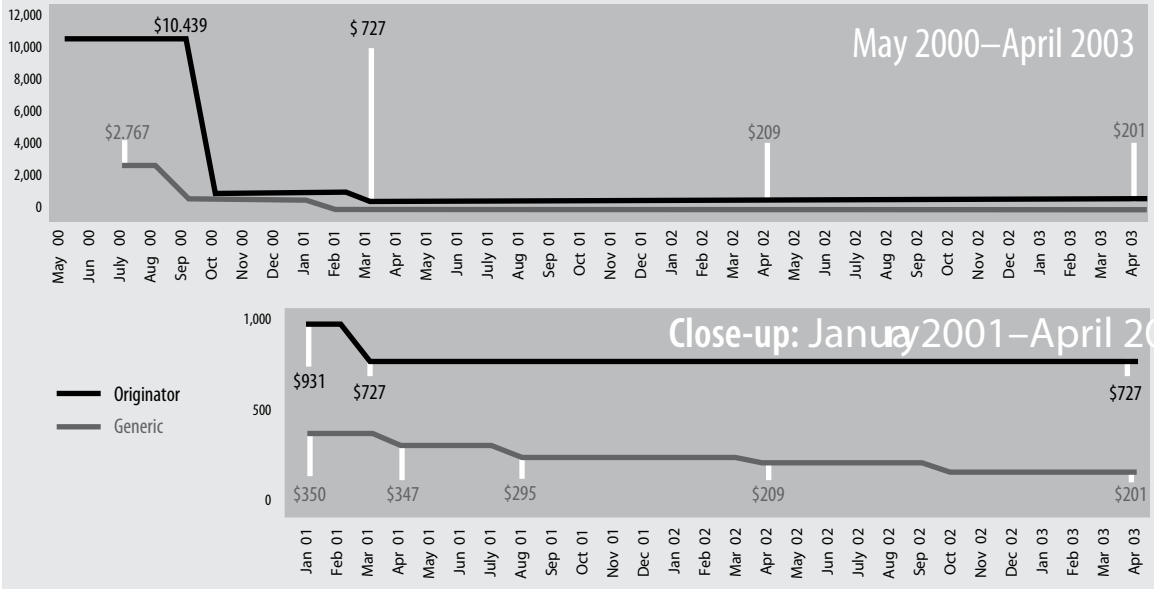
The outcomes for developing countries depend on the national context and the nature of existing domestic legislation. This paper concludes by arguing that within these broad areas, there are ways to interpret TRIPS as a complement and not an obstacle to development.

2 ACCESS TO DRUGS

The AIDS epidemic has brought into sharp focus the linkages between the global intellectual property rights regime and its impact on large-scale provision of drugs. According to the latest report as released by UNAIDS in December 2005, the number of people living with HIV/AIDS globally now stands at approximately 40.3 million people[3]. The past twenty five years has seen an alarming spread of the disease creating in its wake, a development crisis of epic proportions; it also has seen unprecedented advances in medical science to combat and control the virus.

Since the Human Immuno-Deficiency Virus (HIV) was identified as the cause of AIDS, there has been large-scale research to identify and develop compounds that will suppress its replication. In 1987, the US Food and Drug Administration (FDA) approved a failed cancer drug, Zidovudine, (AZT) as a treatment to stifle the replication of HIV in the body. Later on, four other drugs of the same family were introduced and significant reductions in viral load were achieved by introduction of protease inhibitors, which became available in 1996. Since then, the number of ARV agents available has expanded and new treatments, especially the triple therapies, have had an impressive impact in reducing morbidity and mortality. The costs of medicines have been reduced drastically as illustrated in figure 1 from Médecins Sans Frontières (MSF):

Figure 1: THE EFFECTS OF GENERIC COMPETITION A first-line antiretroviral (ARV) triple-combination: lowest world prices per patient per year. (stavudine (d4t) + Lamivudine (3Tc) + nevirapine) A first-line antiretroviral (ARV) triple-combination: lowest world prices per patient per year. (stavudine (d4t) + Lamivudine (3Tc) + nevirapine)



[3] See UNAIDS. 2005. AIDS Epidemic Update. Available online at: http://www.unaids.org/epi/2005/doc/EPIupdate2005_pdf_en/Epi05_05_en.pdf

The drastic decline in the prices of ARVs over the past few years is attributable to a number of developments including: the increased availability of generic ARVs produced by the Indian local pharmaceutical industry; national attempts to legally enforce TRIPS flexibilities in developing countries such as South Africa[4]; the strategic use of government issued compulsory licensing to leverage negotiations with brand name pharmaceutical companies as in the case of Brazil,,; generous donations of ARVs by brand name pharmaceutical companies often brokered by philanthropic organizations; as well as the wide-scale successful lobbying and advocacy efforts of global coalitions of non-governmental organizations (NGOs) and activists. However the price of patented ARVs remains prohibitive for many developing countries, and the question of sustainability still constitutes a major concern.

Another aspect of the sustainability issue is the possibility of increased levels of drug resistance to antiretroviral therapy (ART) especially among patients initially treated with mono-therapy and duo-therapy drug regimens. The protracted use of ARVs over a period of time, possibly exacerbated by improper or inconsistent supervision and misuse , can decrease immunity, reduce the overall effectiveness of treatment and may eventually produce drug resistant mutations of HIV. The phenomenon of drug resistance has resulted in the need to introduce a second line treatment regimen of more sophisticated and far more expensive ARVs which can be up to 30 times more costly than first line generic drugs. ART represents the best hope in improving the quality of life for people living with HIV and AIDS but the main challenge remains one of access.[5]

2.1 THE CURRENT SITUATION

While a large number of ARV drugs currently in use are under patent, most of these drugs can be made available on the international market as less expensive generics. Moreover, at least nine ARVs are due to come off-patent by 2010.[6] Although the numbers are increasing slowly, few developing countries have the technical capacity or the resources to produce generic varieties of ARV drugs. Even though patent protection of ARVs in developing countries has taken place in an *ad hoc* fashion, with the increasing compliance of developing countries to the provisions of TRIPS, brand name drug companies are beginning to be able to patent their products in more countries. In addition, a number of Least Developed Countries (LDCs) have already enacted legislation which extends patent protection to pharmaceutical products despite being exempted from having to afford patent protection to pharmaceutical products until 2016.[7]

Two primary developments with the World Trade Organization (WTO) have played a role in expediting the availability of generic ARVs: the landmark Doha Declaration on TRIPs and Public Health (Doha Declaration) and the WTO General Council Decision of 30 August 2003 (30 August Decision). The Doha Declaration clarified once and for all, the debate around the ability of developing countries to issue compulsory licenses where necessary, in the interests of public health. As such it was a turning point for developing and least-developed countries which have the capacity to manufacture generic drugs. While this was a significant step, the reality is that most developing countries do not have a sufficiently large manufacturing industry to satisfy the demand for generic drugs in their own countries. This meant that a pathway to access generic drugs for countries with insufficient manufacturing capacity remained elusive. For that reason, a deadline was set by WTO members (for the end of 2002) by which a solution should be found for these countries to have a way to access essential medicines.

---

[4] Pharmaceutical Manufacturers' Association v The President of the Republic of South Africa. On 30 October 1997, the South African Parliament passed the Medicines Control and Related Substances Amendment Act 90 of 1997, which was legally challenged by the Pharmaceutical Manufacturers' Association. After intense domestic and international lobbying, the PMA withdrew its application.

[5] This section referred heavily to the Guidance Modules on Antiretroviral Treatments, World Health Organization and UNAIDS, WHO/ASD/98.1

[6] Patent Situation of HIV/AIDS related Drugs in 80 Countries, UNAIDS, WHO, Geneva 2000.

[7] Refer to the TRIPs Council Decision of 29 November 2005 which extended the period by which LDCs were to be TRIPs compliant (with the exception of pharmaceutical patents) from 1 January 2006 to 1 July 2013 or until the LDC status was no longer valid. The statement extending the exemption period for LDCs is available at: http://www.wto.org/english/news_e/pres05_e/pr424_e.htm

After several missed deadlines and protracted negotiations at the WTO, the 30 August Decision was concluded a few days before the Cancún Ministerial meeting in 2003. The Decision expressly allowed developing countries with no or insufficient manufacturing capacity to import generics produced under compulsory license subject to compliance with a number of administratively demanding requirements. These requirements included: the provision of notification on the specific drugs to be imported and the exact quantity needed different physical specifications for medication that was to be consumed in these countries; and implementing measures to prevent re-exportation of drugs meant for developing countries to more lucrative markets. To date, the mechanism contained in the 30 August Decision has not been utilized by any country. Nonetheless, a few days before the recently concluded WTO Hong Kong Ministerial Meeting in December 2005, WTO members reached an agreement to integrate the text of the 30 August Decision into Article 31(f) of the TRIPS Agreement, thereby signaling the first time that a primary instrument of the WTO would be amended.[8]

THE INDIAN PATENT ACT 2005 AND ITS IMPACT ON THE SUSTAINABLE SUPPLY OF DRUGS

India's domestic pharmaceutical industry is a major source of high quality, affordable antiretroviral medicines. By some estimates, more than 30% of all generic drugs in developing countries are supplied by India. Until 2005, India was able to produce and export generic versions of patented drugs because its law did not recognize product patents. But as part of its obligations under TRIPS, India was required to introduce product patent protection for pharmaceuticals by 1 January 2005. The Indian Patent Amendment Act came into force after many deliberations and concerns from developing countries, UN agencies and CSOs. Though the new Act provides for compulsory licensing, the main flexibility under TRIPS, it leaves a few issues unclear. The Act does provide some relief with respect to the continued supply of current ARVs. It states that a generic company can continue producing the said drugs as long it has made significant investment and was producing the concerned product prior to Jan 2005 and continues to manufacture the product covered by the patent on the date of the grant. The Act also allows for export to countries with low manufacturing capacity via issuance of a compulsory license if the product is patented in the importing country or just through a notification if the product has not been patented in the importing country. Unfortunately, the Act allows for application of a Compulsory License only three years after the grant of the patent (making this a TRIPS plus provision) Though the Act allows for continued production and hence supply of current ARVs (first line in most cases) the critical issue of availability of 2nd line and 3rd line ARVs remains unclear.

There has been considerable debate and discussions on whether the Indian generic industry could have lobbied more forcefully for provisions that would have made easier answers. A study (see Padmashree Gehl 2005) based on empirical evidence concluded that large Indian generic companies did not consider it lucrative to invest in the development of a generic version of a patented product for purposes of producing and exporting to a LDC. This is because of the procedural hassles associated with such exports and low economic returns.

This would mean that LDCs will have fewer options for access to generic drugs, but this need not be the case. On one hand, LDCs do not have to comply with TRIPS provisions until 2013 and do not have to introduce product patents in case of pharmaceuticals until 2017, on the other hand, if a product is not patented in an interested importing country, all the Indian Patent Act requires is a notification. This means that if an LDC country would amend its patent law so as to exclude pharmaceutical product patents, it can import new ARVs from India via a simple notification –making the procedure less cumbersome.

Moreover, under paragraph 6(i) of the Decision of the General Council of 30th August 2003, the LDC can then export the product to markets of other developing and/or LDCs as long all of these countries are party to a regional trade agreement (for e.g. COMESA in Southern Africa would probably be applicable in this case) where at least half of the group consists of LDCs as on the UN list. Para 6 (i) also waives the requirement of 'predominantly for supply for domestic market' under Article 31(k) of TRIPS. This proviso has been set by WTO for specifically harnessing economies of scale for the purposes of enhancing LDC purchasing power and facilitating local production of pharmaceutical products.

[8] The agreement to convert the 30 August Decision into a permanent solution in terms of Article 31 of TRIPS is available electronically at: http://www.wto.org/english/news_e/pres05_e/pr426_e.htm

3 THE TRIPS AGREEMENT

Before the entry into force of the TRIPS Agreement in 1995, the choice of patent regimes was entirely a domestic decision. However with the adoption of the TRIPS Agreement, each member country is now obliged:

a) **To recognize patents for inventions in all fields of technology (including pharmaceuticals) with limited exceptions for a period of 20 years at least, without discrimination with respect to availability or enjoyment of patent rights.**

b) **To limit the scope of exceptions to patent rights and to make use of flexibilities available in terms of the TRIPS Agreement only under certain conditions**

c) **To effectively enforce patent rights.**

While this compels all WTO member countries[9] to enact patent legislation, the TRIPS Agreement does not establish a uniform international law, or even legal requirements. While member nations are required to comply with minimum standards, they have a substantial amount of policy space to customize intellectual property provisions found in patent and medicines legislation. Some developed and developing countries have exercised their discretionary prerogative to enact legislation that exceeds the minimum requirements dictated by the TRIPS Agreement. One major area of concern is the extent to which developing countries are prepared and able to take advantage of the space they have under TRIPS. With relation to access to drugs, in particular, TRIPS allows for sufficient flexibility and space for national legislation to ensure adequate access.

3.1 THE EMERGENCE OF "TRIPS PLUS" PROVISIONS IN BILATERAL TRADING AGREEMENTS:

With the unsuccessful conclusion of WTO trading rounds in Seattle in 1999 and the ***Cancún*** Ministerial of 2001, a number of developed countries have indicated their intention to continue with trade liberalization on a bilateral level. This is a result of the increasing difficulty of reaching consensus within the 149 WTO member states and the emerging influence of the G20 and the African Group.. As a consequence, there has been a proliferation of bilateral activity in the past few years between developed and developing countries. The US has concluded a number of bilateral Free Trade Agreements (FTAs) with a number of countries including Singapore, Chile, Australia, Israel, Taiwan, South Korea, Jordan, Morocco and Bahrain. These are complemented by a number of regional FTA arrangements, including the recently concluded agreement between the US and the Central American Free Trade Agreement (CAFTA).[5] In addition, there are a number of bilateral negotiations currently being negotiated such as those between the US and the Andean Community[10] and the US and the Southern African Customs Union (SACU)[11].

[9] Developing countries are now expected to enforce TRIPS provisions while LDCs are exempted until 2013 and until 2016 for pharmaceutical patents.

[10] The Andean Community members are Bolivia, Columbia, Ecuador, Peru and Venezuela.

[11] The SACU countries comprise of Botswana, Lesotho, Namibia, South Africa and Swaziland.

The pursuit of FTAs as a replacement to stalling multilateral negotiations has also occurred with the European Free Trade Area (EFTA)[12] as well as the European Union who are aiming to replace the asymmetrical Cotonou Trading Agreement with Economic Partnership Agreements (EPAs) currently being negotiated with the African, Caribbean and Pacific group of states (the ACP region). The EPA negotiations are currently progressing with an envisaged deadline of the end of 2007.

The scope of bilateral trade agreements appears to be extending beyond the traditional trade negotiating agenda of the WTO, to encompass the so-called 'new generation' trade policy issues such as investment, government procurement, competition policy, environmental and labor standards. Based on analysis conducted on the recently concluded bilateral FTAs, countries are committing themselves to obligations that extend significantly beyond those contained in the TRIPS Agreement and which may prove to be contrary to both development objectives that both Doha Declaration as well as the 30 August Decision provided. On the basis of concerns raised during the Free Trade Area of the Americas (FTAA) negotiations some of the more damaging 'TRIPS plus' provisions that may find their way into the text of an FTA[13] include:

a) **A limitation on the circumstances under which compulsory licenses on pharmaceutical patents may be issued by individual developing country governments which is otherwise not contained in the TRIPS Agreement;**

b) **Extending the minimum period of patent protection beyond the 20 year minimum requirement of TRIPS consequently delaying the introduction of generic pharmaceuticals into developing country markets;**

c) **Conferring a new responsibility onto Drug Regulatory Authorities (DRAs) (most of whom have a limited expertise of patents) to consider the patent status of drugs before granting marketing authorization to manufacturers of generics which also has the effect of slowing down the introduction of essential medicines into markets where these are often most needed;**

d) **The restricting of access to data on pharmaceutical products for drug regulating authorities, which generic companies traditionally rely on to prove the efficacy and safety of their products, and consequently the significant slowing down of the registration of generics in some countries; and**

e) **The potential restriction of parallel imports to limited geographical configurations which may prevent developing countries from sourcing generics from the cheapest global supplier.**

[12] The EFTA countries are Norway, Iceland, Lichtenstein and Switzerland.

[13] As discussed in a document by Médecins sans Frontières available online at: http://www.doctorswithoutborders.org/publications/reports/2003/FTAA_Advocacy.pdf

To diminish concerns that have been repeatedly raised that FTA provisions violate both the spirit and letter of the Doha Declaration, United States Trade Representative (USTR) officials have negotiated side letters[14] which state that FTAs should not prevent the Parties from taking measures to promote access to medicines or to implement WTO decisions regarding the TRIPS Agreement. However, the legal or persuasive value of these side letters remains undecided. Critics[15] warn that they have 'interpretive value' only and do not modify the agreement, therefore unlikely to offset the damaging impact of the TRIPS plus provisions in the text of these agreements.

[14] This side letter has been issued in case of CAFTA (Central American Free Trade Agreement) and is also being discussed in the ongoing Thai-US FTA.

[15] ANNEX: The Relationship between the five US FTAs, TRIPS & the Doha Declaration, Oxfam Briefing Note, July 2004. See also Abbott who argues that such conflicting provisions serve to create legal ambiguity which does not in any way render access to generic medication any more likely. Available online at http://www.geneva.quno.info/pdf/OP14Abbottfinal.pdf

4 INTERPRETING THE OPTIONS AVAILABLE UNDER TRIPS

The TRIPS Agreement allows for a number of important mechanisms that developing country governments can use to ensure more access to ARVs; these include compulsory licensing, parallel importation and the importation of generics products under compulsory license. These are elaborated on below.

4.1 COMPULSORY LICENSING

Compulsory licensing allows a government to license to a company, government agency or other party, the right to use a patent without the titleholder's consent. A competent authority must grant the license to a designated person or company who is expected to compensate the titleholder by paying a determined remuneration. Article 31(f) of TRIPS Agreement allows for compulsory licensing subject to conditions such as:

- **where attempts to obtain voluntary licenses on reasonable commercial terms are unsuccessful;**
- **non exclusive use**
- **use predominantly for domestic supply**
- **temporary use subject to the special circumstances that warranted the licensing, and**
- **subsequent to payment of adequate remuneration to the title holder.**

Although Article 31(h) of TRIPS makes no mention of what constitutes adequate remuneration, the internationally accepted royalty payable to the patent holder ranges from 0.2%-4% of the fee earned by the generic company.[16] This amount is based on the level of development of the country concerned as determined by the Human Development Index (HDI) of the UNDP. This example has been followed for instance by the Canadian government in passing legislation which would allow it to export ARVS produced under compulsory license.

Though the Agreement requires prior negotiation with the patent holder before applying for a compulsory license, there are certain flexibilities attached to this. National legislations can lay down specific provisions and restrict the amount of time allotted to negotiations before an application for issuance of a compulsory license is made. Furthermore, national legislation may reject the patent holder's right to seek an order barring the government or contractor (third party) from using the patent. The Agreement also does not require negotiating a voluntary license in case of government use[17]. This means if the government or government agency decided to use the patent, it does not need to negotiate with the patent holder as long as the use is public non commercial use or in the case of national or extreme urgency. Public non commercial use is sufficient for governments or government agencies to use the patent. Even in case of compulsory licenses issued for use by a third party, it should be noted that TRIPS ***does not*** require countries to declare a state of national emergency. If there is no national emergency, TRIPS only requires that the third party negotiate for a voluntary license first. Despite this, the majority

[16] The UNDP-WHO publication on Remuneration Guidelines for Non-Voluntary Use of a Patent, by James Love assesses and analyses various remuneration guidelines and models that developing countries and LDCs may adopt against the use of a patented drug vide a compulsory license/government license

[17] See http://www.twnside.org.sg/title2/IPR/ipr09.htm for a study on the Malaysian experience in issuing a compulsory license via the Government Use option.

of countries that have issued compulsory licenses in Africa have chosen to declare emergencies before issuing compulsory licenses. The TRIPS Agreement gives member countries the freedom to determine for themselves, the grounds on which compulsory licenses can be granted beyond those that are explicitly mentioned. Developing countries *can* frame patent laws that allow for compulsory licensing according to their specific developmental and public interest needs.

Another ground contained in Article 31 in terms of which a compulsory license can be issued lies in Article 31(k) which authorizes the issuing of a compulsory license on the basis of unfair competition. Moreover, Article 31(k) does not require prior negotiation with the patent holder before a compulsory license can be issued on the basis of unfair competition.

The Human Development Report of 2001 points out that since adopting the TRIPS Agreement, many countries including Canada, the United States, Japan and UK have made use of compulsory licenses for products such as pharmaceuticals, computers, software and biotechnology as anti-trust measures to promote competition and reduce prices[18]. Where the local market is too small to create an economy of scale sufficient enough for the manufacturing of ARVs, a compulsory license can be issued by means of imports of patented products as well, though the patent holder can (through contractual obligations and similar restrictions) attempt to effectively block such imports. It is also possible, as mentioned above, that a compulsory licensee may import from a compulsory licensor in another country, if that product has been licensed in the exporting country. As per the TRIPS Agreement, Article 31(f) merely states that compulsory licensing should cater *predominantly* to the domestic market and places no further restriction on the export of products manufactured under compulsory license. Some of the challenges that arose from Article 31(f) have been subsequently resolved by the 30 August Decision as countries are now able to import and export ARVs based on the needs that exist.

Allowing compulsory licensing is also a critical ingredient in the overall formulation of an effective generics policy, discussed in detail later in the paper. But it is important to note that an effective generics policy requires countries to have a pharmaceutical industry with the capacity to 'reverse engineer' the patented drugs, and manufacture them on a large scale.

VOLUNTARY LICENSING AND THE COMPETITION COMMISSION COMPLAINT: KEY LESSONS IN SOUTH AFRICA-

In South Africa, the voluntary licenses that were agreed between research based companies and their generic counterparts contained severe restrictions imposed by the patent holding companies. For example, voluntary licenses negotiated by Bristol-Meyers Squibb (BMS) and Boehringer Ingelheim in 2003 included conditions that generic Stavudine and Didanosine would only be available to the public sector in South Africa, and that exports would be restricted only to SACU countries. Similarly, the voluntary licensing agreement with GlaxoSmithKline for combivar contained a geographical restriction to SADC countries. These restrictions fell away after the South African Competition Commission found GSK and Boehringer Ingelheim guilty of anti-competitive behavior.

THE COMPETITION COMMISSION COMPLAINT

Eleven Complainants including the Treatment Action Campaign (TAC) filed a complaint at the South African Competition Commission in September 2002 against GSK and BI for charging excessive prices for their patented ARVs. In a landmark decision in October 2003, the Commission found the two brand name pharmaceutical companies guilty of excessive pricing, denying a competitor access to an essential facility and engaging in an exclusionary act. Although the Commission had wanted to refer the matter to the Competition Tribunal, a settlement agreement was reached between the two brand name pharmaceutical companies in question and the complainants of the complaint that has implications for generic companies. A further confidential settlement agreement was also reached with the Competition Commission which agreed not to refer the matter to the Tribunal

[18] Ibid James Love. See also the UNDP's Human Development Report 2001, p 107...

KEY LESSONS LEARNT: THE NEED FOR ENABLING LEGISLATION

This ruling highlights the importance of having in place not only effective policies and regulations, but also institutions that are able to implement applicable policies and legislation. Without an enabling legislative framework and a well staffed Competition commission, the law could not have been used by activists in South Africa to reduce drug prices. With the development of new ARVs and other essential medicines however, it may become more difficult for generic manufacturers to conclude voluntary licensing agreements with brand name pharmaceutical companies. This was highlighted by the recent rejection of a few voluntary licensing applications in South Africa by some patent holding companies. This situation leaves a limited number of suppliers in the local market. It is widely accepted that only once a number of generic manufacturers enter a competitive market do the benefits of reduced prices pass on to the consumer.

Sources: Consumer Project on Technology (cptech) www.cptech.org The Aids Law Project of South Africa www.alp.org.za

4.2 PARALLEL IMPORTATION

Both generic and brand name drug companies charge lower prices for a drug in one country than in another, after taking into account a range of market factors. This means that a country with limited resources can sometimes afford more of a patented or generic drug by purchasing it abroad at a lower price and importing it, rather than buying it directly in its domestic market at the higher price. Parallel importation is regarded as an important flexibility under TRIPS for sustained access to affordable medicines. It is the import and resale of a patented product from another country where it was put on the market by the owner in a legitimate manner, where the import and resale occurs without the consent of the patent holder. Article 6 of the TRIPS Agreement clearly states that nothing in the Agreement shall be used to address the issue of exhaustion of intellectual property rights[19]. More specifically, Article 8.1 allows members to "adopt measures necessary to protect public health and nutrition". Where allowed, parallel imports cover legitimate products.

In principle, parallel imports may prevent market segmentation and differential pricing unless active policy measures are taken to prevent leakages across markets. The other danger with parallel imports is that they can potentially lead to intra-LDC trade, where drugs shift from one country where the drugs are in demand to another depending on price differentials. If there are restrictions on overall availability of drugs in LDCs, then intra-LDC trade can lead to a low equilibrium outcome. While parallel importation is provided for in a number of developing country laws, parallel importation has not been widely used by developing countries as a solution to reducing ARV prices. An option which remains to be fully utilized is the parallel importation of generic drugs that have been produced under compulsory license. Few countries have made use of the opportunity to import generics that have been produced under compulsory license. This flexibility has not been assisted by the geographical restriction of exportation that has accompanied the majority of compulsory licenses that have been issued to date.

[19] The underlying principle behind parallel imports is that since the owner has been rewarded by the first sale, he or she has no right to control the use or resale of the product and therefore his or her right has been exhausted.

A SOUTH AFRICAN CASE STUDY OF PARALLEL IMPORTATION PROVISIONS

On 30 October 1997, the South African Parliament passed the Medicines Control and Related Substances Amendment Act 90 of 1997, which contained provisions including Section 15C which appeared to allow a Minister of State broad discretionary powers to authorize parallel importation.

The Pharmaceutical Manufacturers' Association (PMA) launched a High Court application to prevent the Act coming into operation, because of what it perceived to be the unfair wide-ranging powers which could be improperly used. After intense domestic and international lobbying by activists, the PMA withdrew its application. It appears that the lobbying effort had an extremely negative impact on the public image of brand name pharmaceutical companies and has also been used by generic companies to negotiate voluntary licenses in South Africa for ARVs.

Soon after the case was concluded, the Department of Health (DOH) issued a statement that Section 15C of the Medicines Amendment Act would only be used for parallel importation. Although the provision exists and in theory can be used to import ARVs and other essential medicines from countries where they may be less expensive, this has not happened.

4.3 GENERAL EXCEPTIONS TO EXCLUSIVE RIGHTS

TRIPS also provides for exceptions to exclusive rights under Article 30 of the TRIPS Agreement that allows members to provide limited exceptions[20] to exclusive rights conferred by patents.

4.3.1 EXPERIMENTAL USE

TRIPS does not explicitly allow or disallow the use of patented products for research and experimentation without compensating the inventor. It is argued by some that the production of a rival product based on experimental use may violate certain countries' concepts of the 'doctrine of equivalence'.[21] However TRIPS gives no indication on how broad or narrow this doctrine of equivalence should be, leaving it to national legislation to determine the range. This exception has not been widely used by generic companies to date.

4.3.2 EARLY WORKING 'BOLAR' PROVISION

This provision allows the use of an invention without the patentee's authorization in order to obtain approval of a generic product before the patent expiration date. This is done so that marketing of a generic version can begin immediately after the patent expires. Since generic competition lowers prices, the Bolar exception increases the affordability of off-patent medicines. Since the commercialization of the product doesn't happen while it is on patent, this early working provision is compatible with Article 30. While TRIPS does not explicitly refer to this exception, the WTO Dispute between Canada and the European Union ruled that an early working exception is consistent with TRIPS even in the absence of an extended period of protection for the patent. However, the right to manufacture and stockpile before the expiration of the patent was not deemed consistent[22].

[20] "Members may provide limited exceptions to the exclusive rights conferred by a patent provided 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", TRIPS Agreement, Article 30.

[21] A conceptual framework to determine whether a violation exists when there has been no literal infringement of the patent claims; discussed in detail in Correa (2000), p 87-91

[22] WT/DS114/R, 17 March 2000, EU vs. Canada, where the EU challenged a Canadian law that allows for a similar exception to not only allow tests, but also produce and stockpile for release immediately after the patent expires.

4.4. TRIPS SCOPE AND ENFORCEMENT

As a framework, TRIPS sets standards for member countries in terms of what constitutes a patent regime. But TRIPS does not define what constitutes those standards, leaving it to member nations to determine the details of the standards. For example, while TRIPS clearly indicates that nations must award patents on the basis of novelty, nations are free to determine what constitutes 'novelty'. On the other hand, important terms such as the requirement in Article 31(f) that a drug produced under compulsory license should be predominantly for the local market, are also not clearly defined. This has created much uncertainty which has not helped to facilitate the ability of developing countries to use TRIPS flexibilities.

Developing countries need to be careful against granting trivial or non inventive patents and to ensure that patents are only given to original inventions where an original inventive step has taken place. Developing countries should also take steps to prevent the process of ever-greening which allows the inventor to apply for a new patent based on a new use which has been discovered for an old invention. The TRIPS Agreement does not impose any restrictions on certain conditions, and if drafted carefully, national patent laws could avoid granting patents for these selected chemical forms and continue to be TRIPS compliant.

Article 5 of the TRIPS deals with the granting of patents for "any inventions, whether products processes, in all fields of technology provided they are new, involve an inventive step and are capable of industrial application"[23]. Members are also permitted to exclude commercial exploitation of inventions that would endanger morality or *ordre public*[24] including human, animal or plant life or health.

TRIPS therefore makes it difficult to exclude pharmaceuticals from patentability while at the same time authorizing its distribution and sale. However, if developing countries as a block decided to prohibit the patentability of certain pharmaceutical products on grounds of *ordre public*, then this decision could produce a new 'state practice' that WTO panels would need to take into account[25]. If there were compelling grounds for a temporary expansion of the *ordre public* exception beyond its traditional interpretation, there could also be grounds for an exception to the non-commercial use rule if such products were distributed on a non-profit basis. This depends to a large extent on the manner in which the safeguard provisions are implemented. A blanket refusal to patent an entire family of drugs could also have negative repercussions on future research and development in the long run. However, legislation which limits the filing of patents on grounds of new use (where the same product is patented for a new disease) or which limits the filing of patents that are not sufficiently original or inventive could be beneficial to the public health concerns of a country without necessarily being harmful to innovation.

Article 41.5 clearly states that TRIPS doesn't create an obligation for member countries to enforce the TRIPS Agreement in any manner different from enforcement of national law in general.[26] To this extent there is no compulsion to divert resources or capacity towards enforcement of laws other than the more general efforts to make law enforcement more effective

[23] Article 27 (1), TRIPS Agreement. The terms inventive step and capable of industrial application are deemed synonymous with non-obvious and useful respectively.

[24] There is no universally accepted concept of ordre public; under the European Patent Guidelines it refers to security reasons such as riots or public disorder or inventions that may lead to criminal or other socially offensive behavior, while under US law, it refers to an invention that is "frivolous or injurious to the well-being, good policy or sound morals of a society", leaving tremendous scope for interpretation at the national level, given specific cultural and social contexts.

[25] Carlos Correa, 'Integrating Public Health into National Legislature' p 13.

[26] "..this Part does not create any obligation to put into place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general." Article 41.5 of the TRIPS Agreement.

5 IMPLEMENTING AND AMENDING THE TRIPS AGREEMENT

As per Article 71 of the TRIPS Agreement, the implementation of this Agreement is due for review seven years after its adoption and every two years subsequently. As a result of developments The following implementation issues need to be examined in closer detail while reviewing TRIPS:

5.1 TECHNOLOGY TRANSFER

According to Article 66.2 of the TRIPS Agreement, developing country members are required to provide incentives to enterprises and institutions in their own territories to promote and encourage technology transfer to LDC members in order to enable them to create a sound and viable technological base. However this has clearly not been implemented even as a symbolic measure. Pharmaceutical companies could grant voluntary licenses and set up local plants in developing countries, for the manufacture of ARV drugs an example of how such technology transfer could occur. An examination of voluntary licenses was carried out in South Africa before the South African Competition Commission (See Box above). It found two brand name pharmaceutical companies guilty of excessive pricing in 2003 and that all voluntary licenses had restrictive conditions which limited the products manufactured by generic companies under voluntary license geographically. Furthermore, the royalty rates for the voluntary licenses ranged from 25-40%. It was not until a ruling by the South African Competition that geographical restrictions have largely fallen away and royalty rates dropped to an average of 5%.

5.2 SAFEGUARD PROVISIONS

Articles 7 and 8 of the TRIPS Agreement allow Members to frame laws that promote public interest in sectors of vital importance to socioeconomic development and to enact measures that protect public health and nutrition. Further, they are allowed to "take appropriate measures to prevent the abuse of intellectual property rights or…adversely affect international transfer of technology" provided "such measures are consistent with the provisions in the Agreement". The Doha Declaration on TRIPs and Public Health of 2001, the 30 August Agreement of 2003 and the recently concluded agreement to amend Article 31 of TRIPS provide clearer guidance on how some of the flexibilities in the TRIPS Agreement can be used to facilitate an increase in the availability of ARVs. Developing countries therefore have the clear choice of using the provisions of TRIPS to frame national legislation that serves their specific developmental needs without violating the letter or the spirit of the TRIPS Agreement. To date, there has not been a wide uptake of countries making use of these flexibilities or safeguards. For instance, only a few African countries, Mozambique, Zambia and Zimbabwe, have made use of compulsory licensing or government use mechanisms. In Asia, Malaysia and Indonesia have issued compulsory licenses and government use licenses to combat high prices of ARVs and make them easily available. These safeguards need to be implemented through enactment of national legislations with the support and cooperation of all members of the TRIPS Agreement.

5.3 TECHNICAL COOPERATION

Article 67 of the TRIPS Agreement calls on developed countries to provide financial and technical cooperation to less developed member countries, and to assist them in law making and building of administrative and enforcement capacity. This is a clear area of cooperation that could be made much better use of, particularly as it pertains to quality control and health infrastructure regulations, which allow for patented ARV treatments to be effective and generics to be safe. Unfortunately, to date, this provision has not led to any positive developments in terms of increasing ARVs access in developing countries where they are needed.

5.4 IMPLEMENTATION OF COMPULSORY LICENSING AND PARALLEL IMPORTATION PROVISIONS

Because of the broad and unspecific provisions in the TRIPS Agreement, the issuing of compulsory licenses and utilization of parallel imports has proven to be harder in practice than in theory as illustrated by the Brazilian and South African examples. Developing countries need to use these provisions more often in improving access to ARV drugs and the implementation of these provisions needs to be respected by all members. It remains extremely important that the provisions in domestic legislation that provide for compulsory licensing and parallel importation are worded in such a way that facilitates the timely and effective implementation of flexibilities where necessary. The Doha Declaration on TRIPs and Public Health settled once and for all, the question of whether developing countries were entitled to issue compulsory licenses as a means of increasing the availability of ARVs. It should be remembered that before the Doha Declaration, the issue was one of fierce debate at the WTO. Attempts by developing countries to take advantage TRIPs flexibilities in the case of South Africa (with parallel importation) and Brazil (with compulsory licensing) were fiercely opposed.

The 30 August Decision which was meant to be the pathway for countries without manufacturing capacity to import generics produced under compulsory license, has not been used to date by any country. Developing countries claim that the administratively complex and intricate requirements that must be fulfilled under the 30 August Decision make it practically untenable. For instance, paragraph 2 of the 30 August Decision requires that the importing country notify the TRIPs Council:

a) With detailed information on the different drugs and expected quantities needed; and

b) That it has issued a compulsory license for the afore-mentioned medicines

Other requirements that will be difficult to meet include an undertaking that the exporting country will only export the amounts necessary to meet the needs of the importing member country, that the products produced under compulsory license shall be clearly identified as "30 August products" through different labels and packaging and that before shipping of the products, information must be posted on a website specifying what the exact distinguishing features of the product are and the quantities to be supplied to each destination. Furthermore, not all developing and least developed countries will be able to persuade companies in exporting countries to produce ARVs on a scale which has not yet proven to be economically viable.

Another challenge is that of re-exportation. Most developing countries with insufficient manufacturing capacity are not in the position to offer a guarantee that drugs which are imported under compulsory license will not be re-exported. Other possible reasons for the non-use of the 30 August mechanism include fears at a local level that the issuing of compulsory licenses might have an adverse impact on foreign direct investment (FDI) as well as the lack of capacity at a domestic level to completely comply with the 30 August Decision. As a practical example, a number of countries have expressed doubts about the ability of their customs officials to prevent re-exportation.

Despite the clarity given to the interpretation around TRIPs flexibilities through the Doha Declaration, the 30 August Decision as well as the Agreement to permanently amend Article 31(f), developing countries must continue to play a proactive role in influencing the manner in which the vague language on TRIPS flexibilities can be interpreted; either by insisting on clarifications of the ambiguities that allow for development-friendly interpretations as they might be needed, or by actively using the mechanisms available to them and defending their use if necessary.

TRIPS and Brazil

Brazil has created one of the most ambitious ARV programs among developing countries through creative legislation and administrative procedures.

By 2006, Brazil had registered some 650,000 HIV infections since the beginning of the epidemic. Since 1996, the Brazilian Ministry of Health, , has implemented a policy of universal access to ARV therapy. By December 2000, approximately 95,000 patients received ART through the public health system and by the beginning of 2006, this number had increased to more than 180,000. By 2003, the mortality rate had dropped from 9.7 in 1995 to 6.4 AIDS-related deaths per 100,000 inhabitants. Seventeen different ARVs are now distributed through the public health system (of which eight are locally manufactured), including newer drugs such as atazanavir, tenofovir (Viread) and enfuvirtide. New drugs used for second-line treatment are much more expensive than older drugs. Projections for 2005 estimated that 62.5% of the 310 million dollars Brazil had budgeted for brand name antiretroviral drugs , would be spent on the procurement of only three drugs: efavirenz (Stocrin, lopinavir/ritonavir (Kaletra) and tenofovir

This combination of free access to drugs together with an extensive health infrastructure was supported by national legislation. The Brazilian intellectual property law of 1996 requires the patent holder to manufacture the product in Brazil. If this does not happen, the government can issue a compulsory license to another producer, unless the patent holder can show that local production is not feasible. Both these provisions are well within the parameters of the TRIPS Agreement. The Brazilian AIDS program has shown significant results. There has been a progressive reduction in AIDS mortality, especially in the municipalities of Rio de Janeiro and Sao Paulo, where there was a 70% reduction in AIDS related deaths between 1995 to 2000. There has also been a 60-80% reduction in AIDS related opportunistic infections, a four fold reduction in hospitalization rates and a significant reduction in AIDS related hospital admissions, leading to an overall savings to the Government of more than US$670 million from 1997-2000.

The Issues

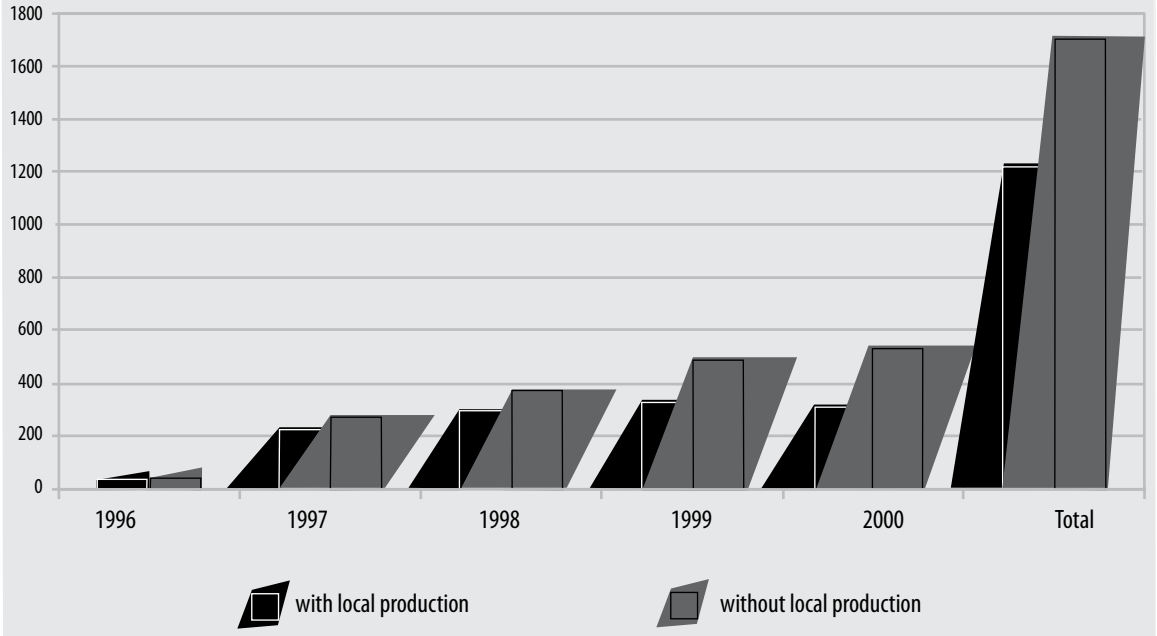
The United States challenged the provisions of Article 68(1) of the Brazilian Intellectual Property Right Law of 1996, which requires patent holders to manufacture locally, failing which, the government is entitled to issue compulsory licenses for local production. Brazil insisted that the law was central to the country's public health policy, and that the threat of compulsory licensing has been instrumental in its negotiations with pharmaceutical companies to reduce prices on imported ARV drugs. On June 25, 2001 the US Government withdrew its WTO Panel against Brazil and in turn, Brazil agreed to hold talks with the US before applying Article 68.

In a related incident, Brazil threatened to use the provision when its negotiations with Roche broke down over lowering prices of nelfinavir, the drug marketed as Viracept by Roche. While this announcement provoked protests by pharmaceutical companies, the move was hailed by developing country governments and activists who saw it as a first step in implementing the TRIPS provisions built in for ensuring public health provision. Eventually, Roche agreed to lower the price by another 40%, as demanded by Brazil and the Article 68 was not invoked.

In the most recent incident, the Brazilian government threatened to revoke the patent for kaletra, which is produced by Abbott Laboratories because of what it saw as excessive pricing of the drug in Brazil. The government threatened to produce the drug locally in government laboratories if the price was not reduced or if Abbott did not grant a voluntary license for the drug. After protracted negotiations, an agreement was reached in October 2005 and the price of kaletra was reduced from USD $ 1.17 per pill to 63 cents thereby saving the national AIDS program a further USD $ 339 million over six years.

Key Lessons

The Importance of Compulsory Licensing: As the Brazilian government has argued, national legislation needs to allow for the use of compulsory licenses; the provision allows for effective negotiations with patent holders, prevents abuse of monopoly power, and where enforced, it protects the price of medicines from currency fluctuations and helps develop local industry and expertise.



The Problems with Implementing TRIPS: The Brazilian case highlights the difficulties that developing countries face in implementing the provisions of TRIPS which are intended to protect their development concerns. In all three cases, Brazil came under tremendous pressure to remove Article 68 from the Intellectual property law, and later to not invoke its use. While it was able to successfully stand up to that pressure, it is easy to see why smaller countries would find it so hard to use the parallel imports or compulsory licensing provisions even though they are expressly permitted to do so by the Doha Declaration and the 30 August 2003 Agreement.

The Impact of Generic Competition: The Brazilian case study epitomizes the impact of generic competition on the price of drugs. On average, the prices of drugs produced locally fell by 72.5% between 1996-2000 while the prices of imported drugs fell by only 9.6% in the same period. As shown below, local production has saved the Brazilian government approximately USD $490 million between 1996-2000 in procurement costs alone. The recent example of negotiations to reduce the price of kaletra will save the Brazilian government USD $ 339 million over a six year period.

Comparison of Expenditures with ARV by Source of Production - Brazil, 1996 – 2000 (In millions of dollars)

Source: Margaret J. Dadian, Family Health International, IMPACT ON HIV, Volume 1, No. 1, October 1998, Ministry of Health, Brazil 2000, 2001; Chequer P. Access to Treatment and Prevention: Brazil and Beyond. 3rd International AIDS Society Conference on HIV Pathogenesis and Treatment, Rio de Janeiro, Monday Plenary, 2005

6 REVIEWING THE TRIPS AGREEMENT

The following areas are identified as key areas that impact on TRIPS and public health issues which developing countries will need to reassess carefully in safeguarding their interests under the TRIPS Agreement:

6.1 PATENTED NEW DRUGS ARE GENERALLY MORE EXPENSIVE THAN GENERIC VERSIONS

Developing countries need to develop capacity to provide generic versions of newly patented drugs by using the provisions of compulsory licensing and parallel imports, and should ensure that enabling provisions exist in domestic patents and related legislations.

6.2 THE INTRODUCTION OF GENERIC DRUGS IS BEING SLOWED DOWN

Developing countries need to collaborate and be able to easily use the exceptions provisions in TRIPS to introduce generic versions in countries that lack production capacity through imports, and through joint ventures between countries with greater production capacity.

6.3 MORE NEW DRUGS FOR NEGLECTED DISEASES ARE NOT BEING DEVELOPED

It has been documented[27] that research and development of most critical and essential drugs in developed nations rely heavily on government or non profit aid. In fact, patents often act as incentives for drug companies to invest in markets that will reap profits from such monopoly gains, neglecting diseases that cause more morbidity and mortality. Non profit initiatives have to be undertaken for research in neglected third world diseases. This should be part of the effort to ensure that the objectives of the TRIPS Agreement dealing with social and economic development meets the needs of least developed countries.

6.4 TRANSFER OF TECHNOLOGY AND FOREIGN INVESTMENT TO THE LEAST DEVELOPED COUNTRIES IS NOT INCREASING

Developing countries need to identify and raise their concerns regarding the implementation of TRIPS and insist on mandated reviews especially immediate implementation and specific time lines with respect to Article 66.2[28] of the TRIPS Agreement. Developing countries also need to spend more time exploring the possibilities of south-south co-operation on transfer of technology issues between developing countries with established generics industries such as India and China on the one hand and those that do not yet have the capacity.

6.5 THERE IS A GROWING NEED FOR DEVELOPING COUNTRIES TO DEVELOP PRODUCTION FACILITIES

Considering that the Indian generics industry provides up to 60% of drugs currently being used by African countries, and given that the sustainable supply of generics from India will face challenges in the future, it is becoming increasingly important for developing countries to establish drug manufacturing facilities. In order to achieve viable economies of scale and to prevent the duplication that would occur if each country established its own ARV drug production facility, regional production options should be explored.

[27] Brook Baker, Closing the Access Gap: The Equitable Access License http://www.essentialmedicine.org/EALPrimer.pdf

[28] Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country. Members in order to enable them to create a sound and viable technological base.- TRIPS Article 66.2

6.6 THERE IS A SPECIAL INTEREST FOR LEAST DEVELOPED COUNTRIES (LDCS) TO MAKE USE THE NON-APPLICABILITY OF TRIPS

A TRIPs Council Decision in November 2005 extended the deadline by which LDCs were to have become TRIPs compliant to 1 July 2013.[29] The ruling does not affect the previous decision which exempts LDCs from having to give patent protection to pharmaceutical products until 1 January 2016. There are a number of regional groupings that are able to procure and manufacture ARVs without having to give regard to patent protection. These include the Economic Community of West African States (ECOWAS) grouping, the East African Community (EAC) and the Southern African Development Community (SADC).

6.7 GUARDING AGAINST TRIPS PLUS PROVISIONS AND MAINTAINING POLICY SPACE PROVIDED BY TRIPS

The emergence of TRIPS plus provisions in bilateral trading agreements being entered into negates any policy space available to developing countries. A number of LDCs are party to the bilateral trading negotiations that could have an adverse impact on public health. Based on the content of already concluded bilateral negotiations, developing and least developed countries should remain vigilant in ensuring that they do not have to accord patent protection that exceeds the protection contained in the TRIPS Agreement.

ALTERNATIVE FRAMEWORKS TO PATENT SYSTEMS

Strong patent protection is often presented as the price to pay in order to encourage the discovery of new drugs and vaccines that are relevant to the needs of developing countries. However, the empirical evidence does not substantiate this claim. In its study of the evidence, the International Commission on Intellectual Property Rights stressed that the utilization of TRIPS flexibilities to weaken patent protection on drugs will not diminish "the incentives for research on diseases specific to developing countries, because it is the lack of demand rather that the IP system which is the determining factor" (Commission on IPR, 2002 Page 39). Recognizing the lack of incentives in the current system to promote research on the diseases of the poor, the World Health Assembly established in 2003 the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) which examined "the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries." In its report of 3rd April 2006 the CIPIH pointed out that where the market has very limited purchasing power as in the case of diseases affecting millions of poor people in developing countries, patents are neither a relevant factor nor effective in stimulating R&D and bringing new products to the market. It further adds that 'monopoly costs associated with patents can limit the affordability of patented health-care products required in the absence of other measures to reduce prices or increase funding' In May 2006, the World Health Assembly considered a draft proposal submitted by Kenya and Brazil to establish a working group to support and strengthen incentives and mechanisms for a needs driven research.

A proposal was presented to the World Health Assembly Executive Board and the World Health Organization Commission on Intellectual Property Rights, Innovation and Health on 24 February 2005, asking for an evaluation of a proposed Medical R&D Treaty, an alternative trade framework for medical research & development. The letter requesting the evaluation was signed by 162 scientists, public health experts, law professors, economists, government officials, members of parliaments and various NGOs and Civil Society Organizations (CSOs). The Treaty aims to replace existing or planned trade agreements that focus on patents or drug prices. The new paradigm includes minimum national obligations for supporting medical R&D, with flexibility regarding the business models, intellectual property rules or other mechanisms (such as open source approaches). There are also priority setting mechanisms, including a system of tradable credits for investments in particular projects which promote social or public interest objectives; thereby creating markets for public goods.

Sources- twnside.org; The R&D Treaty & Comments on the Treaty- cptech.org

[29] Refer to a WTO press statement online at: ttp://www.wto.org/english/news_e/pres05_e/pr424_e.htm

7 OPTIONS OUTSIDE TRIPS

While the availability of patented products is the source of primary concern for developing countries, the availability of these products with reference to the purchasing power of their populations is equally critical. Along with enacting appropriate legislation, countries also need to study the options of differential pricing and an active, aggressive generics policy.

7.1 DRUG DONATIONS

There are a number of drug donations and discounted essential medicines available to developing countries. Some of the sources (aside from direct donations from drug companies) are donations and discounted prices sourced through the Bill Clinton Foundation , the donation of nevirapine for PMTCT programs in developing countries by Boehringer Ingelheim, the donation of diflucan (used to treat opportunistic infections) by Pfizer as well as free drugs sourced through the US President's emergency Plan For AIDS Relief (PEPFAR).

At the World Aids Conference in Durban in July 2000, BI announced an initial 5 year donation of nevirapine to more than 40 countries, including a large number of African countries. The donation is applicable for PMTCT programmes and not for the use of nevirapine in combination ART. Initially, the donation was meant to expire in July 2005 but in December 2003, the timeline was extended beyond 2005.[30] On October 23, 2003, the Clinton Foundation announced an agreement with five suppliers of generic ARVs (Aspen, Cipla, Hetero, Ranbaxy and Matrix laboratories) that significantly cut the price of the most commonly used triple drug therapy combinations to less than $140 per person per year.

PEPFAR programme focuses on fifteen developing and least developed countries most affected by HIV/AIDS.[31] In January 2005, it was announced that PEPFAR provided ARV therapy to 155,000 people in the focus countries. Congress required that 55% of PEPFAR money for the treatment of individuals with HIV/AIDS 2006 through 2008, 75% of the funds are to be spent on the purchase and distribution of antiretroviral drugs. The PEPFAR programme only allows the purchasing of pharmaceuticals that have been approved by the US FDA and the bulk of companies with FDA approval have traditionally been the research based companies.

7.2 HIV/AIDS TECHNICAL NETWORK

The establishment of technical partnerships and networks is common in many areas of socio-economic development. While current networks can widen their mandate to include public health concerns that affect affordability of medicines, an existing network established at the XV International AIDS Conference in Thailand appears to be getting stronger. The idea of establishing networks among developing countries with the human resources and skills required for manufacturing drugs was raised at UNGASS in 2003. On that occasion, the need to define cooperation mechanisms to take full advantage of these resources and

[30] A press statement on the extension of the donation is available online at: http://www.boehringer-ingelheim.com/corporate/asp/news/ndetail.asp?ID=1514

[31] These countries are Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Vietnam and Zambia.

skills in a joint endeavor was clearly identified. The main objectives of the initiative remain: to increase access to drugs and other pharmaceutical inputs for the diagnosis, prevention and treatment of HIV/AIDS (condoms, microbicides, vaccines, laboratory kits etc), to strengthen the technical skills of developing countries to make full use of the flexibilities regarding the management of Intellectual Property Rights as set forth in the TRIPS Agreement and enshrined in the Doha Declaration[32].

At the World Health Assembly held in Geneva from 17-22 May 2004, representatives of 8 countries (South Africa, Brazil, China, India, Nigeria, Russia, Thailand and Ukraine) reaffirmed their commitment to setting up the Network. At the same meeting, the Ford Foundation - convinced of the usefulness of the initiative - undertook to invest 2 million US dollars in the Network over a period of 30 months. Two months after the Assembly had taken place, six of the countries (South Africa and India desisted, instead Cuba and Argentina have since joined) agreed to sign a Joint Declaration of Commitment in the course of the XV International AIDS Conference held in Bangkok, Thailand, on 11-16 July 2004. While the network has committed (Declaration of Commitment) to work together in the area of production of ARVs, price reductions and active use of generics it has also carried out various discussions on TRIPS and patent issues affecting access to ARVs.

7.3 ESTABLISHING AN AGGRESSIVE GENERIC PROMOTION POLICY[33]

Developing countries can pursue an aggressive policy to support production and sale of generic products in addition to the measures they take under the compulsory licensing provision of the TRIPS Agreement. To make full use of TRIPS flexibilities, national patent laws must be designed with specific measures aimed at encouraging the production of generic versions of drugs. For instance, patent officers must be vigilant so as to not grant frivolous patents. Moreover, countries must not adopt measures to undermine the flexibilities and safeguards by incorporating provisions in the patent act or related medicine regulation laws that delay the entry of generics into the markets.

7.4 REDUCING "NEW USE PATENTS"

There has been an increase in the number of "new use" patents that have been filed in the past few years. New use patent provisions allow companies to apply for a new patent for each "new use" of a product. Under this provision, a drug that is currently used to treat AIDS could receive a new 20-year patent monopoly if it were found to be effective against cancer. Countries can include provisions in their patent legislations that prevent new use patents unless there is an innovative step involved.

[32] A series of bilateral negotiations was at the time established between Brazil, India, South Africa and China in view of the technical competence of the four countries in the areas of research, development and manufacture of a range of inputs for prevention and treatment of HIV/AIDS. Subsequently a number of other developing countries expressed interest in the initiative. The Network has met twice so far and its third meeting was just completed in Cuba in May 2006. For more information on the network, undp.org as UNDP has served as an observer in the meetings since the Network's inception.

[33] These measures are explained in more detail below- such as reducing new use and data exclusivity

'PRE-GRANT OPPOSITION' PROVISON UNDER THE INDIAN PATENT ACT 2005

Often due to the volume of patent applications, patent examiners often miss information related to the patent application under consideration- e.g. if it is just a small improvement over an old drug. If attention is brought to information that shows that the patent application is for a 'derivative' or a 'new use' of a known drug, the possibility of invalid patents being granted is reduced.

Anyone can bring such information to the attention of the patent controller through the pre-grant opposition process (as provided under Section 25 of the Indian Patents Act), Generic companies have already filed a number of pre-grant oppositions. In addition to companies, patient groups and public interest organizations are also working to oppose patent applications for essential drugs. Most of the opposition filings and movements have been mobilized by CSOs and groups of people living with HIV/AIDS .

On January 2006, the Indian Patent office rejected Novartis' patent application for its anti cancer drug Gleevec- on the grounds 'new form of a known substance. The rejection was a major victory for Cancer patient Aid Association of India and some generic companies that had submitted a pre-grant opposition to the patent office. In March 2006, an opposition was filed against GSK for Combivir on both technical and public health grounds. As recent as May 2006, a pre grant opposition has been filed against Gilead Sciences on TENOVIR a key AIDS drug.

Pre grant opposition has proved to be a very useful provision that countries can adopt to stop frivolous patents before they are granted. However, just like in most cases of national enforcement of existing flexibilities within the law, heavy mobilization and awareness raising has to be undertaken by CSO groups.

7.5 DATA EXCLUSIVITY

TRIPS mandates protection of undisclosed data submitted to national Drug Regulatory Authorities in order to obtain marketing authorization for new drugs. This registration data has to be protected against disclosure, and against unfair commercial use. Thus, the national authorities may not publish or share such data. Some parties argue for 'data exclusivity' which means that the regulatory authorities would not be allowed to rely on this data for the purpose of registration of generic versions of the drug.

Currently, pharmaceutical companies in the US are allowed to withhold test data (data demonstrating the safety, quality and efficacy of the product as a condition for permitting the marketing of a pharmaceutical product) for five years as compared with the European standard of six to ten years. By implication, as long as the exclusivity lasts, generic producers would either have to submit their own data -which would oblige them to repeat the clinical trials and other tests- or they would have to delay the launch of their product until the end of the exclusivity period. This would delay the entry of generics into the market and affect the price of generics- not to mention the ethical issues involved in repeating clinical trials. Developing countries should make a concerted effort to demand expediting data disclosure procedures so that local manufacturers are able to use the information for generics production once the drugs are off patent. Countries should also guard against the inclusion of test data protection in bilateral trade agreements as there is no obligation in terms of Article 39.3 of the TRIPS Agreement obliging countries to provide additional protection to test data.

7.6 NATIONAL PRICE CONTROL MECHANISMS

Countries can adopt Price Control mechanisms outside the patent law to eliminate or reduce the supernormal profits and make prices of brand leaders more reasonable. A sound Price Control Mechanism may be able to do so in a product patent regime what generic competition can do in its absence. Countries such as Canada, Australia and South Africa have adopted mechanisms that have proven to be very successful. In Canada, for instance, the prices of drugs were 36% lesser than in US in 1987 and in 2001 it was 69% lower than in US.

7.7 REGIONAL PATENTS AND POOLED PROCUREMENT OF RAW MATERIALS

Developing country governments should co-operate on the procurement of raw materials so that local generics producers face far lower costs than if they were to individually negotiate with the suppliers. There are a number of regional patent initiatives in existence such as the West Africa based African Intellectual Property Organization (OAPI) which confers regional patents to the applicants. Hovwever, this generally tends to work against the interests of public health because member countries are not aware of which patents have been filed at the regional secretariat and cannot easily search patents. More needs to be done to ensure that countries are aware of the filing of patents at regional organizations and that flexibilities are available to bypass the applicability of these patents in the event of a public health emergency.

7.8 EFFICIENT REGULATION FOR QUALITY APPROVAL

Developing country governments need to establish efficient regulatory frameworks for ensuring a consistently high quality supply of ARVs. This can be done by entering into agreements with developed countries to expedite approval for these products, and by supporting publicly available bioequivalency studies.

7.9 REGIONAL HARMONIZATION OF REGULATORY STANDARDS

One of the primary factors impeding a quicker introduction of both first and second line ARVs in developing countries is the differing standards of various countries before the granting of marketing approval. A recent attempt by a generic company (with FDA approval) to export ARVs to Ethiopia, Nigeria, Tanzania and Uganda failed because the generic company's products were not included on the WHO's pre-qualification list. There have been recent initiatives within the SADC region to harmonize standards that must be complied with before marketing approval is granted. Such initiatives must be strongly supported and built on in order to facilitate the introduction of new ARVs by generic companies.

7.10 EQUITABLE PRICING

The most common finance mechanism in most developing countries is out-of-pocket payment since these countries do not have well developed social insurance coverage or large scale, equitably distributed subsidized health services. Out of pocket payments in developing countries exceed 90% of total expenditure in developing countries as opposed to 20% in developed countries[34]. Drug prices, therefore, in the context of a low-income country, are important determinants of access to health care. Equitable pricing- also referred to as differential or tiered pricing-refers to the concept of pricing products in different markets according to the consumers' ability to pay as measured by their income levels. Differential pricing has clear benefits and risks; however the risks can be mitigated through careful policy planning.

The main benefits of equitable pricing are increased access and increased revenues. Increased access through greater affordability. And since affordability is a graded and not a zero-one concept, differential pricing ensures access to far more patients than would be possible in its absence. The clearest risk of equitable pricing is that of leakages; pharmaceutical companies have voiced the dangers of low priced drugs being illegally transported back to developed markets, and thereby lowering prices in the high priced markets. Clearly if markets are not segmented, prices will fall in both markets to the lower level. However, this risk can be mitigated by country governments through carefully designed policy that prevents re-importation of these drugs to developed markets. For equitable pricing to be effective, production capacity and effective regulation to ensure the production of quality generics, is required.

[34] World Health Report 2000, WHO pg 7

8 CONCLUSION

The issue of access to drugs within the international patent regime is of critical importance to most developing countries. This paper was an attempt to outline some of the key aspects that are of relevance to public health issues. The current dichotomy between the letter of the TRIPS Agreement and its actual practical interpretation over the last ten years has met with mixed results. Although TRIPS flexibilities have been confirmed in recent years through the Doha Declaration and the 30 August Agreement, the actual use of these flexibilities by developing countries to date has been very low and often, the necessary amendments have not been made in domestic law to give effect to the flexibilities that exist in the TRIPS Agreement. Furthermore, there is now the danger of the flexibilities in TRIPS being curtailed by bilateral trade negotiations. The magnitude of the AIDS epidemic has brought these contradictions to the forefront and has sparked off a movement that is now changing the perceptions of possibilities for poor countries.

Clearly, much scope remains for developing countries to formulate and implement national laws that will address their public health goals. The challenge for developing countries is three fold; to ***interpret*** the TRIPS Agreement by identifying the most applicable flexibilities and to be able to use them effectively in a domestic context; to ***implement*** the Agreement in line with their development goals; and to mobilize themselves to ensure that future negotiations are used to ***review and preserve*** these provisions to make them universally accepted as essential for the development needs of poor countries.

United Nations Development Programme
HIV/AIDS Group, Bureau for Development Policy
304 East 45th Street, 10th Floor
New York, NY 10017
P: 212 906 3688 F: 212 906 5023

www.undp.org/hiv

Joint United Nations Programme on HIV/AIDS
UNAIDS
UNHCR • UNICEF • WFP • UNDP • UNFPA
UNODC • ILO • UNESCO • WHO • WORLD BANK