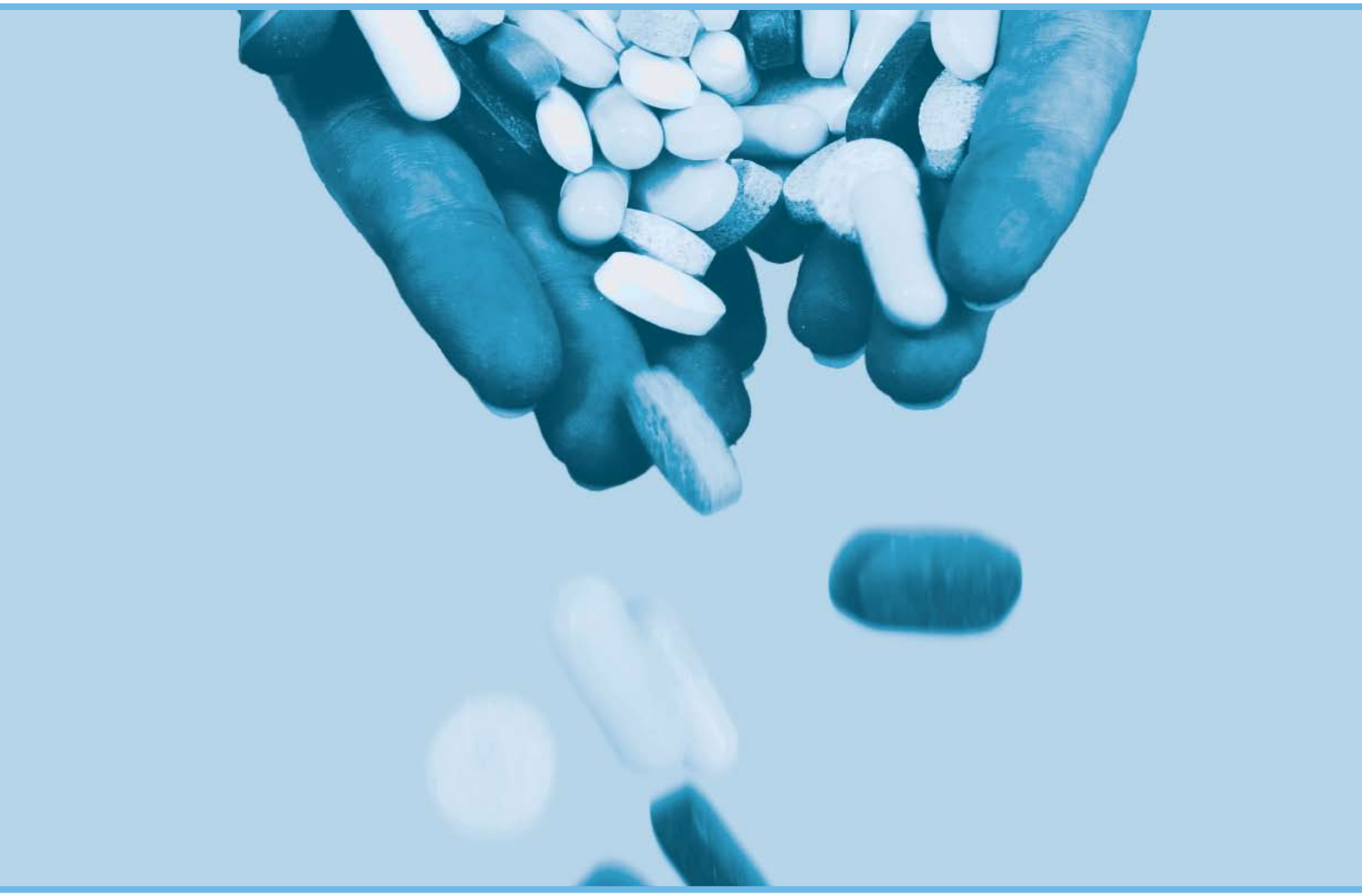

THE TRIPS AGREEMENT AND ACCESS TO ARVs

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Tenu Avafia

and

Savita Mullapudi Narasimhan
*United Nations Development Programme 2006**

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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

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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)