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**IMPLICATIONS OF WTO/TRIPS IN EAST AFRICA -
WITH SPECIAL EMPHASIS ON PHARMACEUTICAL
PATENTS**

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TABLE OF CONTENTS

1.0	INTRODUCTION.....	1
2.0	BRIEF HISTORICAL BACKGROUND TO THE INTERNATIONAL TRADING SYSTEM	1
2.2	The Uruguay Round and the WTO	2
2.3	Intellectual property right before WTO	3
3.0	TRIPS AGREEMENT AND EAST AFRICAN COUNTRIES.....	6
3.1	General Overview of the Agreement	6
3.2	Patent Protection under TRIPS	7
3.3	When TRIPS rule apply in East Africa?	9
4.0	POTENTIAL HUMAN RIGHTS IMPACTS OF TRIPS/PATENT PROTECTION IN EAST AFRICA	10
4.1	Introduction.....	10
4.2	Implications of TRIPS/Patent Protection in human rights.....	10
4.3	Any room for manoeuvre?	14
5.0	A CASE OF PHARMACEUTICAL PATENTS AND HIV/AIDS GENERIC DRUGS IN EAST AFRICA.....	16
5.1	Introduction.....	16
5.2	Pharmaceutical Patents	16
5.3	The issue of access to HIV/AIDS drugs in East Africa	17
5.4	TRIPS and Access to essential drugs.....	18
5.4.1	Parallel Importation	19
5.4.2	Compulsory Licensing	20
5.4.3	Differential Pricing	22
5.5	National Implementation	23
5.6	Recent developments on TRIPS and Access to Essential Drugs in East Africa	25
6.	CONCLUSIONS AND RECOMMENDATIONS.....	26
7.	REFERENCES.....	ii

1.0 INTRODUCTION

In 1994, the Uruguay Round negotiations culminated in the signing of an agreement establishing the World Trade Organisation (WTO). At the heart of the WTO – are legal ground rules that provide the basic foundation for most contemporary developments associated with globalisation. These include free trade, open markets and tariff reductions. The WTO currently remains one of the most powerful multinational trade organisations. With 144 members, 100 of which are developing countries, the body has expanded trade from goods only to include services, intellectual property and foreign direct investments. Along this line of developments, the WTO regime has created one of the most intense debates in international law and policy today. One of these debates relates to strong intellectual property protection under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

TRIPS establishes minimum standards for protection of Intellectual Property Rights (IPRs). As members of the WTO, the three East African countries¹ are under binding obligations to amend/repeal their intellectual property laws to conform with this Agreement. The domestication of the TRIPS will not only affect most of the East African countries and a large part of their economic sectors,² but also a wide range of areas beyond economics. This study examines how patent protection relates to the overall promotion and protection of human rights, and socio-economic rights, in particular. The study concentrates on pharmaceutical patent protection and the new life saving drugs that should be available for treatment of HIV/AIDS in the region. The main thrust of the study is that East African governments should be aware of the human rights implications of TRIPS so that they would be able to structure their intellectual property systems in a way that is consistent with their existing international human rights obligations. Ultimately, the purpose of the study is to identify relevant policy options on implementation of TRIPS at the national levels as well as support the efforts of these countries in the formulation of strategies conducive to the implementation of the Agreement. The next section (section 2) provides a brief historical background of multilateral trading system with reference to intellectual property protection. Section 3 explores various provisions of TRIPS and their relevancy in East Africa. A human rights analysis of the Agreement is covered under Part 4. This is followed by a discussion on pharmaceutical patent and access to HIV/AIDS drugs in East Africa. The last section (6) concludes and recommends accordingly.

2.0 BRIEF HISTORICAL BACKGROUND TO THE INTERNATIONAL TRADING SYSTEM

2.1 The General Agreement on Trade and Tariffs (GATT)

At the end of the Second World War, it was decided that international institutions were needed to assist in the process of economic recovery. At a 1947 United Nations Conference on Trade and Employment in Havana, Cuba, a proposal was discussed to create an International Trade Organization (ITO) to complete the construction of a post-war multilateral economic regime begun several years earlier.

¹ Kenya, Tanzania and Uganda.

² For evaluation of economic implications of the TRIPS Agreement for developing countries, see UNCTAD (1996): “The TRIPS Agreement and Developing countries”, New York and Geneva, UNCTAD/ITE/1.

At the time, the regime consisted of the International Monetary Fund and the International Bank for Reconstruction and Development. The ITO was to be the third pillar and be equipped with strong decision-making and dispute settlement powers to oversee the multilateral trading system. However, the ITO did not come into being as the United States of America - a country that initiated the process - did not ratify it.³ As part of the ITO negotiations, Canada and 22 other countries had begun discussing the process of lowering trade barriers (mainly tariffs) among themselves. In 1947, these 23 countries at a meeting in Geneva adopted a provisional agreement, the General Agreement on Trade and Tariff (GATT).⁴ GATT was supposed to depend on the ITO for its organizational context and secretariat services. Nevertheless, it managed to fill the void left by the failed ITO and emerged as the *de facto* international trade organization.

The main objective of GATT was to conclude “reciprocal and mutually advantageous arrangements” with a view of how to reduce customs duties and other barriers to trade and eliminating all discrimination in international trade. Under the terms of the treaty, each country had to concede most-favoured-nation treatment to all other parties. Each signatory state also granted tariff concessions to the other parties by limiting the customs duties imposed on the importation of foreign goods. Signatories were also obliged not to take certain measures that would result in obstacles to international trade. Certain sectors such as services, agriculture and textiles were taken outside the rules of GATT.⁵

By the 1980s, it became apparent that GATT no longer adapted to the realities of trade as it had been in the 1950s. As the globalisation of the global economy progressed, international investments saw an unprecedented growth, and trade in services-not covered by the GATT rules –began to be a major interest for more (developed) countries and was closely bound up with the increase in global trade in goods.⁶ The GATT rules were also deemed inadequate in other ways, for example in the agriculture sector where the loopholes in the multilateral trading system were widely exploited and attempts at liberalisation were essentially in vain. The institutional structure of the GATT and its system for the settlement of disputes were also becoming sources of concern.⁷

2.2 The Uruguay Round and the WTO

In September 1986, multilateral trade negotiations of the Uruguay Round were launched at Punta del Este, Uruguay.⁸ The Uruguay Round was a complex set of negotiations undertaken to address the prevailing inadequacies of the GATT. The negotiations encompassing practically all the outstanding problems of trade policy

³ See Marcus Noland (2000), “Understanding the World Trade Organisation”, Institute for International Economics.

⁴ See General Agreement on Tariffs and Trade, 55 UNTS 194 (the original GATT Agreement).

⁵ Velasquez, G and P. Boulet (1999): Globalisation and Access to Drugs. Perspectives on the WTO/TRIPS, WHO/DAP/98.9, Revised.

⁶ WTO (2000), Introduction to the WTO: Trading Into the Future, 2nd edition.

⁷ Some authors also believe that once developing countries began to join the GATT in significant number, they soon felt their needs were not addressed adequately by the post-war regime hence a reason for reforms in the GATT system, see Robert House and Makau Mutua, Protecting Human Rights in a Global Economy: Challenges for the world Trade Organisation (2001).

⁸ Although the multilateral trade negotiations launched in September 1986, it was preceded by four or five years of intense manoeuvres, discussions and pre-negotiations at the GATT.

including the extension of the trading system into several new fields, in particular services and intellectual property rights.⁹

The Final Act embodying the results of the negotiations was issued on December 15, 1993, authenticated by 117 nations on 15 April 1994 at Marrakech, Morocco and came into force upon its signature by member nations from January 1995.¹⁰ Many areas that were once under the control of individual countries were brought into the framework of international trade law by being concluded under the prefix 'trade-related'. These areas included services, foreign investments and intellectual property. As Oloka-Onyango and Udagama have observed "in bringing these issues within the purview of the international trade-enforcement regime, not only did WTO assume tremendous powers, but it also raised several new issues vis-a vis the relationship between the organisation and individual states, the broad questions of human rights and the North/South geopolitical divide."¹¹

2.3 Intellectual property right before WTO

Intellectual property very broadly means the legal rights which result from intellectual activity in the industrial, scientific, literary and artist field.¹² Intellectual property is traditionally divided into two branches, industrial property and copyrights.¹³ Intellectual property shares many of the characteristics associated with real and personal property. For example, intellectual property is an asset and as such it can be bought, sold, licensed, exchanged or gratuitously given away like any other form of property. The most noticeable difference between intellectual property and other forms of property however is that, intellectual property is intangible. It therefore cannot be defined or identified by its own physical parameters.

2.3.1 Protection of Intellectual Property at the international level

International treaties on IPRs have been in existence since the end of the 18th century.¹⁴ They have dealt in turn with industrial property, trademarks, industrial designs and models, patents, copyright, etc. The World Intellectual Property Organization (WIPO) created under the 1967 Convention Establishing the World Intellectual Property Organization¹⁵ became the first international organization responsible for enforcing the treaties on intellectual property in effect at that time.

⁹ Someshwar Singh, (2000) "Uruguay Round, Historical Perspective", Third World Network. See also WTO, Trading into the Future at www.wto.org/basics/.

¹⁰ The signature of the WTO Convention means adhering to all the multilateral conventions (multi-lateral Agreements on trade in Goods (GATT), General Agreement on Trade in Service (GATS); and the TRIPS, whereas adhesion to the plurilateral convention is optional. The WTO's main function is to ensure that trade between nations flows as smoothly, predictably, and freely as possible. The prime principle governing the WTO's activities is the *most favoured nations* (MFN). This means that countries should not discriminate between WTO members: any barriers to trade should be applied equally between all countries. For more discussion see WTO: Trading into the Future.

¹¹ J.Oloka-Onyango and Deepika Udagama (2001), "Globalisation and its impact on the full enjoyment of human rights", Progress Report submitted to the United Nations High Commission on Human Rights, August.

¹² WIPO, Introduction to intellectual property reading Materials, Publication No.476 E.

¹³ WIPO, Ibid.

¹⁴ For a historical development of intellectual property law, see Peter Drahos (1998): "The Universality of Intellectual Property Rights: Origins and Development", Intellectual Property and Human Rights, World Intellectual Property Rights Organisation. See also, Fritz Machlup, "An Economic Review of the Patent System" in Fredrick Abbot, Thomas Cottier and Francis Gurry, (1999): Intellectual Property Systems: Commentary and Materials- Part One, Kluwer Law International.

¹⁵ The Convention Establishing WIPO was signed at Stockholm in 1967 and entered into force in 1970. For more discussion on establishment, structure and function of WIPO see www.wipo.org/.

But the WIPO Convention, and in particular the Paris Convention for the Protection of Industrial Property of 1967 only impose general rules such as the rule on national treatment which requires equivalent treatment for foreigners and nationals. The GATT itself did not deal with the level of IPRs protection although it contains some provisions of relevance in Articles III, IX and XX (d). These provisions were hardly discussed until the GATT ministerial meeting in 1982 brought up the problem of counterfeit goods in international trade. Some countries appeared to be influenced by the perception that their competitiveness, dependent on technology and creativity was not adequately protected worldwide by existing rules on intellectual property.¹⁶ The inadequacies of protection and rules related to IPR's enforcement, together with the absence of an international dispute settlement system led them to argue for the inclusion of IP matters into the Uruguay Round.¹⁷

2.3.2 Protection of intellectual property in East African countries

IP law and especially patent law is primarily national law. An inventor who files a patent application in a state is asking that state to recognise his exclusive rights to his invention within the territorial boundaries of that state. The administration and enforcement of IPRs in East African countries must be seen in another dimension to the administration of IPRs and their enforcement in developed countries.

A quick survey conducted in Tanzania, Kenya and Uganda shows that before 1980s, most of the laws regarding the protection of IP were mere replicas of existing laws of their colonizing countries. These laws had been specifically designed to protect the right of the colonizing nationals and their businesses and firms.¹⁸ Immediately after independence, the post-colonial governments still did not attach much priority to the need to protect intellectual property rights. Many industries, with some notable exception of Kenya, were in their infancy, and the domestic manufacturing base was virtually non-existent. What was prevalent in East Africa was a vibrant folklore tradition around which cultural industries clustered in areas such as music, textiles and the like.¹⁹ Against such a background, the study looks in detail at patent legislation of these countries.

(a) Kenya experience

Prior to the enactment and coming into force of the Industrial Property Act, Cap 509 of 1990, Kenya had a patent system that was wholly depended on the British patent system. Under that arrangement, a patent granted in the United Kingdom (UK) was valid for registration in Kenya. This system did not create a conducive environment

¹⁶ According to Ha-Joon Chang one among the reason for the inclusion of TRIPS into the WTO agenda was a reaction by the advanced countries, mainly the USA, against the attempt by the G77 developing countries to call for the reform of the international IPR system through the WIPO during 1970 and the early 1980s. At that time as part of their push for the New International Economic Order (NIEO), the developing countries sought to generate greater transfer of technology from the advanced countries through the reform of the international IPR regime. See Ha-Joon Chang (2001): "Intellectual Property Rights and Economic Development-Historical Lessons and Emerging issues", a background paper prepared for [UNDP Human Development Report](#).

¹⁷ It should be noted however that development of norms in the field of intellectual property has not stopped with the conclusion of the TRIPS Agreement. The Trademark Law Treaty concluded in 1994, simplified and harmonises the trademark registration process in treaty members. On 20 December 1996, the WIPO Diplomatic Conference on Certain Copyright and Neighbouring Rights Questions adopted two treaties: the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty.

¹⁸ See for example the Patent Registration Act, Cap 508 of the Laws of Kenya and The Patent (registration) Ordinance, Cap 217 of 1962 of the laws of Tanganyika.

¹⁹ Van Arkadie, B., (2002): "Globalisation and East African Economies, An Introductory Overview", ESRF.

for Kenyan innovators who had to file an application in UK and if granted patent, have it registered in Kenya.²⁰ Data collected from Kenya Industrial Property Organisation (KIPO) provides that about 97% of the patents granted in Kenya under this system were held by the developed world.²¹ And as shown in Table 1, some of these patents are still in force in Kenya including patents for fluconazole, ciprofloxacin and azithromycin. They will expire on the same date as the corresponding UK patents.

Table 1: patent status of some essential drugs in Kenya granted before 1990

Generic name	Kenya patent number	Protection of...	Foreign priority date	Filing date	Kenya expiry date	Patent status in Kenya
acyclovir	AP160	new composition +use	15/8/87	10/8/88	10/08/08	in force
azithromycin	AP44	new form of azythormycin	9/7/87	15/6/88	15/6/08	in force
ciprofloxacin	KE3875	new composition	17/9/83	4/9/84 (UK) 20/4/89 (KE)	4/9/04	in force
fluconazole	KE3771	basic substance	6/6/81	22/4/82 (UK) 29/9/87	22/4/02	in force
zidovudine	AP11	composition +use	16/3/85	14/3/86	14/3/06	in force

Source: MSF (2000): Patent Protection in Kenya and Uganda

In December 1989, the Kenya Government enacted the Industrial Property Act, Cap 509 after the repeal of the Patent Registration Act Cap, 508. A gazette notice was published on 16th February 1990 bringing the Industrial Property Act into force with effect from 2nd February 1990. Although the new Industrial Property Act, (No.3) of 2001 was enacted by the Kenyan parliament in August 2001 in compliance with TRIPS Agreement, the 1990 Act is still in force.

Table 2: Patent granted under the 1990 Industrial Property Act, for the period 1990-2000[as at 21:09:01]

YEAR	LOCAL	FOREIGN
1990	-	-
1991	-	-
1992	-	-
1993	-	-
1994	2	-
1995	-	1
1996	1	11
1997	5	23
1998	8	5
1999	3	4
2000	6	12
2001	4	4

Source: Kenya Industrial Property Office (KIPO)

(b) Patent rights in Tanzania

Like Kenya, Tanzania used to have a system of patent registration linked to patents granted in the UK. According to the records available since the enactment of the Patent law up to 1967, 1121 patents were registered in Tanzania and the British manufacturers enjoyed over 90% of monopoly on the patent granted.²² Due to the difficulties in setting up a patent system in the country, the Patent (registration)

²⁰ Pascale Boulet, (2000): "Patent Protection in Kenya and Uganda", MSF a discussion paper, "Improving access to essential medicines in East Africa- patent and prices in global economy, Nairobi, 15-16 June.

²¹ Pascale Boulet (2000) *ibid*.

²² Tanzania Business Registration and Licence Authority (BRELA).

Ordinance, Cap 217 of 1962 remained in force until 1987 when a new patent law (Act No.1 of 1987) was enacted. (controversy over coming into force?) This law was expected to give a challenge and the needed motivation to scientists and technologists in their efforts of developing industrial technologies. Its implementation however remains insignificant because of various reasons including lack of tools and scarcity of experts to implement the patent rights.²³

(c) The case of Uganda

Uganda adopted its own patent law on 20 December 1991 based on a patent registration system connected to patent granted in the United Kingdom. This means that patents applied for before 20 December 1991 will expire in Uganda on the same date as in UK. While it was difficult to obtain more information regarding patents rights in Uganda, the study found that the process of revising patent law had already started within the Ministry of Trade and Industry in the country. Initially the Ministry of Health was not been involved in the process.²⁴

3.0 TRIPS AGREEMENT AND EAST AFRICAN COUNTRIES

3.1 General Overview of the Agreement

TRIPS is not strictly speaking, a trade liberalization agreement as it does not prescribe measures designed to open up markets and facilitate free trade. However, it does facilitate free trade in that it prescribes measures for protecting intellectual property rights within the context of more open markets. It is useful to recall three basic features of the Agreement:

- together with some 25 other legal texts, it is an integral part of the agreement establishing the WTO (and therefore subject to the WTO dispute settlement system);
- it covers not only patents but all other main areas of intellectual property rights (such as copy rights, trade mark); and
- it lays down not only the minimum substantive standards of protection that should be provided for in each of these areas of intellectual property rights but also the procedures and remedies that should be available so that rights holders can enforce their rights effectively.

Having said that it should be noted that the scope of this study can only take on the discussion on patents. As a starting point, this study is not against patents and patents legislation as such. True innovation deserve to be recognised and protected. This has been agreed in principle by our countries through the signing of TRIPS. What we need to discuss however is how patents protection relates to the enjoyment of human rights of the East African people.

²³ Dan Kavishe, Presentation on Tanzania Technology and related Policies for the SME Sector.

²⁴ Pascale Boulet (2000).

3.2 Patent Protection under TRIPS

3.2.1 Patent

A patent is a title granted by the state in a specific country (or a regional office acting for several countries – ARIPO (African Regional Industrial Property Organisation)²⁵ for the case of the three East African countries) that gives exclusive rights over the manufacture and use of an invention to the public. In other words, one might say that a patent is a contract between a society as a whole and an individual inventor. Under the terms of this social contract, the inventor is given the exclusive right to prevent others from making, using and selling a patented invention for a fixed period of time in return for the inventor's disclosing the details of the invention to the public. It should be known that a patent is national and there is no international patent.

World Bank figures (Table 3) relating to patent applications show an overwhelming presence of technology holders and applications in developed countries.

Table 3: World Patent Applications in 1997

Region	Application of Patents
High-income countries	2,785,420
East Asia and the Pacific	290,630
Middle East and North Africa	1,716
Sub-Saharan Africa	392,959 only 38 of those filed by residents

Source: World Development Indicators 2000, Washington DC, table 5.12

In other words, the vast preponderance of patents worldwide are held by individuals and enterprises based in developed countries. In this regard, for East African countries the grant of patent almost certainly means increasing payments to US, Europe, Japan based companies.²⁶ The Bulletin of the World Health Organisation however has noted that many developing countries lack the technological infrastructure to benefit from costly Intellectual Property systems directed to the promotion of modern technological research. This therefore makes IP systems out of reach for many innovators or potential innovators in those countries.

3.2.2 How important is a Patent

Although there are several documented reasons as to why governments grant patents, they all single up to one sentence: 'to encourage inventive activity as well as technology transfer and activities associated with the commercialisation or marketing of an invention. According to Irving Kayton,²⁷ patents are intensely practical, real life legal instruments with which an inventor or corporation can protect the investment in time, money, effort and other resources expended in order to create a new contribution to technology. The arrangement therefore permits organisations to plan rationally and effectively in order to carry out business activities relative to new technology in an orderly way.

²⁵ ARIPO is established by The Protocol on Patent and Industrial Designs within the Framework of the African Regional Industrial Property Organisation (the Harare Protocol) of 1982 (as revised in 1999). The Protocol entered into force in 1984. Both Kenya, Tanzania and Uganda are parties to the Protocol.

²⁶ See UNDP Human Development Report, (1999): "Globalisation with a Human Face" at p. 69.

²⁷ Irving Kayton in The Inventor, Issue No.007, July-December 2000, Kenya Industrial Property Organisation.

3.2.3 What can be patented?

The criterion for an invention to be patented is that it must be new,²⁸ involves an inventive step²⁹ and be capable of industrial application (TRIPS, art. 27 (1)). In other words, to be patentable an invention must be novel, useful and non-obvious.

3.2.4 Rights conferred by a patent under TRIPS

Under Article 28 (1) of TRIPS, the patent owner has a legal right to prevent ‘unauthorized’ persons from using the patented process and making, using, offering for sale or importing the patented product or a product obtained directly by the patented process.

3.2.5 Term of protection

Pursuant to article 33 of TRIPS, the duration of protection offered will not cease until expiry of a period of 20 years from the date the patent application is filed. Once this period has expired, people are free to use the invention as they wish. This requisite is contrary to the existing legal framework in East Africa whereby in Kenya, for example, patents are initially granted for seven years from the filling date. However patent owners may then obtain an extension of two five-year periods, on request, if they prove that “the invention is being worked in the country at the date of the requests or that there are legitimate reasons for failing to work the invention” (s.39).

As with the Tanzania experience, the normal validity for patent is 10 years from the date the patent is registered. An extension for another two five-year terms may be granted subject to application being made to the registrar of patent. Patents in Uganda are initially granted for a period of 15 years from the date the patent is delivered. At the request of the patent owner, the patent term may be extended for five years if he or she satisfies the registrar that the patented invention is being “worked in Uganda or that there is a legitimate reason for failing to so work the invention (s.32). In this regard, s.32.2 of the Uganda’s patent law specifies that the patented invention is worked if the patented product is effectively used in Uganda on a scale which is reasonable in the circumstances, but importation does not constitute working.

This study suspects that change in patent protection from the original period in these countries will virtually bring to halt industrialization process of these countries (by the year 2020 for the case of Kenya). In fact, 20 years of protection a patent from copying or readapting goes against the spirit of competitions which the globalisation process is all about.³⁰ In short, the protection of IPRs under TRIPS presents a

²⁸ That is the subject matter of the invention is not or cannot be inferred to be part of what is already known. This is commonly referred to as the “novelty” requirement. New of novelty or new in this context means “new to the public”. Therefore something that has previously been used or known but has not been made available to the public (or instance, it has been kept a secret) is not a bar to patentability.

²⁹ This prevents someone from taking advantage of the patent system and obtaining protection for something that is mere extension or trivial variation of what is known. Generally the test for inventiveness or nonobviousness, is based on what a reasonable person skilled in the field to which the inventions pertains at the time the inventions was made, could consider being nonobvious.

³⁰ The very existence of TRIPS itself in the WTO is also now being called into questions by prominent free-trade economists such as Jagdish Bhagwati.

paradox for international economic law in that it runs against the basic tenets of liberalization and favours monopoly restriction and control.

3.2.6 How can the monopoly of 20 years be limited?

TRIPS allows for limited exceptions to the exclusive rights of the patent holder. This is a situation in which a person can use the patent object with no need to ask the authorization of the holder and without being in an illegal situation. Those exceptions are national legal exceptions and therefore need to be set out in the national patent law and policy. By virtue of Article 30 “members may provide limited exceptions to the exclusive rights conferred by a patent provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”

The article however does not spell out the different grounds on which Member States may base their exceptions, nor the precise cases that can be the subject of such exception to the monopoly. Nonetheless, some authors suggest that reading article 30 together with article 7 and 8 of TRIPS it appears that both promotion and transfer of technology as well as public health, public interest could justify derogation of the patentee’s exclusive rights.³¹

3.3 When TRIPS rule apply in East Africa?

TRIPS provides transitional periods during which Member States are required to bring their national legislation and practices into conformity with its provisions.

3.3.1 Kenya

Being classified as a developing country, Kenya had to domesticate the provisions of the Agreement before 1 January 2000. To this end, the Industrial Property Act 2001 was passed unanimously by Kenya’s parliament in June 2001. But it has yet to come into operation. We learned, however, that the KIPO is currently working on the regulations to operationalize the Act.

3.3.2 Tanzania and Uganda

Tanzania and Uganda are classified as being among the Least Developed Countries (LDCs). In this respect, they have been allowed a transition period of 10 years to bring their intellectual property law completely into line with the rules of the TRIPS. In practice, Tanzania and Uganda are expected to enact their legislation on intellectual property protection by 2006 (art.66 (1)). The Agreement specifically recognises the economic, financial, administrative and technological constraints of the least-developed countries. It therefore provides the possibility for further extension for the transitional period. This possibility has in fact turned into reality by the partial extension of the implementation end line for least developed countries

³¹ Velasquez, G and P.Boulet (1999): Globalization and Access to Drugs. Perspectives on the WTO/TRIPS Agreement, WHO/DAP/98.9 Revised.

for pharmaceutical patents to 2016 under the WTO Ministerial Declaration of 2001.³²

4.0 POTENTIAL HUMAN RIGHTS IMPACTS OF TRIPS/PATENT PROTECTION IN EAST AFRICA

4.1 Introduction

Intellectual property rights has been recognised and protected for many years. In deed, article 27 of the Universal Declaration of Human Rights (UDHR), 1948 provides for the right of everyone to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is author.³³ Since UDHR is of non-binding nature, the same provisions were subsequently incorporated in a similar wording in 15 of the International Covenant on Economic Social and Cultural Rights (ICESCR) in 1966.³⁴ These two instruments now form the legal basis for the argument that intellectual property rights are human rights although there are still philosophical problems with the acceptance of this assertion.³⁵ The philosophical problems notwithstanding, intellectual property rights are now within the normative framework of human rights and any discourse within intellectual property can no longer ignore human rights standards and go scot-free

Traditionally, intellectual property rights have always been characterized by the search for the proper balance between authors' and inventors' rights and the public interest.³⁶ An objective of IP protection is to promote long-term public interest by means of providing exclusive rights to right holders for a limited duration of time. After the expiration of the term of protection, protected works and inventions fall into the public domain. And anyone is free to use them without prior authorization by the right holder. Increasingly, however, the balance between the right holder and the user of intellectual property has shifted dramatically in favour of the former.

4.2 Implications of TRIPS/Patent protection in human rights

TRIPS largely consolidates and strengthens previous international agreements on IPRs. In this respect TRIPS is not substantially new. However, the most important implications of globalization and full observance of human rights of the Agreement lie in the universalization, harmonisation and minimum-standards application of IPR protection (and of course the method of enforceability through WTO dispute settlement mechanisms).³⁷ In simple words, WTO members are now obliged to introduce IP standards that in many cases increase the *scope* of IPR coverage by, for example, removing exceptions for categories of products such as pharmaceuticals; increase the *duration* of coverage; and increase the *geographical* coverage of IPRs.

³² Adopted by the WTO Ministerial Conference, Fourth Session held in Doha-Qatar, November 2001. WT/MIN (01)/DEC/1, 20 November 2001.

³³ Note that the same article provides for the right of everyone to freely participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.

³⁴ The ICESCR is a legally binding treaty which all East African countries have undertaken to abide by

³⁵ see for example Robert Ostergard, Jr., (1999): Intellectual Property: Universal Human Rights? Human Rights Quarterly, Vol. 21 p156-178 at 158. See also Peter Prove, who maintains that Intellectual Property do not possess the character of fundamental human rights but rather of subordinate or instrumental rights, Peter Drahos

³⁶ International Network on Disarmament and Globalisation at www.indp.org/trips.htm.

³⁶ Max Plank Institute (2001), Report to the Sub Commission on Human Rights, Geneva, June.

³⁷ Oloka Onyango and Udagama (2001) at p. 10.

In respect of international human rights law, since a patent holder can utilize the period of monopoly restriction to prevent competition, “create dependencies or simply make windfall profits at the appropriate moment, such protection can have serious consequences for basic human existence”.³⁸ The danger is that such monopoly control can be given higher priority than ensuring the progressive realisation of human rights such as the right to health, food, access to advanced technology and even the right to development. We illustrated this below.

4.2.1 States obligations to fulfil, promote and protect human rights

TRIPS, like any international treaty, takes away a degree of autonomy from States, but it is appropriate to ask whether this affects East African governments’ abilities to promote and protect human rights, including the right to food, health and development. For example, one of the significant departures under TRIPS from previous treaties on intellectual property rights is that the Agreement obliges East African countries to provide patent protection to cover all forms of technology. This is a significant step. Prior to TRIPS, the States were free to decide what level of protection they would give to cover whatever forms of technology they saw as relevant to their development needs. Thus, measures to protect pharmaceuticals for example could be taken where national development, technological and health requirements suggested such action was beneficial. Such a position was in keeping with the 1986 UN Declaration on the Right to Development which declares that “States have the right and the duty to formulate appropriate national development policies that aim at the constant improvement of the well-being of the entire population and of all individuals, on the basis of their active, free and meaningful participation in development and in the fair distribution of the benefits resulting therefrom.”³⁹ The Agreement’s obligation to provide protection for all forms of technology will have a direct impact on East African governments’ ability to decide on national development strategies.

4.2.2 Right to food

The international human rights law recognises everyone’s right to ‘an adequate standard of living for himself and his family including adequate food...and to the continuous improvements of living conditions’. (art. 25 of UDHR and art. 11 of the ICESCR).

The farming system of the poor rural in East Africa works to a large extent according to the principle of subsistence. These people are dependent on the access to means of production and seeds. They have been cultivating their seeds over centuries and exchanged them between their communities. It is quite obvious that when TRIPS is being implemented in East Africa farmers will relinquish their ownership of seed to foreign companies. Consequently this will impact negatively on food production on local farmers who in Kenya, for example, produce 70% of the total food production.⁴⁰ The report of the US based Institute for Agriculture and Trade Policy (IATP) indicates that already in the US, the Monsanto Company

³⁸ Ibid. at p.10

³⁹ See Article 3(2) of the Declaration on the Right to Development, Adopted by General Assembly resolution 41/128 of 4 December 1986.

⁴⁰ Judith Achieng’, “Kenya: A New Bill To Enhance WTO Agreement Under Fire, 29 July 1999”, allafrica.com.

(recently acquired by Pharmacia, Inc.) has employed Pinkerton detectives to find and prosecute farmers who are harvesting seed from its patented crops.⁴¹ If replicated in East Africa, such enforcement of IPR would violate the human rights of hundreds of millions of farming families who depend on recycling seed for survival. This will also constitute a direct violation of article 1 of the ICESCR which stipulates that “in no case may a people be deprived of its own means of subsistence”.

4.2.3 Traditional knowledge

Traditional knowledge can be referred as information that is communally possessed by people. Many of the activities and products based on traditional knowledge are important sources of income, food and health care for large parts of the populations in Tanzania, Kenya and Uganda. This study fears that TRIPS requisite that an invention must be new will strip farmers and local innovators of their right to technology and knowledge. In other words, TRIPS requirement of patentable inventions knocks off indigenous people who have been using inverted arts and technologies for generations. The definition of “patentable subject” almost dismisses the knowledge systems of the innovations of indigenous people and farmers because they innovate communally over time and even generationally. There also remain a risk that traditional knowledge will be appropriated, adapted and patented by scientists and industry for the most part from developed countries with little or no compensation to the custodians of this knowledge and without their prior informed consent.

4.2.4 right to enjoy benefits of scientific progress and its applications

International human rights law recognises the rights of everyone to enjoy the benefits of scientific progress and its applications (Article 15 (1)(b) of ICESCR). TRIPS will have important implications for East African countries regarding the conditions for their access to and use of technology, and their economic and social development. The point is that, the concept of patenting itself (non disclosure of invention for a period of 20 years) makes technology transfer difficult and certainly more costly.⁴² TRIPS will not therefore facilitate technology transfer from developed world to East Africa. Strengthening IPRs protection, in such, may lead to increased royalty payments required by technology-holders. These factors will reduce/strict the ability of East African governments to catch up through imitation and adaptation of advanced technologies.⁴³

4.2.5 the right of people to freely dispose of their natural wealth and resources

⁴¹ See the Report of the Institute for Agriculture and Trade Policy (IATP) to the UN High Commission on Human Rights, August 2000. Geneva.

⁴² The past president of the Licensing Executive Society (LES) of Britain and Ireland, Donal O’Connor admitted that the hypothesis linking increased IPR protection to technological transfer and investment flows for developing countries “has not by any means been proven. It is one that we in LES wish to accept because it is one that we consider attractive” (cited in Shell, S., (1998) Power and Ideas, Albany, State University of New York Press at p. 222).

⁴³ Oxfarm Policy Paper, Intellectual Property and the Knowledge Gap (2002) Discussion paper 12/01.

TRIPS could reduce the right of East African peoples to freely dispose their natural wealth and resources. It obliged each member state to allow the patenting of its own biological resources by foreigners. Thus, for example, in some cases, the countries of origin of genetic resources are obliged to provide patent protection even if a foreign company appropriated unlawfully the resources on which it bases the development of products or processes.⁴⁴ These requirements in TRIPS are not only contrary to human rights but also to the regulations of the Convention on Biodiversity (CBD). Ironically, Kenya, Uganda and Tanzania have also signed CBD, which recognises peoples/indigenous rights to their resources in contradiction with TRIPS.

Similarly, we also fear that measures provided in TRIPS encourage bio-piracy of genetic materials from East Africa by powerful transnational companies. Domesticating TRIPS, Vandama Shiva wrote, is tantamount to “giving multinational corporations licence to plunder genetic wealth of poor countries.”⁴⁵

4.2.6 right to health

The right to health has received considerable coverage under international law. There are a number of international and regional instruments, binding and non-binding that have elaborated on this right giving it great prominence. These include UDHR, ICESCR and the WHO Constitution of 1947. Among the steps to be taken by States parties to achieve the full realisation of this right shall include those necessary for the “prevention, treatment and control of epidemic, endemic, occupational and other diseases” and “creations of conditions which would assure to all medical service and medical attention in the event of sickness”. Against such a background TRIPS have particular relevance especially in developing contexts.

(a) Patents will lead to higher drug prices and thus restricts access

Patent protection increases the likelihood that prices for a patented product will be higher especially if competition is limited in East Africa. Price data suggest that prices of a patented drug drop quickly and dramatically (30 percent) when the patent expires and a generic equivalent comes onto the market.⁴⁶ This study notes that price is an important determinant in access to essential drugs. Thus whenever patents allow companies to price any drug out of the reach of those who need it, public health suffers.

(b) Patent protection will not promote R&D on diseases prevalent in East Africa

One of the main arguments for strong patents is that they are necessary for R&D. Thus patent protection is essential to ensure sufficient research and development for new medicines.⁴⁷ It is therefore argued that the reason there is little investment in

⁴⁴ See Report of the German Commission of Justice and Peace to the UN Commission on Human Rights, 2001

⁴⁵ Vandama Shiva, (2001): *The Violence of the Green Revolution*. This view is also shared by the Indian Minister for Trade and Commerce who once stated that there are nothing but theft of the intellectual property right of the poor by the rich sanctioned by the TRIPS., TWN, 21 July 2000.

⁴⁶ Medecins Sans Frontiers,(2001): “The role of Patents in Access to Essential Medicines, November.

⁴⁷ For a detailed analysis of this assertion, see Harvey E. Bale, (2000): “TRIPS, Pharmaceuticals and Developing Countries: Implications for Drug Access and Drug Development”, Paper presented at a Workshop on the TRIPS Agreement and its impact on pharmaceuticals, Jakarta, Indonesia, May.

tropical disease research is because of patent protection in the countries most affected by these diseases is weak.⁴⁸ While this might be true, we suspect that drug development for neglected diseases-conditions that mainly or only affect people in developing countries including East Africa - will not increase no matter how stringently patents are protected. This is because the people suffering from neglected diseases do not represent a lucrative enough market to drive research.⁴⁹ Data shows that pharmaceutical industry in the developed countries has devoted very limited attention to diseases of particular prevalence in the developing countries. In fact only 1 per cent of the new chemical entities marketed between 1975 and 1997 related to tropical diseases (they rather prefer the 'lifestyle' drugs).⁵⁰ More importantly, we note that there is nothing in TRIPS that obliges the industry to use the increased patented rents for research on diseases prevalent in these countries. Patents, we fears, may even hamper medical research activities by creating control over research knowledge, which can then only be accessed through costly licensing agreements. This kind of arrangement is usually out of reach of governments and research institutes in East African countries.

At present, this study found that TRIPS does not adequately reflect the fundamental nature and indivisibility of all human rights including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food and the right to self- determination. The Agreement has skewed the balance inherent in IP law systems away from the public interests and in favour of IPR holders.⁵¹ In contrast to the rest of the agenda in the Uruguay Round, the negotiations over TRIPS were not about freeing trade. Rather, they were about more protection and tighter control. What does this imply? Given the fact that TNCs are the holders of the largest percentage of IPRs, it is quite clear that the main thrust of the negotiations favoured the enhancement of monopoly corporate power.⁵² Concerns about TRIPS promoting the concentration of ownership of IPRs in developed countries and powerful non-state actors are thus quite understandable. This is particularly the case because prevailing definitions of IPRs in TRIPS take more account of the interests of the producers (owners) of knowledge than they do the users.

4.3 Any room for manoeuvre?

There are a number of provisions in TRIPS that in one way or another may sets the foundation for the balance between the interests of the society and those of the individual in which both the users and producers of technology benefit from the scientific progress. The first one is article 7, which states:

“the protection of intellectual property rights should contribute to the promotion of *technological innovation* and to the transfer and dissemination of technology, to the mutual advantage of producers and users of

⁴⁸ Lanjouw, J., (2001): “A Patent Policy Proposal for Global Diseases”.

⁴⁹ A study done by Health Action International (HAI) in 1998 found that 75 percent of the world’s population in developing countries consume only 14 percent of the word’s drugs supply while 15% of the population in industrialised countries consume 86 percent.

⁵⁰ Z. Mirza, (1999) “WTO, pharmaceuticals and health: impacts and strategies”. International Round Table on “Responses to globalisation: rethinking equity in health”, Geneva, 12-14 July, p.21.

⁵¹ The UNDP Human Development Reports of 1999 and 2000 identify circumstances attributable to the implementation of the TRIPS Agreement that constitute contravening of International Human Rights Law.

⁵² Oloka Onyango and Udagama (2001).

technological knowledge and in a manner conducive to *social economic welfare*, and to a balance rights and obligations.” (emphasis supplied).

This provision clearly sets the foundation for the balance between the interests of the society and those of the individual in which both the users and producers of the technology benefit from the scientific progress. This provision should shape the interpretation of all the other provisions of TRIPS. This imperative finds support in Article 31 of The Vienna Convention on the Law of Treaties, 1969 that: “a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”

Similarly, article 8 (1) of TRIPS *may* allow East African governments to adopt legislative and administrative measures that are conducive to the protection of some of the human rights recognised in the ICESCR, in particular, health care, nutrition, and environment. However such measures are limited in the sense that they have to be consistent with TRIPS as aforementioned.⁵³ Paragraph 2 of this fundamental article should also be mentioned in so far as it once again expresses the need for a well-balanced interpretation of measures to protect IP. These should be protected in such a way that they do not give rise to abuses detrimental to the necessary balance between national objectives and sectoral interests for which the state is the guarantor. Thus in accordance with article 8.2 “appropriate measures provided that they are consistent with the provisions of this agreement may be needed to prevent the abuse of IP by right holders or the resort to practices which unreasonably restrain trade or adversely affect international transfer of technology”. We also note article 66 (2) of TRIPS which encourages international co-operation. Under this provision developed countries are obliged to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least developed countries and to provide, on request technical and financial co-operation in favour of developing and least developed countries.⁵⁴ This obligation tallies with the obligation of international co-operation under the ICESCR.

All the above, it seems that the above provisions are included in TRIPS to make for a balance between the rights of patent holders and their obligations *vis a vis* society. The provisions may open a possibility of establishing national policies on intellectual property taking into account the fundamental human rights of the people. Although we noted these provisions is not the same as saying that TRIPS takes a human rights approach to intellectual property protection. Rather there remain fundamental differences of approach. This is because TRIPS places a kind of strict interpretation that should not affect private property. The various links with the subject matter of human rights - the promotion of public health, nutrition, environment and development – are generally expressed in terms of exceptions to the rule rather than the guiding principles themselves and are made subject to the provisions of the Agreement.

⁵³ TRIPS Agreement, Article 8 states that ‘members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest sectors of vital importance to their social economic and technological development, provided that such measures are consistent with the provisions of this agreement.’

⁵⁴ TRIPS Agreement, article 66 (2)

A human rights approach, on the other hand, would explicitly place the promotion and protection of human rights in particular those in ICESCR, at the heart of the objectives of IP, rather than only as permitted exceptions that are subordinated to the other provisions of the Agreement. This is not to say that the protection of commercial objectives is necessarily incompatible with the promotion and protection of human rights. Nonetheless, if we truly wish to factor the promotion and protection of human rights into the objectives of TRIPS, different ways and strategies of promoting and protecting scientific progress and its results should be explored in particular cases. The next section attempts to analyse the issue of pharmaceutical patents and access to HIV/AIDS drugs in East Africa.

5.0 A CASE OF PHARMACEUTICAL PATENTS AND HIV/AIDS GENERIC DRUGS IN EAST AFRICA

5.1 Introduction

UNAIDS figure indicates that of the more than 28.1 million people living with HIV/AIDS in Sub Saharan African about 4.2 million live in East Africa.⁵⁵ The HIV/AIDS pandemic has a significant impact on the enjoyment of not only the right to health but also other human rights like the right to education and ultimately the right to development. A recent report of UNAIDS illustrates the developmental dimensions of HIV/AIDS; households caring for a family member with AIDS suffer dramatic decreases in income. In the agricultural sector, the sickness of farm workers has resulted in a fall in agricultural output and might threaten food security.⁵⁶ Indeed, HIV is the biggest development challenge for the countries of East Africa and if the spread of the disease is not curbed, there will be a substantial effect across the spectrum of economic variables including GDP growth, poverty, labour supply, domestic savings and productivity.⁵⁷ The UN High Commission for Human Rights has also recognised that the AIDS epidemic “can have a uniquely devastating impact on all sectors and levels of society. In this regard, she called upon states ‘[t]o refrain from taking measures which would deny or limit equal access for all persons to preventive, curative or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS.

5.2 Pharmaceutical Patents

TRIPS through article 27(1) extends patentable subject matter to both products and processes in all fields of technology in all WTO Member States provided they fulfil the criteria for patentability.⁵⁸ This qualified pharmaceutical, both processes and products, for patent protection. As soon as the Agreement applies in a member state, the patent holder should therefore have the legal means to defend against copies of patented drugs.⁵⁹ The extension of patent protection to all pharmaceutical products and process has generated considerable controversy and has placed TRIPS at the

⁵⁵ UNAIDS: AIDS epidemic update December 2001

⁵⁶ UNAIDS, Report on the Global HIV/AIDS Epidemic, Geneva, June 2000, (UNAIDS/00.13E), p. 26.

⁵⁷ Kenya Central Bureau of Statistics, Economic Survey, 2001 at p. 14.

⁵⁸ Article 27(1) states: “Subject to the provisions of paragraph 1 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application....”

⁵⁹ For more discussion on TRIPS and Pharmaceutical patents see, Velasquez,G., P.Boulet (1999).

centre of the global debate about access to medicines especially for HIV/AIDS, tuberculosis and malaria in poor countries.⁶⁰

5.3 The issue of access to HIV/AIDS drugs in East Africa

UNAIDS figures indicate that more than 95% of all HIV-infected people now live in the developing world which has likewise experienced 95% of all death to-date from AIDS. While there are drugs which are known to retard the effects of HIV and increase possibilities of longer life in dignity, it is pathetic to note that the majority of these people can not have access to them. In Kenya for example, where at-least 2.2 million people are infected with HIV, medical experts however say that the number of people on any type of antiretroviral therapy is less than 8,000.⁶¹ According to the Kenya Minister of Trade and Industry, antiretroviral drugs needed by AIDS patients cannot be imported and distributed free of charge because of their exorbitant costs.⁶²

The problem of access to HIV/AIDS lifesaving drugs is common to all East African countries. As HIV/AIDS is quite recent in medical history, most of the life-saving HIV drugs are patented under IPR law against exploitation until patent expires.⁶³ This gives pharmaceutical companies a monopoly and ensures high prices of drugs. While the study acknowledges the relevancy of patent protection and contribution of medical research in offering medical solutions, it also finds that protection and enforcement of pharmaceutical patents could provide a basis for charging higher prices for drugs and for technology transfer which can restrict access to drugs by the poor in East Africa. Three studies using detailed market data on new pharmaceutical products predict upper-bound mean price increases of well over 200 percent with the introduction of product patents.⁶⁴ These studies also shed light on the impact of competition in developing countries that do not allow product patents and have generic drug manufacturing capability.

The World Bank has also noted that IPRs can sometimes prevent the distribution of potential international public goods helpful to poor countries, which can seldom afford the prices charged by patent owners.⁶⁵ Accordingly, the UNAIDS report shows that the high prices of HIV treatments are due, in part, to patent protection which allows control over their manufacture and sale. The problem becomes particularly acute as developing countries have a high dependence on private

⁶⁰ As stated earlier, previously the GATT, the predecessor to the WTO/TRIPS, did not address the issues of the level of protection that should be accorded to Intellectual Property and member states had adopted various approaches towards drug patents. While some used to grant patents for pharmaceutical product and process inventions, some others allowed patent protection only for process inventions, thus not preventing local companies from developing different manufacturing processes for drugs that were not patent protected as a product. Other countries, such as Tanzania and Uganda did not grant patents for pharmaceutical products under their national legislation. Moreover, the term of protection conferred by a patent varied greatly between countries. Some others pharmaceuticals were not patentable. See also UNDP Human Development Report 2000, box 4.9, p.84

⁶¹ Judith Achieng, "Kenya: "Industrial Property Rights Bill Runs Into Trouble", May 1999", allafrica.com.

⁶² Othello Gruduah, Nairobi can manufacture, import HIV/AIDS drugs, [The East African Standard](http://www.theeastafrican.com), November 2001.

⁶³ UNAIDS, (2000): "Patent situation of HIV/AIDS related drugs in 80 countries", Geneva.

⁶⁴ Challu, Pablo(1991): "The Consequences of Pharmaceutical Product Patenting", *World Competition*, Vol.15, No.2, December, pp 65-126; Fink, C., (2000): "How Strong Patent Protection in India Might Affect the Behaviour of Transnational pharmaceutical Industries", Policy Research paper No. 2352, the World Bank, May available at www.worldbank/research, and Watal, Jayashree (2000): "Pharmaceutical Patents, Prices and Welfare Losses: A simulation Study of Policy Options for India under WTO TRIPS Agreement", [The World Economy](http://www.worldbank.org), Vol. 23, No.5, May, pp.733-752.

⁶⁵ World Bank, World Development Report 2000/ 2001, Washington DC, p.84

expenditure for the purchase of medicines compared to developed countries in spite of their higher levels of poverty.⁶⁶ As a result, the report notes, the entire region is suffering from reverse equity-the poor are paying more than the rich. One study found ciprofloxain to be twice as expensive in Uganda as in Norway.⁶⁷ Similarly, another study comparing retail prices of drugs showed ten out of 13 commonly used drugs are more expensive in Tanzania than in Canada.⁶⁸ The huge disparity in average income between the two countries also means that a Tanzanian would have to work 215 days to buy these 13 drugs while a Canadian would only have to work 8 days.⁶⁹

There are admittedly many factors that influence access to drugs. WHO has recognised four principle factors: rational selection and use of drugs, affordable prices, sustainable financing and reliable health and supply systems. While all these factors require a holistic approach the issue of affordability is of relevancy to East Africa. The presence of IPR protection over drugs can play a role in determining the affordability of drugs. In Kenya, for example, where drugs are not subject to price controls and where there is little or no medical insurance, patent holders face no pressure whatsoever to market their drugs at affordable prices.⁷⁰ It is therefore clear that patents protection affects access to HIV/AIDS drugs, in particular to those who live below the poverty line in East Africa.

The study however finds that affordability of drugs also depends on other factors such as level of import duties and tariffs, local taxes, limited competition and mark-ups for wholesaling, distribution, and dispensing. There are cases where particular drugs are not under patent protection either because no patent was initially granted or it has expired. In both situations still access to those drugs will vary from country to country. While we maintain this assertion we still hold that in the context of HIV/AIDS treatment in East Africa, high prices have had a substantial impact of impeding access to drugs to sufferers. This is not to suggest that without patent, everyone will access drugs. There are those in the East African society who will not afford the drug even below cost price. Then there are other barriers that will affect access like lack of information, poor infrastructure etc.⁷¹ Nonetheless, although the price of AIDS drugs is by no means the only obstacle in providing treatment to about 4 million patients in East Africa, it remains an important one. The key question is therefore what measures might East African countries adopt in the TRIPS environment to keep patented medicine prices at the possible low-cost consistent with international human rights obligations.

5.4 TRIPS and Access to essential drugs

TRIPS does not expressly promote affordability of medicine. It rather contains a number of provisions that East African governments may use to strike the desired

⁶⁶ Watal, J, Jayashree, (2001)“Workshop on differential pricing and financing of essential drugs”, background note, WTO secretariat, April at p.25.

⁶⁷ see Press Release of Medecins Sans Frontiers (MSN): “New Study Shows East Africans Pay More Than European for Life-saving Drugs, regional Leaders Call For Action”, Nairobi, June 16, 2000. see also Kirsten Myhr, HAI, (2000) “Pharmaceutical Pricing: Law of the Jungle”, June.

⁶⁸ Bala K, Lanza O, Kaur SR. (1998): Retail drug prices: the law of the jungle. *HAI News*, April,1-16.

⁶⁹ Kirsten Myhr, HAI, (2000) “Pharmaceutical Pricing: Law of the Jungle”, June.

⁷⁰ Medecins Sans Frontiers (MSN), Press Release, June 2000.

⁷¹ See Press Release of International Federation of Pharmaceutical Manufacturers Association, September 21, 2001. See also, Harvey E. Bale, Access to Essential drugs in Poor Countries-Key issues: The Industry Perspective.

balance between private and public interest, such as access to essential drugs. Needless to say, the issue of implementing these provisions is riddled with continuous controversy probably due to the lack of clarity built in those provisions. The provisions are loosely crafted and susceptible to differing interpretations hence the terminologies like “strict interpretation” and “flexible interpretation” used is the arguments for or against strong patent protection. This section explores several policy options permitted under TRIPS- including compulsory licenses and parallel imports for affordable access to patented medicines - might be adopted without running afoul of the obligations imposed by TRIPS.

5.4.1 Parallel Importation

Parallel importation in patented products is legally permissible under what is called ‘the exhaustion of rights’ doctrine. This doctrine states that once a producer of a patented product or its agent has sold its product in good faith to an independent party, the patent holder’s right to determine the conditions under which the product is resold is exhausted. If there are price differences among customers of the original manufacturer, any customer can engage in arbitrage transactions that exploit those differences.⁷² Parallel importation has been therefore described as importation, without necessarily having the consent of the patent holder of a product legally marketed in another country either by the patent holder or with the patent-holder’s consent. Thus, where a patented drug is marketed at a cheaper price in one country, another country can benefit from the cheaper drug through importing it rather than pay the more expensive equivalent directly from the patent holder.⁷³ The use of parallel importation becomes in this way a tool for improved access to medicine for HIV/AIDS sufferers in the region.

For East African countries “parallel importation” can be a significant way of increasing access to not only HIV/AIDS drugs but also other essential drugs where the prices charged by patent holders for their products are unaffordable. Moreover, in situations where the local manufacture of the product is not feasible, and therefore compulsory licenses may be ineffective, parallel importation may be a relevant tool to ensure access to drugs. This measure is of critical importance particularly at this time when the East African countries are over burdened with the need to improve health care due to the HIV/AIDS pandemic. The legal basis for the use of parallel importation is in Article 6 of TRIPS, which explicitly states that practices relating to parallel importation cannot be challenged under the WTO dispute settlement system, provided that there is no discrimination on the basis of the nationality of the persons involved.

Article 6 therefore gives East African countries a green light to incorporate the principle of international exhaustion of rights in their national legislation. It is now widely understood to mean that parallel importation is effectively a matter of national discretion. Although Article 6 is viewed by some critics of TRIPS as an indication of a failed agreement on the issue of exhaustion,⁷⁴ its use is in keeping with the freedom given to member states under Article 8 and states obligations in

⁷² E.M.Scherer and Jayshree Watal (2001): “Post-Trips Options for Access to Patented Medicines in Developing Countries, Commission on Macroeconomics and Health, Working Paper Series No.WG4:1, June at p.31.

⁷³ Carlos.M. Correa, (2001): “Public Health and Patent Legislation in Developing Countries”, Tulane Journal of Technology and Intellectual Property, p.17.

⁷⁴ See for example, Vincent Ciappetta,(2000): “The Desirability of Agreeing to Disagree: The WTO, TRIPS, international IPR Exhaustion and a few other things”, Michigan Journal of International Law, at p.1.

respect of the right to health under International human rights law. Consequently, East African countries can determine the extent to which the principle of exhaustion of rights is applied in their own jurisdictions, without breaching any obligation under TRIPS.

5.4.2 Compulsory Licensing

Compulsory licensing is another way of improving access to affordable drugs through the production of generic substitutes. While drugs are patent protected, generic supply must wait until expiry of the patent term, 20 years under TRIPS. States may encourage generic production by taking appropriate legislative and administrative actions, including through the inclusion of exceptions to patent rights, which permit testing, and approval of generics prior to the expiry of the IPRs. This process is commonly known as ‘*early working*’ or ‘*bolar exception*’. Correa notes that most developed countries like Japan, Canada, United States and others have used this method.⁷⁵ However, it is possible to produce generic substitutes even where the patent is still current. This can be achieved through the practice known as ‘*compulsory licensing*’.

Compulsory licensing is a legal option consistent with Article 31 of TRIPS. (However several other provisions are also highly relevant for compulsory licensing particularly article 1,7,8,27.1,30 and 40).⁷⁶ It is the act of granting a licence to enables a competent government authority to license the use of an invention to a third party or government agency without the consent of the patent-holder. The term ‘*compulsory licensing*’ is neither defined nor mentioned under TRIPS. The Agreement prefers to use the term “other use without the authorisation of the patent owner” under Article 31.

Compulsory licences are generally awarded to promote the public interest or in cases of national emergency by ensuring access to products required for such purpose. In practice, if a new pharmaceutical product introduced to the market were to constitute an important innovation or play an essential role in health policy. AIDS is now widely acknowledge as constituting a ‘*national emergency*’ in all East African countries,⁷⁷ within the meaning of Article 31 of TRIPS, the East African governments may deem it necessary to grant compulsory licenses to allow interested third persons to produce AIDS related drugs in order to ensure that it will be more readily available, or more affordable to the general public.⁷⁸ While compulsory licences are not geared towards establishing technology partnerships between patent

⁷⁵ Carlos. M. Correa (2001): “Health and Intellectual Property Rights”, Bulletin of the World Health Organization, 79(5), p.381. It is worthwhile to start that a number of Kenyan pharmaceutical manufactures have become quite quick at manufacturing generics before the expiration of patents. They file the application to register their generic drug with the Ministry of Health during the life of the patent, so that they can start manufacturing their product the day the patent expires.

⁷⁶ F.M.Scherer and Jayshree Watal (2001) “Post-Trips Options for Access to Patented Medicines in Developing Countries”, Commission on Macroeconomics and Health, Working Paper Series No.WG4:1, June.

⁷⁷ See National Aids Policy of Tanzania, 2001.p.13-14.

⁷⁸ By 30 January 2002 three Kenyan pharmaceutical companies have applied for licenses to manufacture generic anti-retrovirals, including AZT whose patent is held by the British giant GlaxoSmithKline to make it available (three drug combination at a dollar a day) to about an estimated 2.2 million carriers of the aids victim in Kenya. In Uganda, the two pharmaceutical firms applied for compulsory licensing for ARVs drugs, including AZT and 3TC, but the Ministry of Health has not issued a licence citing quality concern.

holders and users, they can be useful in providing a local producer the means of supplying needed products at cut-rates.

The UNDP Human Development Report 2000 notes that generic production of the HIV treatment fluconazole, a treatment for AIDS-related meningitis in India has kept the price at \$55 for 150 mg compared with \$697 in Malaysia, \$703 in Indonesia and \$817 in the Philippines.⁷⁹ According to Medecins Sans Frontiers (MSF) generic drugs are around 70 to 90% cheaper than branded drugs. In some cases they can be 200 to 300% cheaper than the branded equivalent made in the West.⁸⁰ In Thailand Fluconazole, which manages cryptococcal meningitis-an infection affecting one in five of AIDS sufferers- was supplied exclusively by US company Pfizer until 1998. Since local alternatives became available, the cost of a daily dosage of 400mg has fallen from US\$ 14 to 5% of that price. Thus, it costs only USD \$0.30 a day price in Thailand. However this same drug costs USD 18.00 a day in Kenya where it is patent protected.⁸¹

In the context of human rights and particularly the right to have an access to essential drugs, compulsory licensing is therefore a very crucial element in a health-sensitive patent policy. Such licenses may constitute an important tool to ensure affordable drugs through competition without denying the patent owner compensation for his invention thereby promoting the realisation of the right to health.⁸² Empirical evidence demonstrates that many countries have historically resorted to compulsory licenses,⁸³ without necessarily hurting the patent system. Countries like those in Europe, North America, Japan, and many others, for instance, are not only among the main users of the patent system, but also seem to be great users of compulsory licenses.⁸⁴ The recent example of Canada and the US are illustrative. Canada and US were at the verge of issuing compulsory licences for the production of ciproflaxacin in the wake of the bio-terrorism scare of anthrax attacks that followed the September 11 terrorist attacks in New York. Bayer, a German pharmaceutical company holds the patent right for ciproflaxacin. On the strength of this possibility, the governments of both countries managed to out-negotiate Bayer on price cuts for the drug.⁸⁵ This was to cope with what has been described as a “psychological emergency.” HIV/AIDS in the East African case is a real and extreme physical emergency. The governments should not sit back and watch its population ravaged by the scourge. The provision of AIDS drugs is a way of ensuring that those who are infected with HIV contribute to society fully and ensure their ailments with a measure of human dignity.

Compulsory licenses should not however, be seen as a ‘magic wand’ for obtaining affordable access to patented HIV/AIDS drugs in East Africa as there are some

⁷⁹ UNDP, *Human Development Report, 2000*, supra, p. 84.

⁸⁰ BBC: Aids drugs and the developing world, November 1999.

⁸¹ Medecins Sans Frontiers (MSN), Press Release: “New Study Shows East Africans Pay More Than European for Life-saving Drugs, regional Leaders Call For Action”, Nairobi, June 16, 2000.

⁸² See, Carlos .M. Correa (2002): “Integrating Public Health Concerns into Patent Legislation in Developing Countries”, *South Centre*, p. 93.

⁸³ James Love (2001): “Compulsory Licensing: Models For State Practice in Developing Countries, Access to Medicine and Compliance with WTO TRIPS Accord” 21 January. Available at< <http://www.cptech.org/ip/>.

⁸⁴ Such as for IBM’s computer and tabulating card machine patents, General Electric’s fluorescent and Eastman Kodak’s color film processing patents See James Love, *ibid*. See also WIPO publication no. 609(E) for a list of the compulsory licensing provisions in specific countries.

⁸⁵ MSN, The Role of Patents in Access to Essential Medicines, November 2001.

basic limitations.⁸⁶ First, compulsory licensees must have the capability to “reverse-engineer” or import the product without the co-operation of the patent owner.⁸⁷ Increasingly, larger domestic companies in East Africa are raising their R&D investments and are collaborating with multinational companies to achieve advanced capabilities and reach more markets. Such cooperation may be accompanied by tacit agreement to restrict competition in some market. Second, exports of compulsory licensed products from large markets destined for small, least-developed countries can only work where the disease patterns are common to both markets. Third compulsory licensees will be only attracted to large and profitable drug markets, and so essential medicines with small potential volumes or mostly poor patients will not attract many applicants, however important it is from the perspective of public health. Manufacture in government-owned facilities may be a solution in such cases, although an element of public subsidy may be necessary.

5.4.3 Differential Pricing

Though not mentioned in the TRIPS differential or tiered pricing is one of the measures that may be used not by individual governments but through international co-operation to increase access to affordable medicine. Differential pricing has been defined as the adaptation, in some measure, of prices to the purchasing power of consumers in different countries.⁸⁸ This could mean, for example, pricing drugs at lower rates for developing countries but maintaining prices in developed country markets. The logic behind differential pricing is that higher prices can be shared in wealthy markets that can afford them, while letting poorer countries enjoy lower prices.

In terms of TRIPS, the use of differential pricing as a measure by a government in co-operation with the international community to safeguard the right to health by ensuring access to medicine through increased affordability may be justified as falling within the general objectives of TRIPS under article 7 and the measures to protect public health under article 8. However, one of the perceived problems with differential pricing is the possibility of low-price drugs being diverted towards wealthy markets. In the case of patented pharmaceuticals, this would lessen the opportunity to exercise IPRs as a means of recouping costs.

In recent years, a number of pharmaceuticals companies have offered discounted HIV/AIDS drugs to African countries on a country-by-country, drug-by-drug basis. Some of these offers were made under UNAIDS’ ‘Accelerated Access to HIV/AIDS Care and Treatment Initiative’ since May 2000. This initiative brings together five companies, all of which have pledged to supply cut-price (up to 85 per cent)⁸⁹ anti-retrovirals to developing country governments. On March 7, 2001, under pressure from activists, America’s Merck Sharpe announced it would offer Crixivan (indinavir) and Stocrin (Efavirenz), for example, to Kenya for US\$600 (Ksh.47,000/-) and US\$ 500 (Ksh. 40,000) a year per person, respectively. In the US, Crixivan costs about US\$ 6,000 (Ksh.470,000) a year per person. In Tanzania, according to the Muhimbili National Hospital costs for a month’s prescription of

⁸⁶ Scherer and Watal (2001) at p.30.

⁸⁷ Transfer of technology, often recommended as a solution, requires the active cooperation of the patent owner or in the context of South-South cooperation, of his competitors.

⁸⁸ Watal J., (2001). p. 11.

⁸⁹ Paul Redfern, “Now Africa to Import Generics”, *The East African*, Monday 17,2001.

anti retrovirals now is at least 56,000/-Tshs..⁹⁰ Before that, the lowest price for the same was about 450,000/-Tshs.⁹¹

Table 4: price status of some life-prolonging drugs in Tanzania

Drug name	Costs-monthly prescription (Tshs)	Costs subscription differential (Tshs).	monthly before pricing
Erit	66,100	510,000	
Videx	56,700	398,200	
Crixivan	76,900	479,200	

Source: Muhimbili National Hospital, March 2002 (Note: 1 US\$=960 Tshs)

Though this price might be seen as a small amount to some of us here, dozens of East African people who have contracted the virus need extra budgeting to manage the drugs at that price. This is from the fact that the majority of them are living on less than 1 US\$ a day.⁹² We however note that due to price reduction the number of HIV infected people taking the anti retroviral has risen. In Kenya for example, one year after a major price reduction was announced by Sharpe, the number of HIV/AIDS infected people taking crixivan and stocrin has risen fivefold to more than 1000.⁹³

Indeed, it should be clear however that reliance on preferential pricing or on donations leaves East African governments dependent on companies' charity, providing only an ad-hoc disease-specific approach to the problem, rather than a systematic solution. For example, in Uganda it estimated that company discounts under the Accelerated Access Initiative are reaching just 1900 patients.⁹⁴ This is in a country where around 1.4 million people are infected with HIV. Moreover, company discounts and donations provide no guarantee that the best price is being obtained. Secondly, even with the discounts on anti-retrovirals offered by the large companies under the UNAIDS, the governments would have only been able to treat a fraction of sufferers and even this would completely wipe out their drug budgets. In addition, discounts may come with conditions, as illustrated by a recent case in which Abbott Laboratories wanted to make its offer of cheaper AIDS drugs and a diagnostic test conditional on undertakings by recipients to forego the import of generic medicines.⁹⁵ These factors demonstrate that discounts and donations should not be seen as a substitute for national legal frameworks for more sustainable and systematic solutions to the problems of price and access to essential drugs. Nor should they be seen as an alternative to governments' legitimate use of TRIPS provisions for parallel importing and compulsory licensing.

5.5 National Implementation

If East African countries could implement TRIPS as it is, some of the human rights concerns could be minimized. However, this is not so. Recent incidents present a

⁹⁰ Dr. M. Janabi,(2002): "Leadership Role in Managing HIV/AIDS Activities", Dar es salaam, 1 March.

⁹¹ Ibid, see also Peter Nyanje, Medic urges caution use of AIDS drugs, The Guardian, 4 March 2002.

⁹²UNDP, Human Development Report, 2001.

⁹³ More Kenyans on Cheaper Aids Drugs, Horizon, 7 March 2002.

⁹⁴ Medicine San Frontiers, (2001) TRIPS and Access to Essential Drugs.

⁹⁵ James Love (2001).

kind of legal pressure which the pharmaceutical companies are exerting for implementing the TRIPS as it is. A number of cases have been cited where the US government (80% of the pharmaceutical industry is based in the USA) has used extra legal means like threats of economic reprisals/trade sanctions against WTO members that have attempted to adopt legislative and policy measures to give effect to those provisions relating to compulsory license or parallel importation. Let us examine the following case:

(a) The South African Court case

South Africa has the world's highest number of HIV infection.⁹⁶ While the HIV/AIDS crisis continued to escalate, more and more new drugs continue to obtain patent protection in South Africa and because of high prices these new drugs attracted, they increasingly became inaccessible especially by the poor. For example, Ciprofloxacin, patented by Bayer in South Africa, is an important anti-bacterial treatment for sexually transmitted disease, childhood shigellosis (bloody diarrhoea) and chest infections. In South Africa it costs R5.6/500mg tablet, which is twelve times the cost of the generic equivalent in India where it sells for around R0.46.⁹⁷ Consequently and in keeping with its obligation to take legislative measure to promote and protect the right to health under International human rights law, the South African Government in 1997 passed "The Medicines and Other Substances Act, 1997.

The Act includes measures which would allow the government, *inter alia*, to:

- 'shop around' for cheaper patented medicines abroad (parallel importing),
- ensure that pharmacists dispense cheaper generic copies where doctors have prescribed more expensive brand-name drugs,
- introduce a transparent pricing system for all medicines.

In March 1998, the Trade Commission of the European Union issued a warning letter to South Africa's Vice President that Pretoria's drug law was at variance with South Africa's obligations under the WTO. He further alleged that implementation of such law would negatively affect the interest of the European pharmaceutical industry.⁹⁸ The US government on its part embarked on the use of economic threats to force the South African government to amend the law. First by cutting aid in 1998, followed by denial of tariff breaks on exports later in the same year and finally placing the country on the "watch list" in 1999.⁹⁹

On 5 March 2001, 39 of the world's largest pharmaceutical companies took the South African government to court challenging the legislation on the grounds that it

⁹⁶ UNAIDS estimates that about 4.7 million people living with HIV/AIDS. See UNAIDS AIDS epidemic update December 2001.

⁹⁷ James Love (2001).

⁹⁸ Simon Taylor, Intellectual Property-Health List Serve, 14 March 2000. See also European Voice, vol.6 of 9 March 2000.

⁹⁹ See James Love (1999): Notes on the USTR watch Lists and Reports, Available at <http://cptech.org>.

violated their intellectual property rights.¹⁰⁰ The pharmaceutical industry maintained their argument against flexible interpretation of TRIPS to allow compulsory licensing and parallel importation preferring instead to embark on concessionary price reductions which do not guarantee sustainable access to medicine. Nonetheless, the companies had dropped their case in April 2001. This legal landmark could be a breakthrough in getting treatment to millions of people living with HIV/AIDS in South Africa and other developing countries. However, the development may be only a pyrrhic victory. Many observers have pointed to the fact that the withdrawal represents only a temporary respite: according to Samanta Sen, “the decision to withdraw was a tactical move, rather than a sudden and joint discovery of social responsibilities. There were indications enough from the court already that the verdict would go against the drug companies.”¹⁰¹

However, given all the above scenario, we can still raise a major question: is the Agreement going to be ensured by the powerful to protect corporate profit regardless of the cost in human life? How TRIPS can be used to ensure access to innovation and affordability of pharmaceutical is the challenge, the governments, NGOs, consumers and all people interested in justice face.

5.6 Recent developments on TRIPS and Access to Essential Drugs in East Africa

5.6.1 Kenya Industrial Property Act, 2001

Kenya’s passed a new Industrial Property Act 2001. The Act seeks to modernise an important part of Kenya’s regime of intellectual property rights and brings it into conformity with the TRIPS Agreement. The law in Kenya faced concerted lobbying by the pharmaceutical companies against its passage.¹⁰² The Bill had encountered opposition from the public and humanitarian organisations.¹⁰³ Arguably, it would impact negatively on Kenya’s agriculture and health care services, mainly by making the importation of critical chemicals and drugs more difficult due to patent protection. In addition to having a negative effect on Kenya’s ability to provide affordable health care, organisations concerned with Kenya’s property bill said that the proposed legislation would set a bad precedent for Uganda and Tanzania, and weakens these countries’ bargaining position in 2006.¹⁰⁴

In contrast, the country’s new law allows for the importation and production of more affordable medicines for HIV/AIDS and other diseases.¹⁰⁵ Notably, section 81 empowers the government to licence local manufactures to produce generic versions of any medicine locally during a medical crisis. The Act explicitly mentions of high prices as grounds for issuing compulsory licenses. There are fears however that the local manufacture of generic drugs will not commence any time soon, as Kenya’s Ministry of Trade has not published a gazette notice to bring the Industrial Property Act 2001 into force. Critics of the government’s delay say that the government is

¹⁰⁰ See: Pharmaceutical Manufacturers’ Association of South Africa and Others vs. The President of the Republic of South Africa and Others, case no: 4183/98; In the High Court of South Africa (Transvaal provincial division).

¹⁰¹ Samata Sen, “AIDS: more legal battles in the offing”, *The East African*, 23-29 April 2001, p. 7.

¹⁰² Dagi Kimani, “Politics derails HIV generic drugs bill”, *The East African*, 7-13 May 2001, p. 32.

¹⁰³ Dagi Kimani, “Intellectual Property Bill Faces Opposition”, *The East African*, May 29, 2000.

¹⁰⁴ Dagi Kimani, *ibid*.

¹⁰⁵ see also statement by Chris Ouma, Kenya National Aids Programme Coordinator for Action Aid, Kenya Industrial Property Bill May provide a Solution to HIV/AIDS sufferers., November 200, allafrica.com/stories.

dragging its feet due to vested political interests, as well as pressure from multinational drug companies whose regional offices are based in Nairobi.¹⁰⁶ The challenge for the Kenyan government is now to ensure that application of this important law will not be controlled by powerful multinational corporations.

5.6.2 The Doha Ministerial Declaration on TRIPS and Public Health

The fourth WTO Ministerial Conference ended with the adoption of the Declaration on TRIPS and Public Health.¹⁰⁷ This declaration is a very significant achievement as far as the realisation of the right to health is concerned. The declaration recognises the gravity of the public health problems afflicting many developing and least developed countries especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. This is balanced with the recognition of the importance of intellectual property protection for the development of new medicines but also the concerns about the effects of such protection on the price of medicines. In other words, the declaration states that IPR protection is necessary for encouraging medical research, but the society should access the products at affordable prices.

The most important element of this declaration however is the agreement of the WTO members that TRIPS does not and should not prevent members from taking measures to protect public health. It further affirms that the agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and in particular to promote access to medicine for all. The declaration therefore gave teeth to the measures that countries can use to counteract them. These measures include the right to grant compulsory licences (overriding patents) and the freedom to determine the grounds upon which such licenses are granted. Now if drug companies price drugs beyond the reach of people who need them, East African governments can override patents without fear of being dragged into a legal battle.¹⁰⁸ Although declarations are normally considered non-binding, (in fact does have a clear political statement that public health concerns must override commercial interests) this particular one represents the will of the majority of the WTO members. Now it is up to the East African governments to use this power to bring down cost of medicines and increase access to life-saving AID drugs.

6. CONCLUSIONS AND RECOMMENDATIONS

The WTO/TRIPS Agreement sets out the minimum standards for patent protection that the East African countries must abide by. The domestication of the Agreement in these countries is likely to have an impact on people's access to food, health, indigenous/traditional knowledge and technological advancement. The major implications concerning access to HIV/AIDS drugs are linked with the strengthening of the monopoly of working conferred by a patent on its holder and the extension of patent protection to all pharmaceutical products and processes. Such monopoly could have a significant impact on accessibility and affordability of drugs in East Africa. However several policy options- notably, compulsory

¹⁰⁶ Othello Gruduah, Nairobi can manufacture, import HIV/AIDS drugs, The East African Standard, November 2001.

¹⁰⁷ World Trade Organisation, Ministerial Conference, Doha, 9-14 November 2001. Doc no. WT/MIN(01)/DEC/W/.

¹⁰⁸ Paul Redfern, Now Africa to Import Generics, The East African, Monday 17,2001.

licensing, utilizing parallel importation, and enforcing differential pricing might be adopted by the East African governments within the TRIPS environment to address issues of access to and prices of essential drugs.

While it is quite obvious that the interpretation and implementation of the Agreement is in the hands of the States, differential powers, influence and resources clearly place a limitation on the room for manoeuvre actually stipulated within the Agreement. Needless to say, a patent is not an absolute right nor an end in itself, rather it constitutes public policy tool with which to achieve benefits for society as a whole. Public health concerns should be highly considered when implementing TRIPS Agreement at national levels. Here I would like to make some suggestions:

- **Fullest use of the transition period**

The governments (particularly of Tanzania and Uganda) should make the fullest use of the transition period they have been granted to prepare themselves for the consequences of the implementation of the Agreement.

- **Use compulsory licenses to achieve public interest goals:**

In accordance with TRIPS, compulsory provisions should be available and easy procedures for granting a compulsory license should be in place. The grounds for granting compulsory licences include: abusive pricing making the product inaccessible for the majority of the population, patent owner's refusal to deal; non-commercial use by the government; and for public interest (such as public health emergency).

- **Permit parallel imports of pharmaceutical**

National drugs policies and regulations should include the right to shop globally for the best prices. Parallel imports are particularly important for the East African countries with their smaller economies that suffer from inadequate competition. Where allowed, parallel imports have shown to be effective in lowering drug prices.

- **Legal and Institutional framework**

Devise consistent legal and regulatory framework that will foster pharmaceutical companies incentives to continue research into new drugs while at the same time finding the ways of improving access to drugs by the poor.

- **Focus on alternatives that promote R&D for drugs needed locally**

Patents are not the only means for promoting R&D nor do they ensure that needed drugs are brought to market. The countries need to look at a series of other issues that would help stimulate R&D such as budget allocations on research and development.

- **As the impact of the implementation of the TRIPS on access to drugs is currently subject to debate, countries are advised to make maximum use of transitional periods provided for in the Agreement.**

- national drugs policies should define strategies and guidelines for the new regulations on patents, the new conditions for the transfer of technology, the new orientation of R&D etc. All of these elements could have an important impact on access to drugs.
- Ministries of Health should request to be involved in the revision process of patents laws from the beginning. Collaboration between MoH and public health NGOs should be strengthened to ensure that safeguard measures such as compulsory licenses and parallel imports are included in the patent law to avoid potential abuses from patent owners.
- Ensure participation of all segments of population in the formulation of new intellectual property policy.
- Integration of Intellectual property policy making with that of wider national economic policy and strategies for public health - the government need to look into other factors including a broad range of government policies such as the National Health Policy, National Policy on HIV/AIDS/STDs, Industrial Policy, National Trade policy, Investment policy, procurement system and technological policies.

Issues for further discussion:

- The length and scope of patenting in East Africa
- Capabilities of local pharmaceutical manufacturers to produce generic drugs.
- Whether there may be an economic and social welfare benefit to permitting IPRs holders to block parallel imports that outweighs the potential harm to liberalized trade?
- Transition periods for the implementation of the TRIPS- what should be done?
- Why are drug companies uncomfortable with parallel importation of generic retroviral into developing world including Tanzania, Kenya and Uganda to save millions of mankind who are suffering of the disease?
- Then what is the way forward for the East African countries?

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