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The Implications of WTO Agreement on Trade -Related Aspects of Intellectual Property Rights (TRIPS) in Tanzania: A Focus on pharmaceuticals

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TABLE OF CONTENTS

LIST OF ABBREVIATIONS

GATS	General Agreement on Trade in Service
GATT	General Agreement on Tariffs and Trade
IP	Intellectual Property
IPRs	Intellectual Property Rights
ITO	International Trade Organization
LDCs	Least Developed Countries
MNCs	Multinational Corporations
MTN	Multilateral Trade Negotiations
N	Note
R&D	Research and Development
TNCs	Transnational Corporations
TRIMS	Trade Related Investment Measures
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
UNTS	United Nations Treaty Series
US	United States of America
WHO	World Health Organisation
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1.0 INTRODUCTION

In 1994, the Uruguay Round negotiations of the General Agreement on Tariffs and Trade (GATT) resulted in an agreement establishing the World Trade Organization (WTO), which came into being in 1995. Several treaties on trade in goods and services are annexed to the WTO convention and are binding to WTO members. One of these agreements is the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement).

TRIPS agreement sets minimum universal standards for protection in the field of intellectual property rights. To achieve this goal, it obliges all WTO members to modify their intellectual property laws to make them consistent with the standards set forth in the Agreement. The standardization of intellectual property laws especially in the patent field has raised concerns in developing countries about the extent to which the essentially commercial interests protected by Intellectual Property Rights (IPRs) may be given primacy over public interests including that of public health.

This study aims at discussing the TRIPS agreement and to point to some of the implications on implementing the Agreement in Tanzania. A further objective of the study is to highlight those areas in which the Tanzanian government is left with some room for choice in formulating legislation and policy that accord with the TRIPS agreement.

Organization of the study

The study comprises of seven sections including this introductory part. *Section two* provides a brief review of the WTO. *Section three* outlines the TRIPS agreement focusing on its provisions relating to patents. *Section four* highlights the position of IPRs in Tanzania, particularly in terms of the legal framework on patents protection. This is followed by discussion on status of patents exploitation in the country. *Section five* deals with the implication of the TRIPS agreement in Tanzania. The section further examines the possible impact of WTO-induced legislative changes in the patent protection law focusing on pharmaceuticals. This section also makes a case study of pharmaceutical patents and access to life saving HIV/AIDS drugs that should be available to about 1.5 million HIV victims in the country. *Section six* identifies various options available under TRIPS agreement to ensure accessibility of patented drugs. The section will further look at the actual implementation of these measures by basically bringing out the case study of South Africa as among developing countries that have attempted to implement such remedies and the challenges that they have met. The paper concludes in *Section seven.*

2.0 A BRIEF REVIEW OF WTO

2.1 Attempts to create an International Trade Organisation

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 in 1944. At the time, the regime consisted of the International Monetary Fund and the International Bank for Reconstruction and Development (the World Bank). 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.[1] As part of the ITO negotiations, 23 countries including Canada, United States and Britain came to a consensus that there was a need for immediate process of lowering trade barriers (mainly tariff) among themselves. These 23 countries agreed on a set of mutual tariff reductions which were codified as the GATT, 1947. The GATT was intended to be a stepping-stone to the establishment of the ITO. However, the Havana Charter, which would have established the ITO, was never ratified, meaning the Organisation was never formed (due to some disagreement among the major negotiating powers: USA and Britain). The GATT therefore emerged as the *de facto* international trade organisation (agreement) that came into effect from 1 January 1948.[2]

2.2 The GATT

The main objectives of GATT was to conclude "reciprocal and mutually advantageous arrangements" with a view to reducing customs duties and other barriers to trade and eliminating all discrimination in international trade.[3] 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.

[1] See Marcus Noland, "Understanding the World Trade Organisation", Institute for International Economics, 2000.
[2] Through a Protocol of Provisional Application, the signatory countries agreed to bring the GATT into operation provisionally from 1 January 1948, without waiting for the full ITO Charter to come into effect.
[3] See General Agreement on Tariffs and Trade, 55 UNTS 194 (the original GATT agreement).

Over the years, the GATT evolved through several rounds of negotiations to meet these objectives[4]. The negotiations at first concentrated on lowering tariffs before moving on to additional issues such as subsidies and antidumping.

At the beginning of the 1980s, it became apparent that the GATT no longer so well adapted to the realities of trade as it had been in the 1950's. The complexity and volume of world trade were now very different from what they had been 40 years earlier. As the globalisation of the 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 and more countries and was closely bound up with the increase in global trade in goods. [5] 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.

These and other factors convinced GATT members that a new effort to reinforce and extend the multilateral system should be attempted. [6]

2.3 Moving from GATT to the WTO

In September 1986, Multilateral Trade Negotiations (MTN) of the Uruguay Round were launched at Punta del Este, Uruguay. The Round, the eight MTN conducted under the auspices of the GATT, was a complex set of negotiations undertaken to address the prevailing inadequacies of the GATT. The negotiations encompassed practically all the outstanding problems of trade policy including the extension of the trading system into several new fields, in particular services and intellectual property rights. The negotiations and process concluded with the signing of the Final Act in Marrakesh, Morocco on 15 April 1994,[7] and ultimately the establishment of the World Trade Organisation (WTO), which came into being on 1 January 1995.

The main functions of the WTO are: (i) to supervise and enforce the implementation of the Uruguay Round agreements; (ii) to act as a forum for continuing negotiations on trade and investment rules; and (iii) to settle disputes between member countries through a dispute settlement body. [8]

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[4] The first seven rounds of trade negotiations under GATT were: Geneva (1947), Annecy (1948), Torquay (1950), Geneva (1956, Dillon (1960-61, Kennedy (1964-67) and Tokyo (1973-79).

[5] WTO, "Introduction to the WTO: Trading Into the Future", 2nd edition, 2000.

[6] It is also argued 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 for example, Robert Howse and Makau Mutua, "Protecting Human Rights in a Global Economy: Challenges for the World Trade Organisation", 2001.

[7] The Final Act of the Marrakech Agreement was issued on December 15, 1993 and authenticated by 117 nations on 15 April 1994 at Marrakech, Morocco.

[8] See article III, the Agreement Establishing the WTO, 1994.

The WTO includes a series of key principles that governs its activities. Prime among these is the Most Favoured Nations (MFN) principle.[9] This means that countries should not discriminate between WTO members: any barriers to trade should be applied equally between all countries.[10] In addition, a country should not discriminate between its own products and services and those of other countries.[11] Other key principles include increasing free trade through the reduction of tariff and non-tariff barriers and ensuring that those barriers which do exist are consistent. In addition, it is recognised that not all countries are equal and thus less developed countries should be allowed certain privileges to give them greater time to adjust to the global liberalisation of trade for example, longer periods for their industries to adjust to the lowering of tariffs.[12]

In deciding to become members of WTO, states agree to abide by its rules. The signature of the Treaty Establishing the WTO means adhering to all the multilateral conventions (Multilateral Agreements on Trade in Goods including the GATT 1994; General Agreement on Trade in Service (GATS); and the Trade Related Aspects on Intellectual Property Rights (TRIPS) agreement).[13] Adhesion to the plurilateral trade agreements such as the agreement on Trade in Civil Aircraft and Agreement on Government Procurement is optional.

Enforcement of the rights and obligations of the WTO members is ensured through an integrated dispute settlement process, spelled out in the Understanding on Rules and Procedures Governing the Settlement of Disputes.

9 See article 1 of GATT (1994); Article 2 of GATS; and Article 4 of the TRIPS Agreement.
10 See n 5 above.
11 Some exceptions apply to this rule such as establishment of free trade agreements within a region.
12 See Article XI, the WTO agreement; Article 66(2) TRIPS agreement; and Article 4 of TRIMS
13 See Article XIV (1), the WTO agreement.

3.0 PROTECTION OF INTELLECTUAL PROPERTY RIGHTS IN THE WTO

Before we discuss the current position of protection of IPRs under the TRIPS agreement, we briefly define the concept of intellectual property rights and their protection before the establishment of the WTO.

3.1 Meaning of IPRs and their protection before the WTO

Intellectual property rights are legally enforceable but limited monopoly rights granted by the state to innovators in the industrial, scientific, literacy and artistic field.[14] Intellectual Property (IP) 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 IP and other forms of property, however, is that IP is intangible.[15]

A need for legal protection of intellectual property derives from its two main characteristics. First, IP tends to have high costs of development, and secondly, it tends to have low costs of reproduction. While it costs a lot of money and time to bring a new product such as drug into the market, it is relatively easy for other producers to copy and further develop that product thus offering lower prices.[16] It is argued therefore that without protection from such acts, there would be less innovation. "Nobody would be willing to stump up large amounts of money to develop new products if their inventions could be immediately copied and sold cheaply by others".[17] To be precise, the incentive for innovation is a key justification for IPRs. However, as this study will show, the main return to innovation and incentive for IPRs lies in the markets of the wealthy nations.

Protection of IPRs before the WTO

IPRs have been recognized and protected for many years both at the national and international levels.[18] At the international level, a number of treaties on IPRs have been in existence since the end of the 19th century. The main ones are the Paris Convention for the

[14] World Intellectual Property Organisation (WIPO) *Intellectual Property Handbook: Policy, Law and Use* Publication No.489 (E) Geneva: WIPO, 2001.
[15] As above.
[16] See Bale Harvey, "TRIPS, Pharmaceuticals and Developing Countries: Implications for Health Care Access, Drugs Quality and Drug Development", Geneva: International Federation of Pharmaceutical Manufacturers Associations, 2000.
[17] As above.
[18] For a historical development of intellectual property law, see Peter Drahos "The Universality of Intellectual Property Rights: Origins and Development", *Intellectual Property and Human Rights, World Intellectual Property Rights Organisation*, 1998. See also, J. Phillips and F Alison, *Introduction to Intellectual Property*, London: Butterworths, 1995.

Protection of Industrial Property (the Paris Convention) of 1883[19] and the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention) of 1886.[20] These treaties have dealt in turn with industrial property, trademarks, industrial designs and models, patents, copyright, etc. The World Intellectual Property Organization (WIPO) created in 1967 became the first international organization responsible for enforcing these instruments.[21]

It should be noted here that, the conventions administered by WIPO, in particular the Paris Convention, only impose general rules on IPRs such as the rule on national treatment which requires equivalent treatment for foreigners and nationals. They also include a rule on the right of priority which permits the protection of IPRs in several countries. Explained differently, the Paris Convention did not standardize the substance of patent protection initially or in subsequent negotiations. The Convention does not include requirements regarding patentable subject matter, patent terms, use of compulsory licensing or enforcement to mention some of the main aspects in which patent systems differ. This has been left to the discretion of national legislators. In addition, it is well known that the conventions were not binding upon the states that have not ratified them. As a principle in international law, no state is bound by a treaty which it has not ratified – unless of course the treaty codifies principles of customary international law.

Before the Uruguay Round, 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). Under these provisions, measures which would otherwise be inconsistent with the GATT could be taken (subject to certain conditions) to secure compliance with laws or regulations relating, among others, to intellectual property rights. These provisions were hardly discussed until the GATT ministerial meeting in 1982 brought up the problem of counterfeit goods in international trade. Some countries, particularly the United States of America appeared to be influenced by the perception that their competitiveness, dependent on technology and creativity, was not adequately protected worldwide by existing rules on IP.[22] This led them to argue for inclusion of Intellectual property matters into the Uruguay Round, hence the adoption of the TRIPS agreement.

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[19] The Convention entered into force in 1884 and has been revised several times in 1900 (Brussels), 1911 (Washington), 1925 (Hague), 1934 (London), 1958 (Lisbon) and 1967 (Stockholm) and 1979 (Geneva).

[20] The agreement was adopted on 9 September 1886 in Berne. The 1886 text has been revised several times to take into account the fundamental changes in the literary and artistic works. The major revisions took place in 1908 (Berlin), 1928 (Rome), 1948 (Brussels) 1967 (Stockholm) and 1971(Paris) and 1979 (Geneva).

[21] The Convention Establishing the World Intellectual Property Organisation (WIPO) was signed at Stockholm on July 14, 1967 and as amended on September 28,1979.

[22] Peter Drahos "Global Property Rights in Information: The Story of TRIPS at the GATT, Intellectual Property", Ashgate, 1999.

3.2 The TRIPS Agreement

3.2.1 An overview of the Agreement

As indicated earlier, the TRIPS agreement is an integral part of the agreement establishing the WTO. It was adopted with the other WTO agreements annexed to the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations in 1994. TRIPS agreement therefore forms part of the general substantive rules of the WTO, binding on all WTO members.

The TRIPS agreement establishes for the first time a global minimum standard of IPRs protection. Thus, it represents a major departure from the previous level of international IPR coordination, which, as discussed earlier, was not set up to standardize IPRs legislation between countries, but to guarantee non-discrimination in national intellectual property systems.

First, the TRIPS agreement makes it mandatory for WTO members to provide most of the existing types of IPR protection (patents, copyright, trademarks, trade secrets, industrial designs, layout designs of integrated circuits and geographical indications). The exceptions are utility models and plant breeders' rights.[23] Secondly, it specifies detailed requirements for the substantive content of national IPR legislation regarding for example, extent of coverage, terms of protection, and mechanisms for enforcement of rights of the IPRs holders. The minimum standards of IPRs protection under TRIPS agreement are based on the basic provisions of the principal international conventions in force (the Paris and Berne Conventions) with which the TRIPS agreement will coexist without taking their place.[24] Thirdly, it brings national IPR legislation under the coverage of WTO dispute settlement procedures. This means that non-compliance can lead to cross-retaliation in any field "not only in IPRs, by the country whose nationals are affected by such non-compliance".[25]

In all the areas it covers, the TRIPS agreement provides for the application of the principles of national treatment and of most-favoured-nation treatment.[26]

[23] Note however that members are obliged to provide some kind of plant variety protection as provided for in article 27 (3) of the TRIPS agreement.
[24] Article 2 TRIPS agreement.
[25] South Centre, The TRIPS Agreement. A Guide to the South:: The Uruguay Round Agreement on Trade Related Intellectual Property Rights, Geneva, 1997.
[26] Articles 3 and 4 TRIPS agreement.

3.2.2 Application of TRIPS rules

TRIPS agreement entered into force on 1 January 1995. It however provides a transition period during which members are required to bring national legislation and practices into conformity with its provisions.

The general deadline for implementation was one year after that i.e. 1 January 1996.[27] A distinction however is made with regard to transition period between the least-developed countries and developing countries and also between countries with or without a system of patent protection at the time for the establishment of the WTO. Developing countries such as Kenya had to domesticate the provisions of the TRIPS agreement before 1 January 2000. [28] Except for the provisions of national treatment and most favoured nation treatment which had to be implemented on the general deadline, all Least Developed Countries (LDCs) are given a period of 10 years (from the date of general application), with a possible extension, to harmonize their legislation with the TRIPS obligations. [29]

Having described the TRIPS agreement generally, below we specifically focus on its provisions relating to patents.

3.2.3 TRIPS and Patents protection

TRIPS agreement covers specific areas of IPRs. These include copyrights and related rights (section 1), trade marks (section 2), geographical indications (section 3), industrial designs (section 4), patents (section 5) and Layout Designs (topographies) of integrated circuit (section 7). There is no doubt that the area on patents is where TRIPS agreement makes the most difficult demands to the WTO developing country members. It may be noted here that a patent is a title granted by the state (and/or regional patents organizations) conferring a temporary monopoly for the exploitation of an invention upon the person/entity who reveals it, furnishes a sufficiently clear and full description of it and claims this monopoly.[30]

(a) Patentable subject matter

TRIPS agreement obliged members to provide patents for any inventions, whether products or processes in all field of technology.[31] This can include what people normally think of as inventions (e.g. new drugs), as well as processes to create them. The criterion for an

[27] Article 65(1) as above.
[28] Article 65 (2) as above.
[29] Article 66 (1) as above.
[30] G Velasques and P Boulet "Globalisation and Access to Drugs - Perspective on WTO/TRIPS agreement" *Health Economics and Drugs (EDM) Series No. 7.* WHO/DAP/98.9 revised. Geneva: World Health Organisation, 1999.
[31] Article 27 (1) TRIPS agreement.

invention to be patented is that, it must be new, involves an inventive step and be capable of industrial application.[32] However, there are three types of exception to this rule. Under Article 27 (2) and (3), members may not grant patents on:

- inventions the prevention of whose commercial exploitation is necessary to protect *ordre public* or morality especially with regard to protection of human, animal or plant life or health;
- diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and
- certain plant and animal inventions.

While biological processes for the production of plants or animals may be excluded from patentability under Article 27 (3), the same provision states that microorganisms, and microbiological and non-biological processes are not covered and have to be patented. This has raised a number of concerns as "to the nature of some of these biotechnological inventions, which finds their origins in organisms existing in nature".[33] However, it needs to be pointed out that the issue of microorganism is one of the specific aspects for review within the TRIPS agreement.

(b) Scope of protection and rights conferred

Pursuant to the TRIPS agreement, WTO members should provide patent protection for a minimum of 20 years from the filing date of a patent application for any invention either a process or product.[34] Once this period has expired, people are free to use the invention as they wish.

In addition, the TRIPS agreement specifies the rights conferred on a patent owner, including the protection of a product directly made with a patented process, and an exclusive rights to produce, sell and import the protected product or process.[35]

(c) Exceptions to exclusive rights of patent holders

Traditionally, IPRs have always been characterized by the search for the proper balance between inventors and authors' rights and the public interest. That means, finding a balance in the protection of IP between the short-term interests in maximizing access or the long-term interests in promoting creativity and innovation has been a public goal.

[32] As above.
[33] As above.
[34] Article 33 TRIPS as above.
[35] Article 28 as above.

By virtue of Article 30 of the TRIPS agreement, "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. However, reading Article 30 together with Article 7 and 8 of the TRIPS agreement 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.[36]

Article 7 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 technological knowledge and in a manner conducive to s*ocial economic welfare*, and to a balance rights and obligations." (emphasis supplied).

And Article 8 provides 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* in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."(emphasis added.)

In deed, these provisions somehow seek to facilitate legislating limitations to exclusive rights of the patent holders. They clearly set the foundation for seeking a better 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. Although we note the above provisions is not the same as saying that the TRIPS agreement takes a traditional approach of IP protection. Rather, it is strongly questioned whether a balance can be achieved under the present patent regime established by the TRIPS agreement. This is because, the various links with the subject matters of public interests - 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. While avoiding conclusion at this stage, it seems clearly that TRIPS agreement has skewed the balance inherent in Intellectual property law systems away from the public interest and is in favour of IPRs holders. In the first premise, the form of patent protection in

[36] G Velasquez and P. Boulet (n 30 above).

the TRIPS agreement is most relevant to the protection of modern forms of technology such as biotechnology, and most relevant to innovators situated in a selected number of industrialized countries.

Patents strong in developed economies

It may be noted here too that, patents protection under the TRIPS agreement is very relevant to development's level and needs of western countries. This argument is supported by the World Bank figures which show an overwhelming presence of patents holders and applications in developed countries. Table 1 illustrates that the vast majority of world patents are filed and held by individuals and enterprises based in high income countries - reflecting the very uneven distribution of research and development activities.

Table 1: 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

The disproportional ownership of patents between countries of north and the south is also reflected in the UNDP Human Development Report of 1999, which indicates that:

- Industrialized countries own 97% of all patents;
- In 1995, the US received 50% of the global royalties and licensing fees;
- 80% of patents that have been granted in developing countries belong to residents of industrialized countries.

This being the case, it is very likely that patents - being under the hands of multilateral corporations - they are and will be used for corporate rather than the public interests.[37] Before we deal with this issue in detail, it would be relevant to highlight the current status of patents protection and exploitation in Tanzania.

[37] See UNDP, "Globalisation with a Human Face", *UNDP Human Development Report (1999)*.

4.0 POSITION OF INTELLECTUAL PROPERTY RIGHTS IN TANZANIA

4.1 Background to the legal framework

The law on intellectual property rights in Tanzania was introduced, developed and consolidated during the colonial period just as it was to the whole of Africa. This was done so as to intensify colonial exploitation and protect colonial investors.

In respect of patents, the first law was promulgated in 1931, as the Patents (Registration) Ordinance. The Ordinance - modelled after the British Patents, Designs and Trade Marks Act, 1883-1888, was directly linked with the United Kingdom patents system and was apart of it. Under this arrangement, a patent granted in the United Kingdom was valid for registration in Tanganyika. This system did not create a conducive environment for the Tanzania innovators who had to file an application in UK and if granted have it registered in the country. In fact, the arrangement seemed to be specifically designed to protect rights of the nationals of colonizing powers as well as their businesses and firms.[38] This argument is supported by the fact that the linkage of Tanganyika patents systems with the UK was not conducive to the socio-economic situation of the Tanganyika during that time.[39] However, this law was repealed in 1962 by the enactment of the Patent (Registration) Ordinance (Chapter 217 of laws of Tanganyika).

Ironically, under the 1962 Ordinance, the postcolonial legislature adopted the same position by recognizing the colonial patent system as applied before the independence. Among, others, the Ordinance simply provided that 'any person who have been granted a patent in the United Kingdom or any person deriving rights from such guarantee may apply within three years from the date of grant in the United Kingdom for the patent to be registered in Tanganyika'. This means that a grant of patent in the UK was automatically eligible for registration in Tanganyika once a registration has been applied for chapter 217. Nguluma and Wangwe have observed that the requirement that the innovation should first be registered in the UK has contributed to make it difficulty in using the patent system for effective transfer of technology or to encourage and promote local innovation in the country. [40] In the course of time however, the need has arisen of improving the law relating to Intellectual property, more

[38] See Nguluma A. T., "The Role of Law in the development of Science and Technology Related Policies and Strategies in Post Independence Tanzania", PHD thesis, University of Dar es salaam, 1990.
[39] For similar view see Wangwe S.M., "Industrial Property protection and Technological Innovation: A case study of the United Republic of Tanzania": a study prepared at the request of the UNCTAD/ITP/TEC, 1991. See also Nguluma (n 38 above).
[40] See Nguluma (n 38 above) and Wangwe (39 above).

specifically patents, so as to reflect the scientific and technological changes in the country. Consequently, the Patent Act (No.1) of 1987 was enacted.[41]

4.2 The Patent Act of 1987

The Act set up an independent patent system for Tanzania, to extricate the country from the former patent system which was directly linked to the British patent system. The promulgation of this Act seems to be based on two grounds. First, it was a desire and realization on the part of the legislature of the weaknesses of the 1962 Patent Ordinance, which failed to fit in the particular circumstances prevailing in Tanzania at that time. Secondly, the new patent system was intended to form part of the legal framework for the realization of the country's Science and Technology Policy of 1986. It was therefore envisaged that the promotion of science and technology can be achieved through, *inter alia*, the promotion of inventivity and innovation for the facilitation of technology transfer, fair terms through the grant and regulation of patents, utility certificate and innovation certificates.

(a) Patentable subject matter

According to the provisions of the Patent Act of 1987, a patent shall be conferred to an invention if involves an inventive step and is industrial applicable. An invention is a solution to a technical problem.[42]

The law excludes patentability on (i) discoveries, and scientific and mathematical theories; (ii) plant or animal varieties or essentially biological processes for the protection of plant and animals; other than microbiological and the products of such processes; (iii) schemes, rules and methods for doing business, performing purely mental actors or playing games; and (iv) methods for the treatment of the human or animal body by surgery or therapy as well as diagnosis methods; but shall not apply to products for use in any of those methods.[43]

(b) The duration of patents

The law provides that patents shall be granted for a period of 10 years from the date of filing of the application. However, at the request of the patent owner, the patent term *may* be extended if the patent holder satisfies the Registrar that the patented invention is being "worked in Tanzania or that there is a legitimate reason for failing to do so.[44]

[41] The regulations to operationalize the Act - the Patent Regulations of 1988 (G.N No.490 of 1988) – became operative on the 1st November 1994.
[42] Section 7 read with section 8 of the Patent Act, No. 1 of 1987
[43] Section 7 (1) as above.
[44] Section 38 as above.

(c) Rights of patents holder

The law provides that the patent owner has the right to preclude any person from exploiting the patented invention. For the patented products, the holder has a right to prevent any person from making, importing, offering for sale, selling and using the product; or stocking such product for the purposes of offering for sale, selling or using. In term of patented process, the patent holder has the right to prevent unauthorized persons from using the process or offering for sale, importing and making the process.[45]

(d) Limitation of the rights of patents holders

The law provides for situations whereby the government may do one or more of the acts to preclude the rights of patent holder provided under section 35 of the Act. This is where a vital public interest and in particula r national security, health or development of vital sectors of public economy are involved.[46]

(E) Enforcement

In Tanzania, all intellectual property legislations are enforced by the Business Registrations and Licensing Agency (BRELA), which is the government executive agency, established under the Government Executive Agencies Act No. 30 of 1997. BRELA came into operation on 28th of October 1999 by Government Notice No. 294 of 1999. A key objective of BRELA is to ensure businesses operate in accordance with the laid down regulations and sound commercial principles including administer Intellectual Property laws of the country.

Other basis for the protection of IPRs in Tanzania

Apart from the enactment of the Patent Act of 1987, it should be noted that Tanzania is a member of the World Intellectual Property Organization (WIPO) since 1983 and has been a member of the Paris Convention for the Protection of Intellectual Property of 1883 since June 1963. At the regional level, Tanzania is a member of African Regional Industrial Property Organization (ARIPO) signed in Lusaka in 1976 and supplemented by a Protocol in Harare in 1982.[47] This indicates commitments by the Tanzanian government to ensure protection of patents (innovations) within its territory.

Having discussed the statutory recognition of Intellectual property rights in Tanzania, the next part deals with the question of exploitation of the patented inventions in the country.

[45] Section 35 as above.
[46] Section 37 (5) read together with section 54 (1) as above.
[47] Tanzania signed the ARIPO Treaty on 9 December 1978.

4.3 Exploitation of Patents in Tanzania

Between 1962 and 1999, records show that Tanzania registered about 14,467 patents applications.[48] In 1999/2000, there were only 11 patents and 6 patents in the year 2001.[49] Like many other African countries, Tanzania's share of the world's total patents application is very minimal. It may also be noted that about 99 per cent of patents granted in Tanzania belonged to non-residents.[50] This means that patents granted by the Tanzanian government protect technology developed abroad and held by foreign owners.

As regards exploitation of patents, data are very scarce. However, Seyoun has complied a random sample of the patents granted in Tanzania and Kenya. From this sample, he reached to an agreement that out of a total number of 4,000 patents registered in these countries, less than 1% is being worked in the country concerned by the patentees themselves or under licensing agreements.[51] According to Wangwe, patents are not working in Tanzania because most of them are held by transnational corporations (TNCs) which are mainly importing the products into the country while manufacturing is located elsewhere.[52] Within this context, it is evident that majority of patents registered in Tanzania, as elsewhere in sub-Saharan Africa, are used by their owners to secure an import monopoly for their products in the country rather than for local industrial exploitation and production.[53]

Thus, in many cases, foreign inventions patented in Tanzania do not seems to provide opportunity for the country to gain access to much needed technologies. They rather undermine the very purpose for which protection is offered by the Tanzanian government. It is well known that countries have laws to protect IPRs for two main and related reasons. One is to give statutory expression to the moral and economic rights of creators in their creations. Second reason, is to promote, as a deliberate act of government policy, creativity and the dissemination and application of its results and to encourage fair trading; thus contributes to economic and social development. Do poor countries such as Tanzania realize these objectives? We will deal with this question in the next section.

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[48] World Bank, World Development Indicators, 2002.
[49] Wangwe S.M., "Case Study on Institutional Capacity in Intellectual Property Policy, Administration and Enforcement-The case of Tanzania", a study commissioned by the Commission on Intellectual Property Rights, 2002.
[50] As n 48 above.
[51] B Seyoun "The Patent System and Transfer of Technology in East Africa: An analysis with particular emphasis in Kenya and Tanzania" 16 ICC.
[52] Wangwe (n 39 above).
[53] For similar view see AA Yusuf "Intellectual Property Protection in the Countries of Africa" (1995), 10 International Journal of Technology management (special issue on the Management of International Industrial Property) No (2/3): 269-292.

5.0 IMPLICATIONS OF THE TRIPS AGREEMENT IN TANZANIA

5.1 Introduction

Tanzania is a member of the WTO since its establishment.[54] The fact that TRIPS is part of the WTO means that Tanzania as a state party to the WTO is supposed to follow its structures. In accordance with article 66(1) of the Agreement, Tanzania (classified as one of the Least Developed Countries-LDCs) has been allowed a period of transition of 10 years to bring her intellectual property law completely into line with the rules of the TRIPS agreement. In practice, Tanzania is expected to enact her TRIPS compliant-legislation by 2006. TRIPS specifically recognises the economic, financial, administrative and technological constraints of the LDCs. It therefore provides a 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 LDCs for pharmaceutical patents to 2016 under the Doha Ministerial Declaration.[55] This paper argues that the transition period be used strategically by the Tanzanian government to ensuring affordability of essential patents products and processes.

5.2 The Domestication of TRIPS provisions

Prior to TRIPS, the Tanzanian government was free to determine protection of IPRs including patents in the country. For example, the government like many other developing country governments was free to decide on the areas of non-patentability, the duration, terms of patents and the set of exclusive rights conferred on patents-holders according to the country's needs and development objectives. This freedom, which was used by the governments to frame patents law, no longer exists under the TRIPS agreement. The implementation of the TRIPS agreement in Tanzania means that patent protection must be available in all field of technology including pharmaceuticals for a minimum of 20 years from the date of filing, and must be based on both processes and products.

TRIPS also specifies an end to the practice of requiring the patent holder to work the patent in the country itself, as per the WTO principle of national treatment:

> "….patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology *and whether products are imported or locally produced* ."[56] (emphasis added)

[54] Tanzania was a member of GATT since 9 December 1961 and therefore participated in the creation of the WTO.
[55] WTO, *Declaration on the TRIPS Agreement and Public Health Doc* No. WT/MIN(01)/DEC/2, adopted by the Fourth WTO Ministerial Conference, Doha-Qatar, 14 November 2001 at para 7.
[56] Article 27(1), TRIPS agreement.

The overall effect, then, of the TRIPS Agreement, is a much-strengthened patent system in the country. We examine below the effect of strong patents protection in the specific context of pharmaceuticals.

5.3 The Impact of Strong Patents Protection: A Case of Pharmaceuticals

Although social benefits may arise from strong patent protection through discovery of new drugs, the agreement's standards, which derive from developed countries, are not necessarily appropriate for all countries' level of development. The implementation of the TRIPS agreement in Tanzania is likely to impact negatively on health care technologies and accessibility of drugs. We demonstrate this in a little more detail below.

5.3.1 Medical research

As aforementioned, pharmaceutical patents, act as an incentive for the innovation of new drugs.[57] Patents are particularly important for the pharmaceutical industry, first because the industry often put a large sum of money for the testing, development and approval of new drugs, and second, because pharmaceuticals are generally relatively easy to reverse-engineer and thus are open to easy copying in the absence of IP protection. It is likely that the possibility of obtaining patents on new drugs - and therefore a period of exclusivity to recover costs - acts as a major incentive to innovation in the pharmaceutical industry. However it should be noted that while the incentive to innovate has the potential to promote public health, this does not, *ipso facto*, justify the conclusion that IPRs promote access to drugs by poor.

First, as IPRs are limited commercial rights, they are essentially driven towards economic reward; the objective of promoting public health issues would at best appear to be a secondary consideration.[58] As noted by World Health Organization (WHO), the commercial motivation of IPRs means that research is directed, first and foremost, towards 'profitable' disease. Diseases that predominantly affect people in poorer countries - in particular Tuberculosis and Malaria - still remain relatively under-researched.[59] It is therefore submitted that drug development for neglected diseases-conditions that mainly or only affect people in developing countries including Tanzania - is not likely to increase significantly as a result of more stringent patents protection. This is because the people suffering from neglected

[57] It should be noted that there is near absence of any controversy over the role of patent protection for pharmaceuticals in fostering research.
[58] Marie Bystrom and Peter Einarsson, "TRIPS consequences for developing countries. Implications for Sweden Development Cooperation" a report commissioned by the SIDA, May 1, 2001.
[59] UNDP, "Making New Technologies Work for Human Development" UNDP Human Development Report, 2001.

diseases including the majority of Tanzanians do not represent a lucrative market to drive research. [60]

According to WHO, "questions remain as to whether the patent system will ensure investment in medicines needed by the poor".[61] Of the 1,223 new chemical entities developed 21 years ago (between 1975 and 1997) only 11(equivalent to only 1%) were for the treatment of tropical diseases compared to the heavy attention given to 'lifestyle' drugs. [62] In fact, the last major tuberculosis drug was developed more than 30 years ago, while Tuberculosis remains a major cause of deaths in many developing countries, including Tanzania.[63] This suggests that focusing on R&D on 'first world disease' would probably not be reversed through granting strong patent protection. Rather, the monopoly granted by the TRIPS agreement to pharmaceutical TNCs will only facilitate increased investments for R&D on drugs for impotence, obesity and baldness instead of R&D on new and more effective drugs for life threatening including malaria and tuberculosis. After all, we note nothing in TRIPS agreement that obliges the industry to use the increased patented rents for research on diseases prevalent in poor countries (although article 7 may be construed to impose such an obligation).

Second, the grant and exercise of pharmaceutical patents can lead to undue restrictions on medical research, which could run contrary to the requirement to balance the protection of private interests with the promotion of the wide dissemination of medical knowledge. In particular, the practice of granting broad patents - an issue that has become particularly prevalent in the area of biomedical research - can lead to patents being used to block research efforts. The issue is relevant where research into a final product or process - for example, a drug - relies on several levels of innovation, all of which are susceptible to IP protection. In such cases, patents on innovations from the early stages of research can be used to control and possibly block life-saving innovations that depend on the use of the first innovation. [64] In addition, many commentators on patents protection including the WHO have identified the situation where standards for the grant of patents can contribute to "ever-greening" - a process where minor innovations are themselves patented thus extending the life of the patents beyond the original 20-year monopoly.[65] Extending the active patent life beyond the

[60] According to a study done by Health Action International (HAI), 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 in the year 1998.
[61] WHO/EDM/2001.2
[62] As above
[63] Z Mirza "WTO, pharmaceuticals and health: impacts and strategies", Geneva: International Round Table on Responses to Globalisation: rethinking equity in health, 12-14 July 1999.
[64] MA Heller and R.S. Eisenberg, "Can Patents Defer Innovation? The Anti-commons in Biomedical Research", 1 May 1998, Vol 280 *Science* 698-701 < www.sciencemag.org>
[65] Z. Mirza (n 63 above).

limited period of protection could hold up other research efforts. This could have implications on the country's need to accessing new medical technologies.

Finally, TRIPS requires patents to be granted, regardless whether the products are imported or locally produced. This means that patent holders would merely import their product, without having to work for the patent in the country granting the right. In other words, the pharmaceutical MNCs can supply global markets under the patent monopoly, exporting the finished pharmaceutical product instead of transferring technology to local industries in Tanzania.[66] We indicated earlier that patents are not working in Tanzania because most of them are held by TNCs which are importing the products into the country while manufacturing is located elsewhere.[67] Thus the importation of products instead of technology could also have implications on government's effort in scientific and medical research (taking into account in ensuring availability and accessibility of essential drugs).

5.3.2 Accessibility of drugs

As stated above, patents provide the patent owner with the legal means to prevent others from making, using or selling, importing or offering for sale the new-patented drugs for a period of 20 years. This monopoly may have effect on prices of drugs as well as generic manufacturing of drugs in a developed country such as Tanzania. After all, like in many developing countries, the transnational companies dominate the local pharmaceutical market in Tanzania.

(a) High drug prices

Experts in the patents field are in a substantial agreement that pharmaceutical patents, by designs and functions, increase the prices of medicines to consumers because of monopoly over the patented products.[68] In particular, the World Bank has 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.[69] As argued by Cecilia Oh, when medicines are under patent protection, the patent holder has a monopoly on the production and sale of the product for a minimum period of 20 years, and is thus able to exercise a monopoly in the pricing of the product.[70]

The effect of patents and monopolies on prices is demonstrated by a number of studies, which compared prices of patented or branded products and those of generic producers; and prices

[66] C. Oh "TRIPS, Patents and Access to medicines, proposals for clarification and reform" *Third World Network Briefing Paper*, June 2000.
[67] SM Wangwe (n 39 above).
[68] See FM Abbott "The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference", Occasional Paper 7, Friends World Committee for Consultation, Quaker United Nations Office, Geneva 2001.
[69] World Bank, *World Development Report 2000/ 2001*, Washington DC.
[70] C Oh (n 49 above) and FM Abbott (n 51 above).

of the same product sold in different countries. For example the UNDP Human Development Report 2000 indicates that in India generic production of fluconazole, medication used for treating AIDS-related meningitis, has kept the price at US$55 for 150 mg compared with US$697 in Malaysia, US$703 in Indonesia and US$817 in the Philippines where is patent protected.[71]

In addition, despite the fact that multilateral pharmaceutical companies sell their medicines at much higher prices than those of generic producers, earlier studies found that in a country where alternative or generic medicines are available, the price of the branded drugs drop quickly and dramatically (30 percent) because of the competition. In Thailand, for example, fluconazole was supplied exclusively by US company (Pfizer) until 1998. Since local alternatives became available, the cost of a daily dosage of 400mg fell by 15% of the original price.[72] Thus in 2000, fluconazole costed only USD $0.30 a day price in Thailand. However this same drug costs USD 18.00 a day in Kenya where the generic version is not yet into the Kenyan market.[73]

To illustrate further the impact of patents on prices of drugs, the Health Action International conducted a survey on Zantac, an anti-ulcer drug manufactured by Glaxo in 1997. Several generic manufacturers in India produce ranitidine, the generic name for the active substance contained in Zantac. Because of this, the survey found that Glaxo lowered the price of the drug in India (marketed as Zinetac) because of competition. While the price of Zantac (100 tables/150 mg) was US$ 2 in India, the same brand was sold at higher prices in other countries (US$ 97 in Tanzania and US$ 150 in South Africa) because there was no competition from generic producers.[74]

(b) Decline in generic manufacturing

Most pharmaceutical industries in Tanzania are able to produce new drugs by a process of reverse engineering, that is, a method of evaluation of a product in order to understand its functional aspects and underlying ideas. This technique may be used to develop a similar (or even identical) product. Under TRIPS agreement, reverse engineering and other 'legitimate' methods of imitative of the newly discovered drugs are restricted for at least 20 years from the date of filing. Thus once TRIPS agreement come into force, the smaller Tanzania pharmaceutical producers who specialized and depend on manufacturing cheaper generic

[71] UNDP, *Human Development Report, 2000.*
[72] Medecins Sans Frontiers (MSN), "The role of Patents in Access to Essential Medicines", November 2001.
[73] 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.
[73] See, CM Correa "Integrating Public Health Concerns into Patent Legislation in Developing Countries", Geneva: South Centre, 2002.
[74] Health Action International, 1998.

alternatives will find themselves prohibited to produce generic drugs -at least until the expiry of the 20-year period. At this juncture generic production will be only possible under compulsory licensing. This means an increase in the level of royalty payments demanded by techno-holders, if they agree to transfer their technology at all. Two issues arise here. First, obviously most of the small Tanzanian pharmaceutical industries will not be able to pay the royalty. The effect to be foreseen is the decline of the domestic manufacturing of pharmaceutical products. In some cases, domestic production capacity may never be developed, as it will be very difficult to catch up in the technological field. Secondly, as consequences of TRIPS agreement implementation, the original inventors will be able to maintain, through the brand royalty, prices than those that would be realized in the absence of patents.

Furthermore, the impact of TRIPS agreement on prices of newly discovered medicines in Tanzania cannot be studied in isolation. It should be examined in the context of the country's capacity to produce regular drugs. Most of medicines used in the treatment of infectious diseases are imported from generic medicines suppliers from India, Thailand, Egypt and Brazil. These medicines are typically available at lower prices than the branded medicines. Since it will be illegal to produce generic drugs, TRIPS agreement compliance in Tanzania and in these countries means that the major sources of cheaper drugs will be removed.[75] Thus availability of cheaper drugs will be solely the discretion of patents holders.

In sum, the overall effect of introducing strong patents on pharmaceuticals in poor country such as Tanzania is to put access to medicines out of reach for thousands of people. Thus whenever patents allow companies to price any drug out of the reach of those who need it, public health suffers. A case study of access to HIV/AIDS provides a further explanation of the argument.

5.3.3 A case study of TRIPS and access to HIV/AIDS antiretroviral drugs in Tanzania

In Tanzania, like many parts of developing world, HIV/AIDS epidemic has put the spotlight on the issues of TRIPS agreement and affordability of medicines. The latest UNAIDS figures indicate that there are about 1.5 million people living with HIV/AIDS in the country.[76] Accordingly, the WHO has estimated that about 60% of deaths in Tanzania are HIV/AIDS related.[77] Similarly the life expectancy is projected to fall in by 20 years by the year 2010 due to spread of HIV/AIDS.[78]

[75] Oxfam " Patent injustice: How trade rules threaten the health of the people", February 2001.
[76] UNAIDS, Aids Epidemic Up-dates, 2002
[77] WHO, 2002
[78] UNAIDS, Report on the Global HIV/AIDS Epidemic, Geneva 2002.

The HIV/AIDS pandemic has a significant impact in the country. In the developmental dimensions, 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.[79] Indeed, HIV is the biggest development challenge for Tanzania. 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.[80]

In industrialized countries, AIDS deaths have been reduced dramatically partly because of the availability of new life-saving medicines.[81] But as the disease is quite recent in medical history, most of the antiretroviral (ARVs) are patented under IPR law against exploitation until patent expires.[82] As we have seen earlier, patents protection gives pharmaceutical companies a monopoly over manufacture and marketing of drugs, allowing them to fix prices at high rates to maximize profits. In Tanzania, a monthly cost prescription for ARVs is 450,000/Tshs. (Table 2). Clearly, majority of Tanzanians, who receive daily incomes of less than $1 per capita, are not able to access the high costs of ARVs treatment.[83] In this context, the high prices of drugs have had a substantial impact of impeding access to drugs for people living with HIV/AIDS.

Table 2: price status of some life -prolonging drugs in Tanzania, 2001

Drug name	Costs monthly subscription (Tshs).
Erit	510,000
Videx	398,200
Crixivan	479,200

Source: Muhimbili National Hospital, March 2002 (Note: I US$-960 Tshs)

Admittedly, there are many factors that influence access to drugs. WHO recognizes four principal factors: rational selection and use of drugs, affordable prices, sustainable financing and reliable health and supply systems. However, the issue of affordability is of most relevant in Tanzania. Although the price of AIDS drugs is by no means the only obstacle in providing treatment to about 1.5 million AIDS victims in Tanzania, it remains an important one. Many drugs for HIV/AIDS are manufactured by multinational pharmaceutical companies and many of these drugs are patented under TRIPS law against exploitation until the patents expires. In turn, many of the poor people in Tanzania do not have access to such drugs due to their

[79] Economic and Social Research Foundation (ESRF) "The Economic and Social Impacts of HIV/AIDS in Tanzania- Preliminary Report, June 2003. See also HIV strains East African Economies, The Business Times, Friday August 3-9, 2001.
[80] As above.
[81] See K Balasubramanian "The Impact of WTO/TRIPS Agreements on the access to essential drugs for people living with HIV/AIDS", 2001.
[82] UNAIDS, "Patent situation of HIV/AIDS related drugs in 80 countries", Geneva, 2000.
[83] World Bank, Human Development Indicators, 2002.

exorbitant prices. According to the UNAIDS "the high prices of HIV treatments are due, in part, to patent protection which allows control over their manufacture and sale".[84] Therefore, the presence of patents protection over drugs plays a key role in determining the affordability of drugs, not only to those live below the poverty line but also the bulk of the population in Tanzania.

There are arguments that patents are not a significant problem to affordability of drugs, that the problem is poor infrastructure and financing in developing countries such as Tanzania.[85] According to these arguments, there are cases where particular drugs are not under patent protection either because no patent was initially granted or it has expired and yet many people have no access to such drugs.[86] While lack of infrastructure and finance is common to Tanzania, the issue of affordability is of most relevance in the country. But this is not to suggest that without patents prices of medicines will be very low. The study notes that high price of medicine may also be influenced by other factors such as level of import duties and tariffs, local taxes, limited competition and mark-ups for wholesaling and distribution.[87]

Thus, from a standard point of public health, we argue that the overall effect of introducing global pharmaceutical patents system is to reduce the number of individuals who can afford to buy pharmaceutical products as well as ability of the government to access medical technologies. Four decades since independence from colonial rule, Tanzania is still a long way from creating an efficient medical care infrastructure. The government has just started a long-term health sector reform programmes which, among others, is aimed at improving the quality, accessibility and availability of essential hospital care and medicines. While access to medicines has always been clogged by other factors such as poor medical infrastructure, general social insurance scheme and corruption, now Tanzanians have to bear the brunt of international trade rules under which patents are a key factor determining prices for drugs. We stress that patents essentially give their holders a monopoly hence they charge whatever price the market will bear, regardless of the consumer's ability to pay. But governments - which claim to care for their people - have the responsibility to balance public health needs and private profit.

The following section, explore on how to balance the two interests within TRIPS environment.

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[84] UNAIDS (n 78 above).
[85] See Press Release of International Federation of Pharmaceutical Manufacturers Association, September 21, 2001. See also HE Bale "Access to Essential drugs in Poor Countries-Key issues: The Industry Perspective"; Workshop on Differential Pricing and Financing of Essential Drugs, WHO and WTO, 8-11 April 2001, Høsbjør -Norway.
[86] As above.
[87] As above.

6.0 ENSURING ACCESS TO ESSENTIAL DRUGS WITHIN TRIPS PROVISIONS

TRIPS agreement contains a number of provisions that the Tanzanian government may use to strike the desired balance between private and public interest, such as access to essential drugs. This section first explores several policy options permitted under TRIPS which might be adopted by the government without running afoul of the obligations imposed by the Agreement. We will then discuss implementation of these measures at national level.

6.1 The options

In view of the potential negative impact of the TRIPS agreement on patented pharmaceuticals, there are two important policy instruments which might be adopted by the government to balance the public interest with the claims of the patent holders. The first is to engage in parallel importing which means importing patented medicine from wherever it is sold cheapest, irrespective of the wishes of the patent holders. The second is the ability to override a patent by authorizing a compulsory license for production of medicines. These two options are elaborated below.

6.1.1 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.[88]

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".[89] 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.[90] The legal basis for the use of parallel importation is in Article 6 of TRIPS agreement, which explicitly states that practices relating to parallel importation cannot be challenged under the

[88] FM Scherer and J Watal "Post-Trips Options for Access to Patented Medicines in Developing Countries, Commission on Macroeconomics and Health, Working Paper Series No.4: 1, June 2001.
[89] CM Correa "Public Health and Patent Legislation in Developing Countries", *Tulane Journal of Technology and Intellectual Property,* 2001.
[90] As above.

WTO dispute settlement system, provided that there is no discrimination on the basis of the nationality of the persons involved. In this way, parallel importation can be a useful way of increasing access to essential drugs where the prices charged by patent holders for their products are unaffordable. In instances where the local manufacturing of the product is not feasible, such as in Tanzania, and therefore compulsory licenses may be ineffective, parallel importation may be a relevant tool to ensure access to drugs.

It is well known that parallel importation is purely a matter of national discretion. For practical purposes, this means that the Tanzanian government is completely free to decide whether or not to apply the principle of the exhaustion of patent owners' rights. Similarly, the government can determine the extent to which the principle of exhaustion of rights is applied in its own jurisdiction without breaching any obligation under TRIPS.
This measure therefore is of critical importance particularly at this time when Tanzania is over burdened with the need to improve health care due to the HIV/AIDS pandemic.

6.1.2 Compulsory Licensing

Another way of improving access to affordable drugs is through production of generic substitutes (copies drugs). That is, as drugs are patented under TRIPS regime - generic supply must wait until the expiry of the 20 years patent term - 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'.[91] It is also possible to produce generic substitutes even where the patent is still current through the practice known as 'compulsory licensing'.

A compulsory license is an authorization given by a national authority (judicial and or administrative) to a person without or against the consent of the patent owner for the exploitation of a subject matter protected by a patent or other IPRs.[92] In other word, compulsory licensing is an act of granting a license to enable 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 patent owner receives a reasonable remuneration in return, at a rate set by the government or any other authority.

[91] According to Correa this system have been used by many developed countries like Japan, Canada, Unites States and others, see CM Correa "Health and Intellectual Property Rights", *Bulletin of the World Health Organization*, 79(5), 2001.
[92] As above.

Like parallel importation, compulsory licensing is a legal option consistent with article 31 of TRIPS agreement. (However articles 1,7,8, 30 and 40 are also relevant for compulsory licensing). The term 'compulsory licensing' is however not expressly mentioned under TRIPS agreement. The Agreement use the term "other use without the authorization of the patent owner" under article 31. Nevertheless, this description has been connected to the meaning of the concept of compulsory licensing.

Article 31 sets out the general framework for the use of compulsory license. General rules for the grant of compulsory license include the following: -

(a) Individual merit

Under this rule a government is required to consider each case on its individual merits. This means that the government cannot issue a blanket license for a particular category of products or applicants. It has to consider each case to determine whether it deserves authorization.

(b) Prior request

The grant shall only be permitted if the applicant has applied to the patent owner for a licence on reasonable commercial terms and such request has not yielded results within a reasonable period of time. The exceptions to this rule are cases of national emergency, extreme urgency and cases of public non- commercial use.

What amounts to a national emergency or an extreme urgency is not defined in the agreement. It is up to each national government to determine in their national legislation what constitutes national emergencies or cases of extreme urgency. The right holder is however entitled to notice subsequent upon such grant. Note that this is only for information rather than consent. In addition, if such grant has been made by order of court or administrative body, the government is not obliged to fulfill this condition.

(c) Market restriction

The grant shall be predominantly for the supply of the domestic market except if the grant was meant to remedy some anti-competitive practice provided that such practice has been determined through judicial or administrative process to be anti-competitive.

Other general rules:

- The license shall be non exclusive and non assignable
- The license shall terminate as soon as the imperative for its grant ceases
- The patent owner shall be paid adequate remuneration in the circumstances of each case taking into consideration the commercial value of the license
- The grant shall be subject to judicial or administrative review
- Decisions of remuneration is also subject to review

From the above, one can notice that a state party to TRIPS agreement has a wide latitude to utilize this measure without any risk of violating provisions of the Agreement. In addition, the TRIPS agreement specifically refers to various grounds for the granting of compulsory licensing such as national emergency and extreme urgency, anti-competitive practices, public non commercial use and the dependent patents. Article 31 of the agreement however does not specify clearly that this are the only cases authorized. Within this context, we argued that member states are left with a broad scope of action in regard to the grounds and reasons for compulsory licenses under article 31.

In the context of meeting public health objectives, compulsory licensing is a very crucial element in a national patent law and policies. The licenses may constitute an important tool to ensure affordable drugs through competition without denying the patent owner compensation for his invention thereby promoting public health goals.[93] Thus as soon as TRIPS agreement applies in Tanzania, compulsory licensing is one of the policy instrument which can be used by the government to ensure affordability and accessibility of patented drugs not only for HIV/AIDS but other essential drugs. Empirical evidence demonstrates that many countries have historically resorted to compulsory licenses[94] without necessarily hurting the patent system. According to James Love, countries such as 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.[95] The recent example of Canada and the US are illustrative. Canada and US were at the verge of issuing compulsory licenses for the production of ciproflaxacin in the wake of the bio-terrorism scare of anthrax attacks that followed the September 11 terrorist attack in New York and Washington. Bayer, a German pharmaceutical company holds the patent right for ciproflaxacin. On the strength of this possibility, the governments of both countries managed to negotiate with Bayer for price cuts for the drug.[96] This was to cope with what has been described as a 'psychological emergency'.[97]

AIDS is now widely acknowledged as a national emergency in Tanzania,[98] within the meaning of article 31 of TRIPS agreement, the government may deem it necessary to grant compulsory licenses to allow interested third persons to produce HIV/AIDS related drugs in order to ensure that they are available, or more affordable to the general public. The

[93] See CM Correa "Integrating Public Health Concerns into Patent Legislation in Developing Countries", , Geneva: South Centre, 2002.
[94] James Love, "Compulsory Licensing: Models For State Practice in Developing Countries, Access to Medicine and Compliance with WTO TRIPS Accord" 21 January 2001.
[95] As above. See also WIPO publication No. 609(E) for a list of the compulsory licensing provisions in specific countries.
[96] MSN, "The Role of Patents in Access to Essential Medicines", November 2001.
[97] As above.
[98] See National Aids Policy of Tanzania, 2001.

government should not sit back and watch its population ravaged by the scourge. It has a duty to balance the rights of people such as to health care with those commercial rights of drugs manufacturing companies. The affordability and accessibility 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. This could be possible through the grant of compulsory licenses.

It should be noted however that compulsory licenses should not be seen as a 'magic wand' for obtaining affordable access to patented medicines in Tanzania, as there are some basic limitations such as capability undertake to reverse engineer. [99] It is well known that Tanzania has limited industrial capacity to manufacture medicines locally in order to ensure adequate access to drugs. While the TRIPS agreement does not prevent members from granting compulsory licensing for foreign suppliers to satisfy the domestic market, it is argued here that cooperation of the patent owner remains to be important.

Overall, the TRIPS agreement provides a number of safeguards' measures which might be adopted by the WTO member' governments in addressing public health objectives. Thus, where HIV treatments are protected by IPRs, accessing affordable drugs will depend in part on how these measures are exercised. Suffice it to say, there is still a grace period to the implementation of the TRIPS agreement in Tanzania. Therefore, the argument that patents are not the main barriers to accessibility to drugs may hold some degree of truth. The government still has a leeway to import cheap drugs from generic manufacturers and to manufacture generics if it has the technological capacity. This has been clarified in the WTO Doha Ministerial Declaration of 2001 as elaborated below.

6.2 Implementation of the "safeguard" measures at national levels

While safeguard measures are allowable under TRIPS agreement, complexities seem to arise at the implementation stage. We had indicate that some of these measures are incorporated in the domestic systems of most countries including developed ones and that most developed countries have historically engaged in such practices for various purposes. The question that may arise is why implementation of these safeguard measures is such a nightmare for many developing countries? Before we deal with this question, it is important to state that the issue of implementing safeguards provisions is riddled with controversy probably due to the lack of clarity built in those provisions. [100] The provisions are loosely crafted and susceptible to differing interpretations referred as "strict interpretations" and 'flexible interpretations' in the

[99] Scherer and J Watal (n 88 above).

[100] CM Correa (n 93 above).

arguments for or against patents protection. The South African case can illustrate challenges facing poor developing countries in implementing the TRIPS agreement at the national level.

6.2.1 The South African Court case

South Africa has the world's highest number of cases of HIV infection.[101] As the HIV/AIDS crisis continued to escalate, more and more new antiretroviral drugs continue to obtain patent protection in the country. Since these new drugs attract high prices they have been inaccessible to most of those who need them. For example, in 2001, Ciprofloxacin - patented by Bayer in South Africa, an important anti-bacterial treatment for sexually transmitted disease, childhood shigellosis (bloody diarrhoea) and chest infections - costs R5.6/500mg tablet. This was twelve times the cost of the generic equivalent in India where it was sold for around R0.46.[102] Consequently and in keeping with its obligation to promote and protect peoples' rights to access essential drugs, the South African Government 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 Commissioner of the European Union issued a warning letter to South Africa's Vice President that "the country's drug law was at variance with South Africa's obligations under the WTO".[103] According to Taylor, the EU Trade Commissioner further alleged that implementation of such law would negatively affect the interest of the European pharmaceutical industry.[104] As James Love observed, 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".[105]

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 violated their

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101 UNAIDS estimates that in 2001 about 4.7 million people living with HIV/AIDS. See UNAIDS AIDS epidemic up date December 2001.
102 James Love (n 94 above).
103 Simon Taylor, Intellectual Property-Health List Serve, 14 March 2000. See also European Voice, vol.6 of 9 March 2000.
104 As above.
105 See James Love, "Notes on the USTR watch Lists and Reports", 1999. Available at http://cptech.org.

intellectual property rights.[106] The pharmaceutical industry maintained their argument against flexible interpretation of TRIPS agreement 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 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. As stated by Samantha Sen, "the decision to withdraw was a tactical move, rather than a sudden and joint discovery of social responsibilities as there were indications enough from the court already that the verdict would go against the drug companies". [107]

Subsequently, the South African case is a sufficient evidence to believe that implementation of the TRIPS agreement in many developing countries is not only limited by the legal provisions. Rather extra legal measures/pressure like threats of economic reprisals/trade sanctions are likely to be used by developed countries against WTO members to exercise a choice left by the TRIPS agreement. This has been one of the concerns of developing countries since the adoption of the agreement. This concern was reflected in the fourth WTO Ministerial Conference held in Doha-Qatar in 2001. The Conference adopted a Declaration on TRIPs and Public Health, which is elaborated below.

6.2.2 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.[108] This declaration is a very significant achievement as far as affordability of drugs in poor countries is concerned. Here, it is important to mention that Tanzania through Mr. Iddi Simba, the former Minister of Trade, was very instrumental in getting this Declaration adopted.

In the first place, the declaration recognizes 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.[109] 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

[106] *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).
[107] Samatha Sen, "AIDS: more legal battles in the offing", *The East African*, 23-29 April 2001.
[108] *Declaration on the TRIPS Agreement and Public Health Doc* No. WT/MIN(01)/DEC/2, adopted by the Fourth WTO Ministerial Conference, Doha-Qatar, 14 November 2001.
[109] As above, para 1.

medicines.[110] 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 agreement does not and should not prevent members from taking measures to protect public health.[111] 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.[112] Under the Declaration, possible measures include the right to grant compulsory licenses (overriding patents) and the freedom to determine the grounds upon which such licenses are granted.[113] Now if drug companies price drugs beyond the reach of people who need then, Tanzania government can override patents without fear of being dragged into a legal battle. Although declarations are normally considered non-binding, this particular one represents the will of the majority of the WTO members. In addition, the declaration is an authoritative interpretation of the TRIPS agreement given it emanated from the Ministerial Conference of the WTO as provided for under article 9(2) of the Agreement Establishing the WTO.[114]

Now it is up to the Tanzanian government to use this power to bring down cost of medicines and increase access to life-saving AIDS drugs. Kenya already offered a good example for Tanzania. The new Industrial Property Act, Number 3 of 2001, which came into force on May 1, 2002, among other things, allows for the importation and production of more affordable medicines for HIV/AIDS and other diseases.[115] Notably, section 81 of the Act empowers the government to licence local manufactures to produce generic versions of any medicine locally during a medical crisis. However, it is important to recall that the inclusion of the safeguards measures was not that easy. Initially, majority of Kenyans and humanitarian organizations within and outside the country opposed the passage of the Intellectual Property Bill on the ground that it would have negative impact on the county's agriculture and health care services.[116] In the area of health, for example, it was argued that strong patent protection in the proposed law had the potential effect on Kenyan's lives mainly by making the importation of critical chemicals and drugs more difficult due to patent protection.[117] The Bill

[110] As above, para 3.
[111] As above, para 4.
[112] As above.
[113] As above para 5(b).
[114] Art. 9(2) reads "the Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretation of this Agreement and that of the Multilateral Trade Agreements".
[115] Republic of Kenya, the Industrial Property Act, No.3 of 2001. See also a commentary by Othello Gruduah, "Nairobi can manufacture, import HIV/AIDS drugs", *The East African Standard*, November 2001.
[116] Dagi Kimani, "Intellectual Property Bill Faces Opposition", *The East African*, May 29, 2000.
[117] Dagi Kimani, "Politics derails HIV generic drugs bill", *The East African*, 7-13 May 2001.

was also opposed on the ground the proposed legislation would set a bad precedent for Uganda and Tanzania and weakens their bargaining position in enacting their TRIPS agreement compliant laws in the year 2006.[118] However, in the final analysis, the Kenya's legislature had address the concern of its people by make possible the importation and production of affordable medicines for HIV/AIDS and other diseases.[119] The legislation therefore offers a persuasive precedent for Tanzania in enacting her TRIPS agreement compliant Patent Act. Though a challenge remains for the Kenyan government to ensure that powerful multinational pharmaceutical corporations do not control the application of this important law.

[118] Dagi Kimani, as above.
[119] Othello Gruduah, op cit. see also Dagi Kimani, "Cheap generic Aids drugs now Possible", Daily Nation, Wednesday, April 17, 2002.

7.0 CONCLUSIONS

Under the TRIPS agreement, WTO member states have committed themselves to enshrining in national law minimum standards for each of intellectual property rights. The domestication of TRIPS in Tanzania is likely to have an impact on accessibility and availability of medicines in the country. The major implications concerning access to medicines 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 be a basis for high prices of drugs and decline in generic production of medicines.

There are however several actions which might be adopted by the Tanzania government in ensuring a proper balance between the protection of private rights and corporate interests and the promoting of public interests in socio-economic and technological development including that of public heath. Compulsory licensing and parallel imports are policy options clearly allowed under the TRIPS agreement. With regard to compulsory licensing the agreement does not limit the grounds for grant of compulsory licences, and therefore, the Tanzanian government can provide the grant of compulsory licenses for reasons of public interest or health or for other reasons. Another strategy for lowering drug prices is by parallel imports. Since the pharmaceutical industry generally sets prices differently throughout the world for the same medicines, the government or another importer may involve shopping in the world market for the lowest priced drugs rather than accepting the price at which it is sold in the country.

However, we have seen that the interpretation and implementation of these measures to address negative impact of the Agreement is not solely in the hands of TRIPS member states. Rather differential powers, influence and resources place a limitation on these choices that could be legally accommodated within the terms of the TRIPS Agreement. In this connection, the Doha Ministerial Declaration on TRIPS and Public health becomes an important instrument in the interpretation and application of the TRIPS agreement particularly for poor people in developing countries.