HIV AND AIDS IN AFRICA: Compulsory Licensing Under TRIPS And DOHA Declaration

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**ABBREVIATIONS**

- AIDS – Acquired Immune Deficiency Syndrome
- ARVs – Antiretroviral (medicines)
- HIV – Human Immunodeficiency Virus
- IP – Intellectual Property
- IPRs – Intellectual Property Rights
- LDCs – Least Developed Countries
- R&D – Research and Development
- TB – Tuberculosis
- TRIPS – Agreement on Trade-Related Aspects of Intellectual Property Rights
- WHO – World Health Organization
- WTO – World Trade Organization
- WIPO – World Intellectual Property Organization
- UN – United Nations
- UNFPA – United Nations Population Fund
- UNICEF – United Nations Children’s Fund

ABSTRACT

In today’s world, there is a lot of focus on issues such as militancy, global warming, terrorism, racism and even politics. Unfortunately, there is a problem that has killed and is still killing far more people than any of the above issues. That problem is HIV/AIDS.

AIDS is a serious medical condition that predisposes patients towards opportunistic infecting tumors, dementia and death. HIV is the viral agent associated with AIDS.

Africa is without doubt more heavily affected by HIV/AIDS than any other region of the world. Although Nigeria’s HIV/AIDS prevalence rate is still relatively low compared to some countries in Sub-Saharan Africa, however, Nigeria is at a critical point where increased prevention and treatment efforts today could help stem the tide of a much more significant epidemic in the future.

Access to affordable Antiretroviral (ARV) medicines is vital for survival of patients. This is because these ARV can slow down and reverse the progression of the HIV infection subsequently delaying the onset of AIDS by at least 20 years.

Unfortunately the spread of HIV/AIDS in Africa is quickly outpacing the number of people receiving treatment. The implication of this wide spread is that to many Africans, the words HIV/AIDS are equivalent to a death sentence.

This paper will examine the importance of compulsory licensing to facilitate access to life-serving medications for Africans and will explore the global debate on the TRIPS Agreement and public health, as it has evolved over the years. Specifically, it will focus on the implications, and limitations, of the Doha Declaration to compulsory licensing. The paper will further make recommendations for narrowing the divergence between the needs of HIV/AIDS patients and the protection of patent holders Intellectual Property Rights (IPRs).

INTRODUCTION

According to the World Intellectual Property Organization (WIPO), IPRS refer to creations of the mind: inventions, literary and artistic works, symbols, names and designs used in commerce. They are exclusive rights, often temporary granted by the state for the exploration of intellectual creations. These rights are outlined in the Universal Declaration of Human Rights.

1 www.medterms.com
2 www.medterms.com
4 In South Africa, an estimated 2,600,000 are infected with HIV. The situation is not different in other parts of Africa. In Uganda over 800,000 People have died from the HIV/AIDS epidemic.

5 WIPO is one of the 16 specialized agencies of the United Nations, which was created to encourage creative activity to promote the protection of Intellectual Property throughout the world.
6 http://www.wipo.int/about-ip/en/
7 They include Patents, Copyrights, Industrial Designs and Trademarks.
Rights, which sets forth the right to benefit from the protection of moral and material interest and resulting from authorship of any scientific, literary or artistic production.

In the health sector, IPRs can provide an important stimulation for the development of new drugs and medicines. Over the past few years, a number of ARVs have received patent protection in Africa. A patent is a title, granted by the public authorities, conferring a temporary monopoly for the exploitation of an invention on the person who reveals it, furnishes a sufficiently clear and full description of it and claims this monopoly.

The registering of a patent confers a temporary market monopoly on the patent holder who is then able to charge a high price because there is no competition. The rationale is that the development of new drugs requires heavy investment and long-term research, coupled with expensive clinical trials and regulatory approval procedures.

In the context of public health, the challenge for policy makers is to find an optional balance between the rights of patent owners, who provide technological innovations to improve health conditions and the needs of the general public. The rational behind this challenge is that without the rewards provided by the patent system, researchers and inventors would have little incentive to continue producing better and more efficient products for consumers worldwide.

ARGUMENTS ON THE CURRENT PATENT SYSTEM AND ACCESS TO MEDICINES

Reconciling the needs of patients and patent holders is a challenge to efforts to improve access to essential health care. The conflict between encouraging innovative efforts on one hand, and disseminating the fruits of labors on the other hand, has often created a divergence between pharmaceuticals and the user community.

Many have argued that the prevailing patent systems in Africa do not adequately address public health crises. It is argued that the commercial incentives provided by the patent system are not sufficient to ensure the

8 Article 27 of the Universal Declaration of Human Rights provides that everyone has the right freely to participate in the cultural life of the community, to enjoy the arts, to share in scientific advancement and to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

9 For example Combivir, 3TC, Nevirapine, Nelfinavir, Acabavir, Amprenavir and AZT.

10 In the pharmaceutical sector, Research & Development (R&D) costs are often very high & so industries are likely to invest only in

drugs with profit potential. The high cost of R&D in part explains why there are more drugs to treat the health problems of the world’s wealthiest people than to treat conditions suffered by the world’s poorest.
development of new products in areas such as neglected diseases. It is further argued that patent rights are enforced on the basis of commercial and market-based considerations, thereby preventing access to, or leading to an increase in the prices of essential medicines such as HIV/AIDS drugs\textsuperscript{11}.

Patent holders contend that by ensuring long-term patents and a small margin on the costs of drugs, they are rewarded for their years of toil on the one hand, while the public on the other hand is, invariably, assured of much needed innovations. In the light of these concerns pharmaceutical corporations operating within the African region have been accused of opposing attempts by developing countries to reform their patent laws.

**TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY (TRIPS)**

TRIPS, which stands for Trade-Related Aspects of Intellectual Property, is an agreement under the purview of World Trade Organization (WTO). It covers a wide range of subjects from copyrights, trademarks, trade secrets, and competition policy, integrated design to pharmaceuticals. It stipulates that WTO member countries must provide patent protection for approved inventions for at least 20 years, severely redirecting competition and granting monopoly power to patent holders.\textsuperscript{12} Under TRIPS rules, a voluntary license is required if an entity other than the patent holder wants to market the patented product.\textsuperscript{13} However, in cases of a national emergency, urgency, or public non-commercial use, the need for a voluntary license can be waived and a compulsory license issued by a judicial or administrative authority.\textsuperscript{14}

**THE DOHA DECLARATION**

In November 2001, the fourth World Trade Organization (WTO) Ministerial conference was held in Doha, Qatar. The conference resulted in the Doha Declaration, which stressed the importance of implementing and interpreting the TRIPS Agreement in a way that supports public health, by promoting both access to existing medicines and the creation of new medicines. The major focus of the Declaration was how to provide developing and Least Developed Countries (LDCs) that lack domestic manufacturing capacities when compared to developed countries,

\textsuperscript{12} Article 33 of the TRIPS Agreement.

\textsuperscript{13} Under Article 27 of the TRIPS Agreement, WTO members agreed to allow patents to issue on inventions “in all fields of technology”.

\textsuperscript{14} A compulsory license is an authorization to use a patent without the patent-holders permission. (Sara M. Ford “Compulsory Licensing Provisions Under The TRIPs Agreement: Balancing Pills and Patents” (2000) 15 AM. U Int’l L Rev. 941 at 942. Governments may issue a license to allow the use of an invention (e.g. a patented drug) without the consent of the patent holder on grounds of public interest.

\textsuperscript{11} World Intellectual Property Organization (WIPO) Report on Public Health and Patents in

www.wipo.int/patent/law/en/developments/publichealth.html
access to essential medicines.

While recognizing the need for developing and LDCs to have access to essential medicines, the Doha Declaration did not however provide a closed list of diseases and health problems that the agreement should cover. The Declaration specifically names only HIV/AIDS, malaria, and tuberculosis (TB) but states that other epidemics “can represent a national emergency or other circumstance of extreme urgency.”

The Declaration further recognizes that each member has the right to determine what constitutes a national emergency and has the freedom to determine on what grounds compulsory licenses can be granted.

The Declaration states that the WTO and its Member States:

- Recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, TB, malaria, and other epidemics.

- Stress the need for the TRIPS Agreement to be part of the wider national and international action to address these problems.

- Recognize that IP protection is important for the development of new medicines, but are also concerned about its effect on prices.

- Agree that the TRIPS Agreement should not prevent members from taking measures to protect public health. Accordingly, while reiterating the commitment to the TRIPS Agreement, WTO members affirmed that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ rights to protect public health and, in particular, to promote access to medicines for all.

- Affirm the right of WTO members to use, to the full the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

- Recognize that the flexibilities referred to in Paragraph 4 of the Agreement include:
  
a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

b. Each member has the right to grant compulsory licenses and the freedom to determine the

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15 DOHA Declaration on The Trips Agreement and Public health sub-paragraph 5(c).
grounds upon which such licenses are granted.

c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of IPRs is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

- Recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.

Without making specific provisions, the Doha Declaration recognized compulsory licensing as a means to protect public health and to promote access to medicines for countries that lack the manufacturing capacities in the pharmaceutical sector. Many developing countries, have however expressed their concerns over the failure to reach agreement on implementation of the Declaration.

### STRATEGIES TO INCREASE ACCESS TO MEDICINES

Some of the strategies to increase affordability of medicines include:

- **Encourage the manufacture and use of generic drugs including generic substitution.** The cost of certain drugs has plummeted over time owing to the availability of cheaper generic drugs, which has made genuine equivalents accessible to people worldwide.

- **Promoting competition for multi-source pharmaceutical products, which can include generic drugs.**

- **Creating programs to improve drug procurement.** Good pharmaceutical procurement practices are essential to ensure an efficient drug supply system. UNICEF, UNFPA, WHO and the World Bank have identified 12 operational principles for good pharmaceutical procurement. These principles include:

  1. Different procurement functions and responsibilities should be divided among different offices, committees and individuals, each with the appropriate expertise and resources for the specific function.

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16 A generic drug is a drug, which is produced and distributed without patent protection. They are usually as effective as, but much cheaper than brand‐named drugs.
2. Procurement procedures should be transparent, following formal written procedures throughout the process and using explicit criteria to award contracts.

3. Procurement should be planned properly and procurement performance should be monitored regularly; monitoring should include an annual external audit.

4. Public sector procurement should be limited to an essential drugs list or national/local formulary list.

5. Procurement and tender documents should list drugs by their International Nonproprietary Name or generic name.

6. Order quantities should be based on a reliable estimate of actual need.

7. Mechanisms should be put in place to ensure reliable financing for procurement. Good financial management procedures should be followed to maximize the use of financial resources.

8. Procurement should be effected in the largest possible quantities in order to achieve economies of scale; this applies to both centralized and decentralized systems.

9. Procurement in the public health sector should be based on competitive procurement methods, except for very small or emergency orders.

10. Members of the purchasing groups should purchase all contracted items from the supplier(s) which hold(s) the contract.

11. Prospective suppliers should be pre-qualified, and selected suppliers should be monitored through a process, which considers product quality, service reliability, delivery time and financial viability.

12. Procurement procedures/systems should include all assurances that the drugs purchased are of high quality, according to international standards.

- Providing tax advantages when pharmaceutical companies make the charitable donations of medications.17

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17 Crimm, Nina J., “A Tax Proposal to Promote Pharmacologic Research, to Encourage Conventional Prescription Drug Innovation and Improvement, and to Reduce Product
Reducing taxes, tariffs and margins, and developing pricing policies. The high cost of taxes & tariffs in many poor countries is a significant factor that contributes to the high costs of drugs.

Equity pricing and competition for single-source products. Equity pricing policies ensure that, from the point of view of the community and the individual, the price of a drug is fair, equitable, and affordable. Those in favor of equity pricing argue that the poor should pay less for essential medicines.

Use of differential pricing (tiered pricing). Differential pricing involves the sale of the same good to different buyers at different prices, with the aim of improving the affordability of drugs while generating revenue for the pharmaceutical industry. According to WHO, differential pricing has reduced the cost of many ARV HIV/AIDS therapies by up to 90% in low-income countries, although they continue to be sold at market price in developed countries. 18

Price information and therapeutic substitution.

Promotion of competition and use of safeguards compatible with the agreement on TRIPS, such as parallel importation and compulsory licensing. Developed countries should implement the provisions of the Doha Declaration on TRIPS and public health matters, particularly those dealing with the issue of compulsory licenses to less developed countries that cannot produce these vital drugs.

Encourage the non-commercial use of patented drugs by the government and individuals. Such non-commercial use of patented drugs should be permitted since this does not in infringe upon the economic interest of the patent owner. The inherent protection afforded by all spheres of IP is confined to commercial exploitation.

19 According to a WIPO report, developing countries have recently embraced the TRIPS flexibility initiative in the areas of patent and public health. These include countries such as Zimbabwe, Malaysia, Mozambique, Nigeria and Zambia. Recently, a pharmaceutical company in Nigeria entered into discussions with the National Agency for Food and Drug Administration and Control (NAFDAC) to explore the possibility of importing HIV/AIDS drugs in Nigeria to be sold on a non-profit basis.

20 Goods that are imported into a country without the authorization of the IPR holder for that country, but after the goods have been legally placed on sale in another country. Parallel importation and compulsory licensing both provide safeguards against a patent holder charging excessively high prices in a particular market. They are recognized as TRIPS public health safeguards because they enhance the affordability and availability of medicines.
CONCLUSION AND RECOMMENDATIONS

It is clear that there is a massive disconnect between the interests of pharmaceutical companies that provide patent medicines and the interests of countries that desperately need the medicines for survival. Achieving a balance will entail a careful weighing of moral, legal, economic and public considerations. Although it would be tempting to assert that drugs that are critical to human survival should not be patented, particularly in view of the fact that an inventor like Jonas Salk\(^{21}\) has set the pace for such, the reality of the world we live in today is that pharmaceuticals will not be encouraged to invest in R&D if they are certain that they will not recoup the costs of the R&D and clinical trials.

One viable method of narrowing the divergence between the patent system and public health objectives is to encourage governments to fund important scientific research thereby making the drugs more affordable. Furthermore, various health groups and the public should be given a forum to express their views. Where this is neglected, the consequences may be dire. A good example is the incident that took place at a conference on HIV/AIDS where an interest group or an association representing People Living With HIV/AIDS (PLWHA) almost disrupted the conference because they felt they were not represented.

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\(^{21}\) Jonas Salk was an American Medical Researcher who invented the polio vaccine. When asked who owned the patent for vaccine, he replied “There is no patent, could you patent the sun”. 
http://www.populist.com/01.7.buell.html