Promotion and Hindrance in Patent Pharmaceutical for a Thrust on Economic Development in Nigeria: A Case Study

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Abstract: Considering the Non-accessibility and Non-affordability of essential medicinal drugs in the Nigeria and Sub Saharan African countries, the promotion and hindrances faced in the resolution of this pivot issue is been constantly scrutinized for attainment of practical and pragmatic approach. The bulk of the attention stems from the HIV/AIDS epidemic which affects many developing countries acutely, and where much of the infected population is said to be unable to obtain effective therapies because of their prohibitive cost. Significantly ailing vast youth and productively active population suffers from the hazardous diseases like HIV/AIDS, Malaria and Pulmonary diseases, thereby adversely affecting the economic task for development and built up of the nation. Some of the quintessential points are non availability of Pharmaceutical Drugs, Non—existence of proper legal channels in the state, Socio-Eco and Political challenges not addressed appropriately, Fulfillment of Millennium Development Goals (MDG) are wanting to be still effectively implemented, the constraints in the availability, accessibility and affordability of life saving drugs in turn resulting into decelerated economy and other related issues for the development of Nigeria are discussed herewith.

Keywords - Non-accessibility and Non-affordability, Nigeria, HIV/AIDS, Pharmaceutical Drugs, Economic Development.

I. INTRODUCTION

The debate concerning the economic implications of intellectual property rights (IPRs) has gained considerable attention over the past two decades in the context of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the subsequent increase of regional and bilateral free trade agreements in theTRIPS-plus era. The patent requirements of TRIPs are contained in Articles 27–34. Patents must be made available for all "inventions, whether products or processes," and must last for at least twenty years from the date of the filing of a patent application².

Pharmaceutical prices in the developing world have been much in the news lately³. The bulk of the attention stems from the HIV/AIDS epidemic which affects many developing countries acutely⁴ and where much of the infected population is said to be unable to obtain effective therapies because of their prohibitive cost. The hurdles faced by the people for accessibility of medicines and the impact on economic development are matters of grave concern globally. The patents have played significant role in contribution and development of pharmaceutical industries and also different sectors of economic development. Some of the pivotal issues amongst these are such as non accessibility of essential life saving drugs for the treatment of serious diseases like HIV/AIDS, malaria and yellow fever in Sub Saharan African countries one such as Nigeria.

Nigeria is one- third than Texas and is the most populous country in Africa comprising of 250 ethnic groups speaking 4000 dialects. It is situated in the Gulf of Guinea in West Africa representing similarly placed countries in that region. In size it is more than two and half times of California. Of more than 36 million people suffering with HIV/AIDS today, over 95% live in developing countries. Those who live in developing countries do not have access to basic drugs needed to treat HIV related infections and other conditions. More than 2-5 million people die each year from this disease. The introduction of antiretroviral has dramatically reduced

² TRIPs Article 33

¹TRIPs Article 27.1

³ Academic commentaries also abound. See, e.g., Frederick M. Abbott, The TRIPs-Legality of Measures Taken to Address Public Health Crises: A Synopsis, 20001 Widener L. Symposium J. 71; Judy Rein, International Governance Through Trade Agreements: Patent Protection for Essential Medicines, 21 NW. J. Int'l L. & Bus. 379 (2001)

⁴ See David Satcher, The Global HIV/AIDS Epidemic, 281 J. Am. Med. Assn. (April 28, 1999); UNAIDS-WHO, Aids Epidemic Update, December 2000 (available at www.unaids.org/waq/2000/wad00/files/wad epidemic report.htm.

mortality from AIDS in the developed countries.. Currently in most LDC's the high prices condemn the people with AIDS to premature death.

Nigerian reports have shown as to how patent monopoly can affect the availability and affordability of essential medicines that gives comparison of prices in different. The economic condition of such poor country is so weak enough that they are incapable of affording the exorbitant prices of the branded or patented drugs which have captured the world attention and triggered a global campaign for access of affordable medicines over past few years. Another factor is chronic under-investment in healthcare infrastructures which has led to lack of clinics and hospitals, poor distribution networks and low numbers of trained healthcare providers and high level of patient illiteracy.

1.1 COMPULSION FOR THE USE OF PHARMACEUTICAL MEDICINES

The Economy of Nigeria has been consistently stagnant over the years particularly due to the persistent trailing health of the people of Nigeria suffering from hazardous and life threatening diseases like HIV/AIDS, Tuberculosis, Yellow Fever and Malaria hence the need of medicines arise. This is further aggravated by the under-investment in health infrastructure leading to lack of clinics and hospitals, poor distribution networks and low number of trained healthcare providers and high level of patient illiteracy.

Remedial Measures

1.1.1) Legal Barriers

Quality, generic therapy can be made available, if no legal barriers exist that are internationally recognised but have to be specifically included in national legislation as well in the State.

- a.) Affordability Dimensions:
- b.) Rationalization in procurement price policies of medicines
- c.) Entrenching rational use of medicines into the system
- d.) Improving access to public health facilities

1.1.2) Introducing Foreign Direct Investment (FDI) in the State

Internalize the costs of technology transfer through direct investment in a majority-owned subsidiary from the efficient expertise and already infrastructures existing in the developed countries would enhance the affordability and accessibility of drugs at lower cost.

1.1.3) Effect on Economic Development

Complex links to poverty and skewed distribution of income appears to be the key determinants for HIV/AIDS, as in all communicable diseases. The ultimate effects of such conditions in turn, increases vulnerability, reduce the ability to handle risks and ultimately exacerbate marginalization and intensify the conditions of poverty, further increasing the socio-economic impacts of the disease resulting to the erosion of economic development. One of the significant commitments of the World Health Organization (WHO) for Nigeria is advocacy, promotion, prevention, treatment, and rehabilitation of the existing constraints of the Nigerian people especially health based issues.

1.2 WORLD HEALTH ORGANISATION (WHO) COMMITMENT FOR HEALTH DEVELOPEMENT

Most of the health and developmental challenges in Nigeria over the period of the first Country Cooperation Strategy (2002-2007) have not changed significantly⁵. Efforts to militate against continued human abuses in perpetuatity with Nigerian people are still in the state of infancy.

- 1.1.1) The 4 Millennium Development Goals (MDGs) that are directly related to health are
- 1.1.2) Eradication of extreme poverty and hunger in the world
- 1.1.3) Reduce child mortality
- 1.1.4) improve maternal health
- 1.1.5) combat HIV/AIDS, malaria and other diseases.

⁵ www.who.int/countryfocus/cooperation.../ccsbrief_nga_en.pdf

⁶ Sources: National Demographic and Health Survey 1990, 1999, 2003.
Source: Federal Ministry of Health and World Bank. 2005. Nigeria, Health, Nutrition, and Population Country Status Report

⁷ http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_nga_en.pdf

1.3 WORLD HEALTH ORGANISATION (WHO) STRATEGIC AGENDA (2008-2013)

The prioritized agenda includes strengthening health systems within the context of Primary Health Care. The WHO Country Office will advocate and evaluate implementation of the National Health policy and give technical support to important federal and state policy organs; assist in developing a health workforce management system and assist with strategies to improve the availability of essential medicines and health technologies.

$1.4\,$ CURRENT STATUS OF ACCESSIBILITY OF MEDICINAL DRUGS FOR OVERCOMING HEALTH HAZARDS.

Nigeria, because of the non-existence of a proper national drug policy, is importing drugs from different countries, without settling an international tender which would bring down the prices. Nigeria is facing now a huge problem that is making accessible life-saving drugs. Currently, the drugs that were studied (mainly ARVs, OI drugs like antibiotics, antifungals), are not easily available and not affordable.

Nevertheless, quality generic combination treatment is available in the world. If large quantities are demanded, generic producers will in a few years be able to bring down the price of most of the medicines. Nigerian Government can make medicines available at lower rates by using key legal mechanisms. There would be an ethical imperative to provide treatment to the population. These health exceptions are:

1.4.1 Legal Wrangling:

- a.) Compulsory License: It is one of the element in TRIPs that is designed to mitigate the negative consequences of patent monopoly. According to this article, WTO members states may allow the use of compulsory license to a third party without the owner's consent, in specific cases like national emergency, extreme urgency, public non commercial use.
- b.) Parallel Imports: It is based on the principle of exhaustion of rights. When written into national law, this allows cross border trade in a patent product without the permission of the patent's owner. Parallel imports allow countries to import brand name products from countries where they are sold at lower prices. for instance, Nigeria should be able to import drugs from Spain, the cheapest source of drugs in Europe, instead of other countries like UK.

All these exceptions are TRIPs compliance and internationally recognized. Therefore, it is a legal tool that governments should use to improve access to essential medicines

1.5 CONSTRAINTS FACED BY STATES IN RESOLVING THE HEALTH ISSUES

Over the last decade, public health and development issues have become topics of great international concern. Public health in many parts of the world has reached crisis level: Over 14 million people are killed by infectious diseases each year (90% of which are in the developing world); over 40 million people globally are infected with HIV/AIDS (90% of which are in the developing world) and the disease kills over three million people annually; over 500 million people are infected with malaria each year and the disease kills upwards of two million people annually; over eight million people develop active tuberculosis (TB) each year and the disease kills over two million people annually (95% of those afflicted and 99% of deaths resulting from TB are found in the developing world)1 Blame game which is often existing serves no purpose on crucial health issues and in turn the socio-economic development. Hundreds of thousands more people die each year from other, lesser known, diseases which predominantly affect developing countries. Unfortunately, public debate on the issue is most often limited to blaming the pharmaceutical industry and patent regulations under the World Trade Organization (WTO) and its Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for the lack of accessibility and affordability of much needed drugs in developing countries.

Nigeria faces developmental challenges in the economic, political, and social dimensions. Though analytically distinct, these problems are integrally related. Economic stagnation arises from a generalized crisis of governance, just as poor economic performance contributes to the infirmities of the state. The weakness of central political authority, and the insecurity of rulers, exacerbate social tensions and undermine capital formation. Nigeria's deep communal divisions significantly impede state formation and economic growth and are themselves aggravated by political uncertainty and privation. ¹⁰

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⁸ <u>http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_nga_en.pdf</u>

These linkages are variously addressed by Richard Joseph, Democracy and Prebendal Politics in Nigeria: The Rise and Fall of the Second Republic (Cambridge University Press, 1987); Tom Forrest, Politics and Economic Development in Nigeria, 2d ed. (Boulder, Colo.: Westview Press, 1995); and Eghosa Osaghae, Crippled Giant: Nigeria since Independence (Indiana University Press, 1998).

¹⁰ www.cgdev.org/doc/shortofthegoal/chap3.pdf

1.6 ECONOMIC IMPACT

Since more young and productive age people are ill and will continue to die, the demographics of Nigeria as well the Sub Saharan African countries are changing, further increasing the socio-economic impacts of diseases. In September 2003 ECOWAS (Economic Community of Western African States) conference on the AIDS and the workforce reports ILO (International Labour Organization) estimates, 42 million people worldwide living with HIV/AIDS, over 26 million are workers and by year 2020 heavily infected countries will have a workforce by 10-30 percent smaller. As more workers in countries having already high employment rates fall ill and are unable to work, such "labour losses have the potential to impact and aggregate output, tax revenue and overall economic activity".

1.7 GOVERNMENTAL PLANS

This is a key pillar on which the success or failure of National Economic Empowerment and Development Strategy (NEEDS) largely depends. Without effective governance, no meaningful reforms can be implemented. The general direction of policy is to move government away from the production of goods and services that are best left in the hands of the private sector. On its part, government should become an enabler, providing the appropriate environment for private enterprise to thrive to develop a healthy competition and consequently the healthy nation.

The objective of NEEDS is to enable Nigeria achieve a turn around and grow a broad based market oriented economy that is private sector - led and in which people can be empowered so that they can, as a minimum, afford the basic needs of life. It is therefore a pro-poor development strategy with sources of economic empowerment being gainful employment and provision of social safety nets for vulnerable groups. The need for policy reform goals addressed the following key obstacles: poverty and inequality; weak public sectors; poor economic management; and an unfavourable environment for broad-based, private sector-led economic growth.

Prominent among these are the introduction of a national social security system to take care of the unemployed, the ploughing back of extra revenues from the removal of oil subsidy into developing social and economic infrastructure and the need to pay adequate attention to the provision of quality education at all levels to facilitate the production of skilled manpower.

Introduction of Accelerated Privatisation, Liberalisation and Private Sector Development should be enhanced so that the products in market become quality wise cost effective, product become competitive.

II. CONCLUSION

The proper balance between the right of the patent holder and affordability and accessibility of the drugs to the common people in developing and underdeveloped countries is a bigger challenge before international community. The Provision of Compulsory Licensing can be used as suffering from killer HIV/AIDS, malaria, tuberculosis, lung cancer, heart disease etc. In countries like Nigeria and Malawi with an average income of \$170 and 260 a year respectively, the drugs manufactured by top multinational pharmaceutical companies are completely outside the reach of people , where as generic drugs are barely affordable for some.

The funds are dedicated to addressing problem that are responsible for 90 % worlds burden of diseases. The paper explains why this disparity exists and what should be done about it. The disparity exists because

- a.) Multinational pharmaceutical and biotechnology companies have a large scope to improve with regard to research and development investments on the health problems of developing nations to be economically lucrative.
- b.) Governmental agencies that sponsor biomedical research face little political pressure to allocate funds for the problems of developing nations.

To facilitate this effort, developed countries should have established a sufficient trust fund dedicated to research on the health problems of developing nations similar to the GLOBAL AIDS Fund.

The current public health crisis, none are as simple to resolve, relatively speaking, than amending the TRIPS agreement. There are means that have yet to be addressed to balance the interests of commercial pharmaceutical enterprises with the human rights of patients in developing nations. By lobbying our government with creative yet pragmatic ideas, globally equitable healthcare can be reality. Industrialized and developing countries must adopt, adhere to, comply with and respect existing IP laws, rules and regulations.

Developing countries, with the assistance of developed countries, must create a parallel oversight capacity, where there is none today, to manage IP in their countries. Access to medicines and innovation are not and cannot be mutually exclusive; without access, innovation is meaningless; without innovation, there is nothing to

access. The symmetry amongst innovation, free markets, protection of intellectual property, and democratic societies should be inculcated and hence would cater the needs of economic development.

REFERENCES

Books:

- [1] Meuwissen LE, Problems of cost recovery implementation in district health care: A case study from Niger, Health Policy and Planning 2002) 17(3) 304-313.
- [2] Maskus, Keith E., Price effects and competition aspects of Intellectual Property Rights in developing countries, background paper for World Bank, World Development Report 1998/99
- [3] Bhagirath Lal Das, WTO Doha Agenda: the new negotiations on world trade political science: (2003) 119-122
- [4] Frederick M. Abbott: The TRIPs-Legality of Measures Taken to Address Public Health Crises: A Synopsis, 2001

Websites:

- 1. http://www.who.int/countryfocus/cooperation strategy/ccsbrief nga en.pdf
- 2. www.cgdev.org/doc/shortofthegoal/chap3.pdf
- 3. www.who.int/countryfocus/cooperation.../ccsbrief_nga_en.pdf