

Review

Patent rights and essential medicines in developing countries: is access compromised for innovation in Nigeria?

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Globalization has turned the world into a global village of interdependent countries linked by multilateral agreements like the 'Trade Related aspects of Intellectual Property rights (TRIPS) agreement' of the 'World Trade Organizations' (WTO). This agreement which came into effect on 1st January 1995 is applicable to all member countries of the WTO. The TRIPS agreement is expected to encourage new research and development into new products including essential drugs globally. However, there is concern in Low Income Countries (LIC) and Low-Medium Income Countries (LMIC) that this agreement may further reduce the people's access to much needed essential drugs. This may ultimately increase morbidity and mortality indices and will worsen their health and economic status and lead to under-development. This commentary seeks to debate this Health policy issue under the statements: "Patent rights are important for drug companies to induce innovation and research and development. Access to medicines is the problem of patients and governments" Finally, recommendations are made to guide Nigerian policy makers.

Keywords: Intellectual property rights, 'TRIPS', 'WTO', patent rights, access, drugs, essential medicines, prices, developing countries, Nigeria.

INTRODUCTION

Globalisation has turned the world into a global village consisting of interdependent countries linked by multilateral agreements like the World Trade Organizations' (WTO) Trade Related aspects of Intellectual Property rights (TRIPS) agreement. This

came into effect on 1st January 1995 and is applicable to about 148 WTO member countries (WTO, 2006). Prior to this, patents and other intellectual property rights were national issues and most countries like Spain, Norway, Finland excluded pharmaceutical products until 1992 and 1995 respectively (Morgan, 2006). The World Intellectual Property Organization (WIPO) however transferred patent rights to WTO which has dispute resolution capacity. It is to ensure compliance with 'minimum' standards of protection of intellectual property rights or patents. These are rights given to persons over the creations of their mind. Usually there is an exclusive right for 20 years preventing copying of inventions (WTO, 2006). Patents are given only for innovations either a new idea, method or step of a process which has social or industrial applicability (Sterckx, 2004; WTO, 2006). They are valid only in countries where protection is applied for (Akonumbo, 2005). Most developed countries complied

Abbreviations

ARV: Anti-Retro Viral, CL: Compulsory Licenses, EML: Emergency Medicines List, LMIC: Low-medium income countries, NAFDAC: National Agency for Food and Drug Administration and Control, NIMR: Nigerian Institute of Medical Research, NIPRD: Nigerian Institute of Pharmaceutical Research Development, R & D: Research and Development, UNDP: United Nations Development Programme, USD: United States Dollar, WHO: World Health Organization, WTO: World Trade Organization, TRIPS: Trade Related aspects of Intellectual Property rights.

with TRIPS since 1995 but developing countries (Low-medium income (LMIC) had up to 2005 and 'Least developed countries's like Togo, Senegal, Ethiopia are to comply by 2016 (MSF, 2002; Oliveria, 2004).

However, will TRIPS be mutually beneficial for developing countries or will it affect public health by preventing access to essential drugs? These were the concerns raised globally and subsequently led to the Doha Development Agenda and the 'Declaration on TRIPS and public health' made at the WTO ministerial conference in Qatar 2001 (WTO, 2001; WHO, 2006). It gave public health primacy over the TRIPS agreement and encouraged countries to use 'flexibilities' entrenched in TRIPS. These include issuing compulsory licenses (CL) when voluntary licenses are not given by the drug manufacturer and a country faces emergency or any urgency as defined by the government. These licenses authorize a government agency or third party to produce generic version of a patented drug. It can also be used to curb anti-competition acts of a pharmaceutical company. In addition, 'parallel imports' of patented drugs can be made from another country where the price is cheaper and 'Bolar Provision' allows early testing and regulatory approval of generic versions so that they can be introduced as soon as patent expires (Oxfam, 2006; Pecoul, 1999; Abbott, 2005). In reality, many countries are reluctant to use these due to fear of sanctions and litigations from drug companies and their home governments, as well as lack of technological ability (Oliveria, 2004; MSF, 2003; Lanoszka, 2003). Instead, developing countries in Central America, Africa and 'South African Customs Trade Area' are pressured into making bilateral and regional Free Trade Agreements (FTA) with the United States of America (USA) which often include more stringent patent rights conditions than TRIPS; limiting use of compulsory license and extending patent life. These are called '**TRIPS plus**' agreements and negates the spirit of the Doha declaration (Correa, 2006; Morgan, 2006; de Boer, 2008; Blouin, 2007). Nigeria similarly signed the African Growth Opportunity Act in 2000 which is a bilateral trade agreement with USA (USTR, 2008; Weissman, 1999).

Globally, 30% of people and up to 50% in developing countries lack access to essential medicines. This is mostly due to absence or inadequate drugs for neglected usually tropical diseases, irrational drug use mostly through inappropriate selection, wasteful use and prohibitive prices (WHO, 2004; 't Hoen, 2003; Oxfam, 2006). There is also problem of poor supply system, storage, and counterfeit and substandard drugs (Attaran, 2004; Pecoul, 1999). The high cost of drugs is often directly related to the patent status (MSF, 2002; Oxfam, 2006) and poverty has been blamed for poor access to medicines in LMIC (Bate, 2006; Bale, 2001). In Nigeria 70-100% of drug expenditure is paid for privately 'out of pocket' and the government spend less than 2 USD per capita on drugs probably because National Health Insu-

rance is not fully operational (Peterson, 2002; FMOH, 2006). Only 10% of Nigerians have access to drugs (Bate, 2006) and 45% of Tuberculosis (TB) patients are on Daily Observed Treatment (DOTS) (Bale, 2001). Among HIV positive people, only 1% requiring antiretrovirals (ARVs) receive them (Peterson, 2002). This is also true in other developing countries, only 20% (1.3 out of 6.5 million) of people needing ARV have access to them (Westerhaus, 2006; WHO, 2002).

METHODOLOGY

The aim of this paper is to review the literature and discuss the statement "Patent rights are important for drug companies to induce innovation and research and development. Access to medicines is the problem of patients and governments". It will give arguments in favor of using patent rights as incentives for innovation and will also discuss the role of patent rights in the problem of access to drugs in the context of developing countries especially Nigeria. It is based on published and grey literature from internet using PubMed, Google, Google scholar and Scopus search engines. Hand searching was also used to retrieve WTO and WHO documents, dissertations and conference reports

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Patents induce innovation and do not reduce access

The pharmaceutical companies argue that innovations and inventions including knowledge goods like pharmaceutical products (drugs) are to be encouraged. Patent rights also cover, copyrights, trademarks, trade secrets; circuit diagrams and any novelty with social or technological benefits (WTO 2006, WHO 2003). Researchers and drug companies are usually not motivated and will not carry out Research and Development (R&D) when incentives are absent. Absence of patent rights discourages research into neglected diseases in developing countries (WTO, 2006; WHO, 2006; Sterckx, 2004; Cohen-Kohler, 2007).

Morally, patents can be justified on natural rights, distributive rights and utilitarian (economic) grounds. Man has 'rights to his idea' and fairness means he should be rewarded for inventions (Sterckx, 2004). Patent system prevents copying by competitors until profit has been made. It also serves a 'disclosure function' so that applicants reveal inventions and the knowledge can be used globally as basis for new inventions and for economic growth (WTO, 2006; WHO, 2006). In cases of joint inventions patent system serves a 'transactional function'; it prevents conflict and determines how profits are shared (WHO, 2006).

Moreover, R&D efforts are very costly in terms of money and time consumed hence the involvement of commercial (private) sector. About 870 million USD is spent per new molecular entity discovered (Epfia, 2007). It is a risky business where only 1 or 2 molecules out of about 10,000 end up as a drug. The research process is time consuming; averagely 12-13 years is spent from drug discovery to the entry into market (Epfia, 2007). Patents are necessary investments that secure a company's future. It allows companies recoup research expenditure and remain financially viable. Patents also imply that the company is innovative and is of a higher standard than others ('signally function'); thus it attracts capital and the corporate image is enhanced (WHO, 2006).

Notwithstanding, poor access to essential drugs is a global problem with other causes beside patent rights. Only 319 drugs on the WHO Essential Medicines List (EML) are patented; and in 65 countries only 1.4% of EML drugs are patented (WHO, 2002; Attaran, 2004). Since less than 10% of drugs used in developing countries are patented, conciliation of patents will not lead to significant improvement in access to drugs (Bale, 2001). Poor access is rather due to insufficient R&D and drug production especially in developing countries without manufacturing capacity. The local drug industry in Nigeria currently meets 20% of the drug needs as against the projection that it will meet 80% of demand by 2000 (Peterson, 2002). The products are mostly generic analgesics, antimalarials, antibiotics and vitamins. The R&D effort depends on few public sector institutes like the Nigerian Institute of Pharmaceutical Research Development (NIPRD) currently involved in developing local drug against Sickle cell anaemia and Nigerian Institute of Medical Research (NIMR) occasionally in collaboration with the private sector (NIPRD). The National Agency for Food and Drug Administration and Control (NAFDAC) is poorly financed and has been accused of contributing to high costs of drugs through high registration fees (Peterson, 2002).

Other factors include exchange rate, high tariffs and taxes on drugs and chemicals which range between 17-20% in Nigeria making drugs cost 2-64 times more expensive than the international reference price (Bale, 2001; Bate, 2006; Woodward, 2001). Also lack of political will and poor regulation makes Nigeria a market for substandard and counterfeit drugs constituting about 48% of circulating drugs (FMOH, 2006; WHO, 2007). There is low demand in these countries because of poverty. Nigeria with GDP of 915 and over 70% of people living below poverty line and average monthly salary of 52 USD cannot afford drugs (FMOH, 2006; WHO Africa 2006). However evidence suggests that patents are unnecessary for innovations and actually reduce access to drugs especially in developing countries.

Patents reduce access to drugs and are unnecessary for innovation

Health is a fundamental human right and essential medicines are required to maintain it. Therefore it is morally unjust and unethical to compromise access to medicines for commercial interests. Pharmaceutical companies actually use patents to stifle competition, increase price and create monopolies (Abbott, 2005; Correa et al., 2004). Thus they make thrice the profit of other companies and have remained the most profitable business in USA since 1982 (Public citizen, 2002; Sterckx, 2004).

Generic competition is the best strategy of lowering drug prices. Anti-retrovirals (ARV) prices reduced from 10,000 to 136 USD per patient per year with supply of generics from India (MSF, 2003; t Hoen, 2003; Westerhaus, 2006). The threat of introducing generics actually forced down ARV and antibiotic prices in Brazil and USA respectively (during the anthrax scare). Globally, the generic industry runs profitably with low R&D cost and standards are maintained.

Apparently, R&D is not as costly as industry claims, figures are often inflated and higher opportunity costs claimed by the companies. In 1990s actual R&D cost per new molecule discovered was 114-150million USD (Public citizen, 2001). Also, only a small fraction of the profit is reinvested into R&D. In 2000, eleven biggest drug companies spent 30% of their revenue for marketing and administration but a paltry 12% for R&D (de Boer, Public citizen, 2002). Moreover, public funds are used for R&D especially basic research which may be unprofitable (Sterckx, 2004; WHO, 2006). Government contributed 44%, 'not for profit' organizations -7.6% and pharmaceutical companies-48% to the global 106 billion USD spent on R&D (Epfia, 2007). Also 45 out of 50 top selling drugs in the USA in 1992-1997 received government funds during R&D (Public citizen, 2002). Industry often develops drugs from unpatented traditional knowledge like Chinese Artemisin which is received free (WHO, 2006).

Moreover, patents have not induced right innovations, instead old drugs are slightly altered or new dosage forms introduced. A lot of these 'me too' drugs should not be patented. Only drugs reflecting market patterns like anti-cancer, anti-hypertensive and not public health priority are developed. Ninety percent of research is directed against 10% of global disease burden (t Hoen, 2003). Only 31% of 1,223 drugs patented between 1973 and 1997 were truly innovations and only 1% was for tropical diseases. It is doubtful that patents can induce R&D in neglected and tropical diseases as the developing countries have a very small share of the drug market (Sterckx, 2004; WHO, 2002). Patents may rather hinder development as access to information is restricted

during the development phase and companies may duplicate efforts and waste resources (WHO, 2003).

Meanwhile, patents reduce access to drugs in developing world. The population offers a potentially large market for ARVs including patented new second line drugs (Lanozka, 2003; Morgan, 2006; Weissman, 1999). Nigeria has about 2.8 million people living with HIV/AIDS (PLWHA). Access however is further reduced by the 'TRIPS plus' conditions included in the Free Trade Agreements (FTA). Oxfam (2006) estimates that Colombia will need extra 940 million USD for drugs and compromise access of 6 million people by 2020 and Peru will expect 100% increase in drug prices by 193 million USD as a result of these FTAs.

Consequently, there are other incentives for motivating research apart from patents. Companies can be motivated by advance purchase commitments for future products like vaccines. Peer recognition, academic rewards and prizes are time-proven alternatives. Industry can be rewarded with big one-time financial reward and global fame and recognition and they may get R&D tax waivers (Love, 2006; WHO, 2003).

CONCLUSION

Finally, although patent rights serve as incentive for the drug companies and may allow them recoup funds and raise capital for future R&D; it leads to monopolies and stifle competition. The drugs developed are market driven and usually not public health priorities. This will worsen the poor access to essential drugs in developing countries like Nigeria; carrying the double burden of communicable and non-communicable diseases including the HIV pandemic. Drug prices should be reduced to affordable levels.

Enforcing patent rights and enticing these countries to make TRIP-plus agreements will worsen their health and economic status and lead to under-development. This is not the aim of globalization which promises trade liberalization and technology transfer. Countries should be able to use TRIPS flexibilities and adapt patent laws according to national realities without fear of sanctions. It is surprising that developed countries like the USA will grant aid through PEPFAR and Global Fund and still encourage loss of human capital through unaffordable essential drugs, this can only perpetuate the poverty cycle.

RECOMMENDATIONS

These recommendations can be applied for policy development either internationally or nationally. There is need to encourage innovations without making drugs inaccessible, therefore the current patent system should be modified. There should be strict regulation of the

pharmaceutical industry by neutral people without conflicting commercial interests. There should be a system for 'capping' or controlling drug prices and only 'true inventions' should be patented.

The level of public sector involvement should be increased and should not be limited to initiating basic research and development but should continue up to the stage of commercializing the drugs. Capacity will need to be built in the public sector. Some research institutes like Nigeria's NIPRD need to be upgraded and get better funded to ensure cost-effectiveness. There should be increase in research grants given to researchers and institution; this can be raised from both public and private sources. This should be given through an equitable and transparent system. Corporate organizations should be made to contribute to R&D efforts and tax credits can be received for these. Individuals in countries with low drug taxes can be made to pay special R&D taxes.

There is need to strengthen public-private partnerships for R&D as private sector tend to be cost-effective. In Nigeria, more private interest should be generated and it should be linked with public institutes like NIPRD which is currently developing drugs against Sickle cell anaemia. The health systems of developing countries require strengthening to promote access and rational drug use. There is need to improve data management, drug distribution and bulk purchasing mechanisms. There is need to encourage prescriptions of generics. The drug regulatory agency should be adequately funded so as to ensure that good standards and combat drug counterfeiting.

The effort of international organizations like WHO, UNDP, World Bank in advocacy for drug access should be continued. Also their involvement through initiating and funding institutes for R&D of drugs for tropical diseases should be encouraged. International partnerships like the 'International AIDS Vaccine Initiatives' and 'Drugs for Neglected Diseases Initiative' (DNDi) should be strengthened. The American 'Orphan Drug Law' program which has generated modest R&D on drugs with high therapeutic but low economic value can be explored and reproduced in other countries.

Finally, there is need to exploit flexibilities present in the TRIPS agreement. Moreover, experts should closely examine future international treaties, agreements and bilateral FTAs and ensure that they do not compromise the health of the populace. The Nigerian government should reduce tariff on drugs and local manufacturing capacity should be developed. Foreign direct investments and drug donations should be attracted through good governance

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