



POLICY BRIEF

ROLE OF INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER FOR THE PHARMACEUTICAL SECTOR



Role of Intellectual Property and Technology Transfer for the Sector

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1.0. EXECUTIVE SUMMARY

This policy brief arises from a study commissioned by the Scinnovent Centre and undertaken by ACTS under the auspices of the Science Granting Councils Initiative (SGCI). The study focused on building competitive and socially inclusive local pharmaceutical industries in West Africa and addressed five issues: affordability, human resources, research and development, intellectual property and technology transfer. This policy brief presents findings on the role of Intellectual Property and Technology Transfer to support the growth of local pharmaceutical industries in the ECOWAS region.

2.0. INTRODUCTION

Many African countries, through their development plans, have prioritized access to affordable healthcare services. However, the realization of these aspirations has been constrained due to the high costs of imported medicines, which not only increase the health burden but also have negative implications on access and affordability of medicines. Affordability is important since up to 90 % of the populations buy medicines through out-of-pocket payments. As a result, many African countries have started initiatives to promote local pharmaceutical manufacturing, to address the issue of high costs of imported medicines and to tap on additional benefits that local pharmaceutical industries can bring, such as creation of employment opportunities, technology

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and skills transfer and enhancing intra-Africa trade. This has led to the establishment of about 172 local pharmaceutical firms in the ECOWAS region. Nigeria is leading with 120 firms, followed by Ghana with 37 firms, while Senegal and Cote d'Ivoire have five firms each. Benin, Burkina Faso, Cape Verde and Guinea Conakry have one firm each.

However, there are several bottlenecks experienced by the sector, along its value chain (access to inputs, manufacturing, and marketing). These include (a) **access to raw material** - over 90 % of the inputs for local pharmaceutical manufacturing is imported i.e. Active Pharmaceutical Ingredients (APIs); packaging materials, as well as other inputs that are not manufactured in the region; (b) **shortage of skilled labour** - the human resource challenge is not only on the number of pharmacists and other professionals but also on their limited or lack of industrial pharmaceutical knowledge and skills; (c) **expensive pharmaceutical manufacturing equipment and technologies** - the bulk of the pharmaceutical manufacturing equipment are imported, and therefore expensive, (d) **low investment in pharmaceutical R&D** in the region and (e) limited utilization of **TRIPS Flexibilities**; (f) **medicines regulations** in the ECOWAS region, member states have in place basic legal framework for the regulation and control of the manufacture, distribution and utilization of medicines for human use. A review of the systems (Anglophone and Francophone) showed that medicine regulation is still problematic, due to weak infrastructure, weak enforcement power, and inadequate human resource capacity, amongst others. The medicines regulatory sector is also faced with the problems of poor motivation and low retention of staff; high levels of counterfeit and illicit medicines and lack of harmonization of medicines regulation. There are also differences in the requirements for medicines registration in member countries; (g) **accessing market** - the local manufacturers have problems with Procurement of pharmaceutical products by public agencies is usually based on the quoted price, with a tendency to select the lowest bidder. This normally favours international pharmaceutical agencies over local industries due to the low production costs of the former. Furthermore, all donor and development partners funded procurement of essential medicines requires that supplier should have World Health Organization's product prequalification (WHO).

This policy brief examines the role of Intellectual Property and Technology Transfer to support the growth of local pharmaceutical industries in West Africa. It documented the following:

- a. *Data gathered from 16 companies that are producing ARVs and other generic medicines and exporting to neighbouring West African countries, focusing on:*
 - *Nature of the agreement entered into and how these agreements*
 - *The domestic circumstances that led to the negotiations of these agreements*
 - *The extent to which voluntary licensing have contributed to improving access to medicines*
- b. *Progress made in implementing the TRIPs flexibilities policy and guidelines developed by the ECOWAS.*
- c. *Success stories and best practices from elsewhere in Africa and outside Africa*

3.0. APPROACH AND RESULTS

The required information was obtained through desk study, interviews, and stakeholder's consultations, in five ECOWAS countries (Nigeria, Ghana, Cote d'Ivoire, Senegal, and Togo) undertaken by five national consultants, who were contracted in each of these countries. In addition, a scoping desk study was undertaken on Mali, Guinea Conakry, Cape Verde and Benin. In addition to national/in-country studies, comparative country studies were also used to document the differences and similarities in approaches between Anglophone and Francophone countries on some of the issues. Benchmarking studies were also undertaken targeting India, China, Brazil, Morocco and Ethiopia, to identify some best practices. The national consultants prepared national reports, which we moderated during a three-day experience sharing amongst the five consultants which took place in Abidjan. The main findings of this study are outline below:

RESULTS

Importance of Intellectual Property on Access to Antiretroviral Drugs

The provision of antiretrovirals (ARVs) to serve public health needs in the ECOWAS is complicated due to a myriad of factors which include poverty and inadequate funding, a lack of appropriate chemical industry capacity, poor social and medical infrastructure and amenities, inadequate legislation, and the existence of patents on antiretrovirals ARVs. Patents play a significant role in limiting access to affordable ARVs because the patent holders have monopoly on the pharmaceutical products and production process for a number of years. To obtain a patent on new ARVs, a pharmaceutical company or research organization must file a patent application. Patents may be granted for new products such as medicines, or for processes for manufacturing those medicines. Product patents may be granted on new molecules (often referred to as "base" patents or "compound" patents), or on specific forms or formulations of medicines (often referred to as "secondary" patents). The latter could include, for example, a particular salt form, an oral solution or tablet formulation of a given medicine, or a fixed-dose combination that combines more than one ARV compound into a single pill. Some secondary patents (notably those related to liquid dosage forms) are applied to pediatric formulations of medicines. In practice, new ARVs are generally covered by more than one patent or patent application.

Patents are territorial rights, which mean that they have effect only in the specific territory for which they were granted. Despite the territorial nature of patents, it is important to note that the existence of patents on ARVs in the countries where most ARVs are currently manufactured (e.g. Brazil, China, India, South Africa, Thailand) may be sufficient to ensure exclusivity across developing countries to the patent holders. This is because patents in manufacturing countries could be used to prevent the production and therefore prevent export of the patented medicine into other countries. Thus, in order to understand whether there are patents that may have an impact on market competition in a country that imports ARVs, it is often necessary to review the patent status in countries that are likely to manufacture the ARVs as well as the importing country.

Antiretroviral Drugs (ARVs) & Generic Medicines Production in ECOWAS

There are at least sixteen companies spread across Ghana (six companies) and Nigeria (ten companies) that are involved in the production of generic ARVs which are partly motivated by issues related to TRIPS flexibilities.

In Nigeria which contributes to about 60% of the medicines produced in ECOWAS are Ranbaxy Nigeria Limited, Fidson Healthcare Plc, Archy Pharmaceuticals Ltd, May & Baker Nigeria Plc, Gemini Pharmaceuticals Nigeria Limited, Emzor Pharmaceutical Industries Ltd, Drugfield Pharmaceuticals Limited, Swipha Nigeria Ltd Virazid, Evans Medical Plc & Vitabiotics (Nig) Ltd. In Ghana, Danadams Pharmaceutical Industry Ltd is the only locally-based ARVs manufacturer. The other companies; Ernest Chemist Ltd, Pharmanova, Letap, Kinapharma, Ayrton Drugs Manufacturing Company, LaGray Chemical Company are involved with the exports of generics. Danadams Pharmaceutical Industry Ltd. has the ability to fulfill the government's supplemental needs and exports to Togo, Burkina Faso, La Côte D'ivoire and Gambia. During the first year of Danadams Pharmaceuticals Ltd. Operations, it focused on the process leading to the acquisition of regulatory approval for the production of some selected ARVs. The company managed to acquire the regulatory approval for the production of generic versions of ARVs [3]. Danadams Pharmaceuticals Ltd. products are not WHO prequalified for the supply of ARVs, although it has very modern facilities and processes. As a result of this, the procurement of ARVs from Danadams Pharmaceuticals Ltd has to be paid for from Government of Ghana resources and not with the Global Fund. Drug Regulators from Togo and Gambia inspect the plant and approve ARVs for marketing in their respective countries. Although Danadams Pharmaceuticals Ltd has an interesting story, the company has encountered major constraints such as high cost of bioequivalence tests for each product that is required for the acquisition of WHO Prequalification, high cost of APIs when purchased in relatively small quantities and inadequate market share and lack of economies of scale that result from its inability to supply under the Global Fund arrangements.

The journey of Danadams Pharmaceuticals Ltd. with respect to ARVs is

2005: Received authorization for seven (7) ARVs and became a pioneer by being the first company in Ghana to produce "generic" ARVs.

2006: Seven (7) ARVs registered in the Democratic Republic of the Congo

2009: West African Health Organization (WAHO) awards USD 1.2 million contract to Danadams to provide ARVs to Togo and Gambia

TRIPS Flexibilities in the ECOWAS

The TRIPS Agreement was aimed at ensuring that legislation and regulations developed at the national level maintains a balance between the minimum standard of Intellectual Property Rights protection and the interest of the public. The Agreement establishes global minimum standards for protecting and enforcing nearly all forms of intellectual property rights, including

for pharmaceutical products and processes. However, since TRIPS Agreement came into force, all member states of WTO are obligated to comply with TRIPS agreement by incorporating its provisions into the national patent laws, including patent protection for product and processes. By virtue of Article 27 (1) of the TRIPS Agreement, pharmaceutical products or processes, including medicines fall within the scope of patentable subject matters. Strong patent system and its effects on essential medicines has been discussed widely at the levels of WTO, WIPO, WHO, public health institutions, civil societies and NGOs with greater emphasis on the use of TRIPS flexibilities (Sell, 2007). On this development, member states have rights to use the flexibilities to their own advantage for easy access to essential medicines and pharmaceutical products. Doha declaration also reaffirms the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for that purpose. TRIPS flexibilities came with the assumptions that all countries, including the least developed countries have the capabilities to produce essential medicines using compulsory license.

Lack of access to medicines remains a major impediment to public health in many African countries. This has a negative impact on the achievement of the health related Millennium Development Goals. The desire to improve on the accessibility of essential medicines on the African continent motivated the AU Assembly Decision 55, at the Abuja Summit in January 2005 to mandate the African Union Commission (AUC) to develop a Pharmaceutical Manufacturing Plan for Africa (PMPA) within the NEPAD framework, the 2nd Session of the AU Conference of Ministers of Health undertook “to pursue, with the support of our partners, the local production of generic medicines on the continent and to making full use of the flexibilities within the Trade and Related Aspects of Intellectual Property Rights (TRIPS) and DOHA Declaration on TRIPS and Public Health” as an important element of improving access to medicines.

It is evident that ECOWAS, as a region, needs to strengthen its health systems by enhancing access to essential medicines. The region is fast losing opportunities for improving her people’s development and health due to the poor response to the challenges of lack of access to medicines. ECOWAS needs to follow the example of other regional organizations that have made great advances towards harmonization of regulations on access to medicines using TRIPs flexibilities. There is therefore an urgent need to take appropriate actions to ensure effective improvement of access to medicines in the region, using TRIPs Flexibilities. In recent times, several important interpretations have been tested in bilateral negotiations, in national courts and, most importantly, at the WTO Council on TRIPs. The examination of those specific TRIPs flexibilities and safeguards would ensure that the current development at the global level in respect with TRIPs flexibilities and its impact on access to essential medicines inures to the benefit of Member States of the region. So far WAHO has developed the TRIPs flexibilities policy and guidelines for the ECOWAS which was validated and adopted from 28-29 October, 2012 in Accra by Intellectual Property officers from all 15 Member States and key partners such as ARIPO, OAPI, UNDP and WHO. From 15-16 July, 2013, in Bobo-Dioulasso, WAHO also sensitized directors of the ministries of health, trade, judiciary and industry in the 15 ECOWAS member states to create awareness on the existence of the ECOWAS TRIPs policy and guidelines, the need for its incorporation into national laws and the benefits of implementing the provisions of the WTO TRIPs flexibilities to improve access to essential medicines for public health interventions. An Advocacy TRIPs flexibilities document to enhance the implementation

of the TRIPS flexibilities has been developed and was validated by TRIPs experts 'from 19-22 November, 2013 in Bobo-Dioulasso.

The Progress made in implementation of TRIPS Flexibility policies and guidelines

The use of TRIPS flexibilities is rare in West Africa pharmaceutical sector given low technology capabilities among the local firms. The rare local manufacture of ARVs, ACTs and anti-TB medicines does not contravene the TRIPS Agreement since, in most cases; local firms enter into partnership with foreign companies and produce under their licenses.

Ghana: Ghana has since early 1900 used intellectual property legislations. Ghana did not have a Patent Act until 1992 when the Patent law 1992, (PNDCL 305A) was enacted. The Patent Act, 2003, Act 657 governs patent protection, including protection of pharmaceutical patents, in Ghana. From 2009 under the Swiss Ghana Intellectual Property Project began implementing activities to strengthen the intellectual property regime in Ghana, one of the major activities was the review of the intellectual property acts to be further compliant with the TRIPs Agreement and international best practice. Ghana in compliance with its obligations under the WTO and the TRIPS agreement from 2003 to 2006 amended existing intellectual property acts including the Patent Act and introduce new acts to protect other aspects of intellectual property.

Côte d'Ivoire: Côte d'Ivoire is a signatory to the Paris Convention of 20 March 1883, the Patent Cooperation Treaty of 19 June 1970 and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of 15 April 1994. It has also signed the Bangui Agreement establishing the African Intellectual Property Organization (OAPI): Côte d'Ivoire, which is a member of OAPI, the African Intellectual Property Office, which examines and grants patent applications under the Bangui Agreement. The Bangui Agreement is characterized by the absence of substantive examination of patent applications and the absence of patent opposition processes. It should be noted that Côte d'Ivoire has not adopted a "TRIPS plus" type measure, which is an excellent thing for access to medicines. Among the members of OAPI, all West African countries, except Côte d'Ivoire and Equatorial Guinea, are included in the current list of Least Developed Countries (LDCs). LDCs have a transitional period until 2033 to apply the standards of the TRIPS Agreement for pharmaceutical products.

Nigeria: To implement the TRIPS (Trade-Related aspects of Intellectual Property Rights) agreement the regulations have to be fully transposed. Whilst Nigeria does not enjoy the special status of LDCs within the TRIPS agreement, it can take advantage of all other TRIPS flexibilities, such as the definition of patentable subject matter, the scope of patentability criteria, and compulsory licensing. The Nigerian intellectual property system appears to be fragmented as they are managed by three distinct agencies and three ministries.

Senegal: In 2015 Senegal participated in the revision of the Bangui Agreements to comply with the provisions of TRIPS. The Republic of Senegal deposited its instrument of ratification of the Bangui Agreement, Act of 14 December 2015, to OAPI, on March 28, 2017. After Mali and Gabon, Senegal is the third country to ratify through its parliament the Bangui Agreement. ASPIT, through its role of National Liaison Structure with the African Intellectual Property Organization (SNL / OAPI), must translate at the national level the main tasks given to it by the Bangui Agreement, namely the promotion and sensitization on the use of the industrial property

system for economic and social development. And by the end of 2019 a national committee for the implementation of TRIPS will be established in Senegal. (Source *ASPIT*)

Benin is a member of many international/regional intellectual property agreements: Bangui Agreement (OAPI) (since 1983); Patent Cooperation Treaty (since 1987); WIPO Convention (since 1975); WIPO Copyright Treaty (since 2006); WIPO Performances and Phonograms Treaty (since 2006); and WTO/TRIPS (since 1996) IP legislation.

Mali is a member of the Bangui Agreement (OAPI) (since 1984). It is observed that while the countries in question have the right to exercise the flexibilities under the TRIPS Agreement, in reality it is very difficult to make effective use of these flexibilities as a public health policy tool. Although the Doha Declaration on TRIPS and public health allows developing countries to issue compulsory licenses, they lack sufficient manufacturing capacity.

Cape Verde Joined the World Intellectual property Organization in 1997 and has developed the national intellectual property laws and regulations. The National Intellectual Property Policy and Strategy (PENPI), to be developed, should take into account national priorities, especially those identified in national innovation and development plans, as well as the multifaceted challenges facing the country in promoting an environment conducive to the creation of a social awareness about intellectual property (IP).

Licensing of Patents on ARVs and generic medicines

The production of ARVs is not only research and technology-based but also patent controlled and capital intensive. During the life of the patent, the patent holder may exercise the right to block others from manufacturing, selling or importing the patented product without consent. However, the patent holder may also give consent to other manufacturers to make or sell the product under certain conditions^[6]. The current trend is to manufacture ARVs under voluntary licenses which set out the conditions under which consent is given. The details of these licenses are usually confidential and there is limited information available. Licensing terms and conditions generally specify the countries in which a medicine may be made or sold. The patent holder may announce a commitment not to enforce its patents in certain countries. The practical effect of such commitments is often similar to that of licenses; the scope and certainty of these mechanisms vary.

Case Studies

There are two types of agreement i.e. compulsory and voluntary licensing agreement. These have been explored in a number of countries such as compulsory licensing in Ghana, South Africa, Kenya, Zambia, Zimbabwe and Mozambique while voluntary licensing in South Africa. Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself. It is one of the flexibilities in the field of patent protection included in the WTO's agreement on intellectual property the TRIPS Agreement while voluntary license is an authorization given by the patent holder to a generic company, allowing it to produce the patented article, such as a medicine, as if it were a generic. The license usually sets quality requirements and defines the markets in which the licensee can sell the product.

In addition to voluntary licenses, there are also instances in which a government may intervene without the consent of the patent holder and may issue a license allowing the manufacture or importation of a given medicine despite the existence of a patent. This is called a compulsory license and it is allowed by most national patent laws.

Voluntary License for Manufacturing of ARVs

Case: South Africa: In April 2004, the American pharmaceutical company Merck & Co Inc, announced its intention to grant a license to manufacture Efavirenz to Thembalami, a joint venture between Ranbaxy (India) and Adcock Ingram (South Africa). In early March 2005, the South African government announced that seven companies had been selected following a call for tenders launched a year earlier to supply the public sector with antiretrovirals for the next three years. Of the seven companies, Aspen is the company that has won the most contracts, providing eight of the fifteen antiretrovirals needed. Only one other generic company was selected, Cipla Medpro (Cipla's South African subsidiary), which will supply d4T. The remaining treatments will be purchased from the multinational companies Boehringer Ingelheim, Bristol-Myers Squibb, Merck Sharp & Dohme, GlaxoSmithKline and Abbott Laboratories. Thembalami had not registered the generic version it should produce under Merck's voluntary license and was unable to submit this product for tender⁸. Lessons learned:

Voluntary licensing has enabled the local production of some antiretroviral to be launched in South Africa. In general, South Africa's commitment to expanding access to antiretroviral treatment for its population could lead to a significant change in the overall dynamics of the antiretroviral market. However, it is important to note that the proliferation of commercial partnerships between multinationals and local companies in developing countries, in the form of voluntary licences, does not necessarily ensure that there is genuine competition benefiting the expansion of access to medicines. Multinational companies are increasingly developing this type of alliance. Aspen, for example, manufactures 40 % products for GSK.

By becoming subcontractors to multinationals, companies like Aspen are no longer necessarily in a position to play a competitive role. This is one of the disadvantages of the compulsory licensing system provided for in the TRIPS Agreement, which requires the negotiation of voluntary licences as a preliminary step before compulsory licences can be granted in the event of refusal by multinationals. Control of local manufacturers and sale remains in the hands of multinationals when these licenses are granted for a fixed period of time, to certain producers only and under certain conditions, in particular pricing conditions. This then goes against the multiplication of production sources that allow competition and affordable prices to be obtained

Compulsory License for Manufacturing of ARVs

Case 1: Compulsory Licensing in Ghana

In respect to exceptions to patent rights it was proposed to include early working system (Bolar exception). With respect of compulsory license, the grounds for the grant of compulsory licenses

⁸ Local Production of Pharmaceutical and Related Technology Transfer in Developing Countries, 2011: A Series of case studies by the UNCTAD Secretariat.

are limited; the process for obtaining a compulsory license is cumbersome and expensive, the provisions for government⁹ use are inadequate and should be expanded to cover flexibilities available to developing countries also a legal framework in which voluntary licenses are easily negotiated for and obtained as a matter of course be incorporated. It was proposed that the act be amended to reflect the August 30th, 2003 Decision and clarify the situation for voluntary licensing. The reviewed Patent Act has been approved by Cabinet and forwarded to Parliament for consideration.

In Ghana In respect of compulsory license, the Ministry of Health and the Food and Drugs Board developed administrative guidelines¹⁰ for the issue of compulsory license for pharmaceutical products in Ghana. Ghana has since then used the compulsory license regime once and the condition was that the government use order for public health reasons i.e. was issued on 26th October 2005, issued under the emergency situation with regards to HIV/AIDS within the National HIV/AIDS program, was for the importation of Generic ARVs from India, the ARVs were patented by GlaxoSmithKline (GSK), duration of license was for 3 years, royalties were not paid although the Government was prepared to make such payment and the cost of the ARVs dropped by almost 50%. The effective use of compulsory licensing as a tool for gaining access to medicines at affordable prices requires adequate technical knowledge and efficient administrative infrastructure and this has been demonstrated by Ghana.

Case 2: South Africa in the Challenge of Accessibility of Anti-retroviral Drugs:

In 1997, South Africa enacted legislation allowing the import of low-cost generic medicines and establishing a price control mechanism. However, its application was blocked from February 1998 by the legal action of 39 pharmaceutical companies. They attacked the South African government on the grounds that national laws allowing the use of generic versions of patented products were not in conformity with WTO agreements. Following a legal procedure that generated strong international support, they were forced to withdraw their complaint in April 2001. In addition, under South African law, this verdict put the government in a position to grant "compulsory" licences to allow local production or import of generics. The risk of losing control over the manufacture and circulation of generic versions of their products may explain the promptness with which, following the Commission's condemnation, GSK and Boehringer-Ingelheim granted "voluntary" licences to local producers.

Case 3: The first Brazilian offensive concerns Efavirenz: In March 2001, Merck threatened to sue Brazil for illegally importing generics of Efavirenz, a practice that would constitute a qualified infringement of its patent. The Brazilian response is immediate. Far-Manguinhos did indeed import Indian generics. These imports are not intended for commercial exploitation. The public research and production unit has no intention of selling them on the market. In fact, Far-Manguinhos is working on samples of the Indian credits to develop and eventually produce its own copy. A perfectly legal practice since TRIPS allows patent circumvention in the case of governmental and non-commercial use: an R&D programme on a drug and/or the production of

⁹ The Economic Community of West Africa States (ECOWAS) Regional Pharmaceutical Plan (ERPP), 04/2014, WAHO Technical document.

¹⁰ Strengthening Pharmaceutical Innovation in Africa. Council of Health Research for Development (COHRED); New Partnership for Africa's Development (NEPAD), 2009. Berger, M; Murugi, J; Kennedy, A; Kubata,

a generic of a patented drug under compulsory licence to supply a programme of universal access to essential medicines does not constitute an infringement of intellectual property. The threat of Brazilian local production very quickly finds a favourable echo. The company proposes to reduce the price of Efavirenz by 65% from \$2.09 to \$0.84 per tablet. This resulted in an announced savings of \$39 million for the Brazilian Ministry of Health.

A few months later, Brazil attacked Nelfinavir, a Roche patented drug. After six months of unsuccessful negotiations with Roche¹¹, the Brazilian government announces its intention to override the patent. In December 2001, the supply contract between Roche and the Brazilian Ministry of Health expired. It will not be renewed and Far-Manguinhos will be responsible for the local production of the drug. Once again, the procedure is legal since this is a public non-commercial use, a production under compulsory license intended to feed the universal access to retroviral program. Since a quarter of the program's 100,000 patients are on Nelfinavir, local production is expected to reduce the price of the drug by 40%, saving \$88 million. Very quickly, the Ministry launched the compulsory licensing procedure to start local production and import of Indian generics until Far-Manguinhos could ensure the ramp-up of its production to cover domestic needs. Finally, Brazil's intention to produce Nelfinavir locally under compulsory licence leads Roche to propose a 35% reduction in the price of the drug. An agreement was finally signed at the end of August: the reduction for 40% reduction. and Roche is committed to starting local production by 2002 at the latest. Brazil then interrupted the compulsory licensing procedure. In 2003, universal access to antiretroviral drugs programme covered nearly 140,000 people.

Case 4: Compulsory Licensing in Kenya.

Kenya has never issued a compulsory license but came close to in 2004 before German pharmaceutical major Boehringer Ingelheim agreed to enter into a voluntary license agreement with Kenyan drug firm Cosmos to produce generic version to produce generic versions of its patented anti-AIDS drug nevirapine¹². Kenya's parliament rejected a proposal to revoke the government's power to issue compulsory licenses to manufacture products such as generic medicines without patent holder approval, a move welcome a universal access to pharmaceutical. The decision to protect Kenya's ability to acquire affordable generic medicines such as antiretroviral treatments for HIV/AIDS patients, without seeking permission from pharmaceutical firm who hold the drug patent rights

Government can issue compulsory licenses to produce medicines more cheaply than prices offered by drug companies without seeking patent holder consent under the World Trade Organization Agreement on Trade Related Aspects of the Intellectual Property Rights. It was unclear who proposed the latest attempt to scrap the compulsory licensing power. Opponents of the amended demanded the government reveal who is trying to nullify the compulsory licensing provisions and discover the motives for the proposed amendments. Ratifying the amendment would have resulted in the government relinquishing its power to issue compulsory licenses to

¹¹ Policy options for promoting the use of Generic Medicines in Low and Middle income countries, 03/2016.

¹² intellectual property by Paul Garwood on compulsory licensing in Kenya

local manufacturers to produce drugs for public health emergencies¹³. It is turn, would have compelled authorities to negotiate directly with the big pharmaceutical firms that hold the patents to obtain medicines.

Case 5: Compulsory Licensing in Zimbabwe

Zimbabwean Minister of Justice, Legal and Parliamentary Affairs issued a notice in 2002 May, declaring a period of emergency on HIV/AIDS in view of the rapid spread of HIV/AIDS in the nation. The declaration enabled the State or a person authorized in writing by the Minister to make or use any patented drug, including any antiretroviral drugs, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions; and/or to import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions¹⁴. The declaration was made pursuant to Section 34 of the Patents Act in Zimbabwe, which empowers the Minister to authorize the use of patented inventions by any government department or third party, for the service of the state. Section 34 is read together with Section 35, which clarifies that an authorization by the Minister under Section 34 during a period of emergency “shall include power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient”. Section 34(2) further provides that the use of inventions is to be on terms and conditions which the Minister and the patent holder may agree upon.

The declaration enables local production and use of the patented medicines, as well as the import of generic antiretroviral (ARV) medicines (Maonera and Chifamba, 2003). Initially, the period of emergency declared was for only six months, apparently due to concerns of the Ministry of Health and the Medicines Control Authority of Zimbabwe (MCAZ) that the declaration would be challenged by the pharmaceutical companies (Maonera and Chifamba, 2003). When the challenge did not materialize, the declaration was further extended to a period of five years from January 2003 to December 2008¹⁵. It is noted that during the initial period of emergency, no measures were reported, due to the unrealistic time frame. After the extension of time, a number of companies did apply for authorization under the declaration. In April 2003, Varichem Pharmaceuticals [Pvt] Ltd, a Zimbabwean registered company, was granted authority to “Make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the purpose of achieving the objectives of Statutory Instrument 32 of 2003.”

Varichem agreed to “produce ARVs or HIV/AIDS-related drugs under the terms of authorization and supply three-quarters of its produced drugs to State-owned health facilities” at prices that “shall be fixed subject to price control mechanisms to be determined by the Minister”. In addition, the company also agrees to provide proof of the “price differentials between the patentee’s drugs and its own manufactured drug”. The company has reportedly agreed to supply the government with its generic version of Combivir (a combination comprising

¹³ Kenya’s pharmaceutical industry 2005 - EPZA

¹⁴ Love, J. (2001) *Compulsory Licensing: Models for State Practice in Developing Countries, Access to Medicines and Compliance with WTO TRIPS Accord*, UNDP, New York.

¹⁵ Reichman, J. and Hazendahl, C. (2002) *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS and An Overview of the Practice in Canada and the United States of America*, Issues Paper No. 5, UNCTAD and ICTSD, Geneva.

zidovudine + lamivudine) at US\$ 15 per month and to meet 75% of the government needs in respect of the drug. This price level would be helpful in keeping the pharmaceutical expenditure down, as available price data for zidovudine + lamivudine combination indicate a range of manufacturers' prices between US\$ 197 - US\$ 237 per patient per year. Varichem, introduced its first ARV to the Zimbabwean market in October 2003, and now has seven generic versions of ARV medicines on the market. The company is currently supplying ARVs to the Ministry of Health and the Defense Forces, as well as to the private sector. It is understood that two other companies have also been authorized to procure generic ARVs under the declaration. Datlabs, a pharmaceutical manufacturer has been authorized to import ARVs from Ranbaxy in India. Omahn, an agent for the Indian manufacturer, Cipla, has also been authorized to import Cipla products.

Assessment of the impact of the emergency declaration in terms of increased access to medicines is difficult as further information needs to be gathered in terms of the prices of medicines, as well as their distribution to patients in need of treatment in the country. There are currently multiple licensees which should help to ensure competition in the pricing of the generic medicine.

Case 6: Compulsory Licensing in Mozambique

The Ministry of Industry and Commerce in April 2004 granted a compulsory license to enable the local manufacture of a fixed-dose ARV combination. The grant of the license was made in accordance with the provisions of Article 70 No. 1(b), Industrial Property Code of Mozambique (Decree No. 18/99 of May 4). Article 70 No. 1(b) permits the exploitation of an invention without the consent of the patent holder by the Government or by third parties "In a case of emergency or in any other circumstances of extreme urgency, either of an economic or a social nature, or for the development of other sectors that are vital to the national economy, when the circumstances so require." The compulsory license is valid until "the conditions of national emergency and extreme urgency created by the HIV/AIDS pandemic comes to an end", at which stage the Ministry of Industry and Commerce will inform the concerned parties of the expiration of the compulsory license.

In granting the license, the Government noted that the "Triple compound of lamivudine, stavudine and nevirapine has proved to be one of the most effective and economical anti-retroviral treatment, but the three international owners of such single drugs failed to reach agreement to produce this combination" hence the decision to grant a compulsory license to the manufacturer, Pharco Mocambique Lda, to produce the said combination. The notice also required that a remuneration be paid to the patent holders of royalties not exceeding 2% of the total turnover of the said product, in light of the fact that the triple combination of medicines is not marketed in Mozambique by the patent owners, and that it is in the national interest to keep prices as low as possible.

Case 7: Compulsory Licensing in Zambia

The Zambian Ministry of Commerce, Trade and Industry in September 2004 granted a compulsory license for the local manufacture of ARVs. The license was granted to a locally-incorporated company, Pharco Ltd., to produce the same triple fixed dose combinations of

lamivudine, stavudine and nevirapine under the brand names of *Normavir 30* and *Normavir 40*.²³ The license was granted in accordance to the provisions of Sections 40 and 41 of the Patents Act (Chapter 400 of the Laws of Zambia). Section 40 provides for the use of patented inventions for the services of the State, and permits “any Government Department or any person authorized in writing by the Minister may make, use or exercise any invention”, whilst Section 41 enumerates a non-exclusive list of the purposes for which an invention may be used during a period of emergency. The terms of the Zambian compulsory license are very similar to those of the Mozambique license described above. There are however, three notable differences. First, the government license specifies a time frame for its validity. The Patents (Manufacture of Patented Antiretroviral Drugs) (Authorization) Regulations 2004, states that the period of emergency means the period commencing on 1st August 2004 and ending 31st July 2009¹⁶. Regulation 3 therein states that “The Minister, may in writing authorize any Government department or person to manufacture, use or vend, in Zambia, any patented antiretroviral drug during the period of emergency.” Secondly, the Zambian license explicitly prohibits the export of the medicines produced under the license, by virtue of Regulation 4. Finally, the Zambian compulsory license stipulates the payment of royalties not exceeding 2.5% of total turnover of products to the patent holders, as opposed to the 2% required under the Mozambique license.

The reason for the similarity between the Zambian and Mozambique compulsory licences may be due to the fact that the licensee is understood that the same company in both cases. However, no further information on the progress of the local production by Pharco Limited is available. This would be worthy of enquiry and monitoring, to assess the effectiveness of the compulsory licences to achieve the objective ensuring access to medicines.

Lessons Learned

By allowing these producers themselves to manufacture and sell the three molecules, the companies avoided legal circumvention of patents by the South African State.

Brazil was the first country in the South to implement a universal access program for antiretroviral. The programme began in 1997 with the provision of free treatment to more than 20,000 HIV/AIDS patients. The annual budget allocated to the purchase of AIDS drugs was then \$224 million. In 2001, the number of people undergoing treatment reached over 100,000. By then, eight out of twelve drugs distributed free of charge were produced locally by Far-Manguinhos, a public research and production unit, which was free to manufacture most of these unpatented antiretroviral in Brazil. They were discovered before 1995, the date of entry into force of TRIPS. However, health authorities started observing an increasing resistance of patients to first-line treatments composed of non-patented drugs¹⁷. Therefore, second-line treatment was required, this time requiring the prescription of patented drugs. This was the case with Efavirenz, a drug patented by Merck, which alone absorbs 10% of the anti-retroviral budget. Brazil was concerned that the increasing use of patented drugs may threaten the

¹⁶ World Bank (2004) *HIV/AIDS Medicines and Related Supplies: Contemporary Context and Procurement – Technical Guide*, World Bank, Washington DC.

¹⁷ Ebube, N. President, National Association of Pharmacists and Pharmaceutical Scientists in America, April 10, 2017 by Pharma Times.

viability of its universal access to retroviral drugs program, which allowed patients to live with the disease, reduced the number of hospitalizations and ultimately saved significant amounts of money. As a result, the country decided to obtain significant price reductions by mobilizing the legal tools available to negotiate advantageously with companies holding patents.

The Domestic Circumstances that Led to the Negotiations of these Agreements

Compulsory licensing enables a competent government authority to license the use of a patented invention to a third party or government agency without the consent of the patent-holder. Article 31 of the Agreement sets forth a number of conditions for the granting of compulsory licences. These include a case-by-case determination of compulsory licence applications, the need to demonstrate prior (unsuccessful) negotiations with the patent owner for a voluntary license and the payment of adequate remuneration to the patent holder. Where compulsory licences are granted to address a national emergency or other circumstances of extreme urgency, certain requirements are waived in order to hasten the process, such as that for the need to have had prior negotiations obtain a voluntary license from the patent holder. Although the Agreement refers to some of the possible grounds (such as emergency and anticompetitive practices) for issuing compulsory licences, it leaves Members full freedom to stipulate other grounds, such as those related to non-working of patents, public health or public interest. The Doha Declaration states that each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Between 2003 and 2005 a number of African countries namely Cameroon, Ghana, Guinea, Mozambique, Rwanda, Swaziland, Zimbabwe and Zambia had to invoke compulsory license regime to import ARVs into their respective countries to address public health needs. The use of the compulsory regime usually brings with it political tension and does not lead itself to the transfer of technology. The aforementioned countries seem to have used the compulsory license regime once.

The extent to which Licensing have Contributed to Improved Access to Medicines

The production of ARVs is not only research and technology-based but also patent controlled and capital intensive. During the life of the patent, the patent holder may exercise the right to block others from manufacturing, selling or importing the patented product without consent. However, the patent holder may also give consent to other manufacturers to make or sell the product under certain conditions¹⁸. The current trend is to manufacture ARVs under voluntary licenses which set out the conditions under which consent is given. The details of these licenses are usually confidential and there is limited information available. Licensing terms and conditions generally specify the countries in which a medicine may be made or sold. The patent holder may announce a commitment not to enforce its patents in certain countries. The practical effect of such commitments is often similar to that of licenses; the scope and certainty of these mechanisms vary.

¹⁸ Commission on Intellectual Property Rights (CIPR) (2002) *Integrating Intellectual Property Rights and Development Policy*, IPR Commission, London

4.0. CONCLUSIONS AND RECOMMENDATIONS

With reference to the above findings of the study, the following conclusions and recommendations are worthwhile considering:

The companies producing ARVs and generic medicines in the region need to be fully prequalified by the World Health Organization to supply ARVs and other generic medicines and get access to the Global Fund. This will also help in addressing the high cost of bioequivalent tests for products produced locally that require WHO prequalification. The Global Fund will help enhance and improve the capacity of the firms' production of APIs and generic medicines which is currently high and address the inadequate of market share and lack of economies of scale.

All the signatory countries to the Bangui Agreement must plead for the revision of this agreement to allow full use to be made of the flexibilities of the TRIPS Agreement, in particular to exclude from patentability medicines for LDCs, allow the use of compulsory licenses as soon as the patent is granted, and imports under compulsory licenses, allow recourse to parallel imports (duty exhaustion regime) and to allow a substantive examination of patent applications. Revision of the Bangui Agreement to allow full use of the flexibilities of the TRIPS Agreement and substantive examination of patent applications must be provided for, and examiners trained in pharmacology and "secondary" drug patent issues before limiting the practice of ever greening. Transparency must be improved by OAPI and local liaison offices in order to make the status of patent applications public and accessible and substantive examination of patent applications must be accompanied by the possibility for third parties to make comments during the examination procedure. It must also be accompanied by the possibility for third parties to oppose the grant of a patent before it is granted

A regional approach to the use of TRIPS flexibilities will enable similarly situated countries to address their constraints jointly by drawing on each other's expertise and experience and by pooling and sharing resources and information. It will also enhance the efforts to pursue common negotiating positions at the WTO and in other multilateral negotiations such as those on a substantive patent law at the World Intellectual Property Organization (WIPO). In addition, a regional approach coincides with the objective of enhancing South-South cooperation on health and development. Pharmaceutical manufacturers apart from the licenses they procure must be assisted to make use of expired patents to help them improve their product portfolios to spur their growth. As that will be a less costly route for product development.

For full realization of Intellectual Property and Technology Transfer to support production of pharmaceutical drugs in the region, the following specific should be considered:

- a. Due to the importance of IPRs on access to medicine, health, food security, technology transfer, trade and the economy in the West African region, it is important that an Intellectual Property Unit should be established at the ECOWAS Headquarters in Abuja to oversee utilization of TRIPs flexibilities in the region
- b. A resolution should be passed by ECOWAS for all Member States to modify or review their IP laws to meet the TRIPs Council requirements.
- c. A resolution should be passed for all Member States to adopt the ECOWAS TRIPs policy and apply the guidelines

- d. WAHO should strengthen the capacity of Member States to understand and apply the TRIPs flexibilities and related waivers
- e. ECOWAS should take on the responsibility of the required notification to the WTO of actual importation of pharmaceutical products under compulsory license on behalf of all the importing members of the region.
- f. ECOWAS/WAHO should collaborate with international organizations WHO, UNDP, UNIDO, WIPO, GIZ and other development partners to ensure full utilization of TRIPs flexibilities in the region.
- g. ECOWAS/WAHO should create a platform for technology transfer and human capacity development to enable easier utilization of the TRIPs flexibilities and related waivers.
- h. Local manufacturers of pharmaceutical formulations in the West Africa countries should be encouraged to apply for compulsory licences to import active ingredients for the local formulation of essential medicines.
- i. ECOWAS should continue to support the development of traditional medicine and their utilization in health care systems in the West African region
- j. WAHO should continue to support capacity building in pharmaceutical manufacturing in the region and expedite the medicines registration harmonization processes.
- k. ECOWAS should strongly discourage Member States from entering into economic partnership agreements (EPA) as individual states. Agreements should be between ECOWAS and the country or regional group such as the European Union.