# DEVELOPMENT OF A HARMONISED TRIPS POLICY

# FOR ADOPTION BY ECOWAS MEMBER STATES THAT EMPLOY TRIPS FLEXIBILITIES TO IMPROVE ACCESS TO MEDICINES IN THE REGION


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I would like to express my gratitude to all institutions and persons who have in numerous ways supported WAHO to strengthen and improve the accessibility of quality, safe, efficacious and affordable essential medicines in the ECOWAS region.

Member States lack of the use of the flexibilities and laxity in incorporating fully the TRIPs flexibilities in their national laws, to enable them take advantage of the patent system, is reflected in the lack of access to essential medicines in respect of pharmaceuticals covered by patents.

The review of national laws by the committee of TRIPS experts is intended to strengthen the maximum utilization of the TRIPs flexibilities by ECOWAS Member States and also encourage the incorporation into national laws the provisions that fully reflect the flexibilities and safeguards.

The ECOWAS TRIPs flexibilities policy and guidelines generally developed are to strengthen the member states health systems by providing technical and legal guidance for the development and marketing of medicines ensuring that the rights provided by national laws do not impede access to medicines.

To the Trips Experts; Dr ALEXANDRA GRAHAM, Mr SHAFIU ADAMU YAURI, Prof. DRISSA DIALLO Mr CARLOS SANCA, Mrs GRACE AMA ISSAHAQUE, Mrs MARTHA GYANSA-LUTTERODT, MAÎTRE CHEIKH FALL and Dr DENIS LOUKOU BOHOUSSOU, we salute you all for your efforts in supporting WAHO to come out with such documents for the region.

To partners such as the United Nations Development Programme (UNDP), we say bravo for your keenness in supporting the region to strengthen its human resource capacity by assisting in the development of national legislators, government offices and civil society actors in matters of intellectual property protection and public health

African Regional Intellectual Property Organization (ARIPO) and Organisation Africaine de la Propriété Intellectuelle (OAPI), your collaboration with ECOWAS and WAHO would certainly lead the way for effective implementation of the TRIPs flexibilities policy and guidelines in the region.

The validation and adoption of these documents are relevant for ownership by Member States for incorporation of the policy into regional and national legislations and for easy implementation of the TRIPs flexibilities to enable comprehensive access to essential medicines. We therefore appreciate the efforts that stakeholders such as WHO/AFRO, WAEMU, NEPAD Agency and Intellectual Property Offices in Member States have contributed to strengthen these documents.

This statement cannot end without the acknowledgement of the WAHO Professional Officer for Essential Medicines and Vaccines, MRS SYBIL OSSEI AGYEMAN YEBOAH, for working hard to see to the development of these documents for the benefit of the ECOWAS region in accessing essential medicines.

May the ECOWAS region and its population benefit greatly from the TRIPs flexibilities policy and guidelines.

Dr Plácido M. Cardoso
Director General
West African Health Organization

## GLOSSARY

| | |
|---|---|
| ARIPO | African Regional Intellectual Property Organization |
| DC | Developing Countries |
| ECOWAS | Economic Community of West African States |
| ESARIPO | Industrial Property Organization for English-speaking Africa |
| EPA | Economic Partnership Agreement |
| FDB | Food and Drugs Board |
| GIZ | Deutsche Gessellschaff fur Internationale Zusammenarbeit |
| IP | Intellectual Property |
| IPR | Intellectual Property Rights |
| LDC | Least Developed Countries |
| NAFDAC | National Agency for Food and Drug Administration and Control |
| OAPI | Organisation Africaine de la Propriété Intellectuelle (African Intellectual Property Organization) |
| TRIPs | Trade Related Aspects of Intellectual Property Rights |
| UNDP | United Nations Development Programme |
| UNIDO | United Nations Industrial Development Organization |
| UPOV | Union pour la protection des obtentions vegetale (International Union for the Protection of New Varieties of Plants) |
| WAHO | West African Health Organization |
| WAEMU | West Africa Economic Monetary Union |
| WHO | World Health Organization |
| WIPO | World Intellectual Property Organization |
| WTO | World Trade Organization |

## EXECUTIVE SUMMARY

Having considered the various national IP laws and other regional legal instruments that affect ECOWAS Member States, the WAHO Experts Drafting Committee has analysed these provisions in line with recent developments in the Trade Related Intellectual Property Rights (TRIPs) Council.

The review is prepared to strengthen the maximum utilization of the TRIPs flexibilities by ECOWAS Member States and also encourage the incorporation into national laws the provisions that fully reflect the flexibilities and safeguards. The document is driven also by the fragmentation of legislations across the region especially regarding the use of the TRIPs flexibilities with the result of lack of access to essential medicines at the sub regional level. The region however could benefit greatly if the sub regional legislations are harmonised as it relates to TRIPs as Member States take advantage of this piece of regulation to improve access to medicines especially for prioritised communicable and non –communicable diseases across the region.

The ECOWAS TRIPs policy generally is to strengthen the member state health systems by providing technical and legal guidance for the development and marketing of medicines ensuring that the rights provided by national laws do not impede access to medicines. The first chapter introduces the subject matter and provide the justification why the region should have a framework for increasing access to medicines through the use of the TRIPs flexibilities. The actions occurring in other regional blocks gave credence to the need for ECOWAS to move in this direction.

Key areas requiring expansion include research capabilities in allopathic and traditional medicines development and expansion of regional pharmaceutical production. Stronger local technological/domestic innovation resulting from pooling of adequate resources including financing will provide the impetus for regional action. African traditional medicines can be a reliable source of medicines. ECOWAS should support the development of traditional medicine and their utilization in health care systems within the West African region.

Chapter two defines the TRIPs Agreement and all the requirements for its implementation. A critical look at the national legislations of Member States reveals that there are provisions giving effect to the TRIPs flexibilities and safeguards. These provisions however deal with the obvious flexibilities

covering patent exhaustion and use of patented product for experiments. It was also worth noting that a number of countries had provisions for some form of compulsory licensing to prevent the abuse of IP rights. Few countries on the other hand had provisions dealing with new uses or known or previously patented subject matter.

Member States lack of use of the flexibilities and laxity in incorporating fully the TRIPs flexibilities in their national laws, to enable them take advantage of the patent system, is reflected in the lack of access to essential medicines in respect of pharmaceuticals covered by patents.

The third chapter analyzes the member state legislation with the various requirements and what each member state could do to improve and support the ECOWAS vision of increasing access to medicines in the region.

Recommendations made for each of the requirements have action points for ECOWAS/ WAHO Member States. These include the need for Member States to develop appropriate policies, reviews, guidelines and schedules of implementation of the TRIPs Agreement. Secondly, for anticompetitive practises, ECOWAS should encourage Member States to enact national competition laws to ensure that anti-competitive practises or transactions, both domestic and international, do not undermine government efforts to promote access to medicines, economic growth, and freedom of trade and consumer protection.

For the protection of undisclosed information, ECOWAS is to ensure that National Medicines Regulatory Authorities do not police Intellectual Property issues since patents are private rights. ECOWAS recommends that no country should go beyond the minimum requirements in respect of patents as provided by the TRIPs Agreement. ECOWAS further recommends that all LDCs, in amending their legislation, should ensure strict compliance with the guideline on TRIPS flexibilities, to reflect the minimum requirements.

Under compulsory licensing, Member States should allow voluntary and non-voluntary licensing for local production.

Regarding ‘Bolar exception’, Member States are encouraged to incorporate this provision into their national legislations to allow for experimental research.

With regards to patentable subject matter, ECOWAS Member States should clearly exclude from patentability matters of which patents should not be granted (e.g. life forms, plants and animals, new uses etc.). Extension of existing patents and patenting of trivial and/or non-efficacious variants of existing chemical substances should be prohibited to prevent “evergreening”

Finally, under the doctrine of exhaustion of rights, international exhaustion should be incorporated to allow parallel importation whenever a patented product is placed in the market anywhere in the world.

## 1.0. INTRODUCTION

WAHO is working towards harmonization of regulations as part of its health service reform efforts aimed at enhancing access to essential medicines. This reform will also help serve as a catalyst for the integration efforts of the region and assist intra-regional health strategies.

The important role of an effective regional system that integrates current intellectual property (IP) norms and allows access to essential medicines in WAHO member countries cannot be over emphasized. Hence, to improve maximum access to medicines in the region, these efforts have to take advantage of the flexibilities that are available under the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPs Agreement") provisions relating to access to medicines. At present ECOWAS/WAHO member countries do not have a coherent legislation on this issue. The TRIPs Agreement requires that current and future members of the WTO adopt and enforce, through their domestic legislation, minimum standards prescribed for the protection of intellectual property rights.

With the exception of Liberia who is an observer, all the countries in ECOWAS are full members of the WTO and are therefore required to meet this obligation under the TRIPs Agreement. Though the time frame for compliance of the WTO obligation differ for developing and least developed countries in the sub region, the specific area of concern in relation to access to essential medicines borders on the implementation and interpretation of the obligations, rights and flexibilities by Member States in a manner that are internationally acceptable and also enhances access to quality affordable medicines.

The flexibilities afforded by TRIPs can only be utilized if they are incorporated into a country's domestic legislation. This is a first and necessary step in any attempt to use the flexibilities for public health purposes. Countries are therefore required to enact legislations that allow them to fully utilize the TRIPs flexibilities and safeguards. It is therefore important to review the legislations of member countries as it relates to TRIPs, promote harmonized rules across member nations that improve access to medicines in the region.

The review of Member States IP laws is aimed at ensuring that the national legislation on patents incorporates the safeguards and flexibilities under the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement. It is also to ensure that the patent system promotes innovation and improves the competitiveness of the pharmaceutical sector leading to enhanced access to essential medicines in the region. Identify gaps if any in national laws and propose harmonised rules aimed at enhancing access to medicines which reflects fully the TRIPs flexibilities and safeguards in Member States legislation

Currently both industry and research institutions are yet to maximise the usage of patent information and the patent system fully to assist the Member States towards its quest to achieve the aspirations of the Millennium Development Goals in order to improve health and create wealth.

It is worth noting that Article 8 of the TRIPs Agreement states that: “Members may, in formulating or amending their national laws and regulations adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of importance to their socio-economic and technological development provided that such measures are consistent with the provisions of the agreement.”

It is important to review the various national laws and other regional legal instruments that affect ECOWAS Member States and analyse these provisions against recent developments in the TRIPs Council.

1.1. Justification.

It is becoming increasingly evident that ECOWAS, as a region, needs to strengthen its health systems by enhancing access to essential medicines within the region. This effort becomes necessary as the region is fast losing opportunities for improving her people’s development and health. 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 for appropriate methods 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.

Furthermore, from an economic and public health standpoint, a regional approach can provide the following incentives:

- Development and strengthening of regional pharmaceutical production
- Strengthening of research capabilities and the establishment of networks for research and development
- Higher effective demand for the same medicines due to climatic conditions and other geographical reasons.
- Lower consumer drug prices due to increased economies of scale in production, procurement and distribution.
- Stronger local technological capacities and technological transfers
- Domestic innovation resulting from the pooling of adequate resources including financing
- Capacity building in terms of human resource and infrastructure.
- Improvement of cross-border disease control.

## 1.2 AIMS

The purpose of these guidelines is to assist ECOWAS Member States to successfully use the flexibilities of the World Trade Organization's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) to increase access to medicines. WAHO, as part of its mandate to improve access to medicines, acknowledges the World Health Organization (WHO) initiative on Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. This encourages governments to consider, where necessary, the need to adapt national legislations in order to use fully the flexibilities contained in TRIPs, including those recognized by the Doha Declaration on TRIPs and Public Health and the WTO decision of August 30th 2003.

1.3 Objectives.

### *1.3.1. General Objectives*

The objective of this review is to

- Assess existing policy and legislation gaps that may create obstacles to the implementation of the TRIPs Agreement in relation to public health and access to essential medicines.
- Make the necessary recommendations for upgrading of policies, rules and regulations to improve the use of the patent regime in the region by industry and research institutions.
- Examine the patent rules at the national level in Member States and ascertain that they are in line with existing international best practices.

The overall goal is to develop a harmonized TRIPs policy for adoption by ECOWAS Member States that employs TRIPs flexibilities for improvement of access to medicines for treatment of priority endemic diseases, neglected diseases and communicable and non-communicable diseases in the West African region.

### *1.3.2. Specific objectives.*

An ECOWAS TRIPs policy will help to strengthen the ECOWAS health systems by enhancing access to essential medicines in several ways including the following:

- Provide legal and technical guidance for the development and marketing of medicines

- Ensure that the rights provided by national laws do not impede access to medicines
- Provide guidance for implementing TRIPs compliant national legislations or regulations, so that the rights provided can be effectively utilized and enforced by domestic and foreign businesses operating in the region.

## 1.4 Activities of the Terms of Reference

Specific activities of the Terms of Reference for the study include:

1. Review of Member States legislation and potential use of the TRIPs Flexibilities for the improvement of access to medicines in Member States.
2. Identify and analyze existing policy or regulatory deficiencies or gaps that may impede the effective implementation of the TRIPs Agreement which impacts on access to essential medicines in National legislations.
3. Harmonise the rules into a legal framework that enhances regional access to medicines in Member States.

## 1.5 Methodology

The key focus of this report is based on Section 5 of the TRIPs Agreement which covers Patents and the various provisions that impact on access to essential medicines in the region as found in Member States legislations, existing policies and regulatory frameworks. This report examines the prevailing national legislation in all the Member States of ECOWAS with respect to their obligations and compliance under the TRIPs Agreement and the impact on access to medicines.

The report also examines the prevailing legislation in the two main regional intellectual property systems in Africa: the African Regional Intellectual Property Organisation (ARIPO), the African Intellectual Property Organisation (OAPI). All ECOWAS Member States, except Nigeria and Cape Verde, belong to one or the other. The two systems are significantly different in nature with OAPI being the only intellectual property organization for its Member States whereas ARIPO Member States have maintained national systems for obtaining intellectual property rights.

The essential focus of the analysis is to indicate the general use of the flexibilities and safeguards provided by the TRIPs Agreement, identify gaps in national legislations and address challenges, opportunities and benefits to Member States as a regional group.

## 2.0. REVIEW OF ECOWAS MEMBER STATES MEMBERSHIP OF WTO AND REGIONAL IP ORGANIZATIONS

The table below summarizes the status of ECOWAS Member States regarding World Trade Organization (WTO) membership, classification as least developed country (LDC) or developing country (DC), membership of regional intellectual property (IP) organizations and the current patent law existing in the country. All Member States, except Liberia, are members of WTO and so subject to the Agreement on TRIPs.

| | **Country** | **LDC Status** | **WTO Membership** | **Membership/ Regional IP Organization** | **Latest Patent Law** |
|---|---|---|---|---|---|
| 1 | Benin | LDC | 22 Feb 1996 | OAPI | Bangui Agreement Revised 1999 |
| 2 | Burkina Faso | LDC | 3 June 1995 | OAPI | Bangui Agreement Revised 1999 |
| 3 | Cape Verde | DC | 23 July 2008 | N/A | 2006 Decree Law |
| 4 | Cote d'Ivoire | DC | 1Jan 1995 | OAPI | Bangui Agreement Revised 1999 |
| 5 | Ghana | DC | 1 Jan 1995 | ARIPO | 2003 Patent Act |
| 6 | Guinea Bissau | LDC | 31 May 1995 | OAPI | Bangui Agreement Revised 1999 |
| 7 | Guinea | LDC | 25 Oct 1995 | OAPI | Bangui Agreement Revised 1999 |
| 8 | Liberia | LDC | Observer since 2007 | ARIPO | Industrial Property Act 2003 |
| 9 | Mali | LDC | 31 May 1995 | OAPI | Bangui Agreement Revised 1999 |
| 10 | Niger | LDC | 13 Dec 1996 | OAPI | Bangui Agreement Revised 1999 |
| 11 | Nigeria | DC | 1 Jan 1995 | N/A | Patent and Design CAP 344 , LFN 1990 |
| 12 | Senegal | LDC | 1Jan 1995 | OAPI | Bangui Agreement Revised 1999 |
| 13 | Sierra Leone | LDC | 2 July 1995 | ARIPO | Enacted in October 2012 |
| 14 | The Gambia | LDC | 23 Oct 1996 | ARIPO | Industrial Property Act 12, Chapter 95.03, 1989 |
| 15 | Togo | LDC | 31 May 1995 | OAPI | Bangui Agreement Revised 1999 |

## 2.1. African Intellectual Property Organization (OAPI)

Until 1962, patent rights in the majority of francophone countries in Africa were governed by French laws. The French National Patent Rights Institute (INPI) was the National Authority for each of these states, and then grouped within the French Union (Union Française). The majority of the French Union member countries having become independent in 1960, found it necessary to create a single body to act as the national patent rights authority for each of them. Hence, on September 13, 1962, the African and Malagasy Patent Rights Authority (OAMPI) were created by 12 African countries in the agreement known as the 'Libreville Agreement. The creation found its legal justification in article 19 of the WIPO Paris Convention for the protection of intellectual property rights, which states that countries, which are signatories to this convention, reserve the right to undertake separately among themselves, specific agreements for the protection of patent rights, so long as these arrangements are not in contradiction with the provisions of the said convention. The Libreville Agreement was based on three fundamental principles

- The adoption of a uniform legislation of common administrative procedures resulting from a uniform system of patent rights protection.
- The creation of a common authority to serve as a national patent rights protection department for each of the Member States.
- The centralization of procedures such that a single title issued by the organization comprised as many independent national rights as member countries.

The withdrawal of the Malagasy Republic coupled with the need to expand coverage to other categories of intellectual property led the Member States to revise the Libreville Agreement and to create the African Intellectual Property Organization (OAPI) by the adoption of a new convention signed in Bangui on March 2, 1977.

The Bangui Agreement as amended henceforth legislates patent rights in each of the 16 Member States, which now make up the OAPI territory. Current membership of OAPI is Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Cote D'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo. All French speaking ECOWAS Member States belong to OAPI.

Patents granted by OAPI are considered to be independent national rights subject to the legislation of each member state. All members of OAPI are automatically designated. The patent law of all OAPI Members is that set out in the Bangui Agreement.

The Bangui Agreement was amended in 1999 to comply with provisions of the TRIPs Agreement. The revised agreement prescribes the legislation applying in all OAPI countries in the areas of patents, utility models, trademarks and service marks, industrial designs, trade names, geographical indications literary and artistic property, protection against unfair competition including confidential information and layout designs of integrated circuits and protection of plant species.
The revised Bangui Agreement updates the previous agreement in the following main areas:

- Members are required to accede to UPOV Act 1991
- Patent term changed to 20 years rather than 10 years + 2 renewable 5 year periods.
- Compulsory licenses no longer possible if demand is being met by importation.
- Grace period extended by 6 months to 12 Months but still only for disclosures at official exhibitions.
- Exceptions to patent infringement introduced for experimental acts and those associated with scientific and technical research.
- Wording corresponding generally with TRIPs Article 39(3) provided for protecting data submitted for regulatory approval purposes.

The Revised Bangui Agreement entered into force for all OAPI Member States in early 2002 following ratification by at least 10 OAPI states.

### 2.2 African Regional Intellectual Property Organization (ARIPO)

Creation of the Industrial Property Organization for English-speaking Africa (ESARIPO) was done in 1976 with the draft of the Lusaka Agreement which came into force on February 15, 1978. In December 1985, the Lusaka Agreement was amended in order to open up the membership of the Organization to all African states that are members of the United Nations Economic Commission for Africa or the Organization of African Unity (OAU). The name of the organization changed from African Regional Industrial Property Organization to African Regional Intellectual Property

Organization (ARIPO) in 2005. In ECOWAS, Ghana, Liberia, Sierra Leone and The Gambia belong to ARIPO. Nigeria and Cape Verde are not members of either OAPI or ARIPO.

The Harare Protocol, which was adopted in 1982 and came into force in 1984, empowers the ARIPO Office to receive and process patent and industrial design applications on behalf of states party to the Protocol. Under the Protocol an applicant for the grant of a patent or the registration of an industrial design can, by filing only one application, designate any of the Contracting States in which he wishes his invention or industrial design to be accorded protection. The Harare protocol also sets down the basic requirements relating to patentability.

The important difference between OAPI and ARIPO is that Member States of ARIPO have the right to refuse protection in their territory of intellectual property rights granted by ARIPO on the basis that they are contrary to their national legislation.

## 3.0. THE TRIPs AGREEMENT

### 3.1. TRIPs Agreement and Pharmaceuticals

The TRIPs Agreement requires that all World Trade Organization (WTO) members should adopt certain minimum standards regarding intellectual property rights (IPR) by providing both guidance and binding policy directives. Patents for pharmaceuticals and other products are only one part of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) which covers a wide range of subjects, from copyright and trademarks, Geographical indications, Industrial Designs, to Layout designs of integrated circuits and trade secrets.

The agreement attempts to strike a balance between the long term social objective of nurturing future inventions and creations by providing appropriate protection and the short term objective of allowing the use of existing inventions and creations.

The balance works in three ways:

- Invention and creativity should provide social and technological benefits. Intellectual property protection encourages inventors and creators because they can expect to earn some future

benefits from their creativity. This encourages new inventions, such as new drugs, whose development costs can sometimes be extremely high, so private rights also bring social benefits.

- The way intellectual property is protected can also serve social goals. For example, patented inventions have to be disclosed, allowing others to study the invention even while its patent is being protected. This helps technological progress and technology dissemination and transfer. After a period, the protection expires, which means that the invention becomes available for others to use. All of this avoids “re-inventing the wheel”.

- The TRIPs Agreement provides flexibility for governments to fine tune the protection granted in order to meet social goals. For patents, it allows governments to make exceptions to patent holders’ rights such as in national emergencies, anti-competitive practices, or if the right-holder does not supply the invention, provided certain conditions are fulfilled. For pharmaceutical patents, the flexibility has been clarified and enhanced by the 2001 Doha Declaration on TRIPs and Public Health. The enhancement was put into practice in 2003 with a decision enabling countries that cannot make medicines themselves, to import pharmaceuticals made under compulsory licence. In 2005, members agreed to make this decision a permanent amendment to the TRIPs Agreement.

As set out in Article 1.1 of the TRIPs Agreement, members may, but are not required to go beyond the minimum standards. For instance, TRIPs (Article 31) obligates Governments when issuing compulsory licenses, to respect certain procedural requirements. Beyond this procedural minimum standard of protection, there are no substantive restrictions on the discretion of Governments to freely determine the grounds upon which a patented invention may be used without the authorization of the patent owner.

Irrespective of a country's approach to implementation, most TRIPs provisions on IPR minimum standards are drafted in very general terms and need to be elaborated to become operational. For instance, patents may only be granted to inventions that are "new, involve an inventive step and are capable of industrial application" (Article 27.1, TRIPs Agreement). In implementing this provision, every Member will have to reflect these minimum requirements in its domestic law and practice. The TRIPs Agreement does not contain any definition of novelty, inventive step or industrial

applicability. Members are therefore free to determine in their domestic laws under what circumstances an invention is to be regarded as meeting these criteria. For example, each Member may decide if new uses of a known substance fulfil the novelty requirement. Under the TRIPs Agreement, governments in Developing Countries (DC) and Least Developed Countries (LDCs) are provided tools ('flexibilities') to promote access to know-how and the technology for new products. The TRIPs Agreement, it should be noted contain elements which when duly applied may allow a certain balance in its implementation, such as an increase in the amount of knowledge in the public domain and a limit on exclusive rights in order to promote competition.

In accordance with the Preamble, the main aim of the Agreement is to "reduce distortions and impediments in international trade". More specifically Article 7 and 8 deal with the objectives and principles and provide a framework for interpretation and implementation of intellectual property rights (IPRs). Another important "principle " is that "appropriate measures which are consistent with the provisions of the Agreement may be required to prevent the abuse of IPRs by right holders or resort to practices which unreasonably restrain trade, or adversely affect the transfer of technology and regulations".

Consequently, each member state while implementing TRIPs at the National level is expected to pay particular attention to its local circumstances and its peculiar situation by deciding on provisions that respond to their particular public interest and other public health needs of the region. The provisions leave room for adopting different solutions at the national and regional levels. It also stipulates that measures may be adopted with a view to preventing or remedying abuses of Intellectual Property Rights (IPRs).

Under these provisions, a country is at liberty to provide for a variety of measures that promote competition and recognize the right of owners and users of technology. The balance required under such circumstances between the right holders on the one hand and users on the other hand may include the use of parallel imports, non-patentability of substances existing in nature, compulsory licenses and exceptions to exclusive rights.

Given that both nationals and foreigners must receive the same treatment without discrimination (Articles 3 and 4 of the TRIPs Agreement), the challenging task for governments in implementing

TRIPs is to determine which approach is the appropriate one for their country's efforts to promote technological innovation and technology transfer, without at the same time obstructing other policies in such relevant areas as public health and access to scientific and educational data, information and materials.

The above examples show that Member States, when implementing the TRIPs provisions, have considerable leeway (generally referred to as "flexibilities"), so long as they respect the minimum standards expressly stipulated in the TRIPs Agreement to decide where the dividing line between these areas should be drawn. For example, whether to promote broad exclusive rights and a limited public domain, or vice versa.

### 3.2 What are the Requirements of Protection under the TRIPs Agreement?

Article 27.1 of the TRIPs Agreement stipulates that “patents shall be available for any invention, whether products or processes, in all fields of technology” and further stipulates that patents shall be granted for protection of inventions that are “new, involve an inventive step and are capable of industrial application”. The Agreement does not define these requirements and indeed leaves room for flexibility at the national level.

What this means is that countries have ample flexibility to set their basic criteria for patentability: novelty, inventive step and industrial applicability, according to their policy priorities. This means that countries that set high standards for the basic criteria of patentability will result in fewer patents as this will require high standards of inventiveness to ensure that the claimed subject matter is new in absolute terms. The adoption of minimum standards that allows for flexibility has the potential to facilitate entry of generic medicines into the market.

Inasmuch as the TRIPs Agreement affords members considerable flexibility in defining the basic criteria for patentability, it is for ECOWAS member countries to determine whether to set the bar high for patentability or not. It would be in the best interests of countries where the vast majority of patent applications are from abroad, particularly from the perspective of preventing excessive patenting around essential medicines to adopt strict standards of patentability that are likely to reduce the scope of patentability.

### 3.3. Benefits to Regional Trade Areas consisting of more than 50% LDCs

The TRIPs Agreement allows exemptions from IPR protection under certain conditions. For instance, it permits the compulsory issue of licenses for the import, export and production of essential medicines. In addition, Least Developed Countries (LDCs) have been exempted until 2016 from the obligation to implement patent protection in the health sector. Regional Trade Areas constituting more than 50% LDCs that share the same health problem can take advantage of the overall LDC status of the region. It is important to note that the ECOWAS region is constituted of 73% LDC countries. The entire region can therefore be considered as LDC and stands to benefit from using the flexibilities and timelines available to LDCs.

## 4.0 REVIEW OF MEMBER STATES LEGISLATIONS

### 4.1Objectives

> **Article 7: Objectives**
> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

There is no doubt that technological innovation is a source of economic development, because it provides an improvement of the physical, social and economic well-being of the people, which in turn promotes access to medicines, public health and a better nutritional status. In the ECOWAS region efforts are being made by Member States for the development of national policy for the promotion of technological innovation, utilization of research findings. For capacity building in this area some countries are supported by the agencies responsible for IP such as OAPI, ARIPO and WIPO and other development partners

However to allow the implementation of TRIPs Flexibilities, Member States are encouraged to amend their national legislations to implement policies and guidelines developed by ECOWAS/WAHO.

### 4.2 Least Developed Country Members

> **Article 66:** *Least-Developed Country Members*
> 1. In view of the special needs and requirements of least-developed country members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65.
> The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period. […]
> 2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting technology transfer to least-developed country members in order to enable them to create a sound and viable technological base

**Least-developed countries** were given until 1 January 2006 to comply with TRIPs. Following the Doha Ministerial meeting of 2001, Least Developed Countries (LDC) of the WTO have a further period until at least 2016 before having to provide patent protection for pharmaceutical products and

to protect against unfair use of pharmaceutical related data submitted to a regulatory authority. However, it should be noted that the vast majority of LDCs in Africa, including all LDCs in ECOWAS, already provide patent protection for pharmaceutical products.

**Recommendations**

ECOWAS should establish a regional IP office to manage IP issues as well as an office for technology acquisition and promotion to nurture creative talents, technological advancements and competitiveness. The Regional Office should initiate strategies for technology evaluation, acquisition, transfer, promotion and support from developed countries to ECOWAS Member States. The transfer of technology should not be restricted only to developed countries but to developing countries as well.

LDC Member States should take advantage of the opportunity for further extensions of the transition period and for technology transfer from developed countries.

### 4.3 Anti-competitive Practices

The TRIPs Agreement says governments can also act to prevent patent owners and other holders of intellectual property rights from abusing intellectual property rights, "unreasonably" restraining trade, or hampering the international transfer of technology. *Articles 8 and 40*

**Article 40:** *Control of anti-competitive practices in contractual licences*

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grant back conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member. [...]

**Article 8**
*Principles*

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

### 4.3.1 Protection against Anti-competitive Practices in ECOWAS Member States

| MEMBER STATE | RELEVANT SECTION (S) OF THE LAW | COMMENTS |
|---|---|---|
| OAPI Member States | None | Annex 8, article 6 of the Bangui Agreement deals with Unfair Competition. |
| Cape Verde | None | Not found in the IP law. May exist in other laws. |
| Ghana | Section 13. 1b Act 657 2003 | |
| Liberia | None | Section 48 deals with unfair competition. |
| Nigeria | None | Draft Bill 2004 provides for Art. 40. There is a draft bill on the establishment of a National Consumer Protection and Competition Commission |
| Sierra Leone | N/A | Draft Legislation is in place |
| The Gambia | None | Section 36 Cap 95:03 deals with unfair competition |

Protection against anti-competitive practises is not specifically covered in the IP laws of all countries except Ghana. It may exist in other national legislation.

**Recommendations**

There is a need to develop and strengthen national competition laws in order to ensure that anti-competitive practices or transactions (domestic or international), which are detrimental to efficiency and consumer welfare; do not undermine efforts of governments to promote economic growth and freedom of trade. ECOWAS could adopt this in a regional framework document to support countries in this area of work.

### 4.3.2. Protection of undisclosed information

> **Article 39.3:** *Non-exclusive rights in test data*
> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.

Of particular interest in this respect is whether information provided to a pharmaceutical regulatory authority can be relied on by a subsequent applicant seeking to obtain approval for a bio-equivalent product or whether further applicants must provide similar data including for example clinical trial data.

**Recommendations**

Member Countries should be mindful when signing bilateral trade agreements that provides for mandatory protection of test data. National Laws of member countries should take advantage of TRIPs flexibilities as they have considerable discretion in defining what constitutes "Unfair commercial use". Countries can meet their obligations of protecting test data by prohibiting "dishonest "use of data.

### 4.4.1 Protection of undisclosed information (test data) in ECOWAS Member States

| MEMBER STATE | RELEVANT SECTION (S) OF THE LAW | COMMENTS |
|---|---|---|
| OAPI Member States | None | Not provided in the revised Bangui agreement, may exist under National laws |
| Cape Verde | None | Not found in the IP law. |
| Ghana | None | Section 5 of Act 589 of 2000—Unfair Competition in Respect of Secret Information |
| Liberia | None | Not found in the Industrial Property Act 2003 |
| Nigeria | None | Aspects Captured in NAFDAC Act. |
| Sierra Leone | N/A | |
| The Gambia | None | Not found in the Industrial Property Act 12 1989 |

**Recommendations**

ECOWAS should mandate that National Medicines Regulatory Authorities do not police intellectual property issues since patents are private rights.

Protection of test data should not unreasonably prevent or hamper the development of generic medicines.

### 4.3.3 Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.[1]

All countries are compliant except The Gambia that has a term of 15 years.

**Recommendations**

No country should go beyond the minimum requirements for term of protection. All LDC countries are encouraged to amend their laws to reflect the minimum requirements.

Countries are encouraged not to extend existing patent protection beyond 20 years

Research Exception and "Bolar" Provision

> **Article 30:** *Exceptions to Rights Conferred*
>
> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Under the TRIPs Agreement, governments can make limited exceptions to patent rights, provided certain conditions are met. For example, the exceptions must not "unreasonably" conflict with the "normal" exploitation of the patent. Many countries use this provision to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully.

[1] It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

Some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval from drug regulatory or public health authorities without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision.

Guidance on the intended scope of this provision was provided by the Dispute Settlement Body (DSB) of the WTO in the dispute between the EU and Canada. In this case the DSB found that a provision allowing a third party to make and use a patented product for the purposes associated with obtaining regulatory approval for a similar product (the so-called Bolar type exception) was a legitimate exception within the meaning of TRIPs.

Among the exceptions to patent rights that safely fall within the scope of the TRIPs Agreement are those relating to private and non-commercial uses as well as acts done for experimental purposes relating to the subject matter of the invention. The latter was considered especially important in that it allows parties to understand and invent around the patented invention therefore promoting further innovation.

**4.4.1 Provision for General Research and Experimental Use Exceptions**

| MEMBER STATE | RELEVANT SECTION (S) OF THE LAW | COMMENTS |
|---|---|---|
| OAPI Member States | None | |
| Cape Verde | None | |
| Ghana | Section 11 Act 657 2003 | *Could be used for commercial purpose as well e.g. Bolar exceptions* |
| Liberia | Section 17.4.III | |
| Nigeria | Section 6 of CAP 344 | Excludes patent rights on all acts not for industrial or commercial purposes. This section covers research and experimental use. |
| Sierra Leone | N/A | |
| The Gambia | None | No Patent Exceptions |

The Bolar exception is not specifically provided in any of the Member States IP laws but may be covered by other common general exceptions.

**Recommendations**

Member States are encouraged to incorporate this provision into their policies and regulations in order to allow for:

i. Experimental (research) exception

ii. Bolar exception

Disclosure requirements

> **Article 29 :** *Conditions on Patent Applicants*
>
> 1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
>
> 2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

TRIPs Article 29 specifies the requirements that may be imposed on patent applicants. These include the requirement to disclose the best mode for carrying out the invention as well as providing information concerning corresponding applications and grants. The best mode requirement, which is not present in European legislation, is intended to ensure that the applicant does not conceal the preferred embodiment of his invention. Information, such as search and examination reports, on corresponding filings may be of particular assistance to those countries not having the technical capacity to properly examine patent applications.

4.5.1 Disclosure requirement in ECOWAS Member States

| MEMBER STATE | RELEVANT SECTION (S) OF THE LAW | Best Mode | Disclosures of Foreign applications and grants |
|---|---|---|---|
| OAPI Member States | Annex 1 section 1 of Bangui agreement | No | Yes, Annex 1 section 1 of Bangui agreement |
| Cape Verde | Article 28 | No | No |
| Ghana | Section 5(5) of act 657 of 2003 | No | Yes, Section 8(1) of act 657 of 2003 |
| Liberia | Chapter 3, Section 11 (3), 2003 | No | Yes, Chapter 3, Section 14 (1), (2), 2003 |
| Nigeria | Section 3(2) patent and designs act CAP 344, 1970 | No | Yes, Section 23 (1) patent and designs act CAP 344, 1970 |
| Sierra Leone | | No | |
| The Gambia | Yes, CAP 95.03, Section 6 (3),1989 | No | Yes, CAP 95.03, Section 9 (1),1989 |

**Recommendations**

The provisions for best mode requirements need to be included under national patent legislation.

It should also include the requirement to disclose the source or origin of genetic resources and traditional knowledge.

ECOWAS should build technical capacity in countries for key activities under this provision.

### 4.4 Patentable subject matter

Governments can refuse to grant patents for three reasons that may relate to public health:

- inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health — *Article 27.2*
- diagnostic, therapeutic and surgical methods for treating humans or animals — *Article 27.3a*
- certain plant and animal inventions — *Article 27.3b*.

**Article 27:** *Patentable Subject Matter*

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application[(5)]. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *order, public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:
(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

*For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.*

**Recommendations**

### 4.6.1 Patentable Subject Matter in ECOWAS Member States

| MEMBER STATE | RELEVANT SECTION (S) OF THE LAW | COMMENTS |
|---|---|---|
| OAPI Member States | Section 1 and 2 of Bangui agreement | |
| Cape Verde | | |
| Ghana | Section 2,3 and 11 Act 657 2003 | *Amended bill includes expansion of the definition of novelty and non-recognition of new uses* |
| Liberia | Section 8 & 9 | |
| Nigeria | Section 1 of CAP 344 | *Draft bill covers more detailed provisions* |
| Sierra Leone | | |
| The Gambia | Sections 3, 4, 5,6 | *The duration for disclosure is too short; not an advantage for the country and below the TRIPs minimum* |

The TRIPs Agreement does not explicitly exclude from patentability secondary or further uses of known substances. The patentability criteria for new uses must be clearly defined in national legislations. Otherwise two potential problems may arise. The first is the potential for *evergreening* by introducing trivial, non-efficacious variants of existing chemical substances. The second is the denial of a patent because the examiner's interpretation is that a known compound does not constitute novelty thus denying local researchers and manufacturers protection of their inventions. This could stifle innovation in the industry.

**Recommendations**

To address the problem of "evergreening" consideration should be given to preventing the extension of existing patents and patenting of trivial and/or non-efficacious variants of existing chemical substances. Product derivatives of a known chemical substance should be patentable only if, when compared to the original substance, they show significant improvements in therapeutic efficacy.

Consideration should be given to including a clarification that second uses of known pharmaceutical substances qualify for use-bound product claims.

Regarding the patentability of natural substances, consideration should be given to including a clarification that new chemical entities made by chemical modification of natural substances are patentable.

### 4.7. Parallel Imports, Grey Imports and 'Exhaustion of Rights'

> **Article 6:** *Exhaustion*
> For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Wholesalers in developing countries are keen on exporting drugs to earn profits on price differentials across countries. It is the rich economies, however, who commonly prefer not to allow their importation, even if it is the same drug, produced by the same pharmaceutical firm. This is also called re-importation (or parallel trade) as those drugs are produced abroad by the same pharmaceutical firm as domestically or by a licensee under its authorization.
Parallel or grey-market imports are not imports of counterfeit products or illegal copies. These are products marketed by the patent owner or with the patent owner's permission in one country and imported into another country without the approval of the patent owner.

The legal principle here is "exhaustion", the idea that once a company has sold a batch of its product, its patent rights are exhausted on that batch and it no longer has any rights over what happens to that batch. Forbidding or allowing drug re-importation in their territory is associated with the exhaustion regime of IPRs a country adopts. Under national exhaustion, a patent is valid (and monopoly rights are guaranteed) until its expiry in the country. Under international exhaustion, the IPR is considered expired when the first unit is sold anywhere in the world. Thus, with international exhaustion the patent holder cannot bar re-importation, although the IPR is still valid in the domestic country.

The TRIPs Agreement simply says that none of its provisions, except those dealing with non-discrimination ("national treatment" and "most-favoured-nation treatment"), can be used to address the issue of exhaustion of intellectual property rights in a WTO dispute. In other words, even if a

country allows parallel imports in a way that another country might think violates the TRIPs Agreement; this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved. The Doha Declaration clarifies that this means that members can choose how to deal with exhaustion in a way that best fits their domestic policy objectives. *(Article 6 and Doha declaration 5(d))*

### 4.7.1 Exhaustion in ECOWAS Member States

| MEMBER STATE | RELEVANT SECTION (S) OF THE LAW | National/Regional/International |
|---|---|---|
| OAPI Member States | Annex 1, article 8 paragraph 1; *The act provides for parallel importation within the territory of the OAPI Member States* | Regional |
| Cape Verde | Article 6 of Decree 4/2007 of August | National |
| Ghana | Section 11.4a of Act 657 ,2003 *See FDB guidelines on Parallel importations* | International |
| Liberia | Section 17.(4) (a) (i) of Industrial Property Act, 2003 | National |
| Nigeria | Section 3(b) CAP 344 LFN 1990 | National |
| Sierra Leone | N/A | |
| The Gambia | Section 12(4)(a) of Industrial Property Chapter 95.03 | National |

**Recommendations**

Doctrines of international exhaustion should be incorporated in national legislations to allow for parallel importation whenever a patented product is placed in the market anywhere in the world**.**

## 4.8 Compulsory Licensing and the Doha Declaration on TRIPs and Public Health

Perhaps the most important flexibilities available to developing countries for improving access to medicines are provided for in Article 31 and the subsequent Doha Declaration on TRIPs and Public Health and so it is discussed in more detail than previous Articles here.

**Article 31:** *Other Use Without Authorization of the Right Holder*

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: […]

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive; […]

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use; […]

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; […]

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur; […]

.

Compulsory licensing refers to a practice where patent holders are forced to tolerate, against their will, the exploitation of their inventions by third parties. This exploitation is authorized by governments or courts and such authority to use a patented subject matter without the authorisation of the right holder, can be given either to governmental institutions or third parties for reason of public policy or to promote public interest.

But the term "compulsory licensing" does not appear in the TRIPs Agreement. Instead, the phrase "**other use without authorization of the right holder**" appears in the title of Article 31. For this reason, a distinction is often made between **compulsory licenses** and **government use licenses**. The difference between the two is that a government use license refers to a compulsory license issued for public non-commercial use. These licenses are exclusively granted to promote public interests either by the governments themselves or by third parties, such as a private contractor, acting for or on

behalf of the government. . The important difference between the two is that the license is issued for the non-commercial use of the product by the government.

Compulsory licenses are issued in the public interest to address environmental, public health, national security or economic development concerns by promoting third-party production of the patented products at lower prices and/or greater quantities than are otherwise available.

The TRIPs Agreement contains important flexibilities, which have been clarified and expanded in the WTO's 2001 Declaration on the TRIPs Agreement and Public Health (Doha Declaration) and its Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health of August 30, 2003 (Paragraph 6 Decision or the Decision). This Declaration contains important provisions for the interpretation and application of Article 31 of the TRIPs Agreement. The Doha Declaration formally affirms that:

"the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health;"
"the TRIPs Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all;"
"WTO Members have the right to use, to the full, the provisions of the TRIPs Agreement, which provide flexibility for this purpose."

*The Doha Declaration further explains that, within the context of the TRIPs Agreement,* "these flexibilities include":
"the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted;"
". . . 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."

**The Doha declaration**

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: [...]

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences 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 intellectual property rights 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. [...]

### 4.8.1 Importing under Compulsory Licensing ('Par. 6') or "The Decision"

Article 31(f) of the TRIPs Agreement says products made under compulsory licensing must be "predominantly for the supply of the domestic market". This applies to countries that can manufacture drugs — it limits the amount they can export when the drug is made under compulsory licence. And it has an impact on countries unable to make medicines and therefore wanting to import generics. They would find it difficult to find countries that can supply them with drugs made under compulsory licensing.

The legal problem for exporting countries was resolved on 30 August 2003 when WTO members agreed on legal changes to make it easier for countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves.

The decision actually contains **three** waivers:

- Exporting countries' obligations under Article 31(f) are waived — any member country can export generic pharmaceutical products made under compulsory licences to meet the needs of importing countries.
- Importing countries' obligations on remuneration to the patent holder under compulsory licensing are waived to avoid double payment. Remuneration is only required on the export side.
- Exporting constraints are waived for **developing and least-developed countries so that they can export within a regional trade agreement, when at least half of the members were categorized as least-developed countries at the time of the decision**. That way, developing countries can make use of economies of scale.

The Decision does not waive the application of Article 31 (b) of the TRIPs Agreement, which requires that prior to granting a compulsory licence, licence applicants make efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and within a reasonable period of time. This requirement may be waived by national law in the case of a national emergency or other urgent circumstances or in cases of public non-commercial use. National laws may also determine that, in cases where Article 31 (b) cannot be waived and the Decision is to be applied, the period of time be shorter than in normal situations so as to expedite access to needed pharmaceutical products.

Carefully negotiated conditions apply to pharmaceutical products imported under the system. These conditions aim to ensure that beneficiary countries can import the generics without undermining patent systems, particularly in rich countries. They include measures to prevent the medicines from being diverted to the wrong markets and require governments using the system to keep all other members informed, although WTO approval is not required. At the same time phrases such as “reasonable measures within their means” and “proportionate to their administrative capacities” are included to prevent the conditions becoming burdensome and impractical for the importing countries.

### 4.8.2 Provision for Compulsory Licenses in ECOWAS Member States

| MEMBER STATE | RELEVANT SECTION (S) OF THE LAW | COMMENTS |
|---|---|---|
| OAPI Member States | Annexe 1 article 56, ex-officio licences | *There is the need for specific provision for the possibility of importing medicines without the obligation of prior negotiations (see below)* |
| Cape Verde | Art 53. 1a, 1b | |
| Ghana | Section 13 Act 657, 2003 | *In the proposed bill, there is an expansion of the section regarding the remuneration to the patent holder-in line with August 30th 2003 decision* |
| Liberia | Section 19 | *Restricted to country* |
| Nigeria | Schedule 1 of CAP 344, | *The draft provides for compulsory licensing for import and export of pharmaceutical products per DOHA Declarations* |
| Sierra Leone | | |
| The Gambia | Section 12 .6 | *Restricted to country* |

Recommendations

Article 31(b) of the TRIPs Agreement stipulates that in cases of national or other circumstances of extreme urgency or when the compulsory license is issued for public non-commercial use, the requirement for prior negotiation with the rights holder for reasonable commercial terms and conditions may be waived. Article 31(k) of the Agreement also endorses the waiver of the requirement for prior negotiation with the rights holder in situations where the license is granted to remedy anti-competitive practice. These flexibilities should be incorporated in national legislations.

### 4.8.3 Grounds for providing Compulsory Licenses in ECOWAS Member States

| Grounds For Providing Compulsory Licenses | Countries providing for such grounds |
|---|---|
| Failure to exploit or exploit on Reasonable terms | Cape Verde – Article 53(1) (a) of Decree No 4/ 2007 of August 20.<br>Gambia – Cap 95.3 Act 12 of 1989. Section 14(1)<br>Ghana – Section 14 of Act 657<br>Liberia – Industrial Property Act of Liberia, 2003, Section 19.<br>Nigeria- Section 10 ( 2) and 1st Schedule Part 1 Section 1<br>OAPI- Annex 1, Article 46 of the Bangui Agreement |
| Public interest | Cape Verde - Article 52, 53 (1) (c) and 58 of Decree No 4 of 2007<br>Gambia – Section 12(6) of Cap 95.03<br>Ghana - Section 13 0f Act 657 of 2003<br>Liberia – Industrial Property Act 2003, Section 19(1)<br>Nigeria- 1st Schedule Part 1 Section 13<br>OAPI- Annex 1, Article 56 of the Bangui Agreement of 2002 |
| National emergency or health emergency | Cape Verde- Article 52, 53 (1) (c) and 58.<br>Gambia – Section 12(6)<br>Ghana Section 13 ( 1 ) of Act 2003<br>Liberia – Section 19(1)<br>Nigeria- 1st Schedule Part 1 Section 13<br>OAPI- Annex 1, Article 56 |
| Remedy anti-competitive practices, unfair competition | Cape Verde - Article 7 of Decree No 4 of 2007<br>Gambia- Not available<br>Ghana – Unfair Competition Act of 2000 Act 589 and Section 13 (2) of the Patent Act, 2003 Act 657<br>Liberia – Section 19(1) (ii)<br>OAPI- Annex 8, article 7<br>Nigeria – Not available |
| Failure to obtain licence under reasonable terms | Cape Verde – Section 58( 1) ( 3)<br>Gambia- Not available<br>Ghana- Section 14 of Act 657 of 2003<br>Liberia –Section 20<br>Nigeria – 1st Schedule Part 1 Section 1 |

| | |
|---|---|
| | OAPI – Article 46 of the Bangui Agreement |
| Failure to work domestically | Cape Verde – Article 53 (1) ( a)<br>Gambia- section 14(1) of Cap 95.03<br>Ghana – Section 14 ( 1) of Act 657 0f 2003<br>Liberia Section 20<br>Nigeria – 1st Schedule, Part 1, Section 1.<br>OAPI – Article 46 |
| Dependent Patents | Cape Verde Article 53( 1) ( b) and 57 (1 )<br>Gambia – Not available<br>Ghana Section 14 (5) ( a) and ( b )<br>Liberia Section 20 (4)<br>Nigeria- Not available<br>OAPI- Article 47 |
| No apparent provisions | |

**Recommendations**

Both voluntary and non-voluntary licenses should be allowed for local production or export

## 5. GENERAL COMMENTS

Implementation of TRIPs flexibilities in ECOWAS Member States may not only require making specific changes to national laws, but also ensuring that Member States do not assume TRIPs-plus obligations under bilateral or regional treaties. Bilateral agreements established with some developing and developed countries for instance, require the protection of data under a sui generis regime of data exclusivity for at least five years from the date of the first approval of a pharmaceutical product in the country. Some bilateral agreements, moreover, establish "linkage" requirements, so that, without the consent and acquiescence of the patent owner, national health authorities are prevented from granting marketing approval for a generic product as long as a patent over the product is in force.

The implications of these obligations are quite significant, and may delay introduction of generic products, even where compulsory licences are issued. Under the data exclusivity terms, if a compulsory licence were granted in a country to import a pharmaceutical product, a generic company would have to develop on its own all the test data as required for approval. This is a very lengthy,

costly, duplicative and wasteful process given that the data has already been generated by a brand-name company, and will create an enormous obstacle to the use of the Decision. Moreover, the "linkage" between patent protection and marketing approval seems to erect an almost insurmountable barrier to the execution of a compulsory licence or government non-commercial use, since the compulsory licensee or government would be authorized to use the patented invention but not to obtain the regulatory approval to make it available. Countries willing to use the Decision (as importers or exporters) would have to devise ways, including crafting specific exceptions, to overcome these restrictions.

Regarding the issue of compulsory licences, it is important to note that neither the TRIPs Agreement nor the Doha Declaration distinguishes between communicable and non-communicable diseases. As the negotiation of the Decision made clear, it applies to pharmaceutical products for any disease. Even though HIV/AIDS, tuberculosis and malaria are specifically mentioned, each country has the right to determine what constitutes a public health crisis. Similarly, the Decision is not limited to "grave" diseases, since "gravity" in paragraph 1 of the Declaration is generally referred to "the public health problems" and is not intended to qualify the type of diseases to be addressed.

Public interest includes economic development concerns of the country in question. As an example, the Thailand government in recent times issued compulsory licences for five drugs used to treat non-communicable diseases such as cancer and heart disease. They argued that the high incidence of heart disease and cancer was contributing to the morbidity and thus affecting the gross domestic product (GDP), hence the economic development of the nation. It was therefore considered a national emergency and they employed their right to use the TRIPs flexibilities such as compulsory licensing to reduce prices via competition and thereby enhance access to medicines used to treat these conditions.

Paragraph 7 of the Decision states that "Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration". Paragraph 6 of the Decision aims at "harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products" in the context of some regional trade agreements.

This wording suggests that industrial and commercial policy objectives should not be pursued by Member countries under the system established by the Decision, but that Members recognize such objectives cannot be excluded altogether. Thus, eligible importing Members may grant compulsory licenses to foster the development of capacity in their pharmaceutical industry as a sustainable way to address their public health problems, for instance by importing active ingredients under the Decision for the local formulation of medicines. This option should be vigorously pursued by ECOWAS Member States with manufacturing capacities.

Paragraph 6 of the Decision waives Article 31(f) to allow the re-exportation of pharmaceutical products imported under a compulsory license to other developing or least-developed members of the region that experience the same public health problem. The conditions are that: (a) the RTA must be sanctioned by the WTO; and (b) at least half of the Members must be least-developed countries listed as such by the United Nations on the date of the Decision.

In practical application, this provision is of benefit to ECOWAS Member States because it allows the region to make use of economies of scale by bulk procurement by one (or more) of the members. It also facilitates the importation of component materials, formulation into finished products, and export to Member States. In the event of re-exportation to members of the RTA, Paragraph 6 of the Decision does not impose any obligation of notification to the WTO. As an additional flexibility, the regional organization may make the required notification to the WTO of actual importation on behalf of all the importing members of the RTA.

For the avoidance of doubt, Paragraph 6 clarifies that this waiver for RTAs is not intended to "prejudice the territorial nature of the patent rights in question." This means that there still needs to be a voluntary or compulsory license in the importing Members of the RTA if the product is under patent there (unless the importing member is a least developed country electing not to enforce relevant patents).

More generally, the Decision also contains provisions encouraging the development of regional patent regimes, technology transfer, technical assistance, and capacity building.

## 6.0 RECOMMENDATIONS AND CONCLUSIONS

### 6.1 Recommendations

The following are specific recommendations not captured under Section 4.

1. Due to the importance of IPRs on access to medicine, heath, food security, technology transfer, trade and the economy in the West African sub-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
2. 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.
3. A resolution should be passed by ECOWAS for all Member States to modify or review their IP laws to meet the TRIPs Council requirements.
4. A resolution should be passed for all Member States to adopt the ECOWAS TRIPs policy and apply the guidelines
5. WAHO should strengthen the capacity of Member States to understand and apply the TRIPs flexibilities and related waivers
6. WAHO should continue to:
    a. Support capacity building in pharmaceutical manufacturing in the region
    b. Expedite the medicines registration harmonization processes
    c. Have a collective pooled procurement procedure for essential medicines in the region to take advantage of the region's classification as an LDC.
7. 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.
8. 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.
9. ECOWAS/WAHO should create a platform for technology transfer and human capacity development to enable easier utilization of the TRIPs flexibilities and related waivers.

10. Local manufacturers of pharmaceutical formulations in the four DC countries should be encouraged to apply for compulsory licences to import active ingredients for the local formulation of essential medicines.

11. ECOWAS should continue to support the development of traditional medicine and their utilization in health care systems in the West African region

### 6.2 Conclusion

The analysis and recommendations in this report do not provide definitive statements on situations in individual countries in the ECOWAS Member States, until such inputs have been obtained from all stakeholders concerned.

## 7. References


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World Intellectual Property Organization, *Handbook on Intellectual Property*, 2005

## 8.0 Appendices

### 8.1 Appendix 1: Analysis of Regional Intellectual Property Systems in West Africa

| AGREEMENT | OAPI 1999 BANGUI REVISION | ARIPO (HARARE PROTOCOL) |
|---|---|---|
| **WTO Member/Status Least Developed Country LDC/Developing country** | Benin (LDC), Burkina Faso (LDC), Cote D'Ivoire, Guinea (LDC), Guinea Bissau (LDC), Mali (LDC), Niger (LDC), Senegal (LDC), Togo (LDC). | Gambia (LDC), Ghana, Sierra Leone (LDC) |
| **Paris Convention** | Requires joining of Paris. | |
| **Berne Convention** | Requires joining of Berne. | |
| **UPOV (1978 or 1991 Act)** | 1999 Revision requires joining of UPOV 1991. | |
| **Search & Examination** | Search and examination before publication (usually sub-contracted) | Search and examination before publication (usually sub-contracted) |
| **Novelty** | Absolute | Absolute |
| **Exhaustion regime** | Unclear whether it is national or regional Exhaustion | Prescribes for pre grant only. |
| **Early working (Bolar)** | Not specifically provided but may be covered by other common general exceptions | See above<br>. |
| **Compulsory licensing** | Not being worked on territory<br>Demand not being met on reasonable terms.<br>Dependent Patent | See above |
| **2nd Medical use** | Not explicit | Allowed<br>AP868 |
| **Disclosure requirements Foreign filings and search & exam reports** | Not required | May be requested |
| **Disclosure requirements (origin of material)** | No | |
| **Best Mode** | No | Yes |
| **Multiple independent claims** | Probably allowable | Yes |
| **Grace Period** | 12 months (exhibitions only) | 6 Months (exhibitions only) |

| | | |
|---|---|---|
| **Patents on parts of human body including gene sequences** | Not explicitly excluded | Not explicitly excluded<br>Human genetic material – AP411 |
| **Patents on plants and animals** | Not on plant varieties and animal species | Plants – AP655<br>Transgenic plants AP752<br>Transgenic animals – AP411 |
| **General exceptions** | | |
| **Research exceptions** | Acts carried out for experimental purposes in course of scientific and technical research | |
| **Protection of undisclosed information** | Protected against dishonest use except where necessary to protect the public | |
| **Pharmaceutical products** | Yes | Yes |
| **Utility models** | Yes | |
| **Improvement patents** | Certificate of addition available to patentee | |
| **Term of patent protection** | 20 Years | 20 Years |

Source: Thorpe, P.; "*Study on the Implementation of the TRIPs Agreement by Developing Countries*", Commission on Intellectual Property Rights, Study Paper 7.

Note:-As mentioned earlier in this report, it is to be noted that both Nigeria and Cape Verde are not members of either OAPI or ARIPO