

Shashikant, Sangeeta

**Research Report**

## The African Regional Intellectual Property Organization (ARIPO) protocol on patents: Implications for access to medicines

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**56**

# **THE AFRICAN REGIONAL INTELLECTUAL PROPERTY ORGANIZATION (ARIPO) PROTOCOL ON PATENTS: IMPLICATIONS FOR ACCESS TO MEDICINES**

Sangeeta Shashikant





## **RESEARCH PAPERS**

**56**

# **THE AFRICAN REGIONAL INTELLECTUAL PROPERTY ORGANIZATION (ARIPO) PROTOCOL ON PATENTS: IMPLICATIONS FOR ACCESS TO MEDICINES**

**Sangeeta Shashikant\***

**SOUTH CENTRE**

**NOVEMBER 2014**

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\* Sangeeta Shashikant is Legal Adviser, Third World Network. Third World Network (TWN) is an independent non-profit NGO involved in issues relating to development. She can be contacted at [sangeeta@twnetwork.org](mailto:sangeeta@twnetwork.org).



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South Centre  
Ch. du Champ d'Anier 17  
POB 228, 1211 Geneva 19  
Switzerland  
Tel. (41) 022 791 80 50  
Fax (41) 022 798 85 31  
[south@southcentre.int](mailto:south@southcentre.int)  
[www.southcentre.int](http://www.southcentre.int)

## **ABOUT THIS RESEARCH PAPER**

This paper was commissioned by the South Centre to better understand the workings of the African Regional Intellectual Property Organization (commonly known as “ARIPO”) with regard to its Protocol on Patents and Industrial Designs and to examine the effect of implementation of the Protocol (Section on Patents) on the promotion of access to affordable medicines.

Presently the Protocol has 18 Contracting Parties, the majority of which are Least Developed Countries (LDCs). Pursuant to the Protocol, the ARIPO Office receives and processes patent applications and administers patent grants on behalf of its Contracting Parties. In its examination, the paper was to especially focus on the extent to which the Protocol is supportive of the objectives and recommendations of the East African Community Regional Intellectual Policy on the Utilization of Public Health Related WTO-TRIPS Flexibilities. It was also the aim to identify practical recommendations and mechanisms (including an alert mechanism) to minimize adverse effects on access to affordable medicines.

A preliminary draft of the research paper was presented and discussed at a regional Workshop on Strengthening Capacity for Access to Medicines in the EAC Region held from 30-31 July 2014. The workshop was participated by health, IP policy makers and civil society from the EAC region as well as by an official from the ARIPO Office.

In preparing the research paper the author interviewed officials from the ARIPO Secretariat as well as several IP offices. The author would like to express her sincere gratitude for the co-operation of all those who provided information. In particular the author acknowledges with appreciation the information and data provided by the ARIPO Office.

The author also gratefully acknowledges comments and suggestions on drafts of this paper from Professor Carlos Correa, Professor Brook Baker, German Velasquez, K.M. Gopakumar, Primah Kwagala and Nirmalya Syam. Any errors or omissions remain, however, the responsibility of the author.





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## EXECUTIVE SUMMARY

Sub-Saharan Africa (SSA) suffers from numerous communicable and non-communicable diseases, with significant socio-economic effects, and adversely impacting the development prospects of countries in sub-Saharan Africa. Many of these diseases are treatable but access to affordable medicines remains a huge challenge in the region. A particular obstacle to access to medicines is the high, prohibitive costs of medicines enabled by the existence of patents. Patents grant the right holder a monopoly on the patented pharmaceutical for at least 20 years from the date of filing of the patent application, thereby curtailing competition by giving the patent holder freedom to set prices, which in many instances is simply unaffordable to persons who need the medicines.

Competition from generic producers has been instrumental in bringing down the cost of medicines and in scaling up treatment; however such competition is only possible in an environment where patents are not obstacles.

Patenting of pharmaceuticals became globalized with the coming into force of the Agreement on Trade-Related Aspects of Intellectual Property Rights (commonly referred to as the “TRIPS Agreement”) in the World Trade Organization (WTO) in 1995, which set out minimum standards on intellectual property including on patents, which WTO members have to comply with. The pressure to incorporate intellectual property protection within WTO came from a group of mainly developed countries. Although developing countries were not successful in resisting the incorporation of the TRIPS Agreement, a degree of policy autonomy was negotiated to allow countries to accommodate their own needs (also known as “flexibilities”).

The adoption of the TRIPS Agreement has led to widespread concern over the impact of patents on public health, leading to numerous international, regional and sub-regional instruments and initiatives recognizing and reaffirming the importance of TRIPS flexibilities to facilitate the importation of affordable medicines as well as to boost local production capacity. Many countries have used these flexibilities with positive health outcomes for their population.

In the SSA region, some countries have incorporated these flexibilities in their national laws while a few have gone further and utilized these options for public health purposes. However, although some progress has been made in the right direction, for a variety of reasons significant gaps remain in the full utilization of TRIPS flexibilities. An issue particularly specific to the SSA region is that regional IP offices process the majority of patent applications and administer patent grants in the region.

This paper explores the workings of the African Regional Intellectual Property Organization, also known as “ARIPO” which caters for 19 mostly English-speaking countries and assesses the impacts of ARIPO’s instruments and operations on access to affordable medicines. The paper also analyzes the extent to which ARIPO’s patent processing and grant system is supportive of sub-regional efforts of the East African Community (EAC) to fully utilize TRIPS flexibilities to facilitate importation and boost domestic manufacturing of affordable medicines. The paper discusses in detail the East African Community Regional Intellectual Policy on the Utilization of Public Health Related WTO-TRIPS Flexibilities and

the EAC Health Protocol on the same, both developed to facilitate the full utilization of TRIPS flexibilities to not only improve access to affordable medicines in the EAC region but also towards the development of an efficient and effective regional pharmaceutical manufacturing industry as outlined in the EAC Regional Manufacturing Plan of Action (2012-2016).

The paper finds that the successful use of TRIPS flexibilities by EAC States for the benefit of public health in the EAC region is much dependent on the workings of ARIPO, given that the ARIPO Office processes the majority of the patent applications. The findings in Chapters III and IV show that the current operations of the ARIPO does not facilitate full use of TRIPS flexibilities and instead erects patent barriers to the importation and local production of affordable medicines. For the effective implementation of the EAC Policy & Protocol as well as the EAC Regional Pharmaceutical Manufacturing Plan of Action (2012-2016), and the multiple other international and regional initiatives that emphasize use of TRIPS flexibilities, effort has to be made by ARIPO Contracting Parties including EAC States to reform the patent operations of ARIPO so that it advances public health objectives. Nationally as well several immediate steps can be taken. **Some recommendations are as follows:**

#### **At the ARIPO regional level:**

- (1) The Harare Protocol should exempt the territory of LDCs from the grant of any pharmaceutical patents. This means, in the event the ARIPO Office grants pharmaceutical patents, such patents will not be applicable to the LDC territories. LDCs that desire for the ARIPO patent to be applicable to its territory would need to communicate so to the ARIPO Office within a specific time-frame of receiving notification from ARIPO of its intent to grant the patent.
- (2) ARIPO should adopt rigorous patentability standards with regard to pharmaceutical applications, with the aim of avoiding secondary patents and patent evergreening. Specific rules should be established for the examination and grant of pharmaceutical patents paralleling those adopted by Argentina<sup>2</sup>.

ARIPO Contracting Parties including EAC States, and civil society should review (and if necessary, revise) the new patent examination guidelines being established by the ARIPO Office to ensure that they are sensitive to public health concerns.

- (3) ARIPO Office should also improve its examination capacity in particular its infrastructure and human resources and should reduce reliance on foreign examination systems.
- (4) ARIPO should increase its examination and maintenance fees to avoid proliferation of frivolous patents.
- (5) The Harare Protocol should establish administrative pre- and post-grant opposition procedures, to enable any person to file a notice of opposition before the ARIPO Office.

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<sup>2</sup> Joint Resolution of the Ministry of Industry, Ministry of Health and Instituto Nacional de la Propiedad Industrial 118/2012, 546/2012 y 107/2012. See <http://www.moellerip.com/non-patentable-subject-matter-according-to-the-new-guidelines-of-the-argentine-pto-2/> and [http://lists.keionline.org/pipermail/ip-health\\_lists.keionline.org/2012-May/002146.html](http://lists.keionline.org/pipermail/ip-health_lists.keionline.org/2012-May/002146.html).

For effective and workable pre- and post-grant administrative procedures: (a) any person should be allowed to file opposition either directly with the ARIPO Office as well as through national IP Offices; (b) any person should be allowed to challenge the grant not only in a particular country but its validity for the whole of the ARIPO region; (c) the grounds for opposition should include non-compliance with the patentability requirements, insufficiency of disclosure, and other reasons; (d) there should be clarity on the publication of the application and grant in each designated state; (e) the published patent applications should include all relevant data for the identification of the subject matter of the application, such as the complete specification and international non-propriety name (elaborated below) and that information should be freely accessible online; (f) the procedures for filing the oppositions should be specified clearly and preferably the procedure should be free of any charges; (g) adequate time should be provided for the submission of an opposition. The longer the period, the greater the opportunities for the patent office to receive observations/oppositions from third parties as the importance of the patent application may not be immediately recognized<sup>3</sup>; (h) there should be specific time lines and clarity on the procedures for dealing with the filed opposition (e.g. notifying the patentee, constitution of a panel to hear the patentee and the opposing party, appeal procedure etc.) (i) capacity to monitor published patent applications and grants as well as skills necessary to conduct the required analysis to mount the opposition, should be built among local pharmaceutical companies and civil society.

- (6) The Harare Protocol and its regulations should require more detailed disclosure of the invention. “Person skilled in the art” should be defined as a person in the ARIPO region, having average expertise and experience in the technical field of the claimed invention. In addition to setting forth the best mode contemplated by the applicant, the applicant should also be required to disclose *all embodiments of the claimed invention* in order to prevent “Markush Claims”. The Harare Protocol should also require for the description in the patent applications to be adapted to the ordinary skills of the citizen of the country. Insufficient disclosure should result in the application being rejected.
- (7) The Harare Protocol and its regulations should require patent applicants to declare the INN at the time of filing of the application if the INN is already allotted or immediately on allocation. Non-compliance should result in the application being rejected.
- (8) The Harare Protocol and its regulations should be amended to mandatorily require the patent applicant to disclose information on corresponding foreign applications and to supplement the same on a timely basis.
- (9) The ARIPO Office should make freely and publicly available on its website, patent applications published as per Rule 19*bis*; the notification (including the search and examination report upon which the decision to grant is based) to designated states as per Rule 18(4); complete information including the full specification and claims on patents granted, and the ARIPO Journal which contains information on all publications required under the Protocol and the Regulations.

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<sup>3</sup> Indian Patent Law: Section 25 (1) allows the filing of a pre-grant opposition anytime between the publication of the application and the granting of a patent. Section 25(2) allows the filing of a post-grant opposition within one year from the publication of the patent grant.

- (10) The ARIPO website should also host effective search engines and databases that facilitate access to complete information including the description of the invention, full specification, list of claims, about the patent applications and grants.

**At the National level:**

- (11) EAC States should take steps to incorporate the policy approaches prescribed by the EAC Policy and Protocol.
- (12) Pending revision as suggested in (1) EAC LDC States should take urgent action to declare that pharmaceutical patents in its territory are not enforceable.<sup>4</sup>

Intellectual property offices in LDCs should also adopt an institutional policy that on receipt of a notification from the ARIPO Office of its intent to grant a pharmaceutical patent, the IP Office will immediately communicate a written objection to the ARIPO Office.

- (13) EAC States should apply rigorous patentability criteria for pharmaceutical patent applications processed nationally. Specific guidelines on how properly to implement patentability criteria with regard to pharmaceuticals should be developed, and if required, changes to national patent legislation should be pursued. EAC States should also undertake rigorous examination of pharmaceutical patent applications.
- (14) Civil society, intergovernmental organizations such as the South Centre and other public health advocates should implement activities that boost the capacity of EAC States and their IP officials/examiners to undertake rigorous examination of pharmaceutical patent applications, and avoid secondary patents and patent evergreening as well as to better understand the implications of the grant of monopolies for public health.
- (15) EAC States with pre-grant opposition procedures in their national legislations should work to operationalizing such procedures with regard to patent applications processed by the ARIPO Office. See below (17).
- (16) EAC States should also establish transparency mechanisms at the national level. EAC States should make freely available on their respective websites: complete information about ARIPO applications and grants (such as the application published by ARIPO under Rule 19bis of its Regulations, full specification of patents granted, and information contained in the ARIPO Journal) as well as about patent applications processed nationally which are published and granted.
- (17) Further, it is important for EAC States to make publicly available ARIPO's notification of its intent to grant a patent (including the patent application as well as search and examination report upon which the decision to grant is based) issued

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<sup>4</sup> Paragraph 7 of the Doha Declaration on TRIPS & Public Health: "We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement *or to enforce rights* provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement."

according to Rule 18(4) of the Regulations and Administrative Instruction 52(1) of the Harare Protocol. This information should be made publicly available immediately on receipt of the ARIPO notification, and EAC States should invite the public to submit any observations or oppositions they may have on ARIPO's notification.

- (18) Civil society should pursue implementation of the above recommendations. They should also begin to actively monitor pharmaceutical applications processed by ARIPO as well as national IP offices and take appropriate action where the grant would be inconsistent with national interests.





## I. THE CONTEXT

Access to affordable medicines in sub-Saharan Africa (SSA) is a huge challenge, complicated by a number of factors, including poverty and inadequate funding for health, lack of appropriate chemical industry capacity, weak medicines regulatory capacity, poor social and medical infrastructure and systems (including procurement and supply), inadequate legislation and the existence of patents. Patents play a significant or even a determinant role in limiting access to affordable medicines because they grant the patent holder a monopoly on a pharmaceutical product and its product process for a number of years. This curtails competition thus giving the patent holder freedom to set prices, which in many instances are simply unaffordable to persons who need the medicines.

The “price” factor can singularly be determinative of life or death, where a deadly disease is treatable, but the treatment is unaffordable. It can determine whether the government will be able to provide treatment to its people or whether an individual will be able to obtain the treatment he or she requires. For example in 2000, for a triple-combination antiretroviral (ARV) treatment of Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP) the price of the lowest branded treatment was about US\$ 10,439 for a year’s supply (MSF, 2007). The high price tag meant most patients living with HIV/AIDS would not be able to afford treatment and would be condemned to death.

The entry of generic versions of ARVs led to significant price reductions. In 2001, Cipla Ltd., an Indian generic producer, offered the same combination for US\$ 350. Over time with more competition, the cost has reduced drastically. As at June 2013, the combination<sup>5</sup> is available at the cost of US\$ 55 per person per year (MSF, 2013). Competition from and even among generic producers (possible in an environment where patents do not pose an obstacle) has been instrumental in bringing down the cost of treatment and in scaling up ARV treatment.

Patenting of pharmaceuticals became globalized with the coming into force of the Agreement on Trade-Related Aspects of Intellectual Property Rights (commonly referred to as the “TRIPS Agreement”) in the World Trade Organization (WTO) in 1995. This Agreement sets out minimum standards on intellectual property including on patents, which WTO members have to comply with. See Box 1 below.

### Box 1

#### **Patents in a Nutshell**

Article 27.1 of the TRIPS Agreement requires patents to be available for any inventions, whether products or processes, in all fields of technology. However to be granted a patent, the invention has to fulfil the following criteria: novelty, it should involve an inventive step and be capable of industrial application. The minimum duration for patent protection required by TRIPS is 20 years from the filing date of the application. During this period, the right holder has exclusive rights over the patented invention. Often pharmaceutical companies apply for multiple patents in connection with a pharmaceutical

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<sup>5</sup> As of May 2013, five generic sources of d4T/3TC/NVP 30/150/200mg tablet are quality-assured by US FDA or WHO prequalification.

compound (e.g. patents over new forms, derivatives, uses, combinations, formulations and even dosages) – a practice commonly known as “evergreening”<sup>6</sup>, thus keeping the medicine free from competition and enabling high pricing.

The TRIPS Agreement was the result of intense negotiations. The pressure to incorporate IP protection within the multilateral General Agreement on Tariffs and Trade (GATT), what eventually became the World Trade Organization (WTO) came from a group of developed countries which sought to introduce a multilateral framework reflecting the then prevailing IP standards in their countries. Although developing countries were not successful in resisting the incorporation of the TRIPS Agreement, a degree of policy space for governments was negotiated with regard to implementation of the Agreement’s obligations. The TRIPS agreement reflects a somewhat uneasy compromise that was eventually struck between developed and developing countries during the negotiating process (Oh, 2004). As such the TRIPS Agreement contains built-in flexibilities, which developing countries were determined to preserve to allow countries sufficient room to accommodate their own patent and intellectual property systems and development needs.<sup>7</sup>

The impact of patents on public health first came to international attention in 1997 with the attempts of the US government to force revision of the South African Medicines and Related Substances Control Amendment Act (Act 90) of 1997 which sought to create a legal framework (that *inter alia* included international exhaustion of rights-parallel importation) to increase the availability of lower cost medicines in the country. The Act was opposed by the South African Pharmaceutical Manufacturers’ Association, resulting in the filing of a legal challenge by the Association and 39 transnational pharmaceutical companies against the government of South Africa. By 2001, the suit soon became a public relations nightmare for the companies and they finally withdrew it in 2001 (Von Schoen Angerer T., 2001).

In the same year, under international pressure US withdrew its complaint against Brazil in the WTO dispute settlement system over Brazil’s national law on compulsory licensing that included a “local working” requirement.<sup>8</sup> This complaint was a “warning shot” by the Bush Administration to developing countries that had hopes of using flexibilities provided by the TRIPS Agreement and South-South cooperation to develop local pharmaceutical production capabilities and to break their dependency on multinational pharmaceutical companies (Small, 2001).<sup>9</sup> But US actions brought on fierce pressure from the international NGO community concerned about the negative effect of the complaint on Brazil’s successful AIDS programme and South-South cooperation to ensure sustainable supply of generic medicines (t’ Hoen, 2003).

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<sup>6</sup> Evergreening is a term popularly used to describe patenting strategies that are intended to extend the patent term on the same compound. See Report of the WHO Commission on Intellectual Property, Innovation and Health (April 2006), p. 148 Available from <http://www.who.int/intellectualproperty/report/en/index.html>

<sup>7</sup> For further reading see: Raghavan, C., 1990. “Recolonization, GATT, the Uruguay Round and the Third World”, Third World Network, Penang; Drahos P., 2004, “Intellectual Property and Pharmaceutical Markets”, A Nodal Governance Approach, Temple Law Review, vol. 77.

<sup>8</sup> Under that provision, holders of patent rights in Brazil are required to manufacture the product thus protected in the country. If companies do not follow this requirement, Brazil can, after three years, issue a compulsory licence.

<sup>9</sup> In 2000, at an international AIDS conference in Durban, South Africa, Brazil had offered to provide assistance to other developing countries committed to providing universal access to medicines by offering to help them build their own laboratories and to train people to run them. In December 2000, the Health Ministers of South Africa and Brazil had signed a letter of intent for cooperation.

Concerns about TRIPS and its overall impact on access to affordable medicines, at a time when medicines were not available to those that needed them due to the high prices and despite the availability of treatments – especially in the case of HIV/AIDS – sparked off an international debate on access to affordable medicines. The public health crisis afflicting many countries in the developing world, particularly in sub-Saharan Africa and the strong-arming of developing countries by developed countries fuelled the debate focusing intense public attention on the manner in which intellectual property protection impacted peoples' lives and governments' ability to take measures to protect public health.

On 20 June 2001, for the first time ever the WTO's TRIPS Council<sup>10</sup> held a Special Session on TRIPS and Public Health. This historic meeting was a response to Africa Group's call at the TRIPS Council to confront the problem of access to medicines due to high prices resulting from intellectual property protection and to discuss the interpretation and application of the relevant provisions of the TRIPS Agreement with a view to clarifying "flexibilities" to which Members are entitled to gain access to medicines. Fifty developing countries put forward a joint paper presenting their common legal understanding on some of the key provisions of the TRIPS Agreement.<sup>11</sup>

In November 2001, the Africa Group's initiative resulted in the adoption of the Doha Declaration on TRIPS and Public Health<sup>12</sup> whereby the Ministers of the then 142 members of the WTO expressed agreement in the following terms:

*"We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the 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."*

*"In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."*

Subsequently the WTO General Council adopted the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health to address the problem of countries with insufficient or no manufacturing capacity.<sup>13</sup>

See Box 2 below for a list of some key TRIPS flexibilities for public health. Flexibilities available to developing countries to overcome the intellectual property obstacles to access medicines are not self-executing. To make use of them, it is necessary to enact specific legal provisions in domestic and regional laws.

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<sup>10</sup> The TRIPS Council is a body within WTO, open to all WTO members and responsible for administering the TRIPS Agreement.

<sup>11</sup> Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela (WTO Doc. No. IP/C/W/296).

<sup>12</sup> WTO Doc. WT/MIN(01)/DEC/2, 20 November 2001.

<sup>13</sup> WTO Doc. WT/L/540.

## Box 2

**Some Key TRIPS Flexibilities that Facilitate Protection of Public Health****PRE-GRANT FLEXIBILITIES**

**Transition period for least developed countries (LDCs):** Paragraph 7 of the Doha Declaration as implemented by a TRIPS Council Decision of June 2002 exempts LDCs from having to grant or enforce pharmaceutical product patents and data protection until 1 January 2016.<sup>14</sup> On 11 June 2013, the TRIPS Council exempted LDCs from mandatory compliance with the TRIPS Agreement other than Articles 3, 4 and 5, until 1 July 2021.<sup>15</sup> Upon request, these transition periods may be further extended.<sup>16</sup>

**Patentability Criteria:** Certain key terms in relation to patentability criteria have not been defined such as “invention”, “new/novelty”, “inventive step/non-obvious”, “industrial applicability” leaving WTO members considerable discretion as to how to interpret and apply the criteria. Strict patentability criteria limit the number of patents granted. When patentability standards are lax or loosely defined, many secondary patents will be granted on the various forms of new chemical entity such as the formulation, new combination and new uses, with consequences for access to medicines. The TRIPS Agreement does not prevent countries from applying strict patentability criteria and excluding such secondary patents from patentability.

**Exclusions from Patenting:** Countries can also establish elements that are excluded from patenting such as diagnostic, therapeutic and surgical methods for the treatment of humans and animals, plants, animals, discoveries, naturally occurring substances, even if purified or isolated.

**Disclosure Requirement:** When disclosure requirements are minimal, it may be difficult for a local person skilled in the arts to carry out the claimed invention. Thus countries can and should require disclosure of best modes for carrying out the invention and information concerning the applicant’s corresponding foreign applications. In the case of pharmaceutical products, countries can also require disclosure of the international non-proprietary name (INN) of the product.

**Pre-Grant Opposition System:** This allows third parties to submit an opposition to the IP office, objecting to the grant of a patent before it is granted. It is an essential mechanism for maintaining the grant of high quality patents. For effective opposition systems, it should be administrative in nature, bypassing the costly and time-consuming court processes.

<sup>14</sup> WTO Doc. IP/C/25, 1st July 2002. Available from [http://www.wto.org/english/tratop\\_e/trips\\_e/art66\\_1\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm).

<sup>15</sup> WTO Doc. IP/C/64, 12 June 2013. Available from [http://www.wto.org/english/tratop\\_e/trips\\_e/ldc\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/ldc_e.htm).

<sup>16</sup> Article 66.1 of the TRIPS Agreement: “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.”

## **POST GRANT FLEXIBILITIES**

**Exceptions to patent rights:** The TRIPS Agreement allows for “limited exceptions” to the exclusive rights conferred by a patent. The Agreement does not define the exceptions but provides a general test to be used for admissibility. Exceptions once incorporated into national patent laws, operate automatically, without any need for an authorization from the right holder. Important public health exceptions include exceptions for research, experimental, and educational use, for individual prescriptions, for prior use and for early working.

**Early working exception:** This exception also known as the “Bolar exception” permits the use of the patented invention without authorization from the patent owner in order to obtain marketing approval of a generic product from a medicines regulatory authority before the patent expires. This enables the generic product to enter the market as soon as the patent expires.

**Parallel importation:** This is based on the concept of exhaustion of IP i.e. once the patent owner has sold its goods, the patent owner has “exhausted” its property rights in the sold products and thus cannot prevent resale of those goods. The Doha Declaration has clarified that the TRIPS Agreement allows each Member to establish its own regime for such exhaustion. Adopting a regime of international exhaustion, allows a country to import medicines from any country in the world where such medicines are sold more cheaply. This flexibility takes advantage of the different prices charged by a company, in different countries.

**Non-voluntary licenses (compulsory/government use license):** These licenses are granted by administrative or judicial bodies to authorize use of a patent-protected invention by the government or third parties without the consent of the patent holders, but with the patent holder receiving adequate remuneration. The Doha Declaration has clarified that WTO Members are free to determine the grounds upon which compulsory licenses may be granted.

**Post Grant Opposition:** A post grant opposition mechanism, allows third parties to submit an opposition once a patent has been granted. For an effective post-grant mechanism, it should be administrative in nature.

Since the Doha Declaration, multiple regional and international initiatives have recognized that patents have an adverse impact on the price of medicines and thus accessibility of such medicines. These initiatives have called on developing countries to make full use of the TRIPS flexibilities to facilitate production and availability of affordable generics. For more detail see Chapter II below.

Due to a number of factors, including capacity building activities, civil society activism, a desire to improve access to treatment, and a goal of boosting local production, developing countries are increasingly beginning to incorporate health related flexibilities in their industrial property legislation and to utilize these options, resulting in positive public health outcomes for their population.

A concrete example is India, which is described as the “pharmacy of the developing world” in recognition as a low-cost producer of high-quality drugs. In 1970, India taking advantage of the freedom countries had before the creation of the WTO, abolished product patent protection in pharmaceuticals. Even after the entry into the force of the TRIPS Agreement, using the transition period flexibility available to it then, India maintained this position. The absence of product patent protection provided Indian companies the opportunity to develop pharmaceutical capacity, and aided by the entrepreneurial spirit as well as other government policies and public investments in manufacturing and R&D, Indian pharmaceutical companies made enormous progress (Chaudhuri, 2010). In 2005, with India having to become TRIPS compliant (and having to recognize patents on pharmaceutical products), domestic and international pressure led to a number of critical flexibilities being incorporated into the revised patent law. In a post-TRIPS world, pre-grant flexibilities in particular: administrative pre-grant opposition procedures, strict patentability criteria (excluding new uses and forms of known substances, mere admixtures, and methods of treatment from the scope of protection) etc., have been essential in sustaining domestic production and availability of generics domestically as well as abroad on an affordable basis.

Apart from India, Argentina has also introduced rigorous patentability standards, making it harder to get a pharmaceutical patent, which offers little to no real improvement over existing drugs. The detailed guidelines, issued jointly by Argentina’s patents office and health department, requires patent examiners to reject (with some exceptions) new use, new form, and new formulation patents and specifies a number of other frivolous changes to drugs which will no longer be acceptable.<sup>17</sup> Several other countries such as Malaysia, Brazil, Ecuador, Thailand and Indonesia have utilized post-grant flexibilities (e.g. government use licenses) resulting in significantly lower treatment prices and consequently more patients being treated.<sup>18</sup>

Within the sub-Saharan region (SSA), multiple regional and sub-regional initiatives (policies, roadmaps, business plans) such as by the African Union, East Africa Community (EAC), the Southern Africa Development Community (SADC) have acknowledged the importance of utilizing TRIPS flexibilities to import affordable treatment as well as to evolve pharmaceutical manufacturing hubs in the region. See Chapter II for details on these initiatives. Some countries in the SSA region have incorporated these flexibilities in their national laws while a few have gone further and utilized these options for public health purposes.

However, although some progress has been made in the right direction, for a variety of reasons significant gaps remain in the full utilization of TRIPS flexibilities. The reasons include failure to update patent laws (often inherited from their colonial masters), failure to craft flexibilities in a manner that delivers optimal outcome for access to medicines, complex procedures for utilizing flexibilities, lack of political will, resources and capacity.

An issue particularly specific to the SSA region is that the majority of patent applications in the region are processed by regional IP offices, established by

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<sup>17</sup> Joint Resolution of the Ministry of Industry, Ministry of Health and Instituto Nacional de la Propiedad Industrial 118/2012, 546/2012 y 107/2012. See <http://www.moellerip.com/non-patentable-subject-matter-according-to-the-new-guidelines-of-the-argentine-pto-2/> and [http://lists.keionline.org/pipermail/ip-health\\_lists.keionline.org/2012-May/002146.html](http://lists.keionline.org/pipermail/ip-health_lists.keionline.org/2012-May/002146.html).

<sup>18</sup> For further information see Khor, M., 2014, “Compulsory License and “Government Use to Promote Access to Medicines: Some Examples”. Third World Network. See also Oh, 2004.

intergovernmental instruments: the African Regional Intellectual Property Organization, (formerly African Regional Industrial Property Organization), also known as “ARIPO” which caters for 19 mostly English speaking countries and the African Intellectual Property Organization, (better known under the acronym “OAPI” for its French name, *Organisation Africaine de la Propriété Intellectuelle*), which covers about 17 mostly French speaking countries<sup>19</sup>.

This paper focuses on the workings of ARIPO and analyses the extent to which ARIPO’s instruments and operations are supportive of regional efforts to fully utilize TRIPS flexibilities to facilitate importation and local production of affordable medicines.

Chapter II provides a brief introduction to the origins, purpose and basic instruments underpinning ARIPO as well as elaborates on the access to medicines situation in the ARIPO region and the various initiatives including in the SSA region that recognize the full use of TRIPS flexibilities as being essential for better health outcomes.

Chapter III provides an overview of the instruments and practices of ARIPO in connection with patents, with a specific focus on how ARIPO deals with pharmaceutical patent applications and the impact on access to medicines.

Chapter IV examines the impact of ARIPO’s operations on the implementation of the EAC Regional Intellectual Policy on the Utilization of Public Health Related WTO-TRIPS flexibilities and the EAC Health Protocol on Public Health Related WTO-TRIPS Flexibilities, instruments developed by the East African Community (EAC) to enhance use of TRIPS flexibilities to support improved access to medicines and foster pharmaceutical manufacturing, in the EAC region

Chapter V contains conclusions and recommendations on the basis of findings in this paper.

## **II. ACCESS TO MEDICINES SITUATION IN THE ARIPO REGION**

The African Regional Intellectual Property Organization also known as “ARIPO” was established with the adoption of the Lusaka Agreement in Lusaka, Zambia on 9 December 1976.

Its origins can be traced back to the early seventies when a Regional Seminar held in Nairobi on patents and copyright for English-speaking African countries recommended that a regional industrial property organization be set up.<sup>20</sup> In 1973 the United Nations Economic Commission for Africa (UNECA) and the World Intellectual Property Organization (WIPO) responded to a request by these English-speaking countries for assistance in pooling their resources in industrial property matters by establishing a regional organization.<sup>21</sup> Meetings

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<sup>19</sup> Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Comoros, Congo, Côte d’Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo.

<sup>20</sup> See ARIPO’s website at <http://www.aripo.org/index.php/about-aripo>, accessed on 16 April 2014.

<sup>21</sup> See ARIPO’s website at <http://www.aripo.org/index.php/about-aripo>, accessed on 16 April 2014.



were held at the UNECA headquarters in Addis Ababa and WIPO in Geneva leading to a draft Agreement on the Creation of the Industrial Property Organization for English-speaking Africa (ESARIPO). On adoption at a diplomatic conference, this agreement came to be known as the Lusaka Agreement.

According to ARIPO's website "ARIPO was mainly established to pool the resources of its member countries in industrial property matters together in order to avoid duplication of financial and human resources."<sup>22</sup> However Article III of the Lusaka Agreement lists a number of objectives for the establishment of ARIPO including (i) promoting harmonization and development of intellectual property laws "*appropriate to the needs* of its members and of the region as a whole"; (ii) "to establish such common services.....for the co-ordination, harmonization and development of the intellectual property activities affecting its members" and (iii) "to assist its members, as appropriate, in the acquisition and development of technology relating to intellectual property matters."

Since the Lusaka Agreement, several Protocols have been developed to address specific intellectual property areas. Of interest to this paper is the Protocol on Patents and Industrial Designs adopted in Harare on 10 December 1982 to address matters in connection with patents, utility models and industrial designs. This Protocol is commonly referred to as the "Harare Protocol".

The supreme decision making body within the organization is the Council of Ministers that consist of Ministers of ARIPO member states who are responsible for the administration of intellectual property. The Council of Ministers meets about once every two years and is responsible for the orientation of the Organization. The Council of Ministers is supported by the Administrative Council, which consists of the Heads of Offices and deals with the administration of intellectual property in member states. The Administrative Council meets at least once a year. The third organ of the Organization is the ARIPO Secretariat. The Secretariat has been given vast flexibility and is widely known to play a central role in determining issues that are addressed by the Administrative Council and the Council of Ministers and in shaping the ARIPO agenda.

Article IV of the Lusaka Agreement that created ARIPO opens membership to member states of the United Nations Economic Commission for Africa or the African Union (AU).

Presently 19 countries are members to ARIPO's constituting treaty – the Lusaka Agreement. These are: Botswana, the Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Liberia, Rwanda, São Tomé and Príncipe, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe (hereinafter referred to as "ARIPO Members").

Of the 19 countries, Liberia, São Tomé and Príncipe, Somalia, Sudan are LDCs but not WTO members and thus are under no obligation to implement any aspect of the TRIPS Agreement. Further 9 countries (Gambia, Lesotho, Malawi, Mozambique, Sierra Leone, Rwanda, Tanzania, Uganda and Zambia) are WTO Members but fall within the LDC category and thus are exempted from TRIPS implementation except for Articles 3, 4 and 5 of the Agreement so long as the LDC transition period remains in force. See Box 2.

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<sup>22</sup> See ARIPO's website at <http://www.aripo.org/index.php/about-aripo>, accessed on 16 April 2014.

ARIPO Members though bound by the Lusaka Agreement are not automatically bound by the various Protocols that are developed by ARIPO. For example Somalia is a party to the Lusaka Agreement (and thus an ARIPO member) but is not a party to the Harare Protocol.

## **II.1 A Snapshot of Disease Burden in the ARIPO Region**

Health challenges in sub-Saharan Africa are enormous with multiple disease burdens aggravated by widespread poverty, poor water and sanitation facilities and significant infrastructural, financial and human constraints. For example the prevalence of poverty<sup>23</sup> in the ARIPO region (UNDP, 2013): Botswana (23.1 per cent); The Gambia (33.6 per cent); Ghana (28.6 per cent); Kenya (43.4 per cent); Lesotho (43.3 per cent); Malawi 73.9 per cent); Mozambique (59.6 per cent); Namibia (31.9 per cent) Liberia (83.8 per cent); Rwanda; (63.2 per cent); Sao Tome and Principe (no data); Sierra Leone (53.4 per cent); Somalia (no data); Sudan (19.8 per cent); Swaziland (40.6 per cent); Tanzania (67.9 per cent); Uganda (38 per cent); Zambia (68.5 per cent); Zimbabwe (no data).

Specifically within the ARIPO region, the number of people living with HIV (PLHIV) remains high.<sup>24</sup> For example in Tanzania<sup>25</sup> there are 1.4 million PLHIV (children<sup>26</sup> living with HIV – 250,000), in Uganda<sup>27</sup> – 1.6 million PLHIV (children living with HIV – 190 000); in Kenya<sup>28</sup> – 1.6 million PLHIV (children living with HIV – 190 000); in Rwanda<sup>29</sup> – 200 000 PLHIV. The HIV prevalence rate among adults aged 15 and 49 ranges from 0.5 per cent in Somalia to 27.4 per cent in Swaziland.<sup>30</sup> For example, in Tanzania the prevalence rate is 5.0 per cent, in Uganda -7.4 per cent; in Kenya – 6.0 per cent and in Rwanda – 2.9 per cent.

Sub-Saharan Africa has made significant strides in expanding access to antiretroviral (ARVs) therapy with 7.5 million people receiving antiretroviral therapy as of December 2012 (UNAIDS). ARV therapy is considered to be highly effective at reducing viral loads in people living with HIV and slowing the spread of infection across communities and reducing the social costs of the HIV epidemic (UNAIDS). Despite the progress, persistent gaps in treatment remain.

According to UNAIDS: “The trend towards increased antiretroviral therapy coverage across Africa masks significant national gaps” adding “Considerable work remains to reach all people eligible for HIV treatment, with antiretroviral therapy reaching only about one in three eligible according to the 2013 guidelines. Of the 21.2 million people in Africa eligible for antiretroviral therapy in 2013 under the 2013 WHO guidelines, only 7.6 million people were receiving HIV treatment as of December 2012” (UNAIDS).

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<sup>23</sup> Percentage of the population living below the international poverty line \$1.25 (in purchasing power parity terms) a day.

<sup>24</sup> See <http://www.unaids.org/en/regionscountries/countries/>.

<sup>25</sup> HIV and AIDs estimates (2013). See <http://www.unaids.org/en/regionscountries/countries/uganda/>, accessed 6 October, 2014.

<sup>26</sup> Aged 0-14 years.

<sup>27</sup> HIV and AIDs estimates (2013). See <http://www.unaids.org/en/regionscountries/countries/kenya/>, accessed 6 October, 2014.

<sup>28</sup> HIV and AIDs estimates (2013). See <http://www.unaids.org/en/regionscountries/countries/rwanda/>, accessed 6 October 2014.

<sup>29</sup> HIV and AIDs estimates (2013). See <http://www.unaids.org/en/regionscountries/countries/>, accessed 6 October 2014.

<sup>30</sup> HIV and AIDs estimates (2013). See <http://www.unaids.org/en/regionscountries/countries/>, accessed 6 October 2014.

Based on numbers receiving treatment as of December 2012 and estimated numbers of people eligible as of December 2013 under the 2013 WHO HIV treatment guidelines, UNAIDS estimates that in the eastern and southern Africa the treatment gap is at 59 per cent while in the western and central Africa the gap is at 79 per cent.

Paediatric coverage is exceptionally low. In Eastern and Southern Africa, the gap in ARV therapy for children (0-14 years) is at 63 per cent while in western and central Africa the gap is at 89 per cent (UNAIDS). AIDS-related deaths among adolescents (10-19 years) also increased, almost doubling from 2005 and 2012 (UNAIDS).

Domestic contributions account for roughly half of all spending on HIV treatment and care across sub-Saharan Africa. In Western and Central Africa and in the Eastern Africa sub-region domestic HIV funding ranges from 15 per cent to 29 per cent (UNAIDS) and for UNAIDS this “remains a concern for the sustainability of their funding for care and treatment”.

Tuberculosis remains another concerning infectious disease in the region. In 2012, there was estimated 8.6 million incident cases of tuberculosis (TB) with 12 million prevalent cases, 940,000 deaths among HIV negative people and 320,000 deaths among HIV-positive people (WHO, 2013). The WHO African region has 27 per cent of the world’s cases (UNITAID, 2014c). In particular, Kenya, Uganda and Zimbabwe are considered as having a high TB burden. TB control is also underfunded nationally.

TB treatment has become complex, especially with the emergence of multidrug-resistant strains of *Mycobacterium tuberculosis* (MDR-TB), hence the need for new drugs (UNITAID, 2014c). In late 2012, bedaquiline became the first novel TB drug approved in 40 years and in 2013 WHO issued interim guidance for its use in treatment of MDR-TB (WHO, 2013).

While in the African region, there are still more deaths from infectious diseases, the prevalence of non-communicable diseases (NCDs) is rising rapidly and is projected to cause almost three-quarters as many deaths as communicable, maternal, perinatal, and nutritional diseases by 2020, and to exceed them as the most common causes of death by 2030 (WHO, 2011). WHO projections show that NCDs will be responsible for a significantly increased total number of deaths in the next decade and that in the African Region, NCDs will cause around 3.9 million deaths by 2020 (WHO, 2011). Examples of estimates of NCD deaths in the ARIPO region (WHO, 2011): Kenya (103,000); Uganda (106, 400); Tanzania (134, 300); Rwanda (28, 200).

Globally the leading causes of NCD deaths in 2008 were: cardiovascular diseases (17 million deaths, or 48 per cent of NCD deaths); cancers (7.6 million, or 21 per cent of NCD deaths); and respiratory diseases, including asthma and chronic obstructive pulmonary disease (COPD), (4.2 million) and diabetes caused an additional 1.3 million deaths (WHO, 2011).

WHO reports that treatment for NCDs can quickly drain household resources, driving families into impoverishment as direct out-of-pocket payments represent more than 50 per cent of total health expenditures in a large number of low-and-middle-income countries (WHO, 2010). WHO’s Global report on NCDs refers to a review of medicine prices in two multi-country studies which showed that in the public sector, it cost on average from two to eight days’ wages to purchase one month’s supply of at least one cardiovascular medicine and

one day's wage to purchase one month's supply of at least one anti-diabetic medicine (WHO, 2011a).

The data presented above is merely to give a snapshot of the severity of the health challenges facing the ARIPO region. There are numerous communicable and non-communicable diseases afflicting the ARIPO region. Cost of treatment and affordability of treatment is evidently an essential aspect that needs to be dealt with if the region is to deal with the numerous health challenges on a long-term sustainable basis.

## **II.2 ARIPO & Access to Medicines**

Timely and affordable access to medicines is essential to prevent and treat diseases of major concern to public health and overall reduce the disease burden in the region. Accordingly creating a legal and policy environment nationally and regionally that facilitates countries in sub-Saharan Africa to import and/or manufacture affordable critical life-saving medicines and ensuring a reliable, continuous supply of such medicines is an absolute necessity.

In this regard, of particular concern is the availability of effective national and regional actions to deal with the issue of patents that could hinder importation and local production of affordable life-saving medicines. A number of international, as well as regional and sub-regional instruments and initiatives have highlighted the importance of TRIPS flexibilities to facilitate access to affordable medicines

In 2008, following two years of intense negotiations, the Sixty-first WHO Health Assembly adopted a Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property (WHO, 2011b). Several African countries such as Kenya played a critical role in the negotiations leading to the final GSPOA (Shashikant, 2008). The GSPOA acknowledges “the price of medicines is one of the factors that can impede access to treatment” and that flexibilities “could facilitate increased access to pharmaceutical products by developing countries” (WHO, 2011b<sup>31</sup>).

The Strategy requires governments as well as other stakeholders (which would include ARIPO) to *inter alia*: encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products (WHO, 2011b<sup>32</sup>); as well as to promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries (WHO, 2011b<sup>33</sup>).

The 2011 UN declaration on HIV and AIDS commits governments “to optimize” the “use, to the full of existing flexibilities” available under the TRIPS Agreement with the aim to “remove before 2015, where feasible, obstacle that limit the capacity of low-and middle income countries to provide affordable and effective HIV prevention and treatment products, diagnostics, medicines and commodities and other pharmaceutical products, as well as

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<sup>31</sup> See “The Context”.

<sup>32</sup> See Element 5.1(a).

<sup>33</sup> See Element 5.1(b).

treatment for opportunistic infections and co-infections, and to reduce costs associated with life-long chronic care” (United Nations, 2011a<sup>34</sup>).

In 2011, another declaration issued by the UN General Assembly on the prevention and control of non-communicable diseases called on governments to improve “accessibility to safe, affordable, effective and quality medicines and technologies to diagnose and to treat...[NCDs]; [and] provide sustainable access to medicines and technologies.....and promote the use of affordable medicines, including generics...” (United Nations, 2011b<sup>35</sup>).

This was followed in 2013 with the World Health Assembly endorsing the WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020, which called on WHO Member states to promote increased access to affordable medicines and diagnostics and other technologies through the full use of TRIPS flexibilities and for international partners to contribute to such efforts (WHO, 2013b<sup>36</sup>).

The RIO+20 United Nations Conference on Sustainable Development (UNCSD) which met in 2012, also reaffirmed “the right to use, to the full.....flexibilities for the protection of public health, and, in particular, to promote access to medicines for all...” (United Nations, 2012<sup>37</sup>).

At the African regional as well as sub-regional levels similar initiatives have emerged with the aim to improve availability and affordability of medicines in the region and increase self-reliance.

In 2012, the Heads of States of Africa adopted a Roadmap on Shared Responsibility and Global Solidarity for the AIDS, Tuberculosis and Malaria Response in Africa. The Roadmap treats the prevalence of AIDS, TB, malaria and other infectious diseases as an emergency for the region, raising concern also that national responses to AIDS, TB and other infectious disease are highly dependent on external financial and foreign produced medicines and that this “dependency poses grave risk to the Continent” (African Union, 2012a<sup>38</sup>).

A key pillar of the Roadmap is Pillar 2, under which a suite of high priority actions are outlined to ensure accelerated access to affordable and quality assured medicines and health related commodities. This includes investing in regional pharmaceutical manufacturing hubs; greater efforts to ensure that knowledge and technology are transferred to the region and maximum use of flexibilities permitted under the TRIPS Agreement (African Union, 2012a<sup>39</sup>). On the latter point, the Roadmap is supportive of extending the waiver to be TRIPS compliant for least developed countries beyond 2016 to allow for more time to create a sound and viable technological base in the pharmaceutical sector. It also argues for legislative amendment “to better facilitate actions that are needed to import generic drugs from existing suppliers (e.g. from China and India) so that there are no supply disruptions while Africa is building its manufacturing sector” (African Union, 2012a<sup>40</sup>).

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<sup>34</sup> See paragraph 71(a).

<sup>35</sup> See paragraph 45(l).

<sup>36</sup> See Objective 4, pp. 42-45.

<sup>37</sup> See paragraph 142.

<sup>38</sup> See p. 2.

<sup>39</sup> See p. 3.

<sup>40</sup> See pp. 15-16.

Further in 2012, the African Union Commission (AUC), in partnership with the United Nations Industrial Development Organization (UNIDO) developed a business plan to accelerate implementation of the Pharmaceutical Manufacturing Plan for Africa (PMPA).

The business plan states: “One of the key policy and legislative changes needed in order to benefit our continent, its patients and local industry is in the domain of intellectual property rights. Most countries have failed to take advantage of current opportunities presented by TRIPS flexibilities. A few have enacted the TRIPS provisions but the common consensus is that the requirements are too onerous and too time consuming..... The AUC firmly believes that the TRIPS flexibilities present the same opportunity for African pharma as did the Indian Patent Act of 1970 for Indian industry. The Commission is convinced that full exploitation of the flexibilities would lead to a transformation of local industry” (African Union, 2012b<sup>41</sup>). The business plan advocates working together with ARIPO and others for the “simplification of the means by which flexibilities can be exploited” as the “current system is onerous and wasteful” (African Union, 2012b<sup>42</sup>).

In 2004, the Southern African Development Community (SADC)<sup>43</sup> developed a pharmaceutical programme and Protocol on Health followed by a SADC Pharmaceutical Business Plan (2007-2013) aimed at improving sustainable availability and access to affordable, quality, safe, efficacious essential medicines. A component of the business plan was on taking advantage of TRIPS flexibilities to improve access in the region (SADC, 2007).

The importance of maximizing use of TRIPS flexibilities is also stressed in the Pharmaceutical Plan for the Economic Community of West African States (ECOWAS<sup>44</sup>), 2014-2020, adopted in April 2014<sup>45</sup>. The plan aims at achieving self-sufficiency in the production, distribution and safe use of quality affordable essential medicines throughout the region.

The East African Community (EAC)<sup>46</sup> has also established an East African Community Regional Pharmaceutical Manufacturing Plan of Action - ~~2011-2012~~ <sup>2016-2018</sup> to guide the EAC towards evolving an efficient and effective regional pharmaceutical manufacturing industry that will supply national, regional and international markets with the requisite medicines (EAC, 2012). One primary strategic objective of the Plan is the utilization of TRIPS flexibilities towards improved local production of pharmaceuticals (EAC, 2012).

In February 2013, the EAC Secretariat published the “EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation”. Annexed to the EAC Regional

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<sup>41</sup> See pp.79-80.

<sup>42</sup> See pp.79-80.

<sup>43</sup> SADC is a Regional Economic Community comprising 15 member states: Angola, **Botswana**, Democratic Republic of Congo, **Lesotho**, Madagascar, **Malawi**, Mauritius, **Mozambique**, **Namibia**, Seychelles, South Africa, **Swaziland**, **United Republic of Tanzania**, **Zambia**, and **Zimbabwe**. Countries highlighted in bold are also ARIPO Members.

<sup>44</sup> Members of ECOWAS: Benin, Burkina Faso, Cape Verde, Cote d'Ivoire, The **Gambia**, **Ghana**, Guinea, Guinea Bissau, **Liberia**, Mali, Niger, Nigeria, Senegal, **Sierra Leone**, Togo. Countries highlighted in bold are also ARIPO Members.

<sup>45</sup> Press Release: “ECOWAS Member States Poised to Boost Local Quality Medicines Production”. See <http://www.wahooas.org/spip.php?article662&lang=en>, accessed 6 October 2014.

<sup>46</sup> The East African Community (EAC) is a regional intergovernmental organisation of the Republics of Burundi, Kenya, Rwanda, the United Republic of Tanzania, and the Republic of Uganda. Except of Burundi, the rest are also members of ARIPO. See Chapter IV.

Policy are extracts from the “EAC Health Protocol on Public Health Related WTO-TRIPS Flexibilities”. These documents expressly urge EAC Member States to adopt and utilize TRIPS health flexibilities and outlines legislative provisions for doing so. See Chapter IV.

Given that ARIPO Members are part of the abovementioned initiatives, they obviously share the vision, objectives and goals set out. However the realization of these outcomes to the extent it concerns ARIPO Members hinges considerably on the patent filing and grant system of ARIPO.

### **III. HARARE PROTOCOL & IMPLICATIONS FOR ACCESS TO MEDICINES**

In December 1982, in Harare, Zimbabwe, the ARIPO Protocol on Patents and Industrial Designs was adopted (also known as the “Harare Protocol”). The Protocol entered into force in 1984. It has been amended by the Administrative Council of ARIPO, several times<sup>47</sup>, the latest being on 25 November 2013.

As mentioned earlier, parties to ARIPO’s constituting treaty, the Lusaka Agreement do not automatically become members of the Protocol. The Protocol is only binding on ARIPO members that ratify or accede to the Protocol.

Currently 18 countries are party to the Harare Protocol. These are Botswana, The Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, Sierra Leone, Sudan, Swaziland, United Republic of Tanzania, Uganda, Zambia and Zimbabwe. The latest member of the Harare Protocol is the Democratic Republic of Sao Tome and Príncipe, which became a party to the Protocol on 19 August 2014. (Members of the Harare Protocol are hereinafter referred to as “Contracting Parties”).

Of these only six are developing countries (Botswana, Ghana, Kenya, Namibia, Swaziland and Zimbabwe) and thus required to implement the TRIPS Agreement. The remaining contracting parties fall within the LDC category. Of the LDCs, several are not members of the WTO (Liberia, Sao Tome and Príncipe, Somalia and Sudan). It is worth reiterating that non-WTO members need not implement any aspect of the TRIPS Agreement while LDC WTO members are exempted from TRIPS implementation other than Articles 3, 4 and 5 of the Agreement, for as long as the LDC transition period remains in force.

The Protocol empowers the ARIPO Secretariat (also known as the “ARIPO Office”) to receive and process patent, utility models and industrial design applications as well as to grant patents, utility models and industrial design on behalf of its Contracting Parties. Contracting Parties do however retain the right to object to the grant of intellectual property. Once granted, the IP right is governed by national intellectual property legislations and institutions which set out parameters of the rights granted.

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<sup>47</sup> The Protocol on Patents and Industrial Designs was adopted on 10 December 1982 and amended by the Administrative Council of ARIPO on 11 December 1987; 27 April 1994; 28 November 1997; 26 May 1998; 26 November 1999; 30 November 2001; 21 November 2003; 24 November 2006 and 25 November 2013.

Implementation of the Harare Protocol is supported by Regulation<sup>48</sup> for Implementing the Protocol (hereinafter referred to as “the Regulations) and Administrative Instructions<sup>49</sup>, which elaborates on the Regulations.

### III.1 Patent Applications and Grants

Table 1 below provides a breakdown of applications filed and patents granted between 2003 and 2013. It is important to note that once an application is filed, it takes several years before a patent is granted or refused. Further, except in 2009, the numbers of applications and grants have been increasing from year to year and it can be expected that this trend will continue. Almost all (more than 95 per cent) of the applications filed are of foreign origin.<sup>50</sup>

Table 1

#### ARIPO Patent Applications Filed and Granted Between 2003 and 2013

Year	Patent Applications Filed	Grants/Registrations <sup>51</sup>
2003	238	99
2004	244	126
2005	283	164
2006	393	176
2007	427	112
2008	437	120
2009	366	147
2010	424	111
2011	529	155
2012	603	205
2013	692	271

Source: ARIPO Office & WIPO IP Statistics Data Center

Table 2 below provides a breakdown of applications filed and patents granted according to the International Patent Classification (IPC).<sup>52</sup> The IPC is used to classify patents according to the different areas of technology to which they pertain. The majority of the applications filed and granted fall within Classes A and C of the IPC, which also encompass health technologies.

<sup>48</sup> The Regulations for Implementing the Protocol on Patents and Industrial Designs entered into force on 25 April, 1984, and were amended by the Administrative Council of ARIPO on 27 April, 1994; 27 November 1998; 24 November 2000; 21 November 2003; 24 November 2006; 30 November 2011 and 25 November 2013.

<sup>49</sup> The Administrative Instructions were established by the Director General of ARIPO in accordance with Rule 2(5)(a) of the Regulations with effect from 25 April 1984.

<sup>50</sup> Discussion with ARIPO officials on 4 June 2014.

<sup>51</sup> The number of grants should not imply that the rest of the applications have been rejected. It often takes several years for a patent to be granted, thus the examination of applications tends to be carried forward.

<sup>52</sup> The International Patent Classification (IPC) was created under the Strasbourg Agreement (1971), one of a number of treaties administered by the World Intellectual Property Organization (WIPO). The IPC Committee of Experts regularly updates the classification.



Table 2

**Breakdown of ARIPO patent applications filed and granted according to IPC.**

Patent Applications Filed 1/1/2003 to 31/12/2013			Patent Granted 1/1/2003 to 31/12/2013	
Class	Total (1 <sup>st</sup> Class)	Combined Classes	Total (1 <sup>st</sup> Class)	Combined Classes
A (Human Necessities)	715	1976	447	855
B (Performing Operations, Transporting)	283	1360	135	439
C (Chemistry, Metallurgy)	1290	2147	719	830
D (Textile, Paper)	31	1304	10	548
E (Fixed Construction)	211	333	85	95
F (Mechanical Engineering; Lighting; Heating; Weapons; Blasting)	346	932	114	262
G (Physics)	281	648	93	163
H (Electricity)	229	476	83	130

*Source:* ARIPO Office

Most pharmaceutical patent applications fall within IPC sub-class A61K. For the period 2003 to 2013, 587 pharmaceutical patents (falling within the A61K classification) were granted by ARIPO.<sup>53</sup> Table 3 below provides a breakdown of pharmaceutical patent grants by ARIPO (sub-class A61K) in each ARIPO State.

Table 3

**Grants relating to pharmaceuticals by ARIPO per designated state for the duration 1/1/2003-31/12/2013**

State	Totals (A61K)	State	Totals (A61K)
1. Botswana	273	10. Rwanda	0
2. Ghana	543	11. Sudan	538
3. The Gambia	548	12. Sierra Leone	489
4. Kenya	580	13. Swaziland	516
5. Liberia	15	14. Tanzania	450
6. Lesotho	517	15. Uganda	565
7. Malawi	560	16. Zambia	345
8. Mozambique	421	17. Zimbabwe	569
9. Namibia	219		

*Source:* ARIPO Office

It is apparent from the above tables that a significant number of applications filed and patent grants concern pharmaceuticals. Multinational pharmaceutical companies – Pfizer Inc., Pfizer Products Inc, Les Laboratoires Servier and Boehringer Ingelheim International GMBH

<sup>53</sup> Information provided by ARIPO Office.

filed the most patent applications between 2003 and 2013.<sup>54</sup> Table 4 provides a list of the top 20 pharmaceutical patent applicants between 2003 and 2013.

Table 4

**Top 20 Patent Pharmaceutical Applicants Between 1/1/2003 and 31/12/2013<sup>55</sup>**

Applicant	Applicant
1. Boehringer Ingelhiem International GMBH	11. Iceutica Pty. Ltd
2. Pfizer Inc.	12. Pfizer Limited
3. Pfizer Products INC.	13. Warner-Lambert Company LLC
4. Les Laboratoires Servier	14. Bayer Intellectual Property GMBH
5. Gilead Sciences INC	15. Novartis AG
6. Tibotec Pharmaceuticals Ltd	16. Euro-Celtique S.A.
7. Cipla Limited	17. Intermune Inc.
8. Takeda Pharmaceutical Company Limited	18. Ranbaxy Laboratories Limited
9. Panacea Biotech Limited	19. Centre National de la Recherche Scientifique
10. Janssen Pharmaceutica N.V.	20. Medivir AB

Source: ARIPO Office

### III.2 Processing Patent Applications and Registering Patents

An applicant for the grant of an ARIPO patent can by filing only one application designate any of the Contracting Parties in which the applicant wishes to protect his/her invention.<sup>56</sup> The application can be filed with either one of the Contracting Parties or directly with the ARIPO Office.<sup>57</sup> Where an application for an ARIPO patent is filed with an industrial property office of a Contracting Party, the office shall within one month transmit the application to the ARIPO office for further processing.<sup>58</sup> Most patent applications coming through ARIPO originate from the international filing system set up by the Patent Cooperation Treaty (PCT).<sup>59</sup> See Box 3 below for a brief description of the PCT system.

According to Section 3bis(2) of the Harare Protocol when a Contracting Party (also a PCT member) is designated in a PCT international application “for purposes of obtaining a patent under the provisions of this Protocol shall be considered to be an application for the grant of a patent under this Protocol”. Further Section 3bis(2)<sup>60</sup> states that the provisions of the PCT shall apply to such international application in addition to the provisions of the

<sup>54</sup> Information provided by ARIPO Office.

<sup>55</sup> Information provided by ARIPO Office.

<sup>56</sup> Section 2 of the Harare Protocol.

<sup>57</sup> Section 2 of the Harare Protocol.

<sup>58</sup> Section 2(5) of the Harare Protocol.

<sup>59</sup> Discussion with ARIPO officials, 4 June 2014.

<sup>60</sup> Section 3bis(2) of the Harare Protocol: “An international application in which a Contracting State which is also bound by the Patent Cooperation Treaty is designated for the purposes of obtaining a patent under the provisions of this Protocol shall be considered to be an application for the grant of a patent under this Protocol. The provisions of the Patent Cooperation Treaty shall apply to such international application in addition to the provisions of this Protocol and the Regulations under this Protocol; in case of conflict, the provisions of the Patent Cooperation Treaty shall apply.”

Harare Protocol and related regulations and in the event of a conflict, the provisions of the PCT will prevail.

### Box 3

#### **Patent Cooperation Treaty (PCT) in a nutshell**

The PCT is an international treaty, administered by the World Intellectual Property Organization (WIPO). 148 states are parties to the PCT. The PCT makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing a single “international” patent application instead of filing several separate national or regional patent applications. The granting of patents remains under the control of the national or regional patent Offices in what is called the “national phase”. The PCT procedure includes the following steps:

- Filing an international application in compliance with PCT formality requirements.
- An “International Searching Authority (ISA)” establishes an international search report (ISR) aimed at discovering relevant prior art.
- Soon after the expiration of 18 months from the earliest filing date, the content of the international application is disclosed to the world.
- On applicant’s request, the conduct of an international preliminary examination.

On receipt of the patent application the ARIPO office assesses compliance with the formal and physical requirements under the Regulations and the Administrative Instructions.<sup>61</sup> If the application is compliant, a notification of the compliance of the application with the prescribed formal requirements is made to the IP offices and to the applicant.<sup>62</sup> Once it is determined that the formal requirements have been met, Section 3(3) of the Harare Protocol states that the ARIPO Office “shall undertake, or arrange for, the substantive examination of the patent application” to determine whether a patent should be granted.

Examination capacity at the ARIPO office is very limited. The Kenyan Industrial Property Institute (KIPI) has 12 examiners actively involved in examination of patent applications and 4 examiners on other assignments<sup>63</sup>. In comparison, ARIPO which manages patent applications for its 18 Contracting Parties, has only 6 patent examiners<sup>64</sup>. Often the ARIPO Office arranges for the patent applications to be examined by foreign patent offices such as the European Patent Office and the IP offices of Korea and Mexico.<sup>65</sup> In determining whether to grant a patent, the ARIPO Office relies heavily on the results of the PCT or foreign search and examination reports and on the European Patent Office (EPO) guidelines.<sup>66</sup>

<sup>61</sup> Section 3(2)(a) of the Harare Protocol.

<sup>62</sup> Section 3(2)(c) of the Harare Protocol, Instruction 41, Administrative Instructions to the Harare Protocol

<sup>63</sup> Email from Mr. Mboi Misati from the Kenyan Industrial Property Institute (KIPI), on file with author.

<sup>64</sup> Discussion with ARIPO officials, 4 June 2014.

<sup>65</sup> Discussion with ARIPO officials, 4 June 2014. See also Rule 18(1) of the Regulations to the Harare Protocol which states that “For the purposes of the examination under Section 3(3) of the Protocol, the ARIPO Office may transmit the application together with all relevant documents to an authority specified in the Administrative Instructions”. Instruction 48 of the Administrative Instructions clarifies that “The authority referred to in Rule 18(1) shall be any authority which has concluded an agreement to this effect with ARIPO”.

<sup>66</sup> Discussion with ARIPO officials, 4 June 2014. See also Rule 18 (2) of the Regulations to the Harare Protocol which states: “A search and examination report shall be established by the ARIPO Office or by the authority referred to in paragraph (1) and shall contain the conclusions of the examination of the application. Further see Instruction 49 of the Administrative Instructions. A Study commissioned by the World Bank and ARIPO found that “....ARIPO function as de facto registration agencies for patents filed and granted in the developed countries without recourse to any meticulous examination of such patents with regard to new and second uses of existing pharmaceutical products” (Osewe, 2008).

According to ARIPO officials, the ARIPO Office is in the process of finalizing its own guidelines for the examination of patent applications.<sup>67</sup>

Where the ARIPO Office reaches the conclusion that the requirements of the Protocol have not been fulfilled, it notifies the applicant and invites the applicant to submit his/her observations and where applicable an amended application together with a request that the matter be reconsidered.<sup>68</sup> If after reconsideration, the ARIPO Office rejects the application, the applicant may lodge an appeal against the decision of the Office.<sup>69</sup>

Where the ARIPO Office determines that the application is deserving of a patent, it notifies the applicant and each designated state.<sup>70</sup> And where the examination is based on a search and examination report, a copy of the same is to be attached to the notification.<sup>71</sup> According to Rule 18(4) of the Regulations to the Harare Protocol, the notification attaching the search and examination report shall “be made available to the public in each designated State”.

On receiving the notification, Contracting Parties designated in the application have six months to make a written communication to the ARIPO office objecting to the grant of the patent in its territory.<sup>72</sup> If an objection is received from a Contracting State, the patent if granted will have no effect in its territory. If the notified states do not communicate their objection to the ARIPO office, the ARIPO office “shall grant the patent, which shall have effect in those designated States which have not made the communication”.<sup>73</sup>

Discussions with ARIPO officials, and some IP offices revealed that apart from Kenya, which occasionally communicates its objection, most other Contracting Parties either rarely or have never objected to the granting of the patent, on receiving a notification from ARIPO.

According to ARIPO officials, it is not uncommon for the ARIPO office to grant pharmaceutical patents, which are in contravention with the national law as national IP offices often fail to communicate their written objection in a timely manner. See Box 4.

Once granted, a patent is subject to provisions set out in the national patent law of each Contracting Party such as on compulsory licenses, forfeiture or use of the patented inventions in the public interest.<sup>74</sup>

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<sup>67</sup> Discussion with ARIPO officials, 4 June 2014. Despite repeated requests to the ARIPO Office, the guidelines have not been made available to the author.

<sup>68</sup> Section 3(3) and (4) of the Harare Protocol. Rule 18(3) of the Regulations to the Harare Protocol.

<sup>69</sup> Section 3(5) of the Harare Protocol.

<sup>70</sup> Section 3(6)(b) of the Harare Protocol.

<sup>71</sup> Section 3(6)(b) of the Harare Protocol. Rule 18(4) of the Regulations to the Harare Protocol.

<sup>72</sup> Section 3(6) of the Harare Protocol states “Before the expiration of six months from the date of notification.... a designated State may make a written communication to the Office that, if a patent is granted by the Office, that patent shall have no effect in its territory for the reason:

(i) that the invention not patentable in accordance with the provisions of this Protocol, or

(ii) that, because of the nature of the invention, a patent cannot be registered or granted or has no effect under the national law of that State.

<sup>73</sup> Section 3(7) of the Harare Protocol.

<sup>74</sup> Section 3(12) of the Harare Protocol.

## Box 4

“A case in point is Ghana, which did not have patent protection for pharmaceutical products before 1992, but during that period, was designated as a territory to be covered under a patent that ARIPO granted to Pfizer pharmaceuticals for Zithromax. Although Ghana was notified of the grant by ARIPO, it did not make any objection within the time required. The patent holder, ARIPO and other interested third parties therefore erroneously believed that there was a valid patent in force in Ghana, although the grant was void from the beginning”.

*Source:* Osewe, 2008

The main reason given for the failure to object within the allocated time frame is the lack of capacity and resources in national IP or patent offices. National IP offices in the ARIPO region tend to deal with a range of IP matters. In addition to patents, national IP offices also administer trademarks, industrial designs, utility models and often, even matters concerning company and business registrations. In some IP offices (e.g. Tanzania, Zimbabwe) there is a small team of examiners (about 6-10 examiners) that rotate in dealing with trademarks, industrial designs, utility models and patents, though most of the focus is on trademark registration. This limited capacity may not exist in other national IP offices of ARIPO.

A patent applicant also has the option of filing an application for a patent grant in specific countries rather than applying for a region wide ARIPO patent. However even these patent applications filed directly with the national IP office are usually assessed only for compliance with the formal requirements. Most IP offices do not conduct substantive examination of patent applications. According to an IP official, most training programmes for examiners do not build capacity in conducting of substantive examination from a development perspective.

The majority of national IP offices rely on the ARIPO Office to conduct substantive examination of patent applications. Often even applications that are filed in specific individual countries are sent to the ARIPO Office for examination. As mentioned above, in turn the ARIPO Office relies on the search and examination report issued by the PCT system and the examination practises and services of foreign patent offices in particular the European Patent Office.

A survey of patent stakeholders from 44 African countries found that “a large number of African states are at present serving as a dumping grounds for patents, with little examination of the merits of patent applications and little public access to the contents of the patent filings (contrary to the provisions and spirit of national patent laws” (Mgbeoji, 2014). Mgbeoji also notes that presently African patent offices are operating on “trust me” mantra<sup>75</sup>, adding that to transnational companies, the biggest users of the patent system, “Africa is at present a highway, with no speed limits, on which applications are rushed to patent offices”.

The research found that most of the “national patent offices were ill-equipped to discharge their two main functions: examining patent applications and collating patent

<sup>75</sup> “Trust me” mantra was first referred to, by Drahos, P., in his paper “Trust me”: patent offices in developing countries”, American Journal of Law and Medicines, Vol. 34, pp. 151-170, 2008.

information so that it can be made publicly available for public and inventor follow-on use” and “that there was a dearth of substantive examination, and record-keeping and public access to records were poor” (Mgbeoji, 2014). It also found that membership in regional IP bodies such as ARIPO “was not substantially ameliorating the infrastructural deficiencies in the administration of patent law in most of the countries surveyed” (Mgbeoji, 2014).

The research concluded that “weaknesses of African patent offices have the potential to hamper technology transfer and domestic industrialisation on the continent, and that there is a compelling need to re-examine the operational capacities of these offices” (Mgbeoji, 2014).

With regard to pharmaceuticals, “business as usual” (as described above) hinders effective use of public health sensitive TRIPS “flexibilities”, which are increasingly being incorporated in national patent laws to facilitate local production and importation of affordable generic medicines. Consequently there are significant implications for access to medicines.

### **III.3 Processing Pharmaceutical Patent Applications: Implications for Access to Medicines**

Information on the patent status of medicines is often not publicly available. In recent years, more effort has been made to make publicly available information on the status of patent applications and grants at least in connection with ARVs enabling a better understanding of what is at stake. See Table 5.

Table 5

#### **List of filed applications and patents granted in connection with ARVs.**

<b>INN/Compound Name</b>	<b>Patent holder</b>	<b>Expected date of expiration (20 years from filing date)</b>	<b>ARIPO (as at October 2014)</b>
Abacavir sulphate (ABC) hemisulfate salt	Wellcome (GSK)	June/Dec 2010	Expired (AP 196)
composition for pediatric use	Wellcome (GSK)	2018	Granted (AP2009)
In combination with Dolutegravir (DTG, S/GSK 572) & Lamivudine (3TC)	Wellcome (GSK)	2019	Granted (AP1212)
In combination with Lamivudine (3TC) & Zidovudine (AZT)	GSK, ViiV	Jan 2031	Filed (APP201200644)
	Wellcome GSK	2016	Granted (AP652)
Cobicistat (GS-9350)	Gilead	2027, 2028	Granted (AP2985, AP2986)

<b>INN/Compound Name</b>	<b>Patent holder</b>	<b>Expected date of expiration (20 years from filing date)</b>	<b>ARIPO (as at October 2014)</b>
Darunavir Pseudopolymorph/ solvate form	Tibotec	2023	Granted (AP2052)
Prep of key intermediates	Tibotec	2025	Granted (AP2528)
Didanosine (ddI) enteric coated	BMS	2018	Granted (AP1206)
Dolutegravir (DTG, S/GSK 572) In combination with Abacavir sulfate (ABC) & Lamivudine (3TC)	GSK, ViiV	Jan 2031	Filed (APP2012006445)
Emtricitabine (FTC)	IAF Biochem	Feb. 2010	Expired (AP136)
In combination with Tenofovir disoproxil fumarate (TDF)	Gilead	2024	Granted (AP2085)
In combination with TDF & Rilpivirine (TMC 278)	Tibotec (Gilead)	2024	Granted (AP2109)
Etravirine (ETV)	Janssen Tibotec	2019	Granted (AP1683)
Solid formulation	Janssen Tibotec	2020	Granted (AP1636 and AP1639)
Fosamprenavir (FPV)	Vertex (GSK)	2018	Granted (AP1172)
Calcium salt	GSK	2019	Withdrawn (AP2001002039)
Lamivudine (3TC)	IAF Biochem GSK	Feb 2010	Expired (AP136)
Crystal form	IAF Biochem GSK	June 2012	Expired (AP300)
Liquid composition	IAF Biochem GSK	2018	Granted (AP1141)
In combination with Abacavir sulfate (ABC) & Zidovudine	Wellcome (GSK)	2016	Granted (AP652)

INN/Compound Name	Patent holder	Expected date of expiration (20 years from filing date)	ARIPO (as at October 2014)
(AZT)			
In combination with AZT	Glaxo Wellcome	2017 (officially withdrawn)	Lapsed (AP1067)
In combination with ABC & Dolutegravir (DTG, S/GSK 572)	GSK, ViiV	2031	Filed (APP2012006445)
Maraviroc(MVC)	Pfizer	2019	Granted (AP1697)
crystal Form	Pfizer	2021	Granted (AP1965)
Nevirapine (NVP)	Boehringer	Nov. 2010	Expired (AP179)
Rilpivirine (TMC 278)	Janssen Pharmaceutica	2022	Granted (AP1610)
salt forms	(Tibotec)	2025	Granted (AP2487)
In combination with FTC +TDF	Tibotec (Gilead)	2024	Granted (AP2109)
Tenofovir Alafenamide Fumarate(TAF–GS7340)	GileadSciences	2021	Granted (AP1466)
Tenofovir disoproxil fumarate (TDF)			
In combination with FTC	Gilead	2024	Granted (AP2085)
In combination with FTC + Rilpivirine	Tibotec (Gilead)	2024	Granted (AP2109)
Zidovudine (AZT)	Glaxo Wellcome	2006	Expired
In combination with 3TC & ABC	Wellcome (GSK)	2016	Granted (AP652)
In combination with 3TC	Glaxo Wellcome	2017 (officially withdrawn)	Lapsed (AP1067)

Source: Patent Status Database, Medicines Patent Pool<sup>76</sup>

<sup>76</sup> Available at: <http://www.medicinespatentpool.org/patent-data/patent-status-of-arvs/>, accessed on 17<sup>th</sup> November 2014. See also UNITAID (2014b).



### ***III.3.1. Least Developed Countries***

The majority of ARIPO's Contracting Parties are LDCs and thus are under no obligation to recognize pharmaceutical patents so long as the transition period continues (See Box 1). However the Harare Protocol does not exempt such Parties from the processing of patent filings for pharmaceuticals. As with other applications, the ARIPO Office will notify designated offices of its intent to accord patents to the pharmaceutical application received. It is then up to each Contracting Party to communicate their written objection to the grant of a patent, if their national patent law excludes pharmaceutical patents. Failure to communicate a written objection to the ARIPO Office within six months of notification will result in the grant of a pharmaceutical patent extending to all designated Contracting Parties that did not object.

Lapses in the ARIPO notification and objection mechanism (which as noted above is common), raises significant concern for access to affordable medicines. Unless the LDC Contracting Parties have objected to the grant of ARV patents listed in Table 5 as required by the Harare Protocol, these ARIPO granted ARV patents extend to the LDC territories designated in the patent application.

In recent years, some LDCs (e.g. Rwanda and Uganda) have amended their patent laws to incorporate the pharmaceutical product transition period. And it is anticipated that more LDCs will follow suit. However the abovementioned lapses suggest that these LDCs may not reap the full benefits of the waiver, as failure to object will result in the ARIPO office granting a patent covering these LDCs. While pharmaceutical patents granted in LDCs implementing the transition period would lack validity and hence not be enforceable as they cover subject matter excluded from protection the mere existence of an ARIPO issued patent document creates an uncertain environment and could deter others from importing or manufacturing a more affordable generic alternative. The patent holder would also be able to use the patent document to assert its rights (so long as the grant is not invalidated).

### ***III.3.2. Patentability Criteria & Secondary Patents***

Another major concern is ARIPO's approach to the examination of patent applications.

The Harare Protocol states inventions for which the ARIPO Office grants patents shall be "new" (not anticipated by prior art), "involve an inventive step" and be "industrially applicable".

A review from a public health perspective of ARIPO's basic documents<sup>77</sup> and the type of patents that have been granted reveals that the application of patentability standards is lax and the ARIPO Office is open to receiving and granting secondary patents including on the various forms of new chemical entity such as new formulations, dosages, combinations and uses. Such secondary patents, often of questionable validity, have been known to be strategically used by patent-holding pharmaceutical companies to "evergreen" their patent monopoly and unduly delay the entry of generic competition.

Table 5 shows patent grants by the ARIPO office on new forms (e.g. crystal form, salt), formulations and compositions of existing drugs (e.g. paediatric composition) as well as

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<sup>77</sup> The Harare Protocol, the Regulations and Administrative Instructions.

combinations of existing drugs. These patents over minor incremental developments (also known as “evergreening patents”<sup>78</sup> or secondary patents) maybe used to exclude generic competition and block access to affordable medicine.

Rule 7(3) of the Regulations to the Harare Protocol specifies how claims related to medical indications or use claims - first and second medical indications<sup>79</sup> – should be drafted. The ARIPO office obviously approves of claims relating to use including second indication of a known pharmaceutical product although such claims lack novelty and industrial applicability (since what is new is an identified effect on the body) (Correa, 2006). Correa also argues that according to a literal interpretation of the TRIPS Agreement, which only obliges grant of patents over products and processes, WTO Members are under no obligation to grant use claims, including second indications.

Further the TRIPS Agreement (Article 27.2) explicitly allows therapeutic, diagnostic and surgical methods to be excluded from patent protection. A patent covering the second medical indication of a known product is substantially equivalent to a patent over a method of therapeutic treatment (Oh, 2004). Thus by allowing new use patent claims (i.e. claims that describe a therapeutic method of treatment), application of Article 27.2 exclusion at the national level is jeopardised if the relevant contracting party fails to communicate its objection to the patent application.<sup>80</sup> It is worth noting that while many jurisdictions’ patent laws contain provisions stating that method of treatment claims are excluded, some of the same jurisdictions provide a further exception to this exclusion, expressly providing that products for use in such methods do not fall under the exclusion. In the latter case, the impact would be less acute.

Use claims, including second indication can be used strategically by the patent holder to block the entry of generic products. In addition, Correa argues that the “problem of encouraging research into neglected diseases and geographical areas is not helped by the patenting of second indications. This is especially true where the previously-known substance or composition was already in the public domain” (Correa, 2008).

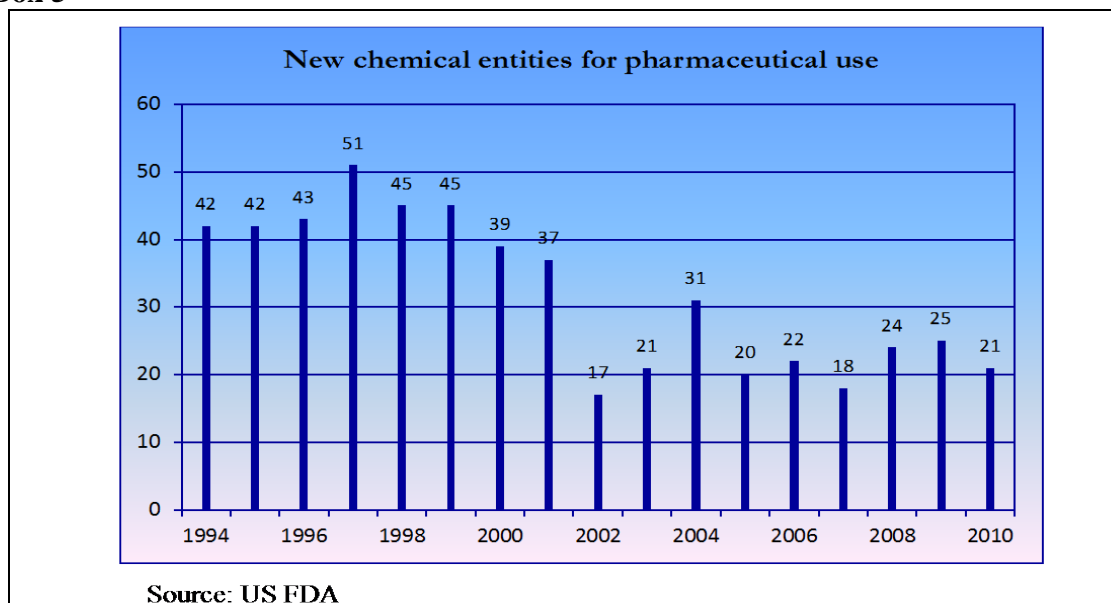
Over the years, the number of newly developed chemical entities has dramatically fallen (See Box 5), but the number of patents over simple changes in chemistry/formulation of existing pharmaceutical products (e.g. polymorphs, combinations, dosage forms, isomers) has continuously increased (Correa, 2011). Thousands of patents are granted per year on these incremental innovations, often trivial for a person skilled in pharmaceutical research and production (Correa, 2011).

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<sup>78</sup> ‘Evergreening’ is generally based on the patenting of minor changes to or derivatives of existing products (e.g. formulations, dosage forms, polymorphs, salts, etc.) in order to indirectly extend the life of the original patent over an active ingredient.

<sup>79</sup> First medical indication – where a new pharmaceutical use is discovered for a product not previously used as a pharmaceutical product. Second medical indication – where a product already known to have a pharmaceutical use is discovered to have a further pharmaceutical use that is unrelated to the known use. An example of second medical indication is the ARV drug Zidovudine (AZT). It was initially investigated as a cancer drug, and it was later discovered that AZT could be used in the treatment of HIV, and the second medical indication was allowed to be patented. Second medical indications are accepted under European jurisprudence and in other countries when framed in accordance with the so called “Swiss claims”: “use of x for the manufacture of product y to treat disease z”.

<sup>80</sup> If an objection is not communicated the patent is invalid and non-enforceable in a country where pharmaceutical products and processes are not eligible for protection.

**Box 5**

Source: Correa, 2011

Secondary patents tend to be used by multinational pharmaceutical companies to prolong the market exclusivity of existing drug, shut out competition and delay generic entry, consequently blocking access to affordable drugs. They constitute an important obstacle towards the realization of the right to health recognized in the International Covenant on Economic, Social and Cultural Rights and increasingly, in the national constitutions of many countries (Correa, 2011).

A case in point is that of a critical HIV medicine – Kaletra – which is a combination of two antiretroviral agents: ritonavir and lopinavir. The basic patent for the underlying compounds was set to expire in 2014 and 2016, respectively, meaning that theoretically generic suppliers should be able to supply Kaletra beginning in 2016 (I-MAK, 2012). However Abbott has also filed a number of trivial and follow-on secondary patents (see Box 6) which threatens to keep out generic competition in certain markets until at least 2028 i.e. 12 years after the basic compound patent expires and 39 years after the first patent for ritonavir was filed (I-MAK, 2012). During the extended patent term Abbott will be able to charge monopoly prices (which will have to be borne by donors, public health systems and patients) in countries where the patents apply. Such non-inventive patents also adversely impact useful research around existing drugs (I-MAK, 2012).

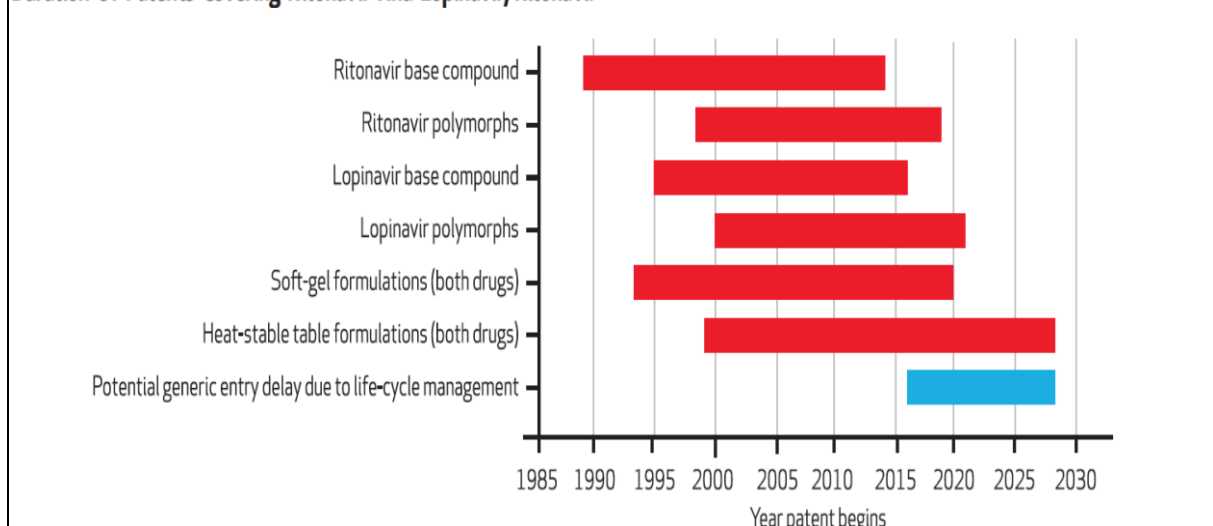
Secondary patents are a problem that affects both developed and developing countries. An inquiry by the European Commission (EC), found that patent holding companies use numerous strategies including creating “patent thickets” around a successful drug (e.g. the filing of up to 1,300 patents EU-wide in relation to a single medicine) (European Commission, 2009). Further in relation to 219 drugs, the European Commission found that:

*“...nearly 40,000 patents had been granted or patent applications.....were still pending...Of the nearly 40,000 cases, some 87 percent were classified by the companies as involving secondary patents, giving a primary:secondary ratio of approximately 1:7. Of the applications still pending, 93 percent were classified as secondary (a primary:secondary ratio of approximately 1:13), whilst 84 percent of the patents granted were classified as secondary (a*

*primary:secondary ratio of approximately 1:5” (European Commission, 2009).*

### Box 6

#### Duration Of Patents Covering Ritonavir And Lopinavir/Ritonavir



Source: Amin, 2012.

The most common types of secondary pharmaceutical patents filed in relation to the drugs include formulations (57 per cent), combinations (7 per cent), polymorphs (5 per cent), salts (4 per cent) (European Commission, 2009). The EC also estimated a loss of around three billion Euros due to delays in the entry of generic products caused by misuse of the patent system (European Commission, 2009).

### III.3.3 Consequences for Access to Medicines

Patents granted by ARIPO have major implications for public health in the region as access to affordable medicines becomes possible only if the right holder decides it will not enforce its patents, or grants a voluntary license, if the government issues a compulsory license or government use, to import or manufacture generic versions, or if the patent is nullified or revoked.

- **Abacavir (ABC)** is included on the WHO Model List of Essential Medicines (EML). It is recommended for infants and children as first-line and second line ARV treatment and for adults as part of an alternative regime. Although the basic patent expired in 2010, secondary patents related to hemisulfate salt, pediatric composition were filed by GSK and granted by the ARIPO (MSF, 2013). In India, civil society opposed the hemisulfate salt patent application leading to its withdrawal (MSF, 2013). In certain countries GSK is aggressively enforcing its patents<sup>81</sup>. In February 2013 the Medicines Patent pool (MPP) and ViiV

<sup>81</sup> For example in Ukraine, GSK has filed a claim to stop patent infringement on hemisulfate salt formulations against four Ukrainian companies and distributors, who had submitted bids to the Ministry of health to supply ABC for adults (MSF, 2013). GSK also filed an injunction to prohibit these companies from selling and importing generic ABC, which could have a chilling effect on suppliers of generic ABC in Ukraine (MSF, 2013).

announced a licence agreement on paediatric ABC covering 118 countries<sup>82</sup>. In April 2014, the same parties announced another license, which among others covered the fixed-dose combination of ABC and dolutegravir (DTG). While the territories included within the scope of the license includes the ARIPO region, manufacturers would only be allowed to produce under the license if the products meet WHO prequalification or stringent regulatory authority standards. This condition may preclude nascent generic producers.

- **Didanosine (ddI):** Enteric coated capsules are included in WHO's Model List of Essential Medicines. Since this product remains patent free in India, generic versions have been launched. For the ARIPO region importation of more affordable generic versions from India would be blocked (MSF, 2013) due to patents on the product. In June 2011, BMS signed an immunity-from-suit agreement with Mylan enabling the generic company to manufacture and sell ddI in sub-Saharan Africa (MSF, 2013).
- **Tenofovir Alafenamide Fumarate (TAF)** is currently in phase III clinical trials and has potential to become a cost-effective and less toxic treatment option (I-MAK, 2013). The compound has been granted patent by ARIPO. I-MAK argues that TAF is not a new compound and it is just "another prodrug of TFV" (tenofovir), and "given the existing prior knowledge for formulating antiviral compounds as prodrugs", it is obvious and not inventive and is also unlikely to meet the Section 3(d) enhanced efficacy standard used in India (I-MAK, 2013). In July 2014, a licensing arrangement between the Medicines Patent Pool and Gilead Sciences to develop generic versions of TAF for 112 countries (including ARIPO Contracting Parties) was revealed. However only generic manufacturers from India and China would be allowed to produce under the license. The patent, which is set to expire in 2021 would particularly hinder local production of more affordable generic versions. Gilead is also likely to file further patent applications around TAF, particularly for co-formulations. (I-MAK, 2013).
- **Etravirine (ETV)** is indicated as a treatment option for adults and children over 6 years of age who are failing second-line regimes. It is anticipated that patents granted on the ETV molecule will hinder entry of robust generic competition which is critical to making the medicine accessible (MSF 2013). There is currently no generic source for the product (I-MAK, 2013). There are no voluntary licenses for the manufacturing of generic Etravirine though Aspen holds a non-exclusive license to register, package and distribute (but not to produce) the drug in sub-Saharan Africa (UNITAID, 2014b). I-MAK has questioned the quality of the sought patents arguing that "various prior art exists which disclose structurally similar compounds" and that "the secondary patent application covering solid oral dosage formulation uses commonly known techniques which should be considered obvious" adding that "claimed improvements alone may not meet the therapeutic efficacy requirement" (I-MAK, 2013).

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<sup>82</sup> MPP and ViiV also entered into a separate non-binding Memorandum of agreement, which promises collaboration on pediatric licensing of pipeline ARVs, development of novel combination pediatric formulations and availability of novel pediatric formulations outside of the existing list of licensed territories.

- **Maraviroc (MVC).** The United States Food and Drug Administration approved MVC in 2007. It is not currently recommended by WHO. Within the ARIPO region, patent covering the compound expires in 2019 while the patent on the crystal form expires in 2021. No specific licenses on MVC have been announced to date<sup>83</sup> and there are no generics on the market (UNITAID 2014b). If the ARV were included in treatment recommendations, market competition for MVC would be limited and access to affordable versions would be hindered. If licensed, it would be applicable to countries covered by the license (UNITAID 2014b).
- **Fix-Dose Combination (FDC)** offers a better treatment option as it combines several ARVs into a single formulation. Patents on any individual ARV included in a FDC or on the combination itself may have an impact on access to medicines (MPP, 2012). ARIPO has granted several patents for specific combinations. Patents on combinations represent a potentially significant challenge to the manufacture and procurement of generic FDC as it would be difficult to design around a patent covering the specific combination (MPP, 2012).

The above-mentioned examples highlight how pharmaceutical patents are obstacles and affordable access is then very much dependent on factors such as whether the patent will be enforced, the terms of voluntary licenses, acts by government to override the patent barrier. In situations where the patent holder agrees to grant voluntary licenses, often the terms of the licenses are confidential and the license to manufacture is only given to certain companies, subject to strict terms and conditions (MSF, 2013).

The examples above are limited to ARVs but the challenge of patents and access to medicines extends to other treatments as well (e.g. cancer, TB, cardiovascular). For example Bedaquiline is a new treatment approved for MDR-TB and under development for drug susceptible tuberculosis (DS-TB). It is marketed by a multinational Johnson & Johnson (J&J)/Janssen Pharmaceutica under the brand name Sirturo. The ARIPO Office has granted at least one patent in connection with bedaquiline<sup>84</sup>, while 3 other patents<sup>85</sup> are still pending approval (UNITAID, 2014). These patents cover the compound base, method of using bedaquiline to treat MDR-TB and latent TB, process to prepare bedaquiline and pharmaceutical formulations. These patents could prevent other competitors from making the product.

A critical conclusion from this analysis is that the extent to which patents pose a barrier to access to medicines in ARIPO's Contracting Parties is very much dependent on the workings of the ARIPO Office. The ARIPO Office guided by the Harare Protocol, its Regulations and Administrative Instructions, is the main focal organization that administers the grant of patent for its 18 Contracting Parties. As highlighted above, its current practices, are neither conducive for importing nor manufacturing affordable pharmaceutical products. Even where Contracting Parties have with the aim of promoting access to medicines

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<sup>83</sup> In July 2010, the patent holder announced intention to license all its current and pipeline products with a geographical scope of all sub-Saharan Africa, low-income countries and least-developed countries (UNITAID 2014b).

<sup>84</sup> WO2005/117875: patent covers the use of bedaquiline for the preparation of a medicament for the treatment of drug-resistant mycobacteria, in particular multidrug-resistant mycobacteria.

<sup>85</sup> WO2004/011436: patent on the base compound bedaquiline with antimycobacterial properties and blocks all manufacturing of the product if granted; WO2006/067048: patent covers the use of bedaquiline for the manufacture of a medicament for the treatment of latent tuberculosis; WO2008/068231: patent covers pharmaceutical compositions/formulations for administration purposes.

incorporated key TRIPS flexibilities, in their national patents laws, the operations of the ARIPO Office as well as the lapses in the notification and objection mechanism of ARIPO, has resulted in rendering the flexibilities somewhat less effective. (See Chapter IV).

Chapter II lists some of the key international, regional and sub-regional initiatives that emphasize on the use of flexibilities as a prerequisite for accelerating access to affordable medicines, reducing dependency on external financing, creating a sound and viable technological base in the pharmaceutical sector and increasing self-reliance. To make headway towards achieving these goals, it is imperative to review and revise the Harare Protocol, its Regulation and Administrative Instructions as well as the workings of the ARIPO Office. Such an exercise should at least result in LDCs being exempt from pharmaceutical patent grants in line with the 2016 and 2021 transition periods (and further extensions granted), adoption of rigorous patentability standards and patent examination practices that avoids secondary patents; incorporation of other key TRIPS flexibilities critical to incorporating a public health perspective into patent examination such as pre and post grant opposition. This is discussed further in Chapter IV.

#### **IV. HARARE PROTOCOL & IMPLEMENTATION OF THE EAC REGIONAL INTELLECTUAL PROPERTY POLICY AND THE EAC HEALTH PROTOCOL ON PUBLIC HEALTH-RELATED WTO-TRIPS FLEXIBILITIES**

The East African Community (EAC) is a regional intergovernmental organisation of the Republic of Burundi, Kenya, Rwanda, the United Republic of Tanzania, and the Republic of Uganda, with its headquarters in Arusha, Tanzania.

The Treaty for the Establishment of the East African Community (hereinafter referred to as “the EAC Treaty”) was signed on 30 November 1999 and entered into force on 7 July 2000 following its ratification by the original three Partner States – Kenya, Tanzania and Uganda. The Republic of Rwanda and the Republic of Burundi acceded to the EAC Treaty on 18 June 2007 and became full Members of the Community with effect from 1 July 2007.

Among the EAC States, except for Kenya, which is a developing country, the rest are LDCs. Further except for the Republic of Burundi, all other EAC states are members of ARIPO and Contracting Parties to the Harare Protocol.

The main objective of the EAC is to deepen co-operation among the Partner States in, *among others*, political, economic and social fields for their mutual benefit. Towards this end, the EAC countries established a Customs Union in 2005 and a Common Market in 2010. Health is a key area of cooperation within the EAC Partner States, as outlined in Chapter 21 of the EAC Treaty. Article 118 of the EAC Treaty, which governs aspects of health, advocates, *inter alia*, joint action towards the prevention and control of communicable and non-communicable diseases, harmonization of health policies and regulations and promoting the exchange of information in order to achieve quality health within the Community and cooperation in development of pharmaceutical products. Development of science and technology and in this context harmonization of intellectual property policies is another area of cooperation mentioned by the EAC Treaty (Article 103).

In February 2013, the EAC Secretariat published a document containing the EAC Regional Intellectual Property Policy on the Utilization of Public Health Related WTO-TRIPS Flexibilities (hereinafter referred to as “the EAC Policy”). Annexed to the EAC Policy is an extract from the EAC Health Protocol on Public Health Related WTO-TRIPS Flexibilities (hereinafter referred to as “the Health Protocol”).

The EAC Policy came about in recognition that “IP regimes must take into consideration the level of development of the various countries and that protection of private interests shall be balanced with protection of the larger public’s interests, to strengthen technological progress and improve access to new technologies and products for the poor” (EAC 2013a). It also acknowledges that WTO instruments afford developing countries and LDCs flexibilities that are essential for access to affordable quality health products and medical devices to address their health concerns and that these flexibilities emphasized in important international negotiated initiatives such as the WIPO Development Agenda of 2007 and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property of 2008 have been championed by the EAC and its Partner States (EAC 2013a).

Further the East Africa Community Regional Pharmaceutical Manufacturing Plan of Action (2012-2016) identifies utilization of TRIPS flexibilities as a key component of its roadmap to the development of an efficient and effective regional pharmaceutical manufacturing industry.

Against this background, to realize the benefits of TRIPS flexibilities, the EAC considered it crucial to develop a regional policy and protocol.

#### **IV.1 EAC TRIPS Policy & Health Protocol**

The overall objective of the Policy is “to guide the EAC Partner States on how their national intellectual property legislation shall be adjusted in order to enable them to fully utilize the Public Health-related WTO-TRIPS Flexibilities”. The “Expected Outcomes” of the Policy are:

- optimise the populations’ access to health products and medical devices;
- broaden the public domain in order to ensure that IP embedded products and services with respect to health are available and accessible at an affordable cost to all of the EAC Partner States’ populations;
- achieve public health objectives;
- promote pharmaceutical manufacturing and innovation industries; and
- improve mutual cooperation in their regional markets for their mutual benefit.

The EAC Policy details the policy approach that should be incorporated in the EAC Partner States’ national IP legislations with regard to public health related TRIPS flexibilities. This policy guidance is reflected in the EAC Health Protocol committing the EAC States to implement the suggested TRIPS Flexibilities.

The EAC Policy and Protocol provide guidance on transition period, mailbox provision, administrative pre- and post-grant oppositions, patentability criteria, exclusions from patent protection, disclosure requirements, research exception, marketing approval/“Bolar” exception, international exhaustion, compulsory licensing including



government use, control of licensing practices and conditions, protection of undisclosed data, compensatory liability for the protection of small-scale inventions and traditional medicines and implementation of the 30 August 2003 Decision of the WTO (also known as the Paragraph 6 Decision). For a summary of the guidance on each of the elements see Annex 1.

The EAC Policy makes clear that implementation of the Policy “shall be the responsibility of the EAC Partner States”. In addition to the above the EAC Policy requires the EAC States to among others: reject any attempts, at national, regional and international levels that may hinder the full utilization of the TRIPS Flexibilities, in the region and the EAC Partner States, via any other policy or legislative framework; undertake to train or sensitize stakeholders on IP and public health; enhance cooperation and linkage between IP stakeholders, especially on TRIPS and public health, at national, regional, and international levels and in particular foster partnership and collaboration of national IP offices in the region; be actively involved in IP and public health-related regional and international processes; avail an environment conducive for establishing regional or national medicine manufacturing capacities including earmarking funds for R&D; provide incentives for the promotion of local pharmaceutical industries; address other policy constraints that hinder the full utilization of TRIPS Flexibilities while taking into consideration the wider objectives of Article 7 and the principles of Article 8 of the TRIPS Agreement.

The EAC Secretariat is tasked with guiding the implementation “in a participatory and integrated manner”. The EAC Secretariat is also required to inter alia: address other policy constraints that hinder full utilization of TRIPS Flexibilities in the EAC region; monitor and evaluate (M&E), on a quarterly basis and against an appropriate set of indicators, the progress and impact of the policy implementation with regard to the relevant national IP laws. For this EAC Secretariat has to establish M&E capacity within the health department and align with the overall EAC M&E framework. Data collection for baselines and progress evaluation has to include participation of the private sector and other key stakeholders in the pharmaceutical manufacturing sector.

## **IV.2 Impact of ARIPO’s Operations on Implementation of the EAC Policy & Health Protocol**

The ARIPO Office processes the majority of patent applications intended for the EAC States. As such the effective implementation of some aspects of the EAC Policy and Health Protocol is very much dependent on the Harare Protocol and the workings of the ARIPO Office with regard to the Protocol.

Chapter III provides an insight into ARIPO’s patent filing, examination and grant system under the Harare Protocol and highlights some of the shortcomings from a public health standpoint. This chapter analyses the extent to which ARIPO’s patent processing and grant system is supportive of the implementation and use of TRIPS flexibilities as detailed in the EAC Policy and Health Protocol. This Chapter focuses only on the following flexibilities: transition period, patentability criteria and exclusions from patentability; administrative opposition procedures; and disclosure requirements, as these aspects are relevant to the Harare Protocol. Other TRIPS flexibilities such as exceptions to patent rights, compulsory licensing, exhaustion of rights, control of licensing practices are national measures and thus fall outside the scope of the Harare Protocol.

#### IV.2.1. Transition period

The EAC Policy and Health Protocol calls on the EAC States to exclude from patent protection pharmaceutical products and processes for as long as the transition period continues. Except for Tanzania (Mainland), all other EAC LDC States have to some extent incorporated this transition into their patent law (See below Table 6). It is anticipated that Tanzania (Mainland) will follow soon as it is in the process of amending its Patents Act of 1987. Except in the case of Tanzania-Zanzibar, other EAC LDC States only apply the transition period to pharmaceutical products. In addition, in most EAC LDC States, the national legislations recognize the application of the transition period flexibility beyond 2016. In the case of Burundi, the national law expressly states that the pharmaceutical product exclusion is only up to 1 January 2016.

**Table 6**

<b>Burundi*</b>	<b>Law No. 1/13 Of July 28, 2009 Relating To Industrial Property in Burundi.</b> Article 17: “The following shall be excluded from patent protection:..... Pharmaceutical products, up until January 1, 2016.”
<b>Kenya</b>	As a developing country, Kenya cannot take advantage of transition period for LDCs.
<b>Rwanda</b>	<b>Law No. 31/2009 Of 26/10/2009 On The Protection of Intellectual Property.</b> Article 18 (8): “The following shall be excluded from patent protection even if they constitute inventions under article 5 (7): of this Law.... pharmaceutical products, for the purposes of international conventions to which Rwanda is party”.
<b>Tanzania-Mainland</b>	Does not exempt pharmaceutical products from patent protection.
<b>Tanzania-Zanzibar</b>	<b>The Zanzibar Industrial Property Act of 2008.</b> Section 3(1)(x): “The following shall be excluded from patent protection....pharmaceutical products and processes until January 1 2016 or the expiry of such later period of extension agreed upon the World Trade Organization Council for TRIPs.”
<b>Uganda</b>	<b>Industrial Property Act 2013.</b> Section 8(3)(f) “The following shall not be regarded as inventions and shall be excluded from patent protection....pharmaceutical products until 1st January 2016 or such other period as may be granted to Uganda or least developed countries by the Council responsible for administering the Agreement on trade related aspects of intellectual property under the World Trade Organization.”

\*Burundi is not a member of ARIPO.

As mentioned in Chapter III, to fully benefit from the LDC transition period, on receiving a notification from the ARIPO Office of its intent to grant patents to the pharmaceutical application received, the EAC LDC State would have to communicate a written objection to the grant of the pharmaceutical patent. It has also been noted above that the ARIPO Office receives very few written objections. Thus although, the legislations of EAC States do explicitly exclude pharmaceutical patents (mainly product patents) from the scope of patent protection, failure to object, results in the ARIPO Office issuing pharmaceutical patents which extends to such States. In effect, these patents should be invalid in such EAC LDC States, as they cover subject matter outside the scope of protection.

However the existence of an ARIPO issued patent certificate (even if ultimately unenforceable) creates an ambiguous legal environment, which could hinder access to medicines. It also negates the intended impact of incorporating TRIPS flexibilities in national patent legislations.

Considering the majority of ARIPO Contracting Parties are LDCs, and that in recent years LDCs have begun incorporating the transition period into their patent laws, as well as that due to capacity constraints LDCs struggle to communicate a written objection to a pharmaceutical grant, it is timely for Members of the Harare Protocol to review the Protocol to facilitate more effective use of the transition period.

Accordingly EAC Members (which are also ARIPO members) should pursue an amendment of the Harare Protocol exempting the territory of LDCs from the grant of pharmaceutical patents. This means that in the event the ARIPO Office grants pharmaceutical patents, such patents will not be applicable to the LDC territories. LDCs that affirmatively wish for the ARIPO patent to be applicable to its territory would be required to communicate so to the ARIPO Office within a specific time-frame of receiving notification of ARIPO's intent to grant the patent.

In the interim, LDCs should take urgent action to declare that pharmaceutical patents covering its territory are not enforceable for as long as the transition period applies. This would very much be in line with the agreement contained in Paragraph 7 of the Doha Declaration on TRIPS and public health<sup>86</sup> as well as the national patent law, where such law excludes pharmaceutical patents.

Intellectual property offices of LDCs should also urgently adopt an institutional policy that on receipt of a notification from the ARIPO Office of its intent to grant a pharmaceutical patent, the IP Office will immediately communicate a written objection to the ARIPO Office. The proposed actions are in line with the WTO decisions on the LDC transition period as well as EAC's vision to become a regional hub for manufacturing generic medicines.

#### ***IV.2.2. Patentability Criteria & Exclusions from Patentability***

The EAC Policy and Health Protocol advocates the application of rigorous patentability criteria with the objective of maintaining broad public domain for the promotion of access to affordable health products for the benefit of public health, particularly by avoiding secondary patents. These EAC documents require EAC states to:

- (a) in defining novelty adopt a wide prior art definition consisting of everything disclosed to the public, whether by use, in written or oral form, including patent applications, information implied in any publication or derivable from a combination of publications, which are published anywhere in the world and which can be actually or theoretically accessed by the general public;

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<sup>86</sup> Paragraph 7 of the Doha Declaration on TRIPS & Public Health: "We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement *or to enforce rights* provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement."

- (b) adopt an inventive standard wherein the invention is non-obvious to a person “highly” skilled in the art;
- (c) strictly apply the industrial application requirement;
- (d) limit the patentability of research tools to only those for which a specific use has been identified;
- (e) to exclude from patentability:
  - Natural substances including micro-organisms, even if purified or otherwise isolated from nature;
  - New medical uses of known substances including micro-organisms;
  - Derivatives of known medical substances unless they show a significantly enhanced therapeutic efficacy or other significant superior properties. For this purpose, Partner States shall determine that structural similarities between the original product and its derivative establish a presumption of lack of novelty. This presumption may be reversed if the patent applicant can demonstrate the derivative’s significantly enhanced therapeutic efficacy or other significant superior properties.

The standard set out for assessing derivatives of known medical substances is vague, especially the latter standard - “other significant superior properties”. Neither the EAC policy nor the Health Protocol defines the type of evidence that would be sufficient to demonstrate “significantly enhance therapeutic efficacy or other significant superior properties”. If it is defined loosely any improvements over existing drug (e.g. easier to store), could potentially satisfy the efficacy requirement, defeating the purpose of the clause i.e. to prevent evergreening (Chaudhuri, 2010). If a stricter definition is adopted, it could serve as an “effective bulwark against many forms of secondary patents” (Chaudhuri, 2010). Further where there are structural similarities between the original product and its derivative, it should result in a presumption of lack of “inventive step” (and not “novelty”), which may be reversed.

**Table 7**

<b>Burundi</b>	<ul style="list-style-type: none"> <li>• Art. 4 Prior art: worldwide, disclosed to the public by any means.</li> <li>• Art. 6 refers to “a person skilled in the art”</li> <li>• Art. 7: Industrial applicability</li> <li>• Art. 17: Exclusion of natural substance, even if purified, synthesized or otherwise isolated from nature. But process of isolation can be patented.</li> <li>• Art. 17: New uses of known products are explicitly excluded from patentability</li> </ul>
<b>Kenya</b>	<ul style="list-style-type: none"> <li>• Sec. 23.2 Prior art: worldwide; written or oral disclosure, use, exhibition or other non-written means.</li> <li>• Sec. 24 refers to “a person skilled in the art”</li> <li>• Sec. 25: Industrial applicability</li> <li>• Sec. 21.3 (e): Public Health related methods of use or uses of any molecule or other substances, excluded if the disease designated by the Health Minister as a serious health hazard or as a life threatening disease.</li> </ul>
<b>Rwanda</b>	<ul style="list-style-type: none"> <li>• Art. 15 Prior art: worldwide; by publication in tangible form, by oral disclosure, by use or in any other way</li> <li>• Art. 16 refers to “a person skilled in the art and involved in that area”</li> </ul>

	<ul style="list-style-type: none"> <li>• Art. 17: Industrial applicability</li> <li>• Exclusion of natural substances, even if purified, synthesized or otherwise isolated from nature. But process of isolation can be patented, Art. 18.1 No. 4</li> <li>• Excludes patents on known substances for which a new use has been discovered; but does not exclude the use itself, provided it is an invention. Art. 18.1 No. 5</li> </ul>
<b>Tanzania-Mainland</b>	<ul style="list-style-type: none"> <li>• Sec. 9.2 Prior art: Everything made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) or by oral disclosure, use, exhibition or other non-written means</li> <li>• Sec. 10 refers to “a person skilled in the art”</li> <li>• Sec. 11: Industrial applicability</li> </ul>
<b>Tanzania-Zanzibar</b>	<ul style="list-style-type: none"> <li>• Sec. 4.2 (a) Prior art: worldwide; disclosure in tangible or oral form including patent applications; everything that can be derived from a combination of patents; use; information disclosed in any other way including material in any deposit institution</li> <li>• Sec. 4.3 refers to “a person highly skilled in the art”</li> <li>• Sec. 4.4, Industrial applicability</li> <li>• Sec. 3.1(iv), Exclusion of natural substances even if purified, synthesised or isolated; except processes for isolation.</li> <li>• Sec. 3.1(v), New uses or forms of known products or processes are explicitly excluded</li> </ul>
<b>Uganda</b>	<ul style="list-style-type: none"> <li>• Sec. 10 Prior art: Everything made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) or by oral disclosure, use, exhibition or other non-written means</li> <li>• Sec. 11 refers to “person skilled in the art”</li> <li>• Sec. 12, Industrial applicability</li> <li>• Sec. 8.3(g), Exclusion of natural substances even if purified, synthesised or isolated; except the processes for isolating those natural substances;</li> </ul>

EAC States have in varying degrees implemented aspects of the EAC Policy and Protocol. See Table 7 above. In any case, due to capacity constraints, the main focus of many IP offices, when processing patent applications is ensuring that the application meets the formal requirements. Substantive examination rarely takes place.

Section 3(10)(a) of the Harare Protocol states that inventions for which patents are granted shall be new, involve an inventive step and be industrially applicable.<sup>87</sup> The prior art

<sup>87</sup> Section 3(10) states: (a) Inventions for which patents are granted by the Office shall be new, shall involve an inventive step and shall be industrially applicable. (b) An invention is new if it is not anticipated by prior art. (c) Everything made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) or by use or exhibition shall be considered prior art provided that such making available occurred before the date of filing of the application or, if priority is claimed, before the priority date validly claimed in respect thereof and further provided that a disclosure of the invention at an official or officially recognized exhibition shall not be taken into consideration if it occurred not more than six months before the date of filing of the application or, if priority is claimed, before the priority date validly claimed in respect thereof. (e) An invention shall be considered as involving an inventive step if, having regard to the prior art, it is not obvious to a person skilled in the art. (f) An invention shall be considered susceptible of industrial

standard adopted to define novelty entails worldwide disclosure encompassing written disclosure, oral disclosure or disclosure by use or an exhibition. It does not however go as far as the EAC policy by expressly including in the prior art concept “patent applications, information implied in any publication or derivable from a combination of publications, which are published anywhere in the world and which can be actually or theoretically accessed by the general public”. Further the inventive standard requires an assessment of non-obviousness to a “person skilled in the art” rather than to a “person highly skilled in the art” advocated by the EAC policy. The Harare Protocol defines industrial applicability as “made or utilized in any kind of industry including agriculture”, though it does not limit the patentability of research tools as proposed by the EAC Policy.

Specifically with regard to pharmaceutical applications, evidence suggests that in practise the ARIPO Office applies low standards of patentability to the examination of such applications, thereby allowing proliferation of secondary patents. This aspect has been discussed in much depth in Chapter III. There are several reasons for such lenient standards: ARIPO’s extremely limited examination capacity, reliance on the practises and services of foreign patent offices<sup>88</sup> e.g. the EPO, the absence of rigorous pharmaceutical examination guidelines. Lax patentability standards lead to “unnecessary limitations on competition without any significant trade-off in terms of innovation to benefit society’s needs” (Correa, 2006).

Given that the ARIPO Office processes the majority of the patent applications for which patents are granted in the EAC States, for effective implementation of the EAC Policy, it is imperative for ARIPO to adopt rigorous patentability standards, with the aim of avoiding frivolous patents. In particular new uses of known substances including second indications, mere admixtures, new forms of known substances such as salts, esters, ethers, polymorphs, metabolites, isomers, combination and other derivatives of known substance, methods of treatment should be excluded from patentability. In addition, as a general rule selection patents<sup>89</sup> should not be granted if the selected components have already been disclosed and thus lack novelty (Correa, 2006). Claims covering a large range of compounds (“Markush claims”) should also not be allowed and patent coverage should be limited to what is actually enabled by the disclosure in the specification (Correa, 2006).

Specific guidelines should be established for the examination and grant of pharmaceutical patents. Correa contends: “Despite the fact that the TRIPS Agreement bans discrimination between fields of technology (Article 27.1), a justified differentiation is viable. This is particularly so in the area of public health, as indicated by the Doha Declaration on the TRIPS Agreement and Public Health”. Such guidelines should include the specific criteria for the approval of pharmaceutical patent applications. A good example is provided by the guidelines on the patentability of pharmaceutical products and processes adopted by the Argentine government in 2012 to limit the evergreening of pharmaceutical patents<sup>90</sup>.

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applicability if it can be made or utilized in any kind of industry including agriculture.

<sup>88</sup> A Study commissioned by the World Bank and ARIPO found “...ARIPO function as de facto registration agencies for patents filed and granted in the developed countries without recourse to any meticulous examination of such patents with regard to new and second uses of existing pharmaceutical products”(Osewe, 2008).

<sup>89</sup> Selection patent applications are those where certain elements (selected from a larger group of elements previously claimed), are claimed independently based on a particular feature not mentioned in the large group. Such a claim, if granted would extend the term of protection for the selected subset beyond the expiration of the original patent.

<sup>90</sup> Joint Resolution of the Ministry of Industry, Ministry of Health and Instituto Nacional de la Propiedad Industrial 118/2012, 546/2012 and 107/2012. See <http://www.moellerip.com/non-patentable-subject-matter->

According to ARIPO officials, the ARIPO Office is finalizing guidelines for the examination of patent applications<sup>91</sup>. It is important for EAC States and civil society to review (and if necessary, revise) these guidelines to ensure that they are sensitive to public health concerns.

The ARIPO Office should also improve its examination capacity in particular its infrastructure and human resources and should reduce reliance on foreign examination systems.

ARIPO should consider increasing its examination and maintenance fees.<sup>92</sup> Patent fees can be used as an instrument to avoid the proliferation of patents, as lack of examination capacity and low patentability standards encourage secondary patents (Correa, 2014). Adjusting patent fees and in that context setting “a higher price” to “reduce strategic behaviour” and reduce the number of claims was favourably considered by a group of experts convened by the EPO to discuss patent (EPO, 2012). Ecuador is an example of this policy<sup>93</sup> as it recently increased examination and registration fees, as well as maintenance fees for patents drastically elevating the cost of obtaining a patent to more than U\$S 100,000, except for certain categories of applicants (such as small companies and universities) (Correa, 2014). These fees are likely to substantially reduce the number of patent applications, many of which are in any case pharmaceutical applications.

As mentioned above, a patent applicant can bypass the ARIPO route and file an application for a grant in specific countries. These applications though small in number, if wrongly granted could also adversely impact access. Similarly, EAC States should apply rigorous patentability criteria for patent applications processed nationally. Guidelines on how properly to implement patentability criteria should be developed, and if required, changes to national patent legislation should be pursued. EAC States should also undertake rigorous examination of pharmaceutical patent applications. To achieve this, it is critical for public health advocates, NGOs, IGOs to implement activities that boost the capacity of EAC States and their IP officials/examiners to undertake thorough examination of pharmaceutical patent applications, and avoiding frivolous patents as well as to better understand the implications of the grant of monopolies for public health.

#### ***IV.2.3. Administrative Pre and Post Grant Opposition***

The EAC Policy and Health Protocol also require EAC States to provide for “effective pre- and post-grant administrative patent opposition procedures”. The aim being to make it easier for interested third parties to file opposition once a patent application is published and after it is granted. Challenging the validity of a granted patent before courts is costly and time-consuming, and most small and medium enterprises as well as the public would be reluctant to take-on the risk of litigation (Correa, 2006). Consequently wrongly granted patents that unduly block competition and prejudice consumers may remain in force for the full duration of the patent grant (Correa, 2006). To address this problem and enhance the examination of

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according-to-the-new-guidelines-of-the-argentine-pto-2/ and [http://lists.keionline.org/pipermail/ip-health\\_lists.keionline.org/2012-May/002146.html](http://lists.keionline.org/pipermail/ip-health_lists.keionline.org/2012-May/002146.html).

<sup>91</sup> Discussion with ARIPO Officials, 4 June 2014.

<sup>92</sup> Fee Schedule according to Regulations as at 25 November 2013: application fee – USD 250; publication fee - USD 300; annual maintenance fee for the first year is USD 40, which for every subsequent year (until year 15) increases by USD 20 and thereafter increases annually by USD50.

<sup>93</sup> See Resolución No. 001-2013 CD-IEPI, Available from [http://www.propiedadintelectual.gob.ec/wp-content/uploads/2013/08/reformas\\_tasas\\_2013.pdf](http://www.propiedadintelectual.gob.ec/wp-content/uploads/2013/08/reformas_tasas_2013.pdf).

patents, many patent laws provide the possibility to third parties to file observations or opposition to the granting of a patent. These mechanisms also support patent examiners to conduct more rigorous examination of patent applications and are particularly important for poorly staffed patent offices.

Several developing countries have robust administrative opposition systems. In India, the pre-grant opposition systems is actively used by generic producers as well as civil society including patient groups, to oppose pharmaceutical patent applications that do not comply with national law requirements. In 2006 civil society opposed GSK's application for a patent on a critical ARV combination AZT/3TC. This opposition resulted in GSK announcing its withdrawal of all patent applications in all countries specifically related to this combination (MSF, 2013). Successful pre-grant opposition by generic companies of Novartis's patent application on imatinib mesylate, a life-saving medicine used for the treatment of chronic myeloid leukaemia (CML) has ensured that the treatment is available from generic companies at an affordable price range of \$100-\$150 per month, rather from Novartis at \$2,500 per person per month (Gopakumar, 2013). It is worth noting that several of the patents granted by ARIPO [e.g. Abacavir (hemisulfate salt); Darunavir (pseudopolymorphs)], were opposed in India, and subsequently were either rejected by the patent office or the application withdrawn by the right holder. The administrative opposition systems in India plays an invaluable role in ensuring that patents do not hinder local production by generic producers and are able to supply affordable generic medicines throughout the world.

Within the EAC region only national legislations of Uganda and Tanzania-Zanzibar provide for pre- **and** post-grant administrative opposition procedures<sup>94</sup> Burundi only provides for pre-grant administrative opposition procedures<sup>95</sup>. Kenya, Rwanda and Tanzania-Mainland provide for post-grant court procedures.

The Harare Protocol itself does not provide for any pre-grant opposition procedures. When the ARIPO Office notifies the IP office of its decision to grant a patent, according to Rule 18 of the Regulations to the Harare Protocol, the notification together with the search and examination report upon which the decision is based should "be made available to the public in each designated State". However the link to national pre-grant opposition procedures, where such procedures exists, is not explicitly addressed in the Harare Protocol. Pre-grant oppositions procedures in national legislation seem to be applicable with regard patent filings processed nationally (and not applications processed by the ARIPO Office). In any case, the 6-month window given to ARIPO members to object to the patent grant by the ARIPO Office is insufficient for an effective pre-grant opposition system.

The Harare Protocol also does not provide for post grant opposition procedures. Once a patent is granted, its invalidation is a national matter.

Administrative pre- and post-grant opposition procedures are crucial to avoid frivolous patents and to safeguard access to affordable medicines. This is more so in the ARIPO context, whereby due to capacity and resource constraints, the IP offices often do not object to the grant of a patent, even if it is not in line with national legislation or interests. Allowing interested parties to intervene before and after the granting of patents will greatly assist these IP offices and improve the quality of patents granted.

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<sup>94</sup> See Sections 28(7)-(12) and section 32(5) and (6) of the Uganda Industrial Property Act, 2013 & Sections 10(7)(a) and 16 of the Zanzibar Industrial Property Act of 2008.

<sup>95</sup> Article 47 and 48 of Law No. 1/13 Of July 28, 2009 Relating To Industrial Property in Burundi.



To operationalize the flexibility of “effective pre and post grant administrative patent opposition procedures” within the context of the EAC, it is important to amend the Harare Protocol, particularly as the ARIPO Office processes the majority of the applications. Recognizing this the EAC Policy and Protocol does require that “All Partner States, which are Members of ARIPO, shall work towards an amendment of the Harare Protocol so as to allow interested parties, before and after the patent is granted, to file before ARIPO patent office a notice of opposition to the grant of the patent on grounds which the ARIPO Members shall consider appropriate”.

It is important to note that for pre- and post-grant administrative procedures to be workable, effective and to the benefit of public health: (a) any person should be allowed to file opposition either directly with the ARIPO Office as well as through national IP Offices; (b) any person should be allowed to challenge the grant not only in a particular country but its validity for the whole of the ARIPO region; (c) the grounds for opposition should include non-compliance with the patentability requirements, insufficiency of disclosure, and other reasons; (d) there should be clarity on the publication of the application and grant in each designated state; (e) the published patent applications should include all relevant data for the identification of the subject matter of the application, such as the complete specification and international non-propriety name (elaborated below) and that information should be freely accessible online; (f) the procedures for filing the oppositions should be specified clearly and preferably the procedure should be free of any charges; (g) adequate time should be provided for the submission of an opposition. The longer the period, the greater the opportunities for the patent office to receive observations/oppositions from third parties as the importance of the patent application may not be immediately recognized<sup>96</sup> (Correa, 2006); (h) there should be specific time lines and clarity on the procedures for dealing with the filed opposition (e.g. notifying the patentee, constitution of a panel to hear the patentee and the opposing party, appeal procedure etc.) (i) capacity to monitor published patent applications and grants as well as skills necessary to conduct the required analysis to mount the opposition, should be built among local pharmaceutical companies and civil society (Correa, 2006).

Further, EAC States with pre-grant opposition procedures in their national legislations should work to operationalizing such procedures with regard to patent applications processed by the ARIPO Office. In line with Rule 18(4) of the Regulations and Administrative Instruction 52(1) of the Harare Protocol, EAC States should make publicly available ARIPO’s notification of its intent to grant a patent (including the patent application as well as search and examination report upon which the decision to grant is based) and invite any observations or oppositions on the same. (See below Section IV.3.)

Further EAC states that do not provide for pre- and post-grant administrative opposition procedures should amend their legislations to incorporate the same into their national laws.

#### ***IV.2.4. Disclosure Requirements***

According to Article 29 of the TRIPS Agreement “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”. It also leaves open the option for the

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<sup>96</sup> Indian Patent Law: Section 25 (1) allows the filing of a pre-grant opposition anytime between the publication of the application and the granting of a patent. Section 25(2) allows the filing of a post-grant opposition within one year from the publication of the patent grant.

WTO members to require the applicant to fulfil other conditions including 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 and/or to provide information concerning the applicant's corresponding foreign applications and grants.

The EAC Policy and the Health Protocol calls on EAC States to require patent applicants (a) to disclose all modes and expressly indicate the best mode for carrying out an invention by experts skilled in the art, who reside in the respective EAC Partner State; (b) to disclose the International Non-proprietary Name<sup>97</sup> (INN) of a pharmaceutical substance or an active pharmaceutical ingredient as soon as it is available; In addition, the EAC Policy states that patent applicants could be required to provide information concerning their corresponding foreign applications and grants.

According to the EAC Policy, the aim of disclosure requirements is to “promote technological learning and follow-on innovations by local innovators” (EAC, 2013a).

In addition, a patent application does not provide a clear picture of the implications of its grant on access to medicines, and as such the name of the new medical entity, often the INN provides a face to an otherwise abstract patent application (Gopakumar, 2013). Further, requiring patent applicants to provide information on their corresponding foreign applications and grants gives the patent examiner more useful information for purposes of examination on how the application was dealt with in other countries.

The EAC Policy and Protocol does not specifically address disclosure requirements with regard to “Markush claims”. In pharmaceutical patenting, oftentimes, the applicant claims a large number of possible compounds (sometimes thousands or millions) without describing them individually, thus there is inconsistency between the description and claims. Such claims should not be allowed and the coverage of the patent should be limited to what is actually enabled by the disclosure in the specification (Correa, 2006).

**Table 8**

<b>EAC State</b>	<b>Disclosure of invention and best mode</b>	<b>Information on Corresponding Foreign Applications</b>
<b>Burundi</b>	Yes. Section 20(1)	Yes. Section 35.
<b>Kenya</b>	Yes. Section 34.5 and 53.2(a)	Yes. Section 53.2(b)
<b>Rwanda</b>	Yes. Section 25	Yes. Section 31
<b>Tanzania-Mainland</b>	Yes. Section 34.2(i)	Yes. Section 22(1)
<b>Tanzania-Zanzibar</b>	Yes. Section 6.4(a)(b)(d)(e)	Yes. Section 9
<b>Uganda</b>	Yes. Section 21.5(a), 21.6, 21.9, 21.10	Yes. Section 25

EAC States generally do require that the description of the invention be disclosed in a clear manner to allow the invention to be carried out by a skilled person and for the disclosure of the best mode for carrying out the invention. Most EAC States do not require the disclosure

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<sup>97</sup> An International Nonproprietary Name (INN) is an official non-proprietary or generic name given to a pharmaceutical substance, as designated by the World Health Organization (WHO).

of **all** modes for carrying out the invention. In some national legislations (e.g. in Rwanda, Uganda), the skilled person is defined as having average expertise in the technical field of the claimed invention in the national context, and the Registrar may require for the description in foreign patent applications to be adapted to ordinary skills of the citizen of the country. In certain national legislations (e.g. in Kenya) the failure to disclose the best mode is a ground for patent invalidation.

Sufficient disclosure enables the reproduction of the invention during the patent term (e.g. in the case of compulsory license) or after patent expiry (Correa, 2006).

The Harare Protocol and its accompanying Regulations do contain provisions regarding the issue of disclosure of invention, though the extent, to which compliance is enforced, is unclear. Section 2(9)(b) of the Harare Protocol provides: “An ARIPO patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art”. Rule 6.1(d) of the Regulations to the Harare Protocol requires that the description “disclose the invention in such terms that it can be understood”. Rule 6.1(f) requires that the description “set forth at least the best mode contemplated by the applicant for carrying out the invention; this shall be done in terms of examples, where appropriate, and with reference to the drawings, if any”. Rule 15 requires an applicant to comply with Rule 6, and failure to comply may (at the discretion of the ARIPO Office) result in refusal of the application.

EAC States also do require information to be provided on corresponding foreign applications. In most cases the information is only to be provided at the request of the Registrar, though in certain legislations (e.g. Tanzania-Zanzibar), the right holder is under obligation to provide the information. Generally the patent laws require information to be provided on (a) the date and number of any application for a patent or other title of protection filed by the applicant with a national industrial property office of another country or with a regional industrial property office; (b) copies of communication concerning the results of any search or examination carried out in respect of the foreign applications; (c) copy of the patent or other title of protection granted on the foreign application; (d) copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application; (e) copy of any decision revoking or invalidating the patent.

Rule 16 of the Regulations to the Harare Protocol incorporates requirement to provide information on corresponding foreign applications, though the information is to be provided only at the request of the ARIPO Office.

Neither the patent law of the EAC States nor the Harare Protocol requires disclosure of INN.

Based on the analysis, the Harare Protocol and its regulations should be amended to require more detailed disclosure of the invention. “Person skilled in the art” should be defined as a person in the ARIPO region, having average expertise and experience in the technical field of the claimed invention. In addition to setting forth the best mode contemplated by the applicant, the applicant should also be required to disclose all embodiments of the claimed invention in order to prevent the grant of patents on a broad group of molecules for which no testing or other empirical evidence is provided (as it is the case of the so-called “Markush claims”). The Harare Protocol should also require for the description in foreign patent

applications to be adapted to the ordinary skills of the citizen of the country. Insufficient disclosure should result in the application being rejected.

The Harare Protocol and its regulations should be amended to require patent applicant to declare the INN at the time of filing of the application if the INN is already allotted or immediately on allocation. This would lessen the burden of Patent Offices while examining patents. It also helps other actors, including the generic industry, consumer groups, patient groups, the health ministry, to examine the quality of patent applications and invoke the necessary safeguard mechanisms contained in the patent legislation to protect public health (Chaudhuri, 2010). Non-compliance should result in the application being rejected.

The Harare Protocol and its regulations should be amended to mandatorily require the patent applicant to disclose information on corresponding foreign applications.

### **IV.3 Enhancing Transparency in Patent Administration**

An important aspect to improving the patent granting system is to enhance transparency in the administration of patents.

The EPO, for example publishes on its website on a weekly basis a European Patent Bulletin. This bulletin, which is freely accessible, contains a variety of information including on applications published, patents granted, oppositions filed. The EPO website also hosts different search engines and databases that enables any member of the public to freely access complete information about the filed applications and patents granted such as on the description of the invention, patent claims, the search report, opposition to the patent grant.

The Indian Patent Office (IPO) also publishes on its website information about patent applications which are published 18 months after the date of filing or priority date whichever is earlier. Its website also hosts a patent search engine<sup>98</sup> which enables anyone to search for granted patents by selecting the listed search criteria (i.e. title of invention, abstract of text, application number, applicant address, name of grantee, patent number, date of filing nationally, inventor name or address, journal number, date of grant, publication date, IPC, PCT International Application Number). Search for granted patents facilitates access to vital information about the patent granted such as the patent number, date of filing, grant and publication, name of the patentee, abstract text and the entire specification including patent claims.

Similarly the search engine enables access to published application by selecting similar criteria. And a search for published application enables access to basic information about the application such as the application number, date of filing, name of applicant, and the abstract text (brief summary of the application).

Additionally the IPO publishes a weekly journal<sup>99</sup> that is publicly available on its website. The journal contains information about patent applications published upon the expiry of 18 months, patents granted, patents surrendered and restored and other notices issued by the patent office.

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<sup>98</sup> See <http://ipindiaonline.gov.in/patentsearch/search/index.aspx>, accessed 17 July 2014.

<sup>99</sup> See <http://ipindia.nic.in/ipr/patent/patents.htm>, accessed 17 July 2014.

The prompt availability of information in India concerning patent applications and grants has enabled generic producers, patient groups and civil society to mount timely oppositions against the patent grant of life-saving medicines, where the grant would have been inconsistent with the requirements of the Indian patent law. Transparency in patent administration has assisted in improving the quality of patents granted.

In comparison, a search of the ARIPO's website reveals no information about the patent applications and grants it administers. Rule 19*bis* of the Regulations does require publication of an ARIPO patent application on the expiry of 18 months from the date of filing or the date of priority, if priority is claimed. Rule 18(4) of the Regulations states that where the ARIPO Office decides to grant a patent, it shall by notification attaching the search and examination report upon which the decision is based communicate the decision to the applicant, the IP office and it should "be made available to the public in each designated State". Rule 20 of the Regulations requires that on grant, a reference to the grant be published in the ARIPO Journal. Rule 2(4) of the Regulation states that the ARIPO Office shall publish a Journal in which it shall effect all the publications provided for in the Protocol and in the Regulations. Presumably these rules are aimed at making the patent administration process transparent and accessible to the public. However the information mentioned in the Rules including the ARIPO Journal is not accessible on ARIPO's website.<sup>100</sup>

Nationally certain EAC States have taken steps to facilitate public access to certain patent information. For example, the Kenyan Industrial Property Office (KIPI) publishes on its website on a monthly basis an IP journal that is freely accessible<sup>101</sup>. The Journal contains some information (though limited) with regard to PCT National phase, PCT granted patents, ARIPO granted patents, patents withdrawn, patents renewed, change of ownership etc.

Considering that the ARIPO Office administers patents for 18 of its Contracting Parties, it would greatly add to ARIPO's credibility to enhance transparency in its administration of patents. As first steps towards improving transparency, the EAC States should require the ARIPO Office to make freely and publicly available on its website, the patent applications published as per Rule 19*bis*; the notification (including the search and examination report upon which the decision to grant is based) to designated states as per Rule 18(4); complete information including the full specification and claims on patents granted and the ARIPO Journal which contains information on all publications required under the Protocol and the Regulations. ARIPO's website should also host effective search engines and

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<sup>100</sup> In an email communication dated 25 July 2014 (on file with author), the ARIPO Office clarified the following: "the ARIPO Journal is currently not available on the website. It is normally mailed to all ARIPO member states, WIPO and the EPO once published. It is also mailed to patent/trademark agents and institutions that have subscribed. Annual subscription for 12 issues of the Journal is USD200 within Africa and USD220 outside Africa. However, the Journal is expected to be publicly available online in 2015 as a result of an on-going ICT infrastructural development and upgrade project between ARIPO and its development partners (WIPO and the Korean Government)."

The ARIPO Office also clarified that the publication after 18 months is done in the ARIPO Journal, which is available as explained above. "However, it is important to note that 95 per cent of ARIPO applications are PCT applications entering the national phase.....Such applications would already have been published during the international phase and as such are not re-published".

On implementation of Rule 18(4) of the Regulations, the ARIPO Office said that "Availability to the public at the designated state level is dependent on how each designated state avails its information to the public, that is, whether through website, journal or gazette. In a nutshell, the method of making it available to the public is solely decided by the designated state."

<sup>101</sup> See <http://www.kipi.go.ke/index.php/past-ip-journals>, accessed 17 July 2014.

databases that facilitates access to complete information including the description of the invention, full specification, list of claims, with regard to patent applications and grants.

This information, if provided promptly and in sufficient detail has potential to work as an early warning mechanism, alerting the relevant stakeholders (e.g. the EAC Secretariat, civil society, local generic producers) to liaise with national patent offices to object to the grant of an ARIPO patent, where such a patent does not meet national requirements. This information is also essential for the establishment and operation of an effective administrative pre- and post-grant opposition system within ARIPO as discussed above.

EAC States should also establish similar transparency mechanisms at the national level. EAC States should make freely available on their respective websites: complete information about ARIPO applications and grants (such as the application published by ARIPO under Rule 19bis of its Regulations, full specification on patents granted and information contained in the ARIPO Journal) as well as about patent applications processed nationally which are published and granted.

Further, it is important for EAC States to make publicly available ARIPO's notification of its intent to grant a patent (including the patent application as well as search and examination report upon which the decision to grant is based) issued according to Rule 18(4) of the Regulations and Administrative Instruction 52(1) of the Harare Protocol. This information should be made publicly available immediately on receipt of the ARIPO notification, and EAC States should invite the public to submit any observations or oppositions they may have on ARIPO's notification. Such a mechanism will greatly assist EAC States in ensuring that patents are only granted to inventions that meet the national patentability criteria and that are in the national interests.

## **V. CONCLUSION**

The successful use of TRIPS flexibilities by EAC States for the benefit of public health of the EAC region, is much dependent on the workings of ARIPO, given that the ARIPO Office processes the majority of the patent applications. The findings in Chapters III and IV show that the current operations of the ARIPO does not facilitate full use of TRIPS flexibilities and instead erects patent barriers to the importation and local production of affordable medicines. For the effective implementation of the EAC Policy & Protocol as well as the EAC Regional Pharmaceutical Manufacturing Plan of Action (2012-2016), and the multiple other international and regional initiatives that emphasize use of TRIPS flexibilities, effort has to be made by ARIPO Contracting Parties including EAC States to reform the patent operations of ARIPO so that it advances public health objectives. Nationally as well several immediate steps can be taken. **Some recommendations are as follows:**

**At the ARIPO regional level:**

V.1 The Harare Protocol should exempt the territory of LDCs from the grant of any pharmaceutical patents. This means, in the event the ARIPO Office grants pharmaceutical patents, such patents will not be applicable to the LDC territories. LDCs that desire for the ARIPO patent to be applicable to its territory, would need to communicate so to the ARIPO Office within a specific time-frame of receiving notification from ARIPO of its intent to grant the patent.

V.2 ARIPO should adopt rigorous patentability standards with regard to pharmaceutical applications, with the aim of avoiding secondary patents and patent evergreening. Specific rules should be established for the examination and grant of pharmaceutical patents paralleling those adopted by Argentina<sup>102</sup>.

ARIPO Contracting Parties including EAC States, and civil society should review (and if necessary, revise) the new patent examination guidelines being established by the ARIPO Office to ensure that they are sensitive to public health concerns.

V.3 ARIPO Office should also improve its examination capacity in particular its infrastructure and human resources and should reduce reliance on foreign examination systems.

V.4 ARIPO should increase its examination and maintenance fees to avoid proliferation of frivolous patents.

V.5 The Harare Protocol should establish administrative pre- and post-grant opposition procedures, to enable any person to file a notice of opposition before the ARIPO Office.

For effective and workable pre- and post-grant administrative procedures: (a) any person should be allowed to file opposition either directly with the ARIPO Office as well as through national IP Offices; (b) any person should be allowed to challenge the grant not only in a particular country but its validity for the whole of the ARIPO region; (c) the grounds for opposition should include non-compliance with the patentability requirements, insufficiency of disclosure, and other reasons; (d) there should be clarity on the publication of the application and grant in each designated state; (e) the published patent applications should include all relevant data for the identification of the subject matter of the application, such as the complete specification and international non-propriety name (elaborated below) and that information should be freely accessible online; (f) the procedures for filing the oppositions should be specified clearly and preferably the procedure should be free of any charges; (g) adequate time should be provided for the submission of an opposition. The longer the period, the greater the opportunities for the patent office to receive observations/oppositions from third parties as the importance of the patent application may not be immediately recognized<sup>103</sup>; (h)

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<sup>102</sup> Joint Resolution of the Ministry of Industry, Ministry of Health and Instituto Nacional de la Propiedad Industrial 118/2012, 546/2012 y 107/2012. See <http://www.moellerip.com/non-patentable-subject-matter-according-to-the-new-guidelines-of-the-argentine-pto-2/> and [http://lists.keionline.org/pipermail/ip-health\\_lists.keionline.org/2012-May/002146.html](http://lists.keionline.org/pipermail/ip-health_lists.keionline.org/2012-May/002146.html).

<sup>103</sup> Indian Patent Law: Section 25 (1) allows the filing of a pre-grant opposition anytime between the publication of the application and the granting of a patent. Section 25(2) allows the filing of a post-grant opposition within one year from the publication of the patent grant.

there should be specific time lines and clarity on the procedures for dealing with the filed opposition (e.g. notifying the patentee, constitution of a panel to hear the patentee and the opposing party, appeal procedure etc.) (i) capacity to monitor published patent applications and grants as well as skills necessary to conduct the required analysis to mount the opposition, should be built among local pharmaceutical companies and civil society.

- V.6 The Harare Protocol and its regulations should require more detailed disclosure of the invention. “Person skilled in the art” should be defined as a person in the ARIPO region, having average expertise and experience in the technical field of the claimed invention. In addition to setting forth the best mode contemplated by the applicant, the applicant should also be required to disclose **all embodiments of the claimed invention** in order to prevent “Markush Claims”. The Harare Protocol should also require for the description in the patent applications to be adapted to the ordinary skills of the citizen of the country. Insufficient disclosure should result in the application being rejected.
- V.7 The Harare Protocol and its regulations should require patent applicants to declare the INN at the time of filing of the application if the INN is already allotted or immediately on allocation. Non-compliance should result in the application being rejected.
- V.8 The Harare Protocol and its regulations should be amended to mandatorily require the patent applicant to disclose information on corresponding foreign applications and to supplement the same on a timely basis.
- V.9 The ARIPO Office should make freely and publicly available on its website, patent applications published as per Rule 19*bis*; the notification (including the search and examination report upon which the decision to grant is based) to designated states as per Rule 18(4); complete information including the full specification and claims on patents granted, and the ARIPO Journal which contains information on all publications required under the Protocol and the Regulations.
- V.10 ARIPO’s website should also host effective search engines and databases that facilitates access to complete information including the description of the invention, full specification, list of claims, about the patent applications and grants.

#### **At the National level:**

- V.11 EAC States should take steps to incorporate the policy approaches prescribed by the EAC Policy and Protocol.
- V.12 Pending revision as suggested in V.1, EAC LDC States should take urgent action to declare that pharmaceutical patents in its territory are not enforceable.<sup>104</sup>

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<sup>104</sup> Paragraph 7 of the Doha Declaration on TRIPS & Public Health: “We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement *or to enforce rights* provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement.”



Intellectual property offices in LDCs should also adopt an institutional policy that on receipt of a notification from the ARIPO Office of its intent to grant a pharmaceutical patent, the IP Office will immediately communicate a written objection to the ARIPO Office.

- V.13 EAC States should apply rigorous patentability criteria for pharmaceutical patent applications processed nationally. Specific guidelines on how properly to implement patentability criteria with regard to pharmaceuticals should be developed, and if required, changes to national patent legislation should be pursued. EAC States should also undertake rigorous examination of pharmaceutical patent applications.
  
- V.14 Civil society, intergovernmental organizations such as the South Centre and other public health advocates should implement activities that boost the capacity of EAC States and their IP officials/examiners to undertake rigorous examination of pharmaceutical patent applications, and avoid secondary patents and patent evergreening as well as to better understand the implications of the grant of monopolies for public health.
  
- V.15 EAC States with pre-grant opposition procedures in their national legislations should work to operationalizing such procedures with regard to patent applications processed by the ARIPO Office. See below V.17.
  
- V.16 EAC States should also establish transparency mechanisms at the national level. EAC States should make freely available on their respective websites: complete information about ARIPO applications and grants (such as the application published by ARIPO under Rule 19bis of its Regulations, full specification of patents granted, and information contained in the ARIPO Journal) as well as about patent applications processed nationally which are published and granted.
  
- V.17 Further, it is important for EAC States to make publicly available ARIPO's notification of its intent to grant a patent (including the patent application as well as search and examination report upon which the decision to grant is based) issued according to Rule 18(4) of the Regulations and Administrative Instruction 52(1) of the Harare Protocol. This information should be made publicly available immediately on receipt of the ARIPO notification, and EAC States should invite the public to submit any observations or oppositions they may have on ARIPO's notification.
  
- V.18 Civil society should pursue implementation of the above recommendations. They should also begin to actively monitor pharmaceutical applications processed by ARIPO as well as national IP offices and take appropriate action where the grant would be inconsistent with national interests.

## ANNEX

### **Summary of Guidance on TRIPS Flexibilities Contained in the EAC Regional Intellectual Property Policy and EAC Health Protocol**













1. **Transition Periods:** EAC Partner States that are LDCs shall exclude from patent protection pharmaceutical products and processes until January 1, 2016 or until the expiry of such later period of extension agreed upon by the WTO Council for TRIPS. EAC Partner States shall abolish any 'mailbox' provision in their national patent laws.
2. **Administrative opposition:** EAC Partner State shall, before and after a patent is granted, provide for the possibility for interested parties to file before its national patent office a notice of opposition to the grant of the patent on grounds, which the Partner State shall consider appropriate. The EAC Partner States, which are also Members of ARIPO, shall work towards an amendment of the Harare Protocol to allow filing of pre and post grant opposition before the ARIPO office.
3. **Exclusions from patentability:** EAC Partner States shall in addition to subject matter already excluded, exclude from patentability:
  - (a) natural substances including naturally occurring micro-organisms, even if purified or otherwise isolated from nature; this shall not preclude the patentability of a process used for the isolation of those natural substances from their original environment;
  - (b) new medical uses of known substances including naturally occurring micro-organisms; it being understood that Partner States seeking to consider new medical uses principally patentable as processes shall strictly apply the patentability requirements on a case-by-case basis;
  - (c) derivatives of known medical substances, unless they show a significantly enhanced therapeutic efficacy or other significant superior properties. For this purpose, Partner States shall determine that structural similarities between the original product and its derivative establish a presumption of lack of novelty. This presumption may be reversed if the patent applicant can demonstrate the derivative's significantly enhanced therapeutic efficacy or other significant superior properties.
4. **Patentability Criteria:** EAC Partner States (a) shall provide for and apply a strict novelty requirement through considering a wide concept of prior art, including everything disclosed to the public whether by use, in written or oral form, including patent applications, information implied in any publication or derivable from a combination of publications, which are published anywhere in the world and which can be accessed by the general public; (b) shall provide that the non-obviousness of an invention shall be determined on the basis of a person who is highly skilled in the art; (c) shall strictly apply the industrial application requirement and limit the patentability of research tools to only those for which a specific use was identified.
5. **Disclosure:** All EAC Partner States shall require patent applicants to disclose all modes and expressly indicate the best mode for carrying out an invention by experts skilled in the art, who reside in the respective EAC Partner State. Additionally patent applicants could be required to provide information concerning their corresponding foreign applications and grants and international non-proprietary names of pharmaceutical substances or active pharmaceutical ingredients as soon as they are available.

6. **Research exception:** EAC States shall determine in their respective national laws that patent rights shall not extend, inter alia, to acts done relating to uses on the patented invention for technological or scientific research whether or not intended for commercial purposes.
7. **Marketing approval/“Bolar” exception:** EAC States shall provide that it is not an infringement of a patent for any person to make, use, construct, sell or offer to sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of the particular Partner State or any other country that regulates the manufacture, construction, use or sale of any product.
8. **International exhaustion:** EAC States shall provide for international exhaustion of patent rights, trademarks and copyrights in all fields of technology.
9. **Compulsory Licensing, including government use:** EAC States shall be free to determine in their IP laws the grounds upon which the competent authorities may issue compulsory licenses including government use. [The EAC Policy and Protocol also addresses in detail the grounds and modalities for issuing compulsory licenses.]
10. **Control of licensing practices and conditions:** EAC States shall adopt appropriate measures to control certain licensing practices and conditions pertaining to intellectual property rights which restrain competition and may have adverse effects on trade and may impede the transfer and dissemination of technology. Appropriate measures may be the refusal of registration of licensing contracts, which contain such licensing practices and conditions.
11. **Protection of undisclosed data:** Partner States (LDC Partner States only upon the lapse of the transition period for LDCs) shall provide for the protection of undisclosed test or other data for new chemical entities, whose origination involves a considerable effort, only against unfair commercial use and disclosure. This shall not prevent the regulatory authorities from relying on originally submitted data to assess the safety and efficacy of data submitted subsequently by a party other than the data originator and relating to similar products in terms of bioequivalence. No Partner State shall take into account, when granting marketing approval by its regulatory authority, the existence or the validity of any intellectual property right in the product in question.
12. **Compensatory liability:** Any Partner State, if it is in its national interests may provide for the protection of small-scale inventions and traditional medicines under a system which entitles the inventor to reasonable compensation for a reasonable period of time, if third parties use the protected invention for follow-on improvements; and the right to use, for a reasonable period of time, the improved invention of the third party.
13. **Paragraph 6 Decision:** EAC States shall take advantage of paragraph 6 of the Paragraph 6 Decision<sup>105</sup> which facilitates the implementation of this Decision for members of a regional free trade agreement, which is composed, of at least 50 per cent LDC members, which share the same health problem, in question.

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<sup>105</sup> WTO's General Council Decision of 30<sup>th</sup> August 2003 (WT/L/540)








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# **SOUTH CENTRE**

**Chemin du Champ d'Anier 17  
PO Box 228, 1211 Geneva 19  
Switzerland**

**Telephone: (41 22) 791 8050  
Fax: (41 22) 798 8531  
Email: [south@southcentre.int](mailto:south@southcentre.int)**

**Website:  
<http://www.southcentre.int>**

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