

East African Community

Regional Intellectual Property Policy on the  
Utilisation of Public Health-Related WTO-TRIPS  
Flexibilities and the Approximation of National  
Intellectual Property Legislation







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**EAC Regional Intellectual Property Policy on the Utilisation  
of Public Health-Related WTO-TRIPS Flexibilities and the  
Approximation of National Intellectual Property Legislation**

**February 2013**

## Objective

The overall objective of this Policy is to guide the EAC Partner States on how their national intellectual property legislation must be adjusted in order to enable them to fully utilise the Public Health-related WTO-TRIPS Flexibilities. It provides a comprehensive 'road map' of how the latter can facilitate optimisation of the populations' access to health and other health-related products. It further identifies the lowest common denominator of intellectual property legislation that can be approximated across all the EAC Partner States.

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Ambassador Dr. Richard Sezibera

## Foreword

The Public Health-related flexibilities afforded by the World Trade Organisation Trade Related Aspects of Intellectual Property Rights (WTO-TRIPS) Agreement can only be utilised if they are explicitly integrated into a country's domestic legislation. As such, a first and necessary step in any attempt to utilise the flexibilities for public health purposes in the region is for Partner States to enact legislations that allow them full flexibility. It is in this regard that the EAC Secretariat, in collaboration with the Partner States, launched an initiative to harmonise policies, legislation and regulations on Intellectual Property with the aim of maximising the benefits of Public Health-related WTO-TRIPS Flexibilities in 2005.

I am therefore pleased to note that the **EAC regional intellectual property policy on the utilisation of Public Health-related WTO-TRIPS Flexibilities and the approximation of national intellectual property legislation** represents the outcome of this initiative which started seven years ago. The policy focuses on supporting the full use of specific TRIPS Flexibilities for optimising access to health products and medical devices in the East African Community Partner States.

The overall objective of this Policy is to guide the EAC Partner States on how their national intellectual property legislation must be adjusted in order to enable them to fully utilise the Public Health-related WTO-TRIPS Flexibilities. It provides a comprehensive 'road map' of how the latter can facilitate optimisation of the populations' access to health and other health-related products. It further identifies the lowest com-

mon denominator of intellectual property legislation that can be approximated across all the EAC Partner States.

The implementation of this policy in the Partner States is expected to: optimise the populations' access to health products and medical devices; broaden the public domain in order to ensure that Intellectual Property (IP) embedded products and services concerning health are available and accessible at an affordable cost to the whole EAC Partner States' population; promote pharmaceutical manufacturing and innovation industries; improve cooperation amongst themselves in the regional market, particularly with regard to pharmaceuticals, for their mutual benefit; and last but not least, contribute to the overall achievement of the region's public health objectives.

In view of the importance of access to affordable quality medicines with regard to the improvement of the health and overall well-being of the people of East Africa, I wish to call upon the EAC Partner States to take appropriate measures as outlined in the policy in order to utilise the Public Health-related WTO-TRIPS Flexibilities to the fullest extent.

**Dr Richard Sezibera**  
Ambassador  
Secretary General  
East African Community



**Deputy Secretary General Jesca Eriyo**

## **Acknowledgement**

The development of the EAC regional intellectual property policy on the utilisation of Public Health-related WTO-TRIPS Flexibilities and the approximation of national intellectual property legislation is the result of a concerted effort by various national, regional and international multisectoral stakeholders. In this regard, the EAC Secretariat wishes to acknowledge the contributions of the EAC Technical Expert Committee on TRIPS and Access to Medicines (TECTAM) who initiated and expertly steered the development of the policy.

Furthermore, the Secretariat wishes to acknowledge the participation, dedication and commitment of the Partner States in the development of this policy. Key national stakeholders were drawn from the National Intellectual Property offices, state law offices, academia, National Medicines Regulatory Authorities (NMRAs), National Ministries of Health, National Ministries of Trade and Industry, National Ministries responsible for East African Community Affairs, parliamentarians from the East African Legislative Assembly (EALA) and the EAC Partner States' National Parliamentary Departmental Committees on Health under the auspices of the EAC Regional Inter-Parliamentary Forum on Health, Population and Development (EAC-RPF-HPD) and also Pharmaceutical Manufacturers' Associations.

The invaluable technical and financial support provided by the Federal Republic of Germany through the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH programme of 'support to the EAC integration process' and coordinated by the EAC-GIZ TRIPS and Pharmaceutical Sector Promotion Project is acknowledged and appreciated. Last but not least, the EAC Secretariat recognises the tireless efforts of the EAC Health Department staff during their successful stewardship of the policy development.

We urge the Partner States to introduce the necessary legal and policy measures highlighted in this policy to facilitate promotion of access to quality medicines.

**Jesca Eriyo**  
Deputy Secretary General  
(Productive and Social Sectors)  
East African Community

## List of Abbreviations

<b>API</b>	Active Pharmaceutical Ingredient
<b>ARIPO</b>	African Regional Intellectual Property Organisation
<b>Art</b>	Article
<b>CET</b>	Common External Tariff
<b>COMESA</b>	Common Market for Eastern and Southern Africa
<b>DRA</b>	Drug Regulatory Authority
<b>EAC</b>	East African Community
<b>EPC</b>	European Patent Convention
<b>EPO</b>	European Patent Office
<b>GIZ</b>	Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH (German Agency for Technical Cooperation)
<b>IP</b>	Intellectual Property
<b>IPR</b>	Intellectual Property Right
<b>LDC</b>	Least-Developed Country
<b>MRA</b>	Medicines Regulatory Authority
<b>NCM</b>	National Consultative Meeting
<b>PCT</b>	Patent Cooperation Treaty
<b>R&amp;D</b>	Research and Development
<b>Sec</b>	Section
<b>TECTAM</b>	Technical Committee on EAC Cooperation on TRIPS and Access to Medicines
<b>TORs</b>	Terms of Reference
<b>TRIPS</b>	Agreement on Trade-Related Aspects of Intellectual Property Rights
<b>UNCTAD</b>	United Nations Conference on Trade and Development
<b>UNDP</b>	United Nations Development Programme
<b>USPTO</b>	United States Patent and Trademark Office
<b>WHO</b>	World Health Organisation
<b>WIPO</b>	World Intellectual Property Organisation
<b>WTO</b>	World Trade Organisation



## 1.0 Introduction and Situational Analysis

Despite Intellectual Property (IP) being a powerful development tool, its usefulness has been the preserve of developed countries and has not been fully utilised for the greatest benefit of developing countries - including Least Developed Countries (LDCs). As a result, in recent years the latter have called for a more careful analysis of IP regimes and emphasised the need for policy space to serve their national development goals. The clear underlying philosophy is 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. Consequently, the minimum IP protection standards required under the international IP regime shall be adapted to the needs of developing countries and LDCs, facilitating the transfer of technology and access to knowledge and information, which is crucial to stimulating innovation and creativity, and addressing public health problems.

This call has been successfully answered in several international multilateral fora including the WTO, and in particular the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement), the Doha Declaration on the TRIPS Agreement and Public Health and various WTO decisions (the WTO Instruments). These 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, which include HIV/AIDS, malaria, tuberculosis and various neglected tropical diseases. These flexibilities have been emphasised under other important international arrangements, thoroughly negotiated and agreed upon, especially the WIPO Development Agenda of 2007 and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property of 2008. The EAC and Partner States have been champions of this cause. As the only developing country amongst the EAC Partner States, Kenya is the only Part-

ner State unable to exploit the TRIPS Flexibilities to the same extent as LDC Partner States. This however should not in any way impede LDC Partner States from making full use of the TRIPS Flexibilities.

There have been various initiatives, at both national and regional levels, launched by the Partner States and the EAC Secretariat aimed at maximising the benefits of the TRIPS Flexibilities. In 2005, the EAC launched an initiative to harmonise its Partner States' policies, legislation and regulations on IP for the facilitation of regional manufacturing, importation and/or trade in essential medicines. In this meeting a Technical Committee on TRIPS and Access to Medicines (TECTAM) was formed to oversee the implementation of this initiative. Following up on this initiative, the EAC considered it crucial to develop this policy and a related protocol. In June 2009, the EAC Secretariat initiated the development of this policy under the coordination of the EAC/GIZ TRIPS and Pharmaceutical Sector Promotion Project and in close collaboration with TECTAM, the EAC Technical Working Group on Medicines and Food Safety (TWGMFS), the EAC Ministries in the Partner States, the EAC Sectoral Committee on Health and a wide spectrum of relevant stakeholders from the public and private sectors as well as from civil society in the East African Community. All activities connected to this policy were commissioned by the EAC Sectoral Council on Regional Cooperation on Health.

This policy is based on the analysis of the EAC Partner States' national legislation as listed in the table below, while a comprehensive analysis of the EAC Partner States' National IP Legislation, especially with regard to WTO-TRIPS and TRIPS Flexibilities, is provided in Annex 2 of this policy.

## List of relevant Partner States' national legislations

	Burundi	Kenya	Rwanda	Tanzania-Mainland	Tanzania-Zanzibar	Uganda
<b>Patents</b>	Intellectual Property Law No. 1/13 of 2009 (Loi No. 1/13 du 28 Juillet 2009 Relative à la Propriété Industrielle au Burundi)	The Industrial Property Act, 2001	Law on the Protection of Intellectual Property (2009)	Patents Act of 1987 (law is currently being amended)	Zanzibar Industrial Property Act No. 4 of 2008	The Industrial Property Bill No. 5 of 2009
<b>Clinical test data protection</b>	Intellectual Property Law No. 1/13 of 2009 (Loi No. 1/13 du 28 Juillet 2009 Relative à la Propriété Industrielle au Burundi)	Pharmacy and Poisons (Registration of Drugs) Rules	Presidential Order – Determining Modalities for Medicines Registration	The Tanzania Food, Drugs, and Cosmetics Act, 2003 and Regulations Guidelines on submission of documentation for registration of human medicinal products, 2008	Zanzibar Industrial Property Act No. 4 of 2008 and Zanzibar Food, Drugs and Cosmetic Act No. 2 of 2006	Trade Secret Protection Act, 2009; Guidelines on Registration of Pharmaceutical Drugs for Human Use in Uganda National Drug Policy and Authority Act 1993
<b>Trademarks</b>	Intellectual Property Law No. 1/13 of 2009 (Loi No. 1/13 du 28 Juillet 2009 Relative à la Propriété Industrielle au Burundi)	The Trade Marks Act, Chapter 506 (as last amended by the Trade Marks [Amendment] Act, 2002)	Law on the Protection of Intellectual Property (2009)	Act on the Control of the Use of Marks and Trade Description, 1963; Merchandise Marks Act, 1963; Trade and Services Marks Act, 1986	Zanzibar Industrial Property Act No. 4 of 2008	The Trademarks Bill, 2008; The Trademarks Act, 2010
<b>Utility models</b>	Intellectual Property Law No. 1/13 of 2009 (Loi No. 1/13 du 28 Juillet 2009 Relative à la Propriété Industrielle au Burundi)	The Industrial Property Act, 2001	Law on the Protection of Intellectual Property (2009)	Patents Act of 1987 (law is currently being amended)	Zanzibar Industrial Property Act No. 4 of 2008	The Industrial Property Bill No. 5 of 2009
<b>Copyrights</b>	Copyright Law No. 1/021 of 2005 (Loi No. 1/021 du 30 Décembre 2005 Portant Protection du Droit D'Auteur et des Droits Voisins au Burundi)	The Copyright Act, 2001	Law on the Protection of Intellectual Property (2009)	The Copyright and Neighbouring Rights Act, 1999	Zanzibar Copyright Act No. 14, 2003 and Regulations	Copyright and Neighbouring Rights Act, 2006
<b>Anti-counterfeits</b>	-	The Anti-Counterfeits Act, 2008	-	-	-	Draft Anti-Counterfeiting Bill, 2009

## 2.0 Rationale, Purpose, Objectives and Expected Outcome of the Policy

### 2.1 Rationale

One shared philosophy across the EAC Partner States is the need to promote a people-centred mutual development and to improve the quality of life of the population. 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 Treaty, which governs aspects of health, advocates improving access to medicines in order to prevent and control diseases, pandemics and epidemics as well as facilitating mass immunisation, achieving quality health within the Community, and developing specialised pharmaceutical products.

In light of this, the EAC Sectoral Council on Regional Cooperation on Health has directed the EAC Secretariat to develop an EAC TRIPS Policy and an EAC TRIPS Protocol. The Policy focuses on the full use of specific TRIPS Flexibilities for optimising access to health products and medical devices in the East African Community (EAC).

### 2.2. Purpose

The EAC Partner States and the EAC Secretariat, in line with their respective public policies and priorities, are committed to utilising the Public Health-related flexibilities contained in the TRIPS Agreement and its related instruments in order to help address public health problems afflicting their populations.

### 2.3. Objectives

The overall objective of this 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 utilise the Public Health-related WTO-TRIPS Flexibilities. It provides a comprehensive 'road map' on how the latter shall facilitate optimising the populations' access to health and health-related products. It further identifies the lowest common denominator of intellectual property legislation that can be approximated across all the EAC Partner States. Specific objectives derived from the main objectives are stated in each policy subsection.

### 2.4. Expected Outcomes

It is expected that this policy will enable EAC Partner States to:

- I. optimise the populations' access to health products and medical devices;
- II. 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;
- III. achieve public health objectives;
- IV. promote pharmaceutical manufacturing and innovation industries; and
- V. improve mutual cooperation in their regional markets for their mutual benefit.

## 3.0 Policy Statements on Amendments of National Legislation

The following section outlines the EAC policy on the required amendments of the EAC Partner States' national legislation. It highlights issues, objectives and policy statements with reference to the EAC Regional Protocol on Health-Related WTO-TRIPS Flexibilities (hereinafter EAC TRIPS Protocol).

### 3.1. Transition Periods

#### *Issues*

The TRIPS Agreement requires WTO Member States to provide patent protection for a minimum term of 20 years from the filing date of a patent application for any invention, including pharmaceutical products or processes. Additionally, Article 70: 8 of the TRIPS Agreement requires the implementation of a 'mailbox' obligation for any Member that 'does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products [...]'.  
At the same time, the TRIPS Agreement and re-

lated instruments exempt LDCs from the obligation to either implement, apply, or enforce patents on pharmaceutical products and processes, as well as clinical test data protection until 1 January 2016 (or later if extended by the TRIPS Council). This therefore means that those LDCs – such as the EAC LDC Partner States - that did make available patent protection for pharmaceutical products on 1 January 1995, and only later chose to suspend it – are not obliged to make a 'mailbox' provision. In view of the above, all EAC LDC Partner States with a 'mailbox' provision in their national (draft) patent laws can abolish this provision. Additionally, EAC Partner States' patent laws can provide for a possible extension of the transition period, as may be agreed upon by the Council for TRIPS.

#### *Objective*

To protect generic pharmaceutical producers who have, during the transition period, used products that may enjoy patent protection after 2016, and mitigate the adverse effects of such a 'mailbox' rule on generic production.

### Policy Statement No. 1 (Ref: Sections 2 and 11 of Annex 1)

- a. All EAC Partner States that are LDCs are to take advantage of the 2016 transition period and provide in their national patent laws for an extension of this period as may be agreed upon by the Council for TRIPS.
- b. All EAC Partner States are to abolish any 'mailbox' provision in their existing or draft national patent laws.

### 3.2. Patentability Criteria

#### *Issues*

Article 27 of the TRIPS Agreement stipulates that, subject to the exceptions provided for in the Agreement, patents shall be made available to all inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application. This requires WTO Member States to grant patent protection if an invention meets the three patentability criteria: Novelty, Inventive Step and Industrial Applicability. However, the TRIPS Agreement does not provide definitions for these three criteria. As such, Members have the flexibility to define these three patentability criteria in their national patent legislations.

Applying a strict application of the three patentability criteria in their patent laws and patent examination guidelines enables EAC Partner States to maintain a broad policy domain in order to benefit public health purposes.

EAC Partner States can choose to assess 'novelty' using **wide prior art definitions** 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.

Further, EAC Partner States can require as ‘inventive step’, that the invention has to be non-obvious to a **person ‘highly’ skilled** in the art. The more expertise taken into account when assessing the non-obviousness of an invention, the more likely it is that that invention is deemed obvious.

Finally, a strict standard for ‘industrial application’ can be inspired by USPTO Guidelines or

EPO jurisprudence. The USPTO Guidelines for the patentability of **research tools** require that their **specific use** be identified. Patent applications for research tools that may be used for a variety of different uses may be rejected under such strict industrial application tests.

### *Objective*

To ensure that EAC Partner States have enough policy space for public health purposes.

## Policy Statement No. 2 (Ref: Section 4 of Annex 1)

EAC Partner States are to strictly define in the patent laws and/or patent examination guidelines the patentability criteria, and apply them strictly, in order to keep a broad public domain. In particular, they shall:

- a. Strictly apply the novelty standard through considering a wide concept of prior art 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;
- b. Clearly define the inventive step standard by referring to a ‘highly’ skilled person;
- c. Strictly apply the industrial application requirement and limit the patentability of research tools to only those for which a specific use has been identified.

### 3.3. Materials Excluded from Patentability

#### *Issues*

Article 27: 3 of the TRIPS Agreement provides that Member States may exclude from patentability:

- Diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- Plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this sub-paragraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Furthermore, given that the TRIPS Agreement does not define the term ‘invention’, Member States have the added flexibility of defining the term in their national patent laws. Member States can therefore exclude from that definition natural substances, new uses and product derivatives.

#### • **Natural Substances**

As EAC Partner States seek to strengthen local generic producers’ capabilities through reverse engineering of that medicines that are based on natural substances including naturally found micro-organisms, they can exclude the same from patentability. Domestic patent laws could explicitly state that natural substances are **not inventions** due to lack of a technical contribution to the art. The law itself or examination guidelines could also clarify that natural substances are excluded from patentability even if they were **isolated** or **purified**. This would not prevent inventors from applying for patents on the **processes** used for isolating a natural substance or the methods of using a natural product or where the **substance itself** was **changed** by means of genetic engineering.

#### • **New Medical Uses**

As EAC Partner States seek to prevent the so-called ‘ever-greening’ of patents, i.e. where new patents are granted for the discovery of a new (first, second or subsequent)

use of a patented substance, they can **explicitly exclude patents on new medical uses of known substances** including micro-organisms in their patent legislation and in patent examination guidelines. EAC Partner States seeking to consider new medical uses, principally patentable as processes under the patentability criteria, can strictly apply the patentability requirements on a case-by-case basis.

- **Derivatives of Medical Products**

In order to prevent slight and insignificant variations of originally patented pharmaceutical substances from restricting the public domain, EAC Partner States can require for their patentability that they show **significantly enhanced therapeutic efficacy** (Indian approach) **or unexpected properties** (US approach). EAC Partner States can make the provision in their domestic laws that structural similarities between an originally patented substance and a new pharmaceutical substance create a presumption of lack of invention, novelty or inventive step. The **burden of proving** the significantly superior properties of the variation would then lie on the patent applicant.

In addition to excluding the above-mentioned from the definition of the term 'invention', EAC Partner States can also provide for the **protection of small-scale inventions and traditional medicines**, so as to accommodate the interests

of domestic inventors. EAC Partner States can reward small-scale innovations through alternative protection systems, such as utility models. Whereas such exclusive rights can generally be useful tools for the promotion of local development, their blocking effects may harm the area of medical innovations and reduce access to such products and treatments. In areas where access is the predominant interest, EAC Partner States can therefore opt for **use-and-pay** or **compensatory liability** regimes. Such regimes will reward small-scale inventors without blocking access. Third parties would be authorised, for a certain period of time, subsequent to a brief period of market exclusivity for the first incremental inventor, to use the protected invention for follow-on improvements (but not for wholesale imitations) as long as they compensated the inventor. EAC Partner States can seek the 'positive' protection of traditional medicines and also follow the use-and-pay approach, provided that such a regime does not contradict their communities' practices and values. Another possible way of protecting traditional medicines is through a legal framework that aims at preventing the misappropriation of such knowledge.

### *Objective*

To maintain a broad public domain for the promotion of access to affordable health products through both importation and local pharmaceutical production of high quality generic medicines.

## Policy Statement No. 3 (Ref: Sections 3 and 12 of Annex 1)

a. EAC Partner States are to exclude from patentability:

- i. Natural substances including micro-organisms, even if purified or otherwise isolated from nature;
- ii. New medical uses of known substances including micro-organisms; EAC Partner States seeking to consider new medical uses principally patentable as processes under the patentability criteria, shall strictly apply the patentability requirements on a case-by-case basis;
- iii. Derivatives of medical products that do not show significantly enhanced therapeutic efficacy/significant superior properties.

b. EAC Partner States, in order to protect small-scale innovations, e.g. in the areas of traditional medicines or genetic resources, shall reward such inventors with a right to compensation from third parties who use the inventions for follow-on improvements (use-and-pay/compensatory liability).



### 3.4. Research Exception

#### *Issues*

Article 30 of the TRIPS Agreement establishes the general basis for exceptions to the exclusive rights envisaged under the Agreement, 'provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.'

In light of the fact that a strong research base is fundamental to the competitiveness of the EAC region vis-à-vis other markets and for the promotion of social welfare in the region, it is important that the right balance is struck between the system of patent rights and the opportunity to conduct research.

A clear research exception permitting the use of patented inventions for research purposes can help to strike that balance. EAC Partner States

can provide for a **research exception** authorising local scientists and researchers to use patented substances for both **scientific** and **commercial research** 'on' a patented substance in order to gain new knowledge about the substance itself. However, the predominant purpose of the commercial research must be the improvement of the patented substances, as opposed to mere reverse engineering and copying of the patented invention. For the use of patented research tools (research 'with' a patented substance), the laws can provide researchers with a right to claim a non-exclusive licence for the use of such research tools against payment of reasonable compensation.

#### *Objective*

To promote scientific and technological progress.

#### **Policy Statement No. 4** (Ref: Section 7 of the EAC TRIPS Protocol)

In order to increase legal certainty with regard to the scope of research exception, EAC Partner States shall amend their patent provisions on research exceptions as follows:

- a. Explicitly authorise research for scientific, non-commercial and commercial purposes. The preponderant purpose of commercial research must be the generation of new knowledge of the patented substance.
- b. Provide a right to claim a non-exclusive licence for the use of patented research tools against payment of compensation.

### 3.5. Marketing Approval – 'Bolar' Exception

#### *Issues*

Another flexibility that can be justified under the TRIPS Article 30 exception provision is the marketing approval or 'Bolar' exception. This mechanism would authorise research activities 'reasonably related' to marketing approval requests, i.e. clinical trials and other preparatory activities on or with a patented pharmaceutical product, prior to the expiry of the patent term. A 'Bolar' exception would enable generic competitors to file applications for domestic and foreign marketing approvals of competing products even before a patent has expired so that the generic products may enter the market immediately after the lapse of the patent term.

#### *Objective*

To ensure early market entry of generic pharmaceutical products.

## Policy Statement No. 5 (Ref: Section 6 of Annex 1)

In order to allow early market entry for generic producers, EAC Partner States shall amend their national patent law provisions on marketing approval/‘Bolar’ exception to:

- a. Authorise the use of patented substances by interested parties for marketing approvals by national and foreign medicines regulatory authorities;
- b. Clarify the scope of the marketing approval/‘Bolar’ exception to the effect that generic producers may use patented substances for acts ‘reasonably related’ to the development and submission of information required for marketing approvals.

### 3.6. Test Data Protection

#### *Issues*

As a requirement for obtaining marketing authorisation, pharmaceutical producers must provide Medicines Regulatory Authorities (MRAs) with information regarding safety, effectiveness and quality that is generated in the preclinical and clinical testing of a medicine. Article 39: 3 of the TRIPS Agreement stipulates that WTO Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilise new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use [...]. The provision only requires protection of undisclosed test data originated from new chemical entities which require considerable effort to generate.

Accordingly, EAC Partner States (LDC Partner States only upon the lapse of the 2016 (or future) transition period for LDCs) can implement a regime of test data protection which allows MRAs to **rely** on the originators’ test data for the approval of generic medicines. Such reliance would be permitted under a **misappropriation** approach, which protects test data only against unfair commercial

use. A compensatory liability approach would also authorise MRAs to rely on originator test data provided. However, the generic competitor, in exchange, would have to pay compensation to the data originator, and this might exceed the local generic producers’ financial capabilities.

In case EAC Partner States become obliged, under constraint of a free trade agreement or in response to overwhelming bargaining power, to adopt a regime of data exclusivity prohibiting reliance, they can mitigate the potentially harmful effects of such a system on local generic producers and medicine availability. In particular, they can authorise MRAs to approve generic medicines for marketing on the basis of the originator data in cases where national health concerns prevail, e.g. in cases of compulsory licensing.

It is equally important that EAC Partner States do not expect MRAs to enforce patent rights by denying marketing authorisation for generic producers before the patent term has lapsed (**patent linkage**).

#### *Objective*

To avoid unnecessary costly and lengthy clinical trials of generic pharmaceutical products.

## Policy Statement No. 6 (Ref: Section 10 of Annex 1)

- a. EAC Partner States (LDC Partner States only upon the lapse of the 2016 (or future) transition period for LDCs) should adopt a system to protect test and other data against unfair commercial use and disclosure, while leaving the local MRAs free to rely on the results of original test data from domestic or foreign approvals when assessing the safety and efficacy of generic competing products (misappropriation approach).
- b. None of the EAC Partner States may establish a linkage between patent protection and marketing authorisation, which would prevent MRAs from granting marketing approval for generic medicines before the lapse of the respective patent.



### 3.7. Disclosure Requirements

#### *Issues*

A sufficiently clear disclosure obligation for patented inventions can help ensure the effective operation of the patent system. To be effective, disclosures of patented inventions need to be: sufficient, complete, thorough and precise in order to enable those skilled in the art to practise the invention based on the information disclosed; sufficiently definite to give the public notice of what constitutes an infringement; identify the best mode of practising the invention known to the inventor when they file a patent application.

EAC Partner States can require patent applicants to **disclose all modes and expressly indicate the best mode** for carrying out an inven-

tion by experts skilled in the art, who reside in the respective EAC Partner State. Additionally, as important guidance for EAC Partner States' patent examiners, patent applicants could be required to provide information concerning their **corresponding foreign applications and grants**. Finally, patent applicants can be obliged to disclose the International Non-proprietary Name (INN) of a pharmaceutical substance or an active pharmaceutical ingredient as soon as the INN is available.

#### *Objective*

To promote technological learning and follow-on innovations by local innovators.

#### Policy Statement No. 7 (Ref: Section 5 of Annex 1)

EAC Partner States shall 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 (INN) of a pharmaceutical substance or an active pharmaceutical ingredient as soon as it is available.

### 3.8. Administrative Opposition Procedures

#### *Issues*

Expanding patent rights into new areas of technology raises the concern that patent examiners unfamiliar with prior art may lack the expertise to assess the novelty or non-obviousness of an invention. National patent laws can therefore provide mechanisms to challenge and revoke the validity of a patent where closer scrutiny reveals that the patentability criteria may not be met.

To ensure the integrity and validity of patents, EAC Partner States could permit competent third parties, within a certain span of time, to **oppose patent applications before national patent offices** and ARIPO (except for Rwanda and Burundi, which are not ARIPO Members). Furthermore, EAC Partner States can enhance the **technical capacities** of the national patent of-

fice staff in order to ensure that patents granted by ARIPO become effective only in the territory of an ARIPO Member that is also an EAC Partner State if the patent has been granted according to national patent laws. Finally, EAC Partner States that are ARIPO Members can **discuss an amendment to the Harare Protocol** (Art. 3.6 and 3.7) to the extent that patents granted by ARIPO become effective in their territory only upon written approval by the respective national patent office.

#### *Objective*

To ensure that patents are only granted to inventions that meet the three patentability criteria and to avoid time- and cost-intensive post-grant litigation.

## Policy Statement No. 8 (Ref: Section 2 of Annex 1)

- a. EAC Partner States, in addition to post-grant tribunal/court procedures, are to provide in their national patent laws for effective pre-and post-grant administrative patent opposition procedures.
- b. EAC Partner States, which are also ARIPO Members, are to discuss an amendment to the Harare Protocol as follows:
  - i. To take account of third party oppositions.
  - ii. To subject patents in their territories, which were granted by ARIPO, to the written approval of the respective national patent offices, which shall be submitted to ARIPO within a reasonable period of time beyond the current six months.

### 3.9. Parallel Importation

#### Issues

Article 6 of the TRIPS Agreement, as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health, provides that Members are free to choose their own regime of exhaustion of IP rights.

In order to promote access to medicines and medical devices, EAC Partner States can adopt a regime of international exhaustion authorising the import, by third parties, of originator products including medicines and active pharmaceutical ingredients for local production from countries where these products are sold at lower prices than in the home country. Differing to the national exhaustion doctrine, international exhaustion means that IP rights are exhausted upon the first sale of a product in any market, regardless of where the sale takes place. According to legal practice in a number of countries, parallel importation also authorises the impor-

tion of generic medicines which have been produced in third countries under compulsory licences. This new approach aims at enhancing access to affordable medicines but deviates from the traditional understanding of the exhaustion doctrine and has not yet been tested before the WTO.

EAC Partner States can also provide for International Exhaustion under **copyright** and **trademark law** to ensure that importing trademarked and copyright-protected pharmaceuticals does not otherwise infringe copyright and trademarks unless the importer repackages and redesigns them.

#### Objective

To enhance access to health products and medical devices.

## Policy Statement No. 9 (Ref: Sections 6, 8 and 9 of Annex 1)

EAC Partner States shall admit international IP rights exhaustion under the following laws:

- i. Patent law
- ii. Copyright law
- iii. Trademarks law

### 3.10. Compulsory Licensing

#### *Issues*

Article 31 of the TRIPS Agreement allows governments to issue compulsory and government use licences. EAC Partner States can make the use of compulsory licensing by providing in their national laws for the following:

- **Broad grounds** for compulsory licensing, e.g. to remedy anti-competitive behaviour or other forms of abusive exercise of exclusive patent rights.
- A provision authorising the **export of up to 100% of their pharmaceutical production** to countries lacking sufficient pharmaceutical capacities (Decision of WTO General Council of August 30, 2003 [Paragraph 6 Decision] or draft Art. 31 bis, TRIPS Agreement). Exporting countries under this system are principally obliged to notify WTO of the granting of export compulsory licences and must adhere to other conditions established under Annex 2 to the draft Art. 31 bis, TRIPS Agreement/paragraph 2 of the Paragraph 6 Decision, unless the pharmaceutical products are exported (or re-exported) within an LDC-dominated trade agreement, which shares the same health problem in question, such as the EAC region. Under draft Art. 31 bis.3, TRIPS Agreement/ paragraph 6 of the Paragraph 6 Decision, exports or re-exports of pharmaceutical products within such LDC-dominated trade agreements or the importation from an EAC Partner State to another EAC Partner State are not subject to the conditions and notification requirements established under Annex 2 to the draft Art. 31 bis, TRIPS Agreement/paragraph 2 of the Paragraph 6 Decision.
- Facilitate the use of the **draft Art. 31 bis, TRIPS Agreement system/Paragraph 6 Decision** as an **importing country**. To this end, it is advisable to draft **guidelines** and **regulations** on the use of this system that require a number of notifications to the WTO. Also, EAC Partner States can exempt importers

under this system from payment of remuneration to the extent that the value of their compulsory licences was taken into account when calculating the remuneration in the exporting country.

- Include in their patent laws a provision stating that the remuneration does not exceed the UNDP recommended figure of 4%, and take into account **anti-competitive conduct** by the patent right holder when determining the amount of **remuneration**.
- A **maximum period of 90 days for prior negotiations** with the patent right holder for voluntary licensing before an application for compulsory licences may be filed. This ensures that the granting of compulsory licences will not be delayed by lengthy negotiations.
- A **waiver of prior negotiations** in case of national emergency, other situations of extreme urgency, public non-commercial use (government use) and to remedy anti-competitive behaviour of the patent right holder.
- An **exclusion of injunctive relief** as a remedy available under independent review of **government use** licences. Thus, governments may not be prevented from using the patented invention during the appeal process.
- In order to fast-track the procedure to grant compulsory licences, EAC Partner States can confer the authority to grant any kind of compulsory licences to **administrative entities** (instead of courts).
- EAC Partner States can put in place institutional monitoring mechanisms for determining and actuating the four situations listed above under paragraph 6, in which prior negotiations can be waived.

#### *Objective*

To authorise both local pharmaceutical production to meet local and external demands, and the importation of generic medicines.

## Policy Statement No. 10 (Ref: Sections 8 and 12 of Annex 1)

EAC Partner States shall:

- a. Be free to determine and stipulate in their national patent laws the grounds upon which compulsory licences may be granted;
- b. Amend the compulsory licensing provisions in patent laws to include a provision authorising the export of up to 100% of pharmaceutical production to countries lacking sufficient pharmaceutical capacities;
- c. Draft guidelines and regulations both as exporting and importing countries on the export/importation of pharmaceutical products into countries with insufficient pharmaceutical manufacturing capacities under draft Art. 31 bis, TRIPS Agreement/Paragraph 6 Decision;
- d. When importing pharmaceutical products under the draft Art. 31 bis, TRIPS Agreement/Paragraph 6 Decision, waive remuneration for import compulsory licences where its value has been taken into account when remunerating the patent right holder in the exporting country;
- e. Include in their patent laws a provision stating that the remuneration shall not exceed the UNDP recommended figure of 4%, and take anti-competitive behaviour into account when determining the amount of remuneration;
- f. Include in their patent laws a maximum period of 90 days for prior negotiations;
- g. Spell out in their patent laws all four situations in which prior negotiations can be waived, namely in case of national emergency, other situations of extreme urgency, public non-commercial use – government use, and to remedy anti-competitive behaviour of the patent right holder;
- h. Exclude injunctive relief as a remedy available under independent review of government use licences;
- i. Authorise administrative entities to grant all kinds of compulsory licenses;
- j. Put in place institutional monitoring mechanisms for determining and actuating the four situations listed above under 2.9.6 in which prior negotiations can be waived.

### 3.11. Anti-Competitive Behaviour and Patent Abuse

#### *Issues*

Article 8: 2 of the TRIPS Agreement envisages that ‘appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology’. The provision clearly favours the adoption of measures deemed necessary for the promotion of competition and the prevention of abuse of the monopoly position by patent holders.

Furthermore, Article 40 of the TRIPS Agreement establishes a regime for the control of anti-competitive practices in contractual licences. Members can take measures to control the licensing practices of pharmaceutical companies and thereby reduce the concentration of market power and increase competition in the pharmaceutical market.

Accordingly, EAC Partner States can **design a policy preventing patent right abuses**. In particular, they can prohibit registry of licensing agree-

ments which contain **anti-competitive licensing terms** restricting technology transfer. Moreover, they can remedy, with compulsory licences, **anti-competitive practices** that may in certain cases constitute patent right **abuses**, which unreasonably restrain trade and competition.

### Objective

To create a pro-competitive environment in order to promote transfer of technology for the development of local pharmaceutical production capacity.

## Policy Statement No. 11 (Ref: Sections 8 and 9 of the EAC TRIPS Protocol)

To prevent anti-competitive behaviour and abuses of patent rights by their owners and to support technology transfer, EAC Partner States shall:

- a. List, borrowing from Kenya, Rwanda, Tanzania-Mainland or Uganda patent laws, licensing terms that may be considered unjustified restrictions of competition, and authorise the patent registrar to refuse the registration of such licensing contracts;
- b. Provide for remedies to patent right abuse, such as compulsory licences.

## 4.0 Implementation Arrangements

The **implementation** of the East African Community Regional Intellectual Property Policy on the Utilisation of Public Health-related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation shall be the responsibility of the EAC Partner States. The EAC Secretariat will guide the implementation in a participatory and integrated manner.

The EAC Partner States will implement this Policy in consideration of:

- The wider objectives of Art. 7 of the TRIPS Agreement:  
*'[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to the social and economic welfare, and to the balance of rights and obligations';*
- The principles of Art. 8 of the TRIPS Agreement:  
*Art. 8 of the TRIPS Agreement provides that: 'Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of*

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

- The WIPO Development Agenda; which attempts to re-establish the public policy aspects of IP rights, emphasising that the protection and enforcement of IP cannot be an end in itself, rejecting a one-size model of global IP law;
- The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, which offers a frame for action for addressing the challenge of incentivising and financing essential health R&D and at the same time promoting access to existing medicines;
- Other EAC and Partner States' development interests and policy objectives.

The EAC and its Partner States will ensure that no other legislative developments in the region (policies and/or legislative frameworks including that on anti-counterfeiting) will hinder and/or undermine full utilisation of the TRIPS Flexibilities to enhance the access of East African populations to medicines.

**EAC Partner States shall:**

- i. reject any attempts, including in trade negotiations, at national, regional and international levels that may hinder the full utilisation of the TRIPS Flexibilities, in the region and the EAC Partner States, via any other policy or legislative framework including that on anti-counterfeiting;
- ii. apply IP enforcement mechanisms available in their law in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse, and especially avoid any erosion of the benefits negotiated under the TRIPS Agreement;
- iii. establish or strengthen a drug regulatory system to ensure that only safe, efficient, and quality medicines are available in the national/regional market;
- iv. put in place guidelines and regulations on the importation of health products and medical devices in line with the WTO-TRIPS Flexibilities;
- v. undertake to train or sensitise stakeholders on IP and public health;
- vi. 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;
- vii. be actively involved in IP and public health-related regional and international processes;
- viii. avail an environment conducive for establishing regional or national medicine manufacturing capacities including earmarking funds for R&D;
- ix. provide incentives for the promotion of local pharmaceutical industries;
- x. address other policy constraints that hinder the full utilisation of TRIPS Flexibilities while taking into consideration the wider objectives of Art. 7 and the principles of Art. 8 of the TRIPS Agreement;
- xi. implement the WIPO Development Agenda of 2007;
- xii. implement the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property of 2008;
- xiii. amend national laws especially on counterfeiting and medicine regulation to be supportive of TRIPS Flexibilities.

**The EAC Secretariat shall:**

- i. address other policy constraints that hinder full utilisation of TRIPS Flexibilities in the EAC region while taking into consideration the wider objectives of Art. 7 and the principles of Art. 8 of the TRIPS Agreement;
- ii. inform the Partner States of the need to initiate and prepare for negotiations in the WTO Council for TRIPS to request for a further extension of the transition periods of 2013 and 2016 by another ten years each to enable the Partner States to acquire capacity;
- iii. develop a proposal for a comprehensive EAC Regional IP Policy taking into consideration development issues such as transfer of technology, innovation, harmonisation/approximation of legal and administrative procedures, TRIPS Flexibilities, and general regional IP policy constraints;
- iv. implement, and encourage Partner States to implement, the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property of 2008, and the WIPO Development Agenda of 2007;
- v. monitor and evaluate, 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. In order to do so, the 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.

# Annex 1: Extract from the EAC Health Protocol on Public Health Related WTO-TRIPS Flexibilities

## Preamble

**WHEREAS** the Council of Ministers of the East African Community (hereinafter the “Community”) comprising the Republic of Burundi, the Republic of Kenya, the Republic of Rwanda, the United Republic of Tanzania, and the Republic of Uganda (hereinafter referred to as the “Partner States”);

**AND WHEREAS** under Article 103.1 (i) and 103.2 of the Treaty for the Establishment of the East African Community (as amended on 14 December 2006 and 20 August 2007) (hereinafter the “EAC Treaty”), the Partner States agreed to undertake to promote co-operation in the development of science and technology within the Community through the harmonisation of policies on the promotion and protection of intellectual property rights; and to undertake such additional activities in that regard as the Council may determine;

**AND WHEREAS** under Article 118 (e) of the EAC Treaty, the Partner States agreed to undertake measures for the promotion of quality health in the Community;

**AND WHEREAS** the Partner States are desirous to optimise access to health products and medical devices in the territory of the Community;

**AND WHEREAS** Articles 38.1 (d) and 38.2 of the Protocol on the Establishment of the East African Customs Union require the Partner States to conclude protocols in the cooperation in intellectual property rights, which shall spell out the objectives, scope of co-operation and institutional mechanisms for co-operation;

**RECOGNISING** the need to approximate norms and policies on intellectual property within the Community with a view of fully utilising the flexibilities provided under the Agreement on Trade-Related Aspects of Intellectual Property Rights [hereinafter the “TRIPS Agreement”] and related instruments in order to address health problems afflicting our peoples;

**CONSCIOUS** of our rights and obligations, as contracting parties to multilateral, regional and bilateral Agreements and other instruments relating to intellectual property especially those under the World Intellectual Property Organisation (hereinafter the “WIPO”), the World Trade Organisation (hereinafter the “WTO”),

the World Health Organisation (hereinafter the “WHO”) and, as applicable, the African Regional Intellectual Property Organisation (hereinafter the “ARIPO”);

**AND CONSCIOUS** of the role intellectual property rights play for innovation as well as for the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, especially public health;

**AND CONSCIOUS** of the EAC regional initiatives on intellectual property rights, including the Draft EAC Bill on Anti-Counterfeiting and the Draft Annex on the Tripartite Policy on Intellectual Property Rights;

**AND CONSCIOUS** of the wider objectives of Article 7 and principles of Article 8 of the TRIPS Agreement and our roles under the WIPO Development Agenda of 2007 and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property of 2008;

**COMMITTED** to the implementation of the EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation, herewith attached as Annex;

**AGREE** as follows:

## Part A: Interpretation

### Section 1 – Interpretation

In this Protocol

“**ARIPO**” means African Regional Intellectual Property Organisation;

“**bioequivalence**” means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of medicine action when administered at the same molar dose under similar conditions in an appropriately designed study;



“**Community**” means the East African Community established by Article 2 of the EAC Treaty;

“**competent authorities**” mean the national body or organisation responsible for the respective action to be undertaken;

“**compulsory license**” means an authorisation given by the competent authority to governments and their contractors or to other third parties, to exploit a patent without the consent of the right holder;

“**customs territory**” means the geographical area of the EAC Partner States and any other country granted membership of the Community under Article 3 of the EAC Treaty;

“**derivatives**” means minor structural modifications of pre-existing compounds;

“**EAC Treaty**” means the Treaty for the Establishment of the East African Community (as amended on 14 December 2006 and 20 August 2007);

“**eligible importing country**” means any Least-Developed Country Member of the WTO and any Member of the WTO that has notified the Council for TRIPS of its intention to make use of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO’s General Council on August 30, 2003;

“**export**” with its grammatical variations and cognate expressions means to take or cause goods to be taken out of the customs territory or out of one Partner State to another;

“**goods**” means all kinds of articles, wares, and merchandise;

“**government use**” means public non-commercial use;

“**Harare Protocol**” means the Protocol on Patent and Industrial Designs within the Framework of the African Regional Industrial Property Organisation;

“**health products**” means pharmaceutical products and in particular vaccines, diagnostics and medicines, and active ingredients for their manufacture, in accordance with WTO decision WT/L/540 and WHA resolution WHA59.24;

“**import**” with its grammatical variations and cognate expressions means to bring or cause goods to be brought into the customs territory or from one Partner State into another;

“**mailbox applications**” means patent applications for pharmaceutical inventions filed in accordance with Article 70.8 of the TRIPS Agreement;

“**Paragraph 6 Decision**” means the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO’s General Council on August 30, 2003;

“**Partner States**” means the Republic of Burundi, the Republic of Kenya, the Republic of Rwanda, the United Republic of Tanzania, and the Republic of Uganda;

“**patent**” means the title granted to protect an invention;

“**Protocol**” means this Draft EAC Regional Protocol on Public Health-Related WTO-TRIPS Flexibilities;

“**third party**” means any natural or juridical person other than the right holder whose rights or economic interests may potentially be affected by the right granted;

“**TRIPS Agreement**” means Agreement on Trade-Related Aspects of Intellectual Property Rights;

“**WHO**” means World Health Organisation;

“**WIPO**” means World Intellectual Property Organisation;

“**WTO**” means World Trade Organisation.



## Part B: Patents

### Section 2 – Use of transition period

#### Subsection 1 – No grant or enforcement of pharmaceutical patents until 1 January 2016 or future transition period

Pursuant to Article 66.1 of the TRIPS Agreement, the Decision by the WTO Council for TRIPS of 27 June 2002, and Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, all Partner States qualified by the United Nations as Least-Developed Countries (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.

#### Subsection 2 – Abolishment of the “mailbox” provision

Partner States providing in their national intellectual property laws for a provision that allows inventors to file mailbox applications during the transition period referred to under Section 2.1 shall abolish this provision.

### Section 3 – Administrative opposition

1. Every 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.
2. The procedures and requirements under Section 3.1 shall be regulated by the respective Partner State as it may consider appropriate.
3. All Partner States, which are also 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.

All Partner States, which are also Members of ARIPO, shall work towards an amendment of Sections 3.6 and 3.7 of the Harare Protocol so as to require that ARIPO patent application designating such Partner State shall only be granted on its behalf and in respect of its territory subject to the written approval of the respective national patent office within a reasonable period of time beyond the current six months. Otherwise such

patents shall not have effect in the respective territory of such Partner State.

### Section 4 – Subject matter excluded from patent protection

All Partner States shall, in addition to the subject matter already excluded under their national intellectual property laws, 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.

### Section 5 – Patentability criteria

1. All Partner States 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.
2. In the context of the inventive step requirement, all Partner States 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.

All Partner States shall strictly apply the industrial application requirement and limit the patentability of research tools to only those for which a specific use was identified.

#### **Section 6 – Disclosure**

1. All Partner States shall require patent applicants to disclose all modes and expressly indicate the best mode for carrying out an invention. For this purpose, Partner States shall determine the level of required disclosure on the basis of the relevant expertise available in the respective Partner State.
2. All Partner States shall require patent applicants to disclose the International Non-proprietary Names of pharmaceutical substances or active pharmaceutical ingredients as soon as they are available.

#### **Section 7 – Rights conferred by the patent**

##### **Subsection 1 – Research exception**

1. All Partner States shall determine in their respective national laws that the rights under the patent 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.
2. All Partner States shall clarify that the preponderant purpose of the commercial research as referred to in Section 7.1.1 must be the generation of new knowledge on the patented substance, including its uses.
3. All Partner States shall use Section 5.3 to limit the patentability of research tools. In cases where research tools are patented, Partner States shall provide in their national intellectual property laws for a non-exclusive license for researchers who wish to use patented research tools, and patent right holders shall only be entitled to receive reasonable remuneration from such researchers. Sections 8.2 and 8.3 shall apply *mutatis mutandis*.

##### **Subsection 2 – Marketing approval/ “Bolar” exception**

All Partner 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.

##### **Subsection 3 – International exhaustion**

All Partner States shall provide for international exhaustion of patent rights in all fields of technology.

#### **Section 8 – Compulsory licensing, including government use**

##### **Subsection 1 – Grounds**

1. All Partner States shall feel free to determine and stipulate in their national intellectual property laws the grounds upon which the competent authorities may issue compulsory licenses, including government use licenses.
2. The grounds referred to in Section 8.1.1 shall include, *inter alia*, the following cases:
  - a. where there is a national emergency or other situations of extreme urgency;
  - b. where the patented invention is used for non-commercial purposes;
  - c. to remedy anti-competitive behaviour or the abuse of patent rights, including cases in which the patented invention is made available at excessive prices only or cases in which refusals to license constitute an abuse of a dominant position;
  - d. where the local demand is not satisfied, because the patented invention is made available to the public in insufficient quantity or quality, or at unreasonably high prices;
  - e. where the public interest, in particular public health so requires;
  - f. where a patented invention claimed in a subsequent patent cannot be used without infringing a previous patent;
  - g. for the purpose of giving effect to the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS

Agreement and Public Health, adopted by the WTO's General Council on August 30, 2003 (Paragraph 6 Decision), to make, use, offer for sale for export, sale for export and to export to an eligible importing country a patented health product, including a patented process regarding that health product;

h. for the importation of a patented health product for the purpose of giving effect to the Paragraph 6 Decision.

3. All Partner States shall draft guidelines and regulations on the implementation of the Paragraph 6 Decision both as eligible importing countries and as exporting countries, including the conditions and notification requirements established by this Decision.

#### **Subsection 2 – Prior negotiations**

1. All Partner States shall provide for a maximum period of 90 days in which an applicant for a compulsory license is to negotiate with the patent right holder for a voluntary license on reasonable commercial terms and conditions.
2. All Partner States shall waive the prior negotiation requirement referred to in Section 8.2.1 in cases of national emergency, other situations of extreme urgency, public non-commercial use and where compulsory licenses are to be issued to remedy anti-competitive behaviour of the patent right holder.

#### **Subsection 3 – Compensation**

1. All Partner States shall provide that the remuneration to the patent right holder in the case of a compulsory license shall not exceed 4 per cent.
2. All Partner States shall require the competent authorities, in determining the amount of adequate remuneration to the patent right holder in the case of a compulsory license, to take into account the need to correct anti-competitive practice and to reduce the amount of remuneration accordingly.
3. In determining remuneration to the patent right holder with respect to any license granted for the export under the Paragraph 6 Decision referred to in Section 8.1.2 (g),

the competent authorities shall take into account the economic value of the authorisation to the eligible importing country.

4. All Partner States shall waive the payment of adequate remuneration to the patent right holder for a license granted under the Paragraph 6 Decision for the importation of a patented health product that is also under patent in the prospective exporting country in respect of that health product for which remuneration is paid in the exporting country.

#### **Subsection 4 – Exclusion of injunctive relief**

1. All Partner States shall grant patent right holders the right to appeal a decision to grant a compulsory license and the amount of remuneration, but shall regulate that any appeal against a government use license shall not suspend the government use during the appeal process.
2. All Partner States shall provide that in case of Section 8.4.1 the patent right holder's sole remedy shall be action for the recovery of compensation.

#### **Subsection 5 – Competence**

For the purpose of fast-tracking the procedure to grant compulsory licenses, all Partner States shall confer the right to grant compulsory licenses, including government use licenses to national administrative entities instead of courts.

#### **Section 9 – Control of licensing practices and conditions**

1. All Partner 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.
2. Appropriate measures referred to in Section 9.1 may be the refusal of registration of licensing contracts which contain such licensing practices and conditions.

## **Part C: Trademarks**

### **Section 10 – International exhaustion**

All Partner States shall provide for international exhaustion of trademark rights in all fields of technology.

## **Part D: Copyrights**

### **Section 11 – International exhaustion**

All Partner States shall provide for international exhaustion of copyrights in all fields of technology.

## **Part E: Trade secrets**

### **Section 12 – Protection of undisclosed data**

1. Partner States (LDC Partner States only upon the lapse of the transition period for LDCs referred to in Section 2) 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.
2. The obligation under Section 12.1 shall not prevent the Partner States' 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.
3. 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.

## **Part F: Miscellaneous**

### **Section 13 – Compensatory liability**

Any Partner State, that deems this to be in its national interest, may provide for the protection of small-scale inventions and traditional medicines under a system which entitles the inventor both to:

- a. reasonable compensation, for a reasonable period of time, if third parties use the protected invention for follow-on improvements; and
- b. a right to use, for a reasonable period of time, the improved invention of the third party referred to under Section 13 (a) (cross-license).

### **Section 14 – Application of the Paragraph 6 Decision to trade between the Partner States of the EAC Customs Union**

All Partner States shall take advantage of paragraph 6 of the Paragraph 6 Decision 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.

## Annex 2: Analysis of National IP Legislation - Overview

### Transition periods

Burundi	Kenya	Rwanda	Tanzania-Mainland	Tanzania-Zanzibar	Uganda
2016 Transition Period, Art. 17 and Art. 381 – data protection  No mailbox rule	Cannot take advantage of transition period for LDCs	Exclusion of pharmaceutical products, for the purposes of international conventions to which Rwanda is party, Art. 18.1 No. 8  No mailbox rule  Prior use, Art. 41.1 No. 3	Does not provide for 2016 Transition Period	2016 Transition Period, Sec. 3.1 (x) and Sec. 72.5 (h) – data protection  Mailbox, Sec. 10.8  Prior use, Sec. 8	2016 Transition Period, Sec. 8.3 (f)  Mailbox, Sec. 28.14  Prior use, Sec. 43.4

### Opposition procedures

Burundi	Kenya	Rwanda	Tanzania-Mainland	Tanzania-Zanzibar	Uganda
Notice of opposition, Art. 47	Provides only for post-grant court procedures, Sec. 103	Provides only for post-grant court procedures to invalidate a patent, Art. 36	Provides only for post-grant court procedures, Sec. 63	Notice of opposition, Sec. 10.7 (a)	Notice of opposition, Sec. 28.7-10

### Patentability criteria

Burundi	Kenya	Rwanda	Tanzania-Mainland	Tanzania-Zanzibar	Uganda
Art. 4 Prior art: worldwide, disclosed to the public by any means  Art. 6 refers to “a person skilled in the art”  Art. 7: Industrial applicability	Sec. 23.2 Prior art: worldwide; written or oral disclosure, use, exhibition or other non-written means  Sec. 24 refers to “a person skilled in the art”  Sec. 25: Industrial applicability	Art. 15 Prior art: worldwide; by publication in tangible form, by oral disclosure, by use or in any other way  Art. 16 refers to “a person skilled in the art and involved in that area”  Art. 17: Industrial applicability	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  Sec. 10 refers to “a person skilled in the art”  Sec. 11: Industrial applicability	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  Sec. 4.3 refers to “a person highly skilled in the art”  Sec. 4.4: Industrial applicability	Sec. 10.2 Prior art: worldwide; written or oral disclosure; use; exhibition or other non-written means  Sec. 11 refers to “a person skilled in the art”  Sec. 12: Industrial applicability

## Natural substances, new uses, product derivatives

Burundi	Kenya	Rwanda	Tanzania-Mainland	Tanzania-Zanzibar	Uganda
<p>Exclusion of natural substances, even if purified, synthesized or otherwise isolated from nature. But process of isolation can be patented, Art. 17</p> <p>New uses of known products are explicitly excluded from patentability, Art. 17</p> <p>Silent on product derivatives</p> <p>Utility model protection for 10 years (Art. 144), requiring not only novelty and industrial applicability but also a sufficiently inventive step (Art. 102)</p> <p>Exclusions from utility model protections for natural substances; known substances for which a new use has been discovered, and pharmaceutical products (Art. 112)</p> <p>Own standards for novelty (Art. 103 f.), sufficient inventive step (Art. 105), and industrial application (Art. 106)</p>	<p>Silent on natural substances</p> <p>Patents on new uses are explicitly allowed, [Sec. 22]; But exclusion on case-by-case basis for public health reasons, Sec. 21.3 (e)</p> <p>Silent on product derivatives (but examination guidelines)</p> <p>Utility model protection for 10 years (Sec. 82.3) for inventions that are new and industrially applicable (Sec. 82.1 and 2).</p> <p>Regarding novelty standard, reference is made to patentability criteria</p>	<p>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</p> <p>Excludes patents on known substances for which a new use has been discovered; but not on the use itself, provided this is an invention, Art. 18.1 No. 5</p> <p>Silent on product derivatives</p> <p>Utility model protection or 10 years (Art. 83) for inventions that are new (Art. 57) and industrially applicable (Art. 58)</p> <p>Exclusions from utility model protections for natural substances (Art. 59.1 No. 4); known substances for which a new use has been discovered (Art. 59.1 No. 5); pharmaceutical products (Art. 59.1 No. 8)</p> <p>Own standards for novelty (Art. 57) and industrial application (Art. 58)</p>	<p>Silent on natural substances</p> <p>Silent on new uses</p> <p>Silent on product derivatives</p> <p>Utility model protection for 7 years (Sec. 73.4) for inventions that are new and industrially applicable (Sec. 73.1)</p> <p>Regarding novelty standard, reference is made to patentability criteria</p>	<p>Exclusion of natural substances even if purified, synthesised or isolated; but process patent for isolation, Sec. 3.1 (iv)</p> <p>New uses or forms of known products or processes are explicitly excluded [Sec. 3.1 (v)]</p> <p>Silent on product derivatives</p> <p>Utility model protection for 10 years (Sec. 24.1), requiring not only novelty and industrial applicability but also a sufficiently inventive step. (Sec. 17)</p> <p>Novelty requirement less strict than for patents; less prior art taken into account (Sec. 17.2 (b)). But compared to other utility model laws, more strict as it requires a sufficient inventive step. (Sec. 17.3)</p>	<p>Silent on natural substances</p> <p>[Sec. 38.1 (c) read with Sec. 9] appears to provide for patents for new uses</p> <p>Silent on product derivatives</p> <p>Utility model protection for 10 years (Sec. 69.3) for inventions that are new and industrially applicable (Sec. 69.1 and 2)</p> <p>Regarding novelty standard, reference is made to patentability criteria</p>

## Disclosure requirements

Burundi	Kenya	Rwanda	Tanzania-Mainland	Tanzania-Zanzibar	Uganda
<p>Adaptation to the national level of expertise may be required, Art. 22</p> <p>Requirement to provide information concerning corresponding foreign patent applications, Art. 35</p> <p>Disclosure of any mode for carrying out invention is sufficient, Art. 20.1</p>	<p>Adaptation to national level of expertise not required</p> <p>Requirement to provide information concerning corresponding foreign patent applications, Sec. 53.2 (b)</p> <p>Disclosure of at least one mode for carrying out invention is sufficient, Sec. 34.5 and 53.2 (a)</p>	<p>Adaptation to the national level of expertise may be required, Art. 25.3 and 25.4 “a person having ordinary skills in the art is understood as a citizen of Rwanda, or any person with habitual residence located in Rwanda, [...]”</p> <p>Requirement to provide information concerning corresponding foreign patent applications, Art. 31</p> <p>Requirement to indicate the best mode for carrying out the invention, Art. 25.1</p>	<p>No adaptation requirement</p> <p>Requirement to provide information concerning corresponding foreign patent applications Sec. 22.1</p> <p>Requirement to indicate the best mode for carrying out the invention, Sec. 34.2. (i)</p>	<p>Adaptation to the national level of expertise, Sec. 6.4 (a), (d) and (e)</p> <p>Requirement to provide information concerning corresponding foreign patent applications Sec. 9</p> <p>Requirement to indicate the best mode for carrying out the invention, Sec. 6.4 (a)</p>	<p>Adaptation to the national level of expertise, Sec. 21.9</p> <p>Requirement to provide information concerning corresponding foreign patent applications Sec. 25</p> <p>Disclosure of at least one mode for carrying out invention is sufficient, Sec. 21.5 (a)</p>

## Research exception

Burundi	Kenya	Rwanda	Tanzania-Mainland	Tanzania-Zanzibar	Uganda
<p>Art. 56 No. 3 permits the use of the patent for experimentation, including scientific and technological research</p>	<p>Sec. 58.1 restricts the research exception to scientific purposes</p>	<p>Art. 41.1 No. 2 authorises acts relating to a patented invention carried out for scientific and technological research purposes and for public non-profit use</p>	<p>Sec. 37.1 restricts the research exception to scientific purposes</p>	<p>Sec. 12.4 (a) (iii) permits the use of the patent for both research for scientific and commercial purposes and authorises research “on” and “relating to the patented invention”</p>	<p>Sec. 44 (a) permits the use of the patent for any acts related to experimental use on the patented invention, and for research for scientific as well as commercial purposes</p>

## Marketing approval (“Bolar”) exception

Burundi	Kenya	Rwanda	Tanzania-Mainland	Tanzania-Zanzibar	Uganda
<p>Art. 56 No. 5 authorises acts “reasonably related” to the marketing approval anywhere in the world</p>	<p>Sec. 54.2 authorises use of patented substance for applying for approval by the Kenya Industrial Property Institute [Sec. 2 (c)]</p>	<p>Art. 41.3 authorises the use, manufacture, construction or sale of the patented invention, insofar as it is necessary for the preparation and production of the information file which must be provided according to a domestic or foreign law governing the manufacture, construction, use or sale of a product</p>	<p>Not provided for</p>	<p>Sec. 12.4 (a) (v) authorises use of patented substance for applying for marketing approval worldwide</p> <p>Authorises acts “reasonably related” to the marketing approval</p>	<p>Sec. 44 (c) authorises use of patented substance for applying for marketing approval worldwide</p> <p>Authorises acts for purposes reasonably related to the development and submission of information required for marketing approval requests</p>

## Parallel importation (international exhaustion)

Burundi	Kenya	Rwanda	Tanzania-Mainland	Tanzania-Zanzibar	Uganda
<p>Art. 56 No. 1: international exhaustion in patent law</p> <p>In addition: Minister may, under certain circumstances as listed, declare patent rights exhausted in order to authorise importation, Art. 58</p> <p>No information on copyright law</p> <p>For trademarks, Art. 312: international exhaustion</p> <p>In addition: Minister may, under certain circumstances as listed, declare patent rights exhausted in order to authorise importation, Art. 313</p>	<p>Sec. 58.2: international exhaustion in patent law</p> <p>Not permitted either under copyright or under trademark law</p>	<p>Art. 40.1: national exhaustion in patent law</p> <p>But Minister may, under certain circumstances as listed, declare patent rights exhausted in order to authorise importation, Art. 40.2</p> <p>Not permitted under copyright law</p> <p>For trademarks, Art. 152.1 national exhaustion with right of Minister to, under certain circumstances as listed, declare trademark rights exhausted (Art. 152.2) and the Minister of Health may take measures to limit the use of marks with the purpose of facilitating [...] access to generic pharmaceutical products and medical devices. (Art. 152.6)</p>	<p>Sec. 37.2: national exhaustion in patent law</p> <p>But Sec. 73.2 of Food, Drugs and Cosmetics Act of 2003 permits parallel importation of medicines</p> <p>Not permitted either under copyright or under trademark law</p>	<p>Sec. 12.4 (a) (i): international exhaustion in patent law</p> <p>Not permitted under copyright law</p> <p>Authorised under the trademark law, Sec. 49.4</p>	<p>Unclear under the patent law, Sec. 43.2, which appears to make the “importation into Uganda” (and not only the marketing of the product) dependent on the consent of the patent right holder</p> <p>Not permitted either under copyright or under trademark law</p>



## Compulsory licensing, including government use

Burundi	Kenya	Rwanda	Tanzania-Mainland	Tanzania-Zanzibar	Uganda
<p>Grounds:</p> <p>Note: 3 to 4 years grace period for several cases under Art. 77</p> <p>Public interest, Art. 77 No. 1</p> <p>Patent abuse and anti-competitive practices, Art. 77 No. 2</p> <p>Dependent patents, Art. 78</p> <p>Refusal to license, Art. 77 No. 3</p> <p>Authorisation for export of up to 100 % (draft Art. 31bis, TRIPS system), Art. 87</p> <p>Exemption from paying remuneration in importing country under draft Art. 31bis, TRIPS system, Art. 80</p> <p>Anti-competitive behaviour not explicitly to be taken into account when determining remuneration</p> <p>Maximum prior negotiations period of 6 months, Art. 85.3</p> <p>Prior negotiations waived in cases of national emergency, other situations of extreme urgency, to remedy anti-competitive behaviour, in cases of government use, Art. 86</p> <p>Appeal may suspend effect of compulsory licenses, Art. 96</p> <p>Authority to grant compulsory licenses: Minister, Art. 79 and Tribunal. Art. 90</p>	<p>Grounds:</p> <p>Public interest, Sec. 80.1 (a)</p> <p>Patent abuse and anti-competitive practices, Sec. 80.1 (b)</p> <p>To satisfy local demand, Sec. 72.1</p> <p>Dependent patents, Sec. 73.1</p> <p>-</p> <p>No authorisation for export of up to 100 % (draft Art. 31bis, TRIPS system)</p> <p>No exemption from paying remuneration in importing country under draft Art. 31bis, TRIPS system</p> <p>No remuneration in cases of anti-competitive behaviour, Sec. 80.1B</p> <p>Prior negotiations for "reasonable period", Sec. 74.1 (a)</p> <p>Prior negotiations waived in cases of national emergency and other extreme urgency, Sec. 74.2 and 80.2</p> <p>No exclusion of injunctive relief in case the patent right holder appeals compulsory license</p> <p>Authority to grant compulsory licenses: Tribunal, Sec. 75.1, 113.1</p>	<p>Grounds:</p> <p>Public interest, Art. 52.1 No.1</p> <p>Patent abuse and anti-competitive practices, Art. 47 No. 2 and Art. 49 or Art. 50.1 No. 2</p> <p>Insufficient use, Art. 47 No. 1 and Art. 48</p> <p>Dependent patents, Art. 47 No. 3 and Art. 50</p> <p>-</p> <p>No authorisation for export of up to 100 % (draft Art. 31bis, TRIPS system)</p> <p>No exemption from paying remuneration in importing country under draft Art. 31bis, TRIPS system</p> <p>Anti-competitive behaviour taken into account when determining remuneration, Art. 53.3</p> <p>Prior negotiations, Art. 51.1 or Art. 53.1</p> <p>Prior negotiations waived in cases of national emergency and other extreme urgency, and cases of non-commercial use, and to remedy anti-competitive behaviour, Art. 53.2</p> <p>No exclusion of injunctive relief in case the patent right holder appeals compulsory license</p> <p>Authority to grant compulsory licenses: Minister, Art. 47 or the Government of Rwanda, Art. 52.</p>	<p>Grounds:</p> <p>Public interest, Sec. 61.1, particularly public health, Sec. 54</p> <p>To satisfy local demand, Sec. 52.1 (a) (ii)</p> <p>Dependent patents, Sec. 53.1</p> <p>Refusal to license, Sec. 52.1 (a) (iv)</p> <p>-</p> <p>No exemption from paying remuneration in importing country under draft Art. 31bis, TRIPS system</p> <p>Anti-competitive behaviour not explicitly to be taken into account when determining remuneration</p> <p>Prior negotiations, Sec. 55 (a)</p> <p>Prior negotiations waived in case of government use license – only hearing of patentee, Sec. 61.2</p> <p>Appeal but no suspension of effects of government use license, Sec. 61.4</p> <p>Authority to grant compulsory license: Court, Sec. 56.1 and Minister, Sec. 61.2</p>	<p>Grounds:</p> <p>Public interest, Sec. 14.1 (a) (i)</p> <p>Patent abuse and anti-competitive practices, Sec. 14.1 (a) (ii) and (iii)</p> <p>To satisfy local demand, Sec. 14.1 (a) (iv)</p> <p>Dependent patents, Sec. 14.1 (a) (vii)</p> <p>Refusal to license, Sec. 14.1 (a) (vi)</p> <p>Authorisation for export of up to 100 % (draft Art. 31bis, TRIPS system), Sec. 14.7</p> <p>Exemption from paying remuneration in importing country under draft Art. 31bis, TRIPS system, Sec. 14.1 (b)</p> <p>Anti-competitive behaviour taken into account when determining remuneration, Sec. 14.1 (b)</p> <p>Strict prior negotiations period of 45 days, Sec. 14.6</p> <p>Prior negotiations waived in cases of national emergency, other situations of extreme urgency, to remedy anti-competitive behaviour, in cases of government use, Sec. 14.6 (b)</p> <p>Exclusion of injunctive relief in case the patent right holder appeals compulsory license, Sec. 14.11 and 73.3</p> <p>Authority to grant compulsory licenses: Minister, Sec. 14.1</p>	<p>Grounds:</p> <p>Public interest, Sec. 66.1 (a)</p> <p>Patent abuse and anti-competitive practices, Sec. 66.1 (b)</p> <p>To satisfy local demand, Sec. 58.1</p> <p>Dependent patents, Sec. 59.1</p> <p>-</p> <p>Authorisation for export of up to 100 % (draft Art. 31bis, TRIPS system), Sec. 44 (e)</p> <p>No exemption from paying remuneration in importing country under draft Art. 31bis, TRIPS system</p> <p>No remuneration in cases of anti-competitive behaviour, Sec. 66.3</p> <p>Prior negotiations for "reasonable period", Sec. 60.1 (a)</p> <p>Prior negotiations waived in cases of national emergency, other situations of extreme urgency, to remedy anti-competitive behaviour, Sec. 60.2 and 66.7</p> <p>No exclusion of injunctive relief in case the patent right holder appeals compulsory license</p> <p>Authority to grant compulsory licenses: Court, Sec. 61 and Minister, Sec. 66</p>

## Competition law

Burundi	Kenya	Rwanda	Tanzania-Mainland	Tanzania-Zanzibar	Uganda
<p>Art. 73, 76 authorise the Tribunal to declare licensing terms invalid if they unreasonably restrict the commercial interests of the licensee</p> <p>Art. 77 No. 2 authorises compulsory licensing as a remedy to anti-competitive behaviour</p>	<p>Sec. 69 lists prohibited licensing terms</p> <p>Sec. 80.1 (b) authorises compulsory licensing as a remedy to anti-competitive behaviour</p>	<p>Art. 45 lists prohibitive licensing terms</p> <p>Art. 47 No. 2 and Art. 49 or Art. 50.1 No. 2 authorises compulsory licensing as a remedy to anti-competitive behaviour</p>	<p>Sec. 48 lists prohibitive licensing terms</p>	<p>Does not provide for a list of prohibited licensing terms</p> <p>Sec. 14.1 (a) (ii) (iii) authorises compulsory licensing as a remedy to anti-competitive behaviour</p>	<p>Sec. 55 lists prohibited licensing terms</p> <p>Sec. 66.1 (b) authorises compulsory licensing as a remedy to anti-competitive behaviour</p>

## Clinical test data protection

Burundi	Kenya	Rwanda	Tanzania-Mainland	Tanzania-Zanzibar	Uganda
<p>Reliance by the DRA on originator test data permitted against payment of compensation in enumerated cases, including in case of compulsory licensing (Art. 376) for a maximum period of 5 years (Art. 375)</p> <p>No patent linkage (Art. 377)</p>	<p>In practice, reliance by the DRA on originator test data is permitted</p> <p>But see Rule 9.1 of the Pharmacy and Poisons (Registration of Drugs) Rules, which generally requires an investigation of pharmaceutical drugs, including clinical trials to be conducted locally</p> <p>Rule 9.2 grants the Pharmacy and Poisons Board authority to dispense with investigations and clinical trials prior to registration</p> <p>Rule 9.3 authorises the Board to register drugs for two years where public interest requires</p> <p>No information on patent linkage</p>	<p>According to communication, Rwanda's law regulating pharmaceutical marketing approval appears to not prevent the Commission from relying on data submitted by previous applicants</p> <p>No information on patent linkage</p>	<p>Guidelines on the Submission of Documentation for Registration of Human Medicinal Products authorise reliance by the DRA on originator test data</p> <p>Guidelines on the Submission of Documentation for Registration of Human Medicinal Products defines the person of the "applicant" as someone "who owns a formula or trademark of a product, who may be a manufacturer [...]"; DRA interprets guidelines as an authorisation to grant marketing approval irrespective of the patent status</p>	<p>Reliance by the DRA on originator test data permitted against payment of compensation in enumerated cases, including in case of compulsory licensing (Sec. 72.5 (c)) for a maximum period of 5 years (Sec. 72.5 (b))</p> <p>No patent linkage (Sec. 72.5 (d))</p>	<p>Sec. 11.2 Trade Secrets Protection Act authorises reliance by the DRA on originator test data</p> <p>No patent linkage (Practice of NDA, Point 2.1 of the Guidelines on Registration of Pharmaceutical Drugs for Human Use in Uganda)</p>



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