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Research Report

Transition period for TRIPS implementation for LDCs: Implications for local production of medicines in the East African community

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**TRANSITION PERIOD FOR TRIPS
IMPLEMENTATION FOR LDCS:
IMPLICATIONS FOR LOCAL
PRODUCTION OF MEDICINES IN THE
EAST AFRICAN COMMUNITY**

Nirmalya Syam



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TRANSITION PERIOD FOR TRIPS IMPLEMENTATION FOR LDCs: IMPLICATIONS FOR LOCAL PRODUCTION OF MEDICINES IN THE EAST AFRICAN COMMUNITY

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SOUTH CENTRE

DECEMBER 2014

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ABSTRACT

Article 66.1 of the WTO TRIPS Agreement grants the least developed countries (LDCs) a transition period during which they do not have to provide intellectual property rights protection according to the minimum requirements of the TRIPS Agreement. This transition period has been granted to LDCs to ensure that LDCs are not constrained by the existence of IP rights from taking suitable measures to develop a sound and viable technological base in different industrial sectors. The TRIPS Council has extended this transition period three times, including a specific extension for pharmaceutical products, and it is possible to seek further extensions of this period. This paper analyzes the implications of the transition period available for local production of pharmaceuticals in LDCs that are Partner States of the East African Community (EAC) – Burundi, Rwanda, Uganda and the United Republic of Tanzania. The paper analyzes the critical challenges for local production of pharmaceutical products in these countries and how the transition period can be utilized fully to address these challenges. Though the EAC Partner States rely predominantly on imported generic medicines, there is a need for local production of medicines as reliance on imports may not be sustainable for these countries. However, the LDCs from the EAC Partner States have only recently begun using the TRIPS transition period and Tanzania has still not introduced the transition period under its national law. Moreover, most of the LDCs from the region are contracting parties to the Harare Protocol under which ARIPO grants pharmaceutical patents that are excluded under respective national laws and would be void *ab initio*. However, the grant of such patents to come into effect in these countries could create confusion. In this context, the paper recommends that all LDC Partner States of the EAC should make use of the general transition period until 2021; that Tanzania should start using the transition period; and that LDCs should seek an extension of the transition period for pharmaceutical products, which expires in 2016. Moreover, national laws should declare any patent granted by ARIPO on pharmaceutical products to be void *ab initio* and a similar amendment could be moved in the Harare Protocol.

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I. INTRODUCTION

The evolution of patent laws in both developed and developing countries shows that governments have adopted a cautious approach towards allowing patents on medicines in order to safeguard the public health interest of ensuring access to medicines for the people. For example, till the late 1970s Switzerland did not allow patents on medicines. This approach was also followed by some developing countries like India till the entry into force of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO).¹ As a consequence, developing country members of the WTO had to abandon the policy of restricting the scope of patents on medicines and chemicals – an approach that is widely recognized as a major factor that facilitated the growth of a competitive generic pharmaceutical industry in many other countries.

However, this important flexibility of excluding any field of technology from the scope of patentability is still available for the least developed countries under the TRIPS Agreement. Under Article 66 of the TRIPS Agreement, LDCs were granted a transition period for 10 years from the date of entry into force of the TRIPS Agreement. Article 66.1 of TRIPS also stated that the transition period shall be extended by the TRIPS Council upon a duly motivated request for such extension being made by any LDC. Thus, the transition period can be extended as often as required based on a duly motivated request from any LDC country.

The transition period allows LDCs to not provide intellectual Property rights (IPR) protection according to the standards of the TRIPS Agreement. During the transition period the LDCs are exempted from implementing all the provisions of the TRIPS Agreement except for Articles 3, 4 and 5 of TRIPS, which contain provisions pertaining to national treatment and the most favoured nation treatment. Thus LDCs can deny patent protection in any field of technology, including pharmaceuticals. This flexibility was given to LDCs in recognition of their special needs and requirements, the economic, financial and administrative constraints faced by LDCs as well as their need for flexibility to create a viable technological base.

The WTO TRIPS Council has granted three separate extensions of the original transition period granted under Article 66.1 of TRIPS. In 2002, the transition period was extended until 2016 only for certain obligations with respect to pharmaceutical products and undisclosed pharmaceutical test data. Without prejudice to that decision, in 2005, the transition period was extended until July 2013 with respect to all provisions of the TRIPS Agreement. In 2013, this general transition period was extended further till 2021 by the TRIPS Council. Thus, two separate extensions for the transition period are currently in operation:

- a specific extension in relation to pharmaceutical products until 1 January 2016 and
- a general extension until 1 July 2021.

¹ Carlos M. Correa (2010), *Designing Intellectual Property Policies in Developing Countries* (Third World Network, Penang, Malaysia), pp. 1-2.

It is possible for LDCs to request further extensions of both the transition periods in the TRIPS Council.

The full utilization of the transition period under TRIPS is an important factor that can complement efforts by governments in LDCs to promote local manufacturing of medicines by ensuring that locally produced medicines are not denied market access due to the existence of patent rights. Local production of medicines may facilitate access to medicines by reducing the prices of drugs and ensuring better availability through price-based competition. Though currently most of the medicines in the EAC countries are imported from abroad, the reliance on imports alone may not ensure access to the new medicines because patents can restrain generic medicines from being available even through importation.

In this context, this paper analyzes the implications of this transition period for local production of pharmaceuticals in LDCs that are Partner States of the East African Community (EAC) – Burundi, Rwanda, Uganda and the United Republic of Tanzania. The paper analyzes the critical challenges for local production of pharmaceutical products in these countries and how the transition period can be utilized fully to address these challenges.

II. TRANSITION PERIOD FOR IMPLEMENTING THE TRIPS AGREEMENT BY LDCS

Inclusion of the TRIPS Agreement as part of the WTO Agreements was the direct result of demands made by developed countries during the Uruguay Round, in response to the powerful lobby of a handful of industries (e.g. entertainment industry, the chemical and pharmaceutical industry) in their countries that would greatly benefit from heightened intellectual property protection worldwide. Few developing countries and only one LDC – Tanzania – were actively involved in these negotiations.

Conclusion of the TRIPS Agreement and its entry into force on 1 January 1995 globalized minimum standards of IP protection that all members of the WTO had to provide. This paved the way for an upward harmonization of intellectual property standards. As a consequence all developing country members of the WTO had to amend their IP laws to provide stronger levels of IP protection.

A substantive change that was introduced to international patent law by the TRIPS Agreement is the obligation for all WTO member States to grant patents for inventions that satisfy the criteria of patentability without any discrimination regarding the fields of technology involved. Article 27.1 of TRIPS states that

... patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced (emphasis added).

In order to facilitate implementation of the TRIPS Agreement, developing countries were given 5 years to comply with the TRIPS Agreement (i.e. by 1 January 2000), with the possibility of delaying for another 5 years (i.e. until 1 January 2005) application of product patents to technology areas that were not patentable as at 1 January 2000.² However, LDCs were treated differently due to their special circumstances and were given a separate transition period under Article 66, with the aim of providing LDCs maximum flexibility to create a sound and viable technological base. Article 66.1 of TRIPS states that

In view of the *special needs and requirements* of least-developed country Members, their *economic, financial and administrative constraints*, and their *need for flexibility to create a viable technological base*, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS *shall*, upon duly motivated request by a least-developed country Member, accord extensions of this period (emphasis added).

Article 66.1 granted LDCs a 10-year transition period (until 2005) which is renewable in recognition of their “special needs and requirements”, “financial and administrative constraints” and “need for flexibility to create a viable technological base”. According to Article 66.1, the TRIPS council “shall” extend the transition period once LDCs submit a duly motivated request for an extension. Essentially, this provision acknowledges that the provisions of the TRIPS Agreement may not be conducive to the social and economic circumstances of LDCs and that LDCs need to have policy space and flexibility to address their development challenges and to create a viable technological base.

The special status of LDCs is also recognized in the preamble of the TRIPS Agreement, which recognizes “... *the special needs of least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base*”.

The transition period granted under Article 66.1 of TRIPS has been extended three times by the TRIPS Council. The TRIPS Council granted a specific extension of the transition period with respect to patents on pharmaceutical products and test data in 2002. This extension will run till 1 January 2016. This extension was followed by a general extension of the transition period till 1 July 2013. Before this general transition period could expire, the TRIPS Council further extended the general transition period till 1 July 2021. Thus, two transition regimes are currently in operation – one specifically for medicines till 1 January 2016, and a general transition period till 1 July 2021 (see box 1).

II.1 Rationale behind the Transition Period for LDCs

The negotiators of TRIPS were mindful of the special needs of LDCs and the unique challenges they would face in the process of technological catch-up as latecomers to technological development. It was recognized that IPRs cannot be effective as an incentive mechanism in the absence of a sound and viable technological base. In order to be effective, IPRs need to apply in a context where there is a significant market, sufficient capital,

² See Article 65.2 and 65.4 of the TRIPS Agreement.

qualified personnel at the firm level, innovation-oriented entrepreneurs, as well as a solid scientific and technological base.³ Mere access to new technology is not adequate for the technological catch-up of LDCs. Rather, LDCs need access to appropriate technology and effectively use such technology in the local context. This requires sufficient levels of absorptive capacity – the ability to assimilate and adopt technological know-how, which is substantially lacking in the LDCs. These primary conditions for benefiting from stronger standards of IP protection are absent in the LDCs. Strong IP protection in such a context can actually stifle technological learning which can severely impede the development of a technological base.⁴

Box 1

Extensions of the Transition Period

2002 TRIPS Council Waiver for Pharmaceutical Products

The TRIPS Council decision of 27 June 2002 (IP/C/25) states that with respect to pharmaceutical products, LDC Members will not be obliged to implement or apply sections 5 and 7 of Part II of TRIPS or enforce rights under those provisions until 1 January 2016. Accordingly LDCs do not have to implement TRIPS provisions on patents and test data protection till 2016. Further, by virtue of a General Council July 2002 decision (WT/L/478), LDCs are also waived until 2016 from obligations under Article 70.9 of TRIPS, to provide exclusive marketing rights for pharmaceutical products.

2005 TRIPS Council General Extension of the Transition Period for LDCs

The 10-year exemption from TRIPS obligations granted to LDCs was set to expire on 1 January 2006. Following a duly motivated request submitted by LDCs as a group, in October 2005, the TRIPS Council adopted a decision (IP/C/40). This decision gave LDCs an extension of 7.5 years i.e. exempted LDCs from having to apply TRIPS provisions, other an Article 3, 4 and 5 until 1 July 2013.

2013 TRIPS Council General Extension of the Transition Period for LDCs

The TRIPS Council adopted a decision on 11 June 2013, granting a further extension of the transition period that was to expire on 1 July 2013. According to this decision – IP/C/64 – the transition period was extended till 1 July 2021. This extension is without prejudice to the 2002 extension for pharmaceutical products.

On this Ha Joon Chang, a prominent academic, also notes

“Economic development is all about absorbing advanced technologies. Anything that makes it more difficult...is not good for economic development. It is as simple as that. In the past...rich countries themselves understood this clearly and did everything to prevent this from happening.... Those countries that are better at absorbing the knowledge inflow have been more successful in catching up with the more economically advanced nations The technological “arms race” between backward countries trying to acquire advanced foreign knowledge and the advanced countries

³ Carlos M. Correa (2010), *supra* note 1, p. 3.

⁴ UNCTAD (2007), *The Least Developed Countries Report 2007: Knowledge, Technological Learning and Innovation for Development*, UNCTAD Secretariat, Geneva, New York, p. 103, available at http://unctad.org/en/docs/ldc2007_en.pdf (last visited 21 April 2014).

trying to prevent its outflow has always been at the heart of the game of economic development.”⁵

It is for this reason that Article 66 was crafted to give LDCs maximum flexibility to develop a viable technological base. Prior to the TRIPS Agreement developed countries had ample policy space to “copy” and “imitate” technologies.^{6 7}

With the advent of the TRIPS Agreement, without a transition period LDCs would have lost all policy space to do what developed countries themselves had done to develop their technological base.

Box 2

UNCTAD, Least Developed Countries Report, 2007⁸

In the case of LDCs, learning will principally revolve around absorbing already existing techniques and adapting them to specific local conditions, namely by imitation. Such imitation ranges from illegal duplication of standard products to deriving inspiration from the latest cutting-edge gadgets. But in most cases of imitation some kind of “reverse engineering” will be essential, based on a variety of skills and activities which would support a purposive search for relevant information and its development through effective interactions within and among firms and other institutions familiar with knowledge acquired from abroad. In that respect, strong IPR protection is likely to hinder rather than to facilitate technology transfer and indigenous learning activities in the early stages of industrialization.

⁵ Ha-Joon Chang (2007), *BAD SAMARITANS: THE GUILTY SECRET OF RICH NATIONS & THE THREAT TO GLOBAL PROSPERITY* (Random House), p. 127.

⁶ Ibid. Ha Joon Chang notes

“...when they were backward themselves in terms of knowledge, all of today’s rich countries blithely violated other people’s patents, trademarks and copyrights. The Swiss ‘borrowed’ German chemical inventions, while the Germans ‘borrowed’ English trademarks and the Americans ‘borrowed’ British copyrighted materials – all without paying what would today be considered ‘just’ compensation.”

⁷ Historical examples of development of IP laws in developed countries shows that strong IP protection has followed technological development and did not precede it. For instance, US refused to protect foreigners’ copyrights until 1891 as it was a net importer of copyright material and saw advantage in protecting only American authors. It also did not recognize copyrights on materials printed outside the US until 1988. The Netherlands abolished patent protection in 1869, allowing Phillips to produce light bulbs without infringing Edison’s patents. The chemicals and textiles industry flourished in Switzerland in the 19th century in the absence of patent protection. India abolished product patent protection for pharmaceutical products in 1970, which allowed the development of a strong generic pharmaceutical industry in India. See Carlos M. Correa (2010), *supra* note 1.

⁸ UNCTAD (2007), *supra* note 4.

III. UTILIZING THE TRANSITION PERIOD FOR LOCAL PRODUCTION OF MEDICINES IN LDCS

Exclusion of pharmaceutical products from patent protection by utilizing the TRIPS transition period can create an enabling environment for generic manufacturing of formulations as well as APIs. Existence of pharmaceutical patents in a country that seeks to promote local pharmaceutical production could impact the freedom of generic companies to manufacture specific products or expand the range of products, which is crucial for utilizing the operational capacity most efficiently and recover the capital expenses incurred. Therefore, utilization of the transition period to support the development of the local pharmaceutical industry is critical for LDCs.

A 2011 report by UNCTAD observed that some LDCs have used the transition period as a major selling point for attracting investment into their local pharmaceutical industry.⁹ However, some LDCs also provided patent protection for medicines despite the availability of the transition period, or have signed free trade and investment agreements that may contain IP provisions curtailing any benefits arising from the transition period. In this context, the report observed that the transition period in itself, though important, will not be sufficient to attract generic companies to invest in local pharmaceutical production.¹⁰ However, the transition period is intended to provide LDCs with the necessary policy space to take measures to facilitate the growth of industrial capacity in desired sectors without being impeded by the existence of patents, which could impede the development of the local industry.

The transition period under Article 66 of TRIPS Agreement has been granted to LDCs with the possibility of extensions recognizing that LDCs lack a sound and viable technological base and therefore would need a transition period so that LDCs are not impeded from developing a sound and viable technological base due to implementation of IP protection according to the standards set by the TRIPS Agreement. This reality of the situation in LDCs is applicable to pharmaceuticals as well as many other fields of technology.

III.1 Utilization of TRIPS transition period by the EAC LDC Partner States

All the four EAC Partner States that are LDCs used to provide patent protection for medicines under their respective national laws even before the TRIPS Agreement.¹¹ However, the industrial property laws in Burundi,¹² Rwanda¹³ and Uganda¹⁴ have been amended over the

⁹ UNCTAD (2011), INVESTMENT IN PHARMACEUTICAL PRODUCTION IN THE LEAST DEVELOPED COUNTRIES: A GUIDE FOR POLICYMAKERS AND INVESTMENT PROMOTION AGENCIES (UNCTAD Secretariat, Geneva, New York), pp. 40-42, available at http://unctad.org/en/Docs/diaepcb2011d5_en.pdf (last visited 21 April 2014).

¹⁰ Ibid.

¹¹ Sisule F. Musungu (2007), *Access to ART and other Essential Medicines in Sub-Saharan Africa: Intellectual Property and Relevant Legislations*, available at <http://apps.who.int/medicinedocs/documents/s18248en/s18248en.pdf> (last visited 21 April 2014).

¹² Law No. 1/13 of July 28, 2009 relating to Industrial Property in Burundi, available at http://www.wipo.int/wipolex/en/text.jsp?file_id=224337 (last visited 24 June 2014).

¹³ Law No. 31/2009 of 26/10/2009 on the Protection of Intellectual Property, available at http://www.wipo.int/wipolex/en/text.jsp?file_id=194215 (last visited 24 June 2014).

¹⁴ The Industrial Property Act, 2013 of 6/1/2014 (on file with the author).

last five years to make use of the transition period under TRIPS and exclude pharmaceutical products from patent protection. Currently only mainland Tanzania has not made use of the TRIPS transition period though the IP law of Zanzibar¹⁵ makes use of the transition period.

In recognition of the need to promote access to medicines, the EAC has developed a regional policy on the use of Public Health-Related WTO-TRIPS flexibilities and the Approximation of National Intellectual Property Legislation, and the Regional Protocol on Public Health-Related TRIPS Flexibilities. The regional policy asks all EAC Partner States that are LDCs 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 by the TRIPS Council. EAC Partner States (LDCs) were also asked to abolish any “mailbox” provision in their existing or draft national patent laws.¹⁶

Along with the Regional Protocol, the EAC Partner States have also adopted the EAC Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA) for 2012-2016. The RPMPOA seeks to promote competitive and efficient pharmaceutical production in the EAC region, facilitate increased investment in pharmaceutical production in the region, strengthen pharmaceutical regulatory capacity in the region, develop appropriate skills and knowledge on pharmaceutical production in the region, utilize TRIPS flexibilities to increase local production of medicines in the region, and mainstream innovation, research and development within the regional pharmaceutical industry.¹⁷

In addition to the EAC Regional Protocol and the RPMPOA, pharmaceutical manufacturing plans have also been developed by the African Union (AU) and the Southern African Development Community (SADC). The AU developed the Pharmaceutical Manufacturing Plan for Africa (PMPA) which was endorsed in 2007 by the AU Heads of State in Accra, Ghana. A partnership was established between the African Union Commission (AUC) and UNIDO in 2011 to implement the PMPA. Pursuant to this, a business plan was developed for implementation of the PMPA,¹⁸ which was approved by the AU Ministers of Health and the African Heads of State Summit in July 2012. The SADC had also developed a Pharmaceutical Business Plan 2007-2013 to secure the availability of essential medicines in the region and support local production of medicines in pursuit of this objective.¹⁹ Like the EAC policy, both the AU and SADC plans stressed on making full use of the TRIPS flexibilities.

All LDC Partner States of the EAC except mainland Tanzania currently provide for the utilization of the transition period for pharmaceutical products till 2016. However, the other LDCs from the region have introduced the transition period in their national laws only

¹⁵ The Zanzibar Industrial Property Act No. 4 of 2008, available at http://www.wipo.int/wipolex/en/text.jsp?file_id=245004 (last visited 24 June 2014).

¹⁶ East African Community (2013), *EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation*, EAC Secretariat, Arusha, Tanzania, available at <http://www.cehurd.org/wp-content/uploads/downloads/2013/05/EAC-TRIPS-Policy.pdf> (last visited 21 April 2014).

¹⁷ James Karuhanga (2013), “EAC embarks on multi-million medicine project”, *The New Times*, 13 May 2013, available at <http://www.newtimes.co.rw/news/index.php?i=15356&a=66831> (last visited 21 April 2014).

¹⁸ African Union (2012), *Pharmaceutical Manufacturing Plan for Africa: Business Plan*, AU Secretariat, Addis Ababa, available at <http://apps.who.int/medicinedocs/documents/s20186en/s20186en.pdf> (last visited 21 April 2014).

¹⁹ SADC Secretariat (2007), *SADC Pharmaceutical Business Plan 2007-2013*, available at http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/SADC%20PHARMACEUTICAL%20BUSINESS%20PLAN%20-APPROVED%20PLAN.pdf (last visited 21 April 2014).

in the past few years. Article 17 of the industrial property law of Burundi (2009) excludes pharmaceutical products from patentability till 2016. In Rwanda, Article 18 of the industrial property law excludes pharmaceutical products from patentability for the purposes of international conventions to which Rwanda is a party. However, the transition periods under the laws of Burundi and Rwanda are not tied to any possible future extension of the transition period by the TRIPS Council. Conversely, in Uganda and Tanzania-Zanzibar not only are pharmaceutical products excluded from patentability till 2016, but the exclusion will be automatically extended if the TRIPS Council agrees to grant any further extension of the transition period. Section 8 (3) (f) of the new Industrial Property Act 2014 of Uganda excludes pharmaceutical products and test data from patent protection until 1 January 2016 or such other period as may be granted to Uganda or LDCs by the TRIPS Council. Section 3 (1) (x) of the Zanzibar Industrial Property Act No. 4 of 2008 excludes pharmaceutical products and processes from patent protection until 1 January 2016 or the expiry of such later period of extension agreed upon by the TRIPS Council.

III.1.1 Membership of ARIPO

Implementation of TRIPS flexibilities in many African countries is significantly impacted by their membership of regional IP organizations like the African Regional Intellectual Property Organization (ARIPO) and Organisation Africaine de la Propriété Intellectuelle (OAPI). The African Union's (AU) Scientific, Technical and Research Commission is also discussing the possibility of establishment of a Pan African Intellectual Property Organization (PAIPO) which will seek to strengthen and harmonize IP protection in Africa, which would be incoherent with AU's goals of maximizing access to medicines.²⁰

Among the LDCs from the EAC region, Rwanda, Tanzania and Uganda are members of ARIPO and are Contracting Parties to the Harare Protocol on Patents and Industrial Designs within the Framework of the African Regional Intellectual Property Organization. Burundi is not a member of any regional IP organization, but may become part of a pan-African IP organization (PAIPO) under the AU if PAIPO were to be established.

The Harare Protocol empowers the ARIPO Secretariat to grant patents on behalf of its Contracting States. The substantive examination of the patent application is conducted by ARIPO and the decision to grant a patent becomes applicable in the Contracting States. The Harare Protocol requires ARIPO to notify each State designated in the application that an application complying with the formality requirements has been filed. Within six months of this notification, the designated State may notify ARIPO that the patent shall have no effect in its territory either because it is not patentable according to the provisions of the Harare Protocol or the nature of the invention is not patentable under the national law of the designated State.

The Harare Protocol does not contain any provision regarding the application of a transition period in any of its Contracting States, though many Contracting States are LDCs who are allowed to benefit from the transition period granted under Article 66.1 of TRIPS and extensions of the period by the TRIPS Council. Therefore, even if an LDC that is a Contracting Party to the Harare Protocol were to exclude pharmaceutical patents from

²⁰ William New (2012), "Move Toward New Pan-African IP Organisation Alarms Observers", *Intellectual Property Watch*, 27 September 2012, available at <http://www.ip-watch.org/2012/09/27/move-toward-new-pan-african-ip-organisation-alarms-observers/> (last visited 21 April 2014).

patentability, if a patent application on a medicine is filed in ARIPO, according to the Harare Protocol the designated LDC will have to issue a notification of rejection within six months.

National laws of some of the EAC Partner States have express provisions that defer to the Harare Protocol. Thus, section 45 of the Industrial Property Act of Uganda states that a patent granted by ARIPO would have the same effect in Uganda as a patent granted under the national law except where the registrar communicates to ARIPO in accordance with the Protocol that the patent granted by ARIPO shall have no effect in Uganda. However, the laws of Burundi and Rwanda do not have express provisions on the relation of national law with patents granted by ARIPO pursuant to the Harare Protocol.

As a study on access to medicines in sub-Saharan Africa observed, though the Harare Protocol allows ARIPO Contracting Parties not to recognize patents granted by ARIPO on a case-by-case basis, rejection of patents granted by ARIPO is not common.²¹ This raises the question about the validity of a patent on a pharmaceutical product that may be granted by ARIPO pursuant to the Harare Protocol in an LDC that excludes pharmaceutical products from patentability. The treaty obligation under the Harare Protocol for such LDCs is to notify the ARIPO about the exclusion of the subject matter from patentability under its national law within a period of six months. Section 3 (6) of the Harare Protocol states that the patent granted shall take effect in those designated countries that have not notified ARIPO within the six month period. However, the provisions of the Harare Protocol cannot have precedence over substantive provisions of the national law and cannot validate the grant of a patent that is expressly excluded from patentability under national law. Such patents would be void *ab initio* under the national law.

Nevertheless, the grant of a patent by ARIPO in accordance with the Harare Protocol but in contravention of the national law of a Contracting Party may in effect give the erroneous impression that a valid patent has been granted and is in existence in the designated country unless it is invalidated through opposition. An example of this is the case of grant of a patent by ARIPO to multinational pharmaceutical company Pfizer Pharmaceuticals for the medicine azithromycin (Zithromax) in 1989. The patent application had designated Ghana, which did not have patent protection for pharmaceutical products till 2009.²² Though Ghana was notified of the grant of patent by ARIPO, no objection was raised within the stipulated time period. This led Pfizer, ARIPO and other third parties to believe that there was a valid patent in force in Ghana.²³

It is also important to note that ARIPO operates under the ARIPO-OAPI-ARCT-WIPO Quadripartite Agreement under which ARIPO acts as a de facto registration agency for patents filed and granted in developed countries without subjecting such patent applications to any meticulous examination.²⁴

²¹ Sisule F. Musungu (2007), *supra* note 11, p. 7.

²² Ghana did not recognize patents on pharmaceutical products till 1992.

²³ Patrick Lumumba Osewe *et al.* (2008), IMPROVING ACCESS TO HIV/AIDS MEDICINES IN AFRICA: TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS FLEXIBILITIES, (The World Bank, Washington, DC), p. 14, available at http://books.google.ch/books?id=dPciaE2fP7gC&pg=PA10&lpg=PA10&dq=ARIPO+patents+and+access+to+medicines&source=bl&ots=vtMstkW5uO&sig=QJL19bcZSiNYXuTfKrLUo_tiUNs&hl=en&sa=X&ei=pFIPU6zCIciitAa3_4CwAQ&ved=0CDAQ6AEwAQ#v=onepage&q=ARIPO%20patents%20and%20access%20to%20medicines&f=false (last visited 21 April 2014).

²⁴ *Ibid.*

In this context, it will be important to see to what extent grants of pharmaceutical patents by ARIPO are applicable to the LDC members of ARIPO. However, there is no data on the website of ARIPO in respect of the patents that have been granted on medicines by ARIPO and the States where such patents are applicable. A patent landscaping on ARVs by Medicines Patent Pool (MPP) shows that 6 patent applications for post-1995 ARVs have been filed in ARIPO out of which 4 have been granted and 2 are pending final determination. The MPP concluded that there has been an increase in patenting of ARVs in many low and middle income countries, including the ARIPO Contracting Parties, in the post-TRIPS era, particularly in countries with significant generic manufacturing capacity but also in many other countries. Secondary patents, i.e. patents on modifications or improvements over an existing patent, are also widely sought and granted. This may extend the exclusivity on those medicines or certain formulations of those medicines beyond the basic patent term on the basis of minor improvements or modifications without any significant advancement over existing knowledge. This can create further barriers to the manufacture and sale of generic medicines by effectively extending the life of a patent monopoly based on minor discoveries.²⁵

An analysis of designated countries in the patent applications in the MPP database shows that at least 10 ARVs have been granted patents by ARIPO, all of which mentions Uganda as a designated country. Some of these applications also mention Tanzania as a designated country and designates Kenya. This means that unless the decision to grant a patent on these ARVs by ARIPO has been rejected within the allowed time by the national patent office of these countries, these patents will take effect under the terms of the Harare Protocol but such patents would be void under the national law. Information is lacking on whether any of these granted patents were rejected by any of the designated national patent offices. Improving access to patent information in ARIPO and national patent offices in the region will help local pharmaceutical companies and procurement agencies to take informed decisions on whether they can enter the market with generic products.²⁶ It may be useful to amend the Harare Protocol to expressly state that no patent granted by ARIPO shall take effect in any designated country if the subject matter is excluded from patentability under the national law of the designated country, notwithstanding six month notice period under section 3 (6) of the Harare Protocol.

²⁵ See Suerie Moon, *et. al.* (2012), “ARV patents on the rise? An analysis of ARV patent status in 75 low-and-middle-income countries”, presentation by Medicines Patent Pool at XIX AIDS Conference, Washington, 25 July 2012, available at <http://www.medicinespatentpool.org/wp-content/uploads/ARV-Patenting-Trends-FINAL2.pdf> (last visited 21 April 2014).

²⁶ Tahir Amin (2008), “Overcoming the Patent Barrier: Ways to Increase Production and Access to Medicines within the Patent System”, Abuja, 18 March 2008, available at <http://www.i-mak.org/storage/Overcoming%20the%20Patent%20Barrier.pdf> (last visited 21 April 2014).

IV. NEED FOR FURTHER EXTENSION OF THE TRANSITION PERIOD

Though some of the LDCs in the EAC region have adopted the transition period for pharmaceutical products in recent years, due to the late adoption of the transition period they will not be able to take advantage of the full transition period. While some of these LDCs have provided for automatic extension of the transition period if the TRIPS Council were to extend the transition period for pharmaceuticals, none of the LDCs have made use of the general transition period that is currently available till 2021.

In view of the technological, financial and administrative constraints that LDCs need to overcome in order to achieve a sound and viable base for local production of medicines, maximum policy flexibility in respect of IP protection and enforcement over the long term will be necessary. In particular, LDCs should view the transition period in a broader systemic context for supporting industrial development of LDCs as that is fundamental to the development of a viable local pharmaceutical industry. Therefore, LDCs should make full use of the general transition period and seek further extensions of this period.

Due to the extension of the general transition period till 2021 without prejudice to the 2002 decision extending the transition period for pharmaceutical products, important issues arise in relation to the availability of the transition period for pharmaceutical products. The first issue is whether there is a need to seek a further extension of the transition period that was granted in 2002 when that decision expires in 2016, and if so, for how long should such an extension be requested? A related issue is whether non-renewal of the 2002 decision would mean that the transition period would expire in 2016 for pharmaceutical products, or whether they would still benefit from the general transition till 2021 and any further extensions of the same? It is important to clarify these questions because according to a press release by the EU after the 11 June 2013 decision the extension of the transition period without prejudice to the 2002 decision implies that LDCs do not have to provide patent protection for medicines only until 2016. However, experts such as Prof. Frederick Abbott²⁷ and Ellen t’Hoen²⁸ have observed that contrary to the interpretation offered by the EU, the extension till 2021 would also apply to patents on medicines.

The 2002 TRIPS Council decision (IP/C/25) states that LDCs will not be obliged to implement or apply sections of the TRIPS Agreement in relation to protection of patents and protection of undisclosed information, with regard to pharmaceutical products. It also states that the decision is without prejudice to the right of LDCs to seek other extensions of the transition period under Article 66.1 of the TRIPS Agreement.

It is important to note that the 2002 decision was triggered by the Doha Declaration on TRIPS and Public Health, which recognized the gravity of public health problems afflicting many developing countries and LDCs and specifically with regard to LDCs asked the TRIPS Council to give effect to the aforesaid decision pursuant to Article 66.1 of the TRIPS

²⁷ Catherine Saez (2013), “What Does WTO Extension For LDCs To Enforce IP Mean For Pharmaceuticals?”, *Intellectual Property Watch*, 2 August 2013, available at <http://www.ip-watch.org/2013/08/02/what-does-wto-extension-for-ldcs-to-enforce-ip-mean-for-pharmaceuticals/> (last visited 4 July 2014).

²⁸ Ellen t’Hoen (2013), [e-drug] TRIPS LDC 2021 extension and 2016 pharmaceutical waiver, e-mail dated 12 June 2013, available at <http://www.essentialdrugs.org/edrug/archive/201306/msg00010.php> (last visited 4 July 2014).

Agreement. Thus, the TRIPS Council recognized this instruction from the WTO Ministerial Conference as a duly motivated request under Article 66.1 and approved the decision adopted by the Ministerial Conference. The momentum of the Doha Declaration pushed the 2002 decision through when it was not certain as to whether the transition period would be extended in 2005 when the 10 year transition period mandated under Article 66.1 expires, or what would be the nature of such an extension. In hindsight, it can be considered to be the right approach that was taken by the WTO member States because the 2005 general extension of the transition period contained several constraining provisions, particularly provisions preventing LDCs from rolling back existing levels of IP protection, which effectively limited the utility of the transition period. However, as the 2005 decision was without prejudice to the 2002 decision, the constraints of the 2005 decision did not apply to pharmaceutical products.

The 2013 extension of the general transition period till 2021 marks a significant improvement over the 2005 decision in that it does not oblige LDCs not to roll back existing levels of IP protection. As the 2013 decision is also without prejudice to the 2002 decision, it would imply that the 2013 decision would not undermine the benefits accruing to LDCs from the 2002 decision. Such a harmonious reading from a public health perspective would suggest that even after 2016, LDCs would not be obliged to apply patent protection for medicines till 2021 and they would even be free to reduce or revoke patent protection for medicines.²⁹

Nevertheless, it would still be important for LDCs to consider seeking an extension of the transition period for pharmaceuticals till 2016 in order to insulate pharmaceutical products from the vagaries and uncertainties of negotiation outcomes regarding any extension of the transition period after 2021.

In order to develop sustainable pharmaceutical manufacturing capability, LDCs have to reduce their dependency on importing API and manufacturing technology from abroad. However, as discussed in this paper, production of APIs requires the development of a viable chemicals industry, and not just the development of an industry that manufactures pharmaceutical formulations. Therefore, the full use of the general transition period till 2021 or beyond must be seen as an integral component of national and regional pharmaceutical manufacturing plan of action for LDCs.

²⁹ Catherine Saez (2013), *supra* note 27.

V. LOCAL PRODUCTION OF MEDICINES: THE SITUATION IN LDC PARTNER STATES OF THE EAC

Though local production of medicines seems to be a self-defining term, it can have different connotations. Local production may be defined in a geographical sense to encompass all production within a defined geographical territory (country or region) regardless of the nationality of ownership and control of the firm. Conversely, local production may also be defined to refer to control of ownership by nationals of a country or countries in a regional group.³⁰ Under the former approach, even production in the country by foreign companies would constitute local production. However, if local production of medicines is seen as production of medicines by domestic companies, it would have significant implications for building national manufacturing capability in pharmaceuticals, which is most needed in LDCs who rely predominantly on import of generic medicines.

Reliance on imports is not sufficient or sustainable to meet the growing demand for essential medicines in these countries. In this context, ownership of production facilities by local nationals may offer several advantages including continuity of production and supply in the face of changing economic circumstances which can avoid disruptions in the pharmaceutical supply chain, building domestic technological capacity and skill development, securing a competitive market environment that may constrain the pricing power of multinational suppliers.³¹

It is also important to understand what is meant by production of medicines in a given context. For some firms, medicine production refers to the production of formulation drugs, while for others with sophisticated technological capability pharmaceutical production could imply manufacturing of active pharmaceutical ingredients (API). An API is the chemical molecule in a medicine that gives it a particular therapeutic effect. The API is combined with other inactive ingredients called excipients to give the medicine a particular form such as tablets, capsules, syrups, drops, intravenous fluids, etc. Sometimes different APIs can be combined using excipients to produce a fixed dose combination (FDC) drug. In order for a country to have sustainable local manufacturing capacity in medicines, it is necessary for them to develop manufacturing capacity in APIs. However, most of the pharmaceutical manufacturers in the EAC region rely predominantly on imported APIs to produce formulations. This is because manufacturing formulations is a less expensive process where knowledge of pharmaceuticals (the process of combining different chemical substances, including the API and excipients to produce a final medical product in a particular form) is sufficient.

While production of some APIs may be expensive and require the use of sophisticated technology, rigorous scientific research, and enormous risks of costly failures and validation trials,³² there may be other APIs that could be easier to produce. For example, Chinese

³⁰ Frederick M. Abbott (2011), TRENDS IN LOCAL PRODUCTION OF MEDICINES AND RELATED TECHNOLOGY TRANSFER (World Health Organization, Geneva), p. 13, available at <http://apps.who.int/medicinedocs/documents/s19063en/s19063en.pdf> (last visited 27 June 2014).

³¹ Ibid.

³² "Formulations and bulk drugs: get the basics right", *The Economic Times*, 30 December 2002, available at http://articles.economictimes.indiatimes.com/2002-12-30/news/27336226_1_bulk-drug-formulations-drug-manufacturers (last visited 21 April 2014).

companies have historically tended to manufacture high volumes of low complexity APIs such as paracetamol.³³ Thus, it may be possible for LDCs from the EAC region to explore production of APIs that are less complex in order to develop their API manufacturing capacity.

Local production of medicines in LDCs, in the current context is the ability by domestic pharmaceutical companies in LDCs to manufacture formulation drugs and their potential to manufacture APIs in the medium to long term. Currently, most of the pharmaceutical manufacturers in Africa are producing formulations only. Even in the formulations segment, technological capacity may vary between firms. Some firms procure ready-made granules³⁴ and compress, coat and package the granules into tablets or pellets, while others may have the capacity to manufacture granules by mixing and blending APIs.³⁵ Most manufacturers in sub-Saharan Africa produce a limited range of simple formulations such as cough and cold sedatives, analgesics, some old generation antibiotics, etc. instead of more complex formulations like ARVs and artemisinin based combination drugs for treatment of malaria.³⁶

While some studies on the viability of local production of medicines in LDCs have pointed to problems of scale leading to high cost of locally produced medicines,³⁷ economies of scale may be a lesser problem in the formulations segment. Research on the economics of pharmaceutical production suggests that technical economies of scale are not particularly significant beyond very low volumes.³⁸ For some medicines, the amount of active ingredient required is very little and therefore it may be possible to produce large numbers of formulations using a single batch of API. For an LDC based firm, the volume of formulations thus produced may be sufficient to meet the national or regional demand. For example, a new antiretroviral medicine – dalutegravir – uses much lower doses of active ingredient (dalutegravir sodium) than other antiretroviral medicines in the same class. As the API is sometimes a major cost component in a medicine, the lower dose of API required to manufacture the formulation of this medicine would mean lower generic production cost and

³³ Janet Bumpas and Ekkehard Betsch (2009), *Exploratory Study on Active Pharmaceutical Ingredient Manufacturing for Essential Medicines*, Health, Nutrition and Population (HNP) Discussion Paper, The World Bank, September 2009, p. 10, available at http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/APIExploratoryStudy.pdf (last visited 21 April 2014).

³⁴ In the pharmaceutical industry, granulation refers to the process of binding different powder particles (active ingredient, excipients and binder agent) to form granules that are required to produce tablets and pellets. Granulation is used to make the blend that is sent for tablet or pellet production have an equal distribution of the active ingredient and excipients in each granule in the correct order and quantity so that the tablets and pellets of the required dosage can be produced. Therefore, granulation is a complex process that precedes the final production of the medicine in tablet or pellet form. For an explanation of the granulation process and technology see Rajesh Agrawal and Yadav Naveen (2011), “Pharmaceutical Processing – A Review of Wet Granulation Technology”, *International Journal of Pharmaceutical Frontier Research*, April-June 2011, vol.1, no.1, pp. 65-83, available at <http://www.ijpfr.com/Dacuments/2011/7.pdf> (last visited 22 June 2014).

³⁵ African Union (2012), *supra* note 18, p. 31.

³⁶ *Ibid.*

³⁷ Warren Kaplan and Richard Laing (2005), *Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines*, Health, Nutrition and Population (HNP) Discussion Paper, The World Bank, available at http://www.who.int/medicines/technical_briefing/tbs/KaplanLocalProductionFinal5b15d.pdf (last visited 21 April 2014).

³⁸ African Union (2012), *supra* note 18, p. 28.

a potentially lower price for the pill.³⁹ Manufacturers can produce 50 or more formulations in a single plant with adaptable equipment.⁴⁰

V.1 Pharmaceutical Manufacturing in LDCs from the EAC

In the EAC region, the pharmaceutical industry remains generally weak. The countries of the EAC region are net importers of pharmaceutical products, particularly from India and China. Pharmaceutical manufacturing in the region involves production of non-complex, high volume essential formulation products like basic analgesics, simple antibiotics, anti-malarial drugs and vitamins.⁴¹ Local production is at a very small scale among the EAC LDCs – Burundi, Rwanda, Uganda and Tanzania. Among these, Tanzania and Uganda are the only countries that have at least 10 local pharmaceutical companies of varying capacity. Burundi and Rwanda each have only 1 local pharmaceutical company.

Countries in the EAC region also do not have adequate drug regulatory capacity to ensure adherence to quality standards. Drug regulatory agencies in Tanzania and Uganda are seeking to become semi-autonomous, while the regulatory infrastructure in Burundi and Rwanda is in its infancy. Medical research institutions generally lack sufficient funding from the government and have to depend on donor funding for research activities, which do not necessarily address regional health priorities.⁴²

Over 90 per cent of the APIs required for production of formulations are imported.⁴³ While a few local firms produce packaging materials, they are very expensive in comparison to similar imported products. Sugar and starch of pharmaceutical grade may be sourced locally, but is also imported in bulk. The production technology and spare parts also have to be sourced from abroad, primarily from India, China and sometimes from Europe. Local personnel do not have adequate knowledge or experience of pharmaceutical production and therefore firms have to recruit expatriates who have such skills and experience. Electricity supply in the region is also intermittent and considered to be the most expensive in the world. Therefore, it is difficult for firms to run plants to their optimum capacity. Adjustments in working hours due to the availability of electricity also increases the labour cost of firms. Most firms, except a few, use labour intensive step-by-step manufacturing instead of automated production lines.⁴⁴

However, these challenges are independent of the relevance of a transition period for implementation of TRIPS. The transition period is only one of the necessary tools to facilitate the development of local production of essential medicines in LDCs, but by no means is it the only tool and it would be erroneous to suggest that by itself the transition period will lead to the development of a competitive local generic pharmaceutical industry. Therefore, there is a need for introducing complementary industry friendly policies like import tax on foreign

³⁹ STOPAIDS (2013), “New HIV drug must get to all who need it”, 14 August 2013, available at <http://stopaids.org.uk/new-hiv-drug-must-get-to-all-who-need-it/> (last visited 21 April 2014).

⁴⁰ Janet Bumpas and Ekkehard Betsch (2009), *supra* note 33, p. 10.

⁴¹ East African Community (2011), *East African Community Regional Pharmaceutical Manufacturing Plan of Action (2012-2016)*, EAC Secretariat, Arusha, Tanzania, p. 17, available at http://feapm.com/fileadmin/user_upload/documents/EAC_Regional_Pharmaceutical_Manufacturing_Plan_of_Action.pdf (last visited 21 April 2014).

⁴² *Ibid.*, p. 20.

⁴³ *Ibid.*, p. 21.

⁴⁴ *Ibid.*, p. 29.

substitutes of locally produced medicines, differential bidding prices in government procurement programmes, etc.

While developing countries seem to have structured import tariffs on formulation drugs, bulk medicines and pharmaceutical inputs for promoting local production of medicines, it has been argued that raising import duties would lead to higher prices for consumers and thus make access to essential medicines unaffordable.⁴⁵ A recent trilateral study by WIPO, WTO and WHO argues that tariffs would lead to an increase in the cost of medicines and thus impact access to essential medicines.⁴⁶ The report quotes a WHO report that recommended the reduction or abolition of any import duties on essential drugs.⁴⁷ Though the current applied tariff rates on formulations and bulk drugs are significantly lower than the bound rate, the report recommends that the bound tariff rate should be cut substantially to align with the applied tariff rate.⁴⁸

However, all the EAC Partner States currently have zero applied tariff on all lines of pharmaceutical products except pharmaceutical waste pharmaceuticals.⁴⁹ Though imports of medicines are substantially high in comparison to locally produced pharmaceuticals in these countries, the imports have not resolved the acute drug shortage that continues to affect these countries. Even the trilateral study by WIPO, WTO and WHO admits that despite a modest improvement in per capita import of formulations by LDCs, the relative level of imports remains very low, particularly given the high disease burden of LDCs.⁵⁰ Therefore, a general reliance on import of medicines for LDCs is not a viable strategy for addressing the need for access to affordable medicines. As concluded in a study on access to imported and locally produced medicines in rural and urban centres in Tanzania, there is a marked urban bias in the availability of imported medicines while local or regionally produced medicines are more equitably available in both urban and rural centres.⁵¹

Moreover, though most of the essential medicines for the treatment of HIV/AIDS, TB and malaria in the region are imported under donor funded programmes like the Global Fund, the Clinton Health Access Initiative (CHAI) and the US President's Emergency Plan for AIDS Relief (PEPFAR), the limited budget of these programmes can only treat a small percentage of the population in these countries who need treatment.⁵² In fact, the high price of

⁴⁵ Muge Olcay and Richard Laing (2005), "Pharmaceutical Tariffs: What is their effect on prices, protection of local industry and revenue generation?", Paper prepared for the Commission on Intellectual Property Rights, Innovation and Public Health, available at <http://www.who.int/intellectualproperty/studies/TariffsOnEssentialMedicines.pdf> (last visited 4 July 2014).

⁴⁶ WIPO, WTO, WHO (2013), PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION: INTERSECTIONS BETWEEN PUBLIC HEALTH, INTELLECTUAL PROPERTY AND TRADE (Book Now Ltd., London), p. 195, available at http://www.wipo.int/export/sites/www/freepublications/en/global_challenges/628/wipo_pub_628.pdf (last visited 4 July 2014).

⁴⁷ *Ibid.*, p. 196.

⁴⁸ *Ibid.*, p. 197.

⁴⁹ EAC Secretariat (2012), COMMON EXTERNAL TARIFF: 2012 VERSION, pp. 140-142.

⁵⁰ WIPO, WTO, WHO (2013), *supra* note 46, p. 195.

⁵¹ Phares G.M. Mujinja, *et. al.* (2014), "Local production of pharmaceuticals in Africa and access to essential medicines: 'urban bias' in access to imported medicines in Tanzania and its policy implications", *Globalization and Health*, vol. 10, available at <http://www.globalizationandhealth.com/content/pdf/1744-8603-10-12.pdf> (last visited 30 June 2014).

⁵² Olulomire Oguniye, *et. al.* (2009), AIDS, AFRICA AND ARVS: DOMESTIC PRODUCTION AS A SOLUTION TO THE TREATMENT GAP, p. 9, available at <https://blogs.commonsgorgetown.edu/globalsolvercommunity/files/Domestic-Production-as-a-Solution-to-the-Treatment-Gap.pdf> <http://www.globalizationandhealth.com/content/pdf/1744-8603-10-12.pdf> (last visited 30 June 2014).

medicines like ARVs charged by multinational pharmaceutical companies, rather than import tariffs, is the predominant reason for the high cost of such medicines in these countries. While the availability of generic medicines from countries like India can make the drugs more affordable, this may not be the case for drugs required for second and third line treatment for HIV/AIDS, or the need for new medicines to combat increasing drug resistance, as generic production of these drugs could be blocked by the existence of patents.⁵³

In this context, a rational approach towards the use of tariff measures to support local production of medicines should be followed. For essential medicines for which currently there is no local manufacturing capacity, a raise in import tariffs may not be feasible. However, a rise in import tariff to strengthen local manufacturing for some simple formulations such as paracetamol, chloroquine, etc., may be considered. Indeed, the UN Special Rapporteur on the right to health recommends levying taxes on medicines that could be locally produced.⁵⁴ As pointed out by the local manufacturers in Uganda, a 10 per cent tax on import of foreign substitutes of medicines that are also produced locally would not have an adverse impact on access to medicines because the retail margins are very high. The re-introduction of a 10 per cent tax on certain imported medicines in Tanzania did not lead to a price increase for the products concerned.⁵⁵

Some of the measures that could be considered to support the local pharmaceutical industry include differential prices for local manufacturers in the bidding process for drug procurement, establishment of regional procurement mechanism, reducing the cost of import of APIs as well as packaging material, prohibition of import of certain simple formulations, enhanced depreciation allowance for plant and machinery, as well as financial support in the form of working capital credits and export incentives. Strengthening regulatory oversight will also complement local production by preventing the entry of substandard medicines into the market. Local preference schemes in medicines procurement by national procurement agencies can help to level the playing field and break down entry barriers faced by local pharmaceutical firms in the face of large overseas suppliers of medicines who can engage in marginal cost pricing.⁵⁶ A regional pooled procurement mechanism could offer the opportunity of improving quality and pooling of local pharmaceutical firms' capacity to meet regional needs for essential medicines. Availability of affordable financing will also be critical for reducing the cost of import of APIs and packaging material for local manufacturers of formulation drugs.

Tax incentives can have a significant impact on the ability of local pharmaceutical companies to supply drugs at low cost. For example, in Nigeria tax incentives on locally produced ARVs have enabled a Nigerian firm – Archy Pharmaceuticals – to rapidly scale-up

⁵³ Ibid., p. 11.

⁵⁴ United Nations (2013), *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, on access to medicines*, Report submitted to the twenty-third session of the Human Rights Council, A/HRC/23/42, 1 May 2013, p. 7, available from http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session23/A-HRC-23-42_en.pdf (last visited 30 June 2014).

⁵⁵ Nazeem Mohamed (2009), "The role of local manufacturers in improving access to essential medicines: Creating opportunities for the scale-up of local pharmaceutical production", Africa Health, November 2009, p. 40, available at http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/MeTA-Uganda_AfricaHealth.pdf (last visited 21 April 2014).

⁵⁶ Sudip Chaudhuri, *et al.* (2010), "Indian generic producers, access to essential medicines and local production in Africa: an argument with reference to Tanzania", *European Journal of Development Research*, vol. 22, number 4, p. 13, available at <http://oro.open.ac.uk/26384/2/FD41259A.pdf> (last visited 21 April 2014).

ARV production.⁵⁷ Generally, a mix of the following types of tax incentives are used by most countries:

- Tax deduction – a percentage of taxable income is deducted from the tax liability. Sometimes super deductions above 100 per cent of the tax liability is offered.
- Tax credits – a percentage of research and development (R&D) expenditure incurred is deducted from the tax liability.
- Depreciation allowance – where firms benefit from a reduced tax liability by offsetting depreciation expenses on plant and machinery by showing a higher depreciation expense in their books in the initial years of operation when productivity is usually high.
- Tax exemption – where a specific tax liability is eliminated.⁵⁸

Many developing countries have explored the use of fiscal incentives to stimulate pharmaceutical manufacturing. Brazil, China, Colombia, India, Malaysia, Singapore and South Africa have offered various types of fiscal incentives to stimulate R&D such as depreciation allowances, exemptions and super-deductions over 100 per cent of R&D expenditure.

Another significant challenge for local pharmaceutical companies is the lack of WHO Good Manufacturing Practice (GMP) certification for their manufacturing plants and WHO pre-qualification for their products, which disqualifies them from procurement tenders supported by international donor agencies. However, implementation of GMP standards could also increase the manufacturing cost for these firms.

V.1.1 Pharmaceutical Manufacturing in Uganda

In Uganda, the demand for health supplies and medicines has been increasing steadily over the last two decades.⁵⁹ A study by UNCTAD points out that though the pharmaceutical sector in Uganda is small and nascent, it has been working towards expanding its local production capacity in recent years. The national drug policy of Uganda seeks to maximize procurement of locally produced medicines, encourages local pharmaceutical manufacturers to produce essential drugs at competitive prices and also encourages procurement agencies to source available essential drugs locally to support the local industry. The local firms in Uganda are only producing formulations rather than manufacturing APIs, which are predominantly imported.⁶⁰

⁵⁷ Roger Bate (2008), *Local Pharmaceutical Production in Developing Countries: How Economic Protectionism Undermines Access to Quality Medicines*, Campaign for Fighting Diseases, p. 8, available at <http://www.libinst.ch/publikationen/LI-LocalPharmaceuticalProduction.pdf> (last visited 4 July 2014).

⁵⁸ Valerie Mercer-Blackman (2008), “The Impact of Research and Development Tax Incentives on Colombia’s Manufacturing Sector: What Difference Do They Make?”, IMF Working Paper, WP/08/178, p. 9, available at <https://www.imf.org/external/pubs/ft/wp/2008/wp08178.pdf> (last visited 26 June 2014).

⁵⁹ UNIDO (2007), *Pharmaceutical Sector Profile: Uganda*, United Nations Industrial Development Organization, Vienna, 2010, p. 7, available at https://www.unido.org/fileadmin/user_media/Services/PSD/BEP/Uganda%20Pharma%20Sector%20Profile_TE_GLO05015_Ebook_.pdf (last visited 21 April 2014).

⁶⁰ UNCTAD (2011), *Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries: A Series of Case Studies by the UNCTAD Secretariat*, United Nations, New York and Geneva, 2011, p. 267, available at http://unctad.org/en/PublicationsLibrary/diaepcb2011d7_en.pdf (last visited 21 April 2014).

The primary challenges for local production of medicines in Uganda are

- 1) Technology, machinery and associated personnel skills have to be brought from outside Uganda
- 2) All APIs as well as almost all excipients and some packaging materials are imported
- 3) Most manufacturers rely on step-by-step manual manufacturing processes which leads to underutilization of productive capacity. Currently, only Quality Chemicals and Abacus Parenteral Drugs Ltd. have fully automated production processes for certain production lines.⁶¹
- 4) Poor electricity supply increases cost of operating back up power generators for manufacturers.⁶²

The increasing burden of HIV/AIDS and the inability of the government to meet the local demand for drugs has been the principal motivation behind the government's efforts to promote local production of medicines. Out of the 11 local pharmaceutical companies 2 companies (Kampala Pharmaceutical Industries and Quality Chemicals Industries Ltd.) currently produce antimalarial formulations and 1 company (Quality Chemicals Industries Ltd.) produces ARVs.

Quality Chemicals Industries Ltd. is the only producer of antiretroviral (ARV) and antimalarial drugs following its establishment as a joint venture between Quality Chemicals Ltd. and the Indian generic company Cipla in 2005. In 2006, Abacus Parenterals was established with 75 per cent Indian and 25 per cent Kenyan ownership to manufacture parenteral drugs such as liquid intravenous fluids. Local production of intravenous fluids brought down prices by 30 per cent, as local production of such products is more economical than importing them due to higher storage and transportation costs.⁶³ The machinery for producing parenterals was imported from the US and other production, sterilization and packaging machinery was sourced from India, France and Japan. Significantly, local production could reduce prices even though the production capacity was not fully utilized due to insufficient market size.

Another constraint for local manufacturers is the difficulty in marketing their products in the face of stiff price competition from imported generic medicines. The initial investment for the technology is high in comparison with generic producers from some developing countries who can sell their products at cheaper prices than newly established local firms. Therefore, there is need for sustained government support through various legal and policy interventions to level the playing field for local producers in the market.

90 per cent of medicines in Uganda's pharmaceutical market are imported, predominantly from India and increasingly from China. Price is the determining factor in the generic market of Uganda where the local industry faces overwhelming competition from generic manufacturers from India and China. As the government is the biggest buyer of medicines, the low price of imported generics leaves out local companies in government tenders. The Uganda Pharmaceutical Manufacturer's Association (UPMA) has been

⁶¹ Ibid., p. 16.

⁶² UNIDO (2007), *supra* note 59, p. 2.

⁶³ Ibid., p. 2.

advocating for price differential between international bidders and the local industry, as pursued by Kenya and Tanzania.⁶⁴

Box 2

Case Study of Quality Pharmaceuticals

With the support of the government, Quality Chemicals Ltd. – a state owned life sciences and distribution company – was transformed from a local distributor of drugs to develop manufacturing capacity through a joint venture with the Indian generic manufacturer Cipla in 2005. Upon the request of the government of Uganda to provide technical assistance in developing local manufacturing of ARVs and anti-malarial drugs under license from Cipla, 36.55 per cent of the stakes in Quality Chemicals was acquired by Cipla through its wholly owned subsidiary Meditab Holdings in the newly formed company – Quality Chemicals Industries Ltd.

Though Uganda did not use the TRIPS transition period to exclude pharmaceutical products from patentability until the new IP law came into force in 2014, the investment by Cipla seems to have been motivated, among other factors, by a perception that Uganda can benefit from the transition period. According to the Yusuf Hamied, the chairman of Cipla, the joint venture between Quality Chemicals and Cipla has been motivated by the availability of the transition period for Uganda as an LDC (UNCTAD).⁶⁵ According to George Baguma, the former director of marketing at Quality Chemicals, the partnership with Cipla has contributed to technology transfer, with more than 200 staff being trained and the company investing in research to continue producing ARVs and anti-malarials.⁶⁶ The plant of Quality Chemicals in Luzira, Uganda and its products received WHO pre-qualification approval in 2010 and in 2012, which attests that the firm has achieved pharmaceutical manufacturing capability of international quality standards on the basis of its collaboration with Cipla.

Following the joint venture agreement with Cipla, Quality Chemicals started manufacturing formulations of ARVs and artemisinin-based combination therapies (ACT) in 2009. However, the locally manufactured ARVs have been more expensive than generic ARVs imported from India, China and other countries.

In spite of the challenges that have confronted Quality Chemicals, Cipla has increased its investment in the firm. In 2013, Cipla gained majority stake of 51 per cent in Quality Chemicals. The acquisition is reported to be part of Cipla's plans to have a direct presence in manufacturing and sales in global markets. With Cipla gaining management control of Quality Chemicals, it will transfer many of its technology capabilities to Quality Chemicals to expand its production and sales focus to many therapeutic segments.⁶⁷

Cipla's investment in Quality Chemicals has been driven by a range of incentives such as the provision of free land by the government to set up the plant, free setup of the entire

⁶⁴ Nazeem Mohamed (2009), *supra* note 55.

⁶⁵ UNCTAD (2011), *supra* note 9, p. 273.

⁶⁶ Rachel Ninsiima (2013), "Drug giants move in to block generics", *The Observer*, 18 June 2013, available at http://www.observer.ug/index.php?option=com_content&view=article&id=25923:drug-giants-move-in-to-block-generics&catid=58:health-living&Itemid=89 (last visited 24 June 2014).

⁶⁷ C.H. Unnikrishnan (2013), "CIPLA buys majority stake in QCIL Uganda", *Livemint*, 21 November 2013, available at <http://www.livemint.com/Companies/buPBA78mkV7YJksm4iKhQO/Cipla-buys-majority-stake-in-QCIL-Uganda.html> (last visited 24 June 2014).

infrastructure (factory and production facilities, road, electricity and water), salaries of Cipla's pharmaceutical experts for training activities with the local staff, and assurance from the government to procure ARVs worth \$30 million per year for 7 years and a 10 year tax holiday. Cipla provided the necessary hardware technology for production including manufacturing and testing technologies, information on sourcing of raw materials, packaging technologies and production plant design, as well as know-how about daily running of the plant, including quality assurance and quality control. Cipla officials provided training to staff from Quality Chemicals in auditing requirements and in WHO GMP compliance. While currently Quality Chemicals only produces formulations, it intends to develop production capacity in APIs in future.⁶⁸

In 2006, the EAC had imposed a 10 per cent tax on all importation of medicines except for ARVs, malaria and TB drugs, but the tax was withdrawn after intense lobbying by the pharmaceutical industry. However, the tax was re-introduced in Tanzania, where it was seen that the tax did not increase consumer prices. Other measures that have been followed in other African countries like Nigeria and Ghana include ban on imports of medicines being manufactured locally.⁶⁹

With regard to IP issues, the existence of basic or second use patents on medicines may have an impact on production decisions by a local manufacturing firm and its ability to expand its production to other formulations. The product line of Quality Chemicals on ARVs suggests that production decisions could have been influenced by the existence of basic or secondary use patents on certain ARVs. Quality Chemicals currently produces three ARVs – Duovir, a combination of lamivudine, stavudine and nevirapine; Effavir 600 (efavirenz); and Nevimune (200 mg of nevirapine).⁷⁰ Out of all these ARVs, only one ARIPO patent application for the liquid formulation of lamivudine mentions Uganda as a designated country.⁷¹ The company also plans to manufacture a combination formulation of tenofovir, efavirenz and emtricitabine on which there is no patent granted by ARIPO. Another product in the pipeline, Duomune – a combination of tenofovir and lamivudine – also does not have any patent in ARIPO. However, the company also plans to manufacture a formulation of tenofovir and emtricitabine on which there is an ARIPO patent in force till 2024 that mentions Uganda as a designated country.⁷²

In contrast to ARVs, Quality Chemicals only produces one anti-malarial drug – Lumartem – under license from Cipla.⁷³ In this segment, Kampala Pharmaceutical Industries has a diversified range of products.⁷⁴ Due to the lack of access to patent information on malaria drugs in the region, this analysis could not assess whether patents were a significant factor in production decisions by KPI. However, a critical challenge for local production of anti-malaria drugs is the fact that the Affordable Medicines for malaria (AMFm) facility has

⁶⁸ UNCTAD (2010), THE LEAST DEVELOPED COUNTRIES REPORT 2010: TOWARDS A NEW INTERNATIONAL DEVELOPMENT ARCHITECTURE FOR LDCS (United Nations, New York and Geneva), p. 253, available at http://unctad.org/en/docs/ldc2010ch7_en.pdf (last visited 24 June 2014).

⁶⁹ Ibid, p. 42.

⁷⁰ Quality Chemical Industries Ltd., http://www.qcil.co.ug/index.php?option=com_k2&view=item&layout=item&id=12&Itemid=62 (last visited 21 April 2014).

⁷¹ Medicines Patent Pool, Patent Status Database, available at <http://www.medicinespatentpool.org/patent-data/patent-status-of-arvs/> (last visited 21 April 2014).

⁷² Ibid.

⁷³ Quality Chemical Industries Ltd., *supra* note 70.

⁷⁴ Kampala Pharmaceutical Industries Ltd., <http://kpi.co.ug/#> (last visited 21 April 2014).

severely reduced the anti-malarials market for local producers in Africa by subsidizing the availability of pre-qualified drugs from other countries at a low cost. This restricts the growth of local manufacturing in this sector and can limit the availability of affordable locally manufactured anti-malarial drugs when the AMFm subsidies may stop for drugs from abroad. In recognition of this challenge, in 2011 the African Leaders Malaria Alliance (ALMA) recommended that the local industry should be provided with appropriate support to reach appropriate quality standards.⁷⁵

The experience with local manufacturing initiatives in Uganda suggests that the policy space for developing local productive capacity in pharmaceuticals available during the TRIPS transition period has to be utilized through appropriate legal and policy interventions that support the development and growth of the local pharmaceutical industry over the long term. The transition period offers a platform, the freedom to operate and manufacture generic medicines without risking patent infringements, which can lead to investments in the local pharmaceutical sector. However, this opportunity has to be guided and supported over the short, medium and long-term through appropriate policy interventions.

V.1.2 Pharmaceutical Manufacturing in Tanzania

The patent law of mainland Tanzania does not utilize the transition period granted to LDCs under TRIPS and does not exclude pharmaceutical products from patentability. However, the industrial property law of Zanzibar excludes pharmaceutical products from patentability. Local production accounts for 30 per cent of the pharmaceutical market in Tanzania and 70 per cent of the national drug requirements are imported. The pharmaceutical sector comprises eight manufacturing industries, all of which import APIs mostly from India and China, and produce formulations.⁷⁶ The reliance on imports of APIs is a significant factor for local formulations producers because the time lag between placing purchase orders for APIs and their delivery delays the start of production (about 6 months) and adds to the working capital costs of the pharmaceutical manufacturer.⁷⁷ This also applies to manufacturers in Uganda and many other countries in Africa.

Most of the local pharmaceutical production is concentrated on less sophisticated medicines such as simple antibiotics, cough and cold preparations, etc. and generally local firms do not have the capacity to produce sophisticated pharmaceutical products. The Tanzania Pharmaceuticals Industry (TPI) – a former state owned company based in Arusha – is the leading manufacturer of ARVs, though a private company (Shelys Pharmaceutical Industry, based in Dar-es-Salaam) has also started manufacturing ARVs following a technology transfer agreement with Roche. However, even the leading manufacturer of ARVs – TPI – has very limited production capacity (100 million units).⁷⁸

Government and donor-funded medicines are largely procured by a semi-autonomous government buying agency, the Medical Stores Department (MSD) by issuing tenders. Local manufacturers are eligible for the preferential margins on bid prices and compliance with

⁷⁵ African Union (2012), *supra* note 18, p. 35.

⁷⁶ Robert M. Mhamba and Shukrani Mbirigenda (2010), *The Pharmaceutical Industry and Access to Essential Medicines in Tanzania*, EQUINET Discussion Paper 83, p. 9, available at <http://equinetafrica.org/bibl/docs/DIS83TZN%20medicines%20mhamba.pdf> (last visited 21 April 2014).

⁷⁷ African Union (2012), *supra* note 18, p. 33.

⁷⁸ Kinsley Rose Wilson, *et.al.* (2012), “The make or buy debate: Considering the Limitations of Domestic Production in Tanzania”, *Globalization and Health*, vol. 8, available at <http://www.globalizationandhealth.com/content/pdf/1744-8603-8-20.pdf> (last visited 21 April 2014).

Tanzanian Good Manufacturing Practices (GMP) standards would be sufficient for government procurement. However, most procurement tenders that are funded by international donors require suppliers to be compliant with WHO GMP and pre-qualification standards. None of the Tanzanian firms except Shelys has been found to be compliant with the WHO standards. Therefore, even though local producers have a potentially substantial local market access advantage over foreign companies in the tender process, in reality they have limited access to the local market.⁷⁹ In spite of preferential treatment in the tendering process, 74 per cent of the purchases by MSD continue to be imports.⁸⁰

In addition to preferential margins in tender prices for local manufacturers, since 2008 a 10 per cent import duty was imposed on all pharmaceutical formulations except ARVs, anti-malarial, anti-TB drugs and imports by MSD. Local manufacturers also benefit from tax exemption on imports of raw materials, components and machinery, as well as exemption from value added tax or excise for domestic formulations. Such interventions can help to break down entry barriers facing local firms that are created by large overseas suppliers with market power engaging in limit pricing.⁸¹

Box 3

ARV Production by Shely's Pharmaceuticals

TPI's foray into ARV production was supported by a technology transfer agreement in 2005 between TPI and a former member of the Research and Development Institute of the Government Pharmaceutical Organization (GPO) of the Ministry of Health of Thailand. However, the technology transfer agreement could not be put into place due to the lack of any legislative framework for the same in Tanzania. In 2006, TPI established a partnership with a German NGO, Action Medeor, to construct a new ARV manufacturing facility with a 2 year grant of US \$6 million from the European Commission. The objective of the grant was to build a facility in line with WHO pre-qualification standards and build technical capacity to produce ARVs. However, the grant amount was very small for these purposes. In the case of the joint venture between Quality Chemicals and Cipla in Uganda, Quality Chemicals had internally raised US \$38 million to construct an internationally certified facility.⁸²

The National Drug Policy of Tanzania that was adopted in 1991 aims to make Tanzania self-reliant in formulations and attain self-sufficiency on the local production of intermediaries and raw materials (API) in the long run. To that end, the policy states that "the promotion and development of the national pharmaceutical industries will become a multi-sectoral activity, both encouraging national and international investment and transfer of technology. *It will provide the necessary protection, until the industries have matured to full competitiveness* (emphasis added)."⁸³ However, in practice the government has struggled to live up to this commitment of providing the necessary protection to the local pharmaceutical industry.

Since independence, the development of the pharmaceutical industry in Tanzania was driven by the State till the 1980s. This prevented private Tanzanian entrepreneurship to take

⁷⁹ Robert M. Mhamba and Shukrani Mbirigenda (2010), *supra* note 77, pp. 10-11.

⁸⁰ Sudip Chaudhuri, *et al.* (2010), *supra* note 56, p. 7.

⁸¹ *Ibid.*, p. 13.

⁸² Kinsley RoseWilson, *supra* note 79.

⁸³ Sudip Chaudhuri, *et al.* (2010), *supra* note 56, p. 15.

advantage of privatization of industries, particularly in pharmaceuticals. On the other hand, privatization since the 1980s led to a weakening of industrial capacities created under State control. This is reflected in the case of TPI and Keko Pharmaceuticals – two major State-owned firms, where after privatization the government stake was reduced to 40 per cent. However, the government has stopped providing any funds to these companies even after reducing its holdings, thereby impairing their growth. Moreover, industrial R&D institutions set up in the early 1980s have not developed strong links with industrial firms and lacks funding.⁸⁴

With a small and weak private sector, there is need for an active role by the government in promoting local production of medicines. Tanzania also lacked the opportunity for technological learning about medicine production that India had due to the existence of patent protection for medicines in Tanzania. However, there is weak political support for full utilization of TRIPS flexibilities. While the ministry of health encourages the use of flexibilities, other government departments continue to push for increased IP protection.⁸⁵

Some of the supportive measures that could be taken in the interest of developing the local pharmaceutical industry include introduction of a “negative list” of products for which imports would be prohibited, close collaboration between the government and the industry in drug production and procurement, achieving economies of scale through regional pooled procurement mechanisms, and assisting local firms to improve drug quality. Some of these measures have been successfully followed by other countries to develop the domestic pharmaceutical industry.

For example, Ghana and Nigeria have prohibited import of certain drugs, which are technologically simple to produce, such as paracetamol tablets.⁸⁶ The ministry of health in Tanzania has recommended the introduction of such a list of import prohibition for drugs for which substantial local production capacities have been created but not utilized. While substituting imports, prices for these medicines could be kept low through intense competition among local manufacturers.⁸⁷

V.1.3 Pharmaceutical manufacturing in Burundi and Rwanda

Rwanda and Burundi currently have very low level of local pharmaceutical manufacturing capability. Both countries have only one pharmaceutical manufacturing company each. In Burundi, a private sector company called the Société Industrielle Pharmaceutique (SIPHAR) produces a narrow range of medicines.⁸⁸ In Rwanda, currently there is no company that

⁸⁴ *Ibid.*, p. 16.

⁸⁵ *Ibid.*

⁸⁶ In 2005, Nigeria banned the import of 18 essential medicines to encourage local production. This has led to the procurement of locally produced medicines below the international reference prices. UNIDO (2011), “Pharmaceutical Sector Profile: Nigeria”, *Global UNIDO Project: Strengthening the local production of essential generic drugs in least developed and developing countries*, pp. 48-49, available at http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/Nigeria_Pharma%20Sector%20Profile_032011_Ebook.pdf (last visited 4 July 2014).

⁸⁷ Sudip Chaudhuri, *et al.* (2010), *supra* note 56, pp. 16-17.

⁸⁸ National Health Development Plan, 2011-2015, Ministry of Public Health and Fighting AIDS, Republic of Burundi, available at http://www.nationalplanningcycles.org/sites/default/files/country_docs/Burundi/burundi_pnds_2011_-_2015-en.pdf (last visited 21 April 2014).

manufactures pharmaceutical drugs locally on a big scale. A public sector company called LABOPHAR manufactures in a small scale some non-sterile drugs such as tablets, capsules, syrups, ointments, suppositories and infusions.⁸⁹

The Ministry of Health of Rwanda has adopted the Third Health Sector Strategic Plan (HSSP III) which seeks to increase local production of medicines and enhance good manufacturing practices.

In 2011, CSM Global Pharma, an Indian joint venture between Cadila Pharmaceuticals and the US based Holtzman group, announced plans to invest US\$ 65 million in a manufacturing facility in Kigali, Rwanda in collaboration with the Rwandan Development Board (RDB).⁹⁰ The plant is planned to become operational in 2015 and manufacture a range of formulations for the local market. The plant is also expected to manufacture APIs to cater to the regional market. According to the RDB the plant is expected to help Rwanda achieve independence from most pharmaceutical imports by locally manufacturing high quality products to be sold at competitive prices. The RDB seeks to attract investment in pharmaceutical production in Rwanda based on the potentially growing market size for medicines in Rwanda, opportunities to tap the EAC market as well as neighbouring States like the Democratic Republic of Congo, and also the availability of the TRIPS transition period for Rwanda as an LDC until 2016.

VI. CONCLUSIONS AND RECOMMENDATIONS

The EAC Partner States are heavily reliant on import of pharmaceuticals. This reliance makes affordable access to medicines for the people in the region unsustainable in the long run unless the EAC Partner States are able to develop local manufacturing capabilities in medicines. The EAC Partner States have to move beyond formulations manufacturing and manufacture active pharmaceutical ingredients. Though currently most of the medicines supplied in the region are sourced from generic companies in developing countries like India and China, the reliance on such firms may not be sustainable in the long run as these firms may be restrained due to the existence of patents from producing and selling generic versions of new generations of medicines that may be required for treatment increasingly.

As local firms expand their manufacturing capacity to produce APIs, multinational firms are likely to use patents as a business strategy to restrain competition from local firms. Therefore, in order to achieve sustainable local manufacturing capacity in the LDCs from the EAC, full utilization of the transition period under Article 66.1 of the TRIPS Agreement to exclude IP protection in pharmaceutical and related industries is necessary to provide a facilitative environment for such industries to thrive.

⁸⁹ Rwanda Development Board, *Pharmaceutical Drugs Sector in Rwanda*, available at http://www.rdb.rw/fileadmin/user_upload/Documents/Manufacturing/Pharmaceuticals_Profile.pdf (last visited 21 April 2014).

⁹⁰ Gareth Macdonald (2011), "Cadila JV to set up plant in Rwanda", available at <http://www.in-pharmatechnologist.com/Regulatory-Safety/Cadila-JV-to-set-up-plant-in-Rwanda> (last visited 21 April 2014).

The LDC Partner States from the EAC currently have the option of denying patent protection for pharmaceutical products both under the specific transition period for pharmaceutical products available till July 2016 as well as under the extended general transition period till 2021. However, three LDCs from the region – Burundi, Rwanda and Uganda – have implemented only the specific transition period for pharmaceutical products in recent years and mainland Tanzania has not implemented the transition period at all. Therefore, the LDC Partner States from the EAC have given themselves very limited opportunity to make full utilization of the transition period under Article 66.1 of the TRIPS Agreement to facilitate local or regional production of pharmaceutical products. These LDCs will therefore be unable to avail of the transition period for the fullest possible duration. Implementation of both the TRIPS transition period for pharmaceutical products as well as the general transition period will be necessary in this context. Utilization of the general transition period is particularly important to support the development of other that can support the local pharmaceutical industry.

For example, the general transition period may be useful in supporting the development of a strong chemicals industry that can graduate to production of APIs. Long-term sustainability of the local pharmaceutical industry would require developing internal capability in manufacturing APIs and reduce dependency and high import costs for obtaining APIs. Particularly, there is a need to develop second line ARVs, as generic companies from India and China will not be able to manufacture and supply APIs for these drugs to local formulations manufacturers.⁹¹ The establishment of a chemicals industry is particularly important in this context. Indeed, many present multinational pharmaceutical companies began their business in the chemicals industry. For example, Boehringer Ingelheim started its operations as a manufacturer of tartaric acid and lactic acid for the food industry in the 19th century.

Even though local pharmaceutical manufacturers in the EAC mainly produce formulations, production decisions may be impacted by the availability of patents on certain medicines. Decisions to expand the range of products manufactured by pharmaceutical companies to maximize utilization of production capacity, may be restricted by the existence of patents on basic medicines or patents on secondary use or particular forms of such medicines. Significantly, three countries in the region – Rwanda, Uganda and Tanzania – are member States of the African Regional Intellectual Property Organization which has granted basic and second use patents on ARVs that may be in force in these countries. ARIPO operates under the framework of the Harare Protocol, which does not contain any provision relating to the use of the TRIPS transition period by LDCs even though many of its Contracting Parties are LDCs.

As the Harare Protocol states that a patent granted by ARIPO without any notification of objection from the designated State that the subject matter is excluded from patentability under its national law, shall take effect in such designated State. In many situations where the ARIPO has granted patents on medicines in designated States that have excluded pharmaceutical products from patentability, this creates an anomalous situation where the patent would be void *ab initio* under the national law, but the existence of a patent granted by ARIPO would give the erroneous impression of the existence of a valid patent. Therefore, there is a need to bring the Harare Protocol into consistency with national laws excluding pharmaceutical products from patentability. As the only country from the EAC region that has

⁹¹ African Union (2007), *supra* note 18, p. 80.

not made use of the TRIPS transition period, Tanzania should expeditiously incorporate the transition period till 2021 under its national law. Moreover, there is need for greater patent information on pharmaceutical patents granted by ARIPO.

A related issue is the possible establishment of a Pan-African Intellectual Property Organization (PAIPO) which could seek to strengthen and harmonize IP protection among all African countries. This could substantially undermine any attempt to use the transition period and other TRIPS flexibilities by LDCs as well as impede the implementation of the regional pharmaceutical manufacturing plan of the EAC as well as the pharmaceutical manufacturing plan adopted by the African Union.

The implementation of the EAC Regional Pharmaceutical Manufacturing Plan of Action as well as the business plan for implementation of the Pharmaceutical Manufacturing Plan of Action (PMPA) for Africa are two major sub-regional and regional initiatives to support local manufacturing of medicines. Full utilization of the TRIPS flexibilities to support local production of medicines is a fundamental element of these plans. The PMPA business plan clearly states the need for African LDCs to seek an extension of the transition period for pharmaceutical products for another 10 years after 2016 and assist LDCs to incorporate the TRIPS flexibilities into their national legislations.⁹² As the example of Quality Chemicals in Uganda suggests, the availability of the transition period can be a significant motivating factor for leading generic companies from developing countries such as Cipla to invest in joint venture partnerships to manufacture locally. Such partnerships can be crucial in the process of long-term development and adaptation technological skills and know-how.

The issues confronting local pharmaceutical companies in LDCs goes beyond intellectual property related issues. Nevertheless, the TRIPS transition period remains even more relevant in this context because it provides the LDCs the maximum flexibility to ensure that necessary policy interventions to support local production of medicines are not constrained by IP protection and enforcement. While there is an attempt to introduce TRIPS flexibilities into national laws of these countries with regard to pharmaceutical patents, it will be necessary for these countries to look at TRIPS flexibilities as a tool for advancing industrial development generally.

In this context, this paper suggests the following recommendations:

- While some countries in the EAC region have implemented the transition period for pharmaceutical products in recent years, Tanzania continues to be the only country that is yet to implement the transition period. All LDCs in the region should implement the transition period under their national laws to benefit from it. Moreover, these countries should also implement the general transition period under TRIPS that is currently available till 2021.
- Those LDCs that are Partner States of EAC and have excluded pharmaceutical products from the scope of patentability under their national laws should treat any pharmaceutical patent issued by ARIPO to be void *ab initio* within their territories.
- There is need for more information about patents that have been granted on medicines by ARIPO and whether those are in force in those countries, as this can impact the manufacturing and marketing of locally produced generic medicines.

⁹² Ibid., p. 79.

- The EAC Partner States should consider moving an amendment to the Harare Protocol declaring that any pharmaceutical patent granted by ARIPO shall not take effect in a Contracting Party that excludes such products from patentability even if a specific notification of such exclusion in relation to the patent application has not been issued by the Contracting Parties patent office. A general notification to ARIPO of the legal provisions under the national law in this respect should be sufficient.
- LDCs should also seek further extension of the transition period for pharmaceutical products beyond 2016 for at least another 10 years without any no roll-back or similar conditions.

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