

THE IMPACT OF THE EXTENSIONS OF PHARMACEUTICAL TRANSITION PERIOD FOR AFRICAN LDCs ON THE IMPLEMENTATION OF TRIPS: THE CASE OF MALAWI

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ABSTRACT

The World Health Organization (WHO) estimates that one-third of the people living in Least Developed Countries (LDCs) are unable to receive or purchase essential medicines that have saved and extended the lives of people in more developed countries. The 2013 UNAID Brief Report pointed out that patent protection is one of the factors which contributed to high costs, placing many essential treatments outside the reach of LDCs. TRIPS Council accords LDCs transition periods in order to allow them to develop their own viable technological base for pharmaceuticals. One would expect LDCs to take advantage of these transition periods and reform their laws to exclude pharmaceuticals from patent protection. Surprisingly, a number of these countries still provide patent protection for medicines despite the availability of the transition period. Today, about two decades into the TRIPs agreement era, LDCs continue to request for further extensions of the transition period. It is against this background that this paper aims to establish whether Malawi and other African LDC members have fully utilised the transitional period extensions for TRIPS implementation with special focus on pharmaceutical transition periods. The paper also brings to light some arguments that have been put for and against the extensions of transition period for LDCs. It also examines challenges faced by Malawi and other LDCs with respect to the implementation of TRIPS regulations and finally it discusses how these extensions have affected the development of pharmaceutical manufacturing and research capabilities in LDCs.

Key words: TRIPS, extensions, transition period, LDCs, pharmaceuticals, intellectual property

1. INTRODUCTION

Africa is the continent with by far the largest share of Least Developed Countries (LDCs). Twenty-five of the thirty-four African LDCs are members to the World Trade Organization (WTO).¹ It is important to highlight from the onset that the adoption of TRIPS Agreement in 1994 by

the global community affected the price and availability of drugs and health in most African LDCs through the imposition of certain minimum standards. The WHO estimates that one-third of the people living in LDCs are unable to receive or purchase essential medicines that have saved and extended the lives of people in developed countries. The 2013 UNAID Brief Report also pointed out that patent protection is one of the factors which contributed to high costs, placing many essential treatments outside the reach of LDCs.²

TRIPS Council accords its members transitional periods in order to allow them to develop viable technological base for pharmaceuticals, as well as protect those in need of increased assistance, investment and technological transfer from the burdens of granting and enforcing intellectual property monopolies. In order to achieve this objective, member states are allowed time to implement the applicable changes to their national laws, in two tiers of transition according to their level of development. The transition period for developing countries expired in 2005 whereas the transition period for LDCs to implement TRIPS expired in 2012 but was later extended to 2013, and until 1 January 2016 for pharmaceutical patents, before it was extended further until January 2033. Article 66.1 of the Agreement also provides that these transition periods are subject to further extensions upon duly motivated requests.

Today, about two decades into the TRIPs agreement era, LDCs continue to request for further extensions of the transition period. However, for developed countries, despite being aware that establishing a modern and meaningful IP legislation takes time, resources, and especially huge investment in infrastructural

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¹ Fikremarcos Merso, *IP Trends in African LDCs and the LDC TRIPS Transition Extension*. Policy Brief No.16

² UNAIDS Issue Brief 2013 *TRIPS Transition Period extension for least-developed countries*.

development, do not seem prepared to let free the LDCs from the TRIPS bondage. However, it is also still not clear whether LDCs submit requests for extensions of transition periods to implement TRIPS provisions and set up a viable pharmaceutical manufacturing base or maybe it is one way of delaying the process of becoming TRIPS compliant so as to avoid introducing pharmaceutical patents in their legislations which has been an ongoing debate in many fora and a major concern for most LDCs.

Despite providing a slightly longer extension period of seventeen years for pharmaceutical protection in LDCs as compared to the previous fourteen year transition period, literature points out that LDCs did not make full use of the previous transition period as their situation has not significantly changed since the last extension decision and that they have not been able to develop their productive capacities and have not beneficially been integrated with the world economy.³ This observation was supported by the calls from non-governmental organisations urging LDCs to actively use the created policy space this renewed transition period provides, and accordingly to take immediate steps to amend their respective national laws to exclude pharmaceutical products from patent protection and test data protection with explicit provisions that this would be a temporary allowance until 1 January 2033, or the expiry of such later transition period that may be granted by the WTO Council for TRIPS.⁴ It also appears that since the adoption of the 2001 Doha Declaration on TRIPS and Public Health, most LDCs have been preoccupied with procuring low cost generic medicines, in particular to access medicines needed for the treatment of HIV.⁵

It is against this background that this paper aims to establish whether Malawi and other African LDC members have fully utilised the transitional period

extensions for TRIPS implementation with special focus on pharmaceutical transition periods. The paper brings to light some arguments that have been put for and against the extensions of transition period for LDCs. It also examines challenges faced by Malawi and other LDCs with respect to the implementation of TRIPS regulations and finally it discusses how these extensions have affected the development of pharmaceutical manufacturing and research capabilities in LDCs.

2. RATIONALE BEHIND TRANSITION PERIOD

Article 66.1 of TRIPS Agreement 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.⁶

Article 66.1 provides for an extension of transition periods for LDCs to apply and implement the provisions of the TRIPS Agreement. Basically, there are currently two separate transition periods in operation within which LDCs are not required to implement the TRIPS Agreement other than Articles 3 on national treatment, 4 on most favoured nation treatment, and 5 on multilateral agreements on acquisition or maintenance of protection, and these are the general transition period and the pharmaceutical period. The general transition period for LDC members was initially due to expire on 1 January

³ WTO, 'Communication from Haiti on Behalf of the LDC Group: Request for an Extension of the Transitional Period under Article 66.1 of the TRIPS Agreement' (5 November 2012) (IP/C/W/583)

⁴ Catherine Saez, *LDC Pharma IP Waiver Until 2033 Approved by WTO TRIPS Council*, (IP Watch, 2015)

⁵ Ellen 't Hoen, *Inside Views: Why The Request by LDCs For an Extension of the Transitional Period for Granting and Enforcing Medicines Patents Needs to be supported?* (IP Watch, 2015)

⁶ Article 66(1), TRIPS Agreement.

2006. However, recognizing their special needs and requirements, the TRIPS Council adopted a Decision on 29 November 2005 that extended this transition period for another 7.5 years under Article 66.1 for LDC Members until 1 July 2013. Haiti submitted a request on 5 November 2012 and on behalf of the LDC group to extend the transition period further, specifically, until a given member graduates from being a LDC.⁷ Following this request, on 11 June 2013 a Decision of the Council for TRIPS decided on an extension of the transition period under article 66.1 for LDCs until 1 July 2021, or earlier, upon graduation from the LDC category.

With respect to pharmaceutical patents protection and data protection, there have been two subsequent extensions for pharmaceutical transition periods. First, the transition period for LDCs was extended until January 2016 following the TRIPS Council's Decision to implement Paragraph 7 of the Doha Declaration. Second, the Doha waiver that specifically addressed pharmaceutical patents was further extended until January 2033 on the basis of a request from the LDC group. However, reports indicate that despite receiving strong support for the renewed extension of transition period from the United Kingdom and the International Federation of Pharmaceutical Manufacturers (IFPMA), other organisations such as United States Trade Representative (USTR) opposed such an extension.⁸

It is important to point out that the primary benefit of an extended transition period lays in the preservation of policy space for LDCs, conserving the autonomy of LDCs to determine appropriate development, innovation, and technological promotion policies, according to local circumstances and priorities.⁹ The extension provides a

window of opportunity for LDCs to put domestic policies in place in order to ensure that the implementation of TRIPS will support and not hinder their social economic development.¹⁰

The extensions granted to the LDCs based on Article 66.1 aim to provide them not merely with more time to comply, but are also meant to help LDCs develop their national policies and economies to ensure that the eventual implementation of the TRIPS Agreement will promote rather than undermine their social, economic and environmental wellbeing.¹¹ This means that LDCs have been presented with a window of opportunity to take advantage of the transition period and develop viable local production capacity for pharmaceuticals. This will in the long run reduce LDC's dependency on imported drugs from countries such as India and China.

It is of significant importance to point out that strong support for extended transition periods has been made by many international communities such as Global Commission for HIV and the Law, UNAIDS and UNDP. In its report of 2012, the Commission recommended that WTO members must indefinitely extend the exemptions for LDC from the application of TRIPS provisions in the case of pharmaceutical products citing reasons that heavy disease burdens on LDCs provide an urgent and compelling case for the international community to take all measures possible to protect and extend health of the people living in these countries.¹² Furthermore, UNAIDS pointed out that an extension would allow the world's poorest nations to ensure sustained access to medicines, build up viable technology bases and manufacture or

⁷ WTO Document IP/C/40

⁸ IFPMA Statement support the Extension available at <http://www.ifpma.org>

⁹ UNAIDS Issue Brief 2013 TRIPS Transition Period extension for least-developed countries.

¹⁰ Arno Hold and Brian Christopher Mercurio, *Transitioning to Intellectual Property: How can the WTO*

Integrate Least Developed Countries into TRIPS? World Trade Institute, October, 2012.

¹¹ 'Extension of the Transition Period for LDCs: Flexibility to Create a Viable Technological Base or Simply (A Little) More Time?' *Intellectual Property Quarterly Update*, South Centre and CIEL, (2006)

¹² UNAIDS Issue Brief, *TRIPS Transition Period extension for least-developed countries*, (2013).

import the medicines they need.¹³ Nevertheless, it is important to commend the efforts made by some African LDCs such as Uganda and Rwanda to make use of existing extended transition periods to develop their legislation and subsequent manufacturing of HIV-related medicines.¹⁴

Article 66.2 of TRIPS calls on developed countries to provide technical and financial assistance to LDCs so as to effectively address the identified priority needs. However, analysts and LDC members have raised concern that the impact of Article 66.2 has been rather limited, and that the existing reporting system is insufficient to monitor the implementation of Article 66.2 in a meaningful way.¹⁵ Moreover, technical assistance for LDCs have been focusing more on capacity building for TRIPS compliance rather than on capacity building and technology transfer for development of pharmaceutical industries in these countries.¹⁶

3. ARGUMENTS FOR AND AGAINST EXTENSION OF TRANSITION PERIODS FOR LDCS

Proponents of these extensions of transition periods have argued that a series of time-limited transition periods and extensions, such as the initial ten-year transition period and the seven-and-a-half-year extension granted in 2005, has been insufficient for technological transformation and capacity building for the vast majority of LDC Members, especially in light of developed countries having failed to facilitate meaningful technology transfer as required by Article 66.2. To that end, a much longer extension is needed during which LDC Members can devote their entire attention to development

objectives.¹⁷ Others have argued that the extension of the specific pharmaceutical transition period for LDCs is still very relevant today. It is one of the WTO mechanisms for increasing access to medicines that work effectively and have been used on a large scale.¹⁸

However, some quarters have argued against extension of transition periods for LDCs stating that an extension is just a convenient way for both developed and LDCs to buy time and to avoid any potential conflicts in the TRIPS council.¹⁹ Another argument against the extension of the specific pharmaceutical transition period is that LDCs are not obliged to implement the TRIPS Agreement as a whole (with the exception of some articles) until 1 July 2033. This implementation deadline may also be further extended upon request of the LDC members.²⁰ As such, the specific pharmaceutical waiver is redundant. Others have also argued that never-ending requests for extensions of transition periods would not resolve anything but would only further postpone the implementation of TRIPS by LDCs. Moreover, extension would undermine the credibility of the TRIPS regime and inevitably lead some to question whether LDCs will ever have to comply with TRIPS. Some have argued that the extension of transition periods is no longer necessary because LDCs are systematically included in the scope of the Medicines Patent Pool license. As such anti-retrovirals (ARVs), which are the most essential medicines in this region, are made available to these countries through licensing. Moreover, it is argued that several companies indicated that they were not going to assert their patents

¹³ Michael Sidibe, Executive Director of UNAIDS, in UNAIDS Press Release *'UNAIDS and UNDP Back Proposal to Allow Least developed Countries to Maintain and Scale up Access to Essential'*, (January 2016)

¹⁴ UNAIDS Technical brief, *Implementation of TRIPS and access to medicines for HIV after January 2016: Strategies and Options for least developed countries*, (2013).

¹⁵ Suerie Moon: Meaningful Technology Transfer to the LDCs: A Proposal for a Monitoring Mechanism for TRIPS Article 66.2, April, 2011.

¹⁶ Global Academics *'Expert Letter on LDC' TRIPS Extensions Request*, (April 27, 2013)

¹⁷ *ibid*

¹⁸ Ellen 't Hoen 2015 Inside Views: *Why The Request by LDCs For an Extension of the Transitional Period for Granting and Enforcing Medicines Patents Needs to be Supported?* IP Watch, (2015).

¹⁹ Arno Hold and Brian Christopher Mercurio, *Transitioning to Intellectual Property: How can the WTO Integrate Least Developed Countries into TRIPS?* World Trade Institute, (October, 2012).

²⁰ Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products" (IP/C/25)

in LDCs.²¹ However this paper finds this argument weak because not all companies provide licenses for products that are needed in the treatment of HIV/AIDS. One study pointed out that the experience of the last decade strongly indicates that an extension alone would not lead to and resolve any IP-related improvements in LDCs but rather postpone further the implementation of TRIPS.²²

4. CHALLENGES FACING LDCS IN IMPLEMENTING TRIPS

It is equally important to point out that 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 LDCs 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.²³ Worse still, while LDCs have not been obliged to implement the TRIPS Agreement thus far, the reality is that most of them have had patent law on the books for many years. LDCs inherited their patent laws in the post-colonial era when they gained independence from high-income countries. At the time of the adoption of the Doha Declaration in 2001, out of thirty African LDCs only two, Angola and Eritrea, did not grant patents for pharmaceuticals.²⁴

There are a number of reasons that explain why most LDCs are challenged to utilise the transition periods and their extensions. First, most LDCs are very comfortable

with the arrangements they have made to procure low cost generic medicines, as such they do not seem to be in a hurry to implement their IP laws. One good example of such a country is Malawi. For example, the process of procuring generic medicines does not require legislative changes and have proven to be practical and effective. Second, the implementation of TRIPS provisions requires some considerable budgetary allocation to update legislation towards TRIPS compliance, and the accompanying recurrent as it applies to ensuring the observance of the legislation.²⁵ A study sanctioned by United Nations Conference on Trade and Development (UNCTAD) on the institutional costs of the implementation of the TRIPS Agreement showed that a country like Egypt would require USD 800,000 one-off cost and an additional annual training cost amounting to USD 1 million.²⁶ Such amounts as these might be unthinkable for most LDCs to spend on IP enforcement alone as they usually have other priority areas such as health, food availability, alarming poverty levels and unemployment.

Regrettably for such LDCs, unlike the other conventions on IP that existed prior to TRIPS, the TRIPS agreement provides for enforcement, and is linked to the WTO obligations, meaning that violation of TRIPS provisions may lead to such punitive measures as trade sanctions.²⁷ This has led many to conclude that, the WTO-TRIPS regulations are a reflection of little awareness of development problems and the incapacities of LDCs, because the sad reality is that the money to be spent by

²¹ Ellen 't Hoen, *Inside Views: Why the Request by LDCs For an Extension of the Transitional Period for Granting and Enforcing Medicines Patents Needs to be supported?* IP Watch, (2015).

²² Arno Hold and Brian Christopher Mercurio, *Transitioning to Intellectual Property: How can the WTO Integrate Least Developed Countries into TRIPS?* World Trade Institute, (October, 2012).

²³ 'Extension of the Transition Period for LDCs: Flexibility to Create a Viable Technological Base or Simply (A Little)

More Time?' *Intellectual Property Quarterly Update*, South Centre and CIEL, (2006).

²⁴ <http://apps.who.int/medicinedocs/en/d/Js2301e/12.html>
²⁵ NBT Report 2004
<https://pdfs.semanticscholar.org/6206/21fada20a5bf7f2f98bf9c915125a06729ef>.

²⁶ NBT Report 2004
<https://pdfs.semanticscholar.org/6206/21fada20a5bf7f2f98bf9c915125a06729ef>.

²⁷ Lumina 2010 LDD 2.

LDCs in implementing these 'WTO rules' would be money unproductively invested.²⁸

Thirdly, formulation of relevant legislation and/or accession to regional and international agreements to a greater extent depends on institutional capacity of the countries. Lack of institutional capacity to formulate legislation reflective of the social and economic needs among LDCs is also a major challenge, which has resulted in most LDCs subscribing to stricter forms of IP protection than would otherwise be needed for their development. However, it is encouraging to note that some selected LDCs such as Burundi, Rwanda and Uganda have managed to amend their IP law over the last seven years to make use of the transition period under TRIPS and exclude pharmaceutical products from patent protection.

5. MALAWI'S PHARMACEUTICAL INDUSTRY STATUS

In Malawi, up to 90% of the population live in rural areas without access to potable water and electricity, engaging in subsistence farming activities, and relying on rain-fed agriculture. The country is landlocked and has one of the largest population densities in sub-Saharan Africa.²⁹ Currently at 18 million, the population of Malawi is expected to double in two decades time.³⁰ Malawi is a member of the Southern African Development Community (SADC). The SADC region is one of the most heavily disease-burdened regions of the world. As an LDC, the country is often characterised by poverty, socio-economic inequalities and injustices, low human development, economic vulnerability and limited technological development.³¹ The country has poor socio-economic indicators, particularly in public health. It has a limited pharmaceutical manufacturing base and thus

depends significantly upon the importation of products from foreign-based manufacturers³².

In the case of newer medicines, some of which are protected by IPRs, Malawi imports from brand name manufacturers. Where patents do not exist, Malawi relies on generic manufacturers based in India and, to some extent, in China and South Africa. With respect to anti-retroviral, Malawi's HIV/AIDS treatment programme, predominantly funded by donors, relies almost exclusively on fixed-dose combination generics imported from India. This reliance is potentially problematic because some of the components of current ARVs especially Second and Third line ARVs are still patent protected in Malawi. It would surely be laughable that in such a country like this, where no single patent has been granted to a local innovator, priority should be laid on aligning their laws to be TRIPs compliant.³³

Another potential access to medicines problem in Malawi is the increase of HIV/AIDS related cancers in Malawi. According to 2010 National Aids Commission (NAC) Report, twenty eight percent of AIDS related deaths are due to cancer.³⁴ Unfortunately Malawi is not well equipped to deal with cancer due to the absence of specialized personnel and due to the high cost of cancer drugs, some of which are still under patent protection. Worse still, only two anti-cancer drugs are on the essential medicines list. Newer anti-cancer drugs including imatinib and sunitinib are unaffordable despite the fact that generic versions of these drugs are produced and available in India. Imatinib is sometimes available courtesy of the Glivec International Patient Assistance programme. However, this is an unsustainable way of making the drug available.

²⁸ Finger and Schuler *The World Economy* 511.

²⁹ World Bank 2007 <https://openknowledge.worldbank.org>

³⁰ International Monetary Fund 2017 <http://www.imf.org/~media/Files/Publications/CR/2017/cr17184>.

³¹ 'Extension of the Transition Period for LDCs: *Flexibility to Create a Viable Technological Base or Simply (A Little) More Time?*', *Intellectual Property Quarterly Update*, South Centre and

CIEL, (2006).

³² CIA World Fact Book, 2006

³³ Chikosa Banda, Robert-Lewis Lettington, *A survey of policy and Practice on the Use of Access to Medicines-Related TRIPS Flexibilities in Malawi*, DFID Health Systems Resource Centre, (2004).

³⁴ NAC Report, 2010.

Malawi's current efforts to regularize its IP regime affecting access to medicines are ad hoc, problematic and reflect a limited technical capacity. Nonetheless, Malawi is in the process of adopting its first IP Policy through the Department of Science and Technology. The Malawi Law Commission has also embarked on the process of revising the 1957 Patents Act. Unfortunately, this project has stalled due to lack of financial resources.

There have been some initiatives to revise the Malawian Patents Act and ensure maximum access to medicines. However, efforts to reform IP law and policy will need the assistance of development partners in increasing the availability of specialist skills on issues such as IP law and international drug procurement. Further assistance in facilitating the thorough review of legislation and associated policies is also urgently required.

Malawi's patent legislation was supposed to become generally TRIPS compliant by July 2013, but this has not yet happened.³⁵ Fortunately the deadline for compliance on the part of LDCs has been extended to 2021. With respect to medicines, Malawi has some flexibility to extend its date of compliance until 2033 under paragraph 7 of the Doha Declaration and under subsequent action by the WTO. The above extensions, however, do not preclude the need for prospective domestic legislative reform to take advantage of existing TRIPS flexibilities.

The need to reflect on the progress Malawi has made towards taking advantage of the TRIPS flexibilities is imperative considering the fact that the Doha Declaration, the 30th August 2003 Decision (on the Implementation of paragraph 6 of the Doha Declaration) and a subsequent decision of the WTO Council in proposing a congruent TRIPS amendment, Article 31bis, present a window of opportunity for countries with insufficient or no manufacturing capacity to take full advantage of TRIPS-based flexibilities to import affordable, good quality medication for their citizens.

These flexibilities include compulsory licensing, parallel importation and deferral of the patenting of pharmaceuticals to 2016. This is especially true given that LDCs have the flexibility of deferring the application of TRIPS provisions to pharmaceutical products and data protection until 2033.

Despite the above, the Malawi government has not managed to take advantage of the Doha Declaration and the 30th August Decision waiver. In particular, it has not yet taken concrete steps to amend its laws to incorporate all permissible TRIPS flexibilities. Moreover, it has maintained laws that provide stronger patent protection than the minimum required by TRIPS (TRIPS-plus). This is, notwithstanding, the fact that the TRIPS legal framework gives them room to avoid such an approach and to enact "public-health friendly" laws.

Whereas the colonial 1957 Patents Act provides for some flexibilities that can potentially be exploited to promote access to medicines, these flexibilities predate TRIPS and are ill-designed to address TRIPS-related access to medicines problems. This has impaired Malawi's ability to take full advantage of TRIPS flexibilities to promote access to medicines objectives. Likewise, despite its flaws, Malawi has also failed to amend its legislation to take advantage of the 30th August Decision or to notify the WTO of its intended use thereof. There is also very little awareness amongst Malawi policy makers of the need to advocate for a better export/import solution pursuant to Article 30 at the WTO and elsewhere.

Malawi has hitherto found it unnecessary to incorporate TRIPS flexibilities into its laws because it has been possible to source first-generation generic ARVs without difficulties with Patent owners. These drugs are primarily sourced from India, a major generic medicines supplier that until 2005 was not obliged to provide product patent protection for pharmaceuticals. The fact that India is now obliged to comply fully with the provisions of the TRIPS will have negative implications for access to post-2005

³⁵ Chikosa Banda, Robert-Lewis Lettington, *A survey of policy and Practice on the Use of Access to Medicines-Related TRIPS*

Flexibilities in Malawi, DFID Health Systems Resource Centre, (2004).

patented medicines. This is especially given that this important source of generic medicines (90% of all generic ARVs) is increasingly becoming constrained by patent law.

Access to newer medicines has generally been problematic considering that these drugs are almost invariably under patent protection. Consequently, Malawi has opted to exclude such medicines from its essential medicines lists on the basis of cost, despite the potential utility of such drugs. This has been detrimental to its citizens who are being denied access to life-saving treatment.

The future access scenario also looks bleak given that LDCs will be required to provide patent protection to pharmaceutical products by 2016 unless the existing waiver is extended. There is therefore an urgent need for Malawi to demonstrate its commitment to the right to health by amending its laws in order to benefit from key TRIPS-compliant flexibilities. Moreover, given Malawi's current system for granting pharmaceutical patents, the right to extend the transition period for medicines will not necessarily suspend the effect of previously granted patents. Thus, provision will need to be made for granting compulsory licenses and/or authorising government use with respect to existing on-patent medicines.

The possibility of utilising transition periods to exclude pharmaceuticals from patentability offers LDCs an opportunity to develop a viable technological base for manufacturing generic pharmaceutical products. However, it is sad to point out that Malawi still provides patent protection for medicines despite the availability of the transition period. The 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.³⁶

In addition, Malawi's underlying patent legislation reflects few of the available TRIPS public health safeguards with the exception of some provision for compulsory licenses and government use. For instance there are elements of Section 18 which are potential relevance to the question of safeguarding public health. One of them is subsection 18.1 (b), which provides that the Registrar of Patents may refuse an application where he determines that the use of the invention in respect of which the application is made would be contrary to law or morality. Subsection 18.1 clearly relates to TRIPS Article 27.2, which allows for the exclusions from patentability on the grounds of ordre public or morality but not on the basis of mere illegality³⁷. However, even where these are available, there is little, or no, capacity to implement them and thus no experience in their use.

There is minimal awareness of the flexibilities that are available, under Articles 31 and 31bis of the TRIPS agreement that Malawi can use to promote access to medicines. There is also very little awareness of the SADC position on pharmaceutical patents and how IP issues relate to the SADC Pharmaceutical Business Plan.³⁸ Where awareness does exist, there is almost no knowledge of the technical details at issue. A lack of awareness of impending TRIPS deadlines and their implications for access to medicines for the poor is also evident. Worse still, there is very little awareness on the part of the Malawian citizens of the implications of government inaction on their right to health. As a result there is no concerted effort on the part of Malawian stakeholders to advocate for the incorporation of TRIPS flexibilities into the Patents Act.

Moreover, Malawi was not among the nine African LDCs that have submitted their individual priority needs to the TRIPS Council. The nine countries include: Sierra Leone

³⁶ Nirmalya Syam, *Transition Period for TRIPS Implementation for LDCs: Implications for Local Productions of Medicines in the East African Community*, South Centre, (2014).

³⁷ Laws of Malawi, Patents Chapter 49:02

³⁸ SARPAM Report, 2013.

(2007), Uganda (2007), Bangladesh (2010), Rwanda (2010), Tanzania (2010), Senegal (2011), Mali (2012), Madagascar (2013) and Togo (2013).³⁹

Implementation of TRIPS provisions in Malawi is significantly impacted by its membership to African Regional intellectual Property Organisation (ARIPO) and party to Harare Protocol on Patents and Industrial Designs. The Harare Protocol, however, does not recognise transition periods and their extensions which are provided for under Article 66 of TRIPS Agreement. Such being the case, it is difficult for Malawi to exclude pharmaceuticals from patent protection. Some of these challenges include the following:

- i. Inadequate institutional, inter-sectoral, cross-sectoral coordination on issues relating to IP and access to medicines.
- ii. Lack of information sharing among key stakeholders.
- iii. Policy incoherence, for example, lack of harmonized policies and guidelines to support access to essential medicine in Malawi.
- iv. Exclusion of key players including Civil Society from the policy formulation and implementation processes.
- v. There is inadequate capacity and expertise in the field of IP in general and IP and access to medicines in specific.
- vi. Market and policy failure. For example, there is inadequate capacity for local pharmaceutical R&D and production.
- vii. Lack of political will and commitment to develop IP policy and legislation to take full advantage of flexibilities.
- viii. Inadequate networking among key stakeholders
- ix. Financial constraints

6. EFFORTS TO ENSURE AVAILABILITY OF ESSENTIAL MEDICINES IN MALAWI

There have been a number of efforts to ensure the availability of essential medicines in Malawi and other LDC members in the SADC region. One such effort was initiated by the Southern African Regional Programme on Access to Medicines and Diagnostics (SARPAM). SARPAM is a DFID funded regional project, which assists SADC member states to implement the SADC Pharmaceutical Business Plan 2007-2013 (PBP). The PBP was adopted by Health Ministers in 2007.⁴⁰ The overall objective of the PBP is to ensure the availability of essential medicines in the SADC region through better collaboration among states. The goal of SARPAM is to increase access to affordable essential medicines in the region through supporting the development of a more efficient and competitive regional pharmaceutical market place. The PBP envisaged the following TRIPS related activities:

1. A regional assessment of IP and medicines legislation in countries to determine their TRIPS compliance and adaptability;
2. Identification of reliable and specialized legal advice resources both within and outside the SADC region and maintain a roster of legal experts who are able to offer technical assistance on TRIPS;
3. Collaboration with development partners to enable countries to protect, include and take advantage of the flexibilities that exist in the TRIPS Agreement as well as to assist countries in bilateral trade negotiations to conclude agreements that are not detrimental to public health.⁴¹

It is important to acknowledge that activities One and Two have meanwhile been achieved. And on action point Three, SARPAM was by 2013 willing to work with other

³⁹ United Nations Committee for Development Policy. *TRIPS Agreement: Transitional Period for Implementing the Agreement*, (Article 66.1, 2016).

⁴⁰http://www.unido.org/fileadmin/user_media/Services/PSD/BE P/SADC%20PHARMACEUTICAL%20BUSINESS%20PLAN%20-APPROVED%20PLAN.pdf

⁴¹ SARPAM Report, 2013.

development partners to support SADC member states improving access to medicines by optimizing the flexibilities in national legislation under the TRIPS agreement.⁴²

7. CONCLUSION

The ‘never-ending’ extension requests speak volumes as to whether it is the right time for LDCs to be strict with IP protection or not, and to further reflect on whether the requirement to accede to such agreements as TRIPS is fair at this point. While LDCs have been provided with automatic extension of the transition period, few of the LDCs have made use of the general transition period that is currently available until 2021. An interactive and collaborative approach among developing countries and LDCs in seeking extensions appears to be at the moment the only sure way for surviving the impending harm which compliance to TRIPS would bring to them.⁴³

That said, the thinking of the present study remains that Malawi and most African LDCs generally have few resources for research and development and few inventions to protect and so there is little to gain from strong patent protection, for instance, until their domestic situation will have improved. 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, it is important to urge LDCs to make full use of the general transition period and seek further extensions of this period. More importantly, the full use of the transition period must be seen as an integral component of national and regional pharmaceutical manufacturing plan of action for LDCs. As argued by Hold and Mercurio, an unconditional extension of the transition period for LDCs to implement TRIPS would only lead to a further postponement of LDCs’ integration into the international IP system without

resolving any of the underlying issues.⁴⁴ As other scholars have argued, extending the period of TRIPS implementation is just one step in addressing the unique challenges of LDCs in Africa but above all there is a need to address the underlying issue beyond extension such as helping LDCs to build their technological base, streamline IP in socio-economic development rather than focusing exclusively on mere implementation and compliance issues.

Finally, it is important to point out that without proper utilisation of the extended period and with continuation of inadequate institutional and infrastructural capacity, building programmes will simply result more time wasted with no progress towards a viable technological base in the LDCs.⁴⁵

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⁴² *ibid*

⁴³ Chaudhury and Gurbani 2002 *JHM* 18.

⁴⁴ Arno Hold and Brian Christopher Mercurio, *Transitioning to Intellectual Property: How can the WTO Integrate Least Developed Countries into TRIPS?* World Trade Institute, (October, 2012).

⁴⁵ Extension of the Transition Period for LDCs: *Flexibility to Create a Viable Technological Base or Simply (A Little) More Time?*, *Intellectual Property Quarterly Update*, South Centre and CIEL, (2006).

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