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

[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 dully 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

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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

in LDCs.[21] However this paper finds this argument weak

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 [illegible]

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 imp lem

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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).

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