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TRANSITION PERIOD FOR PROVIDING PATENT PROTECTION FOR PHARMACEUTICAL PRODUCTS BY LDCS:

THE NEED FOR EXTENSION

Summary

How can Least Developed Countries (LDCs) make effective use of the transition period for the purposes stated in Article 66.1 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), and in particular to promote access to affordable medicines and promote local manufacturing of generic medicines? Should LDCs seek a further extension of the transition period for pharmaceutical products beyond 1 January 2016?

LDCs should request the TRIPS Council for a further extension of the transition period and make effective use of it. The transition period and its further extensions provide crucial policy space to LDCs to design their intellectual property laws below the substantive requirements of the TRIPS Agreement. LDCs need policy space and flexibility to address their development challenges and to create a viable technological base. Excluding pharmaceutical products from patent protection is an important policy for an LDC to improve the health prospects of its population and to develop or sustain local production of medicines for domestic use and export. Moreover, considering the moral imperative behind a request for an extension of the transition period for pharmaceutical products, LDCs should seek extension of the transition period after 1 July 2021 for as long as the circumstances mentioned in Article 66.1 of the TRIPS Agreement continue to prevail in LDCs.

Accordingly, WTO Members in recognizing the special needs of LDCs should agree to grant the extension without any conditions.

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I. Introduction

1. An important flexibility that is available to least developed countries (LDCs) under the WTO TRIPS Agreement (Art. 66.1) is an extendable transition period. During the transition period LDCs need not implement the provisions of the TRIPS Agreement except for Articles 3, 4 and 5 of the TRIPS Agreement which contain provisions pertaining to national treatment and the most favoured nation.

> **TRIPS Article 66.1**
> "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."

2. 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.

3. The transition period under Article 66.1 can be extended if the LDCs submit a "duly motivated request" for such extension to the TRIPS Council. According to Article 66.1 of the TRIPS Agreement "The Council of TRIPS **shall**, upon duly motivated request … **accord** extensions of this period".

4. 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. Currently, the LDCs can utilize a general transition period till 1 July 2021. This general transition period is without prejudice to the specific extension of the transition period for pharmaceutical products that is in force till 1 January 2016.

5. However, in spite of the availability of the transition period and extensions of the same, LDCs have not been able to fully utilize the transition period. While some LDCs have made use of the transition period in recent years, most of these have incorporated the transition period by specifically referring to the extension granted for pharmaceutical products till 1 January 2016.

II. What is the Transition Period?

6. The transition period and its further extensions provide crucial policy space to LDCs to design their intellectual property laws below the substantive requirements of the TRIPS Agreement, in order to provide the LDCs the maximum flexibility in implementing the TRIPS Agreement while addressing their special needs and

requirements, financial and administrative constraints as well as the need for flexibility to create a sound and viable technological base.

7. 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. In particular, all member States of the WTO were required by TRIPS to grant product patents on pharmaceutical products for a minimum period of 20 years.

8. 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 I January 2005) application of product patents to technology areas (such as pharmaceutical products) that were not patentable as at 1 January 2000.[1]

9. However, LDCs were granted an extendable transition period due to their special circumstances and were given a separate transition period under Article 66, with the aim of providing them maximum flexibility to create a sound and viable technological base. Article 66.1 granted LDCs an initial 10-year transition period (until 2005) which could be renewed 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.

10. 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".**

III. Extensions of the Transition Period

11. The transition period that was granted initially for a period of 10 years under Article 66.1 of the TRIPS Agreement has been granted three extensions. The first extension was specially granted with respect to pharmaceutical products in 2002. This extension will expire on 1 January 2016. This extension had guaranteed that even if the original transition period were to expire on 1 January 2005, the LDCs could still continue to prevent the TRIPS obligations from coming into force with respect to pharmaceutical

[1] See Article 65.2 and 65.4 of the TRIPS Agreement.

products. As the term of the general transition period came to a close, the TRIPS Council through a decision granted an extension to the transition period for 7.5 but also introduced severe restrictive terms and conditions. Towards the end of this extended transition period, the TRIPS Council adopted a decision to further extend the transition period for 8 years until 1 July 2021.

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.

IV. Importance of the Transition Period

12. 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. Tanzania was the only LDC that was actively involved in these negotiations.

13. The TRIPS Agreement required all developing country members of the WTO had to amend their IP laws to provide stronger levels of IP protection than they used to provide. 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 I January 2005)

application of product patents to technology areas that were not patentable as at 1 January 2000.[2]

14. LDCs however 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. The special status of LDCs is recognized in the preamble of the TRIPS Agreement, which states **"Recognizing also 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".**

15. 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, 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]

16. 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.[5] [6] The UNCTAD LDC Report of 2007 observes:

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[2] See Article 65.2 and 65.4 of the TRIPS Agreement.

[3] See Carlos M. Correa (2010), *Designing Intellectual Property Policies in Developing Countries*, Third World Network, Penang, Malaysia, p. 3.

[4] See UNCTAD (2007), *Least Developed Countries Report*, p. 103.

[5] 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."

[6] 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.

> "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 (*sic)* 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."

17. Historical examples of evolution 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. This pathway of technological development was also emulated by some developing countries. India abolished product patent protection for pharmaceutical products in 1970, which allowed the development of a strong generic pharmaceutical industry in India.[7]

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

V. Importance of the Transition Period for Industrial and Technological Development in LDCs

19. Since the rationale behind the transition period under Article 66 is to provide LDCs maximum flexibility (by exempting them from most TRIPS obligations) in view of their constraints, special needs and requirements including a viable technological base, the need to extend the transition period will continue to exist so long as these elements have not been addressed. Thus, it is important to see whether the economic conditions on the ground have improved for LDCs since the extension of the transition period in 2005.

20. In this regard, the Least Developed Countries Report (LDC Report) of 2011 done by The United Nations Conference on Trade and development (UNCTAD) provides very useful insights. According the 2011 LDC Report, "… LDCs continue to play a very marginal role in the world economy, and that their growing integration in the global

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

market was accompanied by very limited advances (if any) in their relative position compared with the rest of the world…. From a long-term perspective**, it appears that their marginalization is in many ways worse than in the early 1970s**…. More generally, the picture that emerges … is that **the** *LDCs* **… have not been able to develop their productive capacities and beneficially integrate with the world economy."**[8]

21. Besides the UNCTAD LDC Report, the Istanbul Programme of Action for the Least Developed Countries for the Decade 2011-2020 adopted by the Fourth UN Conference on LDCs states that "Least developed countries' productive capacity is limited, and they have serious infrastructure deficits." The Istanbul Programme of Action also stresses the importance of science and technology for LDCs in this context and states that "All LDCs are lagging behind in these critical areas which are key drivers for transformation and have great potential to change the development landscape of least developed countries if developed and harnessed properly. **Least developed countries have not been able to move beyond outdated technologies that characterize their production processes and outputs. Acquiring new technologies and building domestic capacity and knowledge base to be able to fully utilize acquired technologies and promoting indigenous capacity on a sustainable basis for research and development are needed to enhance the productive capacities in least developed countries."**

22. The fact that LDCs have not been able to develop their productive capacities means that LDCs continue to suffer from the lack of a sound and viable technological base that can contribute meaningfully towards enhancing their innovation capabilities. Even the Istanbul Programme of Action recognizes this and stresses on productive capacity as of the utmost priority for LDCs.

23. Therefore, there is substantial rationale for seeking an extension of the transition period for LDCs and ensuring that they obtain maximum flexibility to develop a sound and viable technological base. Unless there is substantial transformation of this situation by the end of the general transition period on 1 July 2021, the necessity to grant further extensions of the transition period will continue to exist.

VI. Importance of the Transition Period for Access to Medicines

24. The exclusion of pharmaceutical products from patent protection has been fundamental to the development of pharmaceutical industries in all countries during their initial phase. The capacity of a country to locally manufacture the medicines required for meeting the country's disease burden can have significant implications for ensuring affordable access to medicines in the country. Therefore, there is need for a facilitative environment in LDCs to support the development of a strong generic pharmaceutical industry that can supply the required medicines to the population at affordable prices. However, without the transition period, LDCs would be required to provide patent protection to pharmaceutical products and thus limit the space for a local

[8] UNCTAD (2011), *Least Developed Countries Report*, pp. 30-31.

generic pharmaceutical industry to thrive. It would also limit the ability of LDCs to import generic medicines from other countries if the same could not be procured locally. This makes the transition period and its further extensions critical for access to medicines in LDCs.

25. As the current extension of the transition period for pharmaceutical products is set to expire on 1 January 2016, the question arises whether there is a need to further extend the transition period. If the pharmaceutical transition period is not extended, after 1 January 2016, LDCs would still have the ability to deny patent protection for pharmaceutical products under the general transition period currently available till 1 July 2021.

26. There are various reasons why LDCs should pursue a specific extension with regard to pharmaceutical products beyond the current general transition period. The general transition period valid until 1 July 2021 was agreed to, however subject to a particular non-obligatory condition with regard to TRIPS implementation by LDC. As explained above, LDCs successfully pushed back against any binding "no-roll-back" condition. Even so, the inclusion of a non-binding condition could create uncertainty among some policy makers with regard to the application of the transition period by LDCs, which presently grant pharmaceutical product patent but intend to roll-back such protection. Further it would be important to avoid the uncertainty of whether a pharmaceutical extension will be granted after the expiry of the general transition period on 1 July 2021.

27. Access to affordable pharmaceutical products (e.g. medicines, vaccines, diagnostic kits) is a prerequisite, to deal with the numerous public health challenges facing LDCs. LDCs are home to some of the world's most vulnerable people and bear considerable health burdens. In 2011, some 9.7 million of the 34 million people living with HIV worldwide lived in LDCs. Of the people living with HIV in LDCs, 4.6 million were eligible for antiretroviral (ARV) treatment in accordance with the 2010 World Health Organization HIV treatment guidelines, however only 2.5 million were receiving it.[9]

28. According to UNAIDS, "[T]here is concern that without extension of the transition period, access to antiretroviral therapy and other key medicines in LDCs will face real challenges."[10] Explaining the implications of the failure to renew the transition period beyond 2016, UNAIDS states that if the transition period is not extended beyond 2016 the situation regarding availability and pricing of HIV-related medicines will be more complex than the situation in 2001 when the Doha Declaration was adopted. The UNAIDS concludes "There is a real danger that if the LDCs do not get a further

[9] UNAIDS, UNDP, "TRIPS transition period extensions for least-developed countries", Issue Brief, 2013.
[10] UNAIDS, *Implementation of TRIPS and Access to Medicines for HIV after January 2016: Strategies and Options for Least Developed Countries*, UNAIDS Technical Brief 2011, p. 4, http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258_techbrief_TRIPS-access-medicines-LDC_en.pdf.

extension, the progress that has been made to improve access to HIV-related medicines in these countries will be reversed."[11]

29. In the 49 countries which are considered LDCs by the United Nations, non-communicable disease (NCD) burdens are also rising much faster than in higher income countries. Data from low-income countries for instance suggests that cancer incidence is expected to rise by 82 per cent from 2008 to 2030, whereas in high-income countries incidence is expected to rise at a much lower rate of 40 per cent, in part due to widespread access to vaccines and medicines.[12]

30. Excluding pharmaceutical products from patent protection is an important policy for any LDC wishing to improve the health prospects of its population and to develop or sustain local production of medicines for domestic use and export. A concrete example is India, which is described as the "pharmacy of the developing world" in recognition as a low-cost producer of high-quality drugs. In 1970, India taking advantage of the freedom countries had before the creation of the WTO, abolished product patent protection in pharmaceuticals. Even after the entry into the force of the TRIPS Agreement, using the transition period flexibility available to it then, India maintained this position, The absence of product patent protection provided Indian companies the opportunity to develop pharmaceutical capacity, and aided by the entrepreneurial spirit as well as other government policies and public investments in manufacturing and R&D, Indian pharmaceutical companies made enormous progress.

31. With India introducing pharmaceutical product patent regime in 2005, it can be anticipated that access to affordable generic medicines will become increasingly more difficult. Thus it is important for LDCs to fully exploit the LDC transition period to be able to import affordable generics from countries where the product is not patented and to also strengthen local production capacity so that in the longer term they will be able to secure access to affordable medicines.

32. It is worth noting that today multiple international, regional and sub-regional initiatives acknowledge the importance of governments incorporating in patent legislations and fully utilizing TRIPS flexibilities to facilitate access to affordable medicines. The African Union Roadmap on Shared Responsibility and Global Solidarity for the AIDS, Tuberculosis and Malaria Response in Africa; the Pharmaceutical Manufacturing Plan for Africa (PMPA), the EAC East African Community Regional Pharmaceutical Manufacturing Plan of Action for 2012–2016 are some of the initiatives that are specifically supportive of extending the pharmaceutical exemption beyond 2016 as they consider the exemption to be essential to addressing the public health challenges as well to build a sound and viable technological base in the pharmaceutical sector.

33. Thus far at least 25 LDCs have relied on Doha Declaration paragraph 7 to allow the importation/procurement of HIV related generic medicines by declaring any

[11] Ibid., p. 10.
[12] UNAIDS, UNDP, "TRIPS transition period extensions for least-developed countries", Issue Brief, 2013.

existing patents unenforceable.[13] In addition, several LDCs (e.g. Rwanda, Uganda, Burundi) have amended their patent legislations to exclude pharmaceutical products from the scope of protection.

34. A specific decision on pharmaceutical product transition period is absolutely critical to give policy makers the confidence to declare patents unenforceable to facilitate access to and the local manufacturing of affordable pharmaceutical products. It is also critical to encourage policy makers to take immediate steps to amend patent legislations to exclude pharmaceutical products. Furthermore, considering the moral imperative behind a request for an extension of the transition period for pharmaceutical products, LDCs should seek to obtain a period that is longer than the general transition period that is expiring on 1 July 2021.

VII. Importance of the Transition Period for Local Production of Medicines

35. LDCs should also fully exploit the transition period to develop sustainable local manufacturing capability for generic medicines in order to complement the need for access to affordable and quality assured medicines in the 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.

36. 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.[14] 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.[15] 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.

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[13] UNAIDS, *Implementation of TRIPS and Access to Medicines for HIV after January 2016: Strategies and Options for Least Developed Countries*, UNAIDS Technical Brief 2011, p. 4, http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258_techbrief_TRIPS-access-medicines-LDC_en.pdf.

[14] 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).

[15] Ibid.

37. 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 situation in LDCs is applicable to pharmaceuticals as well as many other fields of technology.

38. 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.[16] 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.

39. 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.[17]

40. 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

[16] 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).
[17] Ibid.

pharmaceutics (the process of combining different chemical substances, including the API and excipients to produce a final medical product in a particular form) is sufficient.

41. 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,[18] there may be other APIs that could be easier to produce. For example, Chinese companies have historically tended to manufacture high volumes of low complexity APIs such as paracetamol.[19] 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.

42. 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 granules[20] 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.[21] 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.[22]

43. 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,[23]

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[18] "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).

[19] 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).

[20] 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).

[21] African Union (2012), *supra* note 18, p. 31.

[22] Ibid.

[23] 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

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.[24] 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 a potentially lower price for the pill.[25] Manufacturers can produce 50 or more formulations in a single plant with adaptable equipment.[26]

VIII. Challenges in Making Use of the Transition Period44. In spite of the availability of the transition period under Article 66.1, very few LDCs have made full use of the transition period. A 2011 report by UNCTAD observed some LDCs have 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.

Lack of Awareness and Capacity

45. A major challenge before LDCs is the lack of awareness among policy makers about the transition period and its scope. This lack of awareness is demonstrated by the fact that though LDCs have sought for extensions of the transition period at the TRIPS Council, there has been a lack of a coordinated approach towards implementing the transition period domestically due to differences between trade and public health departments or ministries.[27]

46. The lack of awareness about the scope of the transition period has also impeded the scope of the extension of the transition period granted by the TRIPS Council. Though Article 66.1 states that the TRIPS Council *shall* grant extensions of the transition period upon a duly motivated request by an LDC, in reality the extensions of the transition period have been a negotiated compromise between LDCs and developed countries. In these negotiations, the LDCs have been severely constrained by the lack of awareness and capacity about the scope of the transition period available under Article 66.1 of TRIPS.

47. For example, in 2005 the LDCs had submitted a request for extension of the transition period under Article 66.1 for a period of 14 years. This request was subjected

http://www.who.int/medicines/technical_briefing/tbs/KaplanLocalProductionFinal5b15d.pdf (last visited 21 April 2014).

[24] African Union (2012), *supra* note 18, p. 28.

[25] 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).

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

[27]https://books.google.ch/books?id=T7Y2K8m4LSgC&pg=PA279&lpg=PA279&dq#v=onepage&q&f=false.

to extensive negotiations and the LDCs were granted 7.5 years of extension. However, this extension came with restrictive conditions to which the LDCs had to agree. Thus, the decision of 2005 prevented the LDCs from rolling back their existing levels of IP protection while allowing them to delay TRIPS implementation for 7.5 years. In effect, this meant that many LDCs which were providing levels of IP protection which were higher than required under TRIPS could not roll back their laws even if such level of IP protection were to be inappropriate to their level of development.

48. Moreover, the LDCs had also agreed as part of the extension decision to submit information on their priority needs for technical and financial cooperation in order to enable developed countries to provide technical and financial assistance under Article 67 of TRIPS to facilitate implementation of TRIPS. Thus, the extension of the transition period was linked to Article 67 and the LDCs were obligated to provide information on priority needs assessment. However, the obligation to provide technical and financial assistance under Article 67 of TRIPS is not related to extensions of the transition period under Article 66.1. Technical and financial assistance under Article 67 is to be provided upon request by a developing country or LDC on mutually agreed terms and conditions. Article 67 would come into operation if an LDC decides to implement TRIPS and requests for assistance in this regard. Under Article 66.1, there is no obligation for LDCs to seek such assistance and prepare for implementation of TRIPS.

49. By introducing an obligation on LDCs to submit information on priority needs for technical and financial assistance under Article 67 to implement TRIPS, the 2005 extension sought to push the LDCs towards implementation of TRIPS. LDCs could not roll back existing levels of IP protection that were TRIPS plus in some cases, and they had to submit information on priority needs for technical and financial assistance to implement TRIPS. This restricted the scope of the transition period itself which was meant to provide the LDCs maximum flexibility to waive implementation of TRIPS not only in view of their technical and financial constraints, but also in view of their special needs and circumstances as well as the lack of a sound and viable technological base. Practically, technical assistance for implementation of TRIPS would only be required once LDCs develop into mature economies and possess conditions such as a sound and viable technological base that will enable them to benefit from TRIPS implementation.

50. In effect, the discussion about the transition period after the 2005 extension became a discussion and technical and financial constraints faced by LDCs to implement TRIPS. As the 2005 extension neared its end in 2013, the LDCs initially thought that an extension of the transition period could be sought to provide more time to submit the information on priority needs for technical and financial assistance which had not been submitted by all LDCs by January 2008 as stipulated in the 2005 decision. However, the LDCs had later realized that there was more to the transition period under Article 66.1 than needs assessments for technical and financial assistance. Accordingly they submitted a request for a renewed extension without any "no roll-back" clause and also proposed that the transition period should be delinked from any obligation to provide information about priority needs for technical and financial assistance under Article 67.

Domestic Legal Uncertainty

51. Though it is not necessary for specific incorporation of the transition period in domestic laws, the lack of specific incorporation of the transition period in the domestic laws in many LDCs creates legal uncertainty and restrains LDCs from making maximum use of the transition period. For instance, a review of the primary IP statutes of 39 out of 47 countries from sub-Saharan Africa pointed out that IP protection for pharmaceutical products is widespread in the region even though the majority of countries from this region are LDCs who do not have to grant patent protection on pharmaceutical products at least until 1 January 2016 as the transition period granted by the TRIPS Council in 2002 for pharmaceutical products is still in force.[28] By virtue of the extension of the general transition period till 1 July 2021, the transition period would also be available for a longer term.

52. However, some LDCs have specifically incorporated the transition period for pharmaceutical products in their national legislation in recent years. In 2013 the East African Community adopted developed a regional policy on the use of Public Health-Related WTO-TRIPS flexibilities and the Approximation of National Intellectual Property Legislation which 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.[29] Currently, all EAC Partner States except Mainland Tanzania have specifically introduced the transition period for pharmaceutical products till 2016.

53. It is noteworthy that while LDCs have started specifically incorporating the transition period for pharmaceutical products till 2016 in their legislations, similar initiatives are generally lacking with regard to specific incorporation of the general transition period that is currently available till 2021. In this regard, it would be pertinent for national laws to incorporate the transition period both generally and for pharmaceutical products with reference to Article 66.1 of TRIPS rather than any decision of the TRIPS Council. Moreover, in some national laws the reference to the transition period does not provide for possible extensions of this period if the TRIPS Council were to grant such extensions. Therefore, LDCs should also provide for the possibility of further extensions of the transition period. The absence of such an enabling clause in the domestic law would create legal uncertainty on whether the transition period would apply if the TRIPS Council grants further extension of this period.

External Pressures to Implement TRIPS

[28] 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).
[29] 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).

54. Another major challenge before LDCs that can impede their endeavours to implement the TRIPS transition period comes in the form of external pressures to implement TRIPS. Such pressure is exerted in the form of demands in bilateral or regional trade agreement negotiations to raise the standards of IP protection, as well as in the form of technical assistance provided by developed countries. LDCs that are not members of the WTO are also pressurized to implement TRIPS as a condition in the WTO accession agreements.[30]

55. For example, the European Commission has been negotiating comprehensive Economic Partnership Agreements (EPAs) with the 76 member African, Caribbean and Pacific group of countries (ACP).[31] 39 countries from the ACP are LDCs. The EC has insisted on strengthening IP protection and enforcement in these negotiations. A final EPA with the CARIFORUM countries has been concluded and interim EPAs have been signed with the other group of ACP countries. Except for the EPA with the CARIFORUM, there is not any substantive provision on IP. However, all other ACP countries have committed in their interim EPAs to engage in future negotiations on IP. The IPR provisions in the EU-CARIFORUM EPA can therefore be mirrored in other ACP EPAs. Significantly, the EU-CARIFORUM EPA grants LDCs a transition period to implement their TRIPS obligations by 2021. However, it does not provide for the possibility of further extensions of the transition period in accordance with possible further extensions of the transition period by the TRIPS Council.[32]

56. Similarly, in several bilateral trade agreements with developed countries LDCs have been required to adopt TRIPS plus provisions of protection and enforcement of IP which undermine the transition period available to LDCs. For example, the 1996 Trade Relations and Intellectual Property Agreement between the US and Cambodia limited the freedom of Cambodia to adopt a sui generis system of plant variety protection and required Cambodia to join the International Convention for the Protection of new Varieties of Plants (UPOV Convention). In bilateral agreements with the US, Lao and Bangladesh have been required to adopt TRIPS plus measures.

Misconception about the Value of IP Protection for Technological Development

57. Sometimes, policy makers in LDCs also believe erroneously that implementing TRIPS or higher levels of IP protection and enforcement would encourage patent holders to transfer foreign technologies through licensing and transfer of technology (TOT) agreements. However, LDCs are in the "initiation stage" of industrial development where technological learning is facilitated by incorporating mature technologies through informal channels of technology transfer like acquisition of plant and machinery and reverse engineering. The focus of technological efforts lies in the mastery of operation and low-level design technology, including simple assembly. Majority of firms in LDCs

[30] http://unctad.org/en/docs/ldc2007_en.pdf.
[31] EPAs are being negotiated with a cluster six groups of countries from the ACP – SADC (Southern Africa) , EAC (East Africa), ECOWAS (West Africa), CEMAC (Central Africa) and the CARIFORUM (the Caribbean).
[32] http://www.ciel.org/Publications/Oxfam_TechnicalBrief_5May08.pdf.

are informal micro-enterprises that use mature technologies without undertaking any significant innovation effort. In this context, an UNCTAD study points out that IPRs are unlikely to play any significant role in promoting local learning and innovation.[33] On the contrary, the lack of IPR protection may be essential to facilitate learning by imitation at the initial levels of technological development that exist in LDCs today.[34]

IX. Conclusions and Recommendations

58. The transition period granted to LDCs under Article 66.1 is based on the premise that so long as the "special needs and circumstances" of LDCs – including their special need for ensuring access to medicines, developing sustainable local manufacturing capacity in medicines, ensuring affordable access to copyright protected works for education and research, etc. - , the financial and administrative constraints, and their need for a sound and viable technological base for industrial development are not in place, the LDCs cannot benefit from providing IP protection and enforcement as required under TRIPS. Therefore, the LDCs will continue to need maximum flexibility with regard to implementation of TRIPS, and continue to have the option of having the TRIPS obligations as voluntary for them. This makes it necessary that the transition period is extended for an appropriate duration. Therefore, LDCs should continue to seek extension of the transition period after 1 July 2021 as long as the circumstances mentioned in Article 66.1 of the TRIPS Agreement continue to prevail in LDCs.

59. The transition period initially available under Article 66.1 was for 10 years. However, there is nothing in the TRIPS Agreement to suggest the duration of subsequent extensions of the transition period. In 2005, the transition period was extended for 7.5 years, but in 2013 the extension was granted for 8 years. Thus, there is no pattern of gradually reducing the duration of the transition period. It will be important for LDCs to seek a long extension of the transition period on the basis that the circumstances that justify the transition period are unlikely to be resolved in 5 to 10 years as effectively more than 15 years of transition period along with it extensions , has been inadequate to address these circumstances.

60. It will also be important for LDCs to ensure that the transition period is extended generally for all LDCs. A thematic or sectoral approach to the extension should be avoided.

61. The LDCs should also ensure that the decision by the TRIPS Council to grant an extension of the transition period is not constrained by any conditions. The transition period should be simply extended for the specified duration without any other conditions.

62. A specific decision on further extension of the transition period for pharmaceutical product beyond 1 January 2016 is absolutely critical to give LDCs the

[33] http://unctad.org/sections/ldc_dir/docs/ldcr2007_Correa_en.pdf.
[34] http://unctad.org/sections/ldc_dir/docs/ldcr2007_Correa_en.pdf.

confidence to declare patents unenforceable to facilitate access to and the local manufacturing of affordable pharmaceutical products and to encourage take immediate steps to amend patent legislations to exclude pharmaceutical products.

63. LDCs should also specifically incorporate the transition period in their domestic laws in order to remove legal uncertainty about the applicability or scope of the transition period. Domestic laws should also allow for the transition period to be automatically extended if the TRIPS Council grants any extension.

64. LDCs should not agree to implement TRIPS or TRIPS plus standards of IP protection and enforcement in trade agreements and WTO accession agreements and ensure that the transition period is not undermined by such agreements.

65. LDCs should use the transition period to suitably amend their IP laws commensurate with their social and economic development challenges. In this regard, LDCs can also consider rolling back their current levels of IP protection even below the standards required under TRIPS.

66. Although the transition period has been available to LDCs with the possibility of renewal by the TRIPS Council upon submission of a duly motivated request, the LDCs have not been able to make the fullest use of this transition period. This lack of appropriate use of the transition period is due to a number of factors - lack of awareness about the scope of the transition period under Article 66.1 of the TRIPS Agreement, and the purposes for which this could be utilized, domestic legal uncertainty about the applicability and scope of the transition period, external pressures upon LDCs to implement IP protection in accordance with TRIPS or TRIPS plus standards in free trade agreements, WTO accession agreements, or regional IP agreements. Sometimes governments also believe erroneously that stronger levels of IP protection and enforcement is necessary to encourage foreign technology holders to license their technologies and thus facilitate technology transfer.