TRANSITION PERIOD FOR LDCS

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Legal Basis for LDC Transition Periods

> Article 66 of TRIPS:

"In view of the special needs and requirements of LDCs... their economic, financial and administrative constraints and their need for flexibility to create a viable technological base... Members shall not be required to apply the provisions for a period of 10 years"

Note: For LDCs, TRIPS Agreement was to come into force in 2006. But recognizing the vulnerability of LDCs, the TRIPS Agreement built in a renewable transition period.

≻ <u>Article 66.1</u>

"The Council for TRIPS **SHALL**, **upon duly motivated** request by a least developed country Member, **accord extensions** of this period"

Transition Periods

2 types of transition periods currently available:

A) General Transition Period: For All TRIPS Provisions

B) Specific Transition Period For Pharmaceutical products

A. General Transition Period (For all TRIPS Provisions)

- ➤ Oct. 2005, LDC group requested an extension of transition period as per Article 66.1 of TRIPS.
- ➤ Nov 2005, LDCs as a group were granted an extension of the transitional period for 7.5 years i.e. "until 1 July 2013 or until such a date on which they cease to be a least developed country Member whichever date is earlier" (WTO doc. IP/C/40).
- ➤ Nov. 2012, LDC Group requested a further extension under Article 66.1 of TRIPS.
- ➤ 11 June 2013, WTO TRIPS Council granted a further extension "Least developed country Members shall not be required to apply the provisions of the Agreement, other than Articles 3, 4 and 5, until 1 July 2021, or until such a date on which they cease to be a least developed country Member, whichever date is earlier." (WTO Doc. IP/C/64)
 - > LDCs may rollback their IP laws.
 - **➤** Without prejudice to further extension

B. Pharmaceutical Transition Period

- ➤ Paragraph 7 Doha Declaration: LDCs do not have to implement or apply Sections 5 (patents) and 7 (protection of undisclosed information) of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016.
- February 2015: LDCs submitted a duly motivated request pursuant to Article 66.1 of the TRIPS Agreement seeking a transition period for pharmaceutical products for as long as the WTO Member remains a least developed country.
- ➤ 6 November 2015: pharmaceutical transition period extended until 1 January 2033. Waivers from mailbox and exclusive marketing rights granted.

TRIPS Council Decision 6 November 2015 (WTO Doc. IP/C/73)

Decides as follows:

Least developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 [patents] and 7 [protection of undisclosed information] of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2033, or until such a date on which they cease to be a least developed country Member, whichever date is earlier.

This decision is made without prejudice to the right of least developed country Members to seek other extensions of the period provided for in paragraph 1 of Article 66 of the TRIPS Agreement.

General Council Decision 6 November 2015 (WTO Doc. WT/L/971) LDCs granted waivers from Article 70.8 and 70.9 of the TRIPS Agreement until 1 January 2033. Means LDCs do not have to implement mailbox (mechanism for receiving patent applications) and exclusive marketing right.

Importance of Using Pharmaceutical Transition Period

- ➤ For LDCs most important TRIPS flexibility
- ➤ A major barrier to access to affordable medicines removed.
- ➤ Key to development of local manufacturing capacity.
- e.g. India....no patent protection for pharmaceutical product between 1970 2005....one of the critical government policy that supported developed of a scientific and technological base. They have a multibillion dollar generic industry, which provides for local and foreign markets and contributes to the economy.