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1 ARTICLE 66 OF THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

1.1 Text of Article 66

Article 66

Least-Developed Country Members

- 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. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

1.2 Article 66.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)

1.2.1 Extension of general transition period

- 1. On 29 November 2005, the Council for Trade-Related Aspects of Intellectual Property Rights (Council for TRIPS) adopted a decision (2005 Decision) extending the general transition period under Article 66.1 for least-developed country Members. The terms of the decision include, *inter alia*, the following:
 - "1. 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 2013, or until such a date on which they cease to be a least-developed country Member, whichever date is earlier.

...

- 5. Least-developed country Members will ensure that any changes in their laws, regulations and practice made during the additional transitional period do not result in a lesser degree of consistency with the provisions of the TRIPS Agreement.
- 6. This Decision is without prejudice to the Decision of the Council for TRIPS of 27 June 2002 on "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), and to the right of least-developed country

Members to seek further extensions of the period provided for in paragraph 1 of Article 66 of the Agreement."

2. On 17 December 2011, the 8th Ministerial Conference adopted the following decision concerning the transition period for least developed country Members under Article 66.1 of the TRIPS Agreement:

"We invite the TRIPS Council to give full consideration to a duly motivated request from Least-Developed Country Members for an extension of their transition period under Article 66.1 of the TRIPS Agreement, and report thereon to the WTO Ninth Ministerial Conference."²

- 3. On 11 June 2013, a decision (2013 Decision) of the Council for TRIPS further extended the general transition period under Article 66.1 for least developed country Members until 1 July 2021 or until they cease to be a least developed country Member, whichever comes first.³ While the first and third paragraphs of the 2013 Decision mirror paragraphs 1 and 6 of the 2005 Decision, the following paragraph of the 2013 Decision replaced paragraphs 2 to 5 of the 2005 Decision:
 - "2. Recognizing the progress that least developed country Members have already made towards implementing the TRIPS Agreement, including in accordance with paragraph 5 of IP/C/40, least developed country Members express their determination to preserve and continue the progress towards implementation of the TRIPS Agreement. Nothing in this decision shall prevent least developed country Members from making full use of the flexibilities provided by the Agreement to address their needs, including to create a sound and viable technological base and to overcome their capacity constraints supported by, among other steps, implementation of Article 66.2 by developed country Members."
- 4. On 7 December 2013, the 9th Ministerial Conference in Bali welcomed the Decision taken by the Council for TRIPS to further extend general transition period for least-developed country Members until 1 July 2021.⁴
- 5. On 15 June 2005, i.e. prior to the adoption of a decision to extend the general transition period for all least-developed country Members, the Council for TRIPS adopted a decision extending the Maldives' transition period under Article 66.1 of the TRIPS Agreement. The terms of the latter decision provide that "the Maldives shall not be required to apply the provisions of the TRIPS Agreement, other than Articles 3, 4 and 5, until 20 December 2007". The graduation of the Maldives to developing country status, which was initially planned for 20 December 2007, took effect on 1 January 2011.
- 6. On 29 June 2021, a decision (2021 Decision) of the Council for TRIPS further extended the general transition period under Article 66.1 for least developed country Members until 1 July 2034, or until they cease to be a least developed country Member, whichever comes first. The 2021 Decision mirrors the 2013 Decision, except the fourth recital, which highlights the long-term social and economic impacts of the COVID-19 pandemic on least developed country Members.

1.2.2 Extension of transition period in the pharmaceutical sector

7. In the Doha Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, Ministers agreed that least developed country Members be accorded an extended transition period with respect to the protection and enforcement of rights related to patents

 3 <u>IP/C/64</u>. See also <u>IP/C/M/73</u> and <u>Add.1</u>. For the request submitted by least-developed country WTO Members on 5 November 2012 see <u>IP/C/W/583</u>.

⁶ The UN CDP Secretariat Monitoring Report is available at

 $^{^1}$ <u>IP/C/40</u>. Paragraphs 2–4 of the Decision concern enhanced technical cooperation for least-developed country Members. See also <u>IP/C/M/49</u>.

² WT/L/845

⁴ Bali Ministerial Declaration, <u>WT/MIN(13)/DEC</u>, para.1.6.

⁵ <u>IP/C/35</u>.

http://www.un.org/en/development/desa/policy/cdp/ldc_documents/maldives_monitoring_report_2012.pdf.

7 IP/C/88. See also IP/C/M/100 and Add.1. For the request submitted by least-developed country WTO Members on 1 October 2020 see IP/C/W/668.

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and undisclosed information in the pharmaceutical sector. Ministers instructed the Council for TRIPS to take action to that effect:

- We also agree that that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement."8
- On 27 June 2002, the Council for TRIPS adopted a decision extending the transition period under Article 66.1 for least-developed country Members for certain obligations with respect to pharmaceutical products, in the following terms:
 - "1. Least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016.
 - 2. 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."9
- On 6 November 2015, the Council for TRIPS adopted a decision providing for a further extension of the transition period with respect to pharmaceutical products until 1 January 2033, or until such a date on which they cease to be a least-developed country Member, whichever date is earlier.10

1.3 Article 66.2

- The Doha Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, reaffirmed developed country Members' commitment to provide incentives to transfer technology:
 - "7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2."11
- Following the entry into force of the Protocol Amending the TRIPS Agreement¹², paragraph 6 of the Annex to the TRIPS Agreement recognizes the desirability of promoting technology transfer and encourages Members to use the Article 31bis mechanism to promote this objective and to cooperate in the work undertaken pursuant to Article 66.2 and paragraph 7 of the Doha Declaration:

⁸ WT/MIN(01)/DEC/2.

⁹ IP/C/25. See also IP/C/M/36. At the same meeting, the Council for TRIPS approved a draft waiver for least-developed country Members of obligations under Article 70.9 with respect to pharmaceutical products (JOB(02)/57/Rev.1). The General Council adopted the decision to waive obligations under Article 70.9 with respect to pharmaceutical products on 8 July 2002 (WT/L/478). See the document on Article 70 of the TRIPS Agreement (Practice).

¹⁰ IP/C/73. See also IP/C/M/80. At the meeting of 6 November 2015, the Council for TRIPS approved a recommendation regarding a decision to waive the obligations under Articles 70.8 and 70.9 of the TRIPS Agreement (IP/C/74) which was subsequently adopted by the General Council on 30 November 2015 (WT/L/971). See the document on Article 70 of the TRIPS Agreement (Practice). For the initial request submitted by least-developed country WTO Members on 23 February 2015, see IP/C/W/605.

¹¹ WT/MIN(01)/DEC/2.

¹² WT/L/641. The decision on an "Amendment of the TRIPS Agreement" to which the Protocol Amending the TRIPS Agreement was attached was adopted by the General Council on 6 December 2005 in the light of a statement read out by the Chairman as reflected in paragraphs 29-32 of the minutes of the General Council meeting in WT/GC/M/100. The Amendment Protocol entered into force on 23 January 2017 following acceptance by two thirds of WTO Members, as required pursuant to paragraph 3 of Article X of the WTO Agreement (<u>WT/Let/1236</u>).

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"6. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS."

For Members that have yet to accept the Protocol, the General Council decision of 30 August 2003 on the "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" continues to apply. 13 Paragraph 7 of that Decision mirrors the language of paragraph 6 of the Annex to the TRIPS Agreement.

12. On 19 February 2003, the Council for TRIPS adopted a decision establishing arrangements for the submission by developed country Members of annual reports on their implementation of Article 66.2 and their annual review by the Council for TRIPS. Members may use the e-TRIPS Submission System to provide information on their implementation of Article 66.2 and the e-TRIPS Gateway to access the information that has been submitted by developed country Members. 15

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 $^{^{13}}$ WT/L/540 and Corr.1. This waiver decision implements paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It was adopted by the General Council in the light of a statement read out by the Chairman as reflected in paragraphs 29-31 of the minutes of the General Council meeting in WT/GC/M/82.

¹⁴ <u>IP/C/28</u>. See also <u>IP/C/M/39</u>.

¹⁵ The e-TRIPS Submission System and <u>e-TRIPS Gateway</u> are available at https://www.wto.org/english/tratop_e/trips_e/etrips_e.htm.