

IMPLEMENTATION OF PARAGRAPH 11 OF THE 30 AUGUST 2003 DECISION

Communication from Nigeria on behalf of the African Group

I. INTRODUCTION

1. On 30 August 2003, the General Council adopted a decision¹ (the Decision) to implement paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health². The Decision took the form of two waivers, that is, a waiver to the obligations under Article 31(f) and a second waiver on to the obligations under Article 31(h) of the TRIPS Agreement. The Decision was adopted on the understanding that the Council for TRIPS would prepare an amendment to replace the waivers for each Member on the date on which the amendment takes effect for that Member. In particular, paragraph 11 of that decision provided that:

[11] This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).³

2. Members therefore explicitly agreed that *the amendment will be based, where appropriate, on the Decision*". In this regard, the appropriateness of particular elements should be understood to mean those elements in the Decision that are necessary to ensure the amendment is legally predictable, secure and economically and socially sustainable.

3. This proposal by the African Group is aimed at providing the basis for the amendment. It is proposed to amend Article 31 of the TRIPS Agreement by adding a second paragraph to the Article so that the current text of Article 31 would become Article 31 paragraph 1 and the amendment text would become Article 31 paragraph 2. The proposed amendment would be based on the waivers with modifications, as appropriate. In essence, it is proposed to eliminate a number of provisions in the 30 August Decision as they would be redundant in the context of an amendment or where their purpose

¹ The Decision is contained in WTO document WT/L/540 dated 2 September 2004. Available at <http://www.wto.org>.

² WTO document WT/MIN(01)/DEC/2 dated 20 November 2001. Also available at <http://www.wto.org>.

³ See para 11 of the Decision.

would otherwise be served by other provisions of the TRIPS Agreement, such as the Agreement's already existing provisions on compulsory licences read together with the provisions on enforcement.

II. PROPOSAL FOR AMENDING ARTICLE 31 OF THE TRIPS AGREEMENT

4. The following is the proposed text of the amendment. For consistency and clarity, the actual text of the amendment has been modified including with respect to the arrangement of paragraphs to fit into the TRIPS Agreement. Also note that the footnote would be renumbered appropriately to follow the numbering in the TRIPS Agreement.

Text of Amendment to Article 31 of TRIPS

[Article 31]

[2] The obligations under subparagraph 1(f) of this Article shall not apply to such use that is necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) who notifies⁴ the Council for TRIPS of its intention to use the system established under this paragraph in accordance with the terms set out below.

(a) For the purposes of this paragraph:

(i) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Doha Declaration. It is understood that, among others, active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included;

(ii) "eligible importing Member" means any least-developed country Member, and any other Member with no or insufficient manufacturing capacity in the pharmaceutical sector that has made a notification to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example, only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use;

(iii) "exporting Member" means a Member using the system set out in this paragraph to produce pharmaceutical products for, and export them to, an eligible importing Member.

(b) Where use is made by an eligible importing Member of the subject matter of a patent under this paragraph, adequate remuneration for purposes of subparagraph 1(h) of this Article shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the importing Member, the obligation of that Member under subparagraph 1(h) of this Article shall be waived in respect of those products for which remuneration in accordance with the first sentence of this subparagraph has been paid in the exporting Member.

⁴ It is understood that this notification does not need to be approved by a WTO body in order to use the system set out under this paragraph. The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated for this purpose.

- (c) Products produced under the licence shall be clearly identified as being produced under the system set out in this paragraph through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price.
- (d) Members shall ensure the availability of effective legal means to prevent the re-exportation or unlawful importation into, and sale in, their territories of products produced under the system set out under this paragraph, using the means available under Part III of this Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.
- (e) With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products; where a developing or least-developed country Member is party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 or the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the membership of which is made up of countries on the United Nations list of least-developed countries, the obligation of that Member under subparagraph 1(f) of this Article shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement.
- (f) Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to help importing Members establish their own manufacturing capacities in this sector. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this paragraph 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 and any other relevant work of the Council for TRIPS.
- (g) Members shall not challenge any measures taken in conformity with the provisions of this paragraph under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

III. FINAL REMARKS

5. This proposal presents a viable basis for undertaking an amendment as foreseen in paragraph 11 of the Decision of 30 August 2003. The proposal is based, as appropriate, on the Decision. Only those elements of the decision which are otherwise redundant or whose purpose would otherwise be served by the existing provisions of the TRIPS Agreement have been eliminated.
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