

WORLD TRADE ORGANIZATION

WT/L/540641
~~2 September 2003~~
December 2005
(03-458205-5842)

IMPLEMENTATION OF PARAGRAPH 6 ~~amendment~~ of the DOHA DECLARATION ON the TRIPS AGREEMENT ~~and public health~~

Decision of 30 August 2003 6 December 2005*

The General Council;

Having regard to ~~paragraphs~~ paragraph 1, 3 and 4 of Article ~~IXX~~ of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) ~~(the "Declaration")~~ and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement ~~and to report to the General Council before the end of 2002;~~

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in ~~this Decision~~ the proposed amendment of the TRIPS Agreement, the importance of a rapid response to those needs consistent with the provisions of ~~this Decision~~ the proposed amendment of the TRIPS Agreement;

~~Noting that, in the light of~~ Recalling paragraph 11 of the foregoing, ~~exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h)~~ General Council Decision of Article 31 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement with respect to Public Health;

~~Having considered the proposal to~~ pharmaceutical products ~~amend the TRIPS Agreement submitted by the Council for TRIPS (IP/C/41)~~;

~~Noting the consensus to submit this proposed amendment to the Members for acceptance;~~

Decides as follows:

1. The Protocol amending the TRIPS Agreement attached to this Decision is hereby adopted and submitted to the Members for acceptance.

* ~~This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.~~

2. The Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.
 3. The Protocol shall take effect in accordance with the provisions of paragraph 3 of Article X of the WTO Agreement.
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ATTACHMENT

PROTOCOL AMENDING THE TRIPS AGREEMENT

Members of the World Trade Organization:

Having regard to the Decision of the General Council in document WT/L/641, adopted pursuant to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Hereby agree as follows:

1. The Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") shall, upon the entry into force of the Protocol pursuant to paragraph 4, be amended as set out in the Annex to this Protocol, by inserting Article 31bis after Article 31 and by inserting the Annex to the TRIPS Agreement after Article 73.
2. Reservations may not be entered in respect of any of the provisions of this Protocol without the consent of the other Members.
3. This Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.
4. This Protocol shall enter into force in accordance with paragraph 3 of Article X of the WTO Agreement.
5. This Protocol shall be deposited with the Director-General of the World Trade Organization who shall promptly furnish to each Member a certified copy thereof and a notification of each acceptance thereof pursuant to paragraph 3.
6. This Protocol shall be registered in accordance with the provisions of Article 102 of the Charter of the United Nations.

Done at Geneva this sixth day of December two thousand and five, in a single copy in the English, French and Spanish languages, each text being authentic.

ANNEX TO THE PROTOCOL AMENDING THE TRIPS AGREEMENT

Article 31bis

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

Moved from original par.2 which said: "The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph."

2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) 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 eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

Moved from the original par.3, which said: "Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement 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 eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member."

3. 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 WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and 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 current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) shall not apply 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 that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

Moved from the original par.5 and 5(i), which said:

"5 With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

"(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and 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 current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement 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 that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;"

4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

Moved from the original par.10, which said: "Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994"

5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f).

Moved from the original par.9, which said: "This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement"

ANNEX TO THE TRIPS AGREEMENT

1. For the purposes of Article 31bis and this ~~Decision~~Annex:

- (a) "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 Declaration- on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included¹;
- (b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification² to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ("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. It is noted that some Members will not use the system ~~set out in this Decision~~ as importing Members³ and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;
- (c) "exporting Member" means a Member using the system ~~set out in this Decision~~ to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. ~~The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph.~~

Comment [PMU1]: Moved to par.1

2. The terms referred to in paragraph 1 of Article 31bis are that:

- (a) the eligible importing Member(s)⁴ has made a notification² to the Council for TRIPS, that:
 - (i) specifies the names and expected quantities of the product(s) needed⁵;

¹ This subparagraph is without prejudice to subparagraph-1(b).

² It is understood that this notification does not need to be approved by a WTO body in order to use the system ~~set out in this Decision~~.

³ Australia, ~~Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, the European Communities with, for the purposes of Article 31bis and this Annex, its member States, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom~~ and the United States.

⁴ Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph-6 3 of ~~this Decision~~Article 31bis on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

⁵ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to ~~this Decision~~the system.

- (ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the ~~Annex~~Appendix to this ~~Decision~~Annex; and
- (iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with ~~Article~~Articles 31 and 31bis of ~~the TRIPS~~this Agreement and the provisions of this ~~Decision~~Annex⁶;
- (b) the compulsory licence issued by the exporting Member under ~~this Decision~~the system shall contain the following conditions:
- (i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
- (ii) products produced under the licence shall be clearly identified as being produced under the system ~~set out in this Decision~~ 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; and
- (iii) before shipment begins, the licensee shall post on a website⁷ the following information:
- the quantities being supplied to each destination as referred to in indent (i) above; and
 - the distinguishing features of the product(s) referred to in indent (ii) above;
- (c) the exporting Member shall notify⁸ the Council for TRIPS of the grant of the licence, including the conditions attached to it.⁹ The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

~~3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid~~

⁶ This subparagraph is without prejudice to Article 66.1 of ~~the TRIPS~~this Agreement.

⁷ The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to ~~this Decision~~the system.

⁸ It is understood that this notification does not need to be approved by a WTO body in order to use the system ~~set out in this Decision~~.

⁹ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to ~~this Decision~~the system.

~~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 eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.~~

Comment [PMU2]: Moved to par.2

3. ~~_____~~ In order to ensure that the products imported under the system ~~set out in this Decision~~ are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

4. ~~_____~~ Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system ~~set out in this Decision~~ and diverted to their markets inconsistently with its provisions, using the means already required to be available under ~~the TRIPS~~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.

4. ~~_____~~ 5. ~~_____~~ With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) ~~_____~~ where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and 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 current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement 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 that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

Comment [PMU3]: Moved to par.3

(ii) ~~_____~~ it is recognized that the development of systems providing for the grant of regional patents to be applicable in the ~~above~~ Members described in paragraph 3 of Article 31bis should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of ~~the TRIPS~~this Agreement, including in conjunction with other relevant intergovernmental organizations.

6. ~~_____~~ Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem ~~identified~~faced by Members with insufficient or no manufacturing capacities in ~~paragraph 6 of the Declaration~~pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system ~~set out in this Decision~~ 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 ~~the TRIPS~~this

Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS.

~~7. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.~~

~~9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.~~

~~10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.~~

~~7. 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).~~

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Comment [PMU4]: Moved to par.5

Comment [PMU5]: Moved to par.4

Comment [PMU6]: Superseded by the Amendment decision

| **APPENDIX TO THE ANNEX TO THE TRIPS AGREEMENT**

~~ANNEX~~

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

- (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

~~OR~~_{or}

- (ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.
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