

PROTOCOL
amending the TRIPS Agreement

MEMBERS OF THE WORLD TRADE ORGANISATION;

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 Organisation ('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 Organisation 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.
 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 authorised 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.
 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.
 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.
 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).
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ANNEX TO THE TRIPS AGREEMENT

1. For the purposes of Article 31bis and this 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 recognised 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 included ⁽¹⁾;
- (b) 'eligible importing Member' means any least-developed country Member, and any other Member that has made a notification ⁽²⁾ 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 as importing Members ⁽³⁾ 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 to produce pharmaceutical products for, and export them to, an eligible importing Member.

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

- (a) the eligible importing Member(s) ⁽⁴⁾ has made a notification ⁽⁵⁾ to the Council for TRIPS, that:
 - (i) specifies the names and expected quantities of the product(s) needed ⁽⁵⁾;
 - (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 Appendix to this 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 Articles 31 and 31bis of this Agreement and the provisions of this Annex ⁽⁶⁾;
- (b) the compulsory licence issued by the exporting Member under 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 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

⁽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.

⁽³⁾ Australia, Canada, the European Communities with, for the purposes of Article 31bis and this Annex, its Member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.

⁽⁴⁾ Joint notifications providing the information required under this subparagraph may be made by the regional organisations referred to in paragraph 3 of 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 the system.

⁽⁶⁾ This subparagraph is without prejudice to Article 66.1 of this Agreement.

- (iii) before shipment begins, the licensee shall post on a website ⁽¹⁾ 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 notify ⁽²⁾ the Council for TRIPS of the grant of the licence, including the conditions attached to it ⁽³⁾. 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. In order to ensure that the products imported under the system 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 and diverted to their markets inconsistently with its provisions, using the means already required to be available under 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.
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, it is recognised that the development of systems providing for the grant of regional patents to be applicable in the 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 this Agreement, including in conjunction with other relevant intergovernmental organisations.
6. Members recognise 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.
7. The Council for TRIPS shall review annually the functioning of the system with a view to ensuring its effective operation and shall annually report on its operation to the General Council.

⁽¹⁾ 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 the system.

⁽²⁾ It is understood that this notification does not need to be approved by a WTO body in order to use the system.

⁽³⁾ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

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

 - (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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