COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 27.4.2006
COM(2006) 175 final

2006/0060 (AVC)

Proposal for a

COUNCIL DECISION

accepting, on behalf of the European Community, of the Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), done at Geneva on 6 December 2005

(presented by the Commission)

EXPLANATORY MEMORANDUM

Objective of this proposal

This proposal for a Council Decision aims at accepting, on behalf of the European Community, the Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter referred to as the "TRIPS Agreement"), done at Geneva on 6 December 2005.

On 6 December 2005, the General Council of the World Trade Organization (hereinafter referred to as the "WTO") submitted a proposed amendment to the TRIPS Agreement to the WTO Members for acceptance. This amendment would make permanent a waiver decision on compulsory licences originally adopted in 2003. Once accepted and in force, this amendment will complete a process that began with the Declaration on the TRIPS Agreement and Public Health that ministers made at the Doha Ministerial Conference in November 2001.

This is the first time that a core WTO agreement is amended.

The Doha Declaration on TRIPS and Public Health

On 14 November 2001 at Doha, the Fourth Session of the WTO Ministerial Conference adopted the Declaration on the TRIPS Agreement and Public Health. The Doha Declaration clarifies the relationship between the TRIPS Agreement and public health policies of WTO Members, confirming the right of Members to issue compulsory licences on patents for reasons of public health.

As to WTO Members with no manufacturing capacity in the pharmaceutical sector, which could not import medicines they needed, Paragraph 6 of the Doha Declaration instructed the Council for TRIPS to find an expeditious solution to this problem.

The waiver decision of 30 August 2003

On 30 August 2003, the WTO General Council adopted the decision on the implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health.

This decision allows WTO Members to export patented medicines to third countries with no manufacturing capacity in the pharmaceutical sector, by making use of compulsory licences. It includes substantial safeguards against trade diversion and rules to ensure transparency.

The decision was accompanied by a statement by the chair of the General Council, describing Members' "shared understanding" on how the decision is interpreted and implemented. It says the decision will be used in good faith in order to deal with public health problems and not for industrial or commercial policy objectives. It stipulates that issues such as preventing the medicines getting into the wrong hands are important.

In order to make sure that the system would be aimed at relieving the neediest, developed country Members of the WTO (among which all EU Member States[1]) have taken the commitment not to use the system as importers. High income developing country members have made a statement that they would not use the system except in exceptional circumstances. All WTO Members have the right to act as exporters.

The 30 August 2003 decision takes the form of a provisional "waiver" in the meaning of Article IX:3 of the Marrakech Agreement Establishing the World Trade Organization (hereinafter referred to as the "WTO Agreement") and provides for its replacement by an amendment to the TRIPS Agreement, on which work was to be completed by mid 2004.

Following the waiver, the Commission has proposed to the European Parliament and the Council the adoption of a Regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems[2], the adoption of which is imminent.

The decision of 6 December 2005

The decision of 6 December 2005 is intended to transform the 30 August 2003 waiver decision into a permanent amendment of the TRIPS Agreement.

The amendment will allow any WTO Member to export pharmaceutical products made under a compulsory licence for the purpose of supplying developing countries with insufficient manufacturing capacities. It will ensure a legally secure, predictable, effective and sustainable solution for those countries which want to use the system to get affordable medicines they need.

The new rules will be formally incorporated into the TRIPS Agreement. In accordance with Paragraph 3 of Article X of the WTO Agreement, the amendment takes effect for the Members that have accepted it when two thirds of the WTO Members accept the amendment and thereafter for each other Member upon acceptance by it. WTO Members have set themselves until 1 December 2007 to do this. The waiver remains in force for each Member until the amendment becomes effective for that Member.

The amendment is designed to match the 30 August 2003 decision as closely as possible. Other procedures used in 2003 are also matched, including the statement by the chair of the WTO General Council. In order to achieve this, the 6 December 2005 decision ensures that the legal meaning and weight, and the relationship between the statement and the new rules, are preserved as exactly as possible. This reflects the approach that the EC had defended in the WTO.

A group of developed countries, including the European Community, is listed as announcing that they will not use the system to import. A number of other countries announced separately that if they use the system as importers it would only be for emergencies or extremely urgent situations.

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1 Before accession to the EU, the then ten accession countries made a statement that they would not use the system except in exceptional circumstances. Upon accession to the EU, their commitment is not to use the system as importers at all.

2 COM(2004) 737 final of 29.10.2004.

Contents of the amendment

The amendment itself is composed of three parts:

– Five paragraphs come under Article 31bis (i.e. an additional article after Article 31). The first allows pharmaceutical products made under compulsory licences to be exported to countries lacking production capacity. Other paragraphs deal with avoiding double remuneration to the patent owner, regional trade agreements involving least-developed countries, non-violation and situation complaints, and retaining all existing flexibilities under the TRIPS Agreement.

– A further seven paragraphs are in a new annex to the TRIPS Agreement. These set out terms for using the system, and cover such issues as definitions, notification and transparency, avoiding the pharmaceuticals being diverted to the wrong markets, developing regional systems to allow economies of scale, and annual review in the Council for TRIPS.

– An appendix to the annex deals with assessing lack of manufacturing capability in the importing country. This was originally an annex to the 2003 decision.

The new Article 31*bis* and annex of the TRIPS Agreement are attached to the Protocol of amendment. This is attached to a WTO General Council decision, which adopts the Protocol and opens it for Members to accept it by 1 December 2007.

Conclusion of the Protocol

The European Commission participated, on behalf of the European Community, in the negotiation of the Protocol.

In accordance with paragraph 5 of Article 133 of the EC Treaty, the European Community is competent to conclude agreements in the field of commercial aspects of intellectual property. Therefore, the Protocol should be accepted on behalf of the European Community.

Following the adoption of the Regulation of the European Parliament and the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, the Community will have an exclusive competence over this matter. Member States should therefore not accept the Protocol.

The President of the Council shall be authorised to designate the person empowered to deposit the instrument of acceptance of the Protocol with the WTO Director-General. In its instrument of acceptance, the European Community shall also confirm, in accordance with Article 300 paragraph 7 of the EC Treaty, that the Protocol will be binding on its Member States.

For these reasons, the Commission proposes to the Council to adopt the attached decision.

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2006/0060 (AVC)

Proposal for a

COUNCIL DECISION

accepting, on behalf of the European Community, of the Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), done at Geneva on 6 December 2005

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular paragraph 5 of Article 133 in conjunction with the first sentence of the first subparagraph of paragraph 2 and the second subparagraph of paragraph 3 of Article 300 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the assent of the European Parliament[2],

Whereas:

(1) On 14 November 2001 at Doha, the Fourth Session of the Ministerial Conference of the World Trade Organisation (hereinafter referred to as the "WTO") adopted the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2).

(2) Paragraph 6 of this Declaration instructed the Council for TRIPS 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 Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter referred to as the "TRIPS Agreement").

(3) On 30 August 2003, the WTO General Council adopted a temporary decision implementing paragraph 6 of the Declaration on the TRIPS Agreement and Public Health.

(4) Paragraph 11 of the 30 August 2003 decision provides that 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.

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1 OJ C , p.
2 OJ C , p.

(5) On 6 December 2005, in order to transform the 30 August 2003 decision into an amendment of the TRIPS Agreement, the WTO General Council adopted a Protocol amending the TRIPS Agreement and submitted it to the Members of the WTO for acceptance.

(6) Paragraph 3 of the Protocol provides that 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.

(7) The European Commission participated, on behalf of the European Community, in the negotiation of the Protocol.

(8) In accordance with paragraph 5 of Article 133 of the EC Treaty, the European Community is competent to conclude agreements in the field of commercial aspects of intellectual property.

(9) The Protocol should be accepted on behalf of the European Community.

(10) In its instrument of acceptance, the European Community shall also confirm, in accordance with Article 300 paragraph 7 of the EC Treaty, that the Protocol will be binding on its Member States,

HAS DECIDED AS FOLLOWS:

Article 1

The Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights, done at Geneva on 6 December 2005, is hereby accepted on behalf of the European Community.

The text of the Protocol is attached to this Decision.

Article 2

The President of the Council is hereby authorised to designate the person empowered to deposit the instrument of acceptance of the Protocol with the Director-General of the World Trade Organization.

Article 3

In its instrument of acceptance, the European Community shall confirm, in accordance with Article 300 paragraph 7 of the EC Treaty, that the Protocol will be binding on its Member States.

Done at Brussels,

For the Council
The President

ANNEX

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 31*bis* 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.

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.

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).

ANNEX TO THE TRIPS AGREEMENT

1. For the purposes of Article 31*bis* 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 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 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 31*bis* 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 31*bis* are that:

   (a) the eligible importing Member(s)[4] has made a notification[2] 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

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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 31*bis* 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 organizations referred to in paragraph 3 of Article 31*bis* 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.

Articles 31 and 31*bis* 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

(iii) before shipment begins, the licensee shall post on a website[7] 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[8] 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. 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

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6 This subparagraph is without prejudice to Article 66.1 of 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 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.

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

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 recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31*bis* 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 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 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.

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.