

Intellectual property: agreement on trade-related aspects of rights TRIPS, done at Geneva on 6 December 2005, amending protocol by the WTO

2006/0060(AVC) - 27/04/2006 - Initial legislative proposal

PURPOSE: to accept, on behalf of the EU, the Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

PROPOSED ACT: Council Decision.

CONTENT: the purpose of this Council Decision is to accept, on behalf of the EU an amendment to the WTO TRIPS Agreement. It is the first ever such amendment to TRIPS and has come about due to the chronic shortages of pharmaceutical products in certain developing countries. Initially agreed in 2003 in the form of a “provisional waiver” there was an understanding that the “waiver” should at a later stage become an amendment to the TRIPS Agreement in the form of a Protocol in order to make it more permanent.

In amending TRIPS, WTO Members have committed themselves to exporting patented medicines to third countries with no manufacturing capacity in the pharmaceutical sector, by making use of compulsory licences. At the same time, substantial safeguards against trade diversion and re-importation have been set out. A statement, issued by the chair of the General Council describes Members’ “shared understanding” on how the Decision is interpreted and implemented. The Decision may only be used in good faith and is to be used for the purpose of public health problems only. It may not be used for industrial or commercial policy objectives. The statement also notes that the medicines must not get into the wrong hands.

To guarantee that the system is aimed at the neediest, developed countries in the WTO – including all of the EU Member States – have taken a commitment not to use the system as importers. Similarly, high income developing countries have made a statement that they would not use the system except in exceptional circumstances. The system does, however, allow all WTO members to act as exporters.

To recall, the Commission in 2004 proposed 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. The purpose of this Regulation is to give practical meaning to the implementation of the system described above. Its adoption is imminent. (Please refer to 2004/0258(COD)).

The European Commission, in accordance with Article 133 of the EU Treaty, negotiated on behalf of the European Community for the adoption of the Protocol. Further, upon adoption of the Regulation on compulsory licensing of patents, the Community will have an exclusive competence over this matter and Member States will, as a result, not be able to accept the Protocol individually. The President of the Council will be authorised to designate the person empowered to deposit the instrument of acceptance of the Protocol with the WTO Director General. The Protocol will be binding on its Member States. For these reasons the Commission proposes to the Council that it adopt the proposed Decision.