Pharmaceutical products: compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

2004/0258(COD) - 17/05/2006 - Final act

PURPOSE: to allow companies to manufacture patented medicines under license for export to those countries with insufficient capacity to manufacture them.

LEGISLATIVE ACT: Regulation 816/2006/EC of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

CONTENT: the Council adopted this Regulation (with the German delegation abstaining), following intensive cooperation between the Council and the European Parliament. The two co-legislators agreed to modify the Commission's proposal in order to widen the list of countries eligible to import products licensed under this Regulation.

"Compulsory licensing", which is written into the TRIPS Agreement, allows governments to issue licenses to companies who wish to manufacture patented products - without the permission of the patent holder. In other words, compulsory licensing permits the manufacture and use of generic drugs without the agreement of the patent holder. In order to protect the rights of the patent holder, certain rights are attached to the granting of compulsory licenses. One such right being that holders of compulsory licenses may only produce for the national or domestic market. This "national" requirement, however, leaves countries without a manufacturing base, (typically developing countries with public health problems), vulnerable and unable to import patented drugs made under compulsory licensing.

Without a manufacturing base, access to many medicines is out of the reach of the world's poorest populations. In order to remedy this situation, the WTO in 2003, agreed to a "Decision" which would waive the "national" provision relating to the manufacture of pharmaceutical products produced under compulsory licensing. In doing so developing countries are able to source cheap medicines manufactured outside of their territories.

In adopting this Regulation the Community is implementing the 2003 WTO Decision or "waiver" into the legal order of the EU. (As a reminder, the EU in a related move, is close to approving a WTO Protocol which implements, on a permanent basis, the waiver. Please refer to 2006/0060/AVC).

The issuing of compulsory licences under this Regulation imposes clear conditions upon the licensee as regards the acts covered by the licence, the identification of the pharmaceutical products manufactured under the licence and the countries to which the products will be exported. The Regulation has been designed to create a secure legal framework in a bid to discourage litigation and to avoid abuse of the provisions.

In adopting this Act the EU establishes a procedure for the granting of compulsory licenses in relation to patented products *intended for export to eligible importing countries who require them for public health purposes*. Those countries eligible are

a) any least developed country appearing on the United Nations list;

b) any WTO member, which has notified the TRIPS Council that it wishes to use the system as an importer; and

c) any country that is not a member of the WTO but is listed in the OECD Development Assistance Committee's list of low income countries.

Under the terms of this Regulation, any company in the EU can apply for a license to manufacture pharmaceutical products – without the authorisation of the patent holder. Upon being granted a license the licensee will be allowed to export those products to countries classified as "importing countries". The amount of products manufactured under license may not exceed what is necessary to meet the needs of the importing countries. Further the products made under license must be clearly identified, through specific labelling or marking requirements.

As far as remuneration is concerned the licensee is responsible for paying the patent holder. Remuneration may be 4% of the total price in cases of national emergency or other circumstances of extreme urgency. In all other cases, the remuneration will be determined by taking account of the economic value of the product and according to its use.

Upon granting a compulsory licence the Member States must notify the TRIPS Council of the arrangements. The text of the Regulation makes clear that the compulsory licensing system set up by this Regulation is intended to address public health problems only and should therefore not be used by countries to pursue industrial or commercial policy objectives. Moreover it specifies that products manufactured pursuant to this Regulation reach only those who need them and are not diverted from those for whom they were intended.

Lastly, the European Commission will prepare a report on the application of this Regulation three years after its entry into force.

ENTRY INTO FORCE: 29/06/2006.