Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 133 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) On 14 November 2001 the Fourth Ministerial Conference of the World Trade Organisation (WTO) adopted the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and Public Health. The Declaration recognises that each WTO Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. It also recognises that WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing.

(2) On 30 August 2003 the WTO General Council, in the light of the statement read out by its Chairman, adopted the Decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the Decision). Subject to certain conditions, the Decision waives certain obligations concerning the issue of compulsory licences set out in the TRIPS Agreement in order to address the needs of WTO Members with insufficient manufacturing capacity.

(3) Given the Community's active role in the adoption of the Decision, its commitment made to the WTO to fully contribute to the implementation of the Decision and its appeal to all WTO Members to ensure that the conditions are put in place which will allow the system set up by the Decision to operate efficiently, it is important for the Community to implement the Decision in its legal order.

(4) Uniform implementation of the Decision is needed to ensure that the conditions for the granting of compulsory licences for the manufacture and sale of pharmaceutical products, when such products are intended for export, are the same in all Member States

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and to avoid distortion of competition for operators in the single market. Uniform rules should also be applied to prevent re-importation into the territory of the Community of pharmaceutical products manufactured pursuant to the Decision.

(5) This Regulation is intended to be part of wider European and international action to address public health problems faced by least developed countries and other developing countries, and in particular to improve access to affordable medicines which are safe and effective, including fixed-dose combinations, and whose quality is guaranteed. In that connection, the procedures laid down in Community pharmaceutical legislation guaranteeing the scientific quality of such products will be available, in particular that provided for in Article 58 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[(3)].

(6) As the compulsory licensing system set up by this Regulation is intended to address public health problems, it should be used in good faith. This system should not be used by countries to pursue industrial or commercial policy objectives. This Regulation is designed to create a secure legal framework and to discourage litigation.

(7) As this Regulation is part of wider action to address the issue of access to affordable medicines for developing countries, complementary actions are set out in the Commission Programme for Action: Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction and in the Commission Communication on a Coherent European Policy Framework for External Action to Confront HIV/AIDS, malaria and tuberculosis. Continued urgent progress is necessary, including actions to support research to combat these diseases and to enhance capacity in developing countries.

(8) It is imperative that products manufactured pursuant to this Regulation reach only those who need them and are not diverted from those for whom they were intended. The issuing of compulsory licences under this Regulation must therefore impose 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.

(9) Provision should be made for customs action at external borders to deal with products manufactured and sold for export under a compulsory licence which a person attempts to reimport into the territory of the Community.

(10) Where pharmaceutical products produced under a compulsory licence have been seized under this Regulation, the competent authority may, in accordance with national legislation and with a view to ensuring that the intended use is made of the seized pharmaceutical products, decide to send the products to the relevant importing country according to the compulsory licence which has been granted.

(11) To avoid facilitating overproduction and possible diversion of products, the competent authorities should take into account existing compulsory licences for the same products and countries, as well as parallel applications indicated by the applicant.

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(12) Since the objectives of this Regulation, in particular the establishment of harmonised procedures for the granting of compulsory licences which contribute to the effective implementation of the system set up by the Decision, cannot be sufficiently achieved by the Member States because of the options available to exporting countries under the Decision and can therefore, by reason of the potential effects on operators in the internal market, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(13) The Community recognises the utmost desirability of promoting the transfer of technology and capacity-building to countries with insufficient or no manufacturing capacity in the pharmaceutical sector, in order to facilitate and increase the production of pharmaceutical products by those countries.

(14) In order to ensure the efficient processing of applications for compulsory licences under this Regulation, Member States should have the ability to prescribe purely formal or administrative requirements, such as rules on the language of the application, the form to be used, the identification of the patent(s) and/or supplementary protection certificate(s) in respect of which a compulsory licence is sought, and rules on applications made in electronic form.

(15) The simple formula for setting remuneration is intended to accelerate the process of granting a compulsory licence in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31(b) of the TRIPS Agreement. The figure of 4 % could be used as a reference point for deliberations on adequate remuneration in circumstances other than those listed above,

HAVE ADOPTED THIS REGULATION:

Article 1

Scope

This Regulation establishes a procedure for the grant of compulsory licences in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries in need of such products in order to address public health problems.

Member States shall grant a compulsory licence to any person making an application in accordance with Article 6 and subject to the conditions set out in Articles 6 to 10.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) ‘pharmaceutical product’ means any product of the pharmaceutical sector, including medicinal products as defined in Article 1(2) of Directive 2001/83/EC of the

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European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[(4)], active ingredients and diagnostic kits ex vivo;

(2) 'rights-holder' means the holder of any patent or supplementary protection certificate in relation to which a compulsory licence has been applied for under this Regulation;

(3) 'importing country' means the country to which the pharmaceutical product is to be exported;

(4) 'competent authority' for the purposes of Articles 1 to 11, 16 and 17 means any national authority having competence to grant compulsory licences under this Regulation in a given Member State.

Article 3

Competent authority

The competent authority as defined in Article 2(4) shall be that which has competence for the granting of compulsory licences under national patent law, unless the Member State determines otherwise.

Member States shall notify the Commission of the designated competent authority as defined in Article 2(4).

Notifications shall be published in the *Official Journal of the European Union*.

Article 4

Eligible importing countries

The following are eligible importing countries:

(a) any least-developed country appearing as such in the United Nations list;

(b) any member of the WTO, other than the least-developed country members referred to in point (a), that has made a notification to the Council for TRIPs of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way;

(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 with a gross national product per capita of less than USD 745, and has made a notification to the Commission of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way.

However, any WTO member that has made a declaration to the WTO that it will not use the system as an importing WTO member is not an eligible importing country.

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Article 5

Extension to least-developed and developing countries which are not members of the WTO

The following provisions shall apply to importing countries eligible under Article 4 which are not WTO members:

(a) the importing country shall make the notification referred to in Article 8(1) directly to the Commission;

(b) the importing country shall, in the notification referred to in Article 8(1), state that it will use the system to address public health problems and not as an instrument to pursue industrial or commercial policy objectives and that it will adopt the measures referred to in paragraph 4 of the Decision;

(c) the competent authority may, at the request of the rights-holder, or on its own initiative if national law allows the competent authority to act on its own initiative, terminate a compulsory licence granted pursuant to this Article if the importing country has failed to honour its obligations referred to in point (b). Before terminating a compulsory licence, the competent authority shall take into account any views expressed by the bodies referred to in Article 6(3)(f).

Article 6

Application for a compulsory licence

1 Any person may submit an application for a compulsory licence under this Regulation to a competent authority in the Member State or States where patents or supplementary protection certificates have effect and cover his intended activities of manufacture and sale for export.

2 If the person applying for a compulsory licence is submitting applications to authorities in more than one country for the same product, he shall indicate that fact in each application, together with details of the quantities and importing countries concerned.

3 The application pursuant to paragraph 1 shall set out the following:

a the name and contact details of the applicant and of any agent or representative whom the applicant has appointed to act for him before the competent authority;

b the non-proprietary name of the pharmaceutical product or products which the applicant intends to manufacture and sell for export under the compulsory licence;

c the amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;

d the importing country or countries;

e where applicable, evidence of prior negotiation with the rights-holder pursuant to Article 9;

f evidence of a specific request from:

(i) authorised representatives of the importing country or countries; or

(ii) a non-governmental organisation acting with the formal authorisation of one or more importing countries; or