STATUTORY INSTRUMENTS

S.I. No. 408 of 2008

EUROPEAN COMMUNITIES (COMPULSORY LICENSING OF PATENTS RELATING TO THE MANUFACTURE OF PHARMACEUTICAL PRODUCTS FOR EXPORT TO COUNTRIES WITH PUBLIC HEALTH PROBLEMS) REGULATIONS 2008

(Prn. A8/1651)

S.I. No. 408 of 2008

EUROPEAN COMMUNITIES (COMPULSORY LICENSING OF PATENTS RELATING TO THE MANUFACTURE OF PHARMACEUTICAL PRODUCTS FOR EXPORT TO COUNTRIES WITH PUBLIC HEALTH PROBLEMS) REGULATIONS 2008

I, MARY COUGHLAN, Minister for Enterprise, Trade and Employment, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Council Regulation (EC) No. 816/2006 of the European Parliament and of the Council of 17 May 2006[1], hereby make the following regulations:

1. These Regulations may be cited as the European Communities (Compulsory Licensing of Patents relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems) Regulations 2008.

2. (1) In these Regulations—

"Controller" means the Controller of Patents, Designs and Trade Marks;

"Council Regulation" means Regulation (EC) No. 816/2006 of the European Parliament and of the Council of 17 May 2006[1];

"proceedings" means proceedings or an application under the Council Regulation and these Regulations.

(2) A word or expression that is used in these Regulations and is also used in the Council Regulation has the same meaning as in the Council Regulation.

(3) A reference to an Article in these Regulations is a reference to an Article of the Council Regulation.

(4) A reference to a Patent Rule in these Regulations is a reference to a Rule in the Patent Rules 1992 (S.I. No. 179 of 1992).

3. (1) The competent authority in the State for the purposes of the Council Regulation (including Article 14) shall be the Controller.

(2) The body referred to in Article 14(1) with the authority to review as provided therein shall be the Irish Medicines Board.

(3) The appropriate body within the meaning of Article 17 shall be the High Court.

[1]OJ No. L157, 9.6.2006, p.1.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 24*th October*, 2008.

4. (1) An application under Article 6 for a compulsory licence shall be made to the Controller in the form as set out in the Schedule.

(2) The application and supporting evidence shall be filed with the Controller in duplicate.

(3) The Controller shall afford the rights-holder a reasonable period to comment and provide relevant information pursuant to Article 7.

5. The Controller shall determine the application—

(*a*) on receipt of comments and relevant information by the rights-holder, or

(*b*) where the rights-holder has not provided comments and relevant information, after the termination of a reasonable period.

6. A request—

(*a*) where applicable, under Article 5(*c*), or

(*b*) under Article 16(1),

shall be made to the Controller and contain—

(i) the name and address of the person making the request,

(ii) information identifying the compulsory licence,

(iii) the name of the importing country, and

(iv) the facts and the grounds upon which the person making the request relies,

and shall be accompanied by evidence supporting the request.

7. The Controller may give such directions as he or she thinks fit with regard to proceedings, including—

(*a*) the requirement to reply to the Controller with comments and documents within a period of time that the Controller considers reasonable, and

(*b*) the extension of any period of time for the filing of any document.

8. Where Article 17(2) applies, the Controller and the High Court shall have the power to rule that an appeal referred to therein shall have suspensory effect.

9. (1) Subject to these Regulations and the Council Regulation—

(*a*) sections 92 to 94 of the Patents Act 1992 (No. 1 of 1992), and

(*b*) Patent Rules 67, 69, 71 to 74, 76 and 91 to 97,

shall apply with any necessary modifications in relation to proceedings.

(2) Subject to Patent Rule 95, documents filed under these Regulations or the Council Regulation shall be in the Irish or English language.

SCHEDULE

Regulation 4.

Application for a Compulsory Licence of a Patent relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems under Regulation (EC) No. 816/2006

1. **Applicant:**

Name	
Address	

2. **Number of the Patent/Supplementary Protection Certificate:**

Patent No(s).	
SPC No(s).	

3. **Name and address of the Rights-Holder:**

Please list the names and addresses of all rights-holders of the patent or Supplementary Protection Certificate:

Name	
Address	

4. **Product identity:**

Please state the non-proprietary name or other description by which the product for which a compulsory licence is requested is known:

5. **Duration of licence sought:**

6. **Amount to be produced and importing countries:**

(i) ***In respect of this application:***

The importing country or countries		**The amount of the product which the applicant seeks to produce under the compulsory licence**
Country 1		
Country 2		
Country 3		
Country 4		

(If the applicant is submitting applications for compulsory licences to authorities in other countries, please indicate below the countries in which applications are being made together with details of the quantities to be produced and the names of the importing countries which are listed in those other applications).

(ii) ***Details of applications made in other countries:***

Name of other country where an application for a compulsory licence has been made:		
Duration of licence sought:		
The importing country or countries		**The amount of the product which the applicant seeks to produce under the compulsory licence**
Country 1		
Country 2		
Country 3		
Country 4		

7. **Documents accompanying this application:**

(*a*) Evidence of a specific request indicating the quantity of product required from one or more of the following:

(i) an authorised representative of the importing country or countries;

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

(iii) a competent organ of the United Nations or an international health organisation acting with the formal authorisation of one or more of the importing countries.

(*b*) Evidence of prior negotiation with the rights-holder, including details of the terms, conditions and price proposed in respect of each pharmaceutical product, pursuant to Article 9(1) of Regulation (EC) No. 816/2006 (unless not necessary by virtue of Article 9(2) of that Regulation).

8. **Authorised Agent**

(*Please provide the name and address of the agent (if any) who is authorised to act as agent in all proceedings connected with this application for a compulsory licence and in relation to any licence granted*).

Name of Agent	
Address of Agent	
Telephone No.	
Fax No.	
E-mail	

9. **Address for Service (if different from that at No. 8)**

Address for service	
Telephone No.	
Fax No.	
E-mail	

Signed by or on behalf of applicant:

Dated:

L.S.

GIVEN under my Official Seal,
10 October 2008

MARY COUGHLAN
Minister for Enterprise, Trade and Employment.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation).

These regulations lay down the procedural requirements which apply to requests for compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. The purpose of the regulations is to give full effect to Council Regulation (EC) No. 816/2006 regarding conditions for granting compulsory licences to companies intending to manufacture medicinal products for export to developing countries which do not have sufficient production capacity of their own and which have public health problems.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ón
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
nó tríd an bpost ó
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,
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DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased directly from the
GOVERNMENT PUBLICATIONS SALE OFFICE
SUN ALLIANCE HOUSE, MOLESWORTH STREET, DUBLIN 2,
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(Tel: 01 - 6476834/37 or 1890 213434; Fax: 01 - 6476843 or 094 - 9378964)
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ISBN 978-1-4064-4285-4

€3.05

9 781406 442854

Wt. (B26424). 305. 10/08. Cahill. Gr. 30-15.