REGULATION

No. 1011/2006

on Compulsory Licenses Relating to the Export of Pharmaceutical Products to Developing Countries and to Countries Struggling with Severe Public Health Problems

Article 1

Scope, etc.

This Regulation applies to compulsory licenses under paragraph 5 of Article 49 of the Patents Act No. 17 of 1991, as amended, for the export of pharmaceutical products to developing countries and to countries struggling with severe public health problems, in accordance with the Decision of the World Trade Organization's General Council of 30 August 2003 on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health.

The Reykjavik District Court grants compulsory licenses under this Regulation.

A compulsory license shall only be granted upon fulfilment of the conditions specified in the provisions of this Regulation.

Article 2

Definitions

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

(a) "compulsory license" is defined as a compulsory license under paragraph 5 of Article 49 of the Patents Act No. 17 of 1991, as amended, for the export of pharmaceutical products to developing countries and to countries struggling with severe public health problems, in accordance with the Decision of the World Trade Organization's General Council of 30 August 2003 on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health;

(b) "patent holder" is defined as the proprietor of a patent or the holder of a supplementary protection certificate for pharmaceutical products under Article 65 (a) of the Patents Act No. 17 of 1991, as amended;

(c) "pharmaceutical products" are defined as pharmaceutical products protected by a patent or a supplementary protection certificate under Article 65 (a) of the Patents Act No. 17 of 1991, as amended, or pharmaceutical products produced in accordance with a patented manufacturing process, or active substances necessary for that production, or equipment necessary for medical diagnosis;

(d) "TRIPS" is defined as the Agreement on Trade-Related Aspects of Intellectual Property Rights, which is an annex to the Agreement on the Establishment of the World Trade Organization signed at Marrakesh on 15 April 1994;

(e) the "TRIPS Council" is defined as the council supervising the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights operating under the overall supervision of the World Trade Organization's General Council.

Article 3
Importing countries

The following countries are eligible to import pharmaceutical products manufactured under a compulsory license:

(a) any least-developed country that appears as such on the United Nations' list;
(b) any member of the World Trade Organization, other than members referred to in sub-paragraph (a), that has notified the TRIPS Council in accordance with sub-paragraph (b) of Article 1 and sub-paragraph (a) of Article 2 of the Decision of the World Trade Organization's General Council of 30 August 2003 on the Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health.

Article 4
Application for a compulsory license

Private individuals and legal bodies may submit an application for a compulsory license under this Regulation. The application must be signed by the applicant or his/her/its agent and must include the following:

(a) the name, ID number and address of the applicant and his/her/its agent, if applicable;
(b) the number and name of the patent, or the supplementary protection certificate under Article 65 (a) of the Patents Act, subject to the application for a compulsory license, including the name and address of its patent's proprietor;
(c) the names of the pharmaceutical products that the applicant intends to manufacture and sell for export under the compulsory license, including, if possible, international non-proprietary names approved by the World Health Organization.
(d) the quantity of pharmaceutical products that the applicant seeks to produce under the compulsory license;
(e) the countries to which the applicant intends to export the pharmaceutical products;
(f) evidence of the applicant's unsuccessful efforts to obtain a production license from the patent holder for 30 days before submitting the application for a compulsory license, or evidence of a national emergency or other circumstances of extreme urgency, cf. paragraph 5 of Article 49 of the Patents Act No. 17 of 1991, as amended;

(g) evidence that countries intending to import the pharmaceutical products have notified the TRIPS Council in accordance with sub-paragraph (b) of Article 3, specifying the name and quantity of the pharmaceutical products required;
(h) evidence that the pharmaceutical products are neither protected by patents nor by a supplementary protection certificate for the protection of pharmaceutical products in the importing country, or evidence that the importing country has granted a compulsory license, or evidence that the importing country has notified the TRIPS Council that it intends to grant a compulsory license in accordance with sub-paragraph (a) of Article 2 of the Decision of the World Trade Organization's General Council of 30 August 2003 on the Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health;
(i) other matters as needed in accordance with the Decision of the World Trade Organization's General Council of 30 August 2003.

Article 5
Notification to the patent holder

The District Court shall notify the patent holder as soon as possible of the application for a compulsory license and shall give him/her/it an opportunity to comment upon the application prior to granting the compulsory license.

Article 6
Verification of conditions, the granting of a compulsory license and its substance

The District Court shall verify whether the application fulfils the conditions set forth in this Regulation. The District Court may request the opinion of the Icelandic Patent Office during the procedure. In the event that the information provided for in Article 4 is insufficient, the District Court judge shall grant the applicant an extension of two weeks to provide the information. In the event that the conditions outlined in Article 4 are not met, or if the information is not provided within the two-week extension period, the District Court shall refuse the application for a compulsory license.

If the District Court judge determines that the application should be approved, the judge shall grant a compulsory license. The information provided in the compulsory license shall include:

(a) the names of the pharmaceutical products that the compulsory license holder is authorized to manufacture and export;
(b) the countries to which the pharmaceutical products may be exported;
(c) the quantity of the pharmaceutical products that [the compulsory license holder] is authorized to produce and export, which may not exceed the needs of the importing countries;
(d) a statement that the pharmaceutical products must be packaged and labelled in accordance with Article 8;

(e) a provision that the compulsory license holder shall, before export, post information on his/her/its website in accordance with Article 9;
(f) the duration of the compulsory license.

Concurrently with a decision to grant a compulsory license, the District Court judge shall determine the amount of remuneration to be paid to the patent holder.

Copies of the District Court's decision shall be sent to the patent holder as well as to the Icelandic Patent Office, the latter of which shall record information concerning compulsory licenses in the patent register and post an announcement to that effect in the *Icelandic Patent Gazette*.

Article 7
The scope of a compulsory license

The compulsory license holder is authorized to manufacture only the pharmaceutical products specified in the compulsory license and only in the quantities therein cited. The holder does not have permission to market, sell or export the pharmaceutical products to countries other than those specified in the compulsory license.

Article 8
Labelling and packaging

Pharmaceutical products manufactured under the compulsory license shall be distinguishable from pharmaceutical products manufactured by the patent holder. The pharmaceutical products shall be distinguished from those manufactured by the patent holder through the use of special packaging, colouring or shape, provided that such distinctions are feasible and do not have a significant impact on price. The pharmaceutical products must be labelled in a way indicating that the product was manufactured in accordance with a compulsory license under paragraph 5 of Article 49 of the Patents Act No. 17 of 1991, as amended, and under this Regulation.

Article 9
Information posted on the website of the compulsory license holder

Prior to the export of the pharmaceutical products, the compulsory license holder shall post information in Icelandic and English on his/her/its website regarding the quantities being supplied under the license and the countries to which the pharmaceutical products are to be supplied. Furthermore, information must be posted there specifying how pharmaceutical products manufactured under the compulsory license may be distinguished from the pharmaceutical products of the patent holder. This information must remain on the website of the compulsory license holder for the duration of the compulsory license.

If the compulsory license holder does not host a website in his/her/its own name, the information referred to in paragraph 1 shall be sent to the World Trade Organization,

which will post the information on a website that relates to the Decision of the General Council of 30 August 2003.

The compulsory license holder shall notify the Icelandic Patent Office and the patent holder that the information referred to in paragraph 1 has been posted on his/her/its website or the website of the World Trade Organization, along with the web address.

Article 10
Notification to the TRIPS Council

The Icelandic Patent Office shall notify the TRIPS Council that a compulsory license has been granted. The notification shall include the following information:

(a) the name and address of the compulsory license holder;
(b) the pharmaceutical products covered by the compulsory license;
(c) the quantities of pharmaceutical products to be exported;
(d) the countries to which the pharmaceutical products are to be exported;
(e) the duration of the compulsory license;
(f) the web address of the compulsory license holder that displays the information outlined in paragraph 1 of Article 9.

Article 11
Extension of the duration of a compulsory license

The compulsory license holder may request that the District Court extend the duration of a compulsory license if the licensee has been unable to export the permitted quantities of pharmaceutical products cited in the compulsory license. The patent holder shall be informed as soon as possible of a request by the compulsory license holder for an extension and must be given an opportunity to comment upon the application. The District Court shall only approve such a request if it finds that the compulsory license holder has in other respects fulfilled the conditions outlined in the compulsory license.

Article 12
Revocation of a compulsory license

The patent holder may submit a request that the District Court revoke a compulsory license. The District Court judge may comply with such a request if the court finds that the compulsory license holder has not fulfilled the conditions outlined in the compulsory license. Both the compulsory license holder and the patent holder shall be notified of the decision of revocation.

A copy of a decision to revoke a compulsory license must be sent to the Icelandic Patent Office, which must notify the TRIPS Council of the contents of the revocation as soon as possible.

In the event of a revocation of a compulsory license, the compulsory license holder must as soon as possible see to it that any excess stock of pharmaceutical products manufactured under the provisions of this Regulation be distributed to the countries designated as importing countries in the compulsory license, or see to it that the pharmaceutical products shall otherwise be disposed of.

Article 13
Entry into force

This Regulation, which has been issued pursuant to authorization provided in paragraph 5 of Article 49 of the Patents Act No. 17 of 1991, as amended, enters into force immediately.

The Ministry of Industry, 23 November 2006

Jon Sigurdsson

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Kristjan Skarphedinsson