Joint Ministerial Decision 14905/EFA/3058

"Lodging of an application with the O.B.I. for the granting of a supplementary certificate for protection for pharmaceuticals"

THE MINISTERS

OF THE NATIONAL ECONOMY, OF DEVELOPMENT, AND OF HEALTH AND WELFARE

Having taken into consideration:

1. The provisions:

a. Of Article 2, para. 1 (h) and (j) of Law 1338/1983 'Implementation of Community law' (Government Gazette 34 A') as this was amended by Article 6, para. 1 of Law 1440/1984 'Participation of Greece in the capital, reserves, and provisions of the European Investment Bank, and in the capital of the European Coal and Steel Community and the EURATOM Supply Organisation' (Government Gazette 70 A').

b. Of Article 1, para. 2 of Law 1733/1987 'Transfer of technology, inventions, and technological innovation, and setting up of an Atomic Energy Commission' (Government Gazette 171 A').

c. Of Articles 11 and 12 of Presidential Decree 77/88 'Provisions on the implementation of the Convention on the granting of European patents', which was ratified by Law 1607/1987 (Government Gazette 33/A'/25-2-1988).

Of Law 2077/1992 'Ratification of the Treaty on the European Union ...' (Government Gazette A' 136).

Regulation (EEC) 1768/92 of the Council of June 1992 (EU No. L 182/1 of 2 July 1992).

Article 29 A' of Law 1558/85 (A'/37) as that was added by Article 27 of Law 2081/1992 (A' 154) and replaced by Article 1, para. 2a of Law 2469/1997 (A' 38).

The fact that no charge on the state budget is created by the provisions of the present decision.

The minute of 22 October 1997 of the Administrative Council of the O.B.I.

We have determined

PART ONE

GENERAL PROVISIONS

Article 1

Aim

The aim of the present decision is the determination of the procedure for the granting of a supplementary certificate of protection for pharmaceuticals for which a patent has been granted and which, before their circulation in the market, are subject to an administrative procedure for the granting of a circulation permit in accordance with Directives 65/65/EEC or 81/851 EEC, as the case may be.

Article 2

Definitions

For the purposes of the implementation of this decision, the following shall be meant by:

a. 'Regulation (EEC) 1768/92': Regulation (EEC) 1768/92 of the Council of the European Union of 18 June 1992 'in connection with the introduction of a supplementary certificate of protection for pharmaceuticals' (EU No. L 182/1 of 2 July 1992).

b. 'Directive 65/65/EEC': Directive 65/65/EEC of the Council of 26 January 'concerning convergence of legislative, regulatory, and administrative provisions in connection with proprietary pharmaceuticals' (EU No. 22 of 9 February 1965), as that was later amended and continues in force, including Ministerial Decisions Nos 3221/95 (Government Gazette 782 B', 13 December 1995) and 9392 (Government Gazette 233 B', 7 April 1992) on its implementation in Greece.

c. Directive 81/851/EEC of 28 September 1981 'concerning convergence of legislations of the member-states in connection with veterinary pharmaceutical products' (EU No. L 317 of 6 November 1981), as that was later amended and continues in force, including Ministerial Decision No. 378812/92 (Government Gazette 491 B', 30 July 1992) on its implementation in Greece.

d. "O.B.I.": the Industrial Property Organisation, which has its registered office in Athens (Article 1 of Law 1733/1987).

e. 'Law 1733/1987': Law 1733/1987 'Transfer of technology, inventions, and technological innovation, and setting up of an Atomic Energy Commission' (Government Gazette 171 A'), as that continues in force.

f. 'Pharmaceutical': any substance or compound which is prepared as having therapeutic or preventive properties within the meaning of Article 1, para 1 of Regulation (EEC) 1768/92.

g. 'Patent': the patent granted by the O.B.I. in accordance with Article 8 of Law 1733/87 (Government Gazette 171 A'), or the European patent with force in Greece in accordance with Article 23 of Law 1733/87.

h. 'Certificate': the supplementary certificate of protection which is granted for pharmaceuticals on the terms of Article 3 of Regulation (EEC) 1768/92.

i. 'Circulation permit': the granting of approval of a pharmaceutical in the market in accordance with Directives 65/65/EEC (EU No. L 22 of 9 December 1965), or 81/851/EEC (EU No. 2317 of 6 November 1981), which have been incorporated into the national legislation by Joint Ministerial Decision 16/10399/13-12/31.12.1985 (B798) and Joint Ministerial Decision 300518/2-11/9.11.1984 (B800), respectively, and continue in force in amended form.

PART TWO

PERSONS ENTITLED - PROCEDURE FOR LODGING

Article 3

Right of acquisition of a certificate

A right to protection shall be possessed by the holder of a patent and his general or special successors in title in accordance with the terms of Article 3 of Regulation (EEC) 1768/92.

Article 4

Competent authority

The competent authority for the lodging of the application and the granting of the certificate shall be the Industrial Property Organisation (O.B.I.).

Article 5

Lodging of an application

For the granting of a certificate, the lodging of an application with the O.B.I. in accordance with Article 7 of Regulation (EEC) 1768/92 shall be required.

The application shall be submitted in two copies and shall contain the particulars cited in Article 8 of Regulation (EEC) 1768/92.

To the application shall be annexed, in addition to the particulars of paragraph 2 of this article, the documents legitimating the person lodging them in the case of a legal person and the receipt for the collection by the O.B.I. of the duty for the lodging of an application for the granting of a certificate.

If the terms of the paragraph 2 above of the article are fulfilled, the application shall be accepted for lodging. In this event, the application shall be deemed to be regular, it shall be given a lodging date, and shall be entered in the Reports Register of the O.B.I.

As to the lodging and drafting of documents before the O.B.I., Articles 2, 3, 4 and 9 of Ministerial Decision 15928/EFA/1253 (Government Gazette 778 B') and 19 of Presidential Decree 77/88 (Government Gazette 33 A') shall be implemented.

Article 6

Additional information

Within four months from regular lodging and after written notice from the O.B.I., the applicant must submit to the O.B.I. any missing information and supporting documents in accordance with Article 5, paragraphs 2 and 3 of the present decision. In this event, the application shall be deemed complete.

If after the elapse of the time-limit of paragraph 1 above of this article, the O.B.I. establishes that the data of the application have not been completed, the application shall be rejected.

PART THREE

CERTIFICATE - PUBLICATION

Article 7

Granting of a certificate

If the application is complete and regular in accordance with Articles 5 and 6 of this decision and if the product which it concerns fulfils the terms of Regulation (EEC) 1768/92, the O.B.I. shall grant the certificate without a prior check on the terms of Article 3, para. 1, items (c) and (d) of Regulation (EEC) 1768/92, on the responsibility of the applicant.

After the granting of the certificate, third parties may seek information and copies of the application and of the additional information which concerns the product protected.

The O.B.I. shall, without fail, notify the National Pharmaceuticals Organisation of the granting of the certificate.

Article 8

Publication

The publication stipulated in Article 11 of Regulation (EEC) 1768/92 shall be in the Industrial Property Bulletin.

The publication of the certificate shall also mandatorily give the data of Article 11, para. 1 of Regulation (EEC) 1768/92.

In the event of the application being rejected by the O.B.I. in accordance with Article 6, para. 2 of the present Ministerial Decision, the act of rejection and the particulars of Article 9, para. 2 of Regulation (EEC) 1768/92 shall be published in the Industrial Property Bulletin.

PART FOUR

RIGHTS FROM THE CERTIFICATE - DUTIES

Article 9

Content of right

The certificate shall give its holder, being a natural or legal person, the exclusive rights of Article 10 of Law 1733/87, which shall be implemented mutatis mutandis.

Article 10

Charges

For the lodging of an application for the granting of a certificate, lodging duties shall be paid to the O.B.I.

For the granting of protection, the holder of the certificate shall be obliged to make prepayment of annual duties to the O.B.I., in mutatis mutandis implementation of Article 24 of Law 1733/87.

The level of the lodging duty and of the annual protection duties shall be determined by a decision of the Administrative Council of the O.B.I..

Failure to make punctual payment of the annual protection duties shall entail forfeiture of the rights which stem from the certificate, in mutatis mutandis implementation of Article 16 of Law 1733/87.

PART FIVE

FINAL PROVISIONS

Article 11

Commencement of force

This decision shall come into force on its publication in the Government Gazette.

This decision is to be published in the Government Gazette.