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COUNCIL REGULATION (EEC) No 1768/92

IN THE MATTER OF Application No SPC/GB93/135 for a Supplementary Protection Certificate for a Medicinal Product by The Green Cross Corporation

DECISION

Application No SPC/GB93/135 for a Supplementary Protection Certificate in the name of the Green Cross Corporation was lodged on 30 June 1993 with the United Kingdom Patent Office as the competent industrial property Office pursuant to Article 9(1) of Council Regulation (EEC) No 1768/92 (hereinafter "the Regulation").

Form SP1 requesting the grant of a Supplementary Protection Certificate identified "Soyacal 10%" as the product for which protection was sought and Product Licence No 4447/0012 as the first authorization in accordance with Directive 65/65/EEC or Directive 81/851/EEC to place the product on the market in the United Kingdom. Form SP1 also identified an authorization in Italy dated 24 October 1988 for the product "Soyacal 10%" as the first authorization to place the product on the market in the Community, but did not state the number of this authorization, or the legal provision under which it took place.

The application contained a copy of part of Product Licence No 4447/0012. This formed part of a copy of a letter from the Medicines Control Agency to the licence holder Alpha Therapeutic UK Limited dated 6 February 1991 and entitled "Publication of Licensing Information in the National Gazettes". On the reverse of the first sheet of the letter, it is stated that the Licence has been granted

> "in respect of the product, particulars of which are set out in Part 1 of the attached Schedule. The Licence is subject to the further provisions set out or referred to in Part 2 of the said Schedule".

Part 1 of the Schedule is headed:-

> "Summary of particulars of the product to which the licence relates (Summary of product characteristics for the purpose of EC Directive 65/65 as amended by EC Directive 83/570)"

but summarises a number of the particulars by reference to attachments which were not present. Part 2 of the Schedule was not present.

The application also contained a document in the Italian language headed "Il Ministero Della Sanita". This document referred to "Soyacal 10%" and was dated "24 Ott 1988", and appeared to constitute a copy of an Italian marketing authorization. It was not accompanied by a verified translation.

Article 8(1) of the Regulation reads:-

> "1. The application for a certificate shall contain:-
>
> ....
>
> (b) a copy of the authorization to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Article 4a of Directive 65/65/EEC or Article 5a of Directive 81/851/EEC;
>
> (c) if the authorization referred to in (b) is not the first authorization for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorised and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication."

Articles 10(3) and 10(4) of the Regulation read:

> "3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.
>
> 4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application."

The application did not therefore contain a copy of a notice publishing the Italian authorisation in an appropriate official publication as required by Article 8(1)(c). Nor did it clearly contain information as to the legal provision under which the Italian authorisation procedure took place, also as required by Article 8(1)(c).

Further, the copy of Product Licence No 4447/0012 did not contain in its entirety the summary of product characteristics required by Article 8(1)(b).

Accordingly, an Official Letter was issued under Article 10(3) on 11 October 1993 explaining that the application did not meet the conditions laid down in Articles 8(1)(b) and 8(1)(c).

The Official Letter gave a period of two months for the applicant to rectify these irregularities. The letter also stated:

- that, in accordance with Article 10(4), failure to rectify the irregularities would result in rejection of the application;

- that it was open to the applicant to request an extension of the period by writing to the Office before its expiry, giving reasons for the request; and

- that in any event the application would not be rejected without giving the applicant an opportunity to submit observations or to request to be heard in the matter.

On 22 October 1993, the agents acting for the applicant filed a copy of the complete Schedule from the UK Product Licence. The accompanying letter also stated: "Information on the remaining objections is awaited from our client in Japan". An Official Letter was issued on 29 October 1993 confirming that the requirements of Article 8(1)(b) had now been met, but that the remaining objections remained outstanding. No further reply having been received from the applicant, a further Official Letter was issued on 6 January 1994 informing the applicants that it was intended to reject the application under Article 10(4). The letter also stated that any observations and/or a request to be heard in the matter should be submitted to the Office within a period of one month from the date of the letter, and that, in the absence of any response, a decision would issue rejecting the application.

No such observations and/or request to be heard in the matter having been received in response to the Official Letter dated 6 January 1994 within the stated period, the application is hereby rejected pursuant to Article 10(4) of the Regulation for failure to meet the conditions laid down in Article 8(1)(c).

This being a procedural matter, the period within which an appeal may be lodged with the Patents Court is 14 days from the date below.

Signed this 1st day of August 1994

R. Kennell

R C KENNELL
Senior Examiner, acting for the Comptroller

THE PATENT OFFICE