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COUNCIL REGULATION (EEC) NO 1768/92

Miss Durow
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IN THE MATTER OF Application No SPC/GB95/018 for a Supplementary Protection Certificate in the name of British Technology Group Limited

DECISION

Application No SPC/GB95/018 for a Supplementary Protection Certificate in the name of British Technology Group Limited was lodged on 20 June 1995 with the United Kingdom Patent Office as the competent industrial property office pursuant to Article 9(1) of Council Regulation (EEC) No 1768/92 ("the Regulation").

In accordance with rule 3(2) of the Patents (Supplementary Protection Certificate for Medicinal Products) Rules 1992, the application in suit was made on Form SP1. This identified:

- the product for which protection was sought as "1,2-dimethyl-3-hydroxypyrid-4-one" (also known as "Deferpirone")

- the basic patent protecting the product as EP(UK) 0093498 entitled "Pharmaceutical compositions comprising N-substituted 3-hydroxy- pyrid-2-one or -4-one derivatives"

- 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 as No MF 8000/6033 ("MF6033") dated 22 December 1994

In an official letter dated 18 August 1995 the examiner reported inter alia that:

"The document MF6033 would not appear to constitute an authorization to place the product on the market. In any case it does not appear to have been granted under Directive 65/65/EEC or 81/851/EEC as required by Article 3(b), or to contain the summary of product characteristics required by Article 8(1)(b)."

In a response dated 16 October 1995 the applicants stated:

"We submit that if the Office has any doubt as to whether MF6033 does or does not constitute an authorization to place the product on the market in accordance with Article 3(b), the Office may properly, in its discretion, keep open the present application, without taking a decision or rejecting the application for failure to comply with Article 8(1)(b), pending grant of a full product licence. This would ensure that the applicant's rights to a Certificate are not prejudiced in the meantime by an incorrect decision on behalf of the Patent Office."

However, in the official letter of 24 November 1995 the examiner, referring to the wording of Articles 3 and 7(1), reported:

"On this basis it appears that the application in it's present form must be refused or withdrawn and it is unacceptable to merely stay the proceedings on the grounds that a product authorization may be obtained at some future date."

The examiner's objections to the grant of a certificate not having been resolved in subsequent correspondence, the applicants were offered a hearing but declined to attend. It falls to me therefore to decide the matter based on the papers on file.

The relevant parts of the Regulation are as follows:

ARTICLE 3

Conditions for obtaining a certificate

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application;

...

(b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;

...

ARTICLE 8

Content of the application for a certificate

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;

...

The document MF6033, which is claimed by the applicants to be an authorization to supply Deferpirone BAN in the United Kingdom, actually comprises a single sheet of paper in the form of a letter from the Medicines Control Agency ("MCA") and appears to grant permission for the product to be supplied for a proposed clinical trial. In my experience market authorizations for the United Kingdom at present take the form of Product Licences. The format of these documents varies, but licences issued by the MCA usually comprise a grant document, an authenticated copy of the licence application (Form MLA 201), one or more Schedules and a separate summary of product characteristics. MF6033 appears to lack all of these attributes, particularly the summary of product characteristics which is essential for compliance with Article 8(1)(b) of the Regulation.

Furthermore, the examiner has obtained evidence in the form of a letter dated 6 February 1996, a copy of which was supplied to the applicants, from Frances Law who is of senior rank in the MCA, being the Unit Manager-Administrative Unit Abridged Licensing Group. This letter refers to MF6033 in the following terms:

> "This letter is not a marketing authorization for a medicinal product issued in accordance with Directive 65/65/EEC. The letter is issued permitting the company to supply the product for use in a particular clinical trial only and the company are not at liberty to supply the product in other circumstances."

The applicants have only asserted in the correspondence with the examiner that MF6033 is an acceptable market authorization but have supplied no proof, nor any convincing argument, that it is acceptable.

In view of the evidence from MCA and the absolute requirement of Article 8(1)(b) that the copy of the authorization filed in the Office must contain a summary of product characteristics I find that the application in it's present form fails to meet the conditions for obtaining a certificate as required by Article 3(b) of the Regulation.

I shall now consider whether the applicants are to be allowed to keep the application "open", despite the fact that it does not meet the requirements of the Regulation, or whether the

examiner was correct in his view that the application must be refused or withdrawn. Since at this point in time the applicants have refused to withdraw the application the only option I need to consider is the need for refusal.

In the applicants' letter of 16 October 1995 the following arguments were put:

> "If the preliminary view of the Office is correct, and MF6033 is not to be taken as marketing authorization in accordance with Article 3(b), such that no such marketing authorization has been granted in the United Kingdom, the applicant will nonetheless in due course be entitled to a Certificate at least provided that a valid authorization in accordance with Article 3(b) is granted in the United Kingdom before expiry of the basic patent (i.e. before 23 March 2003) and providing an application is filed in accordance with Article 7. Such a certificate will have a term, subject to payment of fees, of five years."
>
> "If, however, the preliminary opinion of the Office is wrong, and MF6033 does constitute an authorization in accordance with Article 3(b), and if the present application is rejected and the applicants file a further application upon grant of a full product licence they may be held to be out of time under Article 7(1)."
>
> "We respectfully submit that the issue of compliance with Article 8(1)(b), namely the provision of the summary of product characteristics listed in Article 4 of Regulation 65/65/EEC is of secondary importance. If MF6033 constitutes an authorization under Article 3(b), but does not contain a summary of product characteristics required by Article 8(1)(b), then the applicant should be provided an opportunity to produce these once these become available. If MF6033 is not an authorization within Article 3(b), the question of compliance with Article 8(1)(b) becomes immaterial."

I am not convinced by the applicants' argument that the application may be extant until the year 2003 without a valid product licence being granted as this would place third parties at considerable disadvantage because they would be aware that an application for the product Deferpirone had been filed with this Office but would be left uncertain as to whether a

Certificate would ever be granted. On this basis they may be prevented from seeking their own legitimate marketing of the same product. It is, however, clear from the papers on file that the examiner has afforded the applicants two opportunities to file a complete product licence including the summary of product characteristics, allowing two months for response each time, before writing for a third time to offer a hearing. Bearing in mind the fact that I consider the examiner's objections under Articles 3(b) and 8(1)(b) to be well founded, it would seem from a reading of Article 10(2),(3) and (4) that I have no option but to refuse the application. The relevant parts of Article 10 read as follows:

ARTICLE 10

...

2. The authority referred to in Article 9(1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.

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 or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.

...

Since the examiner was in correspondence with the applicants for eight months before offering a hearing it is clear that the applicants have been given ample opportunity under the provisions of Article 10(3) to comply with the outstanding objections and file a complete copy of the product licence. Furthermore, the six month Article 7(1) period had almost completely elapsed before the application was filed, thus giving a total of almost 14 months from the date of the alleged grant of the marketing authorization until the offer of the hearing.

I therefore have no choice but to follow the direction given in Article 10(4) and reject the application.

Returning to the argument of 16 October 1995, the applicants have drawn attention to Article 7(1) which states:

ARTICLE 7

Application for a certificate

1. The application for a certificate shall be lodged within six months of the date on which the authorization referred to in Article 3(b) to place the product on the market as a medicinal product was granted.

...

The applicants are concerned that if my decision on the requirement of a summary of product characteristics to be filed is wrong then it will prevent them obtaining grant on filing a fresh application since the six month period specified in Article 7(1) has already elapsed.

In this situation the applicants have redress in pursuing an appeal against the present decision. However, in my view the fact that an application has been filed and refused does not prevent the filing at a later date of a fresh application protecting the same product provided all the requirements of the Regulation can then be met. This is consistent with Article 3(c) which states:

ARTICLE 3

Conditions for obtaining a certificate

A certificate shall be granted if, in a Member State in which the application referred to in Article 7 is submitted and at the date of the application:

...

(c) the product has not already been the subject of a certificate

...

Consequently only a granted certificate to the product (Deferpirone) would prevent the granting of a fresh application naming the same product, the previous filing and refusal having no effect.

Accordingly, I hereby reject the application in suit for grant of a supplementary protection certificate on the grounds that the product to be protected has not obtained market authorization in accordance with Article 3(b) and a copy of the product characteristics listed in Article 4a of Directive 65/65/EEC or Article 5a of Directive 81/851/EEC has not been filed within the stated time.

Regulation 5 of the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992 extends the existing provisions of the Patents Act 1977 and 1949 to certificates. Accordingly, in accordance with Order 104, rule 19(2)(b) of the Rules of the Supreme Court, any appeal against this decision must be lodged within six weeks of the date of the decision.

Dated this 24 day of April 1996

[redacted]

D L WOOD
Principal Examiner, acting for the Comptroller

THE PATENT OFFICE