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COUNCIL REGULATION (EEC) NO 1768/92

O/132/95

IN THE MATTER OF Application No SPC/GB94/012 for a Supplementary Protection Certificate in the name of Farmitalia Carlo Erba S.r.l.

DECISION

Application No SPC/GB94/012 for a supplementary protection certificate ("SPC") in the name of Farmitalia Carlo Erba S.r.l. (the "applicants") was lodged on 11 July 1994 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 inter alia:

- the product for which protection was sought as "Cabergoline, optionally in the form of the free base or a pharmaceutically acceptable acid addition salt thereof";

- the basic patent protecting the product as GB 2074566 entitled "Ergoline Derivatives", having expiry date of 30 March 2001;

- the first authorization in accordance with Directive 65/65/EEC ("Directive 65") or Directive 81/851/EEC ("Directive 851") to place the product on the market in the United Kingdom as Product Licence No 3433/0169 dated 12 January 1994; and

- the first authorization to place the product on the market in the Community as Netherlands authorization No 15375 dated 21 October 1992 in respect of the product "Dostinex".

In a letter dated 11 July 1994 accompanying the application, the applicants stated that the two authorizations referred to on Form SP1 were directed to medicines containing cabergoline as an active constituent for human use only and were in accordance with Directive 65. However they also drew attention to the fact that, on 7 January 1987, under No 26245, authorization was granted in Italy in accordance with Directive 851 for the sale of the veterinary medicine "Galastop" containing cabergoline as active constituent. However, they submitted that the Netherlands (human) authorization, and not the Italian (veterinary) authorization should be properly regarded as the first authorization in the Community for the product in suit.

In an official letter dated 4 August 1994, the applicants were informed that the preliminary view of the Office was:

"- that unless there are earlier authorizations in the Community (whether pharmaceutical or veterinary), the Italian veterinary authorization of 7 January 1987, and not the Dutch human authorization of 21 October 1992, is the first authorization to place the product on the market in the Community for the purposes of Articles 8(1)(a)(iv), 8(1)(c) and 13(1); and

- that the conditions of Article 8 will need to be met in respect of that authorization rather than the Dutch authorization."

In response, the applicants amended Form SP1 to refer additionally to the Italian authorization pursuant to Article 8(1)(a)(iv) and provided a copy of that authorization pursuant to Article 8(1)(c) together with a verified translation into English.

However, in their accompanying agent's letter dated 3 October 1994, the applicants disputed the Office view that this Italian authorization should form the starting point for calculating the duration of the SPC under Article 13(1).

No agreement on this point having been reached in subsequent correspondence, the matter came before me at a hearing on 24 July 1995 at which Mr Nicholas Pumfrey QC instructed

by J A Kemp & Co appeared for the applicants. Mr R C Kennell also attended on behalf of the Office.

Article 13 reads:

"

ARTICLE 13

Duration of the certificate

1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community reduced by a period of five years.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect."

As Mr Pumfrey stated at the hearing, the matter to be decided in the present case, namely the duration of the SPC to be granted pursuant to the application in suit, is essentially a short point on construction of Article 13, in particular the interpretation of the words in Article 13(1):

"the date of the first authorization to place the product on the market in the Community"

It is not in dispute that an authorization to place the product cabergoline on the market in the Community was in fact that granted in Italy on 7 January 1987. Accordingly, on a plain interpretation of the words in question, I am in no doubt that the date of the first authorization to place the product on the market in the Community was indeed 7 January 1987 and not 21 October 1992 as contended by the applicants.

However, as explained by Mr Pumfrey, for the reasons set out in Yamanouchi Pharmaceutical Company's Application [SRIS 0/112/93], it is also necessary to have regard to the intention of the Regulation before deciding finally on its interpretation.

In this connection, my attention was drawn to the provisions of Article 4. This reads:

" ARTICLE 4

Subject-matter of protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate."

As explained by Mr Pumfrey, the effect of this Article is that the protection conferred by the certificate is automatically extended when a new authorization to place the product in question on the market is granted in the Member State in question. Thus, in the present case, the protection conferred by the SPC granted on the application in suit will be expanded automatically to protect any product for which a UK authorization is granted before the expiry of the SPC, whether for human use in accordance with Directive 65 or for veterinary use in accordance with Directive 851.

I would observe that this provision is necessary to ensure that protection is available in respect of any use of the product as a medicinal product authorised subsequent to the grant of the SPC since Article 3(c) expressly forbids the grant of a second SPC for a product which has already been the subject of an SPC.

As also explained by Mr Pumfrey, if the duration of the SPC is calculated on the basis of the veterinary authorization granted in Italy on 7 January 1987 under Directive 851, then the

duration of the certificate in accordance with Article 13(1) (ie until 6 January 2002) would be significantly less than 15 years from the date of the first human medicinal authorization granted in the Community under Directive 65 on 21 October 1992.

He submitted that this was contrary to the intention of the Regulation as set out in the following Recitals:

> "1. Whereas at the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research;
>
> 2. Whereas this situation leads to a lack of protection which penalizes pharmaceutical research;
>
> 3. Whereas the current situation is creating the risk of research centres situated in the Member States relocating to countries that already offer greater protection;
>
> 4. Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogenous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market;
>
> 5. Whereas, therefore, the creation of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorization has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument;

6. Whereas the duration of the protection granted by the certificate should be such as to provide adequate effective protection; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusivity from the time the medicinal product in question first obtains authorization to be placed on the market in the Community;

7. Whereas all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector must nevertheless be taken into account, whereas, for this purpose, the certificate cannot be granted for a period exceeding five years; whereas the protection granted should furthermore be strictly confined to the product which obtained authorization to be placed on the market as a medicinal product;"

(numbering added for convenience)

Mr Pumfrey submitted that in order to achieve the intention of these Recitals, it was necessary to differentiate between authorizations for human use under Directive 65 and for veterinary use under Directive 851. Thus, in the present case, since the UK authorization on which the application was based was for human use of the product under Directive 65, the first authorization in the Community for the purposes of Article 13 should be the first authorization under that Directive with no account being taken of any early authorization under Directive 81/851/EEC. Similarly, if the UK authorization had been under Directive 851 then only the first authorization in the Community under that Directive should count.

Having considered the Recitals in question, I find that those I have numbered 1, 2, 3, 5 and 7 are in too general terms to enable me to place a different interpretation on Article 13 from what appears to me to be the plain meaning of the words in question.

However, Recitals 4 and 6 appeared to me to be of particular relevance in interpreting Article 13 in the present case. Thus, as regards Recital 4 above, I pointed out to Mr Pumfrey that it would appear that, if his interpretation of Article 13 were adopted, the

outcome would be that in those Member States such as Italy in which the first authorization was for a medicinal product for veterinary use, the duration of the SPC would be based on the date of the Italian authorization and the SPC would expire on 6 January 2002. In contrast, in those Member States such as the UK in which the first authorization was for a medicinal product for human use, the duration of the SPC would be based on the date of the Netherlands authorization and the SPC would expire on 30 March 2006. However, for the reasons explained by Mr Pumfrey, both sets of SPCs will cover all veterinary and medicinal uses authorized in the Member State concerned. Prima facie, this difference in the duration of protection in the different Member States would clearly be contrary to the intention of the Regulation as set out in the above Recital.

As regards Recital 6 above, I pointed out that, again as Mr Pumfrey had already explained, if before the expiry of the SPC an authorization is granted for a veterinary use of the product, this use will automatically be protected by the SPC under Article 4. This means that if the duration of the SPC were to be based on the Netherlands authorization so that the SPC expired on 30 March 2006, the holder of the patent and certificate would enjoy protection for any such veterinary use of the product from 7 January 1987 to 30 March 2006, ie a period of over 19 years from the time the product obtained its first authorization to be placed on the market in the Community. Prima facie, this would conflict with the overall maximum of 15 years exclusivity specified in the Recital.

In response, Mr Pumfrey acknowledged the force of these remarks but submitted that there were two points which I should bear in mind. The first one was that there have been a fair number of SPCs now, and these are necessarily not going to be very common circumstances. I was therefore dealing with slightly exceptional circumstances here.

His second point was that the Regulation must have been based on the assumption that the date of the first authorization in the Community is not going to be very much different from the date when all the other authorizations are going to be received because, if it was very anterior, the net result may well be unfair.

Having considered the matter, I do not find either of these points persuasive. On the contrary, I am satisfied that the interpretation of Article 13 proposed by Mr Pumfrey would in fact be clearly contrary to the intention of the Regulation as set out in the Recitals having particular regard to the Recitals 4 and 6.

Mr Pumfrey also stated that his interpretation of Article 13(1)was supported by the existence of the proposed Council Regulation concerning the Creation of a Supplementary Protection Certificate for Plant Protection Products. He submitted that, in the situation where a product was authorised for use as a plant protection product after having being previously authorised for use as a medicinal product, no account would be taken of the date of the medicinal authorization in calculating the duration of the SPC for a plant protection product. He submitted that a similar distinction should be made under Article 13(1) in respect of medical products for human and veterinary use.

While I am prepared to accept that in the future it may be possible for a first SPC to be granted under the current Regulation in respect of its use as a medicinal product and for a second SPC having a different expiry date to be granted under a new Regulation in respect of its use as a plant protection product, I do not find this of any relevance to the interpretation of Article 13(1) of the current Regulation.

I therefore find that the plain meaning of Article 13(1) is the correct one and that, in the case of the application in suit, the date of the first authorization to place the product "cabergoline" on the market in the Community is the Italian authorization dated 7 January 1987.

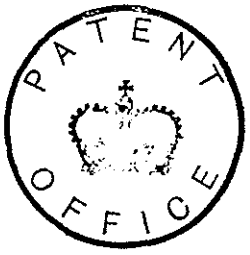
The applicant has not disputed that, on the basis of this Italian authorization, the maximum duration of the certificate pursuant to Article 13 and to rule 5(1)(b) of the 1992 Rules will expire on 6 January 2002.

It is also not in dispute that all conditions for the grant of an SPC are met.

I therefore direct that an SPC be granted in respect of the application in suit with a maximum duration under rule 5(1)(b) of the 1992 which will expire on 6 January 2002.

Regulation 5 of the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992 extends the existing provisions of the Patents Acts 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 7th day of August 1995



[redacted]

L LEWIS
Principal Examiner, acting for the Comptroller

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