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COUNCIL REGULATION (EEC) NO 1768/92

IN THE MATTER OF Application No SPC/GB 93/009 for a Supplementary Protection Certificate for a Medicinal Product by Yamanouchi Pharmaceutical Co Ltd

DECISION

On 15 January 1993, Yamanouchi Pharmaceutical Co Ltd (the "applicants") lodged with the United Kingdom Patent Office Application No SPC/GB 93/009 for a Supplementary Protection Certificate (a "certificate") under Council Regulation (EEC) No 1768/62 (the "Regulation") for the product "Formoterol Fumerate" based on their United Kingdom patent No 1415256 (the "basic patent").

In accordance with rule 3 of the Patents (Supplementary Protection Certificate for Medicinal Products) Rules 1992, the application comprised a Request for grant of Supplementary Protection Certificate on Form SP1 accompanied by the prescribed fee. The application was accompanied by a letter dated 13 January 1993 from the agent for the applicants stating inter alia:

> "I enclose herewith a Request for Grant of a Supplementary Protection Certificate. This application is being made under the Transitional Provisions (Article 19) of the Council Regulation (EEC) No 1768/92 and the Patents (Supplementary Protection Certificate for Medicinal Products) Rules 1992.
>
> Article 19 does not state that there has to be authorisation in the UK - only "in the Community". The first authorisation to place the product on the market in the Community was in France. It was granted on 29 June 1990. A copy of this and a declared translation thereof is enclosed. .....

Three applications for product licences in the UK (covering different doses) were filed on 16 June 1989, Nos PL 0001/0148-0150. These were refused, necessitating more work. New applications will be filed once this is completed. A copy of these three applications is enclosed."

The application was also accompanied by a copy of the notice in the Journal Official de la République Française, a copy of the French authorisation itself and a verified translation into English of each of these French language documents in accordance with rule 113(1) of the Patents Rules 1990, as it applies by virtue of regulation 5 of the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992 (the "1992 Regulations").

In an official letter dated 3 February 1993, the examiner to whom the application was referred informed the applicants that it had been reported to the Comptroller that the application did not comply with the requirements of the Regulation in that, inter alia,

"at the date of the application for the certificate, namely 15 January 1993, no valid authorisation to place the product on the market as a medicinal product had been granted in the member state in which the application was submitted, namely the United Kingdom, as required by Article 3(b) of the Regulation. In addition, the application does not contain a copy of the authorisation to place the product on the market as referred to in Article 3(b), as required by Article 8(1)(b)."

Following further correspondence, the matter came before me at a hearing on 24 August 1993 at which the applicants were represented by Hugh Laddie QC instructed by their agent, T Sharman.

At the hearing, I was handed copies of evidence which the applicants proposed formally to submit in support of the application. This evidence (which has now been lodged) consists of affidavits by the following persons:

(1) Dr Helen Sussman

(2) Dr James Stewart

(3) Dr Hans Mohr

(4) Dr Franz Fischer

(5) Miss Gabrielle Wiederkehr

(6) Miss Lisa Patten

together with exhibits thereto.

As a preliminary matter, Mr Laddie requested a direction under rule 94(1) that affidavits (1) to (5) and exhibit HFM-1 to affidavit (3) should be treated as confidential under rule 94(1). His reasons were that this evidence contains technical information about the product which was not in the public domain and which it would be prejudicial to the applicants and their associates to make open to public inspection. Having considered the evidence in question, I gave the direction requested by Mr Laddie on his undertaking that the content of the formal evidence would be the same as that of the copies handed to me.

I come now to the substance of the matter before me, namely whether the application in suit satisfies the requirements of the Regulation for the grant of a certificate.

It is not in dispute that what were conveniently termed by Mr Laddie as the "standard" requirements for the grant of a certificate are as follows.

First, under Article 3 of the Regulation:

> **"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;
>
> (a) the product is protected by a basic patent in force;
>
> (b) a valid authorisation 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;

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

(d) the authorisation referred to in (b) is the first authorisation to place the product on the market as a medicinal product."

Second, the application must be filed within the period prescribed by Article 7 which states:

"**Application for a certificate**

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

2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted."

Third, contents of the application must comply with Article 8(1) which states:

"**Content of the application for a certificate**

1. The application for a certificate shall contain:

(a) a request for the grant of a certificate, stating in particular:

(i) the name and address of the applicant;

(ii) if he has appointed a representative, the name and address of the representative;

(iii) the number of the basic patent and the title of the invention;

(iv) the number and date of the first authorisation to place the product on the market, as referred to in Article 3(b) and, if this authorisation is not the first authorisation for placing the product on the market in the Community, the number and date of that authorisation;

(b) a copy of the authorisation 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 authorisation 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 authorisation referred to in (b) is not the first authorisation 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 authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication."

Finally, the Office at which the application must be lodged is set out in Article 9(1) as follows:

"**Lodging of an application for a certificate**

1. The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorisation referred to in Article 3(b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose."

It was also not in dispute that the application in suit did not comply with the "standard" requirement contained in Article 3(b) that in the Member State in which the application was submitted, namely the United Kingdom, no authorisation to place the product on the market as a medicinal product had been granted at the date of application.

It also follows that the application did not contain either the number and date of the first authorisation as referred to in Article 3(b) as required by Article 8(1)(a)(iv) or a copy of that authorisation as required by Article 8(1)(b).

Mr Laddie did not dispute that, in the normal course of events, the application should be rejected for failure to comply with these "standard" requirements.

He contended, however, that the application was submitted in accordance with the transitional provisions contained in Article 19 of the Regulation and that it was sufficient for the grant of a certificate that the application met the requirements of that Article.

Article 19 reads as follows:

> **"Transitional provisions**
>
> 1. Any product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product in the Community was obtained after 1 January 1985 may be granted a certificate.
>
> In the case of certificates to be granted in Denmark and in Germany, the date of 1 January 1985 shall be replaced by that of 1 January 1988.
>
> In the case of certificates to be granted in Belgium and in Italy, the date of 1 January 1985 shall be replaced by that of 1 January 1982.

2. An application for a certificate as referred to in paragraph 1 shall be submitted within six months of the date on which this Regulation enters into force."

It is not in dispute that on the date on which the Regulation entered into force, namely 2 January 1993, the basic patent was still in force so that the product was protected by a valid basic patent on that date as required by Article 19(1). Also, the first authorisation in the Community is stated on Form SP1 to have been granted in France on 29 June 1990, ie after 1 January 1985 as required by Article 19(2).

Accordingly, the facts of the case are not in dispute. In particular, no authorisation has yet been granted to place the product on the market in the United Kingdom and the application satisfies the requirements of Article 19.

The matter in issue therefore turns solely on the interpretation of the Regulation as to whether or not it is sufficient that the application in suit satisfies the requirements of Article 19 or whether the application must also satisfy certain "standard" requirements, in particular those contained in Articles 3(b), 8(1)(a)(iv) and 8(1)(b), in order for a certificate to be obtained.

The nub of Mr Laddie's contention on this point was that the Regulation contains two separate regimes for the grant of a certificate: the first being the "standard" regime contained in Articles 3 to 8 and the second being a transitional regime contained in Article 19 taken alone. In support of this contention, he first referred me to the preamble to the Regulation. This includes the following recital:

"Whereas the transitional arrangements applicable to applications for certificates filed and to certificates granted under national legislation prior to the entry into force of this Regulation should be defined;"

However, the application in suit was not filed under national legislation prior to the entry into force of this Regulation. Nor was any certificate so granted. Accordingly, I do not find that

this recital, or indeed any other part of the preamble, gives me any guidance as to the interpretation of the transitional provisions in Article 19 relevant to the matter before me.

Mr Laddie also referred me to a preliminary draft of a proposal for the Regulation entitled "Meeting of government experts on 14 September 1989" (a copy of which was handed to me at the hearing) and to the proposal for the Regulation presented by the Commission of the European Committees including the accompanying Explanatory Memorandum (Exhibit JS-3). In these texts, the transitional provisions were contained in Article 13. This Article included a provision, not present in the Regulation as adopted, which read as follows:

> "1. Any product which, on the date on which this Regulation enters into force, is protected by a valid patent and for which authorisation to place it on the market has not yet been obtained may benefit from the application of this Regulation."

Mr Laddie submitted that this provision was inconsistent with the "standard" requirements in the draft proposal and that this inconsistency demonstrated that it was the intention of Council of Ministers in adopting the Regulation to provide a separate regime for applications filed under the transitional provisions.

However, having considered the matter, I am unable to draw from this unadopted draft provision any inference at all as to the Council's intention as to the interpretation of the Regulation as adopted.

Mr Laddie also drew my attention to the following precedent cases regarding the interpretation of statutes:

> Artemiou v Procopiou [1966] 1 QB 878
> In re Maryon-Wilson's Will Trusts, Blofield v St Hill [1986] 1 Ch.268
> Vickers, Sons & Maxim, Ltd v Evans [1910] AC 444

However, in my view the meaning of Article 19 is clear in itself without the need for recourse to these precedents. Thus, paragraph (1) defines the products to which the

transitional provisions relates and paragraph (2) sets out the nature of these transitional provisions, that is the requirement that the application shall be submitted within six months of the date on which the Regulation enters into force.

I understand these provisions to mean only that the period for submitting an application for a product within the terms of Article 19(1) is the six month period starting on the day the Regulation entered into force. This is more generous than the relevant six month period prescribed by Article 7(1) or (2) in that it allows applications to be filed in respect of products for which the period prescribed by Article 7(1) or (2) had wholly expired prior to the entry into force of the Regulation, which products would otherwise not benefit from the additional protection afforded by a certificate.

Thus, in my view, the only requirement that is different in the case of an application referred to in Article 19(1) is the period for submitting the application under Article 19(2). Apart from this difference, all of the remaining provisions of the Regulation, including the "standard" requirements of Articles 3, 8 and 9, apply in their entirety to applications under Article 19.

Accordingly, except insofar as Article 19(2) prescribes a different period from Article 7 for submitting an application, I do not accept Mr Laddie's submission that the Regulation contains two separate regimes.

In this connection, the inevitable consequence of taking Article 19 alone would appear to be that, in the case of an application submitted under this Article, none of the "standard requirements" of Articles 3, 8 and 9 apply. This does not seem to me a reasonable state of affairs. Mr Laddie submitted that the "standard" requirements could apply insofar as they were not inconsistent with the more generous provisions of Article 19(1). However, I can find no basis in the Regulation for such an interpretation. In my view the only reasonable interpretation is that all of the "standard requirements" apply except where the express provision in Article 19(2) takes precedence.

I am also re-inforced in my view that the "standard" requirements of Article 3 must apply to all applications, whether or not submitted under Article 19, by the invalidity provisions of Article 15(1). This Article reads:

"**Invalidity of the certificate**

1. The certificate shall be invalid if:

   (a) it was granted contrary to the provisions of Article 3;

   (b) the basic patent has lapsed before its lawful term expires;

   (c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation."

It appears clear to me that any application which does not meet with the requirements of Article 3 - ie including the requirement of Article 3(b) - must necessarily be invalid. It also appears axiomatic that the grant of a certificate in respect of a product which indisputably does not fulfil one of the requirements of Article 15(1) would serve no useful purpose. Mr Laddie submitted that Article 15(1)(a) should be so interpreted that a certificate filed in respect of an application complying with the conditions of Article 19 should not be found invalid for non-compliance with Article 3. However, again I can find no basis in the Regulation for such an interpretation.

I come now to the evidence filed in these proceedings. Affidavits (1) to (5) describe the drug, its effects and the efforts by the applicants and Ciba-Geigy to obtain marketing authorisation for its use as a treatment for asthma. My understanding is that this evidence is primarily in response to observations in a letter dated 24 March 1993 to the Patent Office from McKenna & Co in which, inter alia it is submitted that:

"..... patentees should not be allowed to prolong the period in which generic manufacturers are kept out of the market by unjustifiable delay in obtaining marketing authorisations."

However, this submission is not relevant to the matter before me and I can find nothing in these affidavits which assists me in that matter which, as noted above, turns solely on the interpretation of the Regulation.

Affidavit (6) is by Lisa Joan Frederica Patten, a solicitor with Linklaters & Paines. With reference to exhibit LJFP-2 which comprises "copies of extracts of UK Parliamentary debates and reports concerning pharmaceutical patents and the proposed measure [ie the Regulation]", Miss Patten states:

"I note from these extracts that there is mention that patent erosion is likely to be of increasing significance and especially pronounced in the case of medicines for chronic and incurable diseases, such as asthma."

However, again I do not find that this assists me in these proceedings.

Of more relevance, however, is exhibit LJFP-1 which comprises correspondence between Miss Patten on the one hand and Mr Bertold Schwab and Mr Dominique Vandergheynst of DG XV of the Commission of the European Communities on the other. In a first fax to Mr Schwab dated 2 July 1993, Miss Patten states:

"We spoke recently concerning the scope of the SPC Regulation. You kindly agreed to give me your views on our particular area of interest. This was whether a product covered by a valid patent on 2 January 1993 could be protected by an SPC although no marketing authorisation in the Member State concerned had been obtained before that date. For your ease of reference, I attach a copy of the Regulation as adopted.

We briefly discussed the above scenario. You thought, at first sight, that, assuming the patent was in force on 2 January 1993, this special case should not be denied

supplementary protection especially, for example, where marketing authorisation in the relevant Member State was then obtained within the subsequent six months. You doubted whether there would be any supplementary protection if marketing authorisation was obtained some considerable period after the expiry of the patent. If the period between expiry of the patent and grant of marketing authorisation was in terms of years rather than months, this would be an extreme case of patent erosion and as such, one which ought to benefit from the Regulation. On the other hand, it was also desirable for competitors to know whether or not they were free to enter the market at a given date and uncertainty would be introduced if protection depended on when marketing authorisation was obtained, if at all."

In a response dated 16 July 1993, Mr Vandergheynst to whom the fax was passed gives the following "personal information":

"For me, the only possibility of a favourable interpretation could happen in the transitional period of article 19."

This avenue was explored in a further fax from Miss Patten dated 28 July 1993:

"You say that the only possibility of a favourable interpretation could happen in the transitional period of Article 19. Is this because the transitional provisions stand alone, as opposed to being subject to overriding requirements set out in Article 3? For instance, if a patent expired after the Regulation came into force (say, in the UK, on 3 January 1993) and UK marketing authorisation was obtained afterwards (the first authorisation in the Community being obtained after 1 January 1985), would an application for an SPC in the UK filed before 2 July 1993 succeed under the transitional provisions? Such a case seems to fall squarely within the transitional provisions of the adopted Regulation."

Miss Patten received the following response in a fax dated 5 August 1993:

"In answer to your query, I can say yes. This because the three conditions for the transitional provision are fulfilled:-

the patent expires after the Regulation came into force, even if this is one day after;

the first authorisation in the Community is obtained after 1 January 1985, even in the six first months of 1993;

the application for the transitional provision is filed before 2 July 1993."

I note that the general thrust of this personal opinion does not appear to accord with my interpretation that Article 19 does not stand alone. However, having re-considered the matter in the light of the opinion, I still remain of the view that any application, whether submitted under Article 19 or not, must comply with the requirements of Articles 3, 8 and 9.

Mr Laddie also submitted that in the event that I found that Article 19 was ambiguous, I should resolve this ambiguity by adopting the construction which does less injustice. In support of this, he referred me to the decision in Edward Smith v The Directors etc, of the Great Western Railway [1877] 3 AC 165. In doing so, he implied that the grant of the certificate would do the less injustice.

In my view, Article 19 is not ambiguous as to the need to comply with Articles 3, 8 and 9. However, if it were, I am not satisfied that there would be less injustice in refusing the application than in granting a certificate. The reason for this is as follows.

The basic patent GB 1415256 was filed on 18 January 1973 and therefore its twenty year term expired on 17 January 1993. It is not in dispute that no authorisation for placing the product on the market in the United Kingdom had been granted before its expiry.

It is clear that, under the "standard" requirements applying to all future applications, it will a condition for the grant of a certificate that an authorisation to place the product on the

market in the Member State concerned must have been granted before the date of expiry of the patent. This is because otherwise there will be no date for filing the application on which the conditions of both Articles 3(a) and (b) are satisfied, ie on which in the Member State concerned the product is protected by a basic patent in force and a valid authorisation to place the product on the market has been granted.

Thus, since in the future it will not be possible to obtain a certificate where no authorisation is granted in the Member State before the patent expires, it does not seem to me an injustice that this should also not be possible in the present case.

Accordingly, in the light of my finding above that an application filed in accordance with Article 19 must satisfy the "standard" requirements of Articles 3, 8 and 9 and the undisputed fact that in the absence of an authorisation for the United Kingdom the application does not satisfy the requirements of Articles 3(b), 8(1)(a)(iv) and 8(1)(b), I hereby refuse the application in suit for grant of a certificate.

Regulation 5 of the 1992 Regulations 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.

Signed this 8th day of September 1993

L LEWIS
Principal Examiner, acting for the Comptroller

THE PATENT OFFICE