

(21.3.07) is already less than 5 years and as such the SPC would have a zero term.”

The examiner made the final observation that, “...I see no reason to grant your request for an SPC.”

- 4 The application is not an end in itself but as the applicant states in their letter of 10 August 2007:

“...we are applying for an SPC under the provisions of (EEC) Regulation No. 1768/92 in order to reserve our rights to utilise the provisions of Regulation (EC) No. 1901/2006 [the “Paediatric Regulation”] especially Article 36, to apply for a six-month extension to the SPC.”

- 5 I should note that the applicants contend that the examiner’s letter of 29 November 2007 was itself an appealable decision, and have accordingly launched an appeal in the Patents Court for which a date has already been set. The Office did not accept this view, because in the normal course of events the applicant would have been expected to respond to the first official action, and the examiner, having considered that response, would only then have gone on to consider whether to offer a hearing before the Comptroller on any unresolved issues. The fact that this has not happened leads the Office to the view that there is, as yet, no decision against which the applicant can appeal. While the applicants have reserved their position on this point, they have nevertheless consented to an Office decision being prepared on the papers, and to facilitate this, they have submitted a copy of the skeleton argument prepared for the action in the Patents Court which they have agreed can be taken as their response to the examiner’s arguments. This is then the basis on which I shall make my decision.

- 6 The only point in contention is whether an SPC can be granted notwithstanding that a positive value for the term of protection does not result when the calculations are made as prescribed in Council Regulation 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, (hereinafter referred to as “the Regulation” or “the SPC Regulation”). There is no dispute that the current application meets the substantive conditions for obtaining a certificate as set out in the Regulation.

The law and its interpretation

- 7 Grant or rejection of an application is decided by reference to Article 10 of the Regulation which provides that:

“(1) Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9 (1) shall grant the certificate.

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

(5) “

If I am to consider the application further the next logical provision is Article 13 which states:

“(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.

(3) The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.”

8 Article 13(3) shows the route by which the applicants intended to seek a benefit through compliance with the requirements of Article 36 of the Paediatric Regulation, which I reproduce here to confirm the association with the SPC regulation and show how the benefit is obtained:

“(1) Where an application under Article 7 or 8 includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Articles 13(1) and 13(2) of Regulation (EEC) No 1768/92.

The first subparagraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.

(2) The inclusion in a marketing authorisation of the statement referred to in Article 28(3) shall be used for the purposes

of applying paragraph 1 of this Article.

(3) Where the procedures laid down in Directive 2001/83/EC have been used, the six-month extension of the period referred to in paragraph 1 shall be granted only if the product is authorised in all Member States.

(4) Paragraphs 1, 2 and 3 shall apply to products that are protected by a supplementary protection certificate under Regulation (EEC) No 1768/92, or under a patent which qualifies for the granting of the supplementary protection certificate.”

- 9 I have no case law to guide me in this matter but I do have some guidance in the form of the views expressed by the European Commission in the “Record of the meeting of national experts held on 3 February 1995”, (“the first meeting”) the relevant section, namely the second paragraph on page 11, is reproduced below. Additional comments were also provided by the Commission in the “Record of the Second meeting of national “Supplementary Protection Certificate” (SPC) experts held on 9 October 2006 in Brussels” (“the second meeting”), the relevant section from the final paragraph on page 15 is also below:

“[first meeting] The commission representative pointed out that the duration of a certificate was calculated by reference to the principles set out in Article 13 of the Regulation. If under that Article, the duration of the certificate was zero, no certificate should be issued; the application could be considered as no longer serving a useful purpose (the view could be taken that that it did not constitute an application for an extension of basic patent under Article 13).”

“[second meeting] A different issue, but in relation with the proposal of Paediatric Regulation, The COM also want to point out that the extension of the SPC should not apply in case where the SPC duration is “0”. In order for an extension to be granted, the SPC is a *sine qua non*.”

- 10 The applicants have questioned if such material can constitute a legitimate source of interpretation of the Regulation. In the absence of other authority I do believe that these comments of the Commission should be given serious consideration. However given the timing of the first meeting, it would not have been possible at that time for the Commission to have taken into account the possibility of obtaining a paediatric extension in coming to the view that a zero-term SPC should not be granted because it would serve no purpose. The applicants contend that a purpose is indeed provided by the Paediatric Regulation in forming a basis for a paediatric extension. I note support for this view in the Paediatric Regulation, Article 36(4) which I have quoted above and Recital 27 which provide that:

“An application for an extension of the duration of the certificate pursuant to this Regulation should only be admissible where a certificate is granted pursuant to Regulation (EEC) No 1768/92.”

- 11 In their comments at the second meeting the Commission does recognise that a paediatric extension must be based on an SPC, but appears to define an additional prerequisite, namely that the SPC should have a positive term. However, this is not backed up with any reasoning. Moreover, I can find no basis for such a requirement in either the Paediatric or SPC Regulations, nor can I find anything that explicitly forbids the granting of an SPC with a zero or negative term.

Discussion

- 12 Applying the law as set out above to the facts of the present case, the only possible objection to granting an SPC would seem to be that it would be an absurdity to grant an intellectual property right without a positive term. However it seems to me that no harm would be done by this: third parties would not be deceived about the existence or otherwise of rights, and I can see no other possible negative effects. On the other hand there would be real benefits in the sense that there is value and meaning in the potential to obtain a paediatric extension.
- 13 There is the question of the calculation of the period of the SPC, should one be granted. Applying the calculation in Article 13(1) of the Regulation to the data supplied in this application gives a negative answer: the certificate shall take effect at the end of the lawful term of the patent, that is 5th July 2022, and run for a period of minus 3 months and 14 days. This implies that the SPC will never take effect. However if a successful application for a paediatric extension were eventually to be made, this term would be extended by six months under Article 13(3), which would give a positive value and allow the SPC to take effect.
- 14 I note that in some of the correspondence the expression “zero term” has been used to describe the result where a positive value does not result from the calculation in Article 13(3). This expression has been used rather loosely to cover not only the special case where the calculation gives an answer of precisely zero, but also all cases where the term comes out with a negative value. It has not however been argued by the applicants in their skeleton argument, and I can find no basis in either Regulation for concluding, that negative values should be rounded up to zero for the purposes of calculating the period of the SPC. The logic of such a view should be immediately apparent to anyone who has paid money into a bank account that is showing an overdrawn balance.
- 15 I must make it clear at this point that I am not making any decision about the ultimate availability of a paediatric extension. That will be for another day. But if no SPC is granted on the present application, then the possibility of even applying would seem to be ruled out. Accordingly I have no doubt that an SPC should be granted.

Decision

- 16 In accordance with Article 10(1) of the Regulation, Supplementary Protection Certificate No SPC/GB07/046 is hereby granted to Merck & Co., Inc. in respect of the product “sitagliptin phosphate monohydrate” protected by the basic patent No EP (UK) 1412357 B1 entitled “Beta-amino tetrahydroimidazo(1,2-A)pyrazines and

tetrahydrotriazolo(4,3-A)pyrazines as dipeptidyl peptidase inhibitors for the treatment or prevention of diabetes". This certificate will take effect (subject to the payment of the prescribed fees) at the end of the lawful term of the basic patent 5th July 2022 and its maximum period of duration in accordance with Article 13 will expire on 20th March 2022 subject to the provisions of Articles 14 and 15.

A C Howard

Divisional Director acting for the Comptroller