INTELLECTUAL PROPERTY OFFICE

BL O/384/09

15 December 2009

REGULATION (EC) No 469/2009 CONCERNING THE SUPPLEMENTARY PROTECTION CERTIFICATE FOR MEDICINAL PRODUCTS

APPLICANT	Neurim Pharmaceuticals (1991) Ltd
ISSUE	Whether SPC application number SPC/GB/07/051 complies with Article 3(d) and may be granted
HEARING OFFICER	Dr C L Davies

DECISION

Introduction

1 This relates to an application for a supplementary protection certificate (SPC) which was filed by Neurim Pharmaceuticals (1991) Ltd ("the applicants") on 26 September 2007 and accorded the number SPC/GB/07/051. The product for which an SPC is sought was, at the time of filing, "Melatonin". Subsequent to the hearing, on 14 October 2009 an auxiliary request was filed amending the product definition to "Circadin – melatonin", which was to be considered if I was minded to refuse the application based on the original product definition.

2 The application was filed under Regulation (EEC) No 1768/92,[1] which has since been codified under Regulation (EC) No 469/2009.[2] Where arguments were put to me on the basis of various provisions of Regulation (EEC) No 1768/92, I have considered them on the basis of the equivalent provisions of Regulation (EC) No 469/2009 and my decision has been reached in accordance with Regulation (EC) No 469/2009 ("the Regulation").

[1] Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products

[2] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products

3 The basic patent upon which the application relies is EP (UK) 0518468 B1, which was filed on 23 April 1992 with an earliest priority date of 9 May 1991 and was granted on 30 June 1999. The authorisation EU/1/07/392/001 supplied in support of the application was granted on 29 June 2007 in respect of the medicinal product Circadin. Circadin is an insomnia treatment comprising the active agent melatonin and the basic patent concerns the use of melatonin to correct a distortion or deficiency in the plasma melatonin profile of a human subject.

4 In his examination report dated 15 July 2008, the Examiner (Dr Jason Bellia) observed that the application did not comply with Article 3(d), stating:

> *"The authorisation EU/1/07/392/001 does not appear to be the first authorisation to place melatonin on the market as a medicinal product. A composition comprising melatonin has been marketed by CEVA Animal Health since at least 1/1/2001 under the registered trade mark Regulin (see excerpt of the London Gazette). Therefore it is my preliminary view that this application does not comply with the regulation at Article 3(d)."*

It is worth noting that in fact the examiner should have concluded that the Regulin authorisation was granted at the latest on 22 March 2001, it being advertised in the London Gazette in a list of authorisations granted between 1 January 2001 and 22 March 2001, but in practice this has no material effect on his objection or my decision. The medicinal product Regulin is intended for use in sheep to initiate the breeding season earlier in the year than is usual.

5 In their agent's letter of 17 November 2008, the applicants disagreed with the examiner's opinion on this point on three grounds. They suggested that (i) denying an SPC in this instance would be contrary to the rationale of the Regulation; (ii) in order for an earlier authorisation to count under Article 3(d) it had to relate to the same mechanism of action and therapeutic purpose as the later authorisation and (iii) the Regulin authorisation should not be considered to be the first marketing authorisation for the purposes of Article 3(d) as Regulin did not satisfy the medicinal product definition of Article 1(a).

6 In response, the examiner maintained his position in a letter of 15 January 2009. He did not consider that (i) the applicants had fully represented the purpose of the Regulation and was therefore not minded to discard a literal interpretation of the Regulation in order to achieve that purpose and (ii) the mechanism or therapeutic purpose to have any relevance in determining compliance with Article 3(d) as it only referred to product and not to medicinal product. Regarding (iii), he did consider Regulin to be a medicinal product as defined in Article 1(a) on the basis of its biological action and the identity of the legislation under which it was authorised.

7 Following further rejection of the examiner's arguments in respect of (i) and (ii), this matter came before me at a hearing on 1 October 2009 where the applicants were represented by Dr Hugh Goodfellow and Mr Edward Oates of Carpmaels & Ransford.

8 Prior to the hearing, the applicants submitted skeleton arguments which formed the basis of the hearing and hence the framework of my decision. In their skeleton arguments the applicants pursued only (i) and (ii)

The relevant law

9 Article 3, parts (b) and (d) of the Regulation state:

> *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 authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;*
>
> *(d) the authorization referred to in point (b) is the first authorization to place the product on the market as a medicinal product.*

wherein "medicinal product" and "product" are defined in Article 1 as follows:

> *For the purposes of this Regulation:*
>
> *(a) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;*
>
> *(b) 'product' means the active ingredient or combination of active ingredients of a medicinal product;*

10 Directives 2001/83/EC[3] and 2001/82/EC[4] referred to in Article 3 (b) are the directives under which human and veterinary marketing authorisations respectively are granted and replaced Directives 65/65/EEC[5] and 81/851/EEC,[6] which were specified in Article 3(b) of Regulation (EEC) No 1768/92.

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[3] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

[4] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

[5] Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products

[6] Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products

11 The subject matter of protection is governed by Article 4, which states:

> *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 authorisation 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.*

12 Also relevant to deciding whether this application can be granted are various recitals to the Regulation, the 2nd to 5th and 7th to 10th being as follows:

> 2. *Pharmaceutical research plays a decisive role in the continuing improvement in public health.*
>
> 3. *Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.*
>
> 4. *At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation 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.*
>
> 5. *This situation leads to a lack of protection which penalises pharmaceutical research.*
>
> 7. *A uniform solution at Community level should be provided for, thereby preventing the heterogeneous 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 functioning of the internal market.*
>
> 8. *Therefore, the provision 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 authorisation has been granted is necessary. A regulation is therefore the most appropriate legal instrument.*
>
> 9. *The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community.*

10. All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.

Argument and analysis

13 Two main lines of argument were put to me. Firstly, that the Regulation should be interpreted teleologically and on such an interpretation an SPC should be granted; secondly, that the application does in fact meet the requirements of Article 3(d) and should therefore be granted. These of course correspond to the first two of the grounds set out in the agent's letter of 17 November 2008 and highlighted in paragraphs 5 & 6. Although there is a degree of overlap between the two sets of arguments, to ensure I address all the points raised on behalf of the applicants I shall follow this approach.

Teleological interpretation

14 It is established practice that a teleological approach should be taken to the interpretation of Community law and I do not dispute that it is an approach that I should take in relation to the current application. That is to say, I should be careful not to look at the literal wording of Regulation (EC) No 469/2009 but rather look to the purpose behind it, its overall scheme and objectives. This is in line with the decision of the ECJ in case C-292/00 *Davidoff* (paragraph 24) and, in relation to an application for the grant of a supplementary protection certificate under Regulation (EEC) No 1768/92, in case C-482/07 *AHP*. This approach has also been explicitly confirmed in the UK courts, for example in *Draco A.B.'s SPC application* [1996] RPC 417 that referred in turn at page 427 line 18 to page 428 line 6 to a House of Lords decision in *R. v. Henn, R. v. Darby* [1981] A.C. 850 and to paragraphs 2.266 and 2.268 of Volume 51 of Halsbury's Laws of England (4th edition).

15 To this end, use may be made of the recitals to the Regulation and also to the Commission's Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products.[7]

[7] COM(90) 101 final

16 Dr Goodfellow drew my attention in particular to the 1st to 4th and 6th to 9th recitals of Regulation (EEC) No 1768/92, now 2nd to 5th and 7th to 10th of Regulation (EC) No 469/2009, which are set out above. In summary, these recitals make it clear that pharmaceutical research is something to be encouraged and that the delay between filing a patent application relating to a medicinal product and obtaining authorisation to place it on the market means such research is afforded insufficient effective patent protection. Supplementary protection certificates provide a uniform Community solution under which the patent and certificate holder enjoys a maximum of 15 years exclusivity from the time of first authorisation in the Community. A maximum certificate duration of five years is set to take account of all interests at stake, including those of public health.

17 In the Explanatory Memorandum, paragraphs 12, 20 and 29 were highlighted to me and read as follows:

> *12. However, the proposal is not confined to new products only. A new process for obtaining the product or a new application of the product may also be protected by a certificate. All research, whatever the strategy or final result, must be given sufficient protection.*
>
> *20. The proposed system takes the legal form of a new protection certificate,* sui generis*, which is national in character and lies at the interface between two systems, that of prior authorizations for the placing on the market of medicinal products and that of their protection by patent, and which confers on the system its specific characteristics and special nature…*
>
> *29. The purpose of the expression "product protected by a patent" is to specify what types of invention may serve as a basis for a certificate.*
>
> *The proposal does not provide for any exclusions. In other words, all pharmaceutical research, provided that it leads to a new invention that can be patented, whether it concerns a new product, a new process for obtaining a new or known product, a new application of a new or known product or a new combination of substances containing a new or known product, must be encouraged, without any discrimination, and must be able to be given a supplementary certificate of protection provided that all of the conditions governing the application of the proposal for a Regulation are fulfilled.*

18 From this, the conclusion was put to me that, as the pharmaceutical research associated with the medicinal product Circadin resulted in a new, patented invention, the applicants were entitled to an SPC. The SPC was intended to reward investment that concludes with an innovation, i.e. such a granted patent. As commercial returns associated with Circadin only came from first marketing of Circadin, with returns from Regulin being totally unconnected, failure to grant an SPC would mean that the objective of the Regulation, namely to provide pharmaceutical research with sufficient effective protection, was not met.

19 On the face of it, I have more than a degree of sympathy with this conclusion. The applicants have certainly developed an invention, as evidenced by the granted patent, and have invested a considerable degree of time, energy and money bringing it to market. Additionally, as I have indicated above, I fully recognise the need to approach interpretation of Community law, including Regulation (EC) No 469/2009, in a teleological manner. However, in doing so, I must also take account of various pieces of case law that have relevance to this application.

20 Dr Goodfellow drew support for his reasoning that the Regulation sought to give effective protection to patented inventions and therefore, as the applicants had a patented invention, an SPC should be granted in the current case, from the statement of Jacob J in *Draco*, page 439:

> *"The research leading to the Turbohaler was formulation research. I see nothing indicating that formulation research (unless of course it warrants its own patent) is to be protected by the SPC scheme. The scheme is not for the general protection of the fruits of research. It is to compensate for lost time in the exploitation of inventions which are patented."*

However, I see this merely as stating that any kind of patent, including a formulation patent, could form the basis for an SPC. I believe it a step too far to interpret this statement as saying "if there is a pharmaceutical patent, there *must* be entitlement to an SPC". Other conditions of the Regulation would still have to be satisfied, as indicated by the final words of paragraph 29 of the Explanatory Memorandum:

> *"provided that all of the conditions governing the application of the proposal for a Regulation are fulfilled".*

Such conditions would include the requirement of Article 3(d). This is consistent with the views of the Hearing Officer in *Draco*, page 432 lines 44-50:

> *"In addition, although it is apparent from both the recitals and the Memorandum that the purpose of the Regulation is to provide a further period of protection for products, following the expiry of the basic patent, to compensate for the period between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market, it is also apparent from the actual provisions of the Regulation that this additional protection by way of a certificate is not available in all cases."*

The Hearing Officer in *Draco* then went on to list such provisions, starting with the requirement of Article 3(d).

21 I gain further support for my conclusion that a granted patent does not necessarily lead to an SPC and that other conditions must still be met, from the decision of the ECJ in case C-431/04 *MIT*. In this case, the invention centred on a new class of polymers that could be used as a carrier for pharmaceutically active agents. Dr Goodfellow suggested that there was no patentable innovation in this case but that was not so. A patent was granted that, alongside protecting the polymers per se, protected the polymers in combination with a biologically active agent. It was, at least in part, a formulation patent. Undoubtedly there was investment in pharmaceutical research that resulted in innovation, in a granted patent. An application was filed for an SPC on the basis of a marketing authorisation for the medicinal product Gliadel (RTM), which comprised a polymer of the basic patent, polifeprosan, in combination with the active agent carmustine. Gliadel (RTM) was useful as an implant for the treatment of brain tumours, the polifeprosan acting as a biodegradable matrix that slowly released carmustine. The conclusion was reached that the active ingredient, and therefore product for the purposes of the SPC application, could not be considered to be a combination of polifeprosan and carmustine as polifeprosan was not an active ingredient. A combination of an active ingredient and a component that renders possible a pharmaceutical form of the medicinal product necessary for the efficacy of the active ingredient is not a product for the purposes of an SPC. Rather, the product in this case was simply carmustine, which was covered by a much earlier marketing authorisation and therefore no SPC could be granted. Yes, there was a patented invention but that did not mean the other requirements of the Regulation could be ignored.

22 Dr Goodfellow drew my attention to the High Court decision in *Generics (UK) Ltd v. Daiichi Pharmaceutical Co. Ltd, Daiichi Sankyo Co. Ltd* [2009] RPC 4 where an SPC had been granted for the single enantiomer, levofloxacin. Generics (UK) Ltd brought an action for a declaration of invalidity on a number of grounds, the relevant one to us being the fact there were earlier marketing authorisations for the racemate, ofloxacin. It was put to me by Dr Goodfellow that the situation here could be viewed as analogous to that in *BASF AG v Bureau Voor de Industriële Eigendom* [2002] RPC 9, in which two plant protection products containing different proportions of an impurity were considered to be the same product, and that in fact the reason the SPC was held to be valid was that there was an innovation that the Regulation sets out to reward, namely the elucidation of levofloxacin from ofloxacin. Although levofloxacin and ofloxacin shared an active ingredient, it was therefore still possible to get an SPC for levofloxacin. Dr Goodfellow sought to apply a similar "there is innovation that deserves the Regulation's reward" argument to the current application. However, whilst it is true that Kitchin J considered at paragraph 228 that his conclusion that the SPC was valid was consistent with such an aim of the Regulation, this was not the basis on which he reached his conclusion. Furthermore, at paragraph 227 he explicitly rejected the idea that the situation was analogous to that in *BASF*. Rather, the SPC was held to be valid because ofloxacin and levofloxacin were different products. The earlier ofloxacin marketing authorisations were not authorisations to place levofloxacin on the market and therefore the marketing

authorisation for levofloxacin satisfied the requirement of Article 3(d). I do not consider *Generics (UK) Ltd* helps the current application where it does not appear to be disputed that the active ingredient of both the medicinal products Regulin and Circadin is the same, it is melatonin.

23 Comments were also put to me that to link an SPC covering Circadin to a Regulin authorisation would be perverse when Circadin has nothing to do with Regulin. However, the Regulation is set out to make just such a link as evidenced by Article 4, the operative Article of the Regulation, which extends protection conferred by an SPC to *any* use of the product as a medicinal product authorised before expiry of the SPC. This was confirmed by Jacob J in *Draco* at page 439 lines 27-33 when considering the applicant's proposal in that case that a "narrow" SPC should be granted, covering only the particular presentation authorised under the new marketing authorisation. He commented that:

> *"I just do not see how anyone could spell that out of Article 4 which protects the product, i.e. the active ingredient. Moreover if the submission were right it would blow a vast hole in the SPC system. One could evade an SPC with a different formulation of the same active ingredient."*

24 It was suggested to me by Dr Goodfellow that the balance of interests has already been taken into account by limitation of the maximum certificate duration. At first sight, by simple reference to the 10th recital, this seems to be the case. However, it is not just the maximum certificate duration that serves to address this balance. Limiting the SPC strictly to the product and basing it on the first authorisation to place it on the market as a medicinal product also plays a role. As was considered by the ECJ in *MIT*, this is clear by reference to Regulation (EC) No 1610/96 concerning the creation of an SPC for plant protection products, the 4th recital in the preamble to which sets out the plant protection sector's requirement for a level of protection equivalent to that granted to medicinal products by Regulation (EEC) No 1768/92. Paragraph 68 of the Explanatory Memorandum to the Proposal for a European Parliament and Council Regulation (EC), of 9 December 1994, concerning the creation of an SPC for plant protection products[8] states that:

> *…it would not be acceptable, in view of the balance required between the interests concerned, for this total duration of protection for one and the same plant protection product to be exceeded. This might be the case if one and the same product were able to be the subject of several successive certificates.*
>
> *This calls for a strict definition of the product…*
>
> *…although one and the same substance may be the subject of several patents and several authorizations to be placed on the market in one and the same Member State, the supplementary protection certificate will be granted for that substance only on the basis of a single patent and a single authorization to be placed on the market, namely the first granted in the State concerned…*

[8] COM(94) 579 final

Although this passage refers to the need to limit the duration of protection for the plant protection product, the means chosen to do this are clearly by strictly limiting the SPC to the product, not to the plant protection product, and only on the basis of its first marketing authorisation.

25 Following through the line of argument and reasoning above, I therefore conclude that an SPC for the current application cannot be granted on the basis of arguments put to me in relation to taking a teleological approach to the interpretation of the Regulation.

Meeting of Article 3(d) requirements

26 The conclusion was put to me on behalf of the applicants that, in order for an earlier veterinary marketing authorisation to form the basis of an objection under Article 3(d), it had to relate to the same medicinal product, i.e. a similar formulation for the same use and with the same mode of action. As this was not the case for Circadin and Regulin, there was no Article 3(d) objection to make in this case. Dr Goodfellow reached this conclusion on a teleological basis. Case law that ran counter to such a conclusion, and which the examiner had put to the applicants, was considered and dismissed by Dr Goodfellow. In particular, he sought to distinguish the current situation from that case law, namely *Pharmacia* (Case C-31/03) and *Yissum* (Case C-202/05). I shall now consider the arguments in turn.

27 In *Pharmacia*, the issue was interpretation of Article 19(1) of Regulation (EEC) No 1768/92, a transitional provision that read as follows:

> *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.*

In *Pharmacia*, the first human authorisation met this requirement but there was an earlier veterinary authorisation for the same product that did not. The following question was referred to the ECJ:

> *"Is the grant of a supplementary protection certificate in a Member State of the Community on the basis of a medicinal product for human use authorised in that Member State precluded by a [marketing authorisation for that product] as a veterinary medicinal product granted in another Member State of the Community before the date specified in Article 19(1) of the Regulation No 1768/92, or is the sole determining factor the date on which the product was authorised in the Community as a medicinal*

product for human use?"

28 The relevance of the interpretation of the term "first marketing authorisation in the Community" in the context of Article 19(1) of Regulation (EEC) No 1768/92 to its interpretation in the context of Article 3(d) was not disputed by the applicants. Nonetheless, it is worth noting that it is explicitly stated at paragraph 21 of the judgment that:

> *""...the term "First marketing authorisation in the Community" must be interpreted in the same way in each of the provisions of the regulation in which it is used…"*

29 A great deal of effort was expended by Dr Goodfellow and Mr Oates analysing the question to conclude that "that product" meant "that medicinal product", that being the only antecedent for "product" in the question. However, that is applying almost too much of a "literal interpretation" mindset to the question. If you consider it more in the general context of supplementary protection certificates, where the certificate is granted for a product, it is clear that "that product" merely refers to the product for which the certificate will be granted. A certificate is not granted for a medicinal product. In addition, they sought to distinguish the current application from *Pharmacia* on the basis that *Pharmacia* concerned a veterinary marketing authorisation and a human marketing authorisation for the treatment of the same disease. However, I do not consider this to be a valid distinction.

30 It is stated at paragraph 20 of the judgment that:

> *"…the decisive factor for the grant of the certificate is not the intended use of the medicinal product and, second, that the purpose of the protection conferred by the certificate relates to any use of the product as a medicinal product…"*

This passage makes it absolutely clear that both the applicants' reasons for distinguishing the current application from *Pharmacia*, namely that *Pharmacia* related to medicinal products for the same use, and the analysis of when an earlier marketing authorisation should "count", namely only where they relate to the same medicinal product, are without merit. The use of the medicinal product had no bearing on the ECJ decision in *Pharmacia* and does not affect the relevance of the authorisation. To put it plainly, the ECJ did not conclude that the earlier marketing authorisation was relevant because it was for the treatment of the same disease, it did so because it was an authorisation for the same product, the same active ingredient. I therefore do not consider the current application can be distinguished from *Pharmacia* on the basis proposed.

31 In *Yissum*, an application was filed in relation to the product calcitriol, which had previously been authorised for another use. The following question, concerning the interpretation of Article 1(b) of Regulation (EEC) No 1768/92 (which is unchanged in Regulation (EC) No 469/2009), was referred to the ECJ:

> *"In a case in which the basic patent protects a second medical application of a therapeutic agent what is meant by "product" in Article 1(b) of the*

Regulation [No 1768/92] and in particular does the application of the therapeutic agent play any part in the definition of "product" for the purpose of the Regulation?"

32 With reference to both *MIT* and *Pharmacia*, the ECJ considered that product must be strictly interpreted as the active ingredient and the intended use of the medicinal product is not the decisive factor for grant of a certificate. The response to the question was given at paragraph 20 that:

> *"…in a case where a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product"*

Therefore, in the current application, it is not appropriate to take into account the intended use of the medicinal product when considering the relevance of an earlier marketing authorisation under Article 3(d). The applicants sought to distinguish the current application from *Yissum* on the basis that *Yissum* concerned two authorisations for use in humans whilst the current application concerns a human authorisation and an earlier veterinary authorisation. In light of *Pharmacia*, which teaches that an authorisation being for human or veterinary use has no bearing on its relevance, this cannot be a valid distinction to draw.

33 To sum up, it simply seems perverse to argue that you can distinguish the current application from *Pharmacia* on the basis that the two authorisations relate to different diseases when the fact that the two authorisations were for the treatment of different diseases was not considered to be relevant in *Yissum*. Similarly, it seems perverse to try to distinguish from *Yissum* on the basis that one of the authorisations is for veterinary use and the other for human when this was not considered to be relevant in *Pharmacia*. Additionally, I draw support for a conclusion that both *Pharmacia* and *Yissum* are relevant to the current application in the fact that the ECJ considered the decision in *Pharmacia* to be relevant to the decision to be made in *Yissum* when, if the distinctions the applicants are trying to apply in the current case are valid, *Pharmacia* and *Yissum* could themselves be distinguished from each other.

34 It was also suggested to me that the reference in Article 3(d) back to Article 3(b) indicates the earlier authorisation must relate to *the same* medicinal product so that any other approval for more general sale, for example through a chemical catalogue, could not count for the purposes of Article 3(d) but I disagree. It is sufficient that the earlier authorisation relates to *any* medicinal product containing the active ingredient, which is simply what Article 3(d) says. On such an interpretation the suggested "catalogue sale approval" would not count as it would not be an authorisation in accordance with Directive 2001/83/EC or Directive 2001/82/EC.

35 Thus following through the line of argument and reasoning above, I conclude also that an SPC cannot be granted for the current application on the basis of arguments put to me that the requirements of Article 3(d) have been met.

Auxiliary request

36 As indicated in my introduction, having concluded that an application based on the original product definition is not allowable I must now turn to the auxiliary request to amend the product definition to read "Circadin – melatonin". As I have set out above, the product for which an SPC is granted is simply the active ingredient of the medicinal product. No arguments have been put to me that the active ingredient of Circadin is anything other than melatonin. I must therefore conclude that amending the product definition in the manner requested to allow grant of this application is not possible.

37 In making the auxiliary request, I note that the applicants have brought to my attention a number of SPCs that have apparently been granted in the UK with a product definition other than simply the active ingredient. In some of these cases, it is true that a certificate bearing both the medicinal product name and the product name has been issued. However, it is clear that in each case the certificate was granted simply for the product, the active agent, on the basis of the first authorisation to place the product on the market as any medicinal product, either veterinary or human and for the treatment of any disease by any mode of action. I should also point out that the scope of the SPC is determined in accordance with Article 4, not by the definition given on a granted certificate. I therefore do not consider any of these earlier granted certificates to be helpful to the applicants.

38 Finally, the applicants made a supplementary remark when making the auxiliary request on the need to interpret the Regulation teleologically with reference to a recent judgment from the Court of Appeal in *E I du Pont de Nemours & Co v UK Intellectual Property Office* [2009] EWCA Civ 966. As I have indicated above, I accept the need to take a teleological approach to the interpretation of Regulation (EC) No 469/2009 and therefore do not need to consider the comments made in relation to *Du Pont*. However, I will highlight an additional point made at paragraph 31 of *Du Pont* that the system is meant to be "practical, open and transparent". If, when considering an application for an SPC, the examiner had to identify whether the earlier marketing authorisation was relevant for the purposes of Article 3(d) in the way the applicants have suggested, that is to say identify whether it was for the same medicinal product, i.e. a similar formulation for the same use and with the same mode of action, it would mitigate against practicality, openness and transparency. Practicality, openness and transparency would be far better served by simply identifying whether the product was the same, as Article 3(d) plainly states.

Conclusion

39 I conclude therefore that the marketing authorisation for the medicinal product Circadin does not constitute the first authorisation to place the product melatonin on the market as a medicinal product as required under Article 3(d). Furthermore, it is not possible to define the product as “Circadin – melatonin”. I therefore reject the current application for an SPC under Article 10(2).

Appeal

40 Under the Practice Direction to Part 52 of the Civil Procedure Rules, any appeal must be lodged within 28 days.

Dr C L Davies
Deputy Director acting for the Comptroller