INTELLECTUAL PROPERTY OFFICE

BL O/052/09

20 February 2009

COUNCIL REGULATION (EC) 1768/92 CONCERNING THE CREATION OF A SUPPLEMENTARY PROTECTION CERTIFICATE FOR MEDICINAL PRODUCTS

APPLICANT Astellas Pharma Inc.

ISSUE Whether SPC application number SPC/GB/06/002 complies with Article 3 and may be granted

HEARING OFFICER Dr L Cullen

DECISION

Introduction

1 This relates to an application for a supplementary protection certificate (SPC) which was filed by Astellas Pharma Inc. ("the applicants") on 13 January 2006 and accorded the number SPC/GB/06/002. The product for which an SPC is sought is "a product comprising Emodepside". Although as filed the SPC was sought for a combination of Emodepside and Praziquantel [Profender (RTM)].

2 The basic patent upon which the application relies is EP (UK) 0634408 B1, which was filed on 8 March 1993 with an earliest priority date of 17 March 1992, and was granted on 2 January 2002. The authorisations EU/2/05/054/001-017 supplied in support of the application were granted on 27 July 2005.

3 In his examination report dated 9 October 2008 the Examiner (Dr Jason Bellia) observed that that there were two issues in contention, compliance with Article 3(a) and compliance with Article 3(b), and taking these in turn he first observed:

> "It is my preliminary view that the product, "Emodepside/Praziquantel (Profender)", is not protected by the designated basic patent EP (UK) 0634408 B1. I have read the patent and can find no specific or generic indication of the active ingredient praziquantel. You submit a contrary view, in your agents letter of 15 October 2007 you state that "any use on its own or in combination products, is covered as well". You also refer to claim 19 which "covers an anthelmintic agent which comprises

Emodepside." Furthermore, you observe that "it is clear for the IP expert that "comprises" means the agent may contain additional components".

4 In relation to Article 3(b), he commented:

> "Also at issue is compliance with Article 3(b) this matter arises because you requested a change to the product definition to read "A product comprising Emodepside" in your agent's letter of 29 January 2007, this change has not been effected and I remain of the opinion that to do so would be contrary to Article 3(b). I find that "product" as defined in Article 1(b) dictates that a combination of actives A and B constitutes a different product from A alone. Therefore in the present case a product defined by reference to Emodepside alone would require a corresponding authorisation for Emodepside alone to satisfy Article 3(b)."

5 These matters came before me at a hearing on 15 December 2008 where the applicant was represented by Mr Phillip Johnson of Counsel instructed by the agents Stevens, Hewlett & Perkins. At the hearing Mr Johnson agreed that compliance with Articles 3(a) and 3(b) were the issues to be decided and that whereas the patent clearly had as the subject of its claims the active ingredient emodepside, it did not make explicit mention of combinations including emodepside either in the claims or description.

The Relevant Law and its Interpretation

6 Article 3, parts (a) and (b) 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:*
>
> *(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; ►A1 For the purpose of Article 19 (1), an authorisation to place the product on the market granted in accordance with the national legislation of Austria, Finland or Sweden is treated as an authorisation granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate.*

wherein "product" is defined in Article 1(b) as follows:

> *For the purposes of this Regulation:*
>
> *(b) 'product' means the active ingredient or combination of active ingredients of a medicinal product;*

7 The ECJ has previously considered the interpretation of Article 3(a) in *Farmitalia*

Carlo Erba Srl's SPC Application (C-392/97) [2000] RPC 580 and the court concluded that the question of what is protected by a patent is not harmonised at EC level and is therefore a matter for national law.

8 As regards domestic patent law, section 125 of the Patents Act 1977 determines how the scope of an invention is to be determined. The relevant subsections read as follows:

> "(*1) For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.*
>
> *(2)…*
>
> *(3) The Protocol on the Interpretation of Article 69 of the European Patent Convention (which Article contains a provision corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that Article."*

9 Both Article 69 of the EPC and section 125(1) of the Act should be construed in the light of the Protocol on the Interpretation of Article 69 of the EPC, which reads:

> "*Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties".*

10 There is extensive case law on the interpretation of these provisions which govern precisely how patent claims should be construed. All are concerned with the principle that patent claims have to be read in the light of the description and may not always be accorded their literal interpretation. However it is important to appreciate that the purpose of the claims in a patent is to delimit the scope of the monopoly conferred by the patent, and the law on claim construction has developed with that in mind. Accordingly, patent law does not itself have any need for a notion of what is "protected" beyond a consideration of the proper construction of the claims for the purposes of determining what is, or is not, infringing or impugning of patentability.

11 Therefore I need to consider specifically the case law on the interpretation of Article 3(a) to determine what is the meaning of "protected", one such case is *Takeda Chemical Industries Ltd's SPC Applications (No.3)*, [2004] RPC 3, hereafter referred to as *Takeda*. This case concerned products which were combinations of lansoprazole which was specified in the nominated basic patents and certain antibiotics which were not mentioned in the basic patents. Jacob J commented (at paragraph 10),

> "In truth, the combination is not as such "protected by a basic patent in force". What is protected is only the lansoprazole element of that combination. It is sleight-of-hand to say that the combination is protected by the patent. The sleight-of-hand is exposed when one realises that any patent in Mr Alexander's sense protects the product of the patent with anything else in the world. But the patent is not of course for any such "combination"."

12 I find these comments to mean that everything that infringes the basic patent is not necessarily protected by it. Therefore *Takeda* does not readily assist me to determine the meaning of the word protected as used in the Regulation. As an aside I note that Mr Johnson was careful to point out that *Takeda* may have been decided differently had the applicant in that case not already had the benefit of an SPC for lansoprazole alone, and as such offended the Regulation in additional ways. Having read the decision I do not find the pre-existence of an SPC for one of the components to have been instructive in determining compliance with Article 3(a), so I am not inclined to distinguish *Takeda* from the present case where there is no pre-existing SPC for Emodepside.

13 The reasoning in *Takeda* is developed further in *Gilead's SPC application*, [2008] EWHC 1902 (Pats), hereafter referred to as *Gilead*. At paragraph 33 of this judgment Kitchin J proposes a test to decide what is "protected":

> "It is to identify the active ingredients of the product which are relevant to a consideration of whether the product falls within the scope of a claim of the basic patent. It is those ingredients, and only those ingredients, which can be said to be protected within the meaning of the Regulation. So, in the case of a product consisting of a combination of ingredients A and B and a basic patent which claims A, it is only A which brings the combination within the scope of the monopoly. Hence it is A which is protected and not the combination of A and B."

14 At the heart of this test is an analysis of the claim in the basic patent alleged to protect the product. Mr Johnson's arguments sought to compare the claim protecting the product from the *Gilead* case with the claim alleged to protect the product in the present case. Therefore I reproduce each claim below to illustrate Counsel's arguments. In *Gilead*, the claim found to protect the product was claim 27 of EP0915894 B1 which reads:

> "A pharmaceutical composition comprising a compound according to any one of claims 1-25 together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients."

15 In the present case Mr Johnson sought to establish that claim 19 of EP0634408 B1 protects the product, wherein claim 19 reads:

> "An antihelmintic agent which comprises a compound or a pharmaceutically acceptable salt thereof of any of claims 1 to 11 and 14 as an active ingredient"

16 It is Mr Johnson's contention that the phrase "an anthelmintic agent which comprises…" implicitly claims other active ingredients. The phrase "anthelmintic agent" providing the context for the type of formulation and "comprises" which is taken to mean, "includes but is not restricted to" admitting that other undisclosed actives could be present, including other anthelmintic agents. He compares this analysis with the Gilead claim where the words "optionally other therapeutic ingredients" similarly admits undisclosed additional active ingredients.

17 In addition to arguing that the combination of emodepside and praziquantel are covered by claim 19 of EP0634408, Mr Johnson argued an alternative that an SPC can be granted where only one ingredient is claimed in the basic patent.

18 He argued that wording such as "optional other active ingredients", as used in the *Gilead* patent, amounts to a drafting device which if necessary to allow for other active ingredients in the patent scope, creates a barrier to obtaining an SPC for combination products. He contends that this barrier would offend Recital 6 of the Regulation in requiring applicants to catch-up with their competitors outside the EU as they adopt this practice. I do not agree that recital 6 is offended as I do not find the practice of admitting the possibility of combination products by incorporating wording such as "optional other active ingredients" to be a new one.

19 I am not persuaded by Mr Johnson argument that use of the expression 'anthelmintic agent' is more limiting or helpful in suggesting a combination in this case. He contrasted use of this expression with the use of the expression 'a pharmaceutical composition' in the *Gilead* claim which he implied was quite broad in comparison. I do not consider that the use of this expression in claim 19 of EP0634408 is sufficient to suggest that such an agent can include all possibilities including one, two, three …, ten or more etc., active agents or that these active agents would be limited just to those with anthelmintic properties. A composition with at least one anthelmintic agent and at least one active agent that has some other therapeutic effect could still be construed as an anthelmintic agent as one of its components has this property. This I consider is a logical conclusion from Mr Johnson's suggestion and is in my view giving too wide or general an interpretation to the term "anthelmintic agent" in this case. When the expression anthelmintic agent is considered in conjunction with the claims and the description there is nothing to suggest that anything other than an antihelmintic agent comprising one active ingredient chosen from the cyclic peptide compounds disclosed in the basic patent is suggested by this expression. It was agreed by the applicant and confirmed at the hearing that there is no reference to the use of any of the compounds referred to in the basic patent in combination with each other or with other agents to achieve a therapeutic effect.

20 Mr Johnson also invited me to consider the applicant faced with a choice between a less efficacious product comprising a single active ingredient wholly

within the scope of a basic patent and therefore amenable of SPC protection and a combination product which is more efficacious than the single active based product but which does not fall wholly within the scope of the basic patent and as such is precluded from an SPC. In so favouring the less efficacious product the purpose as referred to in recitals 1 and 10 of the Regulation is defeated. This scenario was also considered in *Gilead* where Kitchin J at paragraph 28 of that judgment acknowledged that it could produce a harsh result, but did not decide if such applications should be allowed.

21 It would appear that such a scenario could only result if the applicant was unable to secure a patent on the combination, as additional combination patents could themselves result in SPC protection. Unable as I am to determine whether or not the applicants would have been able to obtain a patent on the combination product, I am reluctant to reinstate a reward owing to a harsh result that I do not, in fact, know that the applicant suffered. This issue was also discussed by the hearing officer in the original Office decision concerning *Gilead Sciences Inc SPC Application* (see paragraph 16 of BL O/006/08) who came to the same conclusion. In the absence of a clear decision by Kitchen J on this matter in *Gilead*, I see no reason to come to a different conclusion. I am therefore not minded to allow the application on these grounds.

22 Finally Mr Johnson addressed me on the relevance of *Biogen v SmithKline Beecham Biologicals SA (C-181/95*) [1997] RPC 833, hereafter referred to as *Biogen*. In this case, it was found that a number of applicants that each held a basic patent for the same product were each entitled to an SPC for that product (all based on the same marketing authorisation). Mr Johnson took it as implicit in this decision that an SPC may be awarded in respect of a basic patent which does not cover the entire scope of the medicinal product. I agree that the basic patent need not cover all of the innovation in the medicinal product to enable an SPC to be granted. To expect otherwise would be to ignore the way that industry uses the patent system to protect various innovations of use or formulation that may all concern the same product. Mr Johnson goes on to argue that if a basic patent need protect only part of the medicinal product in order to enable an SPC, that part could as easily be one of the actives of a combination product as it could be some other aspect of the innovation in the medicinal product. I disagree with this conclusion as it ignores the link between the marketing authorisation and the basic patent which is set out in the Regulation as no more or less than the product, i.e. the active ingredient or combination of active ingredients.

Discussion

23 I have considered Mr Johnson's arguments concerning the comparison of the *Gilead* claims with those of the present case, but I am not persuaded that claim 27 of EP0915894 B1 and claim 19 of EP0634408 B1 have the same scope. In reaching this conclusion I have taken note of the relevant sections of the Act, and protocol as reproduced above as well as the purpose of the claim which Mr Johnson rightly warned me, I am directed to do by *Catnic.* As I interpret it the *Gilead* claim would leave the skilled person in no doubt that the patentee intended to include other active ingredients. Applying a similarly purposive construction to the present claim 19, I find the skilled person would not understand the patentee to have intended to include any active save those

defined in the earlier claims. Indeed I find no material difference between the scope of claim 19 of EP0634408 B1 and claim 25 of *Gilead* which J Kitchin found protected only one of the active ingredients of the combination.

24 Completing this analysis by application of the test in *Gilead* I find that whereas both components fall within the scope of claim 27 in *Gilead* only emodepside falls within the scope of claim 19 of EP0634408 B1 and as such it is only emodepside that is protected.

25 In respect of the alternative argument that an SPC can be granted where only one active ingredient is claimed in the basic patent I am not persuaded that the applicant's have suffered a harsh result or that the purpose of the regulation has been offended and as such I am not minded to find an SPC for the combination product is allowed.

26 In this case, I consider that I am, in effect, being invited by the applicant to accept a similar argument to that presented by SmithKline Beecham (hereafter SKB) in *Biogen* (see paragraph 25 of the decision). SKB considered that the purpose of the regulation was not to reward all basic patent holders but much more generally to safeguard and encourage the development of medicinal products in the EC and that this development of new medicinal products was in fact largely due to the research and investment undertaken by those who have finally obtained marketing authorisation. Thus, in my view, SKB considered that the reward being granted through the SPC was for all the research and development required to obtain a marketing authorisation. The conclusion I take from this is that SKB considered, as does Astellas in the present case, that research and development did not stop with the grant of a patent, it continued, for example, after it was decided which product(s) marketing authorisation would be sought for.

27 However, it was made clear in the *Biogen* decision (see paragraph 26) which refers to recitals 3 & 4 from the Regulation, that the reward being granted through the SPC was to make up for "*the insufficient duration of the effective protection under the patent to cover the investment put into the pharmaceutical research*." This reference is to pharmaceutical research in general and is not a reference to the development of marketable medicinal products although it is expected that this will be an ultimate outcome of such research (see recital 2). Thus there is a clear link to the innovation which is protected by the patent, however elementary the research that the patent is based on. It is acknowledged that the procedure put in place by national authorities to make sure that medicines are safe for human consumption can delay exploitation of the invention, hence the extra period of time to do so provided by the SPC.

28 However, if further research and development leads to the development of a more effective treatment as is suggested by Mr Johnson as the reason for Astellas seeking a marketing authorisation for a combination of emodepside and praziquantel rather than one for emodepside, then if the applicant decided instead to seek authorisation for a combination product that is more efficacious than a single active based product then he does so knowing that an SPC application is likely to be denied because the basic patent does not cover a combination product. This may be a situation that Kitchen J envisaged in *Gilead*

as producing, in his words, “a harsh result” yet I am struck by the fact that it is not one that the applicant is compelled to take or cannot take steps to avoid, for example by seeking a patent for the combination product. In this case, it is not clear why the applicant chose this course of action. The need for a basic patent that defines what is protected by the SPC is fundamental to the scheme of the Regulation. This is both in relation to the applicants’ point of view and to the third parties point of view so that each can clearly understand what is protected by the SPC.

29 Kitchen J in *Gilead* did not suggest a course of action to address the possible “harsh result” referred to in paragraph 27 above. He suggested at paragraph 30 of *Gilead* that the interpretation to be placed on the requirements of the Regulation when a medicinal product consists of a combination of active ingredients where only one is claimed in the basic patent was an issue that a higher court or the ECJ should consider. In the absence of such guidance, I see no reason to come to a conclusion other than the one of have reached above, i.e., as the combination product is not disclosed in the basic patent, an SPC for the combination based on that patent does not meet the requirements of Article 3(a) of the Regulation.

30 Mr Johnson did not address me specifically on the matter of compliance with Article 3(b) which I consider to be a subsidiary matter to that decided in respect of Article 3(a). I find compliance with Article 3(b) to be a simple matter of judging what is the subject of the marketing authorisation, and comparing this to the product for which the SPC is sought. As mentioned in paragraph 2 above the marketing authorisation supplied with the application was for a combination of active ingredients, emodepside and praziquantel. The product for which the SPC is sought is “A product comprising Emodepside”. I do not find agreement here between the subject of the marketing authorisation and the product for which the SPC is sought. Accordingly I do not find Article 3(b) to be complied with.

Conclusion

31 For the above reasons, I conclude that the basic patent does not “protect”, for the purposes of Article 3(a) of the Regulation, the product which is the subject of the application. Furthermore the product as defined in the application as amended does not comply with Article 3(b) of the Regulation. Since in accordance with Article 10(3) an opportunity to correct the irregularity has been given, as required by Article 10(4), I reject the application.

Appeal

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

Dr L Cullen
Deputy Director acting for the Comptroller