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For Creativity and Innovation

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

APPLICANT	Gilead Sciences, Inc
ISSUE	Whether SPC application number SPC/GB/05/041 complies with Article 3(a)
HEARING OFFICER	A C Howard

DECISION

Introduction

1 This relates to an application for a supplementary protection certificate (SPC) which was filed by Gilead Sciences, Inc ("the applicants") on 1 August 2005 and accorded the number SPC/GB/05/041. The product in respect of which an SPC is sought comprises a combination of two active components, namely tenofovir disoproxil (or a derivative thereof) and emtricitabine.

2 The basic patent upon which the application relies is EP (UK) 0915894 B1, which was filed on 25 July 1997 with a priority date of 26 July 1996, and was granted on 14 May 2003.

3 It is accepted that claim 25 of the basic patent covers tenofovir disoproxil and its derivatives, albeit identified under systematic nomenclature. However emtricitabine is not mentioned anywhere in the basic patent. Reliance is placed on claim 27 (when appended to claim 25), which reads as follows:

> "27. 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."

4 The examiner (Jason Bellia) objected, *inter alia*, that the product is not protected by the basic patent as required by Article 3(a) of Council Regulation (EEC)

1768/92 (hereafter "the Regulation") on the grounds that the basic patent does not protect a composition including the active ingredient emtricitabine, notwithstanding that claim 27 would be infringed by such a product. The applicant was given a period of four months in which to rectify the defects that had been identified.

5 In their response, the applicants' agent argued that since claim 27 of the basic patent relates to a composition containing the active compound and optionally other therapeutic ingredients, this protects the composition which is the subject of the application. They submitted that the Regulation does not require the composition to be specifically claimed. The examiner did not accept this argument, and the question came before me at a hearing on 19 November 2007, on which occasion the applicants were represented by Helen M M Jones of Messrs Gill Jennings & Every LLP. Ms Jones was accompanied by Dr Peter Riedl of Reitstotter, Kinzeback & Partners (the applicants' patent attorney) and Isobel C Davies (technical assistant). The examiner also attended.

6 At the hearing a slightly amended description of product was submitted and was adopted as the basis for consideration. The product description now reads as follows:

> "Composition containing both Tenofovir disoproxil optionally in the form of a pharmaceutically acceptable salt, hydrate, tautomer or solvate thereof, together with Emtricitabine."

7 The only issue to be decided is whether the basic patent "protects" the product for which an SPC is sought.

The law and its interpretation

8 Article 3(a) of the Regulation provides as follows:

> "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;"

Wherein "product" is defined in Article 1(b) in the following terms:

> "'product' means the active ingredient or combination of active ingredients of a medicinal product;"

9 Article 10 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) ….. "

10 In the decision of the European Court of Justice in *Farmitalia Carlo Erba Srl's SPC Application* (C-392/97) [2000] RPC 580 (hereafter *"Farmitalia"*), the Court declared that the question of whether a product is protected by a basic patent must be answered by making reference to the rules which govern that patent (paragraph 29). In the absence of Community harmonisation of patent law, this means in practice the rules which are applied nationally. It was however made clear (paragraph 28) that the protection conferred by an SPC cannot exceed the protection conferred by the basic patent.

11 The most relevant English authority is *Takeda Chemical Industries Ltd's SPC Applications (no. 3)* [2004] RPC 3 (hereafter "*Takeda*"). This was a decision of Jacob J (as he was then) in the Patents Court on an appeal from a decision of the hearing officer, Mr Walker, which itself was reported at [2004] RPC 1. The applications in *Takeda* involved combinations of the anti-ulcer agent lansoprazole with other specified actives. However the basic patent neither disclosed nor suggested that lansoprazole might be combined with anything else. There was no dispute that a claim covering lansoprazole *per se* would be infringed by a composition containing lansoprazole and something else, but this was held not to be enough to satisfy the requirement of Article 3(a) of the Regulation that the basic patent should protect the product for which an SPC was sought.

12 Mr Walker had in his decision refused the application because he considered that the product in question (comprising a combination of two actives) was not "identifiable with the invention of [the basic] patent", which disclosed and claimed a product comprising only a single component. According to Mr Walker this meant that the patent could not be said to "protect" the product within the meaning of the Regulation. However, Jacob J, in upholding the decision to refuse the applications, did not take the opportunity to give this approach his explicit stamp of approval. Instead he chose to say that although a claim to A is infringed by a composition comprising the combination A+B, it is "sleight-of-hand" to say the combination is "protected" by such a claim. To quote (paragraph 10):

> "The so-called 'combination' of lansoprazole and an antibiotic would only infringe because of the presence of the lansoprazole. In truth, the combination is not '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. This 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'."

13 What I understand this to mean in the context of the facts of *Takeda* is that the "sleight-of-hand" was the attempt to equate what might amount to infringement with what is "protected" by the patent. This sets an outer boundary to what can be regarded as "protected" by the basic patent in making clear that it is not always appropriate to use a test of infringement to determine the question.

14 Ms Jones also referred me to the German cases of *Idarubicin II* (BGH GRUR 2000, 683) and *Sumatripan* (BGH GRUR 2002, 415). I do not have to follow these but they can provide useful guidance, especially in the absence of binding authority on the precise point. In *Idarubicin II* the court considered whether different chemical forms of an active substance were comprised within the "scope of protection" (*Schutzbereich*) of the basic patent, and held that the principles of patent law should apply. It seems to me that this throws little new light on the question before me. *Sumatripan* followed *Idarubicin II* and included the finding that it was not relevant whether the basic patent could be limited to the product for which an SPC was sought. This I find helpful to the extent that it clarifies that there does not need to be explicit support for the product within the patent. This is not inconsistent with Jacob J's decision in *Takeda*.

15 Ms Jones suggested that I should tackle the question of what is protected by the basic patent by reference to what the skilled addressee would have understood at the priority date. It seems to me that this is a reasonable approach to take. Construing the patent through the eyes of the skilled person is something that is fully consistent with the general law on patents and would therefore accord with the principles laid down by the ECJ in *Farmitalia*. Of course, the ultimate determination of whether the patent "protects" the product in question must be for the court rather than a matter of the opinion of the skilled person.

16 Ms Jones also submitted that an important factor to be taken into consideration was that the rules governing approval of medicines require clinical trials to be carried out for new uses, including products containing known constituents not hitherto used in combination for therapeutic purposes. Clinical trials involve considerable investment and are deserving of protection. However I find such arguments of only limited relevance in the present context; new combinations of constituents are susceptible of independent patent protection (if they meet the general criteria for obtaining a patent), and resulting patents may form the basis for SPCs. There is accordingly already a mechanism available to protect the investment involved in developing such innovations. There are also other regulatory means separate from the patent/SPC framework for protecting clinical test data itself.

Discussion and argument

17 Applying these principles to the present facts, I would take the skilled person to be a person with knowledge in research and clinical practice in treatment of viral infections. There is evidence, which I accept, to show that at the relevant time the

use of emtricitabine as an antiretroviral was known, and that the use of different antiretrovirals in combination was also known in particular for the treatment of HIV infection. Claim 27 optionally covers the combination of one of the compounds according to any of claims 1-25 with another active component, but in the light of the above-mentioned evidence that the use of antiretrovirals in combination was already known at the priority date of the basic patent, I do not believe that the skilled person would have read any special significance into this.

18 The complete line of argument as put by Ms Jones can be summarised as follows:

- It was known at the priority date to combine anti-HIV drugs with others in a combination treatment;
- the basic patent specifically discloses and claims a number of active compounds including tenofovir disoproxil which is an antiretroviral;
- a skilled person would have read into the reference, in the basic patent, to the possibility of combining one of the disclosed products with another active ingredient the likelihood that the latter would be an antiretroviral;
- emtricitabine is an example of an antiretroviral;
- therefore, the basic patent "protects" (within the meaning of the Regulation) a product comprising a combination of tenofovir disoproxil and emtricitabine.

19 The problem I have with this is that it relies on a large dose of hindsight. In common with many composition-of-matter patents in this technical field, the number of products potentially encompassed by the basic patent is huge. Even narrowing consideration to claim 27 when appended to claim 25, the range of possibilities confronting the skilled reader as of the priority date would in practice have been wide, and there is no escape from the fact that there is no teaching in the basic patent about the nature of the additional therapeutic ingredient which can be combined with tenofovir disoproxil. In order to conclude that the specific combination in question is "protected" by the basic patent, I would expect to see much more than we have in claim 27 and the sparse support it draws from the description. As mentioned above, this need not amount to the level of support that would be required to allow addition of a claim to the particular combination, but I believe it should at least provide a clear pointer for the skilled reader in the right direction.

20 I would also observe that a not dissimilar line of argument could have been deployed by the applicant even in the absence of claim 27. To use the expression adopted by Mr Justice Jacob, there is still a "sleight of hand" here, and it is only a little less than would have been the case had there been no claim 27 and no mention of the possibility of combination with another therapeutic ingredient.

Conclusion

21 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. Since, in accordance with Article 10(3), an opportunity to correct the irregularity has already been given, as required by Article 10(4), I reject the application.

Appeal

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

A C HOWARD
Deputy Director acting for the Comptroller