COUNCIL REGULATION (EEC) NO. 1768/92

IN THE MATTER OF Application Nos. SPC/GB/96/030, SPC/GB/96/031, SPC/GB/96/032, SPC/GB/96/033, SPC/GB/96/034 and SPC/GB/96/035 in the name of Takeda Chemical Industries Limited

DECISION

The issue

1 In a decision issued on 6 December 2001 I rejected six requests by Takeda Chemical Industries Limited ("the applicant") for the grant of Supplementary Protection Certificates, following an oral hearing on 25 September 2001. My reasons for rejecting these requests were that:

(a) they did not comply with Article 3(a) of Council Regulation (EEC) No. 1768/92 ("the Medicinal Products Regulation") because none of the products, for which supplementary protection was sought, were protected by a basic patent in force; and

(b) they did not comply with Article 3(b) of the Medicinal Products Regulation because none of the products were the subject of a valid authorisation to place them on the market as a medicinal product.

In this earlier decision I did not, in the light of my findings that the requests should be rejected for non-compliance with Article 3(a) and 3(b), consider it necessary to go on to consider further grounds for rejecting the requests, which had been raised by the examiner prior to the hearing.

2 The applicant appealed my decision and the appeal came before Mr Justice Laddie on 11 March 2002. However, before hearing the substance of the appeal Mr Justice Laddie observed that in my decision I had decided not to address the matter of compliance with Article 3(c) of the Medicinal Products Regulation, which requires that a product should not already be the subject of a certificate. He went on to make the point that the applicant might be disadvantaged if the appeal considered compliance with Article 3(a) and (b) of the Medicinal Products Regulation in isolation from compliance with Article 3(c). This point was well taken by both the applicant and the comptroller, who was represented at the appeal. As a consequence Mr Justice Laddie directed that the case should be remitted to the comptroller to decide those matters left undecided in my earlier decision. There was to be no further oral hearing but the applicant was given 14 days in which to file with the comptroller written submissions. The applicant's patent agent, Dr Gordon Wright of the firm Elkington and Fife, subsequently provided these submissions in a letter dated 25 March 2002, which was faxed to the Patent Office on the same day. In his letter Dr Wright suggested the possibility of a further hearing but in view of Mr Justice Laddie's direction that I should give my decision without a further oral hearing, I do not consider that this

would be appropriate. As an alternative, Dr Wright helpfully offered to deal with any further points the comptroller might wish to raise in writing. The matters I must decide here have been the subject of dialogue between the examiner and the applicant for a very long time and it seems that little or nothing is likely to be gained by extending this dialogue now. Therefore, the time has come for me to consider these matters and I will do so on the basis of the submissions made at the hearing on 25 September 2001 and the supplementary written submissions contained in Dr Wright's letter of 25 March 2002.

Background

3 The background to the applicant's requests for supplementary protection is set out fully in my earlier decision but it is useful to repeat here those facts that have particular relevance to the present decision.

4 The applicant's requests seek supplementary protection for three different combinations of active ingredients. Three of the requests designate European patent no. 0174726 B1 ("EP 0174726") and the other three requests designate European patent no. 0382489 B1 ("EP 0382489"). The relationship between the requests, the two patents and the three combinations of active ingredients can best be shown in the following table.

Application No.	Designated Patent	Product
SPC/GB/96/030	EP 0174726	Lansoprazole, Clarithromycin & Amoxycillin
SPC/GB/96/031		Lansoprazole, Clarithromycin & Metronidazole
SPC/GB/96/032		Lansoprazole, Amoxycillin & Metronidazole
SPC/GB/96/033	EP 0382489	Lansoprazole, Clarithromycin & Amoxycillin
SPC/GB/96/034		Lansoprazole, Clarithromycin & Metronidazole
SPC/GB/96/035		Lansoprazole, Amoxycillin & Metronidazole

5 EP 0174726 relates to pyridine derivatives, such as lansoprazole, found to be useful as anti-ulcer agents. On 23 February 1994 a marketing authorisation was granted for a medicinal product which is sold as Zoton (Registered Trade Mark) and which contains lansoprazole as the sole active ingredient. Subsequently, on the basis of EP 0174726 and this marketing authorisation, the applicant requested and was granted a supplementary protection certificate for lansoprazole. This certificate was granted on 23 September 1994 as SPC/GB/94/011 and will expire on 10 December 2005.

6 During the period running up to the launch of Zoton in the United Kingdom, the applicant, acting through its licensee, Wyeth, carried out further research. This research showed that lansoprazole, in particular when used in combination with certain antibiotics, was effective in the eradication of *Helicobacter pylori*. The antibiotics in question were clarithromycin, amoxycillin and metronidazole. On the back of this further research, a second patent (EP 0382489), relating to the use of pyridine derivatives, such as lansoprazole, for the eradication of *Helicobacter pylori*, was obtained. In 1995 the applicant applied successfully to vary the existing marketing authorisation for Zoton by adding the eradication of *H. pylori* as a new therapeutic indication for lansoprazole when used in combination with appropriate antibiotics. The six requests for supplementary protection, which are the subject of this decision and my earlier decision, were made in 1996 and are based on the varied authorisation and either EP 0174726 or EP 0382489.

Assessment

The Medicinal Products Regulation and its underlying principles

7 As urged on me at the hearing on 25 September 2001 by Mr Alexander, who appeared as Counsel for the applicant, I sought to establish in my earlier decision the general principles underlying the Medicinal Products Regulation so that I could take these into account when interpreting its provisions. The broad conclusions I reached after considering the text of the Medicinal Products Regulation, including its recitals, the jurisprudence of the European Court of Justice and the travaux preparatoires of the Medicinal Products Regulation, were that:

(a) the purpose of the Medicinal Products Regulation is to encourage research by compensating for the period of protection eroded as a result of the time taken to get authorisation to market a medicinal product; and

(b) this compensation should be by way of protection which is both adequate and effective.

8 However, these broad principles must be viewed against recital 9 of the Medicinal Products Regulation which states:

> "Whereas all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector must nevertheless be taken into account, whereas, for this purpose, the certificate cannot be granted for a period exceeding five years; whereas the protection granted should furthermore be strictly confined to the product which obtained authorization to be placed on the market as a medicinal product;"

Thus, while one objective of the Medicinal Products Regulation was to provide adequate and effective protection for medicinal products, the Regulation sought to strike a balance between all the interests at stake, including the public health interest. Addressing this balance, the maximum duration of a certificate was capped at five years from the date on which it takes effect. The Explanatory Memorandum which was contained in the Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products, outlines another way in which account was taken of all the

interests concerned. Paragraph 36 of this Explanatory Memorandum states (with my emphasis):

> "Lastly, the product must not have been the subject of a certificate in the Member State concerned. The certificate is designed to encourage research into new medicinal products so that the duration of protection it affords, together with the effective duration of protection by patent, is sufficient to enable the investments made in the research to be recovered. However, 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 medicinal product to be exceeded. *This might nevertheless 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 within the meaning of Article 2. If a certificate has already been granted for the active ingredient itself, a new certificate may not be granted for one and the same active ingredient whatever minor changes may have been made regarding other features of the medicinal product (use of a different salt, different excipients, different pharmaceutical presentation, etc.).
>
> In conclusion, it should be noted that, *although one and the same product 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 only be granted for that product on the basis of a single patent and a single authorization to be placed on the market*, namely the first chronologically given in the State concerned (the first authorization in the Community being taken only to calculate a uniform duration of different certificates for one and the same product)."

9 In my earlier decision I took account of the principles underlying the Medicinal Products Regulation when interpreting the provisions of Article 3(a) and (b). I must now do the same in relation to Article 3(c). The earlier decision set out various relevant provisions of the Medicinal Products Regulation, including Article 2 which establishes that any patented product which has been subject to authorisation before it can be marketed as a medicinal product, may be the subject of a supplementary protection certificate ("certificate"). However, I feel that it would be useful to quote Article 3 once again in its entirety.

"**ARTICLE 3**

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

10 Article 1 defines the terms "medicinal product", "product", "basic patent" and "certificate", used in Article 3, as follows:

"**ARTICLE 1**

Definitions

For the purpose 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;

(c) "basic patent" means a patent which protects a product defined in (b) as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;

(d) "certificate" means the supplementary protection certificate."

11 Thus, the effect of Article 3(c) is that a request for a certificate for a product, that is an active ingredient or combination of active ingredients of a medicinal product, cannot be granted if that product is already the subject of a certificate when the request is made. In my view, there is a clear relationship between this condition and the objective of the Medicinal Products Regulation to achieve a balance between all the interests concerned. It appears to me that one intention behind Article 3(c) is to prevent a holder of a certificate for a product extending the period of protection for that product by obtaining over time successive certificates on the basis of successive patents. Possibly, the effectiveness of Article 3(c) in achieving a balance between the interests concerned could be questioned. For example, although Article 3(d) requires that the authorisation which is used to support a certificate must be the first to place the product on the market as a medicinal product in the Member State concerned, there is no equivalent requirement that the designated patent must be the first that protects the product. The Medicinal Products Regulation does not seek to impose any ranking between a plurality of relevant patents in the same hands. Instead it gives a patent holder the freedom to choose the patent which would provide the greatest period of supplementary protection, albeit within the limits of protection conferred by that chosen patent in accordance with Article 4 of the Medicinal Products Regulation, which I quoted in my earlier decision. Nevertheless, this freedom, bestowed on applicants, does not deflect me from my general view of the purpose underlying Article 3(c).

The "Biogen" case

12 Whilst I can see that Article 3(c) represents a key compromise between the various interests at stake by restricting the opportunity one and the same patent holder has to obtain successive certificates for the same product, it less clearly takes account of all the interests at stake, particularly those of patent holders, when the same product is protected by different patents in different hands. It was such a situation that led the Tribunal de Commerce, Nivelles, to seek a preliminary ruling from the European Court of Justice ("the Court") on four questions in Case C-181/95 *Biogen Inc. v. Smithkline Beecham Biologicals SA* [1997] RPC 23 ("*Biogen"*). The second of these four questions appears to have a bearing on the matter I must decide in this case:

> "Where one and the same product is covered by several basic patents belonging to different holders, does Regulation No. 1768/92 preclude the grant of a supplementary protection certificate to each holder of a basic patent?"

13 The background to this case was that Smithkline Beecham Biologicals SA ("SKB") produced and marketed a vaccine against Hepatitis-B under licence from Biogen Inc. ("Biogen") and the Institute Pasteur who held relevant patents. SKB had obtained Belgian marketing authorisations for the vaccine but refused to provide copies of these authorisations to Biogen to enable Biogen to obtain certificates on its patents. However, SKB had supplied a copy of the first marketing authorisations for the vaccine to Institute Pasteur which was then able to obtain a certificate for its patent. Having allowed Institute Pasteur to get its certificate, SKB contended that under the Medicinal Products Regulation only one certificate may be granted for each product - that is to say, each identical active ingredient - even where the product in question is based on several patents.

14 Answering this second question first, the Court observed in paragraphs 27 and 28 of its judgment:

> "Article 6 of the Regulation confirms that the certificate is to be granted to the holder of the basic patent or his successor in title. Article 1(c) mentions the basic patents which may be designated for the purpose of the procedure for the grant of a certificate, namely those which protect a product as such, a process to obtain a product or an application of a product. The Regulation thus seeks to confer supplementary protection on the holders of such patents, without instituting any preferential ranking amongst them.
>
> Consequently, where a product is protected by a number of basic patents in force, which may belong to a number of patent holders, each of those patents may be designated for the purpose of the procedure for the grant of a certificate. Under Article 3(c) of the Regulation, however, only one certificate may be granted for each basic patent."

and concluded in paragraph 30 that:

> "....., where a medicinal product is covered by several basic patents, the Regulation does not preclude the grant of a supplementary protection certificate to each holder of a basic patent."

15 At the hearing on 25 September 2001 Mr Alexander addressed me very briefly on what I should make of the Court's statement in its observations that:

> "Under Article 3(c) of the Regulation, however, only one certificate may be granted for each basic patent."

Mr Alexander somewhat dismissively described this statement as a "throwaway line" and one made in the particular context of the *Biogen* case, where the question in issue in the present case did not arise. Mr Alexander based this opinion on the difference between the language used by Court and the language found in the Medicinal Products Regulation. However, I am not prepared to be as dismissive as Mr Alexander without first trying to understand what the Court intended by this statement. It is important that I do so because this single sentence has the potential to impact significantly on the present requests because:

(a) a certificate has already been granted on the basis of EP 0174726 and this patent is now being used again as a basis for three further requests;

(b) these further three requests are each based on the same patent, *viz*. EP 0174726; and

(c) the other three requests are also based on a common patent, *viz* EP 0382489.

Thus, if I simply took this statement by the Court at face value and applied it to the present requests, none of the three requests based on EP 0174726 could be granted because a certificate has already been granted on the basis of that patent and only one of the three other requests based on EP 0382489 could be granted on the basis of this second patent, assuming of course I had not already rejected the requests on other grounds.

16 At the hearing on 11 March 2002 Mr Justice Laddie also focussed briefly on this single sentence in *Biogen*, describing it as a particularly important one. As a consequence Dr Wright addressed it in some detail in his letter of 25 March 2002. Like Mr Alexander at the hearing in September 2001, Dr Wright's main submission on this matter is that the Court was not considering a question of the kind at issue in the present case. Dr Wright also questions the applicability of the statement to the present facts. There can be no doubt that the interpretation of Article 3(c) of the Medicinal Products Regulation was an issue in *Biogen* and I am not immediately convinced that I should disregard what the Court said in this context. As for the applicability of this statement to the facts of the present case, that is something I will consider once I have understood what the Court intended.

17 Dr Wright's submission continues on the same lines as Mr Alexander's by pointing out that the language used by the Court is not the same as that used in the Medicinal Products Regulation. I agree with him on this point. Article 3(c) simply states that "the **product** has not already been the subject of a certificate" and makes no direct reference whatsoever to the "**basic patent**". Dr Wright then develops his submission by stating that the Medicinal Products Regulation provides for a period of supplementary protection in respect of **products** which have been granted marketing authorisation, not in respect of patents as such, although the products must be protected by the designated basic patent. He notes that this is consistent with the fact that the scope of protection of the certificate must be confined to the product which obtained authorisation. Again I do not disagree with Dr Wright. Article 4 of the Medicinal Products Regulation states that 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. However, in my view, none of this helps to explain what the Court had in mind when making its observation and again I am not persuaded that I should disregard it when considering whether the present requests satisfy the conditions for the grant of a certificate. The Court would have been aware that the language it used was not the same as that found in Article 3(c) and that certificates provide for a period of additional protection for products and not patents.

18 Following on Dr Wright urges me to view the Court's observation in the context of the second *Biogen* question which I have already quoted above. I have some difficulty reconciling Dr Wright's comment with the *Biogen* judgment when read as a whole. As I understand him, he is suggesting that I should restrict my view of the applicability of the Court's ruling to situations where the basic patents are in different hands; as that is not the present situation, where both patents are held by the same applicant. Dr Wright's argument would require me to be cautious about applying the Court's observations to the present case if I accepted that it had taken a narrow view. However, this does not seem to me to be the case. In the first sentence of paragraph 28 of its judgment, the Court says (my emphasis):

> "Consequently, where a product is protected by a number of basic patents in force, which *may* belong to a number of patent holders, each of those patents may be designated for the purpose of the procedure for the grant of a certificate."

The use of the word "may" suggests to me that the Court had in mind not only situations where the patents are in different hands but also situations where, as here, the patents are in the same hands. Thus, I am not prepared to set aside the observations of the Court on this ground. I believe these observations were made in the general context of a product protected by more than one patent, irrespective of whether the patents were in the same or different hands.

19 Dr Wright then goes on in his letter to suggest that the Court followed the opinion of Advocate General Fennelly in concluding that where a product is protected by a number of basic patents, each of those patents may be designated for the grant of a certificate. In his letter Dr Wright draws particular attention to what the Advocate General said at paragraph 40:

> "40. The Regulation is a legislative enactment of general application, adopted to achieve certain objectives. The text of the Regulation should be interpreted, as far as possible, to facilitate the achievement of those objectives. Where a provision gives rise to more than one possible interpretation, the alternatives should be examined when the most obvious, literal interpretation fails fully to serve the objective of the Regulation because it is based on partially inaccurate assumptions about the pattern of economic relations in the field addressed by the Regulation and gives rise to contradictions in the legislative text. In my view, Article 3(c) of the Regulation should be read as requiring that the product has not already been the subject of a certificate *procured on the basis of a different marketing authorization*. This implicit condition, unspoken because of the assumptions which guided the draughtsman, is consistent with the structure of Article 3: paragraphs (b) to (d) would then be interpreted as requiring, in logical progression, that there be a valid

> marketing authorisation in respect of the product, that no other marketing authorisation relating to that product have been used as the basis for supplementary protection of its associated patents and that the marketing authorization to be used as the basis of such protection be the first granted in respect of the product in that Member State. Such an interpretation would ensure that the stated purpose of Article 3(c) is achieved, viz. the avoidance of multiple extensions of the period of supplementary protection, while the objectives of the Regulation as a whole could then be pursued without impediment. The holder of any patent associated with the product could designate that patent as a basic patent and, subject to compliance with the conditions prescribed in the Regulations, could be granted a certificate in order to compensate more fully his research activities."

According to Dr Wright it was with the Advocate General's comments in mind, the Court said in the first sentence of paragraph 28 of its judgment (with Dr Wright's emphasis):

> "28 Consequently, where a product is protected by a number of basic patents in force, which **may** belong to a number of patent holders, each of those patents may be designated for the purpose of the procedure for the grant of a certificate."

20 I do not doubt that, as Dr Wright suggests, the Court did have Advocate General Fennelly's opinion in mind when considering its answer to the second question posed by the Tribunal de Commerce, Nivelles, but this does not mean that it adopted the Advocate General's reasoning, even though it eventually came to the same answer. Nevertheless, I have given a great deal of thought to the reasoning of the Advocate General and the Court on this matter and in particular to the comments made concerning Article 3(c). However, I fail to see a connection between the Court's view that:

> "Under Article 3(c) of the Regulation, however, only one certificate may be granted for each basic patent."

and the Advocate General's interpretation of Article 3(c) as stated in the passage quoted above:

> "that no other marketing authorization relating to that product have been used as the basis for supplementary protection of its associated patents".

I think I must assume that when the Court referred to "each basic patent" in the sentence under consideration, it meant to refer to "patent" and nothing else. If the Court had wanted to interpret Article 3(c) in terms of marketing authorisations relating to a product, it seems to me that it would have referred to such authorisations rather than "each basic patent". Thus, once again I am not helped in determining what the Court intended by its statement that only one certificate may be granted for each basic patent.

21 In the absence of anything from the applicant, which explains to my satisfaction the Court's view that "only one certificate may be granted for each basic patent", I am left to find my own explanation. I believe that it is useful to begin by considering what the consequences would be of taking the Court's statement at face value and of granting one but only one certificate for each basic patent. Where a patent holder has more than one patent for one and the same product, the grant of successive certificates for that product, each based on a

respective one of these patents, would allow him to bypass the restriction on the maximum permitted period of supplementary protection. Such a possibility would undermine what was a key compromise between the various interests at stake in the provision of supplementary protection. Consider now a different situation where a single patent protects several different products, some possibly still undergoing the necessary clinical testing for the marketing approval of the corresponding medicinal products. If the patent holder were allowed only one certificate on this single patent, he would have to choose which of the protected products should receive supplementary protection. In other words he would have to decide which product would provide the "golden egg". I note in passing that the Medicinal Products Regulation would not give him very much time in which to make this decision because a request for a certificate must be made within six months of the grant of the marketing authorisation. The wrong choice could mean that the patent holder would not receive adequate and effective supplementary protection to compensate for the time taken to get marketing authorisation for all the products protected by the patent. On the other hand, he would be in a much better position if he could obtain supplementary protection for more than one of the different products based on the same patent. In my view the first of these two possibilities does not sit well with the conclusions I drew in my earlier decision that the purpose of the Medicinal Products Regulation is to encourage research by providing supplementary protection which is both adequate and effective. On the other hand, the second possibility sits better with these conclusions. I do not believe therefore that the Court was suggesting in *Biogen* that a patent holder should make this choice when one patent protects more than one different product. Thus, these two different situations, where the patent holder either has more than one patent for the same product or a single patent for different products, illustrate that taking the Court's statement at face value would conflict with the objectives underlying the Medicinal Products Regulation. It is necessary then to look deeper.

22 In doing so I will start by considering the first sentence of paragraph 28 of the Court's judgment, which I have already quoted twice above and which immediately precedes the statement I am trying to understand. What did the Court mean by "**each** of those patents **may** be designated" in this sentence? The applicant has not addressed me on this matter. However, in line with my conclusion above that the Medicinal Products Regulation aims to prevent the grant of successive certificates for one and the same product on the basis of a series of patents in the same hands, I believe the Court was acknowledging the freedom patent holders have to choose which patent to designate when they hold more than one which protects the same product. I do not believe the Court was suggesting here that the patent holder may designate all such relevant patents to obtain more than one certificate for the same product. It follows that when a patent holder has several patents protecting one and the same product, he can designate only one of those patents for the purpose of supplementary protection for that product. Expressing this in slightly different terms, even if a patent holder has more than one patent for the same product, he cannot obtain more than one certificate for that product. It is therefore my view that it is the restriction to one patent of choice that the Court had in mind in the second sentence of paragraph 28 when it stated "Under Article 3(c) of the Regulations, however, only one certificate may be granted for each basic patent".

23 I must therefore conclude that the Court's statement cannot be taken at face value. It must be considered not only in the context of the other parts of the Court's ruling on the second *Biogen* question but also in the context of the objectives and provisions of the Medicinal

Products Regulation as a whole. Taking this broader view, I think the most plausible conclusion is that when making its observations in the context of the second question, the Court meant that if a patent holder has more than one patent for the same product, he should not be able to obtain more than one certificate for that product.

The Plant Protection Products Regulation

24 On 8 February 1997, very soon after the Court gave its judgment in *Biogen,* certificates also became available for plant protection products when Regulation (EC) No. 1610/96 of the European Parliament and of the Council, concerning the creation of a supplementary protection certificate for plant protection products, ("the Plant Protection Products Regulation") took effect. This new Regulation not only introduced a new class of certificate, it also offered interpretations of various aspects the Medicinal Products Regulation. Recital 17 of the Plant Protection Products Regulation states:

> "Whereas, the detailed rules in recitals 12, 13 and 14 and in Articles 3(2), 4, 8(1)(c) and 17(2) of this Regulation are also valid, *mutatis mutandis,* for the interpretation in particular of recital 9 and Articles 3, 4, 8(1)(c) and 17 of Council Regulation (EEC) No 1768/92,".

Article 3(2) of the Plant Protection Products Regulation, which is one of the detailed rules available for the interpretation of Council Regulation (EEC) No.1768/92, that is the Medicinal Products Regulation, states:

> "**2.** The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders."

In my view Article 3(2) can be used, *mutatis mutandis,* for the interpretation of Article 3 of the Medicinal Products Regulation since they both concern conditions for obtaining a certificate.

25 When addressing me at the hearing on the relevance of Article 3(2) of the Plant Protection Products Regulation, Mr Alexander took the view that this Article does not have application to the present case where the applicant is seeking to obtain certificates for products, comprising combinations of active ingredients, that have not been the subject of a certificate before. In taking this view Mr Alexander seemed to be focussed on just Article 3(c) of the Medicinal Products Regulation and seemed not to attribute any broader meaning to Article 3 of this Regulation on the basis of Article 3(2) of the Plant Protection Products Regulation. Dr Wright does not develop this line of argument in his letter. Thus, in response to Mr Alexander's submission, I must consider whether Article 3(2) of the Plant Protection Products Regulation has any bearing on requests which satisfy the condition specified in Article 3(c) of the Medicinal Products Regulation. In other words, might interpreting Article 3 of the Medicinal Products Regulation in the light of Article 3(2) of the Plant Protection Products Regulation preclude the grant of a request for a certificate for a product, even when that product has not already been the subject of a certificate at the date when the request was made?

26 The first thing I note when considering this question, is that Article 3(2) of the Plant Protection Products Regulation is valid for the interpretation of Article 3 of the other Regulation in general. Thus, I am not inclined to the view that Article 3(2) is necessarily valid for the interpretation of specifically Article 3(c) of the Medicinal Products Regulation. However, I am attracted by the thought that Article 3(2) of the Plant Protection Products Regulation makes explicit a condition which is only implicit in the Medicinal Products Regulation. I believe that this thought is supported by a consideration of those principles underlying the Medicinal Products Regulation, which I have already identified. Indeed, by applying these principles to the Court's observations in *Biogen*, I have already come to a conclusion on that matter, which corresponds to the first sentence of Article 3(2) of the Plant Protection Products Regulation. Thus, I do not accept Mr Alexander's submission that Article 3(2) of the Plant Protection Products Regulation does not apply to the present requests. I take a contrary view that the interpretation provided by Article 3(2) should be applied independently of the condition of Article 3(c) of the Medicinal Products Regulation.

27 Dr Wright does not address in his letter how an interpretation based on Article 3(2) of the Plant Protection Products Regulation might have a bearing on the present requests but he does cast doubt on the validity of interpreting Article 3(c) of the Medicinal Products Regulation by reference to Article 3(2) of this later Regulation. On this matter he refers me to a comment made by Advocate General Stix-Hackl at footnote 42 of her opinion in Case C-127/00 *Aktiebolaget Hässle v. Ratiopharm GmbH* ("*Hässle*"). The footnote is in German but according to a translation supplied by Dr Wright, the Advocate General comments:

> "In this situation it is an open question whether the principle of legal certainty is satisfied when the community legislator requires that the legal consequences of a Regulation may be determined by a certain interpretation found in another regulation and there only in the recitals."

Although I believe I should consider it very carefully, Advocate General Stix-Hackl's opinion is not binding on me and even if it were, it amounts to no more than an expression of doubt. In addition, the Advocate General casts particular doubt on relying on recitals in one regulation to interpret another but in the present case my interpretation has been based on an article in another regulation. Dr Wright does not provide any reasons of his own why I should not rely on those detailed rules identified in recital 17 of the Plant Protection Products Regulation to interpret relevant provisions in the Medicinal Products Regulation. Indeed, Dr Wright helpfully reminds me that in Case C-392/97 *Farmitalia Carlo Erba SRL's SPC Application* [2000] RPC 580 at paragraph 20, the Court has already applied the 13th recital in the preamble to the Plant Protection Products Regulation *mutatis mutandis* to the interpretation of Article 3 of the Medicinal Products Regulation. Thus, I am not persuaded that I am prevented from relying on Article 3(2) of the Plant Protection Products Regulation, *mutatis mutandis*, for assistance in the interpretation of Article 3 of the Medicinal Products Regulation.

Conclusions on interpretation

28 I conclude that when deciding whether the present requests are allowable, I must consider not only the explicit condition of Article 3(c) but also the additional, implicit condition which emerges from a consideration of the principles underlying the Medicinal Products Regulation and which is made explicit by Article 3(2) of the Plant Protection Products

Regulation. However, I do not need to concern myself here with the qualification expressed in the second sentence of Article 3(2) because this only concerns situations where there are co-pending requests by different applicants. I can summarise the two conditions I do need to consider as follows:

(a) a certificate shall not be granted for a product if at the date of application for the certificate, the product has already been the subject of a certificate; and

(b) the holder of more than one patent for the same product shall not be granted more than one certificate for that product.

As is clear from Article 3 of the Medicinal Products Regulation, these conditions apply only to patents and certificates within the United Kingdom. Moreover, for avoidance of doubt, I should repeat my conclusion that Article 3 of the Medicinal Products Regulation does not impose a condition that only one certificate shall be granted on one and the same patent.

What are the products in question?

29 Before I can apply my conclusions on interpretation to the present requests for supplementary protection, I should confirm what the product is in each case. In my earlier decision I took as my starting point the products as specified by the applicant in each of the requests. Therefore for the purposes of:

(a) SPC/GB96/030 and SPC/GB/96/033 the product is a combination of lansoprazole, clarithromycin and amoxycillin;

(b) SPC/GB/96/031 and SPC/GB/96/034 the product is a combination of lansoprazole, clarithromycin and metronidazole; and

(c) SPC/GB/96/032 and SPC/GB/96/035 the product is a combination of lansoprazole, amoxycillin and metronidazole.

These combinations of lansoprazole with two specific antibiotics remain the relevant products for this decision. Additionally, I will take lansoprazole by itself as the product of certificate SPC/GB/94/011 which has already been granted on the basis of EP 0174726.

The applicability of Article 3(c) and Article 3(2) to the present requests

30 I can now turn to the specific matters I must decide and these can be formulated as six questions:

(a) does the existence of the certificate SPC/GB/94/011 for lansoprazole alone, which is based on EP 0174726, preclude further certificates, based on the same patent, for three different combinations of lansoprazole with two specific antibiotics, as requested in SPC/GB/96/030 - SPC/GB/96/032?

(b) can more than one of SPC/GB/96/030 - SPC/GB/96/032 be granted on the basis of the same patent, namely EP 0174726?

(c) can more than one of SPC/GB/96/033 - SPC/GB/96/035 be granted on the basis of the same patent, namely EP 0382489?

(d) can both of SPC/GB/96/030 and SPC/GB/96/033 be granted for the same product on the basis of two different patents, namely EP 0174726 and EP 0382489?

(e) can both of SPC/GB/96/031 and SPC/GB/96/034 be granted for the same product on the basis of different patents, namely EP 0174726 and EP 0382489??

(f) can both of SPC/GB/96/032 and SPC/GB/96/035 be granted for the same product on the basis of different patents, namely EP 0174726 and EP 0382489??

31 Taking each of these questions in turn and answering them by reference to the relevant conditions I have identified above:

(a) Although each of the products of SPC/GB/96/030 - SPC/GB/96/032 contain lansoprazole, they also each contain two antibiotics. This in my view distinguishes these products from the product of the granted SPC/GB/94/011, which is a single active ingredient, lansoprazole. Thus, because the products of SPC/GB/96/030 - SPC/GB/96/032 are different from the product of SPC/GB/94/011, the grant of the earlier certificate to the applicant, based on EP 0174726, does not preclude the grant of these current requests, based on the same patent.

(b) The products identified in each of the requests SPC/GB/96/030 - SPC/GB/96/032 are different, even though lansoprazole is common to all. Thus, although all three requests are made by the same applicant and are based on the same patent, this does not provide grounds for their rejection where the products are different.

(c) The reasoning in (b) applies equally to the SPC/GB/033 - SPC/GB/035 and again there are no grounds for rejecting any of these requests simply because they are based on a common patent.

(d) In my earlier decision I rejected SPC/GB/96/030 and SPC/GB/96/033 because the product common to these requests, which is a combination of two specific antibiotics with lansoprazole, was not protected by either EP 0174726 or EP 0382489. However, if I am wrong on this, and both patents are for the specific combination of active ingredients identified in these requests, only one of the requests could be granted. To do otherwise would contravene the condition made explicit by Article 3(2) of the Plant Protection Products Regulation and mean that the applicant would be granted more that one certificate for the same product and so would obtain supplementary protection for that product in excess of five years. According to my calculations, if granted, SPC/GB/96/30 would take effect on 31 July 2005 and run for five years until 30 July 2010. SPC/GB/96/033 would take effect on 5 February 2010 (just before SPC/GB/96/30 expires) and run until 27 February 2011. Therefore the total period of supplementary protection for the product would be 5 years, 6 months and 27 days.

(e) and (f) For the reasons given in (d) above only one of SPC/GB/96/031 and SPC/GB/96/034 , and only one of SPC/GB/96/032 and SPC/GB/96/035 could be

granted if I am wrong in my earlier decision about what is protected by EP 0174726 and EP 0382489.

Previous Patent Office practice

32 Dr Wright makes a point in his letter that in the past the comptroller has granted more than one certificate in respect of a single patent. Dr Wright refers specifically to three certificates for combinations of active ingredients, which were referred to at the hearing on 25 September 2001 and addressed in my earlier decision. Each of these certificates (SPC/GB/93/003, SPC/GB/93/026 and SPC/GB/99/008) was based on the same patent as an earlier certificate for one of the active ingredients present in the relevant combination. Thus, for example, SPC/GB/98/037 was granted in February 1999 for irbesartan on the basis of European Patent No. 0454511 and subsequently in December 1999 a certificate was granted for the combination of irbesartan and hydrochlorothiazide (HCTZ), also on the basis of European Patent No. 0454511. Dr Wright is therefore correct that it has been the past practice of the comptroller to grant more than one certificate on the basis of one and the same patent in certain situations. However, I consider that the instances, identified by Dr Wright, are not in any way inconsistent with my interpretation in this decision of Article 3 of the Medicinal Products Regulation. They are also consistent with my conclusion above that the earlier certificate for lansoprazole, based on EP 0174726, does not prevent further certificates for combinations of active ingredients, including lansoprazole, based on the same patent.

Summary

33 In summary, I have decided that on an interpretation of Article 3 of the Medicinal Products Regulation, based *inter alia* on Article 3(2) of the Plant Protection Products Regulation, only one certificate for each of the three different products, specified in the requests SPC/GB/96/30 to SPC/GB/96/35, could be granted to the applicant. The products in questions are:

(a) a combination of lansoprazole, clarithromycin & amoxycillin;

(b) a combination of lansoprazole, clarithromycin & metronidazole; and

(c) a combination of lansoprazole, amoxycillin & metronidazole.

Thus, only one of the SPC/GB/96/30 and SPC/GB/96/33, only one of SPC/GB/96/31 and SPC/GB/96/34, and only one of SPC/GB/96/32 and SPC/GB/96/35 could be granted.

34 I have also decided that the requests SPC/GB/96/030 - SPC/GB/96/032 should not be rejected on the ground that one of a plurality of active ingredients present in the designated products has already been the subject of a certificate, namely SPC/GB/94/011.

35 Furthermore, on the basis that SPC/GB/96/030 to SPC/GB/96/032 relate to three different products, I have decided that none of these requests should be rejected on the ground that they designate the same patent. Similarly, I have decided that SPC/GB96//033 to SPC/GB/96/035 which relate to the same three different products, should not be rejected solely on the ground that they designate a common patent.

Opportunity to elect which requests should proceed

36 At the hearing on 25 September 2001 Mr Alexander requested an opportunity to elect which of the six requests the applicant might want to pursue to grant if I found in the applicant's favour on the matters of compliance with Article 3(a) and (b) of the Medicinal Products Regulation but if I decided that some or all of the requests should be rejected because they did not satisfy the condition of Article 3(c). Dr Wright also refers in his letter to the possibility of making the elections contemplated by Mr Alexander at the hearing and in the same letter he enters a reserve on behalf of the applicant.

37 My understanding of Mr Alexander's original request was that this course would be appropriate only if I found for the applicant concerning compliance with Article 3(a) and (b) of the Medicinal Products Regulation. In the event I rejected all six requests on these grounds in my earlier decision. I also have in mind Mr Justice Laddie's comments at the hearing on 11 March 2002, in particular his view that if you look too narrowly at one sub-article without regard to the others, you may end up producing, by a series of apparently logical steps, an illogical or unacceptable answer. However, I find that I am not in a position to prevent the applicant withdrawing any of the present six requests if it so chooses. Of course, any remaining requests would still stand rejected in accordance with my earlier decision which is now the subject of an appeal.

Appeal

38 This being a decision other than on a matter of procedure, any appeal against this decision shall be filed within six weeks after the date of this decision.

Dated this 31st day of May 2002

R J WALKER
Deputy Director, acting for the Comptroller

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