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 issues

1 Takeda Chemical Industries Limited ("the applicant") filed six requests for the grant of a Supplementary Protection Certificate ("certificate") on 28 August 1996. These requests were given the application numbers 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, and sought protection for products comprising three different combinations of active ingredients. Three of the requests designated European patent no. 0174726 B1 ("EP 0174726") and the other three requests designated European patent no 0382489 B1 ("EP 0382489"). All six requests were based on the same first authorisation in accordance with Directive 65/65/EEC to place a medicinal product on the market in the United Kingdom. It is easiest to show the relationship between the requests, the combinations of active ingredients, the European patents and the marketing authorisation in tabular form.

Application No.	Marketing Authorisation	Basic Patent	Product
SPC/GB/96/030	PL095/0264	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

2 After considering these requests, the examiner took the preliminary view that they should be rejected on the grounds that they did not comply with the conditions of Article 3 of Council Regulation (EEC) No. 1768/92 ("the Regulation"). In particular, the examiner's preliminary view was based on non-compliance with the conditions of:

(a) Article 3(a) of the Regulation, which requires the product to be protected by a basic patent in force;

(b) Article 3(b) of the Regulation, which requires that 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; and

(c) Article 3(c) of the Regulation, which requires that the product has not already been the subject of a certificate.

3 The applicant did not accept this view and the matter came before me at a hearing held on 25 September 2001. Mr Daniel Alexander, instructed by the patent agents Elkington & Fife, appeared as Counsel for the applicant. Before the hearing I had the benefit of seeing a skeleton argument provided by Mr Alexander and I thank him for this. The examiner, Mr Jason Bellia, also attended the hearing.

Background

4 EP 0174726 relates to pyridine derivatives found to be useful as anti-ulcer agents. Claim 1 of this patent defines a certain type of pyridine derivative by reference to a generalised chemical structure. Lansoprazole is a specific embodiment of this pyridine derivative. 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, for the treatment of acid-related disorders of the upper gastro-intestinal tract. Subsequently, on the basis of EP 0174726 and this marketing authorisation, the applicant requested and was granted a certificate for lansoprazole. This certificate was granted on 23 September 1994 and will expire on 10 December 2005.

5 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) was obtained. This patent also relates to a certain type of pyridine derivative, lansoprazole being one example, but because this derivative was already known in view of the earlier disclosure in EP 0174726, the claims were drafted in so called "Swiss-type" form which is used to protect second medical use inventions. In particular, the claims of this later patent relate to the use of a certain type of pyridine derivative for preventing or treating infectious diseases caused by the microorganism belonging to *Campylobacter pylori*. *Campylobacter pylori* is nowadays usually referred to as *Helicobacter pylori* or *H. pylori* for short. In 1995 the applicant, again acting through its licensee, Wyeth, applied

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. This variation of the existing marketing authorisation was allowed on 28 February 1996 in the form of a "roll back" authorisation, by which I mean the authorisation for the additional therapeutic indication was incorporated under the number of the original authorisation.

6 Although Zoton originally received marketing authorisation in February 1994, Mr Alexander explained at the hearing that it could not be marketed for the new therapeutic indication until an authorisation for the new indication was allowed in 1996. Thus, according to Mr Alexander, the applicant could not take advantage of EP 0382489 until approximately six years after its 6 February 1990 filing date. The six requests for certificates, which lie at the heart of this case, were made in 1996 and are based on the varied authorisation which was allowed in that year.

Assessment

The Medicinal Products Regulation and its underlying principles

7 It is convenient to consider each of the outstanding issues separately, beginning with compliance with Article 3(a) of the Regulation before moving on to consider, in turn, compliance with Article 3(b) and Article 3(c). However, before I do so, I will set the scene by looking at these and other relevant provisions of the Regulation, which are found in Articles 1 to 4.

"**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.

ARTICLE 2

Scope

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorization procedure as laid down in Council Directive 65/65/EEC or Directive 81/851/EEC may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

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 authorisation to place the product on the market as a medicinal product.

ARTICLE 4

Subject-matter of protection

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 authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate."

8 I am mindful that the Regulation is a Community instrument and as such I must take into account the general principles underlying it when interpreting its provisions. In his skeleton Mr Alexander stated that the text of the Regulation, including its recitals, the jurisprudence of the European Court of Justice and the travaux preparatoires of this Regulation were all consistent with an approach to the grant of certificates, which does not distinguish between the kinds of research work, entitling an applicant to a certificate.

9 By way of support for his view Mr Alexander referred me to Recitals 2, 3 and 8 of the Regulation. I also think that Recital 9 has a bearing on the matters that I must consider. These recitals state (numbering supplied):

"2. Whereas 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;"

"3. Whereas at the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorization 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;"

"8. Whereas the duration of the protection granted by the certificate should be such as to provide adequate effective protection; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusivity from the time the medicinal product in question first obtains authorization to be placed on the market in the Community;"

"9. 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;"

10 I conclude from Recitals 2 and 3 that the purpose of the Regulation is to encourage research by compensating for the period of patent protection eroded as a result of the time taken to get authorisation to market a medicinal product. I find support for this conclusion in *Draco A.B.'s SPC Application* [1996] RPC 417, in which Jacob J described the purpose of the Regulation very succinctly at page 439:

> *"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."*

11 Recitals 8 and 9 reveal the operative policy behind the Regulation and these were also considered by Jacob J in *Draco*. Commenting on these recitals, he said at page 438 (Jacob J's emphasis):

> *"These are important. They reveal the operative policy. There is to be* ***adequate effective protection****. The period of exclusivity under the patent and SPC combined is a maximum of 15 years. This runs from the time the* ***medicinal product in question*** *first obtains authorisation. And the scope of protection is* ***strictly confined*** *to the* ***product which obtained authorization*** *etc.*
>
> *It will be noted that the two recitals use both the phrase* ***medicinal product*** *and* ***product****. Without more there could be ambiguity. This is because authorizations*
>
> *typically are not for active ingredients as such. They are much more tightly drawn, generally to dosage and formulation or presentation. That has to be so because the actual performance of an active ingredient depends on the matters in addition to the active ingredient itself."*

After referring to the definitions in Article 1 of “medicinal product” and "product”, Jacob J went on to say:

> *“I have no doubt, nor do I think anyone else would have any doubt, that recitals 8 and 9 must be read as using these definitions. So* ***strictly confined*** *to the* ***product which obtained authorisation means: strictly confined to the active ingredient*** *of that which is presented for treatment.”*

Thus, the compensation for the time lost in the exploitation of patented inventions should be by way of protection which is both adequate and effective This is achieved by providing for a period of exclusivity under the patent and certificate of up to 15 years and by restricting the scope of protection strictly to the active ingredient or combination of active ingredients of a medicinal product which obtained marketing authorisation.

12 In *Draco* Jacob J focussed on the role of the marketing authorisation in confining the scope of protection conferred by a certificate because this was the issue at the centre of that case. He did not therefore consider in any depth the role of the patent in the scheme of supplementary protection. However, from what I have already concluded on the purpose of the Regulation and its operative policy, it is clear that the protection conferred by a certificate for an active ingredient or a combination of active ingredients cannot go beyond the protection conferred by the basic patent on that active ingredient or combination of active ingredients. In other words, a certificate cannot protect something that was not protected by the basic patent or give something greater protection than was available for that thing under the patent.

13 The definition of “basic patent” in Article 1(c) makes it clear that a patent, designated for a certificate, need not be restricted to one protecting a product as such but it may be a patent protecting a process to obtain a product or an application of a product. Put another way and using Mr Alexander's words, the basic patent may be one which protects a use of a product as defined in Article 1(b). This is consistent with the travaux preparatoires of the Regulation. In his skeleton Mr Alexander quoted paragraphs 12 and 29 of the Explanatory Memorandum which was presented by the Commission with their proposal for the Regulation in 1990. These paragraphs state:

> *“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.”*
>
> *“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."

Thus, a certificate may be founded on a basic patent which protects a new therapeutic indication of an active ingredient or combination of active ingredients, provided that the other conditions of the Regulation are satisfied. One of these conditions, according to Article 3(a), is that this basic patent must be in force on the date when the application for a certificate is made. There is also the condition of Article 3(b), which brings the marketing authorisation into the scheme of supplementary protection in the way I have just considered. This leaves just one further condition which has relevance to this case, and that is the condition of Article 3(c). Although Mr Alexander made various submissions to me on how I should view the law as it relates to Article 3(c), I do not believe I need consider them here for reasons which will emerge later in this decision.

14 This then is the background which I should have in mind when considering the issues arising under Article 3(a) and (b) in this case. I can now move on the consider the first of these issues.

Is the product protected by a basic patent in force?

15 As indicated above, the examiner's preliminary view was that none of the requests complied with the condition of Article 3(a) of the Regulation that the product should be protected by a basic patent in force. The basic patent relied on for each request was clearly designated on the relevant request form, lodged with the Patent Office on 28 August 1996, and in each case it was in force at that time. Each request form also identified the product as one of the combinations of active ingredients specified in the table above. At the hearing I confirmed with Mr Alexander that the products in question were in fact these specific combinations of active ingredients and not simply lansoprazole, so as to be absolutely certain that the Office and the applicant had a common understanding on this matter.

16 Although the designated patents claim a certain type of pyridine derivative, such as lansoprazole, either in its own right or in the context of a Swiss-type claim, neither patent claims or discloses the use of the pyridine derivative in combination with any other active ingredient. More particularly, there is no hint whatsoever in these patents that a derivative, such as lansoprazole, could be used in combination with two antibiotics chosen from clarithromycin, amoxycillin and metronidazole. It is the absence of any such disclosure or any such hint that lay at the heart of the examiner's preliminary view that the product identified in each of the requests was not protected by either of the designated basic patents. The applicant on the other hand took the view that EP 0174726 gives the right to prevent others from using lansoprazole, either alone or in combination with other active ingredients, and that EP 0382489 gives a similar right against others from using lansoprazole, either alone or in combination, in association with the treatment of infectious diseases caused by

H. pylori. Accordingly, in the applicant's opinion, the combinations of active ingredients are protected by both patents. The applicant and the examiner in his preliminary view therefore have a fundamentally different understanding about what "protected by" means in the context of the Regulation.

17 In his submission to me on the correct approach to take when determining whether or not a product is protected by a basic patent in force, Mr Alexander relied on the European Court of Justice's judgment in *Farmitalia Carlo Erba Srl's Supplementary Protection Certificate Application* [2000] RPC 580. In this case the European Court of Justice was faced with two questions, the second one of which was:

> *"According to which criteria is it to be determined whether the product is protected by a basic patent within the meaning of Article 3(a), where the grant of a protection certificate is sought for the free base of an active ingredient including any of its salts, but the basic patent in its patent claims mentions only the free base of this substance and, moreover, mentions only a single salt of this free base? Is the wording of the claim for the basic patent or the latter's scope of protection the determining criterion?"*

Giving its answer to this question at page 585 the Court stated:

> *"26. As Community law now stands, the provisions concerning patents have not yet been made the subject of harmonisation at Community level or of an approximation of laws.*
>
> *27. Accordingly, in the absence of Community harmonisation of patent law, the extent of patent protection can be determined only in the light of the non-Community rules which govern patents.*
>
> *28. As is clear in particular from paragraph 21 of this judgment, the protection conferred by the certificate cannot exceed the scope of the protection conferred by the basic patent.*
>
> *29. The answer to be given to the second question must therefore be that, in order to determine, in connection with the application of Regulation 1768/92 and, in particular, Article 3(a) thereof, whether a product is protected by a basic patent, reference must be made to the rules which govern that patent."*

Thus, in its answer to the second question in *Farmitalia,* the Court said that it was necessary to refer to the rules governing a patent to determine whether that patent protects a product. From this Mr Alexander construed that I must decide the present matter, arising under Article 3(a) of the Regulation, on the basis of English law, more particularly on the basis of the Patents Act 1977 ("the Act"). In view of the Court's answer to the second question in *Farmitalia* I will proceed as suggested by Mr Alexander.

The concept of "protection" by a patent in English Law

18 At the hearing Mr Alexander opined that if you look at the concept of protection of a patent in English law, the conclusion you must reach is that protection is determined by the scope of the claims as properly construed in the light of the specification, but primarily by asking the question what, properly construed, falls within the scope of those claims. So far as this

goes, I would not disagree with Mr Alexander. However, I do not think that equating "protection" with "something falling within the scope of the claims" takes me any closer to answering the question whether the present combinations of active ingredients are protected by the designated patents in this case. I think it helps to clarify the concept of "protection" or "something falling within the scope of the claims" by looking at the function of claims more closely. In his skeleton Mr Alexander made the point that in English law the claims are of special importance as was made clear by Robert Walker LJ in *Cartonneries de Thulin SA v. CTP White Knight Ltd* [2001] RPC 107 when he quoted in paragraph 20 from Lord Russell's speech in *Electrical Musical Industries Ltd v. Lissen Ltd* (1939) 56 RPC 23:

> *"The function of the claims is to define clearly and with precision the monopoly claimed, so that others may know the exact boundaries of the area within which they will be trespassers. Their primary object is to limit and not to extend the monopoly. What is not claimed is disclaimed. The claims must undoubtedly be read as part of the entire document, and not as a separate document; but the forbidden field must be found in the language of the claims and not elsewhere. It is not permissible, in my opinion, by reference to some language used in the earlier part of the specification, to change a claim which by its own language is a claim for one subject-matter into a claim for another and a different subject-matter, which is what you do when you alter the boundaries of the forbidden territory."*

and following on Robert Walker LJ quoted Lord Evershed M.R. in *Rosedale Associated Manufacturers v. Carlton Tyre Saving Co. Ltd* [1960] RPC 59 at page 69:

> *"It is no doubt true and has been well established (see, for example the speech of Lord Russell of Killowen in the EMI case) that you must construe the claims according to their terms upon ordinary principles, and that it is not legitimate to confine the scope of the claims by reference to some limitation which may be found in the body of the specification but is not expressly or by proper inference reproduced in the claims themselves. On the other hand, it is clearly no less legitimate and appropriate in approaching the construction of the claims to read the specification as a whole. Thereby the necessary background is obtained and in some cases the meaning of the words used in the claims may be affected or defined by what is said in the body of the specification."*

19 In his skeleton Mr Alexander also quoted from section 125 of the Act, which provides the statutory basis for determining the extent of an invention in accordance with the guidance provided in *Cartonneries de Thulin* and other authorities. Section 125(1) provides:

> "**125.**-(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."

Section 125(3) requires that The Protocol on the Interpretation of Article 69 of the European Patent Convention ("EPC") should apply for the purposes of section 125(1) as it applies for the purposes of Article 69 EPC. This article, like section 125, provides rules for determining the extent of protection conferred by a patent or a patent application. The Protocol provides:

> "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 drawing 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."

20 During the course of the hearing I explored with Mr Alexander the relevance of section 125 and the Article 69 Protocol and especially the emphasis he placed on the references in both to "the extent of the protection" conferred by a patent. Mr Alexander explained that in his view what is of critical importance is the extent to which the claims of the relevant patent, which define the invention, read on to the subject matter which is sought to be protected by the certificate. In his submission, the Regulation does not require consideration of the reason why any given product would infringe the patent, for example, by filleting the product in a particular way to identify particular aspects of it that would infringe. Compliance with Article 3(a) could be determined by asking the very simple question "does it or does it not infringe?". If I accept, as I have done, Mr Alexander's submission that I should rely on English law to determine what in terms of the Regulation is protected by a basic patent, what this Regulation particularly requires or does not require on this matter does not help me. Nevertheless, it is worth considering the "does it or does it not infringe?" question postulated by Mr Alexander in the context of English law. The relevant provision is found in section 60 of the Act, which concerns the meaning of infringement. Section 60 begins:

> "**60.**-(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say-"

The references in this provision to *"a patent for an invention"* and *"any of the following things ..... in relation to the invention"* indicate, in my view, that the patent protects no more and no less than the invention as construed by reference to the claims in accordance with section 125. Thus, where there is a combination of things and only one of those things is identifiable with the invention of a patent, unauthorised use of the combination will result in the one thing infringing the patent. However, the patent protects just this one thing. The other things making up the combination have no bearing whatsoever on the question of

infringement because they are not identifiable with the invention and so are not protected by the patent.

21 If I apply this view to the Regulation, I can only conclude that the product which is the subject of a certificate, must be identifiable with the invention of the designated basic patent. I find support for this conclusion in the words of Jacob J when he commented in *Draco* on the purpose of the Regulation:

> *"It is to compensate for lost time in the exploitation of* ***inventions*** *which are patented"* (my emphasis).

This ties in with a statement in the Explanatory Memorandum for the Regulation, which is a document that Mr Alexander urged me to consider when interpreting the provisions of the Regulation. Paragraph 29 of the Explanatory Memorandum states (again my emphasis):

> *"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."*

Do EP 0174726 and EP 0382489 protect the combination products?

22 Having concluded that the product "protected by" the basic patent has to be identifiable with the invention of that patent, I can now apply this conclusion to the facts of this case. Rather than starting with the claims of EP 0174726 and EP 0382489 and construing them to identify the inventions of each of these patents, I will take as my starting point the products specified in the requests and consider if they can be identified with the inventions of the respective patents when properly construed. This means considering whether any of the three combinations of lansoprazole with two specific antibiotics, as shown in the table at the beginning of this decision, are identifiable with the invention of EP 0174726 and whether the use of any of these combinations to treat *H. pylori* is identifiable with the invention of EP 0382489. In his skeleton Mr Alexander stated:

> *"6. In February 1994, the patentee's licencee, Wyeth, obtained a marketing authorisation in the United Kingdom for the medicinal product sold under the trade name ZOTON ®, for the treatment of duodenal ulcer and oesophagitis. ZOTON ® contained, as active ingredient, lansoprazole, which was protected by the basic patent EP(UK)174726. ..... ."*

I agree with Mr Alexander that lansoprazole is protected by EP 0174726 because, as an embodiment of the invention of this patent, it is identifiable with the invention.
Mr Alexander went on to state in his skeleton:

> *"7. In the years running up to the launch of ZOTON ® in the United Kingdom, Takeda, acting through its licensee, Wyeth, carried out further research. This showed that lansoprazole, in particular when used in combination with certain specified antibiotics was also effective as a different treatment, namely the eradication of Helicobacter pylori (H. pylori). ..... .*

8. A second patent, EP(UK) 382 489, protects the use of lansoprazole in this new indication. . ..."

I agree with this as well. The use of lansoprazole for the manufacture of a medicament for preventing or treating infectious diseases caused by the microorganism belonging to *H. pylori* is an embodiment of the invention of EP 0382489 and so is protected by this patent. However, my difficulty comes when seeking to establish that combinations of lansoprazole with the specific antibiotics or the use of these combinations are identifiable with the inventions of EP 0174726 and EP 0382489, respectively. Such combinations are not claimed in these patents. EP 0174726 simply claims in its broadest aspects a pyridine derivative represented by a general formula, a method of making the derivative, and a pharmaceutical composition comprising the derivative or its salt and a carrier, excipient or diluent therefor. EP 0382489 claims in its broadest aspect the use of a pyridine derivative represented by a general formula or a pharmacologically acceptable salt thereof for the manufacture of a medicament for preventing or treating infectious diseases caused by the microorganism belonging to *Campylobacter pylori*. As I have already stated, these patents neither disclose nor suggest that the subject pyridine derivatives may be combined with any other active ingredient, in particular with specific antibiotics. Against this background, I do not see that a combination of lansoprazole plus two of clarithromycin, amoxycillin or metronidazole can be identified with the invention of either patent. Thus, I must reject Mr Alexander's submissions on the question of compliance with Article 3(a) and find that neither EP 0174726 nor EP 0382489 protects any of the products specified in the requests for supplementary protection.

Office practice on earlier requests

23 In his skeleton Mr Alexander drew my attention to various certificates previously granted by the Patent Office for combination products.

SPC/GB/93/003	EP(UK) 0012401	lisinopril / HCTZ	granted: 12 August 1994
SPC/GB/93/026	EP(UK) 0012401	enalopril / HCTZ	granted: 25 February 1994
SPC/GB/99/008	EP(UK) 0454511	irbesartan / HCTZ	granted: 21 December 1999

Referring to these certificates Mr Alexander made the point that in no case was there a specific disclosure in the relevant basic patents of the combination of active ingredients, although in each case a combination was generically claimed. Since the hearing I have considered the patents designated for these certificates in the light of Mr Alexander's comments. EP(UK) 0012401 claims the related compounds lisinopril and enalopril. There is also a clear disclosure in the patent that compounds according to the invention, which include the claimed lisinopril and enalopril, may be given in combination with other diuretics, such as hydrochlorothiazide (HCTZ). The other patent, EP(UK) 0454511, claims irbesartan in association with a diuretic. The background to these three granted certificates is therefore different from the current situation where the basic patents relied on contain no indication whatsoever that a compound of the invention, eg lansoprazole, might be combined with other active ingredients, let alone with a pair of specific antibiotics.

Therefore, I consider that these earlier, granted certificates should not influence my decision in the present case.

The Hässle case

24 Finally before I move on to consider the next issue raised by the examiner, I should say something about a case that was refused in Sweden in similar circumstances. During the processing of the present requests, the examiner dealing with them became aware of a case where the Swedish Patent and Registration Office had rejected an application in the name of AB Hässle. This application was for supplementary protection for a combination of two active ingredients, namely felodipin and metoprolol. The grounds for rejection relied on by the Swedish Office were that Article 1(c) and Article 3(a) were not satisfied because the product was not protected by the basic patent relied on by the applicant. At no point in the patent claim or the general part of the description was there a mention or suggestion that any active compound in addition to felodipin would be contained in a pharmaceutical preparation. AB Hässle lodged an appeal against the rejection with the Supreme Administrative Court in Sweden, and the examiner and the applicant in the present case agreed to stay the proceedings on the present requests pending the outcome of this appeal. The Supreme Administrative Court delivered its judgment on 2 February 2000.

25 In this judgment the Supreme Administrative Court considered the distinction between on the one hand a patent's extent or scope of protection and on the other the rights the patent gives on the grounds that something - eg a product which consists of an active substance - falls within the scope of protection. In so doing the Court observed that:

> *"If a certain substance is covered by a patent (falls within the scope of its protection) in the sense that the substance is expressly referred to in the patent claim or is covered by a general definition of the invention therein, this circumstance may, by reason of the rules on infringement of patents, mean that the patent owner enjoys protection not only against others making commercial use of the patent protected substance as such but also against that substance being used in combination with any other active substance that is not covered by the patent. The rules on infringement of patents may in other words entail protection against the use of a combination which is not in itself covered by the patent.*
>
> *The decision of the Patent Appeal Court is based on the understanding that the condition in Article 3(a) implies that the product in question will be covered by the basic patent (falls within the framework of the scope of its protection) in the sense just stated. Where an application for supplementary protection relates to a product which consists of a combination of two active ingredients it is, according to this understanding, a requirement that each of the ingredients in itself - or the*
>
> *combination as such - falls within the scope of protection. AB Hässle asserts for its part that the condition is fulfilled whenever another's use of the product comprises infringement of a basic patent which covers one of the ingredients. In the opinion of the Supreme Administrative Court there are wholly convincing reasons in favour of the former of the alternative interpretations. This alternative concurs with the current terminology and may be regarded in a material respect as most consistent*

> *with the purpose of the Regulation. The Supreme Administrative Court finds that the legal situation, in so far as the question of interpretation at issue here is concerned, is so clear that there is no justification for requesting an interim ruling from the EC Court on the matter."*

Thus, the judgment of the Swedish Administrative Court was that *"protected by a basic patent"* in Article 3(a) of the Regulation means that the product must be covered by the patent in the sense that the product is expressly referred to in a patent claim or is covered by a general definition of the invention in the patent.

26 In his submission to me Mr Alexander considered that I should not give this judgment of the Swedish Administrative Court any weight because, firstly, it relates to a law (ie Swedish law) which the European Court of Justice has said is not the right thing to be looking at for the purposes of the present analysis; and, secondly, even if it were the right thing to be looking at, there are reservations that one may have on the analytical basis of this judgment, which does not appear to have taken account of the relevant authorities. As I have already indicated, Mr Alexander's view was that the approach of English law is the correct approach to take when determining what is protected by a patent giving rights in the United Kingdom. It is for this reason I have applied English law when considering whether the present requests satisfy the condition of Article 3(a) of the Regulation. In following this English law approach, I have nevertheless reached a similar conclusion to that of the Swedish Administrative Court on the application of Article 3(a).

Is there a valid authorisation to place the product on the market as a medicinal product?

27 I can now move on to consider whether the requests comply with Article 3(b) of the Regulation, which requires that a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC. Mr Alexander referred to two such authorisations at the hearing. The first was a UK Marketing Authorisation (PL095/0264) which was varied with the agreement of the Medicines Control Agency on 28 February 1996, and the second was a French Authorisation dated 9 February 1996. It is important to be clear which of these authorisations is relevant to the condition of Article 3(b) of the Regulation. The chapeau to Article 3 states (with my emphasis):

> "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 -"

The application, referred to in Article 7, is the application for a certificate. It follows, when considering Article 3 as a whole, that the authorisation to place a product on the market as a medicinal product, which is the subject of Article 3(b), must be one that has been granted

in the Member State in which the application is submitted. Thus in the present case, the requests for certificates were made in the United Kingdom and so the relevant authorisation for the purposes of Article 3(b) must be the UK Marketing Authorisation. On this basis the corresponding French authorisation referred to by Mr Alexander has no bearing on Article 3(b) and I will restrict my considerations to the UK Authorisation.

28 At the hearing Mr Alexander drew my attention to a letter, dated 28 February 1996, from the UK Medicines Control Agency. In his view this letter varied the terms of the original 1994 authorisation for lansoprazole by providing for an additional indication for lansoprazole when used in combination with appropriate antibiotics. Mr Alexander said that this variation amounted to an authorisation to place a combination of lansoprazole with the appropriate antibiotics on the market as a medicinal product. Following this authorisation it was lawful to market the combination treatment, whereas before it was not lawful to do so. Mr Alexander stated that this fitted well with the aim of the Regulation to compensate for the time when it is unlawful to market a product before an authorisation has been granted.

29 I have no reason to suppose that lansoprazole in combination with appropriate antibiotics could not be marketed lawfully for the eradication of *H. pylori* before the Medicines Control Agency allowed the variation to the original authorisation. Moreover, I do not take issue with documents filed by the applicant shortly before the hearing, which make clear that Zoton should not be used alone to treat *H. pylori* and therefore the combination of Zoton and appropriate antibiotics might be regarded as a new medicinal product. However, what I have to determine on the basis of the Regulation, and particularly on the basis of Article 3(b), is whether the varied authorisation was an authorisation to market a combination of Zoton and appropriate antibiotics as a medicinal product, or whether the varied authorisation was merely an authorisation to market the previously authorised medicinal product (Zoton) for use with appropriate antibiotics as a new therapy.

30 In so far as the letter of 28 February 1996 from the Medicines Control Agency does not in itself comprise a valid marketing authorisation, I have to look deeper. This creates a slight difficulty for the purposes of explaining my reasoning in this decision because this letter as well as a copy of the application to vary the original authorisation and a copy of the variation, as agreed by the Medicines Control Agency, are all subject to a direction of the Comptroller under rule 94(1) of the Patents Rules 1995 that they should be treated as confidential. This direction was issued by the Comptroller in 1996 at the request of the applicant who wanted to protect confidential technical information. However, no such constraints apply to the details of the varied authorisation as they were published in the London Gazette on 31 May 1996. These details are:

Product Licence Number	Company Name	Product Name	Active Ingredients	Indications	Date of Authorisation
00095/0312	Cyanamid (GB) Ltd	Zoton Capsules 30mg	Lansoprazole 30-000mg	Effective in the treatment of acid-related disorders of the upper gastro-intestinal tract, with the benefit of rapid symptom relief. Also effective in combination with antibiotics in the eradication of Helicobacter pylori (H. pylori). Healing and long term management of Gastro Oesophageal Reflux Disease (GORD). Healing and maintenance therapy for patients with duodenal ulcer. Healing of benign gastric ulcer. Also effective in patients with benign peptic lesions, including reflux oesophagitis, unresponsive to H2 receptor antagonists. Eradication of H. pylori from the upper gastrointestinal tract in patients with duodenal ulcer or gastritis when used in combination with appropriate antibiotics. Prescription Only Medicine	27th February 1996

I should explain that the Product Licence Number 00095/0312 was the number of the application made in 1995 for the use of Zoton capsules 30mg in the eradication of *H. pylori*. In the event this application was rolled back and kept the existing Product Licence Number of 095/0264 for these Zoton capsules.

31 This extract from The London Gazette clearly indicates that the medicinal product is "Zoton Capsules 30mg" and that the relevant active ingredient is "Lansoprazole 30-000mg" . There is no suggestion whatsoever that the medicinal product includes appropriate antibiotics as active ingredients. However, there are clear statements in the column headed "Indications" that Zoton is effective in combination with antibiotics in the eradication of *H. pylori*. In these respects, the extract from The London Gazette consistently reflects the content of the documents, particularly the application relating to the use of lansoprazole capsules in the eradication of *H. pylori*, treated as confidential. Thus, I am led to conclude that the authorisation relied on to support the present requests is not an authorisation for a medicinal product comprising a combination of active ingredients, in particular a combination of lansoprazole and appropriate antibiotics.

32 Before I reach a final conclusion on this matter, I must consider Mr Alexander's point that the circumstances of the present case fitted well with the purpose of the Regulation to take account of time lost when a medical product could not be marketed legally. However, it is clear from, for example, Article 4 of the Regulation that the purpose of the Regulation is not to compensate in every case for the lost time taken to obtain authorisation to market a

product. Article 4 provides that an existing certificate for a product shall protect any use of the product as a medicinal product that has been authorised before expiry of the certificate. Thus, it appears that a new use of a product, which has been authorised after a certificate has been granted for that product, is protected by that certificate. Further compensation for the additional time taken to obtain marketing approval for the new use is not envisaged by the Regulation. Mr Alexander sought to distinguish the situation envisaged in Article 4 from the present case by noting that what was authorised in the varied authorisation granted on 28 February 1996 was not simply a new use for lansoprazole but a new combination of active ingredients, that is lansoprazole in combination with appropriate antibiotics, and that this new combination could not be marketed until the varied authorisation had been granted. In considering whether the Regulation was intended to deal with this situation in the way Mr Alexander suggested, I am drawn to Recital 9. In this recital there is the clearest of pointers that to take account of all the interests at stake, the protection granted by the certificate should be strictly confined to the product which obtained authorisation. Thus, if I accepted Mr Alexander's submission and agreed that a certificate could be granted for the combination of active ingredients, including lansoprazole, it seems that this would undermine the purpose of the Regulation as expressed in Recital 9. On the other hand if I stand by my conclusion that the authorisation was simply for the use of Zoton with appropriate antibiotics for the eradication of *H. pylori*, this would be consistent with the purpose of the Regulation in that, by virtue of Article 4 of the Regulation, protection for this new use seemingly would be available under the existing certificate for lansoprazole,

33 On the matter of Article 3(b) I therefore conclude that the varied marketing authorisation which was approved by the Medicines Control Agency on 28 February 1996, is not an authorisation to place on the market a medicinal product comprising lansoprazole and appropriate antibiotics. It is merely an authorisation for the additional therapeutic indication of the medicinal product, Zoton, for the eradication of *H. pylori* from the upper gastrointestinal tract in patients with duodenal ulcer or gastritis when used in combination with appropriate antibiotics. It follows that the condition of Article 3(b) is not satisfied for any of the requests.

Has the product already been the subject of a certificate?

34 The final matter left for me to consider in this case is whether the requests comply with Article 3(c) of the Regulation. In essence the examiner's preliminary view on this matter was if it were accepted that EP 0174726 and EP 0382489 both protected the combination of lansoprazole, clarithromycin and amoxycillin, SPC/GB/96/030 and SPC/GB/96/033 could not both be granted for that combination. Likewise both of SPC/GB/96/031 and SPC/GB/96/033 could not be granted because they both relate to the same combination of active ingredients, and the same goes for SPC/GB/96/032 and SPC/GB/96/035. There was also a question whether further certificates could be based on EP 0174726 since this patent had already been used to support the granted certificate for lansoprazole. However, I have found that none of the six requests satisfy the conditions of Article 3(a) and 3(b) of the Regulation, and I see no need to consider also the position under Article 3(c).

Summary

35 In summary I have decided that:

(a) the products identified in SPC/GB/96/030, SPC/GB/96/31 and SPC/GB/96/32 are not protected by EP 0174726;

(b) the products identified in SPC/GB/96/033. SPC/GB/96/034 and SPC/GB96/035 are not protected by EP 0382489; and

(c) marketing authorisation PL095/0264 as varied on 28 February 1996 is not an authorisation to place any of the products identified in SPC/GB/96/030 to SPC/GB/96/035 on the market as a medicinal product.

Therefore, in accordance with Article 10(2) of the Regulation, I reject all six requests SPC/GB/96/030 to SPC/GB/96/035 on the grounds that none of them comply with the conditions of Article 3(a) and (b) of the Regulation.

Opportunity to elect which requests should proceed

36 At the hearing Mr Alexander requested an opportunity to elect which of the six requests the applicant might want to pursue if I found in the applicant's favour on the questions of compliance with Article 3(a) and (b) but I decided to refuse the requests for non-compliance with Article 3(c). In the event, I have found against the applicant on Article 3(a) and (b) and it was my understanding at the hearing that Mr Alexander recognised that if this were the outcome, there would be nothing the applicant could offer to address the situation. Therefore, I do not need to give the applicant the opportunity to withdraw certain requests and to proceed with others.

Appeal

37 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 6th day of December 2001

R J WALKER
Deputy Director, acting for the Comptroller

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