BL O/222/04

29th July 2004

COUNCIL REGULATION (EEC) No. 1768/92

APPLICANT Yissum Research and Development Company of the Hebrew University of Jerusalem

ISSUE Whether application number SPC/GB/02/023 complies with Article 3(d)

HEARING OFFICER R J Walker

DECISION

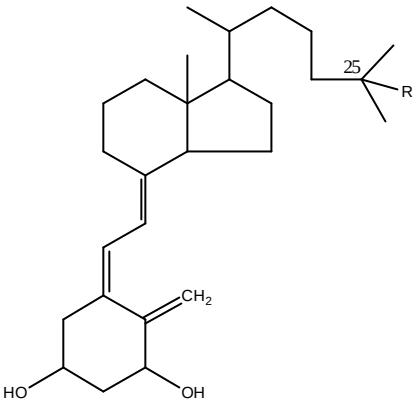
The issue

1 Yissum Research and Development Company of the Hebrew University of Jerusalem ("the applicant") filed an application ("the application") for the grant of a supplementary protection certificate on 11 June 2002 and this application was given the application number SPC/GB/02/023. The application was based on European Patent (UK) No. 0129003 which has the title "Cosmetic and dermatological compositions containing 1-alpha-hydroxycholecalciferol". The application identified the product to be protected as "Calcitriol (chemical name: 1-alpha, 25-dihydroxycholecalciferol)" and stated that the first authorization to place this product on the market in the UK was PL 10590/0047 ("the UK marketing authorization") which was granted on 12 December 2001.

2 According to a copy of the UK marketing authorization, which was supplied with the application, the authorized product is named "Silkis Ointment" ("Silkis" is a Registered Trade Mark) and it comprises calcitriol, as an active, with certain specified excipients. This UK marketing authorization was granted to Galderma (UK) Limited and not to the applicant.

3 European Patent (UK) No. 0129003 was granted on 19 July 1989 but was opposed in proceedings before the European Patent Office. Eventually this patent was upheld in a slightly amended form and was republished as European Patent No. 0129003B2 ("the basic patent"). The basic patent includes twenty five claims but for the purposes of this decision I need only consider the two independent claims 1 and 25 for:

> "1. A composition for use in topical treatment of skin disorders consisting of dermatitis, eczema, psoriasis, lack of adequate skin firmness, dermal hydration and sebum secretion, which comprises between 0.001µg and 1.0 µg per gram of the composition of a compound of the formula:



wherein R is H or OH, and a suitable carrier to manufacture a cream, an ointment or a lotion."

"25. The use of 1-alpha-hydroxycholecalciferol or 1-alpha, 25-dihydroxycholecalciferol for the manufacture of a composition for the topical treatment of skin disorders selected from dermatitis, eczema, psoriasis, lack of adequate skin firmness, dermal hydration or sebum secretion."

When R is OH in the formula represented in claim 1, the compound is 1-alpha, 25-dihydroxycholecalciferol, commonly known as calcitriol.

4 The examiner dealing with the application wrote to the applicant on 1 July 2002 to draw attention to other medicinal products, having calcitriol as the sole active ingredient. These other medicinal products were granted marketing authorizations in the United Kingdom before the authorization for Silkis Ointment. Therefore, in the examiner's view the application did not comply with Article 3(d) of Council Regulation (EEC) No.1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products ("the Regulation"). He identified the previously authorized medicinal products as "Calcijex" (Registered Trade Mark) and "Rocaltrol" (Registered Trade Mark). Calcijex is a sterile, isotonic, clear, aqueous solution containing calcitriol for intravenous injection and is used for the management of hypocalcaemia in patients undergoing dialysis for chronic renal failure. Rocaltrol comprises soft gelatine capsules, containing calcitriol and various inactive ingredients, and it is intended for oral administration to patients with chronic renal failure or post-menopausal osteoporosis.

5 The applicant's patent agent (Eric Potter Clarkson) responded on the 24 December 2002 with a request to amend the application to identify the product as a "Combination of Calcitriol (chemical name: 1-alpha, 25-dihydroxycholecalciferol) with an ointment base" in order to distinguish the product of the application from Calcijex and Rocaltrol. This amendment did not satisfy the examiner and in a further letter, dated 5 February 2003, he maintained his objection under Article 3(d) of the Regulation. In turn the applicant's patent agent wrote on 18 July 2003 with a detailed rebuttal of the examiner's position and requested a hearing if the examiner was still minded to reject the application. The examiner was not persuaded by the arguments put to him and so the matter came before me at a hearing on 1 April 2004. Dr John Miles, a patent attorney with the firm Eric Potter Clarkson, appeared for the applicant. Dr Miles was accompanied by Dr Leila

Zarif, who is patent counsel for Galderma R & D which is a licensee under the basic patent, and by Dr David Martin who is a trainee patent attorney with Eric Potter Clarkson.

Background to the basic patent and UK marketing authorization

6 In his submission to me Dr Miles explained that the innovation behind the basic patent was the discovery that calcitriol is effective to treat psoriasis, among other skin disorders, when used topically. Thus, the innovation was not one of reformulation of a compound for a particular purpose where the compound was already known to be useful for that purpose. The innovation resided in the use of calcitriol for an entirely new purpose. According to Dr Miles this innovation opened up a whole new field of treatment for the debilitating disease of psoriasis. Dr Miles emphasised that Galderma R & D was one of a wide range of companies engaged in extensive innovative research into new uses of known compounds, and that the fruits of such research needed protection in order for the research to be sustainable. According to Dr Miles it was very common in the field of dermatology for new uses to be found for old compounds but the investment needed to bring them to the market was very similar to that for new chemical entities.

7 Dr Miles reminded me that before the benefit of this new treatment for psoriasis could be made available to patients in the United Kingdom, it was necessary for the Medicines Control Agency to consider the safety and efficacy of Silkis Ointment. This required extensive clinical trails and although calcitriol had been used previously to treat other conditions, the standard of clinical trials for Silkis Ointment was on a par with those needed for new chemical entities. Dr Miles estimated the cost of the clinical trials required to obtain marketing authorizations for Silkis Ointment to be at least 23 million Euros. Moreover, the UK marketing authorization for Silkis Ointment was granted approximately 17 ½ years after the filing date of the basic patent.

The Regulation

8 Before I consider whether or not the application complies with Article 3(d) of the Regulation, it would be useful to set out the provisions of the Regulation, which are relevant to the matter I must decide. I am mindful that when interpreting the provisions of the Regulation, I must do so teleologically, that is I must look to its underlying, general principles when seeking to find the meaning of its provisions. In that I am aided by its recitals which state (numbering supplied):

> "1. Whereas pharmaceutical research plays a decisive role in the continuing improvement in public health;
>
> 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;
>
> 4. Whereas this situation leads to a lack of protection which penalizes pharmaceutical

research;

5. Whereas the current situation is creating the risk of research centres situated in the Member States relocating to countries that already offer greater protection;

6. Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market;

7. Whereas, therefore, the creation of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorization has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument;

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;"

There are further recitals, which relate to transitional and other special arrangements, but these do not have a bearing on the matter before me. Therefore, there is no need to reproduce them here.

9 I can now turn to those provisions of the Regulation which were referred to during the hearing and which are central to the matter I must decide:

"**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 as 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[1] or Directive 81/851/EEC[2] 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. For the purpose of Article 19(1), an authorization to place the product on the market granted in accordance with the national legislation of Austria, Finland or Sweden is treated as an authorization 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;

---

[1] Repealed and consolidated into Directive 2001/83 on the Community Code for medicinal products for human use, Article 128 of which provides that references to the repealed Directive shall be construed as references to Directive 2001/83.

2 Repealed and consolidated into Directive 2001/82 on the Community Code for veterinary medicinal products, Article 96 of which provides that references to the repealed Directive shall be construed as references to Directive 2001/82.

(d) the authorization referred to in (b) is the first authorization 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.@

The Applicant's case

10 At the hearing Dr Miles put two distinct lines of argument to me in what he described as the applicant's primary case and the applicant's alternative case. For its primary case the applicant sought to identify the product to be protected as calcitriol, just as it had done in the application as originally filed. In its alternative case the applicant sought to identify the product as a combination of calcitriol and an ointment base. However, before pursuing these separate arguments, Dr Miles urged me to take note of the purpose of the Regulation.

11 According to Dr Miles the Regulation was based on the need to provide sufficient protection to new medicinal products which are protected by a patent and which are the result of long and costly research. In his view this was apparent from the second, third and seventh recitals of the Regulation. He sought to reinforce his view by reference to the Commission's Explanatory Memorandum on its proposal for a Regulation ("the Memorandum"), which was published in April 1990. In particular, Dr Miles drew my attention to paragraph 12 of the Memorandum (his emphasis):

> "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."

From this Dr Miles surmised that research into new therapeutic applications of known compounds must be given protection under the Regulation. Moreover, since the patent system has long given protection to new and inventive uses of known products, for example, in the form of so-called "Swiss type" claims, it would be absurd, in his opinion, if the Regulation did not also protect such innovations. Dr Miles next referred me to paragraph 29 of the Memorandum which he saw as picking up on this theme (again his emphasis):

> "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."

12 Dr Miles sought to distinguish between situations where supplementary protection is sought on the basis of minor changes to a medicinal product and situations where protection is sought for a completely new medicinal product for a new therapeutic application. In doing so he directed my attention to paragraph 11 of the Memorandum (his emphasis):

> "11. The proposal for a Regulation therefore concerns only new medicinal products. It does not involve granting a certificate for all medicinal products that are authorized to be placed on the market. Only one certificate may be granted for any one product, a product being understood to mean an active substance in the strict sense. **Minor changes** to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new certificate."

13 Dr Miles also drew my attention to the Opinion of the Economic and Social Committee on the Regulation, dated 30 January 1991, particularly paragraphs 1.5 and 2.4 of this Opinion which described the Regulation as proposed by the Commission in the following way:

> "1.5. In outlining the content and scope of its proposal, the Commission makes clear that the purpose of the draft Regulation is to restore the effective period of patent protection so as to encourage innovation in the Community's pharmaceutical industry while at the same time avoiding discrimination vis-à-vis other industrial sectors. Another aim is to close the gap between the Community and the USA/Japan with regard to patent protection for basic innovations in the pharmaceutical industry."

> "2.4. The proposed certificate will be issued by national patent offices at the request of the holder of a national or European patent (the "basic" patent) in respect of a product authorized to be marketed in the country concerned. It does not protect the expired patent in its entirety, but only the basic innovation which has also been authorized to be placed on the market."

14 The purpose of the Regulation has also been addressed in several authorities and Dr Miles mentioned in particular the statements of Jacob J, as he was then, in paragraph 2 of *Takeda Chemical Industries Ltd's SPC Applications (No.3)* [2004] RPC 3:

> "2 …… The broad idea behind the Regulation is well known. It is to give patentees "adequate effective protection" in cases where their patent for a medicinal product would provide inadequate remuneration because of delays in marketing authorisation."

and in *Draco A. B.'s SPC Application* [1996] RPC 417 at page 439, lines 50 to 52:

> "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."

Primary case where the product is defined as calcitriol

15 Dr Miles' primary case was that when proper account is taken of the purpose of the supplementary protection certificate scheme, there can be no conflict with Article 3(d) of the Regulation when the product is defined as calcitriol alone. In his view the intention behind Article 3(d) was to prevent minor changes to a medicinal product qualifying for protection. It was not to preclude the grant of a certificate for a new medicinal product for a new therapeutic application.

16 Noting that Articles 3(b) and 3(d) refer to the product being placed on the market "as a medicinal product", Dr Miles submitted that in order to give effect to the Regulation in the way clearly intended, the expression "as a medicinal product" must surely mean "as a **relevant** medicinal product", rather than "any medicinal product". He explained that by "relevant medicinal product" he meant a medicinal product which was directed at the same therapeutic application. In other words, Article 3(d) would be satisfied provided:

> (a) the medicinal product in question was not merely a minor change to a medicinal product covered by an earlier marketing authorization; and
>
> (b) any earlier marketing authorization was for a medicinal product which is substantially different from and has a different therapeutic application from the medicinal product in question.

17 Dr Miles found support for this view in *Draco* at page 427, lines 10 to 16, where the Hearing Officer stated (Dr Miles' emphasis) :

> "According to paragraph 18 of this evidence, the first authorization granted anywhere in the world for budesonide **for the treatment of respiratory disease** was that granted in the United Kingdom in 1981 for Pulmicort and another authorization for a second formulation of budesonide (Pulmicort LS) was granted in the United Kingdom in 1982. However, there was a previous authorization for the topical administration of budesonide **for the treatment of psoriasis, eczema and other dermatoses** and marketing commenced in 1979."

In his view, the Hearing Officer clearly was acknowledging here the relevance of the different therapeutic applications in the different marketing authorizations. Dr Miles went on to highlight a statement made by Jacob J on appeal that the Hearing Officer had found the first authorization to be the one granted for budesonide in 1981. In Dr Miles' opinion this indicated that Jacob J agreed with the Hearing Officer that the first relevant marketing authorization was the one granted in 1981 and not the earlier authorization granted in 1979 for budesonide for the treatment of psoriasis.

18 Setting this in the context of the application, Dr Miles referred me to the Summary of Product Characteristics, contained in the UK marketing authorization, which indicates that the authorization is for calcitriol in an ointment formulation for the treatment of mild to moderately

severe plaque psoriasis. He observed that, as with the basic patent, the UK marketing authorization reflects the innovation in terms of a new use of calcitriol in treating psoriasis. Dr Miles emphasised that the UK marketing authorization does not allow the sale of calcitriol for anything other than the treatment of mild to moderately severe plaque psoriasis. He therefore argued that the authorizations for Calcijex and Rocaltrol were not earlier authorizations in the sense of Article 3(d) because they were directed at different medicinal products for different therapeutic applications when compared to Silkis Ointment. According to Dr Miles Silkis Ointment was a new medicinal product in the sense of the third recital of the Regulation:

> "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."

He also made the point that unless Article 3(d) is construed in the way he suggested, it would seem impossible for a certificate to be granted for a "second medical use" of an active ingredient which was the subject of an earlier marketing authorization relating to the first medical use. This in his view was plainly at odds with the intention of the Regulation.

Alternative case where the product is defined as the combination of calcitriol and an ointment base

19 When presenting the applicant's alternative case, Dr Miles argued that the combination of calcitriol and an ointment base should be regarded as a combination of active ingredients in line with the definition of "product" in Article 1(b). He acknowledged that the UK marketing authorization only explicitly mentions calcitriol as an active ingredient but he argued that there is nothing in the Regulation to require that a certificate should be restricted to compounds identified as an "active ingredient" in a marketing authorization. Moreover, in his view, the Regulation does not require that "an active ingredient" in a combination of active ingredients should be therapeutically active on its own. In his submission to me Dr Miles argued that it is only necessary to have a therapeutic activity in the context of the medicinal product. Thus, the ointment base should be considered as an active ingredient because without it calcitriol would not be effective in the treatment of psoriasis.

20 In support of this proposition Dr Miles referred me to a Witness Statement of Isabelle Preuilh, who in March 2004 was the Project Manager in the Pharmaceutical Development Department at Galderma R & D in France. Dr Miles highlighted statements made by Ms Preuilh that the ointment base actively participates in producing an effective composition for treating psoriasis and is necessary because calcitriol must be in a form which is easily and homogeneously applied onto the skin and which can penetrate through the skin. Dr Miles also drew my attention to a statement made by Ms Preuilh that neither calcitriol alone nor the ointment base alone was effective for the topical treatment of psoriasis.

21 Furthermore, he made the point that the ointment base is required for topical administration which in turn produces the pharmacodynamic properties described in section 5.1 of the Summary of Product Characteristics of the UK marketing authorization:

"Calcitriol inhibits the proliferation and stimulates differentiation of keratinocytes. Calcitriol inhibits proliferation of T cells and normalizes the production of various inflammation factors."

"Topical administration of Silkis Ointment to patients with plaque psoriasis results in an improvement of the skin lesions. This effect is noted from 4 weeks after the start of treatment."

22 Dr Miles also stated that calcitriol is effective in the treatment of psoriasis at a low dosage. He explained that calcitriol was generally very insoluble and required stirring at 80°C for one to two hours just to get low levels of calcitriol dissolved in the ointment base so that it can be spread over the whole area of psoriatic lesions without the risk of high local toxicity. He stressed that it would be inconceivable to administer calcitriol topically as a pure active ingredient without an ointment base since this would lead to undesired side effects.

23 More generally Dr Miles made the point that there is no definition of the expression "active ingredient" in the Regulation nor is there a definition in Council Directive 65/65/EEC. He suggested that this expression, as used in marketing authorizations, serves a different purpose to the definition of "product", as used for supplementary certificate protection, for example in Article 4 where it is used to define the scope of protection. Thus, the criteria used for assessing whether a compound is an "active ingredient" for the purposes of a marketing authorization should not necessarily be used when assessing whether a compound is an "active ingredient" for the purposes of a supplementary protection certificate. In other words, a substance should not be excluded as an "active ingredient" for the purposes of obtaining a certificate merely because the substance is not explicitly identified as an "active ingredient" in a marketing authorization. Instead the term "product", as defined in Article 1(b), should be interpreted in the sense of the product in patent law and the skilled pharmaceutical patent practitioner would look to the claims of the patent to identify the product. In support of this view, he directed me to paragraph 28 of the Memorandum for an explanation of what was meant by "active ingredient" in the Regulation:

"28. …….

…….. However, the qualifier "active" is added to the term "substance" in order to include the concept of an "active ingredient" or "active substance" used in patent law.

Consequently, the term "product" is not understood to mean a proprietary medicinal product or a medicinal product in the wider sense, but in the narrower sense of product used in patent law which, when applied to the chemical and pharmaceutical field, means the active ingredient."

He added that the legislator had not explicitly stated in Article 1(b) that the definition of "product" was synonymous with "active ingredient" in the sense it is used in Council Directive 65/65/EEC because the "product" of the certificate and the "active" of the marketing authorization serve different purposes. The administrative agency choosing the name of the active ingredient does not concern itself with the legal point of defining the product for the

purposes of the Regulation.

24 Dr Miles referred me to *(Case C-392/97) Farmitalia Carlo Erba Srl's Supplementary Protection Certificate Application* [2000] RPC 580 in which one of the questions referred to the European Court of Justice ("ECJ") was:

> "Is it a condition of the application of Article 3(b) that the product in respect of which the grant of a protection certificate is sought is described as an "active ingredient" in the medicinal authorisation?"

In Dr Miles' opinion this is effectively the question I must answer in the alternative case since the answer to this question in terms of whether the "product" in the certificate and the "active ingredient" in the marketing authorization must be the same, applies equally to Article 3(d), not the least because Article 3(d) refers to Article 3(b).

25 The ECJ's judgment in relation to this question was:

> "…….……. that, on a proper construction of Regulation 1768/92 and, in particular, Article 3(b) thereof, where a product in the form referred to in the marketing authorisation is protected by a basic patent in force, the certificate is capable of covering that product, as a medicinal product, in any of the forms enjoying the protection of the basic patent."

When referring to this judgment of the ECJ, Dr Miles stated that he appreciated that it relates to the question of "salts" but nevertheless, in his view, the principles must apply to the present application. To reinforce his view that the Regulation must be construed to fulfill its fundamental objective, which is to provide sufficient, effective protection where there has been innovative research, he quoted paragraph 19 of the *Farmitalia* judgment:

> "…… . If the certificate did not cover the actual medicinal product, as protected by the basic patent and one of the possible forms of which is the subject-matter of a marketing authorisation, the fundamental objective of Regulation 1768/92, as set out in the first and second recitals in the preamble thereto, which is to provide for sufficient protection to encourage research in the pharmaceutical filed, which plays a decisive role in the continuing improvement in public health, could not, for the reasons set out in paragraph 18 of this judgment, be attained."

26 Dr Miles also referred to the judgment in *Draco* to support the applicant's alternative case. In doing so he argued that I should regard calcitriol in combination with an ointment base as an altered form of calcitriol which has a new physical form when compared to calcitriol which was the subject of the earlier authorizations. Moreover, this altered form was the subject of the basic patent and so following Jacob J's logic in *Draco* the application should be allowed. Dr Miles referred in particular to a statement made by Jacob J at page 439, lines 48 to 50 that:

> "I see nothing indicating that formulation research (unless of course it warrants its own patent) is to be protected by the SPC scheme."

According to Dr Miles the present application was not based on mere "formulation research", which would in any event be sufficient for a certificate since the "formulation" is subject to a patent. Rather, in his view, it is a case of a new and inventive therapeutic application opening up a whole new field of treatment which should be given supplementary protection because in the words of Jacob J in *Draco* at page 439, lines 51 and 52 the scheme of supplementary protection:

> "…… is to compensate for lost time in the exploitation of inventions which are patented."

27 Dr Miles developed the alternative case further by arguing that it is reasonable to give the expression "active ingredient" its plain English interpretation since it is not defined in the Regulation or Directive 65/65/EEC. Thus, this expression should be taken to mean an ingredient that has an effect in the context of the medicinal product and its therapeutic use. In his view using this plain English interpretation leads to the conclusion that the combination of calcitriol and ointment base is a combination of active ingredients because calcitriol has the activity set out in the marketing authorization and the ointment base has the activity of enabling the calcitriol to be easily and homogenously applied onto the skin and to then penetrate the skin.

28 Finally, Dr Miles mentioned three supplementary protection certificates, which had been granted by the UK Patent Office and which in his view demonstrated that the Office does not rely on the marketing authorization to determine what the product is for the purpose of a supplementary protection certificate. In his view the grant of these supplementary protection certificates reflected the practice of the UK Patent Office as set out in paragraph SPM1.02 of the Manual of Patent Practice which states:

> "These definitions [of "medicinal product" and "product"] do not always correspond to the terminology used in UK Product Licences and Marketing Authorizations, or the details published in the official Gazettes (see SP0.04). Thus, the product specified in a Product Licence or Marketing Authorization is generally broadly equivalent to the "medicinal product" as defined by Article 1(a), and the "active constituents(s)" or "active ingredient(s)" are generally broadly equivalent to the "product" as defined by Article 1(b)."

Assessment

The purpose and operative policy of the Regulation

29 I should begin by addressing Dr Miles' submission to me on the purpose of the Regulation and its operative policy before I turn to consider the particular matters I must decide. In my view the purpose behind the Regulation emerges from recitals 2 and 3. It is to encourage research into new medicinal products by compensating for the period of effective patent protection lost due to the time taken to obtain marketing authorization for these products. Recitals 8 and 9 are important because they reveal the operative policy behind the Regulation, which is "to provide adequate effective protection" whilst also taking account of all the interests at stake, including those of public health. Thus, the Regulation provides a

maximum of fifteen years exclusivity under the patent and the certificate combined from the time the medicinal product in question is first authorized to be placed on the market. In addition, the protection granted is strictly confined to the product which obtained authorization to be placed on the market as a medicinal product.

30 Claim 25 of the basic patent is of the Swiss type because calcitriol itself was already known and a method of treating psoriasis using calcitriol would not have been patentable by virtue of Article 52(4) of the European Patent Convention. Swiss type claims have become well established because it is recognised that there is benefit in encouraging the discovery of new medical applications for known compounds. This benefit is also recognized by the Regulation since, for example, the basic patent according to Article 1(c) can be one which protects an application of a product. Therefore, I am satisfied that the purpose and operative policy of the Regulation extends to new medicinal products where the innovation resides in a new therapeutic application or use. I find confirmation of this view in paragraphs 12 and 29 of the Memorandum, which I have already quoted. However, as clearly explained in paragraph 29 of the Memorandum and reflected in Article 2, the grant of a supplementary protection certificate depends on all of the conditions for supplementary protection being fulfilled.

The definition of the "product"

31 In considering recitals 8 and 9 and the operative policy behind the Regulation, Jacob J commented in *Draco* at page 438, lines 30 to 35 (Jacob J's emphasis):

> "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 these matters in addition to the active ingredient itself."

Jacob J went on to note that the authors of the Regulation have thought about the difference between the active ingredient and the actual formulation, and in so doing have defined "medicinal product" and "product" in Article 1. He then stated at page 439, lines 1 to 5 (again his emphasis):

> "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 authorization* means: *strictly confined* to the *active ingredient* of that which is presented for treatment."

32 The definition of the product is important not only for determining the scope of protection conferred by a certificate under Article 4 but also for determining whether the conditions for obtaining a certificate, set out in Article 3, are satisfied. Thus, as a first I step must consider what the product is in the case of the medicinal product, Silkis Ointment. I will start by considering the applicant's primary case which is based on a proposal that the product is calcitriol.

The primary case

33 The UK marketing authorization for Silkis Ointment includes the following particulars:

Name:

Silkis Ointment

Pharmacotherapeutic Classification:

OTHER ANTIPSORIATICS FOR TOPICAL USE

Pharmaceutical Form and Strength:

OINTMENT

Actives:

CALCITRIOL

Excipients:

LIQUID PARAFFIN

WHITE SOFT PARAFFIN

DL-ALPHA-TOCOPHEROL

34 From these particulars it is possible to determine that the substances, which form the medicinal product, are a combination of calcitriol, liquid paraffin, white soft paraffin and dl-alpha-tocopherol. As one would expect the marketing authorization specifies all of the components of the medicinal product and the active ingredient is listed separately from the excipients. It is common for medicinal products to include excipients, which are inactive substances serving as a vehicle or medium for delivering a drug or other active substance at an appropriate dosage.

35 In his submission to me on the applicant's alternative case, Dr Miles referred to paragraph SPM1.02 of the Office's Manual of Patent Practice. This sets out the Office's normal practice of equating the "active constituent(s)" or "active ingredient(s)" identified in a marketing authorization with the "product" as defined in Article 1(b). It was on this basis that the examiner, dealing with the application, identified "calcitriol" as the product for the purpose of the Regulation. This of course is how the applicant also defines the product in its primary case. The difficulty I face here is that if I accept this definition of the product, it would prejudge my consideration of the applicant's alternative case where it is argued that I should turn to the basic patent and not the marketing authorization to identify the active ingredient or ingredients. I think the only way forward is to accept the applicant's definition of the "product" as calcitriol alone for the time being and consider the rest of the applicant's primary case on this basis. I can then move on to consider the applicant's alternative definition of the product and if necessary, consider what impact my conclusions there have on the applicant's primary case.

36 The problem the applicant faces is that despite European Patent (UK) No. 0129003B2

protecting a new therapeutic application of calcitriol and so being capable of being regarded as a basic patent in accordance with Article 1(c), the examiner took the view that the UK marketing authorization is not the first authorization to place calcitriol on the market as a medicinal product. As a result the examiner objected that the application did satisfy the condition of Article 3(d) on a natural reading of this provision. However, as I have already noted, the provisions of the Regulation must be interpreted teleologically. Dr Miles in his submission to me sought to overcome this problem by distinguishing the earlier medicinal products from Silkis Ointment on the basis of their different therapeutic applications. He suggested that I should read the references to "a medicinal product" in Articles 3(b) and 3(d) as "a relevant medicinal product", in the sense that relevant medicinal products have the same therapeutic activity, and that I should limit the "product" accordingly. I therefore need to consider whether it would be appropriate to adopt Dr Miles' proposed interpretation of the expression "medicinal product" in order to give effect to the undoubted purpose and operative policy of the Regulation as it concerns new therapeutic applications of known products.

37 At the hearing Dr Miles did not address what is generally recognised as the purpose behind Article 3(d) which is linked via Article 3(b) to Article 7. According to Article 7 an application for a certificate must be lodged within six months of the date of grant of the authorization referred to in Article 3(b) or within six months of the date of grant of the basic patent if this is later. This requirement provides certainty for third parties who have an interest in knowing as early as possible whether the product concerned will be protected by a certificate once the patent has expired. This certainty for third parties would be undermined if a certificate could be based on the same basic patent and a second or third authroization, authorizing, for example, a new therapeutic application of the product concerned. Contrary to Dr Miles' submission, the proper functioning of Article 7 requires the first authorization of Article 3(d) to be the first authorization to place the product on the market as **any** medicinal product.

38 It is also helpful to consider what impact Dr Miles' proposal has on Article 4 which limits the protection afforded by a certificate in two ways, as explained in paragraph 39 of the Memorandum (my emphasis):

> "39. ……
>
> It is thus often the case in the chemical and pharmaceutical field that a patent protects a series of products based on the same formula. However, only some of those products will subsequently be developed and possibly only one may be put on the market. In such a case, **the certificate will only protect the product covered by the authorization** and not all of the products protected by the patent.
>
> **At the same time, the product authorized will itself be limited by the subject protected by the basic patent**. ……."

39 At the hearing I asked Dr Miles what protection he thought the applicant would get from a certificate if I accepted for the purpose of the Regulation that the authorization to place

calcitriol on the market as Silkis Ointment could be distinguished from the earlier authorizations on the basis that the medicinal products are substantially different and for different therapeutic applications. In particular, I asked him if calcitriol in a cream base for the treatment of eczema would infringe the certificate. If I understood Dr Miles correctly he said it would infringe because the calcitriol cream for treating eczema fell within the limits of protection conferred by the basic patent. It seems to me that whilst Dr Miles was ready to suggest that the product placed on the market as a medicinal product should be viewed narrowly, that is on the basis of the activity and constitution of the authorized medicinal product, for the purpose of Article 3(d), he was ready to take a broader view and sought to define the product simply as "calcitriol" for the purpose of determining what the certificate would protect under Article 4. If I accepted Dr Miles' view, claim 25 of the basic patent would allow the applicant to protect the topical use of calcitriol for the treatment of dermatitis, eczema, lack of adequate skin firmness, dermal hydration or sebum secretion, even though these are not the same therapeutic applications covered by the authorization for Silkis Ointment. This cannot be right because the Regulation must surely depend on the same term being interpreted consistently throughout.

40 What on the other hand would be the consequence of applying Dr Miles' interpretation consistently? Consider the case of a product patent, that is one protecting a new chemical entity rather than one protecting a new application of a known entity. If for the purpose of the Regulation the product was restricted to "the product covered by the authorization to place the corresponding **relevant** medicinal product on the market", in other words if it was restricted to the therapeutic activity of the authorized medicinal product, this would seem to restrict unduly the protection conferred by a certificate under Article 4 since as explained in paragraph 42 of the Memorandum:

> "42. On the other hand, the protection granted by the certificate is limited by that of the basic patent. In the case of a product patent, the limitation under the patent will not apply since this type of patent protects all possible uses of the product. However, in the case of an application patent, the certificate will only be able to protect the use or uses claimed in the patent, ……. ."

Thus, according to the Memorandum a certificate, which is based on a product patent, should protect possible future uses of the product not covered by the authorization to place the original entity on the market as a medicinal product. There is no intention that it should be limited to the use authorized by the first authorization and yet this would appear to be the consequence of Dr Miles' proposal. Article 4 specifically caters for this situation in that the subject-matter of the protection can extend to:

> "…… any use of the product that has been authorized before expiry of the certificate."

41 Furthermore, the role of the basic patent in Article 4 becomes hazy if the protection is limited to a therapeutic use on the basis of an authorization. For example, when the patented innovation resides, as in the present case, in a new therapeutic application or use, it is clear once again from paragraph 42 of the Memorandum that the basic patent (and not the "relevant marketing authorization") serves to limit the protection to the use or uses of the product.

42 Thus, Dr Miles' proposal to restrict the "product" by reference to the therapeutic application of the corresponding medicinal product does not sit well with at least Articles 4 and 7.

43 Before I reach a final view on the proposal that references in the Regulation to "a medicinal product" should be read as a "relevant medicinal product", I should address Dr Miles' submission to me that in *Draco* both the Hearing Officer and Jacob J acknowledged the relevance of different therapeutic applications. From the passage, which I have already quoted above and concerning evidence handed up to the Hearing Officer at the hearing, Dr Miles concluded that the Hearing Officer had acknowledged the relevance of the therapeutic applications in the different marketing authorizations, otherwise why would he have pointed these out? Dr Miles found further support for his conclusion in the judgment of Jacob J where the 1981 and 1982 authorizations for budesonide were referred to as "PL1" and "PL2" and a 1990 authorization supporting the application for supplementary protection was referred to as "PL3". Dr Miles relied in particular on a statement by Jacob J at page 436, lines 36 and 37:

> "The hearing officer has held that the first authorization was not PL3. He has found it to be PL1."

Dr Miles concluded from this statement that Jacob J had agreed with the Hearing Officer's view about the relevance of the different therapeutic applications. I think Dr Miles was clutching at straws here. I believe the Hearing Officer focused on the marketing authorizations PL1 and PL2, rather than on the even earlier authorization for the topical administration of budesonide, because these marketing authorizations had been the basis of the examiner's original objection. Indeed, it seems that the Hearing Officer was not even aware of the earlier authorization for topical administration before the hearing since this information was contained in the evidence handed up to him at the hearing. I also believe that by his statement Jacob J was simply reflecting the Hearing Officer's finding at page 434, lines 17 to 19 that (my emphasis):

> "Accordingly, I also find that PL272 dated 11 June 1990 **was not the first authorization** to place the product "budesonide" on the market as a medicinal product as required by Article 3(d)."

44 Indeed, later in his decision the Hearing Officer noted that there is no provision in the Regulation for applying for a certificate in the United Kingdom for a product in respect of which the first authorization to place the product on the market in the Community was obtained before 1 January 1985 and he continued at page 434, lines 31 to 33 by stating (my emphasis):

> "……., I do not need to consider whether PL113 **or the authorization referred to in paragraph 18 of Mr Källstrand's affidavit** was in fact the first authorization for the product "budesonide" in the United Kingdom and in the Community."

Thus, although he did not consider the authorization for topical use of budesonide, referred to in Mr Källstrand's evidence, the reason was not because the authorization related to a different therapeutic application. It was simply because the authorization had been granted

before 1 January 1985.

45 Therefore, I find that I cannot accept the applicant's primary case that the purpose of the Regulation and its operative policy should be given effect by interpreting "the medicinal product" as "the relevant medicinal product". This inevitably leads to the conclusion that the authorization for Silkis Ointment is not the first authorization to place calcitriol on the market as a medicinal product as required by Article 3(d).

The alternative case

46 I can now consider the applicant's alternative case that the product should be defined as a combination of calcitriol and an ointment base because calcitriol would not provide an effective treatment for psoriasis in the absence of the ointment base. It is my understanding that the applicant was not proposing that the ointment base should be restricted to the particular ointment base used in Silkis Ointment, when making this alternative case.

47 I have already quoted a passage from Jacob J's judgment in *Draco* in which he stated at page 438, lines 32 to 35 (my emphasis):

> "They [the authorizations] 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 these matters in addition to the active ingredient itself."

This statement seems to foreshadow the point made by the applicant in the present case that the actual performance of calcitriol for the treatment of psoriasis depends in part on the ointment base. However, in my view Jacob J was not suggesting that substances, such as excipients, on which an active ingredient depends for its actual performance or effectiveness, were necessarily active ingredients for the purpose of the Regulation. Nevertheless, as pointed out by Dr Miles, Jacob J also stated in *Draco* at page 439, lines 47 to 52 (again my emphasis):

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

Thus, Jacob J seems to have envisaged the possibility of formulation research, which has been patented, being protected by a supplementary protection certificate.

48 This chimes with the statement in paragraph 29 of the Memorandum, which I have already quoted but will repeat in part for convenience:

> "29. ……..
>
> 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, ……., must be encouraged, without 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."

49 I have already found that the applicant's primary case fails because the authorization to place Silkis Ointment on the market is not the first authorization to place calcitriol on the market as a medicinal product. It was with this possibility in mind I presume the applicant presented its alternative case which relies on a different definition of the product, namely calcitriol in combination with an ointment base. So far as I am aware there is no earlier authorization for such a combination and so it seems that the condition of Article 3(d) would be satisfied if I accepted this definition of the product. However, in my opinion this alternative case does not take sufficient notice of recital 9 which requires that when account is taken of all of the interests at stake, the protection granted by a certificate should be strictly confined to the product which obtained authorization to be placed on the market as a medicinal product. When Jacob J referred to recital 9 in *Draco* at page 439, lines 2 to 4 he stated:

> "So *strictly confined* to the *product which obtained authorization* means: *strictly confined* to the *active ingredient* of that which is presented for treatment."

Moreover, the passage I have quoted above from paragraph 39 of the Memorandum explains that a certificate will only protect the product covered by the authorization and not all of the products protected by the patent. Thus, in my view the reliance on the expression "ointment base" in the applicant's alternative definition of the product is an unacceptable generalisation of that which is presented for treatment. The operative policy of the Regulation demands that the product be defined in terms of the particular ingredients of the authorized medicinal product. Therefore, almost before I start I find that I cannot accept the applicant's definition of the product in its alternative case. Nevertheless, I can continue to consider the principle of the applicant's case on the basis of its current definition of the product. If I find that it would provide the way forward, I could then give the applicant an opportunity to define the product more precisely in terms of the "active ingredients" of Silkis Ointment. Consideration could then be given whether the application meets the conditions laid down in the Regulation on the basis of the new definition of the product.

50 This leaves me to consider whether an ointment base or more particularly the ingredient or ingredients of the ointment base in Silkis Ointment could be regarded as an active ingredient or a combination of active ingredients for the purposes of defining the product in accordance with Article 1(b).

51 I will deal quickly with Dr Miles' submission that I should give the expression "active ingredient" its plain English interpretation. I have already noted that I should interpret the Regulation teleologically and should not rely on the natural meaning of the language used. Thus, it would be a mistake in my view simply to interpret the expression "active ingredient" on the basis of its plain English meaning without taking account of the purpose and operative policy of the Regulation. For this reason I will not consider this particular argument any further.

52 The witness statement of Isabelle Preuilh addresses the role of the ointment base in Silkis Ointment. It is helpful to refer to paragraphs 4 to 7 of this statement (my emphasis):

> "4. Silkis ointment is an anti-psoriasis composition for topical use and, as such, needs to **contain components which, together, provide the desirable effect of delivering active ingredient** on skin lesions.
>
> 5. Plainly**, calcitriol is an active ingredient in Silkis ointment**.
>
> 6. **The ointment base is also a necessary ingredient** of Silkis ointment for the following reasons. Silkis ointment is for topical use and in order to be effective in the treatment of psoriasis it must be in a form which allows for its application to skin and it must be in a form which allows the calcitriol to a) remain stable in the packaging during storage and use, b) easily and homogeneously applied onto the skin, c) penetrate through the skin.
>
> The ointment form is the most convenient form of calcitriol to achieve the previous mentioned effects and be effective for treating psoriasis by topical route.
>
> For the previous reasons, I do not believe that calcitriol alone, or calcitriol in an aqueous solution, or calcitriol in an oral presentation such as a capsule, is able to do this. In Silkis ointment, calcitriol is able to do this because of the presence of the ointment base which actively participates in producing an effective composition for treating psoriasis. Thus, from a pharmaceutical viewpoint, **the ointment base is a necessary ingredient** of Silkis ointment (without which the calcitriol would not be sufficiently effective in treating psoriasis).
>
> 7. To put it another way, Silkis ointment includes a combination of calcitriol and an ointment base, either of which alone are not effective in the topical treatment of psoriasis."

Thus, Ms Preuilh distinguishes between calcitriol, which she describes as an active ingredient, and the ointment base, which she describes as necessary. There appears to be a slight contradiction in Ms Preuilh's statement whether calcitriol would be effective without the ointment base but I accept that calcitriol would not be sufficiently effective for the treatment of psoriasis when used alone. However, I can find nothing in Ms Preuilh's statement to support the applicant's view that the ointment base is an active ingredient of Silkis Ointment. From Ms Preuilh's perspective it appears that the ointment base merely serves to allow calcitriol to be applied to the skin so that it can penetrate the skin. Thus, from this evidence the ointment base appears to be an excipient and not an active ingredient.

53 Dr Miles also found support for the applicant's alternative case in section 5 of the Summary of Product Characteristics which forms part of the UK marketing authorization for Silkis Ointment. This section of the Summary of Product Characteristics gives information on the pharmacological properties of calcitriol, in particular its pharmacodynamic properties, its pharmacokinetic properties and its preclinical safety data. I have reviewed this information and although there is specific information about the pharmacological properties of calcitriol,

there is nothing to indicate that the other constituents of Silkis Ointment are active. In particular, there is no suggestion that any of the named excipients enhance the pharmacological properties of calcitriol. Thus, as with Ms Preuilh's evidence, I am not persuaded by this information that the ointment base is an active ingredient when used in combination with calcitriol.

54 Indeed I am not persuaded at all by Dr Miles' argument that the ointment base is an active ingredient because without it calcitriol would not be effective in the treatment of psoriasis. In my view the ointment base is no more than an excipient and as observed by Jacob J in *Draco* it is merely something that the actual performance of calcitriol, as the pharmacologically active ingredient, depends on. Moreover, I do not accept Dr Miles' submission that the product is an altered form of calcitriol. It is apparent from the UK marketing authorization that calcitriol is dissolved in the ointment base but in my view this does not alter the form of calcitriol itself.

55 However, at the hearing Dr Miles made the general point that the product for the purpose of the Regulation should be determined by reference to the claims of the relevant patent and should not be restricted necessarily to what the marketing authorization identifies as an active ingredient or ingredients. If Dr Miles is correct on this point, I do not believe that I should be unduly influenced by the distinction drawn between what is active and what is necessary in Ms Preuilh's evidence and the UK marketing authorization. I must recognise that Ms Preuilh's witness statement and the Summary of Product Characteristics both deal with the function of the ointment base in Silkis Ointment from a pharmacological standpoint. Neither considers the ointment base from the perspective of the basic patent and I would not have expected otherwise.

56 In support of his general point Dr Miles referred me to the judgment of the ECJ in *Farmitalia*. In this case Farmitalia had obtained a marketing authorization for a medicinal product, which included idarubicin hydrochloride as the active ingredient, but sought supplementary protection for "idarubicin and salt thereof including idarubicin hydrochloride". The German Bundespatentgericht rejected Farmitalia's application on the basis that a certificate can be granted only for a product which is stated to be an "active ingredient" in the decision to grant marketing authorization under pharmaceutical legislation. In paragraph 18 of its judgment the ECJ noted (my emphasis):

> "18. ……., all the interested parties who have submitted observations have maintained, in particular, that while the certificate could protect only the particular salt form of the active ingredient mentioned as the active constituent in the marketing authorization, whereas the basic patent protects the active ingredient as such as well as salts thereof, including the one which is the subject matter of the marketing authorisation, any competitor would be able, after the basic patent had expired, to apply for and, in some circumstances, obtain marketing authorisation for a different salt of the same active ingredient, formerly protected by the patent. It would therefore be possible for medicinal products which were, in principle, **therapeutically equivalent** to that protected by the certificate to compete with the latter. The result would be to frustrate the purpose of Regulation 1768/92, which is to ensure the holder of the basic patent of exclusivity on the market during a given period extending beyond the period

of validity of the basic patent."

As I have already indicated when outlining Dr Miles' submission to me on the applicant's alternative case, the ECJ accepted this line of argument because the fundamental objective of the Regulation could not be attained if the certificate did not cover the actual medicinal product, as protected by the basic patent and one of the possible forms of which is the subject matter of a marketing authorization. However, I think I should be cautious about the weight I attach to this judgment of the ECJ in the present case. In *Farmitalia* the ECJ was considering alternative active forms, such as salts, of an active ingredient which had been identified in a marketing authorization. In the present case I am not considering alternative forms of calcitriol but a combination of calcitriol with something that is not identified as an active in the authorization for Silkis Ointment. Thus, while *Farmitalia* established that there is some flexibility in the definition of the product, it did not go so far as to establish that excipients, which are identified in an authorization, could be considered as "active ingredients" for the purpose of the Regulation. Indeed this was not an issue that it had to address.

57 Dr Miles also referred to paragraph SPM1.02 of the Office's Manual of Patent Practice which notes that the definition of "product" does not always correspond to the terminology used in UK Product Licences and Marketing Authorizations and he identified three granted supplementary protection certificates, which in his view illustrated the point. The purpose of the Manual is to provide guidance for examiners and applicants alike but it is not binding on me. In any event, I am not surprised by the guidance given in paragraph SPM1.02 in view of the ECJ's judgment in *Farmitalia* and I do not think it helps the applicant's argument to any significant extent. Similarly, my decision should not be influenced by certificates which have been granted in the past. In particular, it would be inappropriate for me to comment on the three granted certificates identified by Dr Miles and I will not do so.

58 So far I have found little or no support for Dr Miles' submission that the active ingredient or ingredients for the purpose of the Regulation should be determined by reference to the claims of the basic patent. However, I am attracted to it as a way of providing supplementary protection for new therapeutic applications of entities where there is no earlier certificate protecting the entity or entities concerned. It is clear from Article 4 that a supplementary protection certificate confers protection on the "product", namely the active ingredient or ingredients, and not on a "medicinal product" which is the substance or combination of substances presented, for example, for the treatment of humans or animals. In line with Jacob J's comment in *Draco* at page 438 lines 30 -35, the distinction between these two terms is critical to the working of the Regulation. Moreover, from Article 3 it can be seen that the product is the subject of the patent which the certificate seeks to extend, and the medicinal product is the subject of a marketing authorization for a substance or combination of substances, including the patent protected active ingredient or ingredients, presented for medicinal use. Thus, the Regulation operates at the interface between patent protection for products and authorizations for medicinal products but most importantly in my view it seeks to extend the patent protection of products which are constituents of authorized medicinal products. Following on from this it seems that the patent must provide the initial focus for determining what the product is and then the marketing authorization used to define the product in terms of the corresponding ingredients of the medicinal product.

59 Therefore, I am inclined to accept Dr Miles' submission that I should not be guided solely by the UK marketing authorization to identify the ingredients of Silkis Ointment which are "active". Rather I believe it is necessary to look initially at the basic patent to identify the product protected by the patent. This approach appears to be consistent with the view of Jacob J in *Draco* when he seemed to see the possibility of formulation research, which warrants its own patent, being protected by a supplementary protection certificate. In many cases this approach would lead to the same conclusion as one where the product is defined solely on the basis of the active(s) identified in the authorization but this will not always be so and the present application is a case in point.

60 Claim 1 of the basic patent does not protect calcitriol alone but it does protect a composition comprising a specific amount of calcitriol and a carrier to manufacture an ointment for use in the topical treatment of psoriasis. I have already found that the combination of calcitriol and an ointment base is not an acceptable definition of the product for the purpose of the Regulation. Thus, a further step is required to define the product and this involves translating what is broadly protected by the basic patent into the corresponding ingredients of Silkis Ointment as listed in the UK marketing authorization.

Summary and Conclusions

61 I have concluded that the purpose and operative policy of the Regulation is such that supplementary protection should be available to products where the innovation associated with the product resides in a new medicinal application for that product, provided all of the conditions for the grant of a supplementary protection certificate are fulfilled. However, the condition specified in Article 3(d) will not be met if an authorization to place a product on the market as medical product is not the first for that product, even if the earlier authorization was for a different medicinal application of the product. It is not possible to distinguish products for the purpose of Article 3(d) on the basis of different therapeutic applications. Thus, I have found that the UK marketing authorization to place calcitriol on the market as Silkis Ointment is not the first in view of earlier UK marketing authorizations for Calcijex and Rocaltrol.

62 Nevertheless, I have recognised that the identification of actives in a marketing authorization to place a product on the market as a medicinal product should not be used to restrict the definition of the product in accordance with Article 1(b). The active ingredients, which define the product, are those protected by the basic patent when strictly confined to the corresponding ingredients of the authorized medicinal product. In the present case I took the view that the product when defined as "a combination of calcitriol and an ointment base" was not strictly confined to the active ingredients of Silkis Ointment, and so was unacceptable.

63 Thus, I must decide that:

(a) the applicant's primary case fails because when the product is defined as calcitriol the application does not meet the condition laid down in Article 3(d); and

(b) the applicant's alternative case, based on a definition of the product as a combination of calcitriol and an ointment base, fails because this definition is not in accordance with

Article 1(b) and does not allow a proper consideration of whether the requirements of Article 3 are met.

64 In view of this decision, the application cannot be granted on the basis of either of the applicant's first and alternative cases. Nevertheless, it seems to me that the application could be amended to re-define the product in the way I have indicated above so that it could proceed. Therefore, I am minded not to reject the application at this stage and to give the applicant an opportunity to amend.

Possible amendment

65 If the applicant wishes to redefine the product, it should request amendment of the application within 28 days of this decision. I shall reject the application if such a request is not made within this period. On the other hand if such a request is made, I will refer the application to the examiner to consider whether it meets the conditions laid down in the Regulation on the basis of the amended definition of the product.

Appeal

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

R J WALKER
Deputy Director acting for the Comptroller