COUNCIL REGULATION (EEC) No 1768/92

0/121/94

IN THE MATTER OF Application No SPC/GB93/033 for a Supplementary Protection Certificate in the name of Aktiebolaget Draco

DECISION

Application No SPC/GB93/033 for a Supplementary Protection Certificate in the name of Aktiebolaget Draco was lodged on 5 May 1993 with the United Kingdom Patent Office as the competent industrial property office pursuant to Article 9(1) of Council Regulation (EEC) No 1768/92 ("the Regulation").

In accordance with rule 3(2) of the Patents (Supplementary Protection Certificate for Medicinal Products) Rules 1992, the application in suit was made on Form SP1. This identified:

- the product for which protection was sought as "Pulmicort Turbuhaler";

- the basic patent protecting the product as GB 1429922 entitled "New steroid acetals processes for their manufacture and preparations containing them";

- the first authorization in accordance with Directive 65/65/EEC or Directive 81/851/EEC to place the product on the market in the United Kingdom as No 0017/0272 ("PL272") dated 11 June 1990;

- the first authorization to place the product on the market in the Community as Danish authorization No 3925 dated 28 June 1989 in respect of the product "Spirocort Turbuhaler".

In an official letter dated 27 May 1993, the examiner reported inter alia that:

> "The identification of the product at item 4 of Form SP1 in terms of the trade mark "Pulmicort Turbuhaler" is not acceptable since (i) this is indicative of the origins of the product rather than its content or composition, and (ii) it appears to relate to a medicinal product as defined in Article 1(a) of the Regulation and not a product which is defined in Article 1(b) as "the active ingredient or combination of active ingredients."

In addition, following submissions from a third party, the examiner reported in a further official letter to the applicants dated 28 July 1993:

> "Having regard to UK Product Licence Nos 0117/0113 and 0017/0128 it appears that ..... Product Licence No 0017/0272 is not the first authorization to place the product on the market in the UK, and that Danish authorization No 3925 is not the first authorization to place the product on the market in the Community. In consequence, the requirements of Articles 3(d) and 19(1) do not appear to be met."

In subsequent correspondence, the applicants' proposed that item 4 of Form SP1 should be amended to read:

> "additive-free budesonide in the form of agglomerated micronised particles"

and contended that accordingly PL272 was the first UK authorization for this product.

However, in the official letter of 19 January 1994, the examiner reported that:

> "The arguments in that letter and the contents of the Product Licences have been carefully considered. However, it is the view of the Office that in each of Licence Nos 0017/0113, 0017/0128 and 0017/0272 the sole active ingredient is budesonide. It therefore appears, having regard to the definitions in Articles 1(a) and 1(b)) that Licences 0017/0113, 0017/0128 and 0017/0272 all constitute valid

authorizations to place the product budesonide on the market in the UK, albeit in the form of different medicinal products."

The examiner's objections to the grant of a certificate not having been resolved in subsequent correspondence, the matter came before me at a hearing on 27 September 1994 at which the applicants were represented by Simon Thorley QC instructed by Mr D L Cannon of J A Kemp and Co. The examiner Mr R C Kennell was also present.

The relevant parts of the Regulation are as follows:

"THE COUNCIL OF THE EUROPEAN COMMUNITIES

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

...

Whereas pharmaceutical research plays a decisive role in the continuing improvement in public health;

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;

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;

Whereas this situation leads to a lack of protection which penalizes pharmaceutical research;

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

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;

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;

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;

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;

Whereas a fair balance should also be struck with regard to the determination of the transitional arrangements; whereas such arrangements should enable the Community pharmaceutical industry to catch up to some extent with its main competitors who, for a number of years, have been covered by laws guaranteeing them more adequate

protection, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the health policies pursued both at national and Community level;

...

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;

...

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

...

ARTICLE 8

Content of the application for a certificate

1. The application for a certificate shall contain:

(a) a request for the grant of a certificate, stating in particular:

(i) the name and address of the applicant;

(ii) if he has appointed a representative, the name and address of the representative;

(iii) the number of the basic patent and the title of the invention;

(iv) the number and date of the first authorization to place the product on the market, as referred to in Article 3(b) and, if this authorization is not the first authorization for placing the product on the market in the Community, the number and date of that authorization;

(b) a copy of the authorization to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Article 4a of Directive 65/65/EEC or Article 5a of Directive 81/851/EEC;

(c) if the authorization referred to in (b) is not the first authorization for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication.

2. Member States may provide that a fee is to be payable upon application for a certificate.

...

ARTICLE 19

Transitional provisions

1. Any product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorization to place it on

the market as a medicinal product in the Community was obtained after 1 January 1985 may be granted a certificate.

In the case of certificates to be granted in Denmark and in Germany, the date of 1 January 1985 shall be replaced by that of 1 January 1988.

In the case of certificates to be granted in Belgium and in Italy, the date of 1 January 1985 shall be replaced by that of 1 January 1982.

2. An application for a certificate as referred to in paragraph 1 shall be submitted within six months of the date on which this Regulation enters into force."

Basic patent 1429922 expired on 8 May 1993, that is three days after the application in suit was filed. However, this fact is not relevant to the matter of the allowability of the application.

This patent relates to physiologically active steroids, processes for their manufacture and to preparations containing them. In particular, claim 1 relates to a steroid having a specified general chemical formula. Claim 18 relates to a pharmaceutical composition containing at least one such steroid and a pharmaceutically acceptable carrier. Examples 39 to 44 describe the following pharmaceutical preparations: ointment, cream, liniment, tincture, suspension for injection and foam aerosol. It is not in dispute that budesonide is a steroid falling within the scope of claim 1 and was thus protected by the basic patent up until its expiry.

As noted above, the application identifies product licence PL272 dated 11 June 1990 as the first authorization to place the product on the market in the UK as a medicinal product. This product licence which was granted to Astra Pharmaceuticals Limited ("Astra") contains the following particulars:

"1. Name of product

Pulmicort Turbohaler 200 [sic].

2. Pharmaceutical Form

Dry powder inhaler device.

.....

4. Active Constituents

Budesonide Micronized 200.0μg/Dose"
(specification 22-133-12/5).

5. Clinical Indications and Route of Administration

Bronchial asthma

Route of administration: Inhalation

8. Other Constituents

None stated

Details of specification 22-133-12/5 are given in a document labelled "Confidential Enc E" to the agents' letter of 19 September 1994. At the hearing, Mr Thorley withdrew a request in the letter that this document should be treated as confidential.

However, the examiner has contended that PL272 is not the first such authorization in the UK in view of Product Licence 0017/0113 ("PL113") which was granted on 30 October 1981, and Product Licence 0017/0128 ("PL 128") which was granted on 13 September 1982.

PL113 also granted to Astra gives inter alia the following particulars of the product to which the licence relates:

"1. Name of Product: Budesonide Aerosol, with or without tube extension.

2. Pharmaceutical form: Aerosol, solid suspended in propellants.

3. Active constituents: 16a, 17a-Butylidenedioxypregna-1, 4-diene-11B, 21-diol-3, 20-dione, 50 μg per puff.

4. Uses: Treatment of bronchial asthma."

This licence as renewed on 30 October 1986 gives further particulars as follows:

"1. Name of product

Pulmicort LS.

2. Pharmaceutical Form

Aerosol.

.....

8. Other Constituents

Sorbitan Trioleate	7.0 mg
Trichlorofluoromethane (Propellant 11)	BPC 358.5 mg
Dichlorotetrafluoroethane (Propellant 114)	BPC 344.5 mg
Dichlorotetrafluoroethane (Propellant 12)	BPC 689.0 mg

.....

11. Pharmacological Particulars

Pulmicort LS inhaler contains the potent non-halogenated corticosteroid budesonide.

Inhaled budesonide possesses a local anti-inflammatory action in the lungs without giving rise to systemic corticosteroid effects."

In the case of PL128 again granted to Astra, the following particulars are given:

"1. Name of Product: Pulmicort.

2. Pharmaceutical foam: Metered dose aerosol.

3. Active constituents: Budesonide 4mg/ml.200μg per puff.

4. Uses: Pulmicort Inhaler contains the potent, non-halogenated corticosteroid budesonide. Clinical studies have shown inhaled budesonide to possess a local anti-inflammatory action in the lungs without giving rise to systemic corticosteroid effects. Investigations with Pulmicort Inhaler have documented good therapeutic results in bronchial asthma, whilst being well tolerated during prolonged treatment.

..."

The licence as renewed on 13 September 1987 also listed the following:

"8. Other Constituents

Sorbitan Trioleate		7.0 mg
Trichlorofluromethane (Propellant 11) [sic]	BP 80	358.0 mg
Dichlorotetrafluoroethane (Propellant 114)	BP 80	344.0 mg
Dichlorodifluoromethane (Propellant 12)	BP 80	68.70 mg"

Evidence in support of the application was handed up to me at the hearing. This evidence is in the form of an affidavit by Göran Källstrand, a vice-president of Astra Draco AB which like the applicants is a member of the Astra group of companies.

In this evidence, Mr Källstrand describes the content and construction of the Pulmicort Turbuhaler and also its use with reference to Exhibits GK1 and GK2. In paragraph 6, he states that the Turbuhaler has proved a major breakthrough in the treatment of inflammatory diseases of the lungs. In paragraphs 7 and 8, he ascribes this success to two features as follows:

> "7. First is the inherent merit of the anti-asthma agent which it contains, namely budesonide. More specifically this agent is a new generation glucocorticosteroid, combining high local activity with reduced side effects.
>
> 8. Second Turbuhaler makes it possible for the patient to inhale a substance in the absence of a disturbing diluting agent, or in other words, additive free ....."

Mr Källstrand supports his contention in paragraph 8 by reference to Exhibits GK3 and GK4. As pointed out by Mr Thorley, GK3 lists the side effects associated with the use of additives, including surfactants and propellants, which as explained in paragraph 9 of the evidence are used to administer budesonide in Astra's earlier Pulmicort and Pulmicort LS inhalers under PL113 and PL128.

Mr Källstrand then goes on to explain in paragraphs 10 to 15 that the Turbuhaler is also more effective than the earlier inhalers (described as pressurised metered dose inhalers and abbreviated to PMDI or MDI) in that it deposits in the patient's lungs a greater percentage of particles below 10 microns, in particular in the range 1-4 microns. He supports this by reference to Exhibit GK5, Figure 1 of which shows the Turbuhaler delivering approximately 55% of the budesonide as 1-4 micron particles compared with about 30% by PMDI, and to Exhibit GK6 and GK7 which describe studies which show that a Turbuhaler deposits twice as many budesonide particles in the lungs than a PMDI and is thus twice as effective.

Finally, Mr Källstrand sets out in some detail the history of the development of budesonide, the development of the Turbuhaler, the development a different formulation (terbutaline) for use in the Turbuhaler and finally the development of a budesonide for such use.

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 UK in 1981 for Pulmicort and another authorization for a second formulation of budesonide (Pulmicort LS) was granted in the UK 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.

Mr Thorley explained that in construing EC law such as the Regulation, I should have regard to the decision of the House of Lords in Regina v Henn and Darby [1981]AC 850, in particular the passage at B on p.905 which reads:

> "The European court in contrast to English courts, applies teleological rather than historical methods to the interpretation of the Treaties and other Community legislation. It seeks to give effect to what it conceives to be the spirit rather than the letter of the Treaties; sometimes, indeed, to an English judge, it may seem to the exclusion of the letter."

He also referred me to the following passages on interpretation of Community legislation at paragraphs 2.266 and 2.268 of Volume 51 of Halsbury's Laws of England (4th edition):

> "2.266 *The text.* The starting point for the interpretation of a provision is the words used, but the clear meaning of a provision and its literal meaning are not synonymous. In some cases, reference to the literal meaning of the text has been sufficient to establish its true construction, but literal analysis of the text is not always appropriate in view of the nature and scheme of the measure in question or the circumstances in which the provision was adopted. The literal meaning of a provision must be discarded if it is inconsistent with the general scheme and the context in which it is to be applied, or where there are discrepancies between the language versions of the text of the provision. In consequence, even if the wording used seems to be clear, it is still necessary to refer to the spirit, general scheme and context of the provision, a fortiori, if the wording is unclear."

"2.268 *The preamble and preparatory material.* Reference may be made to the recitals in the preamble of a measure in order to confirm the interpretation to be given to a provision of Community law.

Documents drawn up in the course of the negotiation and drafting of the ECSC, EEC and Euratom Treaties are not available for use in interpreting provisions of the treaties. The Court of Justice has referred to the opinions of the governments of the member states submitted to the national parliaments during the debates on the treaties in order to discern their common intention or confirm an interpretation of the provision in question, but has effectively ceased to use them as an aid to interpretation, preferring to rely on the content and purposes of the treaties. Preparatory material may be used as an aid in the interpretation of secondary legislation or a convention if it has been published or is otherwise accessible to all the persons affected by the measure."

Mr Thorley also drew my attention to the following passages in the Explanatory Memorandum contained in the Proposal for the Regulation presented by the Commission on 11 April 1990:

"2. .....

This leads to a corresponding loss of a very substantial part of the period of exclusivity granted by the patent. An average period of 12 years between the discovery of a new medical product, at which time the patent application is filed, and its being made available to patients is currently necessary, the effect of which is to reduce the exclusive exploitation period under the patent to only 8 years.

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.

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.

...

23. A Community solution is justified by the fact that any measure affecting health must be considered in an appropriate context. Where appropriate, the Community institutions will hold political discussions on measures that form part of Community health policy.

With regard to the health field, the Commission is aware that objections to this proposal for a Directive will be expressed. Far from ignoring the arguments of those concerned, the Commission has taken account of them in its proposal.

24. The argument concerning health and social security costs is no doubt the most important. Health expenditure is rising continuously throughout the world. At the same time, the shortfalls in the social security systems are a subject of concern to those with political responsibilities. It is therefore legitimate to question the possible effects of this proposal for a Regulation on costs.

The system established by the proposal does not apply to all patented medicinal products placed on the market, but only to those which consist in new medicinal products. A large proportion of the medicinal products sold on the market have only few innovative features, or none at all. These are not covered by the scope of the proposal. Each year, only about 50 new medicinal products are authorized worldwide. It is these that are covered by the proposal for a Directive. As for the transitional arrangement provided for in the proposal, the aim of this is to strike a fair balance between what industry needs and what can reasonably be accepted by society.

Furthermore, the proposal for a Regulation does not affect the Member States' ability to control the prices of medicinal products on their markets.

Lastly, the present proposal, moreover, favours a possible fall in the prices of the medicinal products covered by this proposal in light of the extension of the period for recuperation of investments.

25. Another argument concerns the effect of the proposal on the access of generic products to the market and therefore of competition within the Community between research based Industry and producers of generic products.

It is true that the longer the exclusivity period, the longer the delay before generics enter the market. The aim of the proposal is specifically to ensure that research based industry has a market exclusivity of sufficient length to permit recovery of their investments.

...

28. The concept of a medicinal product as used in everyday speech is more difficult to define in legal terms.

Furthermore, since the objectives of the patent system are different from those of the system of marketing authorization, the definition of a medicinal product in pharmaceutical law cannot be taken to be exactly the same as that in patent law.

What is authorized to be placed on the market is referred to as a "proprietary medicinal product", ie "any ready-prepared medicinal product placed on the market under a special name and in a special pack" (Article 1.1 of Directive 65/65/EEC).

However, it may be the medicinal product that is patented, meaning the active ingredient, the process by which the medicinal product is obtained, or an application or use of the medicinal product.

For the purposes of the certificate, which lies at the interface of the two systems, the terms "product" has been chosen as a common denominator. The exact meaning given to it is defined in Article 1, which is based on the definition of a medicinal product laid down Directive 65/65/EEC. 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.

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."

The basic point at issue in these proceedings is whether the "product", the marketing of which was authorized by PL272, is the same or different from the products the marketing of which was previously authorized by PL113 and 128.

The applicants say it is different and, as was confirmed by Mr Thorley, seek to bring out this difference by defining the product for which protection is sought at item 4 of Form SP1 as:

"additive-free budesonide in the form of agglomerated micronised particles".

On the other hand, the examiner has contended that in each case the product is budesonide per se.

As explained in the agents' letter of 19 September 1994, and acknowledged by Mr Thorley at the hearing, each of the medicinal products authorized for the treatment of bronchial asthma by the three product licences in question uses micronized budesonide of the same specification (22-133-12/5). There is therefore no difference between the three products in this respect.

However, as explained by Mr Thorley, there are two differences between the formulation covered by PL272 on the one hand and those covered by PL113 and PL128 on the other. These differences are conveniently summarised in the above agents' letter as follows:

> "In the case of formulations covered by the earlier Product Licences, the micronized budesonide is suspended in a propellent/surfactant mixture. On the other hand in the case of the present (Pulmicort Turbuhaler) formulation, the micronized budesonide is first subjected to a controlled agglomeration process, as referred to in our letter of 10 December last, before being introduced into the Turbuhaler. In the former case the budesonide component of the licensed formulations is neither additive free nor agglomerated. In the latter case, however, the budesonide component of the licensed formulation is both additive free and agglomerated.
>
> As regards the relevance of the budesonide content of the Pulmicort Turbuhaler being in agglomerated form, it is pointed out that micronized budesonide cannot for practical purposes be used as such unless it is first subjected to the controlled agglomeration process previously referred to."

Mr Thorley submitted that since in the case of PL272 the therapeutic effect was obtained by the use of additive-free agglomerated micronized budesonide, this was the "active ingredient" and hence the "product" as defined in Article 1(b) of the Regulation.

He contended that, in contrast, in the case of PL113 and 128, if budesonide were applied "neat", there would be no therapeutic effect: the therapeutic effect was obtained by applying

budesonide in combination with two other necessary ingredients, namely a surfactant and a propellant. He submitted that, accordingly, in the case of these product licences, the "product" as defined in Article 1(b) was the combination of the three active ingredients necessary to achieve the therapeutic effect, namely budesonide, a propellant and a surfactant.

Having considered the matter, I find that I cannot accept Mr Thorley's submission in this respect. Thus, both of the earlier product licences identify the surfactant sorbitan trioleate and three propellants as "other constituents". In addition, it is apparent from Mr Källstrand's evidence that it is only the gluco-corticosteriod budesonide which is the anti-asthma agent, the sole function of the propellant/surfactant mixture being to act as a carrier for delivering the steroid particles to the patient's lungs. There is no suggestion that either the propellant or the surfactant enhances the pharmacological properties of the budesonide in any way. Indeed, it is clear from the evidence, in particular Exhibit GK3, that these additives are actually detrimental in that they cause adverse side effects such as cough and bronchoconstriction in some patients.

In my view, the fact that the use of a propellant/surfactant mixture is necessary in the PL113 and PL128 inhalers for the delivery of the steroid budesonide does not make them "active ingredients" for the purpose of Article 1(b). I therefore find that the only "active ingredient" in these inhalers is the budesonide.

Mr Thorley also submitted that the agglomerated form of budesonide used in the Pulmicort Turbuhaler of PL272 is a different active ingredient from the non-agglomerated form used in the earlier inhalers of PL113 and 128.

In support of this submission, he referred me to Mr Källstrand's evidence that the research into changing the formulation of the inhaler contents took nine years and cost the equivalent of £5 million which, he contended, demonstrated that this research resulted in a new active substance and not the mere development of an old one.

Having considered the matter, I also find that I am unable to accept this submission. As noted above, the three inhalers in question all use micronised budesonide of the same

specification (22-133-12/5). In addition, as explained in paragraphs 10 and 11 of Mr Källstrand's affidavit, the purpose of the agglomeration is simply to render the budesonide particles flowable, the agglomerates being broken up in the turbulent airstream in the inhalation device upon inhalation to particles having essentially the same size as the particles obtained from a pressurised inhaler. It is clear from the evidence, in particular from Exhibits GK5 and 6, that the Turbuhaler of PL272 provides a more efficient delivery to the lungs of particles of the most desirable particle size than the earlier pressurised inhalers. However, these exhibits simply identify the active ingredient as "budesonide" and there is no suggestion that the budesonide used in the Turbuhaler is a different active ingredient from that used in the pressurised inhalers.

In my view, notwithstanding the time and money spent in the research and development of the Pulmicort Turbuhaler, the mere difference in physical form between the micronised budesonise particles used in the earlier pressurised inhalers and the agglomerated micronised budesonide particles used in the Turbuhaler is not sufficient to enable me to regard the budesonide used in the Turbuhaler as being a different active ingredient from that used in the earlier inhalers of PL113 and 128. I therefore find that the "active ingredient" — and hence the "product" as defined in Article 1(b) — is budesonide in each case, this active ingredient being used in a slightly different physical form in the Turbuhaler.

In coming to the above views, I also had regard to the need to give a teleological construction to Community legislation such as the Regulation. Mr Thorley submitted that a "liberal" interpretation of the term "active ingredient", allowing the applicants' proposed identification of the product as "additive-free budesonide in the form of agglomerated micronised particles", was necessary to give effect to the spirit of the Regulation having regard to the recitals and Explanatory Memorandum which, he submitted, was to ensure that the product of research which is the "equivalent" of introducing a new substance is properly rewarded by the grant of a certificate. He contended that the examiner's "narrower" interpretation would undermine the spirit of the Regulation.

However, such a "narrower" interpretation appears to be required by the last sub-paragraph of paragraph 28 of the Memorandum recited above which states:

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

In my view, this reinforces my finding that the active ingredient used in each of the inhalers in question is the corticosteroid "budesonide", in line with the fact that the basic patent is directed to steriods per se, including budesonide.

In addition, although it is apparent from both the recitals and the Memorandum that the purpose of the Regulation is to provide a further period of protection for products, following the expiry of the basic patent, to compensate for the period between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market, it is also apparent from the actual provisions of the Regulation that this additional protection by way of a certificate is not available in all cases.

Thus, first, in accordance with Article 3(d) the Regulation, a certificate can only be granted in respect of the first authorization to place the product as defined in Article 1(b) on the market as a medicinal product as defined in Article 1(a).

Second, as is apparent from Article 19(1), no certificate can be granted in the UK for a product for which the first authorization to place it on the market as a medicinal product in the Community was obtained before 1 January 1985.

It therefore follows from these Articles that if a first authorisation to place a product on the market in the Community as a medicinal product was granted before 1 January 1985, it is not possible to obtain a certificate based on a later authorisation for a medicinal product comprising that product granted on or after 1 January 1985. It is thus irrelevant how much better the later medicinal product is or how much time and money was spent developing it.

This is of particular relevence in the present case in which the basic patent is directed to a particular class of steroids, the first authorization to place the steroid budesonide protected

by this patent on the market in the Community was at the latest on 30 October 1981 (under PL113), and the applicants are seeking a certificate based on a later authorisation for a medicinal product comprising budesonide, viz PL272.

In my view, notwithstanding the general statements on the purpose of the Regulation in the recitals and Explanatory Memorandum, there is no justification for interpreting the Regulation in the light of the recitals or the Explanatory Memorandum in the way proposed by Mr Thorley since, in my opinion, this would negate the clear effect of the above Articles. In addition, I am unable to find anything in either the recitals or Memorandum to support Mr Thorley's submission that it is an objective of the Regulation to provide protection for a product which is the "equivalent" of a new substance.

I therefore find no justification in the recitals to the Regulation or the Explanatory Memorandum to support an interpretation of the term "product" in accordance with Article 1(b) in such a way as to include the formulation proposed by the applicants.

At the hearing, I was handed up an unsworn copy of an affidavit by Jobst Wibbelmann, a patentanwalt of Munich, Germany, the sworn affidavit being subsequently filed on 30 September 1994. In this affidavit, Mr Wibbelmann refers to a decision of the German Patent Office to grant a certificate in respect of an application by Sandoz. The Exhibits JB1 to JB4 accompanying the affidavit are all in the German language and are not accompanied by a verified translation as required by rule 113 of the Patents Rules 1990. I understand from Mr Thorley's submission that the product which is the subject of the application in question relates to a combination of cyclosporin A and various additives ("Hilfestoffe"). However, I do not find this evidence of any assistance at all in deciding the matter before me.

Mr Thorley also submitted that if I were in doubt as to the question of the interpretation of the Regulation as it related to the matter before me, I should refer the question to the European Court of Justice (ECJ) in accordance with Article 177 of the EC Treaty. However, there is no reasonable doubt in my mind as to the interpretation of the Regulation as it relates

to the matter before me. I therefore decide not to refer the question of the interpretation of the Regulation to the ECJ.

In summary, I find that the "product" as defined by Article 1(b) of the Regulation for which an authorization to place it on the market as a medicinal product in accordance with Article 2 of the Regulation was the corticosteroid "budesonide" and not:

"additive-free budesonide in the form of agglomerated micronized particles".

I also find that Produce Licences PL113 and 128 dated 30 October 1981 and 13 September 1982 respectively were also authorizations to place the product "budesonide" on the market as a medicinal product in the UK.

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).

I accordingly also find that Danish marketing authorization No 3925 granted on 28 June 1989 in respect of the Spirocort Turbuhaler was not the first authorization to place the product "budesonide" on the market in the Community.

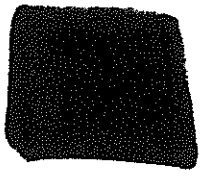
As there is no provision in the Regulation for applying for a certificate in the UK for a product in respect of which the first authorization to place the product on the market in the Community was obtained before 1 January 1985, it is not open to the applicants to amend their application so as to relate to "budesonide" with the first authorization being PL113 dated 30 October 1981.

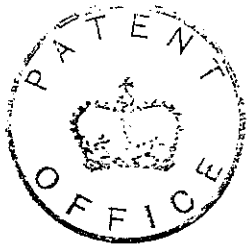
In view of this, I do not need to consider whether PL113 or the authorization referred to in paragraph 18 of Mr Källstrand's affidavit was in fact the first authorization for the product "budesonide" in the UK and in the Community.

Accordingly, I hereby reject the application in suit for the grant of a supplementary certificate on the grounds that it is in respect of the product "budesonide" and the first authorization to place this product on the market in the UK in accordance with Article 3(d) was not Product Licence 0017/0272 granted 11 June 1990 as stated at item 6a of Form SP1.

Regulation 5 of the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992 extends the existing provisions of the Patents Acts 1977 and 1949 to certificates. Accordingly, in accordance with Order 104, rule 19(2)(b) of the Rules of the Supreme Court, any appeal against this decision must be lodged within six weeks of the date of the decision.

Dated this 21 day of OCTOBER 1994





L LEWIS
Principal Examiner, acting for the Comptroller

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