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Datasheet for the decision of 21 February 2008

Case Number: T 0501/05 - 3.3.02

Application Number: 95101762.3

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IPC: A61K 9/72

Language of the proceedings: EN

Title of invention:
Non-chloroflurocarbon aerosol formulations

Patentee:
Schering Corporation

Opponent:
Chiesi Farmaceutici S.p.A.

Headword:
Aerosol formulations/SCHERING

Relevant legal provisions:
EPC Art. 100(c), 56

Keyword:
"Inventive step (no), obvious combination of prior art teachings"

Decisions cited:
G 0005/83

Catchword:
-

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Case Number: T 0501/05 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 21 February 2008

Appellant: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 18 February 2005 concerning maintenance of European patent No. 0653205 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
P. Mühlens

Summary of Facts and Submissions

I. European patent No. 0 653 205, which was filed as application number 95 101 762.3, as a divisional application of the parent application 92 913 922.8 based on international application WO 92/22287, was granted on the basis of fourteen claims.

Independent claims 1, 11 and 14 as granted read as follows:

"1. An inhalation aerosol formulation comprising:

A. An effective amount of mometasone furoate;
B. 1,1,1,2-tetrafluoroethane;
C. Optionally, one or more components selected from one or more of the following:

surfactants;
excipients;
preservatives;
buffers;
antioxidants;
sweeteners; and taste masking agents."

"11. Use of mometasone furoate in association with 1,1,1,2-tetrafluoroethane for the preparation of an inhalation aerosol pharmaceutical composition for oral and/or nasal administration to a patient suffering from asthma."

"14. Use of mometasone furoate in the manufacture of an inhalation aerosol pharmaceutical composition, said composition comprising as propellant 1,1,1,2-

tetrafluoroethane, for the treatment by oral and/or nasal administration of asthma."

II. The following documents were cited *inter alia* during the proceedings:

(1) Scrip, 1991, April 3rd/5th, 12-13
(2) EP-A-0 372 777
(3) H J Lee et al., Drugs of Today, 1989, 25(9), 577-588
(4) EP-A-0 057 401
(5) H Kübler, Aerosol Report, 1991, 30(1), 8-11
(6) WO 91/04011
(14) Expert Declaration of Dr. Joel Sequeira, filed by respondent with letter of 12 January 2006

III. Opposition was filed and revocation of the patent in its entirety was requested pursuant to Articles 100(c), 100(b) and 100(a) EPC (lack of novelty and inventive step).

IV. The appeal lies from the interlocutory decision of the opposition division to maintain the patent in suit in amended form based on the first auxiliary request filed during the oral proceedings before the opposition division.

The first auxiliary request differed *inter alia* from the claim set as granted in that granted claims 2 to 4 and 10 had been deleted. In addition, some of the remaining claims were renumbered and dependencies amended. The claims 1, 11 and 14 as granted, which are reproduced above under point I above, were numbered as claims 1, 7 and 10, respectively.

V. The opposition division considered that the subject-matter of the patent as granted (main request) extended beyond the content of the parent application as originally filed (Article 100(c) EPC).

Concerning the first auxiliary request, the opposition division considered the requirements of Articles 123(2) and 123(3) EPC to be met.

Regarding the objection under Article 100(b) EPC, the opposition division was of the opinion that the opponent's arguments were not convincing since it was clear from the contested patent that the therapeutic activity was attributable to the aerosol itself, and not to the 1,1,1,2-tetrafluoroethane (HFC 134a) propellant alone.

The opposition division considered that the subject-matter of the claims of the first auxiliary request met the requirements of novelty since none of the cited prior art documents disclosed mometasone furoate in association with the 134a propellant.

With respect to the issue of inventive step, the opposition division saw no reason to doubt, in the absence of any proof of the contrary, that the non-chlorofluorocarbon (CFC) inhalation aerosol compositions as claimed were stable and compatible with commonly used valve assemblies of metered dose inhalers.

The opposition division identified document (2) as closest prior art, which disclosed CFC-free medicinal aerosol formulations *inter alia* for inhalation therapy,

comprising a medicament, 134a propellant, and a surface active agent, wherein the medicament may be a steroid such as beclomethasone dipropionate.

The opposition division considered that the selection of mometasone furoate as a steroid drug in a non-CFC aerosol composition suitable for inhalation was not rendered obvious by the cited prior art.

VI. The appellant (opponent) lodged an appeal against said decision and filed grounds of appeal.

VII. With its letter of response of 9 January 2006, the respondent (patentee) indicated that its main request was the request found acceptable by the opposition division (see point IV above), and additionally filed auxiliary requests I-IV.

In response to the communication accompanying the summons to oral proceedings, the respondent further filed with the letter of 21 January 2008 a replacement auxiliary request I, amended to incorporate a minor correction, and additional auxiliary requests V and VI.

Auxiliary request I only differed from the main request in the dependency on claim 1 of dependent claim 6.

Auxiliary request II differed from auxiliary request I in the incorporation at the end of claim 1 of the following feature:

"wherein the formulation contains the following:

Component	Weight Percent
Mometasone furoate	0.01-1
1,1,1,2-Tetrafluoroethane	25-99.99
Excipient	0-75
Surfactant	0-3

"

As a result, dependent claim 2 of auxiliary request I was redundant and was deleted, and subsequent claims and dependencies were renumbered accordingly.

Auxiliary request III was restricted only to use claims, two of which were independent, namely, claims 1 and 4, which were identical to claims 11 and 14 as granted (cf. point I above).

Auxiliary request IV merely differed from auxiliary request III in that the mode of administration was limited to "oral" (i.e. "and/or nasal" was deleted from claims 1 and 4).

Auxiliary request V was based on auxiliary request I wherein all use claims were deleted.

Auxiliary request VI consisted of a single claim corresponding to composition claim 1 of auxiliary request II with the additional feature at the end of the claim "and wherein the mometasone furoate is a powder having a mean particle size of 1 to 5 microns".

VIII. Oral proceedings were held before the board on 21 February 2008.

IX. The appellant's arguments can be summarised as follows:

The appellant did not object to the admissibility of the sets of claims filed with letter of 21 January 2008.

Regarding the issue pursuant to Article 100(c) EPC, the appellant reiterated its arguments raised in the statement of grounds of appeal that the subject-matter of claim 6 of the main request extended beyond the content of the parent application as originally filed. The appellant argued that the subject-matter of claim 6 related to "a formulation **according to any preceding claim** for the treatment of asthma" (emphasis added) and thus also related to the particular inhalation aerosol formulations according to claims 2, 4 and 5 for the treatment of asthma, whereas the parent application as filed only disclosed the treatment of asthma in combination with a more generally defined aerosol formulation (see page 6 and claim 14).

In addition, the appellant raised an objection that the subject-matter of claim 3 of the main request also extended beyond the content of the parent application as filed due to the use of the word "comprising". The appellant submitted that this was a more general disclosure than could be derived from the parent application as originally filed. In particular, claim 12 of the parent application as filed, through its dependency on claims 9 and 1, related to aerosol formulations **consisting essentially of** the defined components. In the appellant's view, this objection applied mutatis mutandis to the corresponding composition claims in auxiliary requests I, II, V and VI.

Concerning the requirements of Article 54(1),(2) EPC, the appellant contested the novelty of the subject-matter of the use claims of the main request and auxiliary requests I to IV. The appellant argued that the claimed therapeutic application of the claimed active pharmaceutical ingredient, i.e. the use of mometasone furoate in the treatment of asthma, had already been disclosed in document (1) and that therefore the novelty of said claims had to be denied, in accordance with the principles of the Enlarged Board of Appeal decision G 5/83 (OJ EPO, 1985, 64).

Turning to the issue of inventive step, the appellant submitted that document (4) represented the closest prior art, since this document disclosed an aerosol formulation comprising the same active ingredient as the patent in suit, namely, mometasone furoate (cf. page 52, lines 10 to 16 together with page 51, lines 3 to 4). Furthermore, in the appellant's view, the aerosol formulation disclosed in document (4) was suitable for inhalation.

The appellant was of the opinion that, since the use of mometasone furoate in the treatment of asthma was already known from document (1), the problem to be solved should be defined as lying in the provision of a further mometasone furoate formulation having no or less adverse effects on the earth's atmosphere.

The appellant submitted that the skilled person would have been prompted by document (5) to replace the CFC propellant dichlorodifluoromethane (CFC 12) (which is one of the propellants used in the example on page 52

of document (4)) with HFC 134a, which was known to have less ozone-depleting effects, in order to arrive at the subject-matter claimed. The appellant emphasised that no prejudice against this replacement could be found in the prior art. In particular, the appellant denied that there was any basis for the conclusion that stability problems were encountered in the formulations of document (2).

The appellant considered that the above analysis applied mutatis mutandis to all the requests on file. Moreover, the appellant submitted that the additional features present in claim 1 of auxiliary request VI related to an arbitrary and broadly defined selection of ranges of concentration and particle size that were within the range suggested or disclosed in the prior art.

X. The respondent's arguments can be summarised as follows:

The respondent maintained that claim 6 of the main request was fully supported by the content of the parent application as filed, since it was clear from the broad general statement on page 6 relating to the treatment of asthma that this was the intended use for all embodiments disclosed in this document. There could therefore be no question of an offence against Article 100(c) EPC.

Concerning the appellant's objection with respect to claim 3 of the main request, the respondent requested that this should not be admitted into the proceedings since it had not been raised previously in the appeal or first-instance proceedings.

In addition, the respondent submitted that, according to the Rules of Procedure of the Boards of Appeal (RPBA), the statement grounds of appeal should contain the appellant's complete case. Since the appellant had no longer contested novelty with respect to document (1) in its statement grounds of appeal or in the subsequent written phase of the appeal proceedings, the respondent argued that the board should, as a matter of discretion, not admit the reintroduction of this objection at oral proceedings.

Furthermore, the respondent denied that document (1) disclosed mometasone furoate for the treatment of asthma by means of inhalation.

In any case, the respondent also submitted that the subject-matter of the use claims of the main request and auxiliary requests I to IV was clearly novel, since document (1) did not disclose several of the features characterizing the composition defined in said use claims, namely, the fact that it was an inhalation aerosol composition and comprised the propellant HFC 134a.

In the context of the discussions on the issue of novelty, the respondent stated that, although they were differently worded, no substantive difference was to be seen between the two independent use claims contained in each of these requests.

With respect to the issue of inventive step, the appellant considered that document (1) was an inappropriate choice as closest prior art owing to the

lack of detail of the disclosure therein with respect to the features of the inhaled formulation of mometasone furoate, which was a consequence of the fact that document (1) was not a scientific publication, but a publication for investors based on Schering-Plough's annual report for 1990.

Moreover, the respondent considered it to be highly questionable whether the skilled person working in the development of pharmaceutical formulations would even consider such a publication as relevant prior art.

Furthermore, the respondent disagreed with the appellant's choice of closest prior art, since document (4) related to corticosteroid derivatives and compositions thereof for topical or local treatment of anti-inflammatory conditions, and therefore did not aim at the same objective as the claimed invention. In addition, the respondent argued that the specific topical aerosol composition disclosed on page 52 of this document would not be considered by the skilled person to be suitable for inhalation since mineral oil was known to clog up the lungs when inhaled and the concentration of active ingredient would not be effective for inhalation applications.

The respondent considered document (2) to be a more realistic starting point for assessing inventive step since it was concerned with inhalation aerosol formulations in which HFC 134a was used as a propellant. Moreover, document (2) dealt with medical aerosol formulations for inhalation therapy and exemplified a specific formulation containing the corticosteroid drug beclomethasone dipropionate.

The respondent submitted that it was evident from document (2) that stability problems were observed with the formulations disclosed therein, as confirmed in particular by examples 7 to 12 disclosing formulations containing beclomethasone dipropionate, which were reported to be turbid, to be initially turbid and then to form a solution, or to directly form a solution.

The respondent defined the problem to be solved as lying in the provision of improved formulations for the treatment of asthma.

The respondent referred to the examples in the patent in suit and the data reported in expert declaration (14) as demonstrating that this problem had been solved by the inhalation aerosol formulation comprising an effective amount of mometasone furoate and HFC 134a propellant.

The respondent maintained that this solution was not rendered obvious by the prior art.

According to the respondent, the skilled person would conclude from document (2) itself that a stable aerosol formulation could not be obtained by simply mixing HFC 134a with a given active pharmaceutical ingredient, since document (2) taught that a compound having a higher polarity than HFC 134a should be added, in order to dissolve increased amounts of a surfactant. In contrast, according to the patent in suit, these additional measures had been found not to be necessary in order to obtain stable aerosol formulations comprising mometasone furoate and HFC 134a propellant.

Furthermore, the respondent was of the opinion that, in view of the stability problems encountered in document (2), the skilled person would have no expectation of success that stable formulations could be obtained on combining the propellant HFC 134a with the drug mometasone furoate. The respondent considered that this deterrent teaching was reinforced by the further cited prior art such as document (6), which illustrated the difficulties encountered in the preparation of stable inhalation aerosols comprising HFC 134a as propellant.

Moreover, the respondent argued that a vast number of medicaments were covered by document (2) on page 5, lines 12 to 35, including beclomethasone, however, mometasone furoate was not mentioned. According to the respondent, no teaching could be found in the prior art that would lead the skilled person to substitute beclomethasone dipropionate in the formulations exemplified in document (2) for mometasone furoate as a solution to the above-mentioned problem.

In this respect, the respondent reiterated that the skilled person would not consider document (1) to be a relevant publication since it was addressed to financial analysts. The respondent further argued that, even were the skilled person to have considered document (1), the disclosure therein would not have suggested the suitability of mometasone furoate in the inhalation treatment of asthma, since the relevant sentence merely referred to the fact that an inhaled formulation of mometasone furoate was in phase II, without specifying the exact nature of the disease to

be treated, which, from the context of the paragraph as a whole, could equally well have been an allergic condition such as allergic rhinitis.

Concerning documents (3) and (4), the respondent submitted that, although these documents did disclose mometasone furoate, this was in the context of topical applications rather than the treatment of asthma. The respondent therefore argued that the skilled person would not be motivated to look to the teaching of these documents.

The respondent did not advance any additional arguments with respect to the restrictions undertaken in the auxiliary requests, except to indicate that the mean particle size in claim 1 of auxiliary request VI had been restricted to a range for which greater stability of the resulting formulations was observed.

XI. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patentee) requested that the appeal be dismissed, or that the patent be maintained on the basis of auxiliary request I filed with the letter of 21 January 2008, auxiliary requests II to IV filed with the letter of 9 January 2006, or auxiliary requests V or VI filed with the letter of 21 January 2008.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments (Articles 100(c), 123 and 76(1) EPC)*

2.1 Claim 6 of the main request, which corresponds to claim 9 as granted, relates to "a formulation according to any preceding claim for the treatment of asthma".

In the parent application as originally filed there are two references to the treatment of asthma: Claim 14 relates to a method of treating asthma by means of an aerosol formulation, whereby the mandatory components are 1,1,1,2-tetrafluoroethane and a medicament selected from a specific list including mometasone furoate; in the description, a corresponding disclosure is to be found on page 6, lines 1 to 26.

Indeed, asthma is the only specific medical indication disclosed in connection with the formulations comprising mometasone furoate. Therefore it is directly and unambiguously derivable from the parent application as filed that said use was envisaged not only for the more generally defined aerosol formulations as defined in claim 14, but also for the corresponding preferred aerosol formulations with defined weight percentages of components, as disclosed on page 10, lines 14 to 17 and in claims 9 to 11.

2.2 Claim 3 of the main request, through its dependency on claims 2 and 1, relates to an inhalation aerosol formulation **comprising** two mandatory components A (an effective amount of mometasone furoate) and B (1,1,1,2-tetrafluoroethane), and further optional components, wherein the weight percentages of components A, B and two of the optional components are defined, and wherein

"the mometasone furoate is a powder having a mean particle size of 1 to 5 microns".

This feature, which appeared in claim 5 of the divisional application as filed, is based on claim 12 of the parent application as filed. As pointed out by the appellant, the wording of claim 12 of the parent application in combination with the claims on which it depends (claims 9 and 1), differs from that of claim 3 of the main request in the use of the term **"consisting essentially of"** instead of "comprising".

The question to be decided is therefore whether it is directly and unambiguously derivable that these two terms are synonymous within the context of the document as a whole.

From the juxtaposition in claim 1 of the parent application as filed of the expression "consisting essentially of" with optional components, it can already clearly be inferred that "consisting essentially of" lacks definite boundaries. Confirmation of this can be derived from dependent claim 9, in which the term "containing" is used. In addition, the term "comprising" is used throughout the description of the parent application as filed, and in particular in the passages disclosing subject-matter corresponding to claims 1 and 9 (see page 4, line 13 and page 5, line 31).

In view of the above, the formulations listed in the claims of the parent application as filed did not include an exhaustive list of components, and the expression "consisting essentially of" is thus to be

understood within this context as being a synonym for "comprising" in the amended claims.

2.3 The appellant made no further objections under Articles 123(2) and 123(3) EPC, and the board sees no reason to differ.

Consequently, the amended sets of claims of the main request and auxiliary requests I to VI meet the requirements of Articles 123(2) and 123(3) EPC.

2.4 The respondent requested that the appellant's objection to claim 3 of the main request as extending beyond the content of the parent application should not be admitted into the proceedings.

The respondent submitted that this objection was introduced for the first time during oral proceedings before the board although an analogous situation arose with claim 6 as granted (due to its dependency on claims 5 and 1).

However, the present main request was filed before the opposition division as first auxiliary request. The opposition division decided that said set of claims met the requirements of Articles 123(2) and 123(3) EPC.

Furthermore, the extent of the initial appeal addressed the requirements of Articles 100(c) and 76(1) EPC.

Hence, the examination of the requirements of Articles 123(2) and 123(3) EPC, including those objections pursuant to the ground of opposition under

Article 100(c) EPC, are within the framework of the present appeal.

Thus, the fact that the respondent did not provide an exhaustive list of all objections applying to the dependent claims, such as claim 3 of the main request, is not relevant.

3. *Article 100(b) EPC*

The board sees no reason to depart from the finding of the opposition division in the contested decision acknowledging sufficiency of disclosure. Since this was no longer contested in appeal proceedings, no detailed reasoning in this respect is required.

4. *Novelty (Articles 52(1) and 54 EPC)*

4.1 In each of the independent product claims on file the claimed composition is in the form of an inhalation aerosol formulation, wherein the mandatory components are mometasone furoate and 1,1,1,2-tetrafluoroethane. None of the cited prior documents discloses a formulation comprising this specific active ingredient together with this specific propellant. Consequently, the novelty of the product claims on file can be acknowledged.

This has not been contested by the appellant.

4.2 As regards the use claims on file, the claims' wording requires in each case the simultaneous presence of mometasone furoate and 1,1,1,2-tetrafluoroethane in the

inhalation aerosol pharmaceutical composition. Consequently, the novelty requirements are met.

4.3 The appellant's contention that the composition of the medicament cannot confer novelty on the subject-matter of a "Swiss-type" use claim is completely unfounded.

It is clearly expressed in Enlarged Board of Appeal decision G 5/83 (OJ EPO, 1985, 64), point 20 of "Reasons for the Decision", that:
"Where the medicament itself is novel in the sense of having novel technical features - e.g. a new formulation, dosage or synergistic combination - the ordinary requirements of Article 54(1) to (4) EPC (1973) will be met and there will in principle be no difficulty over the question of novelty, whether the claim be directed to the medicament per se or to the use of the active ingredient to prepare the medicament".

4.4 The respondent requested that the objection of lack of novelty raised at oral proceedings by the appellant against the use claims should not be admitted into the proceedings.

However, this objection was a reaction to the board's communication sent as an annex to the invitation to oral proceedings, in which the parties were informed of the fact that the independent use claims required a separate analysis in respect of novelty vis-à-vis the content of document (1).

Hence, the respondent could not have been surprised by the appellant addressing the use claims separately during the oral proceedings.

5. *Inventive step (Articles 52(1) and 56 EPC)*

5.1 *Main request - Product claim 1*

5.1.1 The subject-matter of claim 1 relates to an inhalation aerosol formulation comprising as mandatory components the corticosteroid mometasone furoate and the propellant HFC 134a.

Document (2) represents the closest prior art.

Document (2) relates to aerosol formulations comprising a medicament (*inter alia* a steroid), HFC 134a, a surface active agent and at least one adjuvant having a higher polarity than HFC 134a (cf. claim 1 and page 2, lines 33 to 38). Document (2) further discloses that the combination of said adjuvants with propellant 134a provides a propellant system which may be used in aerosol formulations suitable for inhalation therapy and has comparable properties to those of propellant systems based on CFC's (cf. claim 2 and page 2, lines 39 to 50).

Document (2) teaches that: "The addition of a compound of higher polarity than Propellant 134a to Propellant 134a provides a mixture in which increased amounts of surfactant may be dissolved compared to their solubility in Propellant 134a alone. The presence of increased amounts of solubilised surfactant allows the preparation of **stable, homogenous suspensions** of drug particles. The presence of large amounts of solubilised surfactant may also assist in obtaining **stable solution**

formulations of certain drugs" (page 3, lines 13 to 17, emphasis added).

Document (2) then goes on to disclose how stable aerosol formulations using propellant 134a may be prepared by the suitable selection of adjuvant (see page 3, lines 5 to 12 and page 4, lines 11 to 44). This is followed by passages disclosing suitable surfactants and medicaments (see page 4, line 45 to page 5, line 40).

Amongst the medicaments listed are steroids. Beclomethasone is specifically mentioned (page 5, lines 15 and 19). Examples 7 to 12 illustrate six formulations comprising the steroid beclomethasone dipropionate and propellant 134a.

Additionally, in the introductory part of the description of document (2), it is further stated that: "Since the metered dose pressurised inhaler was introduced in the mid 1950's, inhalation has become the most widely used route for delivering bronchodilator drugs and steroids to the airways of asthmatic patients".

Hence, the problem to be solved lies in the provision of a further inhalation aerosol formulation.

The solution as defined in claim 1 relates to a formulation wherein the active ingredient is mometasone furoate rather than beclomethasone dipropionate.

On the basis of the examples reported in the patent in suit and in view of the test results tabulated in

declaration (14), the board is satisfied that the problem posed has been plausibly solved.

It remains to be investigated whether the proposed solution is obvious to the skilled person in the light of the prior art.

The skilled person starting from the beclomethasone dipropionate formulations disclosed in document (2) was aware of the fact that mometasone furoate is a steroid that is structurally related to beclomethasone dipropionate. Mometasone furoate was developed as a steroid showing anti-inflammatory activity for topical applications (see document (3), page 580, left-hand column, last paragraph, and Figure 2).

Furthermore, the skilled person was aware of document (1), which is a publication summarising Schering-Plough's annual report for the year 1990. The second page of this article (page 13), left-hand column, contains the following paragraph (emphasis in italics added):

"The report gives the following information about Schering-Plough's research pipeline:
*** Allergy and asthma**: An oral platelet activating factor antagonist is in early clinical trials for asthma and allergic rhinitis. The report comments that the PAF antagonist may be the only dual-action compound under development which blocks the actions of PAF and histamine. *An inhaled formulation of the corticosteroid, mometasone furoate, which is believed to have fewer potential side-effects than beclomethasone dipropionate, is in Phase II*. Phase III trials with a once-daily

combination product including loratadine have just been completed; the product has added decongestant effects, Schering-Plough says."

Thus, the sentence reproduced in italics teaches the skilled person that mometasone furoate is a suitable drug for inhalation, as well as the feasibility of providing formulations for inhalation. In addition, this passage teaches that mometasone furoate may have advantages over beclomethasone dipropionate in this field of application.

Accordingly, the skilled person faced with the problem defined above would have been prompted by document (1) to substitute beclomethasone dipropionate in the inhalation aerosol formulations disclosed in document (2) for mometasone furoate, and would thus arrive at subject-matter according to claim 1 in an obvious manner.

Consequently, the subject-matter of claim 1 of the main request lacks an inventive step in view of the contents of documents (2) and (1).

Under these circumstances, there is no need to consider the remaining claims of the main request.

5.1.2 The respondent's arguments in favour of inventive step do not hold for the following reasons:

Firstly, the respondent's definition of the problem to be solved cannot be accepted.

No evidence has been provided to make it plausible that the present inhalation aerosol formulation is in any way improved with respect to that disclosed in document (2). The only data available for the present formulations is the stability data disclosed in the expert declaration (14) for examples VI and VII according to the patent in suit.

However, the formulations claimed in claim 1 are much broader than the two tested examples in respect to the presence or absence of adjuvants and excipients. Moreover, in the absence of a proper comparison with the known formulations, no conclusion can be drawn as to the relative merits of the formulations as claimed compared to those disclosed in document (2).

Secondly, the board cannot accept that there is a deterrent teaching in the prior art with respect to stability that would prevent the skilled person from trying to incorporate mometasone furoate into formulations containing propellant 134a in accordance with the teaching of document (2).

Indeed, as outlined above under point 5.1.1, one of the principal objectives of document (2) is the preparation of stable aerosol formulations. Document (2) teaches a number of measures to be adopted in order to achieve stable homogeneous suspensions and solution formulations for aerosol inhalation, which can be optimised according to the particular medicament used and the desired physical properties of the formulation (see e.g. page 3, lines 5 to 17).

The skilled person would therefore conclude that the examples in document (2) were intended to illustrate this teaching, and would therefore regard the variations in properties of the exemplified formulations disclosed therein as representing the expected fluctuations dependant on the exact compositions of the formulations in question. Thus, no basis can be found for concluding that there is a general problem of stability with the formulations according to document (2).

Moreover, the skilled person would derive further confirmation that the teaching of document (2) was generally applicable from the fact that the active ingredients employed in the examples of document (2) vary widely in structure.

Similarly, no confirmation of a deterrent teaching can be derived from the remaining prior art. For example, document (6) teaches that "non-perfluorinated surfactants which are insoluble in a propellant may nevertheless be used with such a propellant to form stable dispersions of powdered medicament provided the powdered medicament is pre-coated with the nonperfluorinated surfactant prior to dispersing the powdered medicament in the propellant" (see page 3, lines 1 to 7). Document (6) thus provides a specific solution to a specific problem. It is not apparent how this specific teaching would dissuade the skilled person of applying the teaching of document (2) to formulations comprising mometasone furoate.

Thirdly, it may be true that the additional measures taught by document (2), i.e. the inclusion of adjuvant

and surfactant, are not required in order to obtain stable aerosol formulations of mometasone furoate in HFC 134a. However, formulations containing these additional components are encompassed by claim 1 of the main request. Hence, this argument put forward by the respondent in favour of inventive step must also fail.

Finally, the board cannot accept the argument that the skilled person would disregard document (1) since it was exclusively addressed to financial analysts. On the contrary, the skilled person working in the area of inhalation formulations would naturally consult all available literature dealing with this topic, including literature providing information on the research pipelines of companies working in this field. Such information is clearly essential in order to keep abreast of the latest developments in a particular field.

Although it is a fact that document (1) does not specifically disclose the nature and constitution of the "inhaled formulation" containing mometasone furoate, document (1) does convey the clear teaching that inhalation formulations with mometasone furoate as active ingredient are feasible and stable. Hence, there is no prejudice whatsoever deterring the skilled person from applying this teaching to document (2) when preparing further inhalation aerosol formulations.

5.1.3 Thus, the main request is rejected for lack of inventive step (Article 56 EPC).

5.2 *Auxiliary request I, II, V and VI - Product claims 1*

5.2.1 Auxiliary requests I and V each contain a claim 1 identical to that of the main request.

5.2.2 The subject-matter of claim 1 of auxiliary request II differs from that of claim 1 of the main request in that ranges for the weight percentages of mometasone furoate, 1,1,1,2-tetrafluoroethane, excipient and surfactant are defined as being 0.01-1, 25-99.99, 0-75 and 0-3, respectively.

In the compositions comprising beclomethasone dipropionate exemplified in examples 7 to 12 of document (2), the corresponding values are approximately 0.1 wt% for beclomethasone dipropionate, approximately 75 wt% for 1,1,1,2-tetrafluoroethane, approximately 25 wt% for the exemplified adjuvants n-pentane and ethanol and approximately 0.1 to 0.25 wt% for the surfactant.

It is noted in this context that ethanol is disclosed in the patent in suit as being one of the preferred excipients (see page 4, line 56 to page 5 line 13, and example I).

The ranges claimed in claim 1 of auxiliary request II thus encompass the values exemplified in document (2), and are therefore considered to be obvious measures within the teaching of document (2).

The respondent did not advance any additional arguments in favour of the inventive step of this request.

Hence, the assessment of inventive step presented under point 5.1 above applies mutatis mutandis to claim 1 of auxiliary request II.

5.2.3 Claim 1 of auxiliary request VI contains the additional feature with respect to claim 1 of auxiliary request II that "mometasone furoate is a powder having a mean particle size of 1 to 5 microns".

Document (2) discloses that "the particle size of the powder for inhalation therapy should preferably be in the range 2 to 10 microns". Therefore, the additional feature incorporated into claim 1 of auxiliary request VI does not provide any further distinction over document (2) and must be viewed as being a further obvious measure within the teaching of this document.

Moreover, the respondent did not provide any evidence for its contention that greater stability was observed in the claimed range with respect to the compositions disclosed in document (2).

Therefore, the same considerations as outlined under points 5.1 and 5.2.2 above apply mutatis mutandis.

5.2.4 Consequently, auxiliary requests I, II, V and VI are also rejected for lack of inventive step (Article 56 EPC).

5.3 *Auxiliary request III and IV - Use claim 4*

5.3.1 Auxiliary requests III and IV each contain four claims relating exclusively to use claims drafted in "Swiss-type" form.

Although the respondent stated that no substantive difference was to be seen between use claim 1 and use claim 4 present in each of these requests, these claims are indeed independent claims which require separate analysis.

Claims 4 of auxiliary requests III and IV relate to the use of mometasone furoate (active drug) in the manufacture of an inhalation pharmaceutical composition (medicament) for the treatment asthma (medical indication) by oral and/or nasal administration (administration route), or only oral administration in the case of auxiliary request IV.

Document (1) represents the closest prior art since it discloses the use of an inhaled formulation of mometasone furoate in the treatment of asthma.

The problem to be solved lies in providing a way of putting the teaching of document (1) into practice.

The solution as defined in claims 4 of auxiliary requests III and IV is characterised in that aerosol inhalation compositions are used comprising HFC 134a as propellant.

On the basis of the content of the patent in suit and in particular the examples, the board is satisfied that the problem posed has been plausibly solved.

It remains to be investigated whether the proposed solution is obvious to the skilled person in the light of the prior art.

Document (1) itself teaches that an inhaled formulation of mometasone furoate has been developed as an alternative to beclomethasone dipropionate with potentially fewer side-effects.

In view of this information, the skilled person faced with the above-mentioned problem would, as a first step, look for information on how to provide inhaled formulations of beclomethasone dipropionate in order to apply the teaching by analogy to the mometasone furoate formulations.

In this context, the skilled person is aware of document (2), which, as outlined above under point 5.1.1, specifically exemplifies inhalation aerosol formulations suitable for oral and/or nasal inhalation therapy comprising beclomethasone dipropionate and propellant 134a (see examples 7 to 12).

Accordingly, the skilled person would have applied the teaching of document (2) in order to put into practice the use of mometasone furoate generally disclosed in document (1), and would thus arrive at subject-matter according to claim 4 in an obvious manner.

The feature in claims 4 of auxiliary request III and IV relating to the administration route as being oral and/or nasal, or only oral in the case of auxiliary request IV, is self-evident in view of the fact that the inhalation aerosol formulations disclosed in document (2) are suitable for that purpose. The respondent did not advance any arguments as to how these features might contribute to an inventive step,

i.e. they have not been linked to any particular technical effect over the use disclosed in documents (1) and (2).

Consequently, the subject-matter of claims 4 of auxiliary requests III and IV lack an inventive step in view of the contents of documents (1) and (2).

Under these circumstances, there is no need to consider the remaining claims of these requests.

5.3.2 The respondent did not make any distinction between the product and use claims in its analysis of inventive step. Hence, the considerations above apply mutatis mutandis.

Moreover, the board cannot agree that with the respondent's reading of document (1).

It is true that the sentence in document (1) disclosing an inhaled formulation of the corticosteroid mometasone furoate does not specify its use in the treatment of asthma (cf. paragraph cited from document (1) on page 22 above). However, the skilled person would read said sentence in the context of the corresponding heading "Allergy and asthma". Inhalation is known to be a widely used route for delivering steroids to the airways of asthmatic patients (cf. document (2), page 2, lines 4 to 6; patent in suit, paragraph [0002]). In contrast, for allergies in general, and allergic rhinitis in particular, local application would be preferred where possible owing to potential systemic side effects of corticosteroids (cf. document (3), pages 577 to 578 and page 580, left-hand column, last

paragraph). The skilled person would therefore directly and unambiguously infer from said paragraph in document (1) that the intended use of the inhaled formulation of mometasone furoate was in the treatment of asthma.

Therefore, since document (1) specifically teaches that mometasone furoate potentially has advantages over beclomethasone dipropionate in inhaled formulations for use in the treatment of asthma, it is maintained that it would have been obvious for the skilled to apply the teaching of document (2) to that of document (1) with a reasonable expectation of success.

5.3.3 Hence, auxiliary requests III and IV are also rejected for lack of inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

N. Maslin U. Oswald