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D E C I S I O N
of 13 May 2003

Case Number: T 0843/99 - 3.3.2

Application Number: 92912490.7

Publication Number: 0588897

IPC: A61K 9/72

Language of the proceedings: EN

Title of invention:
Non-chlorofluorocarbon aerosol formulations

Patentee:
SCHERING CORPORATION

Opponent:
LES LABORATOIRES SERVIER
Rhône-Poulenc Rorer Limited

Headword:
Aerosol formulations/SCHERING

Relevant legal provisions:
EPC Art. 56

Keyword:
"Main request and auxiliary request - inventive step - no: obvious combination"

Decisions cited:
-

Catchword:
-

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Case Number: T 0843/99 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 13 May 2003

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 29 June 1999 revoking European patent No. 0 588 897 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
S. Hoffmann

Summary of Facts and Submissions

I. European patent No. 0 588 897 based on application No. 92 912 490.7 was granted on the basis of 7 claims.

Independent claim 1 as granted read as follows:

"1. An aerosol formulation consisting of:
A. an effective amount of a medicament;
B. 1,1,1,2,3,3,3-heptafluoropropane; and
C. optionally, one or more components selected from one or more of the following:
preservatives;
buffers;
antioxidants;
sweeteners; and
taste masking agents."

II. Oppositions were filed against the granted patent by respondent 1 (opponent O1) and respondent 2 (opponent O2). The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step and under Article 100(b) EPC for insufficiency of disclosure.

The following documents were cited *inter alia* during the proceedings before the Opposition Division and the Board of Appeal:

(11) US-A-3 320 125

(15) WO-A-9 111 496

(17) WO-A-9 111 173

(22) EP-A-550 031

(27) US-A-4 472 393.

III. By its decision pronounced on 19 May 1999, the Opposition Division revoked the patent under Article 102(1) EPC.

It held that neither the main request nor auxiliary requests 1 to 3, all filed during the oral proceedings, met the requirements of inventive step.

In its opinion, document (15) represented the closest state of the art since, as agreed by the parties, the priority date of the patent in suit was not valid. The only distinguishing feature over said disclosure was the presence of the drug mometasone furoate in the claimed formulation.

As document (15) taught however that one of the preferred groups of active agents to be used in the formulations described therein were steroids and as mometasone furoate is a well-known member of this group, the Opposition Division considered that the claimed formulations did not involve an inventive step.

As to novelty, the Opposition Division came to the conclusion that the claims were novel and observed that it was no longer contested by the opponents.

The Opposition Division did not examine the clarity objections as they concerned features which were not amended.

Concerning the objection of insufficiency of

disclosure, the Opposition Division considered that this objection was not sufficiently substantiated and that the examples of the description and the comparative tests filed by the patentee showed that the teaching of the patent could be carried out.

Finally, it rejected auxiliary requests 4 and 5 filed at the end of the oral proceedings as late filed.

IV. The appellant (patentee) lodged an appeal against the said decision.

V. Oral proceedings were held before the Board on 13 May 2003.

VI. In the appellant's view, the claimed formulations were inventive because, as apparent from the comparative experiments filed with its grounds of appeal, these spray formulations containing the specific drug mometasone furoate were unexpectedly stable without addition of surfactant and/or excipient, contrary to formulations with other medicaments.

It also filed document (27) with its letter of 14 April 2003 which, in its opinion, represented the closest state of the art against the patent in suit as it also concerned a mometasone furoate-containing spray.

VII. During the oral proceedings, respondent 1 argued that the comparative examples provided by the appellant failed to demonstrate that the formulations according to the patent in suit were stable as they were not compared with the embodiments of the closest state of the art (27).

Moreover, the period of time during which the claimed formulations remained stable was not defined in the experiments and the drugs which were compared contained either unknown or different amounts of drug so that in any case no conclusion could be drawn from these data.

It further submitted that the absence of surfactant in the claimed formulation could not provide for an inventive step as there was no technical prejudice in the art requiring the mandatory presence of a surfactant and/or excipient for spray formulations.

None of the respondents filed any written arguments during the appeal proceedings and respondent 2 did not attend the oral proceedings.

VIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or auxiliary request 2, both filed on 8 November 1999.

Respondent 1 requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

The main request corresponds to the set of claims as granted with the further indication that the medicament in the claimed aerosol formulations of claim 1 is a "medicament **comprising mometasone furoate**".

No objection under Articles 123(2) and (3) and 84 EPC was raised by the respondents with respect to this set of claims and the Board sees no reason to differ.

Moreover, except for inventive step, none of the conclusions reached by the Opposition Division in its decision were contested by the respondents and the Board again sees no reason to differ.

Inventive step

2.1. The subject-matter of the contested patent relates to an aerosol formulation consisting of an effective amount of a medicament comprising mometasone furoate, a chlorofluorocarbons (CFC's) free propellant, ie 1,1,1,2,3,3,3-heptafluoropropane (TG 227), and optionally one or more components selected from a restricted list (page 2, lines 5 to 8, page 3, lines 12 to 21 and lines 23 to 24, claim 1 of the main request).

According to the description of the patent in suit the claimed formulation is stable (page 2, lines 33 and 34; page 3, lines 1 to 3).

The Board considers that document (27), which, as submitted by the appellant, also concerns a stable aerosol formulation for delivering the drug mometasone furoate, represents the closest state of the art (column 8, lines 59 to 65, in combination with example 4 in column 9, lines 56 to 64).

This document discloses in example 4 an aerosol formulation consisting of the drug mometasone furoate, a mixture of dichlorodifluoromethane and trichloromonofluoromethane as propellant and, as

excipient, Neobee M-5® (Caprylic/Capric glyceride) and mineral oil.

As pointed out by the respondent during oral proceedings, there are no comparative experiments on file which demonstrate any effect achieved by the claimed formulation over this closest prior art embodiment. In particular, there is no evidence showing whether the claimed formulation is more stable than this prior art formulation or even equally stable.

2.2 Accordingly, the problem to be solved by the subject-matter of claim 1 of the main request of the patent in suit as against document (27) can only be seen in the provision of a further formulation for delivering mometasone furoate which is sufficiently stable for its therapeutic purpose, which has no or at least less adverse effect on the earth's atmosphere.

2.3 This problem is solved by the subject-matter of claim 1, ie by the use of 1,1,1,2,3,3,3-heptafluoropropane as propellant in the aerosol formulation containing mometasone furoate and, in the light of working example 1 of the patent in suit, the Board is satisfied that the problem has been plausibly solved.

2.4 Thus the question to be answered is whether the proposed solution, ie providing a formulation consisting of a medicament comprising mometasone furoate and TG 227 as propellant, would have been obvious to the skilled person in the light of the prior art.

In that respect, document (15) teaches that TG 227 is a

particularly suitable propellant for replacing the ozone layer destroying chlorofluorocarbons propellant in aerosol formulations for delivering medicaments such as, among others, steroidal drugs (page 1, paragraph 3, page 2, lines 1 to 9; page 3, lines 13 to 19, and page 4, lines 18 to 22).

Accordingly, the Board is satisfied that the skilled person faced with the problem as defined above under 2.3 would be prompted to replace the propellants mixture disclosed in document (27) by the propellant TG 227 without inventive activity, just by following the teaching of document (15).

2.5 The Board does not agree with the main argument submitted by the appellant, that the claimed formulation is inventive because it does not contain surfactant and/or excipient in combination with the propellant contrary to the prior art teaching.

It is indeed true, as pointed out by the appellant during the oral proceedings, that document (17) discloses that mixtures of hydrofluorocarbons and fluorinated surfactants have properties which render them suitable for use as propellant systems for aerosol compositions and that this teaching is further illustrated on page 10 by an aerosol formulation containing the steroidal drug tipredane with TG 227 and a fluorinated surfactant.

It is also true, as highlighted by the appellant in its written submissions, that various prior art documents recommend in general adding surfactants to an aerosol formulation to stabilise the formulation (see for instance document (22), page 1, lines 12 to 16).

However, as correctly mentioned by respondent 1, document (11) discloses in example 1 an aerosol containing the steroidal drug dexamethasone in a formulation without surfactant and/or excipient and document (15) discloses aerosol formulations without and with surfactant (claim 5 in combination with claim 1 and claim 2).

It is moreover noted that the description of document (15) is consistent with these two alternatives since it recites that surfactants are added "in general" which makes it clear that they are not mandatory (page 2, line 18).

Accordingly, the Board concludes that there is no technical prejudice and no really strong teaching preventing the skilled person from trying to use the propellant TG 227 in combination with the drug mometasone furoate without any surfactant and/or excipient.

To the contrary, the Board is convinced that the skilled person, looking for a new propellant for its particular drug, would always first test its chemical and physical properties in the propellant alone without any additive and then only, depending on its observations, decide whether something should be added and what it should be.

The more so, since as a rule, for economic reasons as well as for medical reasons (for instance, in order to avoid the possible side effects of additives), it is always desirable to provide a formulation containing the minimum number of constituents.

Accordingly, the skilled person in the present case would inevitably realise that the stability of mometasone furoate in TG 227 is sufficient so that there is no need to look further for a suitable surfactant and/or excipient.

2.6 In the light of these facts, the Board can only conclude that the subject-matter of claim 1 of the main request does not involve an inventive step as required by Article 56 EPC.

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

3. *Auxiliary request 2*

This request differs from the main request in that the medicament is now restricted to mometasone furoate alone.

The appellant and respondent argued that the submissions presented with respect to inventive step remained valid for this set of claims as well.

As no further argument has been presented as to why the restriction to mometasone as sole medicament in the aerosol formulation should involve an inventive step, the above conclusions hold good for this request as well.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Townend U. Oswald