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**Datasheet for the decision
of 17 November 2009**

Case Number: T 1308/06 - 3.3.02

Application Number: 01952527.8

Publication Number: 1301210

IPC: A61K 47/38

Language of the proceedings: EN

Title of invention:

Compositions containing therapeutically active components
having enhanced solubility

Applicant:

ALLERGAN, INC.

Headword:

Aqueous compositions containing a quinoxaline/ALLERGAN

Relevant legal provisions:

EPC Art. 123(2)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Main request and auxiliary request contravene Article 123(2)
EPC"

Decisions cited:

G 001/03, G 002/03

Catchword:

-



Case Number: T 1308/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 17 November 2009

Appellant: ALLERGAN, INC.
Applicant: 2525 Dupont Drive
Irvine CA 92612 (US)

Representative: HOFFMANN Eitle
Patent- und Rechtsanwälte
Arabellastraße 4
D-81925 München (DE)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 6 February 2006
refusing European patent application
No. 01952527.8 pursuant to
Article 97(1) EPC 1973.

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
T. Karamanli

Summary of Facts and Submissions

- I. European patent application No. 01952527.8, based on the international application published as WO 02/05822, was filed with 52 claims.

Claim 1 as filed read as follows:

"1. A composition comprising:
a therapeutically active component in an amount effective to provide a desired therapeutic benefit to a patient to whom the composition is administered;
a solubility enhancing component, other than a cyclodextrin, in an amount effective to increase the solubility of the therapeutically active component in the composition relative to the solubility of an identical therapeutically active component in a similar composition without the solubility enhancing component;
an oxy-chloro component in an effective amount to at least aid in preserving the composition;
and a liquid carrier component".

- II. The following document cited during the proceedings is relevant for the present decision:

(1) WO 00/12137

- III. The present appeal lies from a decision of the examining division refusing the application (Article 97(1) EPC 1973) on the grounds that the main request and the auxiliary request, both filed with the letter of 17 November 2004, contained added matter (Article 123(2) EPC). Additionally, the examining division expressed the opinion that novelty had not

been established over document (1) (Article 54 EPC) and that the claims did not meet the requirements of Article 84 EPC.

IV. The applicant (appellant) lodged an appeal against said decision. The appellant filed with its grounds of appeal a main request and an auxiliary request.

Claim 1 of the main request read as follows:

1. Aqueous composition comprising a solution of:
 - a quinoxaline component;
 - a solubility enhancing component other than cyclodextrin;
 - an oxy-chloro preservative component; and
 - a liquid carrier component, whereby the following composition is excluded:

| | |
|--|----------------|
| Sodium chloride | 0.62% (w/v) |
| Potassium chloride | 0.14% (w/v) |
| Calcium chloride (dihydrate) | 0.02% (w/v) |
| Magnesium chloride (hexahydrate) | 0.006% (w/v) |
| Sodium carboxymethylcellulose | 0.5% (w/v) |
| Boric acid | 0.2% (w/v) |
| Sodium borate (decahydrate) | 0.14% (w/v) |
| Brimodine tartarate ⁽¹⁾ | 0.2% (w/v) |
| Stabilized chlorine dioxide ⁽²⁾ | 50 ppm (w/v) |
| Sulfobutylether β cyclodextrin | --- |
| Water, USP | Q.S. to volume |
| pH | 7.4 |

Claim 1 of auxiliary request 1 read as follows:

1. Aqueous composition comprising a solution of:
a quinoxaline component;
a solubility enhancing component other than cyclodextrin;
an oxy-chloro preservative component; and
a liquid carrier component,
whereby compositions containing 0,25 (w/v) brimonidine tartrate and carboxymethyl cellulose are excluded.

- V. On 27 March 2009, the board issued a summons to oral proceedings, annexing thereto a detailed communication expressing its preliminary opinion that the main request and the auxiliary request filed with the grounds of appeal did not meet the requirements of Article 123(2) EPC.

- VI. The appellant did not file any comments on the board's communication sent as an annex to the summons.

- VII. To ensure that the electronic file was complete and that no recent letter from the appellant was lacking, the board asked the registrar to phone the appellant before the Chairman opened the oral proceedings on 17 November 2009. The appellant filed by fax, as a response to the telephone conversation with the registrar, a letter indicating that it was filing a copy of a letter dated 11 November 2009 as an annex. The following was stated in the appellant's letter dated 11 November 2009:

"Applicant herewith withdraws the request for oral proceedings".

VIII. Oral proceedings were held on 17 November 2009 in the absence of the appellant.

IX. The appellant's submissions in relation to Article 123(2) EPC, which were filed with its grounds of appeal, may be summarised as follows:

Claim 1 of the main request specifically excluded composition 1 of document (1). Claim 1 of the auxiliary request excluded compositions containing 0.2% (w/v) brimonidine tartrate and carboxymethyl cellulose.

As regards the main request, the amendment related to the introduction of a disclaimer with respect to an accidental overlap. This amendment was allowable in view of Enlarged Board of Appeal decision G 002/03, since there was a situation of accidental overlap in relation to the content of example 1 of document (1) owing to the fact that the composition was disclosed in said prior art document as a comparative example distinct from and unrelated to the core of the teaching of document (1).

As regards the auxiliary request, the appellant submitted that it did "not contain a disclaimer in the sense of G 002/03". The compositions comprising 2% (w/v) brimonidine tartrate and carboxymethyl cellulose, which were excluded from claim 1 of the auxiliary request, were in fact disclosed in example 2 of the present application. Hence, the exclusion found a basis in the application as filed. Accordingly, the auxiliary request complied with Article 123(2) EPC.

The appellant chose not to file any comments on the Article 123(2) EPC objections, raised in the board's communication sent as an annex to the summons to oral proceedings.

X. The following requests are on file:

The appellant (applicant) has requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the claims according to the main request, or, alternatively, on the basis of the claims according to the auxiliary request, both filed with the grounds of appeal.

Reasons for the Decision

1. *Admissibility*

The appeal is admissible.

2. *Procedural matters*

The duly summoned appellant did not attend oral proceedings. The board was in a position to decide at the conclusion of the oral proceedings, since the case was ready for decision (Article 15(5) and (6) RPBA) and the voluntary absence of the appellant was not a reason for delaying a decision (Article 15(3) RPBA).

3. *Main request*

3.1 Claim 1 of the main request is a generic claim in the "product" category which relates to an aqueous

composition comprising a solution of a quinoxaline component, a solubility enhancing component, an oxy-chloro preservative component and a liquid carrier component.

Claim 1 of the main request originates in principle from claims 1 and 6 as originally filed. However, the deletion of the condition that the quinoxaline component is a "therapeutically active component" (see claim 1 as originally filed and the whole description) contravenes the requirements of Article 123(2) EPC.

Additionally, claim 1 of the main request contains two disclaimers the allowability of which has to be investigated. The disclaimer "other than cyclodextrin" was already present in claim 1 as originally filed and finds an additional basis on page 4 of the description as originally filed. Thus, this first disclaimer is allowable.

The second disclaimer in claim 1, which is preceded by the expression "whereby the following composition is excluded", has been introduced in order to exclude the composition in example 1 (composition 1) of document (1). Document (1) was published on 9 March 2000. Thus, it forms part of the state of the art within the meaning of Article 54(2) EPC.

The aqueous formulations which the present application discloses as the most preferred compositions are ophthalmologic formulations (see page 3, lines 18-21) comprising a quinoxaline derivative such as **Brimonidine tartrate** (see page 6, line 30 and page 7 first paragraph), a solubility enhancing component (SEC) such

as **carboxymethylcellulose** and an oxy-chloro preservative such as a chlorite component (page 7, first paragraph). The chlorite component according to the present application is preferably "**stabilized chlorine dioxides** and alkali metal chlorides" (page 5, last paragraph). In fact, all the examples of the present application relate to ophthalmic solutions of brimonidine tartrate.

Example 1 (composition 1) of document (1) discloses a specific aqueous composition comprising (as pharmaceutically active component) "Brimodine tartarate" (in fact Brimonidine tartrate is the correct expression, i.e. tartrate of 5-bromo-6-(2-imidazolin-2-ylamino) quinoxaline, as clarified in footnote (1) to example 1 of document (1)), sodium carboxymethyl-cellulose and stabilized chlorine dioxide.

Moreover, it is disclosed in document (1) that the composition of example 1 of document (1) passed the United States Preservative Efficacy Test (USPET) and hence, at least from that perspective, is suitable as a pharmaceutical composition (page 16 of document (1)).

Therefore, the composition in example 1 of document (1) cannot be considered as an accidental anticipation of the compositions according to the present application. In fact, the composition in example 1 of document (1) is not only novelty-destroying but also very relevant for the assessment of inventive step for the presently claimed compositions.

Although it is right to say that the composition in example 1 of document (1) was prepared for comparison

purposes, since the compositions claimed in document (1) contain a cyclodextrin (instead of carboxymethyl-cellulose), this does not change the fact that document (1) teaches about its suitability (at least in the light of USPET criteria) for the same purpose as the presently claimed compositions. Hence, the disclaimer at the end of claim 1 cannot be considered to be allowable, since it does not fulfil the conditions set out in decisions G 001/03, OJ EPO 2004, 413, and G 002/03, OJ EPO 2004, 448.

Correspondingly, claim 1 of the main request does not meet the requirements of Article 123(2) EPC.

As a consequence, the main request fails.

4. *Auxiliary request*

4.1 Claim 1 of the auxiliary request filed with the grounds of appeal likewise does not meet the requirements of Article 123(2) EPC.

First of all the quinoxaline component is not required in the claim to be a therapeutically active component, and secondly the disclaimer "whereby compositions containing 0.25 (w/v) brimonidine tartrate and carboxymethyl cellulose are excluded" is not allowable.

The disclaimer at the end of the claim amounts to the exclusion of an artificially defined subgroup which is not disclosed in the prior art document (1).

Moreover, this disclaimer creates an artificial specific subgroup of compositions claimed: those

containing brimonidine tartrate and carboxymethyl cellulose with a concentration of brimonidine tartrate other than 0.25% (w/v).

Moreover, the excluded subgroup finds no support in the application as originally filed. Example 2 on page 32 relates to very specific compositions (all the five samples in Table III of example 2 include additional preservatives, namely boric acid and sodium tetraborate, decahydrate). Hence, the subject-matter defining the newly created subgroup relates to an unallowable generalisation of this particular example.

Correspondingly, claim 1 of the auxiliary request does not meet the requirements of Article 123(2) EPC.

As a consequence, the auxiliary request also fails.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

N. Maslin

U. Oswald