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D E C I S I O N
of 26 June 2003

Case Number: T 1265/01 - 3.3.2

Application Number: 97304994.3

Publication Number: 0891771

IPC: A61K 31/195

Language of the proceedings: EN

Title of invention:
Compositions comprising lysine and ascorbate compounds for the treatment and prevention of cardiovascular diseases

Applicant:
Rath, Matthias, Dr. med.

Opponent:
-

Headword:
Compositions comprising lysine/Rath, Matthias, Dr. med.

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
"The condition set in point (e) of claim 1 finds no basis in the originally filed application"

Decisions cited:
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Catchword:
-

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Case Number: T 1265/01 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 26 June 2003

Appellant: Rath, Matthias, Dr. med.
Ambachtstraat 20
NL-7609 KL Almelo (NL)

Representative: Federhen, Ludwig, Dr.
Kleiner Rechtsanwälte
Silberburgstrasse 187
D-70178 Stuttgart (DE)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 10 July 2001 refusing European patent application No. 97 304 994.3 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: M. Ortega Plaza
J. H. P. Willems

Summary of Facts and Submissions

I. European patent application No 97 304 994.3 (published as EP-A-0 891 771) comprised 10 claims as originally filed.

II. The appeal lies from the decision by the examining division to refuse the application under Article 97(1) EPC.

The decision was based on the set of claims filed on 29 May 2001. Claim 1 read as follows:

"1. A Pharmaceutical lysine-based composition comprising of:

(a) one or more lysine compound(s) selected from the group comprising of lysine, lysine hydrochloride, lysine dihydrochloride, lysine orotate, lysine succinate, and lysine glutamate;

(b) one or more ascorbate compound(s) selected from the group consisting of ascorbic acid, pharmaceutically acceptable ascorbate salts and mixtures thereof; and

(c) one or more proline compound(s) selected from the group comprising of proline, proline hydrochloride, proline dihydrochloride, proline orotate, proline succinate, proline glutamate; or another acceptable proline salts,

(d) a pharmaceutically acceptable carrier, said composition in an amount effective to prevent and treat cardiovascular disease,

(e) The amount of daily dosages of the composition and all of each class of compounds to be varied with respect to the range of Lp(a) genetical concentration in the plasma of the patient, the severity of the danger of developing cardiovascular disease and the severity of the already existing cardiovascular disease."

The examining division *inter alia* considered that amended claim 1 contravened the requirements of Article 123(2) EPC. The reason given by the examining division, was that the amendment relating to the introduction of point (e) into claim 1 was not allowable because there was no basis in the description as originally filed for the dosages of the compounds with respect to the Lp(a) genetical concentration in the plasma of the patient or the severity of the danger of developing cardiovascular disease.

The examining division also considered that the basis indicated by the applicant, namely on pages 2, 10 and 13 of the application as originally filed were not sufficient. In particular, the examining division stressed that the basis mentioned was not sufficient to link any precise dosage of any precise component to the Lp(a) genetical plasma concentration or the danger to develop a cardiovascular disease.

III. The appellant (applicant) lodged an appeal against the said decision and filed an amended set of claims with its grounds of appeal. Claim 1 was modified by the introduction of the word "wherein" before the expression "the amount" in point (e).

The appellant indicated that the amendment to the claim

concerning the introduction of point (e) did not contravene the requirements of Article 123(2) EPC because it related to a disclaimer whose purpose was to establish the novelty of the subject-matter claimed over the prior art.

IV. A communication was sent on 28 February 2003 informing the appellant that the condition set by point (e) for the compositions of claim 1 did not relate to a disclaimer but to a proviso or prerequisite to be fulfilled by the compositions claimed and it therefore required a basis in the application as originally filed.

The appellant was also reminded that claim 1 was a "product claim" and not a "use claim", as the appellant appeared to assume in its grounds for appeal.

V. The appellant filed an amended set of claims with its response of 30 April 2003. Claim 1 read as follows:

"1. **Use of** A Pharmaceutical lysine-based composition **for the prevention and treatment of cardiovascular diseases consisting** of:

(a) one or more lysine compound(s) selected from the group comprising of lysine, lysine hydrochloride, lysine dihydrochloride, lysine orotate, lysine succinate, and lysine glutamate;

(b) one or more ascorbate compound(s) selected from the group consisting of ascorbic acid, pharmaceutically acceptable ascorbate salts and mixtures thereof; and

(c) one or more proline compound(s) selected from the

group comprising of proline, proline hydrochloride, proline dihydrochloride, proline orotate, proline succinate, proline glutamate; or another acceptable proline salts,

(d) a pharmaceutically acceptable carrier, said composition in an amount effective to prevent and treat cardiovascular disease,

(e) wherein the amount of daily dosages of the composition and all of each class of compounds to be varied with respect to the range of Lp(a) genetical concentration in the plasma of the patient, the severity of the danger of developing cardiovascular disease and the severity of the already existing cardiovascular disease." (emphasis added).

The appellant stated in its letter that the requirements of Article 123(2) EPC were met with respect to the condition set in point (e) of claim 1 in view of the contents of the description as originally filed. It cited in particular page 2, second paragraph, and page 13, first paragraph.

The appellant further added to these passages of the originally filed description that it is known in medicine and chemistry that all constituents of amino acids vary in the human body essentially because of the individual genetic codes inherited changed during a person's lifetime by mutations due to influence of whatever kind.

VI. The appellant requested that the decision under appeal be set aside.

VII. The appellant did not request oral proceedings before the Board of Appeal.

Reasons for the Decision

1. The appeal is admissible.

2. The amended feature of claim 1 filed with the letter dated 29 May 2001 and considered by the examining division as unallowable within the meaning of Article 123(2) EPC related to the introduction of point (e) as a condition to be fulfilled by the compositions defined in claim 1.

Amended claim 1 filed by the appellant with its letter of 30 April 2003 relates to the use of the compositions as defined in claim 1 filed on 29 May 2001. The only difference between point (e) of the use claim and point (e) examined by the examining division lies in the introduction of the word "wherein".

Therefore, the Board considers that the introduction of the word "wherein" does not affect the validity of the arguments put forward by the examining division.

Moreover, the condition set in point (e) relates to "the amount of daily dosage of the composition" and in so far the change of category of the claim does not change the arguments put forward by the examining division.

Accordingly, the Board shares the reasoning of the examining division with respect to the lack of a basis in the description as originally filed, with respect to

the condition set in point (e) for the amount of daily dosage of the compositions, and as regards the set of use claims.

The basis stated by the appellant for the said amendment during the appeal proceedings (namely pages 2 and 13 of the application as originally filed) was already discussed in the first-instance proceedings and considered insufficient. The Board also agrees with this analysis made by the examining division.

The appellant's comment with respect to the need for general knowledge in the field concerned for assuming that genetically predetermined concentrations may vary during a person's lifetime is no answer to the examining division's argument of lack of support for the condition to be fulfilled by the daily **dosage** (emphasis added by the Board) for the compositions defined in claim 1.

Finally, it has to be noted that the appellant did not dispute the preliminary analysis made in the communication sent by the Board with respect to the fact that the condition set in point (e) relates to a prerequisite to be fulfilled by the compositions defined in the claim and hence the said condition required a basis in the description as originally filed.

In view of the above reasons, the Board concludes that amended claim 1 does not meet the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

1. The appeal is dismissed

The Registrar: The Chairman:

A. Townend U. Oswald