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**Datasheet for the decision
of 24 March 2010**

Case Number: T 1900/07 - 3.3.04

Application Number: 98830156.0

Publication Number: 0951909

IPC: A61K 35/32

Language of the proceedings: EN

Title of invention:

Combination composition comprising a L-carnitine or an alkanoyl-L-carnitine, a glycosaminoglycan and/or constituent thereof

Patentee:

SIGMA-TAU Industrie Farmaceutiche Riunite S.p.A.

Opponent:

Henkel AG & Co. KGaA

Headword:

Combination composition/SIGMA-TAU

Relevant legal provisions:

EPC Art. 54

EPC R. 55(c), 76(2)(c)

Keyword:

"Legal frame work of the opposition"

"Novelty - (yes)"

Decisions cited:

G 0010/91

Catchword:

-



Case Number: T 1900/07 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 24 March 2010

Appellant I:
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
17 September 2007 concerning maintenance of the
European patent No. 0951909 in amended form.

Composition of the Board:

Chairman: C. Rennie-Smith
Members: M. Wieser
G. Alt

Summary of Facts and Submissions

- I. Appeals were lodged by the Patent Proprietor (Appellant I) and by the Opponent (Appellant II) against the interlocutory decision of the Opposition Division according to which the European patent No. 951 909 could be maintained in amended form (Article 102(3) EPC 1973).
- II. The Opposition Division decided that the legal framework of the opposition was limited to the substantive examination of novelty of claim 1 as granted. They decided that subject-matter of claim 1 of the main request (claim 1 as granted) was not novel in the light of the disclosures in document (4) (Article 54(3) EPC) and in document (1) (Article 54(2) EPC). However, they decided that the subject-matter of the claims of the auxiliary request, filed at the oral proceedings before them, met all requirements of the EPC.
- III. Appellant I requested that the decision under appeal be set aside and that the patent be maintained on the basis of claims 1 to 20 and pages 2 to 7 of the description filed as main request during the oral proceedings.

Appellant II requested that the decision under appeal be set aside and the patent be revoked.

Oral proceedings were requested by both parties should the Board not allow their requests.

IV. The Board expressed its preliminary opinion in a communication dated 30 November 2009 which was annexed to the summons to oral proceedings. Oral proceedings were held on 24 March 2010.

V. Claims 1 and 10 of Appellant I's main request read as follows:

"1. A composition consisting of:

(a) L-carnitine or an alkanoyl-L-carnitine wherein the alkanoyl is a straight or branched group having 2-8, preferably 2-6, carbon atoms, or a pharmacologically acceptable salt thereof;

(b) a glucosaminoglycan and/or a constituent of glucosaminoglycan; and

(c) a pharmacologically acceptable excipient.

10. A composition consisting of:

(a) L-carnitine or an alkanoyl-L-carnitine wherein the alkanoyl is a straight or branched group having 2-8, preferably 2-6, carbon atoms, or a pharmacologically acceptable salt thereof;

(b) a glucosaminoglycan and/or a constituent of glucosaminoglycan; and

(c) a pharmacologically acceptable excipient, and

vitamins, co-enzymes, mineral substances and antioxidants."

Dependent claims 2 to 9 refer to preferred embodiments of the composition of claim 1. Claims 11 to 16 refer to a dietary supplement consisting of compounds (a) and (b) and to preferred embodiments thereof. Claims 17 to 20 refer to preferred embodiments of the compositions of claim 1 or 10.

VI. The following documents are referred to in this decision:

- (1) DE-A-4 401 308
- (2) FR-A-2 627 385
- (3) Trendprodukte in der Kosmetik, Kosmetikjahrbuch 1989, Verlag für chemische Industrie, H. Ziolkowsky KG, Augsburg, D; page 237
- (4) WO 98/33 494
- (5) Römpf Chemie Lexikon, 9th Edition, 1995, Georg Thieme Verlag, Stuttgart, D; page 3969
- (6) McGraw-Hill Dictionary of Scientific and Technical Terms, 5th Edition, 1994, McGraw-Hill Inc., New York, USA; page 713
- (7) US-A-5 667 791

VII. The submissions made by Appellant I, as far as they are relevant to the present decision, may be summarised as follows:

The opposition under Article 100(a) EPC on the ground of lack of inventive step (Article 56 EPC) was not substantiated in the notice of opposition. The Opposition Division correctly decided not to admit this ground for opposition. No consent was given to introduce a fresh ground in the appeal procedure.

None of the cited prior art documents disclosed a composition which consisted of, in the sense of "comprised only", the three components indicated in claim 1 or the seven components indicated in claim 10. The term "excipient" was well known and had a clear meaning for a skilled person in the field of pharmaceutical compositions.

VIII. The submissions made by Appellant II, as far as they are relevant to the present decision, may be summarised as follows:

No arguments were submitted concerning the Opposition Division's decision not to admit the ground for opposition under Article 100(a) EPC in connection with Article 56 EPC.

The term "excipient" was not explicitly defined in the patent. Thus, it could be given the broadest possible interpretation. The compositions disclosed in documents (1), (2), (3), (4) and (7) all contained compounds (a) and (b) of the compositions according to claims 1 and 10 as well as several other compounds and were novelty destroying for the subject-matter of claim 1, as all compounds other than (a) and (b) could be considered to fall under the broad and undefined term "excipient".

Should the Board decide that vitamins, co-enzymes, mineral substances and antioxidants were not to be considered as excipients in the present case, document (4) was novelty destroying for the subject-matter of claim 10. All of the thirty-two components of formulations A and B shown in table 4 on pages 50 and 51 of this document were a member of one of the seven groups of components indicated in claim 10.

Reasons for the Decision

Legal framework

1. The Opposition Division decided that, as a result of the content of the notice of opposition, the legal framework of the opposition was limited to the substantive examination of novelty of claim 1 as granted (page 3, second full paragraph of the appealed decision).
2. The legal framework of an opposition case is defined by the extent to which the patent is actually opposed and by the grounds on which it is opposed.
3. Regarding the extent to which the European patent is opposed, the Opponent (now Appellant II) on page 1 of the notice of opposition, dated 13 August 2004, requested to revoke the patent in its entirety.

The grounds for opposition were indicated on page 2, first paragraph, of the notice of opposition, as being Article 100(a) EPC in combination with lack of novelty

(Article 54 EPC) and lack of inventive step (Article 56 EPC). However, on the following pages the Opponent only substantiated the ground for opposition in accordance with Article 100(a) EPC in combination with Article 54 EPC with regard to claim 1 as granted.

The only statement referring to the requirements of Article 56 EPC was on page 5, lines 2 to 4, which read:

"Aus verfahrensökonomischen Gründen soll die Diskussion der erfinderischen Tätigkeit zurückgestellt werden, bis Patentansprüche vorliegen, die zumindest das Kriterium der Neuheit erfüllen."

4. As far as the extent of an opposition is concerned, if an Opponent requested revocation of the patent in its entirety, it is sufficient to substantiate the ground for opposition in respect of at least one claim of the patent for the requirements of Rule 76(2)(c) EPC (Rule 55(c) EPC 1973) to be met. Rule 76(2)(c) EPC does not refer to claims but rather requires that the notice of opposition should contain a statement of the extent to which the patent was opposed (see Case Law of the Boards of Appeal of the EPO, 5th Ed., 2006, VII.C.5.2.1(b)).

5. The ground for opposition under Article 100(a) EPC in combination with Article 56 EPC has not been substantiated within the time limit prescribed in Article 99(1) EPC as required in Rule 76(2)(c) EPC. This ground for opposition, which has also not been introduced into the proceedings by the Opposition Division under Article 114(1) EPC in accordance with the principles set out in the decision of the Enlarged

Board of Appeal G 10/91 (OJ EPO 1993, 420; see point 16 of the reasons), was not part of the opposition procedure (see point (2) of the decision under appeal).

6. Although not arguing against this issue of the Opposition Division's decision, Appellant II, in the appeal procedure (see letter dated 28 January 2008, pages 8 to 11) submits evidence and arguments substantiating an objection of lack of inventive step of the claimed subject-matter. Thus, Article 56 EPC is a "**fresh ground for opposition**" (see G 10/91 supra, point 18 of the reasons) which in appeal proceedings can be considered only with the approval of the Patentee. As can be seen from Patentee's (Appellant I's) written submissions (letter dated 9 June 2008, page 4, first paragraph) it does not approve the introduction of this fresh ground for opposition.
7. Thus, in summary the Board decides with regard to the legal framework of the present opposition/appeal procedure that the patent in suit was opposed in its entirety under Article 100(a) EPC on the ground of lack of novelty (Article 54 EPC) and no more.

Articles 84, 123(2) and (3) EPC

8. Claims 1 to 20 of Appellant I's new main request differ from claims 1 to 20 as granted only in claim 10. This claim has been reformulated as independent claim referring to a composition **consisting of** compounds (a), (b) and (c), vitamins, co-enzymes, mineral substances and antioxidants, while claim 10 as granted was open to comprise additional compounds.

The subject-matter of this claim is clear and supported by the description and meets the requirements of Article 84 EPC. It is based on claim 10 as originally filed (Article 123(2) EPC). By defining that the claimed composition **consists of** the indicated components, the scope of protection has been limited with regard to the claims as granted. The requirements of Article 123(3) EPC are met.

Novelty - Article 54 EPC

9. Claim 1 refers to a composition **consisting of** the three components (a), (b) and (c). The composition of claim 10 **consists of** seven components (namely (a), (b) and (c) plus four additional components). The dietary supplement of claim 11 **consists of** components (a) and (b).

10. While in everyday language the term "**consisting of**" may have a less restrictive meaning, in drafting patent claims legal certainty requires it to be interpreted to mean "comprising only" (see Case Law of the Boards of Appeal, 5th Edition 2006, chapter II.B.5.2 and Guidelines for Examination C III 4.21). Thus, when a claim refers to a composition **consisting of** defined compounds, the presence of additional components is excluded.

11. While components (a) and (b) of the composition according to claim 1 are defined by their chemical designation, component (c), "a pharmacologically acceptable excipient", is defined by its function.

Appellant II argues that the term "excipient" is not defined in the patent. By referring to document (5), a chemical dictionary, it further argues that, in case of topical compositions which are covered by claim 1, a plethora of different chemical substances can generally be used as excipient. Appellant II concludes that prior art documents disclosing compositions comprising compounds (a) and (b) plus additional components, which due to the lack of a proper definition, can be attributed to the group of "excipients", anticipate the novelty of the subject-matter of claim 1. It considers documents (1) to (4) and (7) to fulfil this requirement.

12. The patent contains in paragraph [0035] a definition of "the composition of the present invention" which is identical to the wording of claim 1. In the following paragraphs [0036] to [0043] the weight ratio of components (a) and (b) and their exact chemical nature is disclosed. According to paragraph [0044] vitamins, co-enzymes, mineral substances and antioxidants are further components of the claimed composition. In paragraph [0065] it is said that the suitable excipients "shall be apparent to any average-skilled expert in pharmacy and pharmaceutical technology."

13. A careful reading of these paragraphs, in particular of the expression "further components" in paragraph [0044], can only lead to the result that at least vitamins, co-enzymes, mineral substances and antioxidants do not fall under the definition "excipient" as used in the patent in suit, as otherwise paragraph [0044] of the patent would be unclear and/or superfluous.

Considering the reference to the general knowledge of an average-skilled expert in paragraph [0065], the Board notes that document (6), a dictionary of scientific and technical terms, contains a definition of the word "excipient" used in the field of pharmacy, as being "any inert substance combined with an active drug for preparing an acceptable and convenient dosage form."

14. In the light of the disclosure in the description and the claims and considering the general knowledge of a skilled person as reflected by the content of a technical dictionary, the Board makes the following findings regarding documents (1) to (4) and (7):

Document (1) refers to cosmetic compositions having anti-cellulite activity comprising, among other substances, a cell-metabolism activating complex consisting of dexapanthenol, vitamin E-nicotinate, vitamin A-acetate, L-lysine and L-carnitine (see claim 1 and examples 1 to 8).

Document (2) discloses in example 10 a liposome composition for cosmetic and/or dermatologic use comprising chondroitin sulphate (compound (b)) and betaine. With reference to page 4, line 16 of the description, Appellant II argues that the word "betaine" in example 10 does not define a specific substance but a group of substances which group is known to include also carnitine. Even if the Board could accept this interpretation, it is a generally accepted principle that a generic disclosure (here a group) does not anticipate any specific example falling within that disclosure (see Case Law of the Boards of

Appeal of the EPO, 5th Edition 2006,
Chapter I.C.3.2.6).

Document (3) discloses a product designated "Carnitiline" consisting of carnitine (compound (a)), a mucopolysaccharide (compound (b)) and caffeine. Caffeine, a well known stimulant, is a physiologically active substance and cannot be considered to be an "excipient" (compound (c)).

Document (4) refers to compositions for prevention and treatment of vascular degenerative diseases which according to claim its 1 comprise antioxidants (bioflavanoids). Formulations A and B, disclosed in table 4 on pages 50 and 51, comprise thirty-two different components, among them acetyl-L-carnitine (compound (a)), chondroitin sulphate (compound (b)), vitamins, co-enzymes, mineral substances and antioxidants.

Document (7) relates to compositions for protection from x-ray induced skin damage comprising L-seleno-methionine and glutathione in a suitable carrier as the active substances (see claim 1 and tables in examples 1 to 5).

15. In the light of the findings in points 10 and 12 to 13 above, none of documents (1) to (4) and (7) discloses the subject-matter of claim 1, which is therefore novel and meet s the requirements of Article 54 EPC.
16. With regard to claim 10, relating to a composition which in addition to compounds (a), (b) and (c) consists of vitamins, co-enzymes, mineral substances

and antioxidants, Appellant II argued that document (4) is a novelty destroying document as all ingredients of formulations A and B disclosed therein can be attributed to one of the groups of compounds of claim 10.

17. Table 1 of document (4) is a list of 33 different physiological functions of components comprised in the disclosed compositions. Table 2 lists the various components and indicates their respective functions by indicating their numbers (from 1 to 33) according to table 1 (wrongly referred to as table 3).
18. The following example shows that Appellant II's argument (see point 16 above) is not tenable:

Fenugreek Seed Powder, which is contained in formulations A and B (Table 4 on page 50, line 8) is described on page 32, lines 21 to 28 of the description. It is said to contain number of alkaloids, including trigonelline and coumarine and the steroidal sapogenin, diosgenine. It reduces serum cholesterol levels and because of its hypoglycaemic effect it is used for the treatment of diabetic complications. According to tables 1 and 2 it is comprised in the compositions of document (4) because it stabilises glucose and amylase factors, for example by increasing glucose tolerance in diabetes, and it controls anti-sclerotic factors by reducing LDL and VLDL, by improving the HDL/LDL ratio and by acting as triglyceride inhibitor.

19. Thus, at least Fenugreek Seed Powder cannot be attributed to any of the compounds or group of compounds of the composition of claim 10 with the consequence that, contrary to Appellant II's argument, the compositions disclosed in document (4) do not exclusively consist of the components indicated in claim 10.

Accordingly, the subject-matter of claim 10 is novel and meets the requirements of Article 54 EPC.

20. Appellant II has not raised any novelty objection to the subject-matter of claim 11, relating to a dietary supplement consisting of compounds (a) and (b). The Board also does not see any basis for such objection in the cited prior art documents.

21. Consequently, the subject-matter of claims 1 to 20 of Appellant I's main request is novel and meets the requirements of Article 54 EPC.

22. Pages 2 to 7 of the description, filed by Appellant I at the oral proceedings, have been adapted to the claims of the new main request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of claims 1 to 20 and pages 2 to 7 of the description filed as main request during the oral proceedings.

Registrar:

Chairman:

P. Cremona

C. Rennie-Smith