

**Internal distribution code:**

- (A) [ ] Publication in OJ  
(B) [ ] To Chairmen and Members  
(C) [X] To Chairmen  
(D) [ ] No distribution

**Datasheet for the decision  
of 17 October 2007**

**Case Number:** T 0817/05 - 3.3.09

**Application Number:** 99939612.0

**Publication Number:** 1112005

**IPC:** A23L 1/30

**Language of the proceedings:** EN

**Title of invention:**

Antioxidant composition comprising Acetyl L-Carnitine and  
alpha-Lipoic Acid

**Patentee:**

Sigma-Tau Healthscience S.p.A.

**Opponent:**

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

**Headword:**

-

**Relevant legal provisions:**

-

**Relevant legal provisions (EPC 1973):**

EPC Art. 54(3), 83

**Keyword:**

"Main request, auxiliary requests 1-3: Novelty established by  
disclaimer (no)"

"Auxiliary request 4: Deletion of disclaimer: Reformatio in  
peius (no), Novelty (yes)"

**Decisions cited:**

G 0001/99

**Catchword:**

An amendment to a claim as allowed by the Opposition Division, by which a disclaimer was deleted together with the omission of an embodiment from which the disclaimer intended to exclude a novelty-anticipating disclosure in a document according to Article 54(3) EPC, does not put the Opponent and sole Appellant in a worse situation than if it had not appealed. The principle of the prohibition of "reformatio in peius" is not violated in accordance with G 1/99.



Case Number: T 0817/05 - 3.3.09

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.09  
of 17 October 2007

**Appellant:** THE REGENTS OF THE UNIVERSITY OF CALIFORNIA  
(Opponent) 1111 Franklin Street, 12 Floor  
Oakland, CA 94607-5200 (US)

**Representative:** Campbell, Patrick John Henry  
J.A. Kemp & Co.  
14 South Square  
Gray's Inn  
London WC1R 5JJ (GB)

**Respondent:** Sigma-Tau Healthscience S.p.A.  
(Patent Proprietor) Via Treviso 4  
I-00040 Pomezia (IT)

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

**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office orally  
announced on 15 March 2005 and posted 18 April  
2005 concerning maintenance of European patent  
No. 1112005 in amended form.

**Composition of the Board:**

**Chairman:** P. Kitzmantel  
**Members:** W. Ehrenreich  
M-B. Tardo-Dino

## Summary of Facts and Submissions

- I. Mention of the grant of European patent No. 1 112 005 in respect of European patent application No. 99 939 612.0, filed on 19 August 1999 as International application No. PCT/IT99/00268 in the name of *Sigma-Tau Healthscience S.p.A.*, was announced on 27 November 2002 (Bulletin 2002/48).

The patent, entitled "*Antioxidant composition comprising Acetyl L-Carnitine and alpha-Lipoic Acid*" was granted with thirteen claims, Claim 1 reading as follows:

"1. A combination composition which comprises:

- (a) acetyl L-carnitine or a pharmacologically acceptable salt thereof; and
- (b)  $\alpha$ -lipoic acid

in a synergistically effective weight ratio."

Claims 2 to 7 were, either directly or indirectly, dependent on Claim 1. Claims 8, 10 and 12 were directed to a dietary supplement on the basis of the combination composition according to Claim 6, and Claims 9, 11 and 13 pertained to a medicament on the basis of the combination composition according to Claim 7.

- II. Notice of opposition requesting revocation of the patent in its entirety EPC was filed by

*The Regents of the University of California*

on 27 August 2003.

The opposition was based on the opposition grounds according to Articles 100(a) and (b) EPC. Under Article 100(a) EPC the Opponent stated that the claimed composition was not novel over the disclosure in

D1 WO-A 98/57627,

a document constituting prior art according to Article 54(3) EPC.

In support of its novelty objection the Opponent also cited, after expiry of the opposition period, the following further documents:

- D2 Packer L.: "Antioxidant Properties of Lipoic Acid and Its Therapeutic Effects in Prevention of Diabetes Complications and Cataracts" in *Ann. NY Acad. Sci.* 1994, Nov. 17, 257-264;
- D3 Biewenga G.Ph., Haenen G.R.M.M., Bast A.: "The Pharmacology of the Antioxidant Lipoic Acid" in *Gen. Pharmacol.* 1997, Sep; 29(3), 315-331;
- D4 Biewenga G.Ph., Haenen G.R.M.M., Bast A: "An Overview of Lipoate Chemistry" in *Lipoic Acid in Health and Disease, New York, 1997, 1-32;*
- D5 Stryer L. *Biochemistry, ed. W.H. Freeman and Company, New York, 1998, 381.*

III. With the letter dated 11 February 2005 the Patent Proprietor filed three sets of claims as bases for auxiliary requests 1 to 3.

Claim 1 of the first auxiliary request differed from Claim 1 as granted in that

- the word "pharmacologically" was replaced by "pharmaceutically" and
- the following disclaimer after "synergistically effective weight ratio" was added: "with the exception of a combination of 250 mg pharmaceutical grade dry acetyl-L-carnitine and 250 mg pharmaceutical grade dry lipoic acid for 4x daily administration in 500 mg gelatine capsules".

The document

D6 *Dictionary of Organic Compounds, 5th ed., vol. 4: J-Peu, ed. Chapman and Hall, 1982, 3578*

was submitted with the letter dated 15 February 2005.

IV. With the interlocutory decision orally announced on 15 March 2005 and issued in writing on 18 April 2005 the Opposition Division maintained the patent on the basis of Claims 1 to 13 according to the first auxiliary request.

It was held that the opposition ground according to Article 100(b) EPC did not prejudice the maintenance of the patent. The Opposition Division held that synergistic properties of mixtures of acetyl L-carnitine with alpha lipoic acid within the weight ratio of 1:1 to 6:1 were sufficiently demonstrated by the examples in the patent specification. In view of this guidance, it was not considered an undue burden for a skilled person to find out further synergistic weight ratios.

The claimed subject-matter was also considered novel over D1. In the Opposition Division's view, the disclaimer in Claim 1 excluding formulation 1 of D1 was sufficient to establish novelty over D1 because a general 1:1 mixture of L-carnitine with lipoic acid could not be derived from the statement on page 3, lines 4 to 9 of this document. This conclusion started from the assumption that the terms "lipoic acid" used in D1 and " $\alpha$ -lipoic acid" used in the patent meant the same compound.

- V. On 21 June 2005 the Opponent (hereinafter: the Appellant) lodged an appeal against the decision of the Opposition Division. The Statement of the Grounds of Appeal was submitted on the same day.

The Appellant disagreed with the Opposition Division's acceptance of sufficiency of the disclosure in the patent and argued that the skilled person was unable, based on the information in the patent specification, to determine effective ratios of acetyl-L-carnitine and alpha lipoic acid outside the exemplified range of 1:1 to 6:1.

The Appellant supported the Opposition Division's interpretation that, in view of the evidence available before it, the term "lipoic acid" used in D1 could be equated with the term " $\alpha$ -lipoic acid" used in the patent in suit.

As to the issue of novelty, the Appellant maintained its position that the disclaimer in Claim 1 was not capable of distinguishing the subject-matter of the patent from the disclosure in D1.

VI. With the letter dated 5 July 2007 the Patent Proprietor (hereinafter: the Respondent) presented the documents:

D7a, D7b: extracts of the Merck Index

and filed three sets of claims for a main request and two auxiliary requests. Seven further auxiliary requests were filed with the letter dated 14 September 2007.

All requests were replaced by corrected sets of claims for a new main request and nine auxiliary requests filed with the letter dated 25 September 2007, the correction concerning replacement of the word "pharmaceutically" in the feature "pharmaceutically acceptable salt" by the word "pharmacologically".

Claim 1 of the main request read as follows:

"1. A combination composition which comprises:

- (a) acetyl L-carnitine or a pharmacologically acceptable salt thereof; and
- (b)  $\alpha$ -lipoic acid

in a synergistically effective weight ratio, with the exception of a combination of 250 mg pharmaceutical grade dry acetyl-L-carnitine and 250 mg pharmaceutical grade dry lipoic acid for 4x daily administration in 500 mg gelatine capsules."

VII. In the oral proceedings, which were held on 17 October 2007, the Board made the point that the disclaimer in Claims 1 of all requests on file was objectionable under Article 84 EPC. As a result, the Respondent



presented a new main request and nine auxiliary requests which replaced all previous requests.

Claim 1 of the new main request was based on Claim 1 of the previous main request with the amendment that the word "combination" had been replaced by "formulation" and the wording: "for 4x daily administration" had been deleted. The Claim now reads as follows:

"1. A combination composition which comprises:

- (a) acetyl L-carnitine or a pharmacologically acceptable salt thereof; and
- (b)  $\alpha$ -lipoic acid

in a synergistically effective weight ratio, with the exception of a formulation of 250 mg pharmaceutical grade dry acetyl-L-carnitine and 250 mg pharmaceutical grade dry lipoic acid in 500 mg gelatine capsules."

Claims 1 of auxiliary requests 1 to 3 differ from Claim 1 according to the new main request by modifications of the wording of the disclaimer, which now read as follows:

Auxiliary request 1:

"... with the exception of a formulation containing 250 mg pharmaceutical grade dry acetyl-L-carnitine and 250 mg pharmaceutical grade dry lipoic acid in 500 mg gelatine capsules."

Auxiliary request 2:

"... with the exception of 500 mg gelatine capsules of 250 pharmaceutical grade dry acetyl-L-carnitine and 250 mg pharmaceutical grade dry lipoic acid."

Auxiliary request 3:

"... with the exception of 500 mg gelatine capsules containing 250 mg pharmaceutical grade dry acetyl-L-carnitine and 250 mg pharmaceutical grade dry lipoic acid."

Claim 1 of auxiliary request 4, drafted without a disclaimer, is a combination of Claims 1 and 2 as granted and reads as follows:

"1. A combination composition which comprises:

- (a) acetyl L-carnitine or a pharmacologically acceptable salt thereof; and
- (b)  $\alpha$ -lipoic acid

in a synergistically effective weight ratio, wherein the ingredient (a) further comprises a "carnitine" selected from the group comprising L-carnitine, propionyl L-carnitine, valeryl L-carnitine, isovaleryl L-carnitine or their pharmacologically acceptable salts or mixtures thereof."

Auxiliary requests 5 to 9 are not discussed because, as will be shown below, it was found that the subject-matter of auxiliary request 4 meets the requirements of the EPC.

VIII. The arguments of the Appellant presented orally and in written form can be summarized as follows:

(a) Sufficiency - Article 83 EPC

According to Claim 1, the relative amounts of the acetyl L-carnitine (a) and the  $\alpha$ -lipoic acid (b) were undefined and only characterized by a weight ratio which had to be "synergistically effective". In this context it should also be noted that the wording "a combination composition which comprises ..." also embraced the presence of any other carnitines in addition to acetyl L-carnitine (a).

A synergistic action of (a) or (a) plus other carnitines with (b), however, was shown in the examples of the patent specification only for a very narrow range of weight ratios of from 1:1 to 6:1, whereas for a mixture of (a) plus other carnitines only 1:1 ratios relative to one another were used.

It was therefore not credible that for any weight ratio outside the range exemplified in the patent specification a synergistic effect occurred and no guidance was given to a skilled person as to how to determine such a synergistically effective weight ratio.

The invention was therefore insufficiently disclosed, contrary to the requirements of Article 83 EPC.

(b) Novelty over D1

- (i) The meaning of the term "lipoic acid" used in D1

The terms "lipoic acid" used in D1 and " $\alpha$ -lipoic acid" according to the patent in suit were synonyms and represented the same compound. This followed from D1 itself, in which reference was made on page 4 to other documents dealing with alpha lipoic acid.

Moreover, in the journal article D2 the author Lester Packer, a recognized specialist in lipoic acid chemistry, used the terms "lipoic acid" and "alpha lipoic acid" interchangeably.

Also figure 2 in D3 characterising the chemical structures of dihydrolipoic acid, lipoic acid and isomers of beta-lipoic acid implied that the structural formula marked with "lipoic acid" represents the alpha form, in contrast to the two isomers of the beta form.

Furthermore, it was clearly indicated on pages 1 and 2 of D4 that the name "lipoic acid" should be given priority over the trivial name " $\alpha$ -lipoic acid".

- (ii) The disclosure in D1

It emerged from D1 in its whole context that the teaching of this document was directed to a combination composition comprising

variable dosages of carnitine and an antioxidant in administratively convenient formulations, with acetyl L-carnitine and lipoic acid as the preferred ingredients of the composition. This could be derived from the passages on page 2, line 31 to page 3, line 11 and page 4, line 28 to page 5, line 4. In particular, Claim 10 of D1 expressly described a combination of acetyl L-carnitine and lipoic acid and included, by its back reference to Claim 6, carnitine/lipoic acid ratios beyond the 1:1 ratio used in formulation 1.

The disclaimer in Claims 1 of the main request and auxiliary requests 1 to 3 just excluding the 250 mg/250 mg acetyl L-carnitine/lipoic acid formulation 1, described on page 5, lines 20 to 22, was therefore not capable of establishing novelty over D1.

Likewise, the combination of acetyl L-carnitine with other carnitines according to Claim 1 of the auxiliary request 4 could not establish novelty over D1 because such a combination was also implicitly disclosed in the passages on page 2, lines 1 to 22 and page 3, line 14.

The subject-matter according to the main request and the auxiliary requests 1 to 4 was therefore not novel over D1.

IX. Concerning sufficiency of disclosure and novelty the following arguments were provided by the Respondent

(a) Sufficiency

According to the case law of the boards of appeal an invention was sufficiently disclosed if it was shown in at least one example how to put the invention into practice. This was the case here. The patent specification showed in a number of examples, which were illustrated by various test reports, that a combination of acetyl L-carnitine (a) and  $\alpha$ -lipoic acid (b) or a of a mixture of (a) with other carnitines and (b) lead to a synergistic pharmaceutical effect in at least one of the therapeutic applications indicated in Claim 8. It was no undue burden for a skilled person to expand the examples to other (a):(b) weight ratios, in particular within the range of 100:1 to 1:10 indicated in Claim 3.

The Appellant's allegation that a synergistic effect at any ratio outside the exemplified weight ratios was not credible was speculative and should have been substantiated with counter-experiments which the Appellant had failed to provide.

(b) Novelty

(i) Lipoic acid -  $\alpha$ -Lipoic acid

The term "lipoic acid" used in D1 was a generic term which embraced  $\alpha$ -lipoic acid, and  $\beta$ -lipoic acid, as set out in D6, as well

as  $\gamma$ -lipoic acid to which reference was made in D1 at page 4, lines 5 to 9.

It furthermore emerged from D7a/b that the entry "thioctic acid" was translated into " $\alpha$ -lipoic acid" rather than into "lipoic acid".

As regards the Appellant's references to D3 and D4 and its argument that the identity of the meaning of "lipoic acid" and " $\alpha$ -lipoic acid" was derivable therefrom, it should be noted that both papers were written by the same authors who apparently used their own terminology. This terminology, however, was not fixed.

It followed from the above that the term "lipoic acid" in D1 was not a synonym for " $\alpha$ -lipoic acid" used as component (b) according to the teaching of the patent. The term "lipoic acid" was therefore a generic term which could not anticipate the disclosure of the specific compound  $\alpha$ -lipoic acid.

(ii) The disclosure in D1

D1 disclosed unit dosages of the carnitine (a) and the antioxidant/lipoic acid (b), for which the amount of the daily administrable active ingredient was defined in mg/kg host. This indication, however, was not tantamount to an unambiguous disclosure that the administration of the recommended doses of (a)

and (b) had to be done in combination but also embraced the variant of a sequential administration of both components. D1 therefore lacked an unambiguous disclosure of a combination composition in the sense of the claimed invention.

Moreover, the combination of acetyl L-carnitine and lipoic acid as disclosed in D1 resulted in D1 from a selection from two separate lists, ie the list at page 3, lines 14 to 30 for various carnitines and the list on page 4, lines 5 to 16 for various antioxidants. This disclosure was therefore not novelty-destroying.

The only formulation in D1 which could be interpreted as a combination composition of acetyl L-carnitine and lipoic acid was the formulation 1 described at page 5, lines 10 to 23. This formulation, containing both components in a weight ratio of 1:1 was, however, excluded by a disclaimer.

D1 did therefore not anticipate the claimed subject-matter.

- X. The Respondent requested the adjournment of the proceedings in the event that the Board declared the disclaimer in Claim 1 [ie the disclaimer in the sets of claims filed with the letter dated 25 September 2005; see points VI and VII] not admissible. Subsidiarily, it requested that the patent be maintained on the basis of the set of claims of the main



request or, alternatively, of one of the auxiliary requests 1 to 9, all filed during the oral proceedings.

- XI. The Appellant requested that the decision under appeal be set aside and the patent be revoked. It objected to an adjournment of the proceedings as requested by the Respondent.

### **Reasons for the Decision**

1. The appeal is admissible.
2. Article 84 EPC objection in the oral proceedings -  
Adjournment of the proceedings

The Respondent's request to adjourn the proceedings was initiated by the Board's objection raised in the oral proceedings that the disclaimer in Claims 1 of the main request and auxiliary requests 1 to 9 as filed with the letter dated 25 September 2007 (see point VI) led to a lack of clarity of the claims, contrary to the requirements of Article 84 EPC, and was therefore not admissible.

In support of its request the Respondent argued that the objection under Article 84 EPC had never been raised before in the opposition and appeal proceedings and that the disclaimer situation constituted a complex legal issue which could not be dealt with at such short notice in the oral proceedings.

As an auxiliary request the Respondent requested that it be given an opportunity to file further requests.

In the Board's judgment the objection as to lack of clarity raised by the Board was not an objection raised

for the first time, which could not be dealt with by the Respondent in the course of the opposition/appeal proceedings. In this connection reference is made to the minutes of the oral proceedings before the Opposition Division. It can be seen from page 2 of the minutes that the disclaimer seeking to exclude an acetyl L-carnitine/lipoic acid formulation in a weight ratio of 1:1 in the sense of formulation 1 of D1 was discussed in the oral proceedings with reference to the provisions of Article 84 EPC. It is therefore the Board's conclusion that the clarity issue was raised in due time and did not give rise to a situation whereby the Respondent was taken by surprise. Thus, an adjournment of the proceedings was not justified.

Under the circumstances, however, the Board was prepared to give the Respondent an opportunity to respond to this objection by presenting new requests. The new requests (main request and auxiliary requests 1 to 9, see point VII) submitted in the oral proceedings were therefore admitted. This course of action was all the more appropriate since, as accepted by the Appellant, the objections under Article 84 EPC were overcome by the new requests.

3. Sufficiency of disclosure - Article 83 EPC

It has to be noted that the patent specification shows by way of several examples that a combination composition comprising (a) acetyl L-carnitine or a mixture of acetyl L-carnitine with other carnitines and (b) alpha lipoic acid shows considerably improved properties (as compared to acetyl L-carnitine alone, carnitine mixture alone or  $\alpha$ -lipoic acid alone) with

regard to reduction of ischaemia (Table 1), diabetic hyperglycaemia (Table 2), reduced accumulation of sorbitol in ocular lenses inducing ocular or peripheral nervous diseases (Table 3), improved potentiation of IGF-1 (insulin-like growth factor) enhancement of isolated brain cell growth (Table 4), prevention of diabetic damage to nerve regeneration (Table 5), reduction in slowing down of neuromuscular conduction (Table 6), in motor coordination abnormality (Tables 7,8) and in neurosensory abnormalities induced by cisplatin (Table 9).

Although the above synergistic properties of the claimed combination composition, when used as a dietary supplement or a medicament, have been shown for a relatively narrow weight range for (a):(b) of from 1:1 to 6:1 the Board has no reason to doubt that the tests described in detail in the patent specification in conjunction with the above tables can also be performed by a skilled person as a matter of routine outside the demonstrated range. In the absence of any proof to the contrary by the Appellant, the Board therefore concludes that a synergistically effective weight ratio of (a):(b) outside the range of 1:1 to 6:1 can be determined by a skilled person without undue burden.

4. The meaning of the term "lipoic acid" in D1

For the assessment of novelty the question has to be clarified whether the term "lipoic acid" used in D1 has the same meaning and represents unambiguously the same compound as the term " $\alpha$ -alpha-lipoic acid" used throughout the patent specification.

In relation to this, the Parties referred to D2 to D5 (cited by the Appellant) and D6, D7a, D7b (cited by the Respondent). The following observations are made by the Board with respect to these documents:

D2: The title reads: "*Antioxidant Properties of Lipoic Acid ...*";

The first sentence of the article and the subsequent third paragraph begins with: "*Alpha-lipoic acid (LA)*". In contrast thereto, the abbreviation "*DHLA*" is used for "*dihydrolipoic acid*". This implies that "*LA*" and "*DHLA*" (the latter being the reduced/hydrogenated form of "*LA*") are different compounds.

D3: Figure 2 depicts four formulae marked "dihydrolipoic acid" (abbreviated DHLA, as in D2 - upper left formula), "lipoic acid" (upper right formula) and the two isomers of "beta lipoic acid" (the two oxidized forms of lipoic acid - lower left and right formulae). It follows from this that the terms "lipoic acid", "dihydrolipoic acid" and "beta lipoic acid" here all represent different compounds.

The formula for "lipoic acid" is structurally identical with the formula shown in D5 which is also marked "lipoic acid". The beta form shown in D3 complies with the structure given in the dictionary D6 under the entry " $\beta$ -Lipoic acid".

D6: The formula indicated in D6 under the entry " $\alpha$ -Lipoic acid" corresponds exactly to the formulae marked in D3 (Figure 2) and D5 with "Lipoic acid".

D4: The formula in Figure 1 of D4 also corresponds to the formulae marked in D3, D5 and D6 with "Lipoic acid" (D3, D5) and " $\alpha$ -Lipoic acid" (D6), respectively. It is pointed out in the table next to the formula and in the paragraph below figure 1 that the terms " $\alpha$ -lipoic acid" and "6,8-thioctic acid" - which are referred to in D7a and D7b - are unofficial names and the term "lipoic acid" should be used instead.

From the above disclosures the following conclusions can be drawn:

- The term "lipoic acid" is never used in conjunction with the hydrogenated form (DHLLA) and the oxidized  $\beta$ -form. The terms "lipoic acid", "dihydrolipoic acid (DHLLA)" and " $\beta$ -lipoic acid" therefore represent different compounds (D2, D3, D5);
- the term "lipoic acid", however is unambiguously used in relation to the  $\alpha$ -form (D6 and D4 in context with D3 and D5). This is fully in line with the disclosure in D2 in which "Alpha-lipoic acid" is abbreviated with "LA" which implies the term **Lipoic Acid**.

It follows from the above that the term "lipoic acid" used in the prior art represents the alpha form.

The Respondent argues (point IX (b)(i)) that the term "lipoic acid" in D1 is also used in relation to the gamma form which is therefore also embraced by this term.

The Board cannot accept this argument. When reading the corresponding passage at page 4, lines 5 to 15 of D1, it is apparent that D1 distinguishes between "lipoic acid" and "lipoic acid derivatives". The corresponding sentence in lines 5/6 reads: "*Exemplary antioxidants include ... lipoic acid, their derivatives, etc.*" and from the next passage: "*For example, lipoic acid derivatives and their methods of production are well described, e.g. ... (Preparation of R/S-gamma-lipoic acid ...) it follows that the gamma-form falls within the term "lipoic acid derivatives".*

The Board therefore concludes that the compound "lipoic acid" used according to D1 - which is disclosed therein as the preferred antioxidant (page 3, lines 6 to 8) - is identical to the alpha-form in the sense of the claimed invention.

*Main Request, Auxiliary requests 1 to 3*

5. Novelty vis à vis D1

Each Claim 1 of the four requests contains a disclaimer by which the formulation 1 of D1, containing 250 mg pharmaceutical grade dry acetyl-L-carnitine and 250 mg pharmaceutical grade dry lipoic acid in the form of 500 mg gelatine capsules, is excluded from the claimed combination composition. The disclaimers merely differ from each other in that they are drafted in different words.

As the Respondent correctly stated in the oral proceedings (point IX(b)(ii)) the acetyl L-carnitine/lipoic acid weight ratio in this formulation is 1:1.

The disclosure in D1, however, is not limited to a 1:1 ratio. Claim 10, by its back-reference to Claim 6, describes an orally administrable dry unit dosage comprising at least 250 mg/kg host/day acetyl-L-carnitine and at least 250 mg/kg host/day lipoic acid. This means that the minimum daily dose of each of the components to be orally administered is at least 250 mg per kg body weight, but does not indicate that both components have to be necessarily applied in equal amounts, ie. in a weight ratio of 1:1. To the same effect is the general disclosure in the paragraph bridging pages 4 and 5 of D1, where it is stated that dosages of the carnitine and antioxidant are in the range of 1 mg/kg to 1 g/kg, preferably 10 mg/kg to 500 mg/kg and more preferably in the range of 20 mg/kg to 200 mg/kg of body weight/day.

The Respondent's argument that D1 fails to disclose that carnitine and lipoic acid were applied in the form of a combination composition in the sense of the invention is not convincing either, when considering the passage at page 5, lines 3/4. It is indicated there that "*Convenient unit dosage containers and/or formulations include tablets, capsules, lozenges, troches, hard candies, powders, metered sprays, creams, suppositories, etc.*" (emphasis by the Board). In the Board's judgment, this is an unambiguous indication that it is suggested according to the teaching in D1 that a unit dosage be applied - for instance one described in Claim 10 and comprising acetyl L-carnitine and lipoic acid - in the form of a container including both components in combination, which - as can be derived from Claim 10 - need not necessarily comprise the two components in a 1:1 ratio.

The disclaimer in Claims 1 of the main request and auxiliary requests 1 to 3 is therefore not apt to exclude the subject-matter disclosed in D1.

The subject-matter specified in Claims 1 of the main request and the auxiliary requests 1 to 3 is therefore not novel. Consequently, these requests are not allowable.

*Auxiliary Request 4*

6. Extension of the scope (Article 123(3) EPC) and "Reformatio in peius"

Claim 1 according to auxiliary request 4 pertains to a combination composition in which component (a) is a mixture of acetyl L-carnitine and other carnitines as specified in granted Claim 2. This combination of Claims 1 and 2 as granted limits the scope of granted Claim 1 by excluding the variant where the combination composition comprises as component (a) acetyl L-carnitine alone. The requirements of Article 123(3) EPC are therefore fulfilled.

The disclaimer which was introduced into claim 1 of the set of claims as allowed by the Opposition Division solely for the purpose of excluding formulation 1 of D1 from the embodiment of the claimed combination composition comprising as component (a) acetyl L-carnitine alone is considered inadmissible because the Claim containing it lacked clarity (see point 2). Furthermore, Claims 1 of the main request and auxiliary requests 1 to 3 submitted in the oral proceedings, in



which the lack of clarity was dealt with by reformulating the disclaimer, could not establish novelty over D1, as shown in point 5 above.

In Claim 1 of auxiliary request 4 the disclaimer was deleted and at the same time the claims according to auxiliary request 4 were restricted to an admixture of (a) acetyl L-carnitine and other carnitines, which therefore no longer embrace embodiments where component (a) is acetyl L-carnitine alone (from which the above-mentioned disclaimer intended to exclude formulation 1 of D1). The claims according to auxiliary request 4 are therefore narrower in scope than the claims as allowed by the Opposition Division.

The Opponent and sole Appellant is thus not put in a worse situation than if it had not appealed. Therefore, the principle of the prohibition of "reformatio in peius" is not violated and the deletion of the inadmissible disclaimer is in conformity with the decision G1/99 (Reasons 15, first alternative).

7. Novelty

A composition comprising as component (a) an admixture of acetyl L-carnitine and other carnitines selected from L-carnitine, propionyl L-carnitine, valeryl L-carnitine, isovaleryl L-carnitine is - contrary to the argument of the Appellant - not disclosed in D1.

As regards the Appellant's reference in this context to page 2, lines 1 to 22 and page 3, lines 14 to 30 of D1 it has to be noted that these passages merely refer to prior art documents concerning the use of carnitines and carnitine derivatives in animal husbandry and human therapy and methods for making carnitine/derivatives

and are not related to any embodiment of the claimed invention; even less are these passages concerned with the claimed combination of carnitines and lipoic acid.

The subject-matter of Claim 1 and directly/indirectly dependent Claims 2 to 12 of auxiliary request 4 is therefore novel over D1.

8. Inventive step

The necessity to discuss the issue of inventive step does not arise because the sole pertinent document D1 constitutes prior art according to Article 54(3) EPC.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to maintain the patent on the basis of the set of Claims 1 to 12 of the 4th auxiliary request as filed during the oral proceedings after any necessary consequential amendments of the description.

The Registrar

The Chairman

G. Röhn

P. Kitzmantel