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**Datasheet for the decision  
of 29 November 2010**

**Case Number:** T 0254/07 - 3.3.02

**Application Number:** 00956522.7

**Publication Number:** 1216041

**IPC:** A61K 31/23

**Language of the proceedings:** EN

**Title of invention:**

High Lipid Diet

**Patentee:**

SOCIETE DES PRODUITS NESTLE S.A.

**Opponent:**

Fresenius Kabi Deutschland GmbH

**Headword:**

High Lipid Diet/SOCIETE DES PRODUITS NESTLE S.A.

**Relevant legal provisions:**

EPC Art. 54, 56

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

-

**Keyword:**

"All requests - novelty (yes): combination of features not specifically disclosed in the prior art"

"Inventive step - (no): obvious to try"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 0254/07 - 3.3.02

**DECISION**  
of the Technical Board of Appeal 3.3.02  
of 29 November 2010

**Appellant:** Fresenius Kabi Deutschland GmbH  
(Opponent) Else-Kröner-Strasse 1  
D-61352 Bad-Homburg v.d.H. (DE)

**Representative:** Weber, Martin  
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**Appellant:** SOCIETE DES PRODUITS NESTLE S.A.  
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**Representative:** Wright, Robert Gordon McRae  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
28 December 2006 concerning maintenance of  
European patent No. 1216041 in amended form.

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** A. Lindner  
J. Van Moer

## Summary of Facts and Submissions

I. European patent No. 1 216 041 based on application No. 00 956 522.7 was granted on the basis of a set of 8 claims. The sole independent claim reads as follows:

"1. Use of a composition comprising at least one lipid which provides between 35% and 75% of the total energy of the composition, the lipid comprising 25% to 70% by weight of total lipid of MCT (medium chain triglycerides), n-6 and n-3 fatty acids in a ratio n-6/n-3 between 2/1 and 7/1, for the manufacture of a medicament, a functional food or a nutritive product for the treatment or prevention of sepsis or inflammatory shock."

II. An opposition was filed against the granted patent. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step.

III. The documents cited during the opposition and appeal proceedings included the following:

- (1) US-A-5 733 884
- (2) EP-A-0 687 418
- (3) EP-A-0 611 568
- (4) EP-A-0 852 913
- (5) US-A-5 055 446
- (7) Proc. of the Nutrition Soc. (1998), 57, 571-576
- (10) Chest (1996), 110, 219-229
- (11) Proc. of the Nutrition Soc. (1998), 57, 395-401
- (12) Minerva Gastroenterol. Dietol. (1997), 43, 169-173
- (13) Internat. J. Vit. Nutr. Res. (1995), 65, 3-20
- (16) EP-A-0 756 827

(17) WO 94/15464

IV. In the decision pronounced on 6 December 2006, the European patent was maintained in amended form on the basis of auxiliary request 1, filed at the oral proceedings.

In said decision the opposition division decided that the subject-matter of the main request was not novel over documents (1), (3) and (4). These documents related to the treatment of patients suffering from chronic wounds, cachexia or inflammatory bowel disease. As these patients were at risk of developing a sepsis, the prevention of sepsis was implicitly disclosed in these documents.

The subject-matter as claimed in auxiliary request 1 was found to meet the requirements of Articles 84 and 123(2) and (3) EPC. Moreover, the subject-matter as claimed in auxiliary request 1 was found to be novel in view of the fact that claim 1 was now restricted to the treatment of sepsis or inflammatory shock, which was not disclosed in documents (1), (3) or (4). As for inventive step, the opposition division defined document (2) as closest prior art, which related to the same problem, i.e. the treatment of sepsis, and which disclosed all the features of claim 1 except a ratio of n-6/n-3 of 2/1 to 7/1. In the light of this prior art, the problem to be solved was defined as the provision of an improved enteral composition for the treatment of sepsis or inflammatory shock. When trying to solve this problem, the skilled person would take document (12) into consideration, which discussed the question whether there was an optimal ratio between  $\omega$ -6 and  $\omega$ -3 acids in

enteral nutrition. However, in view of the fact that document (12) did not contain a clear disclosure to use a  $\omega$ -6/ $\omega$ -3 ratio of 2/1 to 7/1 as claimed, the subject-matter of claim 1 of auxiliary request 1 involved an inventive step over the combination of the teachings according to documents (2) and (12).

V. Both the patentee (appellant-proprietor) and the opponent (appellant-opponent) lodged an appeal against that decision.

VI. With a letter of 12 September 2007, the appellant-proprietor filed a new main request and auxiliary requests I and II. The independent claims read as follows:

*(a) main request:*

"1. Use of a composition comprising a protein source, a carbohydrate source and at least one lipid which provides between 35% and 75% of the total energy of the composition, the lipid comprising 25% to 70% by weight of total lipid of MCT (medium chain triglycerides), n-6 and n-3 fatty acids in a ratio of n-6/n-3 between 2/1 to 7/1, for the manufacture of a medicament, a functional food or a nutritive product for the treatment or prevention of sepsis or inflammatory shock."

*(b) auxiliary request I:*

"1. Use of a composition comprising a protein source, a carbohydrate source and at least one lipid which provides between 35% and 75% of the total energy of the composition, the lipid comprising 25% to 70% by weight

of total lipid of MCT (medium chain triglycerides), n-6 and n-3 fatty acids in a ratio of n-6/n-3 between 2/1 to 7/1, for the manufacture of a medicament, a functional food or a nutritive product for the treatment of sepsis or inflammatory shock, wherein the composition is to be administered enterally."

*(c) auxiliary request II:*

"1. Use of a composition comprising a protein source, a carbohydrate source and at least one lipid which provides between 50% and 75% of the total energy of the composition, the lipid comprising 25% to 70% by weight of total lipid of MCT (medium chain triglycerides), n-6 and n-3 fatty acids in a ratio of n-6/n-3 between 2/1 to 7/1, for the manufacture of a medicament, a functional food or a nutritive product for the treatment of sepsis or inflammatory shock, wherein the composition is to be administered enterally."

VII. Oral proceedings took place on 29 November 2010.

VIII. The appellant-opponent's arguments can be summarised as follows:

Documents (16) and (17) were very pertinent for novelty and inventive step and should therefore be admitted into the appeal proceedings. As regards novelty, each of documents (1), (2), (3), (4), (16) and (17) took away the novelty of the claimed subject-matter.

As regards inventive step, no beneficial effect was shown, as neither example 1 nor example 2 were representative of the subject-matter defined in the

claims. As a consequence, the problem to be solved with regard to document (16), which constituted the closest prior art, merely consisted in the provision of an alternative composition for treating septic patients. The solution to this problem by increasing the lipid content was obvious in the light of document (2) which disclosed nutritional compositions, wherein the lipids provided 45% of the total energy. In connection with the auxiliary requests, the appellant-opponent additionally made reference to documents (3) and (4) which disclosed nutritional compositions for enteral administration, in which the lipids provided up to 45% and 60%, respectively, of the total energy.

IX. The appellant-proprietor's arguments can be summarised as follows:

According to the established case law, late-filed evidence should only be admitted into the proceedings if *prima facie* there were good reasons to suspect that this evidence would prejudice the maintenance of the patent. As a consequence, documents (16) and (17), none of which was pertinent for novelty or inventive step, should not be admitted.

Regarding novelty, none of documents (1), (3) or (4) disclosed treatment or prevention of sepsis or inflammatory shock. Document (2) did not specifically disclose compositions corresponding to the compositions as defined in present claim 1. Document (16) concerned two distinct embodiments, none of which was pertinent for the subject-matter of the present claims. As a consequence, the claimed subject-matter was novel.

Moreover, the claimed subject-matter involved an inventive step over the closest prior art defined by document (16). The problem underlying the present invention could be defined as the provision of an improved composition for the treatment of sepsis, which was solved by selecting a higher fat content. The skilled person would be dissuaded from increasing the fat content by the teaching of the prior art. Thus, document (16) stated (see page 5, lines 35-36) that a fat content providing 20% to 30% of the total energy was ideal for an optimal functioning of the immune system of the patient. In example 1 of document (2), the fat content did not exceed 30% of the total energy either. Document (5), which reported that high amounts of  $\omega$ -6 fatty acids had a significant immunosuppressive effect, dissuaded the skilled person from selecting a ratio  $n-6/n-3 = 2/1$  to  $7/1$ . As regards the examples in the contested patent, the different energy needs of rats and humans had to be taken into consideration. As a consequence, these examples were suitable for demonstrating the alleged improvement regarding prevention of treatment of sepsis.

- X. The appellant-proprietor requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request, or in the alternative on any of the auxiliary requests I or II, filed with letter dated 12 September 2007.

The appellant-opponent requested that the decision under appeal be set aside and that the European patent be revoked.



## Reasons for the Decision

1. The appeal is admissible.
2. Admissibility of documents (16) and (17):

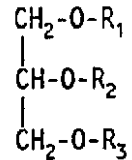
Both documents were submitted by the appellant-opponent with a letter dated 18 May 2010.

### 2.1 Document (16):

Document (16) discloses in a first embodiment the use of a composition comprising a protein source, a carbohydrate source and at least one lipid which provides 20% to 30% of the total energy of the composition, the lipid comprising 30% to 70% of the total lipid of MCT, n-6 and n-3 fatty acids in a ratio of n-6/n-3 of 3.1/1 to 7/1 for the nutrition of septic patients (see page 5, line 17-34). Document (16) discloses in a second embodiment a composition comprising a protein source, a carbohydrate source and at least one lipid which provides 20% to 60% of the total energy of the composition for the nutrition of tumour patients (see page 6, lines 10-18). Document (16) is therefore very pertinent for the evaluation of novelty and inventive step. As a consequence and in view of the fact that it had been submitted six months before the date of the oral proceedings, which means that the appellant-proprietor had sufficient time to study it in detail, the board decided to admit document (16) into the proceedings (Article 13 RPBA).

2.2 Document (17):

Document (17) relates to structured lipids having the structural formula:



wherein at least one of R<sub>1</sub>, R<sub>2</sub>, or R<sub>3</sub> is gamma-linolenic acid, dihomogamma-linolenic acid or an active derivative thereof esterified to the glycerol; a second of R<sub>1</sub>, R<sub>2</sub>, or R<sub>3</sub> is a fatty acid residue esterified to glycerol and selected from the group consisting of C<sub>18</sub>-C<sub>22</sub> n-3 fatty acids, C<sub>6</sub>-C<sub>12</sub> fatty acids and active derivatives thereof; and the third of R<sub>1</sub>, R<sub>2</sub>, or R<sub>3</sub> is a C<sub>6</sub>-C<sub>12</sub> fatty acid or active derivative thereof esterified to the glycerol (see claim 1). Document (17) additionally discloses physical blends of structured lipids, wherein the first structured lipid contains gamma-linolenic acid and/or dihomogamma-linolenic acid and C<sub>6</sub>-C<sub>12</sub> fatty acid residues and a second structured lipid containing n-3 fatty acid residues and C<sub>6</sub>-C<sub>12</sub> fatty acid residues (see page 10, last 5 lines of the penultimate paragraph).

In view of the fact that document (17) does not specifically disclose MCTs, i.e. triglycerides in which each fatty acid residue is a C<sub>6</sub>-C<sub>12</sub> fatty acid residue, the board came to the conclusion that this document is not pertinent and therefore decided not to admit it into the proceedings (Article 13 RPBA).

3. Main request - novelty:

3.1 Documents (1), (3) and (4):

As was correctly pointed out in the decision under appeal (see point 2.1.1 of the reasons for the decision), the compositions disclosed in documents (1), (3) and (4) are encompassed by the compositions defined in claim 1 of the main request. It therefore remains to examine whether they are used for the manufacture of a product for the treatment or prevention of sepsis or inflammatory shock.

3.1.1 Document (1):

The compositions according to document (1) are used for treating acute and/or chronic wounds, in particular with patients suffering from type I diabetes with necrotizing fasciitis (see paragraph bridging columns 3 and 4). Making reference to document (10) (see abstract), which describes necrotizing fasciitis as a soft tissue infection which, when not diagnosed and treated in time, leads to severe sepsis and/or multiple organ system failure, the appellant-opponent reasoned that the treatment of necrotizing fasciitis prevented sepsis. As a consequence, document (1) implicitly disclosed the use of compositions as defined in claim 1 of the main request for the manufacture of a product for the prevention of sepsis.

The board cannot follow this reasoning. A prior art document takes away the novelty if the claimed subject-matter is **directly and unambiguously** derivable therefrom, either by explicit or by implicit disclosure. The

disclosure in document (4) is limited to the treatment of acute and/or chronic wounds, in particular with patients also suffering from necrotizing fasciitis. The treatment or prevention of sepsis is not mentioned therein, neither in explicit nor in implicit form. The skilled person, being aware of the teaching of document (10), will most certainly deduce that the compositions of document (1) might be suitable for preventing sepsis, but these considerations concern inventive step rather than novelty. As a consequence, the subject-matter of claim 1 of the main request is novel over document (1).

### 3.1.2 Document (3):

Document (3) describes the use of a preparation for enteral nutrition for tumour patients suffering from cachexia (see claims 1, 10, 11 and page 2, lines 4-5). According to document (7), cachexia "is not exclusive to cancer, but is also seen in a variety of inflammatory conditions such as sepsis, acquired immunodeficiency syndrome and rheumatoid arthritis" (see page 571, last sentence of the first paragraph). This passage indicates that septic patients may also suffer from cachexia, it does, however, not allow the conclusion that treatment of cachexia may prevent sepsis. As a consequence, document (3) does not disclose the prevention of sepsis, neither by explicit nor by implicitly disclosure.

### 3.1.3 Document (4):

The reasoning applied in point 3.1.1 above also applies to document (4), which describes the use of a preparation for enteral nutrition for the treatment or prophylaxis of inflammatory conditions of the gastro-

intestinal tract such as Crohn's disease (=inflammatory bowel disease (IBD)) (see page 2, lines 6-10, page 3, lines 56-57, claim 1). According to document (11), IBD has a high incidence of septic complications (see page 395, lines 13-16 of the left hand column).

Again, the disclosure in document (4) is limited to the treatment of inflammatory conditions of the gastrointestinal tract. The treatment or prevention of sepsis is not mentioned therein. The skilled person, being aware of the teaching of document (11), will most certainly deduce that the compositions of document (4) might be suitable for preventing sepsis, but, as was already mentioned in point 3.1.1 above, these considerations concern inventive step rather than novelty. As a consequence, the subject-matter of claim 1 of the main request is novel over document (4).

### 3.2 Document (2):

The contemplative example of document (2) discloses a composition for the nutrition of a patient suffering from sepsis comprising all the features of the composition according to claim 1 of the main request except for the ratio n-6/n-3 between 2/1 to 7/1. Thus, as was correctly pointed out in the decision of the opposition division (see 2.1.2), the lipid provides 45% of the total energy, the composition also comprises a protein and a carbohydrate source, the latter being implicitly disclosed by the fact that 10.35 kcal/kg/day are not accounted for by the lipid and protein sources and must therefore be provided by carbohydrates. Moreover, the lipid fraction comprises 35% MCT,

25% soybean oil and 40% marine oil, which yields a ratio n-6/n-3 of about 1.

Claim 5 as well as the passage on page 3, lines 17-19 of document (2) discloses a concentration of 10-40% for both the  $\omega$ -6 and the  $\omega$ -3 fatty acids from which a ratio n-6/n-3 of 4/1 to 1/4 can be calculated. This ratio considerably overlaps with the ratio defined in present claim 1. However, although all the features of present claim 1 are individually disclosed in document (2), document (2) fails to disclose the specific combination thereof. In particular, document (2) does not specifically disclose a composition comprising (a) a protein source, a carbohydrate source and at least on lipid plus (b) wherein the lipid provides between 35% and 75% of the total energy of the composition plus (c) wherein the ratio of n-6/n-3 is 2/1 to 7/1.

As a consequence, the subject-matter of claim 1 of the main request is novel over document (2).

### 3.3 Document (16):

As can be seen from paragraph 2.1 above, the first embodiment of document (16) discloses all the features of present claim 1 except for the total energy content of the lipid(s).

Paragraph 2.1 also shows that the second embodiment of document (16) does neither specifically disclose the nutrition of septic patients nor the ratio of n-6/n-3 fatty acids. As a consequence, neither of the two embodiments takes away the novelty of present claim 1.

In view of the fact that these two embodiments are distinct from each other, it is not possible to mosaic a novelty destroying embodiment by mixing the features thereof.

3.4 The subject-matter of claim 1 of the main request is therefore novel (Article 54 EPC).

4. Main request - inventive step:

The present invention concerns the provision of a medicament, functional food or nutritive product having a high lipid content for the treatment or prevention of sepsis or inflammatory shock (see paragraphs [0001] and [0007] of the contested patent).

Document (16), which is also concerned with the enteral nutrition and therefore with the treatment of septic patients (see page 5, lines 17-34), constitutes the closest prior art. The compositions used for this purpose correspond to the first embodiment of the invention and comprise all the features of the compositions defined in claim 1 except for a lower lipid content (20% to 30% vs. between 35 to 75% of the total energy) (see paragraphs 2.1 and 3.3 above).

For defining the technical problem vis-à-vis document (16), and in particular for determining whether or not the subject-matter as defined in present claim 1 constitutes an improvement, an alternative or merely a further embodiment, the following point has to be taken into consideration: if tests are chosen to demonstrate a beneficial effect based on the distinguishing feature of the invention, the compositions representing the present

invention must correspond to the subject-matter as claimed.

The contested patent contains two examples allegedly demonstrating an improvement over the prior art: the compositions according to example 1, however, differ from the compositions defined in claim 1 of the main request in that the ratio  $n-6/n-3 = 11.25$  (see ratio C18:2 n-6 to C18:3 n-3 in the first table on page 5 of the contested patent) and in that they do not comprise MCT.

In example 2, the lipid content (15% of the total energy) is too low (see paragraph [0071]). In this context, the appellant-patentee held that the tests had been performed with rats and that the diets used for rats had to be correlated to the diets for humans. However, the compositions used in example 2 have a low energy content even for rats. Reference is made to paragraph [0044] of the contested patent which reads: "**For example, a high lipid diet for a rat includes 35% of calories from lipids**" [emphasis by the board]. As a consequence, example 2 is not representative of the subject-matter as claimed in claim 1 of the main request either.

Example 3 relates to a composition according to claim 1 of the main request. However, this composition was not submitted to any tests so that no beneficial effects can be deduced therefrom either.

As a consequence, none of the examples in the contested patent is suitable for demonstrating a beneficial effect over the prior art.



In the absence of any evidence for an improvement vis-à-vis the closest state of the art, the problem underlying the present invention can only be seen as the provision of a further medicament, functional food or nutritive product for the treatment or prevention of sepsis or inflammatory shock. The proposed solution to this problem is the use of compositions as defined in claim 1, which are characterised by a higher lipid content. In view of the information found in the description of the contested patent, the board is convinced that the above problem has been plausibly solved.

It is, however, within the common practice of the skilled person to adjust the energy content of a nutritional composition to the individual needs of the patient. Starting from nutritional compositions with a lipid content providing 30% of the total energy according to document (16), the skilled person would increase the lipid content for a septic patient in need of more energy, all the more so as such compositions are well known in the art. Nutritional compositions as defined in claim 1 of the main request, wherein the lipid provides from 40% to 65% of the total energy content, are e.g. disclosed in document (3) (see claims 1 to 11). In the absence of any unexpected effect, an increase in the lipid content does therefore not involve an inventive step. In this context, it is noted that the skilled person is not dissuaded by the prior art from selecting a higher lipid content. The passage in document (16) cited the appellant-proprietor merely indicates that for the compositions disclosed therein a fat content providing 20% to 30% of the total energy was ideal for an optimal functioning of the immune system of

the patient. In view of the technical problem, which was defined as **the provision of a further medicament, functional food or nutritive product** for the treatment or prevention of sepsis or inflammatory shock, the skilled person would not be dissuaded from selecting a higher fat content. The appellant-proprietor's argument that the skilled person would be dissuaded from selecting a n-6/n-3 ratio of 2/1 to 7/1 in the light of the teaching of document (5) (see point IX above) is not convincing either, as such ratios (3.1/1 to 7/1 are disclosed in document (16), which constitutes the closest prior art. The requirements of Article 56 EPC are therefore not met.

5. Auxiliary request I:

Claim 1 of auxiliary request 1 differs from claim 1 of the main request by deletion of prevention and by restriction to enteral administration.

5.1 Novelty:

The reasoning applied in point 3 above applies *mutatis mutandis* to claim 1 of auxiliary request I. The requirements of Article 54 EPC are therefore met.

5.2 Inventive step:

Both documents (3) and (16) relate to enteral administration (see claim 1 of each document). Moreover, document (16) is also concerned with the treatment of septic patients (see second paragraph of point 4 above). As a consequence, the reasoning applied in point 4 above in connection with claim 1 of the main request applies

*mutatis mutandis* to claim 1 of auxiliary request I. The requirements of Article 56 EPC are therefore not met.

6. Auxiliary request II:

Claim 1 of auxiliary request II differs from claim 1 of the auxiliary request I by limitation of the lipid content to between 50% and 75% of the total energy.

6.1 Novelty:

The reasoning applied in point 3 above applies *mutatis mutandis* to claim 1 of auxiliary request II. The requirements of Article 54 EPC are therefore met.

6.2 Inventive step:

In view of the fact that document (3) discloses nutritional composition in which the lipids provide 40% to 65 % of the total energy (see claim 11), the reasoning applied in point 5.2 above in connection with claim 1 of auxiliary request I applies *mutatis mutandis* to claim 1 of auxiliary request II. The requirements of Article 56 EPC are therefore not met.

**Order**

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

1. The decision under appeal is set aside.
2. The European patent is revoked.

The Registrar:

The Chairman:

N. Maslin

U. Oswald