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**Datasheet for the decision
of 26 April 2007**

Case Number: T 0955/04 - 3.3.09

Application Number: 93107543.6

Publication Number: 0570791

IPC: A23L 1/30

Language of the proceedings: EN

Title of invention:

Low caloric density enteral formulation designed to reduce diarrhoea in tube-fed patients

Patentee:

SOCIETE DES PRODUITS NESTLE S.A.

Opponent:

Fresenius Kabi Deutschland GmbH
Numico Research B.V.

Headword:

-

Relevant legal provisions:

EPC Art. 123(2), 113(1)
EPC R. 67

Keyword:

"Main and auxiliary requests - added subject-matter (yes)"
"Substantial procedural violation (no)"
"Reimbursement of appeal fee (no)"

Decisions cited:

-

Catchword:

-



Case Number: T 0955/04 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 26 April 2007

Appellant II: Fresenius Kabi Deutschland GmbH
(Opponent) Else-Kröner-Strasse 1
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Representative: TER MEER - STEINMEISTER & PARTNER GbR
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Appellant III: Numico Research B.V.
(Opponent) Postbus 7005
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Representative: Jorritsma, Ruurd
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Postbus 29720
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Appellant I: SOCIETE DES PRODUITS NESTLE S.A.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
1 June 2004 concerning maintenance of European
patent No. 0570791 in amended form.

Composition of the Board:

Chairman: P. Kitzmantel
Members: N. Perakis
W. Sekretaruk

Summary of Facts and Submissions

I. Mention of the grant of European patent No 0 570 791 in respect of European patent application No 93107543.6 in the name of SOCIETE DES PRODUITS NESTLE S.A., which had been filed on 10 May 1993 claiming a US priority of 21 May 1992 (US 887361), was announced on 12 December 2001 (Bulletin 2001/50). The patent, entitled "Low caloric density enteral formulation designed to reduce diarrhoea in tube-fed patients", was granted with nine claims. Independent product Claim 1 and independent use Claim 9 read as follows:

"1. An enteral product for providing nutritional requirements to a patient comprising protein including casein, and fat; the product having
a caloric content of less than 1.00 Kcal/ml;
an osmolality of less than 300 mOsm; and
a fiber content of at least 14 g/l."

"9. The use of protein including casein, and fiber in the preparation of an enteral product which has a caloric content of about 0.5 to about 0.8 Kcal/ml; an osmolality of about 100 to about 250 mOsm, and a fiber content of at least 14g/l, for providing nutrition, with reduced incidence or severity of diarrhea, to patients."

Claims 2 to 8 were dependent, directly or indirectly, on Claim 1.

II. A first Notice of Opposition was filed against the patent by Fresenius Kabi Deutschland GmbH on 6 September 2002. Opponent I requested the revocation

- of the patent in its full scope, relying on Article 100(a) EPC (lack of novelty and lack of inventive step).
- III. A second Notice of Opposition was filed against the patent by Numico Research B.V on 12 September 2002. Opponent II requested the revocation of the patent in its full scope, relying on Article 100(a) EPC (lack of novelty and lack of inventive step) and on Article 100 (c) EPC (extension of the subject-matter of the patent beyond the content of the application as filed).
- IV. The oppositions was *inter alia* supported by the following documents:
- D1: US-A-5 104 677
 - D3: EP-A-0 246 747
 - D4: EP-A-0 471 153
 - D6: D.M. Zimmaro et al., J. of Parenteral and Enteral Nutrition (1989), pp 117-123
 - D8: Chapter 8 of Clinical Nutrition, Enteral and Tube Feeding, Second edition (1990), pp 149-173
 - D14: Textbook of Gastroenterology and Nutrition in Infancy, Second edition (1989), p 441
 - D17: EP-A-0 486 425
- V. By its interlocutory decision announced orally at the oral proceedings of 29 April 2004 and issued in writing on 1 June 2004 the Opposition Division held that the grounds for opposition raised by the Opponents did not prejudice the maintenance of the patent in amended form (claims according to auxiliary request F-3 and description adapted thereto).

VI. The Opposition Division decided that the subject-matter of the main request (granted version), of the first auxiliary request as well as of the auxiliary requests of series A to E did not fulfil the requirements of Article 123(2) EPC, because the originally filed application did not disclose calorically unlimited amounts of protein and fat.

Concerning the auxiliary requests of the F series, the Opposition Division held that the subject-matter of requests F-0, F-1 and F-2 was obvious in view of general common knowledge and/or in view of either D3 or D8, while that of request F-3, owing to its restriction to hypo-osmotic products, was considered to involve an inventive step over the closest state of the art represented by D1.

VII. On 2 August 2004 the Patent Proprietor (Appellant I) lodged an appeal against the interlocutory decision of the Opposition Division and requested that the decision be set aside and the patent be maintained as granted, and paid the appeal fee on the same day.

With the Statement setting out the Grounds of Appeal submitted on 29 September 2004, Appellant I provided arguments with regard to the objections raised under Articles 54, 56 and 123(2) EPC. It also filed a new document D29 (an extract from the book entitled "Nutrition in the Prevention and Treatment of Disease" Academic Press 2001, pages 247, 249) in support of its arguments in favour of an inventive step of the claimed subject-matter. Furthermore it filed three auxiliary requests numbered 1 to 3.

Claim 1 of auxiliary request 1 reads as follows:

"1. An enteral product for providing nutritional requirements to a patient comprising protein including casein, and fat; the product having
a caloric content of less than 1.00 Kcal/ml;
an osmolality of 100 to 250 mOsm; and
a fiber content of at least 14 g/l."

Claim 1 of auxiliary request 2 reads as follows:

"1. An enteral product for providing nutritional requirements to a patient comprising protein including casein, and fat; the product having
a fat content that comprises greater than
33 % of the total calories of the product,
a caloric content of less than 1.00 Kcal/ml;
an osmolality of less than 300 mOsm; and
a fiber content of at least 14 g/l."

VIII. On 29 July 2004 Opponent I (Appellant II) lodged an appeal against the interlocutory decision of the Opposition Division and requested that the decision be set aside and the patent be revoked in its entirety, and paid the appeal fee on the same day.

With the Statement setting out the Grounds of Appeal filed on 11 October 2004, Appellant II raised objections under Article 56 and 123(2) EPC against the subject-matter of auxiliary request F-3. In support of its objection raised under Article 123(2) EPC it filed new documents D22 to D26 [D22: Aliment. Pharmacol. Therap., 1989, 3, pages 565-571; D23: Gut, 1992 Apr., 33, pages 479-483; D24: Acta Paediatr. 1992 Jan., 81,

pages 46-50; D25: Clinical Therapeutics, vol. 12, suppl. A, 1990, page 81; D26: Clinical Therapeutics, vol. 12, suppl. A, 1990, pages 95-96].

- IX. On 10 August 2004 Opponent II (Appellant III) lodged an appeal against the interlocutory decision of the Opposition Division and requested that the decision be reversed and the patent be revoked in its entirety, and paid the appeal fee on the same day.

With the Statement setting out the Grounds of Appeal filed on 8 October 2004, Appellant III raised objections under Article 56 and 123(2) EPC against the subject-matter of auxiliary request F-3. In support of the objection raised under Article 56 EPC it submitted a new document D27 (an extract from Clinical Nutrition, Enteral and Tube Feeding 1984, vol. 1, page 185). Appellant III further contested the decision of the Opposition Division, arguing that the Opposition Division committed a substantial procedural violation and requested the reimbursement of the appeal fee.

- X. With the letter dated 19 April 2005, Appellant I submitted further arguments on the issues of inventive step and the inadmissibility of the amendments.

- XI. With the letter dated 28 April 2005, Appellant III raised objections against the granted claims and the auxiliary requests 1 to 3 of Appellant I on the basis of Articles 56 and 123(2) EPC. It also contested auxiliary request 3 on the basis of Article 123(3) EPC.

- XII. With the letter dated 28 July 2005, Appellant II objected to all the requests of Appellant I on the

grounds of lack of novelty, lack of inventive step and unallowable amendments.

With the letter dated 20 April 2007, Appellant I withdrew auxiliary request 3 and filed five "further" auxiliary requests designated A, A.1, A.2, B and B.1, the claims of auxiliary requests A and 2 being identical and Claim 1 of auxiliary request B being identical to Claim 1 of former auxiliary request 1.

- XIII. With the letter dated 23 April 2007 Appellant III submitted further arguments and a new document D28 (EP-A-0 482 715) in support of the objection raised under Article 123(2) EPC.
- XIV. On 26 April 2007 oral proceedings were held before the Board.
- XV. The arguments put forward by Appellant I (Patent Proprietor) in its written submissions and at the oral proceedings can be summarized as follows:
- The expression "a protein including casein" found support in the list of proteins provided in the originally filed application. Though the use of a mixture of the individual protein components of this list was not mentioned, this was customary in this technical field and the skilled person in the art would understand that the exemplified proteins could be mixed if desired.
 - This was also obvious in view of the originally filed description which disclosed the protein list only by way of example (page 3, lines 18-19 of the A-publication).

- The selection of casein from the listed protein alternatives was allowable under Article 123(2) EPC.
- The originally filed application provided support for protein and fat unrestricted to their respective caloric contribution to the enteral product.
- The originally filed description referred to enteral products that met most of the daily nutritional requirements of hospitalized patients (page 2, lines 39-41 of the A-publication), which the skilled person knew comprised fat, proteins and carbohydrates in at least some proportion.
- Therefore the opposed document D17, which contemplated compositions without fat and with a minimum protein requirement of 2% of the total calories, would not be considered as a nutritional product but as a nutritional supplement.
- The same reasoning applied to the late filed document D28, which disclosed protein-free compositions for specific categories of patients.
- Moreover, the expression used in the application "... provides a product having a higher than typical protein content, as a percentage of calories, to help meet protein requirements in a calorie reduced product" (page 2, lines 55-57 of the A-publication) should be construed in the sense that protein was required to be present in some amount and it did not necessitate the limitation of its content to the preferred embodiment of a caloric contribution of more than 17% of the total calories of the product (page 3, lines 16-17 of the A-publication).
- The subject-matter of Claim 9 was essentially the same as that of Claim 1, though rewritten in the

second medical use format with additional features taken from the dependent claims or the description.

- The additional auxiliary requests filed with letter of 20 April 2007 should be admitted as they were filed in an attempt to overcome the objections on file. In particular auxiliary requests A and B corresponded respectively to auxiliary requests 2 and 1, which were filed with the Grounds of Appeal.

XVI. Appellants II and III (Opponents I and II) essentially argued as follows:

- The expression "a protein including casein" did not figure in the originally filed application, where only a list of proteins was disclosed.
- This expression allowed the presence of protein mixtures comprising casein, such mixtures not being supported by the originally filed application.
- The various protein alternatives in the list were separated by the term "or" which did not allow an interpretation whereby mixtures of the individual components were present. Moreover, the examples were carried out using only single protein components thus also not supporting the interpretation alleged by the Patent Proprietor.
- Additionally the selection of casein from the list of proteins found no support in the originally filed application.
- The protein content and the fat content were always related in the originally filed application to their contribution to the total calories of the product. Therefore, contrary to the requirements of Article 123(2) EPC, the absence of such relation in the claimed subject-matter led to an unfounded

generalisation of the originally filed subject-matter.

- The statement in the description referring to an "enteral product that meets most of the daily nutritional requirements of hospitalised patients" need not necessarily be construed to mean that proteins and fats had to be present in the enteral product in particular in view of D17 and D28, which disclosed fat-free and protein-free nutritional compositions.
- Thus that statement could not serve as support for the claimed subject-matter in that it did not limit the contents of fats and proteins to their expressly specified caloric contribution to the enteral product.
- The subject-matter of the use Claim 9 found no support in the originally filed application, on the one hand because no use was explicitly mentioned in the originally filed application and on the other hand because the enteral product of the use Claim 9 had a broader definition than the enteral product of Claim 1.
- The amended description also contravened the requirements of Article 123(2) EPC because many passages were drafted in a broader sense than originally filed.
- The auxiliary requests filed on 20 April 2007 were late filed and no reason was given for this. Hence, they should not be admitted into the proceedings.
- The Opposition Division committed a substantial procedural violation by relying on the new ground, raised for the first time in the reasons for appealed decision, that "a person skilled in the art would consider to work at a physiological level, i.e.

270-300mOsm" (Reasons 7.3), on which the parties had no opportunity to comment under Article 113(1) EPC.

XVII. The Appellant I (Patentee) requested that the decision under appeal be set aside and that the patent be maintained either as granted or, alternatively, on the basis of one of the auxiliary requests A, A.1, A.2, B or B.1, filed with the submission dated 20 April 2007.

XVIII. The Appellants II and III (Opponents I and II) requested that the decision under appeal be set aside and that the European patent No 0570 791 be revoked in its entirety.

Appellant III (Opponent II) further requested reimbursement of the appeal fee.

Reasons for the Decision

1. The appeals are admissible.

2. *Article 123(2) EPC*

2.1 Granted Claim 1 as well as the independent claims of all other operative requests require that the claimed enteral product comprises "protein including casein". This requirement is construed by all parties - and the Board concurs with this interpretation - to mean that the protein component of the enteral product must comprise casein but may also comprise further proteins.

The Board notes, however, that the sole passage in the originally filed application on which the protein

constitution can be based is found on page 3, lines 18-19, of the A-publication. This passage discloses that "(t)he protein content can be provided by, for example, casein, hydrolysed casein, hydrolyzed whey protein, **or** hydrolysed soy protein (*emphasis added by the Board*). This passage provides a list of possible proteins which could be used in the formulation of the enteral nutritional product. No other proteins are mentioned in the description. The wording "provided by" followed by the exemplified proteins separated by commas, the last example being preceded by the coordinating conjunction "or", makes it clear that the elements of this protein list are to be considered as mere alternatives. The grammatical structure of this statement does not allow any other interpretation.

The Board therefore concludes that, contrary to the allegations of the Patent Proprietor, the originally filed application does not disclose directly or indirectly protein mixtures. As the Opponents correctly mentioned this is also in line with the use of only a single protein in the examples (example 1: casein; example 2: hydrolysed whey).

The Board additionally remarks that the compliance of an amendment with the requirements of Article 123(2) EPC is only dependent on the content of the application as filed as understood by the skilled reader and that additional subject-matter that might possibly have been considered by the drafter is irrelevant in this respect even if it would amount to an "obvious modification".

It follows that the presence of the feature "protein including casein" in the granted independent claims

(the main request), and also in the independent claims of the auxiliary requests, extends the subject-matter of the patent beyond that of the originally filed application and thus contravenes the requirements of Article 123(2) EPC.

- 2.2 The Board further notes, in the interests of completeness, that the subject-matter of granted Claim 1 insofar as it relates to an enteral product comprising fat and protein components without indicating their respective caloric contribution also contravenes the requirements of Article 123(2) EPC because this omission does not find support in the originally filed application. The latter, on the contrary, requires with regard to the protein component that "(i)n order to provide sufficient nutritional requirements, the present invention includes a protein content that comprises greater than 17% of the total calories of the product" (page 3, lines 16-17 and 20-21 of the A-publication) and with regard to the fat component that "(a)dditionally the present invention has a fat content that comprises greater than 33% of the total calories of the product". The Board therefore concludes that the disclosure of both protein and fat is inextricably associated with their explicitly specified caloric contribution.

The Board does not concur with the patent proprietor that the originally filed application provides support for the claimed subject-matter devoid of the caloric limitations of fat and protein. Even if the information in the specification concerning "the daily nutritional requirements" (page 2, line 41 of the A-publication) relied upon by the Patentee would, in its favour, be

understood to restrict the compositions to those containing fat, protein and carbohydrate this would not, in the context of the above statements in the specification, extend the disclosure to any fat and any protein content. This conclusion becomes even clearer having regard to the references in the specification to a "higher than typical protein content" and "higher lipid content" (page 2, lines 55-56 and page 3, line 3 of the A-publication), because these statements reinforce the fact that the claimed invention is specific with regard to the caloric contribution of fat and protein.

- 2.3 In view of these fatal deficiencies there is no need to discuss the further objection that the description of the patent also contravenes the requirements of Article 123(2) EPC. It suffices to state that in the Board's judgment this is indeed the case having regard to changes made to the statements in the A-publication in the granted specification, namely "a product **having** a higher protein content", "the composition **has** a higher lipid content", "the present invention **includes** a protein", "the present invention has a fat content that **comprises**" (page 2, line 55; page 3, line 3; page 3, line 17; page 3, line 209) to "a product which **may have** a higher protein content", "the product **may have** a higher lipid content", "the product **may include** a protein content", "the present invention has a fat content that **may comprise**" (*emphases added by the Board*) (column 2, line 48; column 2, line 57; column 3, line 16; column 3, line 24).

Contrary to the arguments of the Patent Proprietor, the requirements of Article 123(2) EPC prohibiting

amendments extending beyond the content of the application as filed are not restricted to the claims but relate as well to the description. Reference is also made in this context to Article 69 EPC which stipulates that for establishing the protection conferred by a European patent the description and drawings shall be used to interpret the claims.

2.4 Since none of the various requests complies with the requirements of Article 123(2) EPC, there is no allowable request on file.

3. *The alleged substantial procedural violation*

3.1 Opponent II contested the decision of the opposition division for the reason that it was deprived of the right to be heard under Article 113(1) EPC in view of the new "ground" - allegedly advanced for the first time in the impugned decision and which had not been put forward by the patent proprietor. The new "ground" was that the person skilled in the art would consider to work at physiological level, ie 270-300 mOsm.

It appears that the word "ground" as used by Opponent II is not to be understood in the way it is used in Article 100 EPC but that instead is intended to mean "reason".

3.2 It is accepted that the wording used by the Opposition Division that "a person skilled in the art would consider to work at a physiological level, ie 270-300 mOsm" does not find literal support in any of the available documents. However, the Board considers that this is irrelevant for the question at issue because

the appreciation of the relevant prior art which led to this conclusion is fully developed in section 7.3 of the Reasons for the decision under appeal. There it is stated that the osmolality range disclosed in D1, the closest prior art, is from 290-380 mOsm, the preferred range being 300-310 mOsm. D6 is discussed by the Opposition Division as fiber supplemented enteral composition disclosing an osmolality of 300 mOsm (page 118). With regard to D3 it is stated that, although not including dietary fiber (and thus being less relevant), specific examples with hypo-osmotic formulas are disclosed but that the general teaching is to use products having less than 350 mOsm, several examples having osmolalities above 300. The Opposition Division then argued that the prior art in general taught towards the use of osmolalities below 300 in order to prevent/treat diarrhea. Summing up this information in the various documents the Opposition Division arrived at the conclusion that "a person skilled in the art would consider to work at a physiological level, ie 270-300 mOsm". This conclusion does not involve facts or evidence not known to the parties.

- 3.3 From the above, the Board concludes that the Opposition Division did not commit any substantial procedural violation. Therefore the request for reimbursement of the appeal fee under Rule 67 EPC is rejected.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The European Patent is revoked.
3. The request for reimbursement of the appeal fee is rejected.

The Registrar:

The Chairman:

C. Moser

P. Kitzmantel