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Datasheet for the decision of 17 June 2008

Case Number: T 1106/05 - 3.3.09

Application Number: 98965885.1

Publication Number: 1056357

IPC: A23L 1/29

Language of the proceedings: EN

Title of invention:
Calorically dense nutritional composition

Patentee:
SOCIETE DES PRODUITS NESTLE S.A.

Opponent:
Numico Research B.V.

Headword:
-

Relevant legal provisions:
EPC Art. 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"Main request: Inventive step (no)"
"Auxiliary request 1 withdrawn"
"Auxiliary request 2, 3: not admitted into the proceedings"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1106/05 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 17 June 2008

Appellant: (Opponent)	Numico Research B.V. Bosrandweg 20 NL-6704 PH Wageningen (NL)
Representative:	van Westenbrugge, Andries Nederlandsch Octrooibureau Postbus 29720 NL-2502 LS Den Haag (NL)
Respondent: (Patent Proprietor)	SOCIETE DES PRODUITS NESTLE S.A. Case postale 353 CH-1800 Vevey (CH)
Representative:	Thomas, Alain 55, avenue Nestlé CH-1800 Vevey (CH)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office orally announced 12 May 2005 and posted 21 June 2005 concerning maintenance of European patent No. 1056357 in amended form.**

Composition of the Board:

Chairman: P. Kitzmantel
Members: W. Ehrenreich
K. Garnett

Summary of Facts and Submissions

I. Mention of the grant of European patent No. 1 056 357 in respect of European patent application No. 98 965 885.1, filed on 30 December 1998 in the name of *Société des Produits Nestlé* as International application No. PCT/EP98/08568 (published as WO-A 99/42001), was announced on 24 July 2002 (Bulletin 2002/30).

II. The patent, entitled *"Calorically dense nutritional composition"* was granted with ten claims, independent Claims 1, 4 and 10 reading as follows:

"1. An enteral composition designed for metabolically stressed patients comprising:

a protein source providing about 15% to about 20% of the energy of the composition;
a carbohydrate source; and
a lipid source including a mixture of medium and long chain triglycerides, the enteral composition having a caloric density of at least about 1.4 kcal/ml."

"4. An enteral composition for a metabolically stressed patient comprising:

about 15% to about 20% of the energy of the composition of partially hydrolysed whey protein;
a carbohydrate source; and
a lipid source including a mixture of medium and long chain triglycerides;

the composition having an energy density of at least about 1.4 kcal/ml and a ratio of non-protein calories per gram of nitrogen of at least about 90:1."

"10. Use of a composition comprising:

a protein source comprising approximately 15% to about 20% of the energy of the composition;
a carbohydrate source; and
a lipid source including a mixture of medium and long chain triglycerides, the composition having a caloric density of at least about 1.4 kcal/ml

in the manufacture of a medicament for providing nutrition to a metabolically stressed patient."

Claims 2 and 3 were dependent on Claim 1 and Claims 5 to 9 were dependent on Claims 1 and 4.

III. Notice of opposition was filed by

Numico Research B.V.

on 24 April 2003.

The Opponent based its opposition on Articles 100(a) and 100(b) EPC and requested revocation of the patent in its entirety because the claimed subject-matter was not new and did not involve an inventive step (Articles 54 and 56 EPC), and because the invention was insufficiently disclosed (Article 83 EPC).

In support of its objections as to lack of novelty and lack of inventive step the Opponent cited *inter alia* the following documents:

D3 Brochure of Fresenius concerning "Fresubin 750 MCT", published in 1989;
D4 J.A. Culpepper-Morgan et al.: "Using Enteral Nutrition Formulas" in *"The Gastroenterologist"*, 1993, Vol. 1, No. 2, pages 143-156;
D5 US-A 5 221 668
D9 Y.H. Hui: Handbook of Enteral and Parenteral Feedings, 1988, pages 94-97, 136-140 and 506-513.

IV. With its interlocutory decision announced at the end of oral proceedings held on 12 May 2005 and issued in writing on 21 June 2005 the Opposition Division maintained the patent in amended form on the basis of Claims 1 to 8 of the second auxiliary request submitted in the oral proceedings.

The subject-matter according to Claim 1 of this request differed from that of Claim 1 as granted in that:

– the protein source consists essentially of partially hydrolysed whey proteins; and
– the lipid source provides 20% to 50% of the energy of the composition.

Claim 3 corresponded to Claim 4 as granted and Claim 8, which corresponded to granted Claim 10, included the same amendments as in Claim 1.

The subject-matter of auxiliary request 2 was considered novel over D9 in that the contribution of

the lipid source to the total energy in the prior art product "Vital High Nitrogen" was only 9.4%.

In the Opposition Division's view the problem to be solved by the claimed invention was the provision of an alternative enteral composition with increased energy density and without elevated protein levels for patients who are metabolically stressed and suffer from gastric reflux. Because this health problem was not mentioned in either D3 or D4 the skilled person had no incentive to combine these documents; nor was there any reason to replace the milk proteins used according to D3 or D5 by partially hydrolysed whey protein.

V. On 19 August 2005 notice of appeal against the decision of the Opposition Division was filed by the Opponent (hereinafter: the Appellant). The Statement of the Grounds of Appeal was filed on 28 October 2005.

The Appellant maintained its objections as to lack of inventive step and insufficiency of disclosure with regard to Claim 8 of auxiliary request 2 and further raised objections under Article 84 EPC.

VI. With its letter dated 7 March 2006 the Patent Proprietor (hereinafter: the Respondent) defended, as its main request, the patent as maintained by the Opposition Division (ie on the basis of auxiliary request 2 in the opposition proceedings). During the oral proceedings, which were held on 17 June 2008, it filed sets of claims according to auxiliary requests 1 to 3.

During these oral proceedings the following issues were discussed:

Main Request

- Clarity (Article 84 EPC);
- Sufficiency of disclosure (Article 83 EPC);
- Inventive step (Article 56 EPC).

Auxiliary Requests 1 to 3

- Admissibility.

In the course of the discussion on admissibility the Respondent withdrew auxiliary request 1. Auxiliary requests 2 and 3 were not admitted by the Board into the proceedings (reasons, point 2).

VII. The Appellant's arguments as to lack of inventive step of the subject-matter of the main request can be summarized as follows (in view of the negative decision on this issue, the arguments as to clarity and sufficiency do not need to be set out):

The closest prior art is represented by the enteral compositions "Vital High Nitrogen" (Vital HN) or "Peptamen®", both products being disclosed in the documents D4 and D9. These compositions belong to the group of "Elemental Formulas" containing protein in the form of free amino acids or peptides which are used for the treatment of patients suffering from impaired gastrointestinal (GI) function, a certain form of metabolic stress.

In particular, the protein source in "Vital HN" and "Peptamen" is based on hydrolysed whey protein, and the fat component includes a mixture of medium chain triglycerides (MCT) and long chain triglycerides (LCT).

The composition "Vital HN", with a lipid source which provides energy below the claimed range (9.4% vs. 20 to 50%), exists as a water soluble powder which can be diluted according to a certain scheme, one leading *inter alia* to a fluid composition with a caloric density of 1.5 kcal/ml, ie within the claimed range of at least 1.4 kcal/ml, whereas "Peptamen" constitutes a ready-to-use enteral composition with a caloric density of 1.0 kcal/ml, ie below the claimed range.

Therefore, the problem to be solved can be seen as the provision of alternative enteral compositions.

It would, however, be a matter of routine for a skilled person to enhance the lipid content in "Vital HN" or the caloric density of "Peptamen", in particular in view of the fact that no unexpected effect by these measures was demonstrated.

A similar approach could be applied with regard to the composition "Fresubin® 750 MCT disclosed in D3, by replacing the (unhydrolysed) lactoproteins by the easily absorbable hydrolysed lactalbumin in accordance with D5.

VIII. The counterarguments of the Respondent were as follows:

Although the products "Vital HN" and "Peptamen®" disclosed in D4/D9 have a number of features in common

with the claimed enteral composition, neither D4 nor D9 represents the closest prior art because the problem underlying the claimed invention, namely the provision of enteral formulas for metabolically stressed patients with increased energy need, which do not provide unnecessary fluid volume or increased protein levels, is not dealt with in these documents.

Although five dilutions are described for the product "Vital HN" there is no guidance in this prior art to select, amongst these five possibilities, exactly that dilution schedule which leads to the claimed caloric density of at least 1.4 kcal/ml in order to solve the problem posed.
Furthermore, the protein source of "Vital HN" contains, besides partially hydrolysed whey protein, other hydrolysed proteins derived from meat and soy, so that the condition of Claim 1 that the protein source consists essentially of partially hydrolysed whey proteins, is not met (emphasis by the Board). There is no indication, either in D4 or in D9, which would induce the skilled person to remove the hydrolysed meat and soy proteins from the protein source in "Vital HN". Moreover, the energy provided by the lipid source is 9.4% which is considerably below the required range of from 20 to 50% of the energy of the composition.

It follows from the above that "Vital HN" would have to be modified by way of several selections in order to arrive at the claimed invention.

The product "Peptamen" differed from the claimed composition by its lower caloric density and there is no teaching in D4 or D9 that the energy density of this

product should be increased. Rather, "Peptamen" is a ready-to-use product and therefore there would be no incentive for a skilled person to modify its caloric density.

Concerning the composition "Fresubin® 750 MCT" disclosed in D3, it should be borne in mind that the protein source consists of an unmodified food protein and that there is no indication that these proteins could be replaced by peptide fragments derived from protein hydrolysis.

IX. The Appellant requested that the decision under appeal be set aside and that the patent be revoked. The Appellant further requested that the auxiliary requests filed during the oral proceedings be not admitted into the proceedings.

X. The Respondent requested that the appeal be dismissed, alternatively that the decision under appeal be set aside and the patent be maintained on the basis of the second or third auxiliary requests filed during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. *Admissibility of auxiliary requests 2 and 3*

In the claims according to auxiliary requests 2 and 3 the following substantial amendments vis à vis the main request were made:

Auxiliary Request 2

- deletion of the word *"essentially"* in Claim 1;
- complete deletion of Claim 3.

Auxiliary Request 3

- deletion of Claims 1, 2 and 8;
- introduction of the feature into Claim 3 *that the lipid source provides 20 to 50% of the energy of the composition*.

The representative of the Respondent argued that the late submission of these requests in the oral proceedings was due to the fact - already complained about in its letter dated 23 May 2008 - that it had not been made aware of the Appellant's letter dated 24 April 2008, providing further arguments as to clarity, extension of scope and inventive step, until 22 May 2008, ie less than one month before the date of the oral proceedings.

The Board cannot accept this argument. The amendments to the claims in these requests seek to overcome objections as to lack of clarity and inventive step which had already been raised by the Appellant in points 3 and 4 of its Statement of the Grounds of Appeal.
As to lack of clarity, the objection raised in points 3.1. and 3.2. thereof concerned the point that the term "consists essentially" in Claim 1 made the required minimum amount of the partially hydrolysed whey protein uncertain, a problem aggravated by

Claim 3, where this term was replaced by the even broader term "comprising".
As to inventive step, in point 4.5 of the Grounds of Appeal it was submitted that it was obvious to increase the energy intake of the commercial product "Vital HN" by enhancing the lipids content to normal levels.
Thus, the amendments sought to be introduced by auxiliary requests 2 and 3 address issues that have been in the proceedings since the outset of the appeal almost three years ago.

In the Board's judgment, any defence to the objections raised in the Grounds of Appeal, including the filing of auxiliary requests taking them into account, could and should have been submitted in direct response thereto (Article 12(2) RPBA: OJ EPO 2007, 536). Since, in accordance with what is said above, auxiliary requests 2 and 3 were filed late, their admittance into the proceedings is a matter for the discretion of the Board, such discretion to be exercised in accordance with Article 13(1) RPBA. In view of the current state of the proceedings and the need for procedural economy, the request for admittance of these requests into the proceedings was not granted.

Since the first auxiliary request was withdrawn, its admissibility need not be considered (see point VI above).

3. Inventive Step - Main Request

3.1 *The patent in suit*

The patent is concerned with enteral nutritional compositions for metabolically stressed patients comprising a protein source, a lipid source and a carbohydrate source. The compositions should meet the condition that patients suffering from metabolic stress have an increased energy requirement but do not need or tolerate protein levels beyond a normal level and also do not tolerate an increased food volume. It is the aim of the patent to formulate a calorically dense elemental diet while providing moderate non-protein calories per gram of nitrogen (paragraphs [0005] and [0009] of the patent specification).

In accordance with Claim 1 of the main request the elemental enteral composition is characterized by the three essential ingredients protein/carbohydrate/lipid and its caloric density in the following manner:

(a) the protein source consists essentially of partially hydrolysed whey protein and provides 15 to 20% of the energy of the composition;
(b) the energy intake by the carbohydrate source is not defined;
(c) the lipid source includes a mixture of medium and long chain triglycerides and provides 20 to 50% of the energy of the composition;
(d) the caloric density is at least 1.4 kcal/ml.

3.2 The closest prior art

As the Respondent states itself in the introductory part of the patent specification (paragraphs [0001] to [0005]), the invention starts from the observation that a large group of patients suffering from metabolic stress need calorically dense nutritional support in the form of enteral elemental diets providing moderate protein levels.
This subject-matter is dealt with in D4 and D9, which are therefore each considered representative of the closest prior art.

D4 discloses on page 149 that elemental formulas are used when digestion is impaired due to the following conditions:
(1) decreased bowel surface area;
(2) decreased intestinal absorption;
(3) decreased intraluminal digestion,
and that they have been used successfully in the treatment of Crohn's disease of the small intestine. These symptoms can all be summarized under the general term "metabolic stress" mentioned in Claim 1 of the main request.

It can furthermore be derived from the paragraph bridging the left column of page 149 and the right column of page 150 that elemental diets contain protein in the form of free amino acids or as peptides of varying lengths and that protein hydrolysates, due to their easier absorption, are preferred. According to page 150 right column, most of the energy of elemental diets is provided by the carbohydrate source and the fat portion varies from low fat to high fat content and

is provided by long chain triglycerides (LCTs) and medium chain triglycerides (MCTs) in various ratios.

Thus, a skilled person intending to provide elemental diets for metabolically stressed patients in accordance with D4 would start from compositions which meet the following conditions:

- the protein source consists essentially of protein hydrolysates, while providing a moderate energy proportion;
- the carbohydrate source provides a considerable proportion of the total energy of the composition;
- the fat portion comprises MCTs and LCTs with varying energy contribution.

Compositions of this kind are disclosed, in terms of their composition and energy balance, in table 5 of D4 and in D9, from which the claimed composition differs by the precise compositional profile of the protein hydrolysate and/or the distribution of the energy contribution.

3.3 The problem to be solved

Starting from one of the enteral compositions exemplified in D4 or D9 and account being taken of the above-mentioned conditions, the skilled person has at his disposal several variants of elemental formulas from which he may choose according to the specific "metabolic stress" disorder to be treated.

In the absence of experimental evidence showing that the variation of certain parameters within the set of

conditions referred to above leads to a surprising and non-predictable effect, the problem to be solved is to be seen merely in providing an alternative enteral composition able to respond to the different nutritional needs of the various forms of "metabolic stress".

In this context, the Respondent's argument that a skilled person would not start from enteral compositions like "Vital HN" or "Peptamen" exemplified in D4 and D9, because these products are intended for a different patient population, ie patients with impaired gastrointestinal (GI) function, is not convincing. In Claim 1 the very general term "metabolically stressed patients" is used without definition of any specific disorders which the patients concerned suffer from. Therefore, a host of different patient groups is embraced, requiring nutritional support by enteral compositions which meet different needs, including moderate protein levels and/or increased energy density. These needs and the nutritional response thereto are all known to a skilled person as is stated in paragraphs [0001] to [0005] of the patent specification.

3.4 Obviousness

A skilled person intending to solve the above problem would therefore contemplate modifying the profile of certain of the enteral compositions listed in D4 or D9 by varying the energy contribution of the constituents and/or their compositional parameters in accordance with one or more of the other elemental formulas listed in the documents.

Following this strategy the skilled person would *inter alia* contemplate enhancing the low caloric density of 1 kcal/ml of the product "Peptamen", which provides a desired moderate protein level (cf. D9, the table at page 138). He would do this in accordance with the high energy formula of "Vital HN" with a caloric density of 1.5 or 2.0 kcal/ml (cf. D9, the table at page 511) in order to respond to the low tolerance for high food volume of some metabolically stressed patients (paragraph [0005] of the patent specification).

Likewise, he would also contemplate modifying the peptide composition of the calorically dense elemental formula "Vital HN" by restricting its protein constituent to partially hydrolysed whey and increasing the fat proportion in accordance with "Peptamen", in order to provide a composition with an alternative protein profile and a modified carbohydrate/fat energy profile.

Thus, a skilled person starting from D4 and/or D9 and seeking to solve the underlying technical problem would arrive at the subject-matter of Claim 1 of the main request without inventive effort.

4. Conclusion

Since the main request is therefore not allowable, and since auxiliary request 1 was withdrawn by the Respondent and auxiliary requests 2 and 3 were not admitted into the proceedings, there is no allowable request on file.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar The Chairman

G. Nachtigall P. Kitzmantel