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**Datasheet for the decision
of 12 June 2018**

Case Number: T 0753/17 - 3.3.09
Application Number: 08858188.9
Publication Number: 2230940
IPC: A23L1/29, A23L1/305, A23C1/04,
A61P3/02, A23L1/308
Language of the proceedings: EN

Title of invention:
HIGH ENERGY LIQUID ENTERAL NUTRITIONAL COMPOSITION

Patent Proprietor:
N.V. Nutricia

Opponents:
NESTEC S.A.
Friesland Brands B.V.
Fresenius Kabi Deutschland GmbH
Even Santé Industrie

Headword:

Relevant legal provisions:
RPBA Art. 12(4)
EPC Art. 123(2)

Keyword:

Late-filed request - request could have been filed in first
instance proceedings (yes)
Amendments - allowable (no)

Decisions cited:

Catchword:



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D E C I S I O N
of Technical Board of Appeal 3.3.09
of 12 June 2018

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 24 March 2017
revoking European patent No. 2230940 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman W. Sieber
Members: M. O. Müller
D. Rogers

Summary of Facts and Submissions

- I. This decision concerns the appeal filed by the proprietor of European patent No. 2 230 940 against the decision of the opposition division to revoke it.
- II. With their notices of opposition opponents 1 to 4 had requested revocation of the patent in its entirety on the grounds under Article 100(a) (lack of novelty and inventive step), 100(b) and 100(c) EPC.
- III. Claim 1 of the main (sole) request filed as "Annex 4" during the oral proceedings before the opposition division read as follows:

"1. A heat-sterilized liquid enteral nutritional composition comprising protein, said protein providing 15 - 18 en% of the total energy content of the composition, said protein including micellar casein and caseinate, wherein the weight ratio of micellar casein to caseinate ranges from 80:20 to 40:60, and the combined amount of micellar casein and caseinate is at least 85 weight% of the total protein, the composition having an energy density of 10 kJ/ml [2.4 kcal/ml], said composition further comprising whey."

The opposition division admitted this request into the proceedings, but did not consider it allowable, since the new range of 15 to 18 en% in claim 1 was not based on the application as filed.

- IV. This decision was appealed by the proprietor (hereinafter: the appellant). The statement setting out the grounds of appeal filed with letter dated 6 July

2017 contained a main request and auxiliary requests 1 to 5.

V. Responses were filed by opponents 1 to 4 (hereinafter: respondents 1 to 4).

VI. With its letter dated 12 April 2018, the appellant filed a new main request and new auxiliary requests 1 and 2 and withdrew all claim requests previously on file.

VII. With its letter dated 14 May 2018, respondent 1 filed its observations on the new claim requests.

VIII. With its letter dated 7 June 2018, respondent 3 filed:

F36: Chronology of requests;

F37: Copy of T 28/10;

F38: Decision 14/15826 of the "Tribunal de grande instance de Paris"; and

F38a: Google screenshot concerning F38.

IX. During the oral proceedings on 12 June 2018, the appellant withdrew its main request. The only requests on file are thus auxiliary requests 1 and 2.

X. Claim 1 of auxiliary request 1 is identical to claim 1 of the main request before the opposition division (see point III above).

Claim 1 of auxiliary request 2 reads as follows:

"1. A heat-sterilized liquid enteral nutritional composition comprising protein, said protein including micellar casein and caseinate, wherein the combined amount of micellar casein and caseinate is at least 85 weight% of the total protein, said composition further comprising whey, said composition comprising:

- a) about 9.6 g of protein per 100 ml of the composition of a mixture of micellar casein and caseinate with a weight ratio of about 65:35, said protein providing about 16 % of the total energy content of the composition;
 - b) fat providing about 35 % of the total energy content of the composition;
 - c) carbohydrate providing about 49 % of the total energy content of the composition,
- said composition having an energy density of about 10 kJ/ml [2.4 kcal/ml]."

XI. So far as relevant to the present decision, the appellant's arguments can be summarised as follows:

Auxiliary request 1 should be admitted into the proceedings, since it differed from the main request before the opposition division only by the deletion of claim 6, which was a reaction to the board's preliminary opinion.

All the features of claim 1 of auxiliary request 1 were based on the application as filed. The energy density of 2.4 kcal/ml required by this claim was disclosed on page 8, line 13 and in all examples of the application as filed. The combined amount of micellar casein and

caseinate and their ratio was disclosed on page 8, line 18 and page 9, lines 6 to 8 of the application as filed. The presence of whey and the feature that the composition was heat-sterilized was disclosed on page 8, lines 25 to 30 and page 21, lines 15 to 17 of the application as filed. Lastly, the range of 15 % to 18 % for the energy percentage of the protein was directly and unambiguously derivable from page 7, lines 23 to 25 of the application as filed.

Also the combination of all the features of claim 1 could be directly and unambiguously derived from the application as filed. The examples of the application as filed provided a pointer to the energy density of 2.4 kcal/ml and the range of 15 % to 18 % defined in claim 1 for the energy percentage of the protein was the most preferred implicitly disclosed range in the application as filed. Lastly, page 21, line 9 contained a pointer to the feature that the composition was heat sterilized.

Auxiliary request 2 should be admitted into the proceedings. It was simply a combination of granted claims. There had been no tactics involved in not filing this request earlier. On the contrary, it was a reaction to the opposition division's surprising finding that the combination of the energy percentage of the protein with its amount in g/100ml was not based on the application as filed.

XII. So far as relevant to the present decision, the respondents' arguments can be summarised as follows:

Auxiliary request 1 should not be admitted into the proceedings since its filing constituted an abuse of procedure.

Claim 1 of auxiliary request 1 was not based on the application as filed. At least a five-fold selection was necessary from the application as filed in order to arrive at the subject-matter of claim 1, namely of the energy percentage, the combined amount of micellar casein and caseinate, the energy density, the presence of a certain amount of whey and the feature that the composition was heat-sterilized. There was no pointer to such a selection. Contrary to the appellant's assertion, the range required by claim 1 for the energy percentage was not the preferred range implicitly disclosed in the application as filed, in fact it was not disclosed in the application as filed at all. Furthermore, the combined amount of micellar casein and caseinate as required by claim 1 was not the most preferred range in the application as filed. Lastly, no pointer at all was present for the remaining features of claim 1.

Auxiliary request 2 should not be admitted into the proceedings. The appellant knew of the added-matter objection against the energy percentage required by claim 1 since early on in the opposition proceedings. More specifically, these objections had been raised already with respondent 1 and 2's letter dated 7 December 2016 against the energy percentage of 15 % to 30 % required by claim 1 of the claim request then on file. Even after the opposition division, on the basis of one of these objections, considered the energy percentage of 15 % to 18 % of the main request filed during the oral proceedings to contain added matter, did the appellant not file additional requests in an attempt to overcome this objection. In fact it did the opposite, namely withdrawing all claim requests save the request that was objected to. The appellant thereby

prevented the opposition division from examining the respondents' further objections under Articles 100(a) and (b) EPC. This was aggravated by the fact that sufficient time would have been available to do so, in view of the fact that the oral proceedings had been scheduled for two days and the only request had been rejected on the first day already.

XIII. The appellant requested that the decision under appeal be set aside and, if either auxiliary request 1 or auxiliary request 2, (both filed under cover of a letter dated 12 April 2018), satisfied the requirements of Rule 80 and Articles 84 and 123 EPC, that this request be remitted to the department of first instance for further prosecution.

XIV. The respondents requested that the appeal be dismissed. In addition, the respondents requested that auxiliary request 2 not be admitted into the appeal proceedings.

Furthermore, respondents 3 and 4 requested that auxiliary request 1 not be admitted into the appeal proceedings.

In addition, the respondents requested that, if one of the appellant's claim requests was found to satisfy the requirements of Rule 80 and Articles 84 and 123 EPC, this request be remitted to the department of first instance for further prosecution.

Reasons for the Decision

Auxiliary request 1

1. Admission

1.1 During the oral proceedings, the board decided to admit auxiliary request 1 into the proceedings. Since this auxiliary request was rejected for not complying with Article 123(2) EPC (see below), there is no reason to provide a detailed reasoning for the board's decision to admit this request.

2. Amendments - Article 123(2) EPC

2.1 Claim 1 refers to a heat-sterilized liquid enteral nutritional composition comprising protein including micellar casein and caseinate. The claim requires that (i) the protein provides 15 % to 18 % of the total energy of the composition, (ii) the combined amount of micellar casein and caseinate is at least 85 weight% of the total protein, (iii) the composition has an energy density of 2.4 kcal/ml and (iv) the composition comprises whey as further protein. Since the combined amount of micellar casein and caseinate is at least 85 weight%, the amount of whey is implicitly limited to less than 15 wt%.

2.2 As regards the energy percentage (feature (i) above), the application as filed (page 7, lines 23 to 29) discloses the following:

"According to another embodiment of the present invention, the protein provides 10 % to 30 %, preferably 12 % to 20 %, more preferably 14 % to 18 %, at least 15 % of the total energy content of

the composition. The % of total energy is also abbreviated as En%; En% is thus short for energy percentage and represents the relative amount that a constituent contributes to the total caloric value of the composition. In another embodiment of the present invention, the protein provides at least 16 % of the total energy content."

This passage contains four lower (10 %, 12 %, 15 % and 16 %) and three upper limits (30 %, 20 % and 18 %) for the energy percentage. In order to arrive at the range defined in claim 1 for the energy percentage (15 % to 18 %), at the very least one selection is needed, namely of 15 % as the lower and 18 % as the upper limit.

2.3 As regards the combined amount of micellar casein and caseinate (feature (ii) above), the application as filed (page 8, lines 16 to 20) discloses the following:

"In one embodiment of the present invention, the combined amount of micellar casein and caseinate in the liquid nutritional composition according to the invention is at least 70 weight%, more preferably at least 85 weight%, more preferably at least 90 weight%, more preferably at least 95 weight% of the total protein present in the liquid nutritional composition."

In order to arrive at the combined amount of micellar casein and caseinate as required by claim 1, "at least 85 weight%" has to be selected out of the four ranges disclosed in the above passage of the application as filed. Hence a second selection has to be made.

2.4 As regards the energy density (feature (iii)), the application as filed (page 8, lines 11 to 13) discloses the following:

"In one embodiment of the present invention, the composition has an energy density of at least 2.0 kcal/ml, preferably at least 2.2 kcal/ml, more preferably at least 2.3 kcal/ml, even more preferably at least 2.4 kcal/ml."

Consequently, in order to arrive at the energy density required by claim 1, a third selection must be made, namely of the specific value of 2.4 kcal/ml out of the most preferred range of at least 2.4 kcal/ml as disclosed in the application as filed.

2.5 As regards the presence of whey and its amount (feature (iv)), the application as filed (page 8, lines 25 to 30) discloses the following:

"As aforementioned, the composition of the present invention should not contain large amounts of proteins other than micellar casein and caseinate. However in a further embodiment of the present invention, the composition may comprise up to about 30 weight% of whey, or less than or equal to 20 weight% of whey, or less than or equal to 15 weight% of whey, or less than or equal to 5 weight% of whey of the total protein present in the liquid nutritional composition."

In order to arrive at the requirement of claim 1 that whey is present as an additional protein in an amount of less than 15 wt%, a fourth selection has to be made, namely of this range out of the various ranges

disclosed in the above passage of the application as filed.

- 2.6 It needs to be examined whether the application as filed contains a pointer to such a fourfold selection.
- 2.6.1 The appellant argued that the range of 15 % to 18 % defined in claim 1 for the energy percentage of the protein was the most preferred implicitly disclosed range in the application as filed. The board does not agree. The lower limit of 15 % is not described in the application as filed (page 7, lines 23 to 29) as a preferred lower limit, nor is it the lower limit of the broadest or narrowest range. On the contrary it lies between the lowest and highest lower limit, i.e. 10 % and 16 %, respectively. Furthermore, even if there was a pointer to 15 % in the application as filed, a pointer would still be missing to the range of 15 % to 18 % as now found in claim 1.
- 2.6.2 The appellant furthermore argued that the examples of the application as filed provided a pointer to an energy density of 2.4 kcal/ml. It is true that all the examples apply such an energy density. However, all examples link this energy density with a specific energy percentage of protein, namely 16.0 %, while the energy percentage in claim 1 is much more broadly defined as 15 % to 18 %.
- 2.6.3 The appellant did not provide arguments for any pointer to the further features of claim 1 discussed above, namely the combined amount of micellar casein and caseinate (at least 85 weight%) and the presence of less than 15 weight% of whey. In fact, if anything, the application as filed points at values different from those required by claim 1, namely at least 95 weight%

as the most preferred embodiment for the combined amount of micellar casein and caseinate (page 8, lines 20 to 21) and less than or equal to 5 weight% as the narrowest range for the amount of whey (page 8, lines 29 to 30).

- 2.7 The combination of the range defined in claim 1 for the energy percentage of the protein with the combined amount of micellar casein and caseinate, the energy density and the presence of a certain amount of whey is thus not directly and unambiguously derivable from the application as filed. Claim 1 of auxiliary request 1 therefore does not meet the requirements of Article 123(2) EPC, so auxiliary request 1 is not allowable.

Auxiliary request 2

3. Admission

- 3.1 Respondents 1 to 4 requested that auxiliary request 2 not be admitted.

- 3.2 Auxiliary request 2 corresponds to auxiliary request 5 filed with the statement of grounds of appeal. According to Article 12(4) RPBA, the board has the discretion to hold inadmissible a request filed with the statement of grounds of appeal if it could have been presented in the first instance proceedings.

- 3.3 Claim 1 of auxiliary request 2 (the only independent claim) no longer contains any range for the energy percentage of protein. The definition of the energy percentage as a range had been objected to under Article 123(2) EPC throughout the opposition proceedings. More specifically, with its letter dated

7 December 2016, respondent 1 objected to the range of 15 % to 30 % defined for the energy percentage, since the combination of the originally disclosed values of 15 % and 30 % into a new range went beyond the content of the application as filed. With its letter of the same day, respondent 2 objected to this range too, since its combination with the combined amount of micellar casein and caseinate was not based on the application as filed. Nevertheless, the appellant maintained claim requests defining the energy percentage of the protein in terms of a range (albeit later restricted to 15 % to 18 %) until during the oral proceedings before the opposition division. During the oral proceedings, the opposition division raised a new objection against this range, namely that there was no basis for combining it with the amount of protein in g/100 ml. In reaction thereto, the appellant replaced all requests on file by a single new main request, in claim 1 of which, the amount of the protein in g/100 ml had been deleted, but which still defined the energy percentage of the protein in terms of a range (15 % to 18 %). On the basis of a reasoning analogous to that of respondent 1, the opposition division rejected this request (after deletion of claims 8 to 10), because an unequivocal teaching to combine the two values of 15 % and 18 % was missing in the application as filed. Since there was no other claim request on file, the opposition division revoked the patent.

- 3.4 Hence, the appellant knew already upon receipt of respondent 1 and 2's letters dated 7 December 2016, i.e. more than one year before the oral proceedings before the opposition division, that there was a potential problem under Article 123(2) EPC in view of the definition of the energy percentage of the protein in terms of a range. Therefore, the appellant should

have envisaged the possibility that the sole claim request maintained before the opposition division would be rejected in view of added matter. It could and in fact should have made an attempt to overcome this added-matter problem by filing a claim request in which this range was deleted, e.g. in the form of auxiliary request 2 now before the board. The appellant did however not do so, even though the oral proceedings had been scheduled by the opposition division for two days and the appellant's sole claim request was rejected already on the first day of the oral proceedings. The appellant thereby prevented the opposition division from coming to a positive decision on added matter and examining the respondents' further objections under Articles 100(b) and (a) EPC.

3.5 The appellant argued that it had been surprised during the oral proceedings by the opposition division's new objection that the combination of the amount of protein in terms of its energy percentage and g/100 ml was not based on the application as filed. This is however irrelevant, since the appellant was given the opportunity to react to this by filing a new claim request, which overcame this objection.

3.6 The appellant further argued that auxiliary request 2 before the board was a reaction to the objection raised by the respondents during the oral proceedings that the combination of the energy percentage with the combined amount of micellar casein and caseinate in claim 1 of auxiliary request 1 was not based on the application as filed.

The board is not convinced by this argument. First of all, auxiliary request 2 was not filed after the respondents had raised this objection during the oral

proceedings, so it cannot be a reaction to this objection. Secondly, as set out above (point 3.3), this objection had been raised already by respondent 2 in its letter dated 7 December 2016. Hence, the appellant knew of this objection already long before the oral proceedings before the opposition division and could, and in fact should have filed a claim request in an attempt to overcome this objection already during the opposition proceedings.

- 3.7 The appellant lastly argued that claim 1 of auxiliary request 2 now before the board resulted from a combination of granted claims, namely claims 1, 3 and 11. Since the amendment was thus straight-forward, the auxiliary request should be admitted into the proceedings.

The board does not agree. First of all, the question to be answered under Article 12(4) RPBA is whether an amendment could have been filed already before the first instance, rather than whether the amendment is straight forward. Secondly, claim 1 of auxiliary request 2 now before the board does not result from simply writing out a claim dependency of a granted dependent claim in full. On the contrary, it results from a combination of *inter alia* granted claims 3 and 11, which are not dependent on each other. Thus the amendment is not straight-forward.

- 3.8 In views of this, the board decided not to admit auxiliary request 2 into the proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Cañueto Carbajo

W. Sieber

Decision electronically authenticated