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**Datasheet for the decision
of 13 December 2022**

Case Number: T 2057/21 - 3.3.09

Application Number: 13189113.7

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A23L33/21, A23L33/00

Language of the proceedings: EN

Title of invention:
High energy liquid enteral nutritional composition

Patent Proprietor:
N.V. Nutricia

Opponents:
Société des Produits Nestlé S.A.
Even Sante Industrie
Fresenius Kabi Deutschland GmbH

Headword:
High energy liquid enteral nutritional composition/NUTRICIA

Relevant legal provisions:
EPC Art. 76(1)

Keyword:

Divisional application - subject-matter extends beyond content of earlier application (yes)

Decisions cited:

T 1177/11, T 1621/16, T 3032/18

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 2057/21 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 13 December 2022

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 25 November
2021 revoking European patent No. 2687106
pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman A. Haderlein
Members: M. Ansorge
 N. Obrovski

Summary of Facts and Submissions

- I. The proprietor (appellant) lodged an appeal against the opposition division's decision to revoke the patent.
- II. With their notices of opposition, opponents 1 to 3 had requested that the patent be revoked on the grounds for opposition under, *inter alia*, Article 100(c) EPC in conjunction with Articles 76(1) and 123(2) EPC.
- III. The opposition division decided that neither the subject-matter of claim 1 of the patent as granted (main request) nor the subject-matter claimed in auxiliary requests 1 to 23 met the requirements of Articles 76(1) and 123(2) EPC.
- IV. Claim 1 of the patent as granted (main request) reads as follows:

"A liquid enteral nutritional composition comprising protein, said protein providing 15% to 30% of the total energy content of the composition, said protein including micellar casein and caseinate, the composition having an energy density of at least 10 kJ/ml [2.4 kcal/ml], wherein the weight ratio of micellar casein to caseinate ranges from 80:20 to 40:60, wherein said composition comprises less than or equal to 15 weight% whey of the total protein, and wherein the combined amount of micellar casein and caseinate is at least 85 weight% of total protein."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the feature "the composition further comprising fat providing between 20 to 40% of the total energy content of the composition, and

carbohydrates providing between 30 to 60% of the total energy content of the composition" has been added.

Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the feature "protein providing 15% to 30% of the total energy content" has been amended to "protein providing 16% of the total energy content".

Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 2 in that the feature "the composition further comprising fat providing 35% of the total energy content of the composition, and carbohydrates providing 49% of the total energy content of the composition" has been added.

Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 2 in that the feature "at least 10 kJ/ml [2.4 kcal/ml]" has been amended to "10 kJ/ml [2.4 kcal/ml]".

Claim 1 of auxiliary request 5 differs from claim 1 of auxiliary request 3 in that the feature "at least 10 kJ/ml [2.4 kcal/ml]" has been amended to "10 kJ/ml [2.4 kcal/ml]".

Claim 1 of auxiliary request 6 differs from claim 1 of auxiliary request 5 in that the feature "9.6 g protein per 100 ml of the composition of a mixture of micellar casein and caseinate with a weight ratio of 65:35" has been added.

Claim 1 of auxiliary request 7 differs from claim 1 of auxiliary request 6 in that the feature "wherein said composition comprises less than or equal to 15 weight% whey of the total protein, and wherein the combined

amount of micellar casein and caseinate is at least 85 weight% of total protein" has been deleted.

Claim 1 of auxiliary request 8 is identical to claim 1 of the main request.

Claim 1 of auxiliary request 9 is identical to claim 1 of auxiliary request 1.

Claim 1 of auxiliary request 10 is identical to claim 1 of auxiliary request 2.

Claim 1 of auxiliary request 11 is identical to claim 1 of auxiliary request 3.

Claim 1 of auxiliary request 12 is identical to claim 1 of auxiliary request 4.

Claim 1 of auxiliary request 13 is identical to claim 1 of auxiliary request 5.

Claim 1 of auxiliary request 14 is based on claim 1 of auxiliary request 6, wherein the feature "A liquid enteral nutritional composition" has been amended to "A heat-sterilized liquid enteral nutritional composition".

Claim 1 of auxiliary request 15 is based on claim 1 of auxiliary request 7, wherein the feature "A liquid enteral nutritional composition" has been amended to "A heat-sterilized liquid enteral nutritional composition".

Claim 1 of auxiliary request 16 is based on claim 1 of the main request, wherein the feature "A liquid enteral

nutritional composition" has been amended to "A heat-sterilized liquid enteral nutritional composition".

Claim 1 of auxiliary request 17 is based on claim 1 of auxiliary request 1, wherein the feature "A liquid enteral nutritional composition" has been amended to "A heat-sterilized liquid enteral nutritional composition".

Claim 1 of auxiliary request 18 is based on claim 1 of auxiliary request 2, wherein the feature "A liquid enteral nutritional composition" has been amended to "A heat-sterilized liquid enteral nutritional composition".

Claim 1 of auxiliary request 19 is based on claim 1 of auxiliary request 3, wherein the feature "A liquid enteral nutritional composition" has been amended to "A heat-sterilized liquid enteral nutritional composition".

Claim 1 of auxiliary request 20 is based on claim 1 of auxiliary request 4, wherein the feature "A liquid enteral nutritional composition" has been amended to "A heat-sterilized liquid enteral nutritional composition".

Claim 1 of auxiliary request 21 is based on claim 1 of auxiliary request 5, wherein the feature "A liquid enteral nutritional composition" has been amended to "A heat-sterilized liquid enteral nutritional composition".

Claim 1 of auxiliary request 22 is based on claim 1 of auxiliary request 6, wherein the feature "A liquid enteral nutritional composition" has been amended to "A

heat-sterilized liquid enteral nutritional composition".

Claim 1 of auxiliary request 23 is based on claim 1 of auxiliary request 7, wherein the feature "A liquid enteral nutritional composition" has been amended to "A heat-sterilized liquid enteral nutritional composition".

V. The parties' relevant arguments, submitted in writing and during the oral proceedings, are reflected in the reasons for the decision set out below.

VI. Requests

The appellant requested that the decision be set aside and that the case be remitted to the opposition division for assessing sufficiency of disclosure and inventive step with regard to the patent as granted (main request) or, alternatively, with regard to one of auxiliary requests 1 to 23.

Respondents 1 to 3 (opponents 1 to 3) requested that the appeal be dismissed.

Reasons for the Decision

Main request (claims of the patent as granted)

1. Article 76(1) EPC

1.1 The appellant argued that the opposition division erred in concluding that the subject-matter of claim 1 extended beyond the content of the parent application as filed. In particular, the appellant submitted that

there was sufficient basis in the parent application as filed for the feature "protein providing 15% to 30% of the total energy" on page 7, lines 23 to 27.

Furthermore, in its view there was a pointer in the parent application as filed to the multiple selections made, in particular in the examples.

1.2 For the following reasons, the board does not agree.

1.2.1 Compared to independent claim 2 of the parent application as filed, the following amendments (i) to (v) were made:

- (i) The feature "protein providing 10% to 30% of the total energy content of the composition" was amended to "protein providing 15% to 30% of the total energy content of the composition" (page 7, lines 23 to 27, of the parent application as filed).
- (ii) The feature "the composition having an energy density of at least 2.0 kcal/ml" was amended to "the composition having an energy density of at least 2.4 kcal/ml" (claim 3 of the parent application as filed).
- (iii) The feature "wherein the weight ratio of micellar casein to caseinate ranges from 80:20 to 40:60" was introduced (page 9, lines 6 to 8, of the parent application as filed).
- (iv) The feature "wherein said composition comprises less than or equal to 15 weight% whey of the total protein" was introduced (page 8, lines 25 to 30, of the parent application as filed).

(v) The feature "wherein the combined amount of micellar casein and caseinate is at least 85 weight% of total protein" was introduced (page 8, lines 16 to 20, of the parent application as filed).

1.2.2 All of the parties agreed that amendments (i) to (v) represent multiple selections requiring a pointer towards this specific combination of features in the parent application as filed in order to meet the requirement of Article 76(1) EPC.

1.2.3 A first point of disagreement between the parties was whether there is a basis in the parent application as filed for amendment (i) (see point 1.2.1 above). The opposition division considered this amendment critical, and so does the board. In particular, the board does not see the implicit disclosure of an upper limit of 30% for the total energy content of the composition with regard to the range specified by the phrase "at least 15%", as alleged by the appellant with reference to page 7, lines 23 to 27, of the parent application as filed. In this context, page 8, lines 3 to 5, of the parent application as filed makes it clear that the term "at least" in the phrase "at least 15%" designates an open range, and not a closed range having an implicit upper limit. Moreover, contrary to the appellant's opinion, the range "at least 15%" is not indicated in the parent application as filed as being the most preferred lower limit.

1.2.4 Even if the crucial issue regarding amendment (i) were merely whether there is a pointer to the multiple selections as argued by the appellant, including a pointer to the range "15% to 30%", the board cannot see such a pointer either in the general part of the

specification or in the examples. All of the examples have a point-like value of 16.0% which cannot be considered to be a pointer to the range of "15% to 30%".

- 1.2.5 The appellant was of the opinion that amendment (i) did not lead to a violation of Article 76(1) EPC since the ruling in T 3032/18 was applicable to the current case by analogy.

The board does not agree, since the case underlying T 3032/18 substantially differs from the case at hand. In T 3032/18, the deciding board considered that the newly created range of "3.0 to 12.0" was derived from the combination of the open broad range "at least about 3.0" and the closed range "from about 4.0 to about 12.0" which was fully enclosed in the broader open range. The newly created range was considered to be unambiguously disclosed in the application as filed.

In contrast to the case underlying T 3032/18, in the present case the closed range "10% to 30%" (disclosed in claim 2 of the parent application as filed and on page 7, lines 23 to 27) is not fully enclosed in the open range of "at least 15%". Rather, this open range merely overlaps with the explicitly disclosed range of "10% to 30%". For this reason alone, the conclusions reached in T 3032/18 cannot be applied to the present case.

- 1.2.6 Like T 3032/18, T 1177/11 also dealt with a situation in which a closed range of "1 wt% to 3 wt%" was fully enclosed within a broader open range of "less than 10 wt%". Thus, the conclusions in T 1177/11 cannot be applied to the present case either.

1.2.7 The appellant further argued that the principles of T 1621/16 (see catchword) were applicable to the present case and that these supported the fact that amendments (i) to (v) were in line with Article 76(1) EPC.

However, for the reasons outlined under point 1.2.4 above, there is no pointer to the combination of features introduced by amendments (i) to (v). Thus, at least the criterion according to which there needs to be a pointer to the combination of features resulting from the multiple selections (as also laid down in T 1621/16, see point 2) of the catchword) is not met in the present case.

1.2.8 The appellant argued that the features introduced by amendments (iv) and (v) were complementary to one other. There were no other proteins mentioned in the parent application as filed, so in the appellant's view there was an implicit teaching of micellar casein, caseinate and whey constituting all of the protein content.

The board does not agree.

While the feature "wherein the combined amount of micellar casein and caseinate is at least 85 weight% of total protein" (amendment (v)) is disclosed on page 8, lines 16 to 20, of the parent application as filed as being preferred, an amount of less than or equal to 15 weight% whey of the total protein (amendment (iv)) is not mentioned as being preferred (see page 8, lines 26 to 30, of the parent application as filed). Thus, the latter passages on page 8 of the parent application as filed do not represent a pointer to the combination of features as introduced by amendments (iv) and (v).

Moreover, not all of the values given for the lower limit of micellar casein and caseinate in the passage on page 8, lines 16 to 20, find complementary values for the maximum values of the whey content in the passage on page 8, lines 25 to 30.

As explained on page 8, lines 25 and 26, of the parent application as filed, the composition of the present invention should not contain large amounts of proteins other than micellar casein and caseinate. This passage has to be understood to mean that proteins other than micellar casein and caseinate may be present in the composition. This is in line with the fact that the liquid enteral nutritional composition according to claim 1 is defined in an open manner by the use of the term "comprising" and not in a closed manner excluding the presence of other proteins. Consequently, in case of having a combined amount of micellar casein and caseinate of, for instance, 85%, the amount of whey protein does not automatically need to be 15% (forming the remainder to add up to 100%). On the contrary, whey protein may be present in lower amounts so that other proteins, such as soy protein, may be present as well. This is also confirmed by the passage on page 8, lines 21 to 24, which indicates that the combined amount of micellar casein, caseinate and whey does not need to be 100% of the total protein. Accordingly, there is no necessary complementarity between the features introduced by amendments (iv) and (v).

In view of the above, the subject-matter of claim 1 does not meet the requirement of Article 76(1) EPC, and therefore the ground for opposition under Article 100(c) EPC prejudices the maintenance of the patent.

Auxiliary requests 1 - 23

2. For the same reasons as outlined above for the main request, the subject-matter of claim 1 of auxiliary requests 1, 8, 9, 16 and 17 does not comply with Article 76(1) EPC either.

3. The subject-matter of claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the feature "protein providing 15% to 30% of the total energy content" has been limited to "protein providing 16% of the total energy content" (a point-like value).

While the appellant argued that there was a basis for this amendment on page 7, lines 27 to 29, of the parent application as filed, the board notes that the embodiment mentioned on page 7, lines 27 to 29, concerns an open range of "at least 16%" and not the point-like value of 16%. Thus, the question arises of whether the examples of the parent application as filed - all of which mention that protein provides 16.0% of the total energy content of the composition - can be generalised.

When analysing whether the feature "protein providing 16% of the total energy content of the composition" can be generalised from the specific examples to the general context of the parent application as filed, it is striking that all of the examples contain specific carbohydrates, i.e. maltodextrose (DE 47) alone or maltodextrose (DE 47) in combination with sucrose and trehalose. These specific carbohydrates are mentioned in the specification as giving rise to a low viscosity (see page 12, line 14, to page 13, line 2). This is also in conformity with

Examples 1 to 5 of the parent application as filed, which indicate that the liquid compositions have specific low viscosity values between 70 mPa·s and 110 mPa·s. In this context, it is noted that achieving a sufficiently low viscosity to allow the composition to be easily consumed orally or administered by tube is one of the crucial properties envisaged in the parent application as filed (see page 3, lines 4 to 15; page 4, line 29, to page 5, line 2; page 6, lines 8 to 12; and page 6, line 26, to page 7, line 1).

Consequently, the feature "protein providing 16% of the total energy content of the composition" is inextricably linked at least to the specific choice of carbohydrates used in the examples, which give rise to a low viscosity. Thus, this amendment to claim 1 represents an unallowable intermediate generalisation.

In view of the above, the subject-matter of claim 1 of auxiliary request 2 does not meet the requirements of Article 76(1) EPC.

4. For the same reasons as outlined above for auxiliary request 2, the subject-matter of claim 1 of auxiliary requests 3 to 7, 10 to 15 and 18 to 23 does not comply with Article 76(1) EPC.

Limiting the energy density of the composition to the point-like value of 2.4 kcal/ml (see claim 1 of auxiliary requests 4 to 7, 12 to 15 and 20 to 23), as exemplified in all of the examples of the parent application as filed, does not change the negative assessment under Article 76(1) EPC, since the problem identified with respect to auxiliary request 2 also

applies to the subject-matter of claim 1 of auxiliary requests 3 to 7, 10 to 15 and 18 to 23.

5. In view of the above, there is no allowable claim request on file.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

A. Haderlein

Decision electronically authenticated