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Datasheet for the decision of 7 August 2024

Case Number: T 1291/22 - 3.3.09

Application Number: 13817809.0

Publication Number: 2934160

IPC: A23L33/00

Language of the proceedings: EN

Title of invention:
LOW VISCOSITY, HIGH CALORIC DENSITY ORAL NUTRITIONAL COMPOSITION AND RELATED METHODS

Patent Proprietor:
ABBOTT LABORATORIES

Opponents:
Nutricia Research B.V.
Fresenius Kabi Deutschland GmbH

Headword:
Oral nutritional composition/ABBOTT

Relevant legal provisions:
EPC Art. 123(2), 83, 54, 56
RPBA 2020 Art. 12(4), 12(6), 13(2)

Keyword:
Amendments - allowable (yes)
Sufficiency of disclosure - (yes)
Novelty - (yes)
Inventive step - non-obvious modification

Decisions cited:
T 2399/10, T 0797/14, T 0842/14

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Case Number: T 1291/22 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 7 August 2024

Appellant: (Opponent 1)	Nutricia Research B.V. Uppsalalaan 12 3584 CT Utrecht (NL)
Representative:	Hoijer, Maarten Anne N.V. Nutricia Uppsalalaan 12 3508 TC Utrecht (NL)
Appellant: (Opponent 2)	Fresenius Kabi Deutschland GmbH Else-Krömer-Strasse 1 61352 Bad Homburg (DE)
Representative:	Fresenius Kabi Deutschland GmbH Patent Department Pharmaceuticals Division Borkenberg 14 61440 Oberursel (DE)
Respondent: (Patent Proprietor)	ABBOTT LABORATORIES 100 Abbott Park Road Abbott Park, IL 60064-3500 (US)
Representative:	Boult Wade Tennant LLP Salisbury Square House 8 Salisbury Square London EC4Y 8AP (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 25 February 2022 concerning maintenance of the European Patent No. 2934160 in amended form.**

Composition of the Board:

Chairman	A. Haderlein
Members:	F. Rinaldi
	A. Jimenez

Summary of Facts and Submissions

I. This decision concerns the appeals filed by opponents 1 and 2 (appellants 1 and 2) against the opposition division's interlocutory decision that the European patent as amended met the requirements of the EPC.

II. With their respective notice of opposition, opponents 1 and 2 had requested that the patent be revoked under Article 100(a) (lack of novelty and lack of inventive step), (b) and (c) EPC.

III. The documents submitted during the opposition proceedings included:

D1: WO 2009/072885 A1
D5: Mintel database: Record ID 1012294 ("Abbott Ensure TwoCal")
D6: WO 2010/140891 A2
D16: WO 2009/072886 A1
D26: WO 2012/008858 A1

IV. In the decision under appeal, auxiliary request 1 (filed by letter dated 25 September 2020) was found to be allowable. This request is the main request on appeal.

V. The wording of product claims 1, 3 and 8 of the main request is relevant to this decision, and is set out below.

"*1. A low viscosity, high caloric density liquid nutritional composition comprising:*
a) protein in an amount of between 8 to 27 grams per 100 mL of the nutritional composition, the protein comprising (i) non-micellar milk protein isolate, non-micellar milk protein concentrate, or both, and (ii) a partially hydrolyzed caseinate; wherein the protein comprises 0-25% by weight of protein from a partially hydrolyzed caseinate; 25-50% by weight of protein selected from the group consisting of whey protein, soy protein, pea protein, potato protein and combinations thereof; and 50 to 75% by weight of non-micellar milk protein isolate, non-micellar milk protein concentrate or a combination thereof;
b) fat in an amount of between 0 and 17 grams per 100 mL of the nutritional composition; and
c) at least one emulsifier selected from the group consisting of lecithin, monoglycerides, diglycerides, polyglycerol esters, milk phospholipids, citric acid esters, datem and emulsifiers with a hydrophilic-lipophilic balance between 5 and 16, and combinations thereof;
wherein the nutritional composition has a viscosity of between 45 and 140 cps at 22°C, a caloric density of 200 to 300 kcal per 100 mL of the nutritional composition, and wherein the total combined amount of fat and protein is 8-27 grams per 100 mL of the nutritional composition."

"*3. A low viscosity, high caloric density liquid nutritional composition according to claim 1, wherein the non-micellar protein is denatured through one or more of hydrolysis, heat treatment, homogenization, or reaction with soluble divalent minerals.*"

"*8. A low viscosity, high caloric density liquid nutritional composition comprising:*
a) protein in amount of between 8 to 27 grams per 100 mL of the nutritional composition;
b) fat in an amount of between 0 and 17 grams per 100 mL of the nutritional supplement;
c) an anti-foaming agent selected from the group consisting of simethicone, dimethylpolysiloxane, silicone dioxide, lecithin, milk phospholipid, and combinations thereof; and
d) a chelating agent selected from the group consisting of monovalent chelating agents, divalent chelating agents, and combinations thereof; in an amount of 0.3 weight% to 0.5 weight%;
where the protein comprises: 50-75% by weight of non-micellar milk protein isolate, non-micellar milk protein concentrate or a combination thereof; and partially hydrolyzed caseinate in an amount of up to 50% by weight of partially hydrolyzed caseinate, or up to 25% by weight of partially hydrolyzed caseinate and 0-25% by weight of at least one protein selected from the group consisting of: micellar milk protein, non-hydrolyzed caseinate, soy, pea, whey, rice, corn, meat, fish, egg albumen, potato, canola, algal protein, mycoprotein and combinations thereof;
wherein the nutritional composition has a viscosity of between 45 and 140 cps at 22°C; wherein the composition has a caloric density of 200 to 300 kcal per 100 mL of the nutritional supplement; and wherein the total combined amount of fat and protein is 8-27 grams per 100 mL of the nutritional composition."

Claim 15 is an independent claim directed to a method for manufacturing a low viscosity, high caloric density liquid nutritional composition. The method involves the the step of adding protein comprising partially

hydrolysed caseinate and non-micellar milk protein selected from the group consisting of non-micellar milk protein isolate, non-micellar milk protein concentrate, and combinations thereof. The wording of this claim is not relevant.

VI. On appeal, the patent proprietor (respondent) filed nine auxiliary requests (numbered 1 to 9). Among other things, appellant 2 filed the following document after notification of the board's communication under Article 15(1) RPBA:

D29: K. Smith, "Dried Dairy Ingredients", Wisconsin Center for Dairy Research, 2008, 5 and 20

VII. The following arguments were raised against the claims of the main request.

- Appellant 2 argued that claim 3 did not comply with the requirement of Article 123(2) EPC. This claim was a combination of claims 1, 3 and 4 of the application as filed. There was no basis in the application as filed for this combination.
- Appellant 1 argued that claim 8 did not comply with the requirement of Article 123(2) EPC and that claim 1 did not comply with the requirement of Article 123(3).
- Appellants 1 and 2 asserted that even when taking the description of the patent into consideration, the skilled person would not have known how to provide the non-micellar protein called for in the claims. In particular, the milk protein isolate and milk protein concentrate used in the examples of the patent were apparently in micellar form. Non-micellar milk protein isolate and non-micellar milk

protein concentrate were not commercially available.

- Appellants 1 and 2 maintained that partially hydrolysed caseinate was not a mandatory feature of claims 1 and 8. The compositions claimed did not need to comprise this ingredient. It followed from this that the subject-matter of claims 1 and 8 lacked novelty over D26. In addition, appellant 1 considered these claims to lack novelty over D1.
- Appellants 1 and 2 stated that inventive step could be assessed from any of documents D1, D6, D16 or D26. Appellant 1 used D1 and D26 as starting points to outline its objections of a lack of inventive step. Appellant 2 based its objections of a lack of inventive step on either D6 or D26 as a starting point. In all cases, the conclusion was that claim 1 lacked an inventive step and the same applied to claims 8 and 15.

VIII. The respondent's arguments, where relevant to the decision, can be summarised as follows:

- Claim 3 did comply with the requirement of Article 123(2) EPC. No new combination of features was generated by the amendment in claim 1.
- Appellant 1's objections against claim 8 under Article 123(2) EPC and against claim 1 under Article 123(3) EPC had not been made prior to the appeal proceedings. They should not be admitted on appeal.
- The skilled person would have known how to produce and identify the non-micellar milk protein products called for in the claim. They simply had to break down the micellar structure of the specified protein.

- The subject-matter of claims 1 and 8 was novel. It was clear from both the wording of the claims and the patent's description that partially hydrolysed caseinate was a mandatory feature of these claims.
- The subject-matter of claims 1, 8 and 15 did involve an inventive step. The closest prior art was example 2 of D26. There were numerous distinguishing features, including the inclusion of partially hydrolysed caseinate. D1 and D6 required micellar caseinate and were not the closest prior art.

IX. Final requests

Appellants 1 and 2 requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed (main request) or, alternatively, that the patent be maintained in amended form based on the claims of one of auxiliary requests 1 to 4 as filed with the reply to the appellants' statements setting out the grounds of appeal, or of one of auxiliary requests 5 to 9 as filed by letter dated 7 March 2024.

Reasons for the Decision

1. *Patent in suit*

1.1 The patent is directed to nutritional compositions displaying high caloric density and low viscosity, and a method for manufacturing such compositions.

1.2 Product claims 1 and 8 of the main request are directed to compositions in which the protein comprises 50 to 75% by weight of non-micellar milk protein isolate, non-micellar milk protein concentrate or a combination thereof, and specified amounts of further protein components. Method claim 15 of the main request is directed to a method for manufacturing a low viscosity, high caloric density liquid nutritional composition. The method involves the step of adding protein comprising partially hydrolysed caseinate and non-micellar milk protein.

2. *Claim interpretation*

2.1 In the decision under appeal, the opposition division acknowledged that there was a discrepancy in claim 1 of the current main request; while claim 1 included the value 0% of a partially hydrolysed caseinate, this ingredient was listed as being compulsory in the nutritional composition of claim 1. However, taking the patent specification into consideration, the range "0-25%" had to be interpreted as "more than 0 to 25%".

2.2 This part of the decision was contested and the following arguments were presented.

2.2.1 The wording used in claim 1 ("comprises 0-25% by weight of protein from a partially hydrolyzed caseinate") meant that the composition of claim 1 did not necessarily comprise partially hydrolysed caseinate. The value 0% made it clear that partially hydrolysed caseinate was merely an optional ingredient of the composition of claim 1.

2.2.2 Moreover, if there were two possible interpretations, then for legal certainty the broader interpretation had to be applied, to the patent proprietor's disadvantage.

2.2.3 Furthermore, the patent's description endorsed the interpretation that partially hydrolysed caseinate was an optional ingredient. Firstly, example 2 of the patent did not (explicitly) disclose that the caseinate used was partially hydrolysed. Secondly, the patent specification referred to two passages of paragraph [0024] of the patent that confirmed this understanding and read as follows:

"*When used in the disclosed liquid nutritional compositions, the partially hydrolyzed caseinate ...*"

"*When present in the disclosed embodiments, the partially hydrolyzed caseinate...*" (emphasis added).

2.2.4 Finally, claim 8 did not require partially hydrolysed caseinate as a mandatory feature.

2.3 Interpretation of claim 1

2.3.1 Claim 1 of the application as filed and claim 1 as granted relate to a low viscosity, high caloric density liquid nutritional composition which comprises, among other things,

(i) non-micellar milk protein isolate, non-micellar milk protein concentrate, or both, and
(ii) a partially hydrolysed caseinate

2.3.2 During the first-instance opposition proceedings, claim 1 as granted was restricted by the addition of features from dependent claim 3 as granted. Among other features, the amount of partially hydrolysed caseinate ("0-25% by weight of protein from a partially hydrolyzed caseinate") was added to claim 1.

2.3.3 Due to this amendment, claim 1 of the main request encompasses the feature:

"(i) non-micellar milk protein isolate, non-micellar milk protein concentrate, or both, and (ii) a partially hydrolyzed caseinate; wherein the protein comprises 0-25% by weight of protein from a partially hydrolyzed caseinate ..." (emphasis added by the board).

2.3.4 A straightforward reading of claim 1 imposes a specific hierarchy of the features in this claim. It is plain to see that the two ingredients (i) and (ii) of the composition of claim 1 are necessarily part of the composition.

2.3.5 After the semicolon, further features of claim 1 are specified. Among other things, the weight% distribution of the various proteins that form the composition's protein fraction is specified. In other words, the semicolon imposes a sequential reading of the claim, which involves two separate requirements. The first requirement is that partially hydrolysed caseinate is part of the composition of claim 1. This first requirement is restricted - but not eliminated - by the

second requirement, namely that the amount is necessarily 0 to 25% by weight of the protein.

2.3.6 Given the specific wording and structure, claim 1 is considered to specify that the partially hydrolysed caseinate cannot be left out of the composition according to claim 1. On the contrary, it is a mandatory ingredient of claim 1. Therefore, in this claim the value 0% has to be read and understood as meaning "above 0%" (or starting from 0%, with 0% being excluded). This is the interpretation which the opposition division correctly adopted.

2.3.7 As an intermediate conclusion, it is plain to see from the wording of claim 1 alone that partially hydrolysed caseinate is a mandatory ingredient. Contrary to the appellants' view, there is only one interpretation that applies.

2.3.8 For completeness, it is noted that the patent specification supports this interpretation.

2.3.9 All three embodiments discussed in detail in the patent (paragraphs [0006] to [0008] and [0010] to [0012]) unambiguously disclose that partially hydrolysed caseinate is a mandatory ingredient. The passage to which appellant 2 referred, paragraph [0024], corroborates this. It starts as follows:

"*As previously discussed, according to the first, second and third embodiments, the compositions include a partially hydrolysed caseinate*".

2.3.10 Within the context of this paragraph, the features specified after the terms "[w]hen used" and "[w]hen present" (see section 2.2.3 above) are understood to

define the specific partially hydrolysed caseinate that is added to the compositions of the patent. These features are not to be understood as definitions of partially hydrolysed caseinate that apply in general, i.e. outside the context of the patent and its compositions.

2.3.11 Finally, while example 2 of the patent does not explicitly disclose that the sodium caseinate used therein is partially hydrolysed, this alone cannot serve to confirm that partially hydrolysed caseinate is merely an optional ingredient of claim 1.

2.3.12 To conclude, in the context of claim 1, the value 0% has to be read and understood as meaning "above 0%".

2.4 Interpretation of claim 8

2.4.1 The appellants gave no specific reasoning for their assessment that according to claim 8 partially hydrolysed caseinate was an optional feature.

2.4.2 Claim 8 discloses that the amount of partially hydrolysed caseinate is "up to 50%" or "up to 25%", depending on the embodiment. Similar considerations to those set out with respect to claim 1 apply to the wording of claim 8. The maximum amount of partially hydrolysed caseinate ("up to 50%" or "up to 25%") in the context of claim 8 implies that the amount of this ingredient is not 0%; partially hydrolysed caseinate is a mandatory ingredient.

2.5 To conclude on claim interpretation, independent claims 1 and 8 of the main request call for partially hydrolysed caseinate as a mandatory ingredient of the low viscosity, high caloric density liquid nutritional

composition. This claim interpretation will be used in the following.

3. *Admittance of D29*

3.1 Appellant 2 filed document D29 after notification of the board's communication under Article 15(1) RPBA. The respondent argued that this document should not be admitted into the proceedings.

3.2 Appellant 2 did not refer to any exceptional circumstances justifying the filing of this document. It had filed D29 merely to demonstrate that according to common general knowledge, to which D29 allegedly belonged, milk protein concentrate and milk protein isolate contained micellar casein and whey protein.

3.3 However, Article 13(2) RPBA makes no exception for documents considered by a party to be proof of common general knowledge. In addition, the typical composition of conventional milk protein concentrate and milk protein isolate as such is not in dispute.

3.4 Therefore, the board cannot see any reason to take this document into account in these proceedings (Article 13(2) RPBA).

4. *Main request - amendments*

4.1 The opposition division decided that the claims of what was then auxiliary request 1 (now the main request) complied with the requirement of Article 123(2) EPC.

4.2 Appellant 2 argued that claim 3 involved added subject-matter. Appellant 1 argued that claim 8 involved added subject-matter.

4.3 Amendment to claim 3

4.3.1 According to appellant 2, claim 3 (of the main request) was based on claim 4 of the application as filed. Claim 1 of the main request was based on a combination of claims 1 and 3 of the application as filed. It followed from this that claim 3 of the main request was a combination of claims 1, 3 and 4 of the application as filed, for which there was no basis in the application as filed.

4.3.2 It is true that claim 4 of the application as filed is not dependent on claim 3 of the application as filed. However, claim 4 of the application as filed discloses possible measures for preparing non-micellar milk protein. The only non-micellar milk proteins mentioned both in the application as filed and in the patent are non-micellar milk protein isolate and non-micellar milk protein concentrate. Therefore, claim 3 of the main request simply sets out the different ways the non-micellar protein of claim 1 of the main request can be made.

4.3.3 Paragraph [0017] of the application as filed further supports this general teaching. While further features are disclosed in this paragraph on how non-micellar proteins are prepared (e.g. homogenisation conditions), the skilled person would realise that they would not be obliged to apply all the specific embodiments or conditions taught in this paragraph. The teaching in claim 4 of the application as filed is generic.

4.3.4 Therefore, claim 3 of the main request does not encompass added subject-matter. Its combination with the subject-matter of claim 1 of the main request would

be directly and unambiguously derivable for the skilled person.

4.4 Amendment to claim 8

4.4.1 Appellant 1 did not raise any objection of added subject-matter with respect to claim 8 of auxiliary request 1 before the opposition division; it did so only on appeal. The respondent argued that this was a new objection which should not be admitted into the proceedings.

4.4.2 As is clear from the minutes of the oral proceedings before the opposition division and the decision under appeal, no objection of added subject-matter was raised against claim 8, despite the fact that the claim wording had been known to the opponents for more than a year before the oral proceedings. Thus, appellant 1 could and should have presented its objection during the opposition proceedings.

4.4.3 Therefore, this objection was not admitted on appeal (Article 12(4) and (6) RPBA).

4.5 To conclude, the main request complies with the requirement of Article 123(2) EPC.

5. *Main request - requirement of Article 123(3) EPC*

5.1 In the decision under appeal (point 19.2.1), it is stated that the opponents had no objections under Article 123(3) EPC. However, in its statement setting out the grounds of appeal, appellant 1 did raise such an objection. The respondent argued that this new objection should not be admitted into the proceedings.

5.2 Appellant 1's objection raised on appeal represents an amendment to its appeal case. It could and should have presented its objection during the opposition proceedings.

5.3 Therefore, this objection was not admitted into the proceedings (Article 12(4) and (6) RPBA).

6. *Main request - sufficiency of disclosure*

6.1 The opposition division concluded that the invention set out in the claims corresponding to the current main request met the requirement of Article 83 EPC.

6.2 The appellants contested this conclusion and presented the following arguments.

6.2.1 Even when taking the description of the patent into consideration, the skilled person would not have known how to provide the non-micellar protein called for in the claims. In particular, the milk protein isolate and milk protein concentrate used in the examples of the patent were apparently in micellar form. The non-micellar protein of claim 1 was not commercially available. Decisions T 2399/10, T 797/14 and T 842/14 were cited to support these arguments.

6.2.2 In the course of the appeal proceedings and during the oral proceedings before the board, appellant 2 further refined its line of argument. It conceded that preparing non-micellar protein was trivial. However, according to common general knowledge the casein in milk protein isolate and milk protein concentrate was in micellar form. It followed from this that the skilled person would not have known how to resolve the

contradiction and produce non-micellar milk protein isolate or non-micellar milk protein concentrate.

6.3 The arguments provided by the appellants have not convinced the board.

6.4 First and foremost, the skilled person knows how to destroy the micellar structure of proteins. Appellant 2 itself confirmed this during the oral proceedings before the board.

6.5 Therefore, to provide the non-micellar components of claim 1, all the skilled person has to do is break down (or denature) the micellar structure which is intrinsic to the milk protein isolate and milk protein concentrate. This way, the micellar structure originally contained in these proteins is destroyed. The resulting proteins are a non-micellar milk protein isolate and a non-micellar milk protein concentrate.

6.6 In doing this, the skilled person is not bound to instructions in the patent in suit. Instead, they can use their common general knowledge and known methods such as calcium depletion.

6.7 Against this background, it is conclusive that the patent outlines only in very generic terms what can be done to provide the non-micellar components of claim 1 ("hydrolysis, heat treatment, reaction with soluble divalent minerals, and combinations thereof" (paragraph [0018]).

6.8 As the respondent explained, micelles are identified by microscopy - and if they are not detected, then the protein examined is non-micellar. While this is not explicitly disclosed in the patent in suit, it is

something that the skilled person would straightforwardly understand upon reading the patent. In view of this, the board does not consider there to be an undue burden for the skilled person to provide nutritional compositions in which the protein comprises 50 to 75% by weight of non-micellar milk protein isolate, non-micellar milk protein concentrate or a combination of the two.

6.9 On this basis, the board cannot identify any lack of sufficiency of disclosure.

6.10 For completeness, the following observations are made with respect to the additional arguments provided by the appellants.

6.10.1 Given that the skilled person can prepare the non-micellar milk protein isolate and non-micellar milk protein concentrate required by claim 1, it is not relevant whether such products can be bought. Nor is it relevant to assess whether the specific commercial milk protein products used in the examples are in a non-micellar form.

6.10.2 It follows from this that decision T 842/14, as cited by the appellants, is not relevant. This decision concerns a case in which the chemical composition of the anti-foam reagents of claim 1 was "made available to the skilled person, if at all, only by being commercially available" (Reasons, 32). In the current case, the situation is different. A specific, commercial product is not required by claim 1, and the skilled person would not be obliged to carry out the invention with a product that they cannot prepare themselves and would have to purchase.

6.10.3 For analogous reasons, T 797/14 is not relevant either. In the case underlying this decision, the preferred and unique coating composition was a product commercialised under a specific trade mark. Its composition and method of production was not public knowledge and was kept secret by the manufacturer. However, this is not the case with the non-micellar protein required by claim 1.

6.10.4 The appellants also referred to T 2399/10. However, this decision is not applicable in the current case either. T 2399/10 refers to an insufficiently disclosed dimensional parameter. The competent board considered that the method for establishing the parameter was neither disclosed in the patent nor to be found in the prior art. In contrast, the terms "non-micellar milk protein concentrate" and "non-micellar milk protein isolate" in the present case are not parameters. Rather, the terms denote a protein that is treated such that it is no longer in the form of micelles. As discussed above, such a protein can be prepared by the skilled person.

6.11 Finally, it is noted that in the decision under appeal it is stated that "calcium-depleted MPC of D26 was considered by all parties as a non-micellar MPC" (Reasons, 19.6.3). D26 is a prior-art document which was used as the closest prior art in the decision under appeal.

6.11.1 For the board, this confirms that in the field of liquid nutritional compositions, the skilled person would have known what a non-micellar milk protein concentrate ("non-micellar MPC") is. They would have been able to identify it in the prior art.

6.11.2 At this juncture it is also noted that the process for obtaining the calcium-depleted milk protein concentrate of D26 disclosed in claim 1 involves both a heat treatment and removal of calcium ions. This corresponds to the process steps for producing non-micellar protein outlined in the patent (see point 6.7 above).

6.12 To conclude, the invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC).

7. *Main request - novelty*

7.1 The opposition division concluded that claim 1 was novel over D1 and D26, among other documents. The appellants contested this.

7.2 The arguments of appellants 1 and 2 on a lack of novelty are based on the interpretation that partially hydrolysed caseinate is not a mandatory ingredient of the composition of claim 1. As explained in point 2 above, the board does not agree with this interpretation.

7.3 Neither D1 nor D26 discloses at least the feature of partially hydrolysed caseinate. Furthermore, the appellants' argument that the caseinate disclosed in D1 and D26 implicitly includes fragments of caseinate which the skilled person would then consider to be (trace amounts of) partially hydrolysed caseinate was not convincing. This is not what the skilled person would directly and unambiguously derive from the disclosure of D1 and D26.

7.4 On this basis, and in agreement with the opposition division's conclusion, the subject-matter of claim 1 is

found to be novel over the disclosure of D1 and D26 (Article 54 EPC).

8. *Main request – inventive step*

8.1 The opposition division concluded that the subject-matter of claims 1 and 8 of the current main request involved an inventive step. D26 was considered to be the closest prior art. Nevertheless, the opposition division also discussed approaches starting from other documents.

8.2 The appellants stated that inventive step could be assessed starting from any of documents D1, D6, D16 or D26.

8.3 Selection of the closest prior art

8.3.1 The assessment of inventive step starting from more than one document should be the exception rather than the rule. In the current case, the opposition division identified D26 as the closest prior art. Among the documents referred to by the appellants for assessing inventive step, this is the only document that relates to a liquid nutritional composition which comprises calcium-depleted (i.e. non-micellar) milk protein concentrate (see also section 6.11 above).

8.3.2 Therefore, D26 is used as the closest prior art in the following.

8.3.3 Neither D1 nor D6 is suitable as a starting point for assessing inventive step. Both documents disclose micellar casein as a mandatory ingredient. This runs counter to the subject-matter claimed and, thus, to the purpose of the patent. In fact, in order to arrive at

the claimed subject-matter starting from D1 or D6, the skilled person would have to replace large amounts (or even all) of the mandatory ingredients of micellar casein. In other words, the skilled person would have to depart from the core teaching of these two documents.

8.3.4 Appellant 2 did not set out why it considered D16 to be the closest prior art and why the claimed subject-matter was obvious starting from this document. In the absence of reasoning as to why the opposition division's conclusions were incorrect, this objection does not have to be considered.

8.3.5 To sum up, the board agrees with the opposition division that D26 is to be considered the closest prior art.

8.4 Closest prior art and distinguishing features

8.4.1 As discussed during the oral proceedings before the board, example 2 of D26 is the fat-containing, high caloric density composition from which the assessment of inventive step is to begin. The liquid nutritional composition disclosed in this example comprises calcium-depleted (i.e. non-micellar) milk protein concentrate as the only source (i.e. 100%) of protein. In view of this, the calcium-depleted protein does not provide 50 to 75% by weight of protein of non-micellar milk protein isolate or non-micellar milk protein concentrate.

8.4.2 Accordingly, claim 1 differs from example 2 of D26 at least by the following features:

- partially hydrolysed caseinate, in an amount of up to 25% by weight of protein
- non-micellar milk protein isolate or non-micellar milk protein concentrate or both, in an amount of 50 to 75% by weight of protein
- whey protein, soy protein, pea protein, potato protein or combinations thereof, in an amount of 25 to 50% by weight of protein

8.5 Technical effect and problem to be solved

8.5.1 It was in dispute between the parties whether the distinguishing features provided any specific technical effect. The patent proprietor's position was that this was the case, whereas the appellants took the view that the distinguishing features simply resulted in a further alternative to the composition of D26.

8.5.2 The opposition division regarded the objective technical problem as being to provide an alternative nutritional composition having high nutritional caloric density and a reduced viscosity. For the sake of argument, and in favour of the appellants' line of argument, the board will start from the same assumption. Considering that the subject-matter of claim 1 is found to involve an inventive step on this basis alone, it is not necessary to decide whether the distinguishing features bring about any additional technical effect.

8.5.3 At the oral proceedings before the board, appellant 2 argued that in view of the distinguishing features, partial problems had to be formulated. The aim of formulating two problems was to call out two different, sequential selections of ingredients replacing the calcium-depleted milk protein concentrate of D26.

However, as the problem formulated by the board does not in itself exclude a sequential selection of ingredients, the question of whether partial problems should be formulated can remain open.

8.5.4 To conclude, the problem to be solved is to provide an alternative nutritional composition having high nutritional caloric density and a reduced viscosity.

8.6 Non-obviousness

8.6.1 In D26, the use of 100% calcium-depleted milk protein is preferred (as in example 2). However, page 8 (lines 13 to 16) of D26 discloses that "[o]ther protein that may be included in amounts up to 49% include whey proteins, preferably provided from a whey protein concentrate ...". Therefore, the only protein explicitly mentioned in D26, aside from the calcium-depleted milk protein concentrate, is whey protein. This protein may be provided as a whey protein concentrate.

8.6.2 Considering that D26 prefers the use of a single protein, namely calcium-depleted milk protein concentrate, the board cannot identify any motivation to add whey protein and then also a third protein, i.e. partially hydrolysed caseinate, while expecting the composition to still have a suitable viscosity. On this basis, the skilled person would not have been motivated to add up to 25% by weight of protein of a partially hydrolysed caseinate to the composition of D26.

8.6.3 The combination of the closest prior art with D6, for example, does not render obvious the subject-matter of claim 1 either. D6 requires high amounts of micellar casein as a mandatory ingredient and only mentions

intact caseinate, whereas D26 suggests preferably using only calcium-depleted milk protein concentrate. The skilled person would not have made the adjustments the appellants suggested because this would have meant combining somewhat opposed teachings.

8.6.4 The main line of argument of appellant 2 on obviousness was that it would be obvious to replace part of the calcium-depleted milk protein concentrate by (intact) sodium caseinate. In this context, several documents were cited, including D1, D5 and D16. All these documents showed that (sodium) caseinate was commonly used in liquid enteral compositions having high energy and a high protein content. Appellant 2 further maintained that commercially available caseinates intrinsically comprised a certain amount of partially hydrolysed caseinate. It followed from this that adding caseinate led to the subject-matter of claim 1.

8.6.5 However, as already explained above, it is not convincing that starting from example 2 of D26, the skilled person would not only add whey protein but also a further, third protein. Nor is it convincing that they would replace part of the calcium-depleted milk protein concentrate with two proteins, whey protein and a further protein, namely (intact) sodium caseinate. On this basis alone, the subject-matter of claim 1 is considered to involve an inventive step.

8.6.6 In view of this, it is not necessary to decide whether adding (intact) caseinate would provide a liquid nutritional composition protein that necessarily falls under claim 1, having regard to the broad definition of partially hydrolysed caseinate of paragraph [0024] of the patent ("the term 'partially hydrolyzed caseinate'

refers to a caseinate in which a portion of the protein has been hydrolyzed ... *e.g.*, 0.5 to 10% hydrolyzed").

8.6.7 In sum, starting from the closest prior art, the subject-matter of claim 1 cannot be regarded as obvious (Article 56 EPC).

8.7 With regard to claims 8 and 15, no different, specific lines of argument were provided. It follows from this that the same conclusions as those set out with respect to claim 1 also apply to claims 8 and 15.

8.8 To conclude, the subject-matter of claims 1, 8 and 15 involves an inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar: The Chairman:

K. Götz-Wein A. Haderlein

Decision electronically authenticated