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Datasheet for the decision of 10 March 2022

Case Number: T 3032/18 - 3.3.09

Application Number: 14169084.2

Publication Number: 2792251

IPC: A23L33/00, A23L33/10, A23L33/17, A23L33/20

Language of the proceedings: EN

Title of invention:
Nutritional emulsions comprising calcium HMB and soluble protein

Patent Proprietor:
ABBOTT LABORATORIES

Opponent:
N.V. Nutricia

Headword:
Nutritional emulsions/ABBOTT

Relevant legal provisions:
EPC Art. 56, 76(1)
RPBA 2020 Art. 13(2)

This datasheet is not part of the Decision
It can be changed at any time and without notice

Keyword:
Main request: admission (yes)
Main request: added matter (no)
Main request: inventive step (yes)

Decisions cited:
T 0002/81, T 1919/11

Catchword:

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Case Number: T 3032/18 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 10 March 2022

Appellant: (Patent Proprietor)	ABBOTT LABORATORIES 100 Abbott Park Road Abbott Park, IL 60064-6008 (US)
Representative:	Boult Wade Tennant LLP Salisbury Square House 8 Salisbury Square London EC4Y 8AP (GB)
Appellant: (Opponent)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 31 October 2018 concerning maintenance of the European Patent No. 2792251 in amended form.**

Composition of the Board:

Chairman	A. Haderlein
Members:	A. Veronese
	F. Blumer

Summary of Facts and Submissions

I. Appeals were filed by the opponent and the patent proprietor against the opposition division's decision finding that European patent No. 2 792 251 B1, as amended according to auxiliary request 3, meets the requirements of the EPC. For ease of reading, the appellants are referred to as the proprietor and the opponent, respectively.

II. The patent derives from European patent application No. EP 14169084, which was filed as a divisional application of earlier European patent application No. 11705722, hereinafter the "parent application".

III. With its notice of opposition, the opponent had requested revocation of the patent in its entirety on the grounds under Article 100(a) (lack of novelty and lack of inventive step), 100(b) and 100(c) EPC.

IV. Claims 1, 6 and 11 of auxiliary request 3 found allowable by the opposition division read:

"*1. A nutritional emulsion comprising fat, carbohydrate, protein, and calcium beta-hydroxy-beta-methylbutyrate (HMB) wherein soluble protein represents from 50% to 100% by weight of total protein in the emulsion; and wherein the emulsion comprises from 0.1% to 8% by weight of calcium beta-hydroxy-beta-methylbutyrate, and wherein the soluble protein is sodium caseinate.*"

"*6. A nutritional emulsion comprising fat, carbohydrate, protein, and calcium beta-hydroxy-beta-methylbutyrate (HMB) wherein soluble protein comprises*

from 50% to 100% by weight of total protein and the emulsion has a weight ratio of soluble protein to calcium beta-hydroxy-beta-methylbutyrate (HMB) of 3:1 to 12:1, and wherein the soluble protein is sodium caseinate."

"*11. The nutritional emulsion of claim 6 wherein the weight ratio of soluble protein to calcium beta-hyroxy-beta-methylbutyrate (HMB) is from 4:1 to 12:1.*"

V. The documents submitted during the opposition proceedings included:

D3: US 2005/0215640 A1

VI. The opposition division found, *inter alia*, that:

- the range of 3:1 to 12:1 in claim 6 was based on paragraph [0046] of the application for the patent and the parent application as filed;

- the claimed subject-matter, which was limited to a nutritional emulsion comprising sodium caseinate, was novel and involved an inventive step over the teaching of D3, the closest prior art.

VII. During the written proceedings, the proprietor filed a main request and auxiliary requests 1 to 12. Auxiliary request 3 corresponds to the request found allowable by the opposition division.

VIII. During the oral proceedings, the proprietor filed a new auxiliary request 3. It then requested that this request be considered the main request and withdrew all remaining requests. It also filed an adapted description.

IX. Claim 1 of the main request is identical to claim 1 of the auxiliary request 3 found allowable by the opposition division, shown above. Claims 6 and 11 differ in that the two ratios "3:1 to 12:1" and "4:1 to 12:1" in claims 6 and 11 were amended to "3.0 to 12.0" and to "4.0 to 12.0", respectively. These claims read:

"*6. A nutritional emulsion comprising fat, carbohydrate, protein, and calcium beta-hydroxy-beta-methylbutyrate (HMB) wherein soluble protein comprises from 50% to 100% by weight of total protein, and the emulsion has a weight ratio of soluble protein to calcium beta-hydroxy-beta-methylbutyrate (HMB) of 3.0 to 12.0, and wherein the soluble protein is sodium caseinate.*" (emphasis by the board)

"*11. The nutritional emulsion of claim 6 wherein the weight ratio of soluble protein to calcium beta-hydroxy-beta-methylbutyrate (HMB) is from 4.0 to 12.0.*" (emphasis by the board)

X. The **opponent's** arguments that are relevant for the present decision can be summarised as follows:

- the new main request was late-filed and ought not to be admitted into the appeal proceedings;

- the ranges "3.0 to 12.0" and "4.0 to 12.0" in claims 6 and 11 added subject-matter extending beyond the content of the parent application as originally filed;

- the claimed subject-matter did not involve an inventive step over D3, the closest prior art; there was no evidence that the claimed emulsion

tasted better than that shown in table 1 of D3, which comprised 46% sodium caseinate by weight of total protein; this applied even more for emulsions containing 50% sodium caseinate by weight of total protein i.e. containing the lowest claimed amount of sodium caseinate; the problem addressed was that of providing an alternative emulsion; its solution was obvious because paragraph [0133] of D3 envisaged variations in the amounts of the ingredients contained in the emulsion of table 1.

XI. The **proprietor's** arguments that are relevant for the decision can be summarised as follows:

- the new main request was to be admitted into the appeal proceedings; the amendments did not create a fresh case and were in reply to the opponent's last submissions;

- the ranges "3.0 to 12.0" and "4.0 to 12.0" in claims 6 and 11 were based on paragraph [0046] of the parent application as originally filed;

- the claimed subject-matter involved an inventive step over D3, the closest prior art; the claimed emulsion differed from that shown in table 1 of D3 in that it contained a higher amount of sodium caseinate; the patent rendered it credible that sodium caseinate improved the bad taste induced by calcium beta-hydroxy-beta-methylbutyrate (HMB); D3 did not mention the bad taste induced by calcium HMB and its reduction; thus, the prior art did not contain any indication of increasing the amount of sodium caseinate in the emulsion described in D3.

XII. The parties' final requests are the following:

- The proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the new main request, filed as auxiliary request 3 during the oral proceedings before the board.

- The opponent requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

Reasons for the Decision

Main request

1. *Admission*

1.1 The main request was filed during the oral proceedings held before the board. The opponent requested that this request not be admitted into the appeal proceedings, it being late-filed.

1.2 The main request differs from the auxiliary request 3 filed in reply to the opponent's appeal - which is identical to the request considered allowable by the opposition division - only in that the ratios "3:1 to 12:1" and "4:1 to 12:1" in claims 6 and 11 were amended to "3.0 to 12.0" and to "4.0 to 12.0", respectively.

1.3 This amendment was made to address the board's negative finding, reached during the oral proceedings, that the omission of the decimal number after the decimal point in the ratios 3:1, 4:1 and 12:1, which characterised claims 6 and 11 of the then-auxiliary request 3, created subject-matter extending beyond the content of the parent application as filed.

1.4 The amendment overcomes the board's negative finding in a straightforward manner because it reinstates the values 3.0, 4.0 and 12.0, disclosed in paragraph [0046] of that parent application.

1.5 The reinstatement of these values is irrelevant for the examination of the pertinent substantive issues. Furthermore, the amendment is considered to be a reaction to the new submissions, which were supported by newly cited case law, made by the opponent in its letter in reply to the board's preliminary opinion in preparation for the oral proceedings and during those oral proceedings. These new submissions resulted in the board deviating from its earlier preliminary opinion that the opposition division's positive finding was to be confirmed.

1.6 For these reasons, the board concludes that, considering the nature of the amendments and the opponent's new submissions, there are exceptional circumstances justified by cogent reasons for admitting the main request (Article 13(2) RPBA 2020).

2. *Added subject-matter*

3. The opponent argued that the two ranges "3.0 to 12.0" and "4.0 to 12.0" in claims 6 and 11 of the main request were not directly and unambiguously disclosed in the parent application as originally filed. Thus, the requirements of Article 76 EPC were contravened.

3.1 The board does not agree and concurs with the proprietor that these ranges are based on the second part of paragraph [0046] of the parent application as filed, which reads:

"*... wherein the nutritional emulsion includes a weight ratio of soluble protein to calcium HMB of at least about 3.0, including from about 4.0 to about 12.0, also including 6.1 to about 12, also including from about 7.0 to about 11.0, and also including from about 8.0 to about 10.0.*" (emphasis added)

3.2 This paragraph explicitly mentions a weight ratio in the range of 4.0 to 12.0, *i.e.* the range of claim 11 of the main request. Therefore, this claim does not contain added subject-matter.

3.3 As far as the range of 3.0 to 12.0 is concerned, the board considers that this derives from the combination of the open range defined by the wording "at least about 3.0" and the following closed range defined by the wording "from about 4.0 to about 12.0".

3.4 The opponent argued that this combination "is not allowable under T 2/81" because, according to this decision, only "*a combination of the preferred disclosed narrower range and one of the part-ranges lying within the disclosed overall range on either side of the narrower range*" can be considered disclosed. Moreover, it argued that this requirement was not fulfilled in the present case because, pursuant to T 1919/11, the wording "at least about 3.0" cannot be considered a range.

3.5 This argument is not convincing either. According to headnote 2 of decision T 2/81:

"*The disclosure of a quantitative range of values (e.g. for concentrations or temperatures) together with an included preferred narrower range also directly*

discloses the two possible part-ranges lying within the overall range on either side of the narrower range. Hence a simple combination of the preferred narrower range and one of these part-ranges is also unequivocally derivable and is supported by the disclosure."

3.6 T 2/81 provides a guideline for cases in which both the broader and the narrower range are closed ranges. However, this decision does not rule out that an analogous reasoning can be applied to cases in which one of the two ranges that are combined is open, being defined by its lower or upper value only.

3.7 In T 1919/11 the board decided that the claimed range was the result of an arbitrary combination of one of the upper limits of a certain value, mentioned in a first sentence of the description as filed, with one of the lower limits, which was mentioned in another sentence of that description. Furthermore, it held that there was "no unequivocal correlation between a particular upper limit and a particular lower limit, because there was no teaching that such an arrangement was intended". For these reasons, the board considered that a new range had been created that was not disclosed in the application as filed (point 2.2.2 of the Reasons). The circumstances of the present case are different because both relevant ranges are disclosed in the same sentence, close to each other. Furthermore, they are unequivocally correlated, since they relate to the same soluble-protein-to-calcium-HMB ratio.

3.8 Therefore, neither T 2/81 nor T 1919/11 gives scope for the contention that a range cannot be directly and unambiguously disclosed by the combination of:

- an open range characterised by the lower limit of a certain value or ratio and

- the upper limit of a closed range defining that same value or ratio,

- wherein the closed range is encompassed within the first open range.

3.9 In the present case what counts is that:

- the two specific values 3.0 and 12.0 are explicitly disclosed in paragraph [0046] as lower and upper limits of two ranges, respectively;

- both ranges correlate to the same ratio of protein to HMB and are disclosed in the same sentence;

- the range of values spanning between the minimum value of 3.0 and the maximum value of 12.0 is encompassed by the open range defined by the wording "at least about 3.0" in paragraph [0046].

3.10 For these reasons, it is concluded that the two ranges "3.0 to 12.0" and "4.0 to 12.0" in claims 6 and 11 are directly and unambiguously disclosed in paragraph [0046] of the parent application as filed. Therefore, the requirements of Article 76(1) EPC are fulfilled.

4. *Inventive step*

The closest prior art

4.1 The parties did not object to the opposition division's finding that D3 is the closest prior art. The board does not have reasons to diverge from this choice. Like

the opposed patent, D3 relates to emulsions comprising calcium beta-hydroxy-beta-methylbutyrate (HMB) and to their use, *inter alia*, for preventing involuntary weight loss and muscular mass in patients suffering and recovering from illnesses. In preferred embodiments, calcium HMB is combined with ω-3 fatty acids. The emulsions also comprise nutritional ingredients, including proteins. Among other proteins, reference is made to sodium caseinate. Table 1 describes an emulsion comprising 0.57% by weight of HMB and sodium caseinate in an amount of 46% of the total protein.

Difference

4.2 The claimed composition differs from that disclosed in table 1 of D3 in that the amount of sodium caseinate represents at least 50% by weight of the total protein.

Technical effect

4.3 As set out in paragraphs [0007], [0012] and [0013] of the patent, it has been discovered that the inclusion of calcium HMB in a nutritional emulsion can result in the development of a bitter flavour or aftertaste, in particular after storage. Paragraph [0014] teaches that these can be minimised or even eliminated by including a soluble protein fraction representing at least 50% of the total protein present in the emulsion. Sodium caseinate is the preferred soluble protein.

4.4 The sensory tests described in paragraph [0078] of the patent show that the taste of emulsions comprising calcium HMB improves when the fraction of highly soluble sodium caseinate is increased:

- The comparison between samples A and C shows that the bitter and soapy sensory notes induced by HMB are significantly decreased when the relative amount of sodium caseinate is increased.

- The comparison between samples B and C shows that the replacement of calcium caseinate with sodium caseinate, which is more soluble, also decreases the bitter and soapy notes.

4.5 The opponent disputed the relevance of these results, arguing that:

- the sensory scale of 1 to 5 with incremental steps of 0.5 did not allow for an interpolation between the observed values; the tested samples comprised very different amounts of sodium caseinate; a linear relationship between the amount of protein present and the observed effect was not supported by evidence and could only be speculated;

- in the absence of this linear relationship, it could not be assumed that an emulsion according to the invention, containing 50% sodium caseinate by weight of protein, had a better taste than that in table 1 of D3, which comprised 46% sodium caseinate by weight of protein.

4.6 The opponent's argument is essentially that an improvement of taste could not be obtained across the entire scope of the claims, in particular when the relative amount of sodium caseinate is 50%, i.e. very similar to that (46%) of the emulsion of table 1 of D3. In its opinion, an improvement not having been achieved, the claimed emulsion was to be seen as alternative to that disclosed in D3. Providing such an

alternative would have been obvious for the skilled person.

5. The board cannot agree with this line of argument and its conclusions.

5.1 First of all, the board agrees with the proprietor that the trend of the results in paragraphs [0078] renders it credible that sodium caseinate decreases the bitter and soapy notes induced by calcium HMB. This is despite the fact that the results were obtained by sensory tests reporting discrete data points. Furthermore, it agrees that this effect is not disclosed either in D3 or in any of the other cited documents.

5.2 As it was noted during the oral proceedings before the board, paragraph [0080] of D3 teaches, in passing, that HMB increases the beneficial dietary effects of ω-3 fatty acids. The amount of ω-3 fatty acid sources - in particular fish oil - included in diets where their use is desirable can therefore be reduced. The objectionable flavours associated with these sources are thereby also reduced. In other words, D3 teaches that, when HMB is included in a composition, the amounts of certain bad-tasting sources of ω-3 fatty acids can be reduced. Yet D3 is completely silent about the bad taste of calcium HMB itself, let alone any possible strategy for preventing it.

5.3 The claimed invention is therefore based on two unexpected findings, namely that calcium HMB induces a bad taste and that this bad taste can be prevented using sodium caseinate.

The problem addressed

5.4 For these reasons, the technical problem addressed can be regarded as the provision of an alternative nutritional emulsion that prevents the bad taste induced by calcium HMB.

Non-obviousness of the solution

5.5 Neither D3 nor any of the other cited documents contains even the slightest indication that sodium caseinate can be used to inhibit the bad taste of calcium HMB.

5.6 It is readily apparent that proteins are included as nutritional ingredients in the emulsions of D3. D3 does not describe any interaction between these proteins and calcium HMB, and in particular any effect on the unpleasant taste of this compound.

5.7 Thus, the skilled person confronted with the underlying problem would not have had any motivation to increase the amount of sodium caseinate in the composition described in table 1 of D3.

5.8 The opponent argued that the skilled person would have considered increasing the amounts of this compound because, according to paragraph [0133] of D3, "various changes in specific ingredients and quantities may be made without departing from the scope of the invention". However, in view of the aforementioned consideration, it is clear that this argument is tainted by hindsight and is therefore not convincing.

5.9 The opponent also referred to the emulsion described in table 4 of D3. This emulsion comprises an undefined

"caseinate" ingredient, and the teaching of this table does not go beyond that of table 1, mentioned above. Thus, even starting from table 4, the outcome would be the same.

5.10 For these reasons, it is concluded that the subject-matter of claim 1, as well as that of the dependent claims, which are narrower in scope, involves an inventive step (Article 56 EPC).

6. *Adaptation of the description*

The proprietor filed an adapted version of the description. The opponent did not raise any objections to the new adapted text.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained on the basis of the following documents:

   - Main request (claims 1 to 12), filed as auxiliary request 3 during the oral proceedings before the board;

   - Description:

     - paragraphs [0001] to [0054] as filed during the oral proceedings before the board;

     - paragraphs [0055] to [0087] of the patent specification.

The Registrar: The Chairman:

A. Nielsen-Hannerup A. Haderlein

Decision electronically authenticated