

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 11 July 2023**

Case Number: T 2732/19 - 3.3.09

Application Number: 11725215.5

Publication Number: 2575830

IPC: A23L29/256, A61K35/20, A61P1/02

Language of the proceedings: EN

Title of invention:
PRE-THICKENED COMPACT LIQUID NUTRITIONAL COMPOSITION FOR
DYSPHAGIA PATIENTS

Patent Proprietor:
N.V. Nutricia

Opponent:
Fresenius Kabi Deutschland GmbH

Headword:
Thickened nutritional compositions/ FRESENIUS

Relevant legal provisions:
EPC Art. 54(2), 56, 83

Keyword:
Auxiliary request VII: Sufficiency of Disclosure, Novelty and
Inventive Step - (yes)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2732/19 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 11 July 2023

Appellant: Fresenius Kabi Deutschland GmbH
(Opponent) Else-Kröner-Str. 1
61352 Bad Homburg (DE)

Representative: Fresenius Kabi Deutschland GmbH
Patent Department
Pharmaceuticals Division
Borkenberg 14
61440 Oberursel (DE)

Respondent: N.V. Nutricia
(Patent Proprietor) Eerste Stationsstraat 186
2712 HM Zoetermeer (NL)

Representative: Nederlandsch Octrooibureau
P.O. Box 29720
2502 LS The Hague (NL)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 5 August 2019
rejecting the opposition filed against European
patent No. 2575830 pursuant to Article 101(2)
EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. The appeal was filed by the opponent (appellant) against the decision of the opposition division rejecting the opposition filed against the European patent.
- II. In 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) and Article 100(b) EPC.
- III. Claims 1 and 4 of the granted patent read, respectively:

*"1. A liquid enteral nutritional composition with an energy density between 1.0 and 4.0 kcal/ml, a viscosity between 150 and 1800 mPas measured at a shear rate of 50/second at 20°C, comprising digestible carbohydrates and fat, wherein the composition further comprises;
at least one of:*

- a1. between 8-20 g protein per 100 ml of the composition, where micellar casein comprises at least 50wt% of the total protein content of the composition,*
- a2. between 16-45 en% protein, where micellar casein comprises at least 50 % of the protein caloric content;*

and said composition further comprising:

- b. water-soluble anionic fibers capable of sequestering of calcium, and*

c. carrageenan between 0.015 and 0.25 g per 100 ml of the composition, for use in treating/preventing malnourishment or undernourishment associated with dysphagia, and/or preventing/treating dysphagia."

"4. A liquid nutritional composition with an energy density between 1.0 and 4.0 kcal/ml, a viscosity between 150 and 1800 mPas measured at a shear rate of 50/second at 20°C, comprising digestible carbohydrates and fat, wherein the composition further comprises:

at least one of:

a1. between 9 to 18 g protein per 100 ml of the composition, where micellar casein comprises at least 50wt% of the total protein content of the composition,

a2. between 16-45 en% protein, where micellar casein comprises at least 50 % of the protein caloric content;

and said composition further comprising:

b. anionic fibers capable of sequestering of calcium, and

c. carrageenan between 0.015 and 0.25 g per 100 ml of the composition."

IV. In its decision, the opposition division found *inter alia* that:

- the claimed invention was sufficiently disclosed because the patent contained sufficient information

to prepare the claimed composition and to use it for the claimed therapeutic applications

- the claimed composition was novel over D4, at least because this document did not disclose compositions having the claimed viscosity

- the claimed subject-matter involved an inventive step; D1 or D7 were the closest prior art; the claimed composition differed from those of D1 and D7 in the presence of carrageenan; as shown in the patent, this agent, together with micellar casein, stabilised compositions comprising large amounts of proteins; the problem was the provision of a stable liquid composition comprising large amounts of protein for treating dysphagia patients. None of the cited documents suggested including carrageenan in the compositions of D1 or D7

V. During the oral proceedings held before the board, the respondent (patent proprietor) requested that the patent be maintained on the basis of auxiliary request VII filed with its letter dated 11 October 2018 (all other requests filed during the appeal proceedings were withdrawn).

VI. Claims 1 and 4 of auxiliary request VII differ from the corresponding claims as granted in that the range defining the viscosity of the claimed composition has been reduced from "150 to 1800 mPas" to "250 to 1800 mPas", measured at a shear rate of 50/second at 20°C.

VII. The appellant's arguments of relevance to the decision can be summarised as follows.

- The patent did not provide sufficient information to prepare the claimed composition; thus, the claimed invention was not sufficiently disclosed.
- The claimed subject-matter was not novel over examples 1 and 3 of D4, as shown by the appellant's calculations.
- The claimed subject-matter lacked an inventive step starting from D11, the closest prior art. The claimed composition differed from that of D11 in the claimed viscosity and amount of carrageenan. These features were not associated with any particular effect. The problem was the provision of an alternative composition. The solution, involving the use of the claimed amount of carrageenan and viscosity, was obvious in relation to the prior art.

VIII. The respondent's arguments of relevance to the decision may be summarised as follows.

- The claimed invention was sufficiently disclosed. The appellant's objections were pure speculation; they were not substantiated by any evidence.
- Claim 1 was novel over example 3 of D4, which did not disclose the viscosity characterising the claimed composition.
- The claimed invention involved an inventive step. D1 and D7, rather than D8 and D11 were the closest prior art. The problem was the provision of a shelf stable liquid composition for dysphagia patients. The solution, involving the inclusion of the claimed amount of carrageenan and anionic fibres in

the compositions of D1 or D7 was not suggested by the prior art and thus not obvious.

Requests

- IX. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

- X. The respondent (patent proprietor) requested that the patent be maintained on the basis of auxiliary request VII filed with its letter dated 11 October 2018 (all other requests were withdrawn).

Reasons for the Decision

Auxiliary request VII

- 1. *Sufficiency of disclosure*
 - 1.1 The claimed invention relates to a pourable liquid composition comprising a large amount of proteins, fats, carbohydrates, carrageenan and anionic fibres. The composition has a specified viscosity, which renders it particularly suitable for nourishing patients affected by dysphagia: see claims 1 and 4 and paragraphs [0001] and [0015] to [0017].

 - 1.2 The appellant contested the opposition division's finding that the invention claimed in the opposed patent was sufficiently disclosed. It considered the objection of lack of sufficiency to apply equally to auxiliary request VII. In its opinion, preparing the claimed composition would have involved an undue burden for the following reasons.

- The claims were formulated very broadly and encompassed an unlimited number of variations; however, the patent did not explain how the claimed composition could be prepared and did not disclose even one working example: the exemplified compositions did not include the claimed amount of carrageenan and did not have the required viscosity.
- Paragraphs [0003], [0005] and [0047] of the patent, D8 and D11 taught that the preparation of compositions comprising large amounts of proteins was very difficult; such compositions were typically unstable; in particular, D11, page 25, lines 21 and 22 taught that in order to prepare a nutritional composition comprising a large amount of proteins, a specific evaporation step was required; otherwise a paste-like texture was obtained; no such step was mentioned in the opposed patent.
- Therefore, there were serious doubts as to whether the claimed composition could be prepared; an extensive research program would in any case have been required to carry out the invention.

1.3 These arguments are not convincing.

1.4 According to established case law of the boards of appeal, in opposition the burden of proof of insufficiency is on the opponents, who should prove that, despite making all reasonable efforts, they were unable to put the invention into practice: see Case Law of the Boards of Appeal, 10th Edition, 2022, section III.G.5.1.2(c).

- 1.5 In the present case, the appellant/opponent has not discharged this burden.
- 1.6 The claimed composition has a specific viscosity and comprises certain ingredients, in particular micellar casein, anionic fibres, carrageenan, carbohydrates and fats. These ingredients, which are well known, are described in paragraphs [0035] to [0044] and [0049] to [0058] of the opposed patent. Information concerning viscosity is given in paragraphs [0060] to [0061].
- 1.7 Furthermore, the patent describes twelve compositions comprising specific amounts of the claimed ingredients and indications concerning the observed viscosity: see tables 2 and 3 in paragraph [0070]. It is true that the steps for preparing these compositions are not described in the patent. Nevertheless, there is no evidence that, using the ingredients specified in the claims, the skilled person would not be able to produce a composition as defined in the claims.
- 1.8 The patent acknowledges that the preparation of stable compositions comprising large amounts of proteins can be problematic. However, it teaches that the formulation problems can be overcome using a combination of micellar casein and carrageenan, paragraphs [0058], [0059] and table 1. It further teaches that anionic fibres also improve stability, paragraphs [0016] and [0049]. There is no evidence that enteral nutritional compositions comprising these ingredients cannot be prepared by standard procedures, e.g. by simply mixing and homogenizing the claimed ingredients, or that when these ingredients are included in the claimed amounts the evaporation step disclosed in D11 is still necessary. It is also noted

that the viscosity of the exemplary composition is significantly higher than that of the compositions of D11. Carrageenan has also been included. This makes it credible that the claimed composition is intrinsically more stable.

- 1.9 The appellant noted that the amount of carrageenan in the compositions mentioned by way of example in the patent does not fall within the claimed range.
- 1.10 However, as argued by the opposition division and the respondent, the skilled person would promptly realize that the amount of carrageenan in the exemplary compositions - 0.0325 mg/100ml - is incorrect. From reading the patent the skilled person would understand, firstly, that 0.0325 mg of carrageenan would not have a significant influence on the viscosity of the claimed composition and secondly, that this amount is about 500 times lower than the lowest and about 8000 times lower than the largest amount - from 0.015 g/100 ml to 0.25 g/100 ml - indicated in claims 1 and 4 and in paragraph [0058] of the description. Thirdly, the skilled person would understand that carrageenan is the only ingredient whose amount is expressed in milligrams instead of grams and fourthly, that, expressed in grams, the amount in all examples would squarely fall within the range specified in claims 1 and 4 of the opposed patent.
- 1.11 This means that, from reading the patent, the skilled person would promptly realise that the amount of carrageenan present in the exemplary compositions should have been expressed in grams, and not in milligrams.

- 1.12 Independent claims 1 and 4 specify that the viscosity of the claimed composition is between 250 and 1800 mPas, measured at a shear rate of 50 [rotations]/second at 20°C. The viscosity of the exemplary compositions is between 450 and 1200 mPas, measured at a shear rate of 100 [rotations]/second at 20°C. Referring to D1 and common knowledge, the appellant argued that, due to the difference in shear rate, it could not be established whether the viscosity of the exemplary compositions fell within the claimed range. It was also surprising that some of the exemplary compositions, which comprised different protein fractions, had the same viscosity and that all values ended with the integer "0". For these reasons, in its opinion, the exemplary compositions had to be disregarded when assessing sufficiency of disclosure.
- 1.13 These arguments are not persuasive either.
- 1.14 Although it is not disputed that the viscosity of a composition is influenced by the shear rate, there is no evidence that the viscosity of the exemplary compositions does not fall within the claimed range. As noted by the opposition division, the viscosity of all the exemplary compositions, measured at 100 rotations per second, falls within the claimed range. There is no evidence that a viscosity outside the claimed range would be observed by increasing the rotation speed from 50 to 100 rotations per second. It is certainly surprising that some foods comprising different protein fractions have the same viscosity and that the viscosity values end with an integer. However, there is no evidence that the indicated values are wrong. Furthermore, the examples show that foods having substantially different protein contents have significantly different viscosities: compare e.g. the

viscosity of the compositions of examples 1 to 4 with that of example 5. Thus, although some of the results in tables 2 and 3 could be considered "surprising", there is no compelling evidence that the values shown are wrong.

1.15 In the absence of such evidence, it cannot be assumed that the exemplary compositions do not fall among the claimed ones. It is therefore concluded that these compositions are representative of the claimed invention and that they provide valuable information for carrying out that invention. It is also considered that, even if it were found that the viscosity of some compositions falls somehow outside the claimed range, the skilled person would be able - e.g. by varying the amount of carrageenan - to modify the viscosity so as to obtain a composition according to the invention.

1.16 The appellant has not provided convincing evidence that the nutritional composition according to the invention, comprising the claimed amounts of the relevant ingredients, cannot be prepared. It is therefore concluded that, relying on the information provided in the patent and common general knowledge, the skilled person would be able to carry out the claimed invention. Hence, the requirement of sufficiency of disclosure is fulfilled (Article 83 EPC).

2. *Novelty*

2.1 The appellant disputed the opposition division's finding that the subject-matter of claims 1 and 4 as granted is novel over the compositions of examples 1 to 3 of D4. The objection as to novelty was not reiterated when dealing with auxiliary request VII. The subject-matter of this request is in any case not

anticipated by D4. The claimed composition differs in fact from those disclosed in D4 at least in the specified viscosity, namely "250 to 1800 mPas", measured at a shear rate of 50/second at 20°C.

2.2 The viscosity of the individual compositions mentioned by way of example in D4 is not indicated. The shear rate used for the measurement is not indicated either. D4 states generically that the viscosity of the exemplified compositions "is between about 20 and 160 cps" at 20°C, paragraph [0076], and that the viscosity was measured "at the highest speed possible to obtain a reading that is on scale", paragraph [0014]. It is, however, impossible to determine from these statements the shear rate used and the observed viscosity for the individual compositions.

2.3 For these reasons, it cannot be concluded that the viscosity of the compositions exemplified in D4 falls within the range specified in the claims.

2.4 The subject-matter claimed in auxiliary request VII is therefore novel over D4 (Article 54(2) EPC).

3. *Inventive step*

3.1 The invention relates to a liquid enteral nutritional composition comprising a large amount of proteins suitable for use in patients affected by dysphagia, see independent claims 1 and 4 and paragraphs [0001], [0015] and [0020]. Dysphagia patients have a loss of sensation in the oral cavity and lack of proper swallowing reflex, causing low viscosity liquid foods to drip into the trachea and be aspirated into the bronchia. These patients are typically malnourished or undernourished. The patent teaches that thickened foods

according to the invention are suitable for dysphagia patients and prevent leaking into the trachea, see paragraphs [0002] to [0005], [0028] and [0032] to [0034].

The closest prior art

- 3.2 The opposition division decided that D1 or alternatively D7 represented the closest prior art, because it focused, like the opposed patent, on the provision of highly viscous compositions for nourishing patients affected by dysphagia.
- 3.3 The appellant disputed the opposition division's choice of the closest prior art, arguing that D11 should have been selected rather than D1 and D7. The appellant did not contest that D1 and D7 related to high-viscosity compositions suitable for administration to dysphagia patients. It argued, however, that these documents did not focus on the primary objective of the claimed invention, namely providing these patients with an enteral nutritional composition having a high energy content and a large amount of protein.
- 3.4 It further submitted that, although D11 related to low-viscosity compositions, this document explicitly addressed the problem of providing an enteral nutritional composition for patients affected by dysphagia and with swallowing difficulties. The compositions of D11 had a high energy content and, like those claimed, comprised large amounts of proteins, in particular micellar casein, as well as fats and carbohydrates, page 1, lines 18 and 24, page 9, line 17 and page 5, line 10. Thus, the compositions of D11 were intended for the same final purpose, albeit taking a different approach to tackling dysphagia.

3.5 Since D11, like the opposed patent, relates to enteral nutritional compositions comprising a high energy content and large amounts of proteins and which are suitable for nourishing dysphagia patients, the board agrees to the appellant's request to consider D11 as the starting point for assessing inventive step.

3.6 The appellant mentioned D8 as an alternative starting point. However, since the appellant focused primarily on D11 and conceded that the teaching of D8 did not go beyond that of D11, only this latter document will be used as starting point for the discussion.

Distinguishing features

3.7 The claimed nutritional composition differs from those shown by way of example in tables 1 and 2 of D11 at least in that it comprises carrageenan, in an amount of 0.015 to 0.25 g/100 ml and in the claimed viscosity, namely "from 250 to 1800 mPas, measured at 20°C, at a shear rate of 50/sec".

3.8 The viscosity of the compositions disclosed in D11 is said to be "low", see page 5, line 10, page 9, line 16, and page 19, line 19. In particular, the viscosity of the compositions mentioned by way of example in D11 is between 60 and 75 mPas at 20°C at a shear rate of 100/s, see examples 1 to 5. The viscosity of the compositions of examples 6 and 7 is not indicated. However, since these compositions comprise a lower amount of proteins, compared to those of examples 1 to 5, it is reasonable to assume that their viscosity is even lower.

3.9 The viscosity of the compositions mentioned by way of example in D11 (60 to 75 mPas) is thus substantially lower than that specified in the claims, namely "250 to 1800 mPas", and in the examples of the opposed patent, namely 450, 550 and 1200 mPas respectively (all measured at 20°C at a shear rate of 100/s).

3.10 Due to this substantial difference, it also cannot be assumed that the viscosity of the compositions mentioned by way of example in D11 would fall within the claimed range, when measured at a shear rate of 50/second.

Technical effect

3.11 The relatively high viscosity of the claimed compositions facilitates oral administration to patients affected by dysphagia, without the risk of leakage into the trachea and aspiration. Furthermore, as submitted by the respondent, using carrageenan as viscosifying agent enables stable viscous compositions comprising high density micellar casein to be obtained. The results in table 1 of the patent show that other viscosifying agents, such as carob gum, guar gum, tara gum, xanthan gum, xyloglycan, agar and gelatin are not stable after two weeks. These results were observed whether or not starch was present in the composition. Thus, the use of carrageenan allows the preparation of stable compositions comprising large amounts of micellar proteins. This is the case even in the absence of starch, an ingredient which is commonly used as a viscosifying agent but which is subject to amylase degradation with consequent reduction of viscosity upon ingestion, paragraph [0017].

3.12 The appellant submitted that the data in the patent did not support the alleged properties of the claimed compositions. In particular, the appellant argued that:

- the compositions in tables 2 and 3 did not have the claimed viscosity, being tested at a different shear rate, and did not contain the claimed amount of carrageenan
- the claims did not exclude the presence of starch
- the tests in table 1 were too short and were conducted on "oversimplified" model compositions which, according to D3, were unsuited to showing that the claimed compositions were "shelf-stable"
- the tested compositions did not comprise anionic fibres or starch, but could comprise citric acid; thus, they did not fall within the claimed scope

3.13 These arguments are not convincing. As already established in the assessment of sufficiency of disclosure, it cannot be concluded, with regard to the viscosity values in tables 2 and 3, that the viscosity of the exemplary compositions is outside the claimed range. As already mentioned before, it is clear that the amount of carrageenan in the exemplary compositions should be expressed in grams.

3.14 Concerning the results of the tests in table 1, it was not disputed that the conditions used to carry out these tests are not indicated. However, it can be assumed that these tests were conducted by a skilled person with all due care, using an experimental setting and amounts of micellar casein and carrageenan which are suited to representing the claimed invention.

3.15 The presence of anionic fibres is said to be beneficial in paragraphs [0049] to [0054], but not essential to

achieving the effects shown in table 1. The presence of starch is not required by the claims either.

3.16 It is not disputed that, as mentioned in D3, simplified models do not necessarily allow the prediction of the properties of final food products. However, D3 acknowledges the usefulness of these models for identifying "functional properties"; there is no reason to assume that the functional properties of carrageenan shown in table 1 will not be maintained in food compositions according to the claims.

3.17 For these reasons, the tests in table 1 are considered to make it credible that the inclusion of carrageenan as viscosifying agent in compositions comprising micellar casein allows the preparation of stable viscous compositions comprising large amounts of proteins which are suitable for administration to patients affected by dysphagia. It is also credible that the use of anionic fibres capable of sequestering calcium ions further stabilises the composition.

3.18 The appellant submitted that the tests shown in table 1 only lasted two weeks, which was too short for assessing long-term stability. However, enhanced stability after this period can in itself be advantageous. Furthermore, there is no reason to assume that the compositions will not be stable for a longer time. Moreover, the claims do not specify a minimum time period for acknowledging that a composition can be considered "stable" or "shelf-stable".

The underlying technical problem

3.19 There is no evidence that the claimed compositions provide an improvement over those of D11. Starting from

D11, the underlying problem can therefore be regarded as the provision of an alternative shelf-stable, ready-to-use liquid composition comprising large amounts of protein, which is suitable for oral administration to patients affected by dysphagia.

Non-obviousness of the claimed solution

3.20 According to the appellant, when confronted with the underlying problem, the skilled person would have considered increasing the viscosity of the compositions of D11 by using carrageenan as viscosifying agent. D11 mentioned a viscosity of up to 200 mPas on page 19, lines 17 to 19. The provision of viscosity-adjusted foods for nourishing patients affected by dysphagia was common general knowledge, as shown in D12. Although low-viscosity compositions like those of D11 could be used in dysphagia patients, the advantages of highly viscous compositions were known. The use of carrageenan as viscosifying agent was already mentioned in D11, and D9 and D10 described its use for stabilising milk protein mixtures. Anionic fibres were also mentioned in D11. Therefore, the proposed solution did not involve an inventive step.

3.21 These conclusions are not convincing.

3.22 The gist of the invention described in D11 is a low-viscosity food composition. D11 is quite adamant on this point and the concept of using low-viscosity compositions is repeated consistently throughout the entire document, see e.g. page 5, lines 8 to 11, page 6, lines 19-20, page 9, lines 15 to 17, page 19, lines 19 to 20 and the examples.

- 3.23 The claimed invention departs significantly from this approach, and actually clashes head-on with the teaching of D11. Furthermore, although D11 mentions carrageenan as a thickener, the preference is to use hydrolysed polysaccharides, see page 15. No mention is made as to any stabilising effects of carrageenan on micellar casein either. Therefore, the skilled person reading D11 would not have considered departing from the teaching of this document, let alone taking into account the teaching of other documents which diverge substantially from the approach proposed in D11.
- 3.24 Furthermore, as noted by the opposition division and the respondent, D9 and D10 teach that the formulation of milk proteins with a number of viscosifying agents is problematic, due to instability. These documents report some favourable stabilising effect using carrageenan. However, the protein content of the compositions used for the stability tests, described in D9, is 3.78%, i.e. far lower than that in the claimed compositions (around 8 to 45%). The appellant mentioned some milk products comprising carrageenan shown in table 7.3 of D10. However, it is not clear whether these products are liquid, nor what their viscosity is and how much protein, in particular micellar casein, they contain. Accordingly, the skilled person would not have reasonably expected liquid enteral compositions comprising the claimed large amount of proteins, let alone micellar casein, as defined in the claims, to be stabilised by carrageenan.
- 3.25 For these reasons it is concluded that, starting from D11 and being confronted with the underlying problem, the skilled person would not have provided the composition defined in claims 1 and 4. Therefore, the

subject-matter claimed in auxiliary request VII involves an inventive step (Article 56 EPC).

4. *Adaptation of the description*

4.1 The respondent adapted paragraphs [0018], [0020], [0021], [0034] and [0055] of the description to the claims of auxiliary request VII. The appellant did not raise any objection against the amendments and the board does not see any reason to raise an objection of its own volition.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent in amended form on the basis of the following documents:
 - claims 1 to 11, filed as auxiliary request VII with the letter dated 11 October 2018
 - description:
 - paragraphs [0001] to [0017], [0019], [0022] to [0033], [0035] to [0054] and [0056] to [0070] of the patent specification
 - paragraphs [0018], [0020], [0021], [0034] and [0055] as filed by e-mail during the oral proceedings before the board

The Registrar:

The Chairman:



H. Jenney

A. Haderlein

Decision electronically authenticated