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**Datasheet for the decision
of 3 May 2021**

Case Number: T 1173/18 - 3.3.09

Application Number: 12812921.0

Publication Number: 2790531

IPC: A23L1/05, A23L1/0526, A23L1/30,
A23L1/308, A61K31/715,
A61K36/185

Language of the proceedings: EN

Title of invention:
COHESIVE THIN LIQUIDS TO PROMOTE SAFE SWALLOWING IN DYSPHAGIC
PATIENTS

Applicant:
Société des Produits Nestlé S.A.

Headword:
Nutritional product promoting safer swallowing/NESTEC

Relevant legal provisions:
EPC Art. 56, 84, 123(2)

Keyword:
Main request: added subject-matter - (no); clarity - (yes);
Inventive step - (yes)

Decisions cited:

T 0099/13

Catchword:



Beschwerdekammern

Boards of Appeal

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Case Number: T 1173/18 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 3 May 2021

Appellant: Société des Produits Nestlé S.A.
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1800 Vevey (CH)

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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 4 December 2017
refusing European patent application No.
12812921.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman A. Haderlein
Members: A. Veronese
E. Kossonakou

Summary of Facts and Submissions

I. The appeal was filed by the applicant (appellant) against the examining division's decision to refuse European patent application No. 12 812 921.

II. The decision was based on a main request and five auxiliary requests, all filed by letter dated 13 October 2017.

III. Claim 1 of the main request reads as follows:

"A liquid nutritional product comprising an aqueous solution of a food grade biopolymer in a concentration of from at least 0,01 wt% to 25 wt%, providing to the liquid nutritional product:

- *a shear viscosity of less than about 100 mPas, preferably of less than about 50 mPas, when measured at a shear rate of $50s^{-1}$, and*
- *a relaxation time, determined by a Capillary Breakup Extensional Rheometry (CaBER) experiment, of more than 10 ms (milliseconds), at a temperature of 20° C,*

wherein the food grade biopolymer is selected from the group consisting of botanical hydrocolloids selected from the group consisting of plant-extracted gums, plant derived mucilages, and combinations thereof."

IV. Claim 1 of auxiliary request 1 differed from claim 1 of the main request in that the temperature for measuring the shear viscosity was specified as follows:

"a shear viscosity of less than about 100 mPas, preferably of less than about 50 mPas, when measured at a shear rate of $50s^{-1}$ and at a temperature of 20°C" (emphasis by the board).

V. The following document was mentioned in the decision:

D2: WO 03/11051 A1

VI. The decision of the examining division can be summarised as follows.

- Claim 1 of the main request did not indicate at which temperature the shear viscosity of the nutritional composition was measured. Since the viscosity varied with the temperature, the claimed subject-matter was unclear.
- The indication in claim 1 of auxiliary request 1 that the viscosity was measured at 20°C added originally undisclosed subject-matter.
- The subject-matter claimed in all the requests lacked inventive step over D2, the closest prior art. The problem underlying the invention was "to promote safer swallowing of liquid food boluses in patients suffering from swallowing disorders". D2 described foods comprising xanthan gum and plant-extracted gums, which were among the thickening agents mentioned in the application. This document suggested "the solution at the basis of the present invention". As far as the claimed viscosity was concerned, this was implicitly disclosed in D2 because the concentration of the thickening agents was the same as suggested in the application.

VII. In its statement setting out the grounds of appeal, the appellant requested that the decision be set aside and that a patent be granted on the basis of the main request or, alternatively, one of the auxiliary requests on which the decision under appeal is based.

VIII. With its statement setting out the grounds of appeal, the appellant filed the following documents:

Annex 1: Shear viscosity and relaxation time of compositions comprising okra and cactus extracts and of compositions comprising xanthan and hydrolysed starch

Annex 2: CD comprising movies showing the viscoelastic properties of cactus, okra and flax seed extracts (CaBER experiments)

Annex 3: G.H. McKinley, 2005, Rheology Reviews, HML Report Number 05-P-04

IX. In reply to a communication issued by the board under Rule 100(2) EPC, the appellant replaced the main request with a request corresponding to previous auxiliary request 1, where the word "about" has been deleted from the claims (new main request).

X. The appellant's arguments relevant for the decision were as follows.

The addition to claim 1 of the indication that the viscosity was measured at 20°C did not add subject-matter; furthermore, this amendment overcame the clarity objection raised by the examining division.

The claimed nutritional product differed from the products of D2, the closest prior art, in that it was

liquid, contained specific botanic hydrocolloids and exhibited a particular viscosity and relaxation time. As shown in Annexes 1 to 3, this product was, contrary to the products of D2, viscoelastic and cohesive. Thus, it could be swallowed without breaking up. The underlying problem was the provision of a liquid nutritional product which could be safely swallowed by patients affected by dysphagia. Nothing in D2 hinted at preparing compositions comprising the claimed ingredients and having the claimed viscosity and relaxation time to solve this problem.

XI. Appellant's requests

The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed by letter of 4 February 2021 or, alternatively, one of the auxiliary requests on which the decision under appeal is based, filed with the letter of 13 October 2017.

Reasons for the Decision

Main request

1. *Added subject-matter*

1.1 Claim 1 was amended to indicate that the viscosity of the claimed nutritional product is measured at 20°C. The board does not share the examining division's view that there is no basis for this amendment in the application as originally filed.

1.2 As recalled in T 99/13 - which deals with, like the present case, an amendment specifying the temperature

at which a viscosity is measured - the assessment of whether an amendment adds subject-matter not disclosed in the application as filed should be conducted from the standpoint of the skilled person on a technical and reasonable basis, avoiding artificial and semantic constructions (see Reasons 2.3).

- 1.3 The description of the patent application as filed teaches that the invention relates to a nutritional product which can be swallowed safely by subjects suffering from dysphagia. Furthermore, it teaches that the gist of the invention resides in the provision of a product having specific rheological properties, namely a particular shear viscosity and relaxation time. These impart cohesiveness to the product, preventing it from breaking apart upon swallowing (see paragraphs [0001], [0002], [0020], [0021], [0043], [00111] to [00113], [00143] and [00144] of the application as filed).

- 1.4 It would be readily apparent to the skilled person reading the application that the claimed product must have both the specified viscosity and relaxation time in the moment and at the temperature when the food is swallowed. Furthermore, it would be obvious that the temperature of 20°C mentioned in paragraphs [0021] and [0043] is that which approximates the temperature of the nutritional composition when administered to and swallowed by a subject, namely room temperature. The skilled person would then conclude that this is the temperature at which both the viscosity and the relaxation time have to be determined in order to characterise the product of the invention. Paragraphs [0021] and [0043], which define in the same sentence the required viscosity, the relaxation time and a temperature of 20°C, are in line with this conclusion.

1.5 The examining division's argument that a skilled person would have considered measuring the viscosity at 37°C, i.e. at a normal body temperature, is not convincing. The skilled person would not assume that the product, which is a drink, is to be heated to 37°C, nor that its temperature would raise immediately during swallowing to reach the body temperature.

1.6 For these reasons, it is concluded that the indication that the viscosity of the nutritional product is measured at 20°C does not add any originally undisclosed subject-matter (Article 123(2) EPC).

2. *Clarity*

The addition to claim 1 of the indication that the viscosity has to be measured at 20°C overcomes the examining division's objection of lack of clarity. The deletion of the expression "about" from claims 1 to 3 further clarifies the scope of the claims.

3. *Inventive step*

3.1 The claimed invention relates to a nutritional product which can be safely swallowed by subjects suffering from dysphagia. As stated in paragraphs [00111] to [00116], before the filing date it was generally known that the control of the bolus during the swallowing process can be improved by increasing its viscosity. Paragraphs [00113], [00116], [00143] and [00144] explain that the invention is based on the finding that a product having a higher extensional viscosity and, as a result, increased cohesion and decreased tendency to break up, reduces the swallowing efforts and build-up in the oropharyngeal and/or oesophageal tracts.

- 3.2 The examining division considered that D2 represents the closest prior art. D2 relates, like the present application, to the manufacture of nutritional products suitable for feeding subjects affected by dysphagia (see paragraphs [0001], [0011], [0013] and [0020]). Thus, the board concurs that that document is a suitable starting point for assessing inventive step.
- 3.3 D2 teaches how to prepare a concentrate thickener composition, which is then mixed with a liquid food, to afford a thickened nutritional product. This final product contains, like that according to the claimed invention, an agent causing an increase of shear viscosity. Some plant-extracted gums, such as guar gum, locust bean gum and carob bean gum, are mentioned among other thickening agents in paragraph [0020]. Xanthan gum, a gum of bacterial origin, is the preferred thickening agent (see paragraph [0021]).
- 3.4 The board concurs with the appellant that D2 does not disclose products having the shear viscosity and the relaxation time specified in claim 1. In particular, D2 does not mention any relaxation time and the viscosity of the exemplified compositions appears to be higher than the claimed one.
- 3.5 The appellant has provided evidence that compositions comprising gums extracted from okra and cactus, which are plant-extracted gums considered as suitable biopolymers in paragraphs [0029] and [0030] of the application, have both the required viscosity and relaxation time. Furthermore, a composition comprising xanthan gum, the preferred thickener of D2 and of bacterial origin, does not exhibit any measurable relaxation time (see Annex 1).

- 3.6 As indicated in the application and further explained by the appellant, liquid nutritional products having the claimed shear viscosity and relaxation time, measured by Capillary Breakup Extensional Rheometry (CaBER), have an improved viscoelasticity and cohesiveness and do not break apart during the swallowing process. There is no reason to doubt that the nutritional products having these rheological properties provide these beneficial effects. Moreover, Annex 3 makes credible that the claimed compositions can be considered viscoelastic fluids.
- 3.7 Thus, starting from D2, the technical problem is the provision of a liquid nutritional product which can be easily swallowed by a patient affected by dysphagia, without breaking apart upon swallowing (see paragraphs [00113], [00116], [00143] and [00144] of the application).
- 3.8 D2 neither addresses this problem nor mentions the importance of preparing compositions having the claimed relaxation time and the associated viscoelasticity properties. As already mentioned above, compositions comprising xanthan gum, the preferred thickener of D2, do not even induce a measurable relaxation time. Although it mentions some gums extracted from plants, D2 does not teach using them in such a manner that the final product fulfils the rheological properties specified in claim 1.
- 3.9 The examining division assumed that "... since some plant-extracted gums are mentioned in D2, and used in the same concentrations, the required viscosity must be considered to be implicitly suggested ...". However, it referred to passages of D2 defining the concentration of xanthan gum, a gum extracted from bacteria which, as

shown in Annex 1, does not even induce a detectable relaxation time. Furthermore, the examining division mentioned viscosity ignoring the relaxation time, an essential technical property of the claimed product correlating to the resistance to break-up.

No incentive can be found in D2 to select from among all the thickeners disclosed in that document plant-extracted gums or plant derived mucilages and to formulate them in such a manner that the resulting product exhibits the required shear viscosity and relaxation time. For these reasons, it is concluded that the subject-matter of claim 1 and of the dependent claims, which are narrower in scope, involves an inventive step.

3.10 In view of this finding, there is no need to deal with the auxiliary requests.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division with the order to grant a patent on the basis of the main request filed on 4 February 2021 and a description adapted to it.

The Registrar:

The Chairman:



A. Nielsen-Hannerup

A. Haderlein

Decision electronically authenticated