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Datasheet for the decision of 13 June 2019

Case Number: T 2748/17 - 3.3.09

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Language of the proceedings: EN

Title of invention:
Food composition for prodromal dementia patients

Patent Proprietor:
N.V. Nutricia

Opponents:
Nestec S.A.
Fresenius Kabi Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 76(1), 100(c)
RPBA Art. 13(1)

Keyword:
Main request and auxiliary request 1 - Added matter (yes)
Second auxiliary request - Admission (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

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Case Number: T 2748/17 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 13 June 2019

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Respondent: (Opponent 1)	Nestec S.A. Avenue Nestlé 55 1800 Vevey (CH)
Representative:	Rupp, Christian Mitscherlich PartmbB Patent- und Rechtsanwälte Sonnenstraße 33 80331 München (DE)
Respondent: (Opponent 2)	Fresenius Kabi Deutschland GmbH Else-Krömer-Strasse 1 61352 Bad Homburg (DE)
Representative:	Fresenius Kabi Deutschland GmbH Patent Department Borkenberg 14 61440 Oberursel (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 17 October 2017 revoking European patent No. 2412250 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	W. Sieber
Members:	D. Rogers
	A. Veronese

Summary of Facts and Submissions

I. The appeal was filed by the patent proprietor against the decision of the opposition division to revoke the European patent Nr. 2 412 250. The patent had been granted on a divisional application of the earlier European patent application No. 08766831.5.

II. With their respective notices of opposition the two opponents 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.

III. In its decision the opposition division found that the subject-matter of the main request and of auxiliary requests 1 and 2, all filed by letter dated 18 July 2017, contained subject-matter extending beyond the content of the patent application as filed as well as of the earlier (parent) patent application as filed (Articles 76 and 123(2) EPC). In particular, the patent application and the parent application did not directly and unambiguously disclose a composition comprising the ingredients enumerated in claim 1 of those requests.

Claim 1 of the main request reads:

"*A composition comprising (a) DHA and EPA, (b) uridine or its equivalents, and (c) choline and/or phosphatidylcholine, wherein the composition further comprises vitamin C, vitamin E, vitamin B12 and folic acid, for use in the treatment of prodromal dementia and/or prodromal Alzheimer's disease in a patient suffering from said prodromal dementia or prodromal Alzheimer's disease, said patient having at least:*

- *a level of more than 350 ng Total-tau per litre cerebrospinal fluid (CSF);*
- *a weight ratio of abeta-42/Phospho-tau-181 of less than 6.5 in CSF*".

IV. Auxiliary request 1 differs from the main request in that the composition of claim 1 is restricted to "*for use in the treatment of a prodromal Alzheimer's disease in a patient suffering from said prodromal Alzheimer's disease*" (the reference to prodromal dementia having being deleted).

Auxiliary request 2 contains a single claim which differs from claim 1 of auxiliary request 1 in that some of the composition's ingredients have been further specified and more ingredients have been added. It reads as follows:

"*A composition comprising DHA and EPA, (b) uridine monophosphate, choline, lecithin, vitamin E, vitamin C, selenium, folate, vitamin B6 and vitamin B12, for use in the treatment of prodromal Alzheimer's disease in a patient suffering from said prodromal Alzheimer's disease, said patient having at least:*

- *a level of more than 350 ng Total-tau per litre cerebrospinal fluid (CSF);*
- *a weight ratio of abeta-42/Phospho-tau-181 of less than 6.5 in CSF*".

V. The patent proprietor (appellant) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the requests before the opposition division, which were re-filed with the statement setting out the grounds of appeal.

VI. Opponents 1 and 2 (respondents 1 and 2) requested that the appeal be dismissed. They further requested that, should the board decide not to dismiss the appeal, the case be remitted to the opposition division for the remaining issues to be dealt with.

VII. In a communication issued in preparation for the oral proceedings the board drew the parties' attention to the points to be discussed during the hearing, which included the issues of whether the combination of ingredients making up the claimed composition was disclosed in the application as filed, and whether the earlier patent application as filed disclosed a treatment of patients "*having characteristics of a prodromal dementia patient*" which appeared to extend beyond "*the prevention of delay of the onset of dementia*".

VIII. On 13 June 2019, oral proceedings took place before the board. During the proceedings the appellant filed a new auxiliary request 2 replacing the previously filed auxiliary request 2.

IX. Claim 1 of the new auxiliary request 2 differs from claim 1 of the previous auxiliary request 2 in that it now refers to "*for use in the treatment of prodromal Alzheimer's disease in a patient suffering from said prodromal Alzheimer's disease, wherein the treatment is the prevention or delay of the onset of Alzheimer's disease*" (amendment over previous auxiliary request 2 underlined).

X. The respondents requested that the new auxiliary request 2 not be admitted into the appeal proceedings.

XI. *The appellant's arguments, where relevant for the decision, may be summarised as follows.*

The patent did not contain added subject-matter compared to the patent application and the parent patent application as filed. All features characterising the claims of the different requests were disclosed in the following sections of the description of the application and of the parent application as filed:

- DHA and EPA: page 6 line 35 - page 7 line 1
- Uridine and its equivalents: page 9 line 27-32 and page 10 line 4-7
- Vitamins C, E, B12, folic acid: page 13 line 1-4
- Choline/phosphatidylcholine: page 11 line 14-16, 21
- Use in the treatment of prodromal dementia in a person suffering from prodromal dementia or prodromal Alzheimer's disease: page 4 line 26-27, page 1-3 and page 4 l. 1-11
- "..a level of more.." and a "..weight ration of..": page 5 line 1-5 and line 26-28.

The change in wording from "*for the prevention or delay of the onset of dementia in a person having characteristics of a prodromal dementia patient*" as used in claim 1 of the parent application as filed to "*for use in the treatment of prodromal dementia and or prodromal Alzheimer's disease in a patient suffering from said prodromal dementia or prodromal Alzheimer's disease*" in claim 1 of the main request and auxiliary request 1 did not change the technical teaching. The treatment of a prodromal patient could not result in anything else than delaying the onset of dementia or Alzheimer's disease in that patient.

The second auxiliary request was filed in the course of the oral proceedings before the board to address the negative finding of the board, reached during the hearing, that the intended use specified in claim 1 of the main and of auxiliary request 1 was not disclosed in the parent application as filed.

XII. *The respondent's arguments, where relevant for the decision, may be summarised as follows*

XIII. In order to arrive at the claimed composition, the skilled person had to make multiple selections from several lists of ingredients disclosed in the application and in the parent application as filed. Example 4 did not provide a pointer towards the combination of the ingredients listed in claim 1. The claimed composition could also not be seen as the result of an overlap between the generic teaching of the sections of the description describing ingredients suitable for the invention and the specific disclosure of the composition used to carry out the tests of example 4.
The parent application as filed did not disclose a treatment of prodromal patients which went beyond delaying and/or preventing the onset of dementia and Alzheimer's disease. The "*treatment of a prodromal patient*" was not necessarily equivalent to the "*prevention or delay of the onset of dementia/ Alzheimer's disease in a patient*". The generic treatment defined in amended claim 1 encompassed therapeutic uses which were not disclosed in the parent application as filed.
Therefore, the claims of the main request and of auxiliary request 1 contained subject-matter extending beyond the content of the parent application as filed.

Auxiliary request 2 had only been filed during the oral proceedings before the board, although it addressed issues which had already been raised by the board in the communication issued in preparation to the oral proceedings. Thus, it should not to be admitted into the appeal proceedings.

Reasons for the Decision

Main request

1. Added subject-matter

1.1 The opposed patent was filed as a divisional application of European patent application Nr. 08766831. Claim 1 of the parent application as filed teaches to use a composition comprising DHA, DPA and EPC, uridine or its equivalents, choline and/or phosphatidylcholine and other ingredients:

"... *for the prevention or delay of the onset of dementia in a person having characteristics of a prodromal patient*".

1.2 This teaching is consistently reiterated in the other sections of the parent application as filed which disclose the claimed invention, namely in the sections "Summary of the invention" (page 4, line 11) and "Description of the invention" (page 4, lines 16, 23 and 24.

1.3 The skilled person would thus promptly recognise that the invention disclosed in the parent application as filed aims and is limited at slowing down (or even preventing) the progression to the clinical stage of

dementia and Alzheimer's disease in patients in a prodromal stage of these diseases.

Claim 1 of the main request instead is directed to:

"*... the treatment of prodromal dementia and/or prodromal Alzheimer's disease in a patient suffering from said prodromal dementia or prodromal Alzheimer's disease..*".

1.4 This claim no longer contains a reference to the prevention or delay of the onset of dementia (or Alzheimer's disease). The claim defines a generic treatment of prodromal dementia and/or prodromal Alzheimer's disease in a patient suffering from said prodromal dementia or prodromal Alzheimer's disease.

1.5 There is no basis in the parent application as filed for claiming such a generic treatment. The first sentence in the parent application as filed (section "Field of the invention") states that the invention relates to a "product which is used in the treatment of a prodromal neurological patients, in particular prodromal dementia patients". However, this generic statement is to be interpreted in the light of the claims and of the aforementioned passages of the description of the parent application as filed which define the invention, and which are strictly limited to a preventive treatment. The appellant relied on the above cited passages in the "Summary of the invention" and "Description of the invention". It is accepted that these passages refer to prodromal patients, but as stated above, they do not disclose the general treatment defined in claim 1 of the main request. Thus, none of these passages provides a basis for amended claim 1.

1.6 According to the appellant the amendment to claim 1 did not reflect any technical change in the treatment which was actually carried out. In its opinion, the only possible therapeutic effect which might be attained in prodromal patients was a delay of the onset of dementia. Therefore, the "treatment" defined in claim 1 corresponded plainly to "delaying and/or preventing dementia or Alzheimer's disease", as defined in the parent application as filed. From a technical point of view these wordings were therefore equivalent and could be used interchangeably.

1.7 The board does not agree that these expressions are technically equivalent. Already the granted set of claims shows that the appellant's argument is not tenable. Whereas granted claim 1 defines a composition "for use in the treatment of a prodromal neurological disorder", dependent granted claim 4 reads as follows:

"4. The composition for use according to any one of the previous claims, for use in the prevention or delay of the onset of dementia or Alzheimer's disease".

The board has difficulties to accept that a dependent claim has the same meaning and scope as the independent claim from which it depends. Normally, a dependent claim defines a more restricted embodiment of the independent claim. Thus, in the board's view the wording used in these claims is not freely interchangeable.

1.8 The board agrees with the respondents that on a plain reading of claim 1 the treatment encompasses a therapeutic method improving *e.g.* the well being of the patient and/or the treatment of neurological damages

which do not necessarily lead to a delay or prevention of the onset of dementia. The appellant has not provided evidence that any treatment of prodromal patients necessarily results in the delay of the onset of dementia.

1.9 For these reasons, the invention defined in claim 1 of the main request cannot be considered equivalent to that disclosed in the parent application as filed. As already mentioned above, no basis for the newly defined treatment method can be found in the parent application as filed. Accordingly, claim 1 contains added subject-matter which is not clearly and unambiguously disclosed in the parent application as filed (Articles 76 and 100(c) EPC).

Auxiliary request 1

2. Added subject-matter

2.1 Auxiliary request 1 differs from the main request only in that the use specified in claim 1 has been limited to "... in *the treatment of prodromal Alzheimer's disease in a patient suffering from said Alzheimer's disease ...*". Although the reference to "dementia" has been deleted, the remaining part of the claim and in particular the way in which the treatment is defined is the same. Thus, the reasons for finding that the main request contains added subject-matter equally apply to auxiliary request 1 (Articles 76 and 100(c) EPC).

Auxiliary request 2

3. Admissibility

3.1 Claim 1 of auxiliary request 2 was amended to indicate that the claimed composition is:

"... *for use in the treatment of prodromal Alzheimer's disease in a patient suffering from said prodromal Alzheimer's disease, wherein the treatment is the prevention or delay of the onset of Alzheimer's disease, ...*".

3.2 According to the appellant, auxiliary request 2 was filed during the oral proceedings as a reaction to the board's negative finding, announced at the hearing, that claim 1 of the main request (and auxiliary request 1) referred to a therapeutic treatment not disclosed in the parent application as filed.

3.3 The board does not consider this as an acceptable justification for such a late filing. The communication issued by the board in preparation for the oral proceedings clearly indicated that the issue relating to a change in the nature of the therapeutic treatment was of relevance for the decision on added subject-matter. During the hearing before the board the appellant conceded that it had understood this issue when preparing for the oral proceedings. However, even being aware of a possible negative decision, it did not file in due time a new set of claims addressing the open points, and waited the oral proceedings for doing so.

3.4 The board considers it not an appropriate conduct by a party to wait until the last minute in the oral

proceedings for filing a request addressing a point highlighted in the communication issued by the board in preparation for those oral proceedings. Therefore, taking into account the stage of the appeal proceedings and the need for procedural economy, the board decided not to admit auxiliary request 2 into the appeal proceedings (Article 13(1) RPBA).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

L. Malécot-Grob W. Sieber

Decision electronically authenticated