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**Datasheet for the decision
of 28 June 2018**

Case Number: T 2274/14 - 3.3.09

Application Number: 08766833.1

Publication Number: 2162019

IPC: A23L1/29, A23L1/30, A61K31/00

Language of the proceedings: EN

Title of invention:
Lipid composition for improving brain function

Patent Proprietor:
N.V. Nutricia

Opponent:
Nestec S.A.

Headword:

Relevant legal provisions:
RPBA Art. 13(1)
EPC Art. 56

Keyword:
Late-filed evidence - admitted (no)
Inventive step - (no, all requests)

Decisions cited:

Catchword:



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Case Number: T 2274/14 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 28 June 2018

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 16 October 2014
revoking European patent No. 2162019 pursuant to
Article 101(3) (b) EPC**

Composition of the Board:

Chairman W. Sieber
Members: J. Jardón Álvarez
D. Prietzel-Funk

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the patent proprietor against the decision of the opposition division to revoke European patent No. 2 162 019.

II. The granted patent contained sixteen claims. Independent claims 1, 12 and 16 read as follows:

"1. Lipid fraction comprising hexanoic acid and/or octanoic acid, at least 0.4 g of eicosapentaenoic acid, and more than 0.4 g α -linolenic acid per 100 g fatty acids of the lipid fraction for use in the support of brain function, wherein the weight amount of the sum of linear fatty acids having 6, 7 or 8 carbon atoms to the weight amount of the sum of fatty acids having 9 or 10 carbon atoms is more than 2.5."

"12. A nutritional or pharmaceutical product for use in the support of brain function, comprising a lipid fraction according to any one of the preceding claims.

"16. Lipid fraction comprising a source of di- and monoglycerides, said source providing 45-100 wt% of hexanoic acid and/or octanoic acid, for use in improving brain function."

Claims 2 to 11 and 13 to 15 were dependent claims.

III. The opponent had requested revocation of the patent in its entirety on the grounds of Article 100(a) (lack of novelty and inventive step), (b) and (c) EPC. The documents cited during the opposition proceedings included:

D1: US 6 835 750 B1;

D2: WO 2007/001883 A2;

D6: E. Freemantle *et al.*, "Omega-3 fatty acids, energy substrates, and brain function during aging", *Prostaglandins, Leukotrienes and Essential Fatty Acids*, 75, 2006, pages 213 to 220;

D11: L. Sek *et al.*, "Evaluation of the in-vitro digestion profiles of long and medium chain glycerides and the phase behaviour of their lipolytic products", *Journal of Pharmacy and Pharmacology*, 54, 2002, pages 29 to 41;

D12: Experimental report submitted by the patent proprietor with a letter dated 12 June 2014, 3 pages;

D13: Declaration by Mr Rieker dated 11 July 2014, filed by the opponent during the oral proceedings before the opposition division, 2 pages; and

D14: Declaration by Ms Mitchell dated 11 July 2014, filed by the opponent during the oral proceedings before the opposition division, 2 pages.

IV. The opposition division's decision was based on a main request (granted claims) and three auxiliary requests.

- On the main request, the opposition division held that claim 1 did not contain subject-matter which extended beyond the application as filed and that the invention was sufficiently disclosed. However, it rejected the request because the subject-matter of granted claim 16 lacked novelty over D1.

- On auxiliary request 1, the opposition division took the view that no technical effect was associated with the features distinguishing the subject-matter of claim 1 (identical to granted claim 1) from the closest prior art D2. In the absence of such an effect, the claimed subject-matter was obvious in view of D2 in combination with D6.

- In these circumstances, the opposition division did not admit late-filed documents D11 to D14 into the proceedings. As to D12, supplementary experiments filed by the patent proprietor to show the presence of an effect due to the distinguishing features, this document could not be taken into consideration because: (i) it could not provide evidence of an inventive step over the entire range claimed; (ii) it did not transparently provide data since, for example, the concentrations were lacking; and (iii) it attempted to prove an effect retrospectively.

V. The patent proprietor (in the following: the appellant) filed the statement setting out the grounds of appeal on 26 February 2015 and requested that the decision under appeal be set aside, and that the patent be maintained as granted (main request) or, alternatively, on the basis of the claims according to auxiliary requests 1 to 4 filed with the statement. It also filed the following evidence:

D15: Study headed "Memory in the radial arm maze as measure for brain function: the effects of MCT, ALA +EPA or the combination of MCT and ALA +EPA" (2 pages).

VI. With its reply dated 1 July 2015, the opponent (in the following: the respondent) requested that the appeal be dismissed. It also filed the following evidence:

D16: Declaration by Ellen Siobhan Mitchell, dated 15 June 2015, 2 pages.

VII. Further submissions were filed by the appellant on 15 February 2107 and by the respondent on 20 April 2017. The appellant's submissions included the following experimental evidence:

D17: "Enhanced neurite outgrowth of PC12 cells after supplementation with specific MCT nutrient blend" S. Lotstra, *et al.*, 3 pages.

VIII. In the annex to the summons to oral proceedings, the board indicated the points to be discussed during the oral proceedings. The board also gave its preliminary view that it tended to agree with the finding in the appealed decision that the subject-matter of claim 16 was anticipated by D1.

IX. In reply to the board's communication the appellant filed with a letter dated 24 April 2018 a new main request and new auxiliary requests 1 to 3 replacing its previous requests on file.

The respondent filed submissions with a letter dated 17 May 2015.

X. During the oral proceedings held on 28 June 2018 the respondent withdrew its objections under Article 100 (b) and (c) EPC, so the only substantive objection maintained was that the claimed subject-matter lacked inventive step.

The claims of the main request are granted claims 1 to 15 (see point II above).

Claims 1 of auxiliary requests 1 and 2 are identical and read as follows (amendments to claim 1 of the main request in bold).

"1. Lipid fraction comprising hexanoic acid and/or octanoic acid, at least 0.4 g of eicosapentaenoic acid, and more than 0.4 g α -linolenic acid per 100 g fatty acids of the lipid fraction for use in the support of brain function, wherein the weight amount of the sum of linear fatty acids having 6, 7 or 8 carbon atoms to the weight amount of the sum of fatty acids having 9 or 10 carbon atoms is more than 2.5, **wherein the brain function is supported in a prodromal patient for a neurological disorder, or in a patient suffering from senile dementia or from Alzheimer's disease.**"

Claim 1 of auxiliary request 3 reads as follows (amendments to claim 1 of the main request in bold).

"1. Lipid fraction comprising hexanoic acid and/or octanoic acid, at least 0.4 g of eicosapentaenoic acid, and more than 0.4 g α -linolenic acid per 100 g fatty acids of the lipid fraction for use in the support of brain function **involving improving nutritional status of neuronal cells**, wherein the weight amount of the sum of linear fatty acids having 6, 7 or 8 carbon atoms to the weight amount of the sum of fatty acids having 9 or 10 carbon atoms is more than 2.5, **wherein the brain function is supported in a prodromal patient for a neurological disorder, or in a patient suffering from senile dementia or from Alzheimer's disease.**"

XI. The arguments of the appellant which are relevant for the present decision may be summarised as follows:

- D12 should have been admitted into the proceedings. The opposition division had not exercised its discretion in a reasonable way. D12 had been filed as a direct reaction to a fresh inventive-step objection made during opposition proceedings. It confirmed that the claimed compositions were an improvement over known compositions, as already stated on page 4, lines 23-24, of the application as filed. Furthermore, D12 confirmed the synergistic combination of medium chain triglycerides (MCTs) and α -linolenic acid (ALA) + eicosapentaenoic acid (EPA). The lack of information concerning the concentrations of the fatty acids in D12 was irrelevant as the components were applied at levels which gave rise to the claimed effect.
- D17 should be admitted into the proceedings. It supported the appellant's view that the opposition division had erred in not admitting D12. D17 had been filed as soon as the data had been obtained and aimed to overcome the deficiencies in D12. It confirmed the synergistic effect of the claimed compositions.
- Starting from D2 as the closest prior-art document, the problem to be solved by the patent in suit was to provide lipid compositions with improved brain function. This problem was solved by the claimed compositions that showed improved brain function. The claimed subject-matter involved an inventive step because there was nothing hinting at such an improvement in the cited documents.

- Even if no improvement was acknowledged, the claimed subject-matter still involved an inventive step because nothing in D2 hinted at the claimed combination of features. In fact, D2 disclosed a long list of agents to be used in combination with MCTs and there was no preference for the two specific fatty acids now required by claim 1. The skilled person would also not combine D6 with D2 as the two documents dealt with different problems to be solved. Such a combination was made with hindsight knowledge of the invention.
- The same reasoning applied to the subject-matter of the auxiliary requests.

XII. The respondent's arguments, in so far as they are relevant for the present decision, may be summarised as follows:

- Documents D12 and D17 should not be admitted into the proceedings, in particular because it could not be verified on the basis of the information in those documents whether the experimental data they contained related to compositions falling within the scope of the claims.
- Document D2 represented the closest prior art. It disclosed the explicit combination of MCTs with fatty acids including ALA and EPA in compositions for the same use as the compositions of claim 1. There was no evidence on file showing any technical effect derived from the distinguishing features of the claim and, consequently, the technical problem resided in the provision of an alternative lipid fraction to the one disclosed in claim 21 of D2.

The selection of ALA and EPA from the list disclosed in D2 was an arbitrary selection. Additionally, D6 already suggested that ALA and EPA optimised brain function.

XIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of the main request or of one of auxiliary requests 1 to 3, all filed with the letter of 24 April 2018.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. Procedural matters

1.1 The appellant requested that the opposition division's decision not to admit D12 into the opposition proceedings be set aside.

1.2 The respondent requested that D12 and D17 not be admitted into the proceedings, but that D11, D13, D14 and D16 be admitted.

1.3 Admission of D12

1.3.1 The appellant had filed D12 one month ahead of the oral proceedings before the opposition division, that is to say, within the time limit fixed by the opposition division under Rule 116 EPC for making written submissions, and had requested its admission into the proceedings. The opposition division declined to do so, and this aspect of the decision is challenged by the appellant in the appeal proceedings.

1.3.2 EPO practice in such cases is that it is not the function of the board to review all the facts and circumstances of the case as if it were the department of first instance, and to decide whether or not it would have exercised its discretion in the same way. A board of appeal should overrule the way in which a department of first instance has exercised its discretion only if it concludes that the department did so in accordance with the wrong principles, or without taking into account the right principles, or in an unreasonable way (see Case Law of the Boards of Appeal of the European Patent Office, 8th edition 2016, IV.E. 3.6).

1.3.3 The non-admission of D12 is discussed in point 4.3.2.2 of the appealed decision. The reasons of the opposition division may be summarised as follows:

- D12 did not provide evidence of an inventive step over the entire range claimed;
- D12 did not transparently provide data; for example the concentrations were lacking; and
- D12 attempted to prove an effect retrospectively whereas said effect should already have been credibly shown by the application. It was not a document which had been triggered by the need for comparison with a piece of close prior art established in the course of the proceedings.

1.3.4 The appellant maintained that the opposition division did not exercise its discretion in a reasonable way. It argued that D12 had been filed in direct reply to the opposition division's preliminary view that inventive

step had to be discussed in the oral proceedings in view of the combined teaching of D2 and D6. D12 dealt with this issue and confirmed the statement on page 4, lines 23-24, of the application as filed that the claimed combination of ingredients fully supported brain function. The claimed compositions were an improvement over prior-art blends, in particular over those in the prior-art documents cited by the opposition division in its communication.

- 1.3.5 The board disagrees. As indicated by the opposition division, the relevance of D12 for the claimed subject-matter is rather questionable due to the lack of information concerning the concentration of the ingredients used in the experiments. In fact, D12 is silent about the amounts used and the skilled person is not in a position to determine whether the experimental data relate to compositions falling under the scope of claim 1.

According to the established jurisprudence (see Case Law of the Boards of Appeal of the European Patent Office, 8th edition 2016, I.D.10.9), when a surprising effect, for instance a synergistic effect, is demonstrated in a comparative test, the comparison must be such that the alleged effect is convincingly shown to have its origin in the distinguishing feature of the invention compared with the closest state of the art.

This is not the case. As explained in detail below in relation to inventive step, the subject-matter of claim 1 is distinguished from the disclosure of D2 essentially by the use of two specific fatty acids selected from the general disclosure of D2, **these acids being used in specific amounts**, and by a given weight ratio of fatty acids having 6 to 8 carbon atoms to

those having 9 or 10 carbon atoms (see point 2.2.5 below). The lack of information about the amounts of fatty acids used in the examples of D12 makes its results meaningless because it is not possible to establish whether or not the alleged improvement is due to the distinguishing features of the claim.

In this context, the board cannot accept appellant's argument that in an *in vitro* study concentrations were deemed to be irrelevant and that what mattered was the improvement over D2 and/or D6. If one were to accept this argument, one would also have to conclude that the experiments were in principle not suitable to demonstrate an effect relating to a composition according to claim 1, which requires a specific amount of ALA and EPA.

1.3.6 In so far as the appellant relied on the filing of D12 within the time limit fixed by the opposition division, the board notes that the preliminary opinion of the opposition division was not a new development in the case, but merely a summary of the objections raised by the opponent in its notice of opposition.

1.3.7 It follows from the above that the opposition division exercised its discretion in accordance with the right principles in a reasonable way. In view of these facts, the board sees no reasons to overturn the opposition division's decision not to admit D12 into the proceedings.

1.4 Admission of D17

1.4.1 The appellant filed D17 on 15 February 2017 during the appeal proceedings. The respondent requested that this document not be admitted into the proceedings because

it had been late filed without any justification and because it could not serve to support the appellant's arguments, in particular with regard to inventive step. Among other objections it pointed out that the compositions used in D17 did not represent compositions according to claim 1 because the amount of α -linolenic acid (ALA) was below the minimum amount required by claim 1.

- 1.4.2 The appellant argued that it had filed D17 in order to overcome the objections of the opposition division concerning the non-admittance of D12 and that it had filed the document as soon it had completed the experiments.
- 1.4.3 The board agrees with the respondent that the compositions used in D17 are not suitable to show any improvement achieved by the claimed compositions because the compositions used are not within the scope of claim 1. They contain only 0.13 g of ALA per 100 g fatty acids of the lipid fraction as calculated by both parties during the oral proceedings, while the claim requires the presence of more than 0.4 g ALA per 100 g fatty acids.
- 1.4.4 Consequently, D17 cannot show any improvement achieved by the claimed compositions over the known compositions. In view of this finding, the board exercising its discretion under Article 13(1) of the Rules of Procedure of the Boards of Appeal decided not to admit D17 into the appeal proceedings.
- 1.5 Admission of other documents
 - 1.5.1 Given that the board has decided not to admit D12, there was no need to decide on the admission of D13 and

D14, which were filed by the respondent to contest the findings in D12.

- 1.5.2 Lastly, D11 and D16 were not relied on by the respondent during the oral proceedings so that there was also no need for the board to decide on their admission.

MAIN REQUEST

2. *Inventive step*

- 2.1 The patent is directed to lipid blends comprising selected fatty acids for improving brain function in a mammal, in particular in the elderly (paragraph [0001]). The patent itself acknowledges that lipid blends have already been used in the manufacture of foods for improving brain function and that these known compositions have drawbacks (paragraph [0003]). The invention aims to provide advantageous lipid formulations for the support of brain function (paragraph [0006]).

In paragraph [0013] it is stated that the claimed compositions have been developed to fully support brain function by improving nutritional status of neuronal cells. According to paragraph [0042], support of brain function is intended to improve skills related to activities of daily living, cognition, social skills, decision-making skills, motoric skills and abilities to live without the help of others. The brain function is also said to be supported in a prodromal patient for a neurological disorder, in a patient suffering from a cognitive decline or in a patient suffering from senile dementia, Alzheimer's disease, diabetes or insulin resistance or in a patient who has experienced a

physical trauma or toxicological trauma
(paragraph [0043]).

2.2 Closest prior art

2.2.1 The board concurs with the opposition division and both parties that the closest prior art is represented by D2.

2.2.2 D2 discloses a method of modulating mitochondrial function in a mammal, comprising administering an effective amount of an agent which induces development of ketosis in the mammal, whereby the mitochondrial function is modulated (claim 1). Such an agent comprises medium chain triglycerides (MCTs) or prodrugs thereof (claim 2). Furthermore, D2 discloses in paragraph [0039] that "oxidative damage and mitochondrial inefficiency have been implicated as central to the etiology of Alzheimer's disease". In other words, the agents of D2 influence the etiology of Alzheimer's disease in a positive manner and thus, like the claimed compositions, support brain function.

2.2.3 The MCTs used in D2 are triglycerides whose fatty acids have 5 to 12 carbon atoms in the carbon backbone (paragraph [0040]). In example 1 the decrease in oxidative damage is demonstrated using a MCT derived from octanoic acid, namely tri-C8:0 MCT.

2.2.4 The agent comprising a MCT may be combined with further ingredients, such as sugars, tricarboxylic acid cycle intermediates, ketone bodies or their precursors, metabolic adjuvants, such as vitamins, minerals, antioxidants, therapeutic agents and therapeutic agents, etc. (paragraphs [0009] to [0017]). Paragraph [0018] particularly refers to an embodiment

comprising a MCT combined with a triglyceride containing one or more essential fatty acids or precursors thereof selected from a group referring, *inter alia*, to alpha-linolenic acid (ALA) and eicosapentaenoic acid (EPA). The same disclosure can be found in claim 21.

2.2.5 In summary, D2 discloses lipid compositions which could comprise the same ingredients as the lipid fraction of claim 1 for the same purpose. However, D2 does not disclose a composition with the specific combination of fatty acids and their amounts required in claim 1, namely a composition comprising hexanoic acid and/or octanoic acid, at least 0.4 g of EPA and more than 0.4 g of ALA per 100 g fatty acids, and wherein the weight ratio of the sum of linear fatty acids having 6, 7 or 8 carbon atoms to those having 9 or 10 carbon atoms is more than 2.5. Thus this specific combination of fatty acids with the amounts used is a selection within the more general teaching of D2.

2.3 Problem to be solved and its solution

2.3.1 According to the appellant, the problem underlying the patent in the light of D2 was to provide an improved lipid composition to support brain function (paragraph [0013] of the patent specification).

2.3.2 This was contested by the respondent, which argued that no technical effect due to the distinguishing features had been demonstrated in the patent.

2.3.3 The board agrees with the respondent that there is no evidence on file showing any improvement achieved by the claimed compositions over those of D2:

- The patent does not contain any working example showing any effect of the claimed compositions;
- D12 and D17, on which the appellant basically relied in the written procedure, have not been admitted into the proceedings by the board, essentially because they were not suitable to support any improvement achieved by the compositions of claim 1 (see points 1.3 and 1.4 above); and
- D15 was not used by the appellant during the oral proceedings because it had been filed for a different purpose.

2.3.4 The board also cannot follow appellant's argument that paragraph [0013] of the specification demonstrates that the above problem has been credibly solved. The sentence cited by the appellant reads:

"The lipid fraction as described below in detail has been developed to fully support brain function. Nutritional status of neuronal cells, in particular of neurons, astrocytes and glial cells **is improved against prior art lipid blends.**" (emphasis by the board).

This general statement simply cannot be used to establish an unexpected effect of the claimed compositions over any prior art composition, in particular those of D2.

2.3.5 Under these circumstances, the problem underlying the patent has to be reformulated in a manner that does not include any advantage over the disclosure of D2, that

is to say, as being to provide further lipid compositions to support brain function.

2.3.6 It is undisputed that this less ambitious problem is indeed solved by the claimed compositions.

2.4 Obviousness

2.4.1 It remains to be decided whether, in view of the available prior art, it would have been obvious for the skilled person to solve the above problem by the means claimed.

2.4.2 In the absence of any improvement, the board agrees with the respondent that the claimed combination of features according to claim 1 would be obvious to the skilled person in view of the teaching of D2 alone. While it is true that D2 does not disclose the specific combination of MCTs and ALA + EPA and that it does not specify in what amounts these components are to be used, the choice of these two fatty acids from the list of fatty acids mentioned in paragraph [0018] or in claim 21 of D2 and the choice of their given amounts are, in the board's view, an arbitrary selection from the more general teaching of D2. The skilled person would infer from the disclosure of D2 that the now claimed compositions would also be useful in supporting brain function.

2.4.3 The appellant argued that the claimed subject-matter involved an inventive step because a huge number of possible compositions were embraced by the broad teaching of D2. The skilled person would not have any motivation to select the composition according to claim 1.

2.4.4 The board is not convinced. As already explained above, the embodiment of claim 21 of D2 specifically discloses MCTs in combination with a rather limited number of essential fatty acids. In the absence of an unexpected effect, it is merely an arbitrary selection within the teaching of D2 that does not involve an inventive step.

Apart from that, the board notes that D6 already suggest that the two essential fatty acids required by claim 1, namely ALA and EPA, can be used to support brain function. D6 discloses in its abstract that:

"We speculate that ALA and EPA may well have useful supporting roles in maintaining brain function during aging but not by their conversion to DHA, ALA is an efficient ketogenic fatty acid, while EPA promotes fatty acid oxidation" (lines 8 to 10).

Even if the teaching of this sentence is regarded as a hypothesis (cf. "we speculate ..."), it provides a clear incentive to try using these two specific fatty acids to support brain function. Thus, the skilled person would be motivated to choose ALA and EPA from the list disclosed in claim 21 of D2.

2.4.5 In view of the above, the board concludes that the subject-matter of claim 1 of the main request does not involve an inventive step in view of the disclosure of D2 alone or, alternatively, in view of D2 in combination with D6.

AUXILIARY REQUESTS 1 TO 3

3. *Inventive step*

3.1 Claim 1 of auxiliary requests 1 and 2 specifies that:

"the brain function is supported in a prodromal patient for a neurological disorder, or in a patient suffering from senile dementia or from Alzheimer's disease".

3.2 Claim 1 of auxiliary request 3 further requires that the brain function involve:

"improving nutritional status of neuronal cells".

3.3 However, these additional features do not alter the assessment of inventive step, because the same features are already disclosed in D2. Indeed, as already explained in paragraph 2.2.2 above, the compositions of D2 are intended to support brain function also in persons suffering from Alzheimer's disease (paragraph [0039]). Moreover, the MCTs used in D2 are said to induce elevated ketone body levels that provide an energy source for extrahepatic tissues, such as neurons (paragraph [0032]).

3.4 In the absence of any evidence that these features lead to any unexpected effect, the objective technical problem for the subject-matter of these requests remains the same as for the main request, namely the provision of further lipid compositions to support brain function. For the same reasons as given above with regard to the main request, the skilled person would arrive in an obvious manner at the subject-matter of claim 1 of these requests.

3.5 This finding was accepted by the appellant as being conclusive given the assessment of the board regarding inventive step of the main request. It confirmed during the oral proceedings that its arguments for inventive step of these requests were the same as for the main

request and explained that it had filed them in order to overcome other objections of the opposition division.

3.6 Therefore the subject-matter of claims 1 of auxiliary requests 1 to 3 lacks an inventive step.

4. In summary, none of the appellant's requests is allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



T. Buschek

W. Sieber

Decision electronically authenticated