Internal distribution code:

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

Datasheet for the decision of 4 February 2021

Case Number: T 0240/16 - 3.3.09

Application Number: 11195555.5

Publication Number: 2436275

IPC: A23L1/29, A23L1/30, A61K31/00, A23L2/52, A61K31/19, A61K31/201, A61K31/202

Language of the proceedings: EN

Title of invention:
Lipid composition for improving brain function

Patent Proprietor:
N.V. Nutricia

Opponents:
Fresenius Kabi Deutschland GmbH
ABBOTT LABORATORIES
Société des Produits Nestlé S.A.

Headword:
Lipid fraction for use in the support of the brain function / NUTRICIA

Relevant legal provisions:
RPBA 2020 Art. 11, 12(2)
RPBA Art. 12(4)
EPC Art. 53(c), 54(5), 76(1), 84, 100(a), 100(c), 123(2), 123(3)

Keyword:
Main request - admission into the appeal proceedings (no)
Auxiliary request 1 - admission into the appeal proceedings (yes)
Auxiliary request 1 - added subject-matter and extension of scope of protection (no) - Clarity (yes)
Auxiliary request 1 - claimed subject-matter limited to a therapeutic application (yes) - Novelty (yes)
Remittal to the opposition division (yes)

Decisions cited:
T 1278/12, T 0052/15, T 0586/16, T 1966/16, T 0731/17, G 0009/91

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

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 0240/16 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 4 February 2021

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)	Fresenius Kabi Deutschland GmbH Else-Kröner-Stasse 1 61352 Bad-Homburg v.d.H. (DE)
Correspondence address:	Fresenius Kabi Deutschland GmbH Patent Department Borkenberg 14 61440 Oberursel (DE)
Respondent: (Opponent 2)	ABBOTT LABORATORIES 100 Abbott Park Road Abbott Park IL 60064 (US)
Representative:	Boult Wade Tennant LLP Salisbury Square House 8 Salisbury Square London EC4Y 8AP (GB)
Respondent: (Opponent 3)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 1 December 2015 revoking European patent No. 2436275 pursuant to Articles 101(2) and 101(3)(b) 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 proprietor against the opposition division's decision to revoke European patent No. 2 436 275. The application for the patent was filed as a divisional application of the earlier European patent application No. 08 766 833.1 (hereinafter the parent application).

II. With their notices of opposition the three opponents had requested that the patent be revoked in its entirety on the grounds under Article 100(a) EPC (lack of novelty, lack of inventive step and lack of industrial applicability) and Article 100(b) and 100(c) EPC.

III. The opposition division's decision was based on a main request (the patent as granted), auxiliary requests 1 and 2, filed during the oral proceedings before the opposition division, and auxiliary requests 3 to 7, filed with a letter dated 17 August 2015.

IV. The following documents are referred to in the present decision:

D5: US-A-5308832
D8: WO-A-99/33355

V. Claim 1 as granted read:

"*1. Lipid fraction comprising hexanoic acid and/or octanoic acid, eicosapentaenoic acid, and more than 0.4 g alpha-linolenic acid per 100 g fatty acids of the lipid fraction for the support of brain function.*"

VI. The opposition division revoked the patent. It held, *inter alia*, that:

- claim 1 as granted was not limited to the therapeutic use of the claimed lipid fraction and claim 13 as granted contained added subject-matter,

- auxiliary request 1 was admitted. The claimed subject-matter complied with the requirements of Articles 83, 84 and 123(2) EPC; however, this subject-matter was not limited to a therapeutic use of the claimed lipid fraction and was not novel over the cited prior art.

VII. During the appeal proceedings the proprietor (appellant) filed the following requests:

- main request and auxiliary requests 1 and 2, with the statement setting out the grounds of appeal,

- auxiliary request 3 to 6, with a letter dated 9 January 2017.

Claim 1 of the main request read:

"*1. Lipid fraction comprising hexanoic acid and/or octanoic acid, eicosapentaenoic acid, and more than 0.4 g alpha-linolenic acid per 100 g fatty acids of the lipid fraction for use in the support of brain function in a patient in need thereof.*"

Claim 1 of auxiliary request 1 read:

"*1. Lipid fraction comprising hexanoic acid and octanoic acid, eicosapentaenoic acid, and more than 0.4 g alpha-linolenic acid per 100 g fatty acids of the*

lipid fraction for use in the support of brain function, 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."

VIII. The appellant's arguments relevant to the decision were as follows.

The main request should be admitted into the appeal proceedings. It had been filed in direct response to the opposition division's finding that the granted claims encompassed non-therapeutic uses, an issue raised for the first time during the oral proceedings before the opposition division. Auxiliary request 1 could not be considered inadmissible either, having being correctly admitted and decided upon by the opposition division.

The claims of auxiliary request 1 complied with Articles 76, 84, 123(2) and 123(3) EPC. The wording "for use" had been inserted in the claims to adhere to the format according to Article 54(5) EPC. This amendment did not give rise to issues of clarity, added subject-matter and/or extension of the scope of protection. The specified treatment, which did not necessarily involve enteral administration, was disclosed in the application for the patent and in the parent application as filed. The replacement of the conjunction "and/or" with an "and", and the indication of the specified diseases in claim 1, did not add subject-matter either. Even if claim 9 did not mention a product, the claimed lipid fraction was inherently a product, in the same way as that of claim 13 of the parent application.

The claims of auxiliary request 1 were drafted in the format according to Article 54(5) EPC. They were limited to a therapeutic treatment of a brain malfunction affecting a patient affected by one of the specified diseases. The "improvement of skills" mentioned in paragraph [0043] of the patent was also to be interpreted in this therapeutic context. The claimed treatment was not disclosed in the cited prior-art documents. In particular, D5 and D8 did not disclose the treatment of a prodromal patient.
The case had to be remitted to the opposition division for a decision to be made on the issues of novelty and inventive step.

IX. The arguments presented by the opponents (respondents) which are relevant to the decision were as follows.

The main request and auxiliary request 1 should not be admitted into the appeal proceedings. The main request was new and addressed objections which had already been raised in the early stages of the opposition proceedings. There was no reason to file this request on appeal. Auxiliary request 1 had been filed and admitted during the oral proceedings before the opposition division; however, the opposition division's decision to admit it was wrong and had to be overruled.

The insertion of the wording "for use in" and "for use according to" in the claims of auxiliary request 1 resulted in a lack of clarity, added subject-matter and extension of the scope of protection. The specified use was not disclosed in the application and in the parent application as filed, in particular as far as it did not involve enteral administration. The lipid fraction in claim 9 was not a product in the same way as that disclosed in claim 13 of the parent application.

Replacing the "and/or" with an "and" in claim 1, and mentioning only some of the originally disclosed diseases, resulted in a double selection creating originally undisclosed subject-matter. Furthermore, while claim 2 as granted and the following claims were limited by the features of claim 1 as granted, the corresponding amended claims were not. Therefore, the scope of protection was extended beyond that conferred by the claims as granted.

The use defined in the claims of auxiliary request 1 was not necessarily a therapeutic treatment in the sense of Articles 53(c) and 54(5) EPC. The claims encompassed the conventional nourishment of patients affected by the listed diseases. This was confirmed by the teaching in paragraphs [0009], [0012], [0015], [0017], [0040] and [0043] of the opposed patent. Paragraph [0043] described the improvement of skills relating to activities of daily living rather than a therapeutic use. Neither the wording "for use" nor the mention of specific patients in claim 1 limited the claimed subject-matter to a therapeutic treatment. As far as they encompassed a non-therapeutic use, the claims defined a lipid fraction suitable for providing ordinary nutrition to the specified subjects. Such a lipid fraction was known in the prior art. Even construing the claims under Article 54(5) EPC, the claimed subject-matter was not novel over D5 and D8. These documents disclosed the treatment of patients affected by a neurological disorder in the prodromal stage.

Respondents 2 and 3 argued that, were the subject-matter of any request to be construed under Article 54(5) EPC and held to be novel, the case should be remitted to the opposition division for

consideration of inventive step (respondent 2), sufficiency, priority, novelty and inventive step (respondent 3).

X. **The requests**

The appellant requested that the contested decision be set aside and that the patent be maintained on the basis of any one of the following requests:

- main request and auxiliary requests 1 and 2, filed with the statement setting out the grounds of appeal of 11 April 2016;

- auxiliary requests 3 to 6, filed with a letter dated 9 January 2017.

The respondents requested that the appeal be dismissed.

Reasons for the Decision

Main request

1. *Admissibility*

1.1 The main request was filed with the statement setting out the grounds of appeal. It refers to a "use in the support of brain function in a patient in need thereof". This same expression is contained in claim 1 of the proprietor's auxiliary request 1, filed with a letter dated 17 August 2015 and annexed to the decision under appeal as Annex 3a, which was withdrawn during the oral proceedings before the opposition division; see point 4 of the minutes of the oral proceedings. The appellant explained that during those oral proceedings, in view of the conclusion on the then main request, the

proprietor did not expect the opposition division to reach a different conclusion on auxiliary request 1. Therefore, the proprietor had decided to withdraw that request and replace it with a new one.

1.2 The appellant has also argued that the new main request filed on appeal addressed the opposition's division finding that the claimed subject-matter encompassed non-therapeutic uses. In its opinion, this issue was raised for the first time during the oral proceedings before the opposition division.

1.3 The board does not consider the appellant's explanation a good reason for filing the new main request on appeal. By withdrawing the previous auxiliary request 1 during the oral proceedings, the proprietor prevented the opposition division from deciding whether the expression "support of brain function in a patient in need thereof" limited the claimed subject-matter to a therapeutic use. The new main request, filed with the statement of grounds of appeal, contains the same definition and raises this issue, on which a decision has not yet been made. Furthermore, the issue of whether the claims are limited to a therapeutic use had already been raised by the opponents in their notices of opposition and by the opposition division in its communication issued in preparation for the oral proceedings; see e.g. point 5.6 of that communication.

1.4 The appellant also considered that the opposition division had at least implicitly ruled on this issue because it held that an even more restricted wording such as that of claim 1 of present auxiliary request 1 was not limited to a medical use in accordance with Article 54(5) EPC. For the board, this argument is not convincing. Firstly, while auxiliary request 1 refers

to particular patient groups, it does not contain the expression "in need thereof", which is also not contained in claim 1 of any of the requests on which the decision under appeal is based. Secondly, if this argument were accepted, any request that is not filed before the opposition division and is broader than the most restricted request underlying the decision under appeal would need to be admitted.

1.5 In conclusion, admitting this request into the appeal proceedings would compel the board to make a decision as if it were the department of first instance on that issue. This course of action would run counter to the primary purpose of *inter-partes* appeal proceedings, which is to give the losing party the possibility of challenging the opposition division's decision on its merits (see decisions G 9/91, point 18 of the Reasons, and T 52/15, point 2.1 of the Reasons).

1.6 For these reasons, the main request is not admitted into the appeal proceedings (Article 12(4) RPBA 2007).

Auxiliary request 1

2. *Admissibility*

2.1 Auxiliary request 1 was filed for the first time during the oral proceedings before the opposition division and was admitted into the opposition proceedings. According to respondent 3 the opposition division did not correctly apply the criteria of "allowability of late-filed amendments on a prima facie basis" set out in the EPO Guidelines, E-III.8.6, when admitting this request. Thus, in its opinion, the decision to admit auxiliary request 1 had to be reversed on appeal.

2.2 This argument is not persuasive. In point 4 of the decision under appeal, the opposition division acknowledges that the claims of the request have been limited and represent a "serious attempt to address the objections held against the patent". Furthermore, it acknowledges that the amendments overcome the objection of added subject-matter which had led to the finding that the main request was not allowable. From the decision it also appears that the opposition division did not consider the amendments to *prima facie* give rise to new objections. This means that, when admitting auxiliary request 1, the opposition division neither exercised its discretionary power in an unreasonable manner nor applied the wrong principles. Accordingly, there is no reason to overrule its decision and to consider this request inadmissible on appeal.

3. *Added subject-matter and extension of the scope of protection (Articles 76, 123(2) and 123(3) EPC)*

3.1 The expressions "for use in" and "for use according to" were inserted in the claims of auxiliary request 1. These amendments were meant to adhere to the wording of Article 54(5) EPC, which foresees that a claim can be directed to a product already known to have been used in medicine for a second or further medical use.

3.2 These amendments do not add subject-matter, because from the application and the parent application as filed, the skilled person readily understands that the invention is directed to the treatment of patients whose brain function is compromised and needs support. The specific patients mentioned in the claims are also disclosed. Reference is made to the last paragraph of page 2, paragraphs 1 to 4 of page 3, to claim 18 of the original application as filed, and to the corresponding

parts of the parent application as filed. From page 3, second and third full paragraphs, page 10, lines 10 to 12 and claim 1 of the application as filed, and the corresponding parts of the parent application as filed, it is also clear that the liquid fraction is not necessarily administered by the enteral route.

3.3 Taking into account the wording and the structure of the entire claim set of auxiliary request 1, the skilled person promptly understands that claims 2 to 16 are characterised by all the features specified in claim 1. This means that the lipid fraction defined in these claims contains, in the same way as that of the corresponding claims of the application and of the parent application as filed, hexanoic acid and octanoic acid. Thus, the insertion of the wording "for use according to" in these claims neither adds originally undisclosed subject-matter nor extends the scope of protection of the patent as granted.

3.4 The conjunction "and/or" in the wording "hexanoic acid and/or octanoic acid" was replaced with "and" and three specific diseases were mentioned in claim 1. These were disclosed, among others, in the application and in the parent application as filed. These amendments result in restriction of the claimed subject-matter rather than in the creation of new subject-matter. No specific composition is singled out for a specific disease. Furthermore, as noted by the appellant, lipid fractions comprising both hexanoic acid and octanoic acid are explicitly foreseen in page 6, lines 1 to 3 and 20 to 21 of the parent application as filed and in the corresponding parts of the application as filed. In addition, those applications teach that the disclosed lipid fractions are suitable for treating all the diseases mentioned in those applications. There is no

indication that a particular lipid fraction is intended for treating a specific disease or group of diseases.

3.5 Claim 9 defines, in the same way as claim 13 of the parent application, a lipid fraction combined with a fibre fraction. It is true that, contrary to claim 13, claim 9 does not mention a "product". Nonetheless, the composition in claim 9 is inherently a "product". It should also be noted that claim 9 is directed to a "lipid fraction according to any one of the preceding claims" (emphasis added). Furthermore, the product disclosed in the parent application in claims 1 and 13 and on page 8, lines 20 to 27, is not necessarily a pharmaceutical or nutritional composition. Therefore, omitting a reference to these compositions does not create new subject-matter either.

3.6 For these reasons, the claims of auxiliary request 1 do not contain subject-matter extending beyond the content of the application for the opposed patent, or the parent application as filed, and do not extend the scope of protection of the patent as granted.

4. *Clarity (Article 84 EPC)*

4.1 The wording "for use according to" was inserted into claims 2 to 16. As mentioned above in point 3.3, from the structure of the claim set, the skilled person readily understands that these claims are directed to subject-matter including all the features specified in claim 1. That person would not have doubts as to the composition of the claimed lipid fraction. Therefore, the aforementioned wording does not render the claimed subject-matter unclear.

5. *Claim construction*

5.1 Claim 1 refers to a "lipid fraction" comprising certain fatty acids. According to the appellant, this is a "lipid fraction *per se*", or in other words, a product which does not contain any further ingredients.

5.2 This interpretation is not convincing. If reference is made to the claim set as a whole, it becomes readily apparent that the lipid fraction of claim 1 can occur in pure form or, alternatively, can be dispersed with other components. Only by adopting this interpretation can the following claims be correctly understood. For example, claim 5 states that the "lipid fraction contributes 45%-70% of the energy of the product". Since no antecedent is given for that product in the preceding claims, this is necessarily the same lipid fraction from claim 1, and this fraction contains an additional energy source.

5.3 This interpretation is in line with paragraphs [0010] and [0028] of the patent in suit, which teach that the lipid fraction can be used to manufacture a nutritional or pharmaceutical product and can be part of a product containing other ingredients. All the compositions disclosed in the examples comprise a lipid fraction dispersed within other ingredients.

5.4 The respondents have argued that the claimed "support of the brain function" encompasses the non-therapeutic support of the brain and, in particular, conventional nourishment of the brain tissue. Therefore, as far as they encompass this non-therapeutic use, the claims cannot be construed as purpose-limited product claims under Article 54(5) EPC. Instead, they define a lipid

fraction suitable for providing nourishment to the brain.

5.5 The board does not agree with this assessment. The skilled person would interpret claim 1 with a mind willing to understand, rather than a mind seeking to misunderstand. That skilled person would realise that there is a causal relationship between the indicated effect, i.e. providing support of the brain function, and the specific disorder or diseases by which the patients listed in the claim are affected. Furthermore, supporting the brain function in this way means treating a brain dysfunction affecting those patients. Senile dementia and Alzheimer's disease are typically characterised by brain dysfunctions. Neurological disorders do not necessarily affect the brain; however, the skilled person would understand that the neurological conditions defined in claim 1 are those which do involve a brain dysfunction and need therapeutic intervention. This intervention can be carried out by administering the lipid fraction as a pharmaceutical formulation or, alternatively, as a nutritional composition, e.g. dispersed in a diet.

5.6 The description of the opposed patent, including the paragraphs mentioned by the respondents, does not suggest a different interpretation of the claims. The section presenting the background of the invention describes the problems arising from the malfunctioning of the brain, and mentions several pathologies involving this malfunctioning. Furthermore, paragraphs [0009], [0012], [0015], [0040] and [0044] refer to the "treatment" of relevant diseases, to "patients", to the "atrophy of brain cells", and to subjects "suffering" from injuries, cognitive decline and other disorders, respectively. None of these passages describes the

administration of the claimed lipid fraction to provide non-therapeutic nourishment. It is true that paragraph [0040] refers to infants and children, and that paragraph [0043] mentions the improvement of skills relating to activities of daily living, including social skills, the ability to use house appliances or to travel; however, these improvements also have to be understood in a therapeutic context: if brain dysfunction hinders a subject's ability to perform these activities, a treatment supporting the brain function and improving the subject's ability to perform those activities is a therapeutic measure. This can occur in elderly people as well as in infants.

5.7 The respondents have drawn attention to T 1278/12. In this decision the board considered that a claim relating to the enteral administration of a composition comprising Bifidobacteria to an infant delivered via Caesarean section did not qualify as a further medical use claim. This is because the disease to be treated was not specified. In the same decision, however, the board considered that a claim relating to the use of that composition "for increasing the biodiversity of microorganisms in the intestinal flora of said infant" defined a therapeutic use. This claim implied that the increase of biodiversity was achieved in infants whose intestinal flora was essentially devoid of Bifidobacteria and needed treatment (see points 7.1.1 and 8 of the Reasons). Therefore, as in the present case, the disease or disorder to be treated was not explicitly mentioned, but could be inferred by the skilled person from the wording of the claims.

5.8 The opponents have also referred to T 586/16; however, the issue ruled upon in this decision was whether the claims contained added subject-matter. Furthermore, the

effect claimed and the subjects mentioned were substantially different from those in claim 1; mention was in fact made of "nutritional support" and of "stressed", "malnourished" and "elder individuals". Therefore, this decision is not relevant either.

5.9 For these reasons, it is concluded that the "support of brain function" in claim 1 defines a therapeutic treatment according to Article 53(c) EPC and does not encompass non-therapeutic nourishment of the brain. Therefore, this claim, as well as the remaining claims, are to be construed as purpose-limited product claims under the provisions of Article 54(5) EPC.

6. *Novelty*

6.1 The respondents objected to the novelty of the claimed subject-matter with regard to several documents; however, the respondents also conceded that, if claim 1 were construed according to Article 54(5) EPC, only D5 and D8 would be relevant. As claim 1 is construed according to this provision, the board only assesses novelty in view of these documents.

6.2 D5 discloses a composition comprising a lipid fraction as defined in claim 1, and its administration as a nutritional product to persons having a neurological injury, such as from trauma to the head; see Table 9 and column 1, lines 5 to 8. The composition provides nutritional support without inducing an increased rate of glucose production and an exaggerated hyperglycemic response in the brain. This is said to reduce the frequency of ischemic events after severe head injury; see column 1, lines 16 to 25 and 46 to 51, and column 2, lines 20 to 33.

6.3 The treatment of patients affected by senile dementia or Alzheimer's disease is not disclosed in D5, however. The treatment of patients affected by a neurological disorder in a prodromal state is not disclosed either. As explained by the patent proprietor, these are patients who are already affected by the disease but are still in a stage in which only early abnormalities have manifested. The fact that the patients described in D5 are at high risk of developing secondary neurological diseases, and that this risk can be reduced, does not imply that they are already affected by those diseases. Therefore, they cannot be referred to as "prodromal patients".

6.4 D8 discloses lipid fractions for treating neurodegenerative disorders; see Table 2 and page 17, line 8. In this case too, however, no mention is made of "prodromal patients" or of patients affected by senile dementia or Alzheimer's disease. It is also noted that neurodegenerative disorders do not necessarily involve a brain dysfunction, since they could only affect the spinal cord, for example. Therefore, D8 does not directly and unambiguously disclose the provision of support of the brain function which is causally linked to the neurodegenerative disorders referred to therein (cf. point 5.5 above).

6.5 For these reasons, the board concludes that the subject-matter of claim 1 of auxiliary request 1, as well as of the remaining claims, which are more limited in scope, is novel.

7. *Remittal of the case*

7.1 The issue of inventive step was not dealt with by the opposition division in its decision. Furthermore, a

decision was made on the issue of sufficiency of disclosure on the assumption that the claims were not limited to a therapeutic use, but rather to a lipid fraction as such which was suitable for such use. As mentioned above, the board arrives at a different conclusion. Therefore, sufficiency of disclosure has to be dealt with again, taking into account the board's finding with regard to the claim construction.

7.2 In this situation, and taking into account the parties' requests, the board considers that remittal is the appropriate course of action. As set out in Article 12(2) RPBA 2020, the primary object of the appeal proceedings is to review the decision under appeal in a judicial manner. This principle would not be respected if the board were to conduct a complete examination of complex issues which were not dealt with by the opposition division. Therefore, special reasons are present for remitting the case (Article 11 RPBA 2020 and decisions T 1966/16 and T 731/17).

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 for further prosecution.

The Registrar: The Chairman:

A. Nielsen-Hannerup A. Haderlein

Decision electronically authenticated