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**Datasheet for the decision
of 25 November 2025**

Case Number: T 0197/24 - 3.3.09

Application Number: 17811314.8

Publication Number: 3550985

IPC: A23D9/013, A61K31/201,
A61K31/202, A61K31/683,
A23L33/00, A23L33/12,
A61P25/32, A61P25/28,
A61P25/24, A61P25/22,
A61P25/16, A61P25/30,
A23L33/115, A61K31/20

Language of the proceedings: EN

Title of invention:
NUTRITIONAL COMPOSITION FOR IMPROVING CELL MEMBRANES

Patent Proprietor:
N.V. Nutricia

Opponent:
Société des Produits Nestlé S.A.

Headword:
Improving cell membranes/NUTRICIA

Relevant legal provisions:
EPC Art. 114(1), 54, 53(c)

Keyword:

Novelty - (no)

Decisions cited:

G 0009/91, G 0010/91, G 0004/93, G 0002/08, R 0014/23,
T 0223/95, T 1020/03, T 0240/16, T 1473/19, T 0450/20,
T 0815/22, T 0583/23



Beschwerdekammern

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Case Number: T 0197/24 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 25 November 2025

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 8 December 2023
revoking European patent No. 3550985 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman A. Haderlein
Members: F. Rinaldi
N. Obrovski

Summary of Facts and Submissions

- I. This decision concerns the appeal filed by the patent proprietor (appellant) against the opposition division's decision to revoke the European patent.
- II. In its notice of opposition, the opponent (respondent) had requested that the patent be revoked under Article 100(a) EPC (lack of novelty), among other grounds for opposition.
- III. The documents submitted during the opposition proceedings included:
- D2: J. C. McCann *et al.* "Is docosahexaenoic acid, an n-3 long-chain polyunsaturated fatty acid, required for development of normal brain function? An overview of evidence from cognitive and behavioral tests in humans and animals", *The American Journal of Clinical Nutrition* 82, 2005, 281-295
- D3: P. M. Kidd "Omega-3 DHA and EPA for Cognition, Behavior, and Mood: Clinical Findings and Structural-Functional Synergies with Cell Membrane Phospholipids", *Alternative Medicine Review* 12(3), 2007, 207-227
- D4: T. Moriguchi *et al.* "Behavioral Deficits Associated with Dietary Induction of Decreased Brain Docosahexaenoic Acid Concentration", *Journal of Neurochemistry* 75 (6), 2000, 2563-2573
- D5: WO 2012/173485 A1

D15: Experimental data (filed by the patent proprietor by letter dated 21 February 2022)

IV. In the decision under appeal, the opposition division held that it was competent to interpret the claims before it and to assess whether they related to a therapeutic use. It then found that the claims under examination were not purpose-limited product claims and that their subject-matter lacked novelty in view of D5.

V. With its statement setting out the grounds of appeal, the appellant filed a main request and auxiliary requests 1 to 7. The appellant also filed the following documents.

D27: P. D. Zelazo "The Dimensional Change Card Sort (DCCS): a method of assessing executive function in children", *Nature Protocols* 1(1), 2006, 297-301

D28: L. C. Graham *et al.* "Chronic consumption of a western diet induces robust glial activation in aging mice and in a mouse model of Alzheimer's disease", *Scientific Reports* 6:21568, published 18 February 2016, 1-13

D29: S. E. Kanoski *et al.* "Western diet consumption and cognitive impairment: Links to hippocampal dysfunction and obesity", *Physiology & Behavior* 103, 2011, 59-68

D30: E. Derbyshire "Brain Health across the Lifespan: A Systematic Review on the Role of Omega-3 Fatty Acid Supplements", *Nutrients* 10, 2018, 10, 1094, 1-18

VI. The following claims are relevant to the current appeal case.

Claim 1 of the main request reads as follows.

"A nutritional composition comprising lipid in the form of lipid globules, wherein

- a. the lipid contains at least 0.5 wt.% alpha-linolenic acid based on total fatty acids and at least 5 wt.% linoleic acid based on total fatty acids, and
- b. the lipid contains at least 10 wt.% palmitic acid based on total fatty acids and at least 15 wt.% of palmitic acid, based on total palmitic acid, is located at the sn-2 position of a triglyceride, and
- c. the lipid globules have a mode diameter based on volume of at least 1 μm and/or at least 45 vol.% have a diameter of 2-12 μm , and
- d. the lipid comprises at least 0.5 wt.% phospholipid based on total lipid wherein a part of the phospholipid is in the coating of the lipid globule and either wherein the nutritional composition is not human milk or wherein the nutritional composition comprises vegetable lipid, for use in improving the fatty acid composition of cell membranes in a human subject, wherein the cell membranes are brain cell membranes, wherein the nutritional composition is administered to infants or young children with an age of 0 to 36 months; wherein the improvement of fatty acid composition of brain cell membranes is achieved when said human subject has an age above 36 months."

Claim 1 of auxiliary request 1 is based on claim 1 of the main request and is further restricted in that the improvement of cell membranes consists in increasing LC-PUFA or increasing DHA.

Claim 1 of auxiliary request 2 is based on claim 1 of the main request and is further restricted in that the improvement of fatty acid composition of cell membranes

is compared to a human subject that was administered a specified control composition.

Claim 1 of auxiliary request 3 is based on claim 1 of the main request and is further restricted by the features which have been added to claim 1 of auxiliary requests 1 and 2.

Claim 1 of auxiliary requests 4 to 7 is based on the claims wording of, respectively, claim 1 of the main request and of auxiliary requests 1 to 3, with the further restriction that the human subject is exposed to or raised in an obesogenic environment and/or consumes after infancy a Western style diet that is high in fat and is high in saturated fatty acids.

VII. The appellant's arguments relevant to the present decision are summarised as follows.

- The opposition division inappropriately examined of its own motion whether claim 1 of the main request was directed to a therapeutic use. Claim 1 addressed improving the fatty-acid composition of brain cell membranes and was restricted to a therapeutic use. In view of this, the claimed subject-matter was novel.
- For similar reasons, the auxiliary requests were also allowable.

VIII. The respondent's arguments relevant to the present decision are summarised as follows.

- The opposition division was entitled to arrive at its own claim interpretation. The term "improving" in claim 1 had to be understood as providing the same fatty acid composition of brain cell membranes

as in breast-fed infants. Claim 1 of the main request lacked novelty over D5.

- Documents D27 to D30 should not be admitted into the proceedings.
- The auxiliary requests were not admissible and/or not allowable.

IX. Final requests

The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division so that inventive step be examined on the basis of the main request or one of auxiliary requests 1 to 7, all filed with the statement setting out the grounds of appeal.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. *Patent in suit*

- 1.1 The patent relates to infant nutrition and its effects on brain development. The section "Background of the invention" of the patent (paragraph [0003]) discloses that early nutrition administered during the period of infancy when rapid growth and development of the brain occurs has long-term consequences for brain function. Furthermore, breast-fed infants score better on visual and developmental tests than do formula-fed infants and they show improved neurodevelopment compared to formula-fed infants. The difference in neurodevelopment between breast-fed and formula-fed infants is

attributed to long-chain polyunsaturated fatty acids (LC-PUFA) in breast milk. Moreover, such LC-PUFA are stated to be better incorporated into membranes when they are present in the diet in the form of phospholipids rather than triglycerides.

1.2 According to the section "Summary of the invention" (paragraph [0009]), the patent aims at increasing the amount of LC-PUFA in the cell membrane composition, in particular brain membrane composition, which leads to increased cell membrane fluidity. Such brain membrane structural effects are stated to correlate with improved brain function, in particular an improvement of cognitive function.

2. *Documents D27 to D30*

2.1 Documents D27 to D30 were filed by the appellant, after it received the respondent's reply to the statement setting out the grounds of appeal. The respondent argued that documents D27 to D30 should not be considered on appeal.

2.2 As will be seen below, documents D27 to D30 are not decisive to the appeal case. They do not change the board's assessment on substantive issues. Therefore, the question of their admittance can remain unaddressed.

3. *Allegation of inappropriate examination by the opposition division*

3.1 Claim 1 of the current main request has the same wording as claim 1 of the main request underlying the decision under appeal.

- 3.2 The appellant argued that the opposition division "embarked on an inappropriate examination as to the therapeutic use of claim 1" and incorrectly decided that the improvement of the brain cell membranes was not therapeutic. It further argued that the opponent had accepted that the use disclosed in claim 1 - namely improving the fatty acid composition of brain cell membranes - was directed to a therapeutic use. Considering that both parties had agreed to such an interpretation, the opposition division had no power to examine of its own motion whether the claim was directed to therapeutic use.
- 3.3 The board disagrees, both factually and legally.
- 3.4 In its notice of opposition, the opponent had argued that the term "improving the fatty acid composition of cell membranes in a human subject" in claim 1 had several equally acceptable interpretations. This rendered the term "unclear to such an extent that it is unsuitable for distinguishing the claimed subject-matter from the prior art". The claim had to be construed "as a conventional product claim, since the use for 'improving the fatty acid composition of cell membranes in a human subject' must be ignored". The opponent's conclusion was that the subject-matter of claim 1 as granted lacked novelty over D5. The opponent maintained the objection of lack of novelty of the (later amended) claim 1 throughout the entire proceedings before the opposition division.
- 3.5 In view of this, the opposition division had good reason to examine the implication of the feature directed to use when it construed the claim and examined the novelty of its subject-matter. The opposition division presented its view on the

interpretation of claim 1 as early as in the annex to the summons. Claim interpretation was also discussed during the oral proceedings, as the minutes show.

3.6 Furthermore, as the respondent correctly noted with reference to T 1473/19 (Catchword 3), claim interpretation is a question of law which must ultimately be answered by the deciding body. This has been consistently confirmed by decisions of the Boards of Appeal, for example T 583/23 (Reasons 1.2) issued by the present board in a different composition. Claim interpretation being a question of law, it is - if decisive for the outcome of the case - always incumbent on the deciding body, even if none of the parties present any arguments (R 14/23, Reasons 7).

3.7 Needless to say, the deciding body is not bound to follow the parties' interpretation(s) when construing the claims (T 450/20, Catchword and Reasons 3.4.3; R 14/23, Reasons 8). Hence, even if the opponent had not argued in favour of construing claim 1 "as a conventional product claim", the opposition division could have assessed - and probably would have had to assess - whether or not claim 1 is directed to a therapeutic use.

3.8 Therefore, nothing objectionable can be seen in the opposition division's examination as to whether the claimed subject-matter was directed to a medical use. On the contrary, under the circumstances of the case before it, the opposition division had every reason to construe the claim also with regard to whether it was directed to a therapeutic use. Moreover, as will be seen below (see point 4.13), the opposition division arrived at the correct conclusion.

- 3.9 For completeness, the following additional observations are made.
- 3.9.1 Contrary to the appellant's view, the exercise carried out by the opposition division cannot be qualified as "re-doing" the examination. The opposition division, faced with the novelty objection presented by the opponent, had to construe the claim before assessing the objections. Using the opposition division's own words, the "*OD cannot see how a substantive examination of novelty should be done otherwise*" (Reasons for the Decision, 2.2.2).
- 3.9.2 With reference to T 223/95, Reasons 4, the appellant further argued that post-grant opposition proceedings under the EPC were in principle contentious proceedings between parties normally representing opposite interests. The parties should be given equally fair treatment. Thus, it was the responsibility of the opponent to present to the opposition division the facts, evidence and arguments in support of the grounds on which the opposition is based.
- 3.9.3 In the case cited by the appellant, the opponent had filed an appeal, and its main line of argument was that the opposition division had an extensive duty to familiarise itself with the know-how of the skilled person, so as to take an informed decision.
- 3.9.4 It is plain to see that the situation in that case is different from the case in hand. In T 223/95, the question was whether an opposition division had an obligation to perform its own investigations into the common general knowledge in the field of the patent under scrutiny. The competent board denied that this was the case. Firstly, this does not rule out that an

opposition division may perform its own investigations to some extent, although it is not obliged to do so. Secondly, the matter referred to in T 223/95 concerns a question of fact (see the reference to "how the person skilled in the art understood a certain technical term [...] at a certain point in time" in T 450/20, Reasons 3.4.3) rather than a question of law, as in the present case.

- 3.9.5 The appellant also referred to G 10/91, Reasons 6. Its argument based on this passage is understood to be that the notice of opposition established the legal and factual framework within which the substantive examination of the opposition has to be conducted. This gave the patent proprietor a fair chance to consider its position at an early stage of the proceedings. In view of this, the opposition division should not conduct investigations on its own.
- 3.9.6 The board notes that G 10/91 essentially concerns the question of whether grounds for opposition other than those submitted and substantiated in the notice of opposition may be considered by an opposition division or a board of appeal. The reference to the "legal and factual framework" in G 10/91, Reasons 6, must therefore be understood in this context.
- 3.9.7 Firstly, Article 100(a) EPC in conjunction with Article 52(1) and 54 EPC concerns a single ground of opposition, namely lack of novelty. Article 54(4) and (5) EPC explicitly refers back to Article 54(2) and (3) EPC and therefore assessing whether the requirements of Article 54(4) or (5) EPC are met does not qualify as introducing a new ground of opposition different from the ground of opposition of lack of novelty.

- 3.9.8 Secondly, even if that were the case, an opposition may, according to point 2 of the order in G 10/91, exceptionally "consider other grounds for opposition, which, *prima facie*, in whole or in part would seem to prejudice the maintenance of the European patent", i.e. grounds of opposition not referred to in the notice of opposition.
- 3.9.9 No different conclusion can be arrived at in view of G 4/93, Reasons 2, also cited by the appellant. This passage refers to certain restrictions on the principle of *ex officio* examination in opposition proceedings which are, however, those addressed in G 9/91 and G 10/91, as is made clear in G 4/93, Reasons 3. These have already been discussed above.
- 3.10 In conclusion, the opposition division used the correct approach to assess whether the feature relating to use in improving the fatty acid composition of cell membranes implied a therapeutic method.
4. *Novelty of the main request*
- 4.1 Claim 1 of the main request is directed to a nutritional composition comprising a specified lipid for use in improving the fatty acid composition of cell membranes in a human subject, wherein the cell membranes are brain cell membranes. A further feature of claim 1 is that the nutritional composition is administered to infants or young children with an age of 0 to 36 months and the improvement of fatty acid composition of brain cell membranes is achieved when said human subject has an age above 36 months.
- 4.2 It is common ground between the parties that if the use or effect set out in claim 1 does not constitute a

therapeutic method under Article 53(c) EPC, claim 1 has to be construed as a product claim suitable for obtaining the effect. In such a case, the subject-matter of claim 1 lacks novelty over D5, in particular over claim 1 of D5.

- 4.3 The appellant argued with reference to G 2/08 and T 1020/03 that a claim did not have to specify that an illness or disease is treated in order to be considered to be directed to a therapeutic use. In light of the Guidelines for Examination in the EPO, it was possible to draft a claim to a composition for use as a medicament defined by its function, for instance as an anti-inflammatory medicament. Furthermore, it was generally acknowledged in the art that polyunsaturated fatty acids had a beneficial effect on brain cell membranes (e.g. from D2 to D4). The appellant concluded that, in view of T 240/16, the skilled person would have understood that certain diseases or disorders associated with an impaired brain membrane fatty acid composition were encompassed by the therapeutic use of claim 1.
- 4.4 The appellant's arguments are not convincing.
- 4.5 Turning first to T 240/16, the claim that the board held allowable in the cited case relates to a specific use, namely the support of brain function in a prodromal patient for a neurological disorder, or in a patient suffering from senile dementia or from Alzheimer's disease. It is plain to see that in the cited decision, the claims are restricted to a use which is unambiguously therapeutic within the meaning of Article 53(c) EPC.

- 4.6 It is true that G 2/08 and T 1020/03 allow applicants and patent proprietors some latitude in formulating claims directed to second or further medical uses within the meaning of Article 54(5) EPC. However, also according to these decisions, making successful use of such a claim format is conditional on the use referred to indeed being a therapeutic use within the meaning of Article 53(c) EPC.
- 4.7 The appellant argued that, according to the Guidelines for Examination in the European Patent Office, a therapeutic use may be defined by its function, for example as an anti-inflammatory medicament.
- 4.8 However, the intended use set out in claim 1 does not involve a functional definition for treating or preventing a disease, unlike the administration of a composition for use as an anti-inflammatory medicament exemplified in the Guidelines. In the latter example, the composition is defined as being a medicament for use against inflammation. Furthermore, the function is inextricably linked to a therapeutic method. This is not the case for the generic, unspecific use in claim 1.
- 4.9 As the respondent explained, the documents cited by the appellant, and in particular D2 and D3, instead explain what constitutes a natural development process for a (young) human being. While it may be that some disorders might be treated by the use set out in claim 1 - as the appellant argued with reference to, for example, paragraph [0058] of the patent - this is not the predominant effect described in the patent.
- 4.10 The use for improving the fatty acid composition of brain cell membranes of claim 1 aims at providing

infant nutrition that allows for normal growth and development of brain cell membranes. This includes normal development of the infant's brain and its functions, including the cognitive functions.

- 4.11 As set out throughout the specification of the patent (e.g. paragraphs [0003] and [0055], and in particular in the examples), the infant nutrition of claim 1 imitates human milk, the so-called "gold-standard" in infant nutrition. This is also what the experiments in D15 (Dimension change card sort test used to assess executive function in children) and the complementary information on the test set-up in D27 show. Using the words of the opposition division, "*modifications or potential improvements on cell structure level do not need to amount to any preventive treatment of a pathology*" (Reasons for the Decision, item 2.2.2).
- 4.12 Under the circumstances of the current case, the considerations set out in T 815/22 (in particular Reasons 1.30 to 1.42) apply *mutatis mutandis* and lead to the same conclusion.
- 4.12.1 The nutritional composition referred to in claim 1 is predominantly directed at providing nourishment to infants and young children. The same applies to the administration of a conventional nutritional formula which is generally considered to be safe, as the skilled person would know and the general public expects.
- 4.12.2 More specifically, conventional nutrition is not regarded as being directly associated with a risk. Rather, such nutrition serves the purpose of providing nourishment to infants and young children, thereby providing normal, healthy development of the infant's

or child's body and brain and their respective functions. As the opponent puts it, there is no indication that infants who receive a standard infant formula develop any functional brain-related diseases.

4.12.3 Obtaining normal, healthy growth cannot be seen to encompass a prophylactic, let alone therapeutic, treatment.

4.13 It follows from this that the use in claim 1 of the main request relates to or at least to a large extent encompasses a non-therapeutic use. Therefore, the use set out in claim 1 does not qualify as a medical use under Article 54(5) EPC, and cannot render claim 1 novel.

4.14 As set out above, the subject-matter of claim 1 is anticipated by the disclosure of D5. Thus, the subject-matter of claim 1 of the main request lacks novelty (Article 54 EPC).

5. *Auxiliary requests 1 to 7*

5.1 The respondent argued that auxiliary requests 2 to 7 should not be admitted into the proceedings. It raised procedural objections under Article 12(4) RPBA and objections under Article 123(2) EPC against auxiliary requests 2, 3, 6 and 7.

5.2 However, these aspects do not need to be assessed because the amendments made in these requests are not suitable for rendering the claimed subject-matter novel.

5.3 In claim 1 of all auxiliary requests, the features that have been added to claim 1 of the main request involve

a further characterisation of the intended use. In more detail, in claim 1

- of auxiliary request 1, the improvement of cell membranes consists in increasing LC-PUFA
- of auxiliary request 2, the improvement of fatty acid composition of cell membranes is compared to a specified control composition
- of auxiliary request 4, the human subject is raised in an obesogenic environment

The remaining auxiliary requests 3 and 5 to 7 involve combinations of features of claim 1 of auxiliary requests 1, 2 or 4.

- 5.4 However, none of the features added is suitable for amending claim 1 of the main request in such a way as to provide a claim that is directed to a therapeutic use under Article 53(c) EPC.
- 5.5 In addition, as regards claim 1 of auxiliary requests 4 to 7, it is not conclusive that an obesogenic environment inextricably affects the health of the individual exposed to it. In other words, what is eaten often in one's neighbourhood does not affect one's nutrition and health on an individual level. This consideration underscores that the subject-matter of claim 1 of auxiliary requests 4 to 7 is also far from being directed at a use which is restricted to a therapeutic method.
- 5.6 For completeness, the teaching in documents D28 to D30 on Western diets and brain health across life span do not change the assessment of the wording of claim 1 and the interpretation of the intended use set out above.

5.7 It follows from this that the features added to claim 1 of auxiliary requests 1 to 7 do not change the conclusion made regarding novelty of the subject-matter of claim 1 of the main request. Therefore, the subject-matter of claim 1 of auxiliary requests 1 to 7 lacks novelty (Article 54 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



K. Götz-Wein

A. Haderlein

Decision electronically authenticated