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**Datasheet for the decision
of 9 December 2019**

Case Number: T 0019/16 - 3.3.01

Application Number: 07729358.7

Publication Number: 2026791

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Language of the proceedings: EN

Title of invention:
MATERNAL SUPPLEMENT

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponent:
N.V. Nutricia

Headword:
DHA supplementation/NESTLE

Relevant legal provisions:
EPC Art. 54, 56, 83, 111
RPBA Art. 13(1)

Keyword:

Novelty - main request (yes)

Inventive step - main request (yes)

Sufficiency of disclosure - main request (yes)



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 0019/16 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 9 December 2019

Appellant: N.V. Nutricia
(Opponent) Eerste Stationsstraat 186
2712 HM Zoetermeer (NL)

Representative: Nederlandsch Octrooibureau
P.O. Box 29720
2502 LS The Hague (NL)

Respondent: Société des Produits Nestlé S.A.
(Patent Proprietor) Entre-deux-Villes
1800 Vevey (CH)

Representative: Santarelli
49, avenue des Champs-Élysées
75008 Paris (FR)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 27 November
2015 rejecting the opposition filed against
European patent No. 2026791 pursuant to Article
101(2) EPC.**

Composition of the Board:

Chairman A. Lindner
Members: J. Molina de Alba
P. de Heij

Summary of Facts and Submissions

I. The present appeal by the opponent (appellant) lies from the decision of the opposition division rejecting the opposition filed against European patent No. 2 026 791.

II. The following abbreviations are used in the present decision:

DHA docosahexaenoic acid
AA arachidonic acid
EPA eicosapentaenoic acid
LCPUFAs long chain polyunsaturated fatty acids
BMI body mass index

III. The evidence filed by the parties during the opposition/appeal proceedings included the following documents:

D2: WO 2004/012727
D4: Abstract of doctoral dissertation by A.B.P. Courville, University of Connecticut, printed from DigitalCommons@UConn on 17 January 2014
D5: U.N. Das, Prostaglandins, Leukotrienes and Essential Fatty Acids, 67(1), 2002, 1-12
D6: U.N. Das, European Journal of Clinical Nutrition, 57, 2003, 218-226
D7: U.N. Das, Nutrition, 19, 2003, 1022-1027
D17: Fats and oils in human nutrition. Chapter 7: Lipids in early development, FAO Corporate Document Repository, retrieved on 20 March 2014 from <http://www.fao.org/docrep/V4700E/V4700E0c.htm>

- D18: Scientific opinion on the essential composition of infant and follow-on formulae, EFSA Journal, 12(7), 2014, 3760
- D23a: What's Happening, Department of Nutritional Sciences, University of Connecticut, December 2006
- D23b: Graduate Catalog, The Graduate School, University of Connecticut, undated
- D23c: Flyer "Nutritional Sciences Departmental Seminars - Spring 2006", University of Connecticut
- D23d: Graduate programs, Uconn University of Connecticut, undated
- D28: Abstract of S.S. Guo et al., Am. J. Clin. Nutr., 1999, vol. 70(1 Part 2), 145S-148S
- D29: Abstract of D.S. Freedman et al., Pediatrics, 2005, vol. 115(1), 22-2730
- D30: Abstract of S.E. Carlson et al., Am. J. Clin. Nutr., 1996, vol. 63(5), 687-697

IV. In the appealed decision, the opposition division considered that the subject-matter claimed in the patent as granted was sufficiently disclosed, novel and inventive.

V. In the statement of grounds of appeal, the appellant requested that the decision be set aside and the patent be revoked. It also filed document D23d.

Subsequently, with a letter dated 28 April 2017, the appellant filed documents D28 to D30.

VI. In its reply to the statement of grounds of appeal, the patent proprietor (respondent) requested that the decision be confirmed and the opposition be rejected. In addition, it filed a set of claims as auxiliary request 1, maintained the ten auxiliary requests filed

in the proceedings before the opposition division, and filed additional documents.

VII. In its preliminary opinion, sent as an annex to the summons to oral proceedings, the board gave a positive opinion on the issues of sufficiency of disclosure and novelty in relation to the patent as granted, and summarised relevant points for the discussion of inventive step. The board was also inclined to admit documents D28 and D29 into the proceedings.

VIII. With a letter dated 15 October 2019, the respondent filed claims of a main request and three auxiliary requests to replace all the claim requests previously on file. The main request contains a sole independent claim, which is identical to claim 1 as granted, reading:

"1. The use of docosahexaenoic acid in the manufacture of a composition for administration to a pregnant woman in at least the third trimester of pregnancy and, after delivery, to the newborn baby for a period not exceeding three months for reducing the risk of development of overweight or obesity of the baby in infancy and/or early childhood."

Dependent claims 3 and 4 of the main request read as follows:

"3. The use of Claim 1, wherein after delivery the composition is administered directly to the baby."

"4. The use of any preceding claim, wherein the composition comprises from 100 to 500 mg of docosahexaenoic acid per daily dose."

IX. Oral proceedings were held before the board on 9 December 2019.

X. The appellant's arguments, where relevant to the present decision, may be summarised as follows.

Public availability of document D4

Document D4 is the abstract of a doctoral dissertation completed in January 2006. Its prospectus defence took place in March 2006, as proven by documents D23a and D23c. The defence was made orally to the Department of Nutritional Sciences of the University of Connecticut, as established by the procedure outlined in documents D23b and D23d. Hence, the content of document D4 was made available to the public before the priority date of the patent in suit (23 May 2006).

Novelty - claim 1 of the main request

Each of documents D5, D6 and D7 anticipates the subject-matter of claim 1.

Document D5 teaches that the high LCPUFAs content of breast milk is the factor responsible for the protecting effect of breastfeeding against the development of obesity in childhood and adults (page 2, left-hand column, lines 20-21; page 7, right-hand column, lines 3-5; and page 8, left-hand column, paragraph 2). Among other LCPUFAs, breast milk is rich in DHA (page 4, left-hand column, last paragraph and Table 1), a component which is decisive in the critical period of brain growth between the third trimester of pregnancy and two years post-term (page 4, left-hand column, paragraph 2 to right-hand column, paragraph 2). Thus, in order to prevent obesity in childhood, D5

recommends the administration of LCPUFAs to women during their third trimester of pregnancy and to infants from delivery to up to two years post-term (page 8, left-hand column, paragraph 2). The fact that DHA is not taught to be administered alone is immaterial, because claim 1 is open to the addition of further LCPUFAs. The cut-off period of three months after delivery in claim 1 is a non-purposive selection and cannot establish novelty over the two-year period of document D5 (see Case Law of the Boards of Appeal of the EPO, 9th edition 2019, page 142). Lastly, the feature "early childhood" does not constitute any difference over the disclosure of document D5, because in the latter "childhood" means pre-school age, i.e. early childhood (page 2, left-hand column, paragraph 1 and title of reference 16). Even if early childhood were considered a sub-range within childhood, it would still fail to establish novelty for being a non-purposive selection.

Document D6 also discloses the link between a sufficient provision of LCPUFAs - especially AA, EPA and DHA - to the infant during the third trimester of pregnancy and up to two years post-term and a reduction of the incidence of obesity later in life (see page 221, left-hand column, paragraph 2; page 222, left-hand column, paragraph 2; page 222, right-hand column; and page 223, left-hand column, last sentence).

Similarly, document D7 discloses the perinatal administration of LCPUFAs, including DHA, to protect infants against the development of obesity later in life (see abstract; page 1023, left-hand column, paragraphs 2-3; and page 1024, right-hand column, paragraphs 3-5).

Inventive step - claim 1 of the main request

Any of documents D5, D6 and D7 may constitute the closest prior art.

Document D5 teaches that breastfeeding protects against the development of obesity in childhood and adults (page 2, left-hand column, paragraph 2). This protection is assigned to the LCPUFAs content of breast milk (page 6, right-hand column, last paragraph). Particularly important is the content of the LCPUFAs DHA and AA, which play an essential role in the brain development during the last trimester of pregnancy and the first months of life; a deficient brain development leads to diseases later in life, including obesity (page 4, left-hand column, last paragraph and right-hand column, last paragraph). For that reason, D5 suggests the administration of LCPUFAs from the third trimester of pregnancy till several months after delivery (page 8, left-hand column, last paragraph). Starting from D5, the use of claim 1 potentially differs in three respects: the selection of DHA among LCPUFAs, the administration period of up to three months after delivery, and the prevention of obesity in infancy and/or early childhood.

The feature "early childhood", however, does not constitute any difference, since, as explained in the discussion of novelty, "childhood" in document D5 also means early childhood.

Regarding the selection of DHA and its administration period, Example 2 of the patent shows the BMI of a group of 21-month old children who had received DHA supplementation from the third trimester of pregnancy till three months after delivery in comparison with a

control group. However, the patent contains no comparative tests with LCPUFAs other than DHA, or for supplementation periods ending before and after three months post-term. Thus, it has not been demonstrated that the particular selections in claim 1 bring about any effect in relation to the teaching of document D5.

Hence, the technical problem to be solved is the provision of a treatment for reducing the risk of overweight or obesity in infancy and/or early childhood.

The solution proposed in claim 1 was obvious from document D5 alone because the latter suggests the administration of LCPUFAs, especially DHA, from the third trimester of pregnancy till several months after birth. It was even more obvious having regard to document D7 (abstract), which teaches that breastfeeding for six months to one year after delivery protects against the development of obesity in a dose-dependent manner thanks to the high content of LCPUFAs in breast milk (page 1023, left-hand column, paragraph 2); stopping the administration of DHA at three months after delivery is arbitrary.

Documents D6 and D7 were written by the same author as document D5 and contain essentially the same teaching (see in particular D6: page 221, left-hand column, paragraphs 2-3 and page 223, right-hand column, paragraph 2; and D7: abstract and page 1023, left-hand column, paragraphs 2-3). Thus, documents D6 and D7 also lead to the conclusion that the use of claim 1 is not inventive.

Sufficiency of disclosure - claims 3 and 4 of the main request

The use in claim 3 is not sufficiently disclosed, because the patent does not make it plausible that the risk of developing overweight or obesity may be reduced by the direct administration of DHA to the baby. The tests in the patent show the administration of DHA exclusively to the mother; after delivery, the baby receives DHA by breastfeeding.

In addition, it is not plausible that the daily doses of 100 to 500 mg in claim 4 produce the claimed effect across their whole range. Although the patent discloses (paragraph [0018]) the dose range for administration to the mother, in so far as claim 4 depends on claim 3, the range is also applicable to the direct administration to the baby. However, the administration of DHA daily doses as high as 500 mg directly to the baby is excessive according to the daily doses recommended by the WHO and the EFSA for newborn babies, namely 20 mg/kg and 100 mg, respectively (D17, page 5, paragraph 3; and D18, Table 7). In this context, the daily dose of up to 317 mg/kg for infants younger than six months disclosed in document D2 (page 25, Table B) is arbitrary and cannot override the recommendations by international health authorities. Regarding the lower end of the range, a dose as low as 100 mg, administered to the mother, will not achieve the claimed effect either.

- XI. The respondent's arguments, where relevant to the present decision, may be summarised as follows.

Public availability of document D4

The appellant has not proven that document D4 was publicly available before the priority date of the

patent. D4 is the abstract of a doctoral dissertation, i.e. a written thesis not an oral presentation. The PhD prospectus defence held in March 2006 and referred to in documents D23a and D23c was not the defence of the doctoral dissertation but that of the proposal describing the research intended to be carried out during the PhD work. This transpires from the procedure outlined in documents D23b and D23d. Hence, as the prospectus defence of March 2006 was held prior to the completion of the doctoral dissertation summarised in D4, it could not disclose its whole content.

Novelty - claim 1 of the main request

Document D5 does not anticipate the subject-matter of claim 1, because it does not disclose a direct link between the administration of specifically DHA in pregnancy and up to three months post-term to reduce the risk of overweight or obesity in infants and children up to six years old. The document is directed to the administration of LCPUFAs (rather than DHA alone) up to two years post-term (rather than up to three months post-term) and with the aim of preventing insulin resistance, diabetes, hypertension and coronary heart disease (rather than obesity). The appellant's arguments on the alleged lack of purposiveness of the selections defined in claim 1 in relation to document D5 belong to the discussion of inventive step rather than novelty.

Likewise, documents D6 and D7 do not disclose the specific use of DHA, the specific administration for a period not exceeding three months after delivery, and the specific aim of reducing overweight or obesity in infancy and/or early childhood.

Inventive step - claim 1 of the main request

Document D5 is the closest prior art. The use of claim 1 differs from the teaching of D5 in the specific use of DHA, its period of administration, and the age of the targeted population (infancy and early childhood).

Example 2 of the patent shows that supplementation with DHA during the period defined in claim 1 results in 21-month old children with leaner body than children who have not received DHA supplementation. This proves the effectiveness of the claimed treatment.

Thus, the technical problem to be solved is the provision of a treatment for reducing the risk of development of overweight or obesity in infancy and/or early childhood.

The use in claim 1 was not obvious. Document D5 reviews the benefits of breastfeeding and recommends to maintain it as long as possible in order to lower the incidence of overweight and obesity later in life (page 2, left-hand column, paragraph 2). The beneficial effect of breastfeeding is not specifically assigned to DHA but to the LCPUFAs content of breast milk depicted in Table 1, which shows that DHA is not the most abundant LCPUFA. Document D5 never refers to DHA alone but rather in combination with other LCPUFAs and in the context of several diseases (hypertension, diabetes and CHD) rather than just obesity. Moreover, the relevant passages are speculative on the physiological reasons underlying the effects observed (page 4, left-hand column, last paragraph to right-hand column, last paragraph; and page 6, right-hand column, paragraphs 1-2). Hence, D5 neither discloses nor suggests a direct relationship between DHA and a reduced risk of obesity.

In its conclusion, D5 suggests supplementation with adequate amounts of LCPUFAs from birth till two years post-term (page 8, left-hand column, last paragraph). Thus, rather than supplementing with DHA alone, D5 proposes supplementation with a composition having the LCPUFAs content of Table 1, and for a period longer than defined in claim 1; it is not derivable from D5 that the same effect can be obtained with DHA alone and for a shorter administration period.

Document D6 also suggests (page 223, left-hand column, last paragraph) supplementing pregnant women and newborns with a balanced LCPUFAs composition, i.e. with a composition containing LCPUFAs in the proportions in which they are present in breast milk. The proposed period of supplementation is also until two years post-term. Hence, starting from D6, the claimed use is not obvious either.

The assessment of inventive step, starting from document D7, is similar to that starting from document D5 or D6.

Sufficiency of disclosure - claims 3 and 4 of the main request

Regarding claim 3, the clinical data of Example 2 of the patent support that a reduction of the risk of developing overweight and obesity during infancy and/or early childhood is achieved by the administration of DHA during the period specified in claim 1. The appellant has not supported its allegation that DHA, which has been proven to be effective when administered by breastfeeding, would not be effective when directly administered to the baby, e.g. by an infant formula.

With respect to the daily dose range defined in claim 4, this range is disclosed in the patent in paragraph [0018], and, as taught in paragraph [0019], it is applicable for direct administration to both the mother and the baby. The doses in claim 4 are commensurate with the preferred DHA intakes proposed in document D2 (page 25, Table B); the recommendations of regulatory authorities are not relevant for the purpose of examining sufficiency of disclosure.

XII. The final requests of the parties were as follows.

The appellant requested:

- that the decision under appeal be set aside and the patent be revoked;
- that documents D28 and D29 be admitted into the appeal proceedings.

The respondent requested:

- that the patent be maintained on the basis of any of the sets of claims filed with the letter dated 15 October 2019 as main request and auxiliary requests 1 to 3;
- that documents D28 to D30 not be admitted into the appeal proceedings.

XIII. At the end of the oral proceedings, the board's decision was announced.

Reasons for the Decision

1. The appeal is admissible. It complies with the requirements pursuant to Articles 106 to 108 and Rule 99(2) EPC.
2. Public availability of document D4
 - 2.1 The parties have disputed whether document D4 was available to the public at the relevant date of the patent.
 - 2.2 It was common ground that the claims of the patent as granted enjoy the priority date of 23 May 2006. The claims are identical to those of both the application as filed and the priority application. Accordingly, the relevant date for establishing whether document D4 belongs to the prior art is the priority date (Article 89 EPC).
 - 2.3 Document D4 is the abstract of a doctoral dissertation by Ms Amber B.P. Courville (University of Connecticut) entitled "*A DHA functional food during pregnancy: Impact on maternal dietary intake, endocrine parameters and markers of infant body composition*". Although D4 refers to a date of completion (January 2006), its publication date or that of the doctoral dissertation to which it relates are unknown.

The appellant relied on documents D23a and D23c, with reference to documents D23b and D23d, to prove that the

content of document D4 was publicly available at the priority date.

Documents D23b and D23d do not bear a publication date. Nevertheless, the parties did not dispute that their content reflects the procedure for the obtention of a Doctor of Philosophy degree (PhD) under which Ms Amber Courville carried out her doctoral dissertation (summarised in document D4) and the PhD prospectus defence mentioned in documents D23a and D23c. The board sees no reason to take another stance.

- 2.4 Having regard to the above considerations, the board holds that, for the following reasons, documents D23a and D23c do not prove that the content of D4 was publicly available at the priority date.

Document D23a announces the PhD Prospectus Defense of Amber Courville to be held in March 2006. Document D23c, dated 20 February 2006, refers to a PhD prospectus defence entitled "*A DHA-Functional Food During Pregnancy: Impact on Maternal Dietary Intake and Infant Body Composition and Endocrine Parameters*" by Amber Courville, scheduled for 1 March 2006.

The fact that documents D23a and D23c refer to a PhD prospectus defence rather than to a doctoral dissertation defence and that the title of the PhD prospectus is slightly different from that of the doctoral dissertation summarised in D4 suggests that the doctoral dissertation and the PhD prospectus are effectively two different works. This is confirmed by the program for the Doctor of Philosophy degree at the University of Connecticut outlined in documents D23b and D23d. From document D23d it is clear that this program is applicable to dissertations in the

Department of Nutritional Sciences. In particular, attention is drawn to points 2. and 3. of the section "Doctor of Philosophy" in document D23d:

Point 2 states: *"...a student is required to write a detailed proposal describing their research, the Dissertation Prospectus, which is defended orally to the Department. When a student has passed both the written and oral component of the General Examination and passed their Prospectus, they are admitted to the PhD candidacy"*.

Subsequently, point 3 states: *"Upon completion of the research described in the Prospectus, the candidate presents and defends his/her dissertation research before their Advisory Committee, Graduate Faculty and peers"*.

The same procedure is described in the sections "Dissertation Proposal" and "Candidacy, Dissertation Preparation, and Final Oral Defense" of document D23b, where it is stated that the evaluation of dissertation proposals *"may take the form of a reading of the proposal or attendance at an oral presentation and discussion of the proposal."*

Hence, documents D23b and D23d reveal that the prospectus is not a doctoral dissertation but a preliminary document where a student, aspiring to a PhD degree, depicts the research project that will be carried out during their PhD work. The prospectus is presented to the corresponding department of the university for approval as a requirement for the student's admission to the PhD candidacy. The doctoral dissertation is the final document containing the

results of the research project proposed in the PhD prospectus.

Thus, documents D23a and D23c prove that Ms Amber Courville defended a research proposal for a PhD work (PhD prospectus) to the Department of Nutritional Sciences of the University of Connecticut in March 2006. However, the content of that proposal is unknown, and obviously it cannot be assumed that it disclosed the final results of the proposed research, which correspond to the content of the doctoral dissertation summarised in document D4.

2.5 Hence, from the documents on file, it cannot be established when the information summarised in document D4 was made available to the public and, in particular, whether it was publicly available before the priority date. Consequently, document D4 cannot be considered as belonging to the prior art (Article 54(2) EPC).

3. Novelty - claim 1 main request

3.1 The issue of novelty of the subject-matter of claim 1 was disputed in relation to documents D5, D6 and D7. In all cases, the discussion focused on three main aspects:

i) whether the documents single out the use of DHA from other LCPUFAs for reducing the risk of obesity;

ii) whether the period of administration from the third trimester of pregnancy to not exceeding three months after birth constitutes a relevant distinguishing feature; and

iii) whether infancy and/or early childhood is also a relevant distinguishing feature.

3.2 The board considers that at least the question in point i) has to be answered in the affirmative, so that the use of claim 1 is novel (Article 54 EPC).

3.2.1 Document D5 is a review article on the relationship between the LCPUFAs present in breast milk and the decreased incidence of obesity, hypertension, diabetes mellitus and coronary heart disease later in life in breastfed infants (see abstract).

Although the document cites DHA specifically in the context of brain development, DHA is not considered in isolation but in conjunction with other LCPUFAs, especially AA (page 4, left-hand column, last paragraph to right-hand column, last paragraph). D5 states that "*DHA and AA accumulate mostly in the central nervous system (CNS)*" and that "*[a]dequate amounts of DHA and AA are essential for optimal function and development of CNS*".

Thus, document D5 assigns the preventive effect of breastfeeding against overweight and obesity to the whole composition of LCPUFAs in breast milk rather than to a specific LCPUFA. For this reason, it suggests the supplementation of infant feed formulae with adequate amounts of various LCPUFAs so that they contain a LCPUFAs composition similar to that present in human milk (page 8, left-hand column, paragraph 2).

This idea, that for the normal development of the infant and the prevention of obesity the whole composition of LCPUFAs in breast milk is important rather than the content of one specific LCPUFA, is

confirmed in other passages of D5. For instance, on page 7 (right-hand column, paragraph 1) the document expresses concerns about the negative consequences in the normal development of infants fed with formulae having a LCPUFAs content different from that of breast milk.

3.2.2 Documents D6 and D7 have the same author and essentially the same content as document D5. They also teach the benefits of breast feeding for *inter alia* preventing overweight and obesity later in life, and attribute those benefits to the composition of LCPUFAs in breast milk (see D6: abstract; page 221, left-hand column, paragraphs 2-3; page 222, left-hand column, paragraph 2 and right-hand column; page 223, left-hand column, last paragraph and right-hand column; D7: abstract; page 1023, left-hand column, paragraph 2; page 1024, right-hand column, last paragraph to page 1025, left-hand column, paragraph 1).

3.2.3 Hence, documents D5 to D7 do not disclose the use of the specific LCPUFA DHA for reducing the risk of overweight or obesity, but the use of a LCPUFA composition as found in breast milk.

3.3 Accordingly, the subject-matter of claim 1 of the main request is novel (Article 54 EPC).

4. Admission of documents D28 to D30

With the letter dated 28 April 2017, the appellant filed documents D28 to D30 for the discussion of inventive step in relation to the link between obesity in childhood and obesity in adulthood. Documents D28 and D29 were admitted into the appeal proceedings

during the oral proceedings before the board (Article 13 RPBA).

Nevertheless, as the board's decision on inventive step (see below) is based on the non-obviousness of the specific selection of DHA as the LCPUFA, a discussion of documents D28 and D29 and the reasons why they were admitted are not relevant to the present decision and can be omitted. Admittance of document D30 does not need to be considered as the appellant withdrew its request for admittance of this document.

5. Inventive step - claim 1 of main request
 - 5.1 The parties concurred that document D5 is a suitable springboard for the assessment of inventive step. The board agrees.
 - 5.2 As discussed in point 3.2, the subject-matter of claim 1 differs from the teaching of document D5 at least in that the risk of overweight or obesity is reduced by supplementation with DHA rather than with a LCPUFA composition as found in breast milk.
 - 5.3 The effect provided by this difference (direct link between DHA supplementation and reduced risk of overweight or obesity in infancy and early childhood) is demonstrated by the comparative tests in Example 2 of the patent. The tests show that 21-month old children that had been supplemented with DHA during the third trimester of pregnancy and up to three months after-term had a leaner body (lower weight and BMI, and similar length) and a slightly larger head circumference than children who had not been supplemented with DHA. Thus, the tests prove that the effect of DHA supplementation may be observed 18 months

afterwards in that the children have a normal development with a reduced risk of overweight and obesity.

- 5.4 On the basis of this effect, the technical problem to be solved may be formulated as the provision of a treatment for reducing the risk of overweight or obesity in infancy and/or early childhood.
- 5.5 The solution proposed in claim 1, i.e. supplementation with DHA from at least the third trimester of pregnancy to a point in time not exceeding three months after-term, solves the problem posed in a non-obvious manner.

As noted above, document D5 studies the benefits of breastfeeding for reducing the risk of developing overweight and obesity later in life. The document considers it essential that both foetus and infant be supplemented with LCPUFAs in the proportions in which they are present in breast milk. Those proportions are disclosed in Table 1. Although the document underlines the importance of specific LCPUFAs, such as DHA and AA, for the correct development of the infant brain during the perinatal period and the reduction of the risk of obesity later in life, it warns that a deviation from the proportions of LCPUFAs in breast milk may be inadequate to support the optimal neural development and may have serious consequences on subsequent health and the development of obesity, hypertension, diabetes mellitus and CHD (page 7, right-hand column, paragraph 1). Hence, the skilled person wanting to reduce the risk of overweight or obesity of an infant at later stages of life would not have contemplated supplementation with DHA alone, deviating from the balance of LCPUFAs in breast milk. They would have rather provided the infant with a feed supplement

containing LCPUFAs in the proportions in which they are present in breast milk.

This is confirmed by documents D6 and D7, which have essentially the same content as D5. In particular, D6 teaches that the balance of LCPUFAs in breast milk, especially that of AA, EPA and DHA, must be kept in the infant feed composition for proper growth and development of the infant (page 223, left-hand column, last paragraph and right-hand column, last paragraph). Similarly, D7 states (page 1023, right-hand column, paragraph 1) that, because the exact amounts of LCPUFAs needed for the proper growth and development of infants are not known, the amounts present in breast milk are taken as the gold standard.

- 5.6 Starting from either of documents D6 and D7, the outcome of the problem/solution approach is the same. These documents teach also the benefits of breast feeding for preventing overweight and obesity later in life, and attribute those benefits to the composition of LCPUFAs in breast milk (see D6: abstract; page 221, left-hand column, paragraphs 2-3; page 222, left-hand column, paragraph 2 and right-hand column; page 223, left-hand column, last paragraph and right-hand column; D7: abstract; page 1023, left-hand column, paragraph 2; page 1024, right-hand column, last paragraph to page 1025, left-hand column, paragraph 1).
- 5.7 The board therefore comes to the conclusion that the subject-matter of claim 1 is inventive (Article 56 EPC).
6. Sufficiency of disclosure - claims 3 and 4 of the main request

6.1 The objection of sufficiency of disclosure raised by the appellant against claim 3 was based on the fact that the evidence in the patent on the administration of DHA to the baby was limited to the administration through the mother by breastfeeding. Therefore, the appellant called into question that the administration of DHA directly to the baby could achieve the therapeutic effect cited in claim 1.

This objection has to be rejected for being a mere allegation. Having the burden of proof, the appellant has not provided any evidence raising serious doubts that the administration of DHA directly to the baby, for instance in an infant feed formula, would not have an equivalent effect as when administered through breast milk. Hence, there are no substantiated reasons to doubt that the effect shown in Example 2 of the patent, when the baby was fed with breast milk containing a DHA concentration of 0.50% of the total fatty acids, would not be achieved if the same amounts of DHA are administered in an infant feed formulation.

6.2 In relation to claim 4, the appellant contested that the claimed effect is achieved across the whole range of DHA daily doses of 100 to 500 mg. In particular, the doses at the upper limit of the range would be excessive for administration to the baby while those at lower limit would be insufficient when administered to the mother.

The board disagrees. Regarding the upper limit of the range, i.e. 500 mg, the appellant referred to the DHA daily doses in infant feed formulae recommended by the WHO (D17, page 3, paragraph 3) and the EFSA (D18, page 22, Table 7), i.e. 20 mg/kg and 100 mg, respectively. The board notes, on the one hand, that neither of D17

and D18 discloses ranges or refers to maximum doses; document D17 states that the DHA content in the formula "*should amount*", and D18 refers to "*adequate amounts for the majority of infants*" (D18). Thus, they do not exclude or ban the administration of higher doses. On the other hand, regulatory criteria are not necessarily criteria for the assessment of sufficiency of disclosure. In the present case, they are effectively not, since documents D17 and D18 do not contain any information that would raise serious doubts that the effect recited in claim 1 would not be achieved by the direct administration of 500 mg/day to the baby. Document D2 (page 25), which discloses preferred DHA intake doses for infants aged below 6 months of 8 to 317 mg/kg, supports this fact.

On the issue of whether the effect is achieved, at least to a certain extent, when the lower daily dose of 100 mg is administered to the mother, the appellant, bearing the burden of proof, has not provided any evidence supporting its allegation.

In conclusion, there are no valid reasons on file to affirm that the effect of claim 1 is not achieved across the whole daily doses range of claim 4.

6.3 The board therefore holds that the claimed subject-matter and the invention to which it relates are sufficiently disclosed (Article 83 EPC).

7. Remittal

In view of the board's conclusions on the issues of novelty, inventive step and sufficiency of disclosure, the patent may be maintained on the basis of the claim set filed on 15 October 2019 as the main request. At

the oral proceedings before the board, however, there was no description on file adapted to those claims.

The appellant considered that, at first sight, there were passages to amend, e.g. all of paragraphs 11 to 15. In order to have sufficient time to examine the whole description and to prepare its discussion on the required amendments, the appellant requested that the case be remitted to the opposition division.

The respondent considered that the description was short and that its adaptation could be dealt with at the oral proceedings. Therefore, it objected to a remittal of the case.

Having consideration to the fact that an adapted description was not available at the oral proceedings and that the adaptation did not seem to be straightforward but that it required some preparation and discussion between the parties, the board decided to remit the case to the opposition division (Article 111(1) EPC).

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 with the order to maintain the patent with the following claims and a description to be adapted thereto:

claims 1 to 9 of the main request, filed with the letter dated 15 October 2019.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated