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Datasheet for the decision of 16 November 2023

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Language of the proceedings: EN

Title of invention:
METHOD FOR REDUCING THE OCCURRENCE OF INFECTION IN YOUNG CHILDREN

Patent Proprietor:
N.V. Nutricia

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

Headword:
Occurrence of infections/NUTRICIA

Relevant legal provisions:
EPC Art. 54, 56, 100(a), 100(b)
RPBA 2020 Art. 13(2)

Keyword:
Grounds for opposition - insufficiency of disclosure (no)
Novelty - (yes)
Inventive step - closest prior art - (yes)

Decisions cited:
R 0005/13, T 1278/12, T 2506/12, T 1287/14, T 1230/15, T 0239/16, T 0728/21

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Case Number: T 1845/21 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 16 November 2023

Appellant: (Opponent 1)	Société des Produits Nestlé S.A. Avenue Nestlé 55 1800 Vevey (CH)
Representative:	Plougmann Vingtoft a/s Strandvejen 70 2900 Hellerup (DK)
Appellant: (Opponent 2)	Fresenius Kabi Deutschland GmbH Else-Krömer-Strasse 1 61352 Bad Homburg (DE)
Representative:	Fresenius Kabi Deutschland GmbH Patent Department Pharmaceuticals Division Borkenberg 14 61440 Oberursel (DE)
Respondent: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 13 July 2021 rejecting the opposition filed against European patent No. 2723195 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Haderlein
Members:	F. Rinaldi
	M. Millet

Summary of Facts and Submissions

I. This decision concerns the appeals filed by opponent 1 and opponent 2 (appellant 1 and appellant 2, hereinafter also: the appellants) against the opposition division's decision to reject the oppositions.

II. In the opposition proceedings, the opponents had requested that the patent be revoked under Article 100(a) EPC, for lack of novelty and lack of inventive step. Opponent 1 in addition requested revocation of the patent under Article 100(b) EPC.

III. The following documents are relevant for the decision:

D3: US 2010/0278781 A1

D7: M. Pierre *et al.*, "Omega-3 polyunsaturated fatty acids improve host response in chronic *Pseudomonas aeruginosa* lung infection in mice", American Journal of Physiology-Lung Cellular and Molecular Physiology, 292, 2007, L1422-L1431

D8: F. Gottrand, "Long-chain polyunsaturated fatty acids influence the immune system of infants", The Journal of Nutrition, 138, 2008, 1807S-1812S

D9: S. Ganapathy, "Long chain polyunsaturated fatty acids and immunity in infants", Indian Pediatrics, 46, 2009, 785-790

D11: "Interim Summary of Conclusions and Dietary Recommendations on Total Fat & Fatty Acids", Joint FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition, November 2008

D26: WO 2006/018314 A2

D32: Commission Directive 2006/141/EC

D33: "39th Annual Meeting of the European Society for Pediatric Gastroenterology, Hepatology and Nutrition, Dresden, Germany, 7-10 June 2006", Abstracts collection

D39: L. M. Minns *et al.*, "Toddler formula supplemented with docosahexaenoic acid (DHA) improves DHA status and respiratory health in a randomized, double-blind, controlled trial of US children less than 3 years of age", Prostaglandins, Leukotrienes and Essential Fatty Acids 82, 2010, 287-293

D40: "Scientific opinion on dietary reference values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol", EFSA Journal 2010; 8(3): 1461 (pages 1 to 8)

D43: WO 2008/153377 A1

D44: M. Makrides *et al.*, "Supplementation of infant formula with long-chain polyunsaturated fatty acids does not influence the growth of term infants", American Journal of Clinical Nutrition, 81, 2005, 1094-1101

D45a: Printout of Internet page from WaybackMachine®: http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=1451 ("A study on the effect of a growing up milk on the occurrence of infections in toddlers")

D50: "Report of the scientific committee on food on the revision of essential requirements of infant formulae and follow-on formulae", European Commission, Health and Consumer Protection Directorate-General, 18 May 2013

IV. The claims relevant to the decision are claims 1, 13 and 14 of the patent as granted (main request). They read as follows.

Claim 1:

"*A composition for use in reducing the occurrence of infection in young children, reducing the number of infectious episodes in young children and/or the treatment and/or prevention of infections in young children, said composition comprising:*

a) long chain polyunsaturated fatty acids (LC-PUFAs) with 20 and 22 carbon atoms, wherein the amount of arachidonic acid (ARA) is less than 0.06 gram per 100 gram fatty acid; and comprising:

(i) 0.3-0.6 gram docosahexaenoic acid (DHA, n-3) per 100 g fatty acids; and
(ii) 0.2-0.4 gram eicosapentaenoic acid (EPA, n-3) per 100 g fatty acids;

and one of b1) or b2):
b1) between 1.5 and 2.5 gram indigestible oligosaccharides per 100 kcal, comprising:
(i) 1.4-2 gram galactooligosaccharides with a degree of polymerization of 2 - 7; and
(ii) 0.1 - 0.5 gram fructopolysaccharides with degree of polymerization of 2 - 150; or
b2) between 4 and 8 gram indigestible oligosaccharides per daily amount, comprising, per day:
i) 3.7 - 6.4 gram galactooligosaccharides with a degree of polymerization of 2 - 7; and

ii) 0.3 - 1.6 gram fructopolysaccharides with degree of polymerization of 2 -150."

Claim 13:

"*A packaged liquid or powder composition suited for children with the age between 10 and 48 months, said composition providing per 100 ml liquid composition or 100 ml in water reconstituted powder composition:*

a. 15 - 25 mg long chain polyunsaturated fatty acids (LC-PUFAs) with 20 and 22 carbon atoms, wherein the amount of arachidonic acid (ARA) is less than 0.06 gram per 100 gram fatty acid; and comprising:

(i) 0.3-0.6 gram docosahexaenoic acid (DHA, n-3) per 100 g fatty acids; and
(ii) 0.2-0.4 gram eicosapentaenoic acid (EPA, n-3) per 100 g fatty acids; and

b. 1 - 1.5 gram indigestible oligosaccharides per 100 ml, and between 1.5 and 2.5 gram indigestible oligosaccharides per 100 kcal, comprising:

(i) 1.4-2 gram per 100 kcal galactooligosaccharides with a degree of polymerization of 2 - 7; and
(ii) 0.1 - 0.5 gram per 100 kcal fructopolysaccharides with degree of polymerization of 2 - 150, and an average degree of polymerization between 10 and 30;

c. 8 to 10 en% protein, 35 to 45 en% fat, and 45 to 55 en% carbohydrates"

Claim 14:

"*A packaged liquid or powder composition for use in reducing the occurrence of infection in young children, reducing the number of infectious episodes in young children and/or the treatment and/or prevention of infections in young children, said composition providing per daily dosage:*

a) 60 - 130, preferably 70 - 120 mg, more preferably 80 - 110 mg long chain polyunsaturated fatty acids (LCPUFAs) with 20 and 22 carbon atoms, wherein the amount of arachidonic acid (ARA) is less than 0.06 gram per 100 gram fatty acids; and comprising:

(i) 0.3-0.6 gram docosahexaenoic acid (DHA, n-3) per 100 g fatty acids; and
(ii) 0.2-0.4 gram eicosapentaenoic acid (EPA, n-3) per 100 g fatty acids; and

b) 4 - 8 gram, preferably 5 - 7 gram indigestible oligosaccharides per day, comprising, per day:

(i) 3.7 - 6.4 gram, preferably 4.5 - 5.6 gram galactooligosaccharides with a degree of polymerization of 2 - 7; and
(ii) 0.3 - 1.6 gram, preferably 0.5 - 1.4 gram fructopolysaccharides with degree of polymerization of 2 -150, and an average degree of polymerization between 10 and 30; and optionally

c. 8 to 10 en% protein, 35 to 45 en% fat, and 45 to 55 en% carbohydrates."

V. The appellants' arguments relevant to the present decision may be summarised as follows.

- For appellant 1, the invention was not sufficiently disclosed over the entire scope. D35 showed that the number of infectious episodes was not reduced. It was also implausible that any type of infection could be prevented. Finally, it had not been shown that infections were successfully prevented or treated.
- For appellant 2, claim 1 lacked novelty in view of D3 and D43, when considering the general teaching of the whole document.
- Appellant 1 regarded D45a as the closest prior art, although D3 might also be used as a starting point. Appellant 2 referred to D3 and possibly D26 as the closest prior art. Starting from D3, no effect had been shown and the technical problem was to provide further compositions. The skilled person would have reduced the amount of arachidonic acid (ARA) for two reasons. First, there was no prejudice in the art against providing nutrition to young children with a low amount of ARA. Second, ARA did not have any effect on reducing infections. Thus, claims 1, 13 and 14 lacked inventive step.

VI. The patent proprietor's (respondent's) arguments relevant to the present decision may be summarised as follows.

- Example 1 and D35 showed that the composition of claim 1 was suitable to reduce infections episodes (up to 5) in young children. There were no verifiable facts substantiating the remaining objections raised by appellant 1.

- Claim 1 was novel. The prior art did not disclose all the features of this claim in combination.
- D45a was not the closest prior art. Examples 1 and 2 in the patent as well as D35 demonstrated an improvement over the closest prior art D3. Even if the technical problem were to be regarded as providing an alternative, there was no straightforward teaching in the art to reduce ARA. Claims 1, 13 and 14 involved an inventive step.

VII. Final requests

The appellants requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeals be dismissed or, alternatively, that the patent be maintained on the basis of one of auxiliary requests 1, 2a-2b, 3a-3d or 4a-4d, filed by letter of 4 December 2019, or auxiliary requests 5, 6a-6b, 7a-7d or 8a-8d, filed by letter of 11 March 2021.

Reasons for the Decision

1. *Patent*

The patent concerns the reduction of the occurrence of infections in young children, preferably aged from 1 year to 3 years. These children are also called toddlers. This aim is achieved by a composition which comprises both indigestible oligosaccharides and long-chain polyunsaturated fatty acids with 20 to 22 carbon atoms (hereinafter also: LC-PUFAs) in specific amounts.

The independent claims of the patent define specific amounts of the following LC-PUFAs: docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and arachidonic acid (ARA).

2. *Admittance of appellant 1's new factual submission*

2.1 At the oral proceedings before the board, appellant 1 for the first time criticised the statistical model applied in D35, a scientific publication discussed throughout the opposition and appeal proceedings. It argued that the model was wrong and that it could not be used to draw conclusions on the raw data presented in the publication.

2.2 The respondent requested that this new factual submission not be admitted into the proceedings.

2.3 Appellant 1 explained that with its submission it was merely rebutting the respondent's argument in the reply to appellant 1's statement of grounds. In the reply, filed in March 2022, the respondent had referred to the results in D35 based on the statistical model.

2.4 However, appellant 1 had waited for more than a year and a half to provide its rebuttal to the respondent's argument. In the meantime, the board had issued its communication under Article 15(1) RPBA 2020 (May 2023). Moreover, appellant 1 itself had made elaborate written substantive submissions on points it considered relevant (September 2023), including the board's communication.

2.5 In view of this, the submission that the model is wrong is not merely a timely rebuttal of a contentious point in the respondent's reply. Rather, the submission is a

new allegation of fact and constitutes an unexpected amendment. Having been presented on appeal at the latest possible stage, namely during the oral proceedings, the amendment is not admitted into the proceedings (Article 13(2) RPBA 2020).

3. *Sufficiency of disclosure*

3.1 The opposition division concluded that the invention in the patent was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

3.2 Appellant 1 disagreed with this finding. In essence, it argued that on the basis of the data in D35, no reduction in the number of infections had been achieved. Moreover, it was implausible that the compositions of claims 1 and 14 exerted an anti-infective activity against any type of infection. Finally, there was no evidence that infections were successfully prevented or treated.

3.3 Before addressing appellant 1's arguments, it is useful to briefly introduce the evidence used by appellant 1 and the respondent.

3.3.1 Example 1 of the patent discloses the results of a clinical study carried out with 767 young children. One group of young children received an "invention diet" which corresponds to the composition set out in claims 1 and 14. The second group received a control diet, with no oligosaccharides and no LC-PUFAs. The results presented in example 1 show that of the 388 children who received the "invention diet" only 299 contracted an infection (77%). In the control group, which had a similar number of participants, the

percentage was higher (83%). The conclusion set out in example 1 is that the results show a trend in the number of infectious episodes.

3.3.2 The study presented in example 1 was published in the scientific publication D35 after the patent's filing date. This document discloses substantially more information on the study than example 1. In particular, more data collected during the study are disclosed. The group receiving the "invention diet" in example 1 is called the "active group" in D35.

3.3.3 With regard to the data in D35, figure 2 shows two bar charts: one for the active group and one for the control group. Each bar chart shows the number of infectious episodes (from 0 to 17) on the X-axis versus the number of children affected on the Y-axis.

3.3.4 Apart from example 1 and D35, there is no further experimental evidence on file.

3.4 Appellant 1 argued that D35 demonstrated that the number of infectious episodes was not reduced. In its view, the data in D35 showed that in the active group the total number of infections and the average number of infections per child was higher than in the control group. Therefore, the invention was not sufficiently disclosed.

3.4.1 Appellant 1 calculated the total and average number from the data in figure 2 of the study D35. However, there is no indication in D35 that the numbers calculated by appellant 1 are relevant in the context of the results of the study. In other words, the calculations, although based on and derivable from the data in D35, have no impact on the assessment made.

3.4.2 In more detail, figure 2 shows that 2 children of the active group (i.e. who received the "invention diet") had 17 infections and that only 1 child receiving the control diet had the same number of infections. A single child (out of 388 children) increases the number of total infections by 17 in the active group. This clearly also has an impact on the average number that can be calculated. However, as unfortunate as it may be for the affected child, this result says something about the predisposition of the individual child rather than the (un)suitability of the composition for the intended use. In short, the results presented by appellant 1 cannot be taken as an indication that the "invention diet" of claim 1 does not work.

3.4.3 The authors of the study focused on no reported episodes of infection and on a low number of reported episodes (up to 5 infections) as the key result of the study. Manifestly, a higher number of infections is not a relevant aspect in evaluating the composition's performance.

3.4.4 It follows that the numbers generated by appellant 1 from the data of figure 2 using its own calculations cannot invalidate the conclusions explicitly set out in D35.

3.5 Appellant 1 argued that it was implausible that all the compositions encompassed by claims 1 and 14 exerted an anti-infective activity against any type of infection (e.g. virus, bacterium, fungus, pneumonia, HIV).

3.5.1 However, beneficial effects of LC-PUFAs or oligosaccharides on infections are generally known from the prior art discussed on appeal, for instance D3. In

this context, the board agrees with T 728/21 (Reasons, 3.3) that the suitability of the claimed composition for the defined therapeutic use may also derive its credibility from the prior art.

3.5.2 Considering this, and for want of any further evidence confirming the hypothesis devised by appellant 1, the argument cannot be given more weight than the experimental results in the patent.

3.6 Appellant 1 took issue with the terms "prevention" and "treatment" in claim 1. In its view, "prevention" meant that "only a few, if any, of the young children in the experimental group were infected". This was not achieved. In its opinion, a treatment was not credibly achieved either.

3.6.1 The board does not accept the restrictive interpretation of the term "prevention" adopted by appellant 1. A preventive effect of 100%, meaning that each and every subject receiving the diet will not contract any infection, is neither realistic nor required. Looking at the term from the angle of the individual child treated, prevention simply means that no infection has occurred within that child. Example 1 of the patent and D35 show that precisely this was achieved. The composition according to claim 1 performs better than the control composition.

3.6.2 As to the term "treatment", a measure that aims at and results in reduced occurrence of infections, in other words a prophylactic treatment, necessarily encompasses both the prevention and the treatment. These two measures go hand in hand. This is the case at least for the reason that the infectious external stimulus (e.g.

a bacterium or a virus) does not invade the affected individual.

3.6.3 In sum, appellant 1 has not provided any verifiable evidence that although a prevention is achieved, as shown above, a treatment is not.

3.7 In conclusion, the ground for opposition under Article 100(b) EPC does not prejudice maintaining the patent as granted.

4. *Main request - novelty*

4.1 The opposition division concluded that the subject-matter of claims 1 and 14 was novel with respect to D3. The combination of features of these claims was not derivable from the disclosure of D3.

4.2 Appellant 2 contested this finding. In its view, considering D3 as a whole, the combination of the amounts of claim 1 was in line with the general teaching of D3. Appellant 2 also argued that the same applied to D43, a patent application belonging to the same patent family as D3 and having an essentially identical disclosure.

4.3 For an invention to lack novelty, its subject-matter must be clearly and directly derivable from the prior art. In other words, a claimed subject-matter lacks novelty only if a clear and unmistakable teaching of a combination of the claimed features can be found in a prior-art disclosure (Case Law of the Boards of Appeal of the EPO, 10th edition, 2022, Chapter I.C.4, second paragraph, and I.C.4.2, second paragraph).

4.4 As the opposition division correctly explained in the decision under appeal, D3 does not disclose a single composition which comprises DHA, EPA, a galactooligosaccharide and a fructopolysaccharide in one embodiment. Instead, several embodiments have to be combined to arrive at the subject-matter of claim 1.

4.5 On this basis alone, the objection of lack of novelty does not succeed. More details on the distinguishing features of claim 1 over D3 will become evident from the following discussion on inventive step.

4.6 No separate reasoning was presented in respect of D43. Consequently, novelty over D43 is also acknowledged.

4.7 To conclude, the subject-matter of claim 1 is novel. The ground for opposition under Articles 100(a) and 54 EPC does not prejudice maintaining the patent as granted.

5. *Inventive step, starting from the closest prior art*

5.1 In the decision under appeal the subject-matter of claims 1, 13 and 14 of the patent as granted was found to involve an inventive step. The opposition division's reasoning may be summarised as follows.

- D3 was the closest prior art, not D26 or D45a.
- The distinguishing features were the amounts of the individual LC-PUFAs, namely ARA, DHA and EPA.
- The technical problem to be solved was providing a composition that reduced the occurrence of infections in young children, reduced the number of infectious episodes in young children and/or was suitable for the treatment and/or prevention of infections in young children.

- Starting from D3 and in light of the cited documents, there was no suggestion to add the specific amount of EPA and to keep the amount of ARA as low as in claim 1. D3 rather pointed to the preferred amounts of 0.12 to 0.8 wt.% ARA and 0.03 to 0.1 wt.% EPA.

5.2 The appellants contested this finding. On appeal, it was common ground between the parties that the conclusions reached for claim 1 would also apply to claims 13 and 14 of the main request.

5.3 In the following, the inventive step of claim 1 is discussed first. The assessment uses the problem-solution approach.

5.4 Selection of the closest prior art

5.4.1 The first step of the problem-solution approach is to select the closest prior art (Case Law of the Boards of Appeal of the EPO, 10th edition, 2022, Chapter I.D.2).

5.4.2 Prior to identifying the closest prior art in its statement setting out the grounds of appeal, appellant 1 extensively outlined what it deemed to be common general knowledge. While a brief introduction of the common general knowledge prior to identifying the closest prior art may occasionally be helpful, an extensive discussion on this matter bears the risk of adding hindsight to a party's argument. Such a discussion might undo the desired effect of the problem-solution approach, namely to assess inventive step as objectively as possible, although the assessment is unavoidably made in full knowledge of the invention. Nevertheless, the board understands appellant 1's submissions in this regard to mean that

the claimed subject-matter is obvious in particular in view of the common general knowledge. The board thus deals with these submissions in the part of the problem-solution approach which concerns the aspect of obviousness.

5.4.3 Appellant 1 considered D3 a suitable starting point for assessing inventive step, but D45a was in its view an even more suitable starting point.

5.4.4 Appellant 2 regarded D3 as the closest prior art. In addition, it considered D26 to be a suitable starting point.

5.4.5 In the following, inventive step will be assessed starting from the disclosure of D3. This is the document that the opposition division, correctly, regarded as the closest prior art in the decision under appeal.

5.4.6 The board concluded that D26 and D45a were not suitable starting points for assessing inventive step. For ease of reference, the reasons will be explained in detail in a separate section of the decision, in point 6 below.

5.5 Disclosure of D3

5.5.1 D3 relates to a method of treatment and/or prevention of a disease or condition in an infant or toddler. The composition used in D3 comprises non-viable bifidobacteria and one or more non-digestible oligosaccharides, preferably galactooligosaccharides and fructooligosaccharides such as fructan. The disease prevented is primarily an allergy, but infections are

also mentioned (e.g. claim 17 and paragraphs [0015] and [0018]).

5.5.2 The specific starting point for assessing inventive step is normally a set of features disclosed in combination in a document, e.g. an embodiment or example. For assessing inventive step it is necessary to establish the distinguishing features over that specific starting point and assess whether it was obvious to arrive at the claimed subject-matter when starting from that specific point (T 1287/14, Reasons 5.2.1).

5.5.3 The appellants started their assessments essentially from example 3 of D3. The example discloses a liquid toddler milk formula comprising, among other things, specific amounts of galactooligosaccharides and fructan and a fat blend. The board agrees that example 3 provides a combination of features suitable for beginning the examination of inventive step.

5.5.4 Example 3 does not disclose the medical indication for which the composition is administered. However, in view of the teaching of D3, the skilled person would regard the milk formula of example 3 as suitable for preventing infections.

5.5.5 The composition of the fat blend of example 3 is not disclosed either. Paragraph [0052] is the only passage of document D3 in which the chemical composition of the fat phase of the nutritional formula is discussed. The long list of preferred ingredients of the fat phase includes, among other unsaturated fatty acids, LC-PUFAs. Preferred ingredients are also EPA and/or DHA and/or ARA. Preferred amounts of the various lipids are also listed. Paragraph [0052] concludes with a

statement that LC-PUFA reduces intestinal permeability and improves the immune system and that together with the other components of D3, it (allegedly) achieves a "synergistic" effect against allergy, atopic dermatitis and infections.

5.5.6 To be clear, the teaching of D3 is such that its composition does not necessarily include LC-PUFA. No such fatty acid is a mandatory ingredient of the composition of D3, let alone of the toddler formula of example 3.

5.5.7 Nevertheless, in favour of the appellants' line of argument, it is assumed that the skilled person would understand that the milk formula of example 3 also comprises LC-PUFA.

5.5.8 The combination of all these features (toddler milk of example 3, which in view of the above implicitly comprises LC-PUFA, and for use in preventing infections) is considered the closest prior art for examining the inventive step of claim 1.

5.6 Distinguishing features of claim 1

5.6.1 In view of the above, the closest prior art does not disclose at least the following features:

- ARA of less than 0.06 gram per 100 gram fatty acids

- DHA of 0.3 to 0.6 gram per 100 g fatty acids

- EPA of 0.2 to 0.4 gram per 100 g fatty acids

5.6.2 It was in dispute whether the closest prior art also disclosed the amount of oligosaccharides called for in claim 1. However, this point need not be addressed.

5.7 Technical effect and problem solved

5.7.1 The relevant issue for examining the technical problem solved is to establish what technical contribution is made by the distinguishing features.

5.7.2 With regard to the effect of reducing the occurrence of infections in young children, the composition according to claim 1 of the main request has not been compared with the closest prior art. Example 1 of the patent only makes a comparison with a control composition that comprises no oligosaccharides and no LC-PUFA. Such a composition does not represent the closest prior art. The composition of the closest prior art has more features in common with the composition of claim 1 than the control composition. Therefore, no improvement over the closest prior art can be acknowledged on the basis of example 1.

5.7.3 Example 1 and D35 use the same test and control compositions. Consequently, D35 is not suitable for showing an improvement over the closest prior art either.

5.7.4 The respondent also referred to example 2 of the patent. In its view, the example demonstrated the beneficial effect of the combination of galactooligosaccharides and fructopolysaccharides together with the high concentrations of DHA and EPA and the low concentration of ARA.

5.7.5 In example 2, different compositions are administered to young children and the serum levels of DHA and EPA are examined. The composition of example 2 administered to group 1 children corresponds to the composition of claim 1. However, there is no convincing explanation as to whether the second composition administered to children of group 2 is representative of the closest prior art. No conclusions can be drawn from the experiments in example 2, which is therefore not suitable for demonstrating an improvement over the closest prior art.

5.7.6 In view of this, no aspect of an improvement can be retained in the formulation of the technical problem. Instead, the technical problem is regarded as providing an alternative composition that reduces the occurrence of infections in young children, reduces the number of infectious episodes in young children and/or is suitable for the treatment and/or prevention of infections in young children.

5.8 Obviousness

5.8.1 The subject-matter of claim 1 could only be assessed as being obvious if the skilled person were to provide the combination of the distinguishing features, i.e. the amounts of ARA, EPA and DHA, together with the features known from the closest prior art.

5.8.2 On appeal, the appellants focused on the contention that the only task for the skilled person starting from the closest prior art would have been to reduce the amount of ARA. In this context two main lines of argument were provided.

- There was no prejudice in the art to provide nutrition to young children with a low amount of ARA.
- ARA did not have any recognised effect on reducing infections.

5.8.3 It is generally accepted that nutrition for infants, i.e. for children less than 12 months of age, requires supplementation with ARA. According to the appellants' first line of argument, there was no prejudice in the art against providing a low amount of ARA in nutrition for young children. This was regarded as common general knowledge. The appellants' view was therefore that the skilled person would reduce the amount of ARA in such compositions. In this context, the parties referred to documents from various fields, namely dietary recommendations of a food authority such as FAO or EFSA (D11, D34, D40, D50), a legal provision (D32) and a scientific publication (D44), among others.

5.8.4 However, the technical problem under examination is providing a further composition that reduces infections in young children. The legal requirements and recommendations for providing nutrition to young children are understandably less strict than for providing nutrition to infants. Yet this does not mean that the less strict requirements and recommendations also apply when a particular effect is sought. Therefore, documents that do not mention the medical indication (infections) would not have been of particular relevance to the skilled person.

5.8.5 None of the documents cited in this context addresses the indication under scrutiny. On this basis alone, the objections raised are not convincing. This is all the more so where the recommendations concern specific

effects on cognitive function and visual development (D34) or infant growth (D44, D50), not prevention of infections.

5.8.6 In addition, it is noted that D3 itself does not suggest distinguishing between infants and toddlers. Throughout D3, the two target groups are mentioned simultaneously, and no indication can be taken from this document that a different treatment is envisaged depending on the age of the child. In view of this, the skilled person would have had no motivation to provide a low amount of ARA when providing a treatment for a toddler.

5.8.7 It is also recalled that in paragraph [0052] of D3, the amounts disclosed for ARA and DHA are similar. More precisely, the lowest amounts of ARA and DHA disclosed are consistently identical, for both the general and the preferred range. Yet the highest amounts of ARA are higher than those of DHA, for both the general and preferred range. While there is no explicit, spelled out disclosure in paragraph [0052] that the amount of ARA is necessarily at least as high as that of DHA, the implicit disclosure in this passage surely conveys this teaching.

5.8.8 According to a second line of argument, the appellants argued that it was not necessary to include ARA in compositions suitable for preventing infections. The documents cited here were D7 to D9, D26 and D39.

5.8.9 According to the appellants, D7 taught that to prevent lung infections, the quantity of omega-6 PUFAs (such as ARA) had to be kept low compared with the quantity of omega-3 PUFAs. However, none of the amounts of ARA tested in D7 is as low as that of claim 1. Moreover,

the amounts for each of ARA, EPA and DHA of D7 are far away from those called for in claim 1. Thus, the fatty acid composition administered to the grown-up mice in D7 is not representative of diets suitable for young children. Instead, the fatty acid composition in D7 is manifestly designed for the experimental set-up of the study. Yet the skilled person would not have been prompted to apply the teaching of D7 to solve the technical problem.

5.8.10 D8 and D9 relate to the prevention of infection, and the focus in these two publications is on infants. D8 provides no specific amounts of DHA, EPA or ARA. D9 even teaches that the concentration of ARA should be at least the same as DHA. Thus, neither D8 nor D9 would have prompted the skilled person to arrive at the composition called for in claim 1.

5.8.11 Appellant 2 referred to D26, a document that, among other things, discloses reducing infections in infants. In appellant 2's view, D26 suggested keeping the concentration of ARA (and their metabolites) low, and consequently the skilled person would have reduced the concentration of ARA.

5.8.12 However, D26 recommends a higher concentration of ARA than that called for in claim 1. Similarly, D26 points to an amount of ARA which is as high as that of DHA. Therefore, combining D3 with D26 would not have provided the skilled person with the distinguishing features called for in claim 1.

5.8.13 Appellant 1 referred to D39. In its view this document taught that ARA could be dispensed with in a toddler formula suitable for preventing infections.

5.8.14 It is true that D39 discloses that toddler formula supplemented with DHA improves respiratory health in young children. However, no explicit teaching as to ARA can be taken from this document. Furthermore, D39 does not mention EPA either. Therefore, combining D3 with D39 would not have provided the skilled person with the distinguishing features of claim 1.

5.8.15 On the role of ARA in the context of infections, the respondent referred to D33, a collection of abstracts of a symposium. The abstract by Mazurak et al. in D33 showed a trend of adding excess ARA to compositions comprising DHA in order to provide anti-infective activity.

5.8.16 An intermediate conclusion to draw in light of all these submissions and considerations is that the role of ARA for preventing infections in young children is not as straightforward as purported by the appellants. Under these specific circumstances, it was therefore not obvious to reduce the amount of ARA with respect to the amount of DHA.

5.8.17 Appellant 2 also provided additional arguments which will be addressed in the following. It maintained that since the technical problem was providing an alternative, essentially any modification was encompassed as a possible solution. The solution could involve, for example, a foreseeable worsening or the provision of a cheaper composition.

5.8.18 Even if the technical problem relates to providing an alternative, the suggested composition still has to provide prevention of infections in young children. The key issue remains whether the skilled person would have arrived at the combination of the claimed

distinguishing features in an obvious way to solve the technical problem.

5.8.19 The argument that a possibly worse and certainly cheaper composition might be provided by leaving out ARA is not convincing either. D3 teaches that some effect on reducing infection is already obtained without any LC-PUFAs (claim 17). This in principle opens the door to leaving out all expensive ingredients, namely DHA, EPA and ARA. Yet even if this argument were accepted, there is still no conclusive and convincing explanation as to why the skilled person would have provided a composition with the distinguishing features of claim 1.

5.8.20 In summary, the appellants' arguments did not convince the board that the opposition division's assessment on obviousness was incorrect. In view of the facts of the current case, the board agrees with the opposition division that the skilled person would have maintained the preferred amounts for ARA, DHA and EPA set out in D3, in which the amounts of DHA and ARA are similar. They would not have provided a composition using the amounts at the top and the bottom ranges disclosed in D3 for EPA and ARA, respectively.

5.8.21 Therefore, in view of the closest prior art, the skilled person would not have arrived at the subject-matter of claim 1 in an obvious way.

5.9 Inventive step of claims 13 and 14

5.9.1 The appellants also contested in passing that claims 13 and 14 of the main request involved an inventive step. However, they did not present a different line of argument for these claims.

5.9.2 It is noted that claim 13 relates to a product claim whereas claim 14, like claim 1, is drafted as a (further) medical use claim. The features of the compositions called for in claims 13 and 14 correspond to those set out in claim 1.

5.9.3 The subject-matter of claims 13 and 14 is considered to solve the same technical problem as claim 1. A different assessment of inventive step need not be made for claims 13 and 14. Therefore, the subject-matter of these claims would not have been obvious to the skilled person.

6. *D26 and D45a are not the closest prior art*

6.1 The appellants referred to D26 and D45a as possible starting points for examining inventive step.

6.2 D26 is similar to D3. Using D26 as the starting point instead of D3 would not lead to a different conclusion on inventive step. Appellant 2 did not contest this assessment.

6.3 As for D45a, appellant 1 considered this document to be the closest prior art.

6.4 A discussion of the entire problem-solution approach starting from a document as a further starting point may be dispensed with if, following a discussion on whether the document is suitable as the closest prior art, the board concludes that this is not the case (see T 1230/15, point 2.4). The understanding that a party is not generally entitled to orally present an entire problem-solution approach at oral proceedings is also

conveyed in R 5/13 (Reasons, 14 and 15). Such an approach ultimately serves procedural economy.

6.5 D45a relates to an announced study on the effect of growing-up milk on the occurrence of infections in toddlers. The hypothesis underpinning the study is the expectation that drinking growing-up milk with added "prebiotics and LCPUFA" results in a lower occurrence of infections.

6.6 The nutrition specialist knows that there is a wide range of oligosaccharides, with different degrees of polymerisation, that are suitable as prebiotics. The term "LCPUFA" designates one long-chain polyunsaturated fatty acid (or possibly more), but from D45a it remains undisclosed precisely which active substances were investigated, let alone what combination of substances was used and what dosage was applied. Nor was there any certainty that the specific, unknown composition investigated would provide the effect sought.

6.7 Appellant 1 cited several decisions to support its view that an announced study was a suitable starting point for assessing inventive step. The following comments are made on this point.

6.7.1 In T 239/16, the prior-art document in question disclosed the treatment of post-menopausal osteoporosis in human females, with 4 mg zoledronate, and an administration pattern (intravenous, once yearly). The only feature of claim 1 under scrutiny that was missing was the confirmed disclosure of any effect ("a certain doubt remains as to whether the yearly treatment ... leads to an effective treatment of osteoporosis").

6.7.2 This is manifestly different in the current case; D45a discloses neither a confirmed effect nor the active substances used.

6.7.3 Similar considerations as for T 239/16 apply to the cases concerning T 2506/12 and T 1278/12. In both cases, the prior-art document under scrutiny already taught the use of well-defined (commercial) products in the context of the technical application called for in the claim under examination.

6.8 Therefore, without the benefit of hindsight, D45a would have provided the skilled person with next to no useful information.

6.9 It is worth noting that in the current case, hindsight is particularly difficult to put aside, the reason being that the results of the study are described in D35, published after the filing date of the patent. D35 is also the document that appellant 1 discussed in detail throughout the appeal proceedings, e.g. in the context of sufficiency of disclosure. Moreover, the results of the study are summarised in example 1 of the patent.

6.10 Be that as it may, appellant 1 argued that after having read D45a, the only thing the skilled person had to do to arrive at the composition tested was "filling the gaps".

6.11 While the exercise of "filling the gaps" under these circumstances may not amount to a research project in itself, it still requires some study within the available prior art. Ultimately, performing this exercise boils down to pure guessing what the composition tested might have been. The skilled person

would have had to guess the oligosaccharides used, their degrees of polymerisation and their amounts. The skilled person would have had no motivation to guess more than one LC-PUFA. Thus, the guessed composition would have been nothing more than the starting point for yet another set of modifications to the composition.

6.12 To conclude, the disclosure of D45a is vague and blurred, so this document is not considered a more promising springboard than D3 for assessing the inventive step of claim 1.

7. *Inventive step, conclusion*

Thus, the ground for opposition under Articles 100(a) and 56 EPC does not prejudice maintaining the patent as granted.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar: The Chairman:

K. Götz-Wein A. Haderlein

Decision electronically authenticated