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Datasheet for the decision of 16 December 2014

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Application Number: 04740058.5

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Title of invention:
INFANT OR FOLLOW-ON FORMULA

Patent Proprietor:
Nestec S.A.

Opponents:
ABBOTT LABORATORIES
Friesland Brands B.V.
N.V. Nutricia

Headword:

Relevant legal provisions:
RPBA Art. 12(4)
EPC Art. 56

Keyword:
Admissibility of claim request (yes)
Inventive step (no)

Decisions cited:

Catchword:

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Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1941/12 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 16 December 2014

Appellant: (Patent Proprietor)	Nestec S.A. Avenue Nestlé 55 1800 Vevey (CH)
Representative:	Rupp, Christian Mitscherlich PartmbB Patent- und Rechtsanwälte Postfach 33 06 09 80066 München (DE)
Respondent I: (Opponent 01)	ABBOTT LABORATORIES 100 Abbott Park Road Abbott Park IL 60064-3500 (US)
Representative:	Boult Wade Tennant Verulam Gardens 70 Gray's Inn Road London WC1X 8BT (GB)
Respondent II: (Opponent 02)	Friesland Brands B.V. Blankenstein 142 7943 PE Meppel (NL)
Representative:	Hatzmann, Martin V.O. Johan de Wittlaan 7 2517 JR Den Haag (NL)
Respondent III: (Opponent 03)	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 10 July 2012**

revoking European patent No. 1638414 pursuant to Article 101(3)(b) EPC.

Composition of the Board:

Chairman W. Sieber
Members: M. O. Müller
K. Garnett

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the proprietor (Nestec S.A.) of European patent No. 1 638 414 against the decision of the opposition division to revoke it.

II. Oppositions were filed by opponent 01 (ABBOTT LABORATORIES), opponent 02 (Friesland Brands B.V.), and opponent 03 (N.V. Nutricia). The opponents had requested revocation of the patent in its entirety on the grounds that the claimed subject-matter was neither novel nor inventive (Article 100(a) EPC; opponents 01, 02 and 03) and that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC; opponents 01 and 02).

III. The documents submitted during the opposition proceedings included:

O1D1: WO 2004/112509 A2;

O1D3: U. N. Das, "Essential Fatty Acids as Possible Enhancers of the Beneficial Actions of Probiotics", Nutrition, volume 18, 2002, pages 786 to 789;

O1D7: E. Isolauri et al, "Probiotics: effects on immunity", Am J Clin Nutr, volume 73 (suppl), 2001, pages 444S to 450S;

O1D8: E. Isolauri et al, "Probiotics", Best Practice & Research Clinical Gastroenterology, volume 18(2), 2004, pages 299 to 313;

O1D9: P. Bourlioux et al, "The intestine and its microflora are partners for the protection of the host: report on the Danone Symposium "The Intelligent Intestine", held in Paris June 3 14, 2002", Am J Clin Nutr, volume 78, 2003, pages 675 to 683;

O1D13: C. J. Field et al, "Polyunsaturated Fatty Acids and T-Cell Function: Implications for the Neonate", Lipids, volume 36(9), 2001, pages 1025 to 1032;

O3D16: P. E. Kankaanpää et al, "The influence of polyunsaturated fatty acids on probiotic growth and adhesion", FEMS Microbiology Letters, volume 194, 2001, pages 149 to 153;

O3D18: "Masterpiece Organic Agriculture Nutrition Powder", MINTeL gnpd, 2004, http://www.gnpd.com;

O3D27: "Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae", European Commission, 2003, 22 pages;

O3D35: M. E. Sanders et al, "Bringing a probiotic-containing functional food to the market: microbiological, product, regulatory and labeling issues", Antonie van Leeuwenhoek, volume 76, 1999, pages 293 to 315;

O3D36: S. E. Soh et al, "Probiotic supplementation in the first 6 months of life in at risk Asian infants - effects on eczema and atopic sensitization at the age of 1 year", Clinical & Experimental Allergy, volume 39, 2009, pages 571 to 578; and

PD1: J. P Chouraqui et al, "Assessment of the safety, tolerance, and protective effect against diarrhea of infant formulas containing mixtures of probiotics or probiotics and prebiotics in a randomized controlled trial", Am J Clin Nutr, volume 87, 2008, pages 1365 to 1373.

IV. The opposition division's decision, which was announced orally on 27 June 2012 and issued in writing on 10 July 2012, was based on a main request and auxiliary requests 1 to 4.

The main request was found not to be allowable since the subject-matter of claim 6 lacked novelty over O1D1. Auxiliary request 1 was found not to be allowable since claim 6 did not meet the requirements of Article 123(2) and 123(3) EPC.

Claim 1 of auxiliary requests 2 to 4, which is the only claim relevant to the present decision, read as follows:

"1. Infant or follow-on formula comprising a source of proteins, a source of lipids, a source of carbohydrates, and the probiotics Bifidobacterium longum BB 536 and Lactobacillus paracasei rhamnosus GG

wherein the source of lipids includes ARA and DHA and the DHA content is between 0.2 and 0.5% of total fatty acids in the lipid source."

These requests were found not to be allowable since the subject-matter of claim 1 was not inventive in view of O3D18 taken as the closest prior art. The subject-matter of claim 1 differed from this document by the selection of two specific strains of probiotics. The effect of this difference was unknown. There were no experimental data in the patent as regards a comparison with other probiotics. Also in the experiments of PD1, the presence of the claimed bacteria did not result in any improvement over a control group (no probiotics) and, furthermore, no comparison was made with other bacteria. Even though a long-term effect was found in PD1, this could not be solely attributed to the probiotics. Furthermore, 03D36 appeared to show that there was no effect of the selected strains. The problem to be solved was therefore the provision of an alternative formula. The choice of the two specific strains, in the absence of any effect, was an arbitrary choice. 03D35 disclosed that the two strains referred to in claim 1 were commonly used in the art. The skilled person would thus have selected these two commonly used strains. Therefore, the subject-matter of claim 1 did not involve an inventive step.

V. On 29 August 2012, the proprietor (hereinafter: "the appellant") filed an appeal and, on the same day, paid the prescribed fee. The statement setting out the grounds of appeal was filed on 20 November 2012 together with a main request and first to sixth auxiliary requests.

Independent claim 1 of the fourth auxiliary request, which later became the main request, is identical to claim 1 of auxiliary requests 2 to 4 before the opposition division (see point IV above).

Independent claim 6 of this request reads:

"6. The use of a combination of probiotic strains said combination comprising Bifidobacterium longum BB 536 and Lactobacillus paracasei rhamnosus GG and a source of lipids including ARA and DHA in the manufacture of a composition comprising a source of proteins, a source of lipids, and a source of carbohydrates for strengthening natural immune defences of an infant or a baby by fully or partly feeding said infant or baby with said formula wherein the DHA content is between 0.2 and 0.5% of total fatty acids in the lipid source."

Claims 2 to 5 are dependent claims.

VI. A response was filed by opponent 01 (hereinafter: "respondent I") with its letter of 24 January 2013 together with a copy of T 807/11.

VII. By letter of 3 May 2013, the appellant filed a reply to the submissions of respondent I.

VIII. By letter of 27 May 2013, opponent 03 (hereinafter: "respondent III") filed its response.

IX. A reply to the appellant's letter of 3 May 2013 was filed by respondent I by its letter of 11 July 2013.

X. By communication of 23 May 2014, the parties were summoned to oral proceedings. In the annex to the summons, the board communicated its preliminary opinion

to the parties. According to this preliminary opinion, the subject-matter of claim 1 of the then main request (identical to claim 1 of the main request on which the present decision is based) differed from that disclosed in O3D18 only in that a combination of specific Lactobacillus and Bifidobacterium strains was present in the claimed formula, rather than Lactobacillus in general. It would need to be discussed during the oral proceedings whether the experimental data contained in PD1 demonstrated that, in view of O3D18, an improved immune defence was achieved by the composition of claim 1. In this respect, it would in particular be discussed whether (i) the bacteria used in PD1 were the ones defined in claim 1, (ii) whether PD1 proved that the combination of the two bacteria strains of claim 1 improved the immune defence, and (iii) whether an improved immune defence was also obtained with the formula of O3D18, since this formula contained Lactobacillus.

XI. With letter of 2 October 2014, respondent I filed:

O1D18: M. van den Nieuwboer et al, "Probiotic and synbiotic safety in infants under two years of age", Beneficial Microbes, XXX 2014 online (in press).

XII. By letter of 27 October 2014, opponent 02 (hereinafter: "respondent II") announced that it would not attend the oral proceedings.

XIII. With letter of 14 November 2014, the appellant filed:

P-D3: Declaration of Laurent Fay and Fabrizio Arigoni, dated 1 September 2009; and

P-D4: M. D. Collins et al, "Deoxyribonucleic Acid Homology Studies of Lactobacillus casei, Lactobacillus paracasei sp. nov., subsp. paracasei and subsp. tolerans, and Lactobacillus rhamnosus sp. nov., comb. nov.", International Journal Of Systematic Bacteriology, April 1989, pages 105 to 108.

XIV. A reply was filed by respondent III by letter dated 14 November 2014.

XV. Respondent II did not file any submissions and did not make any requests.

XVI. On 16 December 2014, oral proceedings were held before the board, at which respondent II was absent. During the oral proceedings, the appellant made its previous fourth auxiliary request to its main request, withdrew the previous main and first to third auxiliary requests and maintained the previous fifth and sixth auxiliary requests as first and second auxiliary requests. Respondents I and III maintained their request that the appeal be dismissed.

XVII. The appellant's arguments, in as far as relevant to the present decision, can be summarised as follows:

The main request should be admitted into the proceedings since it was directed to the substance of the requests filed during opposition proceedings and since there was no requirement in the EPC whereby only those requests that had been examined by the opposition division could be examined by the boards.

The main request was inventive over the closest prior art O3D18. The formula of claims 1 and 6 differed from that of O3D18 in that the claimed formula contained specific Lactobacillus and Bifidobacterium strains while the formula of O3D18 contained Lactobacillus in general. Example 2 of the patent and PD1 showed, by a comparison of a control formula with a formula according to the claims, that the latter led to strengthened natural immune defences. In this respect, O3D36 in conjunction with PD3 showed that the Lactobacillus rhamnosus LPR of PD1 was identical to the Lactobacillus paracasei rhamnosus GG as referred to in the claims, such that the formula applied in PD1 was as required by claims 1 and 6. The effect of a strengthened immune defence was not obtained with the formula of O3D18 (for the appellant's detailed arguments, see point 3.3.3 below). The problem solved in view of O3D18 was therefore to find a formula that resulted in strengthened natural immune defences. The solution as chosen in claims 1 and 6 was not obvious. Even though the prior art suggested that the individual components as referred to in claims 1 and 6 led to the required effect of strengthening natural immune defences, no pointer was present in the prior art to the combination of the claimed components, and in fact O3D16 taught not to combine probiotic bacteria with DHA and ARA. Furthermore, even though O3D35 disclosed the two specific strains of claims 1 and 6, it did not disclose the claimed effect. Finally, it could be deduced from O3D27 that DHA and AA were not truly beneficial, at least not after the first months of life.

XVIII. The respondents' arguments, in as far as relevant to the present decision, can be summarised as follows:

The main request should not be admitted into the proceedings since it could have been filed before the opposition division and since furthermore it complicated the appeal.

Furthermore, the main request lacked inventive step. The closest prior art document O3D18 disclosed an infant formula containing Lactobacillus, DHA and AA. The formula of claims 1 and 6 differed from this formula in that a specific Lactobacillus, namely Lactobacillus paracasei rhamnosus GG, and a specific Bifidobacterium, namely Bifidobacterium BB 536, rather than Lactobacillus in general was present. Example 2 of the patent and PD1 did not show that the claimed formula led to a strengthened immune defence. More specifically, the patent was entirely hypothetical and did not contain any experimental data and the composition of the control in the patent was unclear. Furthermore it was not clear whether the study formula used in PD1 was according to claims 1 and 6 and it was doubtful whether the reduction of the incidence in diarrhea in PD1 could provide any proof of a strengthened immune defence. Irrespective of this, the patent and PD1 did not establish that the immune defence obtained with the claimed formula was better than that in O3D18 since the control formula used in the patent and PD1 did not represent the teaching of O3D18. In fact, on the basis of O1D3, the formula of O3D18 had to be assumed to lead to the same degree of strengthening of the immune defence. The problem solved in view of O3D18 was thus at most the provision of a further formula that strengthened the immune defence. It was already known from O1D7 and O1D8 that probiotic bacteria and from O1D13 that AA and DHA increased the immune defence. Furthermore it could be derived from O1D9 that Bifidobacteria led to an increase in IgA,

which implied a strengthened immune defence. Moreover, O1D3 taught to combine LCPUFAs with Lactobacillus GG. Finally, as evidenced by O3D35, the two specific Lactobacillus and Bifidobacterium strains of claims 1 and 6 were common strains for infant formulae. The claimed alternative thus was obvious in view of the prior art.

Reasons for the Decision

1. The appeal is admissible.

Main request (previous fourth auxiliary request)

2. Admissibility

2.1 According to respondents I and III, the main request should not be admitted into the proceedings since it could have been filed in the proceedings before the opposition division and since furthermore it complicated the appeal.

2.2 The request has however been filed at the earliest possible time during the appeal proceedings, namely with the statement of grounds of appeal (as "4th auxiliary request"). The board can also not accept the respondent's argument that this request would complicate the appeal. Apart from a minor change in claim 6, it is identical to the second auxiliary request before the opposition division. Furthermore, the theoretical possibility that this request could have been filed during first instance proceedings is not by itself sufficient to deny admittance under Article 12(4) RPBA, which gives the board a discretion. Therefore, the board decided to admit this request into the proceedings.

3. Inventive step

3.1 The invention underlying the opposed patent concerns a nutritional composition intended for infants and/or young children (paragraph [0001]).

3.2 All parties agreed that O3D18 is the closest prior art.

3.2.1 This document was published on 19 May 2004, i.e. after the priority date and before the filing date of the opposed patent. The priority of the claims of the main request is not valid since the amount of DHA of independent claims 1 and 6 (for the wording of these claims, see point V above) is not disclosed in the priority document. Therefore O3D18 is prior art under Article 54(2) EPC.

3.2.2 O3D18 is directed to a nutrition powder for children aged 3 to 6 months (see the item: "Product Description"). O3D18 is thus in the same technical field as the opposed patent and thus indeed qualifies as the closest prior art.

3.2.3 O3D18 describes a formula comprising protein, 9g fat, carbohydrates, arachidonic acid (ARA), 30 mg of docosahexaenoic acid (DHA) and Lactobacillus.

The amount of DHA is 30 mg and the amount of fat is 9g, i.e. based on the fat amount, the DHA amount is 0.33%, which is within the range of claims 1 and 6.

Hence, as agreed by all parties, the subject-matters of claims 1 and 6 differ from that disclosed in O3D18 in that a specific Lactobacillus, namely Lactobacillus paracasei rhamnosus GG, and a specific Bifidobacterium,

namely Bifidobacterium BB 536, is present in the formula of these claims while O3D18 only generally refers to the presence of Lactobacilli in the formula.

3.3 The appellant argued that example 2 of the opposed patent and PD1 showed that the claimed formula led to a strengthening of natural immune defences while that of O3D18 did not provide this effect. The problem solved in the light of O3D18 was therefore the provision of an infant formula that strengthened natural immune defences.

3.3.1 The board accepts that in view of example 2 of the opposed patent and PD1 it is credible that the infant formula according to claims 1 and 6 leads to a strengthening of natural immune defences. However, in both the patent and PD1 this infant formula is compared to a formula not containing any probiotic bacteria at all (example 2 of the patent: "similar formula but without probiotics"; PD1: "control formula"). Therefore, the comparison made in the patent and PD1 is not done with a formula representative of the teaching of the closest prior art O3D18, which contains Lactobacilli. Consequently, contrary to the appellant's assertion, the experiments in the patent and PD1 do not prove that, unlike the formula of O3D18, the formula according to claims 1 and 6 leads to the strengthening of natural immune defences.

3.3.2 In fact, the opposite must be assumed on the basis of O1D3. More specifically, in the chapter "Conclusion" on page 788 of O1D3, the following is disclosed:

"The growth inhibitory actions of LCPUFAs [long chain polyunsaturated fatty acids] against pathogenic bacteria and their ability to enhance the adherence of

Lactobacilli to mucosal surface will aid the probiotics in colonizing the gut. Once the gut microflora are established, probiotics enhance gut-specific IgA responses, Th1 immunity, TGf-β, and IL-10 production that protect against atopy. LCPUFAs by virtue of their ability to alter the Th1/Th2 ratio, support these beneficial actions of probiotics." (Insertion in brackets and emphasis added by the board).

Hence, according to O1D3, Lactobacilli in combination with LCPUFAs enhance the IgA response of the gut and thus strengthen natural immune defences. In view of this, the formula of O3D18, which contains Lactobacillus and the two LCPUFAs, DHA and AA, must be assumed to lead to strengthened natural immune defences. Therefore, both the formula of claims 1 and 6 and that disclosed in O3D18 solve the problem formulated by the appellant, namely of strengthening natural immune defences.

3.3.3 The appellant contested this finding but the board does not find the appellant's arguments convincing:

The appellant's first argument (presented only during the written proceedings) was that the composition of O3D18 contained rice powder, cereals, raisin and other potential sources of prebiotics and, according to PD1, prebiotics could lead to higher incidences of diarrhea and/or dampen the effect of probiotics. Therefore, it was likely that the formula of O3D18 did not result in a strengthened natural immune defence.

However, due to the "comprising"-language of claims 1 and 6, these claims cover compositions containing prebiotics. Therefore, if indeed prebiotics dampened the effect of probiotics and possibly thereby prevented

a strengthening of natural immune defences, this would apply also to the claimed formula. Hence, in this case, the formula as referred to in claims 1 and 6 would not solve the problem of strengthening natural immune defences at all.

The appellant's second argument was that O1D3 was not relevant since it did not contain any experimental data but was purely hypothetical. It could therefore not prove that the formula of O3D18 led to strengthened natural immune defences.

However, the same is true for the results reported in example 2 of the patent for which equally no experimental data are given. Hence, if one accepts these results, which the board does (see points 3.3.1 above), then one has also to accept the results reported in O1D3 since the same standard of proof must be applied for both the patent and O1D3.

The appellant's third argument was that O3D16 showed that higher concentrations of AA and DHA inhibited bacterial growth and that any effect on the immune system was highly strain-specific. Therefore, lactobacilli as present in the formula of O3D18 could not be assumed to lead to the same effect as the two specific strains referred to in claims 1 and 6.

It is indeed true that table 1 of O3D16 shows that AA and DHA inhibit the growth of various bacteria strains at higher concentrations and that the degree of inhibition differs between different strains. However, O3D16 does not contain a clear linkage of this inhibited growth to any effects on the immune system. Furthermore, even if one were to assume in the appellant's favour that O3D16 indeed taught that at

higher AA- and DHA-concentrations natural immune defences are no longer strengthened, this would not necessarily imply that the same is true at the concentrations of AA and DHA present in the formula of O3D18. The board therefore does not see how O3D16 could invalidate the above conclusion that the composition of O3D18 can be assumed to strengthen natural immune defences.

3.4 Consequently, the board's conclusion remains valid that both the claimed formula and that of O3D18 strengthen natural immune defences. The problem solved in the light of O3D18 is thus the provision of a further formula that strengthens natural immune defences.

3.5 It has to be examined whether the claimed solution, i.e. the selection of the specific strains Lactobacillus paracasei rhamnosus GG and Bifidobacterium longum BB 536, was obvious in view of the cited prior art.

3.5.1 It was already known from O1D7 and O1D8 that probiotic bacteria strengthen natural immune defences. As to this, see (a) the first full paragraph on the right-hand column of page 447S of O1D7: "Probiotic bacteria are shown to promote the endogenous host defence mechanisms. In addition to the effects of probiotics on nonimmunologic gut defence, which is characterised by stabilisation of the gut microflora (7), probiotic bacteria have been shown to enhance humoral immune responses and thereby promote the intestine's immunologic barrier (14, 26)"; and (b) the second sentence of the last paragraph on page 306 of O1D8: "Indeed an important part of the beneficial effects of probiotics is related to the immunomodulatory effects:

immune-enhancing as well as anti-inflammatory activity."

This effect (expressed as enhanced IgA levels) was in particular known for Lactobacilli and Bifidobacteria. As to this see the above discussed passage of O1D3 for Lactobacilli and the last paragraph of the left-hand column on page 681 of O1D9 for Bifidobacteria: "The presence of Bifidobacterium sp. in the fecal flora of breastfed children is associated with strong stimulation of the antirotavirus IgA response ...".

The skilled person starting from the formula of O3D18 and looking for further formulae providing the desired effect of strengthening natural immune defences would thus have known that Lactobacilli and Bifidobacteria provide this effect. The two specific strains Lactobacillus paracasei rhamnosus GG and Bifidobacterium longum BB 536 chosen in claims 1 and 6 thus represent an arbitrary selection of strains out of the Lactobacilli and Bifidobacteria already known from the prior art to provide the desired effect of strengthening natural immune defences. Such an arbitrary selection, by the very fact of it being arbitrary, does not involve any inventive step. This is even more so since the two specific strains chosen in claims 1 and 6 were known from the prior art as commercially available probiotic bacteria for infant formulae (table 2 on page 295 in conjunction with table 4 and figure 3 on page 305 of O3D35).

3.6 The appellant acknowledged that the prior art provided suggestions that the individual components as referred to in claims 1 and 6 led to the required effect of strengthening natural immune defences but argued that no pointer was present in the prior art to the

combination of the claimed components, in particular the combination of the probiotic bacteria and the LCPUFAs DHA and ARA.

The board does not find this argument convincing. Firstly, the question whether the skilled person would combine probiotic bacteria and DHA/AA does not need to be answered since this combination is already present in the closest prior art O3D18 (Lactobacillus, DHA and AA). Secondly, after discussing the enhanced IgA response resulting from probiotics in the paragraph "Conclusion", O1D3 states that "LCPUFAs by virtue of their ability to alter the Th1/Th2 ratio, support these beneficial actions [enhanced IgA response] of probiotics" (insertion added). Hence, there is a clear pointer to the combination of probiotics and LCPUFAs in the prior art.

3.7 The appellant furthermore argued that it could be deduced from O3D27 that DHA and AA were not truly beneficial, at least not after the first months of life. However, this argument is not relevant for the question whether the selection of the two specific strains as referred to in claims 1 and 6 involves an inventive step.

3.8 The alternative chosen in claims 1 and 6 therefore lacks inventive step in view of O3D18 taken as the closest prior art.

First and second auxiliary requests (previous fifth and sixth auxiliary requests)

4. Claim 1 of the first auxiliary request is identical to claim 1 of the main request and claim 1 of the second auxiliary request is identical to claim 6 of the main

request. Therefore, for the reasons given above with regard to the main request, the subject-matter of these two requests also lacks inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Cañueto Carbajo W. Sieber

Decision electronically authenticated