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Datasheet for the decision of 20 January 2023

Case Number:	T 0578/21 - 3.3.09
Application Number:	12770505.1
Publication Number:	2768311
IPC:	A23D9/00, A61K31/202, A61K31/7016, A61K35/745, A61K35/747, A61K31/702, A61K35/00, A23L33/00, A23L33/115, A23L33/135, A23L33/21, A61P1/00, A61P1/14
Language of the proceedings:	EN

Title of invention:

COMPOSITION FOR USE IN THE PROMOTION OF INTESTINAL ANGIOGENESIS AND OF NUTRIENT ABSORPTION AND OF ENTERAL FEEDING TOLERANCE AND/OR IN THE PREVENTION AND/OR TREATMENT OF INTESTINAL INFLAMMATION AND/OR IN THE RECOVERY AFTER INTESTINAL INJURY AND SURGERY

Patent Proprietor:

Société des Produits Nestlé S.A.

Opponent:

N.V. Nutricia

Headword:

Compositions for treating inflammation in infants/NESTEC

Relevant legal provisions:
EPC Art. 56, 123(2)
RPBA 2020 Art. 13(2)

Keyword:
Auxiliary Request 5: Added subject-matter - (no); inventive step - (yes); admission of late submissions - (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0578/21 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 20 January 2023

Appellant: (Opponent)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Respondent: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Rupp, Christian Mitscherlich PartmbB Patent- und Rechtsanwälte Sonnenstraße 33 80331 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 10 February 2021 concerning maintenance of the European Patent No. 2768311 in amended form.**

Composition of the Board:

Chairman	A. Haderlein
Members:	A. Veronese
	F. Blumer

Summary of Facts and Submissions

I. The appeal was filed by the opponent (appellant) against the decision of the opposition division finding that the European patent, as amended according to auxiliary request 1 filed during the oral proceedings held before the opposition division, meets the requirements of the EPC.

II. The documents cited during the opposition proceedings included:

D6: WO 2005/122790 A1
D12: G. Deshpande et al., Pediatrics, vol. 125(5), 2010, 921-30
D14: WO 2011/012655 A1
D18: M. Good et al., British Journal of Nutrition, Vol.116(7), 2016, 1175-87

III. In its decision, the opposition division found, *inter alia*, that the subject-matter of auxiliary request 1 involved an inventive step considering D6 or, alternatively, D12, as the closest prior art.

IV. In its statement setting out the grounds of appeal, relying on D6, D12 and D14, the appellant set out the reasons why it disagreed with the opposition division's conclusions. In a later letter, it referred to a new document, D19.

D19: Table from Kim et al., Journal of Applied Poultry Research, Vol. 25, 2016, 528-38

V. With its reply to the statement setting out the grounds of appeal, the proprietor (respondent) filed auxiliary requests 1 to 6. In a later letter, it presented tables downloaded from the internet.

VI. The main request (then auxiliary request 1 found to be allowable by the opposition division) and auxiliary requests 1 to 4 were withdrawn during the oral proceedings held before the board. Claim 1 of auxiliary request 5 reads:

"*1. A composition comprising at least one long chain polyunsaturated fatty acid (LC-PUFA), at least one probiotic and a mixture of oligosaccharides, said mixture containing at least one N-acetylated oligosaccharide, at least one sialylated oligosaccharide and at least one neutral oligosaccharide, wherein the neutral oligosaccharide is 2'-fucosyllactose (or FL), wherein said composition is a synthetic nutritional composition; for use in the prevention and/or treatment of intestinal inflammation, such as necrotizing enterocolitis, and/or in the recovery after intestinal injury and/or surgery in infants, who were born preterm or with low-birth weight or experienced intra-uterine growth retardation, and/or suffered from suboptimal intra-uterine nutrition and/or intestinal injury and/or surgery.*"

VII. The appellant's arguments can be summarised as follows.

- The combination of features of claim 1 of auxiliary request 5 was not disclosed in the application as filed.

- The claimed subject-matter did not involve an inventive step starting from D6 or, alternatively, D12 as closest prior art.

- The features distinguishing the claimed composition from the prior art were not associated with any effect; the tests in the patent did not show the contribution of the individual components claimed because the control composition did not comprise any of the claimed compounds; the soybean and the corn oil present in the control composition were not long-chain polyunsaturated fatty acids (LC-PUFAs), as shown by D19.

- The problem was the provision of an alternative composition for treating the relevant diseases.

- The provision of the claimed composition was obvious taking into account the teaching of D14.

VIII. The respondent's arguments can be summarised as follows.

- The objection of added subject-matter was late filed and should not be admitted; furthermore, claim 1 was based on claims 1, 10 and 12 as filed.

- The claimed subject-matter involved an inventive step starting from each of D6 and D12 as the closest prior art.

- The tests in the patent were suitable for showing that the combination of 2'-fucosyllactose with LC-PUFAs and a probiotic agent was more effective than the compositions of the prior art; D18 confirmed the results; furthermore, the soybean and the corn

oil present in the control composition contained LC-PUFAs, as shown in some excerpts downloaded from the internet.

- The problem was the provision of an improved composition for treating the relevant diseases; neither D6 nor D12, alone or in combination with D14, rendered obvious the claimed solution.

Requests

IX. The appellant requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

X. The respondent requested that the patent be maintained on the basis of auxiliary request 5, filed with the reply to the statement setting out the grounds of appeal.

Reasons for the Decision

Auxiliary request 5

1. Auxiliary request 5 is the only relevant request because the main request and auxiliary requests 1 to 4 were withdrawn during the oral proceedings held before the board.

2. *Amendments*

2.1 According to the appellant, the combination of the following features characterising claim 1 of auxiliary request 5 created originally undisclosed subject-matter:

- 2'-fucosyllactose

- the diseases mentioned in claim 1

- the patients mentioned in claim 1

2.2 This argument is not convincing. As submitted by the respondent, claim 1 derives from claim 1 as originally filed and contains the additional features requiring that the neutral oligosaccharide is 2'-fucosyllactose (a compound disclosed in claim 10 as originally filed) and that the patient is an infant, as defined in claim 12 as originally filed.

2.3 Claim 12 as originally filed depends on claim 10 as originally filed, which in turn depends on claim 1 as originally filed. Furthermore, 2'-fucosyllactose is a preferred neutral oligonucleotide in the application as filed (see page 9, line 11 and Table 2). Therefore, the subject-matter of claim 1 of auxiliary request 5 does not contain subject-matter extending beyond the content of the application as filed (Article 123(2) EPC).

2.4 In view of this finding, it is not necessary to address whether the objection of added subject-matter was late filed and should be disregarded.

3. *Admissibility of late-filed facts and submissions*

3.1 Under Article 13(2) RPBA 2020, any amendment to a party's appeal case made after notification of the summons to oral proceedings must, as a rule, not be taken into account unless there are exceptional circumstances justified with cogent reasons by the party concerned.

3.2 In the current case, after receiving the preliminary opinion issued by the board in preparation for the oral proceedings, the respondent filed two excerpts downloaded from the internet. In its opinion, these showed that the soybean and the corn oil present in the composition used as a control in the tests described in the patent contained long-chain polyunsaturated fatty acids (LC-PUFAs). Based on this assertion, the respondent further submitted that the tests were suitable for showing that a combination of probiotics, LC-PUFAs and a mixture of neutral, sialylated and acetylated oligosaccharides induced an unexpected increase of angiogenesis.

3.3 However, the respondent has not provided any argument that exceptional circumstances and cogent reasons justified the filing of new evidence and new submissions at a late stage of the appeal proceedings. The objection that the respondent was attempting to address with its late submissions had been raised by the appellant on page 3 of its statement setting out the grounds of appeal. On this page, the appellant argued that the tests in the patent were not suitable for showing that the features distinguishing the claimed subject-matter from the prior art were associated with an unexpected technical effect because the control composition did not contain any of the claimed ingredients. Thus, there were no reasons for filing new evidence and new submissions in reply to the communication issued by the board in preparation for the oral proceedings.

3.4 For these reasons, the aforementioned new facts and submissions are not admitted into the appeal proceedings. The same applies to D19, filed by the

appellant to address the respondent's late-filed submissions.

3.5 These facts and submissions relate to the content of the control composition (see Table 2 of the patent) which, for the reasons set out in 4.14 below, is not relevant for the present decision.

4. *Inventive step*

The closest prior art and its teaching

4.1 The opposition division decided that D6 and D12 represented the closest prior art. The parties have not disputed this finding, and the board does not see reasons to diverge from it either.

4.2 As far as claim 1 relates generically to the prevention and treatment of "intestinal inflammation" and the treatment of subjects having undergone intestinal surgery, D6 represents the closest prior art.

4.3 D6 discloses a nutritional composition suitable for feeding premature infants comprising eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and arachidonic acid (ARA), which are LC-PUFAs, and at least two distinct oligosaccharides. The oligosaccharides can be, for example, galactooligosaccharides (GOS) and fructooligosaccharides (FOS), which are neutral oligosaccharides (see claims 1 and 3 and page 11, lines 1 to 5). The composition stimulates the integrity of the intestinal barrier (see claim 1 and page 10, line 24). According to D6, this effect is beneficial for treating and preventing intestinal damage and chronic inflammatory diseases, such as inflammatory bowel disease (IBD), and for treating subjects having

undergone intestinal surgery (page 1, lines 10 to 12 and page 11, lines 6 to 20).

4.4 Although it did not dispute that D6 was the closest prior art, the respondent submitted that this document focused on stimulating the integrity of the intestinal barrier rather than inflammation. The respondent conceded that page 4, lines 25 to 26 taught that EPA and DHA were used to balance the potential inflammatory action of ARA metabolites. However, it contended that the gist of the invention disclosed in D6 was improving barrier integrity. None of the tests described in this document showed an effect on inflammation. Thus, no conclusive teaching on intestinal inflammation could be drawn from D6.

4.5 The board does not agree. It is true that D6 focuses on the use of the disclosed composition for stimulating the integrity of the intestinal barrier. However, this document clearly teaches that by inducing this effect, the disclosed composition can be used for treating and preventing IBD, an intestinal inflammation disease, and for recovering from intestinal surgery. Therefore, D6 relates to the use of a composition comprising some of the ingredients of the composition of claim 1 for the treatment and prevention of the conditions listed in that claim.

4.6 As far as claim 1 relates to the prevention and the treatment of necrotising enterocolitis (NEC), D12 is the closest prior art. D12 discloses the use of probiotic supplements for preventing NEC in preterm neonates. It teaches that these supplements reduce the risk of NEC and mortality associated with this condition in preterm infants (see page 921 "objective" and "results" and page 923, left-hand column).

Furthermore, D12 mentions a study showing that the administration of probiotics to infants does not increase the risk of sepsis (see page 923, middle column).

Distinguishing features

4.7 The subject-matter of claim 1 differs from the composition disclosed in D6 in that the composition comprises a probiotic and a specific combination of oligosaccharides, namely a combination of neutral, N-acetylated and sialylated oligosaccharides. In particular, the composition comprises 2'-fucosyllactose as the neutral oligosaccharide.

4.8 The subject-matter of claim 1 differs from the composition disclosed in D12 in that the composition includes LC-PUFAs and oligosaccharides and, in particular, in that the neutral oligosaccharide is 2'-fucosyllactose.

Technical effect

4.9 The patent describes tests showing the effects of two compositions (PUFA-BL-DDWP and PUFA-BL-DDWP-FL) including LC-PUFAs, probiotics and a combination of neutral, N-acetylated and sialylated oligosaccharides and a control composition not comprising any of these ingredients (see paragraphs [0092] to [0107] and Tables 1 to 4 of the patent).

4.10 The composition PUFA-BL-DDWP-FL differs from the composition PUFA-BL-DDWP in that a small portion of the oligosaccharides present in this latter composition was replaced by 2'-fucosyllactose.

4.11 PUFA-BL-DDWP and PUFA-BL-DDWP-FL were administered to rats subjected to maternal separation. The control composition was administered to rats subjected to maternal separation and to non-separated rats. The results show that both compositions, PUFA-BL-DDWP and PUFA-BL-DDWP-FL, increase the expression of some markers of angiogenesis compared to the control (see Table 2 and Figures 2, 3 and 4).

4.12 The patent teaches that the promotion of angiogenesis, i.e. the formation of new blood vessels, is beneficial in patients affected by NEC and other intestinal inflammatory conditions and patients recovering from intestinal injury and surgery (see paragraphs [0001] to [0011]). This was not disputed by the appellant. The results in the patent make it therefore credible that the claimed composition is suitable for treating the relevant conditions.

4.13 The appellant noted that the control composition did not contain any of the relevant ingredients, namely a probiotic, LC-PUFAs or oligosaccharides. Thus, in its opinion, the tests were not suitable for comparing the properties of the claimed composition with those of the closest prior art.

4.14 However, this is not true. Whether the control composition contains the relevant ingredients is irrelevant since the comparison between the effects induced by the compositions PUFA-BL-DDWP and PUFA-BL-DDWP-FL shows that 2'-fucosyllactose is much more effective, compared to other neutral oligosaccharides, in promoting angiogenesis. The replacement of a small amount of the DDWP oligosaccharide mixture with 2'-fucosyllactose (comprising 50% neutral, 20% sialylated and 30% acetylated oligonucleotides) induces, in fact,

a very significant increase in the expression of angiogenesis markers (See Figures 2, 3 and 4).

4.15 The appellant's argument that the results were not statistically significant is not convincing, at least because there is no overlap between the error bars for the relevant results.

4.16 The appellant noted that Table 4 showed that the composition PUFA-BL-DDWP-FL contained more probiotic agents. In its opinion, this could explain the stronger effects of this composition. This argument is not convincing either. The presence of 2'-fucosyllactose appears in fact to be the most striking difference between the two compositions PUFA-BL-DDWP and PUFA-BL-DDWP-FL. Furthermore, it appears that these two compositions were prepared to contain identical amounts of the same probiotic agent, *B. Lactis*: 0.37 g of *B. Lactis* containing 5.40 E+10 cfu/g. Thus, the difference in Table 4 could, as submitted by the respondent, be an error. Moreover, the results shown in D18, an article published after the date on which the application for the opposed patent was filed, confirm that 2'-fucosyllactose significantly reduces the severity of NEC in neonatal mice (see abstract and results).

4.17 For these reasons, and in the absence of any evidence to the contrary, it is concluded that the tests in the patent show that the combination of 2'-fucosyllactose with probiotic agents and LC-PUFAs induces an effect which significantly exceeds that produced by other neutral oligosaccharides.

Technical problem

4.18 Taking into account the aforementioned results, the underlying technical problem can be formulated as the provision of an improved composition for treating and preventing intestinal inflammation, including NEC, and for recovering after intestinal injury and/or surgery in infants as defined in claim 1. The tests in the patent show that this problem has successfully been solved.

Non-obviousness of the claimed solution

4.19 When confronted with the aforementioned problem, the skilled person would not have found in any of the cited prior-art documents an incentive to include 2'-fucosyllactose in the compositions described in D6 and D12.

4.20 D12 does not even mention the use of oligosaccharides. D6 discloses a combination of LC-PUFAs with two distinct oligosaccharides. However, it does not provide a general teaching that all neutral oligosaccharides are effective, and 2'-fucosyllactose is not even mentioned.

4.21 The appellant has drawn attention to D14. This document discloses infant compositions comprising probiotics, LC-PUFAs and a mixture of N-acetylated, sialylated and neutral oligosaccharides and among these, fucosylated oligosaccharides, for improving the health of infants (see claims 1 to 6; page 1, lines 9 to 12; page 7, line 4 to page 8, line 30; page 10, line 19 to page 11, line 26). Among a long heterogeneous list of diseases, a passing reference is also made to "preventing inflammation later in life" (see claim 17). However, no

mention is made of a direct effect on inflammatory conditions, let alone inflammation of the intestinal tract. No mention is made of 2'-fucosyllactose either. Therefore, D14 does not provide any prompt towards the claimed solution.

4.22 For these reasons, it is concluded that the composition defined in claim 1 of auxiliary request 5, which is characterised by the presence of 2'-fucosyllactose, involves an inventive step over the teaching of the cited prior-art documents. The same applies to the dependent claims, which are narrower in scope.

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 on the basis of claims 1 to 9 according to auxiliary request 5, submitted with the reply to the statement setting out the grounds of appeal, and a description yet to be adapted.

The Registrar: The Chairman:

M. Schalow A. Haderlein

Decision electronically authenticated