Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 11 September 2020

Case Number: T 0395/18 - 3.3.09

Application Number: 12703533.5

Publication Number: 2811845

IPC: A23C9/20

Language of the proceedings: EN

Title of invention:
MATERNAL SUPPLEMENT TO ENHANCE IMMUNE SYSTEM OF AN INFANT

Patent Proprietor:
N.V. Nutricia

Opponent:
Société des Produits Nestlé S.A.

Headword:
Oligosaccharides for preventing allergic reactions in infants

Relevant legal provisions:
EPC Art. 54(5), 83, 111(1), 123(2)
EPC R. 106
RPBA 2020 Art. 11, 12(2), 13(1), 13(2), 25(3)

Keyword:
Main request: sufficiency of disclosure - (no)
Auxiliary requests 1 to 6: sufficiency of disclosure - (no)
Auxiliary request 7: added matter - (no); sufficiency of disclosure - (yes)
Admissibility of late filed submissions - (yes)
Violation of the right to be heard - (no)
Serious doubts that a therapeutic effect is achieved - (yes)
Oral proceedings by videoconference

Decisions cited:
G 0001/03, T 0019/90, T 0241/95, T 0609/02, T 0491/08, T 1150/09, T 0184/16, T 0694/16, T 1966/16, T 0731/17

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

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 0395/18 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 11 September 2020

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Respondent: (Opponent)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 10 November 2017 revoking European patent No. 2811845 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Haderlein
Members:	A. Veronese
	E. Kossonakou

Summary of Facts and Submissions

I. The appeal was filed by the proprietor (appellant) against the decision of the opposition division to revoke European patent No. EP 2 811 845 B1.

II. With its notice of opposition the opponent had requested revocation of the patent in its entirety on the grounds under Article 100(a) EPC (lack of novelty and lack of inventive step) and Article 100(b) EPC.

III. The decision of the opposition division was based on a main request and auxiliary requests 1, 2 and 4 to 9 (originally 3 to 8), filed by letted dated 11 August 2017, and auxiliary request 3, filed during the oral proceedings held before the opposition division.

IV. In its decision the opposition division held that:

- The main request and the auxiliary requests were admissible.

- Claim 1 of the main request and each of auxiliary requests 1 and 4 to 9 contained added subject-matter.

- The invention claimed in auxiliary requests 2 to 9 was not sufficiently disclosed. The tests described in the patent were conducted using a mixture of three specific oligosaccharides. It was not plausible that the purported therapeutic effect could be achieved over the broad scope claimed and, in particular, using one oligosaccharide only or an oligosaccharide combination differing from that

used to conduct the tests. For medical use claims, the burden of proof that the therapeutic effect is attained lies with the patentee, as that effect is a functional feature of the claim.

V. In its statement setting out the grounds of appeal, the appellant requested that the decision be set aside and that the patent be maintained on the basis of the main request, or, alternatively, on the basis of one of auxiliary requests 1 to 9, all filed with that statement. Remittal to the opposition division for a discussion on novelty and inventive step was also requested. Two documents were referred to in the statement and enclosed with it:

D13: Gibson G.R. et al., Prebiotics: Development & Application, 2006, John Wiley & Sons, Ltd

D14: WO 2005/039597 A2

D14 corresponds to D6, filed with the notice of opposition. D13 was filed for the first time with the statement setting out the grounds of appeal.

VI. In its reply to the statement setting out the grounds of appeal, the opponent (respondent) requested that the appeal be set aside and, furthermore, that D13 and D14 not be admitted into the proceedings.

VII. By letter dated 18 March 2019 the appellant provided further arguments and amended requests (new main request and auxiliary requests 1 to 8).

VIII. In a letter dated 31 December 2019 the respondent addressed the appellant's arguments and requested that auxiliary requests 1 to 5, 7 and 8 not be admitted into the proceedings.

IX. A summons to oral proceedings before the board was issued on 27 January 2020. In a communication dated 7 April 2020 the board drew attention to the main discussion points. It also expressed the preliminary opinion that claim 1 of the main request contained added subject-matter, whereas claim 1 of auxiliary request 1 fulfilled the requirement of Article 123(2) EPC. The invention claimed in the latter was sufficiently disclosed, since the respondent (which had the burden of proof in this matter) did not succeed in raising serious doubts based on verifiable facts in this respect.

X. In two letters dated 11 August 2020 and 7 September 2020, the respondent, respectively, referred to the board's communication and drew attention to two passages of D13 and to a test described in the patent in suit, which in its opinion threw serious doubts that the invention could be carried out over the claimed scope. It also stated that it no longer objected to the admission of D13.

XI. At the oral proceedings, which took place by videoconference on 11 September 2020, the appellant replaced the main request with auxiliary request 1 and renumbered the other requests accordingly. It also requested that the new submissions presented by the respondent after notification of the board's communication, which were based on D13, D14 and the tests in the patent, be disregarded.

The respondent reiterated its objection to the admittance of the main request and auxiliary requests 1 to 4, 6 and 7 as renumbered and stated that it did not object to the admission of D13 and D14 into the

proceedings. It also requested remittal should any of these requests be found to fulfil the requirements of Articles 83 and 123(2) EPC.

XII. Claim 1 of the main request reads:

"*1. A composition comprising a non-digestible oligosaccharide for use in decreasing or preventing an allergic reaction in a mammalian subject, wherein the composition is administered to a lactating, postpartum female who is breast-feeding the mammalian subject and wherein the non-digestible oligosaccharide comprises galacto-oligosaccharide*".

Claim 1 of auxiliary request 1 differs from that of the main request in that the non-digestible oligosaccharide "*comprises galacto-oligosaccharide and fructo-oligosaccharide*".

Claim 1 of auxiliary request 2 differs from that of the main request in that the non-digestible oligosaccharide "*comprises galacto-oligosaccharide and fructo-oligosaccharide, wherein the fructo-oligosaccharide has a degree of polymerisation between 7 and 100*".

Claim 1 of each of auxiliary requests 3 to 6 differs from that of the main request, *inter alia*, in that the non-digestible oligosaccharide is "*selected from the group consisting of galacto-oligosaccharide and fructo-oligosaccharide, wherein the fructo-oligosaccharide has a degree of polymerisation between 7 and 100*".

Claim 1 of auxiliary request 7 differs from that of the main request in that the non-digestible oligosaccharide "*comprises galacto-oligosaccharide, fructo-oligosaccharide and acidic oligosaccharide*".

XIII. The arguments of the appellant relevant for the present decision were as follows.

- The main request and auxiliary requests 1 to 4, 6 and 7 had to be admitted. They were based on previously filed requests and were limited to preventing or treating allergic reactions. This limitation avoided further discussions as to whether the definition of the therapeutic use was too broad.

- The claims of the various requests did not contain added subject-matter.

- The description and the figures of the patent in suit contained discrepancies. However, the skilled person would have been able to understand the results of the experiments described. The entire set of results made it plausible that the claimed oligosaccharide combination induced the claimed therapeutic effect. There was no evidence that this effect could not be achieved using a galacto-oligosaccharide (GOS) alone, a combination of galacto- and fructo-oligosaccharides (GOS and FOS) not comprising acidic oligosaccharides, or a combination of these compounds different from the specific one tested. The prebiotic properties of these oligosaccharide classes, GOS and FOS in particular, were known in the prior art, as shown in D13 and D14. Thus, it was plausible that the effects observed with the tested combination could be achieved with the compositions defined in each of the requests on file. The passages of D13 mentioned by the respondent had to be disregarded because they did not properly represent the

teaching of the prior art. The invention claimed in each of the requests was sufficiently disclosed.

- The respondent's submissions based on D13, Table 3 of D14 and paragraph [0102] of the patent should not be admitted, as they were late-filed. Since the appellant did not have time to prepare an adequate response to address the submissions based on D13 and D14, taking them into account violated its right to be heard.

XIV. The arguments of the respondent relevant for the present decision were as follows.

- The main request and auxiliary requests 1 to 4, 6 and 7 were filed late during the appeal proceedings. These requests had to be filed within the time limit for filing the statement of grounds of appeal. Thus, they were inadmissible.

- All the requests contained added subject-matter. As far as auxiliary request 7 was concerned, the amendment of the wording "is to be administered" to "is for administration" created new subject-matter.

- The experiments described in the patent did not make it plausible that the tested composition induced the alleged therapeutic effect. The results shown in the description did not correspond to those in the figures. Paragraph [0102] showed that a non-working embodiment was claimed. Furthermore, it was not plausible that the effects observed when administering the tested combination of three specific oligosaccharides could be achieved using: GOS alone, a combination of GOS and FOS not comprising acidic oligosaccharides, or a

combination of GOS, FOS and acidic oligosaccharides different from the one tested. This was also confirmed by D13, representing - according to the appellant itself - common general knowledge, and by D14, Table 3 in particular. The patent itself (paragraph [0092]) supported the view that the presence of acidic oligosaccharides was essential for the therapeutic use. Accordingly, the claimed invention was not sufficiently disclosed.

- The submissions based on D13, D14 and paragraph [0102] of the patent were triggered by the board's communication issued in preparation for the oral proceedings.

XV. During the oral proceedings, upon announcement of the board's conclusion on the issue of sufficiency of disclosure in respect of the main request, the appellant filed the following objection under Rule 106 EPC:

"New arguments have been presented by the opponent/ respondent for the very first time shortly before (submissions dated 11 August 2020) and at the oral proceedings of 11 September 2020. These new arguments involve that based on D13 and D14 the skilled person would conclude that GOS alone or GOS/FOS would not always present a prebiotic effect, by referring to isolated studies. D13 is for the first time mentioned in the submissions of 11 August and D14 is not mentioned at all in writing by the opponent but for the first time at the hearing (other than with respect to their alleged inadmissibility in the response to the Grounds of Appeal).
By presenting these arguments shortly before or during the hearing, the appellant/patentee has been deprived

of the opportunity to provide a proper response. We are convinced that a detailed review of the studies cited in D13 would provide evidence that the skilled person is fully aware of the prebiotic effect of GOS irrespective of the presence of other oligosaccharides. Also, the sections of D14 referred to by the opponent (in particular Table 3) have no relation to the claimed use of preventing allergy. We would be able to provide a sound scientific explanation, if we would have had the time and opportunity to properly defend against these arguments.
The appellant/patentee has requested not to admit these new arguments into the proceedings for these reasons, and yet the Board of Appeal has admitted them. Hence, our right to be heard on these two issues is fundamentally violated. An objection under Rule 106 EPC is herewith submitted."

XVI. Final requests

The appellant requested that the appealed decision be set aside and the patent be maintained on the basis of the main request, or, alternatively, one of auxiliary requests 1 to 7 (corresponding to auxiliary requests 1 to 8 filed by letter dated 18 March 2020).

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. *Admissibility of requests*

1.1 The respondent requested that the main request and auxiliary requests 1 to 4, 6 and 7 not be admitted into the appeal proceedings. These requests were filed as

auxiliary requests 1 to 5, 7 and 8 with the appellant's letter dated 18 March 2019, thus subsequent to the filing of the grounds of appeal. The filing of these requests therefore constitutes an amendment of the party's case, so that their admittance is at the discretion of the board under Article 13(1) of the revised Rules of Procedure of the Boards of Appeal (RPBA 2020, applicable according to the transitional provisions of Article 25 RPBA 2020).

1.2 The board notes that:

- Each of the requests is based on a corresponding request filed with the statement setting out the grounds of appeal and on a further corresponding request which was admitted and examined by the opposition division.

- The new requests differ from the previous ones in that the claimed subject-matter has been limited to the treatment of an allergic reaction, a condition already specified in claim 1 of each of auxiliary requests 1 to 3 and 8 filed during the opposition proceedings, and in the corresponding requests filed with the statement of grounds of appeal.

- The amendments are simple and clearly address the objection that the therapeutic use specified in the previously filed claims (enhancement of an immune system disorder and/or prevention of an immune system disorder) was too broadly defined. Thus, this limitation simplifies the issues to be discussed without giving rise to new ones, which is beneficial for procedural economy. Simplification of the proceedings and prevention of further

discussions were indeed the appellant's justification for filing the requests.

1.3 For these reasons, the main request and auxiliary requests 1 to 4, 6 and 7 are admitted into the appeal proceedings.

2. *Admissibility of submissions by the respondent*

2.1 The appellant requested that certain submissions presented by the respondent after notification of the communication issued by the board in preparation for the oral proceedings be disregarded. These submissions relate to the:

- teaching of paragraphs 4.4.4 and 4.6 of D13

- results presented in paragraph [102] of the opposed patent

- interpretation of the results in Table 3 of D14

2.2 Since the submissions were made after the notification of the summons to oral proceedings dated 27 January 2020, they constitute an amendment of the party's case and their admittance is at the discretion of the board under Article 13(2) of the revised Rules of Procedure of the Boards of Appeal (RPBA 2020, applicable pursuant to Article 25(1) and (3) RPBA 2020).

2.3 The respondent argued that there were compelling reasons to dispute the assumptions and preliminary conclusions presented in paragraph 6 of the communication issued by the board in preparation for the oral proceedings. In particular, it was important

to discharge the burden of proof that the board had shifted to it, contrary to the findings in the contested decision. This should justify the late filing of the arguments concerned.

2.4 The preliminary opinion given by the board in its communication is based essentially on facts and arguments presented by the parties in writing. Nonetheless, the communication crystallised for the first time what the board itself had deduced to be the essential elements of the lengthy arguments presented by the parties when discussing sufficiency of disclosure. In particular, the communication drew attention to some paragraphs of the opposed patent discussing the principle underlying the claimed invention which convey the impression that, at the filing date, the skilled person would have assumed any galacto-, fructo- or acidic oligosaccharide to be suitable, individually, to induce the alleged therapeutic effect (paragraphs [0032], [0033], [0092] and [0102]). Furthermore, the communication drew attention to the results of the tests described in paragraph [0102] of the patent. It also clearly put the burden of proof regarding sufficiency on the respondent, thus contradicting the position taken by the opposition division.

2.5 It is thus accepted that the respondent's first opportunity to address these specific points highlighted by the board was after receiving the board's preliminary opinion.

2.6 Concerning D13, it is noted that this is a document filed by the appellant itself as evidence of common general knowledge relating to the use of oligosaccharides as prebiotics. Furthermore, the parts

cited by the respondent are contained in the same sections of D13 (4.4 and 4.6) mentioned by the appellant in the statement of grounds of appeal. The relevance of these parts, which raises serious doubts as to the assumptions made in the patent, had already been highlighted by the respondent one month before the scheduled oral proceedings, thus, sufficiently in advance for the appellant to discuss their relevance. In this context, it also needs to be noted that at no stage did the appellant request extra time or even a postponement of the oral proceedings in order to deal with those submissions.

2.7 Concerning paragraph [0102] of the patent, it is pointed out that, in its communication, the board underscored the relevance of and drew preliminary conclusions from the results of the tests described in this paragraph. Thus, the respondent had good reasons to re-examine the results in detail and to comment on the board's conclusions. The discussion certainly involved technical considerations. However, the appellant had to be ready to discuss the results described in its own patent at any stage of the proceedings, including in the course of the oral proceedings before the board.

2.8 Thus, in the context of the particular circumstances of the present case, it can be concluded that the respondent had cogent reasons for filing further submissions referring to D13 and to paragraph [0102] of the patent at a late stage of the appeal proceedings. Furthermore, the respondent had to be prepared to address them during the oral proceedings before the board. Thus, these submissions are admitted into the appeal proceedings.

2.9 As far as the late-filed submissions relating to D14 are concerned, the following is to be considered. D14 was filed by the appellant with the statement setting out the grounds of appeal. However, only the relevance of the results described in Table 2 on page 26 was discussed by the appellant. The results shown in Table 3 on page 27 were mentioned by the respondent for the first time during the oral proceedings before the board. The ensuing discussion involved complex considerations as to the experimental setting used and the interpretation of the results. Since neither the appellant nor the board could be expected to address these entirely new issues during the oral proceedings, the new submissions relating to D14 are not admitted.

3. *Objection under Rule 106 EPC*

3.1 The board decided to dismiss the objection raised by the appellant under Rule 106 EPC against the admittance of the respondent's latest submissions based on D13 and D14 for the following reasons, complementary to those mentioned above underlying the decision to admit the respondent's arguments based on D13.

3.2 The appellant was made aware of the relevance of two specific passages in D13 one month before the scheduled oral proceedings, namely by the respondent's letter dated 11 August 2020. D13 is an excerpt of a textbook reflecting - according to the appellant, which submitted the document with the statement setting out the grounds of appeal - common general knowledge in the field of prebiotics. The passages highlighted in the respondent's letter are contained in the two sections (4.4 and 4.6) initially cited by the appellant. Thus, the appellant could reasonably be expected to be prepared to discuss the content of those sections and

the relevance of the cited passages in detail. Furthermore, should it have needed more time to revise the studies cited in the relevant sections, as argued in the objection, it should have reacted promptly, i.e. immediately after receiving the respondent's letter, rather than waiting for the board to announce its conclusions concerning sufficiency of disclosure regarding the main request.

3.3 Even if it were to be considered that the appellant's complaint about the violation of its right to be heard referred to the board not having properly considered its objections and arguments in the discussion of the contested issue, the board notes that, as is also apparent from the minutes of these oral proceedings, the relevant discussion was exhaustive. The complaint rather appears to stem from the board not deciding in the appellant's favour. This ought to be, however, an acceptable outcome to any and all participants to a contentious procedure such as opposition-appeal proceedings before the EPO Boards of Appeal.

The board cannot recognise any violation of the appellant's right to be heard. The arguments of the appellant were duly considered but were not found convincing. Therefore, the objection is dismissed.

3.4 Concerning the relevance of D14, it is noted that, since the new submissions based on this document (Table 3 in particular) presented by the respondent have not been admitted, the objection is moot.

Main request

4. *Sufficiency of disclosure*

4.1 The claimed invention relates to the use of a composition comprising a non-digestible oligosaccharide for decreasing or preventing an allergic reaction in a mammalian subject. The composition is administered to a lactating post-partum female who is breastfeeding the mammalian subject.

4.2 As explained in the description of the patent in suit, the idea underlying the invention is to administer the composition to a mother who is breastfeeding her infant, in order to induce a beneficial programming effect on the immune response of the infant. This results in a beneficial decrease or prevention of allergic reactions in the infant (see paragraphs [0001], [0004], [0005] and [0006] of the patent and the corresponding parts of the patent application as filed).

4.3 Claim 1 is drafted in the format foreseen by Article 54(5) EPC. Accordingly, attaining the claimed therapeutic effect is a functional technical feature characterising the claim. Thus, the issue of whether the claimed therapeutic method can be carried out, and the purported effect achieved, is relevant in the context of the assessment of sufficiency of disclosure (G 1/03, see point 2.5.2). According to numerous decisions of the boards of appeal, unless this effect is already known to the skilled person at the relevant date, the patent application must disclose the suitability of the claimed product for the specified therapeutic application (see Case Law of the Boards of Appeal, 9th edition 2019, II.C.7.2).

4.4 Relying on this case law the respondent argued that the application does not make it plausible that the claimed agent is suitable to induce the alleged therapeutic effect.

4.5 Whether the suitability of a product for a new therapeutic application is plausibly disclosed has to be established by relying on the disclosure in the patent application, taking into account the common general knowledge available at the filing date, as well as any available relevant prior art (see T 184/16, point 2.3). In this context, account must be taken, for example, of the results of *in vivo* or appropriately designed *in vitro* tests described in the application (see T 241/95, point 4.1.2 and T 609/02, point 9), whether the claimed agent shares structural characteristics or properties with known ones (see T 184/16, points 2.5 to 2.8; T 694/16, points 4.8 to 4.9; T 1329/04, points 6 to 11), and whether known facts throw serious doubts that the claimed therapeutic treatment can be carried out (T 491/08, points 1 to 12, citing T 19/90; T 1150/09, points 15 to 22).

4.6 The objection of lack of sufficiency brought forward by the respondent is based essentially on the following arguments:

- that the results of the tests shown in the patent do not provide any evidence that the tested composition is suitable to induce the alleged therapeutic effect,

- that the results, obtained using a mixture of three specific oligosaccharides, do not make the

suitability of a composition comprising only a galacto-oligosaccharide plausible, and

- that verifiable facts throw serious doubts as to that suitability.

4.7 The respondent observed in the first place that there is an inconsistency between the description and the figures in the patent: the numbering of the tests in example 1 does not correspond to that of the results shown in the figures.

4.8 The board agrees with the respondent that, due to this inconsistency, a skilled person would not be able to attribute the data shown in the figures to those mentioned in example 1. However, the information given in paragraphs [0102] to [0107] of the patent (and in the corresponding parts of the patent application), which describe the tests and the results in qualitative terms, is in itself coherent and sufficiently clear for the skilled person to take into account the results at face value. The respondent's argument that the skilled person could consider the figures correct and the description erroneous is not convincing.

4.9 Example 1 describes different tests in which a composition comprising a mixture of galacto-oligosaccharides (GOS), fructo-oligosaccharides (FOS) and acidic oligosaccharides (in a ratio 9:1:2) was administered to female mice during pregnancy or during lactation. The effects of the treatment on the immune responses triggered by an antigen in the dams' offspring were then observed. The tests involved the treatment of dams sensitised with antigen, non-sensitised dams, a placebo group and a sham group.

4.10 The respondent observed that according to paragraph [0102] of the patent, an acute allergic skin response was significantly reduced in the offspring of sensitised dams treated with oligosaccharides during lactation, but not in the offspring of non-sensitised dams. In its opinion, since the claims were not limited to the offspring of sensitised dams, serious doubts existed as to whether the invention could be carried out across the scope of the claims.

4.11 The board does not agree, because the results of the entire set of tests shown in example 1 have to be taken into account. These show that:

- OVA-challenges caused a lower decrease in temperature (indicative of shock) in the offspring of dams treated according to the invention, compared to the control groups; this occurred in the offspring of both sensitised and non-sensitised dams (see paragraph [0103] and compare groups 7 and 9 (sensitised) and groups 4 and 6 (non-sensitised)).

- After challenge with OVA-allergen, the levels of OVA-specific IgE antibodies in the offspring of dams treated according to the invention were lower than in the control group; this again in the offspring of both sensitised and non-sensitised dams (see paragraph [0104] and compare groups 9 and 7 and groups 4 and 6).

- The OVA-specific IgG1 antibody levels also differed significantly between groups 4 and 6 and groups 7 and 9, indicating that the supplementation of oligosaccharides to the dams during lactation is

effective in the offspring, regardless of whether the dams are sensitised (see paragraph [0105]).

4.12 These results indicate that the offspring benefits from the treatment, irrespective of whether the dams were sensitised or not.

4.13 The respondent argued that, since claim 1 is directed to the treatment or prevention of allergic reactions, the negative result shown in paragraph [0102], which relates to an acute allergic reaction, outweighed the positive ones shown in following paragraphs.

4.14 This argument is not convincing either. In the test described in paragraph [0102], the ear thickness of mice was measured after challenge with OVA-challenge. An improvement in this parameter was considered to be an indication that the treatment is beneficial in subjects affected by an acute allergic skin response. However, it can be reasonably expected that subjects affected by this condition will benefit from the effects observed in the other tests, irrespectively of the dams being sensitised or not. A change in ear thickness is only one of the criteria for establishing whether the treatment of these subjects is effective.

4.15 Thus, the results shown in the patent and in the corresponding parts of the patent application provide convincing evidence that the tested composition is suitable for carrying out the treatment defined in claim 1.

4.16 What has to be established next is whether these results, obtained using a mixture of a galacto-, a fructo- and an acidic oligosaccharide, are apt to show the suitability of a composition comprising a galacto-

oligosaccharide only, and furthermore, if verifiable and substantiated doubts exist that the claimed effect can be achieved.

4.17 According to the patent and the patent application, the invention is based on the discovery that the maternal administration of non-digestible oligosaccharides has a beneficial programming effect on the immune response of the offspring. Prebiotic oligosaccharides, and in particular, galacto-, fructo- and acidic oligosaccharides are proposed to induce this effect (see the passage from page 6, line 34 to page 7, line 11 of the patent application). This means that the assumption is made that these oligosaccharides share the same pharmacological properties and can be used interchangeably, alone or in combination, to carry out the invention. Referring to D13 the appellant explained that the prebiotic properties of these compounds, and the anti-allergic properties of prebiotics, were part of the common general knowledge. Thus, it could be assumed that the effects induced by the tested mixture could be achieved by administering the individual oligosaccharides present in the mixture.

4.18 However, these assumptions are contradicted by the very document D13 that the appellant has referred to as representative of the skilled person's common general knowledge. D13 is a textbook on prebiotics published before the date of filing. Paragraphs 4.4.4 and 4.6, which focus specifically on the use of galacto-oligosaccharides as prebiotics in humans and, in particular in infants, state that:

"*GOS have repeatedly shown prebiotic properties in vitro. The bifidogenic effect is often greater than that seen with fructans. This is offset to some degree,*

however, by the rather mixed data obtained in human studies. There have been several, well-designed, human trials in which GOS has not shown a prebiotic effect" (emphasis by the board; see page 107, section 4.6 conclusions and page 104, paragraph 4.4.3 conveying the same teaching).

and that:

"*GOS have also been studied in the context of infant nutrition. Some studies, however, have used mixtures of GOS and FOS, making reliable conclusion about the efficacy of the GOS impossible*" (emphasis by the board; see page 105, section 4.4.4, paragraph 1).

4.19 These statements indicate, in the first place, that the skilled person's common general knowledge would have told them that GOS do not always exhibit prebiotic activity. Furthermore, the skilled person would have known that a study conducted using a mixture of GOS and FOS, and even less of GOS, FOS and acidic oligosaccharides, cannot be relied upon to establish whether a composition comprising GOS alone is suitable to achieve the purported therapeutic effect.

4.20 The appellant argued that no evidence had been provided that GOS were not suitable to carry out the invention. To the contrary, D14, Table 2 confirmed that GOS (together with FOS) were beneficial to the immune system. Furthermore, a detailed review of the studies cited in D13 would have confirmed that, at the filing date, the skilled person was well aware of the prebiotic effect of GOS, irrespectively of the presence of other oligosaccharides.

4.21 These arguments are not persuasive. The fact remains that D13 clearly states that a number of well-designed clinical trials, in which oligosaccharides were administered directly to human subjects, have failed to show the desired effects. The mixed results throw serious doubts as to whether the claimed therapeutic treatment can be carried out, all the more so when considering that the principle underlying the invention – to administer oligosaccharides to a lactating mother in order to achieve a pharmacological effect in a child – departs considerably and constitutes a radical development from the teachings in the common general knowledge reflected in D13, which teaches administering the oligosaccharides directly to the child.

4.22 The appellant contended that, since the GOS was the major component of the tested mixture, it was likely to be the agent responsible for the observed effects.

4.23 This argument is not convincing either. Substantial amounts (35%) of FOS and acidic oligosaccharides are also present in the tested mixture. Since it is well known that the biological activity of similar compounds can vary considerably, no assumptions can be drawn relying on the relative amounts of oligosaccharides present in that mixture. Furthermore, and even more relevant, page 20, lines 20 to 24 of the application as filed, corresponding to paragraph [0092] of the granted patent, states that:

"*The invention is based on the discovery that the administration of a composition comprising a non-digestible acidic-oligosaccharide as described herein to a female breast-feeding an infant has a long term*

impact on the development and enhancement of the immune system in the infant".

4.24 The other oligosaccharides mentioned in the application, GOS and FOS in particular, are not mentioned here. It is thus apparent that acidic oligosaccharides have a crucial role for carrying out the invention. This fact throws additional doubts as to whether the claimed composition, which does not contain an acidic oligosaccharide, is suitable to induce the claimed effect.

4.25 For these reasons, it is concluded that there are serious doubts based on verifiable facts which have not been overcome and that the invention claimed in the main request is not sufficiently disclosed (Article 83 EPC).

Auxiliary request 1

5. *Sufficiency of disclosure*

5.1 Claim 1 of auxiliary request 1 differs from that of the main request in that it relates to a composition comprising galacto- and fructo-oligosaccharides (GOS and FOS).

5.2 According to the appellant, the limitation of the claimed subject-matter to this combination overcame the objection of lack of sufficiency. D14 provided evidence that a composition comprising GOS and FOS was beneficial on the immune system, and D13 did not throw doubts but rather confirmed that the claimed combination had prebiotic properties.

5.3 These arguments are not persuasive. D13 underscores the fact that mixed results are obtained when testing the activity of oligosaccharides (GOS), and that the effects induced by a combination of oligosaccharides of the same class (GOS and FOS, i.e. neutral oligosaccharides) cannot be relied upon to draw any conclusion as to the activity of its individual components. In view of this teaching, the skilled person would be even more reluctant to draw any conclusion as to the activity of the claimed composition, since this does not comprise, like the tested one, an oligosaccharide belonging to a different class (an acidic oligosaccharide). This is all the more so because, as already mentioned above, the patent and the patent application teach that acidic oligosaccharides play a crucial role for carrying out the invention, and the principle underlying the invention departs considerably from the teaching of the prior art (see points 4.18 to 4.24). Thus, the results in D13, D14 and example 1 of the patent are not apt to show the suitability of a GOS/FOS combination in the claimed method, and serious doubts exist that the claimed therapeutic effect can be achieved.

5.4 Accordingly, the invention claimed in auxiliary request 1 is insufficiently disclosed (Article 83 EPC).

Auxiliary requests 2 to 6

6. *Sufficiency of disclosure*

6.1 Claim 1 of auxiliary request 2 differs from that of the main request in that the non-digestible oligosaccharide "comprises galacto-oligosaccharide and fructo-oligosaccharide, wherein the fructo-oligosaccharide has a degree of polymerisation between 7 and 100".

Claim 1 of each of auxiliary requests 3 to 6 differs from that of the main request, *inter alia*, in that the non-digestible oligosaccharide is "selected from the group consisting of galacto-oligosaccharide and fructo-oligosaccharide, wherein the fructo-oligosaccharide has a degree of polymerisation between 7 and 100".

6.2 Despite some differences in how the FOS are characterised (their degree of polymerisation) and in how the treatment, the lactating mother and the allergic reaction are defined, the invention claimed does not differ substantially from that claimed in the previous requests. In particular, the compositions defined in the claims of auxiliary requests 2 to 6 do not comprise an acidic oligosaccharide, and the disease to be treated is an allergic reaction.

6.3 The appellant has not provided any argument as to how the amendments of the claims of these requests could overcome the negative conclusions arrived at when examining the previous requests. Therefore, for the same arguments already discussed above, the invention claimed in auxiliary requests 2 to 6 is insufficiently disclosed (Article 83 EPC).

Auxiliary request 7

7. *Added subject-matter*

7.1 According to the respondent, the replacement of the wording used in claim 1 of the application as filed, "the composition is for administration", with the wording "the composition is administered", adds originally undisclosed subject-matter.

However, this amendment does not lead to any change in the technical teaching. Claim 1 of auxiliary request 7, as well as claim 1 as filed, are drafted as foreseen by Article 54(5) EPC. Despite the different wording, they relate to the same method of treatment, which involves the administration of the relevant composition for the specified use. Therefore, the amendment does not create new subject-matter (Article 123(2) EPC).

8. *Sufficiency of disclosure*

8.1 Claim 1 of auxiliary request 7 differs from that of the main request in that the non-digestible oligosaccharide "comprises galacto-oligosaccharide, fructo-oligosaccharide and acidic oligosaccharide".
Since acidic oligosaccharides are present in the composition, the negative conclusions arrived at when dealing with the previous requests no longer apply.

8.2 The respondent contended that, in view of the paucity of data recited in the patent, it was unreasonable to extrapolate the claims to cover a significantly broader composition as defined in claim 1. The tested composition comprised a very specific mixture containing short-chain-galacto-oligosaccharides (GOS), long-chain-fructo-oligosaccharides (FOS) and pectin-derived acidic oligosaccharides in a ratio 9:1:2. In its opinion, any suggestion gleaned from the limited data presented in the patent application was undermined by significant errors and far exceeded a reasonable interpretation that might have been drawn, had no errors been present. The respondent also drew attention to paragraph 4.5 of D13, "Further developments", which hypothesised that GOS mixtures might have different properties.

8.3 These arguments are not persuasive. In the first place, as already explained above when discussing the main request, despite the errors and inconsistencies between the figures and the description, the information shown in the patent and the patent application is in itself coherent and sufficiently clear for the skilled person to establish that the tested composition is effective for the claimed use.

8.4 In the second place, no facts have been presented throwing serious doubts that a mixture comprising at least one member of each of the three oligosaccharide classes indicated in claim 1 is not suitable to induce the claimed therapeutic effect. None of the documents on file, let alone the aforementioned paragraph 4.5 of D13, provides evidence, and no concrete technical reason has been presented by the respondent as to why a composition comprising at least one member of each of the three oligosaccharides classes specified in claim 1 should not be suitable for the claimed use.

8.5 For these reasons, it is concluded that the invention claimed in auxiliary request 7 is sufficiently disclosed (Article 83 EPC).

9. *Remittal*

Both parties have requested remittal of the case to the opposition division for discussion of novelty and inventive step if a request were found to comply with Articles 83 and 123(2) EPC. The board notes that those last-mentioned patentability requirements were not even broached in the opposition proceedings and would thus be discussed for the first time. As set out in Article 12(2) RPBA 2020, the primary object of the appeal proceedings is to review the decision under appeal in a

judicial manner. This principle would not be respected if the board were to conduct a complete examination of issues which were not dealt with by the opposition division. Thus, special reasons are present for remitting the case (Article 11 RPBA 2020 and decisions T 1966/16 and T 731/17). Accordingly, in exercise of its discretion under Article 111(1), second sentence EPC, the board decides to remit the case to the opposition division for further prosecution.

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 for further prosecution.

The Registrar: The Chairman:

D. Grundner A. Haderlein

Decision electronically authenticated