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**Datasheet for the decision
of 26 March 2025**

Case Number: T 0109/23 - 3.3.09

Application Number: 09793909.4

Publication Number: 2309876

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A61K35/747

Language of the proceedings: EN

Title of invention:
NUTRITIONAL COMPOSITION CONTAINING OLIGOSACCHARIDE MIXTURE

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponents:
Reckitt Benckiser Health Limited
N.V. NUTRICIA

Headword:
Oligosaccharide mixture/NESTLE'

Relevant legal provisions:
EPC Art. 123(2), 54(5), 56, 83
RPBA Art. 13(2)

Keyword:

Main request and auxiliary requests 1, 2 and 3: added subject-matter - (no); sufficiency of disclosure - (yes); inventive step - (no)

Auxiliary request 4: added subject-matter - (no); sufficiency of disclosure - (yes); inventive step - (yes)

Decisions cited:

Catchword:



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Case Number: T 0109/23 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 26 March 2025

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Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
22 December 2022 concerning maintenance of the
European Patent No. 2309876 in amended form.**

Composition of the Board:

Chairman	A. Haderlein
Members:	A. Veronese
	N. Obrovski

Summary of Facts and Submissions

I. The appeal was filed by opponent 2 against the opposition division's decision finding that the European patent as amended according to auxiliary request 2 filed by letter dated 1 June 2021 meets the requirements of the EPC.

II. In their notices of opposition, the opponents had requested revocation of the patent in its entirety on the grounds under Article 100(a) (lack of novelty and lack of inventive step), 100(b) and 100(c) EPC.

III. Claims 1 and 5 of auxiliary request 2 considered allowable by the opposition division read:

" 1. Use of an N-acetylated oligosaccharide, a galacto-oligosaccharide and a sialylated oligosaccharide in the manufacture of a nutritional composition for administration to an infant in the first six months of life to reduce the risk of obesity later in life."

" 5. A nutritional composition for use in administration to an infant in the first six months of life to reduce the risk of obesity later in life, to reduce lipogenesis in the infant and/or to promote beta oxidation of fatty acids by the infant which composition comprises, on a dry matter basis, from 2.5 to 15.0 wt% of an oligosaccharide mixture consisting of N-acetylated oligosaccharide(s), galacto-oligosaccharide(s) and sialylated oligosaccharide(s) with the proviso that the composition comprises at least 0.02 wt% of an N-acetylated oligosaccharide, at least 2.0 wt% of a galacto-oligosaccharide and at least 0.04 wt% of a sialylated oligosaccharide and that the

N-acetylated oligosaccharide(s) comprise 0.5 to 4.0% of the oligosaccharide mixture, the galacto-oligosaccharide(s) comprise 92.0 to 98.5% of the oligosaccharide mixture and the sialylated oligosaccharide(s) comprise 1.0 to 4.0% of the oligosaccharide mixture."

IV. The documents submitted during the opposition proceedings included:

- D2: WO 2007/101675 A1
- D3: WO 2007/090894 A1
- D4: WO 2007/73192 A2
- D9: WO 2005/070390 A2
- D10: Hussain N. et al. Clin Lipidol, 2011, Vol.6(3), pp. 293-303
- D11: Strauss R.S., Ped. Res, 2000, Vol. 48, p. 422
- D15: J.Z.Li et al., Diabetes, 2007, Vol. 56, pp. 2523-2532
- D16: Gillman M.W., Am. J. Clin. Nutr., 2008, Vol.87, pp. 1587-1589
- D18: Houten M. et al., J. Inherit. Metab. dis., 2010, Vol. 33, pp. 469-477
- D19: Urushima T et al., Glycoconjugate Journal, 2001, Vol. 18, pp. 357-371
- D25: Berndt J. et al, Diabetologia, 2007, Vol. 50, pp. 1472-1480
- D30: Kalliomaki M. et al; Am. J. Clin. Nutr. 2008, Vol. 87, pp. 534-8

V. In its decision, the opposition division found *inter alia* the following.

- Claims 1 and 5 as granted did not contain added subject-matter.

- The tests in the mice model described in the patent made it plausible that the claimed use reduced obesity later in life. Thus, the claimed invention was sufficiently disclosed.
- Claim 1 as granted encompassed non-therapeutic uses; as far as these uses were concerned, the claimed subject-matter was not novel over D2 and D3.
- Claim 2 of auxiliary request 1 encompassed a therapeutic treatment of the human body excluded by Article 53(c) EPC.
- The claims of auxiliary request 2 did not violate Article 53(c) EPC. The claimed subject-matter involved an inventive step over D4, the closest prior art, alone or in combination with D2.

VI. With its reply to the appellant's statement setting out the grounds of appeal, the respondent filed a main request and auxiliary requests 1 to 10. Furthermore, it filed the following document.

D31: Martin F.J. et al., Journal of Proteome
Research 2009, Vol.8, pp. 2090-2105

VII. The main request corresponds to auxiliary request 2 considered allowable by the opposition division. Claim 1 of auxiliary requests 1 to 3 is identical to claim 1 of the main request. Auxiliary request 4 differs from the main request in that claims 1 to 4 have been deleted.

VIII. The appellant's arguments of relevance to the decision may be summarised as follows.

- Claim 5 of the main request contained subject-matter extending beyond the content of the application as filed. The combination of features defining use of the claimed amounts of oligosaccharides to induce the specific effects indicated in the claim was not disclosed in the application as filed.
- The claimed invention was insufficiently disclosed. The tests described in the patent were not suitable for showing that the claimed composition induced the claimed effects.
- The claimed subject-matter did not involve an inventive step over D4, the closest prior art. D4 disclosed use of the claimed oligosaccharides to prevent obesity later in life. There was no evidence that the claimed oligosaccharide mixture induced any effect extending beyond the teaching of D4. The problem was the provision of an alternative composition for reducing obesity. The skilled person would have arrived at the claimed solution relying on D4, alone or combined with D2 or D3 and, possibly, D30. This applied to all requests on file. The respondent's argument presented during the oral proceedings that, taking account of D3, the problem was the provision of an improved composition should not be admitted in the appeal proceedings.

IX. The **respondent's** arguments of relevance to the decision may be summarised as follows.

- Claim 5 was based on claim 7 and on passages of pages 4 and 5 of the application as filed.
- The claimed invention was sufficiently disclosed. The patent and the other cited documents provided enough information to carry out the invention and made it credible that the claimed composition induced the claimed effects. The appellant's objections were only based on unsupported allegations and speculation.
- As far as claim 1 was concerned, the appellant's inventive step arguments should not be admitted, in particular insofar as reference was made to D30. The claimed subject-matter involved an inventive step over D4, the closest prior art, alone or in combination with D2 or D3. In view of the results shown in D3, the problem was the provision of an improved composition. Alternatively, it was the provision of an alternative composition. The prior art did not provide incentives to combine the claimed oligonucleotides to solve these problems. Taking into account D2, D3 and the composition of human milk, the skilled person would also not have selected amounts of the relevant oligonucleotides within the ranges given in claim 5 of the main request. These arguments applied to all requests.

The requests

- X. The appellant requested that the decision under appeal be set aside and that the patent be revoked.
- XI. The respondent requested that the appeal be dismissed (main request) or, alternatively, that the patent be maintained on the basis of auxiliary requests 1 to 10,

filed with the reply to the statement setting out the grounds of appeal.

Reasons for the Decision

Main request (auxiliary request 2 of the decision under appeal)

1. *Amendments*

1.1 According to the opponent, claim 5 contained subject-matter not disclosed in the application as filed. This argument is not convincing.

1.2 Claim 5 of the main request substantially corresponds to claim 5 as granted, which was considered by the opposition division not to contain any added subject-matter. It only differs in the deletion of the reference to the preceding claims. The appellant contested the opposition division's finding that claim 5 did not contain originally undisclosed subject-matter, arguing that the application as filed did not disclose the combination of the following features:

- the composition comprising the relevant oligosaccharides, in the claimed amounts
- administration to an infant in the first six months of life
- reduction of obesity later in life, reduction of lipogenesis in the infant and/or promotion of beta oxidation of fatty acids in the infant

1.3 The appellant argued that the application as filed related to two separate embodiments: a first, disclosed in claim 1 and page 4, lines 23 to 26 as filed, related to use of the claimed oligosaccharides in an infant for reducing obesity later in life; a second, disclosed in

claim 7 and in the passage from page 4 line 28 to page 5, line 7 as filed, related to a composition comprising specific amounts of those oligosaccharides for reducing lipogenesis and promoting beta-oxidation of fatty acids. The combination of the features characterising these two separate embodiments in claim 5 created originally undisclosed subject-matter.

1.4 These arguments are not convincing. On reading the application, the skilled person would understand that the invention relates to the administration of a composition comprising a combination of N-acetylated, galacto- and sialylated oligosaccharides in the first six months of an infant's life to induce specific biological effects, namely to reduce the risk of obesity later in life, to reduce lipogenesis and to promote beta-oxidation of fatty acids: see e.g. page 4, lines 25-26, page 5, lines 6-7 and claim 1 of the application as filed. The skilled person would also understand that these effects are inter-related, and that the claimed combination of oligosaccharides, including that comprising the amounts specified in claim 5 and in the passage bridging pages 4 and 5, is meant to induce all the aforementioned effects. This is readily apparent on reading the entire set of claims as filed, and in particular claims 1 to 3 and 5 as filed, and the entire passage spanning page 4, line 15, to page 5 line 7 as filed, as a whole.

1.5 Thus, the appellant's argument that the application discloses two separate embodiments characterised by features whose combination creates originally undisclosed subject-matter is not convincing.

1.6 Therefore, claim 5 does not contain subject-matter extending beyond the application as filed.

2. *Sufficiency of disclosure*

2.1 The appellant contested the opposition division's finding that the claimed invention is sufficiently disclosed, arguing essentially as follows.

- Claim 1 was drafted as a Swiss-type claim and claim 5 as an Article 54(5) EPC claim, which related, at least in some embodiments, - e.g. the treatment of obesity - to a therapeutic use. Achieving the therapeutic effect was a feature characterising those claims. The tests in the patent did not render it credible that the claimed therapeutic effects, and in particular preventing obesity later in life, was achieved.
- Example 2 allegedly showed effects on lipogenesis and fat oxidation in mice. However, the mice were eight weeks old, and thus already adult at the start of the intervention. Hence, the mouse model was unsuited to making the claimed effect credible, let alone an effect later in life.
- The tested experimental diet could not be compared with the control diet, which contained less fibre and provided more calories due to the presence of glucose.
- The lower delta CT values for MTTP and FAS observed in the PCR tests shown in figure 2 indicated that expression of these genes was higher in the mice fed with the experimental diet than in those fed with the control diet. This was contrary to the conclusions drawn by the inventors in the patent. There was no evidence that figure 2 contained an

error. This was confirmed by the fact that the same figure was shown (as figure 6) in D31, a peer-reviewed article published by some of the inventors named in the opposed patent. Neither the authors nor the reviewers had spotted any error in the figure. Hence, figure 2 did not make it credible that the claimed composition achieved the purported therapeutic effects.

- There was no evidence of a correlation between changes in the expression of MTTP and FAS and the development of obesity, in particular later in life. This correlation could not be inferred from the prior art, let alone from D4, D9 to D11 and D18 and D19.
- The results relating to triglyceride concentration in the liver shown in figure 1 and in table 1 of the patent did not render the prevention of obesity plausible either, because they were obtained using diets comprising different amounts of calories, carbohydrate and fibre.

2.2 For these reasons, according to the appellant, the patent did not describe "experimental data plausibly linking the claimed effects to the composition as such". Under these circumstances, the appellant did not carry the burden to demonstrate that the invention could not be put into practice. Thus, the claimed invention was insufficiently disclosed.

2.3 The board does not find these arguments convincing. It concurs with the respondent that the patent provides convincing evidence that, compared to a reference composition, the claimed oligosaccharide composition:

- reduces triglyceride concentration in the liver, as shown in figure 1, and that
- this decrease is associated with reduced lipogenic activity and incorporation of triglycerides into lipoproteins in the liver, as evidenced by the reduced expression of the MTP and FAS genes shown in figure 2 and, furthermore, that
- the results in table 1 provide evidence that the composition causes a shift in lipid metabolism and an enhancement of fatty acid oxidation

2.4 The appellant argued that the experimental composition and the control could not be compared, due to the different carbohydrate and calorie content. However, as explained by the respondent, lactose and glucose were added to the control diet to compensate for the amount of lactose and glucose brought into the experimental diet by the addition of the non-digestible oligosaccharides. This is confirmed in D31, a peer-reviewed article published by some of the inventors named in the opposed patent, which describes the same experiments shown in the patent and the experimental setting used for the experiments.

2.5 The appellant argued that the negative delta CT values in figure 2 of the patent were reflective of higher expression of the MTP and FAS genes. This indicated that the claimed oligosaccharide composition increased, rather than decreased, expression of the MTP and FAS genes. Hence, figure 2 provided evidence that the claimed effects could not be achieved.

2.6 In this context, the parties discussed whether figure 2 of the patent contained an error. According to the

appellant, even assuming the presence of an error, this was not immediately recognisable. Hence, on the basis of the CT values in figure 2, the skilled person would have assumed that the expression of MTTP and FAS was increased by the claimed composition. The appellant noted that figure 2 was shown in peer-reviewed article D31 (as figure 6) and that its authors and the reviewers had not spotted any error either.

- 2.7 These arguments are not convincing. On reading the patent, it is clear that its inventors were of the firm opinion that the results of the experiments described in the patent indicated that the tested oligosaccharide composition decreased expression of the MTTP and FAS genes: see paragraphs [0042] to [0045]. It must be assumed that the inventors were skilled in the art, and that they correctly interpreted the results of their own experiments. Thus, the outcome of the experiments was indeed - as they state - that expression of the MTTP and FAS genes was reduced. The board puts more weight on the inventors' explicit conclusions than on how the results of the experiments were plotted in figure 2.
- 2.8 There are different possible explanations for why figure 2 allegedly contradicts the inventors' conclusions. There could be an error in how the CT scale is presented in figure 2, or in how the tests are described in paragraph [0042]. It also seems possible that the alleged contradiction stems from an incorrect interpretation by the appellant of the reported negative CT values in figure 2.
- 2.9 Thus, despite the apparently contradictory teaching of figure 2, the board considers it credible that the inventors correctly concluded that expression of the

MTTP and FAS genes was decreased. For completeness, the board notes that this is also confirmed by aforementioned peer-reviewed article D31, which describes essentially the same invention as disclosed in the opposed patent. D31 provides a more detailed explanation of the experimental design and of the interpretation of the results. As clearly stated in the right-hand column of page 2102 of D31, the authors concluded on the basis of the results of the tests in figure 6 (figure 2 of the opposed patent) that the administration of oligosaccharides induced a reduction in the expression of the FAS and MTTP genes. As in the case of the opposed patent, the board assumes that the authors of D31, and the scientists who reviewed the article, who were skilled in the art, correctly interpreted, and drew the correct conclusions from, the observed results. This is also in line with the teaching of the prior art as set out below.

2.10 The appellant criticised the animal model used in the patent, on the ground that the mice were already adults at the time when the testing was started. This argument is not convincing either. As explained in paragraph [0040] of the patent, the mice used for the tests were special germ-free mice, fed with an irradiated rodent diet and inoculated with human baby microbiota. This means that, although at eight weeks, when they were inoculated, these mice were adults, their microbiota was neither that found in adult mice nor in adult humans, and was closer to that present in the gut of human infants. D31 confirms that the mouse model used in the patent is a suitable model of human baby microbiota, see page 2091, left hand column and right hand column "Materials and methods". It is also noted that any mouse model of a human subject involves some assumptions and approximations, which have to be

accepted, unless there are serious doubts that the model is unsuitable for representing that subject. In the present case, the appellant was merely presenting unsubstantiated allegations of such doubts.

2.11 Fatty acid synthase (FAS) and microsomal triglyceride transfer protein (MTTP) are enzymes involved in the synthesis of fatty acids and lipoproteins. Thus, it is credible that their inhibition is accompanied by a reduction in lipogenesis. It is also credible that this effect, in combination with the observed reduction in triglyceride concentration and enhancement of fatty acid metabolism in the liver, is beneficial for reducing the risk of obesity. This concept is corroborated by the teaching of D15 and D25, and in particular by the passages mentioned by the respondent: D15, Results and Conclusions on page 2523, table 1 on page 2525, figure 2b on page 2526 and D25, section Conclusions/Interpretation on page 1472, table 1 on page 1474 and page 1479, left hand column.

2.12 Furthermore, it is credible that, if these effects are induced during infancy, the risk of obesity will be decreased later in life. As argued by the respondent, before the relevant date there was considerable evidence that excessive weight gain during infancy correlated with an increased risk of obesity later in life, see points 1 to 4 on pages 1588 and 1589 of D16 mentioned in paragraph [0008] of the opposed patent. It is noted that D16 is an editorial article published before the priority date of the opposed patent which summarises the outcome of several earlier clinical studies and therefore reflects the common general knowledge at the relevant date. For completeness, reference is also made to D4 relied upon by the appellant to argue lack of inventive step. D4 teaches

that non-digestible oligosaccharides contribute to a reduced chance of obesity later in life (page 14, lines 16 to 26).

- 2.13 For these reasons, the board considers that the patent makes it credible that the claimed composition induces the claimed effects, and in particular that it reduces the risk of obesity later in life. Thus it is concluded that at the relevant date the skilled person would have been able to carry out the claimed invention. Accordingly, the claimed invention is sufficiently disclosed.

3. *Inventive step*

Admittance of inventive step objection against claim 1

- 3.1 The respondent alleged that the appellant did not address the arguments relating to inventive step set out in point 11.7.4 of the decision under appeal. For this reason, in its opinion, the inventive step arguments against claim 1 of the main request presented in the statement setting out the grounds of appeal should not be admitted.
- 3.2 The board disagrees. As already set out in the board's communication under Article 15(1) RPBA, the arguments provided on pages 11 to 13 of the statement of grounds of appeal are sufficiently detailed to address the reasons presented in the decision under appeal. In particular, the first three paragraphs of page 12 explain why D4 teaches that each of the claimed oligonucleotides can be used to reduce the risk of obesity later in life. Furthermore, the passage bridging pages 12 and 13 addresses the argument in point 11.7.4 of the decision under appeal that,

starting from D4, there is no need to replace FOSs with sialylated and N-acetylated oligonucleotides to arrive at the claimed invention. This means that the statement setting out the grounds of appeal addresses the decision under appeal and provides sufficient reasons as to why the decision should be set aside. Hence, there are no reasons not to admit the appellant's arguments relating to the objection against claim 1.

Closest prior art

- 3.3 Claim 1 relates to use of the claimed composition to manufacture a nutritional composition for reducing the risk of obesity later in life.
- 3.4 Claim 5 relates to use of a more narrowly defined composition for reducing the risk of obesity later in life, for reducing lipogenesis and for promoting beta oxidation of fatty acids in an infant.
- 3.5 The parties differed as to whether claim 5 is drafted under Article 54(5) EPC and is limited to therapeutic uses of the claimed composition. It was, however, uncontested that the subject-matter of claim 5 is novel over the cited prior art documents because none of them discloses the claimed composition. Irrespective of how it is constructed, claim 5 relates to a composition which is intended to induce specific effects on lipid metabolism in an infant, namely preventing the risk of obesity later in life, reducing lipogenesis and promoting beta oxidation of fatty acids in an infant.
- 3.6 This is confirmed by the description of the patent, which teaches that the nub of the invention is the provision of a nutritional composition for infants inducing the aforementioned effects on lipid metabolism

in an infant, see paragraphs [0009] to [0011], example 2 and the results. Hence, irrespective of how the claim is constructed, these effects on lipid metabolism are relevant to determining the closest prior art.

3.7 The appellant argued that, insofar as claim 5 encompassed non-therapeutic uses, it was not a purpose-limited product claim under Article 54(5) EPC limited to those uses. To this extent, those uses could be disregarded when selecting the closest prior art.

3.8 This argument is not convincing. According to established case law, a central consideration in selecting the closest prior art is that it must be directed to the same purpose or effect as the invention, otherwise it cannot lead the skilled person in an obvious way to the claimed invention (Case Law of the Boards of Appeal, 10th edition, 2022, I.D.3.2). This applies irrespective of whether the relevant purpose or effect is indicated in the claims, and it clearly applies in the present case, where the relevant effects are explicitly mentioned in the claims.

3.9 The opposition division decided that D4 is the closest prior art and the parties did not contest this finding. Like the opposed patent, D4 relates to the provision of a nutritional composition for infants comprising non-digested oligosaccharides which reduces the accumulation of fat and the risk of obesity later in life, see page 1, lines 14 to 16, page 2, lines 9 to 13, page 14, lines 16 to 25 and examples 3 and 4. In particular, example 4 discloses an infant nutritional composition comprising galacto-oligosaccharides and fructo-oligosaccharides and having a label indicating that the composition is for preventing the development of obesity. The board therefore agrees with the

opposition division and the parties that D4 is the closest prior art.

3.10 The appellant argued that D2 or D3 are suitable alternative starting points for assessing inventive step. This argument is not persuasive. D2 and D3 do disclose compositions comprising non-digestible oligosaccharides. However, the compositions are intended for very different purposes, namely to prevent infections of the gastro-intestinal tract and immune-related conditions (D2, page 5, lines 17-18 and 29-30) and to induce protective and immuno-modulating effects by promoting the growth of probiotic bacteria (D3, page 3, lines 28 to 30 and page 4, lines 8 to 8). Nothing in D2 and D3 hinted at the treatment or prevention of metabolic dysfunctions, let alone obesity. Thus, for the reasons already outlined above, D2 and D3 are not suitable starting points for assessing inventive step.

Distinguishing features, technical effect and underlying technical problem

3.11 The opposition division decided that:

- the subject-matter of claim 1 differs from the teaching of D4 in that the composition contains N-acetylated and sialylated oligosaccharides, and that of claim 5 differs, in addition, in the amounts of the oligosaccharides used, and that
- there is no evidence that these differences are associated with a new technical effect, and that
- the underlying problem is the provision of an alternative infant nutritional composition for reducing the risk of obesity later in life (in the

case of claim 5, this problem applies at least to the extent that this claim relates to such use)

- 3.12 The board agrees with the opposition division's findings.
- 3.13 During the oral proceedings before the board, the respondent referred for the first time to D3 and set out a different inventive step approach. It argued that the tests in examples 3 and 4 of D3 showed that, compared to galacto-oligosaccharides alone, a combination of the three claimed oligosaccharides induced a stronger effect on the microbiota. In its opinion, this made it credible that, compared to the compositions of the prior art, the claimed composition induced an improvement in the treatment of obesity later in life. Consequently, the problem was the provision of an improved, rather than an alternative oligosaccharide composition.
- 3.14 The board concurs with the appellant that the new inventive step approach based on the teaching of D3 results in a substantial amendment of the respondent's appeal case. Furthermore, the board considers that this amendment should not be admitted into the appeal proceedings. It is worth noting that, in its reply to the statement setting out the grounds of appeal, the respondent stated that the opposition division had correctly mentioned that "in the absence of evidence that the claimed nutritional composition is improved over the GOS/FOS-containing infant formula disclosed in example 4 of D4, the objective technical problem must be formulated as "the provision of an alternative infant nutritional composition to reduce the risk of obesity later in life".

3.15 The reference to D3 and the substantial change in the formulation of the underlying technical problem represent an unjustified change to the respondent's appeal case. No exceptional circumstances were provided and none could be seen by the board for this change. Thus, this amendment was not admitted into the appeal proceedings (Article 13(2) RPBA).

Obviousness of the solution according to claim 1

3.16 The relevant question which needs to be answered is whether, starting from D4 and confronted with the underlying problem, the skilled person would have considered using the composition comprising N-acetylated, galacto- and sialylated oligosaccharides defined in claims 1 and 5 to reduce the risk of obesity later in life.

3.17 The board is of the opinion that this question is to be answered in the affirmative.

3.18 The respondent argued that D4 focused on compositions comprising relatively low amounts of linoleic acid (LA) and a low ratio between linoleic acid (LA) and alpha-linoleic acid (ALA), which was further supplemented by long-chain polyunsaturated fatty acids (LC-PUFAs). In its opinion, as far as non-digestible oligosaccharides were concerned, D4 only speculated on their uses in combination with those fatty acids. Hence, there was no incentive to provide the claimed composition.

3.19 These arguments are not convincing.

3.20 As submitted by the appellant, D4 teaches that non-digestible oligosaccharides (NDOs) reduce the risk of obesity later in life. This teaching is unambiguous and

self-contained and supported by experimental evidence and a technical explanation. In the passage spanning page 14, line 16 to page 15, line 3, D4 explains that NDOs can be fermented, that they have an insulin tempering effect and that, consequently, they contribute to reducing the chance of obesity later in life. D4 further explains that high insulin levels contribute to increased proliferation of adipocytes, and thereby to an increased chance of obesity later in life. Among the NDOs considered suitable for reducing the risk of obesity later in life, D4 mentions galacto-oligosaccharides (page 15, line 12), sialylated oligosaccharides (page 15, line 16) and N-acetylated oligosaccharides (page 15, lines 25-26, referring to LNT, neo-LNT, fucosylated LNT, and fucosylated neo-LNT, all acetylated oligosaccharides).

- 3.21 Table 5 of example 3 confirms that the administration of galacto-oligosaccharides (i.e. NDOs) significantly decreases plasma blood insulin levels compared to control groups not comprising them.
- 3.22 The respondent noted that the glucose level was not decreased in this test. However, this is irrelevant because, as explained above, it is the decrease in insulin levels, rather than glucose, that reduces adipocyte proliferation and the risk of obesity later in life.
- 3.23 The respondent submitted that the results in example 3 related to a single data point, that there was no comparison to a standard infant formula and that it was "speculative" to extrapolate results observed in rats to humans. These arguments are not convincing either. There is no reason to believe that the results shown in the test are wrong: as already mentioned above, the

significant decrease in the insulin AUC induced by GOS renders the concept underlying the invention disclosed in D4 credible. Furthermore, the opposed patent is itself based on results obtained in a mouse model.

- 3.24 The respondent noted that examples 1 and 2 of D4 related to compositions which did not comprise non-digestible oligosaccharides. However, the infant nutritional compositions of examples 3 and 4 include NDOs and example 4 states explicitly that the composition has a label indicating that it is intended for preventing the development of obesity.
- 3.25 The respondent submitted that the teaching of D4 was limited to the use of non-digestible oligosaccharides in combination with the lipid composition disclosed in this document. In this context, it referred to page 15, lines 6 to 8, stating that the combination of the relevant lipids and non-digestible oligosaccharides synergistically reduced obesity later in life.
- 3.26 This argument is not persuasive either. In the first place, the passages of D4 already mentioned above provide unambiguous self-contained teaching that non-digestible oligosaccharides are beneficial for preventing obesity later in life. The statement that they "synergistically" reduce obesity later in life confirms this understanding and, on the basis of this wording and the teaching of D4, the skilled person would understand that both the lipid composition and the NDOs are effective and that their action is synergistically improved when they are combined.
- 3.27 Furthermore, as noted by the appellant, claim 1 is not limited to use of the claimed NDOs and does not exclude the presence of other components in the nutritional

composition. Thus, it encompasses compositions comprising the lipids of the compositions of D4. For this same reason, contrary to what was mentioned in the decision under appeal (point 11.7.4), starting from example 4 of D4 there would be no need, in order to arrive at the invention, to replace FOSs with acetylated and sialylated oligosaccharides because claim 1 does not exclude the additional presence of FOSs.

3.28 For these reasons the board considers that, when confronted with the underlying problem, the skilled person would have considered, by following the teaching of D4, preparing a nutritional composition for infants comprising the three claimed NDOs. According to page 15 of D4, all three, namely galacto-oligosaccharides (page 15, line 12), sialylated oligosaccharides (page 15, line 16) and N-acetylated oligosaccharides (page 15, lines 25-26, see LNT, neo-LNT, fucosylated LNT, and fucosylated neo-LNT, all acetylated oligosaccharides), are suitable for reducing obesity later in life.

3.29 Hence, simply by implementing the teaching of D4, the skilled person would have prepared and used the nutritional composition defined in claim 1.

Non-obviousness of the solution according to claim 5

3.30 Claim 5 differs from claim 1, in particular, in that it specifies that the relevant oligosaccharides must be included in specific amounts in the composition.

3.31 The appellant drew attention to the first claims of D2 and D3, which disclose a nutritional composition comprising 5-70 wt% of N-acetylated oligosaccharides, 20-95 wt% galacto-oligosaccharides and 2-50 wt%

sialylated oligosaccharides. It argued that D2 and D3 would have provided the skilled person confronted with the underlying problem with the incentive to provide a composition comprising the claimed amounts of the claimed oligosaccharides.

3.32 This argument is not convincing. As already mentioned above, D2 and D3 do not relate to the underlying technical problem of providing an alternative infant nutritional composition for reducing the risk of obesity later in life. Moreover, even if they had taken into consideration the teaching of these documents, the skilled person would not have arrived at the claimed composition, because the amount of N-acetylated oligosaccharides in the oligosaccharides mixture (0.5 to 4%) is lower than that according to the broadest range disclosed in D2 and D3 (5 to 70%). Furthermore, as shown by the respondent's calculations, in D2 and D3 there is a clear preference for higher amounts of both N-acetylated and sialylated oligosaccharides.

3.33 In addition to that, as submitted by the respondent, when confronted with the underlying problem, the skilled person would have prepared compositions containing the relevant oligosaccharides in the amounts which are found in human milk. As explained by the respondent, and confirmed in D13 and D14, human milk contains a large amount of sialylated-oligosaccharides, which exceeds that defined in claim 5. Thus, the skilled person would not have considered preparing a composition comprising the small amounts of sialylated-oligosaccharides specified in claim 5.

3.34 For these reasons, it is concluded that the subject-matter of claim 5 involves an inventive step.

3.35 During the oral proceedings before the board, the appellant formulated a new inventive step objection combining the teaching of D4 with that of D30, D2 and D3. However, it did not indicate any exceptional circumstances for formulating this new inventive step attack referring for the first time to D30 at this very late stage of the appeal proceedings, and the board could not see any either. For this reason, this objection was not admitted into the appeal proceedings (Article 13(2) RPBA).

3.36 In conclusion, the subject-matter of independent claim 1 does not involve an inventive step, whereas that of independent claim 5 does.

Auxiliary requests 1, 2 and 3

3.37 Claim 1 of auxiliary requests 1, 2 and 3 is identical to claim 1 of the main request. Thus, the subject-matter of claim 1 of these requests does not involve an inventive step either.

Auxiliary request 4

3.38 Auxiliary request 4 differs from the main request in that claims 1 to 4 have been deleted.

3.39 Claim 1 of auxiliary request 4 corresponds to claim 5 of the main request which, as mentioned above, involves an inventive step. Since claims 2 to 11 are dependent on claim 1 and are more limited in scope, they also involve an inventive step.

3.40 For these reasons, there are no grounds which prejudice maintenance of the patent on the basis of the claims of auxiliary request 4.

Adaptation of the description

- 3.41 The respondent adapted the description to the claims of auxiliary request 4. The appellant did not object, and the board does not see any reason to raise objections to the adapted description of its own motion either.

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 as amended in the following version:
 - claims 1-11 of auxiliary request 4 filed with the reply to the statement of grounds of appeal
 - description paragraphs [0001]-[0008] and [0011]-[0045] of the patent specification and paragraphs [0009] and [0010] as filed during the oral proceedings before the board
 - drawings of the patent specification

The Registrar:

The Chairman:



K. Götz-Wein

A. Haderlein

Decision electronically authenticated