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Datasheet for the decision of 14 October 2025

Case Number: T 1665/23 - 3.3.09

Application Number: 16747524.3

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Language of the proceedings: EN

Title of invention:
NUTRITIONAL COMPOSITIONS AND INFANT FORMULAS COMPRISING BIFIDOBACTERIUM ANIMALIS SSP. LACTIS AND OPTIONALLY A MIX OF OLIGOSACCHARIDES FOR INDUCING A GUT MICROBIOTA CLOSE TO THE ONE OF BREAST FED INFANTS

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponent:
Chr. Hansen A/S

Headword:
Infant formula/NESTLÉ

Relevant legal provisions:
EPC Art. 54(2), 54(5), 56

Keyword:
Auxiliary requests 1, 2, 7 and 8 : inventive step - (No)
Main request and auxiliary requests 3 to 6 novelty - (No)

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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

Case Number: T 1665/23 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 14 October 2025

Appellant: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Strych, Sebastian Mitscherlich PartmbB Patent- und Rechtsanwälte Karlstraße 7 80333 München (DE)
Respondent: (Opponent)	Chr. Hansen A/S Bøge Allé 10-12 2970 Hørsholm (DK)
Representative:	Uexküll & Stolberg Partnerschaft von Patent- und Rechtsanwälten mbB Beselerstraße 4 22607 Hamburg (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 19 July 2023 revoking European patent No. 3331383 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	N. Obrovski
Members:	A. Veronese
	F. Rinaldi

Summary of Facts and Submissions

I. The appeal was filed by the patent proprietor (appellant) against the opposition division's decision revoking the European patent.

II. In its notice of opposition, the opponent 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. Claim 1 of the granted patent reads as follows:

"*1. A nutritional composition for infants or young children comprising a Bifidobacterium animalis spp. lactis probiotic for use in promoting or inducing a gut microbiota that is closer to the microbiota of infants fed exclusively with human breast milk, in comparison to the microbiota of infants fed predominantly with a conventional nutritional composition not comprising said probiotic, in infants or young children between 0 and 36 months, optionally between 0 and 12 months of age,*
characterized in that *said "promoting or inducing a gut microbiota that is closer to the microbiota of infants fed exclusively with human breast milk" is further* ***characterized by*** *promoting or inducing a gut microflora that has a phylogenetic distance to the microbiota of breast fed infants of less than 0.3 units (measured by Unifrac method), preferably less than 0.25 units,* ***characterized in that*** *said probiotic Bifidobacterium animalis spp. lactis is CNCM I-3446.*"

IV. The documents submitted during the opposition proceedings included:

D1: WO 2009/144137 A1

D2: EP 1 974 743 A1

D6: J. Junick, "Einfluss von Synbiotika auf die intestinale Mikrobiota gesunder Neugeborener", PhD Dissertation at the University of Potsdam, September 2013

D9: T. Yatsunenko et al., Nature, 2012, vol. 426, pp. 222-228

D10: F. Turroni et al., 2012, PLOS one, vol. 7, pp. 1-12

D11: US 2012/0171166 A1

D14: P.G. Steenhout et al., Ann. Nutr. Metab., 2009, vol. 55, pp. 334-340

V. In its decision, the opposition division in particular came to the following findings.

- The claims as granted did not contain added subject-matter and were to be construed under Article 54(5) EPC.

- The subject-matter of the granted claims was novel over the teaching of D1, D2, D6, D11 and D14, which did not disclose the claimed phylogenetic distance of less than 0.3 units.

- The subject-matter of claim 1 as granted did not involve an inventive step over the teaching of D6, the closest prior art. Claim 1 differed from the teaching of D6 only in the phylogenetic distance between the microbiota of the treated infants and that of breast-fed infants. Since this feature would inevitably have been obtained when the study

of D6 was carried out, it could not confer an inventive step.

- The subject-matter of auxiliary request 1, which was limited to the treatment of infants delivered by Caesarean section, did not involve an inventive step over the teaching of D6 combined with that of D2. Both documents disclosed the treatment of infants delivered by Caesarean section. Hence, the claimed treatment was obvious. The same conclusions applied to auxiliary requests 4 to 8.

- Auxiliary requests 3, 9 and 10 were not admitted into the opposition proceedings.

VI. With its statement setting out the grounds of appeal, the appellant filed auxiliary requests 1 to 8.

- Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the "infants are born with a fragile or unbalanced microbiota or dysbiosis of microbiota, such as preterm infants, infants born small for gestational age, infants born by Caesarean-section, hospitalized infants or infants treated or having been treated by antibiotics".

- Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that "promoting and/or inducing a gut microbiota that is closer to infants fed exclusively with human breast milk is further characterized by promoting and/or inducing a healthy growth, a healthy immune system and/or a healthy gut function, especially later in life".

- Claim 1 of auxiliary request 3 differs from claim 1 of the main request in that the infants or young children are "between 0 and 6 months of age".

- Claim 1 of auxiliary request 4 differs from claim 1 of the main request in that the composition "is an infant formula or a follow-on formula".

- Claim 1 of auxiliary request 5 differs from claim 1 of the main request in that the probiotic is present in the composition "in an amount of between 10^6 and 10^8 cfu/g of composition".

- Claim 1 of auxiliary request 6 differs from claim 1 of the main request in that the composition "comprises between 1.6 g and 3 g protein/100 kcal".

- Claim 1 of auxiliary request 7 differs from claim 1 of the main request in that the "infants are infants born by Caesarean-section".

- Claim 1 of auxiliary request 8 differs from claim 1 of the main request in that the infants "are born by Caesarean-section" and in that the composition comprises specific types of oligosaccharides.

VII. The appellant's arguments of relevance to the decision can be summarised as follows.

- Auxiliary requests 1 to 8 had to be admitted.

- The claimed subject-matter related to a therapeutic method of treatment of infants and was to be construed according to Article 54(5) EPC.

- The subject-matter of the granted claims was novel over the cited prior art documents. These did not disclose the formation of a microbiota having the claimed phylogenetic distance from the microbiota of breast-fed infants.

- The subject-matter claimed in auxiliary request 1, which was limited to infants having a fragile microbiota, e.g. born by Caesarean section, was novel and involved an inventive step over D6. D6 disclosed neither an effective treatment of infants born by Caesarean section, nor a more pronounced effect in these infants.

- The tests in the patent showed that infants born by Caesarean section benefited the most from the treatment. The problem was the identification of a patient group in which the treatment was particularly effective. The skilled person would not have expected the claimed treatment to be particularly effective in these infants. Hence, the claimed solution was not obvious. The same conclusions applied to all the auxiliary requests.

VIII. The respondent's arguments of relevance to the decision can be summarised as follows.

- Auxiliary requests 2 to 8 should not be admitted.

- The claimed use was not therapeutic. Thus, claim 1 could not be subsumed under Article 54(5) EPC.

- The definition of the claimed phylogenetic distance was unclear and unsuitable for distinguishing the claimed subject-matter from the prior art. The claims used a different parameter to define a known

treatment. Thus, the subject-matter of the granted claims was not novel over the teaching of D6.

- The subject-matter of claim 1 of auxiliary request 1 was not novel over D6 either. D6 disclosed use of the claimed composition to treat infants born by Caesarean section. These were included in the clinical study described in D6. The skilled person would have inevitably noted that the treatment of these infants was effective.

- If considered novel, the subject-matter claimed in auxiliary request 1 would not have involved an inventive step over the teaching of D6, the closest prior art, alone or combined with the teaching of D5, D7-D9 and D10.

- Confronted with the problem of identifying a patient group in which the treatment was particularly effective, the skilled person would have tested the claimed composition in infants born by Caesarean section. These were identified in D6 as not having a healthy microbiota and being in need of treatment. Thus, D6 provided a clear incentive to conduct further tests on these infants.

- By testing, the skilled person would have arrived at the claimed solution without exercising inventive skill. It was also obvious to characterise the microbiota by the Unifrac method described in D5, D7-D9, D10.

- The same arguments applied to all the auxiliary requests.

The requests

IX. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the board acknowledge that the claimed subject-matter of the patent as granted (main request) or of one of auxiliary requests 1 to 8 meets the patentability requirements decided upon at first instance, and that the case be remitted to the opposition division for the assessment of sufficiency of disclosure.

X. The respondent requested that the appeal be dismissed.

Reasons for the Decision

Main request

1. *Novelty*

1.1 The opposition division found that claim 1 was directed to a composition for use in a therapeutic method of treatment of the human body and should be construed under Article 54(5) EPC.

1.2 The respondent contested this finding. In its opinion, claim 1 did not identify which disease had to be treated or prevented. The expression "promoting or inducing a gut microbiota that is closer to the microbiota of infants fed exclusively with human breast milk" could, but did not necessarily, relate to the treatment or prevention of a disease. Furthermore, the respondent argued that the phylogenetic distance of microbiota measured by the UNIFRAC method specified in claim 1 was unsuitable for distinguishing the claimed subject-matter from the prior art.

1.3 For the sake of argument, and in the appellant's favour, it is assumed that claim 1 relates to a therapeutic use, that it is drafted as a purpose-limited product claim under Article 54(5) EPC, and that the claimed phylogenetic distance is suitable for delimiting the claimed subject-matter from the prior art.

1.4 D6 is a thesis published on the server of the University of Potsdam. The appellant did not contest that its content was made available to the public before the priority date of the opposed patent.

1.5 The thesis describes a randomised-controlled clinical trial in which healthy full-term infants received an infant formula comprising a synbiotic combination consisting of *Bifidobacterium animalis ssp. lactis* CNCM I-3446 (hereinafter CNCM I-3446) and bovine milk oligosaccharides during the first three months of life.

1.6 The intestinal microbiota developed in the group of infants who received this infant formula was compared to the microbiota developed in:

- a group of infants who received a control formula which did not comprise the synbiotic combination comprising CNCM I-3446 and

- a group of breast-fed infants

1.7 In order to compare the distance between the microbiota developed in these infant groups, twelve bifidobacteria species were quantified in the infants' faeces by quantitative real-time PCR assays. The single-copy groEL gene was used as phylogenetic marker for the PCR

assays. Furthermore, the pH of the faeces was compared: see the English abstract and pages 11 and 72 of D6.

1.8 The results of the study indicate that the synbiotic formula comprising CNCM I-3446 stimulated the growth of bifidobacteria and lactobacilli. They furthermore indicate that the intestinal microbiota and the faecal pH of the infants who were treated with the synbiotic formula were closer to those of the breast-fed infants than to the control: see pages 7 and 8 of the English abstract of D6.

1.9 The amount of CNCM I-3446 included in the nutritional composition used for the clinical study described in D6 ($1x10^9$ cfu/100g composition, i.e. 10^7 cfu/g) falls within that specified in claims 13 and 14 of the opposed patent and corresponds to that used to carry out the clinical studies described in the patent. There is no difference as to the oligosaccharides used and the inclusion criteria for the infants were also essentially the same.

1.10 The phylogenetic distance of the microbiota of the groups of infants involved in the clinical study described in D6 was not determined by the "Unifrac" testing method referred to in claim 1 of the opposed patent. As mentioned above, the distance between the microbiota of the tested groups was assessed by quantifying twelve *Bifidobacteria* species by real-time PCR assays based on the groEL phylogenetic marker.

1.11 However, since the clinical study described in D6 was carried out by feeding infants with a nutritional composition which:

- falls within the scope of claim 1 and

- is the same as was used in the clinical studies described in the opposed patent, and the criteria used to recruit the infants were the same,

the phylogenetic distance between the microbiota of the treated infants and that of breast-fed infants must necessarily correspond to that defined in claim 1 by means of the Unifrac method.

1.12 In this context, it is noted that the claimed Unifrac method was not used to determine the phylogenetic distance in the clinical study conducted on infants delivered by Caesarean section described in example 4 of the opposed patent either. Only the total Bifidobacteria count in the faeces was used. During the oral proceedings before the board, the appellant stated that this total Bifidobacteria count was sufficient to make it credible that the claimed Unifrac phylogenetic distance had been achieved.

1.13 This statement, which was not contested, implies that the results obtained in the study of D6 by quantifying twelve different types of Bifidobacteria provide even more robust evidence compared to that in example 4 of the patent that the phylogenetic distance of the microbiota in the treated infants falls within that defined in claim 1 by the Unifrac method.

1.14 In these circumstances, it would have been incumbent on the appellant to provide evidence that the microbiota of the infants treated according to the study protocol described in D6 did not have the claimed phylogenetic distance from that of breast-fed infants.

1.15 Accordingly, although the patent uses a different method to characterise the microbiota of the treated infant population, the microbiota which was formed by the treatment of D6 was necessarily the same.

1.16 In this context, it is noted that the patent teaches that the claimed phylogenetic distance characterises a healthy intestinal microbiota, similar to that induced by breast feeding and moreover that this prevents health events such as diarrhoea, which may manifest if the microbiota is altered. This is the same anti-pathogenic effect as is mentioned in D6. The premises of the study in D6 and in the patent are the same, namely that breast milk induces the growth of a healthy intestinal microbiota, which then has health-promoting effects and reduces the incidence of gastric infections and atopic diseases. On the basis of these premises, the claimed composition was, like that of D6, tailored to induce the growth of a microbiota similar to that induced by breast feeding and to prevent health events occurring in subjects fed by infant formulas: see the English abstract, section 1.1.1 (pages 1 and 2), section 1.3 (pages 7 to 9), section 1.4 (pages 11 and 19).

1.17 For these reasons, the subject-matter of claim 1 as granted is not novel over the teaching of D6.

Auxiliary request 1

2. *Novelty*

2.1 Claim 1 of auxiliary request 1 was limited by specifying that the nutritional composition is administered to infants "born with a fragile or unbalanced microbiota or dysbiosis of microbiota, such

as preterm infants, infants born small for gestational age, infants born by Caesarean section, hospitalized infants or infants treated or having been treated by antibiotics" (emphasis added).

2.2 According to the respondent, the subject-matter of claim 1 was not novel over D6 because infants delivered by Caesarean section were involved in the clinical study disclosed in this document.

2.3 The board does not share this view.

2.4 It is true that infants delivered by Caesarean section were included among the infants involved in the clinical study described in D6. These infants were identified during the randomisation process preceding the trial when the infant groups involved in the study were characterised: see page 12, last paragraph and table 3.3 on page 51.

2.5 However, in that clinical study, the infants were not stratified on the basis of the delivery method, i.e. Caesarean vs vaginal delivery. The outcome of the study derives from a statistical analysis considering - as a whole - an infant population including all infants, irrespective of whether they were delivered by Caesarean section or vaginal delivery.

2.6 This makes it impossible to determine the effects induced by the treatment in the specific infant group delivered by Caesarean section.

2.7 The respondent argued that, when reviewing the full results of the study in D6, the skilled person "could not have avoided noticing the effects" in the infants delivered by Caesarean section.

2.8 This argument is not persuasive because it is based on speculation or likelihood, rather then on directly and unambiguously disclosed teaching in D6.

2.9 For these reasons, it is concluded that D6 does not disclose the formation of a microbiota as defined in claim 1 in infants delivered by Caesarean section.

2.10 Consequently, the subject-matter of claim 1 of auxiliary request 1 is novel over the teaching of D6.

3. *Inventive step*

Closest prior art

3.1 The opposition division found, and the parties agreed, that D6 is the closest prior art for assessing inventive step.

Distinguishing feature

3.2 The claimed subject-matter differs from the teaching of D6 in that the claimed composition is used to treat an infant population born with a fragile or unbalanced microbiota or dysbiosis of microbiota, in particular infants born by Caesarean section.

Technical effect

3.3 The results of the clinical study described in example 4 and in figure 6 of the opposed patent show that the administration of a composition comprising CNCM I-3446 as defined in claim 1 to infants delivered by Caesarean section increases Bifidobacteria counts. This effect is more pronounced in the infants delivered

by Caesarean section, who have a lower Bifidobacteria count at birth, than in those delivered vaginally. The increase in the bifidobacteria count observed when administering the tested formula, rather than the control, is in fact higher in infants born by Caesarean section compared to that in vaginally born infants (see figure 6). According to the appellant, this meant that the treatment was particularly effective in infants born by Caesarean section.

Underlying technical problem

3.4 Taking account of the observed results, starting from D6 as closest prior art, the underlying problem can be seen, as suggested by the appellant during the oral proceedings, as the identification of a patient group in which the administration of the claimed nutritional composition is particularly effective.

Obviousness of the claimed solution

3.5 As already mentioned above, infants delivered by Caesarean section were among the infants recruited to conduct the clinical study described in D6.

3.6 The question which needs to be answered is whether, when confronted with the underlying problem, the skilled person would have considered conducting further studies stratifying the infants according to their birth method, in order to determine the efficacy of the claimed nutritional composition in infants born by Caesarean section.

3.7 The introductory sections of D6 provide a comprehensive and detailed account of what was known shortly before the date of filing of the application for the opposed

patent regarding the development of human intestinal microbiota in infants, drawing upon a large number of earlier clinical studies: see sections 1.1 to 1.4.

3.8 These sections teach that the development of the gut microbiota of an infant is affected by the type of infant nutrition (e.g. breast milk or infant formula), the type of delivery, namely Caesarean or vaginal, and the composition of the maternal microbiota. They moreover teach that the colonisation of the infant's gut plays a relevant role in the infant's health and the composition of the microbiota in the adult. D6 explains that human milk stimulates the growth of beneficial Bifidobacteria, rather than pathogenic bacteria, such as Clostridia, and that the incidence of gastric infections and atopic diseases in breast-fed infants is lower than in formula-fed infants.

3.9 Moreover, D6 teaches that the microbiota of infants born by Caesarean delivery grows more slowly, and that it contains a lower Bifidobacteria and a higher Clostridium count compared to those delivered vaginally: section 1.1.1, page 1 and the passage bridging pages 2 and 3.

3.10 The passage bridging pages 78 and 79 of D6 refers to an earlier clinical study confirming that Caesarean delivery and feeding with nutritional formula are associated with the development of an unhealthy microflora characterised by a higher count and a prevalence of *Clostridium difficile* strains, which is associated with higher risks of atopic diseases.

3.11 This means that D6 identifies infants born by Caesarean section as infants in particular need of a treatment promoting the growth of a gut microflora containing a

high bifidobacteria count which is closer to the microbiota found in breast-fed infants. These are the infants having a microbiota with the lowest bifidobacteria count and thus, for the person skilled in the art, those who can profit the most from the administration of an infant formula comprising such bacteria.

3.12 For this reason, starting from D6 and confronted with the underlying problem, the skilled person would have conducted further studies aimed at determining the efficacy of compositions comprising the claimed Bifidobacterium CNCM I-3446 in infants delivered by Caesarean section.

3.13 The appellant argued that the skilled person would not have expected infants delivered by Caesarean section to benefit from the treatment more than those delivered vaginally.

3.14 However, this argument does not support inventive step because, in view of the teaching of the prior art, there is a clear incentive in D6 to test the relevant composition in infants delivered by Caesarean section. By simply following the teaching of D6, the skilled person would have been prompted to test the claimed nutritional composition in infants delivered by Caesarean section and would have uncovered its particularly beneficial effects in this patient group, namely the induction of a microflora closer to that observed in breast-fed infants as defined in claim 1.

3.15 Claim 1 and D6 use different methods to characterise the phylogenetic differences of infant microbiota. However, analogously to what has already been concluded when discussing novelty, the microbiota which would

have been formed when conducting the studies suggested by D6 would be the same as that defined in claim 1 by reference to the Unifrac method.

3.16 For these reasons, by following the teaching of D6, the skilled person would have arrived at the claimed solution without needing to exercise inventive skill. Consequently, the subject-matter of claim 1 of auxiliary request 1 does not involve an inventive step.

Auxiliary request 2

4. *Inventive step*

4.1 Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the use is intended for "promoting and/or inducing a healthy growth, a healthy immune system and/or a healthy gut function, especially later in life".

4.2 The appellant stated that this claim 1 made it clearer that claim 1 was directed to a medical use. However, it did not provide any argument as to why the additional features overcame the novelty and inventive step objections raised against the previous requests.

4.3 D6 does not describe the effects mentioned in claim 1 as being observed in the infants involved in the described clinical study. However, these effects are exactly those which the skilled person would have expected to observe in view of the pre-existing knowledge in the field: see the abstract and sections 1.1.1, 1.3 and 1.4 of D6, which teach the relevance of a "healthy microbiota" induced by breast feeding to healthy gut function, and to a healthy immune system,

and paragraph [0007] of the opposed patent describing pre-existing technical knowledge in the field.

4.4 Thus, starting from D6 and confronted with the problem of providing an alternative treatment, the skilled person would have considered using the composition of claim 1 in the expectation of achieving these beneficial effects. Hence, the subject-matter of claim 1 of auxiliary request 2 does not involve an inventive step.

Auxiliary request 3

5. *Novelty*

5.1 Claim 1 of auxiliary request 3 differs from claim 1 as granted in that the infants are between 0 to 6 months of age, instead of from 0 to 36 months.

5.2 The appellant argued that this amendment was made to further distinguish the treated infants from those described in D9, but not from those of D6, which was the document used to attack the novelty of claim 1 of the main request. Thus, this amendment does not change the above conclusion on the main request. Consequently, the finding of lack of novelty arrived at when dealing with claim 1 of the main request applies equally to claim 1 of auxiliary request 3.

Auxiliary request 4

6. *Novelty*

6.1 Claim 1 of auxiliary request 4 differs from claim 1 as granted in that the formula is an infant formula.

6.2 Since the formula used in the study of D6 was also an infant formula, the finding of lack of novelty arrived at when dealing with the main request also applies to claim 1 of auxiliary request 4.

Auxiliary request 5

7. *Novelty*

7.1 Claim 1 of auxiliary request 5 differs from claim 1 of the main request in that the amount of CNCM I-3446 present in the nutritional composition is specified.

7.2 However, the amount of CNCM I-3446 contained in the infant formula used for the clinical study described in D6 ($1x10^9$ cfu/100g composition, i.e. 10^7 cfu/g) falls squarely within that specified in claim 1: see section 2.1.3, page 14, first paragraph of D6.

7.3 Thus, the finding of lack of novelty over D1 arrived at when dealing with the main request also applies to claim 1 of auxiliary request 4.

Auxiliary request 6

8. *Novelty*

8.1 Claim 1 of auxiliary request 6 differs from claim 1 as granted in that the amount of protein present in the claimed composition is specified.

8.2 However, the amount of protein present in the infant formula used for the clinical study described in D6 (9.2 g/493 kcal, i.e. 1.84 g/100 kcal) falls squarely within that specified in claim 1: see section 2.1.3, page 13, last paragraph.

8.3 Thus, the finding of lack of novelty over D1 arrived at when dealing with the main request applies equally to claim 1 of auxiliary request 6.

Auxiliary request 7

9. *Inventive step*

9.1 Claim 1 of auxiliary request 7 differs from claim 1 of auxiliary request 1 in that the use is intended specifically for infants delivered by Caesarean section.

9.2 However, this limitation focuses on the embodiment of auxiliary request 1 which has already been found to lack inventive step over D6. Accordingly, the same finding of lack of an inventive step also applies to auxiliary request 7.

Auxiliary request 8

10. *Inventive step*

10.1 Claim 1 of auxiliary request 8 differs from claim 1 of auxiliary request 1 in that the use is intended only for infants delivered by Caesarean section and in that the composition comprises specific amounts of certain oligosaccharides.

10.2 The appellant did not provide any argument as to why these additional features could overcome the novelty and inventive step objections raised against the previous requests.

10.3 As far as the limitation to infants delivered by Caesarean section is concerned, the same findings arrived at when dealing with auxiliary requests 1 and 7 apply.

10.4 Concerning the limitation to infant formula comprising the claimed oligosaccharides, it is noted that the infant formula used in the study of D6 comprised bovine milk oligosaccharides. It is furthermore noted that the use of all the oligosaccharide types mentioned in claim 1 in infant formula for promoting *inter alia* the growth of beneficial microbiota in infants is already disclosed in the prior art: see e.g. D11, paragraphs [0008], [0062] and the claims. The patent does not provide evidence of any effect associated with the use of these specific oligonucleotides, let alone in the claimed amounts. For these reasons, combined with the reasons already set out when dealing with auxiliary request 1, the subject-matter claimed in auxiliary request 8 does not involve an inventive step.

11. *Conclusions*

11.1 In view of the aforementioned findings, it is concluded that none of the requests on file meets the requirements of the EPC.

11.2 The respondent requested that auxiliary requests 2 to 8 not be admitted. In view of the conclusions on the substantive issues, there is no need to address admittance.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

K. Götz-Wein N. Obrovski

Decision electronically authenticated