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Case Number: T 0321/15 - 3.3.09

Application Number: 07857342.5

Publication Number: 2096941

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Language of the proceedings: EN

Title of invention:
NUTRITIONAL COMPOSITION FOR INFANTS

Patent Proprietor:
Nestec S.A.

Opponents:
HIPP & Co.
N.V. Nutricia

Headword:

Relevant legal provisions:
EPC Art. 100(a), 100(b)

Keyword:
Sufficiency of disclosure (yes)
Novelty (yes)
Inventive step (yes)

Decisions cited:
G 0005/83, T 0609/02, T 0433/05, T 0734/12

Catchword:

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Case Number: T 0321/15 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 27 March 2018

Appellant: (Opponent 2)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
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Party as of right: (Opponent 1)	HIPP & Co. Brünigstrasse 141 6072 Sachseln (CH)
Representative:	Schiweck, Weinzierl & Koch Patentanwälte Partnerschaft mbB Landsberger Straße 98 80339 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 28 November 2014 rejecting the oppositions filed against European patent No. 2096941 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chair	D. Prietzel-Funk
Members:	N. Perakis
	F. Rinaldi

Summary of Facts and Submissions

I. The present appeal lies from the decision of the opposition division rejecting the oppositions filed against European patent No. 2 096 941.

Independent claims 1, 12 and 13 as granted read as follows:

"1. A nutritional composition for infants at risk of developing obesity later in life, for use in the prevention of obesity later in life, comprising a protein source which includes at least 20% by weight casein, a lipid source and a carbohydrate source and having a protein content of less than 1.8g/100 kcal and an energy density of less than 650 kcal/litre."

"12. Use of a protein source which includes at least 20% by weight casein, a lipid source and a carbohydrate source for the preparation of a nutritional composition having a protein content of less than 1.8g/100 kcal and an energy density of less than 650 kcal/litre for administration to an infant at risk of developing obesity later in life in the first year of life of the infant so as to reduce that risk."

"13. Use of a protein source, a lipid source and a carbohydrate source for the preparation of a nutritional composition having a protein content of less than 1.8g/100 kcal and an energy density of less than 650 kcal/litre for administration to an infant at risk of developing obesity later in life in the first year of life of the infant so as to promote a rate of growth in that infant which approximates to the rate of growth of a breast fed infant of the same age."

II. In their notices of opposition the opponents requested that the patent be revoked in its entirety on the basis of Article 100(a) (lack of novelty and lack of inventive step) and (b) EPC.

The documents cited in opposition included the following:

D1: WO 2004/112508 A1;

D2: H. Demmelmair *et al*, "Long-term consequences of early nutrition, *Early Human development*, 2006, 82, pp 567-574;

D3: S.J. Fomon *et al*, "What is the safe protein-energy ratio for infant formulas?", *Am J Clin Nutr*, 1995, 62, pp 358-363;

D12: WO 2004/068968 A1;

D13: R. von Kries *et al.*, "Breast feeding and obesity: cross sectional study", *BMJ*, 1999, 319, pp 147-150;

D15: J.L. Inostroza *et al*, "Lower weight gain until 24 months of age in infants of overweight mothers who receive a low protein whey based infant formula (IF) with probiotics", abstract and poster presented at the 4th World Congress of Pediatric Gastroenterology, Hepatology and Nutrition (WCPGHAN), 2012;

D16: J.L. Inostroza *et al*, "Lower weight gain in infants of obese mothers who receive a low protein formula", presented at the 2012 Pediatric Academic Societies Annual Meeting, 28 April to 1 May 2012;

D18: J.H. Stupin *et al.*, "Overweight and Obesity before, during and after Pregnancy, *Geburtsh Frauenheilk*, 2014, 74, pp 639-645;

D19: E. Zambrano *et al.* "Mechanisms by which maternal obesity programs offspring for obesity: evidence from animal studies", *Nutrient Reviews*, 2013, 71 (Suppl. 1), pp 542-554.

III. The opposition division rejected the oppositions. With respect to sufficiency of disclosure, it held that the inventions of the three second medical use claims (claims 1, 12 and 13) were sufficiently disclosed because the therapeutic effects were plausibly achieved in view of the prior-art documents, e.g. D1 and D2, which not only disclosed the risk for infants to develop obesity later in life but also the obesity causality which was attributed to the role of high protein intake. No proof had been provided that the reduction of energy intake would not contribute to the preventive effects. Post-published D15 and D16 confirmed the claimed therapeutic effect. With respect to novelty, the opposition division held that neither D1 nor D12 disclosed all the features of the independent claims. As regards inventive step, it held that the problem to be solved was the provision of a nutritional composition that addressed the nutritional needs of infants at risk of developing obesity later in life. The closest prior-art document was D1, which disclosed infant formulas having a protein content of less than 1.85 g/100 kcal, but did not discuss the energy level at all - the only example provided had an energy density of 670 kcal/litre. The skilled person starting from D1 with the intention to solve the set technical problem would not have found in D1 or any

other prior-art document the motivation to reduce the protein content and the energy density of the nutritional formula of D1. It thus concluded that the subject-matter of the claims also involved an inventive step.

IV. The decision was appealed by opponent 2 (in the following: the appellant) which requested that the opposition division's decision be set aside and that the patent be revoked in its entirety. The appellant reiterated the grounds of insufficiency of disclosure, lack of novelty and lack of inventive step.

V. Opponent 1, who is also a party to these proceedings, did not make any submissions. With a letter dated 28 February 2018 it announced that it would not attend the oral proceedings scheduled to take place before the board.

VI. The patent proprietor (in the following: the respondent) filed observations on the appeal with letter of 10 July 2015 accompanied by six auxiliary requests. It requested that the appeal be dismissed, or, alternatively that the patent be maintained on the basis of any of the auxiliary requests.

VII. On 15 September 2017 the board issued a communication in preparation for the oral proceedings.

VIII. With letter of 6 December 2017 the respondent filed additional arguments.

IX. With letter of 27 February 2018, the appellant raised objections with regard to the auxiliary requests.

X. Oral proceedings were held before the board on 27 March 2018 as scheduled.

XI. The relevant arguments put forward by the appellant in its written submissions and during the oral proceedings may be summarised as follows:

- Interpretation of the claims

The patient group in the subject-matter of claims 1, 12 and 13 is "infants at risk of developing obesity later in life". The definition of the patient group is clear. Moreover, D13 (table 2) discloses a number of risk factors that contribute to later obesity in infants and are not limited to infants born to obese mothers. Therefore, the skilled reader would not look in the description for a different definition of the patient group. The fact that a special explanation is given in the patent to the meaning of infants at risk of developing obesity later in life has no bearing on the claims.

Claim 13 may be in the format of a Swiss-type second medical use claim but it does not concern a therapeutic application in the sense of G5/83 since the use to promote growth does not concern a prophylactic therapy or cure for an aliment or disease. It is to be interpreted as relating to a method of manufacturing a nutritional composition comprising protein lipid and carbohydrate which has less than 1.8 g protein per 100 kcal and an energy density of less than 650 kcal/litre.

- Sufficiency of disclosure

On the basis of the case law of the boards of appeal of the EPO in relation to a second medical use, the therapeutic effect, which is a functional feature, must be linked to the specific composition. In the absence of any technical evidence in the patent in suit, the burden of proof lies with the proprietor/respondent, which has to show that the therapeutic effects can really be obtained. The post-published documents D15 and D16 should not be taken into account in order to remedy the lack of sufficiency of disclosure, which has to be evaluated at the priority/filing date of the patent. D15 and D16 could only be taken into account as confirmation of the therapeutic effects if these effects were plausible, which is not the case.

With respect to the invention underlying claim 13, the therapeutic effect appears to be linked to the presence of satiety-inducing protein casein in a substantial amount, as disclosed in the patent (page 3, lines 13-14). This is absent from claim 13. Furthermore, essential features are missing from this claim in view of paragraph [0015] which discloses that supply of sufficient quantities of nutrients is essential.

- Novelty

The subject-matter of claim 13, which is not a proper Swiss-type claim and which should be interpreted literally, i.e. without considering either the intended-use feature or the alleged limitation to the patient group, lacks novelty in view of D12. This document, which discloses infant formulae with an energy density of 250-500 g/kcal

and a protein content of 1 g/100 kcal, after conversion of the values given in D12 (page 2, lines 18-20, and page 13, lines 8-9) anticipates the nutritional composition of claim 13. Thus this claim lacks novelty.

- Inventive step

D1 is the closest prior-art document. D1 relates to infant formulae that ensure growth and metabolic patterns similar to those of breastfed infants and result in similar health characteristics later in life (page 2, lines 2-5), which intrinsically relate to reduced chance of developing obesity. The subject-matter of independent claims 1, 12 and 13 differs from the disclosure of D1 only with regard to the energy density of the nutritional composition. A protein content of less than 1.8 g/100 kcal is disclosed in D1 (page 3, line 35 to page 4, line 22). Such a content is safe as it derives from D3 (page 363, left column, lines 13-16) and D12. As the claims do not concern a different patient group and as a therapeutical effect has not been shown, no distinction over D1 can be based on these two features. Thus the technical problem in view of D1 is the provision of an alternative nutritional composition for infants which has an effect on growth and/or obesity. The patent does not contain any evidence that the problem is plausibly solved or that it is solved over the entire breadth of the claimed subject-matter. D15 and D16 should not be taken into consideration because they are post-published and because they do not provide the required proof. But even if it were assumed that the technical problem had been solved, the reduction of the energy

content from the value disclosed in D1 (page 10, line 24, and page 13, the table) to that claimed would be obvious to the skilled person in view of D12, which disclosed such an energy content appropriate for nutritional infant formulae (page 2, lines 18-20). Thus the skilled person would obviously apply lower caloric densities than in D1.

XII. The relevant arguments put forward by the respondent in its written submissions and during the oral proceedings may be summarised as follows:

- Interpretation of claims

The skilled reader with a mind willing to understand and having knowledge of the entire patent would understand that the patient group in the claims of the patent in suit is not infants in general at risk of developing obesity later in life but infants born to obese mothers as defined on page 3, line 24, of the patent in suit, these infants having a specific pathological condition as explained in the patent (paragraph [0003]) and confirmed in the post-published documents D18 and D19. D13 is irrelevant since it concerns breastfed infants.

Claim 13 is a second medical use claim. There is a specific patient group under a pathological/ clinical state and a therapeutic effect specific for that patient group. The link between the claimed growth pattern (therapeutic effect) and the risk of developing obesity later in life is found in paragraphs [0012] and [0015] of the patent in

suit and is known from the state of the art (D2: page 568, left column, lines 17-21).

- Sufficiency of disclosure

The inventions underlying claims 1, 12 and 13 are sufficiently disclosed. The patent may not contain any example, it discloses, however, in paragraphs [0012] and [0015] the direct link of the claimed nutritional composition to the claimed therapeutic effects. Also D2 discloses the required link. Thus, the required cause/effect relationship has been shown to be plausible. The appellant, which under these circumstances bears the burden of proof, has not submitted any evidence which would raise serious doubts, substantiated by facts, that the therapeutic effects could not be achieved.

Furthermore, D15 and D16, which show that the therapeutic effects have indeed been achieved, should be taken into consideration as evidence of the sufficiency of disclosure.

Moreover, the therapeutic effects are obtained over the entire scope of the claim. The appellant's argument that the patent requires the presence of the satiety-inducing protein casein is wrong because paragraph [0015] of the patent discloses that the use of casein is only preferable.

With regard to the further essential nutrients of the nutritional composition mentioned in paragraph [0015], they are not disclosed to have any impact on the claimed therapeutic effects. They are typically added to nutritional compositions.

- Novelty

  The subject-matter of claim 13 is novel over the disclosure of D12 on the basis of the different patient group, the different medical indication and the different protein content.

- Inventive step

  The subject-matter of claims 1, 12 and 13 differs from D1, considered by the appellant to be the closest prior art, as regards the protein content, the energy density, the patient group and the respective medical indication. The technical effects are the programmed prevention of obesity later in life (claim 1), a reduction of the risk of developing obesity later in life (claim 12) and a promotion of the rate of growth that approximates to the rate of growth of a breastfed infant of the same age (claim 13), for the target patient group. The technical problem in view of D1 is the provision of a nutritional composition addressing the needs of infants at risk of developing obesity later in life, which reduces this risk, prevents obesity later in life and promotes a rate of growth that approximates to that of a breastfed infant of the same age. The solution of this technical problem is shown in D15 and D16. The problem is plausibly solved over the entire scope of the claim and nothing has been submitted to demonstrate the contrary. The skilled person starting from D1 would not find any motivation in D1 or any other document to reduce the protein content and the energy density disclosed in D1 in order to arrive at the claimed subject-matter. D3 and D12 do not concern infants at risk of developing obesity later in life

and the skilled person starting from D1 and aiming to solve the set technical problem would not consider them and would not reduce the amount of protein and the energy density to arrive at the claimed subject-matter, unless based on hindsight.

XIII. The appellant requested that the decision under appeal be set aside and that the patent be revoked in its entirety. It further requested that auxiliary requests I to VI not be admitted into the proceedings.

XIV. The respondent requested that the appeal be dismissed, alternatively that the patent be maintained in amended form on the basis of any of auxiliary requests I to VI filed with letter of 10 July 2015 with the reply to the grounds of appeal.

Reasons for the Decision

1. The appellant contested the patentability of the granted claims (main request) on the grounds of insufficient disclosure, lack of novelty and lack of inventive step. In order to deal with these issues it is essential to define the subject-matter of the claims since the parties do not agree on its interpretation.

2. There are two issues raised by the appellant with respect to the interpretation of the claims. The first concerns the target patient group "*infants at risk of developing obesity later in life*" and the second the nature of independent claim 13, namely whether it is a second medical use claim in the sense of G 5/83. The board notes that the appellant did not contest that

independent claims 1 and 12 are second medical use claims.

2.1 With respect to the first issue the appellant argues that the claims are clear as regards the patient group, which includes any infant at risk of developing obesity later in life, since it it common knowledge in the field of infant nutrition that any infant that is not breastfed or does not receive breast milk has an increased risk of developing obesity later in life. According to the appellant the fact that in the patent in suit a special explanation is given to the meaning of the patient group has no bearing on the understanding by the public of subject-matter for which protection is sought. The public has no reason to look into the description to understand the scope of the claim.

The board does not agree. In the present case it might be that the claims at first sight appear to clearly mean "any infant" and not a particular (patient) group of them. However when considering the inventions as defined in independent claims 1, 12 and 13 on the basis of the clear and unambiguous instructions in the description, it becomes obvious that the patient group has a specific meaning which is not made explicit in the wording of the claimed subject-matter. Since clarity is not a ground for opposition under Article 100 EPC, the only alternative left to the board is to interpret the patient group on the basis of the description. The respondent has already indicated that the specific meaning of the patient group is provided in paragraph [0016] which discloses:

"In this specification, the following expressions have the meaning assigned to them below:

'infant' means a child under the age of 12 months;

'infant at risk of developing obesity later in life' means an infant born to an obese mother ...

'obese mother' means a woman with a BMI greater than 30 prior to establishment of pregnancy" [BMI stands for body mass index].

Thus the patient group is specific and concerns infants born to obese mothers, which is distinct from infants in general. That this patient group has a different pathophysiological status as compared to infants born to non-obese mothers is disclosed in the patent in suit (page 2, paragraph [0003]):

"Overweight and obesity are classically defined based on the percentage of body fat or, more recently, the body mass index or BMI ... It is known that overweight and obese women who become pregnant have greater risk of developing gestational diabetes. Maternal hyperglycaemia may lead to infants with increased body size and fat mass and such infants are themselves prone to develop obesity and diabetes later in childhood or in adult life. Moreover, recent research has suggested that obese women who themselves have normal glucose tolerance give birth to infants with a higher fat mass than those born to women who are not obese".

This is also disclosed in the post-published documents D18 and D19:

"Overweight and obesity before conception as well as excessive weight gain during pregnancy are associated with endocrinological changes of mother and fetus ...

Human and animal studies have shown that maternal obesity 'programmes' the offspring for further obesity and chronic disease" (D18: abstract)

"Maternal obesity can profoundly affect offspring phenotype and predisposition to obesity and metabolic disease" (D19: abstract).

In view of the above, the expression "infants at risk of developing obesity later in life" in independent claims 1, 12 and 13 is directly related to infants born to obese mothers. Consequently this is the interpretation to be applied for the assessment of the patentability of the granted claims.

2.2 With respect to the second issue, the appellant argued that the functional feature of claim 13, *"to promote a rate of growth in that infant which approximates to the rate of growth of a breast fed infant of the same age"*, does not concern a prophylactic therapy or cure for an aliment or disease despite the fact that it is drafted in the format prescribed by G 5/83. Consequently this claim is not a second medical use claim but a claim relating to a method of manufacturing a nutritional composition comprising protein, lipid and carbohydrate, with less than 1.8 g protein per 100 kcal and less than 650 kcal/litre of energy density.

The board does not agree. The patent in suit associates the more rapid growth in infancy with an increased risk of developing obesity later in life, the latter being a pathological condition. Thus the functional feature in question, which concerns a specific growth pattern, clearly defines a therapy/prophylaxis of/from this pathology. The link is especially provided in the patent in suit (page 2, lines 49-54):

"However, in the specific case of infants born to overweight and obese mothers, the present inventors believe that it may be possible to reduce the risk of future obesity by feeding the at risk infant from the age of about three months with a nutritional composition according to the invention. In other words, it is thought that feeding the at risk infant with a nutritional composition according to the invention from the age of about three months will result in the growth rate of the infant more closely approximating to the normal growth rate of a breast fed infant of the same age". [emphasis added]

and (page 3, lines 13-16)

"[0015] Without wishing to be bound by theory, the inventors believe that for infants at risk of developing obesity in particular, feeding a nutritional composition with a controlled protein and energy content which is moreover preferably relatively rich in the satiety-inducing protein casein could counteract any tendency on the part of the infant to overfeed, particularly as regards protein intake, whilst supplying sufficient quantities of nutrients essential for growth and development and resulting in a growth pattern similar to that observed in breast fed infants". [emphasis added]

It is therefore clear for the skilled person in the art of infant nutrition that the functional feature "to promote a rate of growth in the infant at risk of developing obesity later in life approximating to the rate of growth of a breast fed infant of the same age" defines a way to decrease the risk of obesity later in life of said infant.

Consequently, claim 13 is a second medical use claim.

3. Sufficiency of disclosure

3.1 The appellant objected to the sufficiency of disclosure concerning the inventions underlying independent claims 1, 12 and 13.

However, the composition of the nutritional composition is clearly described in all the independent claims: it contains a protein source, a lipid source, a carbohydrate source, a protein content of less than 1.8 g/100 kcal, an energy density of less than 650 kcal/litre and also at least 20% by weight of casein in claims 1 and 12. These are common features known to the skilled person in the technical field of nutritional compositions. A particular example of such a composition is provided in paragraph [0035] of the patent in suit. As regards the target patient group, it is also clearly defined in paragraph [0016] as already set out above (see point 2.1). Furthermore, the patent in suit discloses the three therapeutic effects claimed. As regards, in particular, the therapeutic effect of independent claim 13, reference is made to point 2.2.

3.2 The appellant's objection boils down to whether it was plausible/credible at the priority date of the patent in suit (because sufficiency of disclosure is required at the priority/filing date) that the therapeutic effects, namely the prevention of developing obesity later in life (claim 1), the reduction of the risk of developing obesity later in life (claim 12) and the promotion of a rate of growth in an infant at risk of developing obesity later in life that approximates to

the rate of growth of a breastfed infant of the same age (claim 13), could be achieved on the basis of the patent as a whole and the common general knowledge.

3.2.1 When considering the patent as a whole, the board comes to the same conclusion as the opposition division and the appellant, namely that it does not contain any technical evidence showing that the claimed therapeutic effects have been achieved. Therefore the board has to assess on the basis of the patent as a whole and the common general knowledge whether it was plausible/ credible at the filing date of the patent in suit that the claimed nutritional composition was suitable to provide the claimed therapeutic effects.

3.2.2 According to the case law of the boards of appeal of the EPO, an application/patent must disclose the suitability of the product to be manufactured for the claimed therapeutic application in order to fulfil the requirement of Article 83 EPC, unless this is already known to the skilled person at the priority date (T 609/02, point 9 of the reasons; T 433/05, point 29 of the reasons; T 734/12, points 18-21 of the reasons).

3.2.3 With respect to the disclosure in the patent in suit, the respondent referred to paragraphs [0012] and [0015], which establish the cause/effect relationship between on the one hand the controlled amount of protein and energy content and on the other hand the claimed therapeutic effects for infants at risk of developing obesity later in life.

3.2.4 With respect to what was known at the priority date of the patent in suit, the respondent referred to D2 (abstract; page 568, left column, lines 17-21, and page 571, left column, lines 46-52), which discloses

the direct link of protein content in infant formulae to the growth and metabolic patterns of those infants, and establish the required cause/effect relationship.

3.2.5 Taking all these facts together, the board acknowledges that at the priority date of the patent in suit the administration to infants at risk of developing obesity later in life of the claimed nutritional composition could plausibly/credibly achieve the claimed therapeutic effects.

3.3 With respect to the post-published D15 and D16, they need not be taken into account for the assessment of sufficiency of disclosure, more specifically the suitability of the claimed nutritional compositions for the achievement of the claimed therapeutic effects. According to the case law of the boards of appeal of the EPO, such post-published documents can only confirm the expectations of the skilled person reading the patent in suit and having knowledge of the prior-art documents D1 and D2 (T 609/02, points 9 and 13 of the Reasons). Whether these documents indeed confirm the reasonable expectations of the skilled person can be left undecided since the board is already convinced of the invoked plausibility as stated above.

3.4 Since it is plausible that the claimed compositions would provide the claimed therapeutic effects, the burden of proof to demonstrate the opposite, namely that this is not the case, lies with the appellant. However, the appellant has not raised any serious doubts, substantiated by verifiable facts, that could call into question the non-suitability of the claimed compositions for the claimed therapeutic effects.

The appellant argued that there was an undue burden put on in view of the time required to carry out experiments related to the risk of developing obesity later in life. The board does not agree. First, the appellant cannot be discharged of the burden of proof by the fact that counter-evidence is time-consuming. Therefore this argument of the appellant is rejected. Second, it would as a first step have been sufficient if the appellant had submitted facts that would have cast serious doubts on the assumption of plausibility, in particular for what reasons the nutritional composition could not be reasonably expected to have the claimed therapeutical effect. No such argument is on file.

3.5 Furthermore, no evidence has been provided that the invention could not be reproduced over the entire scope of the claims or that essential nutrients were absent from the claimed nutritional composition. In particular, with regard to the need to include the satiety-inducing protein casein in the claimed nutritional composition of claim 13 to achieve the therapeutic effect, the board notes that casein is disclosed in the patent in suit as a preferred embodiment (page 3, lines 13-14). Therefore these objections of the appellant are unfounded.

3.6 To conclude, the inventions underlying the subject-matter of claims 1, 12 and 13 are sufficiently disclosed.

4. Novelty

4.1 The appellant stated during the oral proceedings before the board (reference is made to the minutes of these

oral proceedings) that it only objected to the novelty of the subject-matter of claim 13 on the basis of D12.

4.2 D12 discloses infant feeding formulae to be fed to babies in the first two weeks of life (page 3, lines 11-18), comprising 0.5 to 1.0 g of protein per 100 ml of formula and 25 to 50 kcal per 100 ml of formula when made up to the recommended liquid for feeding to babies (page 2, lines 13-20; page 3, lines 11-16; claims 1 and 3). The above composition is converted in order to be compared to the nutritional composition of claim 13 and results in a feeding formula that comprises an energy density between 250-500 kcal/litre and a protein content between 1-4 g/ 100 kcal. The infants of D12 are healthy newborn infants (page 2, line 27). The aim of feeding the disclosed infant formula is to slow the infant's growth by under-nutrition and thus avoid long-term adverse health effects, particularly with regard to long-term vascular health relevant to the development of atherosclerosis and to the later propensity to insulin-resistance and no-insulin dependent diabetes (page 1, line 27, to page 2, line 3).

4.3 The appellant argued that the nutritional composition of D12 falls within the definition of the nutritional composition of claim 13. On the one hand the disclosed energy density range of 250-500 kcal/litre falls within the claimed range of less than 650 kcal/litre and on the other hand the disclosed protein content of 1 g/ 100 kcal falls within the claimed range of less than 1.8 g/100 kcal. Thus the skilled reader of D12 would not have to make a double selection to arrive at the nutritional composition of claim 13 as wrongly argued by the respondent. Since D12 disclosed the nutritional composition of claim 13, this claim lacked novelty. The

appellant insisted on its interpretation of claim 13, that neither the functional feature of the therapeutic effect nor the patient group could provide any differentiation from the disclosure of D12.

4.4 The board arrives at the opposite conclusion because D12 does not disclose the patient group or the functional feature of the therapeutic effect of claim 13. Thus, even if it were admitted that D12 discloses the nutritional composition of claim 13, the subject-matter of this claim is novel over this document.

4.5 For the sake of completeness, the board also acknowledges the novelty of the subject-matter of independent claims 1 and 12 over D12, the respective nutritional composition of which comprises a protein source that includes at least 20% by weight of casein. This feature is not disclosed in D12.

4.6 By the same token, the subject-matter of all dependent claims corresponding to specific embodiments of the independent claims is novel over D12.

5. Inventive step

5.1 Closest prior art

5.1.1 The appellant considered D1 to represent the closest prior art. D1 discloses a combination of nutrients intended for infants that ensures growth and metabolic patterns similar to those of breastfed infants and enables similar health characteristics to be enjoyed in later childhood and adulthood (page 3, lines 24-29). Thus D1, like the patent in suit, lies in the technical field of nutritional compositions for infants and seeks to achieve similar effects. On this basis D1 is

considered as a promising starting point in order to assess inventive step of the claimed subject-matter.

5.1.2 The infant formulae of D1 have a protein content that is preferably no more than 2 g/100 kcal, more preferably less than 1.85 g/100 kcal, most preferably between 1.8 and 1.85 g/100 kcal (page 5, lines 16-18). The infant formulae according to D1 contain a protein source that includes 20-40 wt% casein (page 5, lines 24-26). The standard reconstitution of these formulae from powder with water gives a caloric density of 67 kcal/100 ml, which corresponds to an energy density of 670 kcal/litre. The table of page 13 discloses an energy density of 670 kcal/litre. The infant formulae of D1 ensure growth and metabolic patterns similar to those of breastfed infants and enable similar health characteristics to be enjoyed in later childhood and adulthood (page 3, lines 24-29). These health characteristics are related to a reduced load on immature organs (page 12, lines 1-12), improved gastrointestinal comfort (page 12, lines 19-25) and development of a healthy gut microflora (page 12, lines 27-29).

5.1.3 The subject-matter of independent claims 1, 12 and 13 differs from the disclosure of D1 as regards the protein content of the nutritional composition, which is less than 1.8 g/100 kcal, and its energy density, which is less than 650 kcal/litre. It also differs as regards the target patient group, which is "infants (born to obese mothers) at risk of developing obesity later in life". This patient group is not disclosed in D1.

5.1.4 Furthermore, the board does not agree with the appellant that D1 clearly and unambiguously discloses

protein content values of less than 1.8 g/100 kcal. The value of 1.4 g/100g on page 4, line 4, relates to human milk and the value of 1.6 g/100 kcal on page 4, line 8, relates to prior-art clinical trials.

5.1.5 The technical effect resulting from the differences identified above is a long-term or programmed prevention of obesity later in life, a reduction of the risk of developing obesity later in life and a promotion of a rate of growth that approximates to the rate of growth of a breastfed infant of the same age, for the patient group of infants born to obese mothers and predisposed to develop obesity later in life.

5.2 The technical problem

5.2.1 The technical problem underlying the subject-matter of claims 1, 12 and 13 in view of D1 - defined without any pointer to the claimed solution - concerns the provision of an alternative nutritional composition addressing the needs of infants at risk of developing obesity later in life, i.e. infants born to obese mothers.

5.2.2 It is plausible/credible that the technical problem is solved by the subject-matter according to the independent claims as granted and that it is solved over the entire scope of the claims. The appellant did not substantiate its objection by any data that would raise serious doubts concerning the plausibility of the solution or the solution over the entire breadth of the claims. As already set out above (point 3.4) a long-term experimental set-up is not a legitimate excuse for not having provided counter-evidence or even only arguing seriously in substance against the assumption

of plausibility. Under the present circumstances the burden of proof remains with the appellant.

5.2.3 Confirmation that the technical problem has been solved is provided by the post-published document D16.

D16 relates to infants born to obese mothers, i.e. mothers with a BMI>30, and the increased risks of overweight during childhood. It shows that the weight gain of the infants belonging to the experimental group fed a nutritional composition with a protein and energy content according to the claims is similar to breastfed infants between 3 and 12 months.

5.2.4 The respondent referred also to post-published document D15. However, this document only relates to infants born to overweight mothers, i.e. mothers with a BMI>25, and does not directly relate to infants born to obese mothers with a BMI<30. A clear distinction between these two groups is made in D16, which discloses a different weight gain between these two infant groups.

5.3 Obviousness

5.3.1 The skilled person starting from the nutritional composition of D1 and aiming at an alternative nutritional composition addressing the needs of infants at risk of developing obesity later in life, i.e. infants born to obese mothers, would not find any motivation in D1 or any other prior-art document to reduce both the protein content and the energy density to the values of the claimed nutritional composition in order to prevent obesity later in life or to reduce the risk of developing obesity later in life or to promote a rate of growth in said infants that approximates to

the rate of growth of a breastfed infant of the same age.

5.3.2 The disclosure in D1 of protein content values within the claimed range, namely 1.6 g/100 kcal, concerns clinical trials which failed to reproduce all the indices of human milk protein metabolism or to ensure the satisfactory growth of infants (page 4, lines 6-12). Hence, this disclosure teaches away from using such a low protein content in the formulation of infant nutritional compositions. Furthermore, D1 does not provide any motivation to reduce the energy density of the nutritional composition. In conclusion, D1 itself does not provide the necessary motivation to modify either the protein content or the energy content.

5.3.3 The technical prejudice against using a protein content lower than 1.8 g/100 kcal is not overcome by the disclosure of D3. This document investigates what is a safe protein-energy ratio for infant formula and arrives at the following conclusion (page 362, right column, last line to page 363, line 3):

*"We conclude that the safe protein-energy ratio for milk-based infant formulas during the first 55 d of life lies between 3.73 g/MJ (**1.56 g/100 kcal**) and 5.11 MH (**2.14 g/100 kcal**) ... We suspect that the safe amount lies closer to 3.73 MJ than to 5.11 MJ"* [emphasis added].

The authors of D3 "suspect" that the safe protein amount varies between 1.56 g/100 kcal and 2.14 g/kcal and closer to the lower limit but they do not state that this should be less than 1.8 g/100 kcal. Moreover, D3 does not deal with the reduction of the energy

density, which is disclosed to range between 670 and 700 kcal (page 363, right column, Appendix A, first line), let alone feeding the composition to the specific patient group for obtaining the claimed therapeutic effects.

5.3.4 With respect to reducing the energy density disclosed in D1 so that it becomes less than 650 kcal/litre, the appellant argued that the skilled person would find the motivation in D12, which discloses an energy density varying between 250 and 500 kcal/litre. However, the skilled person would not combine D12 with D1 since none of them concerns infants at risk of developing obesity later in life. Thus this argument of the appellant is based on hindsight.

5.4 In summary, the subject-matter of independent claims 1, 12 and 13 involves an inventive step. By the same token the subject-matter of all dependent claims corresponding to specific embodiments of the independent claims involves an inventive step.

6. As the main request is patentable, the assessment of the patentability of the auxiliary requests becomes redundant.

7. Thus the appeal is not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

M. Cañueto Carbajo D. Prietzel-Funk

Decision electronically authenticated