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Datasheet for the decision of 26 June 2024

Case Number: T 1299/22 - 3.3.09

Application Number: 12798433.4

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IPC: A23L33/00, A23L33/175

Language of the proceedings: EN

Title of invention:
FORMULAS COMPRISING OPTIMISED AMINO ACID PROFILES

Patent Proprietor:
N.V. Nutricia

Opponent:
Société des Produits Nestlé S.A.

Headword:
Optimised amino acid profiles/NUTRICIA

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

Keyword:
Inventive step - (no)
Amendment after summons - exceptional circumstances (no)

Decisions cited:

Catchword:

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Beschwerdekammern

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Case Number: T 1299/22 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 26 June 2024

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Respondent: (Opponent)	Société des Produits Nestlé S.A. Avenue Nestlé 55 1800 Vevey (CH)
Representative:	Plougmann Vingtoft a/s Strandvejen 70 2900 Hellerup (DK)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 11 March 2022 revoking European patent No. 2922414 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Haderlein
Members:	M. Ansorge
	R. Romandini

Summary of Facts and Submissions

I. The proprietor (appellant) lodged an appeal against the opposition division's decision revoking the patent.

II. With its notice of opposition, the opponent had requested that the patent be revoked *inter alia* on the ground for opposition under Article 100(a) EPC (lack of inventive step).

III. The opposition division decided that the subject-matter of claim 1 of the patent as granted (main request) and of claim 1 of auxiliary requests 1 to 4 did not involve an inventive step in view of D3 or D13 as the closest prior art.

IV. The board issued a communication pursuant to Article 15(1) RPBA and gave as its preliminary opinion that none of the claim requests, i.e. the main request and auxiliary requests 1 to 14, appeared to be allowable. In particular, the subject-matter claimed in the main request and auxiliary requests 1 to 4 was considered to lack an inventive step in view of D3 or D13 as closest prior art.

V. By letter received on 20 December 2023, the appellant filed a new document D16, withdrew former auxiliary requests 5 to 14 and filed new auxiliary requests 5 to 9.

VI. Claim 1 of the patent as granted (main request) reads as follows.

"*An infant or follow-on formula comprising a proteinaceous composition comprising:*

a) 3.2-5.0 g threonine per 100 g protein;
b) 0.7-1.1 g tryptophan per 100 g protein;
c) a ratio of tryptophan to the sum of all neutral amino acids isoleucine, leucine, valine, phenylalanine, tyrosine, and methionine of from 0.030 to 0.025; and
d) 5.0-7.8 g isoleucine per 100 g protein, 6.6-10.3 g leucine per 100 g protein, 6.2-9.7 g lysine per 100 g protein, 1.8-2.8 g methionine per 100 g protein, and 5.2-8.1 g valine per 100 g protein,

wherein the formula comprises a protein intake level of:

- 1.4 to 1.8 g of protein per 100 kcal of formula; or

- 0.9 to 1.2 g of protein per 100 ml of formula."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the feature "*1.4 to 1.8 g of protein per 100 kcal of formula; or 0.9 to 1.2 g of protein per 100 ml of formula*" is amended to "***1.5*** *to 1.8 g of protein per 100 kcal of formula; or* ***1.0*** *to 1.2 g of protein per 100 ml of formula*" (emphasis added).

Claim 1 of auxiliary request 2 differs from claim 1 of auxiliary request 1 in that the feature "*a ratio of tryptophan to the sum of all neutral amino acids isoleucine, leucine, valine, phenylalanine, tyrosine, and methionine from 0.030 to 0.025*" is amended to "*a ratio of tryptophan to the sum of all neutral amino acids isoleucine, leucine, valine, phenylalanine, tyrosine, and methionine from* ***0.028*** *to 0.025*" (emphasis added).

Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 1 in that the feature "*wherein the proteinaceous composition further comprises 1.9 - 3.0 g histidine, 3.8 - 5.9 g phenylalanine, 1.2 - 4.0 g cysteine and 2.6 - 8.4 g tyrosine, per 100 g protein*" is added at the end of the claim.

Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 2 in that the feature "*wherein the proteinaceous composition further comprises 1.9 - 3.0 g histidine, 3.8 - 5.9 g phenylalanine, 1.2 - 4.0 g cysteine and 2.6 - 8.4 g tyrosine, per 100 g protein*" is added at the end of the claim.

The wording of auxiliary requests 5 to 9 (filed by letter dated 20 December 2023) has no effect on the case at hand.

VII. The following documents were cited in the case at hand.

D3: L. Huang, "The Essential Amino Acid Requirements of Infants", PhD thesis, Erasmus University Rotterdam, 26 September 2012

D13: WO 2011/119023 A1

D15: S. Kouwenhoven et al., "A modified low-protein infant formula supports adequate growth in healthy, term infants: a randomized double-blind, equivalence trial", Am J Clin Nutr 2020; 111:962-974

D16: N.C.R. Räihä, "Whey Predominant, Whey Modified Infant Formula with Protein/energy Ratio of 1.8 g/ 100 kcal: Adequate and Safe for Term Infants From Birth to Four Months", Journal of Pediatric Gastroenterology and Nutrition, 35:275-281

VIII. The parties' arguments, where relevant, are reflected in the Reasons for the Decision below.

IX. Requests

The appellant requested that the decision be set aside and that the patent be maintained as granted (main request) or, in the alternative, that the patent be maintained on the basis of one of auxiliary requests 1 to 4, filed on 6 January 2021, or one of auxiliary requests 5 to 9, filed on 20 December 2023.

The respondent (opponent) requested that the appeal be dismissed.

Reasons for the Decision

Main request

1. Inventive step

1.1 The appellant argued that the opposition division erred in concluding that the subject-matter of claim 1 of the main request lacked an inventive step in view of D3 or D13 as the closest prior art.

1.2 The main arguments of the appellant were as follows.

- D3 was the closest prior art; D13 was not suitable as closest prior art in the present case. There could only be one closest prior-art document. The appellant disputed that D13 was the most appropriate starting point.

- D3 did not teach a formula with optimised concentrations of threonine, tryptophan, isoleucine, leucine, lysine, methionine and valine combined. It was a matter of hindsight that the individual disclosures of optimal concentrations in D3 would lead to an optimised infant or follow-on formula composition when these were all taken together. There was no disclosure of such a combination of amino acids in D3.

- D3 did not disclose an optimised infant or follow-on formula with optimised amino acid profiles and reduced protein concentrations.

- The effect of the combination of optimised amino profile values and reduced protein levels was balanced growth and a reduced risk of overweight and obesity, as demonstrated in the piglet study of example 6 in the patent.

- The specific amino acid composition and concentrations of claim 1 (diet 3) achieved an optimal growth rate similar to that of high-protein-fed infants (diet 1) but with a smaller protein intake, while a non-optimised amino acid profile, even with the same amount of total protein and caloric content (diet 2), did not achieve this effect.

- As the experimental evidence in Figure 9 of the patent showed, without an optimised amino acid composition (diet 3) this growth was not achieved to the desired extent (diet 2). The results in the patent were confirmed by D15, which tested the claimed formula in healthy, term infants.

- The objective technical problem was to provide an infant or follow-on formula with an optimised amino

acid profile which ensured optimal growth and reduced the risk of overweight and obesity later in life.

- With respect to the question of obviousness, the skilled person would not have considered working at or below the minimum protein content as set in the field, let alone have reasonably expected that this would result in balanced growth of the infant.

- The skilled person would understand that the data disclosed in D3 with respect to the IAAO method could not be used as guidance on the amount of protein that could be used. The data of D3 did not demonstrate the suitability of an infant formula comprising a protein content of 1.8 g/100 kcal with the amino acid concentrations of D3.

- Starting from D13 as closest prior art, a technical effect had been shown, but this was based on the reasons set out for D3 as closest prior art. As in the case of D3, the distinguishing feature of claim 1 over D13 was the combination of reduced protein intake and optimised amino acid composition. The technical effect, objective technical problem and solution were as discussed for D3. The question remains how the skilled person would reasonably find an incentive to lower the protein content to levels that in the field were only acceptable when the protein quality was similar to that of breast milk. It was with the benefit of hindsight that the skilled person would lower the protein concentrations in combination with the optimised amino acid profile in order to improve balanced growth.

1.3 As outlined below, the board does not agree with the appellant.

1.3.1 Concerning the issue of the closest prior art (see point 1.2 above), the board agrees with the opposition division that not only D3 but also D13 is a suitable starting point in the present case. D3 and D13 relate to the same technical field; they also share a similar purpose to that of the patent. In view of the similarity of the technical field and purpose, both documents can be used for an analysis using the problem-solution approach. Since, as shown below, there is a lack of inventive step starting from D13, the question of whether D3 is "even closer" to the claimed subject-matter is not relevant.

1.3.2 D13 describes a nutritional composition comprising protein, digestible carbohydrates and fat, wherein the protein comprises the amino acids leucine, isoleucine and valine in a weight ratio of leucine:isoleucine:valine of (1.1-1.5):(0.9-1):1.0 (see claim 1). D13 further relates to the use of the nutritional composition for the manufacture of a medicament for the treatment of: infants aged between 0 and 24 months; and/or premature infants; infants small for their gestational age; infants with a metabolic disease selected from the group consisting of PKU, MSUD and tyrosinaemia; or infants with a food allergy (see claim 13), and to the use of the nutritional composition for the manufacture of a medicament for the prevention of obesity later in life (see claim 14).

1.3.3 The subject-matter of claim 1 differs from D13 not only in the concentrations of threonine and tryptophan, but also in the concentrations of isoleucine, leucine, lysine and valine. However, the protein content per 100 kcal of formula or per 100 ml of formula as defined in claim 1 is disclosed in D13 (see example 4 of D13).

1.3.4 The parties disagreed on the effect resulting from said difference and on how to formulate the objective technical problem.

1.3.5 In its assessment of inventive step over D13, the appellant argued that a technical effect had been shown for the reasons given for D3 as closest prior art.

This reasoning is unconvincing. The distinguishing features over D3 and over D13 are not the same. While the appellant argued that D3 failed to disclose the feature directed to the reduced protein content per 100 kcal or per 100 ml of formula, this feature is disclosed in D13 (see example 4). The appellant argued that D13 lacked any evidence that the optimised intake of leucine, valine and isoleucine in combination with the reduced protein levels would result in balanced growth. However, there is no evidence on file that the claimed formula shows advantages in terms of more balanced growth.

1.3.6 In addition, there is no evidence on file that the claimed infant formula might be more effective in reducing the risk of obesity later in life than the infant formula of D13 (example 4), keeping in mind that claim 14 of D13 explicitly mentions that the nutritional composition may be used for the manufacture of a medicament for the prevention of obesity later in life.

In view of the above, an improvement over D13 cannot be acknowledged.

1.3.7 Hence, the opposition division correctly formulated the objective technical problem as the provision of a

further infant formula with an optimised level of amino acids which ensures adequate growth of the infants while preventing obesity later in life.

1.3.8 With respect to the question of obviousness, too, the board shares the opposition division's conclusion.

When trying to find an alternative infant formula with an optimised level of amino acids which ensures adequate growth of the infants while preventing obesity later in life, a skilled person would have considered D3, which has the title "The Essential Amino Acid Requirements of Infants". D3 teaches what these requirements are. It also teaches the breakpoints for each amino acid (see Table 1 on page 177 of D3). The core teaching of D3 is to determine a better amino acid profile for formula-fed infants. A skilled person wishing to solve the above problem would be motivated by the teaching of D3 to optimise the amino acid levels of all amino acids present in the infant formula of D13.

For these reasons, the board does not agree with the appellant that the claimed subject-matter could only be regarded as obvious from the perspective of hindsight.

As a consequence, a skilled person would have arrived at the claimed subject-matter in an obvious manner.

In view of the above, the opposition division correctly concluded that the subject-matter of claim 1 of the main request lacked an inventive step starting from D13 in combination with D3.

Auxiliary requests 1 - 4

2. For substantially the same reasons as set out for the main request, the subject-matter of claim 1 of each of auxiliary requests 1 to 4 lacks an inventive step when starting from D13.

The appellant argued that claim 1 of auxiliary requests 1 to 4 specified a protein range of between 1.5 and 1.8 g of protein per 100 kcal of formula, and that in its view this distanced the claimed compositions from examples 3 and 4 of D13, which disclosed 1.36 g and 1.4 g of protein per 100 kcal respectively. Auxiliary requests 2 and 3 brought the claims more into line with the evidence of example 6 of the patent.

The board considers this argument unconvincing. By a routine modification, the skilled person would have slightly modified the protein content per 100 kcal of the formula and as a result arrived at values falling within the claimed range.

Consequently, the subject-matter of claim 1 of each of auxiliary requests 1 to 4 also lacks an inventive step in view of D13 as the closest prior art.

Auxiliary requests 5 - 9 and document D16

3. Article 13(2) RPBA

3.1 Auxiliary requests 5 to 9 and document D16 were filed by the appellant after notification of the communication pursuant to Article 15(1) RPBA. Consequently, their admittance is subject to the provisions of Article 13(2) RPBA.

3.2 According to Article 13(2) RPBA, any amendment to a party's appeal case after notification of a communication under Article 15(1) RPBA, shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

3.3 With respect to D16, the appellant argued that it filed D16 to highlight the point that the skilled person would have been discouraged from reducing protein content in infant formula below 1.8 g/100 kcal. However, no arguments were submitted as to why there might be exceptional circumstances which could justify admitting this document.

3.4 With respect to auxiliary requests 5 to 9, the appellant submitted that in these claim requests the composition was limited to infant formulas defined by a smaller protein/energy ratio. Again, no arguments were submitted as to why there might be exceptional circumstances which could justify admitting these claim requests.

3.5 The board shares the respondent's view that there are no exceptional circumstances which could justify admitting D16 and auxiliary requests 5 to 9 into the appeal proceedings.

Under these circumstances, D16 and auxiliary requests 5 to 9 are not taken into account in the case at hand (Article 13(2) RPBA).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Pinna A. Haderlein

Decision electronically authenticated