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**Datasheet for the decision
of 5 March 2021**

Case Number: T 1429/18 - 3.3.09

Application Number: 11712054.3

Publication Number: 2552242

IPC: A23L1/29, A23L1/305, A61P3/02

Language of the proceedings: EN

Title of invention:
LOW PROTEIN INFANT FORMULA WITH INCREASED ESSENTIAL AMINO
ACIDS

Patent Proprietor:
N.V. Nutricia

Opponent:
Société des Produits Nestlé S.A.

Headword:
Balanced amounts of branched amino acids/NUTRICIA

Relevant legal provisions:
EPC Art. 56, 83
RPBA 2020 Art. 13(2)

Keyword:

Main request: sufficiency of disclosure (yes) - inventive step
(yes)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1429/18 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 5 March 2021

Appellant:
(Patent Proprietor)

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Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
5 April 2018 concerning maintenance of the
European Patent No. 2552242 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. This appeal lies from the interlocutory decision of the opposition division concerning European patent No. 2 552 242 B1.
- II. With its notice of opposition, the opponent had requested revocation of the patent in its entirety on the grounds under Article 100(a) (lack of novelty and lack of inventive step) and Article 100(b) EPC.
- III. The documents submitted during the opposition proceedings included:
- D1: EP 0 492 183 B1
 - D2: G. Bellamonte et al., Ann. Ist. Super. Sanità, Vol. 26(2), 1990, pp. 131-140
 - D3: B.Viadel et al., Int. J. Food Sci. Nutr.; 2000, Vol. 51, 367-372
 - D4: O. Hernell et al., Am. J. Clin. Nutr., Vol. 78, 2003, pp. 296-301
 - D5: WO 2008/054200 A2
 - D6a European Commission: Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae, 2003
 - D6b: Commission Directive 2006/141/EC, December 2006
 - D12: The Ministry of Health of the People's Republic of China, "National Standards on Food Safety of P.R. China", March 2010
- IV. In its decision the opposition division found that the invention claimed in auxiliary request 1 was sufficiently disclosed and involved an inventive step

over D6b, the closest prior art, alone or in combination with the other cited documents.

- V. Claim 1 of auxiliary request 1, found allowable by the opposition division, reads:

"An infant formula comprising protein, digestible carbohydrates and fat, wherein the protein comprises the amino acids leucine, isoleucine and valine in a weight ratio leucine:isoleucine:valine between (1.1-1.5):(0.9-1.1):1.0, and wherein the total protein content is between 1.3 and 1.9 g protein/100 kcal, wherein the protein comprises between 130 and 160 mg leucine per 100 kcal in the total composition, between 100 and 120 mg isoleucine per 100 kcal in the total composition and between 105 and 121 mg valine per 100 kcal in the total composition."

- VI. Appeals against this decision were filed by both the opponent and the patent proprietor. By letter dated 7 January 2021 the proprietor (now respondent) withdrew its appeal and indicated that auxiliary request 2, filed with its statement of grounds of appeal and corresponding to the request found allowable by the opposition division, was its main request.

- VII. The arguments of the opponent (now sole appellant) which are relevant for the present decision can be summarised as follows.

The claimed invention was not sufficiently disclosed, because the claimed formula could not be considered an "infant formula", i.e. a formula suitable to nourish an infant according to the European Commission regulations shown in D6a/b.

In the written proceedings, when discussing inventive step, the appellant had proposed any of D1, D2, D3, D4, D6a and D6b as representing the closest prior art. However, during the oral proceedings, it did not dispute that D6a was the closest prior art and proposed D5 as an alternative closest prior art. The selection of the claimed ratio and amounts of leu, ile and val did not represent an optimisation of the protein fraction of the formula of D6a, because claim 1 encompassed formulas wherein the total amount of protein and the amount of amino acids other than leu, ile and val were lower than those considered necessary to nourish an infant. The problem to be solved was the provision of an alternative formulation. Taking into account the teaching of D6a alone or combined with that of documents D1, D2 and D4, varying the ratio between ile, leu and val and their individual amounts so as to obtain the claimed formulation would have been obvious for the skilled person.

VIII. As far as relevant to the present decision, the respondent's arguments can be summarised as follows.

The patent provided sufficient information for preparing the claimed nutritional formula, and in particular for optimising the content of the branched amino acids leu, ile and val. Relying on this information, nutritional formulas having low protein content could be prepared. Examples 3 and 4 provided specific examples of such formulations. Thus, the claimed invention was sufficiently disclosed.

The claimed subject-matter involved an inventive step over D6a, the closest prior art. The claimed infant formula differed from that of D6a in that it contained a different ratio and different amounts of branched

amino acids: the amounts of val and ile were higher and the amount of ile was comparable to those disclosed in D6a. The tests in the patent showed that the claimed formula contained the correct balance between these branched amino acids. This was very important because leu, ile and val accounted for 35% to 40% of the dietary indispensable amino acids and 14% of the total amino acids in the skeletal muscle. Thus, the underlying problem was that of optimising the protein fraction in an infant formula, in particular as far as the branched portion of amino acids was concerned. None of the prior-art documents provided a pointer to the claimed solution.

- IX. At the end of the oral proceedings before the board, the parties had the following requests.

The appellant requested that the decision under appeal be set aside and the European patent be revoked.

The respondent requested that the appeal be dismissed (i.e. that the patent be maintained on the basis of the main request filed as auxiliary request 2 with the statement of grounds of appeal) or, alternatively, that the patent be maintained on the basis of auxiliary request 3 or 4, both filed with the statement of grounds of appeal.

Reasons for the Decision

Main request

1. *Sufficiency of disclosure*

- 1.1 According to the appellant, the claimed invention was not sufficiently disclosed. The patent did not provide

sufficient guidance for preparing an infant formula, wherein "infant formula" means a formula suitable for nourishing an infant according to the European Commission guidelines shown in D6a/b. The claimed formula could contain as little as 1.3 g protein/100 kcal, an amount which was lower than that, 1.8 g protein/100 kcal, recommended for infant nutrition in D6a (page 26, Table 1; page 49, paragraph 2; and page 50, paragraphs 3 and 5) and in D6b (Annex V). The amount of amino acids other than ile, leu and val contained in the formulas of Examples 3 and 4 of the patent was also lower than that recommended in Table 13 on page 58 of D6a. These formulas were merely "prophetic examples". Furthermore, the tests described in the patent for determining the required amounts of ile, leu and val were conducted using an amount of protein exceeding that in claim 1. Wide confidence intervals were also reported. Thus, the tests could not be relied upon.

- 1.2 The appellant's arguments are not convincing. The claimed invention is based on the finding that the minimum intake requirements of the essential branched amino acids ile, leu and val differ from those according to the recommendations in D6a/b. This finding stems from the results of the indicator amino acid oxidation (IAAO) tests described in paragraph [0047] and in the examples of the patent. As indicated in the patent, and clarified by the respondent, when implementing the IAAO tests, the minimum requirement of a specific amino acid must be determined in a subject fed with sufficient amounts of all other amino acids. Thus, there is no reason to consider the experimental setting inappropriate in the present case.

1.3 The results of the tests in Examples 1 and 2 show that the required amounts of val and ile are higher and those of leu are comparable to the previously recommended ones. As explained in paragraphs [0008], [0009] and [0024] of the patent, these results were used to calculate the ratio and the amounts of leu, ile and val specified in claim 1. Formulas comprising the calculated ratio and amounts of these amino acids and comprising the other essential amino acids are described in Examples 3 and 4. The appellant argued that the results were affected by large experimental errors, and, as a consequence, wide confidence intervals encompassing the lower values of the prior art could be obtained. This argument is not persuasive, because the 95% "population-safe intake" mentioned in the tests is calculated as an excess dosage above the minimum requirement determined from the breakpoint observed in the tests, and not below that minimum, as suggested by the appellant.

1.4 It is undisputed that claim 1 and the examples relate to a formula comprising a total amount of protein and amounts of specific amino acids which are lower than those recommended in D6a/b. However, it is credible that the claimed formula provides the appropriate amounts of leu, ile and val. As stated in paragraph [0005] of the patent, these account for 35-50% of the dietary indispensable amino acids in body protein. This also makes it credible that a formula comprising leu, ile and val in appropriate amounts and ratios, together with the other essential amino acids, will provide nutrition. It is noted that claim 1 does not require the formula to comply with existing regulations or recommendations. Furthermore, the appellant has not provided any evidence that the exemplified formulas, which contain all the essential amino acids, cannot be

used to nourish an infant, at least temporarily, or in specific situations where the administration of low amounts of proteins is desired for specific purposes, e.g. to limit the caloric intake. Examples of low-protein formulas are described for example in D5, cited in paragraph [0006] of the patent. Therefore, the formulas of Examples 3 and 4 cannot be disregarded on the ground that they are mere "prophetic examples", as suggested by the appellant. No evidence that the preparation of the claimed formula involves an undue burden and that further formulas cannot be developed relying on the teaching of the examples has been provided either.

1.5 For these reasons, it is concluded that the claimed invention is sufficiently disclosed.

2. *Inventive step*

2.1 The invention disclosed in the patent in suit relates to an infant formula providing an optimal ratio between the three essential branched-chain amino acids leu, ile and val, see paragraphs [0001], [0007] and [0008]. The patent describes the amino acid requirements according to pre-existing recommendations and explains why these recommendations should be changed in view of the findings disclosed in the patent, see paragraphs [0007] to [0009] and [0020]. It also teaches that using optimal amounts of the branched amino acids leu, ile and val is important for preparing formulas comprising a low total protein content, which are useful for preventing adverse metabolic imprinting, e.g. preventing obesity later in life (paragraphs [0007] and [0010]).

2.2 D6a teaches the importance of administering the correct amounts of amino acids to infants for optimising their

growth and preventing adverse metabolic imprinting, see page 13 of D6a. It also outlines the proposed total protein content in infant formulas (page 26, Table 1; page 29, last paragraph; page 50, paragraph 4.4.3) and the amounts of individual amino acids, including leu, ile and val (Tables 13 and 14 on pages 58 and 59). Taking into account the pertinence and the technical information provided, D6a qualifies better as the closest prior art than the other documents, namely D1, D2, D3, D4 and D6b, proposed by the appellant as closest prior art in the written proceedings.

- 2.3 During the oral proceedings, the appellant did not contest the board's preliminary opinion that D6a was the closest prior art among the aforementioned documents. However, it proposed considering, in the alternative and for the first time in appeal, D5 as the closest prior art. The board cannot identify any exceptional circumstances justified by cogent reasons, and the appellant did not mention any, for formulating a new attack and amending the party's case at such an advanced stage of the appeal proceedings. Thus, this new attack is not admitted into the appeal proceedings (Article 13(2) RPBA 2020).
- 2.4 D6a suggests the preparation of infant formulas having a total protein content of 1.8 g/100 kcal and specific amounts of amino acids (pages 58 and 59, Tables 1 and 2 and comments).
- 2.5 The claimed formula differs from that in D6a in that it comprises different amounts and ratios of the branched amino acids leu, ile and val. The amounts of val and ile specified in claim 1 are higher and the amount of leu is slightly lower than the corresponding amounts shown in D6a.

- 2.6 According to the respondent, starting from D6a, the underlying technical problem is that of optimising the protein fraction of an infant formula and providing the necessary amounts and ratio of the three essential branched amino acids ile, leu and val.
- 2.7 What needs to be established is whether this problem is credibly solved by the proposed solution, i.e. the infant formula according to claim 1.
- 2.8 The claimed ratios and amounts of ile, leu and val were calculated from the IAAO tests shown in the patent. As mentioned above (points 1.2 and 1.3), the board sees no reason that would cast doubt on the results and the ensuing calculations of the optimal ratio and amounts of leu, ile and val. Paragraph [0005] of the patent teaches that these amino acids account for 35-50% of the dietary indispensable amino acids in body protein and 14% of the total amino acids in skeletal muscle. This highlights the importance of incorporating them in appropriate amounts into a nutritional formula, in particular one that comprises a low total amount of protein.
- 2.9 The appellant has noted that the amounts of essential amino acids other than leu, ile and val contained in the exemplified formulas were below those considered necessary for infant nutrition according to D6a and D6b. Thus, these formulas were not suitable to nourish an infant. D6a taught that studies were warranted when diet modifications could be expected to have a negative effect on growth.
- 2.10 This argument is not persuasive, because it ignores the teaching of the patent. Taking into account the

aforementioned results, and the relevant importance of leu, ile and val in infant nutrition, the concept underlying the claimed invention is credible, namely that when these amino acids are administered in the claimed amounts, the total amounts of protein and other amino acids can be lowered below the amounts suggested in D6a/b. It is also credible that by underestimating the required amounts of leu and val, the amounts of other amino acids had been incorrectly determined prior to the invention as well.

- 2.11 Moreover, no evidence has been provided by the appellant that formulas according to the invention cannot be used to nourish an infant or that they negatively influence growth. In particular, it has not been shown that the formulas in Examples 3 and 4 are not suitable to feed infants. It is also noted that these formulas can be useful to nourish an infant, at least temporarily, in specific situations where the administration of low amounts of proteins is necessary for specific purposes, for example to limit the caloric intake or when it is deemed necessary to administer the correct amounts and ratio of the required essential amino acids leu, ile and val. As noted by the respondent, formulas comprising low total amounts of proteins were already known, for example from D5.
- 2.12 The appellant has also argued that the problem is not solved across the entire scope claimed, because claim 1 inevitably encompasses formulas comprising insufficient or negligible amounts of other essential amino acids.
- 2.13 The board does not concur with this assessment. The argument is a mere attempt to tear down the invention, focusing deliberately on embodiments which the skilled person would carefully avoid when construing claim 1

and relying on the teaching of the patent and common general knowledge, as they would not make technical sense. For these reasons, it is concluded that the problem set out in point 2.6 above is credibly solved across the claimed scope and does not need reformulation.

- 2.14 The final question which needs to be answered is whether, starting from D6a as the closest prior art, the skilled person would have had any reason to adjust the ratio and amounts of ile, leu and val according to the claimed invention in order to solve the problem posed, i.e. to optimise the protein fraction of an infant formula and provide the necessary amounts and ratio of the three essential branched amino acids ile, leu and val. The board does not find any pointer to the proposed solution in D6a or in any of the other cited documents. As far as D1, D2 and D4 are concerned, these neither address the underlying problem nor disclose the amounts of ile, leu and val specified in claim 1.
- 2.15 Accordingly, it is concluded that the subject-matter of claim 1 and of the remaining claims, which are narrower in scope, involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



A. Nielsen-Hannerup

A. Haderlein

Decision electronically authenticated