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**Datasheet for the decision
of 12 October 2018**

Case Number: T 0963/15 - 3.3.09

Application Number: 04739936.5

Publication Number: 1638418

IPC: A23L1/305, A23L1/29, A23K1/16,
A23K1/18, A61K38/00, A61K31/195

Language of the proceedings: EN

Title of invention:
AMINO ACID SUPPLEMENTATION FOR A HEALTHY MICROBIOTA ECOSYSTEM

Patent Proprietor:
Nestec S.A.

Opponent:
N.V. Nutricia

Headword:

Relevant legal provisions:
EPC Art. 100(c)

Keyword:
Main, 1st-11th auxiliary request - added matter (yes)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0963/15 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 12 October 2018

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
10 March 2015 concerning maintenance of European
patent No. 1638418 in amended form**

Composition of the Board:

Chairman W. Sieber
Members: A. Veronese
A. Jimenez

Summary of Facts and Submissions

- I. This decision concerns the appeal filed by the opponent against the interlocutory decision of the opposition division finding that European patent No. EP 1 638 418 as amended meets the requirements of the EPC.
- II. With its notice of opposition, the opponent had requested the revocation of the patent in its entirety on the grounds under Article 100(a) EPC (lack of novelty and lack of inventive step), Article 100(b) and Article 100(c) EPC.
- III. The opposition division decided that the proprietor's main request, based on a set of claims filed on 12 December 2014, was allowable. Claims 1 of this request read as follows:
- "1. A nutritional formula for use in restoring an healthy and optimal microbiota ecosystem in humans, which comprises a source of protein, a source of fat and a source of carbohydrate, and supplemented with Threonine, Serine, Proline and Cysteine in an amount efficient to favor the growth and the balance of bacterial microbiota, the formula providing Serine in an amount of 0.07 to 0.35 g/kg body weight/day; Proline in an amount of 0.07 to 0.3 g/kg body weight/day, Threonine in an amount of 0.04 to 0.20 g/kg body weight/day and Cysteine in an amount of 0.03 to 0.15 g/kg body weight/day".*
- IV. This decision was appealed by the opponent (hereafter "the appellant"), who requested that the decision be set aside and that the patent be revoked in its entirety.

Documents D26 and D27 were also filed with the statement setting out the grounds of appeal.

- V. In its response to the appeal, filed by letter dated 25 November 2015, the proprietor (hereafter "the respondent") requested that the appeal be dismissed (main request) or, alternatively, that the patent be maintained on the basis of one of auxiliary requests 1 to 11 filed with that letter. The respondent further requested that D26 and D27 not be admitted into the proceedings.
- VI. The respective claim 1 of auxiliary requests 1-4 differs from claim 1 of the main request in that it defines more specifically the conditions for which the claimed formula is intended in humans, namely:
- "... in the case of chronic diseases or any stress impacting the gut ... " (auxiliary request 1),
 - "... suffering from chronic or acute intestinal inflammation ..." (auxiliary request 2),
 - "... which has been disturbed in the case of psychological, physiological, or environmental stress ... (auxiliary request 3), and
 - "... suffering from ulcerative colitis ..." (auxiliary request 4).
- VII. The respective claim 1 of auxiliary requests 5-9 is based on claim 1 of the main request or auxiliary requests 1-4 and is further limited by the requirement that "Threonine, Serine, Proline and Cysteine are added in the form of free amino acids".

VIII. The respective claim 1 of auxiliary requests 10 and 11 differs from claim 1 of the main request in that it defines more specifically the subject being treated, namely:

- "men" (auxiliary request 10), or
- "elderly people" (auxiliary request 11).

IX. By further letters, the appellant submitted additional arguments and filed another document, D28.

X. In a communication dated 14 August 2018, the board drew attention to the points to be discussed during the oral proceedings. In the hearing, which took place on 12 October 2018, the respondent requested that D28 not be admitted into the proceedings. At the end of the debate, the chairman announced the decision.

XI. So far as relevant to the present decision, the appellant's arguments can be summarised as follows.

Claim 1 of the main request defined a nutritional formula that comprised a source of protein, a source of fat and a source of carbohydrate and was supplemented with serine, proline, threonine and cysteine. The claim further required the formula to deliver a daily intake of these amino acids in amounts falling within specific ranges, which were defined in terms of g/Kg body weight/day. This daily intake was calculated on the basis of the total amount of amino acids present in the formula, regardless of whether these specific amino acids were part of the protein source or were supplemented. Conversely, according to the application as filed, the ranges defining the daily amino acid intake referred to the amino acids added as

"supplementation" only. This was clear from pages 5-7, which linked the daily intake to the supplementation and defined the source of protein as a separate ingredient. The respondent had itself adopted this interpretation when replying to the notice of opposition. By incorporating the ranges defining the amino acid intake with regard to the formula as a whole and no longer distinguishing between the source of dietary protein and supplementation in amino acids, the technical teaching of the application had been changed, resulting in the addition of new subject-matter. This deficiency applied to the main and all the auxiliary requests. The deficiency was not overcome by specifying that the amino acids were added as free amino acids or that particular conditions or subjects were to be treated. The examples did not provide a basis for construing the teaching of the application in a different manner. Nor did the last paragraph of page 4, referring to a supplementation of amino acids in a proportion greater than that required by a healthy man. The originally disclosed invention was in fact not limited to the treatment of a man and encompassed the treatment of infants using normal infant food or breast feeding, which resulted in a "normal" daily amino acid intake.

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

Although the respondent had adopted a different interpretation at an earlier stage of the opposition proceedings, it now agreed that the ranges defining the daily intake of the specific amino acids in claim 1 related to the total amounts of the amino acids present in the composition, including those present in the protein source. This claim construction was in line

with the teaching of the application as filed. Although claim 1 as filed did not mention a protein source, it referred to a nutritional composition that implicitly contained other energy sources. Since the composition was meant to achieve a therapeutic effect, the daily intakes defined in claim 5 and on page 5 as filed had to be calculated taking into account all amino acids present in the composition, including those of a protein source. The "supplementation" was made up only of those amino acids that had to be added to a nutritional composition already comprising nutrients to achieve the specified daily intake. This could be inferred from original claim 5 and page 5, which referred to amounts of amino acids to be used in the composition and to amino acids derived from a protein source. This interpretation was in line with the other sections of the application, starting from page 3, and was not contradicted by the sections of pages 6 and 7 that mentioned the incorporation of an additional source of protein. It was also in line with the last paragraph of page 4, which stated that "*supplementation means that the amino acids are given in a proportion greater than the proportion corresponding to the requirement of a healthy man*". The respective amounts of amino acids present in the control diet and in the diets AA dose 1 and 2 of example 1 also supported this interpretation. The auxiliary requests, and in particular the requirement that the amino acids be provided in free form and the limitation to certain conditions or subjects, reflected even more the teaching of the application as filed. In particular, the limitation to men and elderly people excluded embodiments where infants were fed a normal infant food.

Reasons for the Decision

Main request

Added subject-matter

1. Claim 1 of the main request defines a nutritional formula for use in restoring a healthy and optimal microbiota ecosystem in humans. The formula comprises a source of protein, a source of fat and a source of carbohydrate and is supplemented with the amino acids threonine, serine, proline and cysteine. Claim 1 further requires **the formula** to provide a human with a daily intake of these same amino acids that falls within specific ranges, expressed in terms of g/kg body weight/day.
- 1.1 It was common ground between the parties that these ranges related to the total amount of the specific amino acids present in the composition, including those coming from the source of protein. This is indeed clear from the wording of the claim, which defines "A *nutritional formula ... the formula providing Serine [Proline, Threonine, Cysteine] in an amount of ...*". It was also not disputed that these numerical ranges for the daily intake as such were already disclosed in the original application as filed.
- 1.2 What was contested by the appellant was that the amino acids coming from the source of protein were not taken into account for the calculation of the daily intake in the application as filed. In other words, although the numerical ranges defining the daily intake remained the same, they were used in claim 1 of the main request in a different, originally undisclosed manner.

1.3 Claim 1 of the application as filed defines:

"A nutritional composition for restoring or promoting an healthy and optimal microbiota ecosystem in humans or animals, which comprises at least one amino acid being selected in the group consisting of hydroxyl amino acids, sulfur-containing amino acids or heterocyclic amino acids, or their derivatives, in an amount efficient to favour the growth and the balance of bacterial microbiota."

1.4 The specific amino acids threonine, serine, proline and cysteine and the relevant ranges for the daily intake are defined in dependent claim 5 and on page 5, lines 12-20 of the application as filed. However, neither claims 1 and 5 nor page 5 of the application as filed mention the sources of protein, fat and carbohydrate, which are also features of the composition of claim 1 of the main request. These additional ingredients are disclosed on page 6, lines 15-17, and on page 7, lines 12-15, of the application as filed, which specify that the nutritional formula may comprise:

"apart from the amino acid supplementation as mentioned above, a source of protein, a source of fat and a source of carbohydrate" (page 6, lines 15-17), and that

"the nutritional formula may be prepared by blending together the source of dietary protein, the carbohydrate source and the fat source in appropriate proportions and the supplementation in amino acids according to the invention" (page 7, lines 12-15), [emphasis added by the board].

1.5 It is clear from these passages that the protein source is not part of the "amino acid supplementation" according to the originally disclosed invention. The latter is the one defined in paragraphs 2 and 3 of page 5, which state that the composition is supplemented with amino acids and that threonine, serine, cysteine and proline are added to the composition to supply a daily intake falling within the relevant ranges, expressed in g/Kg body weight/day. It is clear from the wording and the construction of these paragraphs that according to the originally disclosed invention the supplementation alone is meant to provide the necessary daily intake of amino acids and to induce the alleged effect. According to page 5, amino acids can possibly be added on their own in the form of a protein, but those present in the additional protein source mentioned on pages 6 and 7 are not taken into account.

1.6 The respondent argued that, when reading the application as filed, the skilled person would assume the "supplementation" to be made up only of the amino acids which must be added to the protein source to achieve the total daily intake defined in the range specified on page 5. If the amino acids contained in the protein source were not taken into account, specifying amino acid ratios in the claims would be meaningless, because what matters in the end is the total daily amino acid intake. This would be confirmed by the fact that claim 1 and the description (e.g. pages 3-5) refer to a nutritional composition, which by definition contains nutritional ingredients, such as proteins. Accordingly, paragraphs 2-3 of page 5 would teach to top up a nutritional composition with the amounts of amino acids required to achieve the specified daily intake.

1.7 The board does not agree. When reading the application as filed, it is quite clear that the gist of the invention is the preparation of an amino acid supplementation intended, as such, to deliver an amount of the relevant amino acids within the specified range and to induce the alleged effect on the microbiota ecosystem of a human. This can be inferred from page 3, which refers to a "specific amino acid supplementation" and to the reported finding that "... supplementing the diet with specific amino acids microbiota growth can be selectively stimulated ...", and from page 5, which states that the amino acids are added in an amount to ensure a daily amino acid intake within the specified range. This supplementation is the one to which an additional source of protein, fat and carbohydrate may also be added, according to the passages from pages 6 and 7 mentioned above. Thus, according to the originally disclosed invention, the amino acids of a protein source possibly included in the composition are not part of the supplementation.

1.8 During the oral proceedings before the board, the respondent referred to experiment 1 and to the last passage of the original page 4, which reads:

"... the term "supplementation" means that the amino acids are given in a proportion greater than the proportion corresponding to the requirement of a healthy man ..."

1.9 The respondent further argued that only if the amino acids in the dietary source of protein present in the inventive dosage regimes 1 and 2 of example 1 were taken into account, would the condition on page 4 be fulfilled. The amounts of the extra added amino acids alone would not suffice to achieve the proportional

increase referred to on page 4. This would confirm that, according to the originally disclosed invention, the amino acids of the protein source have to be taken into account.

1.10 The board cannot follow this argument. Firstly, neither the claims nor the rest of the application as filed are limited to the treatment of men. Infants, for example, are also treated according to the application as filed. Secondly, as conceded by the respondent during the hearing, the calculation based on this example does not hold true for cysteine.

1.11 Thus, the aforementioned passage from page 4, alone or in combination with example 1, does not support the respondent's view on the interpretation of the application as filed with respect to the disclosure of the values for the amino acid intake.

1.12 Lastly and most importantly, the board cannot follow the respondent's interpretation of the application as filed for the following reason:
As conceded by the respondent in the course of the proceedings (e.g. in the letter dated 25 November 2015, pages 17-18), infants aged 0-1 month fed the recommended daily amounts of protein source consume all four amino acids in amounts falling within the claimed range. Thus, the claims now encompass normal infant feeding. There is no teaching in the application as filed that "normal" feeding is suitable for use in restoring a healthy and optimal microbiota ecosystem in humans. On the contrary, the teaching is that a composition is supplemented (page 5, lines 4-6).

1.13 This leads the board to conclude that by incorporating into original claim 1 the ranges defining the daily

intake of amino acids disclosed in claim 5 and on page 5 as filed, as well as the source of protein originally disclosed on pages 6 and 7, new subject-matter has been created, which amounts to an extension beyond the teaching of the application as filed. For these reasons, the main request is not allowable (Article 100(c) EPC).

Auxiliary requests 1-4

2. Claim 1 of auxiliary requests 1-4 differs from that of the main request, in that it more specifically defines the condition for which treatment is intended using the claimed formula. This limitation does not change the above-mentioned findings, which apply regardless of which condition is to be treated. The application as filed does not disclose specific supplementations for treating subjects affected by these conditions prepared using an approach different from that described above with regard to the main request. For these reasons, these requests are also not allowable (Article 100(c) EPC).

Auxiliary requests 5-9

3. Claim 1 of auxiliary requests 5-9 differs from that of the previous requests in that it further indicates that the amino acids of the supplementation are added in the form of free amino acids. However, as established above with regard to the main request, the ranges defining the amino acid intakes are calculated based on the total amount of amino acids present in the formulation, including those possibly present in the source of protein. Thus, the fact that the amino acids making up the supplementation are added in free amino acid form and that specific conditions are specified (in

auxiliary requests 6-9) does not change the conclusions already reached when dealing with the previous requests. Consequently, auxiliary requests 5-9 are also not allowable (Article 100(c) EPC).

Auxiliary requests 10-11

4. Claim 1 of auxiliary requests 10 and 11 differs from that of the main request in that it more specifically defines the subjects to be treated using the claimed formula, namely men or elderly people. As in the case of auxiliary requests 1-4, this limitation does not change the above-mentioned findings. Although the claims now exclude the treatment of infants, this limitation does not alter the disclosure of the application as filed, in particular with regard to the values of the amino acid intake. In other words, the interpretation of the application as filed remains unchanged, regardless of whether men or elderly people are treated.
- 4.1 Furthermore, the introduction of the word "men" in claim 1 of auxiliary request 10 also introduces new subject-matter. Page 4 of the original application, proposed by the respondent as a basis for the amendment, discloses a "healthy man". However, the men defined in claim 1 (i.e. subjects requiring treatment) cannot be healthy. Accordingly, these requests are also not allowable (Article 100(c) EPC).

Request not to admit D26-D28

5. The respondent requested that D26-D28 not be admitted in the proceedings. In view of the conclusions reached on the requests on file, the issue of the admission of these documents becomes moot, and the board does not need to rule on it.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar:

The Chairman:



M. Cañueto Carbajo

W. Sieber

Decision electronically authenticated