

Internal distribution code:

- (A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

**Datasheet for the decision
of 14 December 2018**

Case Number: T 0370/17 - 3.3.09
Application Number: 08847863.1
Publication Number: 2205100
IPC: A23J3/08, A23J3/30, A23J3/32,
A23J3/34, A23L1/305, A23L1/29
Language of the proceedings: EN

Title of invention:

METHOD FOR DECREASING BITTERNESS AND IMPROVING TASTE OF
PROTEIN-FREE AND HYDROLYZED INFANT FORMULAS

Patent Proprietor:

MJN U.S. Holdings LLC

Opponents:

Abbott Laboratories
N.V. Nutricia
HIPPI & Co.

Headword:

Relevant legal provisions:

EPC Art. 56, 123(2)
RPBA Art. 12(4)

Keyword:

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0370/17 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 14 December 2018

Appellant:
(Patent Proprietor)

MJN U.S. Holdings LLC
225 North Canal Street
25th Floor
Chicago, Illinois 60606 (US)

Representative:

Cawdell, Karen Teresa
Reckitt Benckiser, Corporate Services Limited
Legal Department - Patents Group
Dansom Lane
Hull HU8 7DS (GB)

Respondent:
(Opponent 1)

Abbott Laboratories
100 Abbott Park Rd.
Abbott Park, IL 60064-6004 (US)

Representative:

Boult Wade Tennant LLP
Verulam Gardens
70 Gray's Inn Road
London WC1X 8BT (GB)

Respondent:
(Opponent 2)

N.V. Nutricia
Eerste Stationsstraat 186
2712 HM Zoetermeer (NL)

Representative:

Nederlandsch Octrooibureau
P.O. Box 29720
2502 LS The Hague (NL)

Respondent:
(Opponent 3)

HIPP & Co.
Brünigstrasse 141
6072 Sachseln (CH)

Representative:

Schiweck Weinzierl Koch
Patentanwälte Partnerschaft mbB

Ganghoferstraße 68 B
80339 München (DE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 29 November
2016 revoking European patent No. 2205100
pursuant to Article 101(3) (b) EPC.**

Composition of the Board:

Chairman W. Sieber
Members: F. Rinaldi
 E. Kossonakou

Summary of Facts and Submissions

- I. This decision concerns the appeal filed by the patent proprietor against the decision of the opposition division to revoke European patent No. EP 2 205 100.
- II. With their respective notice of opposition, opponent 1, opponent 2 and opponent 3 requested revocation of the patent based on Article 100(a) (lack of inventive step; opponent 3 also lack of novelty), 100(b) and 100(c) EPC.

The documents cited during opposition proceedings included:

D1: US 6,506,422 B1

- III. The decision of the opposition division was based on a main request and auxiliary requests I and III. Auxiliary request II had been withdrawn at the oral proceedings without having been discussed (minutes, point 19).

Main request:

The main request contained two independent claims, claims 1 and 7. **Claim 1** read as follows:

"1. A method for decreasing the bitterness of a hydrolyzed-protein infant formula comprising:

a) intermixing a protein equivalent source, a carbohydrate source, and a fat source to produce a solution;

- b) *adjusting the pH of the solution to between 6.5 and 7.2, wherein the bitterness of the solution is reduced;*
- c) *reducing the water content of the solution to produce a powder; and*
- d) *intermixing vitamins, minerals, and the powder to produce an infant formula."*

Aside from the fact that **claim 7** referred to a protein-free infant formula, it was identical with claim 1.

Auxiliary request I:

Claim 1 of this request differed from claim 1 of the main request in that step a) read:

"a) intermixing hydrolyzed proteins as a protein equivalent source, a carbohydrate source, and a fat source to produce a solution having a pH of 4.5 to 6.0;"

Auxiliary request II (withdrawn):

Claim 1 of this request differed from claim 1 of auxiliary request I in that the "hydrolyzed proteins" in step a) of the latter were specified to be "extensively hydrolyzed proteins".

Auxiliary request III:

Claim 1 of this request was identical in wording with claim 7 of the main request.

IV. The decision of the opposition division may be summarised as follows:

The grounds of Article 100(c) and 100(b) EPC did not prejudice the maintenance of the patent.

The subject-matter of all the claims of the main request was novel over the cited prior art, whereas that of claims 1 and 7 did not involve an inventive step in view of D1 as the closest prior art.

Claim 1 of auxiliary request I contained added subject-matter.

Auxiliary request III was filed at the oral proceedings at the same time as auxiliary request II was withdrawn. The opposition division did not admit this request into the proceedings because the subject-matter of claim 1 lacked, *prima facie*, inventive step.

- V. In its statement setting out the grounds of appeal, the patent proprietor (**appellant**) requested that the decision of the opposition division be set aside and that the patent be maintained on the basis of the main request or auxiliary requests I to V filed with it.

Main request:

The main request is identical with the main request before the opposition division (see point III. above).

Auxiliary request I:

Claim 1 of this request is based on claim 1 of the main request. However, step a) reads:

"a) *intermixing a protein equivalent source, a carbohydrate source, and a fat source to produce a solution, wherein the protein equivalent source is extensively hydrolyzed proteins and the term "extensively hydrolyzed" means a degree of hydrolysis which is greater than or equal to 50%;*"

Auxiliary request II:

This request is identical with auxiliary request I filed in the opposition proceedings (see point III. above).

Auxiliary request III:

Claim 1 of this request is based on auxiliary request II. However, in step a), the term "hydrolyzed proteins" in the latter is replaced by the term "partially hydrolyzed proteins".

Auxiliary request IV:

This request is identical with auxiliary request III filed during the oral proceedings in opposition (see point III. above).

Auxiliary request V:

Claim 1 of this request is based on claim 7 of the main request (for the wording, see claim 7 in point III. above). However, in step a) the term "protein equivalent source" is replaced by the term "protein-free protein equivalent source" in the current request.

Further, the appellant filed the following document:

D40: "The Merck Index", Tenth ed., 1983, 1136

VI. In their replies to the statement setting out the grounds of appeal, both opponent 1 (**respondent 1**) and opponent 2 (**respondent 2**) requested that the appeal be dismissed and that auxiliary requests I, III, IV and V be held inadmissible. Moreover, respondent 1 filed the following document:

D41: US 5,216,129

- VII. Opponent 3 did not file any request and did not take an active part in the appeal proceedings.
- VIII. The board summoned the parties to oral proceedings and set out its preliminary opinion in a communication dated 6 August 2018.
- IX. Oral proceedings were held on 14 December 2018.
- X. The appellant's arguments relevant to the present decision may be summarised as follows:

Main request - inventive step:

Example 5 of D1 was the closest prior art. The method of claim 1 differed from this example in that (a) vitamins and minerals were added before the step of reducing the water content; (b) the taste improvement was achieved by the addition of caseino-glyco-macropeptide (**cGMP**) and not by adjustment of the pH; (c) the formula was based on free amino acids and cGMP, but not on hydrolyzed protein; and (d) the bitter amino acids were encapsulated. The technical problem was the provision of an alternative method for providing a nutrient infant formula with a pleasant taste, in particular reduced bitterness. D1 did not suggest to adjust the pH to reduce the bitter taste of the formula.

Auxiliary requests:

Auxiliary request I should be admitted, since it was filed for the first time on appeal. Basis for the amendment in claim 1 of auxiliary requests II and III was found in paragraphs [0014] to [0016] of the application as originally filed. As to auxiliary requests IV and V, a protein-free protein equivalent source was not disclosed in D1.

XI. The arguments of respondents 1 and 2 relevant to the present decision may be summarised as follows:

Main request - inventive step:

Example 5 of D1 was the closest prior art and the only distinguishing feature was the process stage at which vitamins and minerals were added. The opposition division was correct in finding that the distinguishing feature was already suggested in D1.

Auxiliary requests:

Auxiliary requests I, III and V could and should have been filed in the opposition proceedings. Therefore, they were not admissible. As to auxiliary request IV, the opposition division's decision to not admit this request into the proceedings was correct and should be confirmed. Moreover, auxiliary requests II and III included added-subject matter and auxiliary request V did not involve an inventive step, since the composition of example 5 of D1 had to be considered protein-free.

XII. The parties' **final requests** were:

The **appellant** requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or of one of auxiliary requests I to V, all requests filed with the statement setting out the grounds of appeal dated 10 April 2017.

Respondent 1 and **respondent 2** requested that the appeal be dismissed and that auxiliary requests I and III - V be held inadmissible.

Reasons for the Decision

1. In view of the fact that discussing inventive step, admissibility and added subject-matter under Article 123(2) EPC is sufficient for examining all the requests of the appellant, no reasoned decision is required on grounds under Article 100 (b) and (c) EPC.

2. Main request - inventive step

2.1 *The invention*

The invention relates to nutritional infant formulas. According to the opposed patent (paragraph [0003]), in recent years, infant formulas have been designed to reduce the incidence of protein allergies caused by cow milk protein often included in such formulas. Typically, proteins are treated with enzymes to break down some or most of the proteins that cause adverse symptoms with the goal of reducing allergic reactions, intolerance and sensitisation. Another alternative is to provide a protein-free infant formula based upon amino acids (paragraph [0004]). However, hydrolyzed protein and protein-free amino acid formulas are often characterised by a bitter taste that is not well tolerated by children. Thus, the aim of the opposed patent is to reduce bitterness in such formulas (paragraph [0005]). The solution proposed entails "intermixing a protein equivalent source, a carbohydrate source, a fat source, vitamins, and minerals in a solution and then adjusting the pH of the formula to between 6.5 and 7.2" (paragraph [0007]).

2.2 *The closest prior art*

2.2.1 It is common ground that example 5 of D1 is the closest prior art.

2.2.2 D1 is directed to a nutritional formula suitable as a complete diet for patients suffering from phenylketonuria (**PKU**) comprising a protein source comprising caseino-glyco-macropptide (**cGMP**) and complementary essential amino acids other than phenylalanine (**Phe**) (claim 1). Formulas for PKU patients are typically produced from protein hydrolysates from which the Phe was removed, or they are made up of mixtures of free amino acids (column 1, line 33 to 40). However, both types of formula "have an extremely bitter taste which is not completely masked by the additional ingredients of the formulas such as sugars" (column 1, line 43 to 46). The formulas according to D1 are suitable for PKU patients, have improved taste and provide a substantially balanced amino acid profile low in Phe.

2.2.3 Example 5 of D1 discloses a process for preparing an infant formula in which a carbohydrate source, a protein source and a mixture of oils is combined with water. The protein source comprises 49% cGMP, the remainder being complementary amino acids. The mixture is then homogenized, vitamins and minerals are added and the pH is standardised to 6.7 to 6.9. The mixture is then spray-dried to provide a powder.

2.3 *Distinguishing features:*

2.3.1 According to the appellant, example 5 of D1 differed from the method of claim 1 by the following features:

- (a) the vitamins and minerals were added before adjusting the pH (and not, as claimed, after adjusting the pH);
- (b) the taste improvement was achieved by using cGMP as the protein source (and not, by adjusting the pH);
- (c) D1 related to a formula suitable for PKU patients based on cGMP and was not a hydrolyzed-protein infant formula; and
- (d) the reduction of bitterness was also achieved by encapsulation of the amino acids.

2.3.2 *Distinguishing feature (a)*

It was uncontested that feature (a) is a distinguishing feature. The board concurs with this.

2.3.3 *Distinguishing feature (b)*

It was a matter of dispute whether the feature "for decreasing the bitterness of a hydrolyzed-protein infant formula" in claim 1 was a limiting feature. For the appellant, a difference resided in the fact that the claimed process was carried out with the *purpose* of reducing the bitterness.

In the appealed decision (Reasons for the decision, point 6.4), the opposition division explained that claim 1 was drafted such that a particular purpose was aimed at (decreasing bitterness) in combination with physical steps resulting in the production of a product (infant formula). It then continued that in such a case "the intended purpose of the method (production of a product) is to be understood in the sense that the

method or process has to be merely suitable for that use, rather than comprising the use as an integral method step (Case Law Book 8th edition, I.C.8.1.3, page 151; T304/08; Guidelines F-IV 4.13). Consequently, the production of an infant formula in D1 without an indication of the particular purpose of reducing bitterness, although the method is nevertheless suitable for it, anticipates a method for that particular purpose."

The board agrees with the opposition division's interpretation of claim 1 and notes that the appellant has not disputed the claim interpretation adopted by the opposition division. Consequently, the method of claim 1 relates to a method *suitable for* decreasing the bitterness of a hydrolyzed-protein infant formula.

In fact, the technical problem identified in D1 is that a formula containing hydrolyzed proteins or amino acids has an extremely bitter taste (column 1, line 43 to 44) and an aim described in D1 is to provide a formula having a good taste (column 2, line 37). This is achieved by the formula of example 5 (column 11, line 25). Thus, the process disclosed in this example is suitable for reducing the bitterness of the infant formula.

As regards the appellant's argument that the taste improvement was achieved by adjusting the pH, the board agrees with respondent 1 that in the pH adjustment step (b) of claim 1, the feature that "the bitterness of the solution is reduced" is not a limitation but simply a fact. According to the opposed patent, if the pH is adjusted to be between 6.5 and 7.2, the bitterness of the solution is reduced. Consequently, if the pH is adjusted in example 5 of D1, the bitterness

of the solution is also inherently reduced, even if it does not explicitly disclose this.

Thus, feature (b) cannot be considered a distinguishing feature over example 5 of D1.

2.3.4 *Distinguishing feature (c)*

The protein source of the infant formula in example 5 of D1 comprises 49% by weight of cGMP, the remainder being complementary amino acids. According to the appellant, these two components were not hydrolyzed proteins within the meaning of the patent in suit. The board disagrees.

The opposed patent does not give a definition for a hydrolyzed protein but defines in paragraphs [0010] and [0011] the term "partially hydrolyzed" to mean a degree of hydrolysis greater than 0% but less than about 50% and the term "extensively hydrolyzed" to mean a degree of hydrolysis greater than or equal to about 50%. Consequently, any protein having a degree of hydrolysis greater than 0% qualifies as a hydrolyzed protein.

The board agrees with respondent 2 that given the rather broad definition in the patent, amino acids can be considered to be extensively hydrolyzed proteins, the degree of hydrolysis being 100%.

As to the cGMP-fraction of this example, the definition of hydrolyzed protein derivable from the opposed patent is broad enough to encompass any protein that has undergone a cleavage step, even the cleavage of a single peptide bond. The appellant itself explained in the statement setting out the grounds of appeal

(page 11, second full paragraph) that cGMP is obtained by (enzymatic) hydrolysis of kappa-casein. It follows from this that the cGMP used in example 5 of D1 must also be regarded as a hydrolyzed protein. Thus, the infant formula of example 5 contains two types of hydrolyzed protein, namely, amino acids and cGMP.

The appellant made reference to document D40 (or to D1) to interpret the "hydrolyzed protein" feature of claim 1. However, what matters for establishing the scope of the claim is what the opposed patent itself states regarding the definition of (partially or extensively) hydrolyzed protein. Consequently, in the context of the present case, it does not matter that other documents may adopt different definitions. Furthermore, D40 does not include a universally accepted definition of "hydrolyzed protein". Instead, it relates to a *sterile* solution of amino acids with a specific nutritive value. From this, it can only be deduced that the definition in D40 concerns a particular type of protein preparations.

The appellant also argued that cGMP is a fully intact protein. However, the fact that cGMP is classified as a macro**peptide** rather than a protein casts doubt on this argument. The term "protein hydrolysates" does not exclude the presence of peptides such as those obtained from kappa-casein by the enzymatic cleavage with chymosin into two defined products, cGMP and para-kappa-casein.

With regard to the appellant's argument that the formula of example 5 does not comprise significant amounts of Phe, the board notes that the presence of Phe is not a feature of claim 1 of the main request. In fact, the claims of all the requests relate to a

protein source in general. Therefore, they encompass the embodiments of D1 which contain a protein source without Phe.

The board concludes that feature (c) cannot be regarded as a distinguishing feature over example 5 of D1.

2.3.5 *Distinguishing feature (d)*

The appellant finally argued that in D1, the amino acids did not have a bitter taste due to their encapsulation. The board acknowledges that D1 states (column 5, lines 33 to 35) that it is "possible to encapsulate those essential amino acids which impart an unpleasant taste" and that in example 4 encapsulated proteins are used. However, as respondent 1 correctly stated at the oral proceedings, example 5 (contrary to example 4) does not contain the header "Encapsulated Formula" and does not describe process steps leading to encapsulated proteins. Consequently, there is no reason to regard the protein equivalent source used in D5 as being in encapsulated form. In this context, it is worth mentioning that encapsulation is not excluded by the wording of claim 1.

Thus, feature (d) cannot be regarded as a distinguishing feature over example 5 of D1.

2.3.6 It follows from this that feature (a), i.e. the sequence of preparation steps, is the only distinguishing feature of the subject-matter of claim 1 with respect to D1.

2.4 *Objective technical problem*

In view of the only distinguishing feature and the absence of any technical effect due to this difference, the board agrees with the opposition division that the objective technical problem is the provision of an alternative infant formula having a good taste. The board has no doubt that this problem is in fact solved by the claimed subject-matter.

2.5 *Obviousness*

In the appealed decision, the opposition division found that D1 suggested that vitamins and minerals could be added at a later stage, after the heat treatment, to avoid thermal degradation (column 6, lines 24-26). The appellant has not disputed this aspect of the appealed decision. The board agrees with the decision that this statement in D1 provides a hint for the skilled person to arrive at the solution of adding vitamins and minerals after pH adjustment and water reduction.

2.6 *Conclusion*

The subject-matter of claim 1 does not involve an inventive step (Article 56 EPC).

3. *Auxiliary request I*

3.1 Respondents 1 and 2 requested that auxiliary request I, not be admitted into the appeal proceedings since this request could have been presented earlier, namely, in the opposition proceedings.

3.2 This request relates to a protein equivalent source which is "extensively hydrolyzed proteins". An auxiliary request which, *inter alia*, relied on this feature as a potential distinguishing feature had been filed in opposition proceedings (auxiliary request II). However, this request had been withdrawn at the oral proceedings (see points III. and IV. above), and no request was pursued where the patent proprietor relied on "extensively hydrolyzed protein" as a distinguishing/inventive feature. Effectively, the patent proprietor prevented the opposition division from considering the "extensively hydrolyzed protein" feature and thereby avoided a decision of the opposition division on how to interpret this potential distinguishing feature.

3.3 In view of these considerations, this request could and should have been presented and discussed in opposition proceedings and is therefore inadmissible (Article 12(4) RPBA).

4. Auxiliary request II

4.1 This request was filed as auxiliary request I in the opposition proceedings. Claim 1 of this request has been amended by, *inter alia*, introducing the definition that the solution has a pH of 4.5 to 6.0. The appellant indicated paragraph [0015] of the application as filed as the basis for the amendment.

4.2 Paragraph [0015] reads as follows:

"Typical hydrolyzed or protein-free infant formulas have a pH range of about 4.5 to 6.0. In a particular embodiment of the invention, the method

involves increasing the pH of the infant formula from between about 4.5 and 6.0 to between about 6.8 and 7.2."

- 4.3 The board agrees with respondent 1 that this passage relates to typical (possibly prior art) infant formulas, which have a pH between 4.5 and 6.0. This passage, even when read in combination with paragraphs [0014] and [0016], does not relate to the solution of step a) of claim 1 or the sequence of steps a) to d) of claim 1. Rather, the passage of paragraph [0015] relates to example 3 of the opposed patent where the pH of the final (reconstituted) formula is adjusted.
- 4.4 Therefore, the board is not persuaded that the amendment in claim 1 is directly and unambiguously derivable from the application as originally filed, in particular, it is not based on paragraph [0015]. The requirements of Article 123(2) EPC are thus not fulfilled.
5. Auxiliary request III
- 5.1 The board saw no reason for finding this request inadmissible. However, since the request failed for another reason, no further elaboration on this issue is necessary.
- 5.2 This request corresponds to auxiliary request II, in which the subject-matter of claim 1 is further delimited by stating that *partially* hydrolyzed proteins are used as the protein equivalent source.

5.3 Nevertheless, this request still includes the feature of adjusting the solution to a pH in the range of 4.5 to 6.0. Thus, for the same reasons explained in points 4.3 and 4.4 above, this amendment adds subject-matter (Article 123(2) EPC), which makes the request not allowable.

6. Auxiliary request IV

6.1 This request was filed as auxiliary request III in the opposition proceedings. The opposition division did not admit this request into the proceedings because it considered that it did not, *prima facie*, comply with the requirements of inventive step. This was explained in the reasons for the decision (point 8.3).

6.2 In the statement setting out the grounds of appeal, the appellant did not argue that it considered the opposition division's exercise of discretion incorrect. In other words, the appellant has not set out why it requests that the opposition division's decision on this aspect be reversed or amended. Thus, the board can only confirm the decision of the opposition division and holds auxiliary request IV inadmissible (Article 12(4) RPBA).

7. Auxiliary request V

7.1 Claim 1 of this request is based on claim 7 of the main request (for the wording, see claim 7 in point III. above). However, the term "protein equivalent source" in step a) is replaced by the term "protein-free protein equivalent source" in the current request.

- 7.2 At the oral proceedings, the question arose as to whether defining the protein equivalent source as being protein-free might change the assessment of inventive step.
- 7.3 As explained above in point 2.3.4, the infant formula prepared in example 5 of D1 contains amino acids and cGMP as the protein equivalent source, which the board regards as hydrolyzed proteins. In the context of this request, the issue to be decided is whether the protein equivalent source cGMP is a protein-free protein equivalent source.
- 7.4 As discussed during the oral proceedings, the board is not aware of a generally accepted definition of a minimum size or minimum molecular weight above which a (macro)peptide is considered a protein. More importantly, neither the claims nor the description of the opposed patent define precisely what the term "protein-free" means. In paragraph [0004], a protein-free formula of the prior art is discussed. However, this has no bearing on how to interpret claim 1. In paragraph [0012] of the opposed patent, the term "protein-free" is defined as **"no measurable amount of protein, as measured by standard protein detection methods** such as sodium dodecyl (lauryl) sulfate-polyacrylamide gel electrophoresis (SDS-PAGE) or size exclusion chromatography" (emphasis added by the board). The board agrees with respondent 1 that this term is equated with an absence of protein, but it says nothing about the peptides which can be obtained from such proteins. The board also agrees with respondent 2 that there are not sufficient details regarding the specific detection methods to be used. In other words, the definition in paragraph [0012] does not allow to discriminate between what the "protein-free" feature

(which occurs twice in the wording of claim 1) includes and what it excludes.

- 7.5 Thus, with respect to the disclosure of example 5 of D1, the subject-matter of claim 1 of auxiliary request V does not contain any additional distinguishing feature, compared with the subject-matter of claim 1 of the main request.
- 7.6 Therefore, the subject-matter of claim 1 still does not involve an inventive step (Article 56 EPC). Therefore, the request is not allowable and a formal decision on admissibility is unnecessary.
8. In summary, none of the appellant's requests is allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Cañueto Carbajo

W. Sieber

Decision electronically authenticated