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Datasheet for the decision of 18 August 2015

Case Number: T 1843/13 - 3.3.09

Application Number: 06791959.7

Publication Number: 1933644

IPC: A23L1/29, B65D1/02

Language of the proceedings: EN

Title of invention:
NUTRITIONAL CONCENTRATE FOR INFANTS

Patent Proprietor:
Van Haren, Han Pierre

Opponent:
N.V. Nutricia

Headword:

Relevant legal provisions:
RPBA Art. 13(1)
EPC Art. 56

Keyword:
Late-filed request - admitted (yes)
Inventive step (yes)

Decisions cited:

Catchword:

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Case Number: T 1843/13 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 18 August 2015

Appellant: (Patent Proprietor)	Van Haren, Han Pierre Weltersweide 18 5961 E J HORST (NL)
Representative:	Algemeen Octrooi- en Merkenbureau B.V. P.O. Box 645 5600 AP Eindhoven (NL)
Respondent: (Opponent)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 26 June 2013 revoking European patent No. 1933644 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman W. Sieber
Members: J. Jardón Álvarez
F. Blumer

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the proprietor of European patent No. 1 933 644 against the decision of the opposition division to revoke the patent.

II. The granted patent contained 8 claims, independent claims 1 and 4 reading as follows:

"1. A method for the preparation of an infant formula concentrate to be used in a package containing a nutritional concentrate for infants comprising the for an infant food essential nutritional components, wherein the method comprises the following steps:

i) preparing in water of a mixture of nutritional components, except fat components,

ii) adding fat components to the mixture according to step i),

iii) adjusting the pH value of the mixture according to step ii), if necessary,

iv) adjusting the amount of dry solid contents of the mixture according to step iii), and

v) supplying the mixture obtained according to step iv) in separate single doses,

wherein the mixture obtained after step iv) is sterilized, and after said sterilization treatment step v) is carried out, or the single doses obtained after step v) are sterilized, wherein the dry solid content of the concentrate lies between 36-75% by

weight, on basis of the total weight of said concentrate, wherein the amount of said infant formula concentrate is suitable to be used as single dose, in which said infant formula concentrate, if necessary, is diluted with a predetermined amount of diluent."

"4. A method for the preparation of an infant formula concentrate to be used in a package containing a nutritional concentrate for infants comprising the for an infant food essential nutritional components, wherein the method comprises the following steps:

x) preparing a first mixture of nutritional carbohydrate free protein components in water,

xi) adding fat components to the mixture according to step x),

xii) sterilizing the mixture obtained after step xi),

xiii) transferring the mixture thus sterilized to a tank,

xiv) separately preparing a second mixture of nutritional components containing carbohydrate,

xv) sterilizing the mixture according to step xiv),

xvi) transferring the mixture thus sterilized according to step xv) to the tank,

xvii) adding one or more sensitive components to the tank,

xviii) adjusting the dry solid content of the mixture obtained after step xvii), and

xix) supplying the mixture obtained after step xviii) to individual single doses,

wherein the dry solid content of the concentrate lies between 36-75% by weight, on basis of the total weight of said concentrate, wherein the amount of said infant formula concentrate is suitable to be used as single dose, in which said infant formula concentrate, if necessary, is diluted with a predetermined amount of diluent."

The remaining claims were directly or indirectly dependent on claims 1 and/or 4.

III. The opponent had requested revocation of the patent in its entirety on the grounds of Article 100(a) (lack of novelty and inventive step), (b) and (c) EPC.

The documents cited during the opposition proceedings included:

D1: WO 2006/099013 A2;

D2: WO 2006/077259 A1;

D3: US 3 052 555 A;

D6: WO 02/089591 A1;

D7: US 5 013 569 A; and

D8: US 5 000 314 A.

IV. The opposition division's decision can be summarised as follows:

- The subject-matter of the claims did not extend beyond the content of the application as filed; the invention was sufficiently disclosed; the priority date was validly claimed and the claimed subject-matter was novel over D1 and D2.

- Starting from D7 as closest prior art, in combination with common general knowledge, the claimed subject-matter lacked inventive step.

V. On 23 August 2013 the patent proprietor (in the following: the appellant) lodged an appeal and paid the prescribed fee. The statement setting out the grounds of appeal was filed on 4 November 2013. In it, the appellant requested that the decision under appeal be set aside and that the patent be maintained as granted.

VI. With its reply dated 27 February 2014 the opponent (in the following: the respondent) argued that claim 1 as granted lacked novelty over D1, and that the subject-matter of granted claims 1 and 4 was not inventive in view of D7. It requested that the appeal be dismissed.

VII. In a communication dated 15 April 2015 the board indicated the points to be discussed during the oral proceedings.

VIII. With letter dated 16 July 2015, the appellant filed further arguments in support of its main request, together with three auxiliary requests.

IX. With letter dated 7 August 2015, the respondent replied to the appellant's submissions and filed the following documents:

D11: WO 2004/054371 A2; and

D12: US 6 099 871 A.

X. Oral proceedings before the board were held on 18 August 2015. After the board had come to the conclusion that the subject-matter of claim 1 as granted was not inventive and that the first auxiliary request appeared to be allowable, the appellant withdrew its pending main request (claims as granted). Then it filed an amended version of the first auxiliary request and an adapted description which became its sole request. Apart from a correction of two typing errors, newly filed claims 1 to 6 were identical to the claims of the previous first auxiliary request. The respondent had no objection in this respect.

Independent claims 1 and 3 of the sole request read as follows (amendments over claims 1 and 4 as granted in bold; added by the board):

"1. A method for the preparation of an infant formula concentrate to be used in a package containing a nutritional concentrate for infants comprising the for an infant food essential nutritional components wherein the method comprises the following steps:

i) preparing in water of a mixture of nutritional components, except fat components,

ii) adding fat components to the mixture according to step i),

iii) adjusting the pH value of the mixture according to step ii), if necessary,

iv) adjusting the amount of dry solid contents of the mixture according to step iii), and

v) supplying the mixture obtained according to step iv) in separate single doses,

wherein the mixture obtained after step iv) is sterilized, and after said sterilization treatment step v) is carried out, or the single doses obtained after step v) are sterilized, wherein the dry solid content of the concentrate lies between **45-60**% by weight, on basis of the total weight of said concentrate, wherein the amount of said infant formula concentrate is suitable to be used as single dose, in which said infant formula concentrate, if necessary, is diluted with a predetermined amount of diluent."

"3. A method for the preparation of an infant formula concentrate to be used in a package containing a nutritional concentrate for infants comprising the for an infant food essential nutritional components, wherein the method comprises the following steps:

x) preparing a first mixture of nutritional carbohydrate free protein components in water,

xi) adding fat components to the mixture according to step x),

xii) sterilizing the mixture obtained after step xi),

xiii) transferring the mixture thus sterilized to a tank,

xiv) separately preparing a second mixture of nutritional components containing carbohydrate,

xv) sterilizing the mixture according to step xiv),

xvi) transferring the mixture thus sterilized according to step xv) to the tank,

xvii) adding one or more sensitive components to the tank,

xviii) adjusting the dry solid content of the mixture obtained after step xvii), and

xix) supplying the mixture obtained after step xviii) to individual single doses,

wherein the dry solid content of the concentrate lies between **45-60**% by weight, on basis of the total weight of said concentrate, wherein the amount of said infant formula concentrate is suitable to be used as single dose, in which said infant formula concentrate, if necessary, is diluted with a predetermined amount of diluent."

Claims 2 and 4 to 6 correspond to claims 3 and 6 to 8 as granted.

XI. The arguments of the appellant, insofar as they are relevant for the present decision, may be summarised as follows:

- The new request should be admitted into the proceedings because it had been filed one month before the oral proceedings, giving the respondent enough time to prepare its case. The claims did not contain any subject-matter which extended beyond the content of the application as filed; they were based only on granted claims.

- The subject-matter of the claims involved an inventive step. The value of the total solid content of the infant formula concentrates now claimed resulted in advantageous concentrates not derivable from the cited prior art. The infant formulae obtained by the claimed method combined the benefits of the ready-to-feed liquid products and powders. D7 dealt with a different problem, namely the preparation of infant formulas having a fatty acid composition that mimicked human milk and gave no hint to the total solid contents now claimed. Moreover, the skilled person would not combine the teaching of D7 with the teaching of D6 that was directed to a method for producing ultra-pasteurised milk concentrates by heating a milk starting product.

XII. The relevant arguments of the respondent may be summarised as follows:

- The appellant's request had been filed at a very late stage of the appeal proceedings without any plausible reasoning. It should have been filed during the opposition proceedings and should not be admitted into the appeal proceedings.

- The claimed subject-matter lacked inventive step starting from D7 as closest prior-art document in

view of the common general knowledge of the skilled person. There was no technical effect associated with the dry solid content claimed in the application as filed. Concentrates with a value within the claimed range were in any case already known in prior art as represented, for instance, by D6 and/or D3. Insofar as it would be obvious for the skilled person to arrive at the claimed range, any effect within the range would be a bonus effect that could not justify an inventive step.

XIII. The appellant requested at the end of the oral proceedings that the decision under appeal be set aside and that the patent be maintained on the basis of claims 1 to 6 filed during the oral proceedings (sole request).

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. Admissibility of the appellant's request

1.1 One month before the oral proceedings before the board, the appellant filed a first auxiliary request. During the oral proceedings two typing errors were corrected and this amended "first auxiliary request" became appellants' sole request.

1.2 The respondent contested its admissibility because the request was filed at a late stage of the proceedings without any explanation as to why the amendments made overcame the objections raised.

1.3 According to Article 13(1) of the Rules of Procedure of the Boards of Appeal (RPBA) any amendment to a party's case after it has filed its grounds of appeal may be admitted and considered at the board's discretion. The discretion has to be exercised in view of *inter alia* the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

1.4 Amended claim 1 results from the combination of granted claims 1 and 2, and amended claim 3 results from the combination of granted claims 4 and 5. The only amendment made in these two claims is the limitation of the dry solid content in the infant formula concentrate from between 36 to 75% by weight to between 45 and 60% by weight, which was the subject-matter of granted claims 2 and 5 respectively.

The respondent had already considered the subject-matter of granted claims 2 and 5 in its notice of opposition. Furthermore, the range between 45 and 60% by weight is identified as a preferred embodiment not only in granted claims 2 and 5 but also in paragraph [0025] of the patent specification, and advantages associated with this range are reported in paragraph [0029]. Thus, the amendments made do not confront the respondent with facts, evidence or arguments not yet in the proceedings, and do not give rise to new issues (e.g. support and clarity).

1.5 Under these circumstances the request was, in spite of its late submission, admitted by the board into the proceedings (Article 13(1) RPBA).

2. Framework of the appeal

The only objection raised by the respondent against the present claims is that they lack inventive step.

3. Inventive step

3.1 The patent relates to methods for the preparation of an infant formula concentrate to be used in a package containing a nutritional concentrate for infants comprising the components essential for an infant food (see paragraph [0001] of the specification). Infant formulae are usually manufactured as powder or liquids and both formulations have some drawbacks in terms of safety, nutrition, handling, and costs (see table on page 3 of the specification). The invention aims to overcome some of these drawbacks by providing highly concentrated infant formulae (see paragraphs [0019] and [0020]).

3.2 Independent claims 1 and 3 are directed to methods for the preparation of infant formula concentrates wherein the dry solid content of the concentrate lies between 45-60% by weight, based on the total weight of the concentrate.

The method of claim 1 comprises the preparation in water of a mixture of nutritional components, except fat components; addition of the fat components; adjustment of the pH, if necessary; sterilisation and packaging in single doses (see claim 1, point X above). The method of claim 3 is similar but the ingredients are heated and transferred into a sterile tank separately, one after the other (see claim 3, point X above).

3.3 Closest prior art

3.3.1 Both parties considered that D7 represented the closest prior-art document. It is directed to an infant food formula approximating human milk comprising a mixture of docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) in a certain ratio, immunoglobulins, proteins, carbohydrates and sufficient water to provide an easily assimilable infant formula, the DHA, EPA and immunoglobulins being micro-encapsulated (see claim 1).

3.3.2 The infant formula of D7 is prepared by dissolving the fat-soluble vitamins in the mixture of fatty acids, and the remaining ingredients in water. Then the fat mixture and the water solution are mixed and homogenised (see column 4, lines 37 to 42). The infant formula is sterilised and subsequently used on a ready-to-feed basis, or stored as a concentrate (see column 4, lines 45 to 47). Typical formulations in the form of concentrated liquids have a total solids content of 12-36 w/v % (column 7, lines 1 to 14). As pointed out in the decision under appeal and as confirmed by both parties, these values will be slightly lower when based on the weight of the concentrate (w/w %).

3.3.3 The method of claim 1 differs from the method of D7 essentially by:

i) providing a concentrate with a high total solid content in the range of between 45% and 60% by weight, on the basis of the total weight of the concentrate; and

ii) supplying the formula in individual doses.

The method of claim 3 differs from the method of D7 additionally by:

iii) separately heating and mixing the sensitive ingredients.

3.4 Problem to be solved and its solution

3.4.1 According to the appellant, the problem underlying the patent in the light of D7 is to provide an improved method for the preparation of an infant formula concentrate which has the benefits of ready-to-feed liquid products and powders (see [0023]).

3.4.2 The board is satisfied that this problem has been credibly solved by the claimed methods. The examples in the patent show the preparation of infant formulae with a total solid content within the limited range of between 45-60% by weight, based on the total weight of the concentrate. Moreover, in this specific range the volume of concentrate is said to be smaller than the volume of the same formula produced as a powder, the reason being the high density of the concentrate (see paragraph [0029] of the specification). This has not been contested by the respondent.

3.5 Obviousness

3.5.1 It remains to be decided whether, in view of the available prior-art documents, it would have been obvious for the skilled person to solve the above-mentioned problem by the claimed method. In particular it is to be clarified whether in the prior art, there is a hint to the distinguishing features.

3.5.2 Concerning the method of claim 1 the board agrees with the respondent that it is within the general knowledge of the skilled person to supply the infant formula in individual doses in order to avoid the risk of contamination (see for instance D8, column 2, lines 1 to 4 and 31 to 33). This feature is therefore obvious for the skilled person.

3.5.3 On the other hand, the finding that concentrates with a rather high solid content, in the range between 45 and 60% by weight, are advantageous compared to the powder formulations cannot be derived from the available prior art.

3.5.4 Document D7 itself gives no hint. The range therein used for the concentrate (a value slightly below 36% by weight as the upper limit) is well below the range now claimed. There is no suggestion in D7 of preparing any other concentrates. In fact, the invention of D7 is directed to specific DHA:EPA ratios and the micro-encapsulation of DHA, EPA and immunoglobulins rather than any variation in concentrated liquids.

3.5.5 There is also no other document on file dealing with the preparation of infant formula concentrates having a solid content between 45 and 60% by weight, let alone mentioning the advantageous effect associated with this range. In particular D3 and D6, relied upon by the respondent, do not provide a hint to the claimed range.

D3 is directed to a method of preparing canned infant milk formula. As pointed out by the appellant, D3 starts with cow's milk whereas the claimed methods require starting with water, resulting in a different type of infant formula. In the method of D3, substantially all the fat content is removed, and the

skim milk is then evaporated to a solid content between 27 and 37% and heated under specific conditions prior to adding further nutritional ingredients (column 1, line 59 to column 2, line 11). D3 is silent as regards the solid content of the final infant formula. The values of 27 to 37% mentioned above refer to an intermediate mixture that is blended with further ingredients.

D6 relates to a method of producing ultra-high-temperature liquid milk concentrate package. Quite apart from the fact that D6 again starts from milk, it does not relate at all to the preparation of infant formulae but to condensed milk. The passage on page 20, lines 7 to 9 cited by the respondent reads: "The milk concentrate includes a total milk solids content of from about 40% to about 46% by weight when it is running through the direct steam injection system, homogenizer, and cooling condenser". It may be true that milk can be concentrated up to 46% by weight, but D6 gives no hint to this in an infant formula concentrate in the expectation of the advantageous properties pointed out above.

3.5.6 Lastly, the respondent also argued that it would have been obvious to the skilled person from common general knowledge to prepare concentrates with a higher solid content than those of D7. Hence, the obtained advantages within the range of 45 to 60% was to be considered merely as a bonus effect.

However, in the board's view, this objection is based on knowledge of the invention and cannot be used to argue that the invention was obvious. Normally, advantages disclosed in the patent can be used to define the objective technical problem, as long it is

plausible that said objective technical problem is solved by the claimed features. In the present case, the board sees no reason to deviate from this approach.

3.6 For this reason, the subject-matter of claim 1 involves an inventive step. This conclusion also applies to the method of independent claim 3 that includes the same feature and, for the same reasons, to the preferred embodiments defined in dependent claims 2 and 4 to 6.

4. During the oral proceedings the appellant filed a description adapted to the amended claims. The amendments were discussed with the respondent, which had no objections in this context.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the following documents:

   - claims 1 to 6 as filed during oral proceedings before the board on 18 August 2015;

   - description pages 2 to 9 as filed during oral proceedings before the board on 18 August 2015; and

   - figure as published (page 13 of the patent specification).

The Registrar: The Chairman:

M. Cañueto Carbajo W. Sieber

Decision electronically authenticated