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**Datasheet for the decision
of 4 February 2016**

Case Number: T 1400/14 - 3.3.09

Application Number: 05075390.4

Publication Number: 1535520

IPC: A23L1/29, A23L1/30

Language of the proceedings: EN

Title of invention:

Infant formula containing prebiotic additive

Patent Proprietor:

N.V. NUTRICIA

Opponent:

Friesland Brands B.V.

Headword:

Relevant legal provisions:

EPC Art. 76(1)

Keyword:

"All requests: Extension beyond the content of the earlier application as filed (yes)"

Decisions cited:

T 0686/99

Catchword:



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Case Number: T 1400/14 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 4 February 2016

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 4 June 2014
revoking European patent No. 1535520 pursuant to
Article 101(3) (b) 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. 1 535 520 against the decision of the opposition division to revoke the patent.

II. The granted patent originated from a divisional application of the earlier European patent application No. 00991317.9 and contained 19 claims, independent claim 1 reading as follows:

"1. An infant formula suitable for infants of less than 6 months old, comprising:

- a. at least one protein component;
- b. at least one lipid component, in which palmitic acid residues make up between 10 and 30% of all fatty acid residues present in the triglycerides and of these palmitic acid residues at least 30% is in the Sn2 position of the triglycerides;
- c. at least one prebiotic component, wherein said prebiotic component comprises galacto-oligosaccharides;
- d. one or more nucleotides; and
- e. a calcium content of above 50 mg/100 kcal, and less than 80 mg/100 kcal."

Claim 18 was directed to the use of components a) to d) for preparing a nutritional composition for feeding infants of less than 6 months old, said composition having a calcium content of above 50 mg/100 kcal, and less than 80 mg/100 kcal.

Claims 2 to 17 and 19 were dependent claims.

- III. With the notice of opposition 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.
- IV. The opposition division's decision was based on a main request (claims as granted) and nine auxiliary requests. It can be summarised as follows:
- The subject-matter of claim 1 of all requests extended beyond the content of the parent application as filed (D1: WO 01/41581 A1). The claimed embodiments resulted from several selections out of equally preferred components disclosed in the parent application as filed. There was no pointer to the specifically claimed combinations. As a consequence, none of the requests met the requirements of Articles 100(c)/123(2) EPC.
 - The opposition division did not deal with other patentability issues.
- V. The patent proprietor (in the following: the appellant) lodged an appeal and filed the statement setting out the grounds of appeal on 7 October 2014, including auxiliary requests 1 to 5. The appellant requested that the decision under appeal be set aside, that the compliance of the main request (claims as granted) or of any of auxiliary requests 1 to 5 with Articles 123(2) and (3) and 84 EPC be acknowledged by the board and that the case be remitted to the opposition division for the further consideration of sufficiency of disclosure, novelty and inventive step.

- VI. With its reply dated 18 February 2015 the opponent (in the following: the respondent) requested that the appeal be rejected as inadmissible, auxiliarily, that the appeal be dismissed. It also supported the appellant's request for remittal if any of the claim requests was seen by the board as complying with Article 123(2) EPC.
- VII. In a communication dated 4 August 2015 the board indicated the points to be discussed during the oral proceedings.
- VIII. Oral proceedings before the board were held on 4 February 2016. At the beginning of the proceedings the appellant withdrew its main request and the respondent withdrew its request that the appeal be rejected as inadmissible.

Claim 1 of auxiliary request 1 reads as follows:

"1. An infant formula suitable for infants of less than 6 months old, comprising:

- a. at least one protein component;
- b. at least one lipid component, in which palmitic acid residues make up 16-24% of all fatty acid residues present in the triglycerides and of these palmitic acid residues at least 30% is in the Sn2 position of the triglycerides;
- c. at least one prebiotic component, wherein said prebiotic component comprises one or more trans-galacto-oligosaccharides;
- d. one or more nucleotides; and
- e. a calcium content of above 50 mg/100 kcal, and less than 80 mg/100 kcal."

Claim 1 of auxiliary request 2 differs from claim 1 of auxiliary request 1 in that component c) is defined as follows:

"c. at least one prebiotic component, wherein said prebiotic component comprises a mixture of one or more trans-galacto-oligosaccharides and one or more fructo-oligosaccharides;"

Claim 1 of auxiliary request 3 reads as follows (difference over claim 1 of auxiliary request 2 in bold):

"1. An infant formula suitable for infants of less than 6 months old, comprising:

- a. at least one protein component **being a hydrolysate obtained by the hydrolysis of one or more milk proteins from cow's milk;**
- b. at least one lipid component, in which palmitic acid residues make up 16-24% of all fatty acid residues present in the triglycerides and of these palmitic acid residues at least 30% is in the Sn2 position of the triglycerides;
- c. at least one prebiotic component, wherein said prebiotic component comprises a mixture of one or more trans-galacto-oligosaccharides and one or more fructo-oligosaccharides **in which the ratio of TOS-to-FOS is between 5:1 and 15:1;**
- d. one or more nucleotides; and
- e. a calcium content of above 50 mg/100 kcal, and less than **77** mg/100 kcal."

Claim 1 of auxiliary request 4 is based on claim 1 of auxiliary request 3, wherein the protein component a) has been further defined to specify that:

"..., wherein the protein component has a phosphorus content of less than 0.75 g P per 100 g protein;"

Claim 1 of auxiliary request 5 is based on claim 1 of auxiliary request 4, with the further limitation that the amount of the palmitic acid residues in the Sn2 position of the triglycerides is "at least 40%" (instead of "at least 30%").

IX. The arguments of the appellant may be summarised as follows:

- Contrary to the view of the opposition division, there was no need for the skilled person to select each of the features of the claim from lists of equally preferred alternatives. Other than the nucleotides, the calcium content, the specific lipid ingredient and the prebiotic ingredient were all preferred embodiments which the skilled person would consider when reading the application as whole.

- The specification provided support for an infant formula with a combination of protein, lipid and prebiotic and a further component. Moreover, the preferred lipid component and the amount of calcium were directly and unambiguously mentioned in connection with one another, and were thus part of a preferred infant formula. Infants of less than 6 months were a particular group mentioned in the application. The choice of nucleotides was the only selection to be made when preparing a calcium-restricted infant formula for infants up to 6 months of age, and it involved a single selection of a further ingredient. This was not to be

considered an amendment introducing subject-matter which extended beyond the content of the original application, since there was no new technical information associated with this limitation.

- The auxiliary requests were restricted in terms of preferred protein, lipid and prebiotic components and limited calcium content, in accordance with the summary of the invention ascribing the advantages to such compositions compared with those commercially available. They would overcome the literal approach of the opposition division to the subject-matter of granted claim 1.
- X. The relevant arguments of the respondent may be summarised as follows:
- The respondent supported the line of argumentation of the opposition division. Additionally, it argued that the claims of auxiliary request 1 allowed for any protein to be used, while only specific proteins were disclosed in the parent application. Moreover, the claims contained several items singled out from more than one list. Nowhere in the parent application was it suggested that the singled out features taken together were associated with any technical effect, let alone any unexpected technical effect.
 - Lastly, contrary to what the appellant maintained, the nucleotides were not selected from a list of further components. The further components were mentioned in the application as filed to be added in addition to the four components previously recited. The selection of one nucleotide from this list did not result in an infant formula as

claimed, but in an infant formula further containing one viscosity-improving component.

- XI. The appellant requested that the decision under appeal be set aside, that the compliance of any of auxiliary requests 1 to 5 as filed on 7 October 2014 with Articles 123(2) and (3) and 84 EPC be acknowledged and that the case be remitted to the opposition division for the further consideration of sufficiency of disclosure, novelty and inventive step. Subsidiarily, the appellant requested that the patent be maintained according to any of auxiliary requests 1 to 5.

The respondent requested that the appeal be dismissed. In addition, it supported the appellant's request for remittal if any of the requests were to be seen by the board as fulfilling the requirements of Articles 76(1)/123(2) EPC.

Reasons for the Decision

AUXILIARY REQUEST 1

1. *Amendments (Articles 76(1)/100(c) EPC)*

- 1.1 The patent in suit was granted on a divisional application of the earlier European patent application No. 00991317.9 (filed on 13 December 2000 as an international application and published as WO 01/41581 A1, D1 in these proceedings). In respect of Articles 76(1)/100(c) EPC, the subject-matter of the patent in suit may not therefore extend beyond the content of the earlier (parent) application as filed.

The relevant criterion in this context is whether the skilled person can derive the claimed subject-matter directly and unambiguously, using common general knowledge, from the parent application as filed as a whole, either explicitly or implicitly.

- 1.2 As set out at the very beginning of D1, the invention of D1 relates to an improved infant formula containing at least an easily digestible lipid component and an improved protein component (page 1, lines 3 to 4; see also claim 1).

The passage at page 4, lines 14 to 24, then describes the infant formula in somewhat broader terms:

"Thus, the present invention provides an infant formula that comprises any combination of two or more, preferably of three or more, and most preferably all, of the following components:

a) at least one protein component (here below referred to as "*component A*");

b) at least one lipid component that can be easily digested by an infant ("*component B*");

c) at least one prebiotic component ("*component C*");

at least one viscosity improving component ("*component D*");

and that optionally further contains any component of infant formula known per se, including but not limited to those described below (here below referred to as "*further components*");...".

Although the disclosure of D1 with regard to the composition of the infant formula remains rather vague, there is a clear preference as to the combination of components A, B and C (page 5, lines 25 to 26):

"More preferably, the infant formula of the invention contains a combination of components A + B + C; and optionally one or more further components".

1.3 It was undisputed that every feature of claim 1 is individually disclosed in D1. Reference is made to the following passages:

- The above-cited passage at page 4 refers to a protein component in general (feature a) of claim 1).
- Page 18, lines 17 to 21 defines the lipid component as follows: "In other - but somewhat less restrictive - words, when the palmitic acid residues make up more than 10%, preferably 16-24% of all fatty acid residues present in the triglycerides used in or as component B of the invention, of these palmitic acid residues, as much as possible, and preferably at least 30% ... should be in the 2- or β -position of the triglyceride" (feature b) of claim 1).
- Page 20, line 5 discloses the use of one or more *trans*-galacto-oligosaccharides as preferred prebiotic components (feature c) of claim 1).
- Page 21, line 23 discloses one or more nucleotides and/or nucleotide analogues as further components (feature d) of claim 1).

- Page 8, lines 3 to 8 discloses a calcium content of more than 50 mg/100 kcal and less than 80 mg/100 kcal for an infant formula for infants less than 6 months old (feature e) and the feature "suitable for infants of less than 6 months old" of claim 1).

1.4 It was also undisputed that the combination of all the features required by claim 1 is not explicitly disclosed in the parent application as filed. The question to be investigated in this appeal is therefore whether this combination is implicitly disclosed in the parent application as filed.

1.5 As to whether or not the generation of a fresh particular combination contravenes Article 123(2) EPC (and the same criteria apply for Article 76(1) EPC), it was set out in T 686/99 of 22 January 2003, not published in OJ EPO, that:

"The content of the application as filed must not be considered to be a reservoir from which individual features pertaining to separate sections can be combined in order artificially to create a particular combination. **In the absence of any pointer to that particular combination**, this combined selection of features does not, for the person skilled in the art, emerge clearly and unambiguously from the content of the application as filed" (point 4.3.3 of the reasons; emphasis added by this board).

1.6 The appellant argued in this respect that the present case was different. There was no need for the skilled person to select each feature of claim 1 from lists of equally preferred alternatives. In fact, D1 clearly addressed the advantages of the combination of low

amount of calcium, content and position of palmitic acid residues in the lipid and oligosaccharides (as prebiotic compounds) in a formula for young infants (page 3, line 6 to page 4, line 13). The only selection to be made would be the choice of nucleotides from the list for further components.

1.7 However, in the board's view, these arguments are not convincing, for the following reasons:

1.7.1 The claimed infant formula does not merely require a single selection of one or more nucleotides from the list for further components. In fact, it requires multiple selections from D1 in order to arrive at the subject-matter of claim 1.

1.7.2 Thus, as pointed out above, D1 does in fact disclose the combination of components A + B + C and optionally one or more further components as being preferred for an infant formula (page 5, lines 25 to 26). However, in the context of this passage, A, B and C are defined in rather general terms, namely as being a protein component (A), a lipid component (B) and a prebiotic component (C). The combination of A + B + C is not at all equivalent to the combination of a) + b) + c) as required in claim 1

In fact, several selections have to be made within the disclosure of D1 in order to arrive at the combination a) + b) + c) as required in claim 1. It would be necessary to choose the broad definition for the protein component and combine it with specific selected embodiments for the lipid component and for the prebiotic component.

1.7.3 As to the lipid component b) of claim 1, it is based on the explicit disclosure on page 18 (see also point 1.3 above). But this passage gives two definitions with regard to the palmitic acid residue content and position in the triglycerides, one apparently being somewhat less restrictive than the other. Furthermore, it is stated at page 18, lines 22 to 25:

"Mixtures of fatty acid triglycerides that contain more than 10%, preferably 16-24% palmitate residues and that meet one or both of the requirements relating to the position of the palmitate residues set out in the above two paragraphs, will also be referred to below as the *"preferred lipid component B"*."

Thus, even for the preferred lipid component B, various, different definitions exist. There is no indication whatsoever in D1 that the somewhat less restrictive definition for the lipid has to be chosen in combination with the remaining features of claim 1.

1.7.4 In addition, it would be necessary to select infants of less than 6 months old as a target group. There is, as pointed out in point 1.3 above, an explicit disclosure for this group in combination with the calcium content required in claim 1. Furthermore, the preceding paragraph bridging pages 7 and 8 indicates that "when the infant formula of the invention contains the preferred lipid component B, an infant formula of the invention may not require amounts of calcium to be present, that are as high as the calcium contents required in the conventional formulas." But even if the preferred lipid component B were the "preferred lipid component B" from page 18, this would still leave room for choices to be made for the lipid component (see point 1.7.3 above). There is simply no indication

whatsoever as to the exact nature of the preferred lipid to be chosen for this age group. Nevertheless, claim 1 requires a specifically defined lipid b).

Apart from that, there is no indication as to the protein or prebiotic component to be selected for this group of infants, or the other group mentioned, namely infants of more than 6 months old.

1.7.5 Lastly, nucleotides are mentioned amongst other possible further components in the paragraph on page 21 under the heading "*VI: further components:*". There is no indication whatsoever in this paragraph that the nucleotides should be used together with a particular type of lipid.

1.7.6 Also, the "key aspects" of the invention as set out at pages 3 to 4 referred to by the appellant, namely the lipid/triglyceride component, the low amount of calcium and oligosaccharides as the preferred prebiotic compound, do not establish an "intermediate teaching" having all the features of claim 1 apart from the nucleotides.

In particular, the definition of the lipid on page 3 is much more general than for component b) in claim 1. And even if that more general statement were to be interpreted as referring to "the preferred lipid component B" of D1, the argument given in points 1.7.3 and 1.7.4 equally applies here. The relevant question is still: why select the specific definition for component b) of claim 1? Furthermore, there is only a general reference to oligosaccharides, not to trans-galacto-oligosaccharides in particular.

1.7.7 Thus, the argument of the appellant that the subject-matter of claim 1 involves only the single selection of nucleotides, when taking into account the teaching provided in D1, must fail. Instead, the appellant has "cherry-picked" elements from the disclosure of D1 and created a new combination of features, without there being any pointer to this new combination in D1.

D1 describes the drawbacks of conventional infant formulae in a general way and presents preferred infant formulae and/or elements thereof as advantageous over prior art formulae. There are numerous alternatives for each component, but there is no hint to the combination of definitions (general and specific) now selected in claim 1. In fact, the components of the infant formulae are presented rather in a parallel manner than in connection to each other. There is no pointer at all to an embodiment with all the required features of claim 1.

1.7.8 This absence of a pointer to the claimed combination of features is corroborated by the fact that none of the examples, which is usually the place where the skilled person would look for the best infant formulae in a patent application, falls within the scope of claim 1. In the only formula for infants of up to 6 months old (example 2), no nucleotides are present. Moreover, the infant formula therein exemplified does not specify whether the lipid used is a lipid meeting the requirements of component b) of claim 1.

1.7.9 In summary, the board agrees with the respondent and the opposition division that the specific combination of features in claim 1 is not clearly and unambiguously derivable from the parent application as filed.

1.8 Therefore claim 1 of auxiliary request 1 contains subject-matter which extends beyond the content of the parent application as filed (Articles 76(1)/100(c) EPC). Consequently, auxiliary request 1 is not allowable.

AUXILIARY REQUESTS 2 TO 5

2. *Amendments (Articles 76(1)/100(c) EPC)*

2.1 In claim 1 of auxiliary requests 2 to 5 the components of the infant formula have been further limited based on preferred and/or more preferred embodiments disclosed in D1 (for more details see point VIII above):

- component c) (auxiliary request 2),
- components a), c) and calcium content (auxiliary request 3),
- components a), c) and calcium content (auxiliary request 4),
- components a), b), c) and calcium content (auxiliary request 5).

2.2 The subject-matter of claim 1 of all these requests still comprises the combination of the specific lipid component b) with the nucleotides. Thus, in order to arrive at the subject-matter of claim 1 of all the auxiliary requests, at least the definition of the lipid component b) from the various "preferred lipid component B" (see point 1.7.3 above) and the nucleotides from the list of further components (see point 1.7.5 above) have to be selected. Again, as set out for auxiliary request 1, there is no pointer to this combination. Also, none of the examples, and in particular example 2, supports the combination present in claim 1 of auxiliary requests 2 to 5.

- 2.3 For these reasons the subject-matter of claim 1 of auxiliary requests 2 to 5 extends beyond the content of the parent application as filed (Articles 76(1) and 100(c) EPC).
3. Consequently, none of the appellant's claim 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