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Datasheet for the decision of 20 June 2017

Case Number: T 0941/13 - 3.3.09

Application Number: 07747355.1

Publication Number: 1996031

IPC: A23L1/29, A23L1/30, A23L1/305, A23L1/308

Language of the proceedings: EN

Title of invention:
Preterm formula

Patent Proprietor:
N.V. Nutricia

Opponent:
Nestec S.A.

Headword:

Relevant legal provisions:
EPC Art. 56
RPBA Art. 13(1), 13(3)

Keyword:
Main request - inventive step (no)
Late-filed auxiliary request - admitted (no)

Decisions cited:

Catchword:

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Case Number: T 0941/13 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 20 June 2017

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Respondent: (Opponent)	Nestec S.A. Avenue Nestlé 55 1800 Vevey (CH)
Representative:	Rupp, Christian Mitscherlich PartmbB Patent- und Rechtsanwälte Sonnenstraße 33 80331 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 5 February 2013 revoking European patent No. 1996031 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	W. Sieber
Members:	J. Jardón Álvarez
	E. Kossonakou

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the patent proprietor (in the following: the appellant) against the decision of the opposition division to revoke European patent No. 1 996 031.

II. The opponent (in the following: the respondent) 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: EP 1 557 096 A1; and

D3: EP 0 376 628 A2.

III. The opposition division's decision was based on a main request and, in the end, twelve auxiliary requests. The opposition division revoked the patent because in its view:

- the subject-matter of claim 1 of the main request and auxiliary request 2 extended beyond the content of the application as filed, thereby infringing Article 123(2) EPC, and

- the subject-matter of claim 1 of all other requests lacked inventive step.

The only request relevant to the appeal proceedings is auxiliary request 1, which corresponds to the main request in the appeal. Claims 1 and 3 of auxiliary request 1 read as follows:

"1. Use of a composition with a threonine content between 100 and 200 mg threonine per 100 kcal comprising:

a. between 5 and 15 wt.% palmitic acid based on total fatty acids; and
b. galactose containing indigestible oligosaccharide,

for the manufacture of a nutritional composition for

(a) enhancing oral tolerance in infants that are born before the end of the 37th week of pregnancy and/or infants that have a weight of less than 2500 grams at birth and/or infants that have a weight of less than 1500 grams at birth and/or infants that have a weight of less than 1000 grams at birth;
(b) reducing gastrointestinal transit times in infants that are born before the end of the 37th week of pregnancy and/or infants that have a weight of less than 2500 grams at birth and/or infants that have a weight of less than 1500 grams at birth and/or infants that have a weight of less than 1000 grams at birth; and/or
(c) reducing the time in which full enteral feeding can be commenced in infants that are born before the end of the 37th week of pregnancy and/or infants that have a weight of less than 2500 grams at birth and/or infants that have a weight of less than 1500 grams at birth and/or infants that have a weight of less than 1000 grams at birth."

"3. A composition with a threonine content between 100 and 200 mg threonine per 100 kcal and that contains non-hydrolysed protein comprising:

a. between 5 and 15 wt.% palmitic acid based on total fatty acids; and
b. galactose containing indigestible oligosaccharide; and
c. between 2 and 25 wt.% medium chain fatty acids based on total weight of fatty acids."

Starting from D1 as closest prior-art document, the opposition division noted that no comparison had been made with the formula disclosed in D1 and saw the problem underlying the subject-matter of claim 1 of auxiliary request 1 as being merely to provide an alternative infant formula. In its view, it would have been obvious for the skilled person to arrive at the claimed combination of features for solving this problem; consequently, the claimed subject-matter lacked inventive step.

IV. The statement setting out the grounds of appeal was filed on 17 June 2013. It included a main request, corresponding to auxiliary request 1 in the opposition proceedings, and four auxiliary requests. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of the main request or one of the auxiliary requests.

V. With its reply dated 29 October 2013, the respondent requested that the appeal be dismissed.

VI. In a communication dated 30 January 2017 in preparation for oral proceedings the board indicated the issues to be discussed during the oral proceedings. It also expressed its preliminary view that the subject-matter of claim 1 of the main request did not extend beyond the content of the application as filed.

VII. On 20 June 2017 oral proceedings were held before the board. During the oral proceedings the appellant withdrew all its previous auxiliary requests and filed a new (sole) auxiliary request.

The main request was maintained and corresponds to auxiliary request 1 before the opposition division (see point III above).

Claim 1 of the auxiliary request reads as follows:

"1. A composition with a threonine content between 100 and 200 mg threonine per 100 kcal and that contains non-hydrolysed protein comprising:

a. between 5 and 15 wt.% palmitic acid based on total fatty acids; and
b. galactose containing indigestible oligosaccharide; and
c. between 2 and 25 wt.% medium chain fatty acids based on total weight of fatty acids.

and said composition comprising below 10 wt.% lauric acid based on total weight of fatty acids."

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

- Starting from D1 as closest prior art, the differences between D1 and the subject-matter of claim 1 of the main request were that (i) the target group of fragile infants was not disclosed, and (ii) the composition used was different. Even if D1 mentioned galactose-containing

oligosaccharides and palmitic acid and appeared to describe a composition with low threonine content, the combination of the three components was not specifically disclosed.

- Contrary to the teaching of D1, which required a low amount of triglycerides having palmitic acid residues in the Sn1- and Sn3-positions, the composition now used relied on the use of galactose-containing indigestible oligosaccharides in order to lower the pH in the intestinal tract and to increase production of lactate. The claimed composition was therefore a non-obvious alternative to the compositions disclosed in D1. Moreover, the target group on which it should be used was different, and it could not be expected that fragile infants would benefit from the compositions now claimed.

- The auxiliary request should be admitted into the proceedings. The claims were based on the claims of previous auxiliary request 2 with two minor amendments, namely the concentration of palmitic acid and of lauric acid that had been amended in order to overcome the Article 123(2) EPC objection raised by the respondent in writing and the finding of the board that the main request lacked inventive step. The respondent should be prepared to discuss the auxiliary request because it included essentially the same features as those already in the requests in the proceedings.

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

- The claims according to the main request extended beyond the content of the application as filed, were insufficiently disclosed and lacked inventive step.

- Concerning inventive step, the respondent essentially agreed with the finding in the appealed decision that the claims of the main request lacked inventive step in view of D1 as the closest prior art. The differences between claims 1 and 3 of the main request and example 4 of D1 might be the use of galactose oligosaccharide instead of fructose oligosaccharide and the use in fragile infants instead of "normal" infants up to 4 months old. However, in the absence of a technical effect deriving from these distinguishing features, the technical problem underlying the claimed subject-matter was merely the provision of an alternative composition for the manufacture of a nutritional composition for fragile infants. The claimed composition would have been obvious to the skilled person from D1 alone, which already suggested all the components of the claimed compositions. The use for fragile infants could not justify an inventive step either, because the problems for these infants were the same as for the target infants in D1. In fact, there was no clear distinction between both groups; rather they overlapped to some extent.

- The auxiliary request should not be admitted into the proceedings. It included a feature taken from the description. A further search for prior art would be necessary to deal with the amended subject-matter.

X. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of either the main request, filed on 17 June 2013 with the statement setting out the grounds of appeal, or the auxiliary request filed during the oral proceedings before the board.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

MAIN REQUEST

1. Preliminary remark

1.1 The respondent argued that the subject-matter of claim 1 of the main request extended beyond the content of the application as filed and that the invention was not sufficiently disclosed.

1.2 Since, however, the board came to the conclusion that the subject-matter of claims 1 and 3 of the main request lacked inventive step (see below), there is no need to elaborate on these other issues.

2. *Inventive step*

2.1 The patent relates to a method for feeding low, very low or extremely low birthweight infants and preterm (or premature) infants (hereinafter referred to as "fragile infants") with a formula particularly adapted to stimulate the feed tolerance of the fragile infant. These fragile infants lack a fully matured intestinal tract, and therefore often suffer from digestive-tract-related problems such as constipation, swallowing

difficulties, cramps and digestion issues (see paragraph [0002] of the patent specification). In particular, a prolonged transit time causes constipation and ultimately also inhibits oral tolerance of the food composition (see paragraph [0006]).

2.2 The patent aims to solve these problems by using a composition (formula) comprising a balanced combination of selected nutrients.

2.3 The main request includes four independent claims, whereby only claims 1 and 3 are discussed in this decision.

Claim 1 is drafted in the form of a second medical use claim ("Swiss-type claim") and is directed to the use of a composition comprising threonine and palmitic acid in specified amounts and galactose-containing oligosaccharide for enhancing oral tolerance, reducing gastrointestinal transit times and/or reducing the time until full enteral feeding can be commenced in fragile infants.

Claim 3 is directed to a composition *per se* containing threonine, palmitic acid and medium-chain fatty acids in specified amounts, galactose-containing oligosaccharide and non-hydrolysed protein. The composition is, preferably, used to feed fragile infants to alleviate the symptoms listed above.

2.4 Closest prior art

2.4.1 The board concurs with the parties that D1 represents the closest prior-art document for the subject-matter of both claim 1 and claim 3.

2.4.2 D1 relates to an infant formula for infants under 6 months old which improves gastrointestinal tolerance (see [0002] and [0003]). In particular, the infant formula of D1 may be used to treat the symptoms of faecal composition, including constipation and high local gas production, which may result in intestinal cramps, etc. (see [0005]). D1 also describes the problem of oral tolerance (see [0006]) and that "infants which are fed conventional formulas may suffer from an impaired immune function which may become evident in rapid development of a rash on the skin of the bottom; undernourishment (impaired growth), malfunctioning (colic) and even damage to the gut (intolerances to food components)" (see [0007]).

D1 also indicates that high amounts of palmitic acid in the Sn1- or Sn3-position of the triglycerides are undesirable, especially in combination with high amounts of divalent cations such as calcium (see [0011]).

2.4.3 D1 discloses various embodiments which solve the above-mentioned problems:

Thus, paragraph [0020] discloses in rather broad terms an infant formula that comprises any combination of two or more of the following:
a) at least one protein component,
b) at least one lipid component that can be easily digested by an infant,
c) at least one prebiotic component, and
d) at least one viscosity-improving component, and optionally further components of an infant formula known *per se*.

Further, claim 1 is directed to an infant formula comprising
a) at least one protein component,
b) at least one lipid component,
c) at least one prebiotic component, wherein said prebiotic component comprises galacto-oligosaccharides, and
d) specific polyunsaturated long-chain fatty acids.

Paragraph [0024] discloses an infant formula wherein
a) the protein component is a protein hydrolysate,
b) the lipid component comprises at least one fatty-acid triglyceride and/or a mixture of fatty-acid triglycerides, in which
- palmitic acid residues make up more than 10%, preferably 16-24%, of all fatty-acid residues present in the triglycerides; and in which
- triglycerides in which the palmitate residue is in the Sn1- or Sn3-position make up no more than 16% of all triglycerides present.

2.4.4 In view of this rather inconclusive disclosure of D1, the board considers Example 4 of D1 to be the most appropriate starting point for the assessment of inventive step.

Example 4 discloses a formula for infants of up to 4 months comprising *inter alia*
- 1.29 g per 100ml of hydrolysed ß-casein/whey (40/60), which contains a threonine content of 105.2 mg (as calculated by the respondent),
- 3.2 g per 100ml of lipids including 0.2 g per 100ml derived from β-palmitate and 1.1 g per 100ml from MCTs (medium chain triglycerides) + coconut oil, and

- 0.5 g per 100 ml of fibre/non-digestible oligosaccharides, namely arabino-oligosaccharides and fructo-oligosaccharides ("FOS").

Taking the value for β-palmitate the respondent calculated the content of palmitic acid based on total fatty acids in this example as being 6.25 wt.% and thus according to claim 1 of the patent. However, the board agrees with the appellant that the calculation does not take into account the further palmitic acid which is inherently present in coconut oil. Thus, the amount of palmitic acid in example 4 of D1 must be higher than the figure of 6.25 wt.% as calculated by the respondent, yet the exact value cannot be determined because the amount of coconut oil is only given together with the MCTs.

2.4.5 It follows from the above that the infant formula of example 4 does not disclose the palmitic acid content and contains FOS instead of GOS. Nevertheless, it should be kept in mind that the palmitic acid content in D2 preferably should make up more than 10%, and (more) preferably 16-24%, of all fatty-acid residues present in the triglycerides (see [0095]). Furthermore, FOS and GOS are equally mentioned as preferred prebiotic components (see [0107] and [0109]). In any case, neither example 4 nor the general disclosure of D1 mentions the target group of "fragile infants".

2.5 Problem to be solved and its solution

2.5.1 According to the appellant, the technical problem to be solved by the claimed subject-matter in view of D1 was to provide an alternative composition that would enhance oral tolerance, and reduce gastrointestinal

transit times and the time until enteral feeding can be commenced for fragile infants.

2.5.2 Although in examples 1 and 2 undefined compositions containing GOS in an undefined concentration are administered to healthy babies (rather than fragile infants), and example 3 merely describes a preterm formula without demonstrating any technical effect, one may assume, in favour of the appellant, that the above-mentioned problem has been solved by the measures taken, namely

the composition of claim 1

- with a threonine content between 100 and 200 mg per 100kcal, and comprising
- between 5 and 15 wt.% palmitic acid, and
- galactose-containing indigestible oligosaccharides;

alternatively, by the composition of claim 3 that additionally comprises:

- non-hydrolysed protein, and
- between 2 and 25 wt.% medium-chain fatty acids based on total weight of fatty acids.

2.6 Obviousness (claim 1)

2.6.1 It remains to be decided whether, in view of the available prior art, it would have been obvious for the skilled person to solve the technical problem as defined above by the means claimed.

2.6.2 The board agrees with the respondent that this would indeed be the case. In particular, the board cannot see any invention in the use of an infant formula embraced

by the general disclosure of D1 for treating fragile infants, for the following reasons:

Firstly, as explained above, the infant formula of example 4 of D1 has a low threonine content as required by claim 1. Furthermore, the skilled person would have known from D1 itself that GOS may be used to replace FOS (see especially [0107]). As to the palmitic acid content, it has already been pointed out that it overlaps with the preferred amount of palmitic acid, with a lower limit of 10%. The skilled person would have certainly considered working within this range of overlap.

Lastly, the specific use for alleviating digestive-tract-related problems in the target group of "fragile infants" cannot justify inventive step either. D1 already teaches that the infant formulas used therein are appropriate for infants younger than 6 months suffering from problems in the gastrointestinal tract (see [0003]). It would thus be obvious to use said formulas for fragile infants suffering from the same problems.

In this context it should be mentioned that there is no clear distinction between "infants of less than 6 months old" targeted in D1 and some of the fragile infants as defined in claim 1. Thus, low birth weight infants, i.e. weighing less than 2500 grams at birth, appear to differ only marginally from infants that have a weight of slightly above 2500 grams at birth and would be categorised rather as "normal" infants of less than 6 or 4 months. The same appears to be true for infants born before the end of the 37^{th} week of pregnancy and those born at the beginning of the 38^{th} week. Thus, the person skilled in the art would

administer the formulas of D1 (including the alternative covered by D1) to fragile infants approaching the group of full-term infants.

2.6.3 The appellant tried to justify the presence of an inventive step by arguing that D1 was a different solution to the same problem. In particular, it pointed out that D1 aimed at avoiding palmitic acid residues in the Sn1- and Sn3-positions of the triglycerides while allowing higher amounts thereof in the Sn2(or ß)-position. In contrast, the composition now claimed reduced the pH of the intestinal tract due to the presence of GOS. The beneficial effect was achieved even if the triglycerides in the compositions contained palmitic acid in the Sn1- and Sn3-positions, thus allowing the use of triglycerides with a different palmitic acid profile from those used in D1. On the other hand, the digestive tract of the fragile infants would be sterile and, in principle, it could not be expected that GOS would stimulate the growth of beneficial micro-organisms.

However, the board is not persuaded. As indicated above, the compositions now used overlap to a certain extent with those known from D1. They are not limited to the use of any triglycerides with a specific palmitic acid profile that might differentiate them from those used in D1.

While it is true that the digestive tract of the fetus is sterile, the baby acquires, within hours of birth, a complex collection of micro-organisms which populates the mouth and then colonises the digestive tract. Claim 1 is not directed to the use of GOS to stimulate the growth of beneficial micro-organisms in newborns.

Even the appellant admitted that GOS was known to be the most valuable oligosaccharide in infant formulas.

2.6.4 It follows from the above that the subject-matter of claim 1 of the main request lacks inventive step.

2.7 Obviousness (claim 3)

2.7.1 The same reasoning applies to the compositions of claim 3 further specifying the mandatory presence of "non-hydrolysed protein" and of "between 2 and 25 wt.% medium chain fatty acids based on total weight of fatty acids".

2.7.2 None of these added features can give rise to inventive step. Like the compositions used in claim 1, those of claim 3 overlap with those known from D1, because both added features are also disclosed in D1. Indeed, the use of non-hydrolysed protein is described in paragraph [0058] stating that:

> "Component A comprises intact proteins, a protein hydrolysate, or a combination thereof" (A being the protein component, see [0020]);

and the use of medium-chain triglycerides is described in paragraph [0040] reading:

> "In the formula of the invention, Medium Chain Triglycerides (MCTs) can be used to replace partially triglycerides containing palmitic acid residues. If so, it is preferred that such MCTs are used in an amount of less than 20 wt.% of the total lipid component B."

2.7.3 In view of this, the subject-matter of claim 3 lacks inventive step for the reasons given above for the subject-matter of claim 1.

AUXILIARY REQUEST

3. Admission

3.1 The auxiliary request was filed by the appellant during the oral proceedings, after the board had decided that the subject-matter of claims 1 and 3 of the main request lacked inventive step, i.e. at the very last moment.

3.2 The appellant justified this late filing as being (i) an attempt to streamline the proceedings with regard to the respondent's objection under Article 123(2) EPC against previous auxiliary request 2 and (ii) an attempt to overcome the finding of the board on inventive step in relation to the main request.

3.3 The respondent contested the admissibility of the request because the amendment concerning the maximum amount of lauric acid now allowed in claim 1 ("comprising **below 10 wt.%** lauric acid...", emphasis by the board) had been taken from the specification. In view of this limitation, a further search for prior art would be necessary in order to deal with the auxiliary request.

3.4 The board agrees with the respondent that the amendment shifts the claim to subject-matter not discussed previously in the proceedings. Claim 1 of previous auxiliary request 2 limited the amount of lauric acid to below 12%, a value that was within the range disclosed in D3 for this component of the infant

formula. The limitation to the now claimed value of below 10 wt.% takes the subject-matter of claim 1 further away from the disclosure of D3, a reaction which could not have been anticipated by the respondent and prevent it from conducting a further search in this context.

3.5 Thus, the filing of the auxiliary request introduces new issues at a very late stage that neither the board nor the respondent could have been expected to deal with during the oral proceedings. The board therefore decided not to admit this request into the proceedings (Article 13(1) and (3) RPBA).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Cañueto Carbajo W. Sieber

Decision electronically authenticated