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Datasheet for the decision of 12 July 2022

Case Number: T 0534/19 - 3.3.09

Application Number: 11797226.5

Publication Number: 2651247

IPC: A23L33/00

Language of the proceedings: EN

Title of invention:
IMPROVED NUTRITIONAL COMPOSITION, ESPECIALLY FOR INFANTS, WITH PARTICULAR FAT PARTICLES

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponent:
N.V. Nutricia

Headword:
Improved nutritional composition/NESTLÉ

Relevant legal provisions:
EPC Art. 83, 56

Keyword:
Sufficiency of disclosure - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0534/19 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 12 July 2022

Appellant: (Opponent)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Schrell, Andreas Gleiss Große Schrell und Partner mbB Patentanwälte Rechtsanwälte Leitzstrasse 45 70469 Stuttgart (DE)
Respondent: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Plougmann Vingtoft a/s Strandvejen 70 2900 Hellerup (DK)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 7 December 2018 concerning maintenance of the European Patent No. 2651247 in amended form.**

Composition of the Board:

Chairman	A. Haderlein
Members:	M. Ansorge
	L. Basterreix

Summary of Facts and Submissions

I. The opponent (appellant) lodged an appeal against the opposition division's interlocutory decision holding the main request allowable.

II. With its notice of opposition, the opponent had requested that the patent be revoked on the grounds for opposition under Article 100(a) EPC (lack of novelty and lack of inventive step) and Article 100(b) EPC.

III. The opposition division decided *inter alia* that the invention could be carried out and that the subject-matter of claim 1 of the main request involved an inventive step in view of D14 (WO 2005/051091 A1) or D23 (WO 2010/027258 A1) as the closest prior art.

IV. Independent claims 1 and 5 of the main request read as follows:

"1. A process for the manufacture of an infant nutritional formula comprising the steps of

a) providing a mixture comprising vegetable fat, protein and carbohydrates,

b) mixing said mixture in a continuous high shear homogenizer rotor stator mixer and subsequently subjecting said mixture to homogenization at a pressure between 0 and 60 bar so as to provide a composition with a monomodal fat particle size distribution wherein 5% or less of the fat particles have a size of less than 0.8 µm, and at least 95% of the fat particles have a size of between 0.8 µm and 5 µm, and 5% or less of the fat particles have a size of more than 5 µm."

"5. An infant nutritional formula which is obtainable by the process according [*sic*] any one of claims 1-4, characterized in that said nutritional formula has a monomodal fat particle size distribution wherein 5% or less of the fat particles have a size of less than 0.8 µm, and at least 95% of the fat particles have a size of between 0.8 µm and 5 µm, and 5% or less of the fat particles have a size of more than 5 µm."

Claims 2 to 4 and 6 to 10 of the main request are directly or indirectly dependent on independent claims 1 and 5.

V. The parties' relevant arguments, submitted in writing and during the oral proceedings, are reflected in the reasons for the decision below.

VI. Requests

The appellant requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

The respondent (proprietor) requested that the appeal be dismissed (main request) or, as an auxiliary measure, that the patent be maintained in amended form on the basis of one of auxiliary requests 1 to 15, filed with its reply to the grounds of appeal.

Reasons for the Decision

1. Sufficiency

1.1 The appellant only conditionally raised an objection under Article 83 EPC, i.e. "in the event and to the

extent that patentee ... argues that there is an obstacle for the skilled person to obtain a desired particle size distribution". However, the respondent did not submit such a line of argument. Instead, it essentially argued under inventive step that a skilled person could arrive at the claimed subject-matter, but would not arrive at it without requiring inventive effort. Thus the question of sufficiency of disclosure does not need to be addressed by the board.

1.2 Moreover, the board shares the respondent's view that the appellant had substantially reiterated its arguments submitted during the first-instance proceedings, but had not explained why the opposition division had erred in its conclusion that the patent met the requirement of Article 83 EPC.

Under these circumstances, the requirement of Article 83 EPC is met.

2. Inventive step

2.1 The appellant raised inventive-step objections in view of D14 and D23 as the closest prior art.

2.2 While D23 contains specific information about the lipid globule particle size distribution, D14 is silent in this respect and does not unambiguously disclose a precise lipid globule size distribution. Thus the board concludes that D23 is the closest prior art.

2.3 D23 relates to a "[p]rocess for making a nutritional composition comprising the steps of a) providing an aqueous mixture comprising lipids, wherein the lipids comprise 50 to 100 wt.% vegetable lipid based on total lipid and wherein 0.2 to 20 wt.% based on total lipid

is phospholipid, and comprising protein, digestible carbohydrate, and optionally non-digestible oligosaccharide, and b) homogenizing said mixture in two steps with 5-100 bar in the first step and 5-50 bar in the second step, and c) preferably sterilizing said homogenized mixture and d) preferably spray drying said sterilized mixture" (see claim 21 of D23).

In addition, it relates to a "[n]utritional composition comprising a) 10 to 50 wt.% vegetable lipids based on dry weight of the composition, and b) lipid globules i) with a volume-weighted mode diameter above 1.0 µm, preferably between 1.0 and 10 µm, and/or ii) with a diameter of 2 to 12 µm in an amount of at least 45 volume %, more preferably at least 55 volume % based on total lipid, and c) 0.5 to 20 wt.% phospholipids based on total lipid, wherein the phospholipids are derived from milk lipids" (see claim 11 of D23).

Examples 1A and 1B of D23 exemplify infant formulae wherein the lipid globules have a volume mode diameter between 4.0 µm and 7.3 µm (first peak) and the volume (%) with a diameter between 2 µm and 12 µm is given as between 70.3% and 74.8%.

2.4 Both parties agreed in that, within D23, examples 1A and 1B are suitable as the closest prior art.

2.5 As can be derived from examples 1A and 1B of D23 (see Tables 1 and 2 of D23), the volume (%) outside the range of 2 µm to 12 µm is 25.2% to 29.7%. With respect to Example 1A, D23 explicitly mentions that a second, much smaller, peak was present at 0.52 µm. Since the infant formula in example 1B of D23 was prepared similarly to example 1A, such a second, smaller, peak is also likely to be present in this example 1B.

2.6 The appellant agreed with the opposition division that the subject-matter of claim 1 differs from D23 in that (i) the homogenisation is performed in a continuous high shear rotor stator mixer and (ii) the fat globules have a different particle size distribution. However, it did not agree with the opposition division's conclusion that the particle size distribution of claim 1 would be narrower, comprising fewer small particles than in D23.

2.7 However, as even confirmed by the figure submitted by the appellant in its letter of 25 February 2022, the lipid globule particle size distribution in the examples of D23 is each broader than that claimed in claim 1 of the main request. The same applies to claim 5 of the main request.

Thus the particle size distribution defined in claims 1 and 5 of the main request is narrower than that described in D23.

2.8 The board does not see any evidence on file for the assumption that in D23 the majority of the fat globules lying outside the range of 2 µm to 12 µm might be larger than 12 µm rather than smaller than 2 µm. While it is true that D23 relates to infant formulae comprising lipid globules larger than standard instant formulae (see page 3, lines 6 to 22 of D23), this does not mean that the majority of the lipid globules outside the range of 2 µm to 12 µm are larger than 12 µm. In view of the fact that example 1A of D23 mentions a second peak at 0.52 µm and example 1B is prepared similarly to example 1A, the majority of the lipid globules outside the range of 2 µm to 12 µm are considered to be below 2 µm. This is in line with the

common general knowledge of a skilled person that the stability of an emulsion decreases when the lipid globule size increases.

2.9 In view of the above, the subject-matter of claim 1 of the main request differs from D23 in that:

- the homogenisation is performed in a continuous high shear rotor stator mixer instead of using a batch rotor stator mixer (first distinguishing feature); and

- the fat globules have a different, narrower, monomodal particle size distribution, comprising fewer small particles (less than 5% below 0.8 µm) (second distinguishing feature).

2.10 The second distinguishing feature is valid not only for the subject-matter of claim 1 of the main request, but equally for the infant nutritional formula of claim 5 of the main request.

2.11 The appellant essentially agreed with the objective technical problem to be solved as formulated by the opposition division, which reads as follows:

"The problem to be solved was to provide an alternative infant formula having a particle size distribution mimicking human milk and being phase-stable, and a method for its manufacture."

The board also considers that the problem to be solved as suggested by the opposition division is correctly formulated.

2.12 As to the question of obviousness, for the reasons outlined below a skilled person starting from D23 and trying to find an alternative infant formula would not have expected an infant formula having fewer small particles still to be phase-stable. In addition, there is no teaching in the prior-art documents cited by the appellant on how to arrive in an obvious manner at a phase-stable monomodal fat particle distribution as required in claims 1 and 5 of the main request.

The crucial question is whether a skilled person having knowledge of D23 not only could, but also would, arrive at the claimed particle size distribution while expecting that such a distribution would still lead to a phase-stable emulsion.

2.13 The appellant argued that D23 motivated the skilled person to consider a particle size distribution comprising a reduced amount of small particles, in contrast to standard infant formulas, as stable. In this context, it submitted that D23 provided a pointer to arriving at the claimed particle size distribution, since the distribution claimed in claim 1 of the main request was merely between the peak given for comparative example 1B1 of D23 (i.e. a comparative standard infant milk formula) and that for examples 1A and 1B2. Providing a particle size distribution between the peak for the comparative standard infant milk formula (comparative example 1B1) and examples 1A and 1B2 (exemplifying the invention of D23) was considered obvious in the appellant's view.

The board is not convinced.

There is no reason why a skilled person having knowledge of D23 would combine comparative example 1B1

of D23 (from which the invention of D23 is clearly delimited) with one of examples 1A and 1B2 of D23 (exemplifying the invention of D23). In the board's view, this could only be achieved with hindsight. As can be taken from page 3 of D23, the core teaching of D23 is to provide infant formulae having a larger lipid globule size than standard infant formulae. In the board's view D23 thus teaches away from contemplating an infant formula having a lipid globule size distribution between standard infant milk formula, presented as comparative in D23, and those claimed in D23.

2.14 Even when assuming for the sake of argument that a skilled person would consider such a lipid globule size distribution between the comparative example 1B1 of D23 and examples 1A and 1B2 of D23, there is still no hint in D23 on how to achieve the narrower particle size distribution required in claims 1 and 5 of the main request. As can be taken from the figure shown in the appellant's letter of 25 February 2022, the particle size distribution in all the examples of D23, including the comparative example 1B1, is significantly broader than that claimed in claim 1 of the main request. There is no hint in D23 supporting the suggestion that arriving at such a narrower distribution might be obvious for a skilled person. In this context, the appellant merely alleged that it was obvious for a skilled person to narrow the big peak, without providing any teaching in one of the cited documents pointing to such a modification.

2.15 The appellant's inventive-step line of argument is mainly based on the contention that the opposition division considered a "prejudice" to exist in the prior art. However, neither the opposition division nor the

respondent had defined any such prejudice. In this context, the opposition division had merely assessed the present case by reference to the skilled person's common knowledge that emulsions having small lipid droplets lead to more-stable oil-in-water emulsions than emulsions having large lipid droplets.

In other words, the opposition division had held that it was not obvious to adopt the claimed particle size distribution in order to arrive at an alternative emulsion having the same stability. This does not mean that the opposition division had argued that there was some sort of "prejudice" in adopting the claimed particle size distribution. In essence, it had dealt with the question of whether a skilled person not only could arrive at the claimed process or product, but whether they would have arrived at the claimed solution.

Thus the board does not find the appellant's "prejudice line of argument" convincing.

2.16 In view of the above, the claimed subject-matter is a non-obvious alternative in view of D23.

Thus the subject-matter of claim 1 of the main request involves an inventive step over D23 as the closest prior art. Since claim 5 of the main request also contains the second distinguishing feature, the same applies to claim 5 of the main request. The same conclusion equally applies to claims 2 to 4 and 6 to 10, being directly or indirectly dependent on claim 1 or claim 5 of the main request.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Haderlein

Decision electronically authenticated