Datasheet for the decision
of 9 December 2011

Case Number: T 1234/09 - 3.3.09
Application Number: 97915412.7
Publication Number: 969728
IPC: A23D 7/02, A23D 9/05,
A23D 7/00, A23C 11/04,
A23L 1/30

Language of the proceedings: EN

Title of invention:
Late addition of PUFA in infant formula preparation process

Patentee:
DSM IP Assets B.V.

Opponents:
UNILEVER N.V. / UNILEVER PLC
Friesland Brands B.V.

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 83, 123(2)

Keyword:
"Added subject-matter - no"
"Sufficiency - yes"
"Novelty - yes"
"Inventive step - yes"

Decisions cited:
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Catchword:
-
Case Number: T 1234/09 - 3.3.09

DECISION
of the Technical Board of Appeal 3.3.09
of 9 December 2011

Appellant: Friesland Brands B.V.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
26 March 2009 concerning maintenance of
European patent No. 969728 in amended form.

Composition of the Board:
Chairman: W. Sieber
Members: J. Jardón Álvarez
K. Garnett
Summary of Facts and Submissions

I. The grant of European patent No. 0 969 728 in respect of European patent application No. 97915412.7, in the name of DSM IP Assets B.V., which had been filed on 21 March 1997 as international application PCT/EP1997/001449, was announced on 11 January 2006 (Bulletin 2006/02). The granted patent contained 13 claims, claim 1 reading as follows:

"1. A process for preparing a foodstuff comprising a C18, C20 or C22 ω-6 polyunsaturated fatty acid (PUFA), the process comprising:
   (a) providing an oil phase and an aqueous phase;
   (b) mixing the oil and aqueous phases to obtain an emulsion;
   (c) optionally, drying the emulsion to obtain a dried material; and
   (d) adding at least one PUFA."

Claims 2 to 13 were dependent claims.

II. Three notices of opposition were filed against this patent by:

N.V. Nutricia (opponent 01) on 11 October 2006;

Unilever N.V. and Unilever PLC (opponent 02) on 10 October 2006; and

Friesland Brands B.V. (opponent 03) on 11 October 2006.

The three opponents requested revocation of the patent in its entirety based on the grounds of Article 100(a)
EPC, for lack of novelty and inventive step. Opponent 03 additionally based its opposition on the grounds of Articles 100(b) and (c) EPC.

Opponent 01 withdrew its opposition by letter dated 25 February 2009.

During the opposition proceedings inter alia the following documents were cited:

D6a: WO 92/13086 A1;

D12: EP 0 624 317 A1;

D15: JP 62/079 732 A (English translation);


D20: US 5 013 569; and


III. By its interlocutory decision announced orally on 5 March 2009 and issued in writing on 26 March 2009, the opposition division decided that the claims of the proprietor's main request met the requirements of the EPC. The set of eleven claims allowed by the opposition division had been filed on 5 February 2009. Claim 1 read as follows:
"1. A process for preparing a foodstuff comprising arachidonic acid (ARA), the process comprising:

(e) providing an oil phase and an aqueous phase;
(f) mixing the oil and aqueous phases to obtain an emulsion;
(g) drying the emulsion to obtain a dried material; and
(h) adding the ARA to the dried material."

Claims 2 to 11 were dependent claims.

The opposition division came to the conclusion that claim 1 satisfied the requirements of Article 123(2) EPC as it was a combination of claims 1 and 11 of the application as originally filed together with the feature of page 3, line 7, namely that arachidonic acid was added to the dried material. The opposition division also concluded that the requirements of Article 83 EPC were satisfied because there were clear instructions in the patent specification as to how step (d) should be carried out. In particular the examples demonstrated mixing of oily ARA with the dried material.

D6a was not novelty destroying because feature (d) of the claim was not directly and unambiguously derivable from it. Moreover, there was no disclosure in D6a of how the infant milk had been prepared, so that also features (a) to (c) of claim 1 were not derivable from D6a.

Finally, the opposition division acknowledged an inventive step because, in its opinion, there was no hint in the available prior art to the late addition of
arachidonic acid after drying. On the contrary, there was a consistent teaching in the cited documents to the addition of polyunsaturated fatty acids before drying.

IV. On 2 June 2009 opponent 03 (appellant) lodged an appeal against the decision of the opposition division and paid the appeal fee on the same day.

In the statement of grounds of appeal filed on 29 July 2009, the appellant requested revocation of the patent in its entirety. The appellant also filed the following further documents:

R1: WO 94/01001 A1;

R2: JP 06-205640 A (English translation); and


V. With its reply dated 15 December 2009, the patent proprietor (respondent) disputed all the arguments submitted by the appellant and requested that the appeal be dismissed and that documents R1 to R3 not be admitted into the proceedings. It also filed sets of claims for six auxiliary requests.

VI. On 7 June 2011 the board dispatched a summons to attend oral proceedings. In the attached communication the board gave its preliminary opinion on the issues relating to added subject-matter and sufficiency of disclosure and outlined the points to be discussed during the oral proceedings. The board also requested
the respondent to consider whether it would be
necessary to adapt dependent claims 7 and 11 of the
claim set maintained by the opposition division to the
wording of claim 1.

VII. On 9 November 2011 both the appellant and the
respondent filed further submissions.

The respondent also filed amended requests based on its
previous requests. Claims 7 and 11 of the main request
were amended in response to the communication of the
board, i.e. the embodiments directed to the preparation
of liquid foodstuffs were deleted from these claims.
Claim 1 of the new main request remained unamended and
was identical to claim 1 as maintained by the
opposition division (see point III above).

VIII. Opponent 02, party as of right to the appeal
proceedings, took no active part in the appeal
proceedings. It did not file any request and informed
the board by letter dated 17 June 2011 that it would
not be represented at the oral proceedings.

IX. Oral proceedings were held on 9 December 2011. During
the oral proceedings the appellant filed a further
document:

R4: "Stability in infant formula powder." BASF Health
& Nutrition, Ti-6 9/7 - 09.91, 4 pages.

The respondent requested that R4 be not admitted into
the proceedings. At the end of the debate the
respondent requested that the patent be maintained on
the basis of claims 1 to 11 of the main request filed
with letter dated 9 November 2011 and withdrew all its auxiliary requests.

X. The arguments presented by the appellant in its written submissions and at the oral proceedings, insofar as they are relevant for the present decision, may be summarised as follows:

- The subject-matter of amended claim 1 extended beyond the content of the application as filed. Claim 1 resulted from a combination of features not disclosed in the application as filed. In particular, the drying step was only optional and the use of arachidonic acid was only one of several choices in the application as filed. Moreover, the specific disclosure of the examples could not be generalized and also did not support the amendments of claim 1.

- The patent itself indicated that it was problematic to disperse the polyunsaturated fatty acids, which are oily liquids, in a solid material after the drying step. This was also supported by the disclosures of D15 and D22, which emphasized this problem. The patent did not contain any teaching as to how to overcome this problem and therefore was not sufficiently disclosed.

- The disclosure of documents D6a and R1 was novelty destroying for the subject-matter of claim 1. Even if not explicitly mentioned, the skilled person would without any doubt derive the addition of arachidonic acid to a dried material from these documents; in particular from claim 10 of R1.
where "dry mixing" was explicitly disclosed. Moreover, there could be no doubt that the dried infant formula was prepared by a process involving steps (a)-(c), because the patent itself indicated that infant formulas were usually prepared following these steps.

Finally, the subject-matter lacked an inventive step in view of the known processes for the preparation of infant formulas and the disclosure of D19. D19 described microencapsulated fish oil in powder form, which could be added to food products such as infant formula. The skilled person, knowing the disclosure of D19, would automatically add the microencapsulated product at the end of the preparation process. Taking account of the fact that the arachidonic acid capsules of D19 were no longer oily, it would be obvious for any skilled person to add them at end to the dried product, thus arriving at the subject-matter of claim 1.

XI. The arguments of the respondent may be summarized as follows:

- Claim 1 resulted from the combination of granted claims 1, 5 and 10. A literal basis for the addition of the polyunsaturated fatty acid to the dried material was to be found on page 3, line 7 of the application as filed.

- The invention as claimed could also be carried out by the skilled person. The description of the patent, as well as the examples, gave full
disclosure of how to carry out the invention. The allegations of the appellant were unproven and no evidence had been filed showing that the invention could not be carried out.

- The claimed subject-matter was novel. Neither D6a nor R1 disclosed any of steps (a), (b), (c) or (d) of claim 1. In D6a arachidonic acid was not added to a dried material, but to a liquid infant formula. R1 did not unambiguously disclose adding the arachidonic acid to a dried material. Moreover none of the documents described how the infant formula was prepared.

- Starting from the disclosure of D12 as the closest prior art, the respondent saw the problem underlying the patent in suit in the provision of an improved process for the preparation of a foodstuff comprising arachidonic acid, resulting in a foodstuff having an improved taste and a neutral smell. The solution according to claim 1, namely the addition of the arachidonic acid to the dried material, avoided the prior art stability problems during heating and was not taught or suggested by the cited prior art.

XII. The appellant requested that the decision under appeal be set aside and that the European patent No. 0 969 728 be revoked.

The respondent requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request filed with the letter dated 9 November 2011.
Reasons for the Decision

1. The appeal is admissible.

2. Late filed evidence

2.1 Documents R1- R3

2.1.1 Documents R1 to R3 constitute new evidence, cited for the first time in the appellant's statement of grounds of appeal. The respondent requested that these documents be not admitted into the proceedings for the reason that they were late-filed and not relevant.

2.1.2 R1 is concerned with the use of a microencapsulated product, dry or wet mixed with an infant formula. The filing of this document was prompted by the amendment made to claim 1 during the opposition proceedings which now requires adding the arachidonic acid "to the dried material", a feature not present in granted claim 1. Moreover R1 was known to the respondent as it is acknowledged in paragraph [0019] of the specification.

Thus, the board sees no reason to hold R1 inadmissible under Article 12(4) RPBA. In fact the filing of R1 appears to be the normal action of a losing party trying to contest the decision of the opposition division with its statement setting out the grounds of appeal.

Hence, R1 is to be taken into consideration in the appeal proceedings.
2.1.3 During the oral proceedings the appellant relied only on R1 and no longer on R2 and R3. Thus there is no reason to decide upon the admissibility of the latter two documents.

2.2 Document R4

2.2.1 During the oral proceedings before the board the appellant requested the introduction of document R4. The appellant argued that it had been unable to retrieve this document until the oral proceedings and that it was relevant for supporting its arguments of lack of inventive step. The relevance of this document was, however, again disputed by the respondent, who requested that it be not admitted into the appeal proceedings.

2.2.2 The appellant indicated that it had been difficult to obtain a copy of this document but the board does not accept this as a justification for such late filing. In fact R4 is mentioned as reference 14 in document D19, a document filed by the appellant on 11 October 2006 with its notice of opposition and the appellant has not indicated why this document could not be retrieved earlier. Under these circumstances, the board exercised its discretionary power conferred by Article 114(2) EPC to disregard this document.
3. Amendments

3.1 It is worth noting at this juncture that claim 1 is identical to claim 1 as maintained by the opposition division (point VII above).

Compared with claim 1 as granted, claim 1 has been amended in that:
- the polyunsaturated fatty acid is arachidonic acid (ARA);
- step (c) is now mandatory (i.e. the word "optionally" has been deleted), and
- it is specified that "the ARA" is added "to the dried material".

3.2 Amended claim 1 is based on claim 1 as filed, with the amendments finding their support in the application as filed as set out below:

3.2.1 The limitation of the fatty acid to arachidonic acid derives directly from claim 11 as filed which refers back to claim 1 ("A process according to any preceding claim wherein the PUFA is arachidonic acid (ARA) or docosahexanoic acid (DHA)"). It is further supported by several passages of the description indicating that the use of arachidonic acid is a preferred embodiment of the claimed process (page 5, lines 35-36; page 6, line 6 and examples 1, 3 and 4). Thus, this amendment fulfils the requirements of Article 123(2) EPC.

3.2.2 The deletion of the word "optionally" in claim 1 results in the process being limited to the preparation of a solid foodstuff. The application as originally filed included the preparation of a foodstuff which
could be a solid (page 4, lines 28-32) or a liquid (page 4, lines 33-36; see also page 10). The deletion of the word optionally limits the claim to the preparation of solid products in accordance with the application as filed and this amendment cannot be objected to under Article 123(2) EPC.

3.2.3 Finally, the addition of the wording "to the dried material" in step (d) ensures that the addition of the arachidonic acid is made at a late stage of the process in accordance with the whole disclosure of the application as filed. Specific support for this amendment can be found, for instance, on page 3, line 7, on page 4, lines 20-21 and on page 7, lines 4-6. This amendment therefore also does not contravene Article 123(2) EPC.

3.2.4 Also the combination of the amended features is directly and unambiguously derivable from the application as filed. Since ARA is the preferred polyunsaturated fatty acid, it would be self-evident to the skilled person that ARA is also preferred in the preparation of a solid foodstuff. Such a preparation with ARA is even demonstrated in examples 1, 3 and 4 of the application as filed.

3.2.5 The argument of the appellant that the application as originally filed embraced further embodiments and that the specific combination of features now in the claim was not disclosed is devoid of merit. The appellant is right in that the application as filed included further embodiments such as the use of other polyunsaturated fatty acids and/or the preparation of liquid foodstuffs. However, the claimed subject-matter has been limited to
an embodiment specifically disclosed in the application as originally filed as explained above in detail.

3.3 The appellant did not raise any objection under Article 123(2) EPC against the remaining claims, i.e. dependent claims 2 to 10. Also the board sees no reason to raise an objection of its own.

3.4 The amendments also clearly restrict the scope of the claims. The board concludes that the subject-matter of the claims fulfils the requirements of Articles 123(2) and (3) EPC.

4. Sufficiency of disclosure

4.1 The patent relates to a process for preparing a foodstuff comprising arachidonic acid, the process comprising steps (a) to (d) (see claim 1, point III above). Undisputedly the skilled person knows how to carry out steps (a) to (c), which are conventional steps for the preparation of infant milk. Concerning step (d), the key step of the claimed process, the patent includes detailed information about how to carry out this step, namely how to add the arachidonic acid to the dried material. Starting at paragraph [0018], the patent specification indicates that arachidonic acid can be added in a variety of forms: if liquid it may be a lipid composition and/or an oil which can be added to give a coating; if solid it may be encapsulated or in a powdered form ([0018]-[0028]). Further the specification includes three working examples showing different ways of how the addition can be carried out.
4.2 The appellant maintained that the addition of fatty materials after drying might be problematic and supported its arguments by reference to the patent itself, which indicates in paragraph [0010] that it can be particularly difficult to disperse the polyunsaturated fatty acid after the emulsification step. Furthermore, the appellant referred to the disclosures of documents D15 and D22, which indicate that it might be difficult to mix oil materials after drying of the emulsion.

4.3 The board finds these arguments not convincing for the following reasons:

4.3.1 None of these disclosures actually shows that it is not possible to carry out the claimed process. In fact, in D15 a fatty acid is added to the powdered milk (page 3, lines 32-34 and example). Thus, D15 supports the argument that the claimed process can be carried out.

4.3.2 In D22, the addition of fat-soluble vitamins after the drying step is merely not recommended and in paragraph [0010] of the patent it is explained that before the filing date of the patent in the conventional processes the fatty acid was added at an earlier stage. The board does not see how these disclosures can question the validity of the detailed information and experiments in the patent in suit.

4.3.3 Moreover, the appellant did not show that it was unable to reproduce the examples of the patent in suit or to prepare a foodstuff comprising arachidonic acid when ARA is added in oil form. The onus of proof in this respect lies with the appellant.
4.4 The board is therefore satisfied that the patent provides the skilled person with many details of how to carry out the claimed process, over the whole area claimed and without undue burden. Consequently, the requirements of sufficiency of disclosure are met.

5. Novelty

5.1 Novelty of the subject-matter of claim 1 has been contested by the appellant in view of the disclosures of documents D6a and R1.

5.2 Document D6a relates to the production of arachidonic acid substantially free of eicosapentanoic acid (claim 1) and its use as an additive in infant formulas having an arachidonic acid content approximating to the concentration in human breast milk (page 13, lines 12-16). In examples 1 and 2 arachidonic acid is prepared and added to the commercial formula Similac®.

5.3 There is no specific disclosure in D6a that the commercial formula Similac® is in dried form, as required by step (d) of claim 1. On the contrary, the units used on page 15, line 14 in the description and in the working examples, "mg per liter" suggest that the infant formula is in a liquid form and not a dried material. Moreover, there is no disclosure in D6a of how the infant milk is prepared. Steps (a)-(c) of the process of claim 1 are also not disclosed in D6a. The disclosure of D6a therefore does not anticipate the subject-matter of claim 1.
Document R1 discloses microencapsulated oil products containing arachidonic acid (see claim 1 and page 8, first paragraph) and its use in foods such as infant formulas (page 1, line 35-page 2, line 7; page 4, line 35; page 9, lines 16-24). The appellant relied mainly on claim 10 of R1, which is directed to the use of the microencapsulated oil product "dry or wet mixed with an infant formula".

In R1 there is no disclosure of a process for preparing a foodstuff comprising arachidonic acid having steps (a)-(d) of claim 1. The examples in R1 relate to the preparation of the microencapsulated oil or fat product; the product can be a stable emulsion (example 1), or, preferably, a free flowing powder (example 2). The product of R1 is to be used in food such as infant formula; such infant formula can be in a liquid or solid form. The addition to a dried material is not explicitly disclosed in R1.

The appellant saw an implicit disclosure in claim 10 as the "dry mixing" therein mentioned could only mean that two solids were mixed.

Even if one were to accept the appellant's interpretation of claim 10 of R1, R1 is silent about how the infant milk was obtained. As pointed out by the respondent, although steps (a)-(c) of claim 1 are conventional for the preparation of infant milk, solid infant milk can also be prepared by other methods. In the absence of such information in R1 the board can only conclude that the process of claim 1 is not directly and unambiguously disclosed in document R1.
5.8 For these reasons the subject-matter of claim 1 is novel.

6. **Inventive step**

6.1 As acknowledged in the introduction of the patent, infant formulas are usually prepared by a process including high temperatures at several steps such as homogenisation and drying (paragraph [0003]-[0005] of the patent specification; see also the disclosure of D12).

When unsaturated fatty acids, such as arachidonic acid, are used in the preparation of the infant formulas, these are conventionally mixed with the oil phase and thus added at an early point in the process. These unsaturated fatty acids, however, may degrade at the elevated temperatures used during the remaining process steps, giving an undesirable bad odour to the final infant formula.

Several approaches had already been proposed in the prior art to avoid this degradation. These include the addition of antioxidants, the addition of the unsaturated fatty acid in one or more "effects" (i.e. stages) of the evaporator (D12, claim 1) or by encapsulating the fatty acids (D20, column 4, lines 37-53).

6.2 Having regard to this prior art the technical problem underlying the present invention is said to be the provision of a process for the preparation of a foodstuff comprising arachidonic acid, wherein the acid
does not degrade, thus resulting in a foodstuff having an improved taste and a neutral smell.

6.3 As a solution to this problem the patent in suit proposes the process of claim 1 which is essentially characterised by the addition of the arachidonic acid at a late stage of the process, namely after the drying of the emulsion. By this simple measure, degradation of the arachidonic acid is avoided because no further heating steps take place in the preparation process.

6.4 The examples in the patent show that this problem has been credibly solved by the claimed process. The examples show different methods of preparing infant formulas according to the invention. Thus in example 1 a homogeneous liquid lipid composition is added in a fluidized bed directly after spray drying and in examples 3 and 4 a powdered composition adsorbed on a solid carrier or as microcapsules is added in a mixer after spray drying. A sensory analysis of the foodstuffs prepared according to the examples indicates that all the infant formulas had a good taste and a neutral smell. On the other hand, an infant formula prepared using a prior art process where the unsaturated fatty acid was added to the starting oil blend is said to result in a product having a bad odour (smelling of fish; see paragraph [0056]).

The board is thus satisfied that the above-mentioned problem has been credibly solved by the measure taken. This finding was not challenged by the appellant.
6.5 Obviousness

6.5.1 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-defined technical problem by the means claimed, namely by the late addition of the arachidonic acid in the manufacturing process.

6.5.2 There is no hint to this solution in the prior art cited by the appellant.

6.5.3 In particular, document D19, on which the appellant mainly relied, does not suggest anywhere the addition of the arachidonic acid at a late stage. D19 relates to the use of microencapsulated marine omega-3 fatty acids in the food industry. It recognizes that the addition of pure marine oils to food products has some problems, such as the taste and smell of fish which can turn rancid in the process of making the food (second page, paragraph linking the middle and the right columns). D19 solves this problem by microencapsulation of the oils, which "results in a highly sophisticated powder where the marine oil is kept protected from the degradation by the coating material used for the encapsulation" (second page, first five lines of the last paragraph). This encapsulation actually ensures that the fish oil remains stable and can be added to the food product "in most cases without altering the existing manufacturing process" (third page, after the heading "Applications").

In summary, D19 does not suggest the addition of the encapsulated fish oil at a late stage of the
proceedings. On the contrary, as a result of its encapsulation the fish oil will not degrade and can be used without modifying the known process, i.e. at the early steps of the prior art processes.

6.5.4 There is also no hint to the late addition of arachidonic acid in the preparation of foodstuffs in the other cited documents. Thus D20, which relates to the addition of polyunsaturated fatty acids to infant formulas, also uses encapsulation to avoid degrading and highlights the stability of the microcapsules under the processing conditions (D20, column 4, lines 53-58 and column 7, lines 19-23). This stability ensures that they do not degrade during the heating steps. A late addition is not suggested in D20.

6.6 The appellant pointed out that D19 made available for the first time the "fish oil" in a powdered form. It was argued that once the skilled person was aware of such a solid product, he would automatically use it in the preparation of infant formulas as the previous bias against the mixing of a powder with an oil would have disappeared.

6.7 The board rejects the appellant's argument because it is clearly based on hindsight. Contrary to the affirmation of the appellant, D19, which was published in December 1994, is not the first disclosure of a fish oil microencapsulated product. D21 already relates to food grade microencapsulated product containing unsaturated fatty acids, namely gamma linolenic acid (D21, first page) and this document is dated 1989, that is to say, eight years before the priority date of the patent.
In this context it is noted that both D12 (priority date 1993) and D20 (priority date 1990) were published after the publication date of D21 and both documents deal with the same problem as the patent in suit and use different approaches to solve the degradation problem. This fact, together with the above discussed comments in D19 itself, clearly indicates that the appellant's argument has been made with knowledge of the invention.

6.8 In view of the above, the board concludes that the person skilled in the art would not have arrived in an obvious manner at the claimed invention in the form of claim 1. Consequently, the subject-matter of claim 1 and, by the same token, of dependent claims 2 to 11 involves an inventive step within the meaning of Article 56 EPC.
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:
   (a) claims 1 to 11 according to the main request filed with the letter dated 9 November 2011;
   (b) the amended description in accordance with the order of the opposition division dated 26 March 2009 for the maintenance of the patent.

The Registrar                    The Chairman

G. Röhn                       W. Sieber