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**Datasheet for the decision
of 22 March 2024**

Case Number: T 0642/22 - 3.3.09

Application Number: 12188961.2

Publication Number: 2548454

IPC: A23L33/00, A23L5/20, A23L13/00,
A23L15/00, A23L17/00

Language of the proceedings: EN

Title of invention:

Aseptically produced infant foods having low concentrations of undesired by-products and methods for making the same

Patent Proprietor:

Société des Produits Nestlé S.A.

Opponent:

Schiweck Weinzierl Koch Patentanwälte Partnerschaft mbB

Headword:

Aseptically produced infant foods/NESTLÉ

Relevant legal provisions:

EPC 1973 Art. 100(b), 100(c), 83, 123(2)
RPBA 2020 Art. 13(2)

Keyword:

Amendments - added subject-matter (yes)

Sufficiency of disclosure - enabling disclosure (no)

Amendment after summons - exceptional circumstances (no)

Decisions cited:

T 0019/90, T 0881/01, T 1274/13, T 2039/16, T 2038/19,

T 1187/20



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Case Number: T 0642/22 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 22 March 2024

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
21 December 2021 concerning maintenance of the
European Patent No. 2548454 in amended form.**

Composition of the Board:

Chairman A. Haderlein
Members: F. Rinaldi
R. Romandini

Summary of Facts and Submissions

- I. This decision concerns the appeals filed by the patent proprietor and the opponent against the opposition division's interlocutory decision that the European patent as amended met the requirements of the EPC.
- II. With the notice of opposition, the opponent requested that the patent be revoked under Article 100(a) (lack of inventive step), (b) and (c) EPC.
- III. The documents submitted with the notice of opposition included the following:
 - D17: H. Reuter (editor), "Aseptic processing of foods", Hamburg: Behr's Verlag, 1993, 25-43, 59-85 and 125-143
 - D18: O. Zoller *et al.*, "Furan in food: Headspace method and product survey", Food Additives and Contaminants, 24 (Supplement 1), 2007, 91-107
- IV. In the decision under appeal, the opposition division concluded, among other things, that Article 100(b) EPC prejudiced the maintenance of the patent as granted; however, auxiliary request 2 was considered allowable.
- V. With its statement setting out the grounds of appeal, the patent proprietor re-filed auxiliary requests 1 to 20, which it had filed during the opposition proceedings.

VI. The wording of claims 1, 2 and 4 of the patent as granted (main request) is relevant for this decision. The claims read as follows:

"1. An infant food product, which is a packaged nutritional composition, aseptically filled, and comprises one or more meats selected from beef, veal, chicken, lamb, pork, turkey, and duck, and/or fish, and/or eggs, and/or crustaceans, wherein said product includes minimal levels of undesired by-products produced during processing as indicated by said product comprising less than 2 micrograms furan per kilogram of food product, wherein said infant product comprising one or more meats selected from beef, veal, chicken, lamb, pork, turkey, and duck is a food product for an infant in a developmental stage of 4 to 6, 6 to 8, or 8 to 12 months of age, wherein said infant food product comprising fish is a food product for an infant in a developmental stage of 6 to 8, or 8 to 12 months of age, wherein said infant food product comprising eggs is a food product for an infant in a developmental stage of 8 to 12, or 12 to 36 months of age, and wherein said infant food product comprising crustaceans is a food product for an infant in a developmental stage of 12 to 36 months of age."

"2. A method for the production of an infant food product which comprises precooking the ingredients separately, mixing the ingredients, subjecting them to UHT treatment at F_0 , $F_0=15$ or $F_0=8$ and aseptically filling packaging containers wherein the food product is a food product comprising one or more meats selected from beef, veal, chicken,

lamb, pork, turkey, and duck, and/or fish, and/or eggs, and/or crustaceans, wherein said infant product comprising one or more meats selected from of beef, veal, chicken, lamb, pork, turkey, and duck is a food product for an infant in a developmental stage of 4 to 6, 6 to 8, 8 to 12, or 12 to 36 months of age, wherein said infant food product comprising fish is a food product for an infant in a developmental stage of 6 to 8, 8 to 12, or 12 to 36 months of age, wherein said infant food product comprising eggs is a food product for an infant in a developmental stage of 8 to 12, or 12 to 36 months of age, and wherein said infant food product comprising crustaceans is a food product for an infant in a developmental stage of 12 to 36 months of age".

"4. The method according to claim 2 wherein the product comprises less than 2 micrograms furan per kilogram of food".

- VII. For the wording of the relevant claims of auxiliary requests 1 to 20, reference is made to the corresponding sections of the reasons set out below.
- VIII. At the oral proceedings before the board, the patent proprietor orally presented a new auxiliary request, which consists of a single method claim. The request is based on an auxiliary request already on file (auxiliary request 16), with all the dependent claims being deleted. More precisely, the sole method claim of the new auxiliary request is based on claim 2 of the main request, in which the term "at F0, F0=15 or F0=8 ... containers" is replaced with the term:

"at F0=100, F0=15 or F0=8 and aseptically filling packaging containers, wherein F0 is the measure of the time required to kill clostridium botulinum bacteria".

IX. The patent proprietor's arguments relevant to this decision are summarised as follows:

- The burden of proof on the issue of whether the invention was sufficiently disclosed was on the opponent; however, it did not succeed in shifting it. The experiments in the patent as well as figures 2 to 6 demonstrated that it was possible to obtain an infant food product having the furan concentration set out in claim 1.
- Claim 2 as granted did not involve added subject-matter. While the term "F0" on its own was clearly wrong, the skilled person would have immediately understood how the term needed to be corrected in light of the patent specification. The term needed to read "F0=100". The same considerations applied to claim 1 of auxiliary requests 1 and 2.
- Auxiliary requests 3 and 20 were both admissible and allowable for the same reasons as the main request.
- The new auxiliary request orally presented at the oral proceedings before the board was admissible. The request constituted a restriction and resolved the issues discussed. Considering that D17 was not prior art, the request was clearly allowable.

X. The opponent's arguments relevant to this decision are summarised as follows:

- The invention set out in claim 1 of the patent as granted was not sufficiently disclosed. The

disclosure of the patent contained errors and did not set out how the experiments had been carried out so as to achieve the low furan concentration required by claim 1.

- Claim 2 of the patent as granted involved added subject-matter. There was no basis in the application as filed for a UHT treatment and the term "F0" alone without the reference bacteria (*Clostridium botulinum*). For the same reasons, claim 1 of auxiliary requests 1 and 2 involved added subject-matter.
- Auxiliary requests 3 to 20 were neither admissible nor allowable. They suffered from the same deficiencies as the claims of the main request.
- The new auxiliary request orally presented at the oral proceedings was not admissible. There was no reason for filing such a request only at the oral proceedings. Furthermore, the request *prima facie* lacked inventive step in view of document D17 as the closest prior art.

XI. Final requests

The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted (main request). Alternatively, it requested that the patent be maintained on the basis of one of auxiliary requests 1 to 20, all filed with the statement setting out the grounds of appeal. Moreover, it requested that the patent be maintained on the basis of the (new) auxiliary request filed orally and based on auxiliary request 16.

The opponent requested that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

1. *Opposed patent*

- 1.1 The patent is based on a European divisional application. The earlier application within the meaning of Article 76(1) EPC has been the subject of appeal proceedings, dealt with by the present board (in a different composition) in decision T 2039/16.
- 1.2 The patent in suit relates to infant food products with a low content of furan, a possibly carcinogenic substance that is undesired in food. Furan can be generated from precursors, such as polyunsaturated fatty acids (PUFAs), ascorbic acid, sugars and amino acids, during heat processing of foods (paragraphs [0002] to [0006]).
- 1.3 Claim 1 of the patent as granted relates to an infant food product comprising meats and/or fish and/or eggs and/or crustaceans having less than 2 micrograms furan per kilogram of food.
- 1.4 Claim 2 relates to a method for the production of an infant food product which involves, among other things, separately pre-cooking the ingredients and a UHT treatment.
- 1.5 Method claim 4, which is dependent on claim 2, specifies that the product obtained comprises less than 2 micrograms furan per kilogram of food.

2. *Sufficiency of disclosure*

2.1 Introductory remarks

2.1.1 The opposition division decided that the invention as set out in claim 1 of the main request lacked sufficiency of disclosure.

2.1.2 Basing its reasoning on decision T 2039/16 (see point 1.1 above), the opposition division stated that the patent did not provide any information on how to achieve a furan concentration of less than 2 micrograms per kilogram of food product in UHT-sterilised infant food products containing significant levels of PUFAs and/or ascorbic acid as furan precursors, as is the case when meat, eggs, fish or crustaceans are present.

2.1.3 The patent proprietor contested this reasoning and presented the following arguments.

- The opponent had not cast serious doubts, substantiated by verifiable facts, that the invention as described in claim 1 could not be carried out. In particular, the burden of proof was not shifted to the patent proprietor. In its view, the opponent could at least have executed the method of the invention (e.g. according to claim 2) to prepare the claimed infant food product and could have determined the resulting furan content.
- Figure 4 of the patent showed a product which had less than 2 micrograms furan per kilogram of food product. Therefore, following the teaching in the patent and using a UHT process, it was possible to obtain the product referred to in claim 1.

- The skilled person would have learned from the experiments underlying paragraph [0083] and figures 2 to 4 of the patent that some precautions had to be taken to achieve the concentration set out in claim 1. For instance, adding fish oil or ascorbic acid to the composition had to be avoided.
- Figures 5 and 6 had to be read in combination with paragraph [0083] of the patent. The experiments associated with figures 5 and 6 as discussed in this paragraph demonstrated that food products comprising less than 2 micrograms furan per kilogram of food were obtained under UHT conditions (F0=8 and F0=15).
- Therefore, the invention as set out in claim 1, and also claim 4, was sufficiently disclosed.

2.1.4 As correctly pointed out by the patent proprietor, according to the Case Law of the Boards of Appeal, a successful objection of insufficient disclosure presupposes that there are serious doubts, substantiated by verifiable facts (Case Law of the Boards of Appeal of the EPO, 10th edition, 2022, Chapter II.C.9, first paragraph and Chapter III.G. 5.1.2c), first paragraph, with particular reference to T 19/90).

2.1.5 However, this does not mean that the opponent necessarily has to provide evidence such as experimental data showing that the claimed furan levels could not be achieved. Instead, the existence of verifiable facts which may give rise to doubts as to the sufficiency of the disclosure may be inferred from the patent itself or from common general knowledge (see, for instance, T 2038/19, Reasons 3; T 1187/20, Reasons 1). Considering the merits of the current case,

the board is satisfied that the opponent has presented such facts, as will be seen from the following.

2.2 Assessment of the patent's disclosure and the proprietor's arguments

2.2.1 The patent teaches (e.g. in figures 2 and 3) that linoleic acid or linolenic acid (i.e. PUFAs) are furan precursors that are particularly prone to generating high furan concentrations after a heat treatment. Samples containing these two precursor substances, which are found in meats and fish, exhibit the highest formation of furan.

2.2.2 As is manifest from the prior art discussed throughout the opposition (appeal) proceedings, food products having the low furan concentration required by claim 1 are known in the art (e.g. D18, table III); however, these products are fruit preparations and do not contain meats or fish.

2.2.3 The difficulty lies in providing an aseptically filled product which comprises fish or meats and yet has a low concentration of furan. These are the products to which claim 1 is directed and which contain the aforementioned precursors. The considerable heat treatment required for providing the aseptically filled food generates furan from the various precursors contained in the food. For this to be made possible over the entire scope, the skilled person has to be given instructions on how to prepare such products.

2.2.4 In this context, it is also noted that the (divisional) application as filed called for a considerably wider concentration range, namely less than 15 micrograms furan per kilogram food. Instead, claim 1 as granted

focuses on a restricted range, which is particularly difficult to achieve and at the same time calls for meats or fish.

- 2.2.5 The patent proprietor has referred in particular to the experiments described in paragraphs [0081] to [0084] of the patent and to their results, which are displayed in figures 2 to 6. These are the only sections of the patent practically addressing a concentration of furan in the range of 2 micrograms per kilogram food product. Other sections of the patent, such as paragraph [0055], refer to "reduced levels of by-products including furan"; however, this generic disclosure must instead be read in context of the wider range of 15 micrograms per kilogram food product, which was disclosed in the (earlier) application as filed.
- 2.2.6 Figures 2 to 6 of the patent disclose bar charts showing the amount of furan measured during the experiments outlined in the patent. The disclosure of how the experiments were carried out is remarkably succinct.
- 2.2.7 In the experiments relating to figures 2 and 3 aqueous model solutions of various precursors of furan are heated and the resulting concentration of furan is established, at two different pH levels. These experiments do not comprise fish or meats. The only conclusion that can be drawn from these experiments is as explained above (see point 2.2.1), namely that heating precursors (e.g. PUFAs such as linoleic acid or linolenic acid) leads to a high concentration of furan.
- 2.2.8 Figure 4 also shows a bar chart. The nine bars of the chart correspond to three sets of experiments ("retort", "UHT normal process", "UHT overprocessed").

In each one of the three experiments, three different samples were studied, namely:

- (1) "no BAB added"
- (2) "0.024% Fishoil + 0.06 Vit. C"
- (3) "0.12% Fishoil + 0.12 Vit. C"

2.2.9 The term "no BAB added" is not explained in the patent. Moreover, the patent does not disclose the composition of the food product used in the experiments, whether it contains meats according to the definition of claim 1 (or fish), and what process steps or conditions are used for preparing and heating the product. Due to the size of the bar chart it is also unclear whether a value of less than 2 micrograms furan per kilogram of food is achieved at all. In conclusion, figure 4 (as well as figures 2 and 3) at best shows that if a precursor consisting of fish oil and vitamin C is added, then the concentration of furan increases.

2.2.10 With regard to the experiments relating to figure 5, the labelling on the y axis of the figure is manifestly wrong, as the patent proprietor itself acknowledged: the values indicated on the y axis are much too low. In addition, the experiments are carried out with a vegetable product, not a product including meats. There is also no information on the specific process steps taken during the preparation of the product (apart from mentioning that the UHT processing occurs at F0=8 or F0=15). Therefore, these experiments are also not suitable for demonstrating that the invention is made possible over the whole, explicitly claimed scope.

2.2.11 Finally, in the experiments relating to figure 6, the food product investigated is a savoury food product comprising cod (i.e. a fish) and mixed vegetables;

however, the labelling on the y axis of the figure is wrong, as is the case for figure 5.

- 2.2.12 In the section of the patent specification discussing the experiments in figure 6 it is stated that "there is about 2 micrograms of furan per kg food product produced as a by-product following processing" (paragraph [0083]). The patent proprietor argued that in view of the disclosure in this paragraph, the labelling on the y axis of figure 6 had to be corrected by a factor of 100. If this was done, figure 6 showed that a value slightly below 2 micrograms of furan per kilogram food product was obtained in experiments executed with a UHT treatment at F0=8 or F0=15 (but not at F0=100).
- 2.2.13 Nevertheless, even if it is accepted that this correction has to be applied, the disclosure of the experiments remains insufficient. As is the case for all other experiments in the patent, essential instructions or information on which steps are taken when the product referred to in figure 6 is prepared are missing. There is also no disclosure of when in the process and how heating (including the UHT processing F0=8, F0=15) takes place.
- 2.2.14 Therefore, on the face of it, the experiments belonging to figure 6 might demonstrate that the inventors of the patent themselves were able to obtain an infant food product which had the concentration of furan of claim 1 and comprised fish; however, the specific recipe and processing conditions under which the inventors were able to obtain that product remain essentially undisclosed. There are no instructions in the patent for how that product was prepared. There is also no example that the skilled person could reproduce for

when they would start to carry out the invention. Finally, there are no instructions on what should be done to adapt the preparation method in the event of failure.

2.2.15 The patent proprietor argued that the skilled person would learn from figures 2 to 6 that the use of precursors such as PUFAs had to be avoided.

2.2.16 However, these instructions are of little help. A wide range of precursors of furan are intrinsically part of fish and meats (and of other ingredients typically associated with infant food products). No general instructions can be found in the patent that precursors are not be used, let alone how to deal with precursors that are intrinsically part of uncooked fish or meats.

2.3 Conclusion

2.3.1 The central question in the present case is whether the skilled person would be able to produce aseptically filled products comprising fish or meats that have a concentration of furan of less than 2 micrograms per kilogram food product. The relevant point in time is the filing date of the earlier patent application.

2.3.2 The passages of the patent cited by the patent proprietor (and the arguments they have presented) are not sufficient to overcome the serious doubts outlined above. All the evidence available to the board points towards the skilled person not having the necessary instructions for preparing a food product comprising fish or meats with a concentration of 2 micrograms furan per kilogram of food product. This is all the more applicable to values ranging below this concentration.

2.3.3 For this reason the board is not convinced that the skilled person would be able to carry out the invention over the whole scope of the claim. As a consequence, the ground for opposition of Article 100(b) EPC prejudices the maintenance of the patent as granted.

3. *Amendments*

3.1 During the opposition proceedings, the opponent had argued, among other things, that the term "F0" in claim 2 as granted was not disclosed in the application as filed without a sterilisation time and the reference bacteria (*Clostridium botulinum*). Therefore, claim 2 involved added subject-matter.

3.2 The opposition division concluded that a claim having the wording of claim 2 as granted did not involve added subject-matter. While the term "F0" on its own was unclear, this deficiency was present in the claim as granted. The skilled person would have immediately recognised that there was an error in the claim, and they would have corrected it in light of the disclosure in paragraph [0084] of the patent specification.

3.3 The (earlier) application as filed does not disclose a UHT treatment in combination with the term "F0" without reference to a value (in minutes) or without mentioning that the term relates to the time required to kill *Clostridium botulinum* bacteria. Therefore, the term "F0" on its own is not disclosed in the (earlier) application as filed. In particular, the term does not imply any restriction of the type or duration of the UHT treatment.

3.4 This finding in itself demonstrates that the amendment involves added subject-matter.

3.5 With regard to the patent proprietor's argument that a skilled person would have corrected the error, the following is observed. The fact that the number of minutes for the UHT treatment is not specified does not mean that the skilled person would be prompted to look for an appropriate restriction in the granted patent, as argued the patent proprietor. The term "F0" alone is simply undefined with respect to e.g. the duration of the UHT treatment. No reason can be found as to why the skilled person would "rewrite" the claim (within the meaning of T 881/01, Reasons 2.1) using a restriction that they would have to look for in the patent specification.

3.6 In other words, while the skilled person may find a possible "correction" for the term "F0" in the patent specification, there is no indication that the patent proprietor (directly and unambiguously) intended to specifically apply this restriction to the subject-matter of claim 2. Instead, the missing text in conjunction with the term "F0" might have been that the term is the measure of the time required to kill *Clostridium botulinum* bacteria.

3.7 Therefore, it is concluded that the ground for opposition of Article 100(c) EPC prejudices the maintenance of the patent as granted.

4. *Auxiliary requests 1 to 20*

4.1 As will be set out in the following, none of auxiliary requests 3 to 20 is allowable. Therefore, admittance of these requests need not be discussed.

- 4.2 Auxiliary requests 1 and 2 encompass a claim having the same wording as claim 2 as granted. For the reasons set out above in point 3, these requests are not allowable under Article 123(2) EPC.
- 4.3 Auxiliary requests 3 to 6 and 20 encompass a claim having the same wording as claim 1 as granted. For the reasons set out above in point 2, these requests are not allowable for lack of sufficiency of disclosure.
- 4.4 Auxiliary requests 7 to 14 and 16 to 18 all encompass at least a dependent method claim having the same wording as claim 4 as granted. All these dependent claims specify that the product obtained by the method comprises less than 2 micrograms furan per kilogram food product. These claims are subject to the same objections as product claim 1 as granted. The patent does not set out a method for achieving the result specified, and neither do the dependent method claims. In conclusion, none of these requests is allowable for lack of sufficiency of disclosure.
- 4.5 Auxiliary request 15 comprises a sole claim. It is based on product claim 1 as granted, to which process features have been added. The process features do not resolve the issues of lack of sufficiency of disclosure, and the patent proprietor did not put forward an argument to this effect, either.
- 4.6 Auxiliary request 19 comprises a single method claim. It is based on claim 2 as granted, to which the restriction was added (among other features) that the product comprises less than 1 microgram furan per kilogram of food product. The same objections of insufficiency as in point 2 apply to this lower value.

Indeed, if a concentration below 2 micrograms per kilogram of food product cannot be reached, the same applies, to a stronger degree, for a concentration below 1 microgram per kilogram of food product.

5. *Admittance of the new auxiliary request*

5.1 At the oral proceedings before the board the patent proprietor orally presented a new auxiliary request consisting of a single method claim (wording; see point VIII above). It intended to use this request for further examination of the case, possibly after a remittal.

5.2 The board issued a communication under Article 15(1) RPBA about six months before the oral proceedings. The patent proprietor filed an extensive submission, in which it discussed the issues raised by the board. Nevertheless, it did not file further auxiliary requests with this submission. The new auxiliary request was presented at the latest possible stage in the appeal proceedings, namely at the oral proceedings.

5.3 In the present case, the board cannot identify any exceptional circumstances which would justify the filing of the request at the oral proceedings (Article 13(2) RPBA). The patent proprietor itself only argued that the new auxiliary request constituted a restriction and allegedly resolved all issues discussed. In addition, since D17 was not prior art, let alone the closest prior art, the request was clearly allowable with respect to the disclosure of this document.

5.4 However, clear allowability of a claim request does not constitute an exceptional circumstance within the

meaning of Article 13(2) RPBA. For this reason alone the board cannot take this request into account. Only for the sake of completeness does the board add the following considerations.

5.5 It is true that the single method claim of the request filed orally comprises additional features which *prima facie* resolve the objection of added subject-matter (see point 3 above). It is also true that the opposition division concluded that D17 was not prior art because the publication date was not explicitly disclosed on the pages of D17 itself.

5.5.1 However, as correctly argued by the opponent, the content of D17 was identical to a document (O3-D3, published in 1993) cited in parallel proceedings underlying a decision by this board (T 1274/13). This decision was cited and discussed throughout the opposition and appeal proceedings for the current case, starting with the notice of opposition. The bibliographic data of D17 and O3-D3 is identical.

5.5.2 Furthermore, this board had set out in its communication under Article 15(1) RPBA that:

- D17 was prior art under Article 54(2) EPC,
- D17 was the closest prior art for assessing the inventive step of the method claim (i.e. claim 2 of the patent as granted) and
- the method claim did not involve an inventive step in view of D17, following the problem-solution approach.

5.6 Therefore, the amendment made at the oral proceedings is not suitable for addressing and resolving all the relevant objections raised in the appeal proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



K. Götz-Wein

A. Haderlein

Decision electronically authenticated