DECISION
of 10 July 2002

Case Number: T 0770/00 - 3.3.2
Application Number: 94906187.3
Publication Number: 0684769
IPC: A23D 7/015

Language of the proceedings: EN

Title of invention:
Low fat spread with non-proteinaceous crystal inhibitors

Patentee:
UNILEVER N.V., et al

Opponents:
Danisco Biotechnology
CARLSHAMN MEJERI AB

Headword:
Low fat spread/UNILEVER

Relevant legal provisions:
EPC Art. 83

Keyword:
"Sufficiency of disclosure (yes): formulation E illustrates the claimed invention and falls within claim 1"
"Remittal to the first instance for further prosecution"

Decisions cited:
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Catchword:
-
Case Number: T 0770/00 - 3.3.2

DECISION
of the Technical Board of Appeal 3.3.2
of 10 July 2002

Appellant: UNILEVER N.V.
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Decision under appeal: Decision of the Opposition Division of the European Patent Office posted 25 May 2000 revoking European patent No. 0 684 769 pursuant to Article 102(1) EPC.

Composition of the Board:
Chairman:  P. A. M. Lançon
Members:  M. Ortega Plaza
          S. U. Hoffmann
Summary of Facts and Submissions

I. European patent No EP-B 0 684 769, which was filed as international application WO-A-94 18846, was granted on the basis of 11 claims.

Independent claim 1 as granted read as follows:

"An edible, oil continuous emulsion spread product comprising:

(a) 30 to 40 wt.% of a fat phase, having 0.05 to 0.5 wt.% based on total composition of a non-proteinaceous fat crystallisation inhibitor having an HLB of from 5 to 10, and from 0.1 to 0.4 wt.% of a non-proteinaceous emulsifier system; and

(b) 70 to 60 wt.% of an aqueous phase containing 0.005 to less than 0.1 wt.% of a dairy protein based on total composition."

II. Notice of opposition was filed against the granted patent by the respondents (opponents).

The patent was opposed under Article 100(a) EPC for lack of novelty and lack of inventive step and Article 100(b) EPC for lack of sufficiency of disclosure.

The following documents inter alia were cited:


D2: US-A-4 632 841
III. The Opposition Division revoked the patent under Article 102(1) EPC.

The Opposition Division considered that the main request (patent as granted) did not meet the requirements of Article 100(b) EPC because the contested patent did not contain any specific example falling within the claimed range. Respondent O1 (opponent O1) had filed experimental data in order to show that examples falling within the claimed scope failed to give satisfactory results, whereas the examples not falling within the claimed range and corresponding to Example E of the contested patent provided satisfactory results.

The appellant (patentee) brought a number of samples to oral proceedings before the Opposition Division but did not provide any experimental data for the reproductions of the experiments filed by respondent O1 as annex to the letter of 8 March 2000 (in particular compositions 2, 3 and 5). On the other hand it did not contest the way in which the experimental data filed by O1 were obtained. The Opposition Division did not have any reason to do so.

The Opposition Division concluded that the experiments carried out by respondent O1 suggested that the subject-matter of the contested patent did not achieve the desired technical result, ie a long-term stable low fat spread.

IV. The appellant (patentee) lodged an appeal against the said decision.

The following documents were produced in appeal...
By the Appellant

(P1): Food emulsifiers - functional properties and applications, by J. Madsen, Danisco Ingredients, Denmark.


By respondent O2

(R1): Monographs for emulsifiers for foods, EFEMA, November 1985, second edition, table of contents and pages 1 to 5.


V. Oral proceedings were held before the Board on 10 July 2002.

VI. The appellant submitted that claim 1 referred to the chemical substances such as "dairy protein" or "non-proteinaceous emulsifier system", this wording being different from that of the examples which related to commercially available products such as lecithin. The word "lecithin" was not used in the claims. Claim 5 of the patent as granted referred to preferred emulsifier systems comprising "phosphatides".
Lecithin was commonly employed in the field of fat spreads and it related to a mixture of phospholipids, in fact containing 45% phosphatides. In support of this statement the appellant cited P3. It concluded that soybean lecithin contains ~45% phosphatides, the rest being other components including acetone insoluble sugar components. Soybean lecithin was the most commonly used lecithin source for fat spreads. To use the expression "lecithin", without further specification, was common in patent applications in the said field and meant a mixture of phosphatides. The appellant cited documents D1 and D2. Example E illustrated the invention and fell within the scope of claim 1.

With respect to the examples submitted by respondent O1 during the opposition proceedings (with the letter of 8 March 2000) the appellant contended that respondent O1 had only stated in its annex I to that letter "that compositions 1 to 6 (shown in table 2) were prepared as described in" the patent in suit, but there were no experimental details given. Therefore, it was not possible to check whether that was the case or not. Additionally, respondent O1 itself had been able to reproduce the invention by repeating Example E.

With regard to its own submitted experimental data filed with the grounds of appeal, the appellant stated that where there is a balance of probabilities, the burden of proof lies with the opponents. The experimental data it had submitted related to examples falling within the claimed scope and they worked. The replacement of soybean oil with sunflower oil had no great influence on the results.
With respect to the amount of whey powder used in the examples, it had not been shown that the dairy protein amount was outside the scope claimed. Example 2 of the patent in suit was to be interpreted within the context of the specific composition and could not serve to cast any doubts on the upper limit of the dairy protein content defined in claim 1.

VII. According to the respondents, there was no indication in the description of the patent in suit leading the skilled person to the conclusion that the lecithin to be used was of ~45% purity. Even if lecithin was considered as a mixture of phosphatides, the level of purity according to the EEC directive (R2) was not less than 60% of acetone insoluble material.

With respect to the distilled saturated and distilled unsaturated monoglycerides employed in the examples it could not be accepted that they had to be considered 95% pure. Looking at the content of P1, page 4, it was clear that the distilled monoglycerides contain 3 to 4% of diglycerides. Diglycerides also fell within the definition given in the patent in suit for the components of the emulsifier system (cf. claim 5) and therefore their amount was also to be accounted for in the calculation of the total amount of the emulsifier system present in the examples of the patent in suit.

At oral proceedings before the Board, respondent O1 submitted some tables of calculations (three sheets). It pointed to the calculations of the amounts of the single components present in the examples of the patent in suit (compositions D to I), those present in the examples submitted by itself in opposition proceedings (compositions 1 to 6) and those of compositions A to C
submitted by the appellant with the grounds of appeal (see Tables 3, 4 and 5 respectively). In these calculations it had used the above-mentioned approach. It pointed to composition E (and compositions 1 and 6), in which the total amount of emulsifier was 0.403, ie in its opinion outside the claimed range.

On page 4, line 6, of the patent in suit it was stated that: "Unless otherwise indicated, wt.% means the percentage of the ingredient based on the total composition", ie the ingredient was meant and nothing else.

Further to the experimental data submitted by the appellant, the respondents contested that they were directly comparable to the examples of the patent in suit or to the examples submitted by respondent O1 in view of the use of sunflower oil instead of soybean oil.

Additionally, respondent O2 questioned whether the patent in suit was sufficiently disclosed with respect to the actual content of dairy protein to be used. The examples used whey powder which contained approximately 12% of dairy protein. Example 2 showed variations in the spreadability behaviour due to the amount of whey powder. In particular it was stated (page 5, lines 39 to 40) that: "It was thus observed that compositions containing more than about 0.2% whey powder had low spreadability and the total protein content level is critical". The skilled person found no indication in the patent in suit on how to proceed with respect to the actual amount of dairy protein in order to reproduce the invention in the whole scope claimed.
The respondents did not contest that the documents introduced by the appellant were prepublished documents.

VIII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution.

The respondents requested that the appeal be dismissed.

**Reason for the Decision**

1. The appeal is admissible.

2. *Sufficiency of disclosure*

   Article 83 EPC requires an invention to be disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. When considering whether the requirements of sufficiency of disclosure are met the contents of the whole patent, ie claims and description, have to be investigated in the light of the general knowledge of the skilled person in the technical field involved. The claims define the matter for which protection is sought and the examples illustrate specific ways of performing the invention. As for the amount of technical detail needed for a sufficient disclosure, this is a matter which depends on assessment of the facts of each particular case, such as the character of the technical field, the corresponding general technical knowledge, and the actual technical detail disclosed.

   In the patent in suit claim 1 relates to an edible, oil
continuous emulsion spread product comprising 30-40% of a fat phase and 70 to 60% of an aqueous phase.

Therefore the following essential components are clear from the reading of claim 1:

Fat phase
a1
    non-proteinaceous
    **fat crystallisation inhibitor** 0.05 to 0.5 wt.%

a2
    non-proteinaceous **emulsifier system** 0.1 to 0.4 wt.%

Aqueous phase
b1
    **dairy protein** 0.005 to less than 0.1 wt.%

The amounts of the components listed in claim 1 refer to wt.% based on the total composition. This is confirmed by page 4, line 6, of the description in which it is additionally stated that: "Unless otherwise indicated, wt.% means the percentage of the ingredient based on the total composition".

The nature of the non-proteinaceous fat crystallisation inhibitor is further defined in claim 1 by its HLB value: "having an HLB of from 5 to 10".

The patent in suit contains examples of several formulations shown in Examples 1 and 2 as compositions D and E (Example 1) and compositions F and G (Example 2). The compositions A-C (Example 1) do not relate to examples illustrating the invention, since
they do not contain polyglycerol ester, i.e. they are devoid of a "non-proteinaceous fat crystallisation inhibitor". Compositions H and I were given within the context of Example 2 in order to illustrate how the amount of dairy protein influences the spreadability behaviour for a specific composition. The source of dairy protein employed is "whey powder".

In the examples of the patent in suit the following specific products have been used:

as component a1, polyglycerol ester, Santone 3-1-SH, supplied by Van den Bergh of Lisle, III, HLB of 7;

as component a2, a mixture of distilled saturated monoglycerides, distilled unsaturated monoglycerides and lecithin;

as component b1, whey powder.

The first question to be answered is whether the examples disclosed in the patent in suit fall within claim 1, in particular whether the exemplified emulsifier system falls within the claimed range. With respect to the aqueous phase and the use of whey powder, there is no reason to doubt that the amounts of dairy protein in the examples fall within the scope claimed and no objection to that effect was raised.

In relation to the oil phase, it must be admitted that lecithin is commonly used in the field of low fat spreads, see documents D1, page 19, and D2, column 5, Example 1, Table 1, in which the component "lecithin" is used without further specification.
Lecithin, "E 322", is defined by the EEC directive (R2) as mixtures or fractions of phosphatides. It represents not less than 60% of substance insoluble in acetone.

R1 refers to lecithin as having the EEC number E 322 (see page 1) and states that it is a mixture of phosphatides. R1 further states that the distribution of the principal components depends on the sources, which may be vegetable oils and seeds (for example soya, maize) or animal sources (for example eggs). The specification on page 4 states that the acetone insoluble material is min. 60%.

P2 refers for lecithin to two commercial products: one as 45% lecithin E 322 (having other components as modified milk solids) and the other as 100% lecithin E 322 (see Admul Lec 2251 and Admul Lec 2879 under the heading "Lecithin Products").

P3 states that the expression lecithin is used either strictly scientifically to mean pure phosphatidyl choline or to mean a mixture of phospholipids and a variety of other compounds. It further states that commercial lecithin is currently available in more than 40 different variations (page 192). On page 193 of P3 it is stated that the main sources for industrial lecithins include vegetal oils (for example soybean, cottonseed, etc.) and animal tissues. Table 4 on page 194 of P3 shows a composition of commercial soy lecithin having an acetone insoluble matter of about 60%.

Respondent O1, when questioned by the Board, stated that the lecithin it had used for providing its compositions 1 to 6 was a mixture of phospholipids. It
stated that it was the commercial product Bolec ZT and was defined as containing about 60%, more accurately 62%, acetone insoluble matter.

In the light of the above evidence, the Board is satisfied that the lecithin commonly used in low fat spreads relates to a mixture of phosphatides relating to acetone insoluble material of at least 60%. Depending on the source chosen for lecithin the amount of phospholipids, especially phosphatidyl choline, will vary. However, it cannot be denied that soybean oil is a source for lecithin commonly used in food technology (soy lecithin).

Thus it is apparent from the above that it is highly doubtful that pure phosphatidyl choline would be used as an emulsifier component of low fat spreads, especially in the absence of any indication in this respect. Hence, commercial lecithin relating to a mixture of phosphatides would be used by the skilled person when reproducing the invention.

The appellant has submitted that the content of phosphatides in the commercially available lecithin suitable for use in food amounts to ~45% phosphatides. It concluded that this is the content to be considered for calculating the total amounts of the emulsifier system present in the examples of the patent in suit. It stated that the value of ~45% could be calculated from Table 4 on page 194 of P3.

Respondent O1 contested these calculations and produced new calculations considering the content of 60% acetone insoluble material as the key to the calculation of the total amount of emulsifier. It further denied that any
further calculations were necessary relating to the amount of distilled saturated and unsaturated monoglycerides, since in the patent in suit diglycerides (possible impurity stated by the appellant in its grounds of appeal and in P1) were also listed as components of the emulsifier system (claim 5).

The Board considers that even if the amount of ~45% is not accepted for lecithin, it is not possible to overlook the fact that calculations using 60% as value lead to total amounts for the emulsifier system of 0.403 (see table 3 filed by respondent O1 during oral proceedings before the Board and Table 4, compositions 1 and 6, relating to the reproduction of composition E of Example 1 of the patent in suit). The percentages given in claim 1 give only the first decimal place and so are less precise than when figures with three decimal places are used. Accordingly, when the values obtained by adding specific figures turn out to have three decimal places, 0.403 for example, they have to be rounded down, ie 0.403% equates approximately to 0.4% and hence it cannot be concluded that this figure is not encompassed in the range from 0.1 to 0.4 wt.% as stated in claim 1. The Board is satisfied that the amount of emulsifier system employed in formulations D and E of Example 1 and F and G of Example 2 fall within the claimed scope.

In conclusion, the Board accepts that formulation E of Example 1 falls within the scope of claim 1.

The second question to be answered is whether the patent in suit contains examples which illustrate the invention. This question must be answered in the affirmative, since respondent O1 confirmed with its own
data that formulation E works (see annex 1 to the respondent's O1 submissions on 8 March 2000, compositions 1 and 6 in Table 2 and results on page 2 of the accompanying letter).

As regards the reproducibility of the invention, respondent O1 has shown that it has been able to reproduce formulation E of Example 1 and that it works (compositions 1 and 6). The fact that it used the commercial lecithin Bolec ZT with about 60% acetone insoluble material demonstrates that there is no difficulty for the person skilled in the art to repeat the examples of the invention.

With regard to the further examples provided by respondent O1, ie the compositions 2 to 5, they were described by itself as having poor stability. Contrary to the appellant's opinion, they relate to total amounts of emulsifier system lower than formulation E, but falling within claim 1. This also applies when using the calculated values in Table 4 (60% lecithin), submitted by respondent O1 during oral proceedings before the Board. However, when submitting the experimental data, respondent O1 did not give details of the method of preparation. It merely stated that the compositions "were prepared as described" in the patent in suit. This statement does not make it possible to check whether the methodology is exactly the same as that of the patent in suit or not. Thus full reliance upon the results is not possible.

On the other hand, it may be true that the experimental data (compositions A to C) filed by the appellant do not allow direct comparison with compositions 2 to 5 submitted by respondent O1 in view of the differences
between sunflower oil and soybean oil, but sunflower oil as well as soybean oil are both liquid vegetable oils covered by the wording (fat phase) of claim 1 so that these data constitute a further example of the patent in suit. When using the calculations given on Table 5 filed by respondent O1, the figures fall within the range claimed and relate to spreads with good stability. The Board is satisfied that formulations A to C filed by the appellant concern emulsifier systems comparable in their total amount and composition to those of compositions 2, 3 and 5 submitted by respondent O1.

Finally, respondent O2 put forward a number of arguments concerning the difficulties which the skilled person encounters in adjusting the amount of dairy protein to be used for a specific protein source. However, no technical proof was provided in this respect.

In the light of the above, the Board has to conclude that the skilled person in the field is able to reproduce the claimed invention, which is illustrated at least by formulation E of Example 1. The invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Order

For these reasons it is decided:

1 The decision under appeal is set aside.
2 The case is remitted to the first instance for further prosecution.

The Registrar:  The Chairman:

A. Townend  P. Lançon