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DECISION
of 6 September 1996

Case Number: T 0292/92 - 3.3.2

Application Number: 83100171.4

Publication Number: 0084341

IPC: A61K 9/10

Language of the proceedings: EN

Title of invention:
Emulsion-type composition

Patentee:
Eisai Co., Ltd.

Opponent:
Henkel Kommanditgesellschaft auf Aktien

Headword:
Emulsion-type composition/EISAI

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (yes) - comparative test"

Decisions cited:
T 0181/82, T 0197/86

Catchword:
-



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D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 6 September 1996

Appellant:
(Opponent) Henkel
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Representative: -

Respondent:
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Decision under appeal: Interlocutory decision of the Opposition Division
of the European Patent Office posted 11 March
1992 concerning maintenance of European patent
No. 0 084 341 in amended form.

Composition of the Board:

Chairman: P. A. M. Lançon
Members: C. Germinario
J. Van Moer

Summary of Facts and Submissions

- I. European patent No. 0 084 341 was granted in response to European patent application No. 83 100 171.4.
- II. Notice of opposition was filed by the Appellants, requesting revocation of the patent in its entirety under Article 100(a) EPC on the ground of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC).

The following documents were cited during the procedure:

- (1) Seifen, Ölen, Fette, Wachse, 100 (14), 1979, pp 343-346;
- (3) Cosmetic & Toiletries, 94, August 1979, p 25-30;
- (4) DE-B-19 00 961
- (5) Reinhard von Kleinsorgen: "Herstellung und Stabilisierung von Emulsionen mit Hilfe von Lecithin", Inaugural-Dissertation 1979, Marburg/Lahn.

- III. The Opposition Division held in its interlocutory decision that the patent could be maintained in amended form (unique request), recognizing that none of the cited prior documents disclosed emulsion-type compositions containing, as an emulsifier, partially hydrogenated egg yolk lecithin and a fatty acid mono-ester of glycerine or propylene glycol in the given ratio.

Having identified the underlying technical problem in improving the stability of the composition, the Opposition Division recognized, on the basis of the experimental example 2 (page 7 to 9 of the patent

disclosure) that the problem was solved and that claim 1 involved an inventive step since no prior document or combination thereof would even suggest the existence of said problem, let alone the solution proposed by the patent under opposition.

The independent claim, maintained by the Opposition Division, and still valid reads as follows:

"An emulsion-type composition for external use containing an effective amount of lecithin for use on the skin, and a fatty acid mono-ester of glycerine or propylene glycol effective as an emulsifier, characterized in that the lecithin is a partially hydrogenated egg yolk lecithin, and in that it contains from 0.2 to 10 parts by weight per 1 part by weight of lecithin of said fatty acid mono-ester of glycerine or propylene glycol."

Dependent claim 2 defines the fatty acid of the monoester as having 8 to 32 carbon atoms. Claim 3 covers the use of the claimed emulsion-type composition to prepare a medicine for external use or a cosmetic.

IV. Appeal against this decision was lodged by the Opponents (Appellants).

In their statement of grounds of appeal and further submission the Appellants indicated documents (1), (3) and (4) as the most relevant prior documents and emphasised that they already disclosed emulsion-type compositions comprising, as an emulsifier, egg yolk lecithin (or a lecithin derivative) and a fatty acid mono-ester of glycerine or propylene glycol in the claimed ratio. Thus the unique difference making the claimed subject matter novel over the prior

compositions was the feature of comprising partially hydrogenated egg yolk lecithin.

On this ground, the Appellants objected to the relevance of the experimental example 2, in the opposed patent, as a comparative test capable of showing any improved stability over the compositions of the prior art. They maintained that the compositions cited as comparative terms did not reflect the closest prior art, since they comprised either the partially hydrogenated egg yolk lecithin or the fatty acid mono-ester of a polyalcohol but never the combination of native lecithin and fatty acid mono-ester as already described in (1), (3) or (4).

The Appellants also objected to the validity of the results shown by the comparative test submitted by the Respondents on 21 August 1992 since the lecithin types used as comparative terms were not properly characterized as to their origin and phosphatidyl content.

Should, nevertheless, the alleged improvement be recognized, the claimed subject matter would, according to the Appellants' arguments, lack inventive step over the teaching in documents (4) and (5), the former describing an emulsifying composition consisting of lecithin derivatives and mono-di-glycerides, the latter disclosing the advantages involved in the use of the hydrogenated lecithin over the native lecithin as an emulsifier.

- V. The Respondents contested the Appellants' arguments concerning the validity of the aforementioned comparative tests.

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

The Respondents requested the appeal be dismissed and the patent be maintained in the amended form as upheld by the Opposition Division.

Reasons for the Decision

1. The appeal is admissible.
2. In the amended claim 1, the lecithin, which was not further characterized in the original claim 1, is defined as being partially hydrogenated egg yolk lecithin. The new characterisation is disclosed in the application as filed in all the examples, but example 3, and in the first paragraph of page 3 of the description. Moreover the amendment involves a more precise, therefore more limited, definition of the essential component of the claimed composition. Accordingly, amended claim 1 complies with the requirements of Article 123(2) and (3) EPC.

The meaning of "partially hydrogenated" must be clear to the skilled man as the expressions "hydrogenated and partially hydrogenated lecithin" were used, and explained in terms of iodine values, in the technical literature at least since 1959 as evident from document (5) (item 5.4.1.). Therefore amended claim 1 also complies with the requirements of Article 84 EPC.

3. *Novelty*

The issue of novelty does not arise, as none of the cited documents discloses emulsion-type compositions

containing partially hydrogenated egg yolk lecithin and a fatty acid mono-ester of glycerine or propylene glycol in whatever ratio. The Appellants acknowledged this in paragraph I of the grounds of appeal, while discussing the unique recognized difference between the invention and said prior art.

4. *Inventive step*

- 4.1 Documents (1), (3) and (4) were cited by the Appellants as the most relevant prior art, though the arguments based on document (4) were later dropped.

Document (4) discloses the use of partially hydrolysed, but not hydrogenated, lecithin of plant origin in mixture with mono-di-glycerides for purpose of stabilizing margarine.

Document (3) discloses, in more general terms, the use of native lecithin (vegetable or egg yolk) in cosmetic compositions and specifically addresses the question of the solubilisation of lecithin by way of fatty amine oxides.

Document (1) describes the chemical properties, cosmetic effect and application in cosmetic compositions of native lecithin (i.e. soybean and egg yolk). The effect of lecithin as an emulsifying, dispersing agent and emulsion stabilizer is specifically addressed in paragraphs 2 and 4. In particular, there is disclosed on page 346, the composition "Tagescreme", which comprises glyceryl monostearate and the commercially available lecithin product "Emulmetik 88" in the ratio 2 parts of monostearate per 1 part of lecithin.

The Board considers this document as the closest prior art since, like the opposed patent, it focuses on the emulsifying and stabilising activity of lecithin.

- 4.2 With regard to the closest prior art, the technical problem underlying the present invention is to improve the stability of the emulsion-type composition of the closest prior art.

The solution of this problem proposed by the patent at issue is to replace the native lecithin by a partially hydrogenated egg yolk lecithin.

- 4.3.1 In the comparative tests, submitted by the Respondents on 21 August 1992, the stability of two emulsion-type compositions according to the invention [(1) and (2)], comprising partially hydrogenated egg yolk lecithins having iodine values of 27 and 20 respectively, are compared with the stability of a composition (3) differing from the former two only in that the egg yolk lecithin is non-hydrogenated and has iodine value of 78. The compositions of the invention proved to be stable and no change in appearance was recognized after three months at 40°C, while in the reference composition a remarkable aqueous phase separation was recognized.

Taking into account this result, the Board has no reason to doubt that the technical problem has been solved.

- 4.3.2 The Appellants contest the reliability of the tests because neither the origin nor the quality of the lecithins in the compared compositions are given. They specifically stress that the phospholipid content in the three compositions may differ so dramatically that no valid comparison may be carried out and accordingly

that the observed improvement in stability is not necessarily due to the hydrogenated lecithin but may result from a different content in phospholipids or in any other accompanying substance due to the different origin.

The Board concedes that, should, as a matter of pure speculation, the compared compositions significantly differ the one from the other, the observed improvement in stability could be the result of factors other than the hydrogenation of lecithin, for example it could be the result of the different phospholipid content.

However the Respondents unambiguously stated, in the communication accompanying the comparative tests, that the origin of the lecithin, in all three compositions, is egg yolk and that the only difference between the compared compositions is the hydrogenation of lecithin. The Board cannot doubt the truthfulness of this statement merely on the basis of the Appellants' unproved allegations. It is to be emphasised that the test was submitted to the EPO in August 1992 and that the Appellants failed, even four years thereafter, to substantiate their allegations by way of any experimental proof or results.

The Board therefore accepts that the only difference among compositions (1), (2) and (3) in the test lies in the different iodine value of the compared lecithins, which is the unique factor essential in the present case.

- 4.3.3 Finally the Appellants expressed the opinion that the control composition (3), in the test, is an artificial construct which does not reflect the real closest prior art.

It should be noted that the Appellants have never identified one single piece of prior art as the closest prior art but rather they relied on documents (1), (3) and (4), and that within the content of these documents they pointed out different compositions.

Given these circumstances, the Board is of the opinion that the control composition (3) represents an acceptable approximation to the different formulations considered by the Appellants and is illustrative of the closest prior art as established in 4.1 above.

Moreover according to the Decisions T0181/82 (OJ EPO, 1984, 401) and T0197/86 (OJ EPO, 1989, 371), when a comparative test is submitted to demonstrate an improved effect over the prior art, the nature of the comparison must be such that the effect is convincingly shown to have its origin in the distinguishing feature of the invention. For this reason it is not incorrect to artificially modify the term of the comparison in such a way that, while remaining within the teaching of the closest prior art, it exhibits the maximum structural resemblance to the invention, differing only by way of such a distinguishing feature.

The conclusion of the Board is therefore that the comparative test is correctly constructed and it is a valid proof that the technical problem is solved by the suggested solution.

- 4.4.1 As to the question whether the proposed solution involves inventive merit, the Appellants maintain that the purpose of improving the stability of emulsions, containing lecithin as an emulsifying agent, is already considered, and the means to achieve it already suggested, by documents (4) and (5). Emphasis is laid specifically on (5), which, in the Appellants' view,

already anticipates the better emulsifying properties of the hydrogenated lecithin vis-a-vis the native substance. This document therefore represents an unambiguous suggestion to replace the lecithin in the compositions of the closest prior art by the hydrogenated product.

- 4.4.2 First of all, the Board notes that the closest prior art, document (1), taken alone, does not disclose the partially hydrogenated lecithin and does not contain any technical motivation for the skilled reader to contemplate the replacement of the native lecithin by other derivatives.

The same applies to document (3), which addresses the question of the solubilisation of lecithin.

- 4.4.3 In so far as combinations of the closest prior art with other documents, namely (4) and (5), are considered, the Board's view is that (4) would teach away from the invention. In fact the lecithin derivative disclosed therein is partially **hydrolysed**, not hydrogenated, lecithin of plant origin. Hence (4) fails to recognize what is the very essential feature of the present invention. As a matter of fact, this document was no more considered in the Appellants' last submissions either.

- 4.4.4 Document (5) is a doctoral thesis on the production and stabilisation of emulsions with lecithin. In items 5.4 and following paragraphs, the possible use of hydrogenated lecithin to produce and stabilize O/W emulsions is discussed. In the context of this discussion, the author underlines that, already on the basis of theoretical considerations, the hydrogenated product should be able to stabilize an emulsion better

than the native lecithin. This sentence is the basis of the Appellants' arguments.

The Board notes, first of all, that this assertion on the allegedly improved properties of the hydrogenated lecithin, is, by admission of the author, not based on direct experimental results but on the evaluation of features such as the higher stability and solubility in oil, which may theoretically influence the emulsifying properties and eventually the stability of the obtained emulsion.

The speculative nature of the author's considerations is also highlighted by the style used in writing the text, specifically by the frequent use of the verb form "sollte" which, in German, stresses the conjectural character of an assertion.

However, the assertion concerning the better emulsifying activity of the hydrogenated lecithin is clearly contradicted by the opinion of other authors and by the general technical content of the same article as defined by the experimental results reported in the document. In fact, according to the two prior references (56 and 220) cited in the last paragraph of item 5.4.1 of this thesis, the emulsifying activity of the partially hydrogenated lecithin should decrease quickly by increasing the degree of saturation therefore by increasing hydrogenation, which is just the opposite of what is maintained by the author.

On the other hand, the scope of the work reported in (5) was not to compare the emulsifying properties of the native and hydrogenated egg yolk lecithins in order to show that the latter involved any improvement, but rather to investigate whether it was feasible at all to prepare stable O/W emulsions using hydrogenated

lecithin as an emulsifier. This is evident from the first paragraph of item 5.4. As a matter of fact the few experimental results reported in the article (item 5.4.3) show that the hydrogenated lecithin does not involve any advantage over the native lecithin. For instance, in both cases, a step of efficient homogenisation is necessary in order to guarantee the stability of the emulsion. Accordingly, on the basis of the observed results, the author could only conclude that, by following the general preparation method, which employs the native lecithin, it was also possible to manufacture emulsions using hydrogenated lecithin (page 136). The technical teaching in the document would not allow any other conclusion.

Therefore, since (5) does not show any improved emulsifying activity, for the hydrogenated lecithin, over the native product, or any improved stability of the emulsion-type composition containing the hydrogenated lecithin, the skilled reader, facing the technical problem defined in 4.2 above, could not find in (5) any technical reason or motivation to replace the native lecithin of the closest prior art by the hydrogenated lecithin of (5) and even less motivation to take into account the partially hydrogenated lecithin of claim 1, which is not at all considered by (5).

In view of the above, the opinion of the Board is that the subject matter of claim 1 is neither suggested by the closest prior art taken alone nor by any combination of it with other prior documents. Therefore the subject matter of claim 1 involves an inventive step.

Dependent claim 2 and claim 3 derive their patentability from that of claim 1.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

P. Martorana

P. A. M. Lançon