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T 256/87 - 3.3.2

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Bezeichnung der Erfindung: Title of invention: Titre de l'invention : Homogeneous enzyme-containing liquid detergent compositions containing saturated fatty acids

Klassifikation / Classification / Classement :

C11D 3/386

Henkel KGaA

ENTSCHEIDUNG / DECISION vom/of/du 26 July 1988

Anmelder / Applicant / Demandeur :

Patentinhaber / Proprietor of the patent / Titulaire du brevet :

The Procter & Gamble Company et al

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence :

EPU/EPC/CBE Art. 52(1), 83, 84

Schlagwort / Keyword / Mot el6 :

"Clarity (yes) - sufficiency (yes) -Patentability (yes)"

Leitsatz / Headnote / Sommaire

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Beschwerdekammern

Boards of Appeal



Case Number : T 256 /87 - 3.3.2

D E C I S I O N of the Technical Board of Appeal 3.3.2 of 26 July 1988

Appellant :
(Opponent)

Henkel Kommanditgesellschaft auf Aktien Postfach 1100 Henkelstrasse 67 D-4000 Düsseldorf 1

Representative :

Respondent : (Proprietor of the patent) The Procter & Gamble Company 301 East Sixth Street Cincinnati Ohio 45202 Procter & Gamble European Technical Center Temselaan 100 B-1820 Strombeek-Bever

Representative :

Ernst. Hubert Procter & Gamble European Technical Center Temselaan 100 B-1820 Strombeek-Bever

Decision under appeal :

Interlocutory decision of the Opposition Division of the European Patent Office dated 7 October 1986, posted on 28 April 1987, concerning maintenance of European patent No. 28 865 in amended form.

Composition of the Board :

Chairman : P. Lançon Members : G. Szabo

R. Schulte

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Summary of Facts and Submissions

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- I. European patent No. 28 865 was granted on 21 March 1984 with ten claims in response to European patent application No. 80 201 058.7.
- II. A Notice of Opposition was filed on 20 December 1984 requesting revocation of the patent under Article 100(a) EPC, for lack of inventive step (Article 56 EPC).

The Opposition was supported, <u>inter alia</u> by the following document:

(6) DE-A-2 709 476.

III. The Opposition Division maintained the patent in an amended form comprising nine claims, in an interlocutory decision dated 28 April 1987. Claim 1 of the amended form reads as follows:-

"A homogeneous aqueous liquid detergent composition comprising:

- (a) from 20% to 50% by weight of an organic synthetic surface-active agent;
- (b) from 3% to 15% by weight of a saturated fatty acid having 10 to 16 carbon atoms in the alkyl chain;
- (c) from 0.025% to 1% by weight of an enzyme;
- (d) from 0.1% to 3% by weight of a carboxylic acid, or the water-soluble salts thereof, having from 1 to 3 carbon atoms; and

(e) from 0.5 to less than 2 millimoles of enzymeaccessible calcium per kilo of the detergent composition,

the pH of the composition, measured as is at 20°C, being from 6.5 to 8.5."

- IV. In its decision, the Opposition Division took the view that Claim 1 as amended was clear (Article 84 EPC) with regard to the crucial feature (e) and met the patentability requirements of Article 52(1) EPC. Furthermore, the disclosure was sufficiently clear and complete for the skilled person to carry out the invention (Article 83 EPC).
 - V. A Notice of Appeal was filed by the Appellant (who is the Opponent) on 29 June 1987, the fee being paid on the same day. A Statement of Grounds was received on
 3 September 1987.
- VI. The Appellant argued that the feature (e) of Claim 1, viz. the requirement for a particular quality of "enzymeaccessible calcium" (EAC) to be present per kilogram of the composition did not meet the requirements of Article 84 EPC. In particular:
 - (i) No method had been described for analytically determining the amount of EAC, in the compositions, even though the narrowness of the range in which it was claimed placed the skilled man in need of an accurate method of determination.
 - (ii) The examples of the patent-in-suit did not disclose either the total amount of calcium or the amount of EAC in the compositions, but only the amount of calcium specially added; in particular, the status

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of calcium which was soluble but strongly bound to one or other of the washing components (the enzyme, the fatty acid or the optional polyacids) did not reveal as to whether wholly or only partially bound EAC was at hand.

(iii) The statement in the description that the EAC corresponded to the soluble calcium in the composition in the absence of any strong sequestrants, was confused by the facts that nine out of ten examples contained significant amounts of substances known to be strong sequestrants for calcium; on a stoichiometric basis these would be more than sufficient to sequester all the calcium present; and to the extent that under these conditions no EAC could be present, the relevant examples fell outside the scope of Claim 1.

(iv) The question thus arose of whether it would be necessary or not for the skilled person to add further calcium in order to arrive at an EAC falling within the range claimed.

VII. The Respondent (who is the Patentee) argued substantially as follows:-

- (i) There was no necessity for an independent analytical method for determining the EAC, since this could be done empirically; at EAC levels above the maximum claimed a precipitate would form; at EAC levels below the minimum claimed the enzyme would be deactivated.
- (ii) In view of this it was unnecessary to know precisely what proportion of the total calcium was present as EAC.

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- (iii) The position was not confused by the optional presence of polyacid substances, since at the formulation levels and pH conditions used in the claimed compositions, the selected substances did not sequester calcium ions to any appreciable extent.
 - (iv) The skilled person was therefore in a position to add supplementary calcium or not according to the empirical results obtained as referred to in subparagraph (i).
- VIII. The Appellant requests that the decision of the Opposition Division be set aside and the patent revoked.

The Respondents request that the appeal be dismissed.

Reasons for the Decision

- 1. The appeal complies with Articles 106 to 108 and Rule 64 EPC; it is therefore admissible.
- 2. The patent-in-suit relates to homogeneous enzymecontaining liquid detergents containing substantial levels of saturated fatty acids.
- 3. Claim 1 as amended in the proceedings before the Opposition Division and forming the basis of the decision under appeal is based on matter present in the application as originally filed. In particular, the lower limit of 0.5 mmole of EAC per kg of composition was a feature of original Claim 5. Furthermore, it does not extend the scope of protection conferred. It therefore complies with Article 123(2) and (3) EPC. This has in any case not been contested.

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The objections of the Appellant centre on the question of whether the amended Claim 1, and in particular the definition of feature (e) is clear as required by Article 84 EPC, and arising from this, whether the teaching contained in the disclosure is sufficiently clear and complete for the invention to be carried out by the person skilled in the art, as required by Article 83 EPC.

The purpose of the calcium in the composition is to stabilise the enzyme against the rapid loss of enzymic activity which would otherwise occur in the aqueous environment of the claimed formulations. The calcium must, however, be present in a form in which it can stabilise the enzyme against deactivation, and the calcium which is present in this form has been called by the Respondent "enzyme accessible calcium" (EAC).

EAC is explained in the description as being, from a practical viewpoint, the soluble calcium in the composition in the absence of any strong sequestrants, e.g. having an equilibrium constant of complexation with calcium equal to or greater than 1.5 at 20°C (cf. page 6, lines 53-55). The fact that the term EAC is not in itself a well known term of art, is not a barrier to clarity, since according to Article 69(1) EPC, the description shall be used to interpret the claims.

The objection of the Appellant concerning the presence of substances capable of sequestering calcium in nine of the ten exemplified compositions does not affect the clarity of the term in the given position, because the EAC is defined there in the absence of <u>strong</u> sequestrants.

The further objection that the stoichiometric excess of these substances would result in the removal of all the EAC so that the affected examples did not fulfil the

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requirements of feature (e) of Claim 1, would only be relevant if this was indeed the true state of affairs. However, it is clear from the patent-in-suit that at the very low levels of 0.5% or so of polyacids used in the examples, residual (unsequestered) calcium (EAC) is still present. This is evident both from the description of the amount of calcium sequestration resulting 0.5% of a mixture of polyphosphonates and polyacids as exemplified (cf. pages 6, lines 49-51), the difference between the amount of calcium added and the EAC in Examples A, B, C and I (cf. Table on page 8) as well as the experimental results themselves. The latter show that at the exemplified polyacid levels a significant degree of retention of enzymic activity is obtained even in the prior art formulations, thus indicating the presence of unsequestered EAC (cf. composition A, having 66% enzymic activity retention, second Table on page 8). Consequently, there are no grounds for supposing the examples fall outside the scope of the claims, or that the designation of the compositions as being "substantially free of sequestrants" or "builder-free" is in contradiction to what is actually disclosed (cf. page 6, line 46, page 2, line 31).

9. Thus, in view of the above, it is evident that the description provides a clear and consistent definition of what is meant by "enzyme-accessible calcium", that the claim is entitled to be read in the light of this, and that the molar range specified in feature (e) of Claim 1, itself precise from the formal point of view and gives clear information as to how much of the EAC must be present in the composition.

Thus, amended Claim 1 is clear as required by Article 84 EPC.

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The further question then arises, however, of whether this information, although clear in itself, is sufficient to enable the skilled person to carry out the invention in the sense of his (a) being able to establish whether a composition containing an amount of EAC falling within the range claimed, and (b) being able reliably to prepare such a composition.

11.

It is true that no direct analytical method is disclosed in the specification for independently determining the amount of EAC. It is furthermore clear from the above that the amount of EAC present in the composition does not necessarily equal the total amount of calcium in the composition or the amount of calcium added, especially in the presence of strong sequestrants for calcium.

There is in this connection, however, the statement in the description referred to above that from a practical standpoint the enzyme-accessible calcium is the soluble calcium in the composition in the absence of any strong sequestrants. This would appear on the fact of it, to enable a determination of EAC by conventional means, at least in the case where strong sequestrants for calcium are absent.

12.

The suggestion by the Appellant that calcium strongly bound by the fatty acid or the enzyme itself cannot be regarded as "soluble calcium" yet may possibly be partially accessible to the enzyme is, in the Board's view, speculative. (See Statement of Grounds, pages 3-4). Firstly, no evidence has been provided showing a third condition of calcium (unprecipitated, unsequestered, yet not "soluble" or not "enzyme-accessible") exists or is a significant factor to be considered in formulating the compositions of the invention. In this connection, the statement made by the Appellant at the oral proceedings before the Opposition Division that repeating Example IX had resulted in precipitation was contradicted at the time by the Respondent and has not been repeated since. The onus was, however, at this state on the Appellant to provide clear and convincing evidence that the situation in relation to "soluble calcium" and EAC was significantly different from what was stated in the patent specification. In the absence of such evidence, the Board sees no reason to do other than to accept what is said in the specification concerning EAC in this respect as representing the true state of affairs.

- 13. The difficulty arises then in the more general case where due to the presence of optional components such as the exemplified polyacids which may have a strong sequestering effect on calcium, the amount of EAC will only be a part of the total soluble calcium present for which analysis can conventionally be made, and no independent direct method of analysing specifically for EAC is available.
- 14. The Respondent has, however, coped with this difficulty by pointing out that the claimed upper and lower limits for the amount of EAC are correlated with other observable phenomena. They correspond to technical limitations significant to the essential performance of the claimed formulations, such that it is impossible to prepare such formulations which are both homogeneous (in the sense that no precipitated calcium is present) and stable (in the sense that the enzyme is not deactivated) unless the EAC lies within the admittedly narrow limits claimed.

The determination of residual enzymic activity in this connection belongs to the state of the art (cf. (6), page 19, second paragraph), so that compositions having below 0.5 millimole/kg of EAC can be reliably identified by their rapid loss of enzymic activity. The precipitation

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of calcium due to quantities of EAC at or above 2 millimoles/kg can be observed directly. The remaining parameters of the claim are completely specified as percentages and therefore the amount of trial and error experimentation involved in adjusting the final parameter (EAC) cannot, in the Board's view, be excessive for the person skilled in the art of formulating such compositions.

It belongs to the general knowledge in the art that calcium ions are useful for stabilising proteolytic enzymes against deactivation in aqueous mediums. Furthermore, it has not been disputed in the proceedings that quantitites of free calcium below about 0.5 millimole/kg are insufficient to stabilise an enzyme (cf. (6), Claim 1, paragraph (c) and page 20, penultimate paragraph). It is moreover commonplace known to any housewife that excessive quantities of calcium will precipitate in the presence of fatty acids. In particular, it has not been disputed that calcium precipitation will occur at unsequestered calcium levels above the 2 mmole/kg upper limit claimed. Since the general behaviour of calcium in the compositions at both insignificant and at excessive levels was evidently well recognised and understood in the art, the Board considers that the skilled person aware of the teaching of the patent-in-suit was in a position to identify and/or formulate compositions as claimed on the basis of disclosure, specifically with an amount of EAC within the narrow range claimed by trial and error and observing the behaviour of the compositions at various levels of added calcium.

Therefore, it would appear that the information given in the specification was sufficient in the context of the general knowledge concerning the behaviour of such

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formulations at various calcium levels for the skilled person to be in a position relatively simply to arrive at and/or identify a composition as claimed specifically having an EAC level as defined in feature (e).

- 16. This possibility of indirectly determining whether the amount of EAC lies within the range claimed, is, of course, effective, irrespective of any inherent levels of calcium associated with particular components, e.g. the enzyme or of whether or not strong sequestering agents are present or of what proportion of the unprecipitated calcium can be regarded as "EAC". Thus, the fact that nine out of the ten examples contain substances which may be capable of sequestering calcium has no significance for the clarity of the claim and, therefore, for the sufficiency of the description in this respect.
- The fact that no direct independent method of specifically 17. determining EAC has been described is not in itself prejudicial to the sufficiency of the description. The claims do not relate to a method of determining EAC. All that is necessary is that the skilled person reading the specification be put in the position of being able to carry out the invention in all its essential aspects and of knowing when he is working within the forbidden area of the claims. The possibilities of indirect empirical investigation referred to above are in the Board's view an acceptable solution which alone is sufficient to fulfil the requirements of Article 83 EPC without undue burden. Consequently, not only is amended Claim 1 clear (Article 84) but the description is also sufficient for the invention to be carried out by the skilled person (Article 83).
- 18. It remains to be determined whether such a claim defines patentable subject-matter in the sense of Article 52(1) EPC.

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In the proceedings before the Board, the Appellant has done nothing more than refer generally to the arguments he brought in Opposition. Since these appear to have been dealt with satisfactorily by the Opposition Division, the Board concurs with the finding of the Division that Claim 1 meets the patentability requirements of Article 52(1).

Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar:

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The Chairman: G