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D E C I S I O N
of 9 June 1994

Case Number: T 0028/92 - 3.3.2

Application Number: 83303417.6

Publication Number: 0097476

IPC: A61K 7/16

Language of the proceedings: EN

Title of invention:
Oral compositions

Patentee:
The Procter & Gamble Company

Opponent:
Henkel Kommanditgesellschaft auf Aktien
Colgate-Palmolive Company
Sara Lee/DE N.V.

Headword:
Oral compositions/PROCTER

Relevant legal norms:
EPC Art. 54, 123(2)

Keyword:
"Novelty main request (no)"
"First auxiliary request extends beyond original disclosure"
"Auxiliary requests filed at oral proceedings - not admitted where divisional applications pending"

Decisions cited:
T 0406/86, T 0160/89, G 0002/88

Catchword:

Case Number: T 0028/92 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 9 June 1994

Appellant: (Proprietor of the patent)
THE PROCTER & GAMBLE COMPANY
301 East Sixth Street
Cincinnati
Ohio 45201 (US)

Representative:
De Minvielle-Devaux, Ian Benedict Peter
Carpmaels & Ransford
43, Bloomsbury Square
GB - London WC1A 2RA (GB)

Respondent: (Opponent 01)
Henkel
Kommanditgesellschaft auf Aktien
TFP/Patentabteilung
D - 40191 Düsseldorf (DE)

Respondent: (Opponent 02)
Colgate-Palmolive Company
909 River Road
Piscataway, New Jersey 08854-5596 (US)

Representative:
Van Gennip, J.S.W., Jr.
Vereenigde Octrooibureaux
Nieuwe Parklaan 97
NL - 2587 BN 's-Gravenhage (NL)

Respondent: (Opponent 03)
Sara Lee/DE N.V.
Keulsekade 143
NL - 3532 AA Utrecht (NL)

Representative:
Van Gennip, J.S.W., Jr.
Vereenigde Octrooibureaux
Nieuwe Parklaan 97
NL - 2587 BN 's-Gravenhage (NL)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office dated 4 November 1991 revoking European patent No. 0 097 476 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: P. A. M. Lançon
Members: I. A. Holliday
S. C. Perryman

Summary of Facts and Submissions

I. European patent No. 0 097 476 relating to oral compositions was granted on the basis of seven claims contained in European application No. 83 303 417.6.

II. Three oppositions were filed against the granted patent.

III. Of the numerous documents cited during the Opposition Proceedings:

DE-A-2 811 097 (1)

remains relevant to the present decision.

IV. In accordance with the decision under appeal, the Opposition Division considered the claimed subject-matter not to be new, since the Patentee failed to establish that the claimed oral compositions do not represent a special combination which was not mentioned in the most relevant prior art documents (1), US-A-3 934 002 (4) and US-A-2 876 167 (6). The Opposition Division also took the view that the claimed subject-matter lacked inventive step since no evidence of any surprising effect in respect of the disclosure was provided by the Patentee.

In view of the lack of novelty, the Opposition Division did not provide detailed arguments in respect of inventive step.

V. The Appellant lodged an appeal against the said decision. Oral Proceedings took place on 9 June 1994.

VI. The arguments of the Appellant both in the written procedure and at the oral proceedings may be summarised as follows:

The Appellant argued that document (1) does not clearly and unambiguously disclose a composition in accordance with Claim 1 of the patent in suit and more particularly argued that this document does not disclose a composition containing a mixture of dialkali metal and tetraalkali metal pyrophosphate sufficient to provide at least 1.5% by weight of pyrophosphate ions, the pH of the composition being from 6 to 10.

The Appellant analysed the disclosure of the specific examples of documents (4) and (6) and argued that none of the latter documents discloses any composition containing a mixture of dialkali metal and tetraalkali metal pyrophosphates in accordance with any of the claims of the patent in suit.

The Appellant submitted a declaration of Mr Leonard in order to establish that the actual levels of ($P_2O_7^{4-}$) ions present in the examples of document (6) were much lower than the theoretical figures and, consequently, that the critical minimum level of pyrophosphate ions set out in the patent in suit had not been attained. Other declarations were filed to support this point of view. The Appellant submitted a declaration of Mr Huetter (dated 27 April 1994) in order to establish that none of the specific examples of (4) disclose compositions according to those of the patent in suit.

The Appellant acknowledged that pyrophosphates were mentioned in document (1), but stressed that no pyrophosphate appeared among the list of the anticalculus agents to be present in the thereby disclosed toothpastes.

The Appellant further argued that US-A-4 340 583 (3), the U.S. equivalent of document (1), does not specifically disclose mixtures of dialkali metal and of

tetraalkali metal pyrophosphates salts. The paragraph starting at line 63 of column 15 and finishing at line 22 of column 16 was referred to, and more particularly the sentence:

"Toothpastes providing substantially similar fluoride treatment benefits and substantially similar cleaning performance are realized when, in the Example 8 composition, the phosphate salt mixture is replaced with an equivalent amount of ..., other mixtures of ...., mixtures of....., tetrapotassium pyrophosphate, tetrasodium pyrophosphate, disodium pyrophosphate,. ... .. or sodium heptametaphosphate; provided such compositions provide a 3:1 slurry pH of from 4.0 to 8.0.".

The sentence should be construed as excluding a mixture of dialkalimetal and tetraalkalimetal pyrophosphates salts, particularly since amounts of tetraalkali pyrophosphates equivalent to those of orthophosphates according to Example 8 of (1) would result in compositions with pH values outside the acceptable ranges. Moreover the use of the term "or" in the list of the considered phosphates clearly excluded mixtures of phosphates except those specifically recited.

Further prior art and declarations relating to the question of the inventive step were filed by the Appellant, but are not relevant when considering novelty.

Accompanying a letter received in the EPO on 29 April 1994, the Appellant filed two auxiliary requests. In product-claim 1 of the first auxiliary request, component (c) was limited to a mixture of dialkali metal and of tetraalkali metal pyrophosphate salts. The second auxiliary request only differs from the first auxiliary

request in that the product-claims have been replaced by process-claims.

At the beginning of the Oral Proceedings the Appellant abandoned the main request (corresponding to the set of claims which was the basis of the decision of the Opposition Division) and announced that the auxiliary requests 1 and 2 submitted with the letter dated 29 April 1994 would now constitute respectively the main and the first auxiliary requests.

During the course of the Oral Proceedings, the Appellant sought to introduce two new auxiliary requests wherein the ratio of the pyrophosphates was specified.

VII. In the written procedure and at the Oral Proceedings the Respondents argued essentially as follows:

Respondents (O1) to (O3) endorsed the decision of the Opposition Division and asked for the dismissal of the appeal filed by the Patentee.

During the Oral Proceedings, Respondent (O1) argued that at neutral pH, irrespective of the alkali pyrophosphate present in the solution, the same type of ions i.e. $P_2O_7^{4-}$ are always present and therefore the calculated equivalent amount according to Example 8 of (1) should correspond to the ionic concentrations according to Claim 1 of the patent in suit. This argument was supported by a declaration of Dr. Gambogi dated 18 May 1994.

Starting from an analysis of the disclosure of documents (1), (4) and (6), Respondent (O2) argued that the relative amounts of components (a) to (d) in the oral compositions of the patent in suit were already disclosed in the said prior art compositions.

Respondent (O3) argued that the disclosure of the prior art should not be construed as limited to the examples alone and therefore, according to the whole contents approach, the claimed subject-matter lacked novelty.

During the Oral Proceedings, the Representative acting on behalf of Respondents (O2) and (O3), contested the admissibility of the late submissions i.e. of the two auxiliary requests submitted by the Appellant with the letter of April 29, 1994 and stressed the lack of clarity of the expression "free ions".

Respondents (O1) to (O3) also contested the admissibility of the two new auxiliary requests submitted during the Oral Proceedings by the Appellant.

The Affidavit of Mr. Van Wazer which discusses the pyrophosphate ion distribution at various pH values and which suggests that such ions will be produced irrespective of the nature of the pyrophosphate used was presented as a further evidence establishing that the amount of $P_2O_7^{4-}$ considered in document (1) for those mixtures of di- and tetrapyrophosphates would comply with those specified in the patent in suit for component (c).

VIII. Claim 1 of **the main request** reads now as follows:

"An oral composition in the form of a toothpaste characterized in that it comprises:

a) from 10% to 70% by weight of a dental abrasive selected from insoluble metaphosphates, alumina, thermosetting polymerized resins, and silica;

b) an amount of a fluoride ion source sufficient to supply from 50 ppm to 3500 ppm of fluoride ions;

c) an amount of a mixture of dialkali metal and tetraalkali metal pyrophosphate salts sufficient to provide at least 1.5% by weight of pyrophosphate ions ($P_2O_7^{4-}$); and

d) water

wherein the pH of the composition is from 6.0 to 10.0 and the composition contains no more than 4.0% by weight of tetrapotassium pyrophosphate ($K_4P_2O_7$)."

Claim 1 of **the first auxiliary request** relates now to method of producing oral compositions in the form of a toothpaste, characterized in that it comprises mixing components (a) to (d) wherein the pH of the composition is from 6.0 to 10.0 and the composition contains no more than 4.0% by weight of tetrapotassium pyrophosphate ($K_4P_2O_7$).

IX. The Appellant requested that the decision under appeal be set aside and as main request that the patent be maintained on the basis of the claims filed as first auxiliary request on 29 April 1994, as first auxiliary request that the patent be maintained on the basis of the claims filed as second auxiliary request on 29 April 1994, as second auxiliary request that the patent be maintained on the basis of the claims headed second auxiliary request filed at the Oral Proceedings on 9 June 1994, and as third auxiliary request that the patent be maintained on the basis of the claims headed third auxiliary request filed at the Oral Proceedings on 9 June 1994.

The Respondents requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. *Admission of the requests of the Appellant*

2.1 The Board has decided to admit the two new requests filed on 29 April 1994. The said requests although late filed appear to represent **bona fide** attempts to overcome the objections raised by the Opposition Division.

2.2 The third and fourth auxiliary requests submitted by the Appellant during the Oral Proceedings were late filed without any proper justification. Having regard to the fact that the claims involved were not obviously allowable, and that the Respondents would need further time to consider these complicated submissions, no substantive decision on the allowability of these further auxiliary requests was possible at the Oral Proceedings. An adjournment at this late stage, with the Board continuing the proceedings itself is not acceptable; see, for example, the decisions T 160/89 of 13 November 1990 (not published, in OJ EPO, Reasons point 5.3) and T 406/86 (OJ EPO 1989, page 302, especially Point 3.1.9).

2.2.1 The alternative of admitting the requests, but referring the matter back to the first instance for further examination is not acceptable in this case either, particularly as here there are still pending divisional applications of the application on which the patent in suit was based. The Board would not wish to increase the number of proceedings in which much the same subject-matter is already being considered by various instances of the EPO.

2.3 It is not part of the purpose of Appeal Proceedings to allow newly introduced requests to be considered endlessly in succession to refused requests, and Appellants who do not introduce their requests in time for the Board and the other parties to examine them must expect such requests not to be admitted at the Oral Proceedings. The Board accordingly decided to refuse to admit the third and fourth auxiliary requests.

3. *Main request*

3.1 The amendment, i.e. the deletion from the claims, which were the basis of the decision of the Opposition Division, of the possibility for component (c) to be a dialkalipyrophosphate alone, results in a claim corresponding to one of the alternatives explicitly covered by the granted claims. This is a restriction of the scope of the claim and fully in accordance with the requirements of Article 123(2) and (3) EPC.

3.2 Claim 1 of the main request relates to a toothpaste containing specific amounts of at least 4 component features (a) to (d), and which satisfies two conditions i.e. the pH of the composition is from 6.0 to 10.0 and the composition contains no more than 4.0% by weight of tetrapotassium pyrophosphate.

Among the numerous prior art documents overlapping with the subject-matter of the patent in suit, the Board considers that document (1) represents the most relevant state of the art.

3.2.1 Example 8 of (1) discloses a toothpaste containing inter alia by weight (related to the total composition) 16% of a precipitated silica abrasive, 0.28% sodium fluoride and water to make up to 100%. Such an amount of NaF would be sufficient to provide fluoride ions within the

range of 50 - 3500 ppm as required by Claim 1 of the patent in suit. Accordingly, features (a), (b) and (d) of Claim 1 of the main request are disclosed in Example 8. This was not disputed by the parties at the Oral Proceedings.

3.2.2 It remains to consider whether document (1) also discloses feature (c) of Claim 1 of the main request together with the prescribed pH range.

It must be borne in mind that in Claim 1 there is no limitation either in the definition of the respective amounts of each of the components of the mixture of pyrophosphates considered as feature (c) of the composition or in the number of di- or tetraalkalipyrophosphates present in the mixture. Accordingly, mixtures consisting almost entirely of one or more dialkali metal pyrophosphates or mixtures consisting almost entirely of one or more different tetraalkali metalpyrophosphates would also be included in the definition of the claimed subject-matter.

3.2.3 The table of page 41 of (1) discloses a mixture of monosodium orthophosphate monohydrate (2.15%) and disodium orthophosphate dihydrate (8.34%) as components of the toothpaste. However, a statement follows Example 8 on pages 42 and 43) which lists about 30 phosphates, of which some are dialkali metal or tetraalkali metal pyrophosphates, which statement specifies that the latter pyrophosphates may replace the phosphate salt mixtures of Example 8, provided two conditions were satisfied, i.e. the replacement amount should be an equivalent **amount** and the pH must be in the range from 4.0 to 8.0.

3.2.4 In respect of the limitation of the disclosure of document (1) to the mixtures of pyrophosphates specifically disclosed in Example 8 and on page 43, lines 3 to 5, the Appellant has failed to persuade the Board that the term "or" has a special meaning which excludes the term "and". The Board is of the view that Example 8 of document (1) clearly embraces the replacement of the specific mixtures of orthophosphates by any mixture of pyrophosphates obtainable by combining at least two of the phosphates listed on page 42 and on page 43, particularly since it is simultaneously stressed in the relevant paragraph that similar advantageous cleaning effects would be obtained (page 42, lines 23-25).

3.2.5 The amount of $P_2O_7^{4-}$ ions generated in the composition of the patent in suit by the pyrophosphates should be at least 1.5% by weight. This feature is not to be found in the closest prior art documents wherein only the weight % of salts are quantified, i.e. the sum of the pyrophosphate ions and the counter anion. This feature is therefore considered by the Appellant to be a new parameter intended to bring some limitation to the scope of the claimed subject-matter. The Board is not however convinced that the determinations of "free" pyrophosphate ions which feature in the declarations of Leonard (dated 09.10.84), Banks (05.11.90), Mac Clanahan (01.03.90) and Huetter (27.04.90) are of significance or have any basis in the original disclosure. Furthermore, the patent in suit gives no indication as to how the ion concentration should be measured, in the actual toothpaste, in contact with saliva in the mouth or dispersed in water. Having regard to the language of the claim: "at least 1.5% by weight of pyrophosphate ions ($P_2O_7^{4-}$)", the Board is inclined to follow the line expressed by Gambogi (declaration dated 18 May 1994). In other words, the amount of pyrophosphate ion present in

the composition does not depend on the proportions actually dissolved in water when the composition is in use but is simply based on the proportion by weight of pyrophosphate ion in relation to the total dry weight of the salt (cf. Keenan et al, General College Chemistry, 1980 Edition, p. 309, filed with Dr. Gambogi's declaration). Accordingly, replacing the orthophosphate mixture specified in Example 8 of (1) with an equivalent weight of a mixture of disodium and tetrasodium pyrophosphate would lead to a content of pyrophosphate ion of at least 1.5% by weight.

3.2.6 The Appellant also advanced the further argument that a second condition should apply to the compositions disclosed in document (1) i.e. that they should present a pH value comprised between 4.0 to 8.0. Tetraalkali pyrophosphate would tend to reduce the pH value and would result in compositions exhibiting a pH value outside of the claimed range of the patent in suit, i.e. a pH value lower than 6 and, therefore, the skilled person would never consider the combination of di- and tetraalkalipyrophosphates.

Contrary to the view of the Appellant, the fact that some of the compounds mentioned in the lists on pages 44-45 of document (1) may not satisfy the pH criteria is not considered by the Board as likely to cause the man skilled in the art to reject the disclosure of this relevant piece of the art or to consider that the expression "equivalent amount" should be given a meaning other than the most common meaning known in this technical field i.e. a weight equivalent amount.

3.2.7 As stressed by the Respondents and as illustrated by the declaration of Mr. Van Wazer, dated 5 October 1993, when considering mixtures of dialkalimetal pyrophosphates or tetraalkali metal pyrophosphates at pH from about 6.0 to

7.5, it is immaterial whether the starting material is monosodium pyrophosphate, disodium pyrophosphate, tetrasodium pyrophosphate or a mixture of any of the above since the pyrophosphate ion distribution in the final compositions will be the same.

As agreed by the parties, the person skilled in the art is well aware of the fact that different pyrophosphates would differently affect the pH values of an aqueous composition, depending upon the amount of counter anion liberated. This is known from the chemical formula of the pyrophosphate and from the ionisation constants.

There is no doubt for the Board that the skilled person bearing this basic general knowledge in mind, would see no restriction in the mixture of pyrophosphates listed in document (1) except possibly those mainly based on tetrapyrophosphates.

Therefore, the man skilled in the art would clearly consider document (1) as specifically disclosing inter alia mixtures of pyrophosphates mainly consisting of disodium pyrophosphate (which is specifically disclosed in the list of page 43) and satisfying the required pH criteria.

3.2.8 The Appellant's argument that pyrophosphates were not mentioned by document (1) as anti-calculus agents is irrelevant when considering the novelty of the claimed subject-matter since a product per se is claimed.

3.3 Accordingly, the Board is convinced that the subject-matter according to the main request of the disputed patent lacks novelty over document (1) (Articles 52(1) and 54 EPC). In the circumstances, it is unnecessary to consider documents (4) and (6).

4. *First auxiliary request*

4.1 This request relates to a method of producing an oral composition in the form of a toothpaste by mixing the components essentially as specified in Claim 1 of the main request.

4.1.1 According to the conclusions of the Enlarged Board's decision G 2/88, (OJ EPO, 1990, 93), such a change of category, i.e. the transformation of the granted product-claims to corresponding method claims is allowable (Article 123 EPC).

4.2 Claim 1 according to the auxiliary request could be construed as merely preparing an oral composition by mixing the components (a) to (d) listed therein. Having regard to the above reasoning in respect of the main request, such a method must be anticipated by preparing a toothpaste in accordance with Example 8 of document (1).

4.3 Alternatively, the claim could be construed as using as component (c) a preformed mixture of dialkali metal and tetraalkali metal pyrophosphates. However, the use of such a preformed mixture is not to be found in the original disclosure. Although the worked examples of the patent in suit used a mixture of di- and tetraalkali metal salts, it is apparent from page 15, lines 23-26 and from the last paragraph of the Example 1, that the various components include the said pyrophosphates, are added one after the other. Accordingly, a claim to the use of such a preformed mixture is not supported by the original disclosure and contravenes Article 123(2) EPC.

4.4 It is to be noted that the the amounts of the various di- and tetraalkali pyrophosphates salts to be used in the method are not quantified. The Board expressed

concern at the Oral Proceedings that commercial disodium and tetrasodium pyrophosphate might contain a certain amount of the tetrasodium and disodium salt respectively.

The Appellant was unable to dispel this concern.

4.5 In the light of the preceding paragraphs, the first auxiliary request must also be refused.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

E. Görgmaier P. Lançon