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**Datasheet for the decision
of 9 April 2013**

Case Number: T 0675/11 - 3.3.07
Application Number: 03726731.7
Publication Number: 1503727
IPC: A61K 7/28, A61K 7/22, A61K 7/16
Language of the proceedings: EN

Title of invention:

Antibacterial dentifrice exhibiting enhanced antiplaque and
breath freshening properties

Applicant:

Colgate-Palmolive Company

Headword:

-

Relevant legal provisions:

EPC Art. 56
RPBA Art. 13

Keyword:

"Admissibility of late-filed requests (yes)"
"Inventive step - all requests (no)"

Decisions cited:

-

Catchword:

-



Case Number: T 0675/11 - 3.3.07

D E C I S I O N
of the Technical Board of Appeal 3.3.07
of 9 April 2013

Appellant: Colgate-Palmolive Company
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 8 November 2010
refusing European patent application
No. 03726731.7 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: J. Riolo
Members: D. Semino
D. T. Keeling

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division announced at the oral proceedings on 20 October 2010 refusing European patent application No. 03 726 731.7. The application as filed comprised 18 claims, independent claim 1 reading as follows:

"1. A dentifrice composition which effects enhanced antiplaque and breath freshening which comprises an orally acceptable vehicle containing a combination of an abrasive having a cationic antibacterial agent and at least one proteolytic enzyme."

II. The decision was based on four sets of claims filed respectively as main request and as auxiliary requests 1 to 3 during the oral proceedings on 20 October 2010.

Claim 1 according to the main request corresponded to claim 1 as originally filed. Claim 1 of auxiliary request 1 included the additional feature that the proteolytic enzyme was "selected from papain, bromelain, chymotrypsin, ficin and alcalase". Claim 1 of auxiliary request 2 corresponded to claim 1 of auxiliary request 1 with the further specification that "the abrasive is a silica having an oil absorption value less than 100 cm³/100 g (100 cc/100 g) silica". Claim 1 of auxiliary request 3 corresponded to claim 1 of auxiliary request 2 with the additional feature that "the proteolytic enzyme is present in the dentifrice in combination with a glucoamylase".

III. According to the decision under appeal the composition of claim 1 of the main request was not novel over the

disclosure of D3 (WO-A-96/29978) and the composition of claim 1 according to auxiliary request 1 was not inventive over the disclosure of D2 (US-A-5 431 903), taken as the closest prior art, in view of the disclosure in D2 itself regarding certain cationic surfactants acting as germicides. The compositions according to auxiliary requests 2 and 3 were similarly not inventive, as no effect related to the added features was shown and those features were known from the available prior art.

- IV. The applicant (appellant) filed an appeal against that decision. With the statement setting out the grounds of appeal, the appellant submitted three sets of claims as main request and first and second auxiliary requests and corresponding amended description. Those sets of claims corresponded respectively to the claims according to auxiliary requests 1 to 3 on which the decision was based.
- V. With a communication sent in preparation of oral proceedings the Board expressed a preliminary view on the issue of inventive step and mentioned other possible issues to be discussed at the oral proceedings including whether the last claim according to all requests met the requirements of Articles 84 and 123(2) EPC.
- VI. With letter of 8 March 2013 the appellant submitted four sets of claims as main request and first to third auxiliary requests with corresponding amended description. The claims of the main, second and third auxiliary request corresponded to those of the main, first and second auxiliary requests filed with the

statement of grounds with a change in the wording of the last claim. Claim 1 of the first auxiliary request corresponded to claim 1 of the main request with the addition that the dentifrice composition is "for use in the treatment of halitosis".

VII. Oral proceedings were held on 9 April 2013.

VIII. The appellant's arguments can be summarised as follows:

Main request - inventive step

- (a) Starting from document D2, which related to improved dental cleaning, as the closest prior art, the skilled person had first to select a specific teaching in D2 from which to start. While some examples of D2 indeed disclosed the combination of papain and silica, there was no reason to start from those specific examples, as the skilled reader was not led to them. Moreover, D2 was not primarily concerned with an antibacterial, the enzyme was not indicated to be proteolytic and no abrasive was described as an essential ingredient.

- (b) The objective technical problem with respect to D2 was to provide a dentifrice with improved reduction in oral malodour through reduction in tongue microflora. This problem was plausibly solved by the claimed composition in view of the examples and comparative examples in the application as filed, which showed the advantages in terms of malodour reduction with respect to compositions not containing the cationic antibacterial agent or the enzyme.

- (c) While the use of certain cationic surfactants which may act as germicides according to D2 itself represented a possibility which could be considered by the skilled person to solve the posed problem, the skilled person would not have necessarily chosen that solution. The main reason therefor was that there was no information in D2 that those germicides would be active on the tongue microflora; as the biological activity in complex compositions as the ones under study was very unpredictable due to the interactions among the components, it could not be expected that they were effective in the absence of a specific indication. In addition, several options were open for addressing the problem of bacterial reduction in the mouth, including the mechanical route and the use of chelating agents; even if one concentrated on the use of antibacterial, not all antibacterial agents active on the dental plaque, could be expected to work on the tongue microflora. Finally, both D2 and D4 (US-A-5 616 314) indicated disadvantages of the use of cationic antibacterial agents, namely their staining capacity and their incompatibility with other ingredients, which would lead the skilled person not to use them. In view of this, the skilled person trying to solve the posed problem, would not be led by the available prior art to the claimed composition, which was thus to be regarded as inventive.

Auxiliary requests - inventive step

(d) The feature added to claim 1 of the first auxiliary request was a medical indication, which specified a recognised disease, was not known from D2 and contributed to the inventiveness of the product. The additional features of claim 1 according to the second and third auxiliary requests concerned the indication of a specific class of silica abrasives and of a second specific enzyme which constituted further differences with respect to the compositions of D2. In spite of the lack of evidence of an effect of these features, their addition to the compositions of D2 was not rendered obvious by the available prior art.

IX. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request or of one of the first to third auxiliary requests, all filed with letter of 8 March 2013 with corresponding amended description.

Reasons for the Decision

Admissibility of the requests

1. All the requests on file were filed one month before the scheduled oral proceedings and are therefore late filed amendments to the appellant's case which are subject to a discretionary decision on their admission into the proceedings (Article 13 RPBA).

1.1 The main, second and third auxiliary requests correspond to the requests filed with the statement of grounds (points IV and VI, above) with a minor amendment in a dependent claim introduced in reaction to possible objections under Articles 84 and 123(2) EPC mentioned in the communication of the Board. The first auxiliary request was newly filed, but contains with respect to the main request a single amendment meant to add a medical indication and thereby solve the objection of lack of inventive step raised in the communication of the Board.

1.2 All the requests can be seen therefore as a reaction to the communication of the Board and introduce minor changes which can be easily addressed by the Board without adjournment of the proceedings. On this basis, the Board, on application of the criteria in Article 13 RPBA, exercises its discretion by admitting the requests filed with letter of 8 March 2013 into the proceedings.

Main Request - inventive step

2. *Closest prior art*

2.1 Document D2 has been considered as the closest prior art both in the appealed decision and in the arguments of the appellant. The Board sees no reason to take a different starting point.

2.2 Document D2 discloses oral compositions which provide antiplaque, antigingivitis and anticalculus benefits with improved oral cleaning properties comprising a surfactant, an enzyme, a chelating agent, a fluoride

- ion source and a suitable oral carrier (summary of the invention, column 2, lines 29 to 41). Several classes of surfactants are disclosed (column 3, line 17 to column 4, line 24), including cationic surfactants, such as cetyl pyridinium chloride, some of which can act as germicides (column 3, lines 38 to 58). Several enzymes are disclosed (column 6, lines 7 to 48), including proteases, such as papain (column 6, lines 17 to 28, 32 to 35). Several optional ingredients may be added (columns 7 to 9), including abrasives (column 7, lines 16 to 67).
- 2.3 Examples II, IV, V and VII of D2 (columns 10 to 12) disclose dentifrice compositions comprising silica as abrasive (20-30%) and papain as enzyme (0.4-0.5%) among several other ingredients (sorbitol, titanium dioxide, citric acid, sodium citrate, sodium lauroyl sarcosinate, cocoamidopropyl betaine, sodium fluoride, FD & C blue #1, water and sodium saccharin are common to all four compositions).
- 2.4 While D2 discloses individually the three essential ingredients of the composition of claim 1 of the main request (an abrasive, a cationic antibacterial agent and a proteolytic enzyme selected from papain, bromelain, chymotrypsin, ficin and alcalase), it does not disclose the three ingredients in combination. The compositions of examples II, IV, V and VII of D2 are those which come closer to the composition of claim 1 of the main request and differ therefrom only in that they do not contain a cationic antibacterial agent.
- 2.5 The compositions of these examples of D2 are therefore the most suitable starting point for the analysis of

inventive step. Their choice in the disclosure of D2 is part of the first step of the application of the problem-solution approach, namely the selection of the closest prior art, which consists in choosing the prior art disclosure (be it a full document or an embodiment within a document) which corresponds to a purpose or technical effect similar to that of the invention and requires the minimum of structural and functional modifications. At this stage of the application of the problem-solution approach no indication is needed in D2, as apparently contested by the appellant, that one should start from that specific embodiment (i.e. those specific examples).

3. *Problem solved*

3.1 According to the application as filed, the technical problem to be solved appears to be "to formulate a dentifrice product capable of delivering an antibacterial agent having enhanced effect in the retardation of bacterial plaque accumulation on teeth, as well as on the tongue, without inhibiting the bioavailability of the antibacterial compound" (page 2, lines 17-20). The appellant reformulated that problem in a more specific way during the appeal proceedings as "to provide a dentifrice with improved reduction in oral malodour through reduction of tongue microflora" (letter of 8 March 2013, page 2, section "Technical Problem") with reference to the effects shown in the examples of the application.

3.2 The evidence on file, in particular the examples and comparative examples relied upon by the appellants, must be taken into account to evaluate whether the

posed problem has indeed been solved with respect to the closest prior art.

3.3 Example 1 in the application as filed (page 11) discloses two compositions (composition 1 and 2) according to the invention, which contain an abrasive (Zeodent-115, Zeodent-165 and Sylodent XWA650 in composition 1 and dicalcium phosphate in composition 2), a combination of enzymes (0.205 wt% papain and 0.1 wt% glucoamylase in both compositions), a cationic antibacterial agent (0.5 wt% cetyl pyridinium chloride in both compositions) and several other ingredients (with deionised water, Pluronic F127, sorbitol, glycerin, sodium tripolyphosphate, flavor, tetrasodium pyrophosphate, tegobetaine, Polysorbate 20 and PEG 600 as the quantitatively most relevant). In addition, example 1 discloses three comparative compositions (C1, C2 and C3), wherein composition C1 and C3 correspond to composition 1 with the replacement of cetyl pyridinium chloride and the enzymes respectively with a corresponding quantity of sorbitol and composition C2 corresponds to composition 2 with the replacement of the enzymes with a corresponding quantity of glycerin.

3.4 Example II in the application as filed shows the reduction of malodour tongue bacteria in an *in-vivo* study for the 5 compositions (pages 12 and 13, table II) and example III shows the reduction of oral malodour in a further study for composition 1, C1, C2 and C3 (pages 13 and 14, table III). In both cases the compositions according to the invention have a larger reduction.

- 3.5 The examples and comparative examples available on file do not offer a reproduction of the relevant examples of D2, from which they differ not only in the ingredients present and in their quantities, but also in the essential ingredients of the composition (see points 2.3 and 3.3, above). Moreover, in those examples a single cationic antibacterial agent (cetyl pyridinium chloride) is tested in two compositions (compositions 1 and 2) which differ only marginally from each other (only the abrasives are different).
- 3.6 Under such circumstances the Board has no elements to evaluate what would happen if the compositions of examples II, IV, V and VII of D2 were compared with compositions which differ therefrom only in the presence of a cationic antibacterial agent. Moreover, no information is available on what influence cationic antibacterial agents different from cetyl pyridinium chloride and belonging to the large class of compounds which is included by that definition could have on the composition.
- 3.7 These concerns of the Board are confirmed by the argument of the appellant - used to show the presence of an inventive step - that the biological activity in complex compositions such as the ones under study is very unpredictable due to the interactions among the components, so that it cannot be expected that a composition is indeed effective without clear evidence.
- 3.8 The Board agrees with that argument of the appellant and considers that the skilled person who analyses the obviousness of a solution is the same as the one who evaluates the plausibility that a problem has been

solved. That person with the available information could only arrive at the conclusion that the examples on file do not offer a comparison with D2 and cannot be extrapolated to a generic composition falling under the wording of the claim.

3.9 Under such circumstances, the Board concludes that the evidence on file does not make it credible that an advantage in terms of reduction in oral malodour is accomplished with respect to the compositions of D2 and over the whole breadth of claim 1 of the main request. No other advantages have been shown, nor claimed by the appellant.

3.10 On that basis and in the absence of an effect or improvement with respect to the closest prior art, the problem to be solved, starting from the compositions of examples II, IV, V or VII of D2, is the provision of further dentifrice compositions.

4. *Obviousness*

4.1 The skilled person, starting from the compositions of examples II, IV, V or VII of D2 and looking for further compositions, would consider without any inventive skill all the alternative ingredients disclosed and suggested in the document itself, including the cationic surfactants which may act as germicides, as e.g. cetyl pyridinium chloride (see D2, column 3, lines 38 to 58), as possible ingredients to be added to the composition.

4.2 The inclusion of such surfactants in the compositions of those examples of D2 would result in a composition

according to claim 1 of the main request, which on that basis is not inventive.

4.3 Also the argument of the appellant that the disclosure of both D2 and D4 would lead the skilled person not to use the cationic antibacterial agents is not convincing for the Board and cannot change this conclusion.

4.4 Indeed D2 discloses that cationic surfactants such as chlorhexadine, although suitable for use in the compositions disclosed therein, are not preferred due to their capacity to stain the oral cavity's hard tissues (column 3, lines 52 to 56), and D4 discloses that cationic antibacterial agents are desired ingredients of oral hygiene compositions as a means of reducing the bacterial plaque population (column 1, lines 18 to 22), but compositions including them may suffer from some disadvantages, as the cationic antibacterial agents tend to leave a brown stain and may be incompatible with some dentifrice ingredients (column 1, lines 23 to 37).

4.5 However, neither of these disclosures may be considered as a proof of a prejudice against using cationic antibacterial agents in dentifrice compositions which would lead the skilled person not to employ them, because in both documents the use of cationic antibacterial agents is suggested (see D2 column 3, lines 38 to 58; D4, column 1, lines 12 to 17) in spite of a warning on possible inconveniencies and a prejudice is not indicated. In any case, the considerations set out in isolated patent specifications cannot generally be taken as proof of a prejudice, which may in principle be demonstrated only

by reference to the literature or to encyclopaedias published before the priority date (Case Law of the Boards of Appeal of the EPO, 6th edition 2010, I.D.9.2).

- 4.6 The composition of claim 1 of the main request does not therefore involve an inventive step.

First auxiliary request - inventive step

5. Claim 1 of the first auxiliary request corresponds to claim 1 of the main request with the addition that the dentifrice composition is "for use in the treatment of halitosis".
- 5.1 The Board is persuaded that the treatment of halitosis may under specific conditions be considered as a therapeutic treatment, but is in many others situations nothing more than a cosmetic one. This is based on the fact that halitosis is in most cases just an unpleasant condition, but can be considered as a disease only in extreme cases (e.g. chronic halitosis).
- 5.2 Leaving aside the question as to whether in the present case it would be possible to distinguish the therapeutic use from the non-therapeutic one, it is noted that the appellant has not attempted to claim only one of the two, but has left a formulation of the claim which by means of the wording "for use in the treatment of halitosis" includes both the therapeutic and the non-therapeutic use.
- 5.3 At least for the case of the non-therapeutic use, the indication that the composition is for use in the treatment of halitosis cannot constitute a further

distinguishing feature with respect to the disclosure of D2, as there is no reason why the compositions of D2 should not be suitable for that use. On the contrary, as they contain proteases which destroy bacteria (see D2, column 6, lines 16 to 28 and the tests on compositions C1 in the patent which includes the enzymes, but not the cationic antibacterial agents) they must be suitable at least to some extent for the treatment of halitosis.

- 5.4 As the additional feature of claim 1 of the first auxiliary request with respect to claim 1 of the main request is not a further distinguishing feature with respect to the disclosure of D2, the composition of claim 1 of the first auxiliary request is not inventive for the same reasons as detailed for the main request (points 2 to 4, above).

Second auxiliary request - inventive step

6. Claim 1 of the second auxiliary request corresponds to claim 1 of the main request with the further specification that "the abrasive is a silica having an oil absorption value less than $100 \text{ cm}^3/100 \text{ g}$ (100 cc/100 g) silica".

- 6.1 There is no information in examples II, IV, V and VII of D2 concerning which kind of silica is used therein (columns 10 to 12). In the general part of D2 some indications are given on the average particle size of silica abrasive particles which are generally used and some examples are given by reference to patents and trade marks (column 7, lines 47 to 63), but the oil absorption value of these silica is not given, nor is

- the parameter mentioned. On that basis it is not known whether the silica used in the examples of D2 has an oil absorption value within the claimed range or not.
- 6.2 The crucial issue here, however, is not whether a silica having an oil absorption value less than 100 cm³/100 g silica is at least implicitly disclosed in D2, but whether by the choice of such a silica an effect or an advantage is achieved.
- 6.3 Indeed, even accepting that the silica indicated in the claim results in a selection of a specific silica abrasive with respect to the general disclosure in D2, in the absence of any evidence or information on the side of the appellant of possible effects or advantages related to the choice of the specific silica, the problem to be solved, starting from the compositions of examples II, IV, V or VII of D2, still remains the provision of further dentifrice compositions.
- 6.4 The addition of a cationic antibacterial agent is an obvious solution to the posed problem (for the reasons given for the main request, see in particular, point 4, above) and the same can be said as regards the additional use of a silica which is known as a possible satisfactory abrasive to be used in similar dentifrice compositions (see D1, column 1, line 66 to column 2, line 55).
- 6.5 On that basis the composition of claim 1 of the second auxiliary request does not involve an inventive step.

Third auxiliary request - inventive step

7. Claim 1 of the third auxiliary request corresponds to claim 1 of the second auxiliary request with the further addition that "the proteolytic enzyme is present in the dentifrice in combination with a glucoamylase".
- 7.1 The compositions of examples II, IV, V and VII of D2 do not contain any glucoamylase. The general part of the description of D2 concerning enzymes to be used in the dentifrice compositions disclosed therein mentions proteases and amylases in a list of possible enzymes, which includes the possibility of compatible mixtures of enzymes (column 6, lines 29 to 32).
- 7.2 In spite of the fact that the specific indication of the presence of glucoamylase constitutes a further difference with respect to the compositions of examples II, IV, V and VII of D2, also in this case there is no evidence or information on the side of the appellant of possible effects or advantages related to the addition of glucoamylase. The problem to be solved, starting from the compositions of examples II, IV, V or VII of D2, is therefore still the provision of further dentifrice compositions.
- 7.3 In addressing this problem, it would be obvious for the skilled person not only to add a surfactant known from D2 itself (see point 4, above) and to use a silica known in the field (see point 6, above), but also to add a further enzyme, which belongs to a class of enzymes specifically mentioned in D2 (see point 7.1, above) and is known as a beneficial enzyme to be used

in combination with proteolytic enzymes in similar dentifrice compositions (see D1, column 3, lines 13 to 19 and examples II to IV with several dentifrice compositions including papain and glucoamylase in combination).

7.4 On that basis the composition of claim 1 of the third auxiliary request does not involve an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

S. Fabiani

J. Riolo