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Datasheet for the decision of 20 October 2015

Case Number: T 1162/11 - 3.3.07

Application Number: 01950570.0

Publication Number: 1294383

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Language of the proceedings: EN

Title of invention:

ORAL COMPOSITIONS COMPRISING ANTIMICROBIAL AGENTS FOR THE PREVENTION OF SYSTEMIC DISEASES

Patent Proprietor:

THE PROCTER & GAMBLE COMPANY

Opponents:

Mercer, Christopher Paul
Colgate-Palmolive Company
SCHÜLKE & MAYR GmbH

Relevant legal provisions:

EPC Art. 56, 104
EPC R. 99(1)(c)
RPBA Art. 12

Keyword:

Admissibility of appeal - (yes)
Late-filed request - admitted (yes)
Apportionment of costs - (no)
Late-filed document - admitted (yes)
Inventive step - (no)

Decisions cited:

T 0358/08

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Case Number: T 1162/11 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 20 October 2015

Appellant: (Patent Proprietor)	THE PROCTER & GAMBLE COMPANY One Procter & Gamble Plaza Cincinnati, OH 45202 (US)
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Respondent: (Opponent 1)	Mercer, Christopher Paul Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Representative:	Mercer, Christopher Paul Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent: (Opponent 2)	Colgate-Palmolive Company 909 River Road P.O. Box 1343 Piscataway NJ 08855-1343 (US)
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Respondent: (Opponent 3)	SCHÜLKE & MAYR GmbH Robert-Koch-Strasse 2 D-22851 Norderstedt (DE)

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 14 March 2011 revoking European patent No. 1294383 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman J. Riolo
Members: D. Semino
P. Schmitz

Summary of Facts and Submissions

I. European Patent No. 1 294 383 was granted on the basis of 6 claims, independent claim 1 reading as follows:

"1. Use of an antimicrobial selected from stannous ion agents; triclosan; triclosan monophosphate; chlorhexidine; alexidine; hexetidine; sanguinarine; benzalkonium chloride; salicylanilide; domiphen bromide; cetylpyridinium chloride (CPC); tetradecylpyridinium chloride (TPC); N-tetradecyl-4-ethylpyridinium chloride (TDEPC); octenidine; delmopinol; octapinol; nisin; zinc ion agents; copper ion agents; essential oils; furanones; bacteriocins; analogs and salts thereof; and mixtures thereof, in the manufacture of a topical oral composition for reducing the risk of development of systemic diseases selected from cardiovascular disease, stroke, diabetes, pneumonia, bronchitis, emphysema, chronic obstructive pulmonary disease, or for reducing the risk of bearing premature and low birth weight infants in humans and other animals, wherein the composition is in a form selected from a mouthrinse, toothpaste, tooth gel, tooth powder, non-abrasive gel, chewing gum, mouth spray, lozenge, and a pet chew product and comprises a pharmaceutically acceptable oral carrier."

II. Three notices of opposition were filed in which revocation of the patent in its entirety was requested.

III. During opposition proceedings, the following documents *inter alia* were cited:

D1: US-A-5 294 433
D6: US-A-5 875 798
D15: US-A-5 875 799

D17: WO-A-92/04884
D18: Position Paper, J. Periodontol., volume 69(7), 1998, pages 841-850
D19: Cohen et al., Compendium of Continuing Education in Dentistry, volume 19(1), 1998, pages 11-24
D21: GB-A-2 317 339
D22: US-A-5 004 597
D23: US-A-5 578 293
D25: US-A-4 894 220
D26: US-A-5 015 466
D27: C.W. Douglass Editor, "The role of triclosan/ copolymer dentifrice in the prevention and control of periodontal disease", Symposium Report, pages 1 to 12
D63: M. Jeffcoat et al., "Use of alcohol free antibacterial mouth-rinse is associated with a decreased incidence of PTB", Abstract Number 222093, SMFM 2011 Meeting, accepted for oral presentation

IV. The decision of the opposition division to revoke the patent was announced at the oral proceedings on 20 January 2011. It was based on three sets of claims filed with letter of 19 November 2010 as main request and first and second auxiliary requests and on a further set of claims filed as third auxiliary request during said oral proceedings.

Claim 1 of the main request compared to granted claim 1 included in the medical indication the specification "by treating chronic periodontal infection". Claim 1 of the first auxiliary request corresponded to granted claim 1 with the specification that "the composition is applied with a frequency of at least thrice per week". Claim 1 of the second auxiliary request included the amendments in claim 1 according to the main request and the first auxiliary request. Claim 1 of the third auxiliary request corresponded to claim 1 of the second auxiliary

request with the limitation of the systemic diseases to "atherosclerosis".

V. The decision of the opposition division, as far as relevant to the present decision, can be summarised as follows:

a) The subject-matter of claim 1 of the main request lacked novelty over documents D18 and D19.

b) The amendment in claim 1 of the first auxiliary request resulted in an extension beyond the content of the application as originally filed.

c) The introduction of both the treatment of chronic periodontal infection and of the treatment frequency in claim 1 of the second auxiliary request solved both the issue under Article 123(2) EPC and the lack of novelty, as D18 and D19 did not specifically define such a treatment frequency.

d) Claim 1 of the second auxiliary request differed from the disclosure of the closest prior art documents D6 and D15, which indicated the relevance of treatment of periodontal disease for systemic diseases and described toothpicks and dental floss loaded with corresponding anitimicrobial agents for that treatment, in the nature of the defined composition to be used. The problem was the provision of alternative compositions for the treatment of chronic periodontal infection thereby reducing the risk of development of systemic diseases, which could be considered as solved, in spite of the absence of experimental data, in view of the explanations in the patent and the available

prior art. The skilled person, looking for alternative methods, would find oral compositions comprising antimicrobial agents in the forms defined in the claim in documents such as D1, D17, D21, D22, D23, D25, D26 and D27, and thereby arrive of the subject-matter of the claim without inventive activity.

e) The limitation to risk reduction of atherosclerosis and of bearing premature or low birth weight infants in claim 1 of the third auxiliary request, in spite of being a genuine response to the findings in respect of the second auxiliary request, did not change the analysis of inventive step with the consequence that claim 1 of the third auxiliary request also did not involve an inventive step.

VI. The patent proprietor (appellant) lodged an appeal against that decision. The notice of appeal included the sentence "We request that the decision under appeal be set aside and that the European patent be maintained as granted, or in accordance with amendments filed with the grounds of appeal". With the statement setting out the grounds of appeal the appellant filed four sets of claims as main request and first to third auxiliary requests and the following pieces of evidence:

D64: Declaration by Matthew J. Doyle, Ph.D. and Robert W. Gerlach, D.D.S. dated 21 July 2011
D65: Y. W. Han, J. Dent. Res., 2011, volume 90(3), pages 289-293
D66: B. S. Michalowicz et al., New England Journal of Medicines, 2006, volume 355(18), pages 1885-1894
D67: J. Katz et al., J. Dent. Res., 2009, volume 88(6), pages 575-578

VII. With their replies to that statement respondent-opponent 1 submitted the following pieces of evidence:

D68: S. Offenbacher et al., J. Periodontol. 1996, volume 67(10), pages 1103-1113
D69: M. Jeffcoat et al., Am. J. Obs. & Gyne. 2011, DOI: 10.1016/j.ajog.2011.07.016 (accepted manuscript)

and respondent-opponent 3 resubmitted a dated version of document D60 (Erklärung von PD Dr. med. Axel Larena-Avellaneda).

VIII. In a communication sent in preparation of oral proceedings, the Board summarised the points to be dealt with, and indicated inter alia that the "risk reduction is always disclosed in the context of "treating and preventing diseases and conditions of the oral cavity" (page 1, first paragraph, last line), which limitation is not present in claim 1 of the main request" (point 5.1 in the context of Article 123(2) EPC).

IX. With letter of 18 September 2015 the appellant filed six sets of claims as main request and as first to fifth auxiliary requests to replace the requests on file, wherein the first and fourth auxiliary request were new and the others corresponded to previous requests partially renumbered.

Claim 1 of the main request corresponded to granted claim 1 with the deletion in the medical indication of the alternative relative to "reducing the risk of developing systemic diseases". Claim 1 of the first auxiliary request contained in addition the specification "by treating and preventing diseases and

conditions of the oral cavity" in the medical indication. This specification was amended to "by treating chronic periodontal infection" in claim 1 according to the second auxiliary request. Claim 1 of the third auxiliary request corresponded to claim 1 of the main request with the specification that "the composition is applied with a frequency of at least thrice per week". Claim 1 of the fourth (respectively fifth) auxiliary request included the amendments in claim 1 according to the first (respectively second) and third auxiliary requests.

X. Oral proceedings were held on 20 October 2015.

XI. The arguments of the appellant, as far as relevant to the present decision, can be summarised as follows:

Main request - inventive step

a) The closest prior art should be a document relating to the composition and not to the medical indication in order to avoid the risk of incorporating part of the solution into the analysis of the prior art, the appropriate choice being document D1. In any case, the presence of an inventive step should be acknowledged also starting from a document concerning the medical indication, such as D6. Document D6 concerned the administration of a therapeutic agent for periodontal diseases by means of a toothpick in order to obtain a systemic effect by passing the agent into the bloodstream and mentioned adverse pregnancy outcomes. However, that teaching was not credible, as the small quantity of agent which was administered and the minimal surface area would transfer to the blood a minimal quantity with

negligible effects. Nothing more could be taken from document D68, which was correctly summarised in the patent and did not disclose any topical composition such as the ones listed in claim 1. Starting from D6 the problem was the provision of an improved method for reducing the risk of bearing premature or low birth weight infants. The tests in D63 showed that the problem was credibly solved, which was plausible already from the teaching in the application as filed. The solution was not obvious, as the link between periodontal disease and pregnancy outcome in the prior art was highly speculative and as it was known that topical compositions such as those listed in claim 1 did not provide systemic delivery and acted very differently from a toothpick by contacting all mouth tissues. Moreover, the skilled person, looking for an effective treatment of periodontal diseases, would have turned to mechanical intervention and not to topical compositions. The fact that the solution looked simple did not render it obvious.

Auxiliary requests - inventive step

b) The features added in the auxiliary requests, which related to the treatment of disease of the oral cavity or of periodontal diseases and to the frequency of treatment, put sone further distance with respect to the disclosure in document D6. This was all the more true in view of the disclosure in D6 referring to the systemic effect by means of the passage of the therapeutic agent into the bloodstream. In view of that the subject-matter claimed in the auxiliary requests was inventive.

XII. The arguments of the respondents (opponents 1, 2 and 3), insofar as relevant to the present decision, can be summarised as follows:

Admissibility of the appeal

a) The appeal was not admissible, as the notice of appeal did not contain any admissible request defining the subject of the appeal. The request to maintain the patent as granted was not present in opposition proceedings and the appellant was not adversely affected by the decision in this respect; in addition, the further request which referred to amendments yet to be filed was unclear. Finally, as the requests filed in appeal were not to be admitted (see point b), below), the appeal was not admissible also for that reason.

Admittance of the claim requests

b) The limitation of the medical indication in claim 1 of the main request to the reduction of risk of bearing premature and low birth weight infants was not present in the requests decided upon in the appealed decision and posed therefore questions which were not decided upon. Moreover, claim 1 of the main request contained an extension with respect to the claims decided upon (the limitation "by treating chronic periodontal infection" was deleted), whose compliance with the requirements of Article 123(2) EPC had not been decided upon. On that basis, it was not legitimate to file the main request only in appeal proceedings and the request should not be admitted under Article 12(4) RPBA. The same held for the auxiliary requests.

Remittal and apportionment of costs

c) If admitted, the requests would raise questions not decided upon by the opposition division, so that a remittal would be necessary. In such a case, the appellant should pay the costs incurred by respondent-opponent 3 in appeal as they were caused by the behaviour of the appellant.

Main request - inventive step

d) Document D1 was not an appropriate starting point, as it did not relate to the same purpose or effect as claim 1 of the main request. Document D6 was the closest prior art and disclosed a method for treating periodontal diseases in order to reduce the risk of systemic diseases including premature births by means of a toothpick including a therapeutic agent. This was clearly achieved by treatment of the bacteria in the periodontal area independently of a passage of the agent into the bloodstream and was in line with the teaching of D68 cited in D6. In any case, the teaching in D6 was as credible as the one in the patent, as both cited document D68 in the same terms as a basis for the link between periodontal disease and pregnancy outcome and no weight was given in the patent (and in claim 1) to the quantity of agent which was administered. Claim 1 differed from the disclosure in D6 only in the form of the topical composition applied. As no comparative data were available to show an effect, the problem was the provision of an alternative form for the same purpose. The listed topical compositions were all known for treating periodontal diseases, so that the solution was obvious. In this respect, it was

relevant that the application as filed was as speculative as the prior art and this fact could not be changed by the studies in D63, which were made several years later. Moreover, even if mechanical treatment was known, it was common to use chemotherapeutic agents, as shown by many documents. On that basis, an inventive step was lacking. This was all the more true, as claim 1 included the use of agents, such as phenol, which were toxic.

Auxiliary requests - inventive step

e) The same arguments were valid for the auxiliary requests, as D6 mentioned the treatment of gingivitis and periodontal diseases and there was no particular effect related to the specific frequency, which was part of the common general knowledge. The interpretation of D6 of the appellant with relation to the route of treatment of systemic diseases was incorrect for the same reasons as outlined for the main request. On that basis, the subject-matter claimed in the auxiliary requests was not inventive.

XIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained according to the main request or first to fifth auxiliary requests filed with letter of 18 September 2015.

XIV. Respondent-opponent 1 requested that the appeal be rejected as inadmissible or that it be dismissed.

Respondent-opponent 2 requested that the appeal be dismissed.

Respondent-opponent 3 requested that the appeal be rejected as inadmissible or that the case be remitted to the opposition division and the appellant be ordered to pay his appeal's costs including future costs or that the appeal be dismissed.

Reasons for the Decision

Admissibility of the appeal

1. Rule 99(1)(c) EPC prescribes that the notice of appeal shall contain a request defining the subject of the appeal. According to the case law this is satisfied if the notice of appeal contains a request to set aside the decision in whole or, (where appropriate) only as to part and it is not necessary in the case of an appeal by a proprietor for the notice of appeal to contain a request for maintenance of the patent in any particular form, which is something which relates to the extent to which the decision is to be amended, and which is therefore a matter for the statement of grounds of appeal under Rule 99(2) EPC (Case Law of the Boards of Appeal of the EPO, 7th edition 2013, IV.E.2.5.2 c), in particular decision T 358/08 of 9 July 2009).

1.1 In the present case the notice of appeal included the explicit request that the decision under appeal be set aside (see point VI, above), which results therefore in the requirements of Rule 99(1)(c) EPC being met.

1.2 This fact cannot be changed by a possible decision on the admittance of the requests filed with the statement of grounds which is under the discretion of the Board (Article 12(4) RPBA). Such a decision will influence which requests must be decided upon on the substance,

but can have no impact on the admissibility of the appeal, which is not a discretionary decision.

1.3 Accordingly, the requirements of Rule 99(1)(c) EPC are fulfilled. The Board has no doubt that all other formal requirements are met (which has not been contested by the respondents).

1.4 In view of that, the appeal is admissible.

Admittance of the claim requests

2. The main request, as well as the second, third and fifth auxiliary requests, were originally submitted with the statement setting out the grounds of appeal, and were subsequently renumbered with letter of 18 September 2015 after addition of two further requests (first and fourth auxiliary). Thus according to Article 12(1) RPBA, the main request and the second, third and fifth auxiliary requests form part of the basis for appeal proceedings.

2.1 However, the respondents considered that they should not be admitted under Article 12(4) RPBA, which gives the Board the discretion to hold inadmissible requests which could have been presented or were not admitted in the first instance proceedings.

2.2 Since in fact almost every claim request could have been presented before the department of first instance, the question within that context is whether the situation was such that the filing of this request should have taken place already at that stage.

2.3 Claim 1 of the main request corresponds to claim 1 of the third auxiliary request decided upon by the opposition division with the limitation of the medical

indication to one of the two alternatives (only reducing the risk of bearing premature and low birth weight infants by deleting the reduction of the risk of atherosclerosis) and the deletion of the specification "by treating chronic periodontal infection" (see points IV and IX, above).

2.4 The opposition division found that the third auxiliary request did not involve an inventive step taking position on both alternatives (see point V e), above). The analysis of inventive step of the main request on file is therefore clearly an issue decided upon by the first instance. This is confirmed by the attacks of the respondent which follow the same lines as those before the opposition division and is not changed by the further amendment, which might be discussed under Article 123(2) EPC, but has no impact on inventive step.

2.5 The main request does not result therefore in a fresh case, which has not been examined by the opposition division. Moreover, the limitation to one of the two alternatives appears to be a genuine attempt of the appellant to overcome the objection by restricting the subject-matter to what in its view may be better supported by the evidence on file.

2.6 Consequently the Board considers it appropriate to admit the main request into the proceedings.

2.7 The same applies to the second, third and fifth auxiliary requests, which contain the amendments of the main, first auxiliary and second auxiliary requests decided upon by the opposition division (see points IV and IX, above).

2.8 As to the first and fourth auxiliary requests, they can be seen as a reaction to the communication of the Board, as the wording was added whose absence was mentioned in that communication as giving rise to objections under Article 123(2) EPC (see points VIII and IX, above). The added wording as such was not objected to by the respondents and the same objections of lack of inventive step were maintained also for those requests.

2.9 Under such circumstances, the Board finds it appropriate to admit also the first and fourth auxiliary requests into the proceedings.

Remittal and apportionment of costs

3. As the main issue which led to the revocation of the patent (lack of inventive step) remains equally relevant for the requests to be decided upon in spite of the amendments (see points 6 to 10, below) with no new substantial fact, evidence or argument, the Board sees no reason which would justify a remittal to the department of first instance. The request of remittal of respondent-opponent 3 is therefore rejected.

4. As the case is not remitted, there are no additional costs on the side of respondent-opponent 3 which could be attributed to the appellant. Therefore, the Board sees no reason of equity for an apportionment of costs different from the one in which each party bears its own costs (Article 104(1)(2) EPC).

4.1 The request of respondent-opponent 3 that the appellant pays the costs incurred by him in appeal is therefore rejected.

Admittance of the evidence filed in appeal

5. Documents D60 (resubmitted in a dated version by respondent-opponent 3 with the reply to the statement of grounds), D64 to D67 (filed by the appellant with the statement of grounds) and D68 to D69 (submitted by respondent-opponent 1 with the reply to the statement of grounds) were timely filed by the parties in appeal (Article 12(1) RPBA). Their admittance into the proceedings has not been contested by the opposing parties and also the Board sees no reason under Article 12(4) RPBA not to admit them. On that basis documents D60 (in the resubmitted version) and D64 to D69 are admitted into the proceedings.

Main request - inventive step

6. While there was agreement among the parties about which features of claim 1 of the main request were disclosed by the potential closest prior art documents D1 and D6, the first point of dispute concerned which of the two should be chosen as closest prior art, namely whether a document concerning a composition as the one used in claim 1, but disclosing the use for a different purpose (D1), or a document disclosing a composition with the same active used for the same purpose, but with the active in a different form (a tooth pick instead of one of the forms listed in claim 1) (D6), should be taken.

6.1 It is well established in the case law that the closest prior art for assessing inventive step is normally a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common (Case Law of the Boards of Appeal of the EPO, 7th edition 2013, I.D.3.1). The

application of such a principle undoubtedly points to the choice of document D6, i.e. a document disclosing a composition conceived for the same purpose, over D1 as the closest prior art.

6.2 While they may be individual cases in which a document relating to the composition as such may be chosen as closest prior art in case of second medical use claims (e.g. if no documents disclosing compositions conceived for the same purpose are available), the Board does not see any reason in the present case to deviate from the general principle. In particular, the risk of incorporating part of the solution in the analysis of inventive step, as mentioned by the appellant, should be taken into consideration when formulating the technical problem, but is of no weight when choosing the closest prior art.

6.3 On that basis, document D6 is the closest prior art.

6.4 Document D6 discloses toothpicks impregnated or coated with therapeutic agents such as zinc salts or other medicaments for treating gingivitis and periodontal disease, that may predispose individuals to several risks, including premature births (field of the invention in column 1, lines 9-18). It is the direct administration of the therapeutic agents to the periodontal tissues that makes it possible to treat the gingivitis and periodontal disease and thus to help prevent systemic diseases from occurring (column 7, lines 39-43). The link is further disclosed between untreated periodontal disease and premature or low birth weight infants (column 5, lines 23-47). A carrier can be mixed with the zinc salt (column 8, lines 13-14).

6.5 The use of claim 1 therefore differs from the disclosure of D6 only in that the manufactured topical oral composition instead of being a toothpick is "in a form selected from a mouthrinse, toothpaste, tooth gel, tooth powder, non-abrasive gel, chewing gum, mouth spray, lozenge, and a pet chew product".

6.6 The Board cannot follow the argument of the appellant that D6 does not provide a credible teaching in view of the teaching that the systemic effect takes place by passing the agent into the bloodstream, of the minimal quantity of medicament applied and of the minimal surface area of application.

6.7 While it is true that passage of the therapeutic agent to the bloodstream is mentioned in D6 (see column 8, lines 13-15: "A carrier or binder can be mixed with the zinc salt and other therapeutic agents which will either speed or slow its passage through the oral tissues and into the bloodstream."), a clear teaching is given in D6 that the prevention effect takes place through local treatment of the periodontal disease (see column 7, lines 39-43: "The toothpick of this invention allows the patient to self-administer the therapeutic agents directly to the periodontal tissues and treat the gingivitis and periodontal disease, and thus help prevent systemic diseases from occurring."), which corresponds to the teaching in the patent in suit (see e.g. paragraph [0020]).

6.8 Also the link between untreated periodontal disease and an enhancement of the risk of bearing premature or low birth weight infants is based on the same study (D68), which is cited with very similar wording in D6 (column 5, lines 23-47) and in the patent in suit (paragraph [0006]).

6.9 While neither in D6, nor in the patent in suit data are available that show an effective reduction in the risk of bearing premature or low birth weight infants (no studies in this respect were done), it is the results presented in D68 (and equally cited in D6 and in the patent) that make it credible in both cases that by treating the periodontal disease a reduction in the risk of bearing premature or low birth weight infants takes place. Indeed in D68 a case-control study of 124 pregnant or postpartum mothers was performed and a clear correlation was found between periodontal disease and preterm low birth weight (see abstract and discussion on pages 1110-1112), which makes it credible that by treating periodontal disease (as in D6 or in the patent in suit) a reduction of the risk of bearing premature or low birth weight infants is achieved.

6.10 In other words, the teaching of D6 is as credible (or as speculative) as the teaching in the patent in suit, all the more as no limitation on the quantity of therapeutic agent is given in claim 1 and as toothpicks were even mentioned as alternative to the now claimed forms of composition in the original application from which the patent stems (page 20, last paragraph).

6.11 With regard to the identified difference (one of the listed forms instead of a toothpick), no comparative data are available to show that an improvement or an advantage is present for the subject-matter of claim 1 of the main request over the disclosure in D6. Even the post-published study in D63, which has been cited by the appellant as evidence for the formulation of the technical problem, concerns the treatment with an antimicrobial mouth rinse containing cetylpyridinium

chloride and its incidence on preterm birth (see objective), but does not provide any comparison with D6.

6.12 Under such circumstances and considering the equal credibility of the teaching in D6 and in the patent in suit (see points 6.9-6.10, above), the technical problem is the provision of an alternative treatment for reducing the risk of bearing premature and low birth weight infants in humans and other animals.

6.13 In view of the teaching in D68 which establishes the link between untreated periodontal disease and an enhancement of the risk of bearing premature or low birth weight infants (see points 6.8-6.9, above), the skilled person, starting from D6, would consider all known ways of treating periodontal diseases as obvious solutions to the posed problem.

6.14 The treatment of periodontal disease by means of topical oral compositions as the ones listed in claim 1 of the main request was undoubtedly known in the art (see e.g. abstracts of D1, D21, D22), which has not been contested by the appellant. The fact that other treatments, such as a mechanical treatment, were also known and possible does not render the treatment by the listed topical oral compositions inventive. On the contrary, it would render obvious also a further alternative treatment.

6.15 On that basis it is concluded that the subject-matter of claim 1 of the main request does not involve an inventive step.

First auxiliary request - inventive step

7. Claim 1 of the first auxiliary request corresponds to claim 1 of the main request with the specification "by

treating and preventing diseases and conditions of the oral cavity" in the medical indication.

7.1 The added feature, which was meant to overcome an objection of extension of the subject-matter beyond the content of the application as filed, is already disclosed in D6 (see analysis in point 6.4, above) and does not constitute therefore an additional difference with respect to this document.

7.2 The analysis of inventive step, therefore, remains the same as for claim 1 of the main request (see point 6, above) with the result that the subject-matter of claim 1 of the first auxiliary request does not involve an inventive step.

Second auxiliary request - inventive step

8. Claim 1 of the second auxiliary request corresponds to claim 1 of the main request with the specification "by treating chronic periodontal infection" in the medical indication.

8.1 While document D6 addresses in its general disclosure the treatment of periodontal disease without any further specification (see e.g. column 1, line 15; column 7, lines 41-42), it discloses in its general part that "Periodontal disease (gum disease) is one of the most prevalent chronic diseases affecting man" (column 1, lines 31-32), which implies that periodontal disease in the context of D6 is to be intended as chronic periodontal disease. The added feature therefore does not constitute also in this case an additional difference with respect to document D6.

8.2 The analysis of inventive step, therefore, remains the same as for claim 1 of the main request (see point 6, above) with the result that the subject-matter of claim 1 of the second auxiliary request does not involve an inventive step.

Third auxiliary request - inventive step

9. Claim 1 of the third auxiliary request corresponds to claim 1 of the main request with the specification that "the composition is applied with a frequency of at least thrice per week".

9.1 Document D6 does not explicitly disclose a frequency of treatment, so that the added feature formally constitutes a further difference for the subject-matter of claim 1 of the third auxiliary request with respect to the disclosure in D6. However, no data are available to show that the frequency chosen has a special effect or advantage, so that the technical problem remains the same as posed for claim 1 of the main request (see point 6.12, above).

9.2 While the use of the listed topical compositions is not inventive for the reasons already outlined for claim 1 of the main request (see points 6.13-6.15, above), the specific frequency appears as an arbitrary one among the normal values which the skilled person would adopt without exercising an inventive activity.

9.3 On that basis, the subject-matter of claim 1 of the third auxiliary request does not involve an inventive step.

Fourth and fifth auxiliary requests - inventive step

10. Claim 1 of the fourth auxiliary request corresponds to claim 1 of the third auxiliary request with the further amendment of claim 1 of the first auxiliary request. Claim 1 of the fifth auxiliary request corresponds to claim 1 of the third auxiliary request with the further amendment of claim 1 of the second auxiliary request.

10.1 As the features added to claim 1 of the first and second auxiliary requests are already disclosed in D6 (see points 7.1 and 8.1 above), the reasoning developed for claim 1 of the third auxiliary request equally applies to claim 1 according to the fourth and fifth auxiliary requests with the consequence that the subject-matter of claim 1 of the fourth and fifth auxiliary requests does not involve an inventive step.

Conclusion

11. As the subject-matter of claim 1 according to all the requests on file does not involve an inventive step, the appeal is to be dismissed and the Board does not need to decide on any further issue.

Order

For these reasons it is decided that:

1. The request of respondent-opponent 3 that the appellant pays his costs incurred by the appeal is rejected.

2. The appeal is dismissed.

The Registrar: The Chairman:

K. Boelicke J. Riolo

Decision electronically authenticated