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Datasheet for the decision
of 19 April 2016

Case Number: T 2325/12 – 3.3.07
Application Number: 04755980.2
Publication Number: 1663122
IPC: A61K8/42
Language of the proceedings: EN

Title of invention:
MOUTH RINSE COMPOSITIONS CONTAINING N-ACYL-ARGININE ALKYL ESTER SALTS

Patent Proprietor:
Colgate-Palmolive Company

Opponent:
Laboratorios Miret, S.A.

Relevant legal provisions:
EPC Art. 56, 84

Keyword:
Inventive step - (no)
Claims - clarity after amendment (no)
Case Number: T 2325/12 - 3.3.07

DEcision
of Technical Board of Appeal 3.3.07
of 19 April 2016

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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted on 30 August 2012
revoking European patent No. 1663122 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. 1 663 122 was granted on the basis of 14 claims, independent claim 1 reading as follows:

"1. A stable aqueous antiplaque oral composition comprising:
(a) a safe and effective amount of antibacterial ester of the formula

\[ R^2\text{CONHCH(CH}_2\text{)}_n\text{NHCNH}_2^+ X^- \]

where \( R^1 \) is an alkyl chain of 1 to 8 carbon atoms, and \( R^2 \) is an alkyl chain of 6 to 30 carbon atoms, and \( X \) is an anion;
(b) a stabilizing surfactant;
(c) a humectant; and
(d) water; said composition not comprising an acidic buffer."

II. A notice of opposition was filed in which revocation of the patent in its entirety was requested.

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

IV. The decision of the opposition division to revoke the patent was announced at the oral proceedings on 28 June 2012. It was based on 4 sets of claims filed as main request with letter of 24 April 2012, as first auxiliary request during oral proceedings on 28 June 2012 and as second and third auxiliary requests with letter of 24 April 2012 (then as first and second auxiliary requests).

Claim 1 of the main request corresponded to granted claim 1 with the addition that the stabilising surfactant comprises "a zwitterionic surfactant". Claim 1 of the first auxiliary request corresponded to claim 1 of the main request with the specification "said composition further comprising an alcohol, wherein said alcohol is monohydric and represented by the formula R'OH, where R' is an alkyl group having between 1 to 8 carbon atoms". Claim 1 of the second auxiliary request corresponded to claim 1 of the main request with the specification of the composition "being substantially free of monohydric alcohol". Claim 1 of the third auxiliary request corresponded to claim 1 of the second auxiliary request with the definition of the antiplaque oral composition as a "mouthwash" composition.

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

a) Document D9 was admitted into the proceedings as *prima facie* relevant.

b) Claim 1 of the main request was not inventive over document D9, taken as the closest prior art. The difference was the presence of citric acid in the compositions of D9, the problem was the provision
of a simplified antiplaque composition and it was obvious to omit citric acid, as it was a non-essential component. D5 could not be taken as the closest prior art, as a buffer was the most important ingredient of its compositions to achieve stability.

c) Claim 1 of the first auxiliary request was not inventive, as the presence of a monohydric alcohol was a further difference, but did not provide any further improvement, so that also its addition was an obvious measure (D9 itself disclosed the possible presence of an alcohol). Claim 1 of the second (which excluded the presence of a monohydric alcohol) and third auxiliary requests (which defined the composition as a mouthwash) were not inventive for the same reasons.

VI. The patent proprietor (appellant) lodged an appeal against that decision. With the statement setting out the grounds of appeal the appellant filed six sets of claims as main request and as first to fifth auxiliary requests.

The main request, as well as the first to third auxiliary requests corresponded to the requests on which the decision was based. Claim 1 of the fourth auxiliary request corresponded to claim 1 of the main request with the addition as a further ingredient of "(e) optionally an antitartar agent, wherein the antitartar agent is compatible with the antibacterial ester, or the antitartar agent is incompatible with the antibacterial ester and is included in one component of a dual component oral composition system in which a first component contains the antibacterial ester and a second component contains the antitartar agent". Claim 1 of the
fifth auxiliary request corresponded to claim 1 of the fourth auxiliary request with the deletion of the word "optionally" in the definition of ingredient (e).

VII. In a communication sent in preparation of oral proceedings, the Board summarised the points to be dealt with, and provided a preliminary view inter alia on inventive step for the main request and for the first to third auxiliary requests (points 3 and 4.2). In addition the Board expressed doubts on the clarity of the fourth and fifth auxiliary requests raising the question "whether it is clear for the skilled person which antitartar agents are compatible and which are not compatible with the antibacterial ester in order to make it possible to delimit what falls and what does not fall under the claim" (point 4.3).

VIII. Oral proceedings were held on 19 April 2014 in the absence of the appellant and of the respondent as announced by letters of 17 March 2016 and 8 April 2016 respectively.

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

Admittance of document D9

a) Document D9, which was already taken into account in examination proceedings, was known to the respondent, so that there was no reason for its late filing. Moreover, it was not prima facie relevant, as it was clearly not novelty destroying and as its use for an inventive step attack was based on hindsight. On that basis, it should not have been admitted in opposition proceedings and should not be admitted in appeal proceedings.
Main request - inventive step

b) Document D5 should be considered as the closest prior art and the presence of an inventive step with respect to it should be acknowledged. The same conclusion was to be reached also starting from document D9. The composition of claim 1 of the main request differed from the one of example 1 of D9 in the absence of a buffer, i.e. in the absence of citric acid monohydrate. This led to a simplified composition with reduced buffering activity, so that the problem was the provision of an improved stable aqueous anti-plaque oral composition containing an anti-bacterial component. The omission of citric acid would be accomplished by the skilled person as a result of hindsight. Moreover, citric acid was present in all examples of D9 and, even if the skilled person decided to remove an ingredient, there were several other components which could be removed. Moreover, citric acid was said to be an essential ingredient in document D5.

First to third auxiliary requests - inventive step

c) The presence of a monohydric alcohol constituted a further difference for the composition of claim 1 of the first auxiliary request with respect to the one of document D9, so that, posing the same problem as for the main request, it was even more difficult to come to the proposed solution, as there was no incentive to remove citric acid, nor any hint to the incorporation of a monohydric alcohol in D9. For the compositions of claim 1 according to the second and to the third auxiliary
requests, the same arguments held, as developed for the main request.

The appellant did not submit any arguments with regard to the clarity of the fourth and fifth auxiliary requests.

X. The arguments of the respondent, insofar as relevant to the present decision, can be summarised as follows:

Admittance of document D9

a) Document D9 was cited in the search report and used in opposition proceedings after amendments were introduced. The opposition division exercised its discretion correctly by admitting it and there was no reason to change that decision. Moreover, overturning the admittance would deprive the decision on inventive step of its basis.

Main request - inventive step

b) The composition of claim 1 of the main request differed from the composition disclosed in D9, which was correctly chosen as the closest prior art, in the absence of a buffer. However, the presence of citric acid was not connected to a specific motivation in D9 and it was obvious to omit citric acid, as any other non-essential component of the composition.

First to third auxiliary requests - inventive step

c) No effect was related to the additional feature in claim 1 of the first auxiliary request and it was known from D9 to use alcohols in the compositions,
so that the same finding of lack of inventive step as for the main request still applied. For the compositions of claim 1 according to the second and to the third auxiliary requests, the same arguments held as developed for the main request.

Fourth and fifth auxiliary requests - clarity

d) In the embodiment with a dual component oral composition system it was not clear where water and the humectant were to be found.

XI. The appellant requested that the decision under appeal be set aside and the patent be maintained according to the main request or one of the first to fifth auxiliary requests filed with the statement setting out the grounds of appeal.

XII. The respondent requested that the appeal be dismissed.

Reasons for the Decision

Admittance of document D9

1. The opposition division decided to admit both document D9 and the objection of lack of inventive step based on it into the proceedings and decided that claim 1 according to all requests lacked inventive step over D9 as the closest prior art. The decision on admittance was based on prima facie relevance of the document.

1.1 This decision was fully in the power of the opposition division in application of Article 114(1) and Rule 81(1) EPC and in view of G 10/91 (OJ EPO 1993, 420; see Headnote, point 2). In doing so the opposition division made use of the correct criteria and, in view of the
conclusion on inventive step, there is no doubt that the opposition division considered the ground of lack of inventive step based on D9 as one which *prima facie* would seem to prejudice maintenance of the patent.

1.2 Under such circumstances, the Board has no room to disregard the document and the corresponding objection.

**Main request - inventive step**

2. With regard to inventive step a first point of dispute concerns the choice of the closest prior art. While according to the decision under appeal and the arguments of the respondent document D9 should be taken, the appellant considers D5 as the most suitable starting point.

2.1 The Board sees no reason to take a different approach from the one in the decision under appeal. In particular, if starting from document D9 (which belongs to the same field of oral hygiene compositions with cationic antimicrobial agents and relates to stabilised composition, see first paragraph of D9) it is concluded that inventive step is lacking, the decision holds good and there is no need to undertake a different analysis.

2.2 There was agreement between the parties that formulation example 1 of D9 (column 8, line 65 to column 9, line 18) discloses an aqueous anti-plaque oral composition comprising all the ingredients listed in claim 1 of the main request (N-α-cocoyl-L-arginine ethyl ester as antibacterial ester, cocamidopropyl betaine as zwitterionic surfactant, sorbitol as humectant and water) in the presence of citric acid monohydrate, which has a buffering effect, and that the composition of claim 1 of the main request differs from this
composition in that it does not comprise an acidic buffer. Also the Board agrees with this analysis.

2.3 As to the technical effect, no comparative tests are available to show the presence of an improvement or an advantage related to the omission of citric acid. Both the patent in suit (see paragraph [0001] and claim 1) and document D9 (see first paragraph and claim 1) aim at developing stable compositions, but there is no information available on file whether by means of the difference any impact on stability of the composition may be achieved.

2.4 With regard to the problem solved with respect to D9, in the absence of evidence which shows the presence of an effect related to the distinguishing feature and in view of the omission of one component, the problem can be seen in agreement with the appealed decision as the provision of a further simplified anti-plaque composition.

2.5 The omission of citric acid cannot be seen as an inventive solution to the problem posed, as citric acid is an ingredient which is given no weight in document D9. While it is true that also other non-essential ingredients could be eliminated from the composition of D9, this simply means that several alternative measures, including the elimination of citric acid, could be seen as obvious. In other words, the omission of citric acid is one of a number of arbitrary choices, which the skilled person, aiming at solving the problem posed, would undertake without any inventive activity.

2.6 The fact that a buffer component is essential in a different composition, such as the one of D5, has no bearing on the clear teaching of D9, nor is it of
relevance that the other examples of D9 make use of different antibacterial agents.

2.7 On that basis it is concluded that the composition of claim 1 of the main request does not involve an inventive step.

First auxiliary request - inventive step

3. Claim 1 of the first auxiliary request corresponds to claim 1 of the main request with the specification "said composition further comprising an alcohol, wherein said alcohol is monohydric and represented by the formula R'OH, where R' is an alkyl group having between 1 to 8 carbon atoms".

3.1 As formulation example 1 of document D9 does not contain a monohydrinic alcohol, the added feature constitutes a further difference for the composition of claim 1 of the first auxiliary request over the disclosure of formulation example 1 of D9 in addition to the distinguishing feature identified for claim 1 of the main request (point 2.2, above).

3.2 However, also in this case no data are available to show that the claimed composition achieves any effect or advantage over the composition of D9, so that the problem posed remains the same as formulated for the main request (point 2.4, above).

3.3 While the omission of citric acid is not inventive for the reasons detailed above (points 2.5 and 2.6, above), the addition of a monohydrinic alcohol as claimed is not inventive in view of the indication in document D9 of alcohol as a possible additional ingredient (paragraph bridging columns 5 and 6) and of the fact that the
choice of a monohydric alcohol according to claim 1 of
the first auxiliary request is an arbitrary choice among
the possible alcohols.

3.4 In view of that, the composition of claim 1 of the first
auxiliary request does not involve an inventive step.

Second auxiliary request - inventive step

4. Claim 1 of the second auxiliary request corresponds to
claim 1 of the main request with the specification of
the composition "being substantially free of monohydric
alcohol".

4.1 The composition of formulation example 1 of D9 does not
contain a monohydric alcohol (see table on top of column
9), so that the same reasoning developed for the main
request (see point 2, above) equally applies, with the
consequence that the composition of claim 1 of the
second auxiliary request does not involve an inventive
step.

Third auxiliary request - inventive step

5. Claim 1 of the third auxiliary request corresponds to
claim 1 of the second auxiliary request with the
definition of the anti-plaque oral composition as a
"mouthwash" composition.

5.1 The composition of formulation example 1 of D9 is a
mouthwash formulation (see column 8, line 66), so that
the same reasoning developed for the main request and
the second auxiliary request (see points 2 and 4, above)
applies, with the consequence that the composition of
claim 1 of the third auxiliary request does not involve
an inventive step.
Fourth auxiliary request - clarity

6. Claim 1 of the fourth auxiliary request corresponds to claim 1 of the main request with the addition as a further ingredient of "(e) optionally an antitartar agent, wherein the antitartar agent is compatible with the antibacterial ester, or the antitartar agent is incompatible with the antibacterial ester and is included in one component of a dual component oral composition system in which a first component contains the antibacterial ester and a second component contains the antitartar agent".

6.1 There is no definition in the claim of what is meant by the terms "compatible" and "incompatible" with regard to the (in)compatibility of the antitartar agent with the antibacterial ester. The Board is not aware of any definition of the term commonly accepted in the field, nor any evidence in this respect has been provided by the appellant.

6.2 Even the description of the patent is not helpful in this respect, as individual examples are indicated (paragraphs [0032] and [0033]) without specifying which condition should be met by an antitartar agent to fall into one or the other category. Moreover, antitartar agents are indicated as being incompatible, such as pyrophosphate and polyphosphate salts, which are used in the compositions of D9 (see e.g. formulation example 1) without any apparent problem of compatibility.

6.3 Under such circumstances, it is not possible for the skilled person to discriminate between antitartar agents which or compatible or incompatible with the antibacterial ester, with the consequence that the
skilled person is not able to delimit what falls and what does not fall under claim 1 of the fourth auxiliary request.

6.4 For these reasons, claim 1 of the fourth auxiliary requests does not meet the requirements of Article 84 EPC.

6.5 The additional feature of claim 1 of the fourth auxiliary request which results in a lack of clarity is taken from the description (paragraphs [0032] and [0033]) and was not present in any of the granted claims. There is no doubt, therefore, that the non compliance with Article 84 EPC has been introduced by the amendment, so that the examination of the requirements of Article 84 EPC is in the power of the Board in line with decision G 3/14 of 24 March 2015 (see catchword).

Fifth auxiliary request - clarity

7. Claim 1 of the fifth auxiliary request corresponds to claim 1 of the fourth auxiliary request with the deletion of the word "optionally" in the definition of ingredient (e).

7.1 As ingredient (e), which results in lack of compliance with the requirements of Article 84 EPC for claim 1 of the fourth auxiliary request, is equally present in claim 1 of the fifth auxiliary request, the same conclusion applies (see point 6, above).

Conclusion

8. As claim 1 according to all requests on file does not comply either with the requirements of Article 56 EPC or
with those of Article 84 EPC, the appeal is to be dismissed and there is no reason for the Board to decide on any other issue.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated