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**Datasheet for the decision
of 4 June 2020**

Case Number: T 0418/17 - 3.3.07

Application Number: 10727321.1

Publication Number: 2585025

IPC: A61K6/00, A61K8/25, A61K8/44,
A61K9/00, A61Q11/00

Language of the proceedings: EN

Title of invention:
THERAPEUTIC ORAL COMPOSITION

Patent Proprietor:
Colgate-Palmolive Company

Opponent:
THE PROCTER & GAMBLE COMPANY

Headword:
Therapeutic Oral Composition / COLGATE-PALMOLIVE

Relevant legal provisions:
RPBA Art. 12(4)
RPBA 2020 Art. 11
EPC Art. 123(2), 100(b), 56

Keyword:

Late-filed evidence - admitted (yes)

Remittal to the department of first instance - (no)

Amendments - added subject-matter (no)

Sufficiency of disclosure - (yes)

Inventive step - (yes)



Beschwerdekammern

Boards of Appeal

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Case Number: T 0418/17 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 4 June 2020

Appellant: THE PROCTER & GAMBLE COMPANY
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
7 December 2016 concerning maintenance of the
European Patent No. 2585025 in amended form.**

Composition of the Board:

Chairman D. Boulois
Members: E. Duval
C. Schmidt

Summary of Facts and Submissions

I. European patent 2585025 (hereinafter "the patent") was granted on the basis of 15 claims. Claim 1 of the patent as granted read as follows:

"An oral care composition comprising at least one arginine compound in free or salt form, at least one mucoadhesive polymer, and at least one component selected from the group consisting of pyrophosphate compounds, zinc salts, potassium salts, strontium salts, and mixtures thereof, wherein the arginine compound is present in D or L form, or as a salt with lauroyl sulfuric acid, and wherein the arginine compound is present in an amount within the range of from 0.6% to 1% by weight."

II. An opposition was filed against the patent on the grounds that its subject-matter was excluded from patentability by Article 53(c) EPC, it lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the application as filed.

III. The opposition division took the interlocutory decision that, on the basis of the main request with claims filed by letter dated 14 September 2016, the patent met the requirements of the EPC.

IV. The decision of the opposition division cited among others the following documents:

D1: US 2009/0202454 A1

D2: WO 2009/100268 A2

V. In particular, the opposition division decided that:

- (a) Paragraph [0028] in connection with paragraph [0024] provided a direct and unambiguous basis for the combination of features of claim 1. The main request thus met the requirements of Article 123(2) EPC.
- (b) The subject-matter of claims 1 and 9 was considered sufficiently disclosed, especially in view of the examples as regards claim 9.
- (c) D2 was seen as the closest prior art. D2 disclosed in Table I a dentifrice with 5% arginine, a mucoadhesive and a potassium salt. The composition according to claim 1 differed in that arginine was present in the range 0.6 to 1%. In the absence of any effect related to this difference, the problem was regarded as the provision of an alternative dentifrice composition for reducing sensitivity of the teeth. The solution was not suggested in D2, and the main request was considered to be inventive.

VI. The opponent (appellant) lodged an appeal against the above decision of the opposition division. With its statement setting out the grounds of appeal, the appellant submitted the following documents:

D4: Markowitz K. "The Original Desensitizers: Strontium and Potassium Salts" J Clin Dent 2009;20(5):145-51.

D5: Schiff T. et al. "Efficacy of a Dentifrice Containing Potassium Nitrate, Soluble Pyrophosphate, PVM/MA Copolymer, and Sodium Fluoride on Dentinal

Hypersensitivity: A Twelve-Week Clinical Study" J Clin Dent 1994;5 Spec No:87-92.

D6: Singh "Pro-Argin: A Breakthrough Technology for Dentin Hypersensitivity Treatment" October December 2013, Vol 1

D7: "ProClude is First Prophylaxis Paste to Significantly Reduce or Eliminate Sensitive Teeth in 28 Day Study" March 19, 2003

D8: "Understanding Dental Caries" Edited by Springer, 2016, page 188.

VII. By letter dated 31 August 2017, the patent proprietor (respondent) defended its case on the basis on the main request upheld by the opposition division, auxiliary requests 1-4 filed with letter dated 14 September 2016 and auxiliary requests 5-9 filed with said letter of 31 August 2017.

Claim 1 of the main request was identical with claim 1 as granted (see I. above).

Claims 1, 7 and 8 of auxiliary request 1 respectively read as follows:

"1. An oral care composition comprising at least one arginine compound in free or salt form, at least one mucoadhesive polymer, and at least one component selected from the group consisting of pyrophosphate compounds, zinc salts, potassium salts, strontium salts, and mixtures thereof, wherein the arginine compound is present in D or L form, or as a salt with lauroyl sulfuric acid, wherein the arginine compound is present in an amount within the range of from 0.6% to 1% by weight, and wherein the composition comprises a pyrophosphate selected from the group consisting of disodium

dihydrogen pyrophosphate ($\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$), tetrasodium pyrophosphate ($\text{Na}_4\text{P}_2\text{O}_7$), tetrapotassium pyrophosphate ($\text{K}_4\text{P}_2\text{O}_7$), and mixtures thereof."

"7. The composition as claimed in claim 1, wherein the composition has a flow reduction above 50%, when measured using a hydraulic conductance test."

"8. An oral care composition according to claim 1, for use in a method of reducing hypersensitivity of the teeth; said method comprising applying said oral care composition to the oral cavity."

VIII. The Board summoned the parties to oral proceedings.

In a communication pursuant to Article 15(1) RPBA, the Board expressed *inter alia* the preliminary opinion that the subject-matter of the main request did not involve an inventive step, whereas auxiliary request 1 appeared allowable.

IX. By letter dated 21 May 2020, the respondent withdrew its request for oral proceedings and cancelled its main request on the condition that the patent be maintained on the basis of auxiliary request 1. In the foregoing, despite the fact that the respondent thus made auxiliary request 1 its highest ranking request, this auxiliary request 1 is still called "auxiliary request 1" for sake of consistency.

The appellant had withdrawn its request for oral proceedings by letter dated 26 February 2019.

The oral proceedings were cancelled.

- X. The appellant's written arguments, as far as relevant to the present decision, can be summarised as follows:
- (a) D4-D8 were relevant in rebutting the appealed decision related to the inventive step. D4 and D5 showed that the agents comprised in the claimed compositions were known to be effective in teeth hypersensitivity. D6 and D7 showed that the skilled person reading D2 was aware of the role of arginine in tubular occlusion and in the treatment of dentinal hypersensitivity. D8 showed that the amount of active ingredients required in a toothpaste was higher than the amount of active ingredients required in a mouthwash. Hence D4-D8 should be admitted into the procedure.
 - (b) The appealed interlocutory decision was based on the main request and did not relate to auxiliary requests 1-9. In order to have a decision on these auxiliary requests both in the first and in the second instance, the case should be remitted to the opposition division for discussion on auxiliary requests 1-9.
 - (c) Auxiliary request 1 did not meet the requirements of Article 123(2) EPC. The subject-matter of claim 1 resulted from the selections of items from two lists, namely the range of 0.6-1 wt% for the amount of arginine from the list of alternatives of paragraph [0028], and the claimed arginine type from the list of paragraphs [0024]-[0027]. Additionally, the specific combinations, in claim 1 of auxiliary request 1, of the specific four pyrophosphates plus a zinc salt, or said pyrophosphates plus a potassium salt, or said pyrophosphates and strontium salt, were not

disclosed clearly and unambiguously in an individualized form.

- (d) The subject-matter of claims 7 and 8 of auxiliary request 1 was not sufficiently disclosed. With respect to claim 8, it had not been credibly shown that the claimed effect was obtained by each of the claimed compositions, in particular by the claimed toothpastes comprising the low amount of 0.6-1 wt% of arginine, because a toothpaste required higher amounts of active ingredients than a mouthwash to be effective due to the dilution upon use. Regarding claim 7, for the same reasons, it was not credible that toothpastes having the claimed amount of arginine would have a flow reduction greater than 50%.
- (e) The subject-matter of auxiliary request 1 did not involve an inventive step

D2 represented the closest prior art. The distinguishing features over D2 were 1) the claimed amount of arginine and 2) the presence of pyrophosphates. With regard to the pyrophosphates, the effect derivable from the comparison of examples F and VII of the patent was a mere additive effect due to the addition of pyrophosphate to the arginine/mucoadhesive polymer system of D2: Composition VII (comprising arginine, a mucoadhesive polymer and pyrophosphate) provided a flow reduction which was about the sum of the flow reductions of Compositions F (comprising arginine and a mucoadhesive polymer) and G (comprising a mucoadhesive polymer and pyrophosphate).

Hence, the problem solved could be seen as the provision of an alternative or at most additive composition in the treatment of dentinal hypersensitivity.

The solution was obvious, and the additive effect was expected, because pyrophosphates were known from D5 to treat dentinal hypersensitivity. D5 taught a dentifrice comprising soluble pyrophosphates in combination with PVM/MA, potassium nitrate and sodium fluoride, i.e. in combination with the same components of the opposed patent, of D2 and D5, and effective in the treatment of dentinal hypersensitivity. Therefore, the skilled person starting from D2, would have been motivated by D5 to add pyrophosphates to the composition of D2 in order obtain an additive effect in the treatment of dentinal hypersensitivity. The effect on tubular occlusion was the mechanism of action and was not relevant for the assessment of inventive step. Lastly, in light of D1 (see page 8 paragraph [0068], page 11, Formulae IV, V and VII) the skilled person would have readily recognized that the soluble pyrophosphates of D5 were the specific four pyrophosphates claimed in claim 1 of auxiliary request 1.

XI. The respondent's written arguments, as far as relevant to the present decision, can be summarised as follows:

- (a) D4-D8 were not *prima facie* relevant. Moreover, D4-D8 had not been filed in response to any change in the facts of the case and they could have been produced at a much earlier stage of the opposition

proceedings. As such, they were not to be admitted into the proceedings.

- (b) For the purposes of Article 123(2) EPC, support for claim 1 of auxiliary request 1 could be found in claim 2 or paragraph [0024] of the application as filed, in combination with paragraph [0028] where the recited amount of arginine of 0.6-1 wt% was indicated to be a preferred amount, and claim 8 or paragraph [0036] indicating that the recited pyrophosphate salts were preferred species.

- (c) Regarding sufficiency of disclosure for claims 7 and 8, the examples of the patent showed mouthwash compositions comprising 0.8 wt% arginine, and having a percentage flow reduction of greater than 50%, which reflected their ability to occlude dentinal tubules and therefore, to reduce hypersensitivity. Consequently a presumption existed that the criteria of sufficiency of disclosure were met. The appellant had failed to rebut this presumption by demonstrating serious doubts substantiated by verifiable facts. The appellant had not provided any appropriate evidence to demonstrate that a toothpaste composition comprising a mucoadhesive polymer, a pyrophosphate and arginine in an amount of 0.6 to 1 wt.% in toothpaste would not be suitable for reducing dentinal hypersensitivity. Additionally, claim 8 required a reduction in hypersensitivity without any limitation on the extent of reduction. Thus, a composition was to be regarded as being suitable for the claimed use, even it provided a small reduction in dentinal hypersensitivity.

(d) As to inventive step, starting from the closest prior art D2 (see the composition of Table 1), the differentiating feature of claim 1 of auxiliary request 1 was the requirement for a lower concentration of arginine of 0.6-1 wt% and the presence of a pyrophosphate selected from the group consisting of disodium dihydrogen pyrophosphate, tetrasodium pyrophosphate, tetrapotassium pyrophosphate, and mixtures thereof.

The patent demonstrated that the provision of a pyrophosphate compound imparted an unexpected improvement in dentinal tubule occlusion (see Tables 3 and 4, composition F vs compositions VII and VIII). Therefore, in light of D2, the objective technical problem was provision of a composition which provided improved dentinal tubule occlusion.

There was no hint or suggestion in D2 that incorporating pyrophosphate compounds into a composition comprising arginine and a mucoadhesive polymer would result in an improvement in dentinal tubule occlusion. D2 did not mention dentinal tubule occlusion, and attributed an anticalculus function to pyrophosphate compounds.

XII. The appellant requests that the decision under appeal be set aside and that the patent be revoked in its entirety.

The appellant further requests that, should the respondent's main request be considered non patentable, the case be remitted to the opposition division for further discussion on auxiliary requests 1-9.

XIII. The respondent requests that the patent be maintained in amended form on the basis of auxiliary request 1 filed with letter dated 14 September 2016, in which case the main request is cancelled. Alternatively, the respondent requests that the patent be maintained in amended form on the basis of the main request as upheld by the opposition division, or one of auxiliary requests 2-4 filed with letter dated 14 September 2016 or one of the auxiliary requests 5-9 filed with letter dated 31 August 2017.

The respondent further requests that none of D4-D8 be admitted into the proceedings.

Reasons for the Decision

1. Admittance of D4-D8 into the proceedings

The appellant submitted D4-D8 with its statement setting out the grounds of appeal, which was filed before 1 January 2020. According to the transitional provisions of Article 25(2) RPBA 2020, the question whether or not D4-D8 should be admitted must therefore be decided on the basis of Article 12(4) RPBA 2007, which gives the Board discretion to hold inadmissible documents that could have been presented in the opposition proceedings.

The respondent considers that D4-D8 should not be admitted into the proceedings because they are not *prima facie* relevant. However, irrespective of this alleged lack of relevance, D4-D8 were submitted by the appellant in reaction to the appealed decision and to the arguments set out therein regarding inventive step. Thus the appellant filed D4-D8 at the earliest stage of the appeal proceedings in an attempt to fill in the

gaps in its previously raised objection of lack of inventive step over D2. In these circumstances, the Board sees no reasons to consider that D4-D8 should have been filed in the proceedings before the opposition division.

For these reasons, D4-D8 are admitted into the proceedings.

2. Remittal to the opposition division

The respondent, by letter dated 25 May 2020, made auxiliary request 1 its highest ranking request. According to the appellant, the decision under appeal is limited to the main request and does not relate to the auxiliary requests. The appellant therefore requests that the case be remitted to the opposition division for further discussion on auxiliary requests 1-9.

Under Article 11 RPBA 2020, the Board may remit the case to the opposition division if there are special reasons for doing so. Although it is the primary object of the appeal proceedings to review the decision under appeal in a judicial manner (see Article 12(2) RPBA 2020), there is no absolute right to have every issue decided at two instances.

In the present case, notwithstanding the fact that the decision under appeal is limited to the main request, auxiliary request 1 does not alter the legal and factual framework, because it results from a combination with a granted dependent claim (namely claim 6). Furthermore, the respondent (see the letter dated 20 July 2018, pages 17-20) was in a position to examine auxiliary request 1. Given that the Board finds

auxiliary request 1 to be allowable (see below), the question of a remittal in relation with auxiliary requests 2-9 is moot.

Accordingly, the Board does not consider a remittal to be justified.

3. Article 123(2) EPC

The subject-matter of claim 1 of auxiliary request 1 results from the combination of claim 1 as filed with:

- the features of claim 8 or paragraph [0036] of the application as filed, showing the pyrophosphates recited in present claim 1 as preferred species,

- the feature relating to the D and L isomers and lauroyl sulfuric acid salt of arginine, presented as preferred arginine compound in dependent claim 2 and paragraph [0024], and

- the feature relating to the presence of 0.6-1% by weight of the arginine compound disclosed in paragraph [0028]. The list of paragraph [0028] is not a list of mutually exclusive alternatives, but rather a convergent list of increasingly narrow weight ranges.

Accordingly, the combination of the above features does not introduce added subject-matter. Regarding the combination of the specific pyrophosphates with zinc salts, potassium salts or strontium salts, claim 1 of auxiliary request 1 does not individualise particular combinations selected within this group. Rather, claim 1 remains general and finds basis in claim 1 as filed, which mentioned mixtures of such compounds.

In conclusion, auxiliary request 1 meets the criteria of Article 123(2) EPC.

4. Sufficiency of disclosure

- 4.1 Claim 8 of auxiliary request 1 is directed at an oral care composition according to claim 1 for use in a method of reducing hypersensitivity of the teeth. Claim 7 relates to a composition as claimed in claim 1 "wherein the composition has a flow reduction above 50% when measured using a hydraulic conductance test".

With respect to both claims 7 and 8, the appellant considers it is not credible that the claimed effect is obtained by each of the claimed compositions, in particular by the claimed toothpastes, because a toothpaste requires higher amounts of active ingredients than a mouthwash to be effective. With respect to claim 7, the appellant also infers from the comparative compositions A, B and D-G shown in the patent that only the combination of fluoride, pyrophosphate, arginine and Gantrez (a mucoadhesive polymer) leads to the claimed flow reduction percentage.

- 4.2 The Board notes that arginine was known at the filing date of the contested patent to treat dentinal hypersensitivity and to have benefits in combating tooth sensitivity (see [0007]-[0008]). Example 1 also tests the desensitizing properties of compositions as claimed through a detailed flow reduction test. Tables 1 and 2 show that compositions comprising 0.8% arginine, a mucoadhesive polymer and pyrophosphate (compositions I-IV) have a flow reduction over 50%. This result is corroborated by Table 3.

Hence, the Board sees no reason to doubt that a composition as claimed comprising between 0.6 and 1% of arginine is able to reduce tooth hypersensitivity to some extent, and that said effect may reliably be measured with a flow reduction test. Furthermore, while the achievement of the effect of reducing hypersensitivity claimed in claim 8 may be related to the question of sufficiency of disclosure, the intensity of said effect is not defined in claim 8 and therefore not relevant to the question of sufficiency of disclosure.

Additionally, regarding claim 7, the Board notes that the evidence cited by the appellant (D1, D2) only shows toothpaste compositions comprising higher amounts of arginine, but is silent about non-functional amounts of arginine. No evidence of a composition falling within the scope of claim 1 and failing to achieve the effect defined in claim 7 can be seen in D8 or in the comparative compositions A, B and D-G shown in the patent.

Hence, the requirements of sufficiency of disclosure are met.

5. Inventive step

5.1 The invention aims at providing a therapeutic oral composition useful in the treatment of dentinal hypersensitivity.

5.2 Both parties regard D2 as the closest prior art. The Board concurs.

D2 discloses (see example 1 and table 1) a composition comprising 5% by weight of L-arginine, zinc nitrate,

and xanthan gum and carboxymethylcellulose. Said xanthan gum and carboxymethylcellulose are used as thickeners in the compositions disclosed in D2 and arginine is presented as active in tooth sensitivity (see [0009] and [0026]). D2 mentions also the necessary adaptation of the amounts of arginine depending on the form of administration; a mouthrinse must therefore have a concentration of arginine comprised between 0.1 to 3 wt% (see [0033]).

- 5.3 The compositions exemplified in D2 do however not present a concentration of arginine comprised between 0.6 and 1% by weight as claimed in auxiliary request 1. The subject-matter of claim 1 of auxiliary request 1 further differs from the example of D2 by the presence of a pyrophosphate selected from disodium dihydrogen pyrophosphate, tetrasodium pyrophosphate, tetrapotassium pyrophosphate, and mixtures thereof.
- 5.4 The presence of the pyrophosphate is associated with an improved reduction in tooth hypersensitivity, as shown by the flow reduction data for comparative composition F and composition VII (see tables 3 and 4 of the patent): both compositions contain arginine in the claimed range and are identical in all respects except for the present of tetrasodium and tetrapotassium pyrophosphate. Composition VII, comprising said pyrophosphates, gives rise to an improved flow reduction in comparison with comparative composition F (65% vs 30%).
- 5.5 Consequently, the Board concurs with the respondent that the problem is the provision of an oral care composition which provides an improved dentinal tubule occlusion.

The appellant considers that the addition of pyrophosphate leads to a mere additive effect, i.e. the dentinal tubule occlusion effect results from both the presence of arginine and the presence of pyrophosphate. In the Board's view, this argument cannot modify the conclusion that an effect credibly arises from the presence of the pyrophosphate, and cannot lead to a formulation of the technical problem as the provision of an alternative composition.

- 5.6 The question remains as to whether D2, D5 and / or D1 make this effect of pyrophosphates on dentinal hypersensitivity or dentinal tubule occlusion obvious.

According to the appellant, D5 teaches a dentifrice comprising soluble pyrophosphates in combination with PVM/MA, potassium nitrate and sodium fluoride effective in the treatment of dentinal hypersensitivity. The Board notes however that, although the composition shown in D5 is said to be effective for reducing dentinal hypersensitivity, this effect is not related to the pyrophosphate component. Likewise, D1 (see page 8, paragraph [0068]; page 11, formulae IV, V and VII) mention the use of soluble pyrophosphates as chelating agents, but do not disclose their effect on dentinal hypersensitivity or dentinal tubule occlusion. Lastly, although the presence of pyrophosphates is generally mentioned in D2 (see paragraphs [0034]-[0035]), these components are considered to be anticalculus agents. Their effect on dentinal hypersensitivity or dentinal tubule occlusion is not derivable from D2 either.

Accordingly, the subject-matter of claim 1 of auxiliary request 1 involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent with the claims of auxiliary request 1 filed with letter dated 14 September 2016 and a description to be adapted thereto.

The Registrar:

The Chairman:



B. Atienza Vivancos

D. Boulois

Decision electronically authenticated