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Datasheet for the decision of 31 August 2020

Case Number: T 1396/18 - 3.3.07

Application Number: 10712276.4

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Language of the proceedings: EN

Title of invention:
ORAL COMPOSITIONS FOR TREATING TOOTH SENSITIVITY AND METHODS OF USE AND MANUFACTURE THEREOF

Applicant:
Colgate-Palmolive Company

Headword:
ORAL COMPOSITIONS FOR TREATING TOOTH SENSITIVITY/ COLGATE

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (no)

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Case Number: T 1396/18 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 31 August 2020

Appellant: (Applicant)	Colgate-Palmolive Company 300 Park Avenue New York, NY 10022 (US)
Representative:	Wibbelmann, Jobst Wuesthoff & Wuesthoff Patentanwälte PartG mbB Schweigerstrasse 2 81541 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 18 December 2017 refusing European patent application No. 10712276.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	M. Steendijk
	Y. Podbielski

Summary of Facts and Submissions

I. The appeal was filed by the applicant (hereinafter: "the appellant") against the decision of the examining division to refuse the European patent application 10712276.4.

II. The appealed decision was based on a single request with amended claims filed on 16 October 2017. Claim 1 of this request related to an oral care composition comprising a bioactive glass, one or more bioadhesive polymers and one or more occlusion agents selected from arginine/ calcium carbonate, arginine bicarbonate/ calcium carbonate, and small particle silica.

The decision under appeal cited the following documents:

D2: WO 2006/055317
D7: WO 00/78270
D10: US 2008/0267891
D11: "Calcium phosphate technologies" published on the website www.dentist.net

According to the decision under appeal, document D2 was the closest prior art for the assessment of inventive step. The compositions defined in claim 1 of the main request differed from those disclosed in D2 in the definition of the occlusion agent.

Having regard to Figures 3 and 4 of the application, the technical problem in respect of the parts of claim 1 relating to compositions containing silica particles, was the provision of an oral care composition with

improved desensitizing effect. Document D10 taught the use of silica particles having an average particle size of 8 µm or less to reduce tooth sensitivity. Thus, the compositions containing silica particles were obvious in view of the combination of D2 and D10.

The application did not provide any evidence of the effect of the arginine complexes defined in claim 1. In any case, any enhanced desensitization would have been obvious in view of the teaching of D7. Thus, also the parts of claim 1 relating to compositions containing arginine complexes as occlusion agents did not involve an inventive step.

Accordingly, claim 1 did not comply with the requirements of Article 56 EPC.

III. With the statement setting out the grounds of appeal filed on 24 April 2018 the appellant submitted a main request as well as auxiliary requests 1-4.

The claims of the main request are identical to the claims of the request underlying the decision under appeal. Claim 1 read as follows:

" An oral care composition comprising bioactive glass having from 40 wt% to 60 wt% of silicon dioxide (SiO_2), from 10 wt% to 30 wt% of sodium oxide (Na_2O), from 10 wt% to 30 wt% of calcium oxide (CaO) and from 2 wt% to 8 wt% of phosphorus oxide (P_2O_5);
one or more bioadhesive polymers; and additionally
one or more occlusion agents selected from arginine/ calcium carbonate, arginine bicarbonate/calcium carbonate, and small particle silica including an ultrafine particle having an average particle size of 1 µm to 10 µm or combinations thereof."

Claim 1 of auxiliary request 1 corresponded to claim 1 of the main request except for the deletion of small particle silica from the listed additional occlusion agents.

Claim 1 of auxiliary request 2 corresponded to claim 1 of the main request except that the additional occlusion agent was the small particle silica (deletion of arginine/ calcium carbonate and arginine bicarbonate/calcium carbonate).

Claim 1 of auxiliary request 3 and claim 1 of auxiliary request 4 corresponded respectively to claim 1 of auxiliary request 1 and claim 1 of auxiliary request 2, except that the one or more bioadhesive polymers were defined as selected from: PEG/ PPG copolymers, polyvinylmethylether/maleic anhydride copolymers, cross-linked PVP, shellac and ester gum, and combinations thereof.

IV. With the summons of 12 July 2019 the Board invited the appellant to attend oral proceedings. A communication pursuant to Article 15(1) RPBA was issued on 31 March 2020. Oral proceedings were held on 31 August 2020. At the end of the proceedings the Board announced its decision.

V. The appellant’s arguments can be summarized as follows:

Paragraph [0092] of the application explained that the arginine bicarbonate/calcium carbonate created an alkaline environment that further enhanced the attachment of the bioactive glass particles on the tooth surface, thereby improving the occluding

properties of the composition. This effect was also supported by document D11. Furthermore, the results presented in Figures 3 and 4 of the application showed that the inclusion of small particle silica allowed for improved occlusion from a composition comprising a bioactive glass, as had indeed been recognized in the appealed decision. In view of document D2 as closest prior art the problem to be solved should therefore be seen in the provision of an oral care composition with improved desensitizing effect.

Document D2 itself mentioned a variety of optional additives, but provided no suggestion towards any improvement from the particular combinations of agents as defined in the claims. The skilled person would have understood that the composition of D2 already contained an agent having occluding properties, namely the calcium and phosphorus releasing glass and would therefore have had no incentive to add to the composition of D2 further substances having occluding properties such as the silica particles disclosed in Dl0 or the arginine material of D7, let alone any expectation of improved properties therefrom.

The further definition of the specific bioadhesive polymers in the claims of auxiliary requests 3 and 4 represented an additional distinction of the claimed compositions with respect to the compositions of document D2, which only concerned combinations of a bioactive glass with hardened resins. The defined polymers allowed according to paragraphs [00132] and [00134] for increased retention of the defined composition. The skilled person would not have arrived at such effective and further distinguished compositions without the benefit of hind-sight.

VI. The appellant requested that that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed on 24 April 2018 or, as an auxiliary measure, on the basis of one of auxiliary requests 1 to 4 filed on the same date.

Reasons for the Decision

Main request

1. Inventive step

1.1 The Board agrees with the examining division that document D2 represents the closest prior art. Document D2 describes dental compositions comprising a water-dispersible polymeric film former and a calcium and phosphorous releasing glass, which are useful to occlude exposed dentin or cementum tubules which cause sensitivity (see D2, page 1 line 27 to page 2 line 2).

The oral care compositions of the main request differ from the compositions disclosed in the examples of document D2 in the presence of one or more of the additional occlusion agents as specifically defined in claim 1. These additional occlusion agents are selected from arginine/calcium carbonate, arginine bicarbonate/ calcium carbonate, and small particle silica including an ultrafine particle having an average particle size of 1 to 10 microns.

The identification of document D2 as closest prior art and the observed difference with the defined subject-matter have not been disputed by the appellant.

1.2 Compositions of claim 1 in which the occlusion agent is arginine/calcium carbonate or arginine bicarbonate/ calcium carbonate

1.2.1 Concerning the effect of the addition of the arginine/ calcium carbonate or arginine bicarbonate/calcium carbonate, the appellant has relied on paragraph [0092] of the application, which states that in certain embodiments the calcium carbonate creates an alkaline environment to further enhance particle attachment, and on the passage in document D11 (under "About SensiStat"), which mentions that calcium carbonate is said to create an alkaline environment that reacts with tubule fluids to further enhance particle attachment.

The Board notes that document D7 also describes that in compositions for treating dental hypersensitivity arginine bicarbonate combined with calcium carbonate provides an alkaline environment and has adhesive properties that favour tubule plugging (see D7 page 8, second paragraph).

The Board therefore accepts that the problem to be solved associated with the addition of the arginine/ calcium carbonate or arginine bicarbonate/calcium carbonate may be seen in the provision of oral care compositions with enhanced properties.

1.2.2 Faced with this problem and starting from document D2 the skilled person would take note of the list of functionally described optional additives presented on page 24 of document D2, that may be included to accomplish the desired result.

In view of this mention of additional functional ingredients in document D2 itself, the skilled person

would be motivatedto find and consider the teaching of document D7, which describes that in compositions for treating dental hypersensitivity arginine bicarbonate combined with calcium carbonate provides an alkaline environment and has adhesive properties that favour tubule plugging (see D7 page 8, second paragraph). With this information at hand the skilled person would have good reason to expect improved properties from the addition of arginine bicarbonate/calcium carbonate to the bioactive glass composition of document D2 and thereby arrive at the claimed solution in an obvious manner.

In this context the Board observes, as already stated in the course of the oral proceedings, that the appellant has not presented evidence substantiating any specific effect of the arginine/calcium carbonate or arginine bicarbonate/calcium carbonate in a composition comprising a bioactive glass, for instance in the form of relevant experimental results, and that the statement in paragraph [0092] of the application and the cited passage from document D11 as to a further enhancement of particle attachment do not specify the nature of the further enhanced particle attachment.The Board is therefore of the opinion that the information which is relied upon by the appellant for substantiating that the identified technical problem is indeed solved, reflects essentially the same information concerning the beneficial effect of arginine bicarbonate/calcium carbonate in compositions for treatment of dental hypersensitivity as already known from document D7.Under these circumstances the Board finds no merit in the argument that on the basis of the information of document D7 it could not be expected that the properties of the oral care

compositions of document D2 are improved by the addition of arginine bicarbonate/calcium carbonate.

1.2.3 The compositions of claim 1 in which the occlusion agent is arginine/calcium carbonate or arginine bicarbonate/calcium carbonate therefore lack lack an inventive step.

1.3 Compositions of claim 1 in which the occlusion agent is small particle silica

1.3.1 Example 2 of the application discloses *inter alia* an experiment to assess the effects of the addition of silica on the occlusion of dentin tubules (see [0145]). It is concluded that the addition of 9% silica "significantly improved occlusion at six treatments". On the basis of this experiment the Board considers it credible that the compositions of claim 1 containing small silica particles as occlusion agent have an improved desensitizing effect compared to the compositions of document D2.

The Board therefore acknowledges that the problem to be solved associated with the addition of the small particle silica may be formulated as the provision of oral care compositions with improved occlusion properties.

1.3.2 Faced with this problem and starting from document D2 the skilled person would take note of the list of functionally described optional additives presented on page 24 of document D2, that may be included to accomplish the desired result.

In view of this list of additional functional ingredients mentioned in document D2 itself, which

includes further desensitizers (see D2, page 24 line 28), the skilled person would be motivated to find and consider the teaching of document D10, which describes oral care compositions comprising an adherent material and silica particles that may have an average particle size of 8 µm or less, which are useful in reducing or eliminating tooth sensitivity and/or occluding dentin tubules (see D10 paragraphs [0007] and [0010]). Moreover, also document D10 indicates that its compositions may comprise further additives such as additional desensitizing agents (see paragraph [0021]). With this information at hand the skilled person would have good reason to expect that the addition of such small particle silica to the bioactive glass composition of document D2 allows for enhanced occlusion properties due to the additional desensitizing and occluding activity of the added silica and thus arrive at the claimed solution in an obvious manner.

In this context the Board notes that the information concerning the effect of the addition of the small particle silica discussed in section 1.3.1 above does not allow for the conclusion of any enhanced effect beyond an expectable mere additive effect.

1.3.3 The compositions of claim 1 in which the occlusion agent is small particle silica therefore also lack an inventive step.

1.4 Accordingly, the Board concludes that claim 1 of the main request does not comply with the requirement of Article 56 EPC.

Auxiliary requests 1 and 2

2. Claim 1 of auxiliary requests 1 defines the compositions of claim 1 of the main request in which the occlusion agent is arginine/calcium carbonate or arginine bicarbonate/calcium carbonate and claim 1 of auxiliary request 2 defines the compositions of claim 1 of the main request in which the occlusion agent is small particle silica.

For the reasons as set out under sections 1.2 and 1.3 the Board considers this subject-matter to lack an inventive step and thus not to meet the requirement of Article 56 EPC.

Auxiliary requests 3 and 4

3. Claim 1 of auxiliary request 3 and claim 1 of auxiliary request 4 correspond respectively to claim 1 of auxiliary request 1 and claim 1 of auxiliary request 2 but more specifically define the bioadhesive polymers, which are selected from PEG/ PPG copolymers, polyvinylmethylether/maleic anhydride copolymers, cross-linked PVP, shellac and ester gum, and combinations thereof.

3.1 The Board observes that the teaching of document D2 cannot be considered as limited to compositions with hardened or hardenable resins only. On the contrary, whereas document D2 mentions formulations with hardened or hardenable resins as one category of embodiments (see for instance D2 page 2 lines 6-8 and page 8), the document also clearly refers to compositions with water-dispersible polymeric film formers as alternative embodiments without any requirement as to hardened or hardenable properties of these film formers (see for instance D2 page 16). However, document D2 does not specifically mention the particular bioadhesive

polymers as defined in the claims of the auxiliary requests 3 and 4. The choice of these bioadhesive polymers thus represents an additional difference with the closest prior art.

The applicant has referred to paragraphs [00132] and [00134] of the application to argue that the defined bioadhesive polymers have increased retention.

The Board notes that paragraphs [00132] and [00134] merely mention that the defined agents are as suitable as bioadhesive polymers and that "Formula A" is an example with a PEG/PPG copolymer for increased retention. This information relied upon by the appellant does not substantiate any special interaction of the defined bioadhesive polymers in the composition that extends beyond the expectable retention effect from the addition of an adherent material.

The Board is therefore of the opinion that the additional difference as defined in accordance with auxiliary requests 3 and 4 is only to be considered as a relevant contribution in the context of selecting a suitable adhesive polymer for use in oral care compositions.

3.2 From document D10 it is evident that polymers as defined in the claims of auxiliary requests 3 and 4 belong to classes of bioadhesive polymers that were known to be useful as adherent material in oral care compositions for treating tooth sensitivity (see D10 paragraph [0011]). It would thus have been obvious to the skilled person to select such bioadhesive polymers for use in oral care compositions.

The Board is therefore of the opinion that the identified additional difference does not involve any inventive merit and concludes that the subject-matter defined in the claims of auxiliary requests 3 and 4 does also not meet the requirement of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated