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**Datasheet for the decision
of 7 October 2019**

Case Number: T 2631/16 - 3.3.07

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Language of the proceedings: EN

Title of invention:

COMPOSITIONS AND METHODS FOR THE TREATMENT OF XEROSTOMIA

Applicant:

Colgate-Palmolive Company

Headword:

Treatment of xerostomia/ COLGATE

Relevant legal provisions:

EPC Art. 56

Keyword:

Inventive step - main and auxiliary requests (no)



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Case Number: T 2631/16 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 7 October 2019

Appellant: Colgate-Palmolive Company
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 9 March 2016
refusing European patent application No.
09707366.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman J. Riolo
Members: A. Usuelli
P. Schmitz

Summary of Facts and Submissions

- I. The appeal of the applicant (appellant) lies from the decision of the examining division to refuse European patent application No.09707366.2. The decision was based on two sets of claims filed on 3 February 2016.

Claim 1 of both requests read as follows:

"1. A basic amino acid, in free or salt form, for use in the treatment, amelioration, inhibition or prevention of dry mouth, which treatment, amelioration, inhibition or prevention comprises administering topically to the mouth of a patient a composition comprising the basic amino acid;
wherein the basic amino acid is arginine;
wherein the arginine is in the form of arginine bicarbonate;
wherein the composition is a mouth rinse;
wherein the mouth rinse is an artificial saliva comprising ions selected from calcium, phosphate, potassium, magnesium, and combinations thereof."

The following documents were among those cited in the decision:

D1: WO 2004/004744

D5: Stony Brook Dentistry Today, 3, 1, 2002

D7: Web page: www.thefreelibrary.com/Ortek+Announces+issuance+of+Second+U.S.+Patent... (19 April 2001)

D13: Web page: www.perio-talk.com/200675/heard-that-treating-sensitive-teeth.html

- II. In the decision under appeal, the examining division stated that the subject-matter of claim 1 of the main request and auxiliary request 1 differed from the

disclosures of D5 and D13 in that it related to compositions in the form of a mouth rinse or an artificial saliva. The technical problem was the provision of alternative compositions containing an arginine bicarbonate/calcium carbonate complex for the treatment of dry mouth. The idea of providing the active ingredient in the form of a mouth rinse or an artificial saliva did not involve any inventive activity. Hence, the main request and auxiliary request 1 did not comply with the requirements of Article 56 EPC.

The examining division also considered that the toothpaste defined in claim 4 of the main request was anticipated by the disclosure of the product "Sensistat Proflow" in D5, and by the disclosure of D13.

III. In its statement setting out the grounds of appeal sent on 19 July 2016, the appellant requested to set aside the decision of the examining division and filed a main request and three auxiliary requests.

Claim 1 of each of these requests was identical to claim 1 of the requests forming the basis of the decision under appeal (see point I above).

The appellant argued that document D13 was not to be used as prior art in that its publication date was uncertain. As to D5 it observed that the examining division failed to take heed of a printing error in the document and concluded, in contrast with the examining division, that "Sensistat" and "Proflow" were two separate products. It further argued that the subject-matter of all the requests was inventive over document D1, selected as the closest prior art, in combination with the other cited documents.

IV. By letter of 17 April 2019, the appellant filed auxiliary request 4. Claim 1 of this request differed from claim 1 of the main request in specifying that the composition had a pH between 6.8 and 7.2.

With the same letter, the appellant submitted the following document:

D15: US 6,524,558

V. In a communication pursuant to Article 15(1) RPBA issued on 15 July 2019 the Board substantially agreed with the appellant in considering uncertain the publication date of D13 and in considering the main request novel over D5. As to inventive step, the Board stated that claim 1 of the main request appeared obvious over D1, taken as the closest prior art, in combination with D7.

VI. On 20 August 2019 the appellant filed auxiliary request 1a to be considered after the main request. Claim 1 of auxiliary request 1a was identical to claim 1 of the main request.

On the same date it also filed the following document:

D20: The Journal of Prosthetic Dentistry, 2001, 85,2,162-169

VII. Oral proceedings were held on 7 October 2019.

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

Document D1 was the closest prior art. The subject-matter of the main request differed from the disclosure of D1 in that a composition containing arginine bicarbonate was used to treat dry mouth. The technical problem was the provision of an alternative active ingredient for the treatment of dry mouth. Document D7 disclosed the use of the product CaviStat containing arginine to increase the pH in order to prevent tooth decay. However, there was no suggestion in D7 that CaviStat could be used to hydrate the mouth or stimulate the production of saliva. Hence, the subject-matter of the main request was not obvious in view of the combination of D1 and D7.

Claim 1 of auxiliary request 4 further specified that the composition had a pH between 6.8 and 7.2. This was against the teaching of D15 that suggested using a pH in the range of 7.5 to 9.5. Thus, the subject-matter of auxiliary request 4 was inventive also on account of the pH of the composition.

IX. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request or, alternatively, on the basis of one of auxiliary requests 1a or 1 to 4 wherein the set of claims of:

- the main request was filed with the statement setting out the grounds of appeal on 19 July 2016
- auxiliary request 1a was filed on 20 August 2019
- auxiliary requests 1 to 3 were filed on 19 July 2016
- auxiliary request 4 was filed on 17 April 2019.

Reasons for the Decision

Main request

1. Inventive step
 - 1.1 Closest prior art
 - 1.1.1 The Board agrees with the appellant that document D1 is the closest prior art. This document describes the use of compositions containing hyaluronic acid in alleviating dry mouth. The subject-matter of the main request differs from the disclosure of D1 in that the product used to treat dry mouth is a composition containing arginine bicarbonate as defined in claim 1.
 - 1.2 Technical problem
 - 1.2.1 Example 2 of the application describes a study performed on eight patients suffering from dry mouth treated with a composition containing arginine bicarbonate.

According to the results reported in paragraphs [0058] and [0059] at day 4 of the treatment most patients felt that the composition hydrated their mouth and left the mouth feeling comfortable. At day 8, most patients believed that the composition provided dry mouth relief, leaving their mouth feeling moist, pleasant and smooth.

On the basis of the results of example 2, the technical problem can be seen in the provision of an alternative treatment of dry mouth.

1.3 Obviousness

- 1.3.1 It remains to be decided whether the skilled person would consider obvious to solve this technical problem by the use of an arginine-based composition comprising ions selected from calcium, phosphate, potassium and magnesium as defined in claim 1.

In this regard D7 is the most relevant secondary document to be considered in combination with the closest prior art. D7 reports on a clinical study to demonstrate the efficacy of the toothpaste CaviStat in the prevention of tooth decay. As the composition of claim 1, CaviStat includes salts of arginine and calcium linked to a cariostatic anion (1st paragraph on page 2). The product can be formulated also as mouthwash (1st paragraph on page 2).

- 1.3.2 In the appellant's view, the skilled person would not consider the teaching of D1 in combination with D7 since the latter does not relate to the treatment of dry mouth.

The Board concurs with the appellant that the clinical study discussed in D7 does not concern the assessment of the effects of CaviStat in the treatment of dry mouth. Nevertheless, this document provides important information as to the composition of CaviStat and the principles underlying its use in the prevention of tooth decay.

Indeed the product is described as "a compound based on saliva chemistry" (5th paragraph) which is "designed to mimic saliva's protective effects" (6th paragraph). The rationale of using CaviStat in the prevention of tooth decay is based on the observation that this condition

occurs more frequently when there is a reduction in the amount of saliva present in the mouth and that CaviStat mimics the effects of saliva. D7 explicitly mentions in the 7th paragraph the problem of tooth decay in patients suffering from xerostomia, i.e. dry mouth.

- 1.3.3 As explained in paragraph [0002] of the description of the present application, "[d]ry mouth or xerostomia is an acute or chronic condition primarily caused by the lack of saliva". The Board considers that the skilled person faced with the problem of providing an alternative product for the treatment of dry mouth, namely a condition due to the absence of saliva, would consider obvious to test the product of D7, i.e. an arginine-based composition which is chemically similar to saliva and which is designed to mimic some of its effects. Indeed, as reported also in the sections "Background of the invention" of the present application ([0005]) and of D1 (page 2, lines 10 and 11), dry mouth is commonly treated with products similar to saliva.

In this regard it is also observed that the experimental study disclosed in example 2 of the patent application does not demonstrate that the composition tested in the experiment stimulates the production of saliva or acts on the causes underlying the disease. It merely indicates that the patients feel that the composition hydrates their mouth and leaves the mouth feeling comfortable. Such effects would however be expected from a product which is based on the saliva chemistry and which is designed to mimic some effects of saliva.

- 1.3.4 The appellant also referred to D20 to argue that the saliva contains a significant number of ingredients

including enzymes and proteins. Thus, the skilled person would not assume that arginine, being one of the many ingredients included in the saliva, would be helpful in treating dry mouth. In this regard the Board observes that the composition of claim 1 could also contain other ingredients which are normally present in the saliva. Hence, this argument is not convincing.

- 1.4 In view of the above, the Board concludes that the skilled person would obviously consider to use an arginine-based composition as defined in claim 1 in the treatment of dry mouth. Therefore, the subject-matter of claim 1 does not comply with the requirements of Article 56 EPC.

Auxiliary requests 1a, 1, 2 and 3

2. Claims 1 of these requests are identical to claim 1 of the main requests. Therefore, these requests also do not fulfil the requirements of Article 56 EPC.

Auxiliary request 4

3. Claim 1 of auxiliary request 4 specifies that the composition has a pH between 6.8 and 7.2.
- 3.1 The Board notes that the application does not provide any evidence of any particular effect associated with the choice of a pH between 6.8 to 7.2. This range also falls in the interval of at least 6.5 disclosed in D1 (page 6, lines 25). Therefore, the specification of the pH of the composition does not provide any inventive contribution to the subject-matter of the claim.
- 3.2 By referring to document D15 (column 4, line 52 to column 5, line 15) the appellant argues that the

skilled person would be led by the prior art to provide compositions having a pH in the range of 7.5 to 9.5.

- 3.2.1 In this regard it is observed that document D15 relates to a composition containing arginine carbonate and calcium carbonate which is capable of reducing or preventing dentinal hypersensitivity (paragraph linking columns 3 and 4). The invention is based on the discovery that arginine carbonate and calcium carbonate provide particles in the oral cavity for plugging the dentinal tubules of teeth (column 4, lines 31 to 60). The relatively high pH of the composition is considered particularly favorable to deposit formation (column 4, lines 52-60). Thus, the teaching of D15 to provide compositions having a pH in the range of 7.5 to 9.5 is linked to the particular mechanism of action of these compositions that requires the formation of particles for plugging dentinal tubules. This effect is important for the treatment of dentinal hypersensitivity. It is however not relevant in the context of treating dry mouth.

Moreover, the compositions of D15 contain calcium carbonate which is not a mandatory component of the compositions of claim 1. Hence, the considerations made in D15 as to the effect of the pH on the formation of a deposit would in any case not be valid for all the compositions covered by claim 1.

Hence, D15 does not teach away from providing a composition having a pH in the range of 6.8 and 7.2.

- 3.3 Thus, claim 1 of auxiliary request 4 does not comply with the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar:

The Chairman:



B. Atienza Vivancos

J. Riolo

Decision electronically authenticated