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**Datasheet for the decision
of 10 February 2022**

Case Number: T 0937/19 - 3.3.07

Application Number: 13151885.4

Publication Number: 2583661

IPC: A61K8/19, A61K8/21, A61K8/24,
A61K8/81, A61Q11/00, A23G4/06,
A23G4/08

Language of the proceedings: EN

Title of invention:
Method of protecting teeth against erosion

Patent Proprietor:
The Procter & Gamble Company

Opponent:
GlaxoSmithKline Consumer Healthcare (UK)
IP Limited

Headword:
Method of protecting teeth against erosion / PROCTER & GAMBLE

Relevant legal provisions:
EPC Art. 100(c), 76(1), 54(2)
RPBA 2020 Art. 11

Keyword:

Divisional application - added subject-matter (main request,
auxiliary requests 1-15: yes; auxiliary request 16: no)

Novelty - (yes)

Remittal - special reasons for remittal



Beschwerdekammern

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Case Number: T 0937/19 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 10 February 2022

Appellant:
(Patent Proprietor)

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 22 January 2019
revoking European patent No. 2583661 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman A. Uselli
Members: E. Duval
L. Basterreix

Summary of Facts and Submissions

I. European patent 2 583 661 (hereinafter "the patent") was granted on the basis of 4 claims. Claim 1 of the patent read as follows:

"Use of a source of metal ions for manufacture of an oral care composition having a pH of from greater than 4.0 to 10.0 for protecting a subject's teeth from erosion after administering to the subject's oral cavity the oral composition, wherein the source of metal ions is selected from the group consisting of stannous ions, zinc ions, copper ions, and mixtures thereof, wherein said metal ions form insoluble compounds or complexes that deposit on the tooth surface, thereby forming a film or coating that protects teeth from erosive damage immediately after use of the oral composition and for at least about one hour thereafter, and wherein the composition comprises no more than 0.01 % by weight of ethylenediamine-tetraacetates and phytates."

II. An opposition was filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the application and the earlier application(s) as filed.

III. The opposition division took the decision to revoke the patent.

IV. The decision was based on the patent as granted as the main request, on auxiliary requests 1-3 filed on 15 August 2017, auxiliary requests 4-7 filed on

5 October 2018, and auxiliary requests 8-23 filed on 4 December 2018.

Auxiliary request 1 had the same claims as the main request, but comprises amended description pages. Similarly, each of the even-numbered auxiliary requests (2, 4, 6 ...), where the claims were amended but the description was left unamended, was also presented in the following odd-numbered auxiliary requests (3, 5, 7, ...) with the same amended claims and with amended description pages.

Claim 1 of auxiliary requests 2-7 differed from claim 1 of the main request by further limitations with regard to the source of metal ions. In claim 1 of auxiliary requests 8-15, the pH was additionally amended to "from 4.5 to 8" or "from 4.5 to 8.0".

Claim 1 of auxiliary request 16 read as follows:

"Use of a source of metal ions and a polymeric mineral surface-active agent for manufacture of an oral care composition having a pH of from 4.5 to 8 for protecting a subject's teeth from erosion after administering to the subject's oral cavity the oral composition, wherein the source of metal ions is selected from the group consisting of stannous ions, zinc ions, copper ions and mixtures thereof, wherein said metal ions form insoluble compounds or complexes that deposit on the tooth surface, and wherein the polymeric mineral surface-active agent is selected from the group consisting of condensed phosphorylated polymers; polyphosphonates; polycarboxylates and carboxy-substituted polymers; copolymers of phosphate- or phosphonate-containing monomers or polymers with ethylenically unsaturated monomers, amino acids, or

with other polymers selected from proteins, polypeptides, polysaccharides, poly(acrylate), poly(acrylamide), poly(methacrylate), poly(ethacrylate), poly(hydroxyalkylmethacrylate), poly(vinyl alcohol), poly(maleic anhydride), poly(maleate) poly(amide), poly(ethylene amine), poly(ethylene glycol), poly(propylene glycol), poly(vinyl acetate) or poly(vinyl benzyl chloride); and mixtures thereof, the source of metal ions and the polymeric mineral surface-active agent thereby forming a film or coating that protects teeth from erosive damage immediately after use of the oral composition and for at least about one hour thereafter, and wherein the composition comprises no more than 0.01 % by weight of ethylenediaminetetraacetates and phytates."

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

D1: EP 2 583 661 A1
D3: WO 2004/054529 A1
D7: US 4,363,794
D8: US 4,335,102
D9: Brudevold et al, Arch. Oral. Biol 1963; 8:135-144
D14: US 804,486
D15: US 3,105,798
D17: EP 2 289 482 A2

VI. The opposition division decided that:

(a) Claim 1 of the main request extended beyond the content of the earlier application as filed (Articles 100(c) and 76(1) EPC). The feature "pH of from greater than 4.0" did not derive from page 10 (3rd paragraph) of the earlier application as filed, where a pH of 4 was intrinsically linked to

the presence of a buffering agent or to the presence of a polymeric mineral surface active agent, both features however missing in claim 1 of the main request.

- (b) Claim 1 of auxiliary requests 2-7 extended beyond the content of the earlier application as filed for the same reasons.
- (c) The late-filed auxiliary requests 8-15 were *prima facie* unsuitable to overcome the added subject-matter objections and were accordingly not admitted into the proceedings.
- (d) Auxiliary request 16 did not raise *prima facie* objections relating to Articles 76(1), 123(2) and 84 EPC, Rule 137(5) EPC and double patenting. Auxiliary request 16 was thus admitted into the proceedings.

The claimed therapeutic effect of reducing erosion was credibly achieved over the whole scope of the claim. Hence the requirements of sufficiency of disclosure were met.

However, the subject-matter of claim 1 of auxiliary request 16 was not novel over D8. In this respect, the feature "for protecting a subject's teeth from erosion" of claim 1 was considered as synonym for "for providing acid-resistance to teeth".

- (e) None of the auxiliary requests 17-23 were *prima facie* novel over D8. Thus, auxiliary requests 17-23 were not admitted into the proceedings.

- VII. The patent proprietor (appellant) lodged an appeal against the decision of the opposition division.
- VIII. With the statement setting out the grounds of appeal, filed on 23 May 2019, the appellant defended its case on the basis of the patent as granted as the main request, and on the basis of the same auxiliary requests 1-23 as those underlying the appealed decision.
- IX. The opponent withdrew its opposition by letter dated 19 July 2019.
- X. The Board set out its preliminary opinion in a communication under Article 15(1) RPBA issued on 22 October 2021.
- XI. Oral proceedings took place before the Board on 10 February 2022.
- XII. The appellant's arguments may be summarised as follows:

(a) Article 76(1) EPC

In claim 1 of the main request, the feature "pH greater than 4.0" was based on page 10, third paragraph, of the parent application as filed. This feature would be read as being technically equivalent to the broad terms "about pH 4" and "about pH 10" of page 10 of the parent application as filed, and hence did not add new technical information. Furthermore, the presence of the buffering agent, mentioned on said page 10, was optional. The presence of the polymeric mineral surface active agent, also mentioned on page 10, was not essential either, as it was interchangeable with metal

ions. Hence neither component was intrinsically linked to the pH range.

(b) novelty over D8

The opposition division correctly held that dental caries and dental erosion were different indications. Thus, as explained in paragraph [0004] of the patent, dental erosion was an irreversible loss of tooth substance from the surface by the action of extrinsic or intrinsic acids. In contrast, dental caries occurred via a reversible demineralisation/remineralisation mechanism, and were formed by subsurface demineralisation or caries caused by bacterial action and the action of acid caused by dental plaque.

D8 disclosed an oral composition based on e.g. stannous fluoride and was directed to caries prophylaxis. Furthermore, example 1 of D8 tested the composition against a pH of 4.5, which was the standard model in the art for assessing caries prophylaxis. It was known in the art that such a buffer would not provide a suitable acid challenge to the tooth surface to model dental erosion. Hence, the references to acid resistance in D8 were references to resistance to the acid challenge associated with dental caries. D8 was silent with regard to dental erosion. Accordingly, the subject-matter of claim 1 of the patent was novel over D8.

XIII. The appellant requests that the decision under appeal be set aside and that the opposition be rejected (i.e. the patent be maintained as granted), or, alternatively, that the patent be maintained on the basis of one of auxiliary requests 1-3 filed on 15 August 2017, auxiliary requests 4-7 filed on

5 October 2018, and auxiliary requests 8-23 filed on 4 December 2018. Should the Board find any claim requests which address the objections raised in the decision under appeal, the appellant requests a remittal to the opposition division for consideration of inventive step.

Reasons for the Decision

1. Main request (patent as granted)
 - 1.1 Articles 100(c) and 76(1) EPC
 - 1.1.1 The patent derives from application 13151885.4 ("the application as filed", published as D1),
filed as a divisional application of the earlier application 10173204.8 ("the parent application", published as D17),
itself filed as a divisional application of the earlier application 02794371.1 ("the grandparent application", published under the PCT as D3).
 - 1.1.2 It follows from G 1/06 that, in order for the patent to comply with Article 76(1) EPC, anything disclosed in the patent must be directly and unambiguously derivable from what is disclosed in each of the preceding applications as filed.

The opposition division objected in particular to the feature "pH of from greater than 4.0 to 10.0" of claim 1 of the main request.

A "pH of from greater than about 4.0 to about 10.0" is disclosed in claim 7 of the grandparent application (D3) and in claim 1 of the application (D1). However,

the parent application (D17) contains no such claim. The relevant question is thus whether the subject-matter of claim 1 of the main request is nonetheless directly and unambiguously derivable from the parent application (D17) as filed as a whole.

- 1.1.3 The passage of the parent application as filed cited as basis by the appellant (page 10, 3rd paragraph of the description of the parent application as filed, corresponding to paragraph [0034] of the published parent application D17) reads:

"The present compositions may contain a buffering agent. Buffering agents, as used herein, refer to agents that can be used to adjust the pH of the compositions to a range of about pH 4 to about pH 10. The oral composition containing a polymeric mineral surface active agent will typically have a slurry pH of from about 4 to about 10, preferably from about 4.5 to about 8, and more preferably from about 5.5 to about 7."

- 1.1.4 In the Board's opinion, the feature of claim 1 "pH of from *greater* than 4.0 to 10.0" differs from the cited passage not only in that:
- the value 4.0 is excluded, and
 - the range is isolated from the presence of a buffering agent or the presence of a polymeric mineral surface active agent, but also in that
 - a digit of precision has been added (e.g. 4 to 4.0).

- 1.1.5 Regarding the exclusion of the value 4.0, the appellant submits that the skilled person would interpret the range in claim 1 on the basis of the description of the patent (including the passage corresponding to page 10, 3rd paragraph of the parent application as filed) and

would not take a precise definition of the pH at the ends of the range as being an essential technical feature of the invention. Accordingly, the ranges in the earlier applications and the present claims would be read as being technically equivalent.

The Board does not share this opinion. The lack of precision of the expression "about pH 4" in the parent application as filed cannot be regarded as an unambiguous basis for the feature "greater than 4.0".

1.1.6 Furthermore, the Board concurs with the opposition division that the pH range of 4 to 10 is only disclosed in combination with the presence of a buffering agent or a polymeric mineral surface active agent. The parent application as filed may disclose compositions lacking the optional buffering agent, or containing metal ions instead of the polymeric mineral surface active agent. However, the parent application as filed does not disclose the pH of 4 to 10 in the absence of these components. Regarding the first part of page 10, 3rd paragraph, the buffering agent is responsible for adjusting the pH (see page 10 line 8), and as such is inextricably linked to the pH feature. As to the second part of page 10, 3rd paragraph, the parent application as filed does not disclose, directly and unambiguously, the combination of the pH feature with the metal ions. This pH range is only disclosed in combination with the separate embodiment pertaining to polymeric mineral surface active agents.

1.1.7 Accordingly, the main request introduces added subject-matter over the parent application, contrary to Article 76(1) EPC.

2. Auxiliary requests 1-7

In each of auxiliary requests 1-7, as in the main request, claim 1 comprises the feature pertaining to "a pH of from greater than 4.0 to 10.0" but does not specify the presence of a buffer or a polymeric mineral surface active agent. Hence, auxiliary requests 1-7 do not comply either with the requirements of Article 76(1) EPC.

3. Auxiliary requests 8-15

In auxiliary requests 8-15, the pH feature has been amended to a range of 4.5 to 8.0 or 8. However, it remains that a pH range of about 4.5 to about 8 is disclosed in the parent application as filed only in relation with the embodiment pertaining to the polymeric mineral surface active agent. Claim 1 of each of auxiliary requests 8-15 does not pertain to this embodiment but only to the metal ions embodiment.

Consequently, it is not necessary to assess whether the opposition division's decision not to admit auxiliary requests 8-15 into the proceedings should be upheld, because these requests do not comply with Article 76(1) EPC anyway.

4. Auxiliary request 16

4.1 The opposition division admitted auxiliary request 16 into the proceedings on account that this auxiliary request did not raise any *prima facie* objections relating to Articles 76(1), 123(2) and 84 EPC, Rule 137(5) EPC and double patenting. The opposition division also found the subject-matter of auxiliary request 16 to be sufficiently disclosed. These findings

have not been contested in the appeal proceedings, nor does the Board see any reason to depart from the conclusions of the opposition division. In particular, the limitation of claim 1 to the use of both "a source of metal ions and a polymeric mineral surface-active agent" together with a "pH of from 4.5 to 8" overcomes the objection of added subject-matter detailed above.

4.2 Novelty over D8

D8 (example 1) discloses a solution with pH 5.0, comprising stannous fluoride, stannous pyrophosphate and a chelating agent such as sodium citrate (see D8, Table 1). The opposition division found that stannous pyrophosphate qualified as a source of Sn metal ions as well as a polymeric mineral surface-active agent. This has not been contested in appeal.

According to D8 (see column 1, lines 20-31), it is well known that stannous compounds can provide tooth enamel and dentin with an improved acid resistance due to the action of stannous ions. If the solution comprises e.g. stannous fluoride SnF_2 , "not only the acid resistance of the tooth enamel is improved by stannous ions, but fluorine is also taken up by the tooth enamel, with outstanding results of caries inhibition, caries control, desensitization of hypersensitive dentin". This property of conferring acid-resistance to the enamel is also achieved by the proposed oral care composition (column 3, lines 12-13).

However, the relevant question is whether D8 discloses the use defined in claim 1 of the main request, namely "protecting a subject's teeth from erosion". Since D8 contains no explicit mention of erosion, the question

is whether such a use is implicit in the disclosure of D8.

As acknowledged in the appealed decision, the indications "dental caries" and "protection from teeth erosion" are different. This is consistent with the information in the patent (see paragraph [0004]), according to which dental erosion is a permanent loss of tooth substance from the surface by the action of e.g. acids, as opposed to subsurface demineralization or caries caused by bacterial action. Dental erosion is a condition that does not involve plaque bacteria and is distinct from dental caries, which is a disease caused by acids generated by plaque bacteria. Thus, erosion cannot be equated with all acidic challenges, but only with demineralisation caused by acids other than those generated by plaque bacteria.

The Board finds that the mention of an improved acid resistance associated with the compositions disclosed in D8 may encompass erosion but does not clearly and unambiguously disclose this precise indication. There is also no evidence that the test protocol described in example 1 of D8, which involves subjecting teeth to an acid at pH 4.5 after treatment with the composition, would be implicitly read by the skilled person as specifically reflecting a use against erosion, rather than a general use against acid challenges or even a use against acid challenges associated with dental caries.

Accordingly, the subject-matter of auxiliary request 16 is novel over D8.

5. Remittal to the opposition division

It follows from the above that the grounds set out in the appealed decision for revoking the patent are overcome by auxiliary request 16.

However, other objections were raised in the opposition proceedings, namely lack of novelty over documents other than D8, and lack of inventive step. Although the opposition division had expressed a negative preliminary opinion in the annex to the summons to oral proceedings dated 15 January 2018, including with respect to novelty over D7, D9, D14 and D15, the decision under appeal does not address these further issues.

Under Article 11 RPBA 2020, the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so.

The Board holds that such special reasons are apparent in the present case because the opposition division has not taken an appealable decision on the above essential outstanding issues. Consequently, the Board considers it appropriate to allow the appellant's request for remittal of the case to the opposition division.

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 for further prosecution.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated