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Datasheet for the decision of 23 June 2022

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Language of the proceedings: EN

Title of invention:
Method of protecting teeth against erosion

Patent Proprietor:
The Procter & Gamble Company

Opponents:

Colgate-Palmolive Company
Henkel AG & Co. KGaA

Headword:
Method of protecting teeth against erosion/The Procter & Gamble Company

Relevant legal provisions:
EPC Art. 83

Keyword:
Sufficiency of disclosure - (no)

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Case Number: T 1414/20 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 23 June 2022

Appellant: (Patent Proprietor)	The Procter & Gamble Company One Procter & Gamble Plaza Cincinnati, OH 45202 (US)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Respondent: (Opponent 2)	Colgate-Palmolive Company 300 Park Avenue New York NY 10022 (US)
Representative:	Jenkins, Peter David Page White & Farrer Bedford House John Street London WC1N 2BF (GB)
Respondent: (Opponent 3)	Henkel AG & Co. KGaA Henkelstrasse 67 40589 Düsseldorf (DE)
Representative:	Henkel AG & Co. KGaA CLI Patents Z01 40191 Düsseldorf (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 2 April 2020 revoking European patent No. 2289482 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	E. Duval
Members:	D. Boulois
	Y. Podbielski

Summary of Facts and Submissions

I. The European patent 2 289 482 had been opposed under Article 100 (a), (b), (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed, and extended beyond the content of the application as filed.

II. The opposition division, in a first decision, found that the claims as granted as main request did not meet the requirements of Articles 76(1) EPC and 123(2) EPC, that auxiliary request 2 did not meet the requirements of Article 123(2) EPC, while auxiliary requests 1 and 3 were not admitted into the opposition proceedings.

III. This first decision of the opposition division was set aside by the Board in decision T 38/16. The Board's decision was based on the claims as granted as main request, which were considered to meet the requirements of Article 76(1) EPC and Article 123(2) EPC. The case was remitted to the opposition division for further prosecution on the basis of the main request.

Claim 1 of the main request and as granted read:

"1. A dentifrice composition comprising
a) a polymeric mineral surface-active agent selected from polyphosphonates; polycarboxylates and carboxysubstituted 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(hydroxy- alkylmethacrylate), poly (vinyl alcohol), poly (maleic anhydride), poly-(maleate) poly(amide), poly(ethylene amine), poly-(ethylene glycol), poly-(propylene glycol), poly(vinylacetate) or poly (vinyl benzyl chloride); and mixtures thereof,
wherein said polymeric mineral surface-active agent is substantive to teeth and deposits a layer that protects teeth from erosive damage; and
b) an effective amount of a source of metal ions selected from the group consisting of stannous, zinc, copper, and mixtures thereof
for use in protecting a subject's teeth against dental erosion challenges following use of the composition."

IV. The appeal lies from the second decision of the opposition division to revoke the patent. The decision was based on the claims as granted as main request, on auxiliary request 1 filed during the oral proceedings of 27 February 2020 and auxiliary requests 2-3 filed with letter of 8 March 2016 and auxiliary requests 4-21 filed with letter of 20 December 2019.

V. The documents cited during the opposition proceedings included the following:
D1: WO 2001/034107
D15: WO 01/34108
D16: WO 01/68046

VI. According to the decision under appeal, none of the main request or auxiliary requests 1-21 fulfilled the requirements of sufficiency of disclosure.

Claim 1 disclosed the functional feature "is substantive to teeth and deposits a layer that protects teeth from erosive damage". Not all embodiments defined

by the structural features of the claim met the claimed functional requirements, that was not all claimed polymers would be able to deposit on the teeth's surface and form a protective layer.

Looking at the list of polymeric mineral surface-active agents disclosed, the common general knowledge at the priority date of the patent, or the patent itself did not provide the skilled person with sufficient guidance on how to select the polymers out of the host of products defined by the structural features of the claim that also met the claimed functional requirements.

Furthermore, in the patent in suit there was not sufficient information available that would lead the skilled person directly towards success through the evaluation of initial failures. Polyphosphates were the only exemplified polymers and it was not credible that the effect was also achieved for polymers which were not structurally related to polyphosphates such as polycarboxylates, carboxysubstituted polymers and polyphosphonates.

VII. The patent proprietor (hereinafter the appellant) filed an appeal against said decision. With the statement setting out the grounds of appeal dated 11 August 2020, the appellant filed auxiliary requests 1-17.

Independent claim 1 of the auxiliary requests read as follows, the differences, unless otherwise indicated, relating to a comparison with the main request.:

Auxiliary request 1

Claim 1 has been amended by adding the feature:

"wherein the protective effect is provided immediately after use of the dentifrice composition and lasts for at least an hour or longer".

Auxiliary request 2

Claim 1 has been amended by adding the features:
"wherein the protective effect is provided immediately after use of the dentifrice composition and lasts for at least an hour or longer,
wherein the polymeric mineral surface-active agent and metal ions deposit on the tooth surface a protective layer or coating comprised of the polymeric mineral surface-active agent and an insoluble film or precipitate of compounds or complexes formed from the reaction of the metal ions with other ingredients of the oral composition and/or components of the enamel surface."

Auxiliary request 3

The subject-matter of claim 1 of auxiliary request 3 read:

1. A dentifrice composition comprising
a) a polymeric mineral surface-active agent **selected from polycarboxylates and carboxysubstituted polymers,** wherein said polymeric mineral surface-active agent is substantive to teeth and deposits a layer that protects teeth from erosive damage; and
b) an effective amount of a source of metal ions selected from the group consisting of stannous, zinc, copper, and mixtures thereof
for use in protecting a subject’s teeth against dental erosion challenges following use of the composition".

Auxiliary request 4

The subject-matter of claim 1 of auxiliary request 4 corresponds to claim 1 of auxiliary request 3 with the addition of the feature:
"wherein the protective effect is provided immediately after use of the dentifrice composition and lasts for at least an hour or longer."

Auxiliary request 5

The subject-matter of claim 1 of auxiliary request 5 corresponds to claim 1 of auxiliary request 3 with the addition of the features:
"wherein the protective effect is provided immediately after use of the dentifrice composition and lasts for at least an hour or longer,
wherein the polymeric mineral surface-active agent and metal ions deposit on the tooth surface a protective layer or coating comprised of the polymeric mineral surface-active agent and an insoluble film or precipitate of compounds or complexes formed from the reaction of the metal ions with other ingredients of the oral composition and/or components of the enamel surface."

Auxiliary requests 6-11

Auxiliary requests 6-11 correspond respectively to the main request and auxiliary requests 1-5, wherein the subject-matter of claim 1 has been restricted to specific metal ions by the deletion of the copper ions, namely:
"b) an effective amount of a source of metal ions selected from the group consisting of **stannous, zinc,** and mixtures thereof".

Auxiliary requests 12-17

Auxiliary requests 12-17 correspond respectively to the main request and auxiliary requests 1-5, wherein the subject-matter of claim 1 has been restricted to stannous metal ions:
"b) an effective amount of a source of metal ions selected from the group consisting of **stannous**".

VIII. A communication from the Board, dated 6 April 2022, was sent to the parties. It stated in particular with regard to sufficiency of disclosure, that it was questionable whether the teaching of the example with a polyphosphate could be extrapolated to all the claimed PMSA.

IX. Oral proceedings took place on 23 June 2022 by videoconference.

X. The arguments of the appellant may be summarised as follows:

Sufficiency of disclosure

The polymeric mineral surface-active agents (PMSA) were known from the art (Cf. D1, D15 and D16) for other therapeutic/cosmetic effects. The PMSA was limited in claim 1 to compounds known to perform the binding function. The examples of the patent showed that a combination of a PMSA capable of undergoing the binding with the tooth surface and metal ions was able to protect the tooth surface (Cf. Table 3).

The technical effect was realised across the whole scope of the claim. The results of the examples could be generalised from a polyphosphate, as in the examples of the patent, to all the claimed PMSAs. The binding was achieved through the strong affinity of phosphate, phosphonate and carboxyl functional groups for the calcium sites of the tooth. The experiments were sufficient to show this.

A table was provided with the grounds of appeal showing data comparing polyphosphate and a polycarboxylate (Gantrez S-95®) in combination with a metal ion, and demonstrating that polyphosphate and polycarboxylate provided similar beneficial effects. It was the functional relationship between the PMSA which was important, rather than the structural relationship. Paragraph [0028] of the patent provided the necessary guidance by explaining that the PMSAs needed three or more phosphate groups so that the phosphate groups could provide attachment to the enamel surface and still provide an anionic charge to give a hydrophilic character to the tooth surface. The polyphosphate of the examples had 21 functional groups, performed well, and this was a good guidance. The requirements of three or more phosphate, phosphonate and/or carboxylate groups was carried through claim 1 which referred to "polymeric mineral surface-active agent".

The ultimate parent in this family of filings was EP 1 569 609 B2 (D32). The claims of this patent focused on Glass H polyphosphate. A copy of the preliminary opinion was on file as D31, wherein the Board concurred with the opposition division in finding that the patent provided a credible explanation why the results obtained with Glass H may be generalised to the whole

claimed scope of polyphosphates. The same principle applied to the present case.

The same arguments applied to the auxiliary requests.

XI. The arguments of respondent 02 may be summarised as follows:

Sufficiency of disclosure

There was no evidence presented to the skilled person that any other PMSA, apart from Glass H polyphosphate, could carry out the alleged invention characterized by the functional features "wherein said polymeric mineral surface-active agent is substantive to teeth and deposits a layer that protects teeth from erosive damage" and a source of metal ions, "for use in protecting the subject's teeth against dental erosion challenges following use of the composition".

In particular, there was no working example in the patent showing any plausible evidence of any technical effect of a composition as recited in claim 1. The conditions under which the PMSA was supposed to be substantive to teeth and to deposit a layer that protect the teeth were not disclosed in the specification. There was indeed no disclosure how to determine whether or not any polymer within the vast scope of the list of polymers recited in claim 1 provided the recited property, even less its concentration in the composition; there was no explanation how to extrapolate the only example with Glass H to any of the claimed polymers, in particular to a polycarboxylate or a carboxy-substituted polymer without any phosphate groups and having possibly only a very few carboxylate groups in a non-linear structure.

There was no plausible evidence that polymers having for example a polycarboxylate or a carboxysubstituted structure, with any polymer backbone, molecular weight, number/distribution of carboxylate groups, in any concentration could provide the therapeutical effect.

The appellant's new argument based on D31 and D32 was groundless and irrelevant. EP1569609B2 (D32) was limited to a very specific polyphosphate which encompassed the Glass H polyphosphate used in the examples and there was no overlap between the current Main Request and the claims of D32. Furthermore, in D31 the Board "generalised" from the specific example of "Glass H polyphosphate", to a linear polyphosphate, and this specific generalisation did not correspond to the present situation.

The conditions under which the dentifrice composition is "for use in protecting a subject's teeth against dental erosion challenges following use of the composition" were also not specified; this feature was not sufficiently disclosed.

The "effective amount" of a source of the metal ions was also not sufficiently disclosed, since there was no teaching how to determine what is an "effective amount".

XII. Requests

The appellant requested that the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution on the basis of the main request, or alternatively on the basis of one of

auxiliary requests 1-17 filed with letter of 11 August 2020.

Respondent 02 requested that the appeal be dismissed. In the event that the Board would find compliance of any request with Article 83 EPC, respondent 02 requested that the case be remitted to the opposition division for further prosecution. Respondent 02 also requested that neither auxiliary requests 3-17, nor the new arguments based D31 and D32, which were presented in the appellant's letter dated 29 April 2022, be admitted into the appeal proceedings.

Respondent 03 did not make any request or submission.

Reasons for the Decision

1. Main request - Sufficiency of disclosure

1.1 Claim 1 of the main request relates to a dentifrice composition comprising a polymeric mineral surface-active agent (PMSA) **"wherein said polymeric mineral surface-active agent is substantive to teeth and deposits a layer that protects teeth from erosive damage"**. The claimed PMSA is selected from:
a) polyphosphonates;
b) polycarboxylates and carboxy-substituted polymers;
c) 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(hydroxy- alkylmethacrylate), poly (vinyl alcohol), poly (maleic anhydride), poly-(maleate) poly(amide), poly(ethylene amine), poly(ethylene glycol), poly-(propylene glycol),

poly(vinylacetate) or poly (vinyl benzyl chloride); and mixtures thereof.

The PMSA is combined with a metal ion in the claimed dentifrice composition for use in protecting a subject's teeth against dental erosion challenges following use of the composition.

The feature "**wherein said polymeric mineral surface-active agent is substantive to teeth and deposits a layer that protects teeth from erosive damage**" characterizing the PMSA is a functional feature defining a technical result necessarily achieved by the claimed PMSA. This feature and the technical result involved are key elements of the claimed invention, since the PMSA is specifically chosen to have affinity to the tooth surface; said PMSA indeed either binds to the tooth surface or forms insoluble compounds or complexes on the tooth surface, thereby forming a protective film that prevents erosive chemicals from contacting the tooth surface and etching away tooth hard tissue (see the specification par. [0003], [0006], [0007]).

Thus, the skilled person must be able to prepare a dentifrice composition and in particular select a PMSA among the claimed list of polymers having the claimed properties.

1.2 In accordance with the case law of the Boards of Appeal the requirements of Article 83 EPC are met if:
(a) at least one way is clearly indicated in the patent specification enabling the skilled person to carry out the invention, and

(b) the disclosure allows the invention to be performed in the whole area claimed without undue burden, applying common general knowledge.

1.3 In the present case, requirement a) is not met. The examples of the contested patent disclose two types of "polymeric mineral surface-active agent", namely a polyphosphate (Glass H) in examples I and II (Formulae A, B and E) and a poly(diphosphonate/acrylate) in comparative Formula D of example II. The polyphosphate of the examples does not fall under the scope of the claims and the poly(diphosphonate/acrylate) is used in a comparative example, so that the contested patent does not comprise any example corresponding to the claimed invention. This point was acknowledged by the appellant.

Hence, there is no evidence presented to the skilled person in the examples that any other PMSA, apart from Glass H polyphosphate, which is outside the scope of the claim, can provide the required property of being substantive to teeth and is able to deposit a layer that protects teeth from erosive damage.

1.4 With respect to requirement b), the issue is whether the disclosure allows the selection of an adequate PMSA from the claimed list and defined by the functional feature "wherein said polymeric mineral surface-active agent is substantive to teeth and deposits a layer that protects teeth from erosive damage".

1.4.1 The PMSA polymers are structurally defined in a very broad way in claim 1 of the main request and in the description of the contested patent; there is no specific structure or specific example given for any of

the listed polymers or copolymers of claim 1 or of the description.

There is furthermore no indication or teaching regarding for instance the polymer backbone, molecular weight, or number/distribution of carboxylate, phosphonate or phosphate groups of any of the claimed polymer or copolymer (see par. [0021] of the specification), not even for the phosphonate copolymers disclosed in the general structures given in paragraphs [0022]-[0026], namely copolymers of acrylic acid and diphosphonic acid, acrylic acid and vinylphosphonic acid, methacrylic acid and vinylphosphonic acid, and acrylic acid and vinyldiphosphonic acid.

Moreover, none of the claimed polymers or copolymers have the same chemical composition or structure than the Glass H polyphosphate, they are even fundamentally different from the exemplified Glass H polyphosphate, as they are not required to comprise a linear polyphosphate having multiple phosphate groups. Even if applicable to all claimed polymers, this conclusion is particularly relevant for the claimed polycarboxylates or carboxysubstituted polymers.

1.4.2 The only concrete structural guidance given in the description relates to the necessary presence of end or side chains of phosphate or phosphonate (par. [0028]). The description specifies indeed that when the PMSA is a polyphosphate, such as the exemplified Glass H Polyphosphate, the polyphosphates desired are those having three or more phosphate molecules so that surface absorption at effective concentrations produces sufficient non-bound phosphate functions, which enhance the anionic surface charge as well as the hydrophilic

character of the surfaces (see par. [0028] of the specification).

This category of polymers is however not covered by the claimed invention, and this structural guidance can in particular not be extrapolated to any of the claimed polymers, in particular not the claimed polycarboxylates or carboxysubstituted polymers.

1.4.3 The description specifies furthermore the properties that the PMSA must show, namely that "*the polymeric mineral surface active agents include any agent which will produce the desired surface protection effects*" (see par. [0020]), and said polymers "i*nclude any agent which will have a strong affinity for enamel surface, deposit a polymer layer or coating on the enamel surface and produce the desired surface protection effects*", or "*polymers with activity must have sufficient surface binding propensity to desorb pellicle proteins and remain affixed to enamel surfaces. For tooth surfaces, polymers with end or side chain phosphate or phosphonate functions may both be preferred although other polymers with mineral binding activity may prove effective depending upon adsorption affinity*" (see par. [0021] of the specification). The description of the patent specifies even further conditions for the selection of an appropriate PMSA, namely "*a preferred polymeric mineral surface active agent will be stable with other components of the oral care composition such as ionic fluoride and metal ions and will not hydrolyze in high water content formulations, thus permitting a simple single phase dentifrice or mouthrinse formulation*" (see par.[0027]). There is again no teaching or guidance in the patent as to which specific polymers might meet all these desired properties and will be able to carry out the invention.

1.5 The insufficiency of disclosure is not remedied by the disclosure of documents D1, D15 and D16, which were mentioned by the appellant. All three documents are patent applications from the appellant, and are not part of the common general knowledge. Said documents are also not cited as reference documents in the description of the present patent.

Finally, they suffer from the same deficiency as the present patent, namely an insufficient teaching with regard to the PMSA, and examples restricted to the use of polyphosphates.

1.6 In its statement of grounds of appeal, the appellant referred to data comparing polyphosphate and a polycarboxylate polymer (Gantrez S-95) in combination with stannous ions versus sodium fluoride paste, to demonstrate the effectiveness of polycarboxylates as PMSA. The table is reproduced below:

Dentifrice test product	**Depth of complete surface loss (µm)**
Stannous + Polyphosphate	8.67
Stannous + 2% Gantrez S-95	12.50
Sodium fluoride paste	21.00

Such post-published data may be taken in account, but only to back-up the findings in the patent and not to establish sufficiency of disclosure on its own. In the present case, the filing of these data does not appear to be relevant and cannot be taken in account for the reasons given below.

First, Gantrez® S-95 polymer is cited as anticalculus agent in the description of the contested patent, but not as a possible PMSA (cf. par. [0046]). Moreover, it is a methyl vinyl ether/maleic acid copolymer (see par. [0046]), which might have free acid functions at acidic pH. Hence, it is questionable whether this polymer is in its polycarboxylic form when incorporated in a dentifrice composition, and whether it falls under the scope of claim 1. For this reasons alone, the data cannot be considered as relevant for the assessment of sufficiency of disclosure.

Moreover, said experiments are not conclusive as to an effect linked with the polymer Gantrez® S-95 in the absence of data provided by the use of Gantrez S95® as such, since it is known from the patent that metal ions have an effect on their own, i.e that they also form a deposit on the teeth (see par. [0006] or [0007] of the specification). This is also shown in Table 3 of the patent:

Table 3

Dentifrice Test Product Containing:	Depth of Complete Mineral Loss (μm)
Stannous + Polyphosphate[1]	0
Zinc Lactate + Polyphosphate[1]	0
Polyphosphate[1]	1.7
Zinc Citrate + Polyphosphate[1]	4.0
Zinc Citrate	10.7
Placebo	13.9
[1] Polyphosphate is Glass H supplied by FMC Corp.	

It appears from Table 3 of the specification that the metal source of ions, here zinc citrate, has a protective effect as such, even without the addition of

a PMSA. It is therefore not possible to exclude that the effect of the association of stannous ions with Gantrez® S-95 is due exclusively to the presence of the stannous salt, and that the addition of the originally undisclosed Gantrez S95® does not have any effect.

In conclusion, the data provided cannot be taken in account for the establishment of sufficiency of disclosure and are furthermore irrelevant therefor.

1.7 The Board could also not follow the appellant's arguments based on documents D31 and D32. The appellant refers indeed to the parent patent D32 (EP1569609 B2) which was maintained in amended form by the opposition division and was limited to specific polyphosphates, and to the Board of Appeal's preliminary opinion (D31) on the issue of whether the results obtained with Glass H may be generalised to the whole claimed scope of polyphosphates.

This case and the arguments related thereto are however clearly irrelevant to the issues in this appeal, since D32 was limited to a very specific polyphosphate which encompassed the Glass H polyphosphate used in the examples. In addition, in D31 the Board considered the generalisation from the specific example of "Glass H polyphosphate" to a linear polyphosphate permissible, which is, however, a reasoning based on entirely different facts compared to the present case.

In view of this, the Board does not need to take a decision on the admittance of the arguments based on these documents into the appeal proceedings, since they are not relevant and have no impact on the decision on sufficiency of disclosure of the present case.

1.8 Consequently, the patent does not meet the requirements of Article 83 EPC.

2. Auxiliary requests 1-17

Independent claim 1 of all auxiliary requests relate to a dentifrice composition comprising a PMSA selected either from the same list of polymers or copolymers as in claim 1 of the main request (auxiliary requests 1, 2, 6, 7, 8, 12, 13, 14) or from "polycarboxylates and carboxysubstituted polymers" (auxiliary requests 3, 4, 5, 9, 10, 11, 15, 16, 17). The claimed PMSA are characterized by the same functional feature as in claim 1 of the main request, i.e. "**wherein said polymeric mineral surface-active agent is substantive to teeth and deposits a layer that protects teeth from erosive damage**", in all independent claims of the auxiliary requests.

The conclusion reached for the main request applies therefore also to all auxiliary requests, which lack sufficient disclosure for the same reasons as the main request (Article 83 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos E. Duval

Decision electronically authenticated