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Datasheet for the decision of 5 September 2019

Case Number: T 0177/16 - 3.3.07

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Language of the proceedings: EN

Title of invention:
Method of enhancing fluoridation and mineralization of teeth

Patent Proprietor:
THE PROCTER & GAMBLE COMPANY

Opponent:
Colgate-Palmolive Company

Headword:
Fluoridation and mineralisation of teeth / PROCTER & GAMBLE

Relevant legal provisions:
EPC Art. 100(a), 54(2), 56, 100(b)

Keyword:
Novelty - implicit disclosure (no)
Inventive step - (yes)
Sufficiency of disclosure - (yes)

Decisions cited:
T 0254/93, T 0486/01

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Case Number: T 0177/16 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 5 September 2019

Appellant: (Opponent)	Colgate-Palmolive Company 300 Park Avenue New York NY 10022-7499 (US)
Representative:	Jenkins, Peter David Page White & Farrer Bedford House John Street London WC1N 2BF (GB)
Respondent: (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)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 11 November 2015 rejecting the opposition filed against European patent No. 1569610 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman J. Riolo
Members: E. Duval
Y. Podbielski

Summary of Facts and Submissions

I. European Patent 1 569 610 (hereinafter "the patent") was granted on the basis of 9 claims. Claim 1 of the patent as granted read as follows:

"The use of a phosphonate group containing polymeric mineral surface-active agent selected from copolymers or cotelomers prepared from copolymerizing acrylate or methacrylate monomers with diphosphonate or polyphosphonate containing monomers in the manufacture of an oral care composition for enhancing fluoride incorporation into and remineralization of a subject's teeth, thereby providing enhanced protection of teeth against caries and cavities and increased resistance to acid demineralization associated with caries processes, wherein the composition further comprises one or more fluoride ion sources."

II. An opposition has been filed against the patent on the grounds that its subject-matter lacked novelty and inventive step and it was not sufficiently disclosed.

III. The opposition division took the decision to reject the opposition.

The opposition division decided that:

(a) The opponent had not discharged its burden of proof to show that the composition of the copolymers identified by their trade names was not constant and that some copolymers did not show the desired effect. Regarding the absence of limitation as to the nature and amount of the fluoride and polyphosphonate, the opposition division pointed to

information in passages of the patent and construed the claim as requiring a minimum amount of diphosphonate. The argument that the terms "enhanced" and "increased" are relative terms was considered as an objection under Article 84 EPC rather than an objection of insufficiency of disclosure. The requirements of sufficiency of disclosure were thus met.

(b) The claimed priority was invalid, hence D1 belonged to the state of the art pursuant to Article 54(2) EPC. However, D1 disclosed neither the effect of the polyphosphonate in the incorporation of fluoride nor its effect on tooth protection. The claimed subject-matter was thus novel.

(c) D12 was seen as a more suitable starting point than D1 for the assessment of inventive step. The subject-matter of claim 1 differed from the teaching of D12 by the use of a diphosphonate or polyphosphonate polymer in combination with the fluoride. This resulted in improved remineralisation of the teeth, acid resistance and fluoride uptake. The objective technical problem was therefore to provide improved remineralisation. The claimed solution was not rendered obvious by the available prior art.

IV. The appeal was filed by the opponent (appellant) against that decision.

V. On 2 July 2019, the Board issued a communication pursuant to Article 15(1) RPBA.

VI. By letter dated 22 August 2019, the respondent filed an auxiliary request.

VII. Oral proceedings were held before the Board on 5 September 2019.

VIII. In the present decision, reference is made to the following documents:

D1: US 2003/0152527
D2: US 6555094
D3: US 2003/0206874
D4: US 2003/0165442
D5: WO 01/34107
D6: WO 94/00103
D7: US 2002/0106336
D8: US 5939052
D9: "A simple model for the effect of fluoride ions on remineralization of partly demineralized tooth enamel", J. Christoffersen et al., Journal of Crystal Growth 67 (1984), p. 102-106
D10: "The effect of fluoride in the remineralization of enamel caries and caries-like lesions in vitro", L.M. Silverstone, Journal of Public Health Dentistry, Vol. 42, No. 1, Winter 1982 p.42-53
D11: "Influence of fluoride and pH on in vitro remineralization of bovine enamel", P.C. Lammers et al., Journal of the European Organization for Caries Research (ORCA), Caries Res. 1992, 26, p.8-13
D12: "Reactivity of fluoride dentifrices with artificial caries III. Quantitative aspects of acquired acid resistance (AAR): F uptake, retention, surface hardening and remineralization", D.J. White, The Journal of Clinical Dentistry, Vol. III, N°.1, 1991, p. 6-14
D13: "Calcium fluoride uptake by human enamel after use of fluoridated mouthrinses", M. Navarro et al., Braz. Dent. J., (2001) 12(3) 178-182.

IX. The appellant's arguments can be summarised as follows:

(a) Claim 1 lacked novelty over document D1. D1 disclosed an oral care composition which included a fluoride ion source and a polymeric MSA falling within the definition set out in claim 1 of the patent. Since D1 stated that the polymeric MSA released from the stannous fluoride an increased ionic form of fluoride, and since the effects of increased release of ionic fluoride were part of the common general knowledge as shown by D9-D13, it was inevitable and immediately apparent to the skilled person that the polymeric MSA provided the therapeutic effects of claim 1. Furthermore, D1 explicitly described the protection of teeth against caries. The purported effects of enhancing fluoride incorporation into and remineralisation of a subject's teeth did not define a new therapeutic application, but consisted in mere explanations of the existing therapeutic application. This explanation did not render the claimed subject-matter novel, following T 254/93 and T 486/01.

(b) Should the Board consider the subject-matter of claim 1 to be novel over D1, D1 would represent the closest prior art. The objective technical problem was to provide an additional use of the polymeric MSA and fluoride ion source. D1 taught that the polymeric MSA provided an increase in the ionic form of fluoride. The skilled person knew from common general knowledge, or from D12, that fluoride ions in solution accelerated remineralisation and fluoride uptake. The skilled person would therefore be led to understand that an additional effect arose from the increased ionic

fluoride. Likewise, starting from any of D2 to D8, the claimed subject-matter was an obvious solution to the problem of providing an additional use of the known polymeric MSA / fluoride ion source system.

(c) Regarding the achievement of the claimed effect, with respect to sufficiency of disclosure and inventive step, the appellant criticised the examples with respect to the absence of indication of experimental error and the lack of information as to the composition of the polymers 1154 and ITC 1087 used. Additionally, it was not credible that all compositions as defined in the claim provided the technical effects set out in the claim, in particular with an infinitesimal amount of fluoride or with infinitesimally small or infinitely large amounts of polymeric MSA or phosphonate monomer therein.

X. The respondent's arguments can be summarised as follows:

(a) D1 did not anticipate the claimed subject-matter because it did not disclose the medical use of enhancing fluoride incorporation into and remineralization of a subject's teeth. In D1, the effect of the polymeric MSA on ionic fluoride release was only used as evidence of the binding of polymeric MSA to stannous ions. There was no disclosure in D1 of the effect of the polymeric MSA on fluoride uptake and remineralisation. It was not sufficient that the effect inherently occurred for D1 to anticipate the second medical use. The claimed subject-matter was consequently novel over D1.

(b) The closest prior art was D12. Should D1 be considered as closest prior art, the objective technical problem would be the provision of a new use. The invention was based on the unexpected ability to promote remineralisation beneath the tooth surface by modifying the tooth surface with a polymeric MSA. The claimed use was not contemplated by D1. D9-D13 did not make reference to the effect of the polymeric MSA either. Since there was no mention of the claimed use in any of D2-D8, the further lines of argument starting from these documents were also unconvincing.

(c) Concerning sufficiency of disclosure, values reported in tables 1-4 were sufficiently far removed for experimental error not to be a significant factor in the analysis of the data. As to the use of trade names for the polymeric MSA, paragraph [0027] removed any doubt that the skilled person could not work the invention. Interpreting the claims as covering infinitesimally small and infinitely large amounts of fluoride was incorrect. Furthermore, the patent provided guidance about suitable amounts and about the polymeric MSA in paragraphs [0021]-[0028].

XI. The appellant requests that the decision under appeal be set aside and that the patent be revoked.

XII. The respondent requests that the appeal be dismissed, or, as an auxiliary measure, that the patent be maintained on the basis of the auxiliary request filed with letter dated 22 August 2019.

Reasons for the Decision

Main request (patent as granted)

1. Novelty

1.1 In the decision under appeal, the opposition division found that the patent does not relate to the same invention as the priority document and is thus not entitled to the claimed priority date. This is not contested by the respondent. As a consequence, D1, published before the filing date, belongs to the prior art pursuant to Article 54(2) EPC.

1.2 It is also not contested that D1 discloses oral care compositions as defined in claim 1: the compositions of D1 may comprise stannous fluoride as fluoride ion source (see [0011] and [0035]) and a polymeric mineral surface active agent (hereinafter "polymeric MSA") as defined in claim 1 (see [0040]-[0041]).

D1 also discloses that the oral care compositions show efficacy for the control of dental caries (see [0002] and [0038]) as a result of the presence of stannous fluoride.

1.3 However, the therapeutic application defined in claim 1 is not only and generally the protection of teeth against caries and cavities but also an increased resistance to acid demineralization associated with caries processes. The claim further defines the effect of enhancing fluoride incorporation into and remineralization of a subject's teeth. Following the appellant's interpretation, the claimed increase and

enhancement are by reference with the same composition lacking the polymeric MSA.

D1 does not contain any explicit disclosure of such effects. The question therefore arises whether D1 implicitly discloses the use of the polymeric MSA to achieve these claimed effects.

1.4 The appellant argued that the effects of fluoride uptake, remineralization and resistance to acid demineralization were implied in D1 by the protection against caries.

The Board shares the appellant's view that the effects of fluoride ions on fluoride uptake, remineralisation and resistance to demineralisation are part of the common general knowledge. As indicated in paragraph [0006] of the patent, fluoride ions in solution accelerate remineralisation of teeth; remineralised teeth often exhibit increase in fluoride uptake and retention; and teeth with increased remineralisation and fluoride uptake also exhibit superior resistance to acid demineralisation. These effects of fluoride ions are also described in documents D9-D13.

1.5 However, this does not lead to the conclusion that the ability of polymeric MSA to enhance these known effects of fluoride ions was known or implied in D1.

D1 primarily focuses on the provision of compositions having effective antimicrobial activity for reducing plaque and gingivitis. The role of the polymeric MSA component is to bind stannous ions and thereby reduce staining and astringency (see claim 1 of D1). In paragraph [0038] of D1, polymeric MSA is stated to bind stannous ions, "as evidenced by ionic fluoride release

from stannous fluoride (SnF_2) and provision of increased ionic form of fluoride upon binding of the stannous" (see also paragraphs [0095]-[0096]). In these passages, the reference to the ability of polymeric MSA to increase ionic fluoride release is intended as evidence for the binding to stannous. The skilled person would not understand this disclosure of an increased ionic fluoride release to imply any increased fluoride activity in uptake, remineralisation and protection against demineralisation. The further statement in paragraph [0038], regarding the polymeric MSA not "having a negative effect on the efficacy of stannous fluoride for the control of dental caries", rather speaks against an implied disclosure that polymeric MSA has an enhancing effect on the efficacy of the fluoride source.

1.6 Accordingly, the Board considers that D1 mentions the control of dental caries resulting from the fluoride source, but fails to disclose any increased resistance to acid demineralization, enhanced fluoride incorporation or remineralization of teeth associated with the use of the polymeric MSA. Contrary to the appellant's opinion, these claimed effects do not simply provide an explanation of the known effect against caries, but define a new technical effect underlying a new therapeutic application. This distinguishes the case before the Board from T 254/93 and T 486/01.

Thus, the requirements of novelty are met.

2. Inventive step

2.1 Whereas D12 is identified as closest prior art in the decision under appeal and by the respondent, the

appellant raises objections of lack of inventive step starting from each of D1-D8, but not starting from D12. Accordingly, the present decision is limited to assessing whether the claimed subject-matter would be rendered obvious if any of D1-D8 were to be chosen as closest prior art.

2.2 The problem underlying the present invention is, as stated in the claim, to enhance fluoride incorporation into and remineralization of a subject's teeth, to provide enhanced protection of teeth against caries and cavities, and increased resistance to acid demineralization associated with caries processes. The claimed solution to this problem is to use a polymeric MSA in addition to the fluoride ion source. According to the description (see paragraph [0005]), polymeric MSA are "known to be effective in reducing (rather than increasing) the crystallization of mineral salts onto substrates in supersaturated solution". The invention relies on the ability of polymeric MSA to "modify the tooth surface to promote remineralization beneath the tooth surface such as in caries prevention".

2.3 In contrast, the main objectives of D1 are to provide compositions having effective antimicrobial activity for reducing plaque and gingivitis and to reduce staining and astringency associated with stannous. D1 also mentions the problem of control of dental caries, and discloses oral care compositions as defined in claim 1, comprising a fluoride ion source and a polymeric MSA. However, as explained above (see point 1. above), D1 does not address the problems of increased resistance to acid demineralization, enhanced fluoride incorporation or remineralization of teeth.

2.4 Starting from D1, the appellant defines the problem as the provision of an additional use for the polymeric MSA and fluoride ion source.

2.5 It is a functional feature of claim 1 that the polymeric MSA leads to the claimed effects of increased resistance to acid demineralization, enhanced fluoride incorporation or remineralization of teeth. According to the appellant, these effects are rendered obvious by the statement in paragraph [0038] that polymeric MSA leads to an increased ionic form of fluoride, and by the fact that increased ionic fluoride content is known, from D12 or from common general knowledge, to enhance fluoride uptake, remineralisation and resistance to demineralisation.

However, in order to infer these effects from D1, the skilled person would first have to isolate this statement of paragraph [0038] from the context in which it appears in D1. In D1, the observation that polymeric MSA leads to fluoride release from stannous fluoride is merely presented as evidence of its binding to stannous, and is contingent upon the choice of stannous fluoride as source of stannous. Other sources of stannous are considered in D1, including stannous chloride and stannous sulfate (see example II).

2.6 Accordingly, the Board considers that D1 cannot lead the skilled person in an obvious way to the claimed invention, because D1 is not directed to the same purpose as the invention, and because it does not render the claimed effects of polymeric MSA obvious.

2.7 Likewise, none of D2-D8 is directed to the problem of enhancing fluoride incorporation into and remineralization of a subject's teeth, providing

enhanced protection of teeth against caries and cavities, and increased resistance to acid demineralization associated with caries processes. Therefore, the same conclusions apply starting from any of D2-D8.

3. Sufficiency of disclosure

3.1 The appellant questions the achievement of the claimed effects of enhanced fluoride incorporation, remineralization and increased resistance to acid demineralization. Since these effects define a functional feature of claim 1, this question pertains to the criteria of sufficiency of disclosure.

3.2 The Board is of the view that the claimed effects are credibly shown, in the examples (see tables 1-4 on pages 10-11 of the patent), by appropriate comparisons of compositions comprising 1100ppm fluoride and differing only with respect to the presence of the polymeric MSA (namely 1.6, 2.5 or 5wt% "ITC 1087" or "Polymer 1154"). The polymers ITC 1087 and 1154 are identified in paragraph [0027] of the patent as diphosphonate/acrylate polymers, and no doubt was substantiated that these polymers fall within the scope of the polymeric MSA defined in claim 1. In each comparison, an improvement with respect to fluoride uptake, remineralisation and acid resistance can be observed for the composition comprising the polymeric MSA. Considering the significant extent of these improvements, an indication of the experimental error associated with these data is not considered necessary.

3.3 The question then arises whether the results shown in the examples can be extrapolated to the whole scope of the claims.

The scope of claim 1 is limited not only by the features pertaining to the components of the oral care composition but also by the functional feature relating to the therapeutic use. Sufficiency of disclosure for this claimed invention must be assessed on the basis of the patent as a whole.

Following paragraph [0005] of the patent, the polymeric MSA promotes remineralisation by modifying the tooth surface. This proposed mechanism, which is independent of the nature of the fluoride ion source, makes it credible that the effects observed in the examples arise with any fluoride ion source, and not just with e.g. sodium fluoride.

The Board shares the respondent's view that claim 1 should not be interpreted so as to cover compositions comprising infinitesimally small or infinitely large amounts of fluoride. The patent provides guidance on the amounts of fluoride suitable to work the invention (see paragraph [0021]). The examples employ fluoride contents falling within these usual amounts, and extreme values departing from such usual amounts would be not read into the claims by the skilled person.

As to the polymeric MSA, its key features for binding to the tooth surface are defined in claim 1, namely the presence of (meth)acrylate monomers and of diphosphonate or polyphosphonate monomers. The patent specification further provides guidance concerning not only its structure (see paragraphs [0022]-[0027]), but also the suitable amounts of polymeric MSA (see paragraph [0028]).

Lastly, the assertion that the claimed effect would not be achieved for all the compositions covered by the claim is not substantiated. In the circumstances, the Board cannot accept the appellant's argument, according to which the credibility of the effect is so far stretched that the burden of proof should rest with the respondent.

In conclusion, the Board considers that the patent as a whole contains sufficient information to carry out the claimed invention and obtain the technical effects shown for the examples over the whole scope of the claims. Accordingly, the requirements of sufficiency of disclosure are met.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos J. Riolo

Decision electronically authenticated