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**D E C I S I O N**  
**of 11 May 2000**

**Case Number:** T 0542/96 - 3.3.2

**Application Number:** 90201676.5

**Publication Number:** 0405682

**IPC:** A61K 7/18

**Language of the proceedings:** EN

**Title of invention:**

Dental remineralization

**Patentee:**

Colgate-Palmolive Company

**Opponent:**

The Procter & Gamble Company

**Headword:**

Xylitol-Fluoride/COLGATE-PALMOLIVE

**Relevant legal provisions:**

EPC Art. 83, 54, 56, 100

**Keyword:**

"Novelty: (yes) - Remineralisation of teeth as novel  
therapeutic application"

"Inventive step: (no) - synergistic effect irrelevant to the  
assessment of the inventive step of a composition, which is  
clearly suggested in the prior art"

"Grounds of opposition in appeal proceedings"

**Decisions cited:**

J 0012/85, G 0009/91, T 0401/95

**Catchword:**

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Case Number: T 0542/96 - 3.3.2

**D E C I S I O N**  
**of the Technical Board of Appeal 3.3.2**  
**of 11 May 2000**

**Appellant:** Colgate-Palmolive Company  
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**Representative:** van Gennip, Johannes Simeon Wilhelmus  
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**Respondent:** The Procter & Gamble Company  
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**Representative:** Brooks, Maxim Courtney  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 29 April 1996  
revoking European patent No. 0 405 682 pursuant  
to Article 102(1) EPC.

**Composition of the Board:**

**Chairman:** P. A. M. Lançon  
**Members:** C. Germinario  
R. E. Teschemacher

## Summary of Facts and Submissions

- I. European patent No. 0 405 682 was granted pursuant to European patent application No. 90 201 676.5 on the basis of a set of 7 claims for all the designated Contracting States.

The text of granted claim 1 reads:

*"The use of a combination of 10-20% xylitol, based on the total composition, and at least one fluoride ion-providing compound in a total amount sufficient to provide 150-1800 ppm of fluoride ions, with sodium fluoride providing a predominant proportion of such a fluoride ions, in the manufacture of a non-astringent dentifrice or mouth wash for providing an improved remineralizing effect."*

- II. Notice of opposition was filed by the respondent, requesting revocation of the patent under Article 100(a) EPC on the grounds of lack of novelty and inventive step and Article 100(b) on the ground of insufficiency of disclosure.

The following documents were cited, *inter alia*, during the proceedings before the opposition division:

- (2) US-A-3 932 604,
- (4) EP-A-0 251 146,
- (5) EP-A-0 138 705,

- (7) Factors Relating to Demineralisation and Remineralisation of the Teeth - Proceedings of a Workshop 5-10 October, 1985, Antalya, Turkey; Ed. S.A. Leach, IRL PRESS, Oxford, Washington: "In vivo remineralisation of shallow enamel lesions under the influence of xylitol and fluoride containing toothpastes", pages 153 to 161.

III. The opposition division held that the invention of the patent in suit was disclosed in a manner sufficiently clear and complete for it to be carried out by the skilled person, and that the claimed subject-matter was novel over the teaching in documents (2) and (4) which although describing dentifrices and oral compositions comprising xylitol and fluoride-ions, did not disclose the remineralising effect caused by these compounds.

In assessing whether the claimed invention involved an inventive step, the opposition division indicated document (7) as the closest prior art, since this document already disclosed xylitol- and fluoride-containing tooth-pastes having a remineralising effect on tooth enamel. Moreover, the skilled person would have found the necessary information as to the claimed amounts of the two compounds in other documents, such as document (5), which already anticipated a synergistic effect of xylitol and fluoride in anti-caries compositions.

The opposition division therefore held that the claimed subject-matter did not involve an inventive step.

IV. The appellant lodged an appeal against this decision, and produced with the statement setting out the grounds of appeal two affidavits from a Mr Moreno and a Mr Gaffar. With a further letter of 11 April 2000, it filed a new set of claims, as auxiliary request, wherein claim 1 and 2 as granted were incorporated in a new claim 1.

Oral proceedings were held on 11 May 2000.

V. The appellant argued that, with the exception of document (7), none of the other prior documents disclosed the remineralising effect of the combination xylitol-fluoride ions, therefore none of them could be prejudicial to the novelty or inventive step involved in the claimed subject-matter. On the other hand, document (7) taught that the changes in enamel hardness and fluoride content in the surface enamel of teeth treated with different dentifrices were not significantly affected by the presence of xylitol and/or fluoride in such compositions. Therefore document (7), because the amount of xylitol used was too high, failed to recognise any synergistic remineralising effect of xylitol and fluoride, the effect which, by contrast, was at the basis of the invention in issue. To stress this aspect of the invention, it also suggested replacing the word "improved", referring to "remineralising effect" in claim 1, with the word "synergistic".

VI. The respondent raised in writing and during the oral proceedings objections against the sufficiency of disclosure of the invention, novelty and inventive activity involved in the claimed subject-matter. In the respondent's contentions, the wording of claim 1

implied that a net remineralising effect was achieved. As a matter of fact, however, remineralisation and demineralisation were in equilibrium, therefore no net remineralisation was possible without a concomitant prevention of demineralisation. Moreover, the method used for assessing the amount of remineralisation implied such a high inherent variability that the results illustrated in example 2 of the patent could not be considered as significant and were therefore unable to show that the desired effect was actually achieved.

VII. The appellant requested that the decision under appeal be set aside and the patent be maintained as granted. Alternatively, it requested that the patent be maintained on the basis of the set of claims submitted as auxiliary request in the letter dated 11 April 2000. In addition, it declared its willingness to replace in claim 1, last line the word "improved" by "synergistic", if necessary. Furthermore, it objected to the introduction of the novelty and sufficiency of disclosure objections, since it was the sole appellant and the patent had been revoked because of lack of inventive step.

The respondent requested that the appeal be dismissed.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Scope of the examination of the appeal*

In respect of the respondent's objections to

sufficiency of disclosure and novelty, the appellant disputed the power of the board to decide on these grounds for opposition. The appellant argued that the opposition decision had decided in respect of these issues in its favour. If the respondent had intended to challenge the opposition division's position it should have filed a separate appeal. The respondent's failure to do so had the consequence that only the question of inventive step was at issue in the appeal proceedings.

The board cannot agree with this opinion. Under Article 107, first sentence, EPC a party can only appeal if it is adversely affected by the decision of the first instance. A party is adversely affected if a decision does not accede to its requests (J 12/85, OJ EPO 1986, 155). In the present case the patent was revoked in accordance with the respondent's request. Therefore, the respondent was not in a position to file an appeal.

The principle of *reformatio in peius* invoked by the appellant is not to be construed to apply separately to each issue which was the subject of the decision of the opposition division. Rather, the board has to examine pursuant to Article 111(1) and 102(1) EPC whether the grounds for opposition on which the decision under appeal was based prejudice the maintenance of the patent (G 9/91, OJ EPO 1993, 408, Reasons, point 18; T 401/95, dated 28 January 1999, not published). Since the objections to sufficiency of disclosure and novelty were introduced in the proceedings before the department of first instance they are also a subject of these appeal proceedings.

*Main request*



3. Article 83 EPC

In the Board's view, it is indisputable that a skilled person would be able to prepare a dentifrice or a mouth wash comprising xylitol and at least one fluoride ion-providing compound in the claimed amounts. As to the "improved remineralising effect" cited in the claim as an essential result to be achieved, the Board considers that the word "improved" is meaningless in the specific context, since no comparative term is stated in the claim. For this reason, the qualification "improved" is immaterial in assessing the repeatability of the invention. Moreover, the fact that a remineralising effect is actually produced by a mouth wash according to the invention, is shown by the results illustrated in example 2. On the basis of these results, it is reasonable to expect that not only a mouth wash but also a dentifrice according to the invention would be able to cause at least some degree of tooth remineralisation. On the other hand, the respondent, although objecting to the repeatability of the invention, failed to produce any evidence convincing the Board that the invention, as claimed, could not be realized by the skilled person.

For these reasons, the Board concurs with the opinion of the opposition division that the disclosure of the invention meets the requirements of Article 83 EPC.

4. *Novelty*

Among the many prior art documents cited during the opposition proceedings, only document (2) relates to dentifrices containing both xylitol and a fluoride ion providing compound ( $\text{Na}_2\text{PO}_3\text{F}$ ), in the claimed amounts,

(see the table at the bottom of column 2 and examples I, II and III). The object of document (2) is to provide a non-cariogenic dentifrice for use in oral hygiene (see column 1, lines 37 and 38).

In view of the fact that document (2) already discloses the use of xylitol and fluoride for the manufacture of a dentifrice having anti-caries activity, the Board is called upon to decide whether the remineralising effect cited in claim 1 under consideration can be recognised on its own as a second therapeutic indication, of the known combination of substances, with respect to the caries-preventing activity disclosed in document (2).

Although the prevention of caries remains indeed the main scope of the remineralisation of tooth enamel, as pointed out by the appellant at the oral proceedings, the patent description states, on page 2, lines 15 and 16, that "By remineralisation, pre-existing tooth decay and caries can be reduced or eliminated...". The respective reference to "tooth decay" and "caries" indicates that the two expressions are not synonyms and that they identify different and not necessarily overlapping situations. This is evident in view of the considerations that even a sound enamel may be hardened by remineralisation and that a hardened enamel exhibits improved resistance to acid attack and to mechanical shocks as argued by the appellant during the oral proceedings.

On this basis, it may be accepted for the purpose of this decision that claim 1 is directed to a second therapeutic application of the combination of xylitol and fluoride in the given amounts.

No other cited prior document calls into question the novelty of the subject-matter of claim 1, either because different amounts of xylitol or fluoride are cited (see documents (5) or (7)) or because the disclosed composition also comprises astringent substances which are excluded from the scope of claim 1 (see document (4)).

In view of the foregoing, the Board holds that the subject-matter of claim 1, and accordingly claims 2 to 7, is novel.

5. *Inventive step*

5.1 Document (7) was indicated by the opposition division and by the parties as the closest prior art. The Board shares this opinion, since (7) is the sole document expressly referring to the remineralising effect on tooth enamel.

This document investigates the effect of xylitol and/or fluoride ion containing tooth pastes on the remineralisation of softened and sound enamel in vivo. Four identical base-pastes additionally comprising respectively 35% glycerine (composition G), 35% xylitol (composition X), 35% glycerine plus 500 ppm F (composition GF), or 35% xylitol plus 500 ppm F (composition XF) were compared for their remineralizing and fluoridating effect. In fact the scope of the investigation was to assess the extent to which the different compositions of the tooth pastes could influence the remineralisation of teeth. However, as clearly recognised by the authors and as is evident from the results reported in table II and III and figures 1 to 3, no significant difference between the

enamel hardness or fluoride content of the four toothpaste groups could be found.

The Board does not dispute the authors' conclusions, but needs to stress that the scope of the experimentation reported in (7) was not that of investigating the very existence of a remineralising effect caused by a toothpaste. This effect was already known before the publication date of document (7), as acknowledged by its authors in the sentence: "Extensive remineralisation of the surface softened enamel has been reported within four weeks when a 1500 ppm fluoride containing toothpaste was used" (see "Discussion"). Not only is the occurrence of this effect not called into question by document (7), but, on the contrary, it is fully confirmed by the experimental results it describes. On the basis of these results, specifically those reported in table II and illustrated in figure 1, the authors conclude that "surface softened enamel can be remineralised almost completely in vivo if the enamel is brushed twice a day with a toothpaste", including any of those they studied. (see Discussion", second full paragraph). Therefore, document (7) clearly teaches that the dentifrice containing 35% xylitol and 500 ppm fluoride-ions exhibited a significant remineralising effect on tooth enamel, although this effect was not meaningfully greater than that observed when brushing the teeth with any of the other base pastes.

- 5.2 Although the existence of an advantage over the prior art is not a necessary condition under the EPC for assessing the inventive step of the claimed subject-matter, any advantage over the closest prior art is normally taken into account in formulating the

technical problem to be solved by the invention.

At the oral proceedings, the appellant argued that the net remineralising effect showed by the compositions of the patent in suit was significantly higher than the one produced by any one of the compositions of document (7).

The Board cannot share this opinion. In fact, the level of remineralisation reported in (7) is determined by the enamel hardness measurement based on the mean indentation length and by the fluoride content in the different layers of the enamel measured with a fluoride electrode. According to the present invention, the remineralisation values reported in example 2 have been measured with the method described by Mellberg et al. based on microdensitometric scans of an enamel sandwich. It is evident to the Board that no meaningful comparison may be made between data obtained by markedly different analytical methods.

If nevertheless the Board were to accept that a comparison between the results reported in example 2 of the patent and in document (7) could make any sense, it remains the fact that such a comparison would not justify the recognition of any significant improvement in the case of the patent in suit. Example 2 of the patent reports, in the case of the mouthwash comprising xylitol and fluoride, a remineralisation effect of 17%. The Board considers that this result is not statistically different from the remineralisation value derivable from either the decrease in indentation length illustrated in table II and figure 1 or the increase of fluoride content illustrated in table III and figure 2 of document (7) for the xylitol-fluoride

paste.

On the basis of these facts and in the absence of any reliable comparative test, it must be concluded that the remineralising effect of the composition of the patent in suit is essentially the same as the effect reported in the closest prior art document.

- 5.3 Therefore the technical problem to be solved by the present invention as against document (7) is to provide alternative means for remineralising tooth enamel.

The solution proposed by the patent is the use of the combination of at least one fluoride-ion providing compound and xylitol for the manufacture of a non-astringent dentifrice or mouth wash in which xylitol is present in an amount ranging from 5% to 20%.

- 5.4 As discussed above, document (7) discloses the remineralising effect exhibited by a dentifrice comprising 500 ppm of fluoride ions (NaF) and 35% xylitol, which is an amount higher than that used in the present invention.

In assessing whether the sole feature imparting novelty to the claimed subject-matter (ie the lower xylitol amount) is obviously derivable from the prior art, it must be kept in mind that the closest prior art, document (7), is a piece of scientific literature intended to investigate the capability of specific compositions to remineralise the teeth. More specifically, the purpose of this document is to elucidate whether or not the presence, in given amounts, of certain components in the dentifrices investigated could influence the level of

remineralisation. However, there is in (7) neither any teaching about the relationship between the remineralising effect and the concentration of each component nor any intention to define ranges of concentration within which the reported results would be maintained. This aspect was simply not considered by the authors of (7).

In the Board's opinion, it is within the competence of the skilled person, in an attempt to reduce to practice the technical teaching supplied in scientific literature, to introduce minor experimental modifications, which are not expected to affect the desired results but which may be justified by purely practical considerations such as the economics of reducing the technical teaching into practice or the safety of the finished product. Determining the lowest amounts of a used substance which still achieves the desired effect is indeed one of those activities which the skilled person usually performs without inventive effort.

In this activity, the skilled person would have been unambiguously assisted by the knowledge that a lower xylitol amount was in line with the known use of xylitol in the dentifrices and other dental compositions as showed in many prior documents, such as (2), (4) or (5). In document (2), three examples out of a total of five indicate amounts of xylitol of 10% or less. In document (4) the xylitol amount ranges from 0.1% to 10% and, in document (5), the preferred amount is 10% to 25% with all the examples citing 20% or less.

From the foregoing, the Board concludes that the feature imparting novelty to the claimed subject-matter

was obviously derived from the prior art.

- 5.5 In writing and during the oral proceedings, the appellant relied strongly on the results reported in example 2, which evidenced a synergistic effect between xylitol (20%) and fluoride in the remineralisation of enamel. In the appellant's contention, no synergistic effect occurred in (7), since in that case the amount of xylitol used was too high.

The Board, although recognising the results reported in example 2, wishes to underline that no convincing arguments or results have been produced by the appellant to make it even plausible that the synergistic effect of xylitol and fluoride is actually due to or depends on the claimed percentage of xylitol, and thus that a functional relationship does exist between the feature imparting novelty to the claimed subject matter and the effect invoked by the appellant to support an inventive step.

In fact, document (7) had already made it plain that, as was observed in the control-group, the action of brushing the teeth with a generic dentifrice-base caused a degree of remineralisation comparable to that obtained with a dentifrice comprising xylitol or fluoride or both. In other words, the contribution to the final effect of the simple use of a generic dentifrice-base would appear to be higher than the contribution of fluoride ions or xylitol taken alone. For this reason, no meaningful distinction between the different groups could be drawn. On the contrary, the synergistic effect reported in example 2 of the patent in suit was not observed by using a dentifrice but by using a mouthwash, thereby eliminating any effect due



to the use of a dentifrice. It follows that example 2 does not provide any conclusive evidence that the synergistic effect reported in the patent could still be observed once xylitol and fluoride ions were formulated into a dentifrice according to claim 1. Nor has any evidence been produced that such a synergistic effect is not implicit in any xylitol-fluoride ion combination, comprising the tooth paste of document (7).

Finally, a comparative test, on which an appellant may wish to rely to show an inventive step, can only be meaningful if it compares the invention with the closest prior art. In the present case, the compositions used in example 2 for comparison (ie xylitol or fluoride taken alone) simply do not represent the closest prior art. That is represented by the composition of document (7) which already comprised both xylitol and fluoride ions. The final net remineralising effect of the compositions of the invention and the closest prior art is the only decisive factor in assessing the inventive step of the claimed subject matter. How this effect is obtained, and whether any possible synergistic relationship between the components of each composition may contribute to the achievement of that final net effect, is completely irrelevant to the assessment of inventive step.

For this reason also the replacement of the expression "improved remineralising effect" in the text of claim 1 by "synergistic remineralising effect", as proposed by the appellant during the oral proceedings, could have no influence on the final outcome of the proceedings.

5.6 In view of all these arguments, the Board holds that the subject-matter of claim 1 does not involve an inventive step.

6. *Auxiliary request*

According to claim 1 of the auxiliary request, sodium fluoride is the sole fluoride-ion providing compound in the dentifrice or mouthwash as used.

The amendment results from the incorporation of granted claim 2 into granted claim 1. The Board is satisfied that the amended claim does not contravene the requirements of Article 123(2) and (3) EPC.

Since the compositions of the closest prior art, document (7), already comprised sodium fluoride as the sole fluoride ion providing compound, the amendment does not change the findings of the Board in relation to the main request. The view of the Board is therefore that the subject-matter of claim 1 in the amended form does not involve an inventive step.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman

M. Dainese

P. A. M. Lançon