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**D E C I S I O N**  
of 16 January 2002

**Case Number:** T 0286/97 - 3.3.7

**Application Number:** 87306049.5

**Publication Number:** 0254452

**IPC:** A61K 7/16

**Language of the proceedings:** EN

**Title of invention:**  
Oral composition

**Patentee:**  
LION CORPORATION

**Opponent:**  
SmithKline Beecham plc

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 56

**Keyword:**  
"Inventive step - problem and solution - non-obvious  
combination of known features"

**Decisions cited:**  
T 0219/83

**Catchword:**  
-



Case Number: T 0286/97- 3.3.7

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.7  
of 16 January 2002

**Appellant:**  
(Opponent)

SmithKline Beecham plc  
New Horizons Court  
Great West Road  
Brentford  
Middlesex TW8 9ET (GB)

**Representative:**

Reeves, Julie Frances  
SmithKline Beecham plc  
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**Respondent:**  
(Proprietor of the patent)

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**Representative:**

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**Decision under appeal:** Decision of the Opposition Division of the European Patent Office posted 13 January 1997 rejecting the opposition filed against European patent No. 0 254 452 pursuant to Article 102(2) EPC.

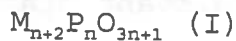
**Composition of the Board:**

**Chairman:** R. E. Teschemacher  
**Members:** B. J. M. Struif  
B. L. ter Laan

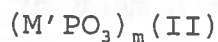
## Summary of Facts and Submissions

- I. European patent No. 0 254 452 in respect of European patent application No. 87 306 049.5, filed on 8 July 1987, was granted on the basis of three claims, claim 1 reading as follows:

"A dentifrice comprising (i) 0.1% to 10% by weight, based on the total amount of the dentifrice, of at least one polyphosphate selected from either linear polyphosphates of the formula (I):



wherein M represents Na or K and  $3 \leq n$ , excluding insoluble sodium metaphosphate, or cyclic polyphosphates having the formula (II):



wherein M' represents Na or K and  $m = 3, 4$  or  $6$  and (ii) 0.01% to 2% by weight, based on the total amount of the dentifrice, of anethol in an aqueous medium".

Claims 2 and 3 were dependent on claim 1.

- II. A notice of opposition was filed against the granted patent, in which the revocation of the patent in its entirety was requested on the grounds of Article 100(a) EPC with respect to lack of novelty and inventive step. The opposition was *inter alia* supported by the following documents:

D1: DE-A-35 26 654

R1: FR-A-2 130 275 (cited after the nine months opposition period but admitted into the proceedings by the opposition division).

Additionally, the patentee, with a letter dated 3 April 1995, and the opponent, with a letter dated 18 April 1996, each submitted a test report.

III. The opposition division rejected the opposition and decided that the patent could be maintained as granted. The decision can be summarized as follows:

- (a) Claim 1 was regarded as novel, in particular over D1.
- (b) D1 and R1 were considered as relevant state of the art. The problem underlying the patent in suit vis-à-vis D1 was seen as to provide a dentifrice having an excellent antibacterial effect, effectively preventing the development of dental calculus and periodontal diseases. It was solved by a specific combination of polyphosphates and anethol.

Although the opponent's tests showed a high antibacterial activity of anethol alone, and conflicted in this respect with the data of the patent in suit, all test results present showed a strong antibacterial and/or anticalculus activity for the claimed combination and could be regarded as evidence that the problem had been solved.

Neither D1 nor any of the further cited prior art documents suggested the combination of polyphosphates and anethol in a dentifrice composition for providing the specific technical effect, so that the claimed subject-matter also involved an inventive step.

IV. The opponent (appellant) filed a notice of appeal against the above decision. With the statement of the grounds of appeal the appellant submitted a second test report allegedly carried out by a third party (Prof.

David Beighton from Kings College Dental School in London), but not provided with any declaration or signature of that third party.

V. Oral proceedings were held on 16 January 2002 in the absence of the appellant (Rule 71(2) EPC), who had announced in writing that he would not attend.

VI. The appellant's written arguments only concerned inventive step:

According to R1, soluble polyphosphates had an antimicrobial effect and were active in the inhibition of plaque and dental calculus. Such materials were also used in D1, which furthermore mentioned anethol as a flavouring agent. Thus, the claimed dentifrice composition included two known ingredients, which combination could not be inventive since no surprising or synergistic effect had been shown. This was supported by the appellant's two test reports which were based on two different measuring methods, one of which was also used in the patent in suit.

Furthermore, whilst claim 1 of the patent in suit related to any dentifrice composition for any use, the alleged inventive step was only based on an antibacterial activity against *Actinomyces viscosus*. As *Actinomyces viscosus* was only one of many bacterial species making up plaque, the claims should be restricted to the inhibition of *Actinomyces viscosus* in a use-type of claim.

VII. The arguments of the respondent (patentee), given in writing and at the oral proceedings can be summarized as follows:

As to inventive step, the nearest prior art was R1, which referred to the antibacterial effect of polyphosphates to inhibit the formation of dental plaque and calculus. Thus, the problem of the patent in suit was to improve the antibacterial effect, which problem was solved by the claimed combination, as shown by the respondent's consistent experimental evidence. Having regard to the antibacterial effect of anethol alone, the appellant's test data were contradictory in themselves. In case of conflicting evidence the benefit of the doubt should be given to the patentee.

As to the appellant's request to restrict the claims to use-claims, the respondent was entitled to its claims as long as the claimed composition effectively solved the problem posed. Since *Actinomyces viscosus* played a major role in calculus formation, its efficient inhibition supported the present claims.

VIII. The appellant had requested in writing that the decision under appeal be set aside and that European patent No. 0 254 452 be revoked, or, alternatively, be restricted to the inhibition of *Actinomyces viscosus* in a use-type of claim.

IX. The respondent requested that the appeal be dismissed and that the patent be maintained as granted, or, alternatively, on the basis of one of the four auxiliary requests as indicated in the letter dated 14 November 1997.

## Reasons for the Decision

1. The appeal is admissible.

### *Novelty*

2. Novelty was not an issue in appeal and the board sees no reason to deviate from the decision of the opposition division in this respect.

### *Closest prior art document*

3. The patent in suit concerns an oral composition in the form of a dentifrice.
  - 3.1 The appellant and the opposition division referred to D1 as the closest prior art, whilst the arguments of the respondent started from R1.
  - 3.2 D1 describes an oral composition for preventing and remedying dentinal hypersensitivity, comprising aluminum and a carboxylate compound in a solubilized state, in which the molar ratio of the carboxylate compound to aluminum is lower than 6 and the pH of the composition is higher than 5 (claim 1). When the enamel or cement of a tooth is lost, external stimuli applied to the surface of the exposed dentin cause the fluid in the dentinal tubuli to flow, thereby exciting the sensory nerve, which causes pain (page 6, lines 15 to 19). Thus, D1 aims at providing an oral composition which is effective for the occlusion of the tubular orifices and effectively prevents and remedies dentinal hypersensitivity, which is simple to apply and which does not cause damaging or staining of the teeth (page 9, lines 19 to 26).

According to D1, the composition may be used in the form of a toothpaste, toothpowder, ointment (liquid or gel), mouthwash, dental floss, oral band etc. (page 10, lines 19 to 22). It may, apart from the aluminum and carboxylate compounds in their solubilized state, also contain a water-soluble phosphoric acid compound. These compounds enhance the prevention and remedy of dentinal hypersensitivity (page 12, lines 10 to 14). They may include e.g. tripolyphosphoric acid, hexametaphosphoric acid or their sodium or potassium salts alone or in combination and are present in their solubilized form. The amount of soluble phosphoric acid compound lies in the range of 0.01 to 10% by weight of the composition (page 12, lines 16 to 26; pages 26 and 27, tables 2 and 3). The oral composition preferably further comprises a flavour to reduce the metallic and astringent taste of the soluble aluminum compound, in particular 1-menthol. Other flavours are also mentioned, including anethol in an amount of 0.001 to 3% by weight (page 20, lines 28 to 34 and page 21 lines 26 to 34). The composition may also contain an abrasive agent as a further component, such as insoluble sodium metaphosphate (page 13, lines 17 to 27, in particular line 24). In example 11 (page 42), 1-menthol and anethol are used in combination with insoluble sodium metaphosphate.

- 3.3 R1 discloses a composition for reducing the risk of dental caries comprising a tensio-active compound for inhibiting the formation of dextrane in the mouth, and/or an antimicrobial compound selected from the group of sodium tripolyphosphate, sodium hexametaphosphate, FD & C Red No. 3, hop extract resins, and certain L-lysine derivatives (claim 1). The composition may contain an amount of about 0.1 to 10 weight percent of the tensio-active compound (claim 3) and an amount of 0.002 to 5% by weight of the antimicrobial compound (claim 4).



According to R1, cariogenic organisms, in particular salivary streptococci, have a special capability of developing a water-insoluble dextrane from saccharose, which dextrane is believed to be a major constituent of the dental plaque normally associated with caries (page 1, lines 6 to 16). R1 aims at providing a composition which is effective in preventing caries (page 1, line 40 to page 2, line 2), containing compounds that have an antimicrobial effect against cariogenic streptococci (page 2, lines 2 and 3). In the examples, the use of various concentrations of sodium tripolyphosphate and sodium hexametaphosphate is shown (tables 1 to 4).

- 3.4 According to the patent in suit, calculus is a hard deposit, having a high inorganic content, formed on the surfaces of teeth, and is believed to be a major cause of the development of gingivitis and periodontitis. The formation of calculus is considered to be caused by the deposition of amorphous or microcrystalline calcium phosphate on membraneous portions of bacteria or the substances between bacteria in the plaque, which gradually becomes dense and changes to hydroxyapatite. It is known that the main bacteria forming organic matrices in old plaque or in plaques in gingival sulcus, in which the above-mentioned calcification occurs, are filamentous bacteria or rod-shaped bacteria belonging to *Actinomyces*, *Leptotrichia*, *Bacteroides* and *Fusobacterium*. Accordingly, inhibition of the growth of these bacteria would effectively suppress the formation of calculus, and thus prevent the development of periodontal diseases (page 2, lines 5 to 17). Thus, the problem of the patent in suit is directed to the development of a dentifrice having an excellent calculus preventive effect or an effective antibacterial action against filamentous bacteria (page 2, lines 52 to 54).

3.5 As can be seen from the above, D1 mentions polyphosphates and anethol as optional components of an oral composition and refers to the ability of preventing and remedying dentinal hypersensitivity, but it is not related to the problem posed or the purpose aimed at in the patent in suit. On the other hand, R1 mentions the antibacterial effect of certain soluble polyphosphates, thus inhibiting or reducing the formation of dental plaque. Although D1 contains more features in common with the composition according to the patent in suit than R1, the antimicrobial effect of the polyphosphates described in the latter is more related to the problem of the development of calculus and periodontal diseases, to which the patent in suit seeks to provide a solution.

3.6 Since a proper starting point for assessing inventive step should correspond to the same or a similar technical problem as the patent in suit, requiring the minimum of structural and functional modifications (cf. Case Law of the Boards of Appeal of the European Patent Office, 3rd Edition 1998, I.D.3.1), the board considers R1 as the closest state of the art.

*Problem and solution*

4. Although the polyphosphates in R1 are said to have an antimicrobial effect leading to the reduction of plaque formation, the inhibition of calculus formation and bacterial growth could still be improved. Therefore, the problem to be solved can be seen in providing a dentifrice which has an improved calculus preventive effect or a more effective antibacterial action against filamentous bacteria responsible for the formation of calculus, in line with the patent specification (page 2, lines 52 to 54).

4.1 According to the patent in suit, this problem is solved by a dentifrice composition comprising anethol in an amount of 0.01% to 2% by weight and a specified polyphosphate in an amount of 0.1 to 10% by weight, as defined in claim 1.

4.2 In the examples of the patent in suit a culture media containing 0.04% sodium tripolyphosphate, sodium tetrapolyphosphate and sodium metaphosphate ( $\text{Na}_{n+2}\text{P}_n\text{O}_{3n+1}$ ,  $n = 40$  and  $128$ ) and 0.03% of anethol was inoculated with *Actinomyces viscosus* 19246 and incubated at a temperature of 37°C for 2 days under anaerobic conditions. The degree of the bacterial growth was monitored by measuring the optical density (OD) at 550 nm.

Table 1 of the patent in suit shows the antibacterial effect of five different sodium polyphosphates in the absence as well in the presence of anethol, compared to a sample containing neither of the compounds. The latter sample has an OD of 0.85. The OD values in the presence of the polyphosphate compounds vary from 0.52 to 0.78. The OD in the presence of anethol alone is 0.74, whereas the values in the presence of both anethol and a polyphosphate compound vary from 0.06 to 0.46. In all tested combinations of table 1 the calculated sum of the individual antibacterial effects of anethol and of the polyphosphate is consistently less than that measured when the components are used in combination. Thus, a synergistic effect of the claimed combination for *Actinomyces viscosus*, which belong to the filamentous bacteria, has convincingly been demonstrated in the patent in suit.

4.3 The in-vitro experiments of the appellant cannot discredit the results of the patent in suit. The test report filed during the proceedings before the opposition division shows a comparison of the

antibacterial effect based on conditions similar to those of the patent in suit, but apart from the measurement of optical density ( $OD_{540}$ ), also using a measurement based on the total viable counts (TVC). The experimental results based on the OD method show an improvement over the control experiment for the polyphosphate compounds without anethol. The effect of the combined use of anethol and polyphosphate compound shows the same tendency of a strong antibacterial effect as in the patent in suit. That tendency was also confirmed by the TVC-measurements.

However, according to the above mentioned test report, the antimicrobial effect of anethol alone, measured with the OD method (table page 2, first line) is considerably greater than the effect obtained according to the patent in suit. This result is confirmed by the measurement based on the TVC method (table page 3, first line) and is probably the reason why no synergistic effect is shown in the appellant's first test report - with the exception of a slight (synergistic) effect for the combination of anethol with sodium tetrapolyphosphate (tables pages 2 and 3) or with sodium metaphosphate (n=150, table page 3).

- 4.4 Whereas according to the appellant's first test report the antimicrobial effect of anethol by itself was considerable, the appellant's additional experimental results of the second test report show only a slight or no antibacterial effect of anethol by itself against several *Actinomyces species* (tables page 5), which is in line with the results of the patent in suit. Accordingly, in the second test report, the appellant himself describes the effect of anethol alone as "very slight" and confirms that "these results are in line with Lion's (patentee's) results" (page 5, paragraph at the bottom).

Therefore, the second test report raises doubts as regards the correctness of the measured antibacterial effect of anethol alone in the appellant's first test report. Since the results of both of the appellant's test reports would not appear to be in conformity with each other and the first test report would rather support the data of the patent in suit, the synergistic effect cannot be questioned on the basis of the two test reports filed by the appellant.

4.5 The appellant also stated that the OD measuring method does not provide reliable results when compared with the measuring method based on total viable counts (TVC). However, no reasons or explanations are given why the latter measurements would be more reliable than the former ones. Not only would the measuring method based on optical density appear to be an appropriate standard method to determine the growth of the microorganisms - as demonstrated by Figure 1 of "Dentistry Microbiology", 4th edition page 43, 15th April 1986 and Figure 2, page 43 of "Essentially Microbiology", published 30th January 1989 (first edition published 1 April 1983) both submitted with the respondent's letter of 2 September 1996 -, but also both measuring methods appear to be consistent with each other.

4.6 Consequently, since (a) the appellant's argument is not supported by the totality of its own experimental data available in the proceedings and (b) the OD method has not been shown to be unreliable, the argument of the appellant that no synergistic effect had been demonstrated, must fail.

4.7 The appellant further argued that the claimed dentifrice composition only showed an antibacterial activity against *Actinomyces viscosus* and did not solve the problem in its entirety.

However, the respondent, in its letter of 3 April 1995 in which in vivo experiments on rats were described, has shown that a dentifrice according to example 1 of the patent in suit was more effective in calculus prevention (31%) than the same dentifrice without anethol (18%) or without either anethol and tripolyphosphate (4%). Therefore, it has been shown that the claimed combination effectively reduces the formation of dental calculus even if no data for the anticalculus effect of anethol alone has been presented.

4.8 Moreover, the appellant has filed no evidence of its own to show that the problem posed would not be solved in its entirety. The onus of proof in this respect lies, however, with the opponent (appellant), which he has failed to discharge (T 219/83, OJ EPO 1986, 211).

4.9 For the above reasons, the board comes to the conclusion that the claimed composition provides an effective solution to the above-defined technical problem.

*Inventive step*

5. It remains to be decided whether the claimed subject-matter is obvious having regard to the documents on file.

5.1 R1 teaches that tripolyphosphate and hexametaphosphate have a considerable antimicrobial effect and can be used to inhibit the formation of dextrane and the development of plaque. However, this document does not mention anethol. Thus, there is no suggestion in R1 that anethol in combination with polyphosphate would enhance the antibacterial effect and hence reduce the

formation of dental calculus or periodontal diseases. Therefore, the claimed subject-matter is not rendered obvious by R1 alone.

5.2 The teaching of D1 relates to an oral composition for preventing dentinal hypersensitivity without damaging or staining the teeth, which comprises a combination of aluminum with a carboxylate. The flavour component anethol and the soluble polyphosphates mentioned in D1 are only optional components and are furthermore referred to in two lists of a certain length (page 12, lines 16 to 20 and page 21, lines 26 to 29). As the antibacterial effect and the prevention of dental calculus are not mentioned in D1, it contains no incentive to select the specific combination as claimed from the lists of optional components with a view to solving the above-defined problem. Therefore, a combination of D1 with R1 would not be evident but even if these two documents would be combined, such a combination would not lead to the present combination of features.

As the other documents cited during the proceedings are more remote, a combination of one or more of these documents with R1 does not render the claimed subject matter obvious either.

5.3 In as much as the solution of the technical problem according to claim 1 does not arise in an obvious way when considering R1 and D1 in combination, the same arguments apply if D1 instead of R1 were to be chosen as the closest prior art document and the same conclusion would be reached.

5.4 For the above reasons, the claimed subject matter as granted involves an inventive step.

6. The appellant requested that the patent be restricted to the inhibition of *Actinomyces viscosus* in a use type of claim. However, the boards can only consider a text submitted to it, or agreed, by the proprietor of the patent (Article 113(2) EPC). Thus, only the proprietor (respondent) is entitled to request such amendments to the claims. Since the grounds for opposition as submitted by the appellant do not prejudice the maintenance of the patent as granted, the appeal must be dismissed.

### Order

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


The appeal is dismissed.

The Registrar:

  
C. Eickhoff



The Chairman:

  
R. Teschemacher