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D E C I S I O N
of 28 September 2000

Case Number: T 0337/96 - 3.3.2

Application Number: 90304950.0

Publication Number: 0397452

IPC: A61K 7/16

Language of the proceedings: EN

Title of invention:

Anti-calculus toothpaste compositions having improved shelf-like

Patentee:

Beecham Inc.

Opponent:

Henkel Kommanditgesellschaft auf Aktien

Headword:

Anti-calculus/BEECHAM

Relevant legal provisions:

EPC Art. 54, 56

Keyword:

"Novelty (yes): essential feature not defined in the prior document"

"Inventive step (no): obvious alternative composition"

Decisions cited:

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Catchword:

-



Case Number: T 0337/96 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 28 September 2000

Appellant: Henkel
(Opponent) Kommanditgesellschaft auf Aktien
TFP/Patentabteilung
D-40191 Düsseldorf (DE)

Representative: -

Respondent: Beecham Inc.
(Proprietor of the patent) One Franklin Plaza
Philadelphia
PA 19101 (US)

Representative: Reeves, Julie Frances
SmithKline Beecham plc
Corporate Intellectual Property
Two New Horizons Court
Brentford
Middlesex TW8 9EP (GB)

Decision under appeal: Interlocutory decision of the Opposition Division
of the European Patent Office posted 20 March
1996 concerning maintenance of European patent
No. 0 397 452 in amended form.

Composition of the Board:

Chairman: P. A. M. Lançon
Members: C. Germinario
C. Rennie-Smith

Summary of Facts and Submissions

- I. European patent No. 397 452, based on application No. 90 304 950.0 was granted on the basis of two different sets of 12 claims, one set for the contracting states AT, DE, DK, LU, NL and SE and the other set for the contracting state ES.
- II. An opposition was filed by the Appellant under Article 100(a) EPC on the ground of lack of novelty and lack of inventive step.

The following documents were cited during the proceedings before the Opposition Division:

(2): US-A-4 627 977

(4): EP-A-0 295 116

(5): EP-A-0 236 290

(7): Die Chemie, 55 (1942), pages 356-359

- III. In its interlocutory decision of 5 March 1996, posted on 20 March 1996, the Opposition Division maintained the patent under Article 102(3) EPC on the basis of the claims of the main request of 2 February 1996 as further amended during the oral proceedings before it.

Claim 1 for the contracting states AT, DE, DK, LU, NL and SE reads as follows:

"A toothpaste composition which comprises: an anti-calculus agent comprising at least 4% by weight, based on the total weight of the toothpaste, of a water-

soluble alkali metal tripolyphosphate salt; a phosphatase enzyme inhibitor comprising a fluoride ion source, a silica dental abrasive as the sole abrasive and an orally acceptable vehicle; the toothpaste having a pH of from 8 to 10."

Claim 1 for the contracting state ES relates to a method for preparing said toothpaste composition.

Claim 6 was also amended by replacing "diphenyl ether" by "compound" in order to remove an inconsistency between the term "diphenyl ether" and the same compound as defined in the claim by way of its chemical formula. The Opposition Division took the view that this change in the text of claim 6 was an allowable correction under Rule 88 EPC.

The Opposition Division held the subject-matter of claim 1 was novel over the cited documents because, as regards document (5), it did not disclose compositions in which silica was the sole abrasive agent, and as regards the other documents, they did not individualise the specific combination of ingredients, pH and amounts of claim 1 of the patent in suit.

The Opposition Division also found the claimed subject-matter involved an inventive step over document (5), which was regarded as the closest prior art. In particular, it recognised the improved stability of the compositions of the patent in suit and emphasised the unpredictable contribution of the silica in achieving this result.

IV. The Appellant (Opponent) lodged an appeal against this decision.

Oral proceedings were held before the board on 28 September 2000. During the oral proceedings, the Board intimated that, contrary to the view taken in the opposition proceedings, document (5) was not necessarily the closest prior art, and that document (2) could be seen as the closest prior art.

- V. In writing and during the oral proceedings, the appellant questioned the novelty of the claimed compositions over each of document (4) (Examples 5 and 6) and document (2) (Example 2C). Although recognising that in both cases the indication of the pH was missing, it argued that as the prior art compositions contained the same ingredients in the same percentages as the compositions of the patent in suit, there was no reason to suppose that their pH was not the same as in the claimed compositions.

The Appellant also argued that the claimed compositions lacked an inventive step over document (5), since that document actually suggested the use of silica as the abrasive agent, which was the sole point of novelty over the claimed invention. Also, the higher stability of the composition in the pH range of 8 to 10 could be easily derived by the skilled person from the teaching either of document (5) itself or of document (7).

- VI. On the question of novelty over documents (4) or (2), the Respondent (Patentee) stressed that the pH of the claimed toothpaste was determined by all its ingredients, therefore the Appellant's view as to the pH of the prior compositions was based on a mere unsupported allegation.

As to the inventive step, the Respondent emphasised

that both documents (2) and (5) suggested pH values of less than 8 as preferred. Therefore the skilled person was not encouraged to select a pH in the range 8 to 10 as claimed in claim 1.

However, it admitted during the oral proceedings that the technical problem underlying the invention, at least as against document (5), was not that of improving stability over the formulations of (5) by increasing the pH, but simply that of providing alternative stable toothpastes.

In addition to these arguments, the Respondent also stressed that document (5) envisaged the use of silica not as the sole abrasive in the composition but always in combination with calcium pyrophosphate.

As to document (7), the Respondent maintained that this document taught that low concentrations of polyphosphate gave greater stability and that, within a pH range of 7 to 10, no stability difference could be observed. This taught away from the presently claimed compositions showing a higher stability in the pH range of 8 to 10 combined with a concentration of polyphosphate of at least 4%.

VII. The Appellant requested that the decision under appeal be set aside and that the patent be revoked.

The Respondent requested that the appeal be dismissed and that the patent be maintained in the amended form approved by the Opposition Division.

Reasons for the Decision

1. The appeal is admissible.
2. Claim 1 (in both versions for different contracting states) was amended and claim 6 (again, in both versions) was corrected during the opposition proceedings. The board considers that these claims comply with the requirements of Article 123(2) and (3) and Rule 88 EPC. No objections in this regard have been prosecuted by the Appellant during appeal proceedings.

3. *Novelty*

The composition according to claim 1 is defined by way of its ingredients and, among other parameters, by way of its pH value that ranges from 8 to 10.

Example 2 of document (2) discloses a dentifrice composition containing sodium tripolyphosphate (STPP); see formulation C. Although this composition comprises all the ingredients of the toothpaste of claim 1, namely 5% of STPP, sodium fluoride as a fluoride ion source, silica as the sole abrasive (Syloid 244) and orally acceptable vehicles (see column 9, lines 22 to 23), its pH is not indicated. Nor has any attempt been made by the parties to reproduce the earlier composition which might have easily clarified the question of its pH. In these circumstances, the appellant's allegation that, given the components of the earlier formulation, its pH should be between 8 and 10 (as claimed in the patent), cannot be accepted by the Board as sufficient to deny the novelty of the claimed composition over formulation C of document (2).

During the oral proceedings, the Appellant also contested the novelty of claim 1 by reference to Examples 5 and 6 of document (4) which describe two compositions comprising STPP, sodium fluoride and a silica derivative in the same amounts as in the claimed toothpastes. However, in this case as well, the pH of the compositions is not given.

In view of the fact that these compositions additionally comprise zinc citrate which, as is well known, contributes to the determination of the pH value, the board considers that in absence of any experimental evidence it cannot be concluded that the pH of these compositions undoubtedly falls within the alkaline range required by claim 1 of the patent in suit.

Since for the purpose of novelty no other more pertinent document was cited, the Board concludes that the subject-matter of claim 1 is indeed novel.

4. *Inventive step*

- 4.1 Document (5) was considered by the parties and by the Opposition Division as the closest prior art.

Document (5) discloses toothpastes containing a tripolyphosphate salt as anti-calculus agent and calcium pyrophosphate as abrasive agent. Formulation C in Table 2 (Example 2) contains 5% of tripolyphosphate, a fluoride source and has a pH of 8.5; thus this composition differs from the presently claimed compositions only in that it comprises calcium pyrophosphate instead of silica as the abrasive agent.

Therefore, the essence of the present invention, when compared with document (5), if this document were taken as the closest prior art, would reside in the choice of a new abrasive agent. This interpretation would undermine the main aspect of the invention as disclosed in the filed application, namely the choice of a specific pH able to stabilise high concentrations of the anti-calculus agent.

A further important aspect is that document (5) reports the results of accelerated aging tests to evaluate the stability of the anticalculus agent. However, first, the testing method used there differs from that used to determine the stability of the composition of the patent in suit (see Example 6), so that no meaningful comparison between the stability of the claimed and prior compositions is actually possible. Second, Table 3 in document (5), which summarises the test results, contains at least one evident error, as was recognised by the Opposition Division, which means any interpretation of these results must be pure speculation.

For these reasons, the Board does not consider document (5) to be the closest prior art.

By comparison, document (2) concerns oral compositions, such as toothpastes, containing an anti-calculus agent. The scope of this invention is that of protecting that agent from de-activation caused by hydrolysis. This result is achieved by adding to a usual anticalculus composition comprising polyphosphate salts a linear polymeric polycarboxylate salt in association with a fluoride source. The composition of Example 2, formulation C, comprises 5% of sodium tripolyphosphate

as anti-calculus agent, a silica as abrasive and a fluoride source. Thus all the essential ingredients of the composition of claim 1 of the patent in suit are already present, including silica as the sole abrasive. No pH value is however indicated for this specific composition, although a pH of less than 8 is indicated as preferred in column 4, lines 48 to 54. Therefore, in the board's view and as already emphasised in relation to novelty, the pH represents the only difference between formulation C and the present invention.

The choice of document (2) as the closest prior art would acknowledge the importance of the pH factor as intended in the application as filed which specifically stressed the contribution of an alkaline pH to the stabilisation of the tripolyphosphates.

For these reasons the board considers that document (2) is indeed the closest prior art, since it represents a more realistic starting point in the assessment of the inventive step, if any, involved in the claimed subject-matter.

4.2 The technical problem

As seen above, document (2) gives a specific solution to the problem of the stability of tripolyphosphate containing compositions, namely the use of linear polycarboxylates and a fluoride source. No evidence exists and no argument was produced which could justify a conclusion of the board that the tripolyphosphate stability achieved via the invention of the patent in suit is higher than the stability obtained via the teaching of document (2). Since no improvement over the closest prior art can be taken into account, the

problem to be solved by the invention as against document (2) is therefore that of providing alternative stable toothpastes containing a relative high concentration of tripolyphosphate salt.

- 4.3 The solution suggested by claim 1 of the patent in suit consists in a composition having a pH between 8 and 10.

The examples provided in the patent, namely the aging test reported in the table of Example 6, show that a good stability is achieved when the pH is within the claimed ranges. In the light of this evidence, the board is satisfied that the technical problem has been solved by the claimed compositions.

- 4.4 Thus the question is whether it would have been obvious for the skilled person, seeking to prepare an alternative composition having a satisfactory stability, to consider the pH as the suitable factor and, having identified this factor, to consider the values from 8 to 10 as a suitable range.

Taking into account the fact that the active agent of the anti-calculus compositions in question is a polyphosphate salt, namely a tripolyphosphate salt, the skilled person would have considered first and foremost those factors known to have an influence on the stability of this active agent and would have avoided those modifications of the prior compositions which would obviously and predictably affect its stability.

The pH value is indeed one such factor strongly influencing the hydrolysis rate of polyphosphates, well known to the skilled person having been so reported in the scientific literature since at least 1942 (that is

the year of publication of document (7)). This document does not deal directly with toothpastes or other compositions but with the very basic chemistry of polyphosphates. However, the Board is satisfied that a basic knowledge of the chemical properties, and specifically the chemical stability, of the substance representing the most important ingredient of a composition forms a necessary part of the technical knowledge of any person skilled in the preparation and use of such compositions, all the more so if the chemistry of the substance in question is straightforward and, as here, such basic knowledge has been long-established. Therefore the skilled person would have considered the pH of the composition as a suitable candidate factor without exerting any inventive effort, not least because document (7) offered a detailed report on the influence of the pH on the hydrolysis rate of polyphosphates.

- 4.5 One of the polyphosphates studied in (7) is in fact sodium tripolyphosphate which is the active ingredient of the composition of the present invention (see (7) page 356, right-hand column, second paragraph).

Different passages of this document show that, when subjected to extreme experimental conditions of high temperature or a strongly acid environment, the tripolyphosphate is dramatically hydrolysed in a few hours. However, the stability at 100°C increases with the increase of the pH into the alkaline range until a maximum of stability is reached at pH 10 (85-90% recovery), and thereafter decreases again with further increase of the pH until 13 (65% recovery), as reported on page 357, fourth paragraph of the right-hand column, and as clearly illustrated in Table 4 on page 358.

Even if these results are obtained in conditions which do not exactly reproduce the chemical environment of toothpaste compositions, they nevertheless, in the Board's view, would suggest to the skilled person that an alkaline pH approaching pH 10 is necessary to achieve the best stabilisation of tripolyphosphate, or at least to improve the chance of stabilising tripolyphosphate.

On the other hand, that the pH should not be higher than 10 is not only suggested in (7) but is above all an obvious necessity dictated by the very use of the composition which requires physiologically acceptable conditions.

Under such circumstances, the choice of a pH range from 8 to 10 is an obvious compromise between the teaching in document (7) and the physiological requirement to be met by a toothpaste.

During the oral proceedings, the Respondent argued in relation to document (7) that the observations reported in the last part of the text (page 359), relating to the effect of the polyphosphate concentration on the hydrolysis rate, would encourage the skilled person to use low concentrations of polyphosphates, in contrast to the conditions stated by claim 1, ie at least 4%.

However, the Board notes, on the one hand that the concentration limit stated in claim 1, ie 4%, represents indeed a "low concentration" as compared with that indicated in document (2), ie 5%, on the other hand, that it is immediately evident from the results reported in document (7), last paragraph of the lefthand column of page 359, that the influence of the

tripolyphosphate concentration on the hydrolysis rate is observed mostly at pH 7, which is outside the claimed range, but that no remarkable influence was observed at the claimed pH 10. Therefore, no contradiction between the teaching in (7) and the claimed conditions can be recognised by the Board.

In view of the foregoing, the Board considers that claimed compositions are obvious alternatives of the compositions disclosed in document (2), and consequently that the claimed subject-matter does not involve an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside
2. The patent is revoked

The Registrar:

The Chairman

A. Townend

P. A. M. Lançon