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Bezeichnung der Erfindung:
Title of invention:
Titre de l'invention : Denture cleansing composition and process for its preparation

Klassifikation / Classification / Classement : A 61 K 7/30

## ENTSCHEIDUNG / DECISION

vom / of / du 27 January 1987

Anmelder / Applicant / Demandeur :

Patentinhaber / Proprietor of the patent /
Titulaire du brevet : Reckitt and Colman Products Ltd.

Einsprechender / Opponent / Opposant : OI Blendax-Werke R. Schneider GmbH & Co
OII Henkel KGaA

Stichwort / Headword / Référence : Compositions/Reckitt and Colman

EPÜ / EPC / CBE Article 56

Kennwort / Keyword / Mot clé : "Inventive step" - "Selection of ingredients"

**Leitsatz / Headnote / Sommaire**

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Case Number : T 91 /85

# D E C I S I O N
of the Technical Board of Appeal 3.3.1
of 27 January 1987

Appellant : (Proprietor of the patent)
Reckitt and Colman Products Ltd.
P.O. Box 26 1-17, Burlington Lane
London W4 2RW (GB)

Representative :
R.J. Oulton
H.L. Cottrell & Co.
Kings Building
South Church Side
Hull
North Humberside HU1 1RR (GB)

Respondent : (Opponent)
OI Blendax-Werke
R. Schneider GmbH & Co.
Rheinallee 88
D-6500 Mainz 1

OII Henkel KGaA
Postfach 1100
D-4000 Düsseldorf 1

Representative :

Decision under appeal : Decision of Opposition Division of the European Patent Office of 9 October 1984 posted on 15 February 1985 revoking European patent No. 0 010 412 pursuant to Article 102(1) EPC.

Composition of the Board :

Chairman : K. Jahn
Member : R. Andrews
Member : E. Persson

## Summary of Facts and Submissions

I. The mention of the grant of the patent No. 0 010 412 in respect of European patent application No. 79 302 199.9, filed on 12 October 1979 and claiming priority of 13 October 1978 from a prior application in South Africa, was announced on 3 November 1982 (cf. Bulletin 82/44) on the basis of 17 claims for the Contracting States BE, CH, DE, FR, GB, IT, LU, NL and SE and 7 claims for the Contracting State AT. Claim 1 for the first mentioned Contracting States read as follows:

"A solids denture cleansing composition for dissolution in an aliquot of water to form a denture cleansing bath of pH $\leqslant$ 4.5 comprising a permonosulphate, a tartar removal component and a carbonate characterised in that the composition is anhydrous, the permonosulphate comprises 10% to 40% by weight of the component and comprises, at least one permosulphate of formula $M^1HSO_5$ wherein $M^1$ is at least one alkali metal cation, the tartar removal component consists of at least one bisulphate of formula $M^2HSO_4$ wherein $M^2$ is an alkali metal cation, and/or an organic acid selected from succinic acid, malic acid, tartaric acid, citric acid, and mixtures of such acids, and the carbonate consists of at least one substantially chloride-free anhydrous alkali metal carbonate of formula $M^3{}_2CO_3$ wherein $M^3$ is at least one alkali metal cation, said chloride-free anhydrous metal carbonate being in sufficient amount to develop an initial pH of $\leqslant$ 4.5 in the denture cleansing bath the free surface moisture content of the composition being $\leqslant$ 0.5% by weight of the composition."

Claim 11 for these Contracting States related to a tablet comprising the composition as claimed in Claim 1 and

consisting of a unit dose of the composition capable of dissolving in an aliquot of water in less than 5 minutes.

The claims for the Contracting State Austria related to a process for the preparation of the compositions and tablets as defined above.

II. On 28 May 1983 and 14 July 1983 the Respondents filed oppositions citing, inter alia, the following three documents relied on in the appeal proceedings

(1) AT-A-264 015
(2) DE-A-2 025 338 and
(3) GB-A-1 527 010

and requested the revocation of the patent on the grounds of lack of novelty and inventive step.

III. By a decision of 9 October 1984, posted on 15 February 1985, the Opposition Division revoked the patent. In this decision the novelty of the subject-matter was acknowledged. However, it was considered that the subject-matter did not involve an inventive step in the light of the combined teaching in the cited prior art, since a person skilled in the art faced with the problem of improving the handling properties of the acid denture cleansing compositions disclosed in document (1) would be aware of the necessity to control the moisture content of such compositions in view of the disclosure in the remaining cited documents. Furthermore, from his common general knowledge a skilled person knows that alkali metal carbonates or bicarbonates react with organic acids to form alkali metal salts with the simultaneous formation of water and carbon dioxide. Accordingly, to prevent premature reaction, it is necessary to use solid organic acids and to avoid contact with water. For the control of

the moisture content of the composition the skilled person can use an internal desiccant (cf. document (2)) or external drying means (cf. document (3)). Moreover the determination of the maximum free surface moisture content of the composition was a matter of routine experimentation.

IV. A notice of appeal was lodged by the proprietor of the patent against this decision on 21 March 1985 with payment of the appropriate fee. A Statement of Grounds together with statutory Declarations by Professor Rees, Dr. Aulton and Mr. D. Lindsay was filed on 24 June 1985. The Appellant argued, **inter alia**, that the selection of the particular combination of ingredients in the specified amounts together with the specified type and quantity of water is not obvious in the light of the cited prior art. Furthermore there is a prejudice against using sodium bisulphate as the tartar removal component and replacing the sodium bicarbonate as taught in document (1) by sodium carbonate. Also the problems of tabletting on a conventional high-speed tabletting apparatus a composition which provides all the chemical requirements of an acid reacting denture cleansing composition, is stable and quickly dissolves in water, was not taken into consideration by the Opposition Division. The Appellant also requested an award of costs.

V. Both the Respondents argued that it can be deduced from documents (2) and (3) that preparations intended for tabletting should be dry. The transfer of this measure known for neutral or weakly alkaline preparations to acidic preparations is merely a matter of course for the skilled person. In the absence of any documentary support for a prejudice against using sodium carbonate in place of sodium bicarbonate as disclosed in document (1) this argument must be rejected, particularly since the

equivalence of sodium carbonate and sodium bicarbonate for the present purpose is demonstrated in documents (2) and (3). Further the subjective submissions from the three experts regarding the difficulties of tabletting acid reacting denture cleansing compositions cannot be used to support the argument that a prejudice existed against tabletting such compositions.

VI. In the oral proceedings held on 27 January 1987, the parties restated their previous arguments. The Appellant withdrew his request for an award of costs and submitted amended Claims 1 to 10 for the Contracting States other than Austria and amended Claims 1 to 6 for the Contracting State Austria together with an amended description. Claim 1 of the first set of claims reads as follows:

"An anhydrous denture cleansing tablet for dissolution in an aliquot of water to form a denture cleansing bath of pH$\leq$ 4.5 including a permonosulphate, a tartar removal component and a carbonate characterised in that the tablet is capable of dissolving in less than five minutes; the permonosulphate is a triple salt, $KHSO_4.K_2SO_4.2\ KHSO_5$, and is present in an amount sufficient to provide from 10 to 40% by weight of the composition of $KHSO_5$; the tartar removal component comprises sodium bisulphate and/or tartaric acid; the carbonate is substantially chloride-free anhydrous sodium carbonate, $Na_2CO_3$, which is present in sufficient amount to develop an initial pH of $\leq$ 4.5 in the bath, and the free surface moisture content of the composition for tabletting is $\leq$ 0.2% by weight of the composition".

Claim 1 for the set of claims for the Contracting State Austria relates to a process for preparing this tablet.

The Appellant requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the above-mentioned claims and description submitted during the oral proceedings. Alternatively the Appellant requested that the patent be maintained in amended form on the basis of claims which differ in essence from those of the main request in that the expression "produced by a conventional high-speed tabletting apparatus" is introduced into Claim 1 of each set of claims together with the said amended description.

Respondent I also argued that although great emphasis was placed in the Statutory Declarations filed by the Appellant on the different types of moisture, viz. bound or free surface moisture, the disputed patent was completely silent on the question of bound water and also gave no indication of a lower limit for the free surface moisture content. Both Respondents contended that document (1) discloses acid reacting denture cleansing tablets and mentions all the ingredients of the claimed tablet except sodium carbonate. However the equivalence of sodium carbonate to the sodium bicarbonate disclosed in (1) as a source of carbon dioxide is clearly shown in documents (2) and (3).

Both Respondents requested that the appeal be dismissed.

**Reasons for the Decision**

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.

2. There are no formal objections under Article 123 EPC to any of the versions of the present claims since they are all supported by the original disclosure and do not extend the scope of protection conferred. Claim 1 of both sets of

claims in accordance with the main request finds support in the original Claims 1, 2, 4, 5, 8 and 11 to 13. The expression "produced by a conventional high speed tabletting apparatus" introduced into the claims in accordance with the auxiliary request is supported by the disclosure in lines 26 to 27 of Column 2 of the printed patent specification.

3. The patent-in-suit relates to a denture cleansing tablet for dissolution in water to form a denture cleansing bath with a pH of $\leq$ 4.5 and which comprises potassium permonosulphate, a tartar removal component and a carbonate.

Such tablets are already known from document (1) which discloses denture cleansing compositions, some of which may be in the form of tablets capable of dissolving in water in 7.5 to 15 minutes (see Examples 7 and 8) to form a denture cleansing bath having an initial pH of between 1 and 5, preferably between 1.5 and 4.5 (cf. Claim 1). The tablets comprise at least one oxidising agent, such as potassium permonosulphate, sodium chlorite, sodium chlorate or salts of peroxymonophoshoric acid or persulphuric acid (cf. page 2, lines 11 and 12), an acid reacting substance, such as sulphamic acid, citric acid, tartaric acid, adipic acid, sodium bisulphate or urea phosphate (cf. page 1, lines 30 to 34), and a compound which with an acid reacting substance on dissolution in water evolves a gas, such as sodium bicarbonate (cf. page 2, lines 51 to 53). However, following the teaching of this document it is not possible to produce tablets on a conventional high-speed tabletting apparatus and the tablets obtained using a hand press do not dissolve sufficiently quickly in water, i.e within five minutes (cf. the statement on page 6 of the Statutory Declaration of D. Lindsay).

4. In the light of this closest prior art the technical problem underlying the patent-in-suit has to be seen in providing denture cleansing tablets which dissolve more quickly in water to give a denture cleansing bath of pH $\leqslant$ 4.5 and which do not exhibit cracks or undergo capping when produced on a conventional high-speed tabletting apparatus.

According to the patent-in-suit this problem is solved by using the triple salt, $KHSO_4.K_2SO_4.2KHSO_5$, as the oxidising agent, sodium bisulphate and/or tartaric acid as the tartar removal component, and substantial chloride-free anhydrous sodium carbonate in a sufficient amount to develop an initial pH of $\leqslant$ 4.5 in the cleansing bath. Furthermore the free surface moisture content of the composition for tabletting must be $\leqslant$ 0.2% w/w.

In view of the Examples in the disputed patent and the information in the Statutory Declaration of D. Lindsay the Board is satisfied that this technical problem is credibly solved.

5. After examination of the cited documents the Board has reached the conclusion that this technical teaching is not disclosed in any of them and the claimed subject-matter is, therefore, novel. Since novelty is no longer in dispute, it is not necessary to consider this matter in detail.

6. Document (1) discloses that all the ingredients referred to in Claim 1 of the main request, except for sodium carbonate and the triple salt, $KHSO_4$, $K_2SO_4.2\ KHSO_5$, are suitable ingredients for acid reacting denture cleansing compositions. It further discloses (cf. the paragraph bridging pages 2 and 3) that the inclusion of a compound

which with the acid reacting substance on dissolution in water evolves a gas, especially sodium bicarbonate, in powdered compositions improves the speed of dissolution of such mixtures and renders them particularly suitable for being pressed into tablets. This document is however wholly silent on the moisture content of the compositions for tabletting. This is, however, a critical feature of the disputed patent.

6.1 It is clear from the evidence brought forward by the Appellant in the form of the Statutory Declarations that it is impossible to predict whether a composition, particularly one containing a high proportion of active ingredients as the present composition, can be tabletted on a conventional high-speed tabletting apparatus. Since one of the effects for the formation of a tablet is time-dependent, by extending the time under pressure using a slow-acting press tablets may be obtained from compounds which undergo time-dependent plastic deformation. However, this is no guarantee that these compounds can be tabletted at high speeds and in the case of failure to produce tablets at high speeds it is necessary to decide which parameters need to be modified to provide the correct balance of all the effects involved in the formation of tablets. This entails subjecting an immense number of different formulations to trial runs under different tabletting conditions.

6.2 Although a list of suitable ingredients for the preparation of acid reacting denture cleansing compositions and Examples illustrating the preparation of tablets from certain of these ingredients are disclosed in document (1), a skilled person in the art faced with the technical problem underlying the disputed patent as stated above would not be able to deduce any teaching from this

document either alone or combined with the other cited prior art which would lead him to the particular combination of the selected ingredients claimed in the patent-in-suit.

6.3 From the disclosure in documents (2) and (3) it may be concluded that a person skilled in the art would consider that sodium carbonate and sodium bicarbonate to be equivalent to each other as regards sources of carbon dioxide in effervescent compositions (cf. (2), second paragraph on page 4; (3), page 3, lines 68 to 74). However, the Board is of the opinion that the question to be asked is not whether the skilled person in the art could have replaced the sodium bicarbonate of the prior art compositions by sodium carbonate but whether he would have done so in the expectation of rendering the prior art compositions tablettable at high speeds and more quickly dissolvable in water (cf. T 2/83, OJ 6/1984, page 265, particularly point 7 on page 270).

In the Board's view none of the cited prior art documents gives any indication that part of the solution to the present technical problem lay in the replacement of the sodium bicarbonate used in the prior art tablets and generally preferred in the prior art as a source of carbon dioxide by sodium carbonate.

6.4 The Appellant and both Respondents are agreed that the skilled person in the art would be aware of the necessity to control the moisture content of acid reacting denture compositions for tabletting even though document (1) is completely silent on the question of the moisture content of the compositions disclosed therein. The necessity of controlling the moisture content of enzyme and active oxygen containing denture cleansing tablets having upon dissolution in an aqueous medium a pH of 6 to 7.5 is

disclosed on page 2, lines 100 to 106 and page 5, lines 73 to 77 and 86 to 88 of document (3). However, this prior art does not distinguish between the different types of moisture, viz. free surface moisture and bound water. It is evident from the Statutory Declaration of Professor Rees that it is not only the quantity of moisture present that is critical for successful tabletting but also its nature. With respect to the different types of moisture it is clear from the disputed patent (cf. the paragraph bridging Columns 5 and 6) that only moisture which is available for reaction and which can be measured by the specified methods is critical for successful tabletting. Furthermore the Board takes the view that it is not necessary to specify a minimum value for the amount of free surface moisture in the absence of any evidence demonstrating that the present compositions containing less than a specified amount of free surface moisture cannot be successfully tabletted. There is no teaching in the prior art which would enable the skilled person in the art to deduce that a maximum of 0.2% w/w of free surface moisture was essential for the successful tabletting of the present selected ingredients at high speeds.

6.5 Therefore it may be concluded that the cited prior art did not give any indication that the solution to the technical problem underlying the disputed patent lay in the selection of very specific ingredients from a wide range of available ingredients in specific amounts together with a specific quantity of free surface moisture.

7. In the opinion of the Board the subject-matter of the main claims of both sets of claims in accordance with the main request, therefore, involves an inventive step.

Claims 2 to 5 for the Contracting States other than Austria and Claims 2 to 6 for the Contracting State Austria relate to preferred embodiments of their corresponding main claims and their patentability is derived from those claims. Claims 6 to 10 for the Contracting States other than Austria, which relate to the preparation of the tablets according to the invention, are allowable in view of the patentability of the tablet per se.

8. In the light of the above it is not necessary to consider the Appellant's argument that there was a prejudice against using sodium carbonate and sodium bisulphate in acid reacting denture cleansing tablets.

9. Under the above circumstances consideration of the Appellant's auxiliary request is obviously superfluous.

**Order**

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

1. The decision under appeal is set aside

2. The case is remitted to the Opposition Division with the order to maintain the patent in amended form on the basis of the description and both sets of claims in accordance with the main request submitted during the oral proceedings.

The Registrar

The Chairman

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