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DECISION of 15 January 2001

Case Number: T 0454/97 - 3.3.2

Application Number: 87303049.8

Publication Number: 0241277

IPC: A61K 6/08

Language of the proceedings: EN

Title of invention:

Method of preparing radioopaque cross-linked poly(carboxylic acid) dental cement

Patentee:

DENTSPLY INTERNATIONAL, INC.

Opponent:

THERA Patent GmbH Co. KG Gesellschaft für industrielle Schutzrechte

Headword:

Dental cement/DENTSPLY INTERNATIONAL

Relevant legal provisions:

EPC Art. 54, 56, 123(2)

Keyword:

- "Added matter no adequate disclosure"
- "Novelty yes generic term does not anticipate a specific type of cement"
- "Inventive step no obvious alternative"

Decisions cited:

Catchword:



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Boards of Appeal

Chambres de recours

Case Number: T 0454/97 - 3.3.2

DECISION
of the Technical Board of Appeal 3.3.2
of 15 January 2001

Appellant: DENTSPLY INTERNATIONAL, INC.

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Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted 12 March 1997 revoking European patent No. 0 241 277 pursuant

to Article 102(1) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo

S. U. Hoffmann

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Summary of Facts and Submissions

I. European patent No. 0 241 277 entitled "method of preparing radioopaque cross-linked poly(carboxylic acid) dental cement" based on application
No. 87 303 049.8 was granted on the basis of 10 claims.

Independent claim 1 as granted reads as follows:

"A method of preparing a radioopaque cross-linked poly(carboxylate) dental cement comprising blending a fluorine containing glass powder, prepared using components wherein strontium, represented as SrO, comprises from 5 to 35% by weight of the glass, polyacrylic acid having a molecular weight of from 20,000 to 125,000, and water to provide a powder blend of glass and polyacrylic acid to produce a dental cement having a radioopacity equal to or greater than that of dentine or dental enamel."

II. Opposition was filed against the granted patent by the respondent. The patent was opposed under Article 100(a) EPC, for lack of novelty and inventive step.

The following documents were inter alia cited during the proceedings:

- (1) US-A-3971754
- (2) WO-A-80 00409
- (4) US-A-4337186

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- (9) Zahnärztliche Werkstoffe, $\underline{2}$, (1981), pages 67-70 and 89-91
- (12) DE-A-2061513
- III. The decision of the Opposition Division of 25 February 1997 posted on 12 March 1997 established that the subject-matter of the patent in suit as granted did not meet the requirements of Articles 52(1) and 56 EPC and that the patent had to be revoked under Article 102(1) EPC.

The arguments in the decision may be summarised as follows:

The Opposition Division held that the patent as granted was novel over document (1) because, in its opinion, the term cement used in said document did not exclusively and unambiguously refer to a product obtained by reacting glasses with poly(carboxylic acids) in aqueous solutions.

As for inventive step, it however concluded that the subject-matter of the patent in suit was obvious over the combination of document (2) with document (1).

In its view, the only essential difference to be seen in document (2) over the subject-matter of the patent in suit lay in the absence of strontium in the glass of the disclosed cement.

It accordingly defined the problem to be solved over this prior art document as the provision of a method for preparing radioopaque dental cements.

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It therefore concluded that the use of a strontium glass to that end was obvious in the light of document (1) since this document taught precisely that strontium containing glasses were X-ray opaque and that they could be used for preparing dental cements.

IV. The appellant (patentee) lodged an appeal against the said decision and filed an amended set of claims on 14 July 1997.

Independent claim 1 of this set of claims reads:

"A method of preparing a radioopaque cross-linked poly(carboxylate) dental cement comprising blending an aluminofluorosilicate glass powder containing 12 to 35% by weight Sr, represented as SrO, of the glass, polyacrylic acid having a molecular weight of from 20,000 to 125,000 and water to provide a powder blend of glass and polyacrylic acid to produce a dental cement having a radioopacity equal to or greater than that of dentine or dental enamel." (emphasis added)

- V. Oral proceedings were held before the Board on 15 January 2001.
- VI. The appellant's submissions both in the written procedure and at the oral proceedings can essentially be summarised as follows:

Regarding the amendments in claim 1 of the set of claims filed on 14 July 1997, it referred to paragraphs 2 and 3 of page 3 of the application as filed disclosing the lower value of strontium of 12% and the aluminofluorosilicate glass.

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Concerning novelty over document (1), it argued that this document failed to disclose the combination of a polycarboxylic acid with an acid-leachable glass containing both fluorine and strontium as characterised in claim 1 as it only described the use of a radioopaque glass filler in an epoxy-resin binder composition.

The appellant was moreover of the opinion that document (4) represented the closest state of the art because this document was also concerned with the radioopacity, the setting times and the compression strength of dental cements.

As the solution to achieve adequate compression strengths and setting times (ie the use of a metal salt as additive) advocated in document (4) was radically different from the one described in the patent in suit (ie use of a Strontium modified glass), the appellant concluded that the subject-matter of the contested patent involved an inventive step.

As regards the disclosure in document (1), it expressed the view that it was not relevant as it related to non-reactive filler whereas the patent in suit concerned ionomer cements involving fundamentally different problems.

It also filed a test report to show that strontium was the most advantageous radio-opaquing material among those disclosed in document (1).

As to document (12) which disclosed an aluminofluorosilicate cement containing lanthanum (La), the appellant concluded that it was also clear from the

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test report that the subject-matter of the contested patent was inventive over this disclosure as it showed that strontium was unexpectedly better than lanthanum with respect to setting time, X-ray opacity and compression strength.

VII. The respondent (opponent) contested these arguments.

Its submissions in support of its requests can be summarised as follows:

It first argued that the replacement, in claim 1 of the set of claims filed on 14 July 1997, of the expression "fluorine containing glass powder" by the expression "aluminofluorosilicate glass powder" without excluding the presence of alkaline earth metals other than strontium was not supported by the original disclosure, which contravened Article 123(2) EPC.

It further maintained its novelty objection over document (1) raised during the opposition procedure. In its view the term "cement" used in the introduction of document (1) referred to the same type of product described in the contested patent. Accordingly, as the glass disclosed in this document was also a strontium aluminofluorosilicate glass, it concluded that the skilled person would consider that the cements mentioned in (1) and the cements of the contested patent were identical.

As regards inventive step, it was of the opinion that document (12), which disclosed an aluminofluorosilicate cement containing La, could also be regarded as the closest state of the art. In its view, it was obvious to select, just by routine experiments, the best radioopacifying elements among those disclosed in

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document (1) and to replace La by Sr accordingly.

VIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims filed on 14 July 1997.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

- 1. The appeal is admissible.
- 2. Article 123 EPC
- 2.1 The set of claims filed on 14 July 1997 corresponds to the set of claims as granted with claim 1 being amended, in substance, by restricting the range amount of SrO in the glass powder to 12 to 35% instead of 5 to 35% and by indicating that the glass powder is an aluminofluorosilicate glass powder.

The lower value of 12% for the amount of SrO and the term aluminofluorosilicate are adequately disclosed in the application as originally filed on page 3, line 12, and on page 3, second paragraph, respectively.

Moreover, as these amendments restrict the protection conferred when compared with the claims as granted, the Board concludes that these amendments fulfil the requirements of Article 123(2) and (3) EPC.

2.2 The Board does not accept the argument of the respondent that claim 1 should indicate that the strontium aluminofluorosilicate glass is substantially

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free of other alkaline earth metals in order to fulfil the requirements of Article 123(2) EPC.

It is true that the description as originally filed mentions on page 3, paragraph 3, lines 15 to 17, that "the glass (should) be a strontium aluminofluorosilicate glass substantially free of other alkaline earth metals...".

The disclosure of the application as filed is however not restricted to this sentence. The same paragraph recites indeed that it is only "most convenient that all the alkaline earth metal in the glass be strontium". Moreover, the wording of the second paragraph of page 3 makes it clear that the strontium aluminofluorosilicate according to the patent in suit can also contain other alkaline earth metals. This paragraph reads in fact as follows:

"According to the invention, therefore, there is provided an alkaline earth metal aluminofluorosilicate glass, for use as an ion-source in a poly(carboxylic acid) cement composition, in which at least a part of the alkaline earth metal is strontium."

3. Novelty

Document (1) has been cited as prejudicial to the novelty of the subject-matter of claim 1 of the patent in suit.

Document (1) relates to dental filling materials, and more particularly to compositions useful in dental restoration practice. Among others, cements are mentioned as an example of such compositions (column 1,

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lines 5 to 8).

The preparation of strontium aluminofluorosilicate glasses is moreover disclosed in most of the examples given in this document as a filler to be incorporated in an organic restorative matrix.

According to the description column 2, lines 11 to 18, the x-ray absorbing atoms (ie lanthanum, strontium, tantalum and hafnium) are present in the glass in a concentration between 5 to 60%, preferably 25 to 40%.

The only organic matrix mentioned and described in this document is however a resin matrix made of condensation products from the reaction of bisphenol A with glycidyl methacrylate (Example 1, claim 1).

Accordingly, document (1) clearly does not disclose expressis verbis blending an aluminofluorosilicate glass powder containing 12 to 35% by weight of Sr, represented as SrO, of the glass, polyacrylic acid having a molecular weight of from 20000 to 125000 and water to produce a dental cement.

It remains however to examine whether, as argued by the respondent, such a method for preparing a dental cement is implicitly disclosed in said document for the skilled person.

In that respect, the Board agrees that document (1) discloses that strontium aluminofluorosilicate glass powder can be used for the preparation of "cements", ie not only in combination with a binder resin as organic matrix.

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The Board nevertheless notes that, as the word "cements" used in document (1) is not further explained in the document, the skilled person referring to a text book such as document (9) would conclude that this term is a generic term which encompasses a great variety of cement types such as, for instance, ethoxybenzoic acid cements, carboxylate cements, glasionomer cements and so on (see (9): page 67, right-hand column, lines 1 to 13).

Therefore, the Board is convinced that the skilled person could not understand the term "cements" used in document (1) as inevitably meaning a cement made by blending a glass powder, polyacrylic acid and water.

It could accordingly even less read in document (1) that the polyacrylic acid has a molecular weight of from 20000 to 125000.

It is moreover pointed out in that respect that, contrary to the respondent's statement, the molecular weight of the polyacrylic acid used for preparing cements made by blending a glass powder, polyacrylic acid and water is not inevitably comprised within 20,000 and 125,000 as shown by document (12), which deals precisely with such cements and which also foresees the use of polyacrylic acid with molecular weights of 1500 and 150000 (page 7, paragraph 3).

Under these circumstances, the Board concludes that the subject-matter of claim 1 fulfils the requirements of novelty under Article 54 EPC.

4. Inventive step

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4.1 The contested patent relates to a method of preparing radioopaque cross-linked poly(carboxylate) dental cement by blending aluminofluorosilicate glass powder containing Sr, polyacrylic acid and water, which has a radioopacity equal to or greater than that of dentine or dental enamel and still acceptable properties with regard to strength, hardness, translucency (column 1, lines 3 to 5, column 1, line 47, to column 2, line 3).

The Board considers that document (12), concerning also a method of preparing poly(carboxylate) dental cement by blending aluminofluorosilicate glass powder, polyacrylic acid and water, represents the closest prior art (page 3, paragraph 1).

This document discloses the use of a polyacrylic acid having a molecular weight of from 1500 to 150000 and the preparation of a lanthanum aluminofluorosilicate glass powder (page 7, paragraph 3; page 6, lines 14 and 15, and Example XI of the table on page 7).

As the radioopacifying effect is an inherent property of high atomic weight atoms such as lanthanum in particular, it is clear to the skilled person that the cement obtained with the above-mentioned glass powder is a radioopaque one. In that respect, document (1) for instance confirms this well-known property of lanthanum (column 2, lines 1 to 4).

Although document (12) is mainly concerned with the setting times of the cements and with their compression strength, it can also be assumed that these cements have acceptable properties with regard to hardness in general and translucency since they are clearly intended to be used by dentists in dental restoration

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practice (page 3, end of paragraph 1; page 4, paragraph 3, and values (a) and (b) of Examples 1 to 5).

4.2 Since claim 1 on which the present decision is based does neither exclude the presence of lanthanum nor of any other components, the difference between the method of document (12) and the method of the patent in suit lies in the presence of a certain amount of strontium in the lanthanum aluminofluorosilicate glass powder to be blended with polyacrylic acid and water (ie beside lanthanum the glass powder must contain between 12 and 35% by weight Sr, represented as SrO, of the glass).

Neither the contested patent nor the various documents on file nor the appellant's submissions show any particular effect for this difference over prior art document (12).

The Board agrees with the appellant that the comparative examples filed with the appellant's letter dated 14 July 1997 show that strontium, when used as sole radioopacifying atom, is more effective than lanthanum alone with respect to the setting time, the X-ray opacity and the compression strength of the prepared cement.

However, as emphasised by the appellant in its letter dated 14 July 1997, "...any change of the composition for achieving one of the goals will influence the other properties, since all properties are consequences of the physical composition."

Accordingly, the comparisons made for strontium versus lanthanum alone instead of a lanthanum/strontium

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mixture comprised by claim 1 on which the present decision is based cannot be taken into account for the assessment of inventive step.

In view of the foregoing, the Board concludes that no particular effect has been demonstrated for the specific combination of features according to claim 1.

Accordingly, the problem to be solved by the subjectmatter of claim 1 of the patent in suit as against document (12) can only be seen in the provision of an alternative method for preparing a cross-linked poly(carboxylate) dental cement.

- 4.3 This problem is solved by blending the particular ingredients of claim 1 and, in the light of the description and examples of the patent in suit, the Board is satisfied that the problem has been plausibly solved.
- 4.4 Thus the question to be answered is whether the proposed solution, ie blending an aluminofluorosilicate glass powder which contains between 12 and 35% by weight Sr, represented as SrO of the glass, would have been obvious to the skilled person in the light of the prior art.

In that respect, document (1) precisely describes in Example 2 an aluminofluorosilicate glass which, beside lanthanum, also contains strontium. Among the four x-ray adsorbing atoms disclosed in (1), namely La, Sr, Ta and Hf, strontium even appears to be the preferred one since it is present in the aluminofluorosilicate glasses prepared in all the examples except one. In addition, the amount of Sr contained in the

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aluminofluorosilicate glasses of Examples 4 and 5 is within the range of 12 to 35% claimed in the patent in suit (see also under point 3).

This document moreover teaches that such a glass can be used for preparing a dental filling material which is X-ray opaque and which has low toxicity, high mechanical strength and optical translucency matching tooth enamel, and cements are mentioned in the document as an example of the envisaged dental filling material (column 1, lines 61 to 65, and column 2, lines 11 to 14).

The Board stresses that, although the term "cements" in document (1) is not restricted to cements made by blending a glass powder, polyacrylic acid and water as discussed under point 3, it is however clear to the skilled person that such cements are also encompassed by this wording.

Accordingly, the Board is satisfied that the skilled person faced with the problem of the provision of an alternative method of preparing a cross-linked poly(carboxylated) dental cement would replace some lanthanum by some strontium in the prior art lanthanum aluminofluorosilicate glass powder without inventive activity just by following the teaching of document (1).

4.5 The Board does not agree with the main argument submitted by the appellant, that document (1) addressed the radioopacity problem in connection not with a cement made by blending a glass powder, polyacrylic acid and water (ie a glass ionomer cement) but a non-reactive filler involving fundamentally different

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problems and that the skilled person would not combine the teaching of document (1) with a document concerning glass ionomer cement, for two reasons:

- firstly, because the teaching of document (1) is clearly not restricted to non-reactive filler as it also mentions cements as an example of the suitable dental filling materials envisaged
- secondly because the x-ray absorbing atom lanthanum which is disclosed together with strontium and tantalum in document (1) is also successfully used in a glass ionomer cement as shown by document (12).

Accordingly, the Board is convinced that there is no technical prejudice preventing the skilled person from considering the teaching of document (1) for preparing glass ionomer cements.

4.6 In the light of these facts, the Board can only conclude that the subject-matter of claim 1 does not involve an inventive step as required by Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

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A. Townend U. Oswald