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**Datasheet for the decision
of 23 September 2008**

Case Number: T 0678/05 - 3.3.02

Application Number: 94109741.2

Publication Number: 0630641

IPC: A61K 6/083

Language of the proceedings: EN

Title of invention:

Method and dispenser for making dental products

Patentee:

DENTSPLY INTERNATIONAL, INC.

Opponent:

VOCO GmbH

Kuraray Co., Ltd.

S & C Polymer Silicon- und Composite-Spezialitäten

Headword:

Static mixing/DENTSPLY INTERNATIONAL, INC.

Relevant legal provisions:

EPC Art. 54, 56

Relevant legal provisions (EPC 1973):

-

Keyword:

"Main request - novelty (yes)"

"Main request and auxiliary requests 1-6 - inventive step (no):
use of a static mixer for preparing dental products is
obvious"

Decisions cited:

-

Catchword:

-



Case Number: T 0678/05 - 3.3.02

DECISION
of the Technical Board of Appeal 3.3.02
of 23 September 2008

Respondent:
(Opponent 2)
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Decision under appeal:
Interlocutory decision of the Opposition
Division of the European Patent Office posted
1 April 2005 concerning maintenance of European
patent No. 0630641 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
J.-P. Seitz
J. Riolo
J. Van Moer

Summary of Facts and Submissions

- I. European patent No. 0 630 641 based on application No. 94 109 741.2 was granted on the basis of a set of 27 claims.

The independent claims read as follows:

"1. A method of forming a dental product, comprising: providing a first polymerizable paste composition comprising an oxidizing agent and at least one polymerizable acrylic compound and a second polymerizable paste composition comprising a reducing agent and at least one polymerizable acrylic compound, mixing said polymerizable paste compositions in a static mixer to form a polymerizing paste composition having a redox catalyst system for the polymerization of said acrylic compound, forming and curing said polymerizing paste composition to provide a dental product, wherein methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are excluded.

15. A device for forming a dental product: comprising, a static mixing conduit, a first container having a first chamber enclosing a first polymerizable paste composition comprising an oxidizing agent, and at least one polymerizable acrylic compound, and a second container having a second chamber enclosing a second polymerizable paste composition comprising at least one polymerizable acrylic compound and a reducing agent adapted to form a free radical polymerization catalyst system with said oxidizing agent, said static mixing conduit enclosing a static mixing member, said first and

second containers being adapted to be connected in fluid flow communication with said static mixing conduit, each said container being permeable to oxygen."

II. Oppositions were filed against the granted patent by VOCO GmbH (opponent 01), by the respondent-opponent 02 and by the appellant (opponent 03). The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step and for non-compliance with the requirements of Article 52(4) EPC 1973, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC because its subject-matter extended beyond the content of the application as filed. Opponent 01 withdrew his opposition by letter of 21 February 2005.

III. The following documents were *inter alia* cited during the opposition and appeal proceedings:

- (1) US-A-5 037 473
- (3) K. Eichner, Zahnärztliche Werkstoffe und ihre Verarbeitung, Band 2 Werkstoffe unter klinischen Aspekten, 1981, Dr. Alfred Hüthig GmbH Heidelberg, pages X to XI and 125 to 158
- (20) EP-A-0 563 749
- (22) US-A-4 753 536
- (26) Gebrauchsanleitung Luxatamp-Automix, DMG Hamburg, 1993
- (27) Der freie Zahnarzt, 3/1992, p. 52

IV. In the decision pronounced on 22 February 2005, the opposition division maintained the patent in amended form on the basis of the main request filed at the oral

proceedings of 22 February 2005. Its principal findings were as follows:

The exclusion of methods as defined by Article 52(4) EPC 1973 in claim 1 did not contravene the requirements of Articles 83, 84 and 123(2) EPC. In connection with the requirements of Article 123(2) EPC it was further held that the reduction of a list of originally six compounds to three compounds (dental appliance, denture and denture reline) was allowable as was the introduction of the feature "said container being permeable to oxygen" (claim 14), for which there was a basis in the application as originally filed. Novelty was acknowledged, as there was no evidence that the alleged prior use was made public before the effective filing date of the contested patent. In connection with the written evidence, it was held that document (3) did not specifically disclose the use of a static mixer. As for inventive step, document (3) was considered to represent the closest prior art and it was concluded that the method of claim 1, which comprises static mixing of polymerizable materials comprising an accelerator for forming a dental appliance, denture or denture reline, was not derivable from the prior art. The same applied *mutatis mutandis* to the device.

V. The appellant lodged an appeal against that decision.

VI. Oral proceedings took place on 23 September 2008. The independent claims of the requests on file read as follows:

(a) main request:

"1. A method of forming a dental appliance, denture or denture reline, comprising: providing a first polymerizable paste composition comprising an oxidizing agent and at least one polymerizable acrylic compound and a second polymerizable paste composition comprising a reducing agent and at least one polymerizable acrylic compound, mixing said polymerizable paste compositions in a static mixer to form a polymerizing paste composition having a redox catalyst system for the polymerization of said acrylic compound, forming and curing said polymerizing paste composition to provide the dental appliance, denture or denture reline, wherein methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are excluded.

14. A device for forming a dental appliance, denture or denture reline comprising, a static mixing conduit, a first container having a first chamber enclosing a first polymerizable paste composition comprising an oxidizing agent, and at least one polymerizable acrylic compound, and a second container having a second chamber enclosing a second polymerizable paste composition comprising at least one polymerizable acrylic compound and a reducing agent adapted to form a free radical polymerization catalyst system with said oxidizing agent, said static mixing conduit enclosing a static mixing member, said first and second containers being adapted to be connected in fluid flow communication with said static mixing conduit, each said container being permeable to oxygen for maintaining inhibition of polymerization of

the polymerizable paste compositions therein for at least 12 months at 23°C."

(a) auxiliary request 1:

Claim 1, which is the sole independent claim, is identical with claim 1 of the main request.

(b) auxiliary request 2:

"1. A method of forming a denture reline to improve the fit of a denture to the soft tissue contours of the mouth, comprising:

- (a) providing a first polymerizable paste composition comprising an oxidizing agent and at least one polymerizable acrylic compound and a second polymerizable paste composition comprising a reducing agent and at least one polymerizable acrylic compound,
- (b) mixing said polymerizable paste compositions in a static mixer to form a polymerizing reline paste composition having a redox catalyst system for the polymerization of said acrylic compound,
- (c) extruding the polymerizing reline paste composition directly onto a denture, and
- (d) forming and curing said polymerizing reline paste composition to provide a denture reline,

wherein methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are excluded."

(c) auxiliary request 3:

"1. A method of forming a denture reline to improve the fit of a denture to the soft tissue contours of the mouth, comprising:

- (a) providing a first polymerizable paste composition comprising an oxidizing agent and at least one polymerizable acrylic compound and a second polymerizable paste composition comprising a reducing agent and at least one polymerizable acrylic compound,
- (b) mixing said polymerizable paste compositions in a static mixer to form a polymerizing reline paste composition having a redox catalyst system for the polymerization of said acrylic compound,
- (c) extruding the polymerizing reline paste composition directly onto a denture, and
- (d) forming and curing said polymerizing reline paste composition to provide a denture reline by shaping the polymerizing paste composition to areas of the soft tissue of the mouth, said polymerizing paste composition substantially self curing in the mouth within less than 5 minutes,

wherein methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are excluded.

(d) auxiliary request 4:

The sole independent claim 1 is identical with claim 1 of auxiliary request 1, except that the disclaimer has been deleted.

(e) auxiliary request 5:

The sole independent claim 1 is identical with claim 1 of auxiliary request 2, except that the disclaimer has been deleted.

(f) auxiliary request 6:

The sole independent claim 1 is identical with claim 1 of auxiliary request 3, except that the disclaimer has been deleted.

VII. The appellant's arguments relevant for this decision can be summarised as follows:

As to novelty, it was argued that the subject-matter as presently claimed was anticipated by documents (3) and (20). With regard to inventive step, document (3) was defined as closest prior art, as it disclosed compositions for dental restoration which were identical with the paste/paste compositions defined in the claims of the contested patent. Document (3) did not specifically mention the use of a static mixer for the mixing step. The problem to be solved could therefore be defined as follows: provision of a method for preparing dental appliances, dentures and denture relines which is easier to carry out and which yields products characterised by an enhanced colour stability and a reduced porosity. The use of a static mixer was rendered obvious by document (26), where all these effects were mentioned in connection with a static mixer in the form of a double-barrelled syringe. The person skilled in the art would combine the teaching of document (3), which

concerned compositions for dental restoration, with the teaching of document (26), which related to the preparation of temporary bridges and crowns, as all these compositions were identical. In addition, the allowability of the disclaimer in connection with Articles 83, 84 and 123(2) EPC was contested.

VIII. The respondent-patentee's arguments relevant for this decision can be summarised as follows:

Regarding novelty, it was held that neither of documents (3) and (20) disclosed a static mixer. In connection with inventive step, he argued that the invention of the contested patent in its most preferred embodiment related to the preparation of a reline denture. Reline dentures were characterised by very specific properties and were quite different from compositions for dental restoration. As a consequence, document (3) did not constitute the closest prior art. Instead, a document relating to reline dentures such as document (1) had to be chosen. Document (1) concerned reline compositions in the form of powder/liquid compositions. Starting from this document, the provision of reline dentures characterised by a reduced yellowing over a prolonged period of time represented the problem to be solved. In the light of this problem, the person skilled in the art had no reason to replace the powder/liquid compositions of document (1) by the highly viscous paste/paste compositions, which were typically used in the preparation of material for dental restoration on account of the high amount of filler used therein. Moreover, in the light of the problem to be solved, the skilled person would not take into consideration document (26), as temporary bridges and crowns were not

concerned with the problem of yellowing due to the short period of time in which they were used. Furthermore, document (26) disclosed neither static mixing nor the use of paste/paste compositions nor the use of redox catalyst systems. As a consequence, document (26) was not pertinent at all. As for the objections raised in connection with the disclaimer of claim 1, the respondent-patentee held that the disclaimer was allowable; however, he was prepared to delete it if necessary.

- X. The appellant (opponent) requested that the decision under appeal be set aside and that the European patent No. 630641 be revoked.

The respondent (patentee) requested that the patent be maintained on the basis of their main request (corresponding to the former first auxiliary request filed with letter dated 25 August 2008), or alternatively on the basis of either of auxiliary requests 1 to 6 filed during the oral proceedings held before the board.

Reasons for the Decision

- 1. The appeal is admissible.
- 2. Admissibility of auxiliary requests 1 to 6:
 - 2.1 As regards auxiliary requests 1 to 3, the only modification as compared to the previous requests consists in the deletion of the claims relating to the device, which may be seen as a reaction to an objection

pursuant to Article 123(2) EPC raised by the board in the annex to the summons to oral proceedings dated 12 February 2008 (see paragraph 6). The remaining method claims were not amended.

2.2 In auxiliary requests 4 to 6, the disclaimer concerning the exclusion of methods as defined by Article 52(4) EPC 1973 was additionally deleted. This deletion may also be seen as a reaction to the comments made by the board in the annex to the summons to oral proceedings dated 12 February 2008 (see paragraph 5). In addition, the respondent-appellant had already indicated in his letter dated 25 August 2008 that he would be prepared to delete the disclaimer, if necessary (see last paragraph on page 2). The appellant could therefore not be surprised by the deletion of the disclaimer.

2.3 As a consequence, auxiliary requests 1 to 6, although filed only at the oral proceedings before the board, are admissible.

3. Main request:

3.1 Novelty:

The appellant held that documents (3) and (20) were detrimental to the novelty of the subject-matter as claimed.

3.1.1 As regards document (3), the appellant admitted that there was no specific disclosure of a static mixer. However, claim 1 clearly indicates that the mixing of the polymerizable paste compositions is carried out in a static mixer. Likewise, independent claim 14 relates to

a device comprising, among other things, a static mixing conduit and a static mixing member, which are not disclosed in document (3) either.

3.1.2 In connection with document (20), it is noted that both claims 1 and 14 of the present main request require the presence of at least one polymerizable acrylic compound in both paste compositions. In contrast thereto, document (20) relates to compositions for the preparation of temporary bridges and crowns, where the second paste does not contain a polymerizable acrylic compound (see document (20), claim 1 (b)).

3.1.3 As a consequence, the subject-matter as claimed in the main request meets the requirements of Article 54 EPC.

3.2. Inventive step of claim 1:

3.2.1 The present invention concerns a method for preparing dental appliances, dentures and denture relines which can be readily carried out in a dental laboratory or office and which avoids air entrapment and, as a further consequence thereof, stain, plaque formation and bacterial contamination (see page 4, lines 1-3 from the bottom and page 5, first and second complete paragraphs of the application as filed).

3.2.2 There was disagreement among the parties as far as the closest prior art is concerned: the appellant defined document (3) as closest prior art, while the respondent-patentee cited document (1). The board came to the conclusion that neither of these two documents constitutes the closest prior art for the following reasons:

Document (3) concerns dental filling materials on the basis of paste/paste compositions which are identical with the compositions defined in present claim 1 (see document (3), page 129, table 8.4). However, in view of the fact that the invention as presently claimed relates to the preparation of orthodontic appliances, dentures and denture relines, the person skilled in the art would not start from a document that is concerned with dental restoration.

Document (1) discloses reline compositions including polymerizable acrylic compounds. However, the compositions used therein are based on powder/liquid compositions and thus structurally very different from the paste/paste compositions used in the contested patent.

- 3.2.3 The board came to the conclusion that document (26) constitutes the closest prior art. This document discloses a double-barrelled syringe comprising a two-component material based on multifunctional methacrylic esters for the preparation of temporary crowns and bridges. The syringe comprises a cannula for mixing, which means that there is static mixing. In this context, reference is also made to document (27), which relates to the same device as document (26) and which specifies that the cannula comprises in its interior a device in spiral form which efficiently mixes the material during extrusion. Although document (26) does not specifically mention paste/paste compositions, the board came to the conclusion that this feature is implicitly disclosed by the use of double-barrelled syringes (Doppelkartuschen), which are designed for mixing paste/paste compositions.

Moreover, document (26) mentions a catalyst paste (see left hand column, paragraph headed "Systemvorteile"), which is a further proof for the use of paste/paste compositions. The citation of the catalyst paste also implies that a redox catalyst system is included. It is additionally emphasised that the term "acrylic compound" used in claim 1 of the present main request also includes methacrylic compounds (see pages 14-16 of the application as filed), i.e. compounds disclosed in document (26). The devices according to document (26) are characterised by an exact application, where air entrapment during mixing is avoided, by high resistance to abrasion and by high colour stability. These advantageous properties allow the preparation of long-term temporary dental appliances (see left hand column, paragraph headed "Eigenschaften").

3.2.4 It follows from this that the preparation of temporary crowns and bridges according to document (26) is identical with the method of claim 1 of the main request except for the feature that the polymerizable acrylic compound is present in both pastes. In the light of these findings, the preparation of further dental compositions constitutes the problem to be solved. This problem was solved by the preparation of dental appliances, dentures and denture relines as defined in claim 1 of the main request involving the use of paste/paste compositions, wherein the polymerizable acrylic compound is present in each of the two pastes. In view of the examples of the patent in suit, in particular examples 7-8 and 10-15, the board is satisfied that the problem defined above was plausibly solved.

3.2.5 It remains therefore to assess, whether this solution involves an inventive step: starting from the teaching of document (26), the skilled person does not get any instructions as to where the multifunctional methacrylic esters should be put: they can be added to either one of the accelerator or the catalyst pastes, or they can be included into both pastes. Therefore, the person skilled in the art has to choose one of the three options in order to put the teaching of document (26) into practice. The patent in suit does not appear to contain any evidence that the distribution of the polymerizable acrylic monomer in both pastes leads to a non-obvious effect as compared to adding it to one paste only. In the absence of such an effect, this particular choice of the distribution of the polymerizable acrylic monomer is but one out of three equally promising options, which constitutes an arbitrary choice that cannot give rise to an inventive step. As a consequence, the requirements of Article 56 EPC are not met.

3.3 In the light of this finding, it is not necessary to evaluate whether or not the disclaimer in claim 1, which had been introduced for purely legal reasons in order to exclude non-patentable subject-matter, is allowable under Article 52(4) EPC 1973 or under Articles 83, 84 and 123(2) EPC.

3.4 As a further consequence, discussion of independent claim 14 is not necessary either.

4. Auxiliary request 1 - inventive step of claim 1:

Claim 1 of auxiliary request 1 is identical with claim 1 of the main request. As a consequence, the conclusions

reached in paragraphs 3.2 and 3.3 above apply *mutatis mutandis* to claim 1 of auxiliary request 1.

5. Auxiliary request 2:

5.1 Inventive step of claim 1:

Again, document (26) constitutes the closest prior art, and again the preparation of further dental compositions constitutes the problem to be solved with regard to the closest prior art. As compared to the main request, the subject-matter of claim 1 of auxiliary request 2 is now further distinguished from the disclosure of document (26) by the restriction of the claimed method to the preparation of denture relines and by the introduction of extruding the polymerizing reline paste compositions directly onto a denture (step (c) of claim 1) after the mixing step. It therefore has to be established whether the preparation of reline dentures including step (c) as defined above is obvious over the teaching of document (26).

The respondent-patentee held that this would not be the case, as the preparation of denture relines is concerned with a completely different problem. In contrast to document (26), where the problem of colour stability was a direct consequence of the entrapment of air during spatulation, the invention as defined in claim 1 of auxiliary request was directed to the avoidance of yellowing, which occurred due to the presence of the redox system, in particular of the amine, rather than to the presence of air. As the yellowing of a reline denture could be observed only after a prolonged period of time, the teaching of document (26), which related to

temporary bridges and crowns, gave no guidance at all. Moreover, the respondent-patentee stressed that relined dentures, as far as their composition and their properties were concerned, were quite different from temporary bridges and in particular from filling material as disclosed e.g. in document (3).

As far as colour stability is concerned, the board notes that the arguments presented by the respondent-patentee do not appear to be in line with the teaching of the application as filed: reference is made to the last three lines of page 4, which clearly indicate that air entrapment during spatulation provides sites for stain. The fact that the colour stability of the denture relines prepared according to the method as presently claimed is linked to air entrapment is confirmed by the examples (see Table 7: examples 7 and 8 vs. comparative examples 9 and 10), which clearly show that the smaller difference in the total colour change ΔE is the consequence of static mixing and thus of less air entrapment. As document (26) also applies static mixing, the board cannot acknowledge that the patent in suit relates to a different technical teaching, as far as colour stability is concerned.

With regard to the differences in the composition between denture relines on the one hand and temporary bridges or dental restoration material on the other hand, it is noted that the use of polymerizable composite materials both for filling tooth cavities and for forming dental restorations in general was known before the priority date of the contested patent (see document (22), column 1, lines 18-21). Notwithstanding the fact that, depending on the intended use, there may be some

variations as far as additives such as filling agents or physical parameters such as viscosity are concerned, the basic composition involving polymerizable composites is the same, no matter whether the material is used for forming temporary bridges or denture relines or even for filling cavities. This teaching of document (22) is incidentally confirmed by the contested patent, where the same composite material is used for a wide variety of applications including denture relines, bridges, crowns and restorative material (see page 5, first complete paragraph of the application as filed). It was also known from document (22) that a static mixer in the form of a double-barrelled syringe allows the mixing of compositions of any desired viscosity and that static mixing maximises the physical properties of the compositions thus treated (see column 1, lines 27-31 and column 3, lines 19-22).

As a consequence, the person skilled in the art, starting from the teaching of document (26) and knowing that materials for forming denture relines and materials for forming long-lasting temporary bridges have the same basic composition and that the use of a static mixer improves the properties of all kinds of dental products, would apply the method discussed in paragraph 3.2.5 above also for the preparation of colour-stable denture relines. He would also apply step (c) of claim 1, as document (26) contains the teaching that the composition extruded from the cannula can be directly applied (see left-hand column, paragraph headed "Systemvorteile"). The subject-matter of claim 1 of auxiliary request 2 therefore does not involve an inventive step either (Article 56 EPC).

5.2 Reference is made to paragraph 3.3 above, which applies *mutatis mutandis* to claim 1 of auxiliary request 2.

6. Auxiliary request 3:

6.1 Inventive step of claim 1:

The subject-matter of claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 2 by the additional feature "by shaping the polymerizing paste composition to areas of the soft tissue of the mouth, said polymerizing paste composition substantially self-curing in the mouth within less than 5 minutes", which was added at the end of step (d). However, the addition of this feature cannot establish an inventive step either, as the self-curing compositions according to document (26) are also introduced into the mouth and then removed after 2½ to 3 minutes. As a consequence, the subject-matter of claim 1 of auxiliary request 3 does not meet the requirements of Article 56 EPC either.

6.2 Reference is made to paragraph 3.3 above, which applies *mutatis mutandis* to claim 1 of auxiliary request 3.

7. Auxiliary request 4:

7.1 Inventive step of claim 1:

Claim 1 of auxiliary request 4 is identical with claim 1 of the main request except for the deletion of the disclaimer. As the evaluation of the inventive step made in paragraphs 3.2.1 to 3.2.5 above is completely independent of the question whether or not claim 1 of the main request without the disclaimer contains

subject-matter excluded by the provisions of Article 52(4) EPC 1973, the subject-matter of claim 1 of auxiliary request 5 for the same reasons as indicated in the said paragraphs 3.2.1 to 3.2.5 above does not involve an inventive step either.

7.2 In view of the finding in paragraph 7.1 above, an evaluation of whether the deletion of the disclaimer is allowable under Article 52(4) EPC 1973 or under Articles 84, 123(2) or 123(3) EPC is not necessary.

8. Auxiliary request 5:

8.1 Inventive step of claim 1:

Claim 1 of auxiliary request 5 is identical with claim 1 of auxiliary request 2 except for the deletion of the disclaimer. As the evaluation of the inventive step made in paragraph 5.1 above is completely independent of the question whether or not claim 1 of auxiliary request 2 without the disclaimer contains subject-matter excluded by Article 52(4) EPC 1973, the subject-matter of claim 1 of auxiliary request 5 for the same reasons as indicated in the said paragraph 5.1 above does not involve an inventive step either.

8.2 In view of the finding in paragraph 8.1 above, an evaluation of whether the deletion of the disclaimer is allowable under Article 52(4) EPC 1973 or under Articles 84, 123(2) or 123(3) EPC is not necessary.

9. Auxiliary request 6:

9.1 Inventive step of claim 1:

Claim 1 of auxiliary request 6 is identical with claim 1 of auxiliary request 3 except for the deletion of the disclaimer. As the evaluation of the inventive step made in paragraph 6.1 above is completely independent of the question whether or not claim 1 of auxiliary request 3 without the disclaimer contains subject-matter excluded by Article 52(4) EPC 1973, the subject-matter of claim 1 of auxiliary request 6 for the same reasons as indicated in the said paragraph 6.1 above does not involve an inventive step either.

9.2 In view of the finding in paragraph 9.1 above, an evaluation of whether the deletion of the disclaimer is allowable under Articles 84, 123(2) or 123(3) EPC or under Article 52(4) EPC 1973 is not necessary.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar:

The Chairman:

D. Meyfarth

U. Oswald