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File Number: T 18/91 - 3.3.2
Application No.: 82 301 104.4
Publication No.: 0 059 649
Title of invention: Dental compositions

Classification: A61K 6/08

D E C I S I O N
of 26 February 1993

Applicant: Imperial Chemical Industries Plc.
Opponent: 01) Blendax GmbH
02) Etablissement Dentaire Ivoclar
03) Espe Stiftung & Co. Produktions- und
Vertriebs KG
04) Kuraray Co., Ltd.

Headword:

EPC Art. 54, 56, 84 EPC

Keyword: "Clarity (of main request) - no"
"Novelty - yes"
"Inventive step - no - obvious combination of known features"



Case Number : T 18/91 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 26 February 1993

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Decision under appeal : Decision of the Opposition Division of the
European Patent Office dated 3 April 1990 posted
on 12 November 1990 revoking European patent
No. 0 059 649 pursuant to Article 102(1) EPC.

Composition of the Board :

Chairman : A.J. Nuss
Members : I.A. Holliday
E.M.C. Holtz

Summary of Facts and Submissions

I. European patent No. 0 059 649 was granted on the basis of ten claims contained in European patent application No. 82 301 104.4. Having regard to prior art which had arisen under Article 54(3) EPC separate sets of claims existed for the Contracting States BE, DE, FR, GB, NL and SE and for AT, CH, IT, LI and LU respectively.

II. Oppositions were filed against the granted patent by:

- (01) Blendax GmbH
- (02) Etablissement Dentaire Ivoclar
- (03) Espe Stiftung & Co
- (04) Kuraray Co. Ltd.

Numerous documents were cited; the following remain relevant to the present appeal:

- (1) US-A-4 089 763
- (1a) DE-A-2 419 887
- (2) Kilian, Polymer Science and Technology, 14, 411 (1981)
- (3) DE-A-2 506 650
- (4) GB-A-569 974
- (5) GB-A-1 357 416
- (7) GB-A-1 408 265
- (7a) DE-A-2 251 048
- (8) GB-A-2 016 994
- (9) GB-A-2 018 666
- (9a) DE-A-2 914 537.

III. In accordance with the decision under appeal, the Opposition Division revoked the patent.

The Opposition Division considered document (1) to be the closest prior art since it related to light curable dental compositions which contained, as photosensitisers, diketones of similar formula to those of the patent in suit. In relation to (1), the problem to be solved lay in improving the depth of cure.

The decision referred to document (2) which discussed and compared visible light curing systems based on diketone with a reducing agent, especially an amine, with the alternative chemical cure using amine and peroxide. In the light thereof, the Opposition Division considered that there was sufficient incentive in documents (3) and (4) to induce one skilled in the art to try a combination of diketone sensitised light curing and a peroxide based chemical curing in order to obtain a deeper cure.

- IV. The Appellant lodged an appeal against the said decision. Oral proceedings took place on 26 February 1993.

- V. The arguments of the Appellant both in the written procedure and at the oral proceedings may be summarised as follows:

The Appellant discussed the three mechanisms used to achieve cure of dental compositions. Mechanism (A) involved a visible light cure using a mixture of diketone and peroxide. Mechanism (B) was the known cure using α -diketone and reducing agent and finally Mechanism (C) related to the known chemical cure using as initiator an organic peroxide and an accelerator, especially an aromatic amine.

The Appellant argued that it was surprising that Mechanism (A) achieved a cure of such depth, pointing to Examples 1 and 2 of the patent in suit. Even better results were

achieved when a reducing agent was present, i.e. when Mechanism (B) became involved. It was argued that Mechanism (C) played no part in the cure and accordingly the Opposition Division had misunderstood the invention. The amines used as reducing agents in Mechanism (B), e.g. dimethylaminoethyl methacrylate (DMAEM), were quite different from the tertiary amines, e.g. dimethylaniline, used to catalyse peroxide curing.

Document (3) was considered broad and speculative and not relevant since it related to a "two-pack" system in which peroxide and amine were present in separate containers to be mixed by the dental practitioner just prior to use. Document (4) was alleged to teach away from the patent in suit since heat was involved when curing by means of the ketone/peroxide catalysts disclosed therein and in any event the curing times involved were far too long.

The Appellant introduced document (5) referring to Examples therein which showed no improvement in properties by combining a peroxide cure with a photochemical cure, e.g. induced by a ketone such as benzoin methyl ether.

To summarise: the Appellant, whilst admitting that the prior art was replete with examples of dental compositions involving ketone induced visible light curing systems and of compositions employing peroxide initiation, argued that there was no incentive to combine them.

With the statement of appeal, the Appellant offered amendment to the claims (both sets) specifying that the compositions had "acceptable shelf-life" and were packed in a single container.

Accompanying a letter received in the EPO on 11 August 1992, the Appellant filed four auxiliary requests, each relating to "use claims".

VI. In the written procedure and at the oral proceedings the Respondents argued essentially as follows:

Respondent (01) referred to the claims and to various passages in document (1a), arguing that the subject-matter of the patent in suit, in particular Claims 1 and 2 of the main request, lacked novelty in the light of its disclosure.

In considering the inventive step of independent Claim 2, the Respondents agreed that either document (1) or the German equivalent (1a) was an appropriate starting point. In seeking to improve the depth of cure, four of the cited documents (3), (4), (8) and (9) would suggest to the skilled person that a combination of light induced curing with peroxide cure would be likely to yield a deeper cure. Document (3) in particular referring to the combination of cure, by peroxide, once the light source had been removed.

As far as Claim 1 is concerned the Respondents considered document (4) to be a more appropriate starting point. At the priority date of the disputed patent, camphorquinone (CQ) was the most commonly used sensitiser in light-curing compositions. A substitution of CQ for the ketones disclosed in (4) would lead to the compositions currently claimed.

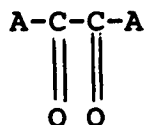
The Respondents also raised objection under Article 84 EPC to the amendment referring to "an acceptable shelf-life", which was considered to be unspecific and unclear designation.

The auxiliary requests were considered to relate to the same inventive concept as the main request and accordingly the same objections concerning inventive step applied to them. In addition objections were raised under Article 123 to the said auxiliary requests.

VII. Claims 1 and 2 of the main request, for the designated States AT, CH, IT, LI and LU read as follows:

"1. A visible light cure fluid dental composition which comprises at least one polymerisable ester of acrylic or methacrylic acid, from 40% to 90% by weight of the composition of at least one particulate filler, and a visible light sensitive catalyst characterised in that the catalyst comprises camphorquinone and at least one organic peroxide which has a ten hour half life temperature of less than 150°C and has the formula R-O-O-R in which the groups R, which may be the same or different, are hydrogen, alkyl, aryl or acyl groups, no more than one of the groups being hydrogen and that the composition has acceptable shelf life and packed in a single container.

2. A visible light cure fluid dental composition which comprises at least one polymerisable ester of acrylic or methacrylic acid, from 40% to 90% by weight of the composition of at least one particulate filler, and a visible light sensitive catalyst characterised in that the catalyst comprises (i) at least one ketone having photosensitive catalytic action selected from fluorenone and alpha-diketones having the formula



in which the groups A, which may be the same or different, are hydrocarbyl or substituted hydrocarbyl groups and in which the groups A may be further linked together by a divalent link or by a divalent hydrocarbyl or substituted hydrocarbyl group or in which the groups A together may form a fused aromatic ring system, (ii) at least one organic peroxide which has a ten hour half life temperature of less than 150°C and has the formula R-O-O-R in which the groups R, which may be the same or different, are hydrogen, alkyl, aryl or acyl groups, no more than one of the groups being hydrogen and (iii) a reducing agent which is capable of reducing the ketone when the latter is in an excited state and that the composition has acceptable shelf life and packed in a single container."

Claim 1 of the main request for the Contracting States BE, DE, FR, GB, NL and SE reads the same as above but includes the disclaimer "and provided that where the composition contains 20% or more of polymerisable silane, no amine is present in the polymerisation catalyst". Claim 2 for the above States contains the disclaimer "and characterised in that the composition does not contain 20% or more of polymerisable silane".

The first auxiliary request deletes the references to "acceptable shelf life".

Auxiliary request A relates to the use of a mixture corresponding to Claim 1 of the main request as a visible light sensitive catalyst in a fluid storage stable dental composition.

Auxiliary request B relates to the use of a mixture corresponding to Claim 2 of the main request as a visible light sensitive catalyst in a fluid storage stable dental composition.

Auxiliary request C is in effect a combination of requests A and B.

Auxiliary request D relates to the use of a peroxide in admixture with camphorquinone (Claim 1) or the more generally defined diketone (Claim 2) as a visible light sensitive catalyst in a fluid storage stable dental composition.

VIII. The Appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims annexed to the decision under appeal with the addition at the end of Claims 1 and 2 of either of the words "and that the composition has acceptable shelf life and packed in a single container", or alternatively "and that the composition is packed in a single container" (main request and first auxiliary request respectively), alternatively on the basis of either of sets C, A, B or D (in descending order as listed) as submitted on 11 August 1992 (2nd, 3rd, 4th and 5th auxiliary requests respectively).

The Respondents requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.
2. Formal matters
 - 2.1 Claims 1 and 2 of the main request (both designations) satisfy the requirements of Articles 123(2) and (3). Although the description is of broader scope, there is

basis on page 14, lines 3-15 of the application documents (page 6, lines 21-27 of the printed specification) for packaging in a single container; reference to "shelf life" occurs on page 11, lines 15-18 of the original disclosure (page 5, line 43 of the printed specification). The scope of the claims is also restricted by the proposed amendment.

- ~~2.2~~ ~~The Board agrees with the objections of the Respondents~~ that the reference to "acceptable shelf life" contravenes Article 84 EPC (cf. point VI above). The expression "acceptable shelf-life" is clearly a vague concept without any generally recognised technical meaning in the present context. Nor is there any help in the description as to how to interpret the expression which cannot therefore be considered appropriate in defining the matter for which protection is sought. Accordingly the main request must be rejected for lack of clarity of both Claims 1 and 2.

Since, in any event, the designation of a dental composition packed in a single container must imply a shelf life at least of several months in order that the composition might remain useful to a dental practitioner, the considerations below in relation to Article 56 in respect of the auxiliary request would also apply to the main request.

3. The Board proposes to deal first with Claim 2 of the first auxiliary request since this claim has given rise to most of the discussion both in the written procedure and at the oral proceedings. Claim 2 for the designations AT, CH, IT; LI and LU will be considered first since it is not complicated by the presence of a disclaimer.
4. The subject-matter of Claim 2 is a visible light cure fluid dental composition comprising five essential

components: (i) at least one polymerisable ester of acrylic or methacrylic acid, (ii) a particulate filler, (iii) at least one ketone selected from fluorenone and α -diketones of a specified formula (iv) at least one organic peroxide, and (v) a reducing agent.

4.1 In the opinion of the Board the closest prior art is document (1a) which is a German application based on two British priorities one of which forms the priority for US document (1) selected as the closest prior art by the Opposition Division. The reason for selecting the German document is that it contains more information.

4.1.1 Document (1a), an earlier application by the Appellant, also relates to dental compositions containing polymerisable ethylenically unsaturated material. It is to be noted that the vinyl urethane polymer used in Example 24 of (1a) appears essentially the same as that employed in Example 1 of the patent in suit. The compositions of document (1a) contain inorganic filler in similar proportions to those used in the patent in suit.

4.1.2 Claim 17 of (1a) refers to curing the composition with a peroxide and accelerator. Claim 18 refers to a catalyst activated by radiation and Claim 19 appendant thereto relates to the use of fluorenone and the α -diketones mentioned in Claim 2 of the patent in suit; camphorquinone is specifically mentioned on page 23 of document (1a) and is used as catalyst in Examples 4 and 24 thereof. Claim 20 of (1a) defines a tertiary amine useful as a reducing agent in the curing process in essentially the same terms as those set out on page 5, lines 25-29 of the patent in suit; DMAEM, the preferred tertiary amine in the compositions of the patent in suit is employed in several of the worked Examples of (1a).

4.2 Thus starting from document (1a), the problem to be solved can be seen in improving the depth of cure when using a ketone in association with a reducing agent in a light activated curing system. Obtaining such a deeper cure would avoid the dentist having to apply the filling in layers, with a consequent saving in time.

4.3 The problem is solved by using an organic peroxide together with the ketone and reducing agent. Having regard to the Examples of the patent in suit and the experimental data on file, the Board is satisfied that the problem has in fact been solved.

5. The Board is convinced that the subject-matter of Claim 2 is novel over the prior art cited.

5.1 Curing using peroxide and accelerator described on pages 19-20 (typewritten numerals) of document (1a) can only be seen as an alternative to the light activated curing using ketone and reducing agent disclosed on pages 20-27. It is to be noted that such light activated cures are employed in Examples 1-5, 7-12 and 14-25 of (1a); Example 13 employs a mixture of benzoyl peroxide and dimethyl-p-toluidine as curing agent. There is no suggestion in document (1a) that such a peroxide cure might be combined with the light activated ketone/reducing agent cure. Even though separate items belonging to different embodiments may be described in the same document, it is not permissible to combine them unless the document specifically suggests such combination (cf. decision T 305/87, OJ EPO 1991, 429; Reasons, point 5.3).

5.2 As is apparent from the extensive analysis of the prior art set out on pages 14-23 of the contested decision, none of the other cited documents discloses in combination the

specific features set out in Claim 2 of the patent in suit.

6. It remains to consider whether or not Claim 2 satisfies the requirements of Article 56 in respect of inventive step.

6.1 The composition of Claim 2 differs from that disclosed in document (1a) in that peroxide is combined with a ketone photosensitiser in the presence of a reducing agent. As indicated above a peroxide cure is considered in (1a) merely as an alternative to a light activated ketone system. Accordingly, document (1a) considered in isolation provides no strong incentive to combine them.

6.2 However, at least four of the documents considered during the appeal proceedings do suggest such a combination in connection with a deeper or shorter cure.

6.2.1 Although document (4) was published as early as 1945 and does not specifically refer to packaging in a single container, its teaching cannot be ignored. Polymer chemistry has made considerable progress since the publication of (4); in particular the (meth)acrylic esters used in (1a) and the patent in suit had not then been developed. Nevertheless (4) is concerned with a curing system for ethylenically unsaturated monomers which comprises a photosensitive ketone, e.g. benzoin or diacetyl (page 1, lines 95-100) together with which a conventional peroxide catalyst may be employed. According to page 2, lines 7-10, presence of the peroxide will ensure that the curing process will continue after the light source has been removed. The use of a reducing agent in association with the ketone was not then recommended. The light source is a tungsten filament lamp, i.e. visible light. Although not recognised as such at the time, this

appears to the Board to be an early manifestation of "Mechanism A" referred to by the Appellant.

The Appellant has argued that having regard to the long curing times of approx. 10 minutes, the teaching of document (4) would have been disregarded. The Board, however, is inclined to agree with the Opposition Division that, within the context of the materials and technology then available, ~~the long curing times would not have~~ acted as a disincentive.

6.2.2 The Appellant has dismissed document (3) as broad and speculative and earlier questioned its relevance since it is concerned with ultraviolet and not visible light curing. However, the fact cannot be denied that it was teaching of which the skilled person would have been aware at the priority date of the patent in suit. Having regard to Kilian (2) (paragraph bridging pages 412 and 413), it appears that essentially the same mechanism is involved in ultraviolet and visible light curing. As was agreed by the parties at the oral proceedings, the argument in favour of visible light is that it avoids the harmful effects of ultraviolet radiation both on the patient and the dentist.

Although (3) is oriented towards a two-pack curing whereby the parts are mixed by the dentist prior to use, it is nevertheless a strong indication that when seeking to improve the depth of cure obtained by light curing, a combination of a peroxide with an ethylenically unsaturated monomer and an amine reducing agent would lead to the curing continuing after removal of the light source and hence to a deeper cure (see especially paragraph bridging pages 3 and 4).

- 6.2.3 Document (5), introduced by the Appellant, also contains a strong incentive to introduce a peroxide into a photopolymerisable dental composition comprising an acrylic monomer and a photosensitising agent. In the passage beginning at line 53 on page 10, it is stated that the presence of the peroxide leads to more complete polymerisation in a shorter time than using a photosensitising agent alone. The Appellant has argued that Examples I and IV of (5), which contain peroxide show no improvement in compressive strength over Examples VI and VII which do not contain peroxide. In the opinion of the Board, these results are not comparable; whilst a curing time of two minutes is mentioned for Examples I and V, the specification is silent concerning the curing time in the absence of peroxide. It is to be noted that the passage on page 12, lines 50 to 64 comments on shelf stability of the composition once mixed and that storage in a single container is also envisaged (lines 59 to 61).
- 6.2.4 Document (9) and its equivalent (9a) referred to by the Respondents relate to methods of manufacturing a tooth crown by photopolymerising a (meth)acrylate composition using various ketones as photosensitisers. According to the description on page 2, lines 18-24, it is possible to promote the curing by adding a peroxide. Such a method of curing forms the subject-matter of Claims 10 and 11, the latter specifically referring to a diacyl peroxide. There is reference to storage stability on page 2 but only to the effect that the peroxide content should be less than 2% to avoid premature polymerisation.
- 6.2.5 Having regard to the preceding, in the judgment of the Board the skilled man seeking to improve the depth of cure obtainable using the composition of document (1a) would have the incentive to try the addition of peroxide to the ketone photosensitiser/reducing agent curing system with a

reasonable expectation of success (cf. decision T 2/83, OJ EPO 1984, 265). The scientific explanation of the mechanisms involved when curing the compositions currently claimed (see Point V above) could only be taken into consideration if such would have deterred the man skilled in the art from trying the combined addition; this is clearly not the case here. Accordingly, the subject-matter of Claim 2 for the designated States AT, CH, IT, LI and LU lacks inventive step.

7. Claim 2 for the other designated States is essentially the same as that considered above except for the presence of the disclaimer. The said disclaimer was inserted in order to exclude the subject-matter of EP-B-0 058 514 which was cited under Article 54(3) EPC. Since polymerisable silanes do not form an essential feature of the compositions currently claimed, the same conclusion as to inventive step must also apply to Claim 2 for the designated States BE, DE, FR, GB, NL and SE.
8. Claim 1 of the patent in suit has a different scope and specifies as essential components: (i) at least one polymerisable ester of (meth)acrylic acid, (ii) a particulate filler, (iii) camphorquinone as visible light sensitive catalyst and (iv) at least one organic peroxide. The claim for AT, CH, IT, LI and LU will be considered first since it does not contain a disclaimer.
- 8.1 In respect of Claim 1, the Board regards document (4) as the closest prior art. As has already been noted, the photopolymerisable composition according to (4) comprises (inter alia) esters of (meth)acrylic acid, fillers and pigments, a ketone, e.g. benzoin, as light sensitiser and a peroxide, e.g. benzoyl peroxide. A tungsten filament lamp is used in curing, i.e. visible light, and the curing time is stated to be ten minutes.

- 8.1.1 The problem to be solved can be seen in reducing the curing time to a value compatible with the comfort of the patient and the convenience of the dental practitioner.
- 8.1.2 The problem is solved by substituting camphorquinone for the ketone sensitizers disclosed in (4). As cure times of 30 seconds or less are recorded in the patent in suit, the Board is satisfied that the problem has been solved.
- 8.2 Since camphorquinone is not mentioned in document (4), the subject-matter of Claim 1 is novel over its disclosure. It is also apparent from the analysis of the prior art referred to in point 5.2 above that none of the other cited documents discloses the composition of Claim 1. Novelty can thus be accorded.
- 8.3 It was not disputed by the parties at the oral proceedings that camphorquinone was a preferred visible light sensitizer for photopolymerisable dental compositions at the priority date of the patent in suit. This is confirmed by its use in various compositions mentioned in the cited prior art, e.g. document (1a), page 23, Examples 4 and 24; document (7), page 3, lines 11-39; document (7a), Claim 13.
- 8.3.1 Thus, the skilled person, who would be expected to take account of developments involved in solving identical or similar problems, when seeking to reduce the curing time of the dental compositions known from (4), would have had the incentive to try if substituting camphorquinone for one of the ketone catalysts then used would lead to a quicker cure. Accordingly, the subject-matter of Claim 1 also lacks inventive step.
- 8.4 For the reasons set out in point 7 above, the same conclusion must also be reached in respect of Claim 1 for the other designated States.

9. The four auxiliary requests relating to "use claims" remain to be considered.

9.1 Claims 1 and 2 of the patent in suit relate to dental compositions. The alleged advantageous properties of the said compositions are associated with an effect: namely that by using a mixture of at least one peroxide and a ketone sensitiser possibly in the presence of a reducing agent, cures of greater depth may be obtained. The ketone may be camphorquinone (Claim 1) or according to Claim 2, either fluorenone or a diketone of the specified formula. For the reasons given above, the Board has decided that the said effect cannot be associated with an inventive step.

9.2 In the judgment of the Board, the use claims of each of the requests set out in Appendices A to D are associated with the same effect. Accordingly, the same reasons must apply and an inventive step must be denied for each of the sets of use claims.

9.2.1 In the letter received on 11 August 1992, the Appellant stated that the claims of Appendix D had been drafted having regard to decision G 2/88. As explained at the oral proceedings, the Board does not consider that this decision of the Enlarged Board is pertinent to the present case. G 2/88 was concerned with a new non-medical use of a known material whilst in the present case the composition itself is novel (cf. points 5 and 8.2 above). Although the claim relates to the use of a peroxide (a known material), such use is in admixture with a ketone sensitiser in dental compositions. The Appellant's argument that this new use is surprising must be denied having regard to its use together with ketones disclosed in documents (3), (4),

(5) and (9). This use of peroxide is also associated with the same effect noted in point 9.1 above. The reasoning must again apply and inventive step must also be denied to the claims of Appendix D.

9.3 Since the claims of the auxiliary requests must be refused for the reasons set out above, it is not necessary for the Board to consider whether the change of category of claim would offend Article 123 EPC.

Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

P. Martorana

A.J. Nuss