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Datasheet for the decision of 5 June 2014

Case Number: T 1025/10 - 3.3.07

Application Number: 01962033.5

Publication Number: 1307171

IPC: A61K6/083

Language of the proceedings: EN

Title of invention:
DENTAL COMPOSITIONS COMPRISING BISACRYLAMIDES AND USE THEREOF

Patent Proprietor:
DENTSPLY International Inc.

Opponent:
Ivoclar Vivadent AG

Relevant legal provisions:
EPC Art. 56, 104
RPBA Art. 13

Keyword:
Late-filed document - admitted (yes)
Inventive step - main request (no)
Late-filed request - admitted (yes)
Inventive step - auxiliary request (no)
Apportionment of costs - (no)

Decisions cited:
T 0789/89

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Case Number: T 1025/10 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 5 June 2014

Appellant: (Patent Proprietor)	DENTSPLY International Inc. 570 West College Avenue P.O. Box 872 York, PA 17405-0872 (US)
Representative:	Hartz, Nikolai Wächtershäuser & Hartz Patentanwaltspartnerschaft mbB Weinstrasse 8 80333 München (DE)
Respondent: (Opponent)	Ivoclar Vivadent AG Bendererstrasse 2 FL 9494 Schaan (LI)
Representative:	Muth, Heinz-Peter Uexküll & Stolberg Patentanwälte Beselerstrasse 4 22607 Hamburg (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 24 March 2010 concerning maintenance of the European Patent No. 1307171 in amended form.**

Composition of the Board:

Chairman: R. Hauss
Members: D. Semino
P. Schmitz

Summary of Facts and Submissions

I. The appeal lies against the decision of the opposition division announced at the oral proceedings on 22 January 2010 concerning maintenance of the European Patent No. 1 307 171 in amended form.

II. The granted patent comprised 8 claims, claim 1 reading as follows:

"1. A dental composition that comprises at least a bisacrylamide, a polymerizable monomer, at least an amine and/or an initiator, a stabilizer, pigments and an organic and/or inorganic filler, wherein said bisacrylamide is **characterized by** the following formula:

wherein
R_1 is a substituted or unsubstituted C_1 to C_{18} alkyl, R_2 is a difunctional substituted or unsubstituted C_1 to C_{18} alkylene, a difunctional substituted or unsubstituted cycloalkylene, difunctional substituted or unsubstituted C_5 to C_{18} arylene or heteroarylene, difunctional substituted or unsubstituted C_5 to C_{18} alkylarylene or alkylheteroarylene, difunctional substituted or unsubstituted C_7 to C_{30} alkylene arylene."

III. A notice of opposition was filed against the granted patent requesting revocation of the patent in its entirety on the grounds of lack of novelty and lack of inventive step and extension of the subject-matter of

the patent beyond the content of the application as filed, in accordance with Article 100(a) and (c) EPC.

IV. During opposition proceedings the following documents *inter alia* were cited:

D1: EP-A-1 222 910
D2: WO-A-99/03444
D3: US-A-5 545 676
D5: "Erklärung zur Vorlage beim Europäischen Patentamt" by Dr. Salz filed with letter dated 21 December 2009
D6: Danusso et al., La Chimica e L'Industria, Volume 49(5), 1967, pages 453 to 457
D7: "Erklärung zur Vorlage beim Europäischen Patentamt" by Dr. Klee filed during the oral proceedings on 22 January 2010

While documents D1 to D3 were cited in the notice of opposition, where document D2 was taken as the closest prior art for the objection of lack of inventive step, documents D5 and D6 were filed by the opponent one month before the oral proceedings before the opposition division and document D7 was filed by the patent proprietor at the oral proceedings.

V. The decision was based on a set of claims filed with letter of 14 May 2008 as main request and a further set of claims filed on 22 January 2010 during oral proceedings before the opposition division as auxiliary request 1. Claim 1 of the main request was identical to granted claim 1. In claim 1 of auxiliary request 1 the expression "R_1 is a substituted or unsubstituted C_1 to C_{18} alkyl" was replaced by "R_1 is benzyl".

VI. The decision of the opposition division, as far as relevant to the present decision, can be summarised as follows:

a) The main request did not meet the requirements of Article 123(2) EPC in view of the amendment of the term "substituted or unsubstituted alkylene" defining R_1 in claim 2 as originally filed into "substituted or unsubstituted alkyl" in claim 1 as granted. The amendments could not constitute a correction under Rule 139 EPC and violated therefore the requirements of Article 123(2) EPC. While it appeared that a mistake had occurred, the proposed correction was not obvious, as there was a second plausible way to correct, namely by deleting the term "unsubstituted". A similar objection applied to granted claim 3.

b) In auxiliary request 1 the definition of R_1 by the term "benzyl" in claim 1 and the deletion of claims 3 and 8 as granted solved the issues related to Article 123(2) EPC.

c) Document D1 could not be seen as a relevant document for the novelty of claim 1 of auxiliary request 1, as it did not disclose any benzyl radical and its priority date was posterior to the priority date valid for the subject-matter of claim 1.

d) The subject-matter claimed in auxiliary request 1 differed from the composition of document D2, taken as the closest prior art, in the selection of a particular bisacrylamide with a benzyl substituent and in the selection of a polymerizable monomer, an amine and/or an

initiator, a stabilizer, pigments and an organic/ inorganic filler to make a dental cement composition. As the technical effect of the difference was not known, the technical problem was the provision of an alternative dental cement. The solution was inventive as the teaching of D2 was too remote to render the invention obvious and none of the cited documents (in particular D3 and D6) disclosed a bisacrylamide with a benzyl substituent or the use of bisacrylamide as dental cement.

e) The comparative tests in D5 did not relate to the bisacrylamide claimed in auxiliary request 1 and were not admitted into the proceedings. The same applied to document D7 which related to the comparative tests of D5. D6, which was cited in the patent in suit, was admitted into the proceedings.

VII. The patent proprietor (appellant) lodged an appeal against that decision. In the statement setting out the grounds of appeal the appellant maintained the main request and requested *inter alia* that the opponent be apportioned the costs incurred for the experimental efforts undertaken by the appellant to rework the experiments of D5.

VIII. With the reply to the statement of grounds the opponent filed a further piece of evidence concerning the reproducibility of the experiments of D5:

D8: Experimental report dated 30 November 2010 of the Eidgenössischen Materialprüfungs- und Forschungsanstalt (EMPA)

IX. With letter of 20 December 2011 the appellant filed two further pieces of evidence concerning the reproducibility of the experiments of D5:

D9: Experimental report dated 21 September 2010 prepared by Dr. Wolter of the Fraunhofer Institut für Silikatforschung ISC, Würzburg
D10: Experimental report dated 15 December 2011 prepared by Mr Häusler of the Fraunhofer Institut für Silikatforschung ISC, Würzburg

X. With letter of 19 February 2014 the opponent withdrew the opposition.

XI. In a communication sent in preparation of oral proceedings the Board summarised the points to be dealt with including the issue under Article 123(2) EPC on which the main request had been refused by the opposition division (point 2 of the communication) and the main point with respect to inventive step, namely whether effects and improvements with respect to the closest prior art had been proven in order to formulate the solved problem accordingly (point 4 of the communication). To this regard the Board noted that, while disagreement was present on the reproducibility of the tests provided by the opponent with D5, apparently no evidence was available on the side of the appellant to show that improvements were indeed achieved.

XII. In reaction to that communication the appellant filed with letter of 19 May 2014 a set of 6 claims as auxiliary request.

Claim 1 of the auxiliary request differed from claim 1 of the main request in the deletion of the term

"unsubstituted" in the definition of the rest R_1 which therefore read "R_1 is a substituted C_1 to C_{18} alkyl".

With the same letter four documents were filed as evidence of the presence of an effect with respect to the composition of document D2, namely:

D11: U. Salz and T. Bock, "Adhesion Performance of New Hydrolytically Stable One-component Self-etching Enamel/Dentin Adhesives", Journal of Adhesive Dentistry, Volume 12(1) 2010, pages 7 to 10
D12: Declaration of Dr. J. Angermann dated 31 October 2012
D13: Declaration of Dr. J. Angermann dated 16 December 2011
D14: Declaration of Dr. J. Angermann dated 7 December 2011

XIII. Oral proceedings were held on 5 June 2014.

XIV. The arguments of the appellant, as far as relevant to the present decision, can be summarised as follows:

Inventive step

a) Using D2 as the closest prior art, the difference with respect to the claimed subject-matter resided in the fact that D2 did not disclose bisacrylamides as defined in claim 1, but only bisacrylamides which were unsubstituted at the nitrogen. Moreover, D2 did not anticipate the selection of a polymerizable monomer, an amine and/or an initiator, a stabilizer, pigments and an organic/inorganic filler to make a dental composition in combination with the specific bisacrylamide.

b) The technical problem with respect to D2 was the provision of a dental composition having improved hydrolysis stability and providing improved curing properties. The solution according to claim 1 had given rise to a new generation of hydrolysis stable dental compositions which could be stored under high acidity conditions in an aqueous mixture at ambient temperature. This was due to the hydrophobic alkyl substituents of the bisacrylamides at the amide nitrogen atoms as compared to the hydrophilic unsubstituted amide groups. Evidence of the improvement in hydrolysis stability was given by documents D11 to D14, filed by the opponent in parallel proceedings. D11 showed that only the dental compositions which contained bisacrylamides according to the claim had an excellent hydrolysis stability. D12 showed that the bisacrylamide disclosed in D2 was not sufficiently stable and could not be used therefore in a commercial product. D13 and D14 showed that bisacrylamides according to the claim had excellent hydrolysis stability. In particular the substituted bisacrylamide indicated as V-439 was more stable than the unsubstituted V-398. In this respect it was not clear why some other substituted bisacrylamides were slightly less stable. The results of the tests in D5 should be disregarded, as the experiments reported therein were not reworkable. While the dental composition covered both embodiments involving free radical polymerisation and others in which a Michael addition polymerisation took place, the improvement in hydrolysis stability related to both situations.

c) There was no suggestion in the available prior art of the proposed solution. D2 was centered on the handling properties of the compositions, indicated the presence of a handling modifier as the crucial feature to obtain the desired viscosity at different shear rates and indicated that the polymerisable monomer could be any of a large variety of polymerizable components cited in D2. Moreover, it did not mention the problem of hydrolysis stability, but related to non-aqueous compositions and contained no pointer to the substituted bisacrylamides. As no other document gave any further hint, the presence of an inventive step should be acknowledged.

d) The same arguments were valid for the inventiveness of the subject-matter of the auxiliary request.

Apportionment of costs

e) Shortly before the oral proceedings before the opposition division the opponent had filed document D5 including new experiments, which could not be reworked. This was clear from careful attempts of an external research institute which were ordered by the appellant. Moreover, the opponent was unwilling to provide the necessary information to reproduce the experiments of D5. Under such circumstances it was a matter of equity that the opponent be apportioned the costs incurred for the experimental efforts undertaken by the appellant.

XV. The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis

of the main request filed with letter dated 14 May 2008, or the auxiliary request filed with letter of 19 May 2014. Additionally, it was requested that the opponent be apportioned the costs incurred for the experimental efforts undertaken by the appellant.

Reasons for the Decision

Status of the opponent

1. In line with the case law the opponent, which was the respondent to the appeal of the patent proprietor, by virtue of the withdrawal of the opposition ceased to be party to the appeal proceedings in respect of the substantive issues. However, the status of the opponent as a party to the proceedings is unaffected as far as the question of apportionment of costs under Article 104 EPC is at issue (see T 789/89, OJ 1994, 482).

Admission of documents D11 to D14

2. After the Board indicated in the communication sent in preparation of the oral proceedings that no evidence was available on the side of the appellant to show that improvements with respect to the closest prior art represented by document D2 were achieved, the appellant filed documents D11 to D14 in order to provide the missing evidence.

2.1 Documents D11 to D14 indeed concern the central issue of hydrolysis stability for compositions comprising bisacrylamides. The Board has no difficulty in understanding the tests provided therein and there is no other party to the proceedings which would require further time to provide counter-arguments.

2.2 On that basis the Board finds it appropriate to exercise its discretion under Article 13 RPBA by admitting documents D11 to D14 into the proceedings.

Main request - amendments

3. The issue under Article 123(2) EPC on which the main request fell in opposition proceedings does not need to be decided upon, because the main request is not allowable for the reasons set out below (points 4 to 6).

Main request - inventive step

4. *Closest prior art*

4.1 Document D2 was chosen as the closest prior art both in the decision under appeal and in the arguments of the appellant. The Board has no reason to choose a different starting point.

4.2 Document D2 discloses a dental resin cement material comprising a filler, a polymerizable resin, a polymeric handling modifier and a polymerization initiator (claim 1). If desired, the composition can contain adjuvants such as pigments (page 19, lines 12 to 14) and optionally it may contain stabilizers (page 19, lines 14 and 15).

4.3 As to the polymerizable component several compounds are disclosed (page 10, line 7 to page 16, line 13). Preferred polymerizable components can be substituted acryl amides and methacrylamides, examples of which are methylene bisacrylamide and methylene bismethacrylamide (page 12, lines 6 to 8). Mixtures of polymerizable

material are also contemplated (page 16, lines 11 to 13).

4.4 On that basis the dental composition of claim 1 of the main request differs from the disclosure in D2 in that the bisacrylamides are substituted at the two nitrogen positions (R_1 is a substituted or unsubstituted C_1 to C_{18} alkyl, but not a hydrogen as in the bisacrylamides mentioned in D2) and that in addition to the bisacrylamide, the filler and the initiator, a second monomer, a stabilizer and pigments are necessarily present (all ingredients are mentioned individually in D2, but not necessarily in the combination as claimed in claim 1 of the main request).

4.5 This analysis has been agreed by the appellant.

5. *Technical problem solved*

5.1 The patent focuses on the problems of the conventional methacrylates used for dental applications, whose hydrolysis under acidic or basic conditions frequently leads to long-term failure (paragraph [0002] of the granted patent). Indeed it has been the central argument of the appellant in the analysis of inventive step that the use of bisacrylamides in the claimed composition leads to improved hydrolysis stability.

5.2 As the closest prior art already discloses the use of bisacrylamides, it needs to be determined whether the evidence on file permits an improvement in hydrolysis stability to be acknowledged as a consequence of the replacement of the bisacrylamides mentioned in D2 (not substituted at the nitrogen atoms) with the bisacrylamides in claim 1 of the main request (substituted at both nitrogen atoms). The evidence

cited in this respect by the appellant is constituted by documents D11 to D14.

5.2.1 Document D11 analyses the hydrolysis stability of several dental compositions (abstract and table 1) and compares the storage stability of commercial products (page 8, second column, "Storage Stability"), including AdheSE One F and Xeno V, both containing bisacrylamides (table 1, composition). According to D11, the results of the test show that methacrylamide-based adhesives are stable to aqueous acid and exhibit much superior storage stability than conventional methacrylate-based adhesives (abstract, "Conclusions").

5.2.2 Document D11, however, does not give any detail on the chemical structure of the bisacrylamides used in the tested commercial products and does not provide a comparison between bisacrylamides with different structures (in particular substituted at the nitrogen and unsubstituted). Even assuming, as alleged by the appellant, that the bisacrylamides in the commercial product Xeno V (produced by the appellant) fall under the chemical formula given in claim 1 of the main request, no conclusion over D2 can be reached without a comparison between the bisacrylamides disclosed in D2 and those indicated in the claim, which is entirely missing in D11.

5.2.3 Documents D12, D13 and D14 concern experiments undertaken to analyse the hydrolysis stability of several bisacrylamides stored for several days in bottles opaque to light at 37° under acidic conditions.

5.2.4 D12 concerns methylene bisacrylamide (one of the bisacrylamides mentioned in D2) and shows that after 4 weeks the purity has decreased by 11.6% (page 2, table

2 and first paragraph). According to D2 this is due to the length of the chain between the two nitrogen atoms (R_2 in the formula of claim 1), as it is stated that methylene bisacrylamide has a lower hydrolysis stability than analogous bisacrylamides with longer spacer groups (page 2, last sentence).

5.2.5 Indeed, this consideration is confirmed by the results in D13. Ethylene bisacrylamide (compound V-398, according to D13, table 1), which differs from methylene bisacrylamide only in that the spacer is an ethylene instead of a methylene (a chain with two carbon atoms instead of a chain with a single one), has a decrease in purity of only 1.5% after 20 days (table 3 in D13) and no hydrolysis products are identified after this period (table 4 in D13).

5.2.6 In D13 a comparison is also offered between two bisacrylamides which differ only in the presence of alkyl substituents at the nitrogen atoms, namely ethylene bisacrylamide (compound V-398, according to D13, table 1) and di-isopropyl ethylene bisacrylamide (compound V-724, according to D13, table 1). While V-398 has a decrease in purity of 1.5% after 20 days at storage conditions, the decrease in purity is of 3% for V-724, showing that the unsubstituted bisacrylamide is better than the substituted one in this respect. According to D13 no hydrolysis products were identified after 20 days in both cases (Table 4).

5.2.7 No other comparison between bisacrylamide unsubstituted at the nitrogen atoms and the corresponding substituted ones is offered by D13. Indeed other substituted bisacrylamides are tested (V-439, V-392, V-440 in table 1), all including a longer spacer group (C_3 or C_6), but there is no information on the corresponding

unsubstituted bisacrylamides, so that a comparison is not possible. If at all, these tests can only confirm that all bisacrylamides with a spacer longer than a simple methylene are more storage stable than the methylene bisacrylamide (tables 3 and 4).

5.2.8 D14 includes the same results as D13 in term of hydrolysis stability (see D13 and D14, pages 1 and 2).

5.2.9 The evidence in D12 to D14 therefore does not support the allegation of the appellant that the introduction of alkyl substituents at the nitrogen atoms improves the hydrolysis stability of the bisacrylamide. On the contrary, the only comparison which is available shows that the decrease in purity after 20 days is lower for the unsubstituted bisacrylamide than for the substituted one (see point 5.2.6, above). Moreover, the tests show that the crucial parameter for the storage stability is the length of the spacer group and that unsatisfactory results are obtained with a methylene spacer.

5.2.10 As the bisacrylamides comprised in the claimed composition include those with a methylene group (R_2 can be a C_1 alkylene) and differ from those of D2 only in the presence of an alkyl substituent at the nitrogen atoms, it cannot be acknowledged in view of the evidence on file that their hydrolysis stability is improved or even maintained with respect to the bisacrylamides of D2.

5.3 As to the specific combination of ingredients of claim 1 of the main request, no effect or advantage was claimed to be present by virtue of it. Indeed the appellant acknowledged that, while in the case of the presence of an amine in appropriate amounts a Micheal

type polymerization takes place, the claim includes embodiments with an initiator and without an amine, in which a free radical polymerization takes place, as is the case for the composition of D2.

5.4 In the absence of effects or advantages which can be acknowledged over the composition known from the closest prior art, the problem solved by the subject-matter of claim 1 of the main request with respect to the disclosure of D2 is the provision of a further dental composition.

6. *Obviousness of the solution*

6.1 The skilled person starting from the compositions of D2 and looking for further dental compositions would find the addition of optional ingredients explicitly mentioned in D2 in all possible combinations as an obvious measure to solve the posed problem.

6.2 Similarly the arbitrary choice of slightly different bisacrylamides (i.e. those with an alkyl substituent at the nitrogen atoms) with respect to the ones mentioned in D2 would be an obvious measure while looking for further dental compositions. In this respect it is relevant to note that the appellant never claimed that the substituted bisacrylamides were not known, as is confirmed for instance by document D6 (table 1, last two chemical formulas).

6.3 On that basis the subject-matter of claim 1 of the main request does not involve an inventive step.

Admission of the auxiliary request

7. After the Board indicated in the communication sent in preparation of the oral proceedings that the Board had difficulties in accepting the amendment of the term "alkylene" to "alkyl", as there were two possible corrections of the mistake in the original application which were not equivalent, the appellant filed an auxiliary request in which the definition of R_1 was limited to a substituted C_1 to C_{18} alkyl with the argument that this was covered by the two possible corrections of the obvious mistake.

7.1 The filing of the request was done as soon as possible after the appellant understood the reasons why the Board was inclined not to accept the amendment of the term "alkylene" to "alkyl" and included only a clear limitation of the definition of R_1 (from "a substituted or unsubstituted C_1 to C_{18} alkyl" to "a substituted C_1 to C_{18} alkyl"). Moreover, the Board has no difficulty in analysing the amended request.

7.2 On that basis the Board finds it appropriate to exercise its discretion under Article 13 RPBA by admitting the auxiliary request into the proceedings.

Auxiliary request - inventive step

8. No additional arguments were provided by the appellant for the inventiveness of claim 1 of the auxiliary request with respect to claim 1 of the main request, as the only amendment which was introduced was related to the objection under Article 123(2) EPC which formed the basis of the decision of the opposition division and which had been preliminarily maintained in the communication of the Board.

8.1 The same analysis of inventive step as detailed for the main request (points 4 to 6) equally applies to claim 1 of the auxiliary request, whose subject-matter does not involve therefore an inventive step.

Apportionment of costs

9. While the notice of opposition contained an objection of lack of inventive step for granted claim 1 with respect to document D2 as the closest prior art and acknowledged the difference therefrom in the bisacrylamides used in granted claim 1 in view of the presence of substituents at the nitrogen atoms which were not hydrogen atoms, there were no tests on file analysing the effects related to such a difference until one month before the oral proceedings before the opposition division. At that point the opponent filed some test results in the form of document D5 to show that the presence of the substituents did not have any impact on the hydrolysis stability of the claimed composition (D5, page 3, section 3). The reproducibility of these tests was put into question by further tests included in document D7 filed by the appellant at the oral proceedings before the opposition division (D7, last paragraph, "Feststellung"). Further evidence regarding the reproducibility of the tests in D5 was filed by the parties in appeal (the opponent filed D8, see point VIII, above; the appellant filed D9 and D10, see point IX, above).

9.1 The analysis of inventive step undertaken in the current decision (see points 4 to 6, above) shows that the availability of tests meant to show possible effects and advantages related to the replacement of hydrogen with alkyl substituents at the nitrogen atoms

was the decisive point in the determination of inventive step (see point 5.2, above). This was the case since the beginning of the opposition proceedings, since the current analysis takes as starting point the document used for lack of inventive step in the notice of opposition (document D2) and identifies the presence of the substituents at the nitrogen atoms as the crucial difference (see points 4.4 and 5.1, above) as was the case in the notice of opposition.

9.2 As alleged advantages to which the patent proprietor merely refers without offering sufficient evidence to support the comparison with the closest prior art, cannot be taken into consideration in determining the problem effectively solved by the claimed subject-matter (Case Law of the Boards of Appeal of the EPO, 7th edition 2013, I.D.4.2), the onus had been on the appellant since the start of the opposition proceedings to show that improvements were achieved by means of the difference in structure, in the absence of which the problem with respect to D2 was simply that of providing a further composition. In this respect the filing of D5 by the opponent, which was meant to show that no improvement was present, did not change the situation with respect to the absence of tests, in that also before the availability of these tests no improvement could be acknowledged, nor did it shift the burden of proof, which already lay with the appellant.

9.3 Under these circumstances it was not necessary for the appellant to show that the opponent's experiments were not reworkable, but it was necessary to file tests which showed the occurrence of the effects the appellant alleged to be present. Reworking the opponent's tests was not a necessary means of defence,

because D5 had no bearing on the case, as long as the appellant had not shown any advantage.

9.4 Moreover, the fact that the experts of the two parties did not agree on what happened while performing these tests corresponds to the not uncommon situation in which technicians of the opposing parties come to apparently contradictory results. This cannot however be considered as conclusive evidence of a malicious or abusive nature of the tests of the opponent.

9.5 As a consequence the Board fails to see any reason of equity which would justify a different apportionment of costs (Article 104(1) EPC). For these reasons the request that the opponent be apportioned the costs incurred for the experimental efforts undertaken by the appellant is rejected.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

2. The request for a different apportionment of costs is rejected.

The Registrar: The Chairman:

V. Commare R. Hauss

Decision electronically authenticated