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**Datasheet for the decision
of 21 April 2015**

Case Number: T 1301/11 - 3.3.07

Application Number: 97954969.8

Publication Number: 0991368

IPC: A61C5/00, A61C5/04, A61K6/083,
A61K6/097, A61K6/04, A61C5/12

Language of the proceedings: EN

Title of invention:
POLYMERIZABLE ISOLATION BARRIERS AND METHODS FOR FORMING AND
USING SUCH BARRIERS

Patent Proprietor:
Ultradent Products, Inc.

Opponent:
GDF

Headword:

Relevant legal provisions:
EPC Art. 100(b), 54, 56
RPBA Art. 13(1)

Keyword:
Late-filed request - admitted (yes)
Sufficiency of disclosure - main request (yes)
Novelty - main request (yes)
Inventive step - main request (yes)

Decisions cited:

G 0001/03

Catchword:



**Beschwerdekammern
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Case Number: T 1301/11 - 3.3.07

**D E C I S I O N
of Technical Board of Appeal 3.3.07
of 21 April 2015**

Appellant: GDF
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
12 April 2011 concerning maintenance of the
European Patent No. 0991368 in amended form.**

Composition of the Board:

Chairman J. Riolo
Members: A. Usuelli
D. T. Keeling

Summary of Facts and Submissions

- I. The appeal of the opponent (appellant) lies from the decision of the opposition division concerning the maintenance of the European patent No. 991 368 in amended form.
- II. The patent had been opposed under Article 100 (a) EPC on the grounds that its subject-matter lacked novelty and inventive step. Furthermore, the ground of opposition that the patent was not sufficiently disclosed (Article 100(b) EPC) was introduced by the opposition division under Article 114 EPC. The documents filed during the opposition proceedings included the following:
- D1: US 5,534,562
D9: US 4,482,535
D9a: First Declaration of Mr Wagner dated 5 November 2010
D9b: Second Declaration of Mr Wagner dated 19 November 2010
- III. The opposition division's decision was based on two sets of claims filed with letter of 6 November 2010 as main request and auxiliary requests 1. Claims 1 and 2 of auxiliary request 1, which was held patentable by the opposition division read as follows:

Claim 1:

"1. A polymerizable isolation barrier for isolating a dental substrate to confine a dental treatment composition to an area defined by the isolation barrier, the polymerizable isolation barrier comprising:

- at least one monomer selected from the group consisting of alkylmethacrylates, alkylhydroxymethacrylates, and alkylaminomethacrylates;
- at least one curing agent for curing the at least one monomer; and
- at least one element selected from the group which includes:

- an organic polymerization strength reducer comprising at least one of:

- an alcohol selected from the group consisting of cetyl alcohol and stearyl alcohol

- or

- a polyol selected from the group consisting of polyethylene glycol, polypropylene glycol and propylene glycol

or

- a tissue adherence accentuator comprising at least one of:

- a gum selected from the group consisting of xanthan gum, guar gum and tragacanth gum,

- a cellulose material selected from the group consisting of ethyl cellulose and hydroxypropyl methyl cellulose,

- a high molecular weight polyol having a molecular weight of at least 600 and selected from the group consisting of polyethylene glycols and polypropylene glycols,

- or

- a polymer selected from the group consisting of polysiloxanes, carboxy polymethylene, and water-soluble polyethylene oxides."

Claim 2:

"2. A polymerizable isolation barrier as claimed in claim 1, in which the at least one monomer is selected

from the group consisting of triethylene glycol dimethacrylate, polyethylene glycol dimethacrylate, butane diol dimethacrylate, 2-hydroxy ethyl methacrylate, glycerol dimethacrylate, bis GMA, and urethane dimethacrylate."

IV. According to the decision under appeal:

- a) The amendments introduced in claims 15 to 26 of the main request were not occasioned by a ground of opposition, as required by Rule 80 EPC.
- b) The subject-matter of auxiliary request 1 complied with Article 123(2) and (3), Article 84 and Rule 80 EPC. The requirements of sufficiency of disclosure and novelty were also met.
- c) As to the requirement of inventive step, either D1 or D9 could be used as the closest prior art. The technical problem was formulated as the provision of an isolation barrier to protect gum tissue which was easily removable. Neither D1 nor D9 provided any suggestion leading to the subject-matter of claim 1. The requirements of Article 56 EPC were therefore met.

V. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal dated 21 July 2011, the appellant submitted the following documents:

- D10: DE 4133494
- D12: US 4,846,165
- D14: US 5,380,772
- D16: WO93/07230
- D18: US 5,534,559

- VI. With the reply to the statement of the grounds of appeal filed on 8 March 2012, the patent proprietor (respondent) *inter alia* requested to dismiss the appeal and to maintain the patent according to the set of claims allowed by the opposition division or alternatively to maintain the patent on the basis of one of the first to seventh auxiliary requests filed therewith.
- VII. The Board issued on 16 March 2015 a communication pursuant to Article 15(1) RPBA in which several considerations were made in particular in relation to the issue of novelty vis-à-vis some of the documents cited by the appellant during the appeal proceedings.
- VIII. With letter of 1 April 2015 the respondent replaced the requests then on file by four new sets of claims consisting of a main request and three auxiliary requests.

Claim 1 of the main request differed from claim 1 of the request maintained by the opposition division (see point III above), in the deletion from the list of tissue adherence accentuators of the following group of substances:

- a) a cellulose material selected from the group consisting of ethyl cellulose and hydroxypropyl methyl cellulose,
- b) polysiloxanes

Claim 2 of the main request was identical to claim 2 of the request maintained by the opposition division.

- IX. On 21 April 2015, oral proceedings were held before the Board. After a discussion on the clarity of the main request filed on 1 April 2015, the respondent filed two new sets of claims as main request and first auxiliary request. Previous main request and first auxiliary request, filed on 1 April 2015, were withdrawn.

The main request filed during the oral proceedings differed from the previous pending main request submitted on 1 April 2015 (see VIII above) only in the deletion of claim 2.

- X. As far as relevant to the present decision, the appellant's arguments in relation to the main request filed during the oral proceedings may be summarised as follows:

Sufficiency of disclosure

Claim 1 comprised two alternative embodiments, namely products containing a polymerization strength reducer and products containing a tissue adherence accentuator. The absence of one of the two classes of components, had the consequence that the properties deriving from this component were not present. For instance, in products which did not contain a polymerization strength reducer it was not possible to control the degree of polymerisation. The patent did not provide any information in relation to this issue. The requirement of sufficiency of disclosure was not met also in view of the broad scope of the claims. In particular, the definition of the monomers included a broad variety of substances with different properties.

Novelty

The subject-matter of claim 1 was anticipated by the disclosures of D14 and D18. Document D14 related to a product containing a polymerizable compound having at least one double bond. Examples of these compounds included acrylates and methacrylates. Furthermore, the product could also include as optional component a polyhydric alcohol such as polyethylene glycol and alcohol waxes , such as cetyl alcohol or stearyl alcohol. Hence, D14 disclosed products comprising the same monomers defined in claim 1 and substances included in the list of polymerization strength reducers. Also document D18 disclosed polymerisable compositions based on acrylates or methacrylates. Additionally, these compositions contained polyethylene oxide which was included in the list of tissue adherence accentuators of claim 1.

Inventive Step

The patent addressed the problem of providing polymerizable isolation barriers which had the function of isolating dental surfaces during a dental treatment. The claims were not limited to products which lightly bonded to the gums and were easily removed as argued by the patent proprietor, since neither the polymerization strength reducers nor the tissue adherence accentuators were essential components of the polymerizable isolation barrier. Various prior art documents disclosed products suitable for isolating dental surfaces. The most relevant products were disclosed in D9, D10, D12, D16 and D1.

- XI. As far as relevant to the present decision, the respondent's arguments in relation to the main request filed during the oral proceedings may be summarised as follows:

Sufficiency of disclosure

The description as filed supplemented by the declarations of Mr Wagner demonstrated that the isolation barriers of the invention could be prepared and that they had the properties described in the patent. The appellant had provided no evidence to substantiate its allegation of insufficient disclosure.

Novelty

Neither document D14 nor document D18 anticipated the subject-matter of claim 1. Starting from the disclosures of these documents it was necessary to select an appropriate monomer and an appropriate additional component in order to obtain a product in accordance with the claims of the patent in suit. The products disclosed in the examples of these documents were not relevant.

Inventive step

Document D9 was the most suitable starting point for the assessment of inventive step in that it disclosed polymerizable compositions to be applied on the surface of the teeth which were easily removable. The product claimed in the patent in suit differed from the composition of D9 at least in the presence of a polymerization strength reducer or a tissue adherence accentuator. The experiments carried out by Mr Wagner showed that the compositions of D9 formed a fluid that could not reliably adhere to tooth or gum tissue. The technical problem was to modify the composition of D9 to enable it to adhere sufficiently to soft gum tissue and protect said tissue during dental treatments.

Document D9 did not address the same problem. In contrast to the compositions of the invention, the compositions of D9 were polymerised before application to teeth. The other documents considered by the appellant, in particular, D1, D10, D12 and D16 related to products conceived for very different uses such as permanent applications to teeth. The skilled person would not have considered the teaching of these documents when confronted with the technical problem addressed by the present invention.

XII. The appellant requested that the decision under appeal be set aside and the patent revoked.

XIII. The respondent requested that the patent be maintained on the basis of the claims of the main request or the claims of the first auxiliary request filed during the oral proceedings before the Board of appeal or on the basis of the claims of the second or third auxiliary requests filed with letter of 1 April 2015.

Reasons for the Decision

Main request

1. Admittance

During the oral proceedings held on 21 April 2015 the Board questioned the clarity of the claims of the then pending main request filed on 1 April 2015, observing that some of the specific monomers recited in dependent claim 2 did not appear to be covered by the definition of monomers in claim 1.

The respondent responded to the Board's observation by submitting a new main request differing from the

previous pending main request in that claim 2 was deleted.

No objection was raised by the appellant as to the admissibility of the new main request filed during the oral proceedings.

In consideration of the above circumstances, the Board decides to admit the main request into the appeal proceedings (Article 13(1) RPBA).

2. Sufficiency of disclosure

2.1 The appellant based its objection mainly on the argument that neither the polymerization strength reducer nor the tissue adherence accentuator are essential components of the claimed polymerizable composition. Accordingly, the physical and chemical properties induced by these components might not be present in the final composition.

Indeed, the wording of claim 1 indicates that the polymerizable material must contain at least one element selected from a first group of substances which are collectively defined as polymerization strength reducers or from a second group of substances which are collectively defined as tissue adherence accentuators. Hence, neither of the two classes of substances represents a mandatory feature of claim 1. However, claim 1 does not require either the claimed polymerizable composition to have any specific property or to provide any specific technical effect arising from the presence of these classes of compounds. In assessing the requirement of sufficiency of disclosure it is essential to verify whether a technical effect expressed in a claim is indeed achieved over the whole

scope of the claim (G0001/03, OJ 2004, 413, Reasons 2.5.2). In the present case since there is no technical effect expressed in claim 1 in relation to the presence of a polymerization strength reducer or a tissue adherence accentuator, the argument submitted by the appellant is not relevant in the context of assessing the requirement of sufficiency of disclosure.

2.2 The sole technical effect expressed in claim 1 is that the polymerizable compositions should be useful for isolating a dental substrate during a dental treatment. The appellant, however, did not present any argument in relation to this effect. The Board notes in this respect that the patent disclose several examples of polymerizable compositions useful for isolating dental substrates. The effectiveness of the claimed compositions in isolating dental and gum tissues during dental treatments is furthermore confirmed in the declarations of Mr Wagner (see D9a paragraph 9 and D9b paragraph 7).

2.3 As to the further argument of the appellant, that the requirement of sufficiency of disclosure is not met in view of the broad definition of the monomers, the Board observes that claim 1 relates to a polymerizable composition comprising monomers which belong to the class of methacrylates, i.e. a well-known class of substances. Furthermore, information concerning the preparation of the polymerizable material can be gathered from paragraph [0054] of the description or from the examples.

In the absence of any corroborating evidence from the side of the appellant which might support his objection, the Board considers that the skilled person would be able to carry out the claimed invention.

Therefore, the requirement of sufficiency of disclosure is met.

3. Novelty

Claim 1 has been objected under Article 54 EPC in view of the disclosures of documents D14 and D18.

- 3.1 Document D14 relates to a modelling liquid used for building up dental porcelain, which comprises *inter alia* a photopolymerizable compound and an initiator (claim 1). Furthermore, the liquid can comprise as optional ingredient an organic solvent (claim 2) and an organic material (claim 5).

The photopolymerizable compound is a monomer containing at least a double bond. Suitable compounds are disclosed in a long list which starts in column 9 (line 10) and ends at the bottom of column 15. Besides some methacrylate derivatives which are included in the monomers listed in claim 1 of the patent in suit (e.g. methyl methacrylate; column 9, line 12), the list includes also substances which are not covered by claim 1, in particular the acrylates derivatives.

Suitable substances useful as organic solvent or as organic material are disclosed from column 15, line 11 to column 18, line 53. The list of substances includes compounds which are listed in claim 1 of the patent in suit as polymerization strength reducers. Such compounds are polyethylene glycol, propylene glycol and polypropylene glycol, which are disclosed in D14 as examples of suitable solvents (column 17, lines 4 to 13) and cetyl alcohol and octadecyl alcohol (i.e. stearyl alcohol) which are disclosed in D14 as examples

of suitable organic material (column 18, line 52). In addition to these substances, the list starting from column 15 of D14 includes also many compounds which are neither covered by the definition of polymerization strength reducer nor by the definition of tissue adherence accentuator of claim 1.

It follows from the above that to arrive at the claimed polymerizable composition a double selection from the disclosure of D14 is necessary, namely the selection of a monomer according to claim 1 from the group of photopolymerizable compounds and the selection of at least one compound from polyethylene glycol, propylene glycol, polypropylene glycol, cetyl alcohol or stearyl alcohol from the list of the solvents or from the list of organic materials. Since document D14 does not contain any pointer leading the skilled person directly and unambiguously to that particular combination of photopolymerizable compounds and solvents or organic materials, the subject-matter of claim 1 is novel over the generic disclosure of this document.

As to the examples of D14, it was not disputed by the appellant that none of them discloses compositions according to the patent in suit.

The subject-matter of claim 1 is therefore novel over D14.

- 3.2 The invention disclosed in document D18 relates to a process for curing ethylenically unsaturated compounds using a particular photoinitiator (column 1, line 35 to column 2 line 44). The ethylenically unsaturated compounds can optionally be used in a mixture comprising also binders (column 8, lines 13 to 40).

Examples of compounds useful as ethylenically unsaturated monomers are disclosed in a list starting from line 50 of column 5. In addition to compounds which are included in claim 1 of the patent in suit (e.g. methyl and ethyl methacrylate), the list comprises also several monomers such as acrylonitrile, vinyl esters, vinyl ethers and alkylstyrenes (column 5, lines 54 to 59) which are not covered by claim 1.

Compounds suitable for use as binders are disclosed in column 8, from line 25 to line 40. The list includes *inter alia* polyethylene oxide, which is one of the tissue adherence accentuators recited in claim 1 of the patent in suit (column 8, lines 32 and 33). The remaining compounds mentioned in D14 as suitable binder are neither covered by the definition of polymerization strength reducer nor by the definition of tissue adherence accentuator in claim 1 of the patent in suit.

It was not disputed by the appellant that none of the examples of D18 anticipates the subject-matter of claim 1 of the patent in suit.

Thus, also in this case to arrive at a composition falling within the scope of claim 1 a twofold selection from the disclosure of D18 is required, namely the selection of a monomer according to claim 1 of the patent in suit from the group of ethylenically unsaturated monomers and the selection of polyethylene oxide from the possible binders. However, in the absence of any pointer to such a specific combination of features, the subject-matter of claim 1 cannot be directly and unambiguously derived from document D18.

Claim 1 is therefore novel over the disclosure of D18.

3.3 In the light of the above, the Board concludes that the requirements of Article 54 EPC are met.

4. Inventive step

4.1 The patent in suit addresses the problem of protecting dental and gum tissues during dental treatments. In particular, the invention relates to compositions which are applied on the surface to be protected and then are polymerised to provide a substance which slightly adheres to the tissues and is easily removable (see paragraph [0001]).

Closest prior art

4.2 According to the established case law, in selecting the closest prior art, the first consideration is that it must be directed to the same purpose or effect as the invention (Case Law of the Boards of Appeal of the European Patent Office, 7th edition 2013, I.D.3.2).

4.3 It was not disputed by the parties that none of the prior art documents are directed to the same purpose as the invention, namely providing products for protecting dental and gum tissues during dental treatments. In that circumstance the Board considers that the selection of the most suitable starting point for the assessment of inventive step should be made by considering the properties and the effects of the products disclosed in the prior art.

Following this approach, document D9 is considered to represent the closest prior art. This document relates to film-forming cosmetic compositions to be applied on the teeth. Like the materials of the invention, the materials disclosed in D9 weakly adhere to the surface

to which they are attached and are easily removable (column 1, line 30 to 36).

- 4.4 During the oral proceedings before the Board, the respondent presented its arguments on inventive step starting from D9 as closest prior art. In its written and oral submissions in relation to the requirement of inventive step, the appellant referred to various prior art documents, including document D9, without however selecting any document as the closest prior art.

Technical problem

- 4.5 According to the patent in suit, the technical problem is to provide a material which lightly adheres to gum tissues, protects them during dental treatments and can be easily removed.

As a solution to this problem the patent proposes a polymerizable composition which differs from the composition of D9 mainly in that it comprises at least one organic polymerization strength reducer or one tissue adherence accentuator as defined in claim 1.

- 4.6 The two declarations of Mr Wagner (documents D9a and D9b) and the experimental reports attached thereto, show that polymerizable compositions based on methacrylate monomers and containing at least one organic polymerization strength reducer as defined in claim 1 or one tissue adherence accentuator as defined in claim 1, are able to isolate gum tissues and protect them during dental treatments such as bleaching with peroxides. Furthermore, these compositions adhere weakly but reliably to gum and teeth and are easily removed therefrom (D9a, paragraph 9; D9b, paragraph 7).

Document D9a includes also data relating to experiments carried out using the compositions disclosed in column 2 lines 42-57 of D9. Mr Wagner declares that these compositions do not adhere reliably to the gum or teeth and do not adequately prevent an agent applied to teeth from contacting the gum to which the compositions were applied (D9a, paragraphs 10 and 15).

In view of these results the Board is satisfied that the technical problem defined in paragraph 4.5 above is solved by the claimed compositions.

Obviousness

- 4.7 The main question to be answered in the context of obviousness is whether the skilled person would modify the compositions of document D9 by adding at least one of the five substances included in the list of organic polymerization strength reducers of claim 1 of the patent in suit and/or by adding at least one of the seven substances included in the list of tissue adherence accentuators of claim 1 of the patent in suit.
- 4.8 Document D9 does not contain any teaching on how the compositions disclosed therein should be modified in order to render them suitable for isolating gum tissues during dental treatment. Furthermore, this document does not mention any of the substances listed in claim 1 as possible organic polymerization strength reducer or tissue adherence accentuator.
- 4.9 The appellant referred in its submissions to the teachings of various documents in particular D1, D10, D16 and D12.

As underlined by the respondent, documents D1, D10 and D16 relate to compositions intended for permanent applications to teeth. Thus, D1 discloses compositions useful for priming or sealing a dental substrate, in order to obtain strong adhesion when followed by a resinous material or cement (see column 5, line 20-27). The dentin primers are reported to be stable over time (column 4, lines 30-31). D10 and D16 disclose resinous dental compositions which form polymers having excellent resistance to abrasion and exhibiting very large adhesive force to enamel and dentine (D10, paragraph bridging pages 4 and 5; D16, last paragraph of page 9). Hence, the materials disclosed in these documents do not appear to present the properties that would render them suitable for protecting gum tissues, such as the ability to adhere weakly to gum and teeth and to be easily removed therefrom. The skilled person confronted with the problem set out above would therefore not consider the teaching of these documents.

- 4.10 As to D12, the Board notes that this document relates to compositions that after polymerization present some properties similar to the materials of the patent in suit, such as ease of removal from soft tissues (column 11, lines 29 to 37). Document D12 relates however to the problem of providing intra-oral treatment membranes used especially to dress or bind up wounds in the oral cavity (column 3, lines 21-34). No mention is made in this document of the problem of protecting gum tissues during dental treatments. Moreover, the compositions disclosed in D12 contain as polymerizable material urethane acrylate oligomers (see column 4, line 55 to column 6 line 63; examples and claim 5). The polymers obtained by the polymerization of the composition of D12 are therefore different from the polymers of the patent in suit which derive from the polymerization of

monomer mixtures comprising only the three methacrylate derivatives of claim 1. There is furthermore no indication in D12 that the polymerizable compositions disclosed therein contain one or more of the substances listed in claim 1 of the patent in suit as organic polymerization strength reducer or tissue adherence accentuator. In this respect the Board agrees with the respondent that the polypropylene glycol mentioned in example 1 is not present as such in the mixture but is reacted with the diisocyanate derivative to form the urethane oligomers (column 13, lines 46 to 51).

Thus, document D12 does not provide any relevant teaching in the direction of the invention of the patent in suit.

- 4.11 On that basis the Board decides that the main request involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to to the opposition division with the instruction to maintain the patent on the basis of the claims of the main request filed during the oral proceedings before the Board of Appeal and a description to be adapted.

The Registrar:

The Chairman:



N. Schneider

J. Riolo

Decision electronically authenticated