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Case Number: T 2468/11 - 3.3.07

Application Number: 02752717.5

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Language of the proceedings: EN

Title of invention:
MULTI-PART DENTAL BLEACHING SYSTEMS AND METHOD FOR BLEACHING TEETH USING SUCH SYSTEMS

Applicant:
Ultradent Products, Inc.

Headword:

Relevant legal provisions:
EPC Art. 56
RPBA Art. 13(1)

Keyword:
Inventive step -
main request and auxiliary requests 1 to 5 (no)
Late-filed auxiliary requests - admitted (yes)
Inventive step - auxiliary request 6 (yes)

Decisions cited:

Catchword:

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Case Number: T 2468/11 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 5 May 2015

Appellant: (Applicant)	Ultradent Products, Inc. 505 West 10200 South South Jordan, Utah 84095 (US)
Representative:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 24 June 2011 refusing European patent application No. 02752717.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	J. Riolo
Members:	A. Usuelli
	P. Schmitz

Summary of Facts and Submissions

I. The appeal of the applicant (appellant) lies from the decision of the examining division announced at the oral proceedings on 7 April 2011 to refuse European patent application No. 02752717.5.

II. The documents cited during the examination proceedings included the following:

D1: WO98/30169
D2: US 5,746,598
D3: WO01/17481

III. The decision was based on three sets of claims filed with letter dated 7 March 2011 as main request and auxiliary requests 1 and 2, and an additional set of claims filed during the oral proceedings as auxiliary request 3.

Claim 1 of the main request read as follows:

"1. A multi-part dental bleaching system comprising: an aqueous dental bleaching composition that comprises at least one dental bleaching agent and that has an acidic pH; and a neutralizing composition comprising less than 1% unbound water suitable for mixing with the aqueous dental bleaching composition and that comprises at least one polymeric thickening agent mixed with at least one particulate base selected from the group consisting of metal oxides, metal hydroxides, ammonium hydroxide. and metal carbonates, wherein the at least one particulate base would cause the neutralizing composition to have a pH in a range of 11 to 14 if mixed with sufficient water to produce a pH reading."

Claim 1 of auxiliary request 1 read as follows:

"1. A multi-part dental bleaching system comprising: an aqueous dental bleaching composition that comprises at least one dental bleaching agent and that has an acidic pH, wherein the dental bleaching composition comprises at least 20% available hydrogen peroxide; and a neutralizing composition suitable for mixing with the aqueous dental bleaching composition and that comprises at least one polymeric thickening agent mixed with at least one particulate base selected from the group consisting of alkali metal oxides, alkaline earth metal oxides, alkali metal hydroxides, alkaline earth metal hydroxides, ammonium hydroxide, and alkali metal carbonates, wherein the at least one particulate base would cause the neutralizing composition to have a pH in a range of 11 to 14 if mixed with sufficient water to produce a pH reading, the neutralizing composition comprising less than 1% of unbound water to prevent the polymeric thickening agent from prematurely breaking down or hydrolyzing."

Claim 1 of auxiliary request 2 differed from claim 1 of auxiliary request 1 in indicating that the dental bleaching composition comprised at least 30% available hydrogen peroxide instead of at least 20%.

Claim 1 of auxiliary request 3 differed from claim 1 of the main request in indicating that the dental bleaching composition had a pH of 4 or less.

The requests also included independent claims directed to a method of manufacturing a two-part dental bleaching system and a cosmetic method of bleaching a person's teeth.

IV. In its decision the examining division held that the subject-matter of claim 1 of the pending requests did not comply with the requirements of Article 56 EPC.

Document D3 was considered to represent the closest prior art. According to the examining division, the bleaching system defined in claim 1 of the main request differed from the product disclosed in D3 in the use of a particulate base as defined in claim 1 which caused the neutralising composition to have a pH in a range of 11 to 14. It was not shown that this difference had some technical effect in comparison to the composition of D3. For the person skilled in the art it would have been obvious to use a strong base for neutralising the acidic bleaching composition. It was also evident that the use of a strong base had the advantage of reducing the amount of neutralising composition required to neutralise the bleaching mixture. The subject-matter of claim 1 was therefore obvious in view of the teaching of D3.

The teaching of document D3 rendered obvious also the subject-matter of claim 1 of auxiliary requests 1 to 3.

V. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal, sent on 4 November 2011, the appellant submitted four sets of claims consisting of a main request and three auxiliary requests which were identical to the sets of claims refused by the examining division.

At the same date, the following document was submitted by the appellant:

D5: Additional experimental data

VI. In a telephone call between the rapporteur and the appellant's representative on 14 April 2015 the experiments of D5 were considered. In particular, it was observed that in all the compositions tested the thickening agent was the product CARBOPOL®. In contrast thereto, claim 1 of all the requests was not limited to any specific thickening agent. The possibility of limiting the definition of the thickening agent to some specific classes of polymers was also discussed.

The same concepts were reiterated by the Board in a communication issued on 24 April 2015.

VII. With letter of 22 April 2015 the appellant submitted three additional sets of claims as auxiliary requests 4 to 6.

Each claim 1 of auxiliary requests 4 to 6 was based on claim 1 of the main request (see point III) but contained a narrower definition of the polymeric thickening agent. In particular:

In claim 1 of auxiliary request 4 the polymeric thickening agent was specified to be hydrolysable

In claim 1 of auxiliary request 5 the polymeric thickening agent was specified to comprise at least one of an acrylic acid-based polymer, carboxypolymethylene, pluronic, a cellulose ether, a polysaccharide gum, a protein, or a starch.

In claim 1 of auxiliary request 6 the polymeric thickening agent was specified to comprise at least one of an acrylic acid-based polymer or carboxypolymethylene.

Like the other requests, auxiliary requests 4 to 6 also included independent claims directed to a method of manufacturing a two-part dental bleaching system and a cosmetic method of bleaching a person's teeth.

VIII. Oral proceedings were held on 5 May 2015.

IX. The appellant's arguments are summarised as follows:

The closest prior art for the assessment of inventive step was document D3, which disclosed a two-component teeth whitening system. The dental bleaching system of claim 1 of the main request differed from the product of D3 in the selection of specific particulate bases which caused the neutralising composition to have a pH in the range of 11 to 14. The objective problem was to provide a dental bleaching system having high bleaching potency and ultimate stickiness and having a high concentration of hydrogen peroxide. The problem was solved by providing a two-part system comprising a low pH stable bleaching composition and a neutralising composition including a particulate base in a non-aqueous form. Document D3 did not provide any hint to use a strong particulate base. Contrary thereto, D3 disclosed the use of activator gels comprising a weak base such as tetrapotassium pyrophosphate. Moreover, this base was not present in particulate form since it was added to large amounts of heated water. Thus, document D3 did not indicate the importance of avoiding the use of a base containing water. The use of a strong base resulted in an improvement of the neutralisation property of the neutralising composition, as shown by the experimental results disclosed in table 12 of document D5. The neutralising composition of D3, containing tetrapotassium pyrophosphate as base, did not have the same neutralisation property and therefore

had to be used in large amounts to be effective. Document D3 was furthermore silent with regard to the issue of stability. The experimental data disclosed in D5 illustrated the degradation of the polymeric thickening agent at a high pH when water was present. This degradation resulted in a drop of the viscosity of the composition. Surprisingly, no degradation of the thickening agent was observed in the composition of the invention. This unexpected effect was due to the use of a neutralising composition comprising less than 1% of water and a base in particulate form.

The bleaching system defined in claim 1 of auxiliary requests 1 and 2 differed from the product of D3 also in having a higher amount of available hydrogen peroxide. The composition of D3 contained 25% by weight or less of carbamide peroxide. This amount was equivalent to 19% of available hydrogen peroxide. Document D3 neither disclosed nor suggested a dental bleaching composition having at least 20% or at least 30% of hydrogen peroxide.

The subject-matter of auxiliary request 3 related to bleaching systems which were characterised *inter alia* in that the bleaching composition had a pH of 4 or less. The use of a strong base in particulate form made it possible to neutralise such a bleaching composition, despite its low pH, without affecting the stability of the thickening agent.

Auxiliary requests 4 to 6 contained a narrower definition of the polymeric thickening agent. The inventors had observed that the thickening agents were not stable in basic environments. These problems of stability were caused by processes of hydrolytic degradation of the thickening agents. The use of a

neutralising composition containing a very low amount of water and a base in particulate form made it possible to improve the stability of the thickening agents.

X. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims of the main request or auxiliary requests 1 to 3, all filed on 4 November 2011, or of auxiliary requests 4 to 6 filed on 22 April 2015.

Reasons for the Decision

Main request

1. Inventive step

The invention defined in claim 1 concerns a multi-part dental bleaching system comprising a bleaching composition and a neutralising composition.

Closest prior art

1.1 The Board agrees with the examining division and with the appellant that document D3 represents the closest prior art. This document discloses a two-part bleaching system comprising as a first component a dental peroxide gel and as a second component an activator gel (see claim 1). The activator gel has a pH of from about 9 to about 10 (page 6 lines 3 and 4) and acts therefore as a neutralising composition for the peroxide gel which has a pH from about 5 to about 8 (page 3, lines 8 and 9). Particularly relevant are the systems comprising activator gel 5 which contains *inter alia* 250.6 g of tetrapotassium pyrophosphate as base and 400.4 g of water (pages 7 and 8). The preparation of

the activator gel includes a step in which the tetrapotassium pyrophosphate is added to heated water (page 11, lines 7 to 10). The appellant explained in his submissions of 4 November 2011 that in view of this preparation the tetrapotassium pyrophosphate is not present in the activator gel in the form of a particulate base. The Board has no reason to contest this explanation.

As observed by the appellant, the dental bleaching system of present claim 1 differs from the bleaching system of D3 in that the neutralising composition comprises a particulate base as defined in claim 1 wherein said base would cause the composition to have a pH in a range of 11 to 14 if mixed with sufficient water to produce a pH reading.

Technical problem

1.2 During the appeal proceedings the appellant submitted experimental report D5. The results of the experiments described in this report are to be assessed in the context of defining the technical problem.

1.3 A first set of data disclosed in D5 relates to the thickening ability of neutralising compositions containing CARBOPOL® as thickening agent. The composition disclosed in Table 1 of D5 is a composition in accordance with claim 1 of the main request and is characterised in that it contains, as base, potassium hydroxide in particulate form. No water is present in this composition. The other neutralising compositions tested again contain potassium hydroxide but include also 5% or 10% of water (Tables 2, 3, 5 and 6).

The results disclosed in Tables 4 and 7 show that while the composition according to the invention has a viscosity above 69,000 cps, the other compositions have viscosity ranging from around 2,000 cps to around 8,500 cps.

In the appellant's opinion, the low viscosity of the compositions of Tables 2, 3, 5 and 6 is caused by the use of an aqueous base which has a negative impact on the stability of the polymeric thickening agent.

1.4 As pointed out above, all the neutralising compositions tested in D5 contain CARBOPOL® as thickening agent, i.e. a carboxypolymethylene polymer (page 11, lines 3 and 4). On the other hand, the Board notes that claim 1 does not contain any restriction as to the nature of the polymeric thickening agent. The description states that a "wide variety of thickening agents may be used within the scope of the invention" (page 10, lines 20 and 21). Suitable polymers, in addition to carboxypolymethylene derivatives, are for instance cullolosic ethers, proteins and starches (page 10, lines 24 to 25).

In the Board's view, there is no evidence or technical reason that could explain why the observations made in respect to neutralising compositions containing CARBOPOL® as thickening agent should be considered of general validity and therefore extendable to any neutralising composition included in claim 1. There is in particular no evidence that the drop of viscosity observed when the thickening agent is in contact with a strong base in the presence of water would always occur no matter which thickening agent is used. Thus, in the Board's opinion the experimental data of D5 are not sufficient to prove convincingly that the use of a

strong particulate base in the absence of water always results in a better stability of the thickening agent and provides a higher viscosity of the neutralising composition.

Hence, the first set of experiments disclosed in D5 do not allow any conclusions to be drawn which could be generalised to the whole scope of claim 1 and therefore taken into account for defining the technical problem.

1.5 The purpose of the second set of experiments included in D5 was to show the improved neutralisation properties of the neutralising compositions according to the invention as compared to the neutralisation properties of activator gel 5 of D3.

The Board considers it credible that the neutralising compositions according to the application are more effective in neutralising the acidity of the bleaching solution already from the fact that they contain a strong base while activator gel 5 of D3 contains tetrapotassium pyrophosphate which is a weak base. Moreover, the neutralising compositions according to the application in suit also have a higher pH than the activator gels of D3. In view of the above, the Board does not consider it necessary to discuss in detail the second set of experiments disclosed in D5.

1.6 In the light of the considerations set out in points 1.2 to 1.4 above, the Board concludes that the technical problem over D3 can be defined as the provision of a multi-part dental bleaching system characterised in that the neutralising composition has an improved neutralising capacity.

Obviousness

1.7 Confronted with the problem of rendering the activator gels of D3 more effective in neutralising the acidity of the bleaching agent, the skilled person would arrive without any inventive effort at the idea of replacing the weakly basic tetrapotassium pyrophosphate with a strong base such as for instance a metal hydroxide. After all, as acknowledged also in the description of the application (page 2, lines 13 to 23), strong bases are commonly used to neutralise the acidity of peroxide compositions. Furthermore, he would also regard an aqueous base or a base in particulate form as equally suitable for the purpose of neutralising the acidity of a composition.

1.8 In the light of the above, the Board concludes that the subject-matter of claim 1 of the main request does not meet the requirements of Article 56 EPC.

Auxiliary request 1

2. Inventive step

Claim 1 of this request differs from claim 1 of the main request mainly in indicating that the bleaching agent comprises at least 20% available hydrogen peroxide. Furthermore, the feature requiring the amount of unbound water in the neutralising composition to be less than 1% is qualified by the indication that this low amount is "to prevent the polymeric thickening agent from prematurely breaking down or hydrolysing".

2.1 The bleaching gel of D3 contains a maximum of 25% by weight of carbamide peroxide. The appellant states in his submissions of 4 November 2011 that this amount corresponds to 19% of available hydrogen peroxide. This

conclusion is not contested by the Board. It must therefore be assessed whether this increase in the amount of available hydrogen peroxide can give rise to an inventive step.

As discussed above, the use of a strong base enhances the neutralising capacity of the neutralising composition. It follows that the neutralising composition can be used also with bleaching compositions having a high content of hydrogen peroxide which, as explained for instance in D1 (last paragraph of page 6), must have a low pH in order to be stable.

The possibility of providing a bleaching agent containing a high amount of available hydrogen peroxide is therefore an expected advantage which derives from the use of a strong base in the neutralising composition. Since the skilled person would obviously consider the use of a strong base to improve the neutralisation properties of the neutralising composition, he would also take advantage of this improvement by increasing the amount of hydrogen peroxide in the bleaching composition.

It follows that a higher amount of available hydrogen peroxide does not render the subject-matter of claim 1 inventive.

2.2 As to the further amendment introduced in claim 1 (see point 2 above), the Board observes that neither D5 nor any other document on file supports the conclusion that the presence of water would always result in a lack of stability of the polymeric thickening agent (see also point 1.3 above). Hence, the indication that the low amount of water would "prevent the polymeric thickening agent from prematurely breaking down or hydrolysing" is

irrelevant when the thickening agent remains stable in the presence of water.

Thus, the functional feature introduced into claim 1 does not render inventive the subject-matter claimed.

2.3 On that basis, claim 1 of auxiliary request 1 does not involve an inventive step.

Auxiliary request 2

3. Inventive step

Claim 1 of this request differs from claim 1 of auxiliary request 1 in indicating that the dental bleaching composition comprises at least 30% available hydrogen peroxide instead of at least 20%.

The considerations set out in point 2.1 above are independent of the specific amount of available hydrogen peroxide recited in the claim and apply therefore also to claim 1 of auxiliary request 2.

It follows that this request too does not comply with the requirements of Article 56 EPC.

Auxiliary request 3

4. Inventive step

Claim 1 of auxiliary request 3 differs from claim 1 of the main request in indicating that the dental bleaching composition has a pH of 4 or less. In the two-component bleaching system of document D3, the bleaching gel has a pH from about 5 to about 8 (page 3, lines 8 and 9).

4.1 An evident advantage deriving from the improvement of the neutralisation properties of a neutralising composition is the possibility of using this composition also for the neutralisation of very acid bleaching compositions. As explained in D1 (last paragraph of page 6), a bleaching composition needs to be acid in order to stabilise the hydrogen peroxide.

4.2 For the reasons given in respect to the main request, a skilled person would obviously consider the use of a strong base, in liquid or particulate form, in order to improve the neutralisation properties of a neutralising composition. Having reached this objective, he would take advantage of the possibility of increasing the acidity of the bleaching composition, since this would result in a better stabilisation of the hydrogen peroxide. Hence, the skilled person would arrive without any inventive effort at the idea of providing a bleaching system in which the bleaching component has a lower pH.

The subject-matter of auxiliary request 3 is therefore obvious.

Auxiliary requests 4 to 6 - Admittance into the appeal proceedings

5. Auxiliary requests 4 to 6 were filed by the appellant on 22 April 2015, in reaction to the observations made by the Board in relation to the experiments of D5 (see point VI above).

The filing if these requests is regarded as a genuine attempt to address the issues concerning the breadth of the definition of the thickening agent.

Auxiliary requests 4 to 6 are therefore admitted into the appeal proceedings (Article 13(1) RPBA).

Auxiliary request 4

6. Inventive step

Claim 1 of this request is based on claim 1 of the main request but has been amended to specify that the polymeric thickening agent is hydrolysable.

6.1 This limitation introduced by the appellant aimed at addressing the objection raised by the Board as to the possibility of generalising to the whole scope of claim 1 the results disclosed in D5 concerning the viscosity of CARBOPOL®-containing compositions.

6.2 As discussed in point 1.4 above, the first set of experiments disclosed in D5 shows that a neutralising composition containing CARBOPOL® and a strong base in particulate form has a higher viscosity than a neutralising composition containing CARBOPOL® and the same strong base in water.

Although the presence of water must play a role in the fall in viscosity, there is no evidence in document D5 of a hydrolysis of CARBOPOL®. In other words there is no proof that the reduction of viscosity is linked to the fact that the thickening agent is hydrolysable. Accordingly, it cannot be concluded that any hydrolysable thickening agent would behave the same way as CARBOPOL®. Thus, the results of the experiments disclosed in D5 cannot be generalised to the whole scope of claim 1.

It follows that the definition of the technical problem and the considerations concerning the obviousness of the solution, set out in respect to the main request hold good also for the subject-matter of auxiliary request 4. Hence, this request too does not comply with the requirements of Article 56 EPC.

Auxiliary request 5

7. Inventive step

Claim 1 of auxiliary request 5 differs from claim 1 of the main request in specifying that the polymeric thickening agent comprises at least one of an acrylic acid-based polymer, carboxypolymethylene, pluronic, a cellulose ether, a polysaccharide gum, a protein, or a starch.

7.1 Despite the amendment, claim 1 still covers bleaching systems including as thickening agent a variety of substances of different chemical nature. The Board therefore sees no reason for extrapolating the results of the first set of experiments of D5 to the whole group of neutralising compositions covered by claim 1. The considerations set out in respect to the main request therefore also apply to the assessment of inventive step of auxiliary request 5.

It follows that the subject-matter of auxiliary request 5 does not meet the requirements of Article 56 EPC.

Auxiliary request 6

8. Inventive step

Claim 1 of auxiliary request 6 differs from claim 1 of the main request in indicating that the polymeric thickening agent comprises at least one of an acrylic acid-based polymer or carboxypolymethylene.

Closest prior art

8.1 The closest prior art is again D3. In the two-part bleaching systems disclosed in this document, the activator gel contains as thickening agent Klucel® GFF which is a cellulosic gum (page 6, line 3). A further substance disclosed in D3 as a possible thickening agent is fumed silica (first paragraph of page 6). There is no mention in D3 of the possibility of using an acrylic acid-based polymer or carboxypolymethylene as thickening agent.

Thus, the dental bleaching system defined in claim 1 of auxiliary request 6 differs from the bleaching system of D3 in that the neutralising composition contains a particulate base as defined in claim 1 and a polymeric thickening agent comprising at least one of an acrylic acid-based polymer or carboxypolymethylene.

Technical problem

8.2 CARBOPOL®, used as thickening agent in the experiments of D5, is a carboxypolymethylene polymer (see page 10, line 30 to 32 of the application in suit). An acrylic acid-based polymer is also a polymeric compound containing a carboxypolymethylene chain. Due to the structural homogeneity of the polymers mentioned in claim 1 as thickening agents, the Board considers in this case that the results of the experiments of D5 can be generalised to the whole scope of claim 1.

8.3 Since all the compositions tested in D5 contain CARBOPOL® as thickening agent, the experiments disclosed in this document do not allow any comparison with the compositions disclosed in D3 which contain Klucel® GFF as thickening agent.

It is nevertheless possible to conclude on the basis of the first set of experiments of D5 that compositions containing CARBOPOL® and a base in particulate form are stable and maintain a high viscosity, while compositions containing CARBOPOL® and an aqueous base are unstable and do not possess sufficient viscosity (see point 1.3 above). For the reasons explained in point 8.2 above, it can fairly be assumed that compositions containing an acrylic acid-based polymer will behave in the same manner.

8.4 On the basis of these effects, the technical problem can be defined as the provision of a multi-part dental bleaching system which is stable and has a good viscosity.

Obviousness

8.5 Documents D1 and D2 disclose one-part bleaching compositions containing the same polymeric thickening agents as present claim 1. D1 refers in particular to the use of PEMULEN®, i.e. a polyacrylate derivative (page 7, lines 11 to 15), while in D2 the preferred thickening agent is CARBOPOL® (column 5, lines 7 to 9). As neutralising agent, both documents disclose the use of a strong base, namely sodium hydroxide. However, in contrast to the compositions of the application in suit the neutralising agents of D1 and D2 are part of aqueous solutions (D1, page 7, lines 25 to 36 and examples; D2, examples 1 to 8).

8.6 Neither D1 nor D2 provides data in relation to the stability of the thickening agents and to the viscosity of the compositions. Hence, the skilled person would have no particular reason to search for solutions aiming at the improvement of the viscosity profile.

8.7 Even assuming that the problems concerning the viscosity of the composition were observed, a skilled person would still have to find the cause of such problems. However, there is no indication in D1 or D2 that the presence of a strong base in an aqueous system negatively affects the stability of the thickening agent thereby causing a fall in viscosity. Most importantly, there is no teaching in D1 and D2 that combining the polymeric thickening agents disclosed therein with a base in particulate form would preserve the stability and viscosity of the system.

Thus, the combination of a polymeric thickening agent, as defined in claim 1, with a strong base in particulate form is not suggested by the cited documents.

8.8 In view of the above the Board concludes that the subject-matter of claim 1 meets the requirements of Article 56 EPC.

8.9 Auxiliary requests 6 contains two additional independent claims concerning a method for preparing a two-part dental bleaching system (claim 21) and a cosmetic method for bleaching a person's teeth using a multi-part bleaching system (claim 25). Since the bleaching systems defined in claims 21 and 25 have the same features as the bleaching system of claim 1, it

follows that these claims likewise meet the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the instruction to grant a patent on the basis of the claims of auxiliary request 6 filed on 22 April 2015 and a description yet to be adapted.

The Registrar: The Chairman:

N. Schneider J. Riolo

Decision electronically authenticated