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Case Number: T 1846/08 - 3.3.07

Application Number: 00974089.5

Publication Number: 1210062

IPC: A61K 7/16

Language of the proceedings: EN

Title of invention:
Increased peroxide content tooth bleaching gel

Applicants:
Discus Dental, LLC

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 56, 123(2)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Inventive step - obvious alternative (Main and First to Third Auxiliary Requests)"
"Amendments not allowable - added subject-matter (Fourth Auxiliary Request)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1846/08 - 3.3.07

D E C I S I O N
of the Technical Board of Appeal 3.3.07
of 8 September 2011

Appellant: Discus Dental, LLC
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 8 April 2008 refusing European patent application No. 00974089.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: J. Riolo
Members: F. Rousseau
D. Keeling

Summary of Facts and Submissions

I. The appeal lies from the decision of the Examining Division posted on 08 April 2008 refusing European patent application No. 00 974 089.5, filed as international application No. PCT/US00/40861 on 11 September 2000. The decision of the Examining Division was based on the sets of claims according to the then pending Main and First to Fourth Auxiliary Requests, which related to two-component dental bleaching systems with a dental peroxide gel based on a mixture of carbamide peroxide and hydrogen peroxide.

II. According to the impugned decision, the subject-matter of the Main, First and Second Auxiliary Requests lacked an inventive step in view of the two-component dental bleaching systems defined in US-A-5 928 628 (D2), representing the closest state of the art.
The Examining Division held in particular that no experimental evidence had been submitted which would demonstrate an unexpected effect brought about by the combination of carbamide peroxide and hydrogen peroxide, when compared with the two-component systems used in D2 that only employed hydrogen peroxide. The problem to be solved by the present invention was therefore regarded as to provide an alternative component having tooth bleaching activity. Two component dental systems were held to be disclosed in documents D2, US-A-5 902 568 (D4), US-A-5 648 064 (D5) and US-A-4 687 663 (D6), which documents disclosed the use of either hydrogen peroxide or carbamide peroxide as bleaching actives, but did not advise against the use of mixtures of those peroxides. Their combined use for providing an alternative first component having tooth bleaching

activity was suggested and therefore obvious to the skilled person in view of US-A-5 858 332 (D1) and US-A-4 990 089 (D3) that relate to single dental bleaching systems using mixtures of hydrogen peroxide and carbamide peroxide as peroxide source. The Third and Fourth Auxiliary Requests were refused as their subject-matter was not based on the application as filed.

III. With their statement setting out the grounds of appeal dated 18 August 2008, the Applicants (hereinafter the Appellants) made a request for oral proceedings and submitted five sets of claims as their Main and First to Fourth Auxiliary Requests. The respective independent claims 1 of those requests read as follows (the deletions made in the claims as filed being indicated in strikethrough and the additions made, in bold and underlined):

Main Request

"1. A two-component dental bleaching system wherein the components are adapted to be admixed and applied to the teeth from a dental tray for sustained contact, said system comprising:
as a first component, a dental peroxide gel comprising ~~both~~ carbamide peroxide and hydrogen peroxide; and
as a second component, an orally compatible activator gel**; wherein neither the dental peroxide gel nor activator gel incorporates a radiant-energy or heat-energy absorbing substance for use as an activator**."

First Auxiliary Request

"1. A two-component dental bleaching system wherein the components are adapted to be admixed and applied to the teeth from a dental tray for sustained contact, said system comprising:
as a first component, a dental peroxide gel comprising ~~both~~ carbamide peroxide **at a weight percentage from about 10% to about 25%** and hydrogen peroxide **at a weight percentage from about 0.5% to about 10%, based on the total weight of the first component**; and
as a second component, an orally compatible activator gel."

Second Auxiliary Request

"1. A two-component dental bleaching system wherein the components are adapted to be admixed and applied to the teeth from a dental tray for sustained contact, said system comprising:
as a first component, a dental peroxide gel comprising ~~both~~ carbamide peroxide **at a weight percentage from about 10% to about 25%** and hydrogen peroxide **at a weight percentage from about 0.5% to about 10%, based on the total weight of the first component**; and
as a second component, an orally compatible activator gel**; wherein neither the dental peroxide gel nor activator gel incorporates a radiant-energy or heat-energy absorbing substance for use as an activator**."

Third Auxiliary Request

Compared to claim 1 of the Second Auxiliary Request, claim 1 of the Third Auxiliary Request included the feature that the orally compatible activator gel comprises sodium fluoride and potassium nitrate.

Fourth Auxiliary Request

Compared to claim 1 of the Second Auxiliary Request, claim 1 of the Fourth Auxiliary Request defined that (i) the dental peroxide gel comprises hydroxypropyl cellulose and has a pH from 5 to 8 and (ii) the compatible activator gel comprises sodium fluoride, potassium nitrate and tetrapotassium pyrophosphate wherein the activator gel has a pH from 9 to 10. In addition, the word "about" had been deleted at each occurence.

IV. The Appellants were summoned to attend oral proceedings to take place on 08 September 2011. In a communication dated 29 July 2011 sent in preparation of the oral proceedings, the Board gave a reasoned preliminary negative opinion on inventive step of the subject-matter of claim 1 according to any of the Main and First to Fourth Auxiliary Requests. Claim 1 of the Fourth Auxiliary Request was also held to contravene the requirements of Article 123(2) EPC.

V. In reply to the Board's communication, the Appellants merely informed the Board with a letter dated 22 August 2011 that they would not attend oral proceedings. That letter did not contain any argument or amended claims. The oral proceedings took place as scheduled and were

held in the absence of the Appellants according to Rule 115(2) EPC.

VI. The arguments of the Appellants, as far as they are relevant for the present decision, can be summarised as follows:

(a) The technical problem solved over D2 by the two-component dental bleaching system according to the Main Request was to provide a two-component tooth whitening composition with increased peroxide content to facilitate the tooth whitening process. This problem was solved by a two-component dental bleaching system comprising as a first component, a dental peroxide gel containing carbamide peroxide and hydrogen peroxide, and as a second component, an orally compatible activator gel, wherein neither the bleaching gel nor the activator gel incorporates a radiant energy or heat energy absorbing substance for use as an activator. Document D2 did not suggest using as a first component in the two-component system a dental peroxide gel containing carbamide peroxide and hydrogen peroxide. Further, document D2 did not suggest the advantages in connection with the present invention as outlined in the experimental part of the application. Thus, the claimed subject-matter according to the Main Request was based on an inventive step over document D2 taken alone.

(b) Document D1 was concerned with stable, one-part, premixed viscous/gelled dental bleaching compositions that includes higher concentrations of bleaching agent for bleaching tooth surfaces.

Document D1 explained in great detail the disadvantages of two-part compositions in its introductory part. Therefore, the skilled person facing the problem of providing an improved two-component tooth whitening system would not consider document D1. In addition, document D1 disclosed the use of radiant energy or heat energy absorbing substances for use as an activator, which were not part of the claimed two-component dental bleaching system. Therefore, the claimed subject-matter defined in the Main Request was based on an inventive step over a combination of documents D2 and D1.

(c) Concerning the First Auxiliary Request, reference was made to the argumentation presented for the Main Request. In addition, neither document D2 nor any of D1 or D3 suggested using a dental peroxide gel comprising carbamide peroxide at a weight percentage from about 10% to about 25% and hydrogen peroxide at a weight percentage from about 0.5% to about 10% as defined in independent claim 1. On the contrary, document D1 taught away from the present invention as concentrated hydrogen peroxide solutions were used when it was desired to manufacture a bleaching composition having high concentrations of bleaching agents and carbamide peroxide was employed as one option in connection with lower concentrated hydrogen peroxide solutions when it was desired to manufacture a bleaching composition having lower concentrations of bleaching agent. In contrast thereto, the present invention as defined in claim 1 employed carbamide peroxide in connection with bleaching compositions

having higher concentrations of bleaching agent. Therefore, the subject-matter according to the First Auxiliary Request was based on an inventive step over the cited prior art.

(d) The claimed subject-matter according to the Second and Third Auxiliary Requests was held to be inventive for the same reasons as those given in connection with the Main and First Auxiliary Requests. In addition, the bleaching system according the Third Auxiliary Request comprised sodium fluoride, which was suitable for protecting the teeth against caries, and potassium nitrate, which was a preferred desensitizer. None of documents D1 to D3 suggested the specific combination of features forming part of claims 1 and 14, including the use of sodium fluoride and potassium nitrate.

(e) Concerning the Fourth Auxiliary Request, claim 1 was based on original claims 11 and 12 in combination with the description page 3, lines 2 to 9; page 3, lines 14 to 15; page 6, lines 1 to 4; and page 6, lines 11 to 16. Claim 1 met therefore the requirements of Article 123(2) EPC. For inventive step, it was referred to the argumentation given for the requests of higher ranking.

VII. The Appellants requested in the statement setting out the grounds of appeal dated 18 August 2008 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 of one of the First to Fourth Auxiliary Requests,

which were all attached to the statement setting out the grounds of appeal.

VIII. The decision was announced at the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

Main Request

2. The Board is satisfied that the subject-matter of claim 1 according to the Main Request meets the requirements of Articles 123(2) and 84 EPC, as well as of Article 54 EPC. There is no need in the present appeal decision to give a reasoning in respect of those issues, as claim 1 of the Main Request is not allowable for other reasons.

Inventive step

Closest prior art

3. The purpose of the present invention is to provide a two-component tooth whitening composition with increased peroxide content to facilitate the tooth whitening process (page 2, lines 22 to 23). Document D2 is concerned with the provision of a two-component dental bleaching system that achieves an accelerated bleaching action (column 1, lines 5-10). The Board, in line with the Examining Division is therefore satisfied that D2 represents the closest prior art and thus the starting point for assessing inventive step.

Problem and solution

4. The Appellants argued that the problem to be solved over D2 was to provide a two-component tooth whitening composition with increased peroxide content to facilitate the tooth whitening process. However, this problem cannot be considered to be solved by the subject-matter of present claim 1 which does not define, even implicitly, any amount of peroxide and is therefore open to amounts of peroxide lower than those defined in D2. The Appellants also referred to advantages obtained "*in connection with the present invention as outlined in the experimental part of the application*", but failed to define the advantages allegedly obtained and the experimental part concerned. In the absence of any reference by the Appellants to a concrete advantage brought about by the presently claimed compositions, let alone to any reference to an advantage obtained in comparison to the compositions of the closest prior art and any experimental evidence in this respect, the problem solved over D2 by the subject-matter of claim 1 according to the Main Request can only be formulated as the provision of further bleaching systems.

Obviousness

5. It remains to be decided whether or not the skilled person starting from D2 and wishing to solve the above defined problem would have been guided by the available prior art to apply the additional measure defined in claim 1 of the present Main Request, namely the use of carbamide peroxide in combination with hydrogen peroxide. It is not disputed in this context that the compositions according to D2 do not contain a radiant energy or heat energy absorbing substance, so that the express exclusion of said substance in the Main Request does not represent any additional measure applied to the state of the art according to D2 that contributes to the solution of the above defined problem.

6. The bleaching gels according to D2 can be prepared using diverse peroxide and peroxy compositions (D2, column 3, lines 66-67). Carbamide peroxide is moreover known to be the most commonly used dental bleaching agent as indicated in D1 (column 1, lines 37-39), while that document teaches a bleaching agent selected from hydrogen peroxide, carbamide peroxide or mixtures thereof (column 5, lines 24-65, in particular lines 59-63). Thus, the skilled person starting from document D2 and wishing to provide further bleaching systems would have found it obvious in view of document D1 to use instead of hydrogen peroxide a mixture of hydrogen peroxide and carbamide peroxide as bleaching agent. Replacing hydrogen peroxide in the closest prior art by another bleaching agent known to perform the same function does not contribute to inventive step, when the skilled person is merely seeking to provide further bleaching systems.

7. Consequently, the subject-matter of claim 1 according to the Main Request does not involve an inventive step within the meaning of Article 56 EPC. The Main Request is therefore rejected.

First Auxiliary Request

8. The subject-matter of claim 1 according to the First Auxiliary Request differs from that of the Main Request in that it is not restricted to compositions that do not contain a radiant-energy or heat-energy absorbing substance and the amounts of carbamide peroxide and hydrogen peroxide are defined based on the total weight of the first component to be within the ranges of from about 10% to about 25% and from about 0,5% to about 10%, respectively. Claim 1 according to the First Auxiliary Request allows therefore amounts of peroxide as low as 10,5% by weight, if based on the total sum of hydrogen peroxide and carbamide peroxide, or of at most 19% by weight if based on the amount of hydrogen peroxide introduced into the composition as such and in the form of carbamide peroxide. It follows therefore that the bleaching systems according to claim 1 of the First Auxiliary Request do not solve the problem vis-à-vis D2 of providing systems with increased peroxide content. For the reasons indicated in above point 4, the problem solved by the subject-matter of claim 1 according to the First Auxiliary Request is therefore also the provision of further bleaching systems.

9. According to column 5, lines 59-63 of document D1, carbamide peroxide solutions and hydrogen peroxide solutions can be mixed together in varying

concentrations to yield bleaching compositions having a wide spectrum of bleaching agent concentrations. The concentration ranges for hydrogen peroxide and carbamide peroxide as defined in the First Auxiliary Request are not critical for solving the problem defined above, since no unexpected effect has been shown to be associated with these particular concentration ranges. Picking out at random a lower and an upper limit for the amounts of carbamide peroxide and hydrogen peroxide is within the routine activity of the skilled person faced with the mere problem of providing further bleaching systems. Therefore, the arbitrary choice of the concentration ranges for hydrogen peroxide and carbamide peroxide defined in claim 1 of the First Auxiliary Request cannot provide the claimed two-component bleaching compositions with any inventive character. Thus, the First Auxiliary Request is also not allowable.

Second Auxiliary Request

10. The negative conclusion on inventive step applies for the same reasons to the Second Auxiliary Request, which combines the features of the Main and First Auxiliary Requests. The Second Auxiliary Request is therefore also rejected.

Third Auxiliary Request

11. Compared to the Second Auxiliary Request, the Third Auxiliary Request contains the feature that the activator gel contains sodium fluoride and potassium nitrate. The use in tooth whitening compositions of sodium fluoride as an anti-caries agent (see D4, column 3, lines 21-30 and D5, column 4, line 66), as well as of potassium nitrate as a desensitizer (see D5, column 6, lines 9) is, as evidenced by these documents, state of the art. The considerations in respect of inventive step given for the requests dealt with above are not affected by those additional measures, which merely performed in the compositions according to claim 1 of the Third Auxiliary Request their known function. Thus, the Third Auxiliary Request is also not allowable for lack of inventive step.

Fourth Auxiliary Request

12. Compared to the Third Auxiliary Request, the Fourth Auxiliary Request contains among others the additional feature that the activator gel contains tetrapotassium pyrophosphate, i.e. the activator gel according to claim 1 of the Fourth Auxiliary Request is defined to comprise *inter alia* a combination of sodium fluoride, potassium nitrate and tetrapotassium pyrophosphate. Among the passages of the application as filed indicated by the Appellants as supporting present claim 1, only claims 11 and 12 and page 6, lines 11 to 16 are concerned with the use of sodium fluoride, potassium nitrate or tetrapotassium pyrophosphate. Claims 11 and 12 as originally filed, which both depend only on claim 1, define either an activator gel

comprising (i) sodium fluoride and potassium nitrate or (ii) potassium nitrate and tetrapotassium pyrophosphate, but not a combination of those three compounds. The passage at page 6, lines 11 to 16, only indicates that the activator gels may include a desensitizer which is preferably potassium nitrate. The same passage indicates that "*in some embodiments of the activator gels provided in accordance with the present invention, sodium fluoride is added to protect the teeth against caries*", but fails to indicate that the embodiments concerned relate to compositions already comprising potassium nitrate and tetrapotassium pyrophosphate. Hence, the passages indicated by the Appellants do not provide a direct and unambiguous disclosure in the application as filed for the use in combination of sodium fluoride, potassium nitrate and tetrapotassium pyrophosphate. Hence, the Appellants failed to demonstrate that amended claim 1 according to the Fourth Auxiliary Request is based on the application as filed. Therefore, the Fourth Auxiliary Request must be also rejected as its subject-matter does not comply with the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar The Chairman

C. Eickhoff J. Riolo