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**Datasheet for the decision
of 16 April 2010**

Case Number: T 0847/08 - 3.3.07

Application Number: 04001866.5

Publication Number: 1444975

IPC: A61K 7/16

Language of the proceedings: EN

Title of invention:

Personal care compositions with portable packs

Applicant:

PBL Technology Limited

Opponent:

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Headword:

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Relevant legal provisions:

EPC Art. 54, 56

Relevant legal provisions (EPC 1973):

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Keyword:

"Novelty (yes) - after amendment"

"Inventive step (yes) - after amendment"

Decisions cited:

-

Catchword:

-



Case Number: T 0847/08 - 3.3.07

D E C I S I O N
of the Technical Board of Appeal 3.3.07
of 16 April 2010

Appellant: PBL Technology Limited
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Representative: Bentham, Andrew
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 27 November 2007
refusing European patent application
No. 04001866.5 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: S. Perryman
Members: B. ter Laan
F. Rousseau

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division issued on 27 November 2007 to refuse European patent application No. 04 001 866.5. The application as filed comprised 22 claims, claim 1 reading as follows:

"1. A semi-solid composition suitable for use in personal oral, dental, or skin care, characterised in that the composition comprises a semi-solid gel; the gel comprising at least one pharmaceutically acceptable active ingredient intimately mixed with at least one gelling agent; the at least one gelling agent providing, upon solidification, a semi-solid gel having a gel framework comprising sufficient containment means for the at least one active ingredient during storage; the gel framework being capable of breaking apart when the composition is forcibly disrupted by a person and making the at least one active ingredient available for use in a personal oral, dental, or skin care procedure."

Claim 6 read:

"6. A semi-solid dental care composition as claimed in claim 2 including active ingredients characteristic of a dentifrice, such as a surface-active agent, a foam stabiliser, a dentally acceptable abrasive; a flavouring agent, a colouring agent, and a humectant, characterised in that the composition includes one or more gelling agents in an amount sufficient to maintain structural integrity at a temperature up to about 40 degrees Celsius yet permitting the structure to break apart when forcibly disrupted by a person."

Claim 7 read:

"7. A bead comprised of a semi-solid composition as claimed in claim 6, characterised in that each bead is homogenous and non-encapsulated and includes sufficient active ingredients for a single procedure."

Claim 8 read:

"8. A bead comprised of a semi-solid composition as claimed in claim 7, characterised in that the bead has a mass in the range of from about 0.4 gram to about 1 gram."

Claim 10 read:

"10. A kit or pack for use in dental care, including at least one bead of a semi-solid gel as claimed in claim 7; characterised in that the at least one bead is stored within a compartment within the pack."

Claim 11 read:

"11. A kit or pack for use in dental care as claimed in claim 10, characterised in that the pack further provides an application tool including means for contacting a plurality of surfaces of the person's teeth, so that after disruption of a bead and release of the at least one active ingredient adjacent to the teeth, use of the tool promotes cleansing of the teeth."

Claim 12 read:

"12. A kit or pack as claimed in claim 10, characterised in that each compartment comprises a depression formed in a deformable sheet and covering means for covering the depression."

II. The following documents were *inter alia* cited in the decision:

D1 DE-A-4 238 421,
D3 EP-A-0 711 544
D4 US-A-5 961 990 and
D7 FR-A-2 822 700.

III. The decision under appeal was based on a main and four auxiliary requests. The reasons for refusal were that the claimed subject-matter of the main request was not novel over D4 and D7, the first, second and third auxiliary requests were not novel over D7, and the fourth auxiliary request was not inventive in the light of the combined disclosure of D1 and D7, with D1 as the closest prior art document, although also D7 could be used as a starting point.

IV. On 23 January 2008 a Notice of Appeal was lodged against that decision, together with payment of the prescribed fee. The statement setting out the grounds of the appeal was filed on 3 April 2008, together with a new set of 13 claims as the main request, a new document, as well as a declaration by Mr Christopher Sissons.

After a communication from the Board in preparation of the oral proceedings, in which several problems under Articles 123(2), 84, 83, 54 and 56 EPC were addressed, the appellants, with a letter dated 11 December 2009, filed eight new sets of claims as the main and seven auxiliary requests, as well as a declaration by Mr Carl Ernest Alexander.

V. At the oral proceedings before the Board, held on 14 January 2010, after discussion of several objections raised under Articles 84, 54 and 56 EPC regarding the requests filed with letter of 11 December 2009 as well as requests amended during the oral proceedings, a new single request, titled "Further New Main Request", replacing the ones then on file, was submitted.

The claims of that request read as follows (the additions compared to the claims as originally filed are indicated in bold, deletions by strike-through):

"1. A semi-solid **homogenous and non-encapsulated gel bead** ~~composition suitable~~ for use **in single-dose form** in personal ~~oral, dental, or skin~~ care, characterised ~~in that the composition comprises~~ **said bead** ~~a semi-solid gel; the gel comprising at least one~~ pharmaceutically acceptable active ingredients **characteristic of a dentifrice** intimately mixed with at least one gelling agent; ~~the at least one gelling agent providing, upon solidification, a semi-solid gel having~~ a gel framework comprising sufficient containment means for the ~~at least one~~ active ingredients during storage; the gel framework being capable of breaking apart when the ~~composition~~ **bead** is forcibly disrupted by a person and making the ~~at least one~~ active ingredients available for use in a personal ~~oral, dental, or skin~~ care procedure; **wherein said bead is for use with an application tool including means for contacting a plurality of surfaces of the person's teeth so that after disruption of a bead and release of the active ingredients adjacent to the teeth, use of the tool promotes cleaning of the teeth; and wherein the gelling**

agent includes agar at a concentration in the range of from 0.4 to 1.1 percent by weight.

2. A bead as claimed in claim 1, which has a mass in the range of from 0.1 to 2.5 gram.

~~3.~~ A bead ~~comprised of a semi solid composition~~ as claimed in claim ~~62~~, characterised ~~in that the bead~~ **which** has a mass in the range of ~~from about~~ 0.4 to about 1 gram.

~~4.~~ A kit or pack for use in dental care, including at least one bead of a semi-solid gel as claimed in claim ~~71~~, characterised ~~in that the at least one bead is~~ stored within a compartment within the pack.

~~5.~~ A kit or pack **for use in dental care** as claimed in claim ~~104~~ characterised ~~in that the pack further~~ ~~comprises~~ **further comprising** an application tool including means for contacting a plurality of surfaces of the person's teeth, so that after disruption of a bead and release of the at least one active ingredient adjacent to the teeth, use of the tool promotes cleansing of the teeth.

~~6.~~ A kit or pack as claimed in claim ~~104~~, characterised ~~in that~~ **wherein** each compartment comprises a depression formed in a deformable sheet and covering means for covering the depression.

~~7.~~ A method ~~for~~ **of** manufacture of beads ~~of a semi-solid composition~~ as claimed in claim 1, characterised ~~in that the~~ **which** method includes the steps of mixing water with at least one of the pharmaceutically

acceptable active ingredients together with the at least one gelling agent at a temperature sufficient to melt the gelling agent, then cooling the mixture to a lower temperature at which the composition is still melted, then optionally of adding and mixing at least one further active ingredient, then of expelling the mixture from an orifice.

~~208.~~ A method ~~for manufacture of beads of a semi solid composition~~ as claimed in claim ~~197~~, ~~characterised in that the~~ **wherein**, after expulsion from the orifice, the mixture is cooled so as to cause solidification, then the solidified mixture is separated into one or more homogenous beads each having a desired mass.

~~219.~~ ~~Apparatus for the manufacture of packs or kits including active ingredients according to the method claimed in claim 19, characterised in that~~ **A method as claimed in claim 7, wherein** the apparatus **used in the manufacture** includes means for deposition of a controlled amount of the melted composition from the orifice into at least one of a plurality of depressions formed in a deformable sheet, means to allow the molten composition to solidify, thereby forming at least one cast-in-place bead, and means to enclose the at least one bead by placement of a covering sheet over the depression, so that a pack holding at least one cast-in-place bead is thereby manufactured.

~~2210.~~ ~~Apparatus as claimed in claim 19, characterised in that~~ **A method as claimed in claim 7, wherein** the apparatus **used in the manufacture** includes means for inclusion in the pack or kit of toothbrushes.

VI. The appellants' arguments submitted in writing and during the oral proceedings can be summarised as follows:

- (a) The claims found a proper basis in the application as originally filed.
- (b) The claims were clear and the skilled person was capable of preparing a bead according to the claimed subject-matter.
- (c) Regarding novelty, none of the cited documents disclosed the use of agar for non-encapsulated dentifrice beads, let alone in the amounts now being claimed.
- (d) D1, which was the closest prior art document, disclosed an encapsulated bead enclosed by a coating made of soft gelatine.

D4 described the use of agar in skin preparations such as creams meant for spreading on the skin, not in single-dose compositions for tooth brushing. Moreover, the context of D4 was that of a slow release composition, whereas a dentifrice required a quick release of active ingredients. Therefore, D1 would not be combined with D4 to arrive at the claimed beads.

D3 disclosed encapsulated microparticles, with coatings made of agar, used as an ingredient of a dentifrice. Hence, a combination of D1 with D3 would not lead to non-encapsulated beads as claimed.

D7 also described slow release compositions that were too sticky for brushing and hence taugth away from dentifrice applications. Moreover, it did not describe the use of agar.

The other documents were less relevant. Therefore, the claimed beads were inventive.

VII. The appellants requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims submitted as Further New Main request on 14 January 2010 and a description to be adapted thereto.

VIII. At the end of the oral proceedings, the following decision was announced:

The appellants were given a period of two months to submit a description adapted to the claims submitted at the oral proceedings on 14 January 2010.

IX. On 27 January 2010, by letter dated 25 January 2010, the appellants filed a new description of 36 numbered pages, pages 25 to 28 being blank, and four sheets of drawings, as well as a typed set of 10 claims.

Reasons for the Decision

1. The appeal is admissible.

Amendments

2. The typed version of the claims filed with letter dated 25 January 2010 is identical to the version with handwritten amendments submitted during the oral proceedings. Therefore, the typed version can be accepted.

- 2.1 The basis for the change from a composition to a homogeneous and non-encapsulated gel bead can be found in original claim 7, which referred to original claim 6, the contents of which (dentifrice ingredients) also form a basis for present claim 1. According to original page 6, line 15 to page 7, line 10, in particular page 6, lines 18 to 20, the composition is formed into discrete beads. Agar is mentioned on page 6, lines 22 to 24, its amount on page 6 line 24. That the bead is for use with an application tool including the means as defined in present claim 1, is based on original claim 11 as well as on original page 8, lines 8 to 11 and original page 11, lines 3 to 7. The deletions are mainly of an editorial nature or also based on the instances cited above.

Claims 2 and 3 are preferred embodiments of the bead of claim 1; claim 2 finds its basis on original page 7, lines 6 to 8, claim 3 is based on original claim 8 and original page 7, lines 10 to 11.

Claims 4 to 6 concern kits or packs comprising a bead according to claim 1; they are based on original claims 10 to 12.

Claims 7 to 10 are directed to the manufacture of the beads according to claim 1; they find their basis in original claims 19 to 22.

As the amendments therefore are based on the application as originally filed, the claims fulfil the requirements of Article 123(2) EPC.

- 2.2 As the means of achieving the desired effect, i.e. the presence of a specified amount of agar, is now incorporated in claim 1, the claims are clear in that respect. However, for the weight percentage of 0.4 to 1.1, no reference is given. Therefore, to the amount in claim 1 should be added: "of the bead", in conformity with the amended description, page 6, line 12 (Article 84 EPC).

Support for that amendment can be found on page 6, lines 22 to 24, of the application as originally filed, read in the light of the examples, in particular original example 5, as well as page 22, lines 12 to 15 (Article 123(2) EPC).

- 2.3 The typed version of the description filed with letter dated 25 January 2010 reflects the amendments found to be necessary under Article 84 EPC as discussed during the oral proceedings. It contains however some errors that should be corrected:
- page 3, line 18 should read: "...a unit dose...";
 - page 5, line 23: "case" should be "care";

- page 5, line 28 should read: "...available for use...";
- page 6, line 10: "...within the mouth, during use.";
- page 6, line 14: "...amount of at least one of a surface-...";
- page 7, line 5 should be: Example 1;
- page 7, lines 6 and 7: "...grams, so that a single bead is capable of providing sufficient active ingredients for a single dental care procedure. More preferably, each bead has a weight of 0.4...";
- page 8, line 15 should read: "... wherein the active ingredients of the semi-solid composition..."
- page 8a, line 1 should read: "The invention also provides a method **of** manufacture...";
- page 9, line 1: "... may ..."
- page 9, line 7 should read: "The method may include the steps of mixing the components in a defined order and at a defined temperature sufficient to melt the gelling agent, meanwhile...";
- page 14, line 21: Example 10 should be Example 3;
- page 15, line 15: "REFER**E**NCE";
- page 24, line 9: "Tests of the above Examples...";
- page 31, line 15: "...such as brushes ~~and razors~~."
- page 34, lines 26 and 27: "...toothpastes ~~or oral or skin care formulations~~, but held..."

The description thus adapted to the amended claims can be accepted in the light of Articles 123(2) and 84 EPC.

- 2.4 The description contains general indications of how to prepare the claimed beads and in Example 1 exact details are given of the mixing order of the ingredients and mixing conditions. On the basis of that information, the skilled person is capable of preparing

the claimed beads. In view of the structure of the beads, the Board is satisfied that the effects the beads should have according to claim 1, are also achieved, so that the requirements of Article 83 EPC are fulfilled.

Novelty

3. D1 discloses a package for toothpaste or a mouth therapeutic agent, characterised in that a single dose amount of toothpaste or mouth therapeutic agent is enclosed by a capsule that is to be opened in the mouth (claim 1). The capsule is preferably soluble in the mouth and made of soft gelatine (claims 2 and 3, column 2 lines 14 to 20). This document discloses the use of single dose tooth paste capsules which however are encapsulated and do not contain any agar.
- 3.1 D3 describes a dentifrice composition comprising capsule particles containing agar as a main component of a coat-forming substance and having an average particle size of from 0.3 to 3 mm, and vehicles for use in oral cavity (claim 1). Those encapsulated particles constitute 0,1 to 10 % by weight of a dentifrice composition (page 4, lines 48 to 50, examples); they do not contain all the ingredients of a dentifrice and are not single dose dentifrice beads by themselves.
- 3.2 D4 discloses a protective cosmetic particulate gel delivery system for a topically applied active agent comprising discrete gel particles formed of an agar gel and characterized by further comprising a restraining polymer dispersed in the agar gel, the restraining polymer having sufficient molecular weight to prevent

egress of the restraining polymer from the agar gel, having retention groups to bind the active agent to the restraining polymer for retention in the gel particles and being present in a proportion sufficient to deliver an effective amount of the active agent wherein the gel particles are manually crushable on the skin to increase the surface area of the gel particle material and expose the restraining polymer to the skin or other body surface for release of the active agent (claim 1). In the examples the amount of agar used to make the beads exceeds 1,5% by weight, which is above the present upper limit of 1,1% by weight. They are meant to be incorporated in traditional creams or lotions but could also be used per se (column 10, lines 55 to 56). The beads of D4 are not specified to contain the ingredients of a dentifrice and no indication of the use of the beads per se as a dentifrice is given. The only instance mentioning teeth is found in column 5, lines 13 to 18, where the skin is mentioned as the delivery target, including teeth wound tissue, but not the teeth themselves.

- 3.3 D7 describes dentifrice oral hygiene composition presented in the form of an ingestible product characterized in that it is in a single dose form, containing a concentrated hydrophilic and/or lipophilic gellifying matrix that allows retention of the active ingredients contained in the composition, so as to provide a long lasting activity in the oral cavity (claim 1). The composition may be in the form of a semi-solid gel (claim 2). The gel matrix may consist of a galactomannan, a carboxymethyl cellulose or a carrageenan (claim 5), or of micronised silica or an acrylate derivative (claim 6). Agar is not mentioned.

- 3.4 Since none of the above cited documents, or any of the other documents on file, disclose the combination of features now being claimed, the claimed subject-matter is novel (Article 54 EPC).

Inventive step

4. The application concerns personal dental care compositions with portable packs. Such compositions and packs are known from D1, which the examining division as well as the appellants considered to be the closest prior art document. Since D7, contrary to D1, does not disclose the use of agar, and D3 does not disclose the use of the beads in single dose form, the Board sees no reason to deviate from that point of view.
- 4.1 D1 aims at a convenient, practical and hygienic package for dental products such as dentifrice, that moreover enhances the acceptance of brushing the teeth (column 1, line 47 to column 2, line 13). Therefore, those advantages, as summed up on pages 33 to 36 of the application as originally filed, which are linked to the use of single dose beads, cannot serve to define a problem that the subject-matter now being claimed would solve over D1. However, the non-encapsulated beads are simpler to mix, make and pack, and the mouth feel is reported to be better and the residue less than that of beads having an outer coating. For that reason, the problem solved by the subject-matter now being claimed can be seen as to provide beads that are simpler to prepare and have a more pleasant mouth feel than those of D1.

- 4.2 The question that remains to be answered is if it was obvious for the skilled person to use agar as a gel matrix in order to solve the above defined problem. Since D1 does not mention the use of agar, nor the use of a gel matrix, that document in itself cannot render the subject-matter now being claimed obvious.
- 4.2.1 D3 discloses the use of agar only in the coating of encapsulated beads that are part of a dentifrice. Therefore, D3 cannot lead the skilled person to using agar as a gel matrix for beads to be used in single dose form.
- 4.2.2 D4 teaches the use of agar gel beads in a delivery system for a topically applied active agent, the latter being retained by a restraining polymer (column 8, lines 18 to 28). The beads are incorporated in multiphase cosmetic formulations (Abstract; column 1, lines 23 to 27; column 8, lines 19 to 28). The application of the formulations refers to the skin, not teeth, and dentifrice is accordingly not mentioned as one of the possible applications (column 11, line 63 to column 12, line 3 and see point 3.2 above). Moreover, although a possible use of single beads is mentioned, there is no indication that beads containing less agar than those of the examples of D4 would be suitable for use in a single dose form and to be packaged as such. Therefore, D4 does not lead the skilled person, starting from D1, to the present beads.
- 4.2.3 The other documents on file are more remote than D1, D3 and D4 and do not provide any incentive to use agar as a gel matrix for non-encapsulated, homogeneous dentifrice beads as now claimed.

4.2.4 In view of the above, the subject-matter of Claim 1 involves an inventive step so that the requirements of Article 56 EPC are fulfilled.

4.3 The other claims are directly or indirectly dependent on claim 1, so that those, too, comply with 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 first instance with the order to grant a patent on the basis of claims 1 to 10 as filed with letter dated 25 January 2010 with the correction as indicated under point 2.2 above and a description according to pages 1 to 36 as filed with letter dated 25 January 2010, with the corrections as indicated under point 2.5 above and the page numbering yet to be adapted.

Registrar:

Chairman:

S. Fabiani

S. Perryman