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**Datasheet for the decision
of 14 September 2015**

Case Number: T 1128/12 - 3.3.10

Application Number: 05730732.4

Publication Number: 1748806

IPC: A61L31/10, A61P9/10, A61L31/16,
A61L31/12, C08L33/10,
C08L71/02, A61K31/445

Language of the proceedings: EN

Title of invention:
BIOCOMPATIBLE POLYACRYLATE COMPOSITIONS FOR MEDICAL
APPLICATIONS

Applicant:
Abbott Cardiovascular Systems Inc.

Headword:

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

Keyword:
Amendments - added subject-matter (no)
Inventive step -
(yes) Regardless of whether or not alleged improvement has
been shown, alternative is non-obvious

Decisions cited:

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 1128/12 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 14 September 2015

Appellant: Abbott Cardiovascular Systems Inc.
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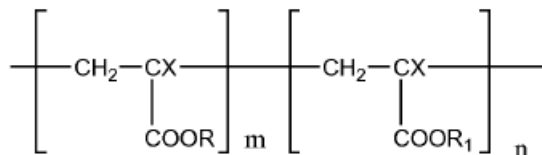
Decision under appeal: **Decision of the Examining Division of the European Patent Office posted on 28 December 2011 refusing European patent application No. 05730732.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman P. Gryczka
Members: J. Mercey
C. Schmidt

Summary of Facts and Submissions

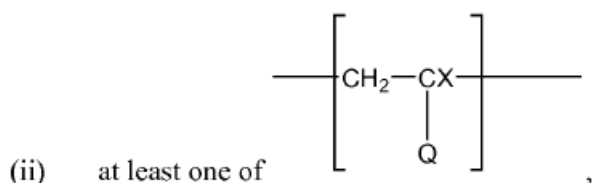
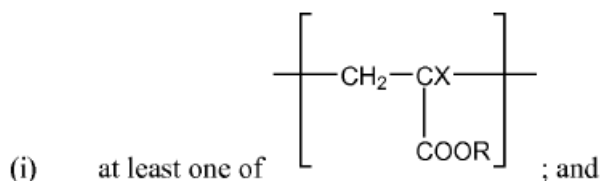
- I. The appeal lies from the decision of the Examining Division refusing European patent application No. 05 730 732.4 with the European publication No. 1 748 806.
- II. *Inter alia* the following documents were cited in the examination proceedings:
- (1) WO 2004/009145 and
 - (2) US-A-6 673 385.
- III. In the decision under appeal, the Examining Division found that the subject-matter of claim 1 of each of the then pending main and auxiliary requests 1 to 4 lacked inventive step over a combination of document (1) with *inter alia* document (2).
- IV. In a communication dated 11 March 2015 accompanying a summons to oral proceedings, the Board indicated that the subject-matter of the main request and auxiliary requests 1 to 5 filed with the Statement of Grounds would appear to lack an inventive step.
- V. With letter dated 20 July 2015, the Appellant (Applicant) filed a main request and four auxiliary requests, said requests superseding all previous requests. Claim 1 of the main request reads as follows:
- "A composition comprising:
- (a) a biologically compatible structural component comprising a linear acrylic polymer, wherein the linear acrylic polymer is a linear acrylic homopolymer or a linear acrylic copolymer having the structure:



wherein

- (i) X is hydrogen or a methyl group;
- (ii) each of R and R₁ is independently methyl, ethyl, n-propyl, iso-propyl, n-butyl, sec-butyl, iso-butyl, tert-butyl, lauryl, or 2-hydroxyethyl;
- (iii) m is a positive integer; and
- (iv) n is 0 or a positive integer; and

(b) a biobeneficial component comprising a copolymer having a biobeneficial and an acrylate moiety, which copolymer is a random, block, graft or brush copolymer comprising:



wherein

- (iii) X is hydrogen or a methyl group;
- (iv) R is methyl, ethyl, n-propyl, iso-propyl, n-butyl, sec-butyl, iso-butyl, tert-butyl, lauryl, or 2-hydroxyethyl; and
- (v) Q is a fragment providing the copolymer with biobeneficial properties, wherein Q is derived from superoxide dismutase-mimetics (SODm), diazenium diolate type nitric oxide donors, polycationic peptides, or mixtures thereof,

wherein the mass ratio between the structural component and the biobeneficial component is from 99:1 to 1:1;

wherein the SODm is manganese (II) dichloroaminoethyl thiolated pentaazatetracyclohexacosatriene (SOD-40470);

wherein the diazenium diolate type nitric oxide donors are selected from

N-{4-[1-(3-aminopropyl)-2-hydroxy-2-nitrosohydrazino]butyl}-diazen-1-ium-1,2-diolate, 1-{N-methyl-N-[6-(N-methylammonio)hexyl]amino}diazen-1-ium-1,2-diolate, and Z-1-[N-(2-aminoethyl)-N-(2-ammonioethyl)amino]diazen-1-ium-1,2-diolate; and

wherein the polycationic peptides are selected from poly(L-arginine), poly(D-arginine), poly(D,L-arginine), poly(δ -guanidino- α -aminobutyric acid), a racemic mixture of poly(L-arginine) or poly(D-arginine)."

- VI. The Appellant submitted that there was a basis for the subject-matter of claims 1 to 10 of the main request in the application as filed, such that the requirements of Article 123(2) EPC were fulfilled. The Appellant argued that the subject-matter of the main request was inventive over document (2), since the present compositions had a higher structural integrity than those of Examples 2 and 3 of document (2) in view of the presence of the linear acrylic homopolymer or linear acrylic copolymer. This was because the biobeneficial moiety disrupted the intermolecular interactions between the polymer chains of the acrylic copolymer to which it was attached, consequently reducing the structural integrity of a coating composition comprising such a composition. Furthermore,

there was no suggestion, either in document (2) or in any of the other cited prior art, to replace the polyethylene glycol (PEG) or sulfanato biobeneficial moieties in the copolymers of Examples 2 and 3 of document (2) with the very specific superoxide dismutate mimetics, diazenium diolate type nitric oxide donors and polycationic peptides according to present claim 1. Nor did any of the cited documents teach adding a linear acrylic homopolymer or a linear acrylic copolymer as defined in claim 1 in a 99:1 to 1:1 mass ratio to the copolymers of document (2).

VII. The Appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request or, subsidiarily, on the basis of auxiliary requests 1 to 4, all requests filed with letter dated 20 July 2015. It further requested that the oral proceedings set for 20 August 2015 be cancelled in the event that the Board considered the claims of the main request to be allowable. These oral proceedings were, thus, duly cancelled.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. *Amendments (Article 123(2) EPC)*

2.1 Claim 1 is based on original claims 1, 2, 3, 5, 8, 24, 26 and 27, together with page 10, lines 21 to 22 and page 11, lines 1 to 9 of the application as filed, original claim 27 being dependent on claim 26, which is

itself dependent on claim 24. Page 3, lines 2 to 8 of the application as filed discloses the features of original claims 2, 3 and 5 in combination. The formulae defined in claim 1 for the structural component (a) and the biobeneficial component (b) from original claims 8 and 24, respectively, also find a basis in the formula I on page 7, lines 1 to 12 and the A and B units of formula II on page 9, lines 5 to 15 of the application as filed, which are the most general formulae defined in the application as filed for these two components, such that their combination results in no added subject-matter. The specific biobeneficial moieties taken from pages 10 and 11 have been combined merely with generic definitions.

- 2.2 Claims 7 and 9 are based on the medical article of original claim 31 and the method for fabricating a medical article of original claim 58, together with the passages indicated in point 2.1 above for the definition of the coating composition.
- 2.3 Dependent claims 2 to 6, 8 and 10 are based on original claims 9, 25, 6, 7, 22, 32 and 59, respectively.
- 2.4 Therefore, the amendments made to the claims do not generate subject-matter extending beyond the content of the application as filed and the Board concludes that the requirements of Article 123(2) EPC are satisfied.

3. *Inventive Step*

- 3.1 The present invention relates to a coating composition for a stent for treating *inter alia* restenosis comprising a structural component (a) comprising a linear acrylic polymer, and a biobeneficial component

(b) comprising a copolymer having a biobeneficial moiety and an acrylate moiety.

3.2 The subject-matter of claim 1 of the present main request has been restricted when compared to claim 1 of the narrowest request before the Examining Division, namely auxiliary request 4, in that the linear acrylic polymer of component (a), and the copolymer having a biobeneficial moiety and an acrylate moiety of component (b), are defined by virtue of formulae, and the biobeneficial moiety may be derived only from superoxide dismutate mimetics, diazenium diolate type nitric oxide donors and polycationic peptides, and indeed very specific ones at that.

3.3 Document (2), which the Board considers to represent the closest prior art, discloses stents coated with a copolymer made from methylmethacrylate, n-butylmethacrylate and polyethylene glycol methacrylate (see Ex. 2) and n-butylmethacrylate, polyethylene glycol methacrylate and sulfonato ethyl methacrylate (see Ex. 3), the polyethylene glycol methacrylate and sulfonato moieties having anti-restenotic properties (see col. 2, line 65 to col. 3, line 8). Hence, in contrast to document (1), which was considered by the Examining Division to represent the closest prior art, the coatings disclosed in document (2) already have both a biobeneficial moiety, namely a moiety derived from a poly(alkylene glycol) or sulfonic acid, and a structural moiety, namely the acrylate moiety, which contributes to the structural integrity of the coating.

3.4 In view of this state of the art, the Appellant submitted that the problem underlying the present application was the provision of a composition suitable for coating a medical device, which coating not only

provides the device with advantageous biological properties for *in vivo* use, but also provides improved structural integrity, and furthermore is economical and versatile in use.

3.5 As the solution to this problem, the application proposes a composition comprising a copolymer having a biobeneficial and an acrylate moiety, characterised in that the biobeneficial moiety is derived from superoxide dismutate-mimetics (SODm), namely manganese (II) dichloroaminoethyl thiolated pentaazatetracyclohexacosatriene, diazenium diolate type nitric oxide donors, namely N-{4-[1-(3-aminopropyl)-2-hydroxy-2-nitrosohydrazino]butyl}-diazene-1-ium-1,2-diolate, 1-{N-methyl-N-[6-(N-methylammonio)hexyl]amino}diazene-1-ium-1,2-diolate, and Z-1-[N-(2-aminoethyl)-N-(2-ammonioethyl)amino]diazene-1-ium-1,2-diolate, and/or polycationic peptides, namely poly(L-arginine), poly(D-arginine), poly(D,L-arginine), poly(δ -guanidino- α -aminobutyric acid), a racemic mixture of poly(L-arginine) or poly(D-arginine), and that the composition also comprises a biologically compatible structural component comprising a linear acrylic homopolymer or a linear acrylic copolymer having the formula given in claim 1.

3.6 The question of whether or not the problem as formulated by the Appellant has been solved in all aspects may be left aside, since the Board holds that even if the technical problem is reformulated as merely the provision of alternative coating compositions for implantable medical devices, the proposed solution is not obvious.

3.7 As a matter of fact, there is no suggestion, either in document (2), or in any of the other cited prior art,

to replace the polyethylene glycol or sulfonato biobeneficial moieties in the copolymers of Examples 2 and 3 of document (2) with moieties derived from superoxide dismutate mimetics, diazenium diolate type nitric oxide donors and polycationic peptides, let alone with moieties selected from the very specific compounds of these types according to present claim 1, there being no prior art on file which teaches that said compounds have anti-restenotic properties. Document (2) teaches the use of anti-restenotic monomers in general which may be polymerised to form a suitable biocompatible coating (see col. 2, lines 50 to 53 and 65 to 67), but the only monomers specifically taught are vitamin E methacrylate, dimethyl amino ethyl methacrylate, vinyl pyrrolidone, sulfonated dextran and methacryloxy phosphoryl choline (see col. 3, lines 2 to 6). Nor does document (1), which discloses a polymeric coating for a stent comprising an active agent (see claims 1 and 7), teach that the active agent may be any of the superoxide dismutate mimetics, diazenium diolate type nitric oxide donors and polycationic peptides of present claim 1, the list of useful therapeutic agents from page 15, line 21 to page 17, line 6 not including any of these specific compounds, said agents also not being chemically incorporated into a polymer of the coating, but merely blended therewith. Nor do any of the cited documents teach adding a linear acrylic homopolymer or a linear acrylic copolymer as defined in claim 1 in a 99:1 to 1:1 mass ratio to the copolymers of document (2). Thus, although document (1) teaches (see claim 2) a stent coating comprising a linear acrylic homopolymer and/or a linear acrylic copolymer corresponding to the definition (a) of present claim 1, the Board sees no motivation for the skilled person to add such a polymer to the acrylate copolymer comprising a biobeneficial moiety of document (2).

3.8 For these reasons, the Board concludes that in the light of the prior art cited by the Examining Division, the composition according to claim 1, and by the same token the medical article and the method for fabricating such a medical article comprising said composition of claims 7 and 9, respectively, together with the subject-matter of dependent claims 2 to 6, 8 and 10, involves an inventive step within the meaning of Articles 52(1) and 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 order to grant a patent on the basis of claims 1 to 10 of the main request filed with letter dated 20 July 2015 and a description yet to be adapted.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated