Examiners' Report Paper A 2010 (Chemistry)

Introduction

Paper A was concerned with bioactive glass compositions that are very good for *in vivo* creation of bones, ie the generation of bone tissue in the body. The glass compositions described in the clients letter can easily be formed into fibres in contrast to the compositions of the prior art. The advantage of using fibres is that their well-defined structure allows for very regular bone growth. This is in contrast to powders used in the prior art.

The client's letter describes that the good fibre formation is due to the presence of Al_2O_3 and K_2O in certain, well-defined, amounts. The application further describes the prior art bioactive glass composition from which the present invention is a further development.

The fibres can be used as such, as bundles or woven into fabrics, like a net. The fibres can also be cut into small, regular particles. In this form they can be used as a coating to be applied to prostheses. Also dental implants can be coated with these particles. The particles can also be formed into a paste, that can be injected in places where bone growth is needed. This paste is obtained by mixing the fibres with a binder. A very useful binder is a solution of a specific dextran in water.

The letter also contains an indication that the client also would like to obtain protection for the product *per se* without any reference to the medical application.

Two prior art documents are cited. The first document is a general background document about bioactive glass compositions. Also the dextran-containing binder for making a paste is described in this document. The general prior art composition mentioned in the client's letter is the composition disclosed in this document.

The second document discloses the compositions of the examples. However, the document does not mention that this composition can be formed into fibres or suggest any uses for the glass. The document mentions that experiments around the specific compositions are being performed. The candidates were supposed to realise that the specific compositions were not novel.

Independent claims:

A total of 70 marks were available for the independent claims.

Candidates were expected to draft the following independent claim directed to the fibre, for which a maximum of 40 marks could be awarded.

1 *Glass fibre, the fibre having a diameter of less than 50 µm and comprising the following components:*

SiO_2 40 – 55 wt.%
P_2O_5 4-8 wt.%
CaO and/or MgO 10-40 wt%
Na_2O up to 28 wt%
K_2O and Al_2O_3 in total 2-9 wt.%, of which Al_2O_3 should be between 0.5 and 2.5 wt.%.

The candidates were expected to define the composition starting from the prior art composition described in the client's letter. The invention is based on replacing sodium oxide from this standard glass with potassium oxide and alumina. There would also be no support in the client's letter for any other bioactive glass composition to add the potassium oxide and alumina to. There is no basis that any composition having 2-9 wt.% K_2O and Al_2O_3 of which Al_2O_3 should be between 0.5 and 2.5 wt.% would solve any problem. A group of candidates defined the fibres merely by the presence of 2-9 wt.% K_2O and Al_2O_3 of which Al_2O_3 should be between 0.5 and 2.5 wt.%, without defining the other components of the bioactive glass composition. This lead to a deduction of up to 12 marks.

Many candidates did not define the upper diameter of the fibres. Such a claim without an upper diameter of the fibres could be defended in view of the client's wish to also protect products outside the bioactive field. Such a claim could, therefore, attract full marks. Also claims with an upper limit of 50 µm could obtain full marks. Many candidates also included a lower limit of 10 µm for the fibres. This limitation was seen as an unnecessary limitation, since technical constraints (as mentioned in the client's letter) in making fibres could be overcome and provide useful bioactive fibres. Candidates who limited their claims like this, lost up to 2 marks.

Some candidates drafted the claim as a product-by-process claim. Such a definition was clearly less preferred since this was not necessary in the present case. This lead to a deduction of up to 10 marks.

A large number of candidates defined the amount of Na_2O to be up to 30 wt.%. However, it was clear from the paper that part of the Na_2O was replaced by K_2O and Al_2O_3. Since this amount of K_2O and Al_2O_3 was at least 2 wt%, the amount of Na_2O needed to be changed to *up to 28 wt.%.* Omission of this amendment could lead to a deduction up to 5 marks. Other definitions taking into account this change in the amount of Na_2O were, of course, also awarded full marks. For example, the following definition was also acceptable: *Na_2O, K_2O and Al_2O_3 up to 30 wt.%, with K_2O and Al_2O_3 in total 2-9 wt.%, of which Al_2O_3 should be between 0.5 and 2.5 wt.%.*

Some candidates did not define that alumina needs to present in an amount of 0.5 wt.%. From the paper it is clear that the invention lies in a glass composition including and Al_2O_3 in certain ratio and concentrations (see page 4, paragraph 3). From the penultimate paragraph on this page it is clear what those ratios and amounts should be. Candidates who did not specify the amount of alumina could lose up to 5 marks.

Quite a few candidates limited their claim to **bioactive** glass fibres. Even though this is only a slight limitation on the claim (it merely defines the suitability of the fibres for bioactive application), this was considered to go against the wishes of the client, since page 1, 2nd paragraph mentions that the client also wants his claims directed to non-bioactive applications. This could lead to a deduction of 2 marks.

Quite a few candidates also drafted a claim to the composition *per se*, in which they excluded the specific compositions of document 2. This formulation also excluded all examples presented in the client's letter, leading to a claim that was not awarded any marks

Candidates who claimed the combination of a non-patentable composition claim with a claim to the fibres could only get 10 marks for the fibre claim.

Candidates who presented a set of claims that does not fulfil the requirements of Rule 43(2) EPC could not get full marks.

2 *Fibre bundle, net or gauze consisting of the fibres according to claim 1.*

A total of 6 marks was available for this claim. Some candidates did not direct claims to all three products. Each product missing led to a deduction of 2 marks. Candidates who drafted this claim as a use claim and not to the product *per se* lost up to 3 marks.

3 *Powder obtainable by chopping the fibres of claim 1 into a length of 10-100 µm.*

A total of 5 marks was available for this claim, Quite a few candidates did not specify the length of the chopped fibres even though it was clear from the paper that this was a requirement of the powder. Candidates who did not define the length of the chopped fibres lost up to 3 marks. Both claims with upper and lower limit for the fibre length and only upper limit attracted full marks. A definition not using the product-by-process wording was also acceptable.

4 *Paste containing the powder of claim 3 and a binder.*

Up to 5 marks were available for this claim. Some candidates limited their claim to the specific dextran binder. In doing so they would lose up to 3 marks.

5 *Medical prosthesis coated with a powder as defined in claim 3.*

A total of 10 marks were available for this claim.

6 *Process for making a prosthesis according to claim 5 comprising coating a paste as defined in claim 4 or plasma spraying a powder as defined in claim 3 onto a prosthesis.*

Up to 4 marks were available for this claim.

7 *Glass composition comprising the following components:*

SiO_2 40 – 55 wt.%
P_2O_5 4-8 wt.%
CaO and/or MgO 10-40 wt%
Na_2O up to 28 wt%
K_2O and Al_2O_3 in total 2-9 wt.%, of which Al_2O_3 should be between 0.5 and 2.5 wt.%
for use in medicine.

A total of 10 marks were available for this first medical use claim. Candidates who directed their claim to the first medical use of the glass fibre could also obtain full marks.

Quite a few candidates did not realise that claims directed to the method of using the fibre or to the use of the fibre were excluded from patentability under Article 53(c) EPC. Candidates were expected to be familiar with this fundamental requirement of the EPC. Such claims, therefore, did not attract any marks.

8 *Glass composition comprising the following components:*

SiO_2 40 – 55 wt.%
P_2O_5 4-8 wt.%
CaO and/or MgO 10-40 wt%
Na_2O up to 28 wt%
K_2O and Al_2O_3 in total 2-9 wt.%, of which Al_2O_3 should be between 0.5 and 2.5 wt.%
for use in a method of regenerating bone tissue.

Wording according to Article 54(5) EPC as introduced with EPC 2000, as presented above, for this second medical use claims was preferred. Wording the claim using EPC 1973 Swiss-type formulation was also considered acceptable, because G2/08, that mentions that Swiss-type claims are no longer allowed, was only published in 2010 and therefore not relevant for the EQE 2010. Such formulations could, therefore, also attract full marks.

A total of 5 marks were available for this claim.

As mentioned above, some candidates formulated general use claims for the fibres and powder. These claims are, therefore, directed to a method of treatment, which is excluded from patentability under Article 53(c) EPC. Accordingly no marks were awarded for these use claims.

Some candidates directed a claim to the treatment of hypertension. This was based on the last paragraph of page 3 of the client's letter. However, this passage does not describe that the fibres provide for the treatment of hypertension. The passage merely defines that use of the present fibres (with less Na_2O) does not create problems with hypertension. The passage certainly does not disclose that the fibres can be used to treat hypertension. Candidates who drafted such a claim, received no marks for that claim.

The applicant's letter indicated that for financial reasons the applicant was not prepared to pay any claims fees. No more than 15 claims were therefore expected, which was realised by most candidates. The few candidates who did have more than 15 claims did not get any marks for claims 16 and higher.

Dependent claims:

A total of 15 marks were available for the dependent claims.

The candidates were also expected to draft a few useful dependent claims. The following dependent claims were considered to provide good fallback positions:

1. *Fibre according to claim 1 which also contains boron oxide in an amount of 2-7 wt.%. (4 marks available).*

2. *Paste according to claim 5 where the binder is dextran having a molecular weight of 10 000 to 100 000 dissolved in water at a concentration of 0.5 to 2.0 g/ml water. (4 marks available).*

3. *Paste according to claim 2 where the glass is used at a concentration of 0.5 to 1.5 g/g of the dextran solution (2 marks available)*

4. *Medical prosthesis according to claim 6 characterised in that the prosthesis is a dental implant or a hip implant. (2 marks available)*

For further dependent claims a total of 3 marks was available.

Description:

For the description a total of 15 marks were available. Candidates were expected to introduce a short summary of document 1 and document 2 and to draft the introductory portion of the description. It was especially important that the problem the application set out to solve was clearly formulated.

Many candidates presented their description as a communication to the EPO and not as a real description, by for example stating that *claim 1 is novel over document 1 because…* It is stressed that candidates are expected to draft the introductory portion of a description and candidates lose some marks if their description is not drafted in that way.

There is a danger that candidates rely overly on issues of past papers without getting a solid understanding of the requirements of the EPC. It is true that medical indication has never before been an issue in paper A since the introduction of EPC 2000, but candidates are expected to have understanding of all requirements of the EPC, especially those of patentability and its exceptions. Although practicing previous papers is indispensible, it cannot replace a thorough knowledge of the patentability requirements.

Model claims:

1. Glass fibre, the fibre having a diameter of less than 50 μm and comprising the following components:

SiO_2 40 – 55 wt.%
P_2O_5 4-8 wt.%
CaO and/or MgO 10-40 wt%
Na_2O up to 28 wt%
K_2O and Al_2O_3 in total 2-9 wt.%, of which Al_2O_3 should be between 0.5 and 2.5 wt.%.

2. Fibre according to claim 1 which also contains boron oxide in an amount of 2-7 wt.%.

3. Fibre bundle, net or gauze consisting of the fibres according to claim 1.

4. Net or gauze as claimed in claim 3 in the form of a bandage.

5. Powder obtainable by chopping the fibres of claim 1 into a length of 10-100 μm.

6. Paste containing the powder of claim 5 and a binder.

7 Paste according to claim 6 where the binder is dextran having a molecular weight of 10 000 to 100 000 dissolved in water at a concentration of 0.5 to 2.0 g/ml water.

8. Paste according to claim 7 where the glass is used at a concentration of 0.5 to 1.5 g/l of the dextran solution

9. Medical prosthesis coated with a powder as defined in claim 5.

10. Medical prosthesis according to claim 9 characterised in that the prosthesis is a dental implant or hip implant.

11. Medical prosthesis according to claim 10 in which the dental implant is coated at its root only.

12. Medical prosthesis according to claims 9 or 10 in which the prosthesis is made of titanium, stainless steel or alumina.

13. Process for making a prosthesis according to claim 9 comprising coating a paste as defined in claim 6 or plasma spraying a powder as defined in claim 5 onto a prosthesis.

14. Glass composition comprising the following components:

SiO_2 40 – 55 wt.%
P_2O_5 4-8 wt.%
CaO and/or MgO 10-40 wt%
Na_2O up to 28 wt%
K_2O and Al_2O_3 in total 2-9 wt.%, of which Al_2O_3 should be between 0.5 and 2.5 wt.%
for use in medicine.

15. Glass composition comprising the following components:

SiO_2 40 – 55 wt.%
P_2O_5 4-8 wt.%
CaO and/or MgO 10-40 wt%
Na_2O up to 28 wt%
K_2O and Al_2O_3 in total 2-9 wt.%, of which Al_2O_3 should be between 0.5 and 2.5 wt.%
for use in a method of regenerating bone tissue.

EXAMINATION COMMITTEE I

Candidate No.

Paper A (Chemistry) 2010 - Marking Sheet

Category		Maximum possible	Marks awarded	
			Marker	Marker
Independent claims	Glass Fibre	25		
	Derived Products	30		
	Medical Uses	15		
Dependent claims		15		
Description		15		
Total		**100**		

Examination Committee I agrees on ..... marks and recommends the following grade to the Examination Board:

☐ PASS (50-100)

☐ COMPENSABLE FAIL (45-49)

☐ FAIL (0-44)

01 July 2010

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Chairman of Examination Committee I