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Datasheet for the decision of 25 November 2014

Case Number: T 2210/11 - 3.3.08

Application Number: 00903199.8

Publication Number: 1141385

IPC: C12Q1/68

Language of the proceedings: EN

Title of invention:

TARGET MOLECULE ATTACHMENT TO SURFACES

Applicant:

SurModics, Inc.

Headword:

Activated slide microarray/SURMODICS

Relevant legal provisions:

EPC Art. 123(2), 54, 111

Keyword:

Main Request, Auxiliary Requests: admissibility (yes); Main Request: added subject-matter (no); novelty (yes); Main Request, Auxiliary Requests: remittal to the first instance (yes)

Decisions cited:

Catchword:



Beschwerdekammern **Boards of Appeal** Chambres de recours

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Case Number: T 2210/11 - 3.3.08

DECISION of Technical Board of Appeal 3.3.08 of 25 November 2014

Appellant:

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Decision under appeal: Decision of the Examining Division of the

European Patent Office posted on 7 March 2011

refusing European patent application No. 00903199.8 pursuant to Article 97(2) EPC.

Composition of the Board:

M. Wieser Chairman Members: P. Julià

D. Rogers

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Summary of Facts and Submissions

- I. The appeal lies against the decision of the examining division dated 7 March 2011, whereby the examining division refused to grant a patent on the European patent application no. 00 903 199.8, published as International patent application WO 00/40593 (hereinafter, "the application as filed"). Basis for the refusal were a Main Request and an Auxiliary Request, both filed with letter of 31 January 2011.
- II. Claims 1, 2, 12 and 22 of the Main Request read as follows:
 - "1. A method of attaching a target molecule to a substrate, the method comprising:
 - a) providing a reagent composition comprising a hydrophilic polymer backbone having a random distribution of thermochemically reactive groups formed by polymerization of monomers having a polymerizable group separated by a spacer group from a thermochemically reactive group, and optionally monomers having a polymerizable group separated by a spacer group from a photo reactive group, and monomers which are neither photo reactive nor thermochemically reactive, wherein the thermo chemically reactive groups on the hydrophilic polymer backbone are configured and arranged to form covalent bonds with functional groups on the target molecule;
 - b) coating and immobilizing the reagent composition on the substrate to form a bound composition;
 - c) providing a solution comprising target molecule having one or more functional groups reactive with the

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thermochemically reactive groups provided by the bound composition;

- d) applying one or more spots of the solution with a volume of between 0.01 nanoliter and 100 nanoliters to the substrate; and
- e) allowing the thermo chemically reactive groups provided by the bound composition to form covalent bonds with the functional groups provided by the target molecule in order to attach the target molecule to the substrate, without use of attracting groups to attract the target molecule to the bound reagent."
- "2. The method of claim 1, wherein the hydrophilic polymer backbone is formed by polymerization of a solution of monomers that includes between 2.5 mole % and 10 mole % of a monomer that comprises the thermochemically reactive group."
- "12. An activated slide for binding target molecule in a sample, the slide comprising:
- a) a substrate; and
- b) a bound composition attached to the substrate, wherein the bound composition comprises a hydrophilic polymer backbone having a random distribution of thermochemically reactive groups formed by polymerization of monomers having a polymerizable group separated by a spacer group from a thermochemically reactive group, and optionally monomers having a polymerizable group separated by a spacer group from a photo reactive group and monomers which are neither photo reactive nor thermochemically reactive, and wherein the bound composition is configured and arranged to form covalent bonds with functional groups

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on the target molecule without use of attracting groups to attract the target molecule to the bound composition."

"22. A microarray comprising a substrate, a bound composition disposed on the substrate, and target molecule covalently coupled with the bound composition, wherein the microarray is prepared by a method according to any one of claims 1 to 11."

Claims 3-11 and 13-21 were directed to specific embodiments of claims 1 and 12, respectively. Claims 23-24 were directed to specific embodiments of claim 22.

- III. The Auxiliary Request was identical to the Main Request except for the introduction of the subject-matter of claim 2 into independent claims 1 and 12. The numbering and the dependencies of the claims were amended correspondingly.
- IV. The examining division considered both requests not to fulfil the requirements of Articles 123(2) and 54 EPC.

According to the examining division, the range cited in claim 2 of the Main Request had no basis in the application as filed and covered new embodiments. Thus, claim 2 of the Main Request and claims 1 and 11 of the Auxiliary Request comprising the subject-matter of this claim, went beyond the disclosure as originally filed and thereby, contravened the requirements of Article 123(2) EPC.

With reference to Example 14 of document D3 (infra), the examining division considered the subject-matter of the product-claims 12-21 of the Main Request not to be

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novel. The objection applied also to the product-claims 11-20 of the Auxiliary Request. None of these requests were thus considered to fulfil the requirements of Article 54 EPC

V. With the statement setting out its Grounds of Appeal, the applicant (appellant) filed a new Main Request and a first and second Auxiliary Requests. Oral proceedings were requested as an auxiliary measure.

The Main Request differed from the Main Request at first instance only in that claim 2 was deleted and in that claim 11 (former claim 12) was amended to read as follows:

- "11. An activated slide for binding target molecule in a sample, the slide comprising:
- a) a substrate; and
- b) a bound composition attached to the substrate, wherein the bound composition is attached to the substrate according to the method of any one of claims 1-10."
- VI. The appellant was summoned to oral proceedings. In a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), annexed thereto, the appellant was informed of the board's preliminary, non-binding opinion on the issues of the case.

In particular, the board informed the appellant that its newly filed claim requests were considered to be admissible. Moreover, it was informed that the amendments introduced into the product-claims of the Main Request overcame the objection under Article 54

EPC raised by the examining division. As regards Article 56 EPC, the board noted that no objection had been raised under this article in the decision under appeal and that, during the examination of the application, all comments made with regard to inventive step were of general nature only and did not address the relevance of the essential technical feature present in the now amended product-claims. Therefore, the board informed the appellant of its intention to remit the case to the examining division for further prosecution.

The appellant was summed to oral proceedings. However, in view of the board's positive opinion on the requirements of Articles 123(2) and 54 EPC with regard to the Main Request (i.e. the only two issues decided in the decision under appeal), the appellant was informed that these proceedings would be cancelled in case it was formally requested, as Main Request, to set aside the decision under appeal and to remit the case to the department of first instance for further prosecution of the case.

- VII. With a letter of 23 October 2014, the appellant requested the board to cancel the scheduled oral proceedings, to set aside the decision under appeal and to remit the case to the examining division for assessment of inventive step of the product claims 11-20 of the Main Request.
- VIII. Oral proceedings were cancelled by the board.
- IX. The following documents are cited in this decision:
 - D1: US 5,217,492 (publication date: 8 June 1993),

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D3: WO-A2-99/16907 (publication date: 8 April 1999).

X. The appellant's arguments, as far as relevant for the present decision, can be summarized as follows:

The objection raised by the examining division under Article 123(2) EPC was overcome by the deletion of the subject-matter of claim 2. The objected product-claims were reworded by adding an explicit reference to the method-claims. Since these methods contained the essential feature (production of small dense spots resulting from the application of only 0.01 to 100 nanoliters of the target solution to the substrate) on which, according to the examining division, an inventive step could be based, the products prepared by these methods were equally novel and inventive.

XI. The appellant (applicant) requested to set aside the decision under appeal and to remit the case to the examining division for the assessment of inventive step, in particular of the product-by-process claims 11-20 of the Main Request.

Reasons for the Decision

Admissibility of the appellant's new claim requests

- 1. The board considers that appellant's new claim requests have been filed in direct reply to the objections raised by the examining division in the decision under appeal.
- 1.1 The Main Request is identical to the Main Request before the examining division except for i) the deletion of claim 2, which was objected under Article

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- 123(2) EPC in the decision under appeal; and ii) the introduction of amendments into claim 11, in order to overcome an objection raised under Article 54 EPC for lack of novelty over document D3.
- 1.2 The first Auxiliary Request is identical to the Main Request except for the deletion of claims 11 to 20 directed to an activated slide. Thus, this request only contains claims directed to a method of attaching a target molecule to a substrate and claims relating to a microarray.
- 1.3 The second Auxiliary Request is identical to the first Auxiliary Request except for the deletion of all claims directed to a microarray.
- 2. In view of the examination procedure, the board takes the view that these new claim requests could not have been filed at an earlier stage of the proceedings.
- 2.1 Former claim 2, now deleted, had been introduced by the appellant in reply to the summons to oral proceedings issued by the examining division. The subject-matter of this claim was not present in any of appellant's previous requests and thus, the objection raised under Article 123(2) EPC against this subject-matter could not have been raised and addressed at earlier stages of the proceedings (cf. pages 2-3, point 2.1.1 of the decision under appeal). The deletion of former claim 2 overcomes an objection raised, for the first time in the proceedings, in the decision under appeal.
- 2.2 Claim 1, which is identically contained in the Main Request before the examining division and now before the board, had been amended in the examination phase in order to overcome objections raised by the examining

division for lack of novelty over documents D1 and D3 (cf. pages 1-2, point 3 of the communication of the examining division dated 6 October 2010). In the decision under appeal, no objection under Article 54 EPC was raised against claim 1, referring to a method. However, similar amendments were not considered by the examining division to render novel the subject-matter of claims directed to a product in the light of the disclosure in document D3. This objection under Article 54 EPC was maintained in the decision under appeal (cf. pages 3-4, point 2.1.2). The amendments now introduced into product-claim 11 of the Main Request are a direct reply to the decision taken by the examining division, to the comments made on page 4, point 2.2 of the decision under appeal and to the acknowledgement of novelty of the method claim 1 of the Main Request in the decision under appeal (cf. page 6, last paragraph).

3. In view of these considerations, the board admits the new Main Request and the new first and second Auxiliary Requests into the appeal proceedings.

Main Request

Article 123(2) EPC

4. The deletion of previous claim 2 clearly overcomes the objection raised by the examining division under Article 123(2) EPC (cf. point 1.1 supra). In the decision under appeal no other objection under this article was raised and the board sees no reason to raise one of its own. The Main Request fulfils the requirements of Article 123(2) EPC.

Article 54 EPC

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- In the decision under appeal, the sole objection raised under Article 54 EPC was directed against the product-claims relating to an activated slide (cf. pages 3-5, points 2.1.2 to 2.3 and page 6, point 2.4.2 of the decision under appeal). The amendments introduced into product-claim 11 of the Main Request define this product by reference to the method of claim 1, i.e. in terms of a product-by-process claim (cf. point V supra). The claimed activated slide is defined by the presence of a substrate and of a bound composition, which is attached to the substrate by the method of claim 1. This method has not been objected under Articles 54 or 56 EPC in the decision under appeal (cf. point IV supra).
- Several criteria have been set out in the case law established by the Boards of Appeal for a product-by-process claim to be patentable. In particular, it must not be possible to define or describe the product in any other way, and the claimed product itself must fulfil all the requirements for patentability, i.e. to be novel and inventive independently of the process (cf. "Case Law of the Boards of Appeal of the EPO", 7th edition 2013, II.A.7 et seq., page 274). Thus, it has to be assessed whether the process features can establish novelty of the claimed product by causing it to have different properties than products previously described in the prior art (cf. "Case Law", supra, I.C. 4.2.7, page 124).
- 5.2 When carrying out the analysis referred to above, the board acknowledges that step (d) of claim 1, which requires "applying one or more spots of the solution with a volume of between 0.01 nanoliter and 100 nanoliters to the substrate" (cf. point II supra), results in a specific technical feature, namely the

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presence of small (dense, reduced, discrete, etc.) spot sizes of the target molecule attached to the reagent bound to the substrate (cf. page 8, lines 10-18 and page 9, line 26 to page 10, line 11, in particular page 10, lines 3-5 of the application as filed). Although document D1 refers to "discrete spots" (cf. column 5, line 19) and document D3 to the use of "microscope slides" (cf. page 3, line 28), the actual volume and concentration of the target molecule in these spots is not defined. Thus, step (d) of the method claim 1 confers to the activated slides of claim 11 a technical feature which differentiates it from products previously described in the prior art on file.

6. Thus, the subject-matter of claims 11-20, directed to "an activated slide for binding target molecule in a sample ... wherein the bound composition is attached to the substrate according to the method of any one of claims 1-10" (cf. point V supra), overcomes the sole objection raised by the examining division under Article 54 EPC (cf. point IV supra). No other objections were raised under this article and the board sees no reason to raise one of its own. The Main Request fulfils the requirements of Article 54 EPC.

Article 56 EPC

- 7. No objections were raised under Article 56 EPC in the decision under appeal. However, the board notes that:
- 7.1 In the communication of the examining division dated 6 October 2010 annexed to the summons to oral proceedings, objections were raised against both the method- and the product-claims for lack of novelty over documents D1 and D3, and for lack of inventive step over document D1 alone. The objection under Article

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character and merely referred to a previous communication of the examining division (cf. page 3, fourth paragraph of the communication of the examining division dated 6 October 2010). There was indeed an objection under Article 56 EPC against the product-claims in a previous communication of the examining division dated 9 October 2007. However, also this objection, which was based on document D1, was of general nature and not elaborated in detail (cf. page 3, point 4.1 of the communication of the examining division dated 9 October 2007). Thus, the examining division has failed to provide a "problem and solution approach" based on document D1, the sole document which has been cited in the context of Article 56 EPC.

7.2 Moreover, with regard to the requirements of Article 56 EPC, there is no reference in any of the communications of the examining division to the relevance of the essential technical feature now present in the product-claim 11 by reference to its method of production, namely the small (dense, reduced, discrete, etc.) spot sizes of the target molecule attached to the reagent bound to the substrate (cf. point 5.2 supra).

The sole comment on this feature in the decision under appeal is found in the context of Article 54 EPC (where only document D3 is cited). However, this comment ("essential technical features on which an inventive step could be based even according to the applicant"; cf. page 4, point 2.2 of the decision under appeal) is ambiguous and does not represent a detailed response to the comments made by the appellant when introducing this feature (cf. page 8, fourth and fifth paragraphs, page 10, fifth and sixth full paragraphs of the appellant's letter dated 31 January 2011).

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This cannot substitute for a detailed "problem and solution approach" as required in the established case law for assessment of the requirements of Article 56 EPC (cf. "Case Law", supra, I.D.2 et seq., page 165).

- 7.3 In the board's view, the contribution of the technical feature now present in the product-claim 11, as well as the advantages allegedly associated thereto, have to be assessed by using the "problem and solution approach". This has to be done by taking into account the prior art documents on file (containing references to the terms "discrete spots" and "microscope slides" in column 5, line 19 and page 3, line 28 of documents D1 and D3, respectively) and, if necessary, by introducing new prior art documents that might reflect the common general knowledge of the skilled person. This procedure would allow a correct interpretation of these terms and the assessment of the alleged advantage.
- 8. In view of the procedural history of the case, as summarized above, and of the appellant's formal request for a remittal of the case to the department of first instance (cf. point VII supra), the board refrains from carrying out such a detailed "problem and solution approach" with possible introduction of new prior art documents and, in order to give the appellant the benefit of two instance, remits the case to the department of first instance for further prosecution.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

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The case is remitted to the examining division for further prosecution upon the basis of claims 1-23 of the Main Request filed with the statement of Grounds of Appeal under cover of a letter dated 20 June 2011.

The Registrar:

The Chairman:



K. Götz-Wein

M. Wieser

Decision electronically authenticated