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Datasheet for the decision of 4 September 2019

Case Number: T 0569/15 - 3.3.08

Application Number: 05854033.7

Publication Number: 1885869

IPC: C12Q1/00, C12Q1/54, C12Q1/32, C12Q1/26, C12Q1/28

Language of the proceedings: EN

Title of invention:
SIZE SELF-LIMITING COMPOSITIONS AND TEST DEVICES FOR MEASURING ANALYTES IN BIOLOGICAL FLUIDS

Patent Proprietor:
Ascensia Diabetes Care Holdings AG

Opponent:
Roche Diagnostics GmbH

Headword:
Measuring analytes in biological fluids/ASCENSIA

Relevant legal provisions:
EPC Art. 113(1), 123(2), 54

Keyword:
Main request - novelty (no)
First auxiliary request - added subject-matter (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0569/15 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 4 September 2019

Appellant: (Patent Proprietor)	Ascensia Diabetes Care Holdings AG Peter-Merian Strasse 90 4052 Basel (CH)
Representative:	Struck, Norbert Gille Hrabal Brucknerstrasse 20 40593 Düsseldorf (DE)
Respondent: (Opponent)	Roche Diagnostics GmbH Sandhoferstr. 116 68305 Mannheim (DE)
Representative:	Dey, Michael Weickmann & Weickmann Patent- und Rechtsanwälte PartmbB Richard-Strauss-Strasse 80 81679 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 27 January 2015 revoking European patent No. 1885869 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	B. Stolz
Members:	D. Pilat
	J. Geschwind

Summary of Facts and Submissions

I. European patent No. 1 885 869 is based on European patent application No. 05854033.7 (published as International patent application WO 2006/065900; hereinafter "the patent application") and was opposed on the grounds of Articles 100(a), (b) and (c) EPC. The opposition division considered both the main request and auxiliary request 1 to contravene Article 56 EPC and revoked the patent.

II. The patent proprietor (appellant) lodged an appeal against the decision of the opposition division.

III. The opponent (respondent) replied to appellant's statement of grounds of appeal.

IV. As an auxiliary measure, both parties requested oral proceedings.

V. The parties were summoned to oral proceedings. In a communication pursuant to Article 17(1) RPBA, the parties were informed of the board's provisional, non-binding opinion on some of the legal and substantive matters of the case.

VI. In reply to the board's communication, the appellant, with a letter dated 18 July 2019, without making any substantive submissions, informed the board that it would not participate in the oral proceedings.

VII. Oral proceedings were held on 4 September 2019 in the presence of the respondent only.

VIII. Claim 1 of the main request reads as follows:

"1. A reactive formulation for measuring the amount of an analyte in a biological fluid comprising:
- (a) an enzyme system for reacting with said analyte;
- (b) a water-soluble swellable polymer matrix; and
- (c) water-insoluble particles having a nominal size of 0.05 to 20 µm;
wherein the weight ratio of said water-insoluble particles to said water-soluble swellable polymer matrix is 1/2 to 2/1,
characterized in that the reactive formulation is applied as a coating having a thickness of 6 to 16 µm."

IX. Independent claims 10, 18, 28 and 39 relate to methods or products which include the formulation as defined in claim 1. Dependent claims 2 to 9, 11 to 17, 19 to 27, 29 to 38 and 40 to 49 define preferred embodiments thereof.

X. The claims of the first auxiliary request are identical to the claims of the main request except that claims 1 and 10 include in addition an "indicator" and claims 3 and 12 include in addition a "tetrazolium salt indicator".

XI. The following documents are cited in this decision:

D5: EP 995994 A2 (publication date 26 April 2000);

D5a: Experimental Data: Trockenschichtdicke des Reagensfilms gemäß D5 (EP 995994 A2), Beispiel 2;

D10: Degussa-Brochure "Precipitated Silicas and Silicates".

XII. Appellant's only submissions on file concerned the issue of lack of inventive step.

Despite all the objections raised under Articles 123(2), 83, 54 and 56 EPC by the respondent in its reply to appellant's statement of grounds of appeal and the board's preliminary opinion in relation to them, the appellant did not make any further substantive submissions.

XIII. Respondent's submissions, insofar as relevant to the present decision, may be summarized as follows:

Main request

Article 54 EPC - Novelty

Example 2 of document D5 disclosed a procedure for the production of a detection layer which was composed of 2 film layers. A first composition was coated on a 125 µm thick polycarbonate foil at a weight per unit area of 89 g/m^2 and dried. It defined a first film layer including water-soluble xanthan (3.4 g), water-soluble polyvinylpyrrolidone (3.5 g) and polyvinylpropionate dispersion (60.8 g in 50% in water makes 30.4 g) and water-insoluble particles Transpafill (sodium aluminium silicate, having an average agglomerate size of 8 µm (62.1 g)) (see document D10). The ratio of water-insoluble particles to water-soluble polymer matrix was calculated as 1,66. This first composition included also all the elements for an enzymatic glucose detection: a glucose dehydrogenase, a mediator bis-(2-hydroxyethyl)-(4-hydroximinocyclohexa-2,5-dienylidine)-

ammonium chloride and an optical indicator 2,18-phosphomolybdic acid hexasodium salt. A second composition was then coated as a second film layer on the first film layer at a weight per unit area of 104 g/m^2 and dried.
Since, there was no teaching of the thickness of the first film layer, a first film layer formulation was prepared according to [0114] and applied on a solid support according to the process of [0115] of document D5. The thickness of the dry film layer was determined by different measurement methods which yielded results ranging from 9.0 to 24.2 µm (see document D5a). Thus, the disclosure of the example 2 of document D5, in the light of the experimental evidence presented in document D5a, deprived the subject-matter of claim 1 of novelty.

First auxiliary request

Article 123(2) EPC

The first auxiliary request was amended to include the presence of an indicator in claims 1 and 10.

There was no basis in the patent application for an amended claim 1, derived from original claim 7 referring back to independent original claim 1, additionally including an indicator.

There was no a basis in the patent application for an amended method of claim 10 defining a formulation including a water-soluble swellable polymer matrix, and water-insoluble particles having a nominal size of 0.05 to 20 µm, characterized in that the weight ratio of said particles to said polymer matrix was 1/2 to 2/1,

and the film had a thickness of 6 to 16 µm, and said formulation comprised in addition an indicator.
The passages of the application cited by the appellant referred to the terms "membrane" or "coating" having a thickness of about 6-16 µm, but did not refer to the term "film" used in claim 10. An exchange of the terms "membrane" or "coating" by the term "film", each having a different technical meaning in the context of the patent application, contravened Article 123(2) EPC.

Thus, there was no direct and unambiguous basis in the patent application for a combination of features as claimed in amended claims 1 and 10. They infringed Article 123(2) EPC.

XIV. The appellant requested that the decision under appeal be set aside and that the patent be maintained either on the basis of the main request or alternatively based on the first auxiliary request underlying the decision under appeal.

XV. The respondent requested that the appeal be dismissed.

Reasons for the Decision

Article 113(1) EPC

1. By its decision not to attend the oral proceedings and not to file substantive arguments in reply to the issues raised in the board's communication pursuant to Article 17(1) RPBA, the appellant has chosen not to make use of the opportunity to comment on the board's provisional opinion, either in writing or at the oral proceedings, although this opinion was partially to the appellant's disadvantage. According to Article 15(3) RPBA, the board is not obliged to delay any step in the

proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying on its written case.

2. In the light thereof, the present decision is based on the same grounds, arguments and evidence on which the provisional opinion of the board was based.

3. The main request and the first auxiliary request are identical to the main request and first auxiliary request underlying the decision under appeal.

Main request

4. The respondent raised objections under Articles 123(2) and 83 EPC. In view of the board's conclusion on novelty of the main request (*infra*), there is no need to enter into a discussion of their merits.

Article 54 EPC

5. Claim 1 is directed at a reactive formulation for measuring the amount of an analyte in a biological fluid comprising

- (a)...
- (b) a water soluble swellable polymer matrix; and
- (c) water-insoluble particles having a nominal size of 0.05 to 20 µm;
  wherein the weight ratio of said water-insoluble particles to said water-soluble swellable polymer matrix is 1/2 to 2/1, characterized in that the reactive formulation is applied as a coating having a thickness of 6 to 16 µm.

6. The respondent submitted that the formulation of claim 1 was anticipated by document D5 when read in light of the experimental results reported in document D5a.

7. Document D5 discloses functional layers of high precision and test strips containing these functional layers. It discloses in particular the production of test strips including glucose dehydrogenase and the procedure for the production of a detection layer which is composed of two film layers (see example 2). A first composition is coated on a 125 µm thick polycarbonate foil at a weight per unit area of 89 g/m^2 and dried. It is defined as a first film layer and includes water-soluble xanthan gum (3.4 g), water-soluble polyvinylpyrrolidone (3.5 g) and polyvinylpropionate dispersion (60.8 g in 50% in water, i.e. 30.4 g) corresponding to feature (b) of claim 1, and water-insoluble particles Transpafill (62.1 g of sodium aluminium silicate () having an average agglomerate size of 8 µm as reported in document D10 (see page 12) corresponding to feature (c) of claim 1. The ratio of water-insoluble particles to water-soluble polymer matrix is 1.66 (i.e. = 62.1 g / 37.3 g (3.4 g + 3.5 g + 30.4 g)). The first layer composition includes moreover all the elements for an enzymatic glucose detection: a glucose dehydrogenase, a mediator bis-(2-hydroxyethyl)-(4-hydroximinocyclohexa-2,5-dienylidine)-ammonium chloride and an optical indicator 2,18-phosphomolybdic acid hexasodium salt (see [0114],[0115]) corresponding to feature (a) of claim 1.
Since there is no disclosure of the thickness of the first film layer in document D5, the respondent prepared a first film layer formulation according to paragraph [0114] of document D5 and applied it onto a solid support according to the process described in paragraph [0115]. The thickness of the dry film layer

determined by different measurement methods ranged from 9.0 to 24.2 µm, with average values ranging between 9 and 14,4 µm (see document D5a).

8. The board notes that the claim does not specify any particular method for determining the thickness of the coating. Furthermore, the board has no reason to assume that the preparation of the film layer in dry form, whose thickness is measured in document D5a, was not carried out according to the protocol described in paragraphs [0114] and [0115] of document D5. The validity of the experimental results cannot be contested. Thus, the dried first reactive film layer described in example 2 of document D5, whose thickness was determined as ranging from 9.0 to 24.2 µm, falls within the scope of claim 1.

9. Accordingly, the main request lacks novelty over document D5 in the light of the experimental results provided in document D5a.

First auxiliary request

Article 123(2) EPC

10. The respondent asserted that claims 1 and 10 contravened Article 123(2) EPC, because there was no basis in the patent application for a reactive formulation as defined in claim 1 comprising, in addition, an indicator. There was no basis either for a method of measuring the amount of an analyte in a biological fluid as defined in claim 10 comprising a film containing an enzyme system for reacting with said analyte and an indicator in a formulation as defined in claim 1 deposited on a non-porous substrate.

11. The board, in its communication pursuant to Article 17(1) RPBA, pointed out that both claims, 1 and 3, of the first auxiliary request did not meet the requirements of Article 123(2) EPC.
The board could not find any disclosure in the patent application nor was one provided by the appellant for a reactive formulation for measuring the amount of any undefined analyte in a biological fluid, according to amended claim 1, comprising the features (a),(c), and (d), wherein (c) and (d) have a certain relationship, in combination with an indicator (b). Nor could it find a disclosure of the subject matter of claim 3 wherein said analyte is glucose and the enzyme system is either hexokinase or glucose oxidase in combination with a tetrazolium salt indicator. The same conclusion applies to claims 10 and 13.

In fact, the only mention of an unspecified indicator appears to be in paragraph [0016] where the indicator is however mentioned in the context of an enzyme system for reaction with glucose. As for tetrazolium salt indicators, paragraph [0029] mentions merely their usefulness in combination with dehydrogenase-co-factor combinations.

12. The appellant did not provide any argument to the contrary, neither in response to the respondent's objections nor to the the board's provisional opinion in relation to the objections under Article 123(2) EPC.

13. Under these circumstances, the board has no reason to change its provisional opinion.

The board concludes that claims 1 and 3 extend beyond the content of the patent application, contrary to Article 123(2) EPC.

14. The rationale and conclusions drawn for the formulation of amended claims 1 and 3 apply mutatis mutandis to the method of amended claims 10 and 13.

Thus, claims 1, 3, 10, and 13 of the first auxiliary request infringe Article 123(2) EPC.

15. In the absence of an allowable request, the appeal has to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

L. Malécot-Grob B. Stolz

Decision electronically authenticated