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Datasheet for the decision of 22 January 2014

Case Number: T 1318/10 - 3.2.02

Application Number: 03258046.6

Publication Number: 1430831

IPC: A61B5/00, A61L2/00, C12Q1/00

Language of the proceedings: EN

Title of invention:
Method for manufacturing a sterilized and calibrated biosensor-based medical device

Applicant:
LifeScan, Inc.

Headword:

Relevant legal provisions:
EPC Art. 123(2), 54(1), 54(2), 56

Keyword:
Amendments - added subject-matter (no)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

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Case Number: T 1318/10 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 22 January 2014

Appellant: (Applicant)	LifeScan, Inc. 1000 Gibraltar Drive Milpitas, CA 95835 (US)
Representative:	Mercer, Christopher Paul Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 28 January 2010 refusing European patent application No. 03258046.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: E. Dufrasne
Members: D. Ceccarelli
P. L. P. Weber

Summary of Facts and Submissions

I. The applicant has appealed the Examining Division's decision, dispatched on 28 January 2010, to refuse European patent application No. 03 258 046.6.

II. The impugned decision was based on a main and an auxiliary request and considered the following documents:

D1: US-A-2002/0023852;
D3: "Analytical Characterization of Electrochemical Biosensor Test Strips for Measurement of Glucose in Low-Volume Interstitial Fluid Samples", Collison M E et al, Clinical Chemistry 45:9, 1665-1673, 1999.

The Examining Division found that the subject-matter of claim 1 of the main request extended beyond the content of the application as originally filed, lacked support in the description, lacked novelty over the disclosure of document D3 and lacked an inventive step over the disclosure of document D1. The auxiliary request was not admitted into the proceedings under Rule 137(3) EPC.

III. The notice of appeal was received on 7 April 2010 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 7 June 2010.

IV. After communication of the Board's provisional opinion, the appellant requested that the decision under appeal be set aside and that a patent be granted based on claims 1 to 8 of the set of claims labelled "NEW FIRST AUXILIARY REQUEST" or, in the alternative,

claims 1 to 8 of the set of claims labelled "NEW SECOND AUXILIARY REQUEST", both filed with letter dated 13 December 2013, description pages 1 to 13 filed with letter dated 19 December 2013 and figures 1 to 4 as published.

V. Independent claim 1 of the set of claims labelled "NEW FIRST AUXILIARY REQUEST" reads as follows (compared to claim 1 of the main request on which the impugned decision was based, additions are underlined, deletions are struck through):

"A method for manufacturing sterilized and calibrated disposable integrated biosensor-based medical devices, the method comprising:

assembling a plurality of disposable integrated biosensor-based medical devices each including a biosensor and a lancet integrated theretogether, the biosensor including a biosensor reagent composition;

packaging the disposable integrated biosensor-based medical devices, thereby creating packaged disposable integrated biosensor-based medical devices;

thereafter sterilizing the assembled packaged disposable integrated biosensor-based medical devices, thereby creating a plurality of sterilized, packaged disposable integrated biosensor-based medical devices;

thereafter, compensating for the effects of the sterilization step on the analytical performance of the packaged disposable integrated biosensor-based medical devices by calibrating the biosensor reagent composition of the sterilized, packaged disposable integrated biosensor-based medical devices, the calibrating step utilizing a fraction of the sterilized, packaged disposable integrated biosensor-based medical devices to obtain calibration information ~~at least one calibration coefficient wherein a~~

~~plurality of sterilized and calibrated disposable integrated biosensor based medical devices are obtained~~.

Claims 2 to 8 are dependent claims.

VI. The appellant's arguments are summarised as follows:

Compared to claim 1 of the main request on which the impugned decision was based, claim 1 of the set of claims labelled "NEW FIRST AUXILIARY REQUEST" recited throughout that the disposable integrated biosensor-based medical devices were packaged. This amendment was based on page 7, lines 1 to 3 of the application as filed and addressed the objection under Article 123(2) EPC as formulated in the impugned decision. A basis for the term "calibration information" was found on page 7, lines 11 to 13 of the application as filed. The requirements of Article 123(2) EPC were thus met.

While document D3 disclosed that a sterilisation step had some effects on the response of biosensor-based medical devices, it did not disclose that a compensation of these effects should be performed after the sterilisation step. D3 showed, on the contrary, that the effect of a particular sterilisation on the response of a particular test strip could systematically be predicted in advance and be compensated before the test strip was even manufactured. D3 therefore suggested that it would not be economically reasonable to perform the calibration after the integration and the sterilisation, since that might result in the rejection of a batch of devices, which would entail wasting the value that had been added by the integration and the sterilisation steps.

For these reasons, document D3 was neither novelty-destroying nor rendered obvious the subject-matter of claim 1 of the set of claims labelled "NEW FIRST AUXILIARY REQUEST".

Document D1 did not disclose disposable integrated biosensor-based medical devices, as the term "disposable" should be given the meaning of "single-use" when read in context. Document D1 rather disclosed a continuous-use, reusable sensor with a disposable lancet. Furthermore, document D1 disclosed an individual calibration process for each device, which took place at the point of use, with the device already embedded beneath a patient's skin. Said calibration process was not going to be used to calibrate other devices that might have been manufactured in the same batch. Because of this late calibration process, which would then also compensate the effects of the sterilisation step, there was no hint in document D1 to compensate for these effects earlier in the manufacturing process. Hence, the disclosure of document D1, even in combination with that of document D3, would not render obvious the subject-matter of claim 1 of the set of claims labelled "NEW FIRST AUXILIARY REQUEST".

Reasons for the Decision

1. The appeal is admissible.

2. Set of claims labelled "NEW FIRST AUXILIARY REQUEST"

2.1 *Basis in the original application - Article 123(2) EPC*

The subject-matter of claim 1 of the set of claims labelled "NEW FIRST AUXILIARY REQUEST" is based on claims 7, 8 and 9, together with page 1, line 31 to page 2, line 6, page 5, lines 15 to 21 and 29 to 33, page 6, lines 7 to 17 and page 7, lines 6 to 14 of the application as filed. The re-introduction of the term "packaged", compared to claim 1 of the main request on which the impugned decision was based, clearly overcomes the objection under Article 123(2) EPC as formulated in said decision.

The Board is satisfied that the requirements of Article 123(2) EPC are fulfilled.

2.2 *Support in the description – Article 84 EPC*

Said re-introduction of the term "packaged" renders moot also the objection formulated in the impugned decision as to lack of support in the description. In particular, the subject-matter of claim 1 finds support on page 2, lines 27 to 29 of the description as filed with letter dated 19 December 2013.

The Board is satisfied that the requirements of Article 84 EPC are fulfilled.

2.3 *Novelty - Article 54(1) and (2) EPC*

The Board notes firstly that no cited document considers the problems associated with methods for manufacturing sterilised and calibrated disposable integrated biosensor-based medical devices.

Document D1 primarily concerns a way to indicate that packaged sensors have been properly sterilised and have not been exposed to an excessive temperature. It suggests that sensor materials that withstand sterilisation should be used, so that the continued proper operation of the sensors is maintained (second half of paragraph [0049]). Without entering into the question of the proper meaning of the term "disposable", the Board notes that document D1 does not disclose that, after a sterilisation step, the effects of the latter on the analytical performance of packaged disposable integrated biosensor-based medical devices should be compensated by calibrating the biosensor reagent composition of the sterilised devices, the calibrating step utilising a fraction of said devices to obtain calibration information, as recited in claim 1. A calibration in D1 is only mentioned as a stabilisation process to be performed for each device in situ (paragraph [0072]) or in the context of remote programming (paragraph [0075]). It is also noted that novelty over document D1 was not questioned in the impugned decision.

Document D3 is concerned with sensors substantially changing their response due to a sterilisation procedure (page 1668, left column, third paragraph, and figure 4). In document D3, too, the Board does not see any disclosure that, after a sterilisation step, the effects of the latter on the analytical performance of

packaged disposable integrated biosensor-based medical devices should be compensated by calibrating the biosensor reagent composition of the sterilised devices, the calibrating step utilising a fraction of said devices to obtain calibration information, as recited in claim 1. Although it can be argued that a recalibration of the sensors for compensating the effects of the calibration step is implicitly disclosed in document D3, the Board does not share the Examining Division's view, expressed in the impugned decision, that it must be concluded that calibration information is necessarily derived from the utilisation of a sample of the packaged disposable integrated biosensor-based medical devices. As the appellant argues, the calibration information may also be predicted in advance.

Hence, the Board concludes that the subject-matter of claim 1 of the set of claims labelled "NEW FIRST AUXILIARY REQUEST" is novel.

2.4 *Inventive step - Article 56 EPC*

The Board is of the opinion that document D3, cited on page 2, lines 11 to 16 of the description, is the closest prior art, since it is the only cited document which deals with sensors substantially changing their response due to the sterilisation procedure (page 1668, left column, third paragraph, and figure 4).
Document D1, in contrast, merely suggests that sensor materials should be used, so that the continued proper operation of the sensors is maintained (second half of paragraph [0049]).

In the terms of claim 1, document D3 discloses a method for providing sterilised and calibrated disposable

integrated biosensor-based medical devices (page 1666, right column, first paragraph), the method comprising:

assembling a plurality of disposable integrated biosensor-based medical devices each including a biosensor and a lancet integrated theretogether, the biosensor including a biosensor reagent composition (page 1666, right column, first paragraph);

sterilising the biosensors and the lancets, thereby creating a plurality of sterilised disposable integrated biosensor-based medical devices (page 1666, right column, second paragraph);

compensating for the effects of the sterilisation step on the analytical performance of the disposable integrated biosensor-based medical devices by calibrating the biosensor reagent composition of the sterilised, disposable integrated biosensor-based medical devices (since the effects of the sterilisation are analysed - figure 4 - a subsequent recalibration is implicit).

Document D3 does not disclose:

-) packaging the disposable integrated biosensor-based medical devices before sterilisation;

-) sterilising the disposable integrated biosensor-based medical devices in the assembled and packaged state;

-) utilising a fraction of the sterilised, packaged disposable integrated biosensor-based medical devices to obtain calibration information;

-) calibrating the disposable integrated biosensor-based medical devices in the assembled and packaged state.

The Board notes in particular that, whenever document D3 refers to packages (i.e. page 1668, left column, third paragraph), said packages do not include the assembled disposable integrated biosensor-based medical devices comprising both a biosensor and a lancet integrated theretogether, but only the biosensors (e.g. test strips) as commercially available. Reference is especially made to page 1668, right column, first paragraph, where it is explicitly stated that:

> "the test strips used in this study were unmodified (i.e., test strips were not combined with ISF collection needle adapters)."

From this passage it can also be derived that the test strips were not sterilised together with the respective needles, but alone.

The effect of these differentiating features is that disposable integrated biosensor-based medical devices are obtained which are ready for use while still being packaged.

The objective technical problem to be solved is therefore regarded as providing a simple and inexpensive method for manufacturing disposable integrated biosensor-based medical devices that are both sterile and accurately calibrated (see also page 2, lines 11 to 14 of the application as filed).

Neither document D3 nor document D1 deals with said

problem, because they do not consider the problems associated with any method of manufacture. Moreover, at least the concept of utilising a fraction of the sterilised, packaged disposable integrated biosensor-based medical devices to obtain calibration information for the remaining devices is not disclosed in any cited document.

It must therefore be concluded that the skilled person would not arrive at the subject-matter of claim 1 of the set of claims labelled "NEW FIRST AUXILIARY REQUEST" without exercising an inventive activity.

3. The Board therefore considers the appellant's highest-ranking request to be allowable. It follows that there is no reason to examine the set of claims labelled "NEW SECOND AUXILIARY REQUEST".

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 8 of the set of claims labelled "NEW FIRST AUXILIARY REQUEST" filed with letter dated 13 December 2013;

   - description pages 1 to 13 filed with letter dated 19 December 2013; and

   - figures 1 to 4 as published.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated