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Datasheet for the decision of 8 May 2019

Case Number: T 2549/17 - 3.2.02

Application Number: 12170606.3

Publication Number: 2508129

IPC: A61B5/145, A61B5/1495, A61B5/1486, G01N27/327

Language of the proceedings: EN

Title of invention:
Processing analyte sensor data

Applicant:
Dexcom, Inc.

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 111(1)

Keyword:
Novelty - (yes)
Inventive step - (yes)
Appeal decision - remittal to the department of first instance (yes)

Decisions cited:
T 0683/12, T 2576/17, T 2578/17

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2549/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 8 May 2019

Appellant: (Applicant)	Dexcom, Inc. 6340 Sequence Drive San Diego, CA 92121 (US)
Representative:	Hill, Justin John Dentons UKMEA LLP One Fleet Place London EC4M 7WS (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 11 July 2017 refusing European patent application No. 12170606.3 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	S. Böttcher
	M. Stern

Summary of Facts and Submissions

I. The applicant lodged an appeal against the decision of the Examining Division to refuse European patent application No. 12170606.3 because the subject-matter of claims 1 and 8 then on file was found to lack novelty and inventive step over D1 = WO-A-00/49941.

II. The present case is related to the cases underlying decisions T 2578/17 and T 2576/17, as well as T 683/12.

III. Notice of appeal was received on 8 September 2017. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 27 October 2017.

IV. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed with the statement of grounds of appeal.

V. With a communication dated 28 November 2018, the appellant was informed that the Board intended to set aside the decision and to remit the case to the department of first instance for further prosecution.

VI. By letter of 11 December 2018, the appellant announced that it conditionally withdrew its request for oral proceedings subject to the remittance to the department of first instance.

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

"A method of determining stability of a continuous analyte sensor (10) during an initial instability

period from implantation during which the analyte sensor may be unstable for environmental, physiological, or other reasons, the method comprising:
receiving a data stream from a continuous analyte sensor, the data stream comprising a plurality of sensor data points;
receiving reference data from a reference analyte monitor, the reference data comprising a plurality of reference data points;
providing a plurality of matched data pairs by matching reference data points to substantially time corresponding sensor data points; and
determining the stability of the substantially continuous analyte sensor over the initial instability period of time by evaluating a plurality of matched data pairs."

VIII. Claim 8 of the main request reads as follows:

"A system configured to determining stability of a continuous analyte sensor during an initial instability period from implantation during which the analyte sensor may be unstable for environmental, physiological, or other reasons, comprising:
a sensor data module operatively connected to a continuous analyte sensor (10) that receives a data stream comprising a plurality of time spaced sensor data points from the analyte sensor;
a reference input module adapted to obtain reference data from a reference analyte monitor, the data comprising a plurality of reference data points;
a processor module that forms a plurality of matched data pairs by matching reference data points to substantially time corresponding sensor data points;
a start-up module associated with the processor module programmed to determine the stability of the continuous

analyte sensor over the initial instability period of time by evaluating a plurality of matched data pairs."

IX. The appellant's arguments relevant for the present decision are essentially those on which the following reasons for the decision are based.

Reasons for the Decision

1. The appeal is admissible.

2. Subject-matter of the invention

The application relates to a method (claim 1) and a system (claim 8) for determining the stability of an implanted analyte sensor (e.g. a glucose sensor) over time.
The method of claim 1 and the system of claim 8 are described in paragraphs [0344] to [0348] of the description, and illustrated in the flow chart in Figure 6.

During an initial period after implantation the sensor may be unstable because of different stages of tissue ingrowth. In order to determine the stability of the sensor the correlation between sensor and reference values is used. For this purpose matched data pairs are provided by matching reference data points to corresponding sensor data points, and the matched data pairs are evaluated.

3. Novelty - Article 54 EPC

D1 relates to calibration methods for glucose monitors and discloses a method of determining stability of such

a glucose sensor. In detail, D1 teaches the monitoring of sensor data after installation of the sensor in the body to determine when initial transients are diminished and the sensor is at a stable stage (page 12, lines 26-29).

D1 also discloses creating data pairs by matching reference data points to corresponding sensor data points. However, these matched data pairs are used only for calibration purposes (page 18, lines 5-24), and not for determining the stability of the sensor. Since this calibration is performed after the stabilisation of the sensor (page 19, lines 6-8), matched data pairs are formed only when the sensor is sufficiently stable, and not during the instability period.

Hence, D1 does not disclose the step of determining the stability of the analyte sensor by evaluating the plurality of matched data pairs. The subject-matter of claim 1 is therefore novel over D1.

The subject-matter of claim 8 is also novel since D1 does not disclose a start-up module programmed to determine the stability of the analyte sensor by evaluating the plurality of matched data pairs.

4. Inventive step - Article 56 EPC

The subject-matter of claim 1 differs from D1 in that the stability of the analyte sensor is determined by evaluating a plurality of matched data pairs.

The problem to be solved by this feature may be regarded as to provide a more accurate method of determining the stability of the sensor.

In the Board's view, the skilled person does not get any pointer from D1 to evaluate matched data pairs for determining the stability of a sensor.

In the minutes of a telephone consultation dated 19 June 2017, the Examining Division had stated that the method step of evaluating matched data pairs for determining the stability did not involve an inventive step since it was a "simple alternative" to observing transients in the sensor data as described in D1.

However, the evaluation of a plurality of matched data pairs is more complex, since it requires obtaining sensor data and reference data and the matching of corresponding data points. Hence, this method cannot be seen as a "simple alternative" to the method described in D1. The evaluation of matched data pairs rather provides a more accurate method of determining the stability of the sensor.

The Examining Division had additionally referred to the decision T 683/12 concerning the parent application. However, in this application the distinguishing feature was different. Therefore, the reasoning given in this decision is not decisive for the present case.

Consequently, the Board considers the subject-matter of claim 1 to meet the requirements of Article 56 EPC.

Claim 8 relates to the corresponding system configured to determining stability of a continuous analyte sensor. For the same reasons that apply to claim 1, its subject-matter therefore involves an inventive step.

5. As the claims of the main request have not been examined with regard to the other requirements of the

EPC (in particular clarity), the case is remitted to the department of first instance for further prosecution pursuant to Article 111(1) EPC.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated