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**Datasheet for the decision
of 18 May 2016**

Case Number: T 0683/12 - 3.2.02

Application Number: 04779357.5

Publication Number: 1648293

IPC: A61B5/00

Language of the proceedings: EN

Title of invention:
PROCESSING ANALYTE SENSOR DATA

Applicant:
DexCom, Inc.

Headword:

Relevant legal provisions:
EPC Art. 56, 84, 115, 123(2)
RPBA Art. 13(1)

Keyword:
Amendments - added subject-matter (no)
Claims - clarity - main request (yes)
Observations by third parties - relevant (no)
Inventive step - main request (no)
Late-filed auxiliary request - admitted (no)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 0683/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 18 May 2016

Appellant: DexCom, Inc.
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Representative: Hill, Justin John
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted on 11 November 2011 refusing European patent application No. 04779357.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman E. Dufrasne
Members: C. Körber
P. L. P. Weber

Summary of Facts and Submissions

- I. On 11 November 2011, the Examining Division posted its decision to refuse European patent application No. 04779357.5 for lack of clarity, lack of novelty and unallowable added subject-matter.
- II. An appeal was lodged against this decision by the applicant by notice received on 28 November 2011, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 29 February 2012.
- III. By communication of 17 February 2016, the Board summoned the appellant to oral proceedings and forwarded its provisional opinion.
- IV. On 14 April 2016, observations by a third party under Article 115 EPC were received, which comprised clarity objections against claim 1 of the main request. These observations were forwarded to the appellant with communication of 21 April 2016.
- V. By letter dated 18 April 2016 the appellant submitted further arguments as well as a main and first to nineteenth auxiliary requests.
- VI. Oral proceedings were held on 18 May 2016. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the new main request or, in the alternative, the new first auxiliary request, both filed during the oral proceedings.
- VII. The following document is of importance for the present decision:

D1: WO-A-00/49941.

VIII. Independent claims 1 and 10 of the new main request read:

"1. A method for initializing a continuous analyte sensor (10) the method comprising:
(a) receiving a data stream from a continuous analyte sensor (10), the data stream comprising a plurality of sensor data points;
(b) receiving reference data from a reference analyte monitor, the reference data comprising at least two reference data points;
(c) providing at least two matched data pairs by matching the at least two reference data points to time corresponding sensor data points; and
(d) determining a stability of the continuous analyte sensor based on sensor signal strength with respect to analyte concentration,
wherein if it is determined that the stability of the sensor is not sufficient then steps (a) to (d) are repeated, or
wherein if it is determined that the stability of the sensor is sufficient, then the at least one matched data pair is used to calibrate the sensor."

"10. A system for initializing a continuous analyte sensor (10), comprising:
a sensor data module (111) operatively connected to a continuous analyte sensor that receives a data stream comprising a plurality of time spaced sensor data points from the analyte sensor (10);
a reference input module (112) adapted to obtain reference data from a reference analyte monitor, the data comprising at least two reference data points;

a processor module (113) that forms at least two matched data pairs by matching the at least two reference data points to time corresponding sensor data points; and
a start-up module associated with the processor module programmed to determine stability of the continuous analyte sensor (10) based on sensor signal strength with respect to analyte concentration,
wherein the system is configured to continue initializing when it is determined that the stability of the sensor is not sufficient, and
wherein the system is configured to use the at least one matched data pair to calibrate the sensor if it is determined that the stability of the sensor is sufficient."

Claims 2 to 9 and 11 to 19 are dependent claims.

Claim 1 of the new first auxiliary request corresponds to claim 1 of the new main request with its last paragraph being amended as follows:

"wherein if it is determined that the stability of the sensor is sufficient, then the at least two matched data pairs are used to calibrate the sensor and
(e) initializing display of analyte sensor data upon determination of stability."

Claim 7 of the new first auxiliary request corresponds to claim 10 of the new main request with the following feature being added at the end:

"..., and wherein the start-up module is configured to initialize display of analyte sensor data upon determination of stability."

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

The calibration method of D1 was not suitable for initializing a continuous analyte sensor. D1 taught a method of calibration of a sensor once the sensor had undergone initialization, as disclosed at page 12, lines 6 to 8 and in the paragraph bridging pages 12 and 13. Thereafter, the sensor signal was monitored and an alarm was generated when the sensor sensitivity was too high or when the signal was unstable or out of a clinically acceptable range, the alarm notifying the user that re-calibration was required, as described at pages 16 to 18. The disclosure of sensor sensitivity being used at the top of page 20 only related to the calibration procedure and not to the determination of stability, as defined in claim 1 of the new main request. The influence of interfering factors such as noise was thereby avoided. The processes of initialization and calibration were separated in D1. In contrast, the invention used an interchangeable initialization/calibration process, realizing that these processes are neither completely time-independent nor mutually exclusive. Contrary to the system of D1, the claimed system was not based on an assumption that the system was initialized when taking in reference values, forming matched data pairs, and even calibrating. A technical advantage of this feature was to improve the reliability of the sensor continuing to perform stability checks during calibration, allowing the sensor to start up sooner with a failsafe to ensure reliable calibration. This technical advantage was not disclosed, taught or even suggested by D1. Further, it had been recognized that initial stability was not necessarily a predictable one-time event that behaved the same every time, so therefore, the invention allowed initialization to work calibration with

stability evaluation (together) over a period of instability, for example, during an initial time period post implantation, which could vary between about one minute and six weeks, as stated in the application. This allowed users to start up (calibration) whilst the device kept checking for stability that may occur (before or) after calibration. It was thus possible for the sensor to start up as soon as possible after "break-in", but not so soon as to display [in]accurate values. In contrast, the duration of the two-step initialization procedure disclosed at page 12 of D1 was about 60 minutes.

The new first auxiliary request should be admitted since it was submitted in order to address the obviousness objection that arose from the preceding discussion of the new main request during the oral proceedings. By adding the feature taken from dependent claim 19, it was avoided that inaccurate data were seen by the patient. The new first auxiliary request was thus responsive to the raised objection, increasingly limiting the subject-matter of the new main request and hence convergent. Consequently, it should be prima facie allowable.

Reasons for the Decision

1. The appeal is admissible.
2. New main request
 - 2.1 Amendments

Claim 1 is based on original claim 1 with the following amendments:

- deletion of the word "substantially" before the term "continuous analyte sensor", as disclosed, for instance, in paragraph [0292] of the original application published as WO-A-2005/011489;

- replacement of the expressions "at least one sensor data point/reference data point/matched data pair" by "at least two sensor data points/reference data points/matched data pairs" [emphasis added], as disclosed inter alia in paragraph [0007];

- specification in step (d) that the stability of the continuous analyte sensor is based on sensor signal strength with respect to analyte concentration, wherein if it is determined that the stability of the sensor is not sufficient then steps (a) to (d) are repeated, or wherein if it is determined that the stability of the sensor is sufficient, then the at least one matched data pair is used to calibrate the sensor, as disclosed in paragraph [0345] and paragraphs [0347] and [0348] in combination with Figure 6.

Analogous amendments have been introduced in claim 10.

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

2.2 Clarity

The objections raised under Article 115 EPC against the main request then on file are not applicable to the independent method claim of the new main request, which clearly defines the order of the method steps and wherein it is clear that stability determination takes place before calibration.

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

2.3 Inventive step

Document D1 as closest prior art discloses at page 12, line 7 to page 13, line 5 a method for initializing a continuous analyte sensor from which the subject-matter of claim 1 is distinguished in that determining the sensor's stability is based on **sensor signal strength with respect to analyte concentration** as defined in step (d).

Since the cited passage refers to an "initialization procedure", a "method for initializing" the sensor as claimed is clearly disclosed, in contrast to the appellant's view. The Board agrees with the fact that the preferred initialization procedure described in lines 16 to 24 of page 12 does not relate to a stability determination as mentioned in step (d); however, in the following lines 26 to 29 it is stated that alternatively, "the data processor 200 may apply an algorithm to the sensor data to determine when initial transients are sufficiently diminished and the sensor is at a significantly stable state to begin calibration". In the Board's view, this is equivalent to the condition defined at the end of claim 1, viz. "if it is determined that the stability of the sensor is sufficient, then the at least one matched data pair is used to calibrate the sensor". In this respect, the Board does not rely on other passages of D1 relating to re-calibration such as, for instance, the second paragraph of page 16, cited by the appellant in order to demonstrate a possible distinction.

The only passage dealing with the above-mentioned distinguishing feature is paragraph [0345] of the patent application. This passage does not mention any specific advantages associated therewith. The feature is only presented as one example of sensor sensitivity as a possibility to be used for determining the stability of the sensor. In the following paragraph [0346] it stated that sensitivity is evaluated for a time period believed necessary for sufficient tissue ingrowth, which may be between about one minute and six weeks. The appellant argued that this is in contrast to the duration of about 60 minutes as mentioned in lines 12 to 16 of page 12 of D1, with respect to the initialisation/stabilization process. The Board cannot recognise any technical advantage in this respect since the value stated in D1 lies well within the range mentioned in the application. Moreover, this value is stated in the context of the initialization/**stabilization** procedure described in lines 16 to 24 of page 12 of D1 which does not relate to a stability **determination** as mentioned above. Furthermore, the claim is silent regarding any temporal conditions. The Board also does not agree with the appellant's argument that determining stability based on sensor sensitivity avoids the influence of interfering factors, such as noise. Accordingly, no technical advantages can be recognised that are convincingly achievable by the above-mentioned distinguishing feature.

Under these circumstances, this feature is to be regarded as a simple alternative that the skilled person would obviously consider without the exercise of an inventive step. This is even more so since the evaluation of sensor sensitivity is explicitly mentioned in D1 in the context of re-calibration, which is required when an unstable signal alarm is generated,

as described, for instance, in lines 7 to 24 of page 16. Even though this passage does not relate to signal instabilities occurring during the initialization procedure as mentioned above, the skilled person would consider this teaching when determining initial stability.

It follows that claim 1 of the new main request does not involve an inventive step within the meaning of Article 56 EPC.

3. New first auxiliary request - admissibility

At the beginning of the oral proceedings before the Board, the appellant stated that the main and the first to nineteenth auxiliary requests filed with its letter of 18 April 2016, i.e. after the arrangement of the oral proceedings, were to replace the requests filed with the statements of grounds of appeal. After a discussion of the main request, the appellant withdrew this request and the first to fourteenth auxiliary requests. After discussion of the fifteenth auxiliary request, the appellant submitted an amended version thereof as its new main request and an amended version of the previously withdrawn first auxiliary request. After discussion of the new main request, the appellant withdrew the amended version of the previously withdrawn first auxiliary request and submitted the present "new first auxiliary request".

In the new first auxiliary request, the independent claims of the new main request were amended to specify that the display of analyte sensor data is initialized upon determination of stability.

Taking account of Article 13(1) of the RPBA, the admission of the new first auxiliary request is subject to the Board's discretion, since it was submitted after the filing of the grounds of appeal and thus represents an amendment to the appellant's case.

According to the settled case law of the boards of appeal, as cited in section IV.E.4.4.1 of "Case Law of the Boards of Appeal of the EPO" (7th ed. 2013), the criteria to be considered when exercising the discretion cited in Article 13(1) RPBA, e.g. current state of the procedure, are not exhaustive but may include other aspects such as the number of amended claim sets, their convergence and prima facie allowability.

The new first auxiliary request was submitted at an extremely late stage of the proceedings, viz. towards the end of the oral proceedings. The number of amended claim sets that required prior consideration by the Board amounts to more than twenty. They incorporate entirely different features going into different directions and cannot be said to be convergent. The aspect of providing a visual output when stability reaches a predetermined level, which closely corresponds to the amendment introduced in the new first auxiliary request, was present in all of the requests filed with the statement of grounds of appeal, but removed from the main and most of the auxiliary requests filed with the appellant's letter of 18 April 2016, which formed the basis of the discussion at the beginning of the oral proceedings. This cannot be regarded as a consistent line of defence.

It is also questionable whether the added feature renders the claims prima facie allowable with respect

to inventive step. The appellant stated that initialization of the display upon determination of stability avoids unreliable data being seen by the patient. However, in view of the fact that in lines 19 to 20 of page 28 of D1 it is taught that out-of-range values are not used to display a blood glucose value, the added feature is not prima facie suited to contribute to inventiveness.

Accordingly, the Board finds it appropriate to exercise its discretion under Article 13(1) RPBA with the effect of not admitting the new first auxiliary request.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated