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**Datasheet for the decision
of 3 August 2023**

Case Number: T 2126/18 - 3.2.02

Application Number: 10195509.4

Publication Number: 2329770

IPC: A61B5/145

Language of the proceedings: EN

Title of invention:
Transcutaneous analyte sensor

Patent Proprietor:
DexCom, Inc.

Opponent:
Roche Diagnostics GmbH

Headword:

Relevant legal provisions:
EPC Art. 54, 76(1), 83, 84, 123(2)

Keyword:

Novelty - (yes)

Divisional application - subject-matter extends beyond content
of earlier application (no)

Sufficiency of disclosure - (yes)

Claims - clarity (yes)

Amendments - added subject-matter (no)

Decisions cited:

Catchword:



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Case Number: T 2126/18 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 3 August 2023

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
16 August 2018 concerning the maintenance of
European Patent No. 2329770 in amended form**

Composition of the Board:

Chairman D. Ceccarelli
Members: S. Böttcher
Y. Podbielski

Summary of Facts and Submissions

- I. Both the opponent and the patent proprietor filed an appeal against the interlocutory decision of the opposition division to maintain the patent on the basis of auxiliary request 7.
- II. Oral proceedings before the Board took place on 3 August 2023.
- III. The appellant/opponent ("the opponent") requested that the decision under appeal be set aside and that the patent be revoked.

The appellant/patent proprietor ("the proprietor") requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request filed on 2 October 2017 or, as an auxiliary measure, that the patent be maintained on the basis of one of auxiliary requests 1-11 filed during the proceedings before the opposition division or on the basis of main request A or one of auxiliary requests 1A-5A and 8A-11A filed with the reply to the opponent's statement of grounds of appeal.

- IV. Claim 1 of the main request reads as follows.

"A method for self-diagnosis of a continuous analyte sensor, the method comprising:

receiving a stream of sensor data from a continuous analyte sensor, the stream comprising at least one sensor data point;

converting the sensor data into calibrated data using a

conversion function;

performing a self-diagnostic test on the sensor data or the calibrated data, wherein the self-diagnostic test tests for aberrant values in sensor data;

setting a suspended mode of operation of the continuous analyte sensor responsive to a failure identified by the self-diagnostic test, and

remaining in the suspended mode of operation until received sensor data is not found to be aberrant."

V. The following documents are referred to in this decision.

D1c WO 2006/017358 A1 (parent application)

D2 WO 03/094714 A1

D14e WO 2005/011489 A1

VI. The arguments of the opponent may be summarized as follows.

Main request - clarity

Claim 1 lacked clarity because of the ambiguous definition of which data (raw sensor data or calibrated sensor data or anything else) was actually tested for aberrancy. In particular, since in the feature "wherein the self-diagnostic test tests for aberrant values in sensor data" the term "sensor data" was used without any article, the sensor data tested for aberrant values could even be data different from both "the sensor data" and from "the calibrated data" mentioned earlier in the claim. Hence, a third kind of data could be meant. In addition, the "received sensor data"

mentioned in the last feature of claim 1 could even be a further, fourth kind of data.

According to claims 4 and 5, the test was performed on a stream of sensor data. Hence, claims 4 and 5 were contradictory to claim 1 when the latter was interpreted to define a test for aberrant values that was performed on sensor data or calibrated data, but not on the stream of sensor data.

The interpretation that the data tested for aberrant values could be sensor data before calibration was contradictory to Figure 18 and the description of the patent (paragraph [0284]) stating that calibrated data was used in this test.

Moreover, claim 1 lacked clarity, since after suspension of the sensor (i.e. when no stream of data could be received) it was not possible to check whether received data was still aberrant.

Consequently, claim 1 and, accordingly, the whole claim set was unclear.

Main request - added subject-matter

Claim 1 covered a "mixed approach", wherein a self-diagnostic test was performed on the calibrated data, while uncalibrated sensor data was used for deciding whether to remain in the suspended mode. Such a "mixed approach" was not disclosed in the original application documents or in the parent application.

Paragraph [0673] of the application as filed mentioned the suspended mode with regard to block 262 of Figure 18. However, this figure disclosed the evaluation of

calibrated sensor data (paragraph [0663]).

Furthermore, the feature "remaining in the suspended mode of operation until received sensor data is not found to be aberrant" had only been disclosed in context with suspending the display or suspending the calibration (paragraph [0673]). From paragraphs [0686], [0681], [0345] and [0673] it had to be concluded that there was a functional link between what was suspended and the possibility to recover from the suspended mode. The omission of the features "suspending the display or suspending the calibration" in claim 1 resulted in an inadmissible intermediate generalisation.

According to paragraph [0668], consecutive sensor values had to be checked for aberrancy. This was essential to determine whether the signal-to-noise ratio exceeded a set threshold. The omission of the term "consecutive" in claim 1 constituted an unallowable intermediate generalisation.

Moreover, the feature "remaining in the suspended mode..." had only been disclosed in context with a suspension of the system, and not a suspension of the sensor as defined in claim 1.

For these reasons, claim 1 did not meet the requirements of Articles 76(1) and 123(2) EPC.

Main request - sufficiency of disclosure

It was not understandable how the feature "remaining in the suspended mode of operation until received sensor data is not found to be aberrant" should be realized in practice, after the continuous analyte sensor had been suspended. After suspension of the continuous analyte

sensor, it was not possible to receive any sensor data. Hence, a check for aberrancy could not be carried out.

Therefore, the requirements of Article 83 EPC were not met.

Main request - novelty in view of D2

D2 related to a transcutaneous, continuous glucose monitor (Figure 1). It disclosed a method for self-diagnosis of the sensor system, the method comprising comparing blood glucose readings to an out-of-range limit (page 32, lines 13 to 22). This could be regarded as a test for aberrant values in sensor data.

D2 further disclosed the feature "remaining in the suspended mode until received sensor data is not found to be aberrant". As mentioned on page 32, lines 30 to 33, when a first ISIG value (a signal generated by the glucose sensor) exceeded the out-of-range limit, the corresponding blood glucose value was not displayed. In accordance with claim 15 of the main request, this could be considered a suspended mode of operation. If the next value was not out-of-range, the device returned to normal operation and did not activate an alarm. Thus, the device remained in the suspended mode until the next value not being out-of-range put it back to normal mode.

Furthermore, it was disclosed on page 32, lines 16 to 22, that an alarm was activated when a calculated blood glucose level exceeded an out-of-range limit. In that case, the blood glucose values were no longer calculated and a re-calibration was needed. This could be regarded as a suspended mode of operation. After such re-calibration the sensor data was no longer

aberrant and the device returned from the suspended mode to the normal mode of operation. Hence, this disclosure also anticipated the last feature of claim 1, which did not exclude that intermediate steps were performed by a user during the suspended mode before sensor data was received which was not found to be aberrant.

Main request - novelty in view of D14e

The feature "the self-diagnostic test tests for aberrant values in sensor data" was disclosed in paragraphs [0366], [0371] and [0374] of D14e, mentioning the evaluation of clinical acceptability.

Furthermore, the features "setting a suspended mode of operation (...) responsive to a failure identified by the self-diagnostic test" and "remaining in the suspended mode of operation until received sensor data is not found to be aberrant" were disclosed in paragraphs [0379] and [0381], by reference to a fail-safe mode in which estimated sensor data was not displayed to the user. This fail-safe mode might result in a recalibration, which was also an option as described in the last sentence of paragraph [0306] of the patent.

Hence, the subject-matter of claim 1 lacked novelty in view of D14e.

Main request - inventive step

The opponent did not maintain any objections as to inventive step.

VII. The arguments of the patent proprietor may be summarized as follows.

Main request - clarity

Claim 1 was entirely clear to the person skilled in the art, especially when taking into account the disclosure of the patent as a whole and common general knowledge.

The feature "wherein the self-diagnostic test tests for aberrant values in sensor data", referred to the self-diagnostic test mentioned in the previous feature. Hence, it was clear that the data mentioned in this feature could only be the data used for this test.

Furthermore, it was clear to the person skilled in the art that calibrated data was still sensor data.

Dependent claims 4 and 5 further defined the self-diagnostic test as a comparative test. This definition did not involve a contradiction to claim 1.

Paragraph [0288] and Figure 18 of the patent related to an exemplification of the self-diagnostic test for aberrant values and should not be read to be either exclusive or essential. It was further mentioned in paragraph [0299] that the self-diagnostic module of block 256 (Figure 18) could run on different kinds of data, including raw data, filtered data and calibrated data.

In the context of the claim it was clear that "received sensor data" mentioned in the last feature was the data on which the test had been performed.

Hence, the claims did not lack clarity.

Main request - added subject-matter

The specific combination of a self-diagnostic test for aberrant values performed on raw sensor data and leading to suspension mode was directly and unambiguously disclosed in paragraphs [0668] and [0671] to [0673] of the parent and original application as filed.

Furthermore, paragraph [0673] introduced the suspended mode in the first sentence and described further exemplary embodiments where "in general" the suspended mode suspended display of data or insertion of matched data pairs into the calibration set. The use of the wording "in general" demonstrated that these features were not deemed essential but rather preferably or optional and therefore not including these features into the subject-matter of claim 1 did not amount to an intermediate generalization.

Paragraphs [0685] and [0686] mentioned the suspended mode without referring to "consecutive" values. Hence, the omission of these features did not constitute an unallowable intermediate generalisation.

Claims 4 and 5 were a subset of claim 1 and defined further method steps that were performed in addition to the steps of claim 1.

Thus, the subject-matter of claim 1 complied with the requirements of Articles 76(1) and 123(2) EPC.

Main request - sufficiency of disclosure

The patent disclosed the invention in a manner

sufficiently clear and complete for it to be carried out by a person skilled in the art.

The opponent did not prove that there were serious doubts in this regard.

Main request - novelty in view of D2

D2 disclosed on page 32, lines 30 to 33, a method of filtering out a single out-of-range value. This could not be regarded as setting a suspended mode of operation, which rather required a change in the operation of the system. Furthermore, D2 did not disclose the suspension of the display. It was merely mentioned in the last sentence of the above-mentioned passage that out-of-range ISIG values were not used to display a blood glucose value. Hence, an out-of-range value would be excluded from the calculation of the glucose value, while other ISIG values would still be used in the calculation and for the display of a blood glucose value.

Moreover, the last feature of claim 1 required that the sensor values were tested subsequently after setting the suspended mode in order to determine the moment when the values were no longer aberrant. "Until" meant that as soon as the values were not aberrant, the system returned to the normal mode. In the disclosure of page 32, lines 16 to 22, of D2, after the activation of the alarm, no subsequent test for aberrant values was made.

Hence, D2 did not disclose a suspended mode of operation, and even less the method step of remaining in the suspended mode until received sensor data was not found to be aberrant. Therefore, the subject-matter

of claim 1 did not lack novelty over D2.

Main request - novelty in view of D14e

The patent proprietor did not make any submissions as to novelty of the subject-matter of claim 1 over D14e.

VIII. In a communication pursuant to Article 15(1) RPBA 2020, issued on 14 June 2023 the Board conveyed its preliminary view that the subject-matter of claim 1 did not lack novelty in view of D14e.

Reasons for the Decision

1. Subject-matter of the patent

The patent relates to transcutaneous measurement of glucose in a host by means of a sensor system.

The sensor system comprises a transcutaneous sensor 32 extending from a mounting unit 14 into the skin of the host (e.g. Figures 11B and 14). The mounting unit has an electronics unit 16 with a processor providing programming to process data streams.

The claims of the main request relate to a method for self-diagnosis of a continuous analyte sensor, for example to determine accuracy, reliability and/or clinical acceptability of the sensor data. In particular, claim 1 relates to a method comprising

- receiving a stream of sensor data from the sensor,
- converting the sensor data into calibrated data
- performing a self-diagnostic test on the sensor data

- or the calibrated data wherein the self-diagnostic test tests for aberrant values in sensor data,
- setting a suspended mode of operation responsive to a failure identified by the self-diagnostic test, and
- remaining in the suspended mode of operation until received sensor data is not found to be aberrant.

2. Main request - clarity

2.1 The main request includes the additional (i.e. additional with regard to the claim as granted) method steps of "wherein the self-diagnostic test tests for aberrant values in sensor data" (first amendment) and "remaining in the suspended mode of operation until received sensor data is not found to be aberrant" (second amendment). These additional features have been taken from the description of the patent. Hence, objections of lack of clarity directed to these features have to be considered.

2.2 Claim 1 defines a "stream of sensor data" which are then converted to "calibrated data". It then defines a self-diagnostic test to be performed "on the sensor data or the calibrated data". This reference to "the" sensor data means the data before calibration. However, the test can be performed, according to the express wording of the claim, also on the calibrated data. Further on, the claim specifies that the self-diagnostic test tests for aberrant values "in sensor data". This reference to sensor data is not introduced by the definite article "the". Hence, this method step does not refer to "the sensor data" mentioned before.

2.3 Rather, it is clear from the reference to "the self-diagnostic test" in the first amendment that the data on which the test is performed is meant. In this

regard, the Board agrees with the patent proprietor that calibrated data is still sensor data, namely, data that was initially received from a sensor.

2.4 Thus, taking into account that, according to the claim, the test can be performed on data before or after calibration, it has to be concluded from the wording of the claim alone, that "sensor data" tested for aberrant values includes sensor data before and after calibration. This interpretation is in accordance with the description, since the description does not exclude that sensor data can also be calibrated data, in addition to data before calibration. On the contrary, after calibration the data is often called "calibrated sensor data" or even still "sensor data" (e.g. in paragraphs [0284], [0288], [0289], [0290]). In other words, in the description, "sensor data" means simply "data received from the sensor" and covers both data before calibration and calibrated data.

2.5 The Board acknowledges that block 256 in Fig. 18 refers to calibrated sensor data. However, it is mentioned in paragraph [0299] that the self-diagnostics module of block 256 can use other data than calibrated data. Hence, there is no contradiction between claim 1 and the description of the patent.

2.6 Furthermore, the Board considers that the "received sensor data" mentioned in the second amendment also refers to the data on which the self-diagnostic test is performed. This data can be raw data even if the self-diagnostic test was performed on calibrated data. The opponent's allegation that a further, unknown kind of data is used to determine whether the system should remain in the suspended mode is technically not

sensible.

2.7 In dependent claims 4 and 5 a further method step of receiving a second stream of data is defined and the type of self-diagnostic test is defined as a comparison between the first data stream and a second data stream. Contrary to the opponent, the Board does not observe any contradiction between these claims and claim 1, since claim 1 includes the option that the test is performed on the sensor data stream, i.e. on "the sensor data".

2.8 The opponent further considered claim 1 to lack clarity since, after suspension of the sensor, it was not possible to check whether received data was still aberrant because no stream of data could be received.

However, the claim does not specify that in the suspended mode of operation the continuous analyte sensor cannot receive data.

Furthermore, according to the description (paragraphs [0294], [0306], [0307]), it is not the sensor which is set in the suspended mode, but (a part of) the system. Hence, the Board considers that in claim 1, the term "continuous analyte sensor" implies the whole sensor system, including sensor 32, mounting unit 14 and electronics unit 16 referred to in the description [paragraphs [0044] to [0047]]. Hence, the suspended mode of operation does not mean that the sensor 32 no longer provides any data.

2.9 Consequently, the claims are clear, in compliance with Article 84 EPC.

3. Main request - added subject-matter

3.1 In the opponent's view, claim 1 of the main request included added subject-matter both in view of the parent application D1e and in view of the application as originally filed.

It is noted that the description of the parent application and the application as originally filed are identical.

3.2 As mentioned above, the Board considers that the test for remaining in the suspended mode can be made with raw data even if the self-diagnostic test was performed on calibrated data. This "mixed approach" referred to by the opponent is in accord with the disclosure of paragraph [0673] of the parent application D1e and the application as originally filed, stating that "the system remains in suspended mode until received sensor data is not found to be aberrant". It is noted that this paragraph belongs to the description of the flow chart of Figure 18 which refers to calibrated sensor data (block 256, paragraph [0667]). However, it is disclosed in paragraph [0678] that the self-diagnostic module in block 256 of Figure 18 can also use other data, for example, raw data or filtered data.

Hence, the "mixed approach" referred to by the opponent is disclosed in the original application and in the parent application.

3.3 Claims 4 and 5 specify a further method step of receiving a second stream of sensor data which is then

compared with the first stream of sensor data. These claims represent a subset of claim 1, and they do not introduce any added subject-matter in claim 1.

- 3.4 Furthermore, the opponent alleged that the suspended mode and the possibility to recover from the suspended mode was only disclosed in the context of suspending the display or suspending the calibration, and that the omission of these aspects constituted an unallowable intermediate generalisation.

However, the Board does not see any functional link between the specific conditions of the suspended mode in relation to the display or the calibration and the ability of the system to self-recover. Paragraphs [0673], [0686], [0681] and [0345], referred to by the opponent, do not show to such a link, either.

- 3.5 Furthermore, the omission of the term "consecutive" from claim 1 does not constitute an unallowable intermediate generalisation since paragraph [0686] mentions the aberrant value check without any reference to consecutive sensor values.

- 3.6 The opponent further raised an objection relating to the issue of whether the sensor or the system is suspended. Since, as mentioned at point 2.7 above, the term "continuous analyte sensor" in the claim has to be understood as including the whole sensor system as explained above, this objection is moot.

- 3.7 Thus, claim 1 of the main request meets the requirements of Articles 76(1) and 123(2) EPC.

4. Main request - sufficiency of disclosure

This objection relates to the issue of what has to be understood under suspended mode of operation of the continuous analyte sensor. Since, in the Board's view, the term "continuous analyte sensor" in the claim has to be understood as including the whole sensor system as explained at point 2.7 above, this objection is moot.

Hence, the invention as defined in claim 1 of the main request is sufficiently disclosed, in compliance with Article 83 EPC.

5. Main request - novelty in view of D2

5.1 D2 relates to continuously monitoring blood glucose and discloses a method comprising the steps of receiving a stream of sensor data from a continuous analyte sensor (page 12, lines 27 to 32) and converting the sensor data into calibrated data using a conversion function (page 17, lines 7 to 14). D2 also discloses performing a test on the sensor data by comparing blood glucose readings to an out-of-range limit (page 32, lines 13 to 22). This can be regarded as a self-diagnosis test for aberrant values in sensor data.

In detail, it is mentioned that ISIG values (continuous electrical current signals generated by the glucose sensor, page 12, lines 27 to 32) are converted to blood glucose readings. If the resulting blood glucose level exceeds an out-of-range limit, an out-of-range alarm is activated (page 32, lines 13 to 18).

It is further mentioned in lines 30 to 34 on page 32 that in particular embodiments more than one ISIG value must exceed an out-of-range value before an alarm is activated. In that case, the ISIG values that are out-

of-range are not used to display a blood glucose value. The opponent considered this teaching to correspond to the suspended mode as defined in claim 1.

The Board agrees with the proprietor that not using single out-of-range ISIG values for the calculation and display of a blood glucose value cannot be considered a suspended mode of operation of the sensor system. A suspended mode rather requires a change in the operation of the system. It cannot be derived from D2 that the operation of the system is changed when an out-of-range value is received. In D2, the first out-of-range ISIG value is filtered out from the stream of data, such that an alarm is activated only after several out-of-range values have been received. Moreover, the previous and subsequent values, which are not out-of-range, are still used in the calculation of the blood glucose value. Accordingly, the display of the blood glucose values is not suspended.

- 5.2 The opponent further considered that, after an alarm had been activated, the system remained in the suspended mode of operation until it was re-calibrated, and, hence, until received sensor data was not found to be aberrant.

The Board does not agree with this view. The feature "remaining in the suspended mode of operation until received sensor data is not found to be aberrant" in claim 1 means that as soon as the received sensor data is no longer aberrant, the system returns to the normal mode of operation. Thus, claim 1 requires that the system continues testing for aberrant data also after the suspended mode has been set. Such a causality between the finding that the received sensor values are no longer aberrant and the quitting of the suspended

mode is not disclosed in D2. In D2, the system remains in the suspended (alarm) mode until a re-calibration has been performed. It is not mentioned in D2 that the self-diagnostic test is still performed after the alarm has been activated.

5.3 It follows from the above, that D2 does not disclose the feature "remaining in the suspended mode of operation until received sensor data is not found to be aberrant". Hence, the subject-matter of claim 1 does not lack novelty in view of D2 (Article 54 EPC).

6. Main request - novelty in view of D14e

6.1 D14e relates to processing of data from a continuous glucose sensor (paragraphs [0004] to [0006]). The data processing comprises receiving a stream of sensor data from a continuous analyte sensor and converting the sensor data into calibrated data using a conversion function (paragraph [0106]).

6.2 According to the opponent, paragraphs [0366], [0371] and [0374] of D14e disclosed the method step of performing a self-diagnostic test for aberrant values in sensor data.

In these paragraphs, evaluation of clinical acceptability of reference data or sensor data is mentioned. According to paragraph [0365], clinical acceptability is defined as "a deviation between time corresponding glucose measurements (e.g. data from a glucose sensor) and data from a reference glucose monitor". Reference data is data from a reference glucose monitor, which can be a finger stick test (paragraph [0335]).

6.3 The opponent further referred to paragraphs [0379] and [0381] of D14e for the disclosure of the last two method steps of claim 1 relating to the suspended mode.

These paragraphs relate to a fail-safe module which controls the user interface based upon the clinical acceptance of the reference data which is used to calibrate the sensor data. The fail-safe mode is entered if the reference data is not considered clinically acceptable, i.e. if errors in the reference analyte values are detected.

6.4 As mentioned above, reference data is data from a reference glucose monitor, and not data from the continuous analyte sensor. Thus, D14e does not disclose testing for aberrant values in sensor data (of the continuous glucose monitor), setting a suspended mode in response to identifying aberrant values in the sensor data and remaining in the suspended mode of operation until received sensor data is not found to be aberrant.

6.5 Therefore, the subject-matter of claim 1 does not lack novelty in view of D14e (Article 54 EPC).

7. It follows from the above that none of the objections put forward by the opponent precludes the maintenance of the patent on the basis of the main request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent in amended form in the following version:
 - claims 1-15 of the main request filed on 2 October 2017
 - description: paragraphs 1-288, 290-293, 295-299 and 301-336 of the patent specification, and paragraphs 289, 294 and 300 filed on 3 July 2018
 - the figures of the patent specification.

The Registrar:

The Chairman:



A. Chavinier-Tomsic

D. Ceccarelli

Decision electronically authenticated