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Datasheet for the decision of 29 February 2024

Case Number: T 1431/20 - 3.2.02

Application Number: 10195519.3

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Language of the proceedings: EN

Title of invention:
Transcutaneous analyte sensor

Patent Proprietor:
DexCom, Inc.

Opponents:
Roche Diabetes Care GmbH
Senseonics, Incorporated

Headword:

Relevant legal provisions:
EPC Art. 76(1), 123(2)
RPBA 2020 Art. 11

Keyword:
Divisional application - subject-matter extends beyond content of earlier application (no)
Amendments - extension beyond the content of the application as filed (no)
Remittal to the department of first instance - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

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Case Number: T 1431/20 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 29 February 2024

Appellant: (Patent Proprietor)	DexCom, Inc. 6340 Sequence Drive San Diego CA 92121 (US)
Representative:	Hill, Justin John Dentons UKMEA LLP One Fleet Place London EC4M 7WS (GB)
Respondent: (Opponent 1)	Roche Diabetes Care GmbH Sandhofer Strasse 116 68305 Mannheim (DE)
Representative:	Peterreins Schley Patent- und Rechtsanwälte PartG mbB Hermann-Sack-Straße 3 80331 München (DE)
Respondent: (Opponent 2)	Senseonics, Incorporated 20451 Seneca Meadows Parkway Germantown, MD 20876 (US)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 30 January 2020 revoking European patent No. 2335584 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The patent proprietor filed an appeal against the decision of the opposition division to revoke the patent.

II. Oral proceedings before the Board took place on 29 February 2024.

III. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted.

Respondents 1 and 2 (opponents 1 and 2) requested that the appeal be dismissed.

IV. The following document is referred to in this decision:

D1e WO 2006/017358 A1, parent application as published

V. 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; and setting in response to the result of the self-diagnostic test a mode of operation of the continuous analyte sensor, the setting a mode of operation comprising setting a mode selected from the group consisting of a start-up mode, the start-up mode

comprising determining a new conversion function, a normal mode, the normal mode comprising continuously converting and displaying sensor data, and a suspended mode,
the suspended mode comprising suspending the continuous conversion or the display of sensor data."

VI. The arguments of respondent 1 may be summarized as follows:

Main request - claim 1 - added subject-matter

Paragraphs [0330] to [0345] of D1e did not provide a clear and unambiguous disclosure for granted claim 1. The combination of features of claim 1 resulted in a non-disclosed technical teaching, because the selection of a certain mode (start-up mode, normal mode and suspended mode) was not originally disclosed "in response to the result of the self-diagnostic test" (i.e. in response to a single result of a single self-diagnostic test).

Claim 1 combined the features of paragraphs [0330], [0336], [0338], [0339], [0341], [0342], [0344] and [0345]. The claimed combination was a result of cherry-picking some of the features disclosed in paragraphs [0330] to [0345], while others, i.e. the features of paragraphs [0331] to [0335], [0337], [0340] and [0343], were not selected. This particular combination could not be derived directly and unambiguously from the parent application as filed.

Paragraphs [0330] and [0336] did not disclose that the mode of operation was set in response to the result of the self-diagnostic test. Furthermore, the detailed description at paragraphs [0663] to [0686] and Figures

18 and 19 did not disclose that the start-up mode and the normal mode were set in response to the result of the self-diagnostic test, but based on other criteria.

Moreover, according to claim 1 all transitions from one specific mode to one of the other two modes were possible in response to a single test result of a single self-diagnostic test based on the sensor data or calibrated data. However, not all transitions from one specific mode to either one of the other two modes were originally disclosed. For instance, the transition from the start-up mode to the suspended mode was not disclosed at all in paragraphs [0680] to [0686].

Furthermore, the feature that a new conversion function was determined during the start-up mode was not originally disclosed. Paragraph [0339] only generally mentioned that "a conversion function" was determined, but not necessarily a new conversion function.

Hence, claim 1 included subject-matter extending beyond the content of the parent application as filed, contrary to the requirements of Article 76(1) EPC.

Main request - dependent claims - added subject-matter

The features of granted claims 2 to 6 had only been disclosed in context with a transition from the normal mode to the suspended mode, but not in context with a change from the suspended mode to the normal mode, and neither in context with a change from the start-up mode to the normal mode.

According to claim 1, a start-up mode of operation could be set "in response to the result of the self-diagnostic test", whereas according to claim 7 a start-

up mode of operation could be set "in response to a sensor initialization". These two different procedures were not disclosed in combination.

Claim 8 defined setting the normal mode after having determined a new conversion function during the start-up mode. This was in contradiction to a change from the start-up mode to the normal mode "in response to the result of the self-diagnostic test on the sensor data or the calibrated data". Furthermore, claim 8 referred to "the new conversion function". This link to the new conversion function mentioned in claim 1 was not disclosed in the parent application.

The features of granted claims 9 to 12 were only disclosed in context with the embodiment of Figure 19, but not in context with the feature combination of granted claim 1 which was in contradiction to the embodiment of Figure 19. In particular, the features of granted claims 9 to 12 were not disclosed in paragraphs [0330] to [0345].

Hence, all dependent claims included added subject-matter.

VII. The arguments of respondent 2 may be summarized as follows:

Main request - claim 1 - added subject-matter

Paragraphs [0330]-[0345] did not relate all to "the same" embodiment. Due to the use of the indefinite article "a" or "an", the wording of the paragraphs rather suggested that they were to be taken independently of one another. Hence, the combination of the features of paragraphs [0330], [0336], [0338],

[0339], [0341], [0342], [0344] and [0345] in claim 1 was an arbitrary selection of seven out of fifteen paragraphs.

On the other hand, if paragraphs [0330]-[0345] related to one single embodiment, the failure to include the features of paragraphs [0331]-[0335], [0340] and [0343] in the claim amounted to an unallowable intermediate generalization.

Paragraphs [0615], [0653] to [0655], [0673], [0675], [0678], [0680] to [0682] and [0685] did not disclose the claimed combination either. In particular, the selection of one mode out of three, in response to the result of the (single) self-diagnostic test was not disclosed. Such a selection could not be derived from Figure 19 either. Fig. 19 disclosed a mode being set after a self-diagnostic test, but it did not directly and unambiguously disclose a mode being set in response to the result of a self-diagnostic test.

Moreover, claim 1 encompassed all possible transitions between the modes. However, in the description of the parent application there was, for instance, no disclosure of selecting the start-up mode at a time when the system was already in the start-up mode. Hence, claim 1 encompassed undisclosed transitions from one mode to another.

Paragraph [0339] disclosed a start-up mode that comprised determining a conversion function, but the limitation to it being a "new" conversion function was absent.

Consequently, claim 1 did not meet the requirements of Article 76(1) EPC.

Main request - dependent claims - added subject-matter

Claim 3 recited evaluating "a rate of rate of change" of the calibrated data or sensor data, whereas paragraph [0332], on which this amendment should be based, disclosed evaluating "a rate of acceleration" of the data. Acceleration was a second derivative with respect to time, while claim 3 encompassed a second derivative with respect to any variable. Hence, claim 3 constituted an undisclosed generalization.

Claims 9 to 12 were said to be based on paragraphs [0667] and [0671], along with Fig. 18. However, these paragraphs included additional features which were not claimed, resulting in an unallowable intermediate generalization. Furthermore, claim 11 did not correctly reflect the disclosure of paragraph [0673].

Hence, claims 3 and 9 to 12 included added subject-matter, contrary to Articles 76 and 123(2) EPC.

VIII. The arguments of the appellant may be summarized as follows:

Main request - claim 1 - added subject-matter

Paragraphs [0330], [0336], [0338], [0339], [0341], [0342], [0344] and [0345] of the parent application could be considered an ample basis for claim 1. All these paragraphs related to the thirty-seventh aspect and were not mutually exclusive.

The step of setting a mode of operation from a group consisting of a start-up mode, a normal mode and a suspended mode was literally disclosed in paragraph

[0336] which was dependent on paragraph [0330]. The person skilled in the art would inherently derive from paragraph [0330] that the mode of operation was set in response to the self-diagnostic test. Paragraphs [0338], [0341] and [0344] supported this, while paragraphs [0339], [0342] and [0345] related to details of each of the possible modes. Hence, the claimed combination of features was not an arbitrary selection among a large number of possible combinations.

Furthermore, Figure 19 and the corresponding paragraphs [0675] to [0682] also disclosed that the mode of operation was set in response to the selected self-diagnostic test. This was made clear by the arrow in Figure 19 pointing from the self-diagnosis test to setting the mode of operation. Paragraph [0680] related to the three modes, which were further exemplified in paragraphs [0681], [0682] and [0686].

On reading paragraph [0336], the person skilled in the art would have appreciated that each of the modes inherently had to be available to be set in response to the result of the self-diagnostic test. It was technically meaningless that only one mode of operation was available in response to the result of the self-diagnostic test.

Furthermore, the wording of claim 1 did not imply that all possible transitions were possible between the three different modes. Hence, it was not necessary that the parent application disclosed every possible transition from one mode to another.

As to the term "new conversion function", the parent application provided numerous references to the conversion function being recalculated or reinitialised

(e.g. paragraphs [0681] and [0653] to [0655]). Hence, this expression was directly and unambiguously disclosed in the parent application as filed.

Hence, claim 1 did not contravene the requirements of Article 76(1) EPC.

Main request - dependent claims - added subject-matter

Support for the features of claims 2 to 8 could be found at paragraphs [0331], [0332], [0333], [0334], [0335], [0337] and [0340].

The amendment from "rate of acceleration" as per the terminology of paragraph [0332] of the parent application as filed to "rate of rate of change" of granted claim 3 had been made to address a clarity objection raised by the examining division.

Paragraph [0681] of the parent application as filed directly and unambiguously disclosed the start-up mode being set in response to a result of the self-diagnostic test, as defined in claim 1, and/or as a result of sensor initialization, as defined in claim 7. Paragraph [0681] of the parent application as filed also disclosed setting the normal mode after having determined a new conversion function. There was no contradiction with claim 1 requiring that the normal mode was set in response to the self-diagnostic test.

Support for the features of claims 9 to 12 could be found at paragraphs [0667], [0671], [0673] and [0672] and Figure 18 of the parent application as filed.

Hence, the dependent claims also met the requirements

of Article 76(1) EPC.

Reasons for the Decision

1. Subject-matter of the patent

The present patent relates to a sensor system, for instance for transcutaneous measurement of glucose in a host.

The sensor system may comprise 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 may have an electronics unit 16 with a processor providing programming to process data streams.

The claims of the patent relate to a method for self-diagnosis of a continuous analyte sensor to determine accuracy, reliability and/or clinical acceptability of the sensor data (paragraphs [0284] to [0300] and [0306] to [0307] and Figures 18 and 19 of the patent). In particular, claim 1 as granted relates to a method comprising (in essence)

- receiving a stream of sensor data from the sensor,

- converting the sensor data into calibrated data using a conversion function

- performing a self-diagnostic test on the sensor data or the calibrated data, and

- setting in response to the result of the self-diagnostic test a mode of operation of the continuous analyte sensor, setting a mode of operation comprising

setting a mode selected from the group consisting of
- a start-up mode, the start-up mode comprising determining a new conversion function,
- a normal mode, the normal mode comprising continuously converting and displaying sensor data, and
- a suspended mode, the suspended mode comprising suspending the continuous conversion or the display of sensor data.

2. Main request - claim 1 - added subject-matter

2.1 The application is a divisional application of European patent application 05771643.3, published as WO 2006/017358 A1 under the PCT (D1e). The description of the parent application and the present application as originally filed are identical.

2.2 The Board agrees with the appellant that paragraphs [0330], [0336], [0338], [0339], [0341], [0342], [0344] and [0345] of the parent application D1e provide direct and unambiguous support for claim 1. In particular, the person skilled in the art would directly and unambiguously derive from paragraph [0330] that the step of setting a mode of operation of the continuous analyte sensor is performed in response to a result of the self-diagnostic test. Paragraph [0336] referring back to the setting of a mode of operation recited in paragraph [0330] discloses the three available modes one of which is selected according to the test result. Paragraphs [0338], [0341] and [0344] support what the person skilled in the art already derives from paragraph [0330], namely, that the respective mode is set in response to the result of the self-diagnostic test. In addition, paragraphs [0339], [0342] and [0345] relate to details of each of the possible modes. Hence, the claimed combination of features is not an arbitrary

selection among a large number of possible combinations. It was rather the result of a logical limitation of the disclosure of paragraph [0330] in view of further defining the modes of operation in the subsequent paragraphs.

2.3 Furthermore, Figure 19 and the corresponding paragraphs [0675] to [0686] of D1e also disclose that the mode of operation is set in response to the selected self-diagnostic test. At paragraph [0678], block 286 of the flow chart of Figure 19, i.e. the operation of the self-diagnostics module, is described. From this block an arrow is drawn towards block 288, relating to the mode determination module described at paragraph [0680]. Hence, it is clear that the mode is set in response to the result of the self-diagnostic test. Finally, paragraphs [0681], [0682] and [0686] explicitly disclose that the start-up mode, the normal mode and the suspended mode are set in response to a result of the self-diagnostic test.

2.4 As to the objection that not all the possible transitions between the three different modes were disclosed in the parent application, the Board considers that claim 1 does not disclose that all transitions between the modes must be possible. Claim 1 merely defines that a self-diagnostic test is performed and that, in response to the result of this test, a mode of operation is set. Hence, for different tests different modes, selected from the group of three modes, can be set. As mentioned at paragraph [0680], the setting of a mode of operation includes that the sensor remains in the mode in which it previously was.

2.5 Both respondents argued that the term "new conversion function" was not disclosed in the application as

originally filed. However, in the Board's view, the expression "a conversion function" used in paragraph [0339] encompasses both the first conversion function (which is determined upon initialisation of the sensor system) and a new conversion function (which is determined after a re-calibration).

Furthermore, the Board agrees with the appellant that the description includes ample references to re-calculation of the conversion function in the start-up mode. This re-calculated conversion function is the new conversion function according to the claim wording.

2.6 Therefore, claim 1 does not extend beyond the content of the parent application as filed. The requirements of Articles 76(1) and 123(2) EPC are met.

3. Main request - dependent claims - added subject-matter

3.1 The Board agrees with the appellant that support for claims 2 to 8 can be found in paragraphs [0331] to [0335], [0337] and [0340], respectively. As mentioned above, claim 1 does not require that every possible transition from one mode to another must be possible. Hence, the fact that the self-diagnostic tests specified in claims 2 to 6 were disclosed in context with a transition from the normal mode to the suspended mode, does not add subject-matter.

3.2 The replacement of the term "rate of acceleration" with "rate of rate of change" in claim 3 does not add subject-matter since it is clear, in context, that "rate of change" is a derivative with respect to time. Hence, "rate of rate of change" can be considered equivalent to "rate of acceleration".

3.3 Dependent claim 7 does not require that the start-up mode can exclusively be set in response to a sensor initialisation. It merely specifies a further criterion for setting the start-up mode. This is in accordance with paragraph [0681] of D1e stating that the start-up mode is set in response to the self-diagnostic test and/or in response to a sensor initialisation.

3.4 Likewise, claim 8 does not require that the normal mode is only set after a new conversion function has been determined, but specifies a criterion for setting the normal mode, in addition to being set in response to a self-diagnostic test. It is noted that claim 1 does not require that the normal mode is set when the system was in the start-up mode before. There is therefore no contradiction between claims 1 and 8.

The use of the definite article "the" in connection with the conversion function in claim 8 instead of "a" as in paragraph [0340] of the parent application does not result in a contradiction between claims 1 and 8 either. The (new) conversion function is already defined in claim 1.

3.5 Claims 9 to 12 are based on paragraphs [0667] and [0671] to [0673], as put forward by the appellant. The Board does not see any contradiction between the feature combination of claim 1 and the embodiment of Figure 19, to which these paragraphs refer. Furthermore, the Board does not agree with respondent 2 that the feature combination of claims 9 to 12 constitutes an unallowable intermediate generalisation, since the additional features mentioned in paragraphs [0667] and [0671] to [0673] are presented as optional. The wording of claim 11 is equivalent to the

corresponding wording in paragraph [0673].

3.6 Hence, the dependent claims of the patent as granted do not include added subject-matter.

4. It follows from the above considerations that the ground for opposition under Article 100(c) EPC does not prejudice the maintenance of the patent as granted.

5. Remittal to the department of first instance

5.1 During opposition proceedings, both respondents had raised further objections as to insufficiency of disclosure, lack of novelty and lack of inventive step, none of which had been considered in the impugned decision. Hence, in respect of these issues, there is no decision to be reviewed.

5.2 In view of the primary object of the appeal proceedings to review the decision under appeal in a judicial manner (Article 12(2) RPBA), there are special reasons within the meaning of Article 11 RPBA for remitting the case to the opposition division for further prosecution under Article 111(1) EPC.

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 for further prosecution.

The Registrar: The Chairman:

A. Chavinier-Tomsic D. Ceccarelli

Decision electronically authenticated