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Datasheet for the decision
of 20 February 2024

Case Number: T 0948/19 - 3.2.02

Application Number: 12193934.2

Publication Number: 2561807

IPC: A61B5/145, A61B5/1495,
A61B5/1486, A61B5/1473,
A61B5/1468

Language of the proceedings: EN

Title of invention:
Methods for processing analyte sensor data for sensor calibration

Patent Proprietor:
DexCom, Inc.

Opponents:
Abbott Diabetes Care Inc.
Roche Diabetes Care GmbH

Headword:

Relevant legal provisions:
EPC Art. 54
RPBA Art. 11

Keyword:
Novelty - main request (no) - auxiliary request (yes)
Remittal to the department of first instance - (yes)

Decisions cited:

Catchword:
In a last-instance decision, when a request is not allowed on other grounds it is normally superfluous to address further objections raised against that same request that were found unconvincing after having been discussed at oral proceedings. However, the situation is different for a decision of an opposition division, which may be the subject of an appeal. In this case, if the Board is not convinced by the reasons the opposition division gave in support of precluding the maintenance of the patent on the basis of a certain request, the lack of a decision to review in respect of the aforementioned further objections may result in a remittal for the consideration of said further objections, resulting in a delay in the proceedings (point 7 of the Reasons).

Case Number: **T 0948/19 - 3.2.02**

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 20 February 2024

Appellant: (Patent Proprietor)	DexCom, Inc. 5555 Oberlin Drive San Diego, California 92121 (US)
Representative:	Hill, Justin John Dentons UKMEA LLP One Fleet Place London EC4M 7WS (GB)
Respondent: (Opponent 1)	Abbott Diabetes Care Inc. 1360 South Loop Road Alameda, CA 94502 (US)
Representative:	Boult Wade Tennant LLP Salisbury Square House 8 Salisbury Square London EC4Y 8AP (GB)
Respondent: (Opponent 2)	Roche Diabetes Care GmbH Sandhofer Strasse 116 68305 Mannheim (DE)
Representative:	Altmann Stößel Dick Patentanwälte PartG mbB Theodor-Heuss-Anlage 2 68165 Mannheim (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 31 January 2019 revoking European patent No. 2561807 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Böttcher
	C. Schmidt

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
        20 February 2024.

III.   The appellant (patent proprietor) requested that the
        decision under appeal be set aside and that the patent
        be maintained as granted (main request), on the basis
        of auxiliary request 2, or on the basis of any of main
        request A, auxiliary request 1, auxiliary request 1A,
        auxiliary request 2A, auxiliary request 3, auxiliary
        request 4, auxiliary request 3A, auxiliary request 4A,
        as filed with the statement of grounds of appeal dated
        10 June 2019.

        The respondents (opponent 1 and opponent 2) requested
        that the appeal be dismissed.

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

        "A method of calibrating a continuous glucose sensor in
        a sensor system comprising the continuous glucose
        sensor, comprising:

        receiving sensor data from the continuous glucose
        sensor implanted in a host;

        providing prior distribution information;

        the sensor system using the prior distribution
        information to select a slope and/or baseline;

and

using the selected slope and/or baseline in calibrating
the sensor data;

wherein the prior distribution information is
information obtained prior to sensor insertion for
selecting the baseline and/or the slope, wherein the
prior distribution information comprises a distribution
of slopes and/or baselines."

V.   Claim 1 of auxiliary request 2 reads as follows:

"A method of calibrating a continuous glucose sensor in
a sensor system comprising the continuous glucose
sensor, comprising:

receiving sensor data from the continuous glucose
sensor implanted in a host;

providing prior distribution information;

the sensor system using the prior distribution
information to select a slope and baseline;

and

using the selected slope and baseline in calibrating
the sensor data;

wherein the prior distribution information is
information obtained prior to sensor insertion

for selecting the baseline and the slope, wherein the
prior distribution information comprises a distribution

of slopes and baselines,

wherein both the baseline and the slope are selected based on the prior distribution information in that, of multiple possible calibration lines, the calibration line is selected that has the slope and the baseline closest to the maximum joint probability of both the slope and the baseline distributions."

VI.   The following documents are referred to in this decision:

       D1   US 2002/0043651
       D9   WO 00/49941

VII.   The arguments of the appellant can be summarised as follows:

       Interpretation of the term "prior distribution information"

       The person skilled in the art would consider the ordinary meaning of the term "prior distribution information" to apply. By specifying that "for example a distribution of slopes and/or baselines typically obtained may be determined (or estimated) from retrospective analysis of a sample set of implanted sensors" (paragraph [0350]), the patent made it clear that the term "distribution" had a probabilistic nature.

       Furthermore, the term "prior distribution information" was a term of art within the field of Bayesian statistics, and it implicitly involved a probabilistic element.

Hence, it was clear from the patent and from the common general knowledge of the person skilled in the art that the term "distribution information" meant more than "providing a set of values".

Main request – novelty in view of D9

D9 failed to disclose the provision of "prior distribution information". Accordingly, D9 did not disclose that "the sensor system uses the prior distribution information to select a slope and/or baseline... wherein the prior distribution information is information obtained prior to sensor insertion for selecting the baseline and/or slope, wherein the prior distribution information comprises a distribution of slopes and/or baselines".

The three offset values mentioned on page 22 of D9 did not involve any probabilistic element as was required by the term "prior distribution information". They merely set rules as to the conditions under which a sensor had to be adjusted. Therefore, the set of values could not be regarded as a distribution of baselines.

Furthermore, D9 did not disclose the selection of a baseline. Rather, the offset values were subtracted from the sensor data to calculate the sensitivity.

Hence, the subject-matter of claim 1 of the main request was novel in view of D9.

Main request – novelty in view of D1

D1 related to in vitro polyhydroxylate sensor calibration by calibrating the sensor versus concentration of glucose (paragraph [0150]). There was

no disclosure that the calibration was performed while the sensor was implanted in a host.

Furthermore, the calibration curves determined in paragraphs [0150] to [0152] did not include any probabilistic element and could not be regarded as including prior distribution information.

Hence, D1 did not consider "prior distribution information" wherein the "prior distribution information is obtained prior to sensor insertion for selecting the baseline and/or the slope" and "comprises a distribution of slopes and/or baselines".

Hence, the subject-matter of claim 1 of the main request was novel in view of D1.

Auxiliary request 2 - *novelty in view of D9*

D9 did not disclose a distribution of slopes and baselines. It did not disclose the selection of a calibration line from multiple calibration lines either.

Hence, the subject-matter of claim 1 of auxiliary request 2 was novel in view of D9.

Auxiliary request 2 - *novelty in view of D1*

D1 taught in vitro polyhydroxylate sensor calibration by calibrating the sensor versus concentration of glucose (paragraph [0150]).

According to the last clause in paragraph [0150], the slope and offset were calculated for the best-fit curves. In this regard, linear regression might be

employed to result in the best slope and baseline. However, D1 did not disclose that a joint probability of both slope and baseline was calculated and taken into account for selecting a calibration line from multiple calibration lines.

Hence, D1 did not disclose that "the calibration line is selected that has the slope and the baseline closest to the maximum joint probability of both the slope and baselines distributions".

Therefore, the subject-matter of claim 1 of auxiliary request 2 was novel in view of D1.

VIII. The arguments of respondent 1 can be summarised as follows:

Interpretation of the term "prior distribution information"

Claim 1 had a very broad scope since it did not define how the prior distribution information was used to select the slope and/or baseline.

The term "prior" simply meant prior to sensor insertion. Hence, "prior distribution information" could be any distributed information provided prior to sensor insertion.

The claim made no reference to the distribution information having a probabilistic nature. In fact, this appeared to be an optional feature since it was referred to only in the dependent claims. Furthermore, the examples mentioned in paragraphs [0350] to [0352] of the description could not be used to limit the scope of the claim.

Main request – novelty in view of D9

D9 disclosed a method of calibrating a continuous glucose sensor, comprising the step of providing prior distribution information, the distribution information being the threshold values 4 and 7 and the offset values 0, 3 and 5 (page 20, line 19, to page 22, line 10). The offset values were used in calculating the SPSR curves (Figure 12), i.e. the distribution information was used to select a slope and/or baseline. The offset values and threshold values were obtained prior to the implantation of the sensor (page 21, line 28, to page 22, line 10).

The claim was not limited to the examples of distribution information given in paragraphs [0350] to [0352] of the patent; rather, it required any distributed information provided prior to sensor insertion.

Therefore, the subject-matter of claim 1 was not novel over D9.

Main request – novelty in view of D1

D1 disclosed a method of calibrating a continuous glucose sensor in a sensor system comprising the provision of prior distribution information (paragraphs [0150] to [0152], and [0232]). The calibration curves mentioned in paragraph [0232], which contained known relationships between a sensor signal and the concentration of polyhydroxylate analyte, and the environmental information also given therein could be regarded as the prior distribution information. The sensor system used the prior distribution information

to select a slope and/or baseline, as disclosed in
paragraphs [0232] to [0234]. Evidently, the selected
slope and/or baseline was used in calibrating the
sensor data (paragraph [0232]).
It was clear from the term "known relationships" that
the prior distribution information was information
obtained prior to sensor insertion for selecting the
baseline and/or the slope. The ten curves mentioned in
paragraph [0151] formed a distribution of slopes and/or
baselines.

D1 explicitly disclosed the calibration of a continuous
glucose sensor implanted in a host (paragraphs [0013],
[0014], [0075], [0084], [0171] and [0178]).

Therefore, D1 deprived the subject-matter of claim 1 of
the main request of novelty.

Auxiliary request 2 - *novelty in view of D1*

D1 disclosed selecting both the slope and the offset
that would provide the best-fit curve
(paragraph [0150], last sentence). This was inherently
the same as selecting the slope and baseline closest to
the maximum joint probability. Both were selecting the
calibration line (or slope) that had the best fit based
on the two inputs. In that respect, it did not matter
whether the slope and baseline were selected
independently or jointly. Therefore, D1 disclosed all
of the features of claim 1 of auxiliary request 2.

The use of the plural,"curves", in paragraph [0150]
indicated that one curve was selected for each sensor.

Hence, the subject-matter of claim 1 of auxiliary

request 2 lacked novelty in view of D1.

IX.   The arguments of respondent 2 can be summarised as
        follows:

Interpretation of claim 1

The skilled person would understand the term
"distribution" as a range of values of a parameter. It
was not permissible to define a minimum number of
values or certain statistical properties as implicit
features of the term "distribution" since such a
definition would be arbitrary and not in line with the
common understanding in the technical field of the
patent.

The term "prior distribution information" had to be
interpreted broadly and the way in which the prior
distribution information was generated was left
completely open by the claim.

Claim 1 also left open how the baseline was selected
from the prior distribution information comprising the
distribution of slopes and baselines. In particular,
the feature of claim 1 "using the prior distribution
information to select a slope and/or baseline" referred
to the usage of prior distribution information directly
or non-directly, for example including further
intermediate steps.

Main request – novelty in view of D9

D9 described that the single point sensitivity ratio
(SPSR), i.e. the slope of a calibration line, was
determined using a single paired calibration point
(page 19, last paragraph). When the SPSR was less than

a sensitivity threshold value, an offset value was used
to calculate a modified SPSR (page 20, lines 25 to 31).
Further, it was mentioned that the threshold values and
the associated offsets had been empirically selected
based on the characteristics observed from testing a
particular type of glucose sensors (page 21, line 28,
to page 22, line 10). Thus, prior to insertion of the
sensor, a distribution of offset values was determined
and threshold values were derived. The threshold values
provided were then used to select a corresponding
baseline (offset value). Hence, D9 described selecting
a baseline from prior distribution information.

Furthermore, as described on page 21, lines 1 to 15, of
D9, the determined MSPSR (comprising the selected
offset) was used for calibrating the sensor data
(ValidISG).

Thus, D9 disclosed all of the features of claim 1.
Consequently, the subject-matter of claim 1 of the main
request was not novel in view of D9.

Main request - novelty in view of D1

As outlined in paragraphs [0231] and [0232] of D1, the
calibration lines determined according to the method
described in paragraph [0150] were used for calibrating
the received sensor data ("calibration curves with
known relationships for correlating detector signal
with the concentration", "…software may contain
calibration curves which contain known relationships
between a particular detected emission signal and the
concentration…"). Accordingly, the distribution of
slopes and offsets was used to select the slope and
baseline for the calibration. Thus, document D1
disclosed the provision of prior distribution

information comprising a "distribution of slopes and
baseline" and that this distribution was used for the
selection of a slope and/or baseline.

Therefore, the subject-matter of claim 1 of the main
request lacked novelty in view of D1.

Auxiliary request 2 - *novelty in view of D9*

D9 also disclosed a distribution of slopes, namely the
SPSR values, from which the thresholds for the
selection of the offset values were determined.

D9 further described the modified linear regression
sensitivity ratio (MLRSR) in the paragraphs on pages 22
and 23. A linear regression inherently resulted in the
maximum joint probability of both the slope and the
baseline distributions. As the skilled person knew,
linear regression could be considered a joint
probability model with specific assumptions.

In addition, D9 described using the prior distribution
information to select a slope. D9 described (page 25,
lines 22 to 25, and page 26, lines 16 to 20) that a
calibration factor was determined for each paired
calibration data point and, thus, a distribution of
slopes was provided. One slope was selected by
averaging.

Thus, the subject-matter of claim 1 of auxiliary
request 2 was not novel in view of D9.

Auxiliary request 2 - *novelty in view of D1*

D1 disclosed in paragraph [0150] that "data for all
calibration runs are compared; the slope and offset

calculated for the best-fit curves". The proposed
fitting implicitly resulted in the selection of the
slope and baseline closest to the maximum joint
probability.

Hence, the subject-matter of claim 1 of auxiliary
request 2 lacked novelty over D1.

Reasons for the Decision

1.   Subject-matter of the patent

The patent refers to a method of calibrating a
continuous glucose sensor in a sensor system comprising
said continuous glucose sensor. Specifically, the
method should avoid or reduce dependence on using the
finger prick method during calibration
(paragraph [0005] of the patent). The method comprises
- receiving sensor data from the continuous glucose
sensor implanted in a host;
- providing prior distribution information;
- the sensor system using the prior distribution
information to select a slope and/or baseline; and
- using the selected slope and/or baseline in
calibrating the sensor data.

The prior distribution information is information
obtained prior to sensor insertion for selecting the
baseline and/or the slope, wherein the prior
distribution information comprises a distribution of
slopes and/or baselines.

The prior distribution information is used to select
the slope m and the baseline b.

2.   Interpretation of the term "prior distribution
          information"

          The Board notes that it is not clear from the claim
          itself what is meant by prior distribution information,
          nor is it clear how this information is used to select
          the slope or baseline.

          In the description of the patent, only one specific
          kind of "prior distribution information" is mentioned,
          namely information concerning a distribution of slopes
          and/or baselines determined (or estimated) on the basis
          of a retrospective analysis of a sample set of
          implanted sensors (paragraph [0350]). However, this is
          referred to in the description as an example of
          distribution information, and the claim is not limited
          to this example. The Board therefore agrees with
          respondent 1 that prior distribution information could
          be any distributed information provided prior to sensor
          insertion. Hence, in accordance with paragraph [0353],
          third sentence, of the patent, distribution information
          can be interpreted as information relating to the
          distribution of possible values for a variable, and how
          often they occur. The Board considers this to be the
          distribution information used in the embodiment of
          paragraph [0352], first sentence, of the patent.

          The Board acknowledges that in Bayesian statistics the
          term prior (probability) distribution is a term of art.
          However, the patent, which refers to prior distribution
          information, does not include any reference to Bayesian
          statistics, and it cannot be derived from the patent
          that the term prior distribution information
          encompasses a probabilistic element in the distribution
          of values.

Furthermore, claim 1 does not refer to any criteria for selecting a slope and/or baseline. In any case, claim 1 does not require that the most probable slope or baseline is selected.

3.   Main request - novelty in view of D9

D9 relates to calibration methods for an implanted glucose monitor (page 19, line 17, to page 24, line 20, and Figures 13 and 14).

It is mentioned on page 19, line 24, to page 22, line 10, that a single point sensitivity ratio (SPSR) is determined using a single paired calibration point. This SPSR value can be regarded as the slope of the calibration line. It is further described that this SPSR can be modified to compensate for a less linear performance of sensors having high sensitivity. To calculate the modified SPSR (MSPSR), a distribution of offset values (namely the values 0, 3 and 5) is provided, one of which is selected. These offset values relate to the baseline of the calibration line (page 21, lines 4 to 6). Which offset value is selected, and as a consequence which baseline is selected, depends on an associated threshold value for the single point sensitivity ratio as specified on page 22, lines 5 to 10. The distribution of offset values is obtained empirically by prior testing of a particular type of glucose sensors (page 21, lines 28 to 30). It is therefore obtained prior to sensor insertion. The selected baseline value is then used in calibrating the sensor data (page 21, lines 4 to 6).

Hence, according to the above interpretation of claim 1, D9 discloses the use of prior distribution information (i.e. the threshold associated with a

particular offset value) for selecting a baseline and the use of the selected baseline in calibrating the sensor data.

Consequently, the subject-matter of claim 1 of the main request lacks novelty in view of D9.

4. Main request - novelty in view of D1

D1 discloses the calibration of implantable glucose sensors. In paragraphs [0231] and [0232], D1 describes a correlator for translating the detected sensor signal into a concentration for the polyhydroxylate analyte. It is mentioned that the software of the correlator contains calibration curves, i.e. sets of slopes and baselines, which contain known relationships between a particular detected signal and the concentration of polyhydroxylate analyte. These calibration curves are determined according to the calibration methods described in paragraphs [0150] to [0152]. Hence, they constitute a distribution of slopes and baselines obtained prior to sensor insertion. It is inherent that the correlator selects one of these calibration curves to translate the detected signal into a concentration for the polyhydroxylate analyte, and that some information related to the distribution of calibration curves has to be used to select one calibration curve. Thus, D1 implicitly discloses that the prior distribution information (which can be any information related to the distribution of calibration curves) is used to select a slope and baseline.

The Board does not agree with the appellant that D1 only discloses in vitro calibration. The steps of receiving the sensor data and correlating it with an analyte concentration are described in

paragraphs [0231] to [0232] in connection with an
implanted glucose monitoring system as referred to in
paragraphs [0013], [0014], [0075], [0084], [0171] and
[0178]. In D1, merely the step of providing prior
distribution information, i.e. the determination of the
set of calibration curves, is done in vitro. Hence, the
prior distribution information is obtained prior to
sensor insertion, while the calibration of the sensor
data is performed after sensor insertion, as required
by the claim.

Hence, the subject-matter of claim 1 of the main
request lacks novelty in view of D1.

5.   Auxiliary request 2 - novelty in view of D9

As mentioned above, D9 discloses prior distribution
information comprising a distribution of baselines. For
one slope (SPSR) the appropriate baseline (offset
value) is selected from the distribution of baselines
according to the threshold conditions presented on
page 22, lines 8 to 10. However, D9 does not disclose a
distribution of slopes and baselines. Furthermore, D9
does not disclose the selection of a calibration line
from multiple calibration lines, as required by claim 1
of auxiliary request 2.

The Board does not agree with respondent 2 that the
linear regression described on pages 22 and 23 and in
Figure 15 of D9 results in the maximum joint
probability of both the slope and the baseline
distributions. Rather, in D9 linear regression is used
to calculate the best-fit straight line correlated with
multiple paired calibration data points. Hence, the
linear regression results in one best-fit calibration
line, but not in multiple calibration lines from which

the one closest to the maximum joint probability is
selected.

Respondent 2 further referred to the averaging of the
MSPSR values mentioned on page 25, lines 22 to 25.
However, determining an average MSPSR value is not the
same as selecting from multiple calibration lines the
one closest to the maximum joint probability.

Hence, the subject-matter of claim 1 of auxiliary
request 2 is novel in view of D9.

6.   Auxiliary request 2 - novelty in view of D1

D1 discloses in paragraph [0232] that multiple
calibration curves are provided from which (inherently)
one is selected to calibrate the detected signal data.
Hence, D1 discloses a distribution of slopes and
baselines obtained prior to sensor insertion. However,
D1 does not disclose the criteria according to which
this selection is performed. Hence, D1 does not
disclose that the calibration line selected from of
multiple possible calibration lines is the one that has
the slope and the baseline closest to the maximum joint
probability of both the slope and the baseline.

The respondents considered the best-fit curves
mentioned in paragraph [0150] of D1 to represent the
curve with the maximum joint probability. According to
respondent 1, the use of the plural, "curves",
indicated that one curve for each sensor was provided.

The Board does not agree with the respondents' view.
Paragraph [0150] describes how the calibration curve of
one individual sensor is obtained, namely by
calculating the slope and baseline of the line that

fits best through a plurality of calibration data pairs. However, paragraph [0150] does not relate to the selection of one calibration line from the multiple calibration lines provided by the software of the correlator as mentioned in paragraph [0232].

Hence, the subject-matter of claim 1 of auxiliary request 2 is novel in view of D1.

7.   Remittal to the department of first instance

During the opposition proceedings, both respondents raised further objections as to a lack of novelty, added subject-matter, insufficiency of disclosure and a lack of inventive step, none of which had been considered in the decision of the opposition division. In respect of these issues, including those that were discussed at the oral proceedings such as added subject-matter and sufficiency of disclosure, there is no decision to be reviewed. It is true that during the oral proceedings the opposition division considered objections of added subject-matter and sufficiency of disclosure against the main request, coming to the conclusion that none of these objections, which would also have applied to the auxiliary requests, was convincing (pages 2 and 3 of the minutes). However, neither these findings nor the reasons underlying them are present in the decision under appeal.

In view of the primary object of the appeal proceedings being to review the decision under appeal in a judicial manner (Article 12(2) RPBA 2020), the Board is therefore of the opinion that the absence of reasoning regarding these other objections represents a special reason within the meaning of Article 11 RPBA 2020 for remitting the case to the opposition division for

further prosecution under Article 111(1) EPC. In this
context, the following should be noted:

In a last-instance decision, when a request is not
allowed on other grounds it is normally superfluous to
address further objections raised against that same
request that were found unconvincing after having been
discussed at oral proceedings. However, the situation
is different for a decision of an opposition division,
which may be the subject of an appeal. In this case, if
the Board is not convinced by the reasons the
opposition division gave in support of precluding the
maintenance of the patent on the basis of a certain
request, the lack of a decision to review in respect of
the aforementioned further objections may result in a
remittal for the consideration of said further
objections, resulting in a delay in the proceedings.

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:

G. Magouliotis   M. Alvazzi Delfrate

Decision electronically authenticated