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Datasheet for the decision of 19 June 2024

Case Number: T 0427/22 - 3.2.02

Application Number: 17733827.4

Publication Number: 3478155

IPC: A61B5/00, A61B5/145

Language of the proceedings: EN

Title of invention:
METHOD FOR PROVIDING A SIGNAL QUALITY DEGREE ASSOCIATED WITH AN ANALYTE VALUE MEASURED IN A CONTINUOUS MONITORING SYSTEM

Applicants:
Roche Diabetes Care GmbH
F. Hoffmann-La Roche AG

Relevant legal provisions:
RPBA 2020 Art. 13(2)
EPC Art. 54, 56, 84, 123(2)

Keyword:
Amendment after summons - exceptional circumstances (yes) - taken into account (yes)
Claims - clarity (yes)
Amendments - added subject-matter (no)
Novelty - (yes)
Inventive step - (yes)

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Boards of Appeal

Chambres de recours

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

Case Number: T 0427/22 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 19 June 2024

Appellant: (Applicant 1)	Roche Diabetes Care GmbH Sandhofer Straße 116 68305 Mannheim (DE)
Appellant: (Applicant 2)	F. Hoffmann-La Roche AG Grenzacherstrasse 124 4070 Basel (CH)
Representative:	Altmann Stößel Dick Patentanwälte PartG mbB Theodor-Heuss-Anlage 2 68165 Mannheim (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 5 October 2021 refusing European patent application No. 17733827.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	N. Obrovski

Summary of Facts and Submissions

I. The applicants (the appellants) filed an appeal against the decision of the examining division refusing European patent application no. 17733827.4 for lack of novelty and lack of inventive step in view of the following documents:

D1 US 2014/0182350 A1

D5 A. Facchinetti et al., "*An Online Failure Detection Method of the Glucose Sensor-Insulin Pump System: Improved Overnight Safety of Type-1 Diabetic Subjects*", IEEE Transactions on Biomedical Engineering 60(2), February 2013, 406-16, XP011490358

The contested decision was based on a main request and auxiliary requests 1 to 11. The examining division held that none of these requests were allowable. In regard to auxiliary request 8, the examining division considered that the subject-matter of claim 1 of that request did not involve an inventive step over the combination of D1 with D5 (point 9 of the decision).

II. In their statement setting out the grounds of appeal, the appellants requested that the decision under appeal be set aside and that a patent be granted on the basis of one of auxiliary requests 1, 1A, 2, 2A, 5, 5A, 8, 8A, 9 and 9A, with auxiliary requests 1, 2, 5, 8 and 9 underlying the decision and auxiliary requests 1A, 2A, 5A, 8A and 9A submitted with the statement.

III. The Board gave its preliminary opinion on the case in a communication under Article 15(1) RPBA.

IV. At the oral proceedings held before the Board on 19 June 2024, the Board expressed the preliminary view that the subject-matter of claim 1 of auxiliary request 8 was novel and inventive but that claim 1 was unclear. In response to this objection, the appellants filed a new auxiliary request 8B and withdrew all other claim requests.

V. Claim 1 of auxiliary request 8B (claim 1) reads as follows (amendments to claim 1 of auxiliary request 8 highlighted by the Board):

"*A method (110) for providing a signal quality degree (112) associated with an analyte value (114) measured in a continuous monitoring system (118), the method (110) comprising the steps of:*

a) receiving a measured analyte value (114) from a biosensor (116), wherein the biosensor (116) is adapted for measuring the analyte values (114), and wherein the biosensor (116) is comprised in a continuous monitoring system (118) or controlled by the continuous monitoring system (118);

b) determining at least two impact parameters (136), wherein each of the impact parameters (136) is influenced by an operational status of the continuous monitoring system (118), and wherein each of the impact parameters (136) is capable of exerting an influence (138) on a signal quality of the biosensor (116),

wherein the at least two impact parameters (136) are selected from at least one ~~parameter related to~~ element of a covariance matrix of a Kalman filter and at least one of:

- the current rate of change;

- the current potential of a counter electrode;

- the current wear time of the biosensor (116);
- a time passed since the last calibration of the biosensor (116); and
- a sensitivity and/or an admittance of the biosensor (116),
wherein the influence of each of the impact parameters (136) on the signal quality of the biosensor (116) is expressed by a weight (144) being assigned to each of the impact parameters (136); and

c) determining the signal quality degree (112) associated with the measured analyte value (114) by combining the weights (144) and the corresponding impact parameters (136); and providing the signal quality degree (112) associated with the analyte value (114)."

VI. The appellants' arguments relevant to the present decision can be summarised as follows.

With the limitation inserted in claim 1, auxiliary request 8B overcame the Board's clarity objection raised for the first time at the oral proceedings. Moreover, the person skilled in the art would readily understand that the Kalman filter specified in claim 1 was not any Kalman filter but a Kalman filter used to process the measured analyte value from the biosensor. The subject-matter of claim 1 was thus clear.

Furthermore, the person skilled in the art starting from D1 would have had no motivation to select one of the impact parameters as an element of a covariance matrix of a Kalman filter, even taking into account D5. The subject-matter of claim 1 was therefore not only novel but also involved an inventive step.

Reasons for the Decision

1. The subject-matter of the application

1.1 The application at issue relates to a method as defined in claim 1 for providing a signal quality degree associated with an analyte value measured in a continuous monitoring system. The application also relates to various methods and devices involving the signal quality degree as well as corresponding computer program products, as defined in the further independent claims.

These methods and devices can be used, for example, for continuous monitoring of the analyte glucose, where analyte values are measured by a biosensor in an interstitial fluid subcutaneously and/or *in vivo*, where the biosensor is implantable or partially implantable (page 1 of the description, second paragraph).

1.2 The signal quality degree is intended to indicate an accuracy of the analyte value as measured by the biosensor. For example, it can be a number between 0 and 1, where 0 indicates insufficient quality and 1 indicates sufficient quality (page 5, last paragraph; page 18, second paragraph). This number can be used as a control input to an artificial pancreas and/or to generate alerts throughout the life of the biosensor (page 6, first paragraph).

1.3 To this end, the application proposes determining at least two impact parameters which have an influence on the signal quality of the biosensor and combining them, with appropriate weighting, to provide the signal quality degree associated with the measured analyte value.

1.4 According to claim 1, the at least two impact parameters are selected from at least one element of a covariance matrix of a Kalman filter and at least one of the current rate of change, the current potential of a counter electrode, the current wear time of the biosensor, a time passed since the last calibration of the biosensor, and a sensitivity and/or an admittance of the biosensor.

As noted on page 13 of the description, a Kalman filter is a filtering algorithm commonly used in real-time signal processing that uses a plurality of measured values, potentially subject to measurement inaccuracies, and generates estimates that are more accurate than a single measurement alone. The description explains that the elements of the covariance matrix of the Kalman filter can be used as one of the impact parameters to derive the signal quality degree as this matrix provides a measure of the uncertainty in the filtering.

2. Admittance of auxiliary request 8B

2.1 The appellants filed auxiliary request 8B in reaction to a new clarity objection raised by the Board for the first time during the oral proceedings, according to which the expression "selected from at least one parameter related to a Kalman filter" in claim 1 of auxiliary request 8 did not clearly define how this at least one parameter was "related to" the Kalman filter.

2.2 By specifying that this parameter is an element of a covariance matrix of the Kalman filter, the amendment to claim 1 in auxiliary request 8B overcame this new clarity objection. Moreover, as argued by the appellants and contrary to the preliminary opinion of

the Board set out in its communication under Article 15(1) RPBA, the person skilled in the art would clearly understand that the Kalman filter referred to in claim 1 is a Kalman filter used to process the measured analyte value received from the biosensor. Claim 1 is therefore clear.

Furthermore, the amendment to claim 1 in auxiliary request 8B is supported by the passage of the description as originally filed on page 13, lines 17 to 18 and thus does not add subject-matter. Nor does claim 1 of auxiliary request 8B as a whole contain any added subject-matter. The Board notes that no added-matter objection was raised against auxiliary request 8 in the decision under appeal either.

In view of the Board's preliminary view on novelty and inventive step - which was confirmed during the Board's deliberation, see points 4. and 5. below - it followed that auxiliary request 8B was *prima facie* allowable.

2.3 For these reasons, the Board considered that there were exceptional circumstances under Article 13(2) RPBA justifying the admittance of auxiliary request 8B. The Board therefore decided to admit auxiliary request 8B.

3. Claim 1 - clarity and added subject-matter

As stated above, the Board is satisfied that claim 1 of auxiliary request 8B is clear and does not contain added subject-matter.

4. Claim 1 - novelty and inventive step over D1

4.1 The only objection raised by the examining division against auxiliary request 8, namely an inventive-step

objection to claim 1 of that request based on the combination of D1 with D5, to the extent that it also applies to claim 1 of auxiliary request 8B, does not convince the Board.

4.2 As stated by the examining division in the decision under appeal (point 1.1.1 of the Reasons in combination with points 9.1 and 9.2) and acknowledged by the appellants (point 2.5.1 of the statement of grounds of appeal), D1 discloses a method for determining a signal quality degree associated with an analyte value measured in a continuous monitoring system (see in particular paragraph [0250]: "produce an indicator of the overall quality of the computed glucose value") from various impact parameters, referred to in D1 as "data quality metrics" or "risk factors" (such as the current wear time of the biosensor, see paragraph [0207]: "the number of days the sensor has been in use (e.g., implanted)"), which are combined with predetermined weights (paragraph [0250]: "resulting degrees of membership for all data quality metrics are scaled according to pre-determined weights and combined"), i.e. as in the application at issue.

The Board agrees that D1 does not disclose that at least one of the impact parameters is selected from at least one element of a covariance matrix of a Kalman filter, as required by claim 1. Indeed, D1 is completely silent on such a filter. The subject-matter of claim 1 is therefore novel in view of D1.

4.3 The examining division argued in the decision (point 9.3 of the Reasons) that D5 would have obviously led the person skilled in the art starting from D1 to use as an impact parameter a parameter related to a Kalman filter, so that they would have arrived at the

subject-matter of claim 1 without an inventive step. This is not convincing.

It is true that D5 discloses a method for detecting the failure of a glucose sensor involving a Kalman filter (see block 2 in Figure 2 and section III.A on page 408: "Kalman predictor"), in particular for calculating at each time t a certain number P of retrospective glucose predictions $\hat{y}(t-P+k|t-P)$, k=1..P (see equation 5 on page 409). Notably, the covariance matrix Σ_{xk} of the Kalman filter is used to calculate a confidence interval centred on each of the predicted glucose values (see section III.B and equation 7 on page 409). A failure alert is generated if at least one of the last P measured glucose values is outside its respective confidence interval (page 409, left column, last paragraph; see also the examples in Figure 3 on page 410).

However, contrary to the examining division's argument, the person skilled in the art would not, without the benefit of hindsight, extract from the self-contained failure detection method disclosed in D5 the teaching that an element of the covariance matrix Σ_{xk} can be used as a risk factor within the meaning of D1, in particular on an equal footing with the other risk factors disclosed in D1, and can be combined with the latter, with some weighting, to determine a signal quality degree as taught in D1.

4.4 The Board notes that among the suitable risk factors listed in paragraph [0207], D1 also mentions a deviation from an expected behaviour of the glucose measurements ("expected vs. unexpected behavior"). How to detect such a deviation is not detailed in D1. The Board accepts the appellants' argument that, contrary

to the preliminary view of the Board in its communication under Article 15(1) RPBA, this disclosure would not have led the person skilled in the art starting from D1 to the subject-matter of claim 1 in an obvious manner.

Indeed, even if it is known, as stated in the description of the application at issue (page 13, last three lines), that the covariance matrix of a Kalman filter provides a measure of the uncertainty in the filtering of the measured values processed by such a filter, the person skilled in the art would not have been motivated, without the benefit of hindsight, to implement a Kalman filter in the system of D1 in order to detect the above-mentioned deviation, to consider an element of the covariance matrix of the Kalman filter a risk factor within the meaning of D1 and to combine it, with appropriate weighting, with the other risk factors disclosed in D1 to determine the signal quality degree.

At most, the person skilled in the art, having knowledge of D5, would have implemented the failure detection method disclosed in D5 as a whole, in addition to and in parallel with the determination of the signal quality degree disclosed in D1. However, this would not have led to the subject-matter of claim 1.

4.5 It follows that the subject-matter of claim 1 involves an inventive step starting from D1.

5. Claim 1 - novelty and inventive step over D5

The Board is also satisfied that the subject-matter of claim 1 is novel and inventive over D5. D5 is completely silent on the other impact parameters

defined in claim 1 with which the at least one element of a covariance matrix of a Kalman filter is combined. Even with the knowledge of D1, the person skilled in the art starting from D5 would have had no motivation to modify the self-contained method disclosed in D5 to take account of these other impact parameters.

6. Remaining claims

6.1 The remaining claims 2 to 14 of auxiliary request 8B are identical to those of auxiliary request 8, except claim 6, in which the same amendment has been made as in claim 1. This amendment also does not add any subject-matter.

6.2 The examining division did not object to the remaining claims of auxiliary request 8. The Board has no objection either. These claims are either dependent claims depending on claim 1, or they define devices or systems configured to carry out the method of claim 1 or a corresponding computer program product. It follows that the subject-matter of these claims is also novel and inventive over D1 and D5.

7. Remittal to the examining division

7.1 It follows from the foregoing that the claims of auxiliary request 8B, which is the only claim request maintained by the appellants, are allowable.

7.2 However, the description as originally filed is not adapted to these claims.

7.3 The Board therefore considers it appropriate to remit the case to the examining division for adaptation of

the description. The appellants agreed to this course of action.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division with the order to grant a patent with the following claims and a description to be adapted thereto:
   - claims 1 to 14 of auxiliary request 8B filed in the oral proceedings before the Board

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated