Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 27 November 2025

Case Number: T 0653/24 - 3.2.02

Application Number: 20204077.0

Publication Number: 3797682

IPC: A61B5/05, A61B5/00

Language of the proceedings: EN

Title of invention:
METHOD FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION

Patent Proprietor:
DexCom, Inc.

Opponents:
Roche Diabetes Care GmbH
Abbott Diabetes Care Inc.

Headword:

Relevant legal provisions:
EPC Art. 76(1)
RPBA 2020 Art. 11, 12(2)

Keyword:
Divisional application - subject-matter extends beyond content of earlier application (main request: yes; auxiliary request 1: no)
Remittal - (yes)

Decisions cited:
G 0002/10

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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

Case Number: T 0653/24 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 27 November 2025

Appellant: (Patent Proprietor)	DexCom, Inc. 6340 Sequence Drive San Diego, CA 92121 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent: (Opponent 1)	Roche Diabetes Care GmbH Sandhofer Strasse 116 68305 Mannheim (DE)
Representative:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
former Respondent: (Opponent 2)	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)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 7 March 2024 revoking European patent No. 3797682 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 opposition division's decision to revoke the patent. The opposition division held that neither the main request (patent as granted) nor any of auxiliary requests 1 to 80 met the requirements of Article 76(1) EPC.

II. The appellant requested that the decision be set aside and that the patent be maintained as granted (main request) or on the basis of one of auxiliary requests 1 to 79 filed on 23 November 2023, auxiliary request 80 filed during oral proceedings before the opposition division on 23 January 2024 and auxiliary requests 81 to 160 filed with the statement of grounds of appeal. They further request remittal to the opposition division for consideration of grounds other than added subject-matter.

Respondent 1 (opponent 1) did not file any reply to the appeal.

Respondent 2 (opponent 2) withdrew their opposition on 27 December 2024.

III. The parties were summoned to attend oral proceedings on 9 December 2025.

IV. The appellant announced in their letter dated 12 November 2025 that they would not attend the oral proceedings.

V. The Board cancelled the oral proceedings.

VI. Claim 1 of the main request reads as follows.

"A method for calibrating a glucose sensor comprising a membrane containing glucose oxidase,
characterised in that the calibration method makes use of a predictive relationship between *in vitro* sensitivity and *in vivo* sensitivity."

VII. Claim 1 of auxiliary request 1 reads as follows.

"A method for calibrating a glucose sensor comprising a membrane containing glucose oxidase,

characterised in that the calibration method makes use of a predictive relationship between *in vitro* sensitivity and *in vivo* sensitivity,

wherein calibration consists of solving the line $y = mx + b$, where y denotes the sensor signal (in units of A/D counts), x the estimated glucose concentration (mg/dl), m the sensor sensitivity to glucose (counts/mg/dl), and b the baseline signal (counts); and

wherein a predicted sensitivity value is used for sensitivity m, this value being arrived at using a predictive relationship existing between *in vitro* sensitivity and *in vivo* sensitivity whereby $m \approx f(m_{in\ vitro})$."

VIII. The appellant's arguments can be summarised as follows.

Main request - Article 76(1) EPC

As explained in the parent application on page 24, lines 10 to 25, sensors based on glucose oxidase have always exhibited linear behaviour. This was confirmed

by the disclosure of D28 (U. Fischer: "Fundamentals of Glucose Sensors", Diabetic Medicine, 1991, 8, section "Design and Functional Characteristics" starting at page 313). The linear relationship y = mx + b between sensor signal and glucose concentration was therefore implicit in claim 1. Hence, the omission of the step of solving a linear equation as conversion function did not constitute an unallowable intermediate generalisation.

The disclosure about using a predictive sensitivity was not related to the sensor being a short term sensor. Hence, the omission of the feature "short term sensor" did not constitute an unallowable intermediate generalisation.

The omission of the feature "one and the same sensor" did not constitute an unallowable intermediate generalisation. This feature could be considered to be implicit in claim 1.

Thus, claim 1 met the requirements of Article 76(1) EPC.

Reasons for the Decision

1. The patent relates to the calibration of an implantable or transcutaneous glucose sensor. The sensor comprises a membrane that contains the enzyme glucose oxidase. This enzyme is widely used for monitoring glucose in patients with diabetes.

Glucose oxidase catalyses the conversion of oxygen and

glucose to hydrogen peroxide (H_2O_2) and gluconate (paragraph [0010] of the patent). The amount of H_2O_2 produced in this reaction can be measured by means of a working electrode. H_2O_2 reacts with the surface of the electrode, producing an electric current to be measured as a sensor signal (paragraph [0022] of the patent).

The glucose sensor has to be calibrated in order to convert the sensor signal into a glucose concentration (paragraphs [0054] and [0055] of the patent). In the case of a linear relationship between the glucose concentration and the sensor signal, the conversion function $y = mx + b$ has to be solved, where y denotes the sensor signal, x the estimated glucose concentration, m the sensor sensitivity and b the baseline signal.

Typically, at least two paired measurements (x_1,y_1; x_2,y_2) at different glucose concentrations are required to determine m and b for the particular sensor. "Paired measurement" means that the sensor signal and, independently (e.g. by a finger stick blood sample measurement), a reference value of the glucose concentration have to be measured at the same time. From these two measurements, the sensitivity m and the baseline b can be determined mathematically.

In order to avoid finger stick measurements, the patent suggests making use of prior information for the sensitivity m and/or the baseline b. The prior information can be information from *in vitro* calibration i.e. the determination of m and b from measurements taken by the sensor of a controlled solution, i.e. a solution with a known glucose concentration.

According to claim 1, the calibration method makes use of a predictive relationship between *in vitro* sensitivity and *in vivo* sensitivity. This means that the *in vitro* sensitivity of a particular sensor is determined and, on the basis of a known relationship between *in vitro* sensitivity and *in vivo* sensitivity, the corresponding *in vivo* sensitivity is determined and used to establish the conversion function, which can then be used to convert the sensor signals of the implanted sensor into glucose concentration values. An example of the definition of such a predictive relationship is described in paragraph [0386] of the patent (example I).

2. Main request - Article 76(1) EPC

2.1 The present patent is based on a divisional application of four earlier applications, the earliest of which had been published as WO 2006/099151 (parent application). Only this application has been addressed in the appealed decision.

2.2 A predictive relationship between *in vitro* sensitivity and *in vivo* sensitivity of a glucose sensor having a membrane containing glucose oxidase and its use in a calibration method are not present in the original claims of the parent application but are mentioned in the paragraph bridging pages 24 and 25 of the parent application. In this paragraph, it is also mentioned that the predicted sensitivity m, possibly together with a predicted baseline b, can be used to determine the conversion function $y = mx + b$ for the particular sensor, while avoiding one or both of the two paired measurements. Hence, it is required that a linear conversion function can be assumed for the calculation of the glucose concentration x from the sensor signal

y, as mentioned in the preceding paragraph (page 24, lines 10 to 24). The linear conversion function, which is not present in claim 1 of the main request, is thus inextricably linked with the claimed predictive relationship.

2.3 Indeed, the opposition division held that claim 1 included added subject-matter as it did not contain the step "calibration consists of solving the line $y = mx + b$", as it did not specify the sensor as a short term sensor and as it did not mention the predictive relationship between *in vitro* and *in vivo* sensitivities of one and the same sensor. The omission of these features was considered to constitute an unallowable intermediate generalisation (point 3.1.1 of the decision).

2.4 The appellant argued that the linear relationship $y = mx + b$ between sensor signal and glucose concentration was implicit in claim 1 since sensors based on glucose oxidase always had a linear behaviour.

The Board does not agree. Claim 1 does not imply that the relationship between the sensor signal and the glucose concentration was linear such that the conversion function had the form $y = mx + b$. Indeed, other forms of conversion function, for instance polynomials, are possible, something which is in fact also acknowledged in the parent application (see page 110, first paragraph). Hence, the omission of the feature that the sensitivity m is used in a conversion function of the form $y = mx + b$ presents the person skilled in the art with new technical information (see G2/10, point 4.5.1) and constitutes an unallowable intermediate generalisation.

2.5 By contrast, as further argued by the appellant, the disclosure about using a predictive sensitivity is not related to the sensor being a short term sensor. It is immediately apparent to a person skilled in the art that a predictive sensitivity can be used irrespective of whether the sensor is a short term or a long term one. Hence, the omission of the feature "short term sensor" does not constitute an unallowable intermediate generalisation.

2.6 The Board also agrees with the appellant that the feature "one and the same sensor" is implicit in claim 1. The claim mentions only one sensor and one predictive relationship. Hence, the person skilled in the art understands that in the claim a predictive relationship exists between this sensor's *in vitro* sensitivity and its *in vivo* sensitivity. Therefore, there is no omission in this respect.

2.7 Hence, claim 1 does not meet the requirements of Article 76(1) EPC since it does not define the conversion function as a linear equation y = mx + b. The main request is therefore not allowable.

3. Auxiliary request 1 - Article 76(1) EPC

Auxiliary request 1 meets the requirements of Article 76(1) EPC since the feature concerning the conversion function has been included in claim 1 and former claims 3 and 4 (which were considered by the opposition division to include added subject-matter, see points 3.1.3 and 3.1.4 of the decision) have been deleted.

Hence, the ground of opposition under Article 100(c) EPC does not prejudice maintenance of the patent on the

basis of auxiliary request 1.

4. Remittal to the opposition division

The primary object of the appeal proceedings is to review the decision under appeal in a judicial manner (see Article 12(2) RPBA 2020).

In the present case, no decision has been made for any issue other than added subject-matter (Article 76(1) EPC).

These circumstances constitute special reasons within the meaning of Article 11 RPBA 2020 to remit the case to the opposition division, in accordance with the appellant's 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 for further prosecution.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated