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Datasheet for the decision of 29 January 2020

Case Number: T 0395/15 - 3.4.02

Application Number: 04813255.9

Publication Number: 1711802

IPC: G01N27/327, C12Q1/00, G01N33/487

Language of the proceedings: EN

Title of invention:
SYSTEMS AND METHODS FOR IMPROVING ELECTROCHEMICAL ANALYTE SENSORS

Patent Proprietor:
DexCom, Inc.

Opponents:
Abbott Diabetes Care Inc.
Roche Diagnostics GmbH

Relevant legal provisions:
EPC 1973 Art. 84
EPC Art. 123(2)
RPBA Art. 12(4), 13(1)

Keyword:

Added subject-matter (main request: yes)
Consideration of an auxiliary request submitted during first-instance proceedings (first auxiliary request: yes)
Clarity of claims (first and second auxiliary requests: no)
Admission of amended claims filed during oral proceedings (third auxiliary request: no)

Decisions cited:

T 0745/03, T 0221/06, T 1685/07

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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 0395/15 - 3.4.02

D E C I S I O N
of Technical Board of Appeal 3.4.02
of 29 January 2020

Appellant I: (Patent Proprietor)	DexCom, Inc. 5555 Oberlin Drive San Diego, California 92121 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Appellant II: (Opponent 2)	Roche Diagnostics GmbH Sandhoferstr. 116 68305 Mannheim (DE)
Representative:	Weickmann & Weickmann PartmbB Postfach 860 820 81635 München (DE)
Party as of right: (Opponent 1)	Abbott Diabetes Care Inc. 1360 South Loop Road Alameda, CA 94502 (US)
Representative:	Duxbury, Stephen Arnold & Siedsma Bavariaring 17 80336 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 15 December 2014 concerning maintenance of the European Patent No. 1711802 in amended form.**

Composition of the Board:

Chairman	R. Bekkering
Members:	F. J. Narganes-Quijano
	T. Karamanli

Summary of Facts and Submissions

I. The patent proprietor and opponent 2 lodged an appeal against the interlocutory decision of the opposition division finding European patent No. 1711802 as amended according to the seventh auxiliary request then on file to satisfy the requirements of the EPC.

II. The oppositions filed by opponent 1 and opponent 2 against the patent as a whole were based on the grounds for opposition of added subject-matter (Article 100(c) EPC), insufficiency of disclosure (Article 100(b) EPC) and lack of novelty and lack of inventive step (Article 100(a) EPC together with Articles 54(1) and 56 EPC).

During the appeal proceedings the parties have referred, among other documents, to the following documents:

D7: US 2002/0177764 A1

D15: "Effect of Acetaminophen on the Accuracy of Glucose Measurements Obtained with the GlucoWatch Biographer", M.J. Tierney *et al.*; Diabetes Technology & Therapeutics Vol. 2 (2000), pages 199 to 207.

III. In the decision under appeal the opposition division held *inter alia* that

- the subject-matter of dependent claim 4 of the main request (patent as granted) and of the fifth auxiliary request then on file extended beyond the content of the application as originally filed (Article 100(c) and 123(2) EPC, respectively);

- amended dependent claim 4 of the first and the sixth auxiliary requests then on file was not clear (Article 84 EPC);

- the subject-matter of claim 1 of the second, third and fourth auxiliary requests then on file was not new over the state of the art; and

- the patent as amended according to the seventh auxiliary request complied with the requirements of the EPC.

IV. In a communication annexed to the summons to oral proceedings the board presented a preliminary assessment of the case on appeal.

V. With the letter dated 20 December 2019 the patent proprietor filed claims according to auxiliary requests 1 to 20.

VI. Oral proceedings were held on 29 January 2020 in the absence of the duly summoned opponent 1.

During the oral proceedings the patent proprietor filed *inter alia* claims according to a third auxiliary request and the following documents:

A1: "Timing of Changes in Interstitial and Venous Blood Glucose Measured With a Continuous Subcutaneous Glucose Sensor", M. S. Boyne *et al.*; Diabetes Vol. 52 (November 2003), pages 2790 to 2794

A2: "Evaluation of Conventional Blood Glucose Monitoring as an Indicator of Integrated Glucose Values Using a Continuous Subcutaneous Sensor", S. R. Zavalkoff *et al.*; Diabetes Care Vol. 25 (2002), pages 1603 to 1606.

The chairman noted that opponent 1 had filed no request and had made no submissions in the appeal proceedings.

The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as amended on the basis of the claims of the main request filed by letter dated 20 December 2019 as fourth auxiliary request or, as an auxiliary measure, of one of the first auxiliary request filed by letter dated 20 December 2019 as eighth auxiliary request, the second auxiliary request filed by letter dated 20 December 2019 as seventh auxiliary request, and the third auxiliary request filed at the oral proceedings of 29 January 2020.

Opponent 2 requested that the decision under appeal be set aside and that the patent be revoked.

At the end of the oral proceedings the chairman announced the decision of the board.

VII. Claim 1 and dependent claim 4 of the main request read as follows:

"1. A method for identifying a signal interference in an analyte-measuring device, the method comprising:

providing at least one electrochemical sensor;

measuring a first signal output obtained at a first bias potential setting;

measuring a second signal output at a second bias potential setting;

comparing the first signal output with the second signal output to determine a differential measurement, thereby identifying an interference in the signal outputs, characterised in that the method further

comprises deriving an analyte concentration from the first signal output and the second signal output to determine an analyte concentration, wherein the analyte measuring device is a continuous subcutaneous or transdermal device."

"4. A method according to Claim 1 wherein said method identifies an interfering species, and wherein the comparison identifies a presence of an interfering species in a liquid."

Claim 1 of the first auxiliary request is identical to claim 1 of the main request.

Claim 1 of the second auxiliary request differs from claim 1 of the main request in that the expression "an analyte" is replaced at the three occurrences of this expression by the expression "a glucose", and in that the expression "the analyte" is replaced by the expression "the glucose".

Claim 1 of the third auxiliary request differs from claim 1 of the second auxiliary request in that the last phrase "wherein the glucose measuring device is a continuous subcutaneous or transdermal device" is replaced by the phrase: "wherein the glucose measuring device is a subcutaneous or transdermal device for continuous measurement of glucose concentration".

Reasons for the Decision

1. The appeals of the patent proprietor and of opponent 2 are admissible.

2. *Main request - Article 123(2) EPC*

2.1 The claims of the present main request correspond to the claims of the fifth auxiliary request underlying the decision under appeal. During the first-instance proceedings dependent claim 4 as granted was objected to by opponent 2 under Article 100(c) EPC. This objection was found persuasive by the opposition division in respect of the then main request (patent as granted) (Article 100(c) EPC) and also of the then fifth auxiliary request - and now main request - (Article 123(2) EPC), and during the appeal proceedings the patent proprietor has disputed the opposition division's finding in this respect.

2.2 Claim 1 is directed to a method "for identifying a signal interference in an analyte-measuring device", the method comprising, among other steps, the step of comparing a first signal output of an electrochemical sensor at a first bias potential setting with a second signal output at a second bias potential setting "to determine a differential measurement, thereby identifying an interference in the signal outputs". Dependent claim 4 further requires that the method "identifies an interfering species, and wherein the comparison identifies a presence of an interfering species in a liquid."

2.2.1 In the decision under appeal the opposition division held that the identification of the interfering species required by dependent claim 4 constituted a further, additional step that went beyond the step of claim 1 relating to the identification of an interference in the signal outputs, and that this additional step implied the determination of the cause of the

interference in the signal outputs. In addition, there was no basis in the application as originally filed in support of a method as defined in claim 1 and further including the mentioned additional step.

2.2.2 The patent proprietor contested the opposition division's view in this respect and submitted that the skilled person would not understand the features of dependent claim 4 as requiring an additional step, but only as a limitation of the identification capability of the method of claim 1, in particular in the sense that the identification of a signal interference required by claim 1 constituted the identification of an interfering species or that the interference in the signals was due to the presence of an interfering species. In addition, claim 1 of the main request was based on independent claim 17 as originally filed directed to a method of identifying a signal interference, and the features of dependent claim 4 were based on claim 1 as originally filed directed to a method of identifying an interfering species and reformulated during the examination of the application as a dependent claim. The skilled person would have understood that the differential measurement identified an interference in the signal outputs as defined in claim 1 of the main request and also identified the presence of an interfering species as disclosed on page 8, lines 21 to 31, of the description as originally filed and as defined in dependent claim 4 of the main request, and he would have also understood that the method of claim 1 as originally filed did not constitute an alternative to, but a subset of the method defined in independent claim 17 as originally filed.

2.2.3 In the board's view, however, although the formulation of claim 4 "[the] method [of claim 1] identifies an interfering species, [...] wherein the comparison identifies a presence of an interfering species in a liquid" can be interpreted - as submitted by the patent proprietor - as specifying that the identification of an interference in the signal outputs defined in claim 1 provides itself the identification of an interfering species, the formulation of dependent claim 4 is relatively broad and the claim also encompasses, as held by the opposition division, the identification of the presence of an interfering species on the basis of the comparison of the first and the second signal outputs as a further step to the step of identifying an interference in the signal outputs defined in claim 1. The board notes in this respect that any ambiguity in the construction of dependent claim 4 arises - as submitted by opponent 2 - from the broad formulation of dependent claim 4, and that in these circumstances the board does not see in the patent proprietor's submissions any reason that would justify in the present case narrowly construing the subject-matter of the claim as submitted by the patent proprietor or on the basis of the description of the patent specification.

In addition, independent claims 1 and 17 as originally filed are respectively directed to the identification of an interfering species and to the identification of a signal interference. The section "Summary of the Invention" on pages 2 to 4 of the description as originally filed also discloses - as submitted by opponent 2 - two distinct groups of embodiments respectively directed to the identification of an interfering species and to the identification of a signal interference, namely a first group constituted

by the "first" and the "second" embodiments (page 2, line 14, to page 3, line 8) and a second group constituted by the "third" and the "fourth" embodiments (page 3, lines 15 to 33) disclosed in the mentioned section. Moreover, the presence of an interfering species gives rise - as disclosed on page 1, lines 22 to 31, of the description as originally filed - to an interference in the signals, but an interference in the signals may also be caused - as submitted by opponent 2, in particular by reference to the passage on page 1, lines 31 and 32, of the description as originally filed - by reasons other than the presence of the interfering species under consideration. In the board's view no combination of the identification of an interference in the signals as defined in claim 1 with the further step of identifying an interfering species as encompassed by the formulation of dependent claim 4 can be directly and unambiguously derived from all these passages.

Furthermore, the patent proprietor's submissions that the skilled person would have understood - in particular, under consideration of the passage on page 8, lines 24 to 31, of the description as originally filed relating to the identification of an interfering species in the signals measured in a glucose-measuring device - that the identification of an interfering species was disclosed in the application as originally filed as a "subset" of the identification of an interference in the signals, might support the narrow construction of the subject-matter of dependent claim 4 submitted by the patent proprietor (see point 2.2.2 above, first sentence), but these submissions do not support supplementing the method defined in claim 1 with the mentioned additional step of identifying an interfering species as also encompassed by the formulation of dependent claim 4.

2.2.4 In view of the above considerations, the board concludes that dependent claim 4 introduces subject-matter which extends beyond the content of the application as originally filed because the subject-matter of claim 4 encompasses the identification of an interfering species as a further, additional step of the method of identifying a signal interference defined in claim 1, and this feature is not directly and unambiguously derivable from the content of the application as originally filed (Article 123(2) EPC).

3. *First auxiliary request - Admission and Article 84 EPC 1973*

3.1 Claim 1 of the first auxiliary request is identical to claim 1 of the main request, and dependent claim 4 of the main request has been omitted in the claims of the first auxiliary request, thus overcoming the objection under Article 123(2) EPC addressed in point 2 above.

3.2 Opponent 2 requested that the first auxiliary request not be admitted into the proceedings. In support of its request opponent 2 essentially submitted that the patent proprietor had replaced several times during the proceedings a set of numerous auxiliary requests by another set of numerous auxiliary requests, that the independent claims within the different sets of auxiliary requests provided numerous permutations of features being introduced, cancelled, reintroduced, combined, etc., that the different versions of the claims created an obscure and unacceptable procedural situation in the sense set out in decision T 1685/07, that such a pick-and-mix approach was inadmissible according to decisions T 221/06 and T 745/03, and that, consequently, the auxiliary requests on file

constituted an abuse of procedure. In addition, the sets of claims on file did not fulfil the criterion of convergence set forth in the established case law ("Case Law of Boards of Appeal", EPO, 9th edition 2019, V.A.4.12.4).

The board first notes that the claims of the first auxiliary request correspond to the claims of the ninth auxiliary request already submitted during the first-instance proceedings and on file at the time the decision under appeal was taken and, in addition, this request was not withdrawn during the proceedings, but resubmitted as twenty-seventh auxiliary request with the statement of grounds of appeal filed by the patent proprietor - and subsequently renumbered as eighth auxiliary request with the letter dated 20 December 2019, and again renumbered as first auxiliary request during the oral proceedings before the board. Therefore, the first auxiliary request does not fall within the category of requests "which could have been presented or were not admitted in the first instance proceedings" referred to in Article 12(4) RPBA 2007 (which is applicable in accordance with Article 25(2) RPBA 2020 (OJ EPO 2019, A63)) and the admission of which is at the discretion of the board. Consequently, as stipulated by the Article 12(4) RPBA 2007, this request is to be taken into account by the board.

As regards the submissions of opponent 2 relating to the lack of convergence in the different amendments made to the independent claims of the different sets of auxiliary requests filed during the proceedings, the board notes that this convergence criteria relates to the relationship between successive amendments made during appeal proceedings and the admission of the same

(see the first paragraph of section V.A.4.12.4 of "Case Law of Boards of Appeal", EPO, 9th edition 2019, referred to by opponent 2). The mentioned criterion of convergence has therefore no impact on the consideration of the present first auxiliary request because, apart from the deletion of dependent claims as granted, the claims have only been modified with respect to the granted claims by the incorporation of one single feature in the independent claims. Similar considerations apply to the submissions of opponent 2 relating to the procedural and/or substantive consistency of a plurality of sets of amended claims filed during appeal proceedings (decisions T 745/03 (point 2 of the reasons), T 221/06 (point 2 of the reasons) and T 1685/07 (point 6 of the reasons)) because the submissions concern the interrelationship between successive amended sets of claims and they are not applicable to the issue under consideration relating to the admissibility of a set of claims constituting a first auxiliary request and which, in addition, was already filed during the first-instance proceedings and maintained during the subsequent proceedings. It also follows from these considerations that, at least as far as the present first auxiliary request is concerned, no abuse of procedure can be inferred from the submissions of opponent 2.

For these reasons, the request of opponent 2 not to admit the first auxiliary request into the proceedings is rejected.

3.3 Claim 1 differs from claim 1 as granted by incorporation of the feature "wherein the analyte measuring device is a continuous subcutaneous or transdermal device". During the written appeal proceedings opponent 2 submitted in respect of the

mentioned feature that it was not clear for the skilled person what was meant by a subcutaneous or transdermal device being "continuous".

The patent proprietor submitted that the claimed "device" referred, in its context, to a device for measuring, and that therefore the skilled person would understand the expression "continuous subcutaneous or transdermal device" as a device capable of continuously measuring, i.e. of carrying out a series of measurements without sampling between measurements (paragraph [0028] of the patent specification). In addition, this meaning of the expression "continuous subcutaneous or transdermal device" corresponded to the conventional meaning used in the technical field under consideration at the priority date of the patent as shown, firstly, in document D7 disclosing the differences between a measurement of glucose concentration at a single point in time (paragraphs [0003] and [0004]), such as in a finger-prick test, and continuous glucose monitoring, where a device takes measurements over an extended time period (paragraphs [0006] and [0010]), and, secondly, in document D15.

However, claim 1 requires that "the analyte measuring device is a continuous subcutaneous or transdermal device", and - as submitted by opponent 2 - it is unclear in the context of claim 1 what is meant by a subcutaneous or transdermal device being continuous. More particularly, the expression "subcutaneous or transdermal device" refers only to a structural arrangement, and it is unclear in the formulation of the claim whether "continuous" refers to the structure of the device - and in this case, as submitted by opponent 2, in what sense the structure of the device is continuous - or to the function of the device. In

addition, the arguments of the patent proprietor are not persuasive because neither the formulation of the claim nor the references to common general knowledge would support the contention that the skilled person - more specifically, as submitted by the patent proprietor, the skilled person willing to understand - would clearly understand the term "continuous" as referring not to the structure of the device itself, but to the measurement function of the device. In particular,

- document D7 refers to "'continuous', chronic monitoring" (paragraph [0006]) and to "a continuous analyte concentration measurement system" (paragraph [0010]), and in these expressions the adjective "continuous" directly qualifies a function ("monitoring" and "measurement"), and not a "device" or a "subcutaneous or transdermal device" as is the case of the claimed feature under consideration; and

- no specific passage of document D15 has been submitted by the patent proprietor in support of its submissions relating to the meaning of the expression "continuous subcutaneous or transdermal device".

As regards the reference of the patent proprietor to paragraph [0028] of the patent specification, the board notes that a mere reference to the description does not overcome an objection of clarity under Article 84 EPC 1973 and that, in any case, the mentioned paragraph does not refer to a "continuous subcutaneous or transdermal device".

In view of these considerations, the board concludes that amended claim 1 of the first auxiliary request does not meet the requirement of clarity of Article 84 EPC 1973.

4. *Second auxiliary request - Admission and Article 84 EPC 1973*

4.1 The subject-matter of claim 1 of the second auxiliary request differs from that of claim 1 of the first auxiliary request in that the term "analyte" has been replaced by "glucose".

4.2 According to the patent proprietor, the adjective "continuous" described the device, and the mentioned replacement clarified the meaning of the expression "continuous subcutaneous or transdermal device" in its technical context as referring to a device for the continuous measurement or monitoring of glucose. In support of its view, the patent proprietor submitted during the oral proceedings documents A1 and A2 as evidence on how the expression "continuous glucose device" was understood by the person skilled in the field of glucose measurement at the priority date of the patent.

Opponent 2 submitted that documents A1 and A2 were filed late, and that they constituted articles from a technical journal which could not replace a dictionary or constitute evidence of the common general knowledge. Accordingly, these documents should not be admitted.

The board considers that amended claim 1 constituted an attempt to overcome the objection of clarity under consideration without adding complexity to the case or introducing new deficiencies, and that documents A1 and A2 contributed to the understanding of the term "continuous" in the technical field under consideration. For these reasons the board considered appropriate to exercise its discretion under Article 13(1) RPBA 2007 (which is applicable in accordance with

Article 25(3) RPBA 2020) to admit the second auxiliary request and documents A1 and A2 into the proceedings.

4.3 Claim 1 relates now a glucose measuring device, but the claim still requires that this device is "a continuous subcutaneous or transdermal device". Therefore, the claim is not clear for the same reasons given in point 3.2 above in respect of claim 1 of the first auxiliary request.

The patent proprietor submitted that, as shown in documents A1 and A2, the term "continuous" was conventionally used in the field of glucose sensors as referring not to the structure of the device, but to its function, i.e. to the glucose measurement, and that the skilled person would understand the term "continuous" of claim 1 in this sense.

However, both documents A1 and A2 refer to CGMS, i.e. to "continuous glucose monitoring systems" (A1, page 2790, left column, last paragraph, and A2, page 1603, first paragraph), and in these expressions the term "continuous" qualifies not just a system or - as is the case in claim 1 - a "device", but the "glucose monitoring" function of a continuous glucose monitoring system. Similar considerations apply to the expressions "continuous subcutaneous glucose sensors" used in document A1 (title) and "continuous subcutaneous sensors" used in document A2 (title) - under the assumption that both constituted well-established expressions at that time - because in both cases the term "continuous" qualifies the sensing function implicit in the term "sensor". In addition, as submitted by opponent 2, claim 1 does not require a "continuous monitoring device", but only a "continuous subcutaneous or transdermal device". Therefore, the

patent proprietor's submissions do not persuade the board that the skilled person would understand the term "continuous" in the claimed expression "continuous subcutaneous or transdermal device" as referring to the glucose measurement function of the device and not to some other feature of the device as, for instance, its structural arrangement.

The board concludes that amended claim 1 of the second auxiliary request does not meet the requirement of clarity of Article 84 EPC 1973.

5. *Third auxiliary request - Admission*

5.1 During the oral proceedings, and in reaction to the objection of lack of clarity addressed in point 4 above, the patent proprietor amended claim 1 of the second auxiliary request by replacing the feature "the glucose measuring device is a continuous subcutaneous or transdermal device" by the feature "the glucose measuring device is a subcutaneous or transdermal device for continuous measurement of glucose concentration", the amended claim 1 constituting claim 1 of the third auxiliary request. According to the patent proprietor, the amendments were essentially of a linguistic nature, and the amended feature was based on the sentence bridging pages 5 and 6, and on the last paragraph on page 4 of the application as originally filed.

Opponent 2 submitted that the third auxiliary request was late filed, that there was no justification for filing it at such a late stage of the appeal proceedings, i.e. the oral proceedings, and that there was no clear basis in the application as originally filed for the mentioned amendment, and that for these

reasons the third auxiliary request should not be admitted into the proceedings.

5.2 The board first notes that the objection of lack of clarity under consideration was already raised by opponent 2 in its reply to the statement of grounds of appeal filed by the patent proprietor (letter of reply dated 11 September 2015, page 14, fifth paragraph) and subsequently addressed by the board in point 7.3.3 of its communication annexed to the summons, and that the patent proprietor had had sufficient opportunity to react to this objection - as it actually did in its letter dated 20 December 2019 (cf. point 2.2.6). In addition, no new issue was raised during the discussion of the mentioned objection at the oral proceedings that would have justified subsequently filing the amended claim 1 in reaction thereto.

In addition, the amendment was carried out in an attempt to overcome the mentioned objection of lack of clarity, but it raised new issues, and in particular the question of whether the amendments of claim 1 (i.e. the deletion of the term "continuous" in the expression "continuous subcutaneous or transdermal device" and the inclusion of the feature "for continuous measurement of glucose concentration") complied with Article 123(2) EPC, in particular on the basis of the passages of the application as originally filed mentioned by the patent proprietor. More particularly, the sentence bridging pages 5 and 6 of the description as originally filed ("In some embodiments, the analyte-measuring device is a continuous device, for example a subcutaneous, transdermal, or intravascular device.") only refers to "a continuous device" and is silent as to the continuous measurement of glucose concentration. Furthermore, the last paragraph on page 4 of the

description as originally filed ("The term [signal output] broadly encompasses a single point, or alternatively, a plurality of time spaced data points from a substantially continuous glucose sensor, which comprises individual measurements taken at time intervals ranging from fractions of a second up to, for example, 1, 2, or 5 minutes or longer.") does not refer to "continuous measurement" of glucose concentration as now claimed, but to a continuous glucose sensor and to a plurality of measurements taken with the sensor at predetermined time intervals. In these circumstances, it is not *prima facie* apparent that the claimed feature "continuous measurement of glucose concentration" of amended claim 1 would be directly and unambiguously derivable from the application as originally filed by the person skilled in the art using its common general knowledge. In particular, the question of whether the common general knowledge that the person skilled in the technical field under consideration would have possessed at the relevant date would have led the skilled person to understand a "continuous measurement of glucose concentration", where the application as originally filed only discloses a plurality of measurements of glucose taken with a continuous glucose sensor at predetermined time intervals, would have required a complex discussion at the oral proceedings, possibly under consideration of further documentary evidence relating to the mentioned common general knowledge.

In view of these considerations, during the oral proceedings the board declined to exercise its discretion under Article 13(1) RPBA 2007 in favour of the patent proprietor and decided not to admit the third auxiliary request into the proceedings.

6. In the absence of an admissible and allowable request of the patent proprietor, the board concludes that the patent is to be revoked under Article 101(3)(b) EPC in accordance with the request of opponent 2.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

M. Kiehl R. Bekkering

Decision electronically authenticated