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**Datasheet for the decision
of 7 September 2021**

Case Number: T 2678/18 - 3.4.02

Application Number: 05733254.6

Publication Number: 1733043

IPC: G01N27/327, C12Q1/00

Language of the proceedings: EN

Title of invention:

METHOD FOR IMPLEMENTING THRESHOLD BASED CORRECTION FUNCTIONS
FOR BIOSENSORS

Patent Proprietor:

Ascensia Diabetes Care Holdings AG

Opponent:

Abbott Diabetes Care Inc.

Relevant legal provisions:

EPC Art. 54(1), 100(a)
EPC R. 103(1)(a)

Keyword:

Novelty (all requests: no)
Substantial procedural violation and reimbursement of the
appeal fee (yes)



Beschwerdekammern

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Case Number: T 2678/18 - 3.4.02

D E C I S I O N
of Technical Board of Appeal 3.4.02
of 7 September 2021

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 3 September 2018 rejecting the opposition filed against European patent No. 1733043 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairwoman T. Karamanli
Members: F. J. Narganes-Quijano
A. Hornung

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division rejecting the opposition filed against European patent No. 1733043.

The opposition filed by the appellant against the patent as a whole was 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 of inventive step (Article 100(a), together with Articles 52(1), 54 and 56 EPC).

II. During the appeal proceedings reference was made, among other documents, to the following documents considered during the first-instance opposition proceedings:

E1: US 5695623 A
E2: US 6576117 B1
E3: EP 1486778 A2
E4: US 2001/0016682 A1
E5: WO 99/32881 A1
E6: WO 02/097391 A2
E7: US 6391645 B1.

III. In its decision, the opposition division held *inter alia* that none of the grounds for opposition considered during the proceedings prejudiced the maintenance of the patent as granted. The opposition division was, in particular, of the opinion that the subject-matter of claim 1 as granted was new over each of documents E1 to E5, and involved an inventive step over document E1 in combination with document E5, over document E5 in

combination with document E2, and over document E2 in combination with each of documents E4 to E7.

- IV. With the statement setting out the grounds of appeal, the appellant submitted *inter alia* that the first-instance proceedings were tainted by a substantial procedural violation.
- V. By its reply dated 28 May 2019, the respondent (patent proprietor) submitted claims according to a first to third auxiliary request.
- VI. Oral proceedings were held on 7 September 2021.

The appellant requested that the decision under appeal be set aside and that the European patent be revoked. In addition, reimbursement of the appeal fee was requested.

The respondent requested that the appeal be dismissed (main request) and, in the alternative, that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the claims of one of the first to third auxiliary requests filed by letter dated 28 May 2019.

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

- VII. Claim 1 of the main request (patent as granted) reads as follows:

"A method for implementing threshold based correction functions for a biosensor comprising the steps:

applying a sample to the biosensor and obtaining a primary measurement of an analyte value;

obtaining a secondary measurement of a secondary effect;

characterized in the further steps of

comparing said secondary measurement of the secondary effect with a threshold value;

responsive to said compared values, identifying a correction function from a plurality of potential correction functions based on said compared values; and

applying said identified correction function to said primary measurement to provide a corrected analyte value."

Claim 1 of the first auxiliary request differs from claim 1 of the patent as granted in that the term "potential" in the second sub-paragraph of the characterizing part of claim 1 of the main request is omitted.

Claim 1 of the second auxiliary request differs from claim 1 of the patent as granted in that the preamble of claim 1 further reads

"wherein the step of obtaining a secondary measurement of a secondary effect include [sic] the step of obtaining a temperature measurement;"

and in that the second sub-paragraph of the characterizing part of claim 1 of the patent as granted is replaced by the following wording:

"responsive to said compared values, identifying a correction function to correct for temperature effects from a plurality of potential correction functions to correct for temperature effects based on said compared values; and".

Claim 1 of the third auxiliary request differs from claim 1 of the second auxiliary request in that the term "potential" in the second sub-paragraph of the characterizing part of claim 1 of the second auxiliary request is omitted.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request (patent as granted) - Ground for opposition of lack of novelty (Article 100(a) together with Articles 52(1) and 54(1) EPC)*
 - 2.1 The appellant submitted that, contrary to the opposition division's view, the subject-matter of claim 1 as granted was not new in view of the documents considered during the proceedings, and in particular in view of document E2.

 - 2.2 Document E2 is directed to the determination of the concentration of an analyte (glucose in a blood sample) on the basis of the value of a current measured using a biosensor (abstract, together with the paragraph bridging columns 5 and 6).
 - 2.2.1 According to document E2, the determination of the analyte concentration from the measured current value involves the use of a series of operations. In particular, in the embodiment disclosed in column 12, line 32 et seq., of document E2 a concentration value of the analyte (glucose) is produced by conversion from

a value $I_b(5)''$ according to a calibration curve table, the mentioned value $I_b(5)''$ having previously been obtained by multiplying a value $I_b(5)'$ by a temperature correction coefficient (column 15, lines 38 to 41). In addition, this value $I_b(5)'$ is previously determined by first comparing the measured temperature with two predetermined temperature values, namely 30 and 35°C, and then selecting one from among three different functions, each relating the value $I_b(5)'$ to two current values $I_b(5)_I$ and $I_b(5)_{II}$ (column 15, lines 23 to 36), which in turn - as the opponent emphasised with reference to column 13, lines 37 to 41 - had been obtained by a further correction of a current value $I_b(5)$, representing a primary measurement of the analyte concentration (E2, column 12, line 32, to column 15, line 22).

Therefore,

- the measured current value from which the concentration value of the analyte is calculated constitutes "a primary measurement of an analyte value" as claimed,

- the temperature measurement constitutes "a secondary measurement" as claimed, and

- the resulting concentration value of the analyte is constituted by a value of the analyte obtained from the measured current value and corrected by application of one of the three mentioned functions selected - and therefore identified - according to a comparison of the measured value of temperature with the two predetermined temperature values, each constituting a threshold value within the meaning of the claimed subject-matter.

In addition, the resulting corrected value of the analyte concentration is hematocrit-corrected (E2,

column 15, lines 1 to 37) and also implicitly corrected in temperature as "a secondary effect" as claimed because the selection of the function depends on the measured temperature (column 15, lines 23 to 37). Alternatively, the resulting corrected value of the analyte concentration is also explicitly temperature-corrected as claimed because the operations of selecting and then applying one of the three functions and subsequently multiplying by a temperature-dependent - and therefore temperature-correction - coefficient (see column 15, lines 23 to 41) constitutes as a whole the operation of selecting and then applying one of three composed functions each constituted by the product of a respective one of the three mentioned functions and the temperature-corrected coefficient, and the general formulation of claim 1 does not exclude that the claimed "correction functions" are constituted by the mentioned composed operation functions.

Finally, it follows from the above considerations that the method disclosed in document E2 constitutes a method "for implementing threshold based correction functions for a biosensor" as claimed.

- 2.2.2 The opposition division and the respondent were of the view that document E2 disclosed the correction of a current value representative of an analyte concentration, but not the application of an identified correction function to a primary analyte measurement as defined in claim 1. The respondent also submitted in this respect that document E2 only disclosed adjusting a parameter (parameter P2) calculated from current measurements in response to the analyte concentration (column 3, lines 61, to column 4, line 2) on the basis of a temperature correction coefficient (column 5, lines 24 to 33), and that the document did not disclose

the application of an identified correction function to the analyte concentration value.

The board, however, cannot follow the view of the opposition division and of the respondent that the claimed "primary measurement of an analyte value" is to be identified with a measurement of the analyte itself and that it cannot be identified with the measurement of the current from which the analyte value is then derived. In both document E2 and in the patent specification (page 2, lines 36 to 42), the analyte itself is not properly measured, but determined as a function of the measured value of the current. In particular, as already noted in point 2.2.1 above, first paragraph, in document E2 the value of the analyte is obtained from current measurements (current value $I_b(5)$, corresponding to parameter P2, see column 12, lines 36 to 49), and the measured value of the current is - as submitted by the appellant by reference to page 3, lines 28 to 39, and paragraph [0009] of the patent specification - correlated to the analyte concentration and it constitutes itself - contrary to the respondent's submissions - "a primary measurement of an analyte value" within the broad meaning of this expression used in claim 1.

- 2.2.3 The respondent also submitted that document E2 disclosed adjusting quantities based on a temperature correction coefficient (column 5, lines 24 to 33) and it disclosed one single correction function, i.e. it did not disclose the claimed step of identifying a correction function from a plurality of potential correction functions based on the compared values, and referred in this respect to column 4, lines 12 to 18 and lines 43 to 46, and column 13, lines 31 to 46 of document E2. In addition, the embodiment disclosed in

column 15, lines 23 to 41, of document E2 focused on compensation of hematocrit as a secondary effect, and in this embodiment the temperature was used as a secondary measurement for comparison and correction of the hematocrit effect (column 7, lines 39 to 48), and not as a threshold of hematocrit, so that document E2 did not disclose obtaining a secondary measurement of a secondary effect as claimed.

However, as already noted in point 2.2.1, third paragraph, the method of document E2 involves not only hematocrit correction, but also temperature correction (column 4, lines 12 to 22, and column 15, lines 23 to 41) as a secondary effect as claimed, the temperature correction being carried out according to the measured temperature as a secondary measurement of a secondary effect as claimed. In any case, as submitted by the appellant, claim 1 leaves open whether the "corrected analyte value" is corrected in the claimed secondary effect or corrected to give account of some other effect.

In addition, the flowchart of Fig. 2 of document E2 shows that the measured temperature (step 3 in Fig. 2) is compared with a first threshold T_L (" $T < T_L$ " in step 6) corresponding to the claimed threshold and, depending on the result of the comparison, a correction function from a plurality of correction functions (see the three different quantities at the bottom of step 6 each of which constitute, together with the subsequent operation in step 7 involving multiplication by a "temperature correction coefficient" that is temperature dependent, a different correction function) is selected, and therefore identified, depending on the result of the comparison, wherein in the event that the measured temperature does not satisfy the condition

" $T < T_L$ ", one out of two correction functions is subsequently selected depending on whether the measured temperature is lower or not than a further threshold T_H (step 6). In the board's view these operations constitute a step of "identifying a correction function from a plurality of potential correction functions based on said compared values" as claimed.

2.2.4 During the oral proceedings the respondent also referred to the method of implementing threshold based correction of secondary effects disclosed in Fig. 2 and in paragraphs [0025] and [0026] of the patent specification in support of novelty of the claimed method over the method disclosed in document E2. However, the corresponding arguments are based on specific features of the mentioned method disclosed in the description that are not defined in the method claimed in claim 1 of the patent as granted, and the respondent's submissions in this respect are not convincing.

2.2.5 In view of the above considerations, the board concludes that the method defined in claim 1 is not new over the disclosure of document E2 and that, therefore, the ground for opposition of lack of novelty (Article 100(a) together with Articles 52(1) and 54(1) EPC) prejudices the maintenance of the patent as granted.

3. *First to third auxiliary requests*

3.1 The claims of the first to third auxiliary requests were submitted by the respondent in reply to the appellant's statement of grounds of appeal. These claims are identical to the corresponding claims of the first to third auxiliary requests filed during the

first-instance proceedings with the letter dated 11 August 2017. In these circumstances, the board has no reason to question whether the claims of the first to third auxiliary requests are to be taken into account in the present appeal (*cf.* Article 12(4) RPBA 2007, which applies in the present case according to Article 25(2) RPBA 2020).

3.2 As regards the issue of novelty of the first to third auxiliary requests, the board notes the following:

i) Claim 1 of the first auxiliary request differs from claim 1 of the main request only in the deletion of the term "potential" in the feature "identifying a correction function from a plurality of potential correction functions [...]". The deletion of this term has no substantive effect on the considerations in point 2 above. Therefore, the method defined in claim 1 of the first auxiliary request is not new over the method disclosed in document E2 for the same reasons given in point 2 above in respect of claim 1 of the patent as granted.

ii) Claim 1 of the second auxiliary request differs from claim 1 of the patent as granted in that the claim further requires that the step of obtaining a secondary measurement of a secondary effect includes the step of obtaining a temperature measurement, and that the correction functions are correction functions to correct for temperature effects. As already noted in points 2.2.1 and 2.2.3 above, in document E2 the secondary measurement of a secondary effect is constituted by the measurement of temperature, and the correction functions implement a correction of temperature effects. Therefore, the method defined in claim 1 of the second auxiliary request is not new over the method disclosed in document E2 for the same

reasons given in point 2 above in respect of claim 1 of the patent as granted.

iii) When compared with claim 1 of the patent as granted, claim 1 of the third auxiliary request incorporates the amendments of claim 1 of both the first and the second auxiliary requests. Therefore, the method defined in claim 1 of the third auxiliary request is not new over the method disclosed in document E2 for the same reasons given in the previous sub-paragraphs i) and ii) in respect of claim 1 of the first and the second auxiliary requests.

In view of these considerations, the board concludes that claim 1 of each of the first to third auxiliary requests is not new (Article 52(1) and 54(1) EPC) and that, therefore, none of the first to third auxiliary requests is allowable.

4. Since the ground for opposition of lack of novelty prejudices the maintenance of the patent as granted and none of the first to third auxiliary requests are allowable, the patent is to be revoked (Article 101(2), first sentence, EPC and Article 101(3)(b) EPC).
5. *Substantial procedural violation - Reimbursement of the appeal fee (Rule 103(1)(a) EPC)*
 - 5.1 The appellant requested the reimbursement of the appeal fee by reason of a substantial procedural violation during the first-instance oral proceedings.
 - 5.1.1 According to the section of the minutes of the first-instance oral proceedings pertaining to the discussion of the issue of inventive step, "For the sake of

efficiency, the chairman of the opposition division asked the opponent to present her best attack against inventive step." (point 4 of the minutes).

Subsequently, after the discussion of inventive step on the basis of document E1 as closest state of the art (point 4.1 of the minutes), "Another opportunity [was] given to the opponent [...]. The opponent wished to present the combinations E5 + E1 then E5 + E2. The opposition division then asked the opponent to present a single combination, E5 + E1 or E5 + E2. This restriction was perceived by the opponent as an infringement of the right to be heard and the opponent explicitly requested that this point be included in the protocol." (minutes, point 4.2, first paragraph).

The combination of documents E5 + E2 was then discussed and, after the parties had been informed that the appellant's submissions did not convince the opposition division, they were informed that the opposition division did "not see any reason why it should be successful with other documents than E2. The division declared that the discussion of inventive step had been concluded. The opponent wished it minuted that further inventive step arguments had not been discussed (see letter of 03.08.2018)." (minutes, point 4.2, last paragraph). Finally, after the chairman of the opposition division had stated the parties' requests, "The opponent again emphasized that her right to be heard had not been respected." (minutes, point 5).

It follows from the above that during the oral proceedings

- the appellant intended to present a line of argument of inventive step based on the combination of document E5 with document E1, and the opposition

division denied the appellant an opportunity to do so, and

- subsequently, the appellant also intended to present further comments on the issue of inventive step, and in particular on arguments previously presented with its letter dated 3 May 2018 [wrongly cited as letter dated "03.08.2018" in the passage of point 4 of the minutes mentioned above], and the opposition division also denied the appellant an opportunity to do so, and that, as submitted by the appellant, these circumstances amounted to a breach of the appellant's right to be heard under Article 113(1) EPC.

5.1.2 It is noted that the line of argument based on the combination of document E5 with document E1 was mentioned for the first time during the oral proceedings, but that the opposition division denied the appellant even an opportunity to comment on the possible relevance of the mentioned combination of documents for the outcome of the case.

It is also noted that in its written decision the opposition division concluded that the line of argument of lack of inventive step based on document E2 as closest state of the art - in particular, in combination with any of documents E1 and E4 to E7 - was not persuasive, that this line of argument was submitted in writing by the appellant in point 2.4 of the letter dated 3 May 2018 [wrongly cited as letter dated "03.08.2018" in the passage of point 4 of the minutes mentioned above], but that during the oral proceedings the opposition division denied the appellant the possibility to submit further comments on this line of argument. The respondent's submissions that the written decision was based in this respect on

the appellant's arguments already submitted in writing and that therefore the appellant had already provided arguments and had been properly heard cannot be accepted, among other reasons because that would amount to confining the right to be heard in respect of written submissions to the written proceedings and/or the right to oral proceedings to the hearing of only new arguments, which would be at variance with both Articles 113(1) and 116 EPC. In addition, the respondent's submission that repetitions of already provided arguments are unnecessary to ensure procedural economy appears to assume that during the oral proceedings the appellant intended to only repeat its arguments submitted in writing. However, this constitutes an unverifiable presumption because the appellant was denied the opportunity to comment and therefore neither the respondent nor the opposition division could ascertain whether the appellant intended to only repeat its previous written submissions or to enforce them with further, new arguments.

In addition, the right to be heard under Article 113(1) EPC constitutes one of the fundamental procedural rights of a party to proceedings, and due consideration of this right cannot be compromised solely by a question of efficiency or of procedural economy.

- 5.1.3 In view of the above considerations, the board is of the opinion that the appellant's right to be heard under Article 113(1) EPC was violated during the first-instance oral proceedings, amounting to a substantial procedural violation. In addition, it cannot be excluded that, in the event that the appellant would have had during the first-instance oral proceedings the opportunity to present the further arguments and comments referred to in points 5.1.1 and 5.1.2 above,

the opposition division would have come to the conclusion that the subject-matter of claim 1 of the patent as granted did not involve an inventive step, and in that case there would have been no need for the appellant to file an appeal - at least not in respect of the patent as granted. In view of all these considerations, and since the appeal is found by the board to be allowable, the reimbursement of the appeal fee requested by the appellant is, in the board's opinion, equitable and justified in the circumstances of the case (Rule 103(1)(a) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The European patent is revoked.
3. Reimbursement of the appeal fee is ordered.

The Registrar:

The Chairwoman:



L. Gabor

T. Karamanli

Decision electronically authenticated