

Internal distribution code:

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

**Datasheet for the decision
of 12 November 2019**

Case Number: T 0680/17 - 3.5.05

Application Number: 13151120.6

Publication Number: 2590097

IPC: G06F19/00, A61B5/00, A61B5/145

Language of the proceedings: EN

Title of invention:
Analyte testing method and system with high and low blood
glucose trends notification

Patent Proprietor:
Lifescan Scotland Limited

Opponent:
Roche Diabetes Care GmbH

Headword:
Trend notification/LIFESCAN

Relevant legal provisions:
EPC Art. 113(2), 123(2), 56

Keyword:

Admissibility of appeal - (yes)
Amendments - added subject-matter (yes)
Inventive step - (no)

Decisions cited:

Catchword:



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
Fax +49 (0)89 2399-4465

Case Number: T 0680/17 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 12 November 2019

Appellant: Lifescan Scotland Limited
(Patent Proprietor) Beechwood Park North
Inverness, Highland IV2 3ED (GB)

Representative: Carpmaels & Ransford LLP
One Southampton Row
London WC1B 5HA (GB)

Appellant: Roche Diabetes Care GmbH
(Opponent) Sandhofer Strasse 116
68305 Mannheim (DE)

Representative: Altmann Stößel Dick Patentanwälte PartG mbB
Dudenstrasse 46
68167 Mannheim (DE)

Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
10 January 2017 concerning maintenance of the
European Patent No. 2590097 in amended form.**

Composition of the Board:

Chair A. Ritzka
Members: E. Konak
G. Weiss

Summary of Facts and Submissions

- I. Appeal was filed by both the opponent and the patent proprietor against the interlocutory decision of the opposition division finding that, on the basis of auxiliary request 1, the patent in suit met the requirements of the EPC.

- II. The opposition division decided that the subject-matter of the claims as amended during the opposition proceedings did not extend beyond the content of the application as filed and involved an inventive step over the following documents:

E2: EP 2 031 534 and

E3: Peragallo-Dittko V., "Blood Glucose Monitoring", Internet disclosure with URL <http://www.diabetesselfmanagement.com/managing-diabetes/blood-glucose-management/blood-glucose-monitoring/>, 20 July 2006.

- III. The patent proprietor requested that the decision under appeal be set aside and the patent be maintained as granted (main request), or alternatively on the basis of auxiliary requests 1 or 2, filed with the statement setting out the grounds of appeal.

- IV. The opponent requested that the decision under appeal be set aside and the patent be revoked in its entirety. It further requested the reimbursement of the appeal fee. With regard to the appeal filed by the patent proprietor, the opponent requested that this appeal be held inadmissible.

V. The opponent filed *inter alia* the following document related to E3 which was an internet citation:

E3a: Peragallo-Dittko V., "Blood glucose monitoring. What do the numbers tell you?", Diabetes Self Management, September-October 2005, pages 65-68

VI. The board summoned the parties to oral proceedings. In response to the preliminary opinion of the board issued before the oral proceedings, the patent proprietor filed auxiliary requests 2 to 4 to conditionally replace auxiliary request 2 on file if they were deemed admissible by the board.

VII. Oral proceedings were held before the board. At the end of the oral proceedings, the opponent withdrew its request for the reimbursement of the appeal fee.

VIII. Claim 1 of the patent in suit (main request) reads as follows:

"A method of notifying a user of high or low trends in blood glucose values obtained with a diabetes management unit having a microprocessor coupled to a display, memory and user interface buttons, the method comprising:

performing with the microprocessor, a plurality of blood glucose measurements of the user;

storing in the memory, the plurality of blood glucose measurements;

determining whether a most recent blood glucose measurement at a given time during a day is below a first threshold, or above a second threshold and whether the most recent blood glucose measurement at a given time during a day is flagged as a measurement

made before a meal or a measurement made during a fasting period upon the determining being true, evaluating with the microprocessor, whether at least one blood glucose measurement of the plurality of blood glucose measurements performed within a time frame of X hours about the given time of the most recent blood glucose measurement over a period of N recent days, is lower than the first a [sic] threshold or higher than the second threshold; and upon achievement of the evaluating step, annunciating that in the same time frame over the N number of days, the plurality of blood glucose measurements indicates a blood glucose trend lower than the first threshold or higher than the second threshold."

- IX. Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the text "N recent days" has been replaced with the text "N most recent days".
- X. Claim 1 of auxiliary request 2 differs from claim 1 of auxiliary request 1 in that the text ", if above the second threshold" has been added after the conjunction "and" in the determining step.
- XI. Claim 1 of auxiliary request 3 reads as follows (with the additions with respect to claim 1 of auxiliary request 1 underlined and the deletions struck through):
- "A method of notifying a user of high or low trends in blood glucose values obtained with a diabetes management unit having a microprocessor coupled to a display, memory and user interface buttons, the method comprising:
- a. performing with the microprocessor, a plurality of blood glucose measurements of the user;

- b. storing in the memory, the plurality of blood glucose measurements;
- c. determining whether a most recent blood glucose measurement at a given time during a day is below a first threshold, or above a second threshold and ~~whether the most recent blood glucose measurement at a given time during a day is~~ flagged as a measurement made before a meal or a measurement made during a fasting period;
- d1. upon the determining step c being true that the most recent blood glucose measurement is below the first threshold, evaluating with the microprocessor, whether at least one blood glucose measurement of the plurality of blood glucose measurements performed within a time frame of X hours about the given time of the most recent blood glucose measurement over a period of ~~N~~ the most recent N days, is lower than the first a threshold; ~~or higher than the second threshold;~~ and
- e1. upon achievement of the evaluating step d1, annunciating that in the same time frame over the N number of days, the plurality of blood glucose measurements indicates a blood glucose trend lower than the first threshold ~~or higher than the second threshold;~~
- d2. upon the determining step c being true that the most recent blood glucose measurement is above the second threshold and flagged as a measurement made before a meal or a measurement made during a fasting period, evaluating with the microprocessor, whether at least one blood glucose measurement of the plurality of blood glucose measurements performed within the time frame of X hours about the given time of the most recent blood glucose measurement over the period of the most recent N days, is higher than the second threshold; and

e2. upon achievement of the evaluating step d2, announcing that in the same time frame over the N number of days, the plurality of blood glucose measurements indicates a blood glucose trend higher than the second threshold."

- XII. Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 3 in that the text ", if above the second threshold" has been added after the conjunction "and" in step c.

Reasons for the Decision

1. Admissibility of the patent proprietor's appeal
 - 1.1 The opponent, referring to points 8 and 14 of the minutes of the oral proceedings held before the opposition division, argued that the patent proprietor had replaced its main request during the oral proceedings with another request entitled "New First Request" which corresponds to auxiliary request 1, on which basis the contested decision maintained the patent in suit. It held that the patent proprietor had thus withdrawn its main request to later re-file it during the oral proceedings and that the opposition division re-admitted this withdrawn request without any legal basis. Thus, the proprietor was actually not adversely affected by the decision and consequently its appeal was not admissible.
 - 1.2 As a matter of fact and experience, participants of oral proceedings may from time to time misunderstand each other's statements. Statements regarding the filing, replacement and withdrawal of requests are not exempt from this. Therefore, the chair conducting the

oral proceedings normally asks for confirmation of the requests currently on file at different time points during the oral proceedings and before the division reaches a final decision. In the present case, it is clear from the minutes of the oral proceedings that there was such a misunderstanding during the oral proceedings. This misunderstanding seems to have become apparent to the proprietor at the time corresponding to point 14 of the minutes where it corrected the status of its requests. As a consequence of the principle of party disposition (Article 113(2) EPC), this correction corresponds to the proprietor's requests valid at that time.

1.3 The opponent argued that there was extensive case law concerning the correction of procedural statements made in the written procedure, according to which such a correction could only be possible before it was made public. Since the oral proceedings before an opposition division are public, the public was informed immediately that the main request was withdrawn, and therefore this statement of withdrawal could not have been corrected anymore. However, this analogy does not hold. Errors made in writing during a written procedure which are then notified to the public by the EPO cannot be compared to an error made in speech during oral proceedings which was never notified to the public by the EPO without the ensuing correction.

1.4 Therefore, the board does not agree with the opponent's argument that the main request was ever withdrawn. As the proprietor's main request was rejected in the contested decision, the proprietor is adversely affected by the decision and thus entitled to appeal (Article 107 EPC).

2. Claim interpretation

2.1 A major matter of dispute between the parties is the correct interpretation of the statement "determining whether a most recent blood glucose measurement at a given time during a day is below a first threshold, **or** above a second threshold **and** whether the most recent blood glucose measurement at a given time during a day is flagged as a measurement made before a meal or a measurement made during a fasting period" in claim 1 of the patent in suit.

2.2 A statement with more than one logical connective intrinsically gives rise to clarity problems, namely the correct order in which the logical connectives should be read. This is the reason why in logic and programming, expressions comprising more than one logical connective are habitually clarified by means of parentheses, and often an order of precedence is predefined to set the rules for use in the absence of parentheses.

2.3 As the disputed statement in the present case does not have any clarifying parentheses and the order of precedence of the logical connectives is not clear as such, the disputed statement is intrinsically unclear.

2.4 If a claim is unclear as such, the usual way of interpreting it is to look at the description and the drawings. In the present case, paragraphs [0038] and [0040], "embodiments" 2 and 5 in paragraph [0064] as originally filed, and figures 3 and 4 of the application as originally filed were the passages taken into consideration in the opposition proceedings and the submissions of the parties in appeal.

2.5 From "embodiments" 2 and 5 in paragraph [0064] as originally filed, it is not possible to derive any meaningful teaching in this respect. Embodiment 5 reads "the method of any one of the embodiments 1-4, in which **the determining further comprises** confirming whether the most recent blood glucose measure was flagged as (a) a measurement made before a meal or (b) a measurement made during a fasting period" and does not specify which sub-step of the determining step in embodiment 2 should include the confirming step.

2.6 Therefore, the only meaningful embodiment which can be used to interpret the unclear statement in claim 1 remains the one in paragraphs [0038] and [0040] as originally filed in combination with figures 3 and 4, to which these paragraphs refer. It is beyond dispute that the only interpretation supported by this embodiment would be the reading "determining (whether a most recent blood glucose measurement at a given time during a day is below a first threshold **OR** (whether a most recent blood glucose measurement at a given time during a day is above a second threshold **AND** whether the most recent blood glucose measurement at a given time during a day is flagged as a measurement made before a meal or a measurement made during a fasting period))".

2.7 In its preliminary opinion issued before the oral proceedings, the board informed the parties of its claim interpretation as above. The parties did not comment on it and the board sees no reason to depart from it.

3. Main request

3.1 Added subject-matter

- 3.1.1 The contested decision found two different violations of Article 123(2) EPC in claim 1 of the main request.
- 3.1.2 The first violation (point 1.5 of the reasons in the contested decision) was based on the premise that claim 1 of the main request had two "coexisting" interpretations, one of which was based on paragraph [0064] of the application as originally filed. As the board cannot see any meaningful teaching in this paragraph (see 2.4 above), it also does not agree with any of the conclusions drawn from it.
- 3.1.3 The second violation (point 2 of the reasons in the contested decision) concerned the omission of the word "most" in the amended expression "N recent day" in claim 1 of the main request. Although paragraphs [0038] and [0040], as originally filed, consistently referred to "the most recent N days" or "the previous N number of days", this limitation was absent in claim 1 of the main request. The board agrees with this finding. The proprietor argued in its statement setting out the grounds of appeal (see page 4, last paragraph) that "dependent claim 6 of the underlying PCT application referred to 'the recent N number of days' without the term 'most'". However, claim 6 as originally filed reads "the method of claim 2, in which the second threshold comprises about 150 mg of glucose per deciliter of blood" and does not comprise any of the wording cited by the proprietor. The board noted in its preliminary opinion issued before the oral proceedings that "embodiment" 6 in paragraph [0064] as originally filed did have the wording cited by the proprietor and therefore the proprietor might indeed have been referring to this passage. However, the board added that even if it were so, it would not be possible to

derive any meaningful teaching from this unclear paragraph (see 2.5 above). The proprietor did not comment on this.

3.1.4 A further objection under Article 123(2) EPC was raised by the opponent, concerning the order of the two steps in "determining whether a most recent blood glucose measurement at a given time during a day is [...] above a second threshold and whether the most recent blood glucose measurement at a given time during a day is flagged as a measurement made before a meal or a measurement made during a fasting period". As stated above, paragraphs [0038] and [0040] of the application as originally filed, in combination with figures 3 and 4, are the only possible basis for claim 1 of the main request. The opponent convincingly argued that the embodiment in this passage prescribed an order of checking whether the most recent blood glucose measurement is above a second threshold and only then (arrow "Yes" between boxes 502 and 504 in figure 4) checking the flagging. This prescribed order was absent in the determining step of claim 1 of the main request, the resulting generalisation containing subject-matter extending beyond the content of the application as originally filed. The proprietor did not comment on this, either.

3.1.5 Therefore, for the reasons given under points 3.1.3 and 3.1.4 above, claim 1 of the main request does not meet the requirements of Article 123(2) EPC.

3.2 Admissibility of E3a

3.2.1 The board communicated in its preliminary opinion issued before the oral proceedings that it was minded not to admit the late-filed document E3a, as it could

have been filed during the opposition proceedings, and furthermore the date of publication of the internet citation E3 had never been a matter of dispute so as to necessitate the filing of a publication, i.e. E3a, with the same content as E3.

3.2.2 However, at the oral proceedings the proprietor itself requested that E3a be admitted into the proceedings. It argued that E3a was the "actual" E3. Following the source URL at the end of E3 in the Wayback Machine would lead you to a webpage with the content of E3, but with the following additional link at the end: "Also in this article:

Blood Glucose Meter Averages: Don't Be Fooled".

Following this link would then lead you to another part of the article which was missing in E3 as filed by the opponent, but was present in E3a. The proprietor presented printouts of these webpages as evidence. Consequently, the board admitted E3a.

3.3 Inventive step

3.3.1 The opponent's main attack on inventive step is based on E3, second page, fourth paragraph, which is the same text as E3a, second page, first full paragraph.

3.3.2 In its written submissions, the proprietor argued that there was no disclosure of using thresholds in E3. 246 mg/dl mentioned in the relevant passage was simply indicated as being "out of range". This argument does not convince the board, as being "out of range" means being below or above a threshold. In the present case, given the skilled person's general knowledge with regard to normal range of blood glucose values, it is also clear that this value is above the higher threshold. As it is also a reading performed "before

lunch", it is clear that this value is flagged as a measurement made before a meal. Therefore, the board agrees with the opponent that E3/E3a discloses determining whether a most recent blood glucose measurement at a given time during a day is above a second threshold and whether it is flagged as a measurement made before a meal, i.e. the determining step of claim 1 of the main request.

3.3.3 The opponent argued that in E3/E3a, after this determination step, earlier values were checked for further deviations and only after a further deviating value had been identified was the deviation considered relevant. However, the proprietor held that according to E3/E3a the user already knew their pattern upon obtaining the reading 246 mg/dl, so there was no need to evaluate previous values. The contested decision likewise states that in E3 the user knows their usual pattern before making the most recent measurement. Accordingly, the contested decision concluded that E3 did not disclose an evaluation of previous measurements "upon the determining of step c being true", as required in claim 1 of the main request.

3.3.4 The board is not convinced by the reasoning of the proprietor and the contested decision. The expression "know your pattern" in the relevant passage in E3/E3a is rather idiomatic and does not mean much by itself. It is also clear that the word "pattern" is not used in this passage in the same sense as the "low trend" or "high trend" in the patent in suit. E3/E3a instead refers to a series of blood glucose readings consisting of 118 mg/dl, 110 mg/dl and 113 mg/dl as "your usual pattern". It is clear that these values are all in the normal blood glucose range, and are neither a "low trend" nor a "high trend". Therefore, the board does

not agree that the user in E3/E3a already "knows their pattern", in the sense that they already know their low or high trend. E3/E3a instead refers to a "high trend" as being "noteworthy" (last word of the relevant paragraph).

- 3.3.5 At the oral proceedings, the proprietor argued that E3/E3a taught what "isn't noteworthy", but not what would be "noteworthy". The relevant passage did not even specify that the values of 118 mg/dl, 110 mg/dl and 113 mg/dl were normal or in general what was normal. However, the opponent convincingly argued that E3/E3a defines three paragraphs before the relevant paragraph "What's normal?", where it also mentions the target range defined by the ADA, and specifies in the paragraph preceding the relevant paragraph the target range used in the example as the ADA target range, i.e. 70-130 mg/dl. It was also self-explanatory from the description of what was not noteworthy in this passage that the recurrence of an out-of-range value within three days in a row would be "noteworthy".
- 3.3.6 The board therefore agrees with the opponent that E3/E3a indeed discloses the algorithm underlying the method of claim 1 of the main request. In particular, upon determining that the most recent blood glucose reading is above a threshold and a measurement made before a meal ("So you check your blood glucose **before lunch** ... get a reading of **246** ... You know that your reading is **out of range, so what?**"), it evaluates whether there are other high readings within the same time frame over the most recent three days ("**three days in a row before lunch** ... doesn't **fit** your **usual pattern**").

3.3.7 In E3/E3a, these steps are performed by the user, whereas in claim 1 of the main request they are performed by a microprocessor. However, the board agrees with the opponent that implementing this algorithm as software running on a blood glucose meter that is well-known in the relevant art does not involve an inventive step. The proprietor argued at the oral proceedings that there was no disclosure in E3/E3a of how the algorithm could be implemented in a blood glucose meter. The opponent convincingly refuted this argument by drawing attention to the fact that E3/E3a was not written for a technical audience but for laypeople, namely patients, and expressed its teaching in terms of how the patient should interpret their blood glucose readings, however for a person skilled in the art reading E3/E3a the implementation of the disclosed algorithm as software in a blood glucose meter would be straightforward. The proprietor then argued that the section of E3a with the title "Blood Glucose Meter Averages: Don't Be Fooled", which is missing in E3, did disclose a particular glucose meter implementation which relied on blood glucose averages. It would thus be against the teaching of E3a to implement another algorithm in a blood glucose meter. However, the board agrees with the opponent that this section cannot be called the blood glucose meter implementation of E3a. It instead mentions blood glucose meters on the market and warns its audience, i.e. laypeople, not to be "fooled" by potentially misleading blood glucose averages calculated by these meters.

3.3.8 Therefore, the subject-matter of claim 1 of the main request does not involve an inventive step (Article 56 EPC).

4. Auxiliary requests 1 and 3

4.1 As the order of steps prescribed in paragraphs [0038] and [0040] and figures 3 and 4 of the application as originally filed, discussed under point 3.1.4 above, is also absent in the determining step of claim 1 of auxiliary requests 1 and 3, claim 1 of these two requests does not meet the requirements of Article 123(2) EPC.

5. Auxiliary requests 2 and 4

5.1 Admissibility of the requests

5.1.1 Auxiliary requests 2 and 4 were filed in reply to the board's preliminary opinion issued before the oral proceedings.

5.1.2 The opponent requested that these requests not be admitted into the proceedings, because they were late-filed and were *prima facie* not allowable.

5.1.3 However, the proprietor convincingly argued that the particular objection of added subject-matter that these requests intended to overcome was the one discussed under point 3.1.4 above and was raised by the opponent for the first time in its letter of reply to the proprietor's statement setting out the grounds of appeal. The proprietor was not directed by the board to react to this letter. Therefore, the board's preliminary opinion issued before the oral proceedings was indeed the first chance during the proceedings for the proprietor to file these requests.

5.1.4 Therefore, the board decided to admit these requests (Article 13(1) RPBA).

5.2 Inventive step in auxiliary request 2

5.2.1 Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the objections under Article 123(2) EPC (see points 3.1.3 and 3.1.4 above) were successfully addressed. The amendment which is of relevance to the issue of inventive step is that the order of execution of the steps of determining whether a most recent blood glucose measurement at a given time during a day is above a second threshold and determining whether the measurement is flagged as a measurement made before a meal or a measurement made during a fasting period was specified such that the execution of the latter step is conditional upon a positive result of the first step (cf. "if above the second threshold").

5.2.2 The proprietor argued that the overall teaching of E3/E3a was that there were many factors that could influence blood glucose levels. E3/E3a did not attach any significance to the order in which any factor was taken into account. The passage in E3, second page, fourth paragraph or E3a, second page, first full paragraph actually taught the reverse order, as the measurement was already flagged as a measurement made before a meal in the user's mind even before the result of the measurement was read. These arguments do not convince the board. The board agrees with the opponent that the points that the proprietor raised are not relevant. There are logically two ways of carrying out these two steps, either the first one before the second or the other way round. It would thus not involve an inventive step to choose one of these possibilities. Furthermore, as the opponent noted, when checking two conditions automatically on a glucose meter, it would

make more sense to first check the condition that occurs less often, namely whether the value is out of range, rather than a "before a meal" or "fasting period" flag.

5.2.3 Therefore, the subject-matter of claim 1 of auxiliary request 2 does not involve an inventive step (Article 56 EPC).

5.3 Inventive step in auxiliary request 4

5.3.1 Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 2 in that each of the evaluating and annunciating steps were split into two for the two situations that may be detected by the determining step: (1) the most recent blood glucose measurement at a given time during a day is below a first threshold or (2) the most recent blood glucose measurement at a given time during a day is above a second threshold and the measurement is flagged as a measurement made before a meal or a measurement made during a fasting period.

5.3.2 The proprietor argued that claim 1 of auxiliary request 4 included the low trend situation which was not disclosed in E3/E3a. The opponent countered that the relevant passage in E3/E3a refers to a reading being "out of range" which also covers values indicative of a low trend. More crucially, the opponent questioned whether this split had any effect on the scope of protection sought, compared to claim 1 of auxiliary request 2, as the high trend situation, also described in E3/E3a, was still within the scope of the claim. The proprietor submitted that claim 1 of auxiliary request 4 clearly requires the steps to be carried out for both situations. The board is however not convinced of this argument, since a blood glucose measurement cannot be

below the lower threshold of the normal range and above the higher threshold of the normal range at the same time and therefore one cannot carry out all of the steps d1, e1, d2 and e2. Consequently, the reasons for the lack of an inventive activity in claim 1 of auxiliary request 2 apply equally to claim 1 of auxiliary request 4.

5.3.3 Therefore, the subject-matter of claim 1 of auxiliary request 4 does not involve an inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.
3. The appeal of the patent proprietor is dismissed.

The Registrar:

The Chair:



K. Götz-Wein

A. Ritzka

Decision electronically authenticated