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Datasheet for the decision of 26 July 2024

Case Number: T 1741/22 - 3.5.05

Application Number: 16153964.8

Publication Number: 3203396

IPC: G06F19/00

Language of the proceedings: EN

Title of invention:
System and method for analyzing glucose monitoring data indicative of a glucose level, and a computer program product

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

Headword:
New medical data/ROCHE

Relevant legal provisions:
EPC Art. 84, 56
RPBA 2020 Art. 20(1), 20(2)
Guidelines for examination, Part G, Chapter II, 3.3

Keyword:
Claims - clarity (no)
Inventive step - (no): no credible technical effect produced by deriving additional data from medical measurements

Decisions cited:
G 0001/04, G 0001/19, T 2681/16, T 1091/17, T 1910/20, T 0335/21

Catchword:
The mere generation of further data from measurement data already collected from the human body is not a technical effect (T 2681/16 and the Guidelines for Examination not followed). See Reasons 2.3 of the decision.

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Case Number: T 1741/22 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 26 July 2024

Appellant 1: (Applicant 1)	Roche Diabetes Care GmbH Sandhofer Straße 116 68305 Mannheim (DE)
Appellant 2: (Applicant 2)	F. Hoffmann-La Roche AG Grenzacherstrasse 124 4070 Basel (CH)
Representative:	Bittner, Thomas L. Boehmert & Boehmert Anwaltspartnerschaft mbB Pettenkoferstrasse 22 80336 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 16 February 2022 refusing European patent application No. 16153964.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	K. Bengi-Akyürek
Members:	E. Konak
	C. Heath

Summary of Facts and Submissions

I. The appeal is against the examining division's decision to refuse the present application. The examining division decided that the **main request** and **auxiliary requests 1 to 4** did not comply with Articles 84 and 56 EPC.

II. In the present decision, reference is made to the following prior-art document:

D1: US 2014/0188400 A1.

III. Oral proceedings were held before the board on 26 July 2024.

The appellants' final requests were that the decision under appeal be set aside and that a patent be granted on the basis of the claims of the **main request** or of one of **auxiliary requests 1 to 4** re-filed with the statement of grounds of appeal, or on the basis of the claims of one of **auxiliary requests 5 to 14** filed with the statement of grounds of appeal.

At the end of the oral proceedings, the board's decision was announced.

IV. Claim 1 of the **main request** reads as follows:

"A system for analyzing glucose monitoring data indicative of a glucose level in a bodily fluid, comprising:
- an input device (3),
- a data processing device (1),
- an output device (4),

- a display device (5), and
- machine readable instructions that are executed by the data processing device, wherein the machine readable instructions cause the data processing device (1) to
    - receive continuous glucose monitoring data via the input device (3), the continuous glucose monitoring data
        - indicating a glucose level sampled for a person in a bodily fluid at a plurality of sample times over a measurement time period in a continuous glucose level measurement, and
        - comprising a plurality of continuous glucose profiles, each of the glucose profiles comprising a plurality of glucose values with a glucose value for each of the plurality of sample times over the measurement period;
    - for the plurality of continuous glucose profiles, determine at least one of a plurality of minimum glucose values and a plurality of maximum glucose values for a selected group or each of the plurality of sample times;
    - provide first display signals representing at least one of the plurality of minimum glucose values and the plurality of maximum glucose values for the selected group or each of the plurality of sample times;
    - output the first display signals via the output device (4) to the display device (5); and
    - display a first graphical representation according to the first display signals on the display device (5)."

Claim 1 of **auxiliary request 1** differs from claim 1 of the main request as follows (with the deletions ~~struck through~~):

"[...]
- for the plurality of continuous glucose profiles, determine at least one of a plurality of minimum glucose values and a plurality of maximum glucose values for ~~a selected group or~~ each of the plurality of sample times;
- provide first display signals representing at least one of the plurality of minimum glucose values and the plurality of maximum glucose values for ~~the selected group or~~ each of the plurality of sample times;
[...]"

Claim 1 of **auxiliary request 2** differs from claim 1 of auxiliary request 1 as follows (with the additions underlined):

"[...]
- provide continuous first display signals representing a continuous curve of at least one of the plurality of minimum glucose values and the plurality of maximum glucose values for each of the plurality of sample times;
[...]"

Claim 1 of **auxiliary request 3** differs from claim 1 of auxiliary request 2 as follows (with the additions underlined):

"[...]
- for the plurality of continuous glucose profiles, determine
  - at least one of a plurality of minimum glucose values and a plurality of maximum glucose values for each of the plurality of sample times; and

- an ambulatory glucose profile for the plurality of glucose values of the plurality of glucose profiles;
- substitute, for one or more sample times,
- one of the plurality of minimum glucose values by a pre-determined low glucose value if the minimum glucose value is determined higher than the pre-determined low glucose value and / or
- one of the plurality of maximum glucose values by a pre-determined high glucose value if the maximum glucose value is determined smaller than the pre-determined high glucose value;
- provide continuous first display signals representing a continuous curve of at least one of the plurality of minimum glucose values and the plurality of maximum glucose values for each of the plurality of sample times, and further representing the ambulatory glucose profile;

[...]"

Claim 1 of **auxiliary request 4** differs from claim 1 of auxiliary request 3 as follows (with the additions underlined and the deletions ~~struck through~~):

"[...]

- an ambulatory glucose profile for the plurality of glucose values of the plurality of glucose profiles, the ambulatory glucose profile representing a median curve, 25th and 75th percentile curves and 10th and 90th percentile curves for the glucose values collected over a period of time;
- substitute, for one or more sample times,
- one of the plurality of minimum glucose values by a pre-determined low glucose value if the

minimum glucose value is determined higher than the pre-determined low glucose value and / or
- one of the plurality of maximum glucose values by a pre-determined high glucose value if the maximum glucose value is determined smaller than the pre-determined high glucose value;
wherein at least one of the pre-determined low glucose value and the pre-determined high glucose value corresponds to a percentile of the plurality of glucose values assigned to the plurality of glucose profiles, the percentile being selected from a 10th percentile and a 90th percentile;
[...]"

Claim 1 of **auxiliary request 5** differs from claim 1 of the main request as follows (with the additions underlined and the deletions ~~struck through~~):

"[...]
- for the plurality of continuous glucose profiles, determine ~~at least one of~~ a plurality of minimum glucose values and/or a plurality of maximum glucose values for a selected group or each of the plurality of respective sample times;
- provide first display signals representing ~~at least one~~ of the plurality of minimum glucose values and/or the plurality of maximum glucose values for the selected group or each of the plurality of respective sample times;
[...]"

Claim 1 of **auxiliary request 6** differs from claim 1 of auxiliary request 1 as follows (with the deletions ~~struck through~~):

"[...]

- for the plurality of continuous glucose profiles, determine ~~at least one of~~ a plurality of minimum glucose values and/or a plurality of maximum glucose values for each of the plurality of respective sample times;
- provide first display signals representing ~~at least one of~~ the plurality of minimum glucose values and/or the plurality of maximum glucose values for each of the plurality of respective sample times;

[...]"

Claim 1 of **auxiliary request 7** differs from claim 1 of auxiliary request 2 as follows (with the additions underlined):

"[...]
- for the plurality of continuous glucose profiles, determine ~~at least one of~~ a plurality of minimum glucose values and/or a plurality of maximum glucose values for each of the plurality of respective sample times;
- provide continuous first display signals representing a continuous curve of ~~at least one of~~ the plurality of minimum glucose values and/or the plurality of maximum glucose values for each of the plurality of respective sample times;

[...]"

Claim 1 of **auxiliary requests 8 and 9** differs, respectively, from claim 1 of auxiliary requests 3 and 4 as follows (with the additions underlined):

"[...]
- for the plurality of continuous glucose profiles, determine

- ~~at least one of~~ a plurality of minimum glucose values and/or a plurality of maximum glucose values for each of the plurality of respective sample times; and

[...]

- provide continuous first display signals representing a continuous curve of ~~at least one of~~ the plurality of minimum glucose values and/or the plurality of maximum glucose values for each of the plurality of respective sample times, and further representing the ambulatory glucose profile;

[...]"

Claim 1 of **auxiliary requests 10 to 14** differs, respectively, from claim 1 of auxiliary requests 5 to 9 as follows (with the additions underlined):

"[...]

- comprising a plurality of continuous glucose profiles, each of the glucose profiles comprising a plurality of glucose values with a glucose value for each of the plurality of sample times over the measurement period, wherein the plurality of glucose profiles is determined on different days by sampling the glucose level on each day over the measurement period, wherein the measurement period is 24 hours;

[...]"

Reasons for the Decision

1. Main request and auxiliary requests 1 to 9

1.1 The board fully agrees with the clarity objections raised in the contested decision. Claim 1 of the **main**

request and **auxiliary requests 1 to 4** is practically unintelligible without referring to the description and the drawings. Moreover, the amendments to claim 1 of **auxiliary requests 5 to 9** fail to resolve this issue. Most essentially, the temporal scope and relationship of "measurement (time) period(s)" and "sample times" is not clear in claim 1 of any of these claim requests.

The appellants argued that the claims were broad but indeed clear, as the skilled person would not take into consideration "time periods" which would medically not be meaningful. However, the board sees no justification in formulating a claim so abstract that it covers a broad range of meaningless selections of measurement periods, such as one-hour periods on the same day, leaving the reader with an undue burden to speculate on the intended scope of the claims.

1.2 Therefore, claim 1 of the main request and auxiliary requests 1 to 9 does not meet the requirement of Article 84 EPC.

2. Auxiliary request 10 - Inventive step (Article 56 EPC)

2.1 Claim 1 of **auxiliary request 10** contains the following limiting features (board's labelling):

(a) A system for analysing glucose monitoring data indicative of a glucose level in a bodily fluid, comprising: an input device, a data processing device, an output device, a display device, and machine-readable instructions that are executed by the data processing device,
(b) [wherein the machine-readable instructions cause the data processing device to] receive continuous glucose monitoring data via the input device, the

continuous glucose monitoring data indicating a glucose level sampled for a person in a bodily fluid at a plurality of sample times over a measurement time period in a continuous glucose level measurement, and comprising a plurality of continuous glucose profiles, each of the glucose profiles comprising a plurality of glucose values with a glucose value for each of the plurality of sample times over the measurement period, wherein the plurality of glucose profiles is determined on different days by sampling the glucose level on each day over the measurement period, wherein the measurement period is 24 hours;

(c) [wherein the machine-readable instructions cause the data processing device to] for the plurality of continuous glucose profiles, determine a plurality of minimum glucose values and/or a plurality of maximum glucose values for a selected group or each of the plurality of respective sample times

(d) [wherein the machine-readable instructions cause the data processing device to] provide first display signals representing the plurality of minimum glucose values and/or the plurality of maximum glucose values for the selected group or each of the plurality of respective sample times;

(e) [wherein the machine-readable instructions cause the data processing device to] output the first display signals via the output device to the display device; and display a first graphical representation according to the first display signals on the display device.

2.2 The appellants argued that the distinguishing features of claim 1 of auxiliary request 10 over **D1** were **features (c) and (d)**, i.e. determining and displaying minimum/maximum glucose values. They stated that the

technical effect of the distinguishing features was to provide an "improved analysis of glucose monitoring data". In particular, "the plurality of minimum/maximum glucose values may correspond to medically relevant outlier values", which "would otherwise be averaged out in the context of known methods employing percentiles as in D1". They emphasised that the technical effect did not lie in a mere "presentation of information" but in that "new data was generated". Accordingly, they formulated the objective technical problem as providing a system for "improved analysis of glucose monitoring data for guidance of a patient or physician".

2.3 However, the board is not convinced that features (c) and (d) contribute to the technical character of the invention.

2.3.1 The appellants persistently emphasised, also at the oral proceedings before the board, that the invention generated "**new data**" from glucose monitoring data. However, if the mere generation of "new data" were sufficient to contribute to the technical character of the invention, Article 52(2) and (3) EPC would contain meaningless limitations of patentable subject-matter, as e.g. mathematical methods are supposed to constantly generate "new data".

2.3.2 A subset of "new data" that might have been relevant for assessing the contribution to the technical character of the invention in the context of the case at hand could have been a new "collection" of data practised on the human or animal body. Here, the board uses the word "collection" within the same meaning as in **G 1/04** referring to "(i) the examination phase [of a diagnostic method] involving the collection of data" (**G 1/04**, Reasons 5). More recent jurisprudence of

the Enlarged Board of Appeal seems to prefer the word "measurement" (**G 1/19**, Reasons 85 and 99), which involves the calculation of the physical state of an object (i.e. a certain glucose level in a "bodily fluid" in the case at hand). As stated in **G 1/19** (Reasons 99), it is generally acknowledged that *measurements* have technical character since they are based on an interaction with physical reality, such as the human or animal body (see **G 1/04**, Reasons 6.4.1).

2.3.3 In the case at hand, features (c) and (d) do not involve the actual *measurement* of the respective glucose level in a bodily fluid. Instead, they process *already* measured and received continuous glucose monitoring data to generate and display further "new data", namely a plurality of minimum/maximum glucose values, in order to support a physician in their purely intellectual deductive decision phases of diagnosis and therapy. Such subsequent processing of certain measurement data collected from the human or animal body is "predominantly of a non-technical nature" (*ibid.*). Thus, it cannot contribute to the technical character of the invention.

2.3.4 This interpretation of the Convention and of the conclusions of the Enlarged Board of Appeal have also been adopted in earlier decisions of this board (see e.g. **T 1091/17**, Reasons 1.8; **T 1910/20**, Reasons 1 and 2; **T 335/21**, Reasons 1.2 and 1.3).

2.3.5 However, at the oral proceedings before the board, the appellants referred to **T 2681/16** and to the Guidelines for Examination in the EPO in support of their view. In particular, the appellants considered the case in **T 2681/16** to be analogous to the case at hand. The competent board in that case dealt with distinguishing

features related to an algorithm to process already acquired, i.e. measured, blood glucose data points. The board acknowledged that these features, when taken in isolation, were non-technical, and could support the presence of an inventive step only if they credibly contributed to producing a technical effect serving a technical purpose (Reasons 3.2.3). However, the board then accepted the technical effect alleged by the appellant (Reasons 3.2.4), namely "providing an overall measure of the glucose variability (i.e. equally sensitive to both hypo- and hyperglycemic events) and a prediction of glycemic events that were better than, or at least alternative to, those used in [the closest prior art]". Whereas the board concluded that this technical effect was not achieved over the whole scope of the claim in a higher-ranking request (Reasons 3.2.5 ff.), it was satisfied that this effect was achieved over the whole scope of the claim in a lower-ranking request (Reasons 6.2.1).

2.3.6 This board is not in agreement with and therefore deviates from the interpretation of the Convention given in **T 2681/16**. According to Article 20(1) RPBA, should a board consider it necessary to deviate from an interpretation of the Convention given in an earlier decision of any Board, the grounds for this deviation shall be given, unless such grounds are in accordance with an earlier decision or opinion of the Enlarged Board of Appeal according to Article 112(1) EPC. In particular, the board disagrees with the finding in **T 2681/16** that providing an overall "measure" of the glucose variability and a prediction of glycemic events amounts to a *technical* effect. The board is well aware of the tendency of applicants to use the word "measure(ment)" liberally in order to give inventions the veneer of technicality. This is mainly because it

is generally acknowledged in the jurisprudence of the Boards of Appeal that "measurements" have technical character. Admittedly, the applicants' use may indeed well correspond to the meaning of the word in common parlance. However, a prerequisite for a "measurement" with technical character, within the meaning of the jurisprudence of the Boards of Appeal, is an *interaction* with "physical reality" for the calculation of the physical state of an object, even if the measurement may be carried out indirectly, e.g. by means of measurements of another physical entity (see **G 1/19**, Reasons 99). In the present case and in the case underlying **T 2681/16**, where the "physical reality" is typically the "patient's blood", the interaction with the physical reality ends once blood glucose measurements are carried out, directly on the relevant physical entity "blood", or indirectly e.g. on another bodily fluid. The *provision* of overall glucose variability and a prediction of glycemic events are mathematical steps or intellectual activities which take place in the absence of this *interaction* with the physical reality and are therefore not "measurements" in this sense. In other words, the taking of a *sample* on the patient is an interaction with "physical reality". Generating *new data* as a consequence of this interaction may result in "measurements" of a technical nature. But generating (and displaying) *further data* by an evaluation or interpretation of these measurements (as done according to features (c) and (d) here) amounts to "measurements" generated merely by a cognitive or mathematical exercise that is inherently non-technical.

2.3.7 As to the Guidelines for Examination in the EPO (in its applicable version of March 2022 and also in its current version of March 2024), section G-II, 3.3,

which relates to the technical contribution of mathematical methods, lists

> "providing a medical diagnosis by an automated system processing physiological measurements"

among "examples of technical contributions of a mathematical method". As providing a "medical diagnosis" - whether done by a physician or by an automated system - is devoid of any technical character (see e.g. **G 1/04**, Reasons 5.3 and 6.3), this example is clearly erroneous. As there is no further explanation, let alone a reference to any case law, the board sees no reason to speculate on how the Guidelines came up with this example (cf. Article 20(2) RPBA).

2.4 In view of the above, the subject-matter of claim 1 of auxiliary request 10 does not involve an inventive step (Article 56 EPC).

3. Auxiliary request 11 - Inventive step

3.1 Claim 1 of **auxiliary request 11** differs from claim 1 of auxiliary request 10 in that the phrase "a selected group or" was deleted in **feature (c)** and the corresponding text "the selected group or" was deleted in **feature (d)**.

3.2 The appellants emphasised that through this amendment "medically relevant outlier values were provided for each and every sample time of the underlying measurement time period", resulting in a more comprehensive data set. They stated that the same objective technical problem was solved by claim 1 of auxiliary request 10.

3.3 However, whether the "minimum/maximum glucose value" are determined only for a *selected* group or for *each and every* sample time has no bearing on the assessment whether **features (c) and (d)** contribute to the technical character of the invention.

3.4 Therefore, the subject-matter of claim 1 of auxiliary request 11 does not involve an inventive step either (Article 56 EPC).

4. Auxiliary request 12 - Inventive step

4.1 Claim 1 of **auxiliary request 12** differs from claim 1 of auxiliary request 11 in that **feature (d)** was amended, i.e. "provide continuous first display signals representing a continuous curve of the plurality of minimum glucose values and/or the plurality of maximum glucose values for each of the respective sample times" (with the additions underlined).

4.2 The appellants emphasised that "together with the provision of a plurality of minimum/maximum glucose values, the course of medically relevant outlier values may be interpolated for improved analysis of the glucose trajectory". They stated that the same objective technical problem was solved as by claim 1 of auxiliary requests 10 and 11.

4.3 However, whether the "minimum/maximum glucose values" are determined in a *continuous* or *discrete* manner has no bearing on the conclusion that **feature (d)** does not contribute to the technical character of the invention.

4.4 Therefore, the subject-matter of claim 1 of auxiliary request 12 likewise does not involve an inventive step (Article 56 EPC).

5. Auxiliary requests 13 and 14 - Inventive step

5.1 Claim 1 of **auxiliary request 13** differs from claim 1 of auxiliary request 12 in that **features (c) and (d)** were amended as follows (with the additions underlined):

(c) for the plurality of continuous glucose profiles, determine a plurality of minimum glucose values and/or a plurality of maximum glucose values for each of the plurality of sample times; and an ambulatory glucose profile for the plurality of glucose values of the plurality of glucose profiles;
substitute, for one or more sample times, one of the plurality of minimum glucose values by a pre-determined low glucose value if the minimum glucose value is determined higher than the pre-determined low glucose value and/or one of the plurality of maximum glucose values by a pre-determined high glucose value if the maximum glucose value is determined smaller than the pre-determined high glucose value

(d) provide continuous first display signals representing a continuous curve of the plurality of minimum glucose values and/or the plurality of maximum glucose values for each of the plurality of respective sample times, and further representing the ambulatory glucose profile.

5.2 Claim 1 of **auxiliary request 14** differs from claim 1 of auxiliary request 13 in that **feature (c)** was amended as follows (with the additions underlined):

(c) for the plurality of continuous glucose profiles, determine a plurality of minimum glucose values and/or a plurality of maximum glucose values for

each of the plurality of sample times; and an ambulatory glucose profile for the plurality of glucose values of the plurality of glucose profiles, the ambulatory glucose profile representing a median curve, 25th and 75th percentile curves and 10th and 90th percentile curves for the glucose values collected over a period of time;
substitute, for one or more sample times, one of the plurality of minimum glucose values by a pre-determined low glucose value if the minimum glucose value is determined higher than the pre-determined low glucose value and/or one of the plurality of maximum glucose values by a pre-determined high glucose value if the maximum glucose value is determined smaller than the pre-determined high glucose value
wherein at least one of the pre-determined low glucose value and the pre-determined high glucose value corresponds to a percentile of the plurality of glucose values assigned to the plurality of glucose profiles, the percentile being selected from a 10th percentile and a 90th percentile.

5.3 The appellants argued that, in particular, the substitution according to amended feature (c) had the technical effect that outlier information that can potentially lead to confusion were substituted, generating even more "new data", to "maintain a balance between necessary warnings and avoidable confusing information". As to the objective technical problem solved, they reiterated the same problem as for claim 1 of the higher-ranking requests.

5.4 The board is not persuaded. These amendments relate to non-technical, cognitive effects which likewise cannot contribute to the technical character of the invention.

5.5 Therefore, the subject-matter of claim 1 of auxiliary requests 13 and 14 does not involve an inventive step either (Article 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

B. Brückner K. Bengi-Akyürek

Decision electronically authenticated