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Datasheet for the decision of 26 April 2023

Case Number: T 0335/21 - 3.5.05

Application Number: 11714655.5

Publication Number: 2539843

IPC: G06F19/00

Language of the proceedings: EN

Title of invention:
METHODS AND SYSTEMS FOR PROVIDING THERAPEUTIC GUIDELINES TO A PERSON HAVING DIABETES

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

Headword:
Therapy change recommendation/ROCHE

Relevant legal provisions:
EPC Art. 56, 123(2)
RPBA 2020 Art. 12(4)

Keyword:
Inventive step - (no)
Amendment to case - amendment within meaning of Art. 12(4) RPBA 2020 - amendment admitted (no)
Amendments - allowable (no)

Decisions cited:
T 1814/07, T 0690/11, T 0823/11, T 0450/14, T 0634/18

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Case Number: T 0335/21 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 26 April 2023

Appellant: (Applicant 1)	Roche Diabetes Care GmbH Sandhofer Strasse 116 68305 Mannheim (DE)
Appellant: (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 17 November 2020 refusing European patent application No. 11714655.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	A. Ritzka
Members:	E. Konak
	K. Kerber-Zubrzycka

Summary of Facts and Submissions

I. The appeal is against the examining division's decision to refuse the application on the grounds that neither the main request nor any of auxiliary requests 1 to 4 met the requirements of Article 56 EPC in view of the following document:

D4: US 2009/240127 A1

The contested decision also found that auxiliary request 4 did not meet the requirements of Article 123(2) EPC, either.

II. Oral proceedings were held before the board. At the end of the oral proceedings, the appellants' final requests were that the decision under appeal be set aside and that a patent be granted based on the main request submitted by letter dated 2 October 2020, on which the decision under appeal was based, or, alternatively, based on one of auxiliary requests 1 to 10 submitted with the statement setting out the grounds of appeal. Auxiliary requests 3 to 6 are identical to auxiliary requests 1 to 4 on which the contested decision is based.

III. Claim 1 of the main request reads as follows:

"A method, comprising:
detecting a pattern of an abnormality in blood glucose data collected from an individual with a computing device ,; [sic]
generating a change in therapy recommendation for the individual with the computing device based on said detecting the pattern; and

outputting a customized testing protocol customized to detect whether the change in therapy successfully addressed the abnormality with the computing device".

Claim 1 of auxiliary request 1 reads as follows:

"A method, comprising:
- detecting a pattern of an abnormality in blood glucose data collected from an individual with a computing device;
- generating a change in therapy recommendation addressing the particular pattern at issue for the individual with the computing device based on said detecting the pattern; and
- outputting a customized testing protocol customized depending on the abnormality being addressed appropriate to detect whether the change in therapy successfully addressed the abnormality with the computing device".

Claim 1 of auxiliary request 2 reads as follows:

"A method, comprising:
- detecting a pattern of an abnormality in blood glucose data collected from an individual with a computing device;
- generating a change in therapy recommendation addressing the particular pattern at issue for the individual with the computing device based on said detecting the pattern;
- outputting a customized testing protocol customized depending on the abnormality being addressed appropriate to detect whether the change in therapy successfully addressed the abnormality with the computing device; and

- determining, based on structured testing data entered according to the customized testing protocol, whether the change in therapy was successful in addressing the abnormality with the computing device".

Claim 1 of auxiliary request 3 reads as follows:

"A method, comprising:
- detecting a pattern of an abnormality in blood glucose data collected from an individual with a computing device, wherein the blood glucose (bg) level of the individual was measured for two or more days, at least one blood glucose measurement was taken per day, each blood glucose measurement corresponding to at least one daily event for the individual, and a pattern is defined as two or more hypoglycemic or hyperglycemic blood glucose measurements before or after the same event;
- generating a change in therapy recommendation comprising a change of medication, a lifestyle change or a combination thereof for the individual with the computing device based on said detecting the pattern; and
- outputting a customized testing protocol customized to detect whether the change in therapy successfully addressed the particular pattern at issue with the computing device".

Claim 1 of auxiliary request 4 reads as follows:

"A method, comprising:
- detecting a pattern of an abnormality in blood glucose data collected from an individual with a computing device, wherein the blood glucose (bG) level of the individual was measured for two or more days, at least one blood glucose measurement was taken per day,

each blood glucose measurement corresponding to at least one daily event for the individual, and a pattern is defined as two or more hypoglycemic or hyperglycemic blood glucose measurements before or after the same event, the daily events being one or more of eating breakfast, eating lunch, eating dinner and going to sleep;
- generating a change in therapy recommendation comprising a medication adjustment or addition, an exercise recommendation or dietary modification for the individual with the computing device based on said detecting the pattern; and
- outputting a customized testing protocol customized to detect whether the change in therapy successfully addressed the particular pattern at issue with the computing device, wherein the customized testing protocol includes starting and ending dates for blood glucose measurements to be taken, how many daily blood glucose measurements are to be taken, and which daily events correspond to the blood glucose measurements to be taken".

Claim 1 of auxiliary request 5 reads as follows:

"A method, comprising:
- detecting a pattern of an abnormality in blood glucose data collected from an individual with a computing device, wherein the blood glucose (bG) level of the individual was measured for two or more days, at least one blood glucose measurement was taken per day, each blood glucose measurement corresponding to at least one daily event for the individual, and a pattern is defined as two or more hyperglycemic blood glucose measurements after breakfast;
- generating a change in therapy recommendation comprising a medication adjustment or addition, an

exercise recommendation or dietary modification for the individual with the computing device based on said detecting the pattern; and
- outputting a customized testing protocol customized to detect whether the change in therapy successfully addressed the pattern with the computing device, wherein the customized testing protocol prompts the individual to check blood glucose levels before and after breakfast".

Claim 1 of auxiliary request 6 reads as follows:

"A method, comprising:
- detecting a pattern of an abnormality in blood glucose data collected from an individual with a computing device, wherein the blood glucose (bG) level of the individual was measured for two or more days, at least one blood glucose measurement was taken per day, each blood glucose measurement corresponding to at least one daily event for the individual, and a pattern is defined as two or more hypoglycemic blood glucose measurements before or after the same event, the daily events being one or more of eating breakfast, eating lunch, eating dinner and going to sleep;
- receiving background information about the individual with the computing device including medications being used;
- generating a change in therapy recommendation wherein said generating the change in therapy recommendation includes selecting the change in therapy recommendation based at least in part on the background information and comprising a medication adjustment in a medication class of the individual comprising one or more of sulfonylureas, glinides, long-acting insulins, and rapid-acting insulins for the individual with the

computing device based on said detecting the pattern; and
- outputting a customized testing protocol customized to detect whether the change in therapy successfully addressed the particular pattern at issue with the computing device, wherein the customized testing protocol includes starting and ending dates for blood glucose measurements to be taken, how many daily blood glucose measurements are to be taken, and which daily events correspond to the blood glucose measurements to be taken, and wherein the customized testing protocol starts collecting data one hour before when the hypoglycemic event normally occurs and until three hours after the predicted hypoglycemic event".

Claim 1 of auxiliary request 7 reads as follows:

"A method, comprising:
- detecting a pattern of an abnormality in blood glucose data collected from an individual with a computing device, wherein the blood glucose (bg) level of the individual was measured for two or more days, at least one blood glucose measurement was taken per day, each blood glucose measurement corresponding to at least one daily event for the individual, and a pattern is defined as two or more hypoglycemic or hyperglycemic blood glucose measurements before or after the same event;
- generating a change in therapy recommendation addressing the particular pattern at issue, comprising a change of medication, a lifestyle change or a combination thereof for the individual with the computing device based on said detecting the pattern;
- outputting a customized testing protocol customized depending on the abnormality being addressed appropriate to detect whether the change in therapy

successfully addressed the particular pattern at issue with the computing device; and
- determining, based on structured testing data entered according to the customized testing protocol, whether the change in therapy was successful in addressing the abnormality with the computing device".

Claim 1 of auxiliary request 8 reads as follows:

"A method, comprising:
- detecting a pattern of an abnormality in blood glucose data collected from an individual with a computing device, wherein the blood glucose (bG) level of the individual was measured for two or more days, at least one blood glucose measurement was taken per day, each blood glucose measurement corresponding to at least one daily event for the individual, and a pattern is defined as two or more hypoglycemic or hyperglycemic blood glucose measurements before or after the same event, the daily events being one or more of eating breakfast, eating lunch, eating dinner and going to sleep;
- generating a change in therapy recommendation addressing the particular pattern at issue, comprising a medication adjustment or addition, an exercise recommendation or dietary modification for the individual with the computing device based on said detecting the pattern;
- outputting a customized testing protocol customized depending on the abnormality being addressed appropriate to detect whether the change in therapy successfully addressed the particular pattern at issue with the computing device, wherein the customized testing protocol includes starting and ending dates for blood glucose measurements to be taken, how many daily blood glucose measurements are to be taken, and which

daily events correspond to the blood glucose measurements to be taken; and
- determining, based on structured testing data entered according to the customized testing protocol, whether the change in therapy was successful in addressing the abnormality with the computing device".

Claim 1 of auxiliary request 9 reads as follows:

"A method, comprising:
- detecting a pattern of an abnormality in blood glucose data collected from an individual with a computing device, wherein the blood glucose (bG) level of the individual was measured for two or more days, at least one blood glucose measurement was taken per day, each blood glucose measurement corresponding to at least one daily event for the individual, and a pattern is defined as two or more hyperglycemic blood glucose measurements after breakfast;
- generating a change in therapy recommendation addressing the particular pattern at issue, comprising a medication adjustment or addition, an exercise recommendation or dietary modification for the individual with the computing device based on said detecting the pattern;
- outputting a customized testing protocol customized depending on the abnormality being addressed appropriate to detect whether the change in therapy successfully addressed the pattern with the computing device, wherein the customized testing protocol prompts the individual to check blood glucose levels before and after breakfast; and
- determining, based on structured testing data entered according to the customized testing protocol, whether the change in therapy was successful in addressing the abnormality with the computing device".

Claim 1 of auxiliary request 10 reads as follows:

"A method, comprising:
- detecting a pattern of an abnormality in blood glucose data collected from an individual with a computing device, wherein the blood glucose (bG) level of the individual was measured for two or more days, at least one blood glucose measurement was taken per day, each blood glucose measurement corresponding to at least one daily event for the individual, and a pattern is defined as two or more hypoglycemic blood glucose measurements before or after the same event, the daily events being one or more of eating breakfast, eating lunch, eating dinner and going to sleep;
- receiving background information about the individual with the computing device including medications being used;
- generating a change in therapy recommendation addressing the particular pattern at issue, wherein said generating the change in therapy recommendation includes selecting the change in therapy recommendation based at least in part on the background information and comprising a medication adjustment in a medication class of the individual comprising one or more of sulfonylureas, glinides, long-acting insulins, and rapid-acting insulins for the individual with the computing device based on said detecting the pattern;
- outputting a customized testing protocol customized depending on the abnormality being addressed appropriate to detect whether the change in therapy successfully addressed the particular pattern at issue with the computing device, wherein the customized testing protocol includes starting and ending dates for blood glucose measurements to be taken, how many daily blood glucose measurements are to be taken, and which

daily events correspond to the blood glucose measurements to be taken, and wherein the customized testing protocol starts collecting data one hour before when the hypoglycemic event normally occurs and until three hours after the predicted hypoglycemic event; and
- determining, based on structured testing data entered according to the customized testing protocol, whether the change in therapy was successful in addressing the abnormality with the computing device".

Reasons for the Decision

1. Main request

1.1 Claim 1 of the main request claims a method having the following steps:

a) detecting a pattern of an abnormality in blood glucose data collected from an individual with a computing device;
b) generating a change in therapy recommendation for the individual with the computing device based on said detection of a pattern;
c) outputting a customised testing protocol customised to detect whether the change in therapy successfully addressed the abnormality with the computing device.

1.2 The appellants argued that steps b) and c) were novel over D4 and had the technical effect of facilitating automated therapy recommendations and effective control of the efficacy of such recommendations. They therefore formulated the objective technical problem to be solved by claim 1 as being to provide improved technologies for automated guidance in diabetes care. However, recommending a therapy and customising a testing

protocol are not technical tasks. Rather, they are intellectual activities devoid of technical character. Accordingly, a therapy recommendation is not a technical effect and, moreover, it does not acquire technical character merely by being generated by a computing device. The same is true of customising a testing protocol to test whether the changed therapy has been successful.

1.3 At the oral proceedings, the appellants argued that the method of claim 1 was performed in a medical context and should therefore be treated differently. In support of their argument, they referred to T 1814/07, point 3 of the reasons, in which the board had regarded the examining division's approach in that case as being inappropriate for medical systems. According thereto, in a system for providing medical health care services, the assessment as to patentability could be influenced by the nature of the (method) steps. The solution of a medical problem, e.g. how to determine a new diagnosis or treatment, could not therefore be equated with, for example, the solution of a business problem. In the case at hand, a therapy recommendation was generated which was only a recommendation, unrelated to the physician's intellectual decision on a therapy to be followed. Thus, it had to be recognised that there was a technical effect. The appellants argued that the same principle was followed in other decisions and referred, in particular, to T 823/11, T 450/14 and T 634/18.

Contrary to what the appellants seem to believe, T 1814/07 does not give carte blanche for attributing technical character to any method performed in a medical context. Instead, as cited by the appellants, T 1814/07 teaches that the technical contribution of the distinguishing features depends on the nature of

the steps performed in medical methods, which often involve a combination of steps of a technical and non-technical nature. In the last paragraph of point 3 of the reasons, the board indeed re-emphasised that it cannot be concluded that all of the features of a claim directed to a medical device for medical diagnosis or treatment are necessarily to be considered when assessing inventive step. It was conceivable, for example, that in a particular case the only difference compared with the prior art could be the intellectual method used to arrive at a diagnosis *strictu sensu*, and this had no technical effect. The case at hand is such a case; the only differences lie in intellectual methods of recommending a therapy and customising a testing protocol. The other decisions cited by the appellants have no relevance to this matter except for being related to inventions in the medical field.

1.4 The appellants argued that the abnormality detected by the computing device in step a) of the method of claim 1 was an internal state of that computing device and the change in therapy recommendation was a technical effect ensuring the proper functioning of the device. They referred to T 690/11, page 13, in support of their argument. However, a changed therapy recommendation has nothing to do with the proper functioning of the computing device which generates it. Finally, the appellants argued that the distinguishing features have the technical effect of saving test strips. However, again, there is no causal link between the distinguishing features and the alleged effect.

1.5 For these reasons, the subject-matter of claim 1 of the main request does not involve an inventive step (Article 56 EPC).

2. Admission of auxiliary requests 1 to 2 and 7 to 10

2.1 In view of the primary object of the appeal proceedings being to review the decision under appeal in a judicial manner, an appellant's appeal case must be directed to the requests on which the decision under appeal was based (Article 12(2) RPBA). Any part of an appellant's appeal case which does not meet this requirement is to be regarded as an amendment and may only be admitted at the discretion of the board (Article 12(4) RPBA). In the present case, the contested decision was not based on auxiliary requests 1 to 2 or auxiliary requests 7 to 10. Therefore, these requests constitute amendments within the meaning of Article 12(2) and (4) RPBA.

2.2 As for the reasons for submitting auxiliary requests 1 to 2 and 7 to 10 in the appeal proceedings, the appellants argued that they had prepared and presented extensive arguments at the oral proceedings, in spite of which the examining division had refused the application. However, if an applicant's arguments regarding the requests on file do not convince the examining division, the available remedy is appeal proceedings based on those requests, not on other, new requests.

2.3 At the oral proceedings, the appellants referred to the statement in Article 12(4) RPBA according to which "the board shall exercise its discretion in view of, inter alia, the complexity of the amendment, the suitability of the amendment to address the issues which led to the decision under appeal, and the need for procedural economy", and argued that the amendments made in the new requests were not complex and had been filed together with the appeal. The appellants also referred to Article 12(6) RPBA, according to which the board

shall not admit requests which should have been submitted in the examination proceedings, and argued that it would have made no sense in the case at hand to file the new requests in the examination proceedings since the examining division was not convinced by previous amendments that the appellants had made. However, it is mere speculation to argue that the examining division would not have been convinced by the new requests when an applicant refrains from filing them before the examining division. As for procedural economy, filing additional auxiliary requests on appeal clearly runs counter to this principle.

2.4 Thus, the board has decided not to admit auxiliary requests 1 to 2 and 7 to 10 into the appeal proceedings.

3. Auxiliary request 3

3.1 With regard to auxiliary request 3, the appellants submitted the same arguments as for the main request. They further emphasised that D4 does not disclose recommending a change of medication or lifestyle. However, recommending a change of medication, not to mention recommending a change of lifestyle, does not have technical character. It follows that the distinguishing features of claim 1 of auxiliary request 3 do not contribute to the technical character of the invention.

3.2 Therefore, claim 1 of auxiliary request 3 does not involve an inventive step (Article 56 EPC).

4. Auxiliary requests 4, 5 and 6

4.1 Claim 1 of auxiliary requests 4 and 6 contains the amendment that "the customized testing protocol includes starting and ending dates for blood glucose measurements to be taken, how many daily blood glucose measurements are to be taken, and which daily events correspond to the blood glucose measurements to be taken". As the basis for this amendment, the appellants referred to page 15, lines 8 to 10, of the description as filed. The relevant paragraph reads as follows: "*The methods and systems described herein for providing therapeutic guidelines may permit the person having diabetes to modify some or all of the operating parameters on which the therapeutic guidelines may be based. Such operating parameters may include, but are not limited to, the starting and ending dates for the bG measurements, how many daily bG measurements are taken, which daily events correspond to the bG measurements, and so forth.*" This passage refers to operating parameters on which the therapeutic guidelines may be based and not to the customised testing protocol. At the oral proceedings, the appellants argued that the application was written in US style and that although the terminology was not quite consistent the skilled person would have understood from this passage, and from other passages such as the paragraph bridging pages 23 and 24, and page 16, lines 3 to 5, and more generally from the whole of the application, that the therapeutic guidelines and the customised testing protocol should essentially be based on the same parameters. While this is a plausible explanation, the amendment in question is not directly and unambiguously derivable from the application as filed. Therefore, the amendment in question extends beyond the content of the application as filed (Article 123(2) EPC).

4.2 Claim 1 of auxiliary request 5 contains, *inter alia*, the amendment "wherein the customized testing protocol prompts the individual to check blood glucose levels before and after breakfast". As the basis for this amendment, the appellants referred to page 26, lines 14 to 19; page 31, lines 13 to 20; page 34, line 29, to page 35, line 1; and page 35, lines 8 to 10, of the description as filed. The relevant passages read as follows: "*For example, the user may have a pattern of repeated, daily hypoglycemic events before breakfast (or other meals), but it should be recognized that other patterns may occur as well. As will be explained in greater detail below, if a pattern is detected, the computing device will then develop a customized recommended therapy regimen as well as structured testing protocol that will address the particular pattern at issue*" (no basis for the customised testing protocol prompting the user to check anything); "*By way of example, when the user has a pattern of hyperglycemia following breakfast, as is determined in stages 222 and 224, the computing device 30 recommends a structured testing regimen as represented by the forms in FIGS. 10 and 11, depending on the recommended lifestyle change in stage 248. FIG. 10 shows an example of a structured testing form that is used when the computing device 30 recommends an exercise change in stage 248. As shown, blood glucose levels are measured before and two hours after breakfast, and the corresponding measurement times are recorded*" (no basis for the customised testing protocol prompting the user to check anything); "*The form will prompt Jane to check blood glucose levels before and after breakfast, and it also logs her medication dose and administration time [...])*" (the customised testing protocol prompting the patient to check blood glucose levels before and after breakfast is generated if their physician makes a

medication adjustment after the patient contacts the physician, not after an automatic change in therapy recommendation); and "*This new form, which can be similar to the one shown in FIG. 11, instructs Jane to test her blood before and after breakfast and choose her breakfast foods from the list provided*" (this form is only generated if the patient is recommended to change their lifestyle and they select dietary modification as their strategy). Therefore, the amendment in question extends beyond the content of the application as filed (Article 123(2) EPC).

5. Since none of the requests is allowable, the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

B. Brückner A. Ritzka

Decision electronically authenticated