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Datasheet for the decision of 17 March 2023

Case Number: T 0049/21 - 3.5.05

Application Number: 09803731.0

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IPC: G06F19/00

Language of the proceedings: EN

Title of invention:
STRUCTURED TESTING METHOD FOR DIAGNOSTIC OR THERAPY SUPPORT OF A PATIENT WITH A CHRONIC DISEASE AND DEVICES THEREOF

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

Headword:
Use cases/ROCHE

Relevant legal provisions:
EPC Art. 56
RPBA 2020 Art. 12(4), 13(2)

Keyword:
Inventive step - (no)
Amendment to case - admissibly raised and maintained (no)
Amendment after summons - exceptional circumstances (no)

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Case Number: T 0049/21 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 17 March 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:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 1 September 2020 refusing European patent application No. 09803731.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	A. Ritzka
Members:	E. Konak
	E. Mille

Summary of Facts and Submissions

I. The appeal is against the examining division's decision to refuse the application. The examining division decided that the main request and auxiliary requests 1 to 5 then on file did not involve an inventive step (Article 56 EPC) in view of the following document:

D1: US 2008/177149 A1

II. With the statement setting out the grounds of appeal, the appellants re-filed the main request and auxiliary requests 1, 2, 4 and 5, on which the contested decision is based, and filed a new auxiliary request 6. They requested that the decision be set aside and that a patent be granted on the basis of one of these requests. They further requested oral proceedings as an auxiliary measure.

III. The board summoned the appellants to oral proceedings. In a communication pursuant to Article 15(1) RPBA 2020, it gave its preliminary opinion that the main request and auxiliary requests 1, 2, 4 and 5 did not meet the requirements of Articles 84 and 56 EPC and that the board was minded not to admit auxiliary request 6 into the appeal proceedings.

IV. Oral proceedings were held before the board. During the oral proceedings, at 11.59 hrs, the appellants filed a further auxiliary request 6.

V. The appellants' final requests were that the decision be set aside and that a patent be granted on the basis of the main request or auxiliary requests 1, 2, 4 or 5, on which the contested decision is based, or auxiliary

request 6 filed with the statement setting out the grounds of appeal, or auxiliary request 6 submitted at 11.59 hrs during the oral proceedings before the board.

VI. Claim 1 of the main request and claim 1 of auxiliary request 1 are identical and read as follows:

"A device (24) for diagnostic or therapy support of a patient (12) with a chronic disease, comprising:
a display (108);
a user interface (146); and
a processor (102) coupled to the display (108) and the user interface (146); and
program (34) instructions that when executed by the processor (102) causes the processor (102) to:
prompt a plurality of medical use cases or questions related to the chronic disease for selection on the display (108),
receive a selected medical use case or question via the user interface (146),
select automatically a structured collection procedure (70) for the diagnostic or therapy support of the patient (12) with the chronic disease based on the selected medical use case or question from a plurality of structured collection procedures (70) stored in a memory (110), and
implement the selected structured collection procedure (70),
said structured collection procedure (70) having parameters (220, 222, 224, 226, 228, 230, 232, 237, 238, 240) defining a schedule of events (222), each of said events (237) comprising at least one or more of a performance time (238), guidance (230) to perform the event (237), a request (240) for patient action, a request (240) for information,

and a request (240) for collection of at least one type of biomarker data."

Claim 1 of auxiliary request 2 differs from each claim 1 of the higher-ranking requests in that the following text was added:

"[...], and wherein the parameters (220, 222, 224, 226, 228, 230, 232, 237, 238, 240) of the structured collection procedure (70) further define at least one entry criterion (226) which establishes one or more conditions needed to be met in order for a processor (102) to perform the schedule of events (222)."

Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 2 as follows (with the added text underlined):

"[...]
wherein each of said events (237) comprises a request (240) for collection of at least one type of biomarker data wherein biomarker is a blood glucose value, an interstitial glucose value, an HbA1c value, a heart rate measurement, a blood pressure measurement, lipids, triglycerides, or cholesterol,
and
wherein the parameters (220, 222, 224, 226, 228, 230, 232, 237, 238, 240) of the structured collection procedure (70) further define at least one entry criterion (226) which establishes one or more conditions needed to be met in order for a processor (102) to perform the schedule of events (222) and wherein the at least one entry criterion (226)

establishes the conditions needed to be met prior to obtaining biomarker data from the patient."

Claim 1 of auxiliary request 5 reads as follows:

"A method (300) of performing a structured collection procedure (70), comprising:
providing a
collection device (24) for diagnostic or therapy support of a patient (12) with a chronic disease, the collection device (24) comprising:
a display (108);
a user interface (146); and
a processor (102) coupled to the display (108) and the user interface (146);
causing the processor (102) to execute (102) program (34) instructions to:
prompt a plurality of medical use cases or questions related to the chronic disease for selection on the display (108),
receive a selected medical use case or question via the user interface (146),
select automatically a structured collection procedure (70) for the diagnostic or therapy support of the patient (12) with the chronic disease based on the selected medical use case or question from a plurality of structured collection procedures (70) stored in a memory (110), and
implement the selected structured collection procedure (70),
said structured collection procedure (70) having parameters (220, 222, 224, 226, 228, 230, 232, 237, 238, 240) defining a schedule of events (222), each of said events (237) comprising at least one or more of a performance time (238), guidance (230) to perform the event (237), a request (240) for

patient action, a request (240) for information, and a request (240) for collection of at least one type of biomarker data, and
authorizing the structured collection procedure (70) on the collection device (24),
wherein authorizing means that a password is received via the user interface (146) to unlock the structured collection procedure."

Claim 1 of auxiliary request 6 filed with the statement setting out the grounds of appeal differs from claim 1 of auxiliary request 2 as follows (with the deleted text ~~struck through~~ and the added text underlined):

"[...]
said structured collection procedure (70) having parameters (220, 222, 224, 226, 228, 230, 232, 237, 238, 240) defining a schedule of events (222), each of said events (237) comprising at least ~~one or more of a performance time (238), guidance (230) to perform the event (237), a request (240) for patient action, a request (240) for information, and~~ a request (240) for collection of a blood glucose value ~~at least one type of biomarker data,~~ and wherein the parameters (220, 222, 224, 226, 228, 230, 232, 237, 238, 240) of the structured collection procedure (70) further define at least one entry criterion (226) which establishes one or more conditions needed to be met in order for a processor (102) to perform the schedule of events (222)
wherein the entry criterion is a biomarker measurement(s) provided to the processor indicating a certain condition which must have occurred or be present in order for the entry criteria for the particular structured collection procedure to be

satisfied, and after the condition of the entry criterion has been satisfied and confirmed by the processor, the schedule of events is then automatically run by the processor."

Claim 1 of auxiliary request 6 filed at 11.59 hrs during the oral proceedings differs from claim 1 of auxiliary request 4 as follows (with the deleted text ~~struck through~~ and the added text underlined):

"A device (24) for diagnostic or therapy support of a patient (12) with a chronic disease, the chronic disease being diabetes, comprising:

a display (108);

a user interface (146); and

a processor (102) coupled to the display (108) and the user interface (146); and

program (34) instructions that when executed by the processor (102) causes the processor (102) to:

prompt a plurality of medical use cases or questions related to the chronic disease for selection on the display (108), said medical use cases or questions comprising at least one of: a desire to know the effects of eating a particular food; a desire to know the best time to take medication before and/or after a meal; and a desire to know the effects of exercise on bG levels,

receive a selected medical use case or question via the user interface (146),

select automatically a structured collection procedure (70) for the diagnostic or therapy support of the patient (12) with the chronic disease based on the selected medical use case or question from a plurality of structured collection procedures (70) stored in a memory (110), and

implement the selected structured collection procedure (70),

said structured collection procedure (70) having parameters (220, 222, 224, 226, 228, 230, 232, 237, 238, 240) defining a schedule of events (222), each of said events (237) comprising a request (240) for collection of at least one type of biomarker data wherein the biomarker is a blood glucose value, and comprising at least one or more of a performance time (238), guidance (230) to perform the event (237), a request (240) for patient action, and a request (240) for information, ~~and a request (240) for collection of at least one type of biomarker data,~~

~~wherein each of said events (237) comprises a request (240) for collection of at least one type of biomarker data wherein biomarker is a blood glucose value, an interstitial glucose value, an HbA1c value, a heart rate measurement, a blood pressure measurement, lipids, triglycerides, or cholesterol,~~

and wherein the parameters (220, 222, 224, 226, 228, 230, 232, 237, 238, 240) of the structured collection procedure (70) further define at least one entry criterion (226) which establishes one or more conditions needed to be met in order for a processor (102) to perform the schedule of events (222) and wherein the at least one entry criterion (226) establishes the conditions needed to be met prior to obtaining biomarker data from the patient."

Reasons for the Decision

1. Main request and auxiliary request 1

1.1 Claim 1 of the main request and claim 1 of auxiliary request 1 are identical. In its preliminary opinion, the board raised doubts regarding their clarity, in particular the clarity of the expression "medical use cases or questions related to the chronic disease", and their support in the description, especially for a patient device executing the method underlying claim 1 involving prompting the patient with a plurality of medical use cases or questions and accordingly selecting a structured collection protocol. At the oral proceedings, the appellants explained that a medical use case was a broad but clear term for a scenario or a question that a patient with a chronic disease might have in mind, of which examples were given on page 29, line 14 ff and page 51, line 15 ff of the description. The invention involved a clinician prescribing structured collection procedures for various possible scenarios in advance, which were all stored on the patient device. When the patient faced a particular scenario, they could select it from scenarios displayed ("prompt[ed]" in the wording of the claims) on their device, and the corresponding pre-stored structured collection procedure would be accessed from the device storage. The description supported this interpretation on page 27, line 11 ff, on page 29, line 9 ff and in the paragraph bridging pages 56 and 67. In light of these explanations, the board was satisfied that claim 1 was clear and supported by the description.

1.2 The contested decision found that this claim lacked an inventive step over D1. In the statement setting out the grounds of appeal, the appellants argued that claim

1 differed from D1 on account of the following features set in bold, some of which were also identified as distinguishing features in the contested decision:

F5.1) prompt a plurality of medical use cases or questions related to the chronic disease for selection on the display,
F5.2) receive a selected medical use case or question via the user interface,
F5.3) select automatically a structured collection procedure for the diagnostic or therapy support of the patient with the chronic disease **based on the selected medical use case or question from a plurality of structured collection procedures** stored in a memory, and
F5.4) implement the **selected** structured collection procedure.

At the oral proceedings, the appellants also argued that D1 did not disclose a schedule of events within the meaning of the last feature of claim 1; however, the allegation of fact that claim 1 might have further distinguishing features is an amendment to the appellants' appeal case, which cannot be taken into account unless there are exceptional circumstances (Article 13(2) RPBA). The appellants argued that they became aware of this further distinguishing feature only while preparing for the oral proceedings. This can by no means be an exceptional circumstance justifying an amendment to the appeal case as there has been no change in the disclosure of D1 since the appellants filed their appeal. Therefore, the board did not take this alleged further distinguishing feature into account. Moreover, the board notes that paragraph [0040] of D1 discloses that "the system 10 may be used [...] to establish or design an overall diabetes

therapy or diabetes therapy schedule [...] and/or to modify an existing overall diabetes therapy or diabetes therapy schedule that will thereafter be followed by the patient."

1.3 The appellants argued that, in D1, there was one preprogrammed use case in the patient device. When the patient faced a different use case, the only way to accommodate this situation was to visit the clinician for them to prescribe a new structured collection procedure for this new use case. Referring in particular to paragraphs [0056] and [0105], the appellants argued that the device in D1 offered the patient no flexibility or autonomy to select the structured collection procedure corresponding to their current use case. The distinguishing features of claim 1 offered more patient autonomy and enabled the patient to select a useful collection procedure without visiting the clinician, also preventing useless measurements, and thus avoiding the waste of resources such as test strips and the degradation and wear of sensors, thereby extending the lifetime of the collection device, which were all technical effects. The skilled person, who was a software engineer in the case at hand, would not have modified D1 without an inventive step.

1.4 As the appellants also confirmed at the oral proceedings, the device in claim 1 stores a plurality of structured collection procedures prescribed by the clinician. It is up to the clinician supervising a patient's therapy how much autonomy their patient should be allowed. In the passages of D1 referred to by the appellants, it is also stated that "the programming of the at least one device of the system will therefore typically be also carried out on a patient-by-patient

basis to provide information collection instructions to the patient in a manner the results in a desired amount or degree of patient guidance and autonomy throughout a specified information collection time period, which may typically range from a few days to several weeks or months" (paragraph [0056] of D1). Since the skilled person is a software engineer, as also accepted by the appellants, they would implement any collection procedure prescribed by a clinician to a patient with the level of autonomy the clinician wishes to give to their patient, without an inventive step, including the possibility of selecting a different collection procedure in certain use cases. The further effects put forward by the appellants are secondary chain effects of this non-inventive decision to give a patient more autonomy with regard to the selection of collection procedures.

1.5 Therefore, claim 1 of the main request and of auxiliary request 1 does not involve an inventive step (Article 56 EPC).

2. Auxiliary request 2

2.1 Claim 1 of auxiliary request 2 differs from each claim 1 of the higher-ranking requests in that the following feature was added:

F6) wherein the parameters of the structured collection procedure further define at least one entry criterion which establishes one or more conditions needed to be met in order for a processor to perform the schedule of events.

2.2 In the contested decision, the examining division regarded this feature as being disclosed in paragraph

[0056] of D1, according to which the data collection procedure was carried out on a periodic, e.g. daily, basis and involved reminders to the patient when data had to be entered. The appellants argued that when reminders in paragraph [0056] of D1 were displayed, the schedule of events had already started, contrary to the requirement in feature F6 that the entry criterion establishes the conditions to be met before performing the schedule of events.

Paragraph [0056] of D1 discloses that the structured collection procedure is patient-specific and is determined by the healthcare professional on a patient-by-patient basis. Therefore, in the board's view, D1 discloses that the parameters of the structured collection procedure define at least the identity of the patient to whom the structured collection procedure was prescribed, which qualifies as an "entry criterion" as defined in feature F6. The appellants argued that there was no explicit disclosure in D1 that the processor checked the patient's identity to perform the schedule of events; however, in the context of D1 in which the patient device provides patient-specific support to a patient in their therapy, it would be obvious to perform such a check.

2.3 Therefore, claim 1 of auxiliary request 2 does not involve an inventive step (Article 56 EPC).

3. Auxiliary request 4

3.1 Claim 1 of auxiliary request 4 differs from each claim 1 of the higher-ranking requests in that the following features were added:

F7) wherein each of said events comprises a request for collection of at least one type of biomarker data wherein biomarker is a blood glucose value, an interstitial glucose value, an HbA1c value, a heart rate measurement, a blood pressure measurement, lipids, triglycerides, or cholesterol,
F8) wherein the at least one entry criterion establishes the conditions needed to be met prior to obtaining biomarker data from the patient.

3.2 In the contested decision, the examining division regarded these additional features as being disclosed in paragraph [0066] and Figures 5 and 6 of D1. The appellants argued that D1 did not disclose a schedule of collection requests which is only performed when one or more conditions as an entry criterion into the schedule are met; however, this is a reiteration of feature F6 as already discussed in auxiliary request 2, which does not involve an inventive step.

3.3 Therefore, claim 1 of auxiliary request 4 does not involve an inventive step (Article 56 EPC).

4. Auxiliary request 5

4.1 Auxiliary request 5 consists of one claim which is based on independent method claim 15 of the main request, which, besides features corresponding to those of claim 1, had the added feature of "authorizing the structured collection procedure on the collection device" (F5.6). In claim 1 of auxiliary request 5, this feature was further defined as follows:

F9) wherein authorizing means that a password is received via the user interface to unlock the structured collection procedure for use.

4.2 In the statement setting out the grounds of appeal, the appellants argued that "additionally requiring receipt of the password [...] solve[d] the technical problem of balancing patient autonomy and the potential waste of resources so that useful patient data can be obtained".

4.3 In its preliminary opinion, the board noted that requiring password entry to access features of a computing device was a notoriously known measure which did not involve an inventive step. Furthermore, since passwords were for access control, the board could not follow what they had to do with patient autonomy or the waste of resources.

At the oral proceedings, the appellants pointed to page 38, lines 1 to 12 of the description, which describe a situation in which a clinician sends a password to the patient so that the patient can access one or more structured collection procedures hidden on their device. The appellants argued that there would thus be no need for the patient to visit the clinician to unlock hidden structured collection procedures on their device, increasing patient autonomy. Furthermore, since the patient would not be able to access unauthorised structured collection procedures, the potential waste of resources through the use of such irrelevant structured collection procedures would be prevented. Although passwords were a common measure for access control, their use in the context of accessing previously hidden structured collection procedures on a patient device was inventive.

The board is not convinced by these arguments. Passwords are a notoriously known access control measure in all fields of human endeavour. Their use to

control access to hidden features on a computing device is thus obvious. As a side note, their alleged effects to do with patient autonomy or the waste of resources are not mentioned in the cited passage of the description, nor is the claim limited to this specific constraint.

4.4 Therefore, claim 1 of auxiliary request 5 does not involve an inventive step (Article 56 EPC).

5. Auxiliary request 6 filed with the statement setting out the grounds of appeal

5.1 This request was not made and maintained in the examination proceedings. Therefore, it is an amendment within the meaning of Article 12(4) RPBA, which can only be admitted at the discretion of the board. As for reasons for submitting this new request in the appeal proceedings, the appellants argued that it could not have been filed earlier because they had not been aware of the objection to auxiliary request 4 under point 16.5 of the contested decision before they received the written decision. This objection had not been raised at the oral proceedings before the examining division, as could also be seen from the minutes. This request was to address that specific objection.

These arguments did not convince the board. In point 16.5 of the contested decision, the examining division merely added an "additional remark" to its objections, which are under points 16.1 to 16.4 on which the decision is based. The fact that the written decision has an additional remark does not give the applicant the right to continue examination in appeal proceedings. Furthermore, the minutes of the consultation on 10 June 2020 (dispatched on

17 June 2020) show (point 3.2) that the point raised in this additional remark, namely the alleged effect of saving resources not being derivable from the claim wording, had already been communicated to the appellants before the oral proceedings. Therefore, this request should have been filed in the examination proceedings.

Therefore, the board did not admit this request (Article 12(4) RPBA).

6. Auxiliary request 6 filed at 11.59 hrs during the oral proceedings

6.1 This request was filed at the oral proceedings before the board. Therefore, it is an amendment to the appellants' appeal case made after notification of a summons to oral proceedings. According to Article 13(2) RPBA, it should not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the appellants. The appellants argued that this request was a response to the objections under Article 84 EPC in the board's preliminary opinion. At the same time, it addressed inventive-step objections raised in the contested decision and the conclusions of the board during oral proceedings. These are not cogent reasons justifying the filing of an amendment to the appellants' appeal case, since the board did not maintain its objections under Article 84 EPC raised in its preliminary opinion. As for the inventive-step objections by the examining division, they should have been addressed in the examination proceedings and not on appeal. Finally, it is not exceptional that the board concludes on the discussions during oral proceedings. Therefore, the

board did not admit this request (Article 13(2) RPBA).

7. Since there are no allowable requests, the appeal has to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

K. Götz-Wein A. Ritzka

Decision electronically authenticated