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Datasheet for the decision of 29 June 2022

Case Number: T 3119/19 - 3.5.05

Application Number: 12723830.1

Publication Number: 2707825

IPC: G06F19/00

Language of the proceedings: EN

Title of invention:
SYSTEMS AND METHODS FOR HANDLING UNACCEPTABLE VALUES IN STRUCTURED COLLECTION PROTOCOLS

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

Headword:
Unacceptable values/ROCHE

Relevant legal provisions:
EPC Art. 56
RPBA Art. 12(4)

Keyword:
Inventive step - (no)
Late-filed request - submitted with the statement of grounds of appeal - admitted (no) - request could have been filed in first instance proceedings (yes)

Decisions cited:
T 1670/07, T 0752/19

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Case Number: T 3119/19 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 29 June 2022

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 24 July 2019 refusing European patent application No. 12723830.1 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	A. Ritzka
Members:	E. Konak
	F. Blumer

Summary of Facts and Submissions

I. The appeal is against the examining division's decision to refuse the application on the grounds that the main request and auxiliary requests 1 to 3 *inter alia* did not involve an inventive step (Article 56 EPC) with regard to the following document:

D1: US 2011/015511 A1

II. With their statement setting out the grounds of appeal, the appellants maintained these requests and filed auxiliary requests 4 and 5. They requested that the decision be set aside and that a patent be granted on the basis of one of these requests, and requested oral proceedings as an auxiliary measure.

III. In its preliminary opinion issued in preparation for the oral proceedings, the board raised objections under Article 56 EPC and informed the appellants that it was minded not to admit auxiliary requests 4 and 5.

IV. Oral proceedings were held before the board.

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

"A collection device configured to guide a diabetic patient through a structured collection protocol, comprising:

a meter configured to measure one or more selected biomarkers;

a processor disposed inside the meter and coupled to memory, wherein the memory comprises collection procedures;

a display unit; and

software having instructions that when executed by the processor causes the processor to:

query the diabetic patient via the display unit regarding compliance with adherence criteria;

instruct the diabetic patient to collect at least one sample in a sampling set of biomarker data, wherein each sampling set comprises a sufficient plurality of samples recorded over a collection period;

compare samples to an acceptable range, wherein the acceptable range encompasses biomarker values that would be expected upon compliance with the adherence criteria;

inform the diabetic patient if the collected sample is an unacceptable value which falls outside of the acceptable range; and

perform at least one additional task after observing an unacceptable value

wherein the additional taks [sic] is at least on [sic] one of the following: collecting at least one additional sample, replacing the unacceptable value with another sample in the sampling set, restarting the sampling set, terminating the structured collection protocol, contacting a healthcare provider, or combinations thereof, or calculating a therapeutic result using only acceptable values of the sampling set."

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

"[...]

~~software~~ the processor having instructions that when executed by the processor causes the processor to:

[...]
inform the diabetic patient ~~if~~ that the collected sample is an unacceptable value which falls outside of the acceptable range; and
[...]"

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

"[...]
prompt the patient to provide an explanation for sample values that deviate from the acceptable range; and
perform at least one additional task after observing an unacceptable value
wherein the additional task may be performed automatically in response to an algorithm, or may be performed after querying the diabetic patient for guidance on the additional task to be performed, and
[...]"

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

"[...]
prompt the patient to provide an explanation for sample values that deviate from the acceptable range; if the patient provides no explanation for the discrepancy, the collection device asks additional questions to facilitate explanations for the unacceptable values; and
[...]"

Claim 1 of auxiliary requests 4 and 5 differs from claim 1 of auxiliary requests 1 and 2, respectively, as follows (with additions underlined):

"[...]
query the diabetic patient via the display unit regarding compliance with adherence criteria; and
after the diabetic patient has confirmed adherence
[...]"

Reasons for the Decision

1. Main request

1.1 The contested decision found claim 1 of the main request to lack inventive step over the disclosure of D1. The appellants argued in their statement setting out the grounds of appeal that the subject-matter of claim 1 of the main request differed from the closest prior art D1 in

- querying the diabetic patient via the display regarding compliance with adherence criteria; and

- informing the diabetic person if the collected sample is an unacceptable value which falls outside of the acceptable range.

1.2 Regarding the first of the alleged distinguishing features, i.e. querying the diabetic patient via the display regarding compliance with adherence criteria, the board was not convinced that this feature is new, since D1 discloses in paragraph [0034] displaying the question "*Have you been fasting for the last 8 hours?*"

to the patient before taking a sample, to establish whether they had complied with the adherence criteria.

1.3 Regarding the second one, i.e. informing the diabetic person if the collected sample is an unacceptable value which falls outside of the acceptable range, D1 also discloses in paragraph [0034] comparing a sample value taken to an "acceptable range" ("[...] *after the sample is taken, the processor can assess the received data for reasonableness using other acceptance criterion(s). For example, based on prior data, a fasting bG sample should be between 120-180 mg/dl, but the received value was of 340 mg/dl, and thus fails such acceptance criteria since it is outside the predefined range for an acceptable value*." (emphasis by the board).

1.4 The appellants argued at the oral proceedings that the comparison to an acceptable range in the cited passages was not linked to querying the patient regarding compliance with adherence criteria as claimed in claim 1. Instead, it stated that "*other acceptance criterion(s)*" were used. However, it is clear from the preceding sentences that before a sample is taken the patient is asked a question regarding adherence and that after the sample is taken the sample value is compared to an acceptable range. It should be noted that the terminology used in D1 is slightly different from that of the application at hand. In D1, "*adherence criteria*" is a subset of the broader term "*acceptance criteria*" (see D1, paragraph [0031], first sentence; paragraph [0033], first sentence; paragraph [0034], first and second sentences). Accordingly, D1, paragraph [0034] calls the question "*Have you been fasting for the last 8 hours?*" regarding adherence an "acceptance criterion" and the subsequent comparison to an acceptable range "[other] acceptance criterion(s)".

1.5 Following the comparison to an acceptable range, if the value was found unacceptable D1, paragraph [0034] discloses prompting the patient for an additional sample. However, D1 does not disclose informing the patient why this additional sample is required, namely because the previous value falls outside an acceptable range. Thus this is the sole distinguishing feature of claim 1 of the main request.

1.6 In the statement setting out the grounds of appeal, the appellants had argued that the distinguishing features of claim 1 had the technical effect that only desired calculations were performed and that they were properly performed. However, the device of D1 also rejects an unacceptable value. Additionally informing the patient of the reason why the value was rejected does not have any effect on the calculation itself. Therefore this alleged effect cannot be derived from the distinguishing feature identified above.

1.7 At the oral proceedings, the appellants argued that informing the patient that a value fell outside an acceptable range helped the patient to realise possible effects of their behaviour on test results and guided them in an interactive manner. Educating the patient ensured more reliable collection of data, reduced errors and thus optimised resources in the long term, e.g. prevented wasting test strips as indicated in the second paragraph on page 35 of the description. The distinguishing feature thus had a technical effect.

However, this line of argument is an example of a broken technical chain (see T 1670/07, point 11 of the Reasons; T 752/19, point 2.5 of the Reasons): the alleged technical effect of reducing wastage of test

strips is achieved through a chain starting with information provided to the patient which is then broken by the patient's mental activities. The alleged technical effect cannot be achieved independently of the cognitive content of the information presented to the patient and the patient's subsequent mental activities. Therefore the distinguishing feature does not solve any objective technical problem.

1.8 For these reasons, the subject-matter of claim 1 of the main request does not involve an inventive step over D1 (Article 56 EPC).

2. Auxiliary requests 1 to 3

2.1 Claim 1 of auxiliary request 1 is the same as claim 1 of the main request except for minor amendments to address clarity objections raised by the examining division. Therefore it lacks inventive step for the same reasons as for the main request (Article 56 EPC).

2.2 Regarding claim 1 of auxiliary requests 2 and 3, the appellants argued that the additional features of prompting the patient for an explanation for the deviation of the sample value from the acceptable range and asking them additional questions to facilitate this explanation would help them identify and eventually better understand the reasons for a value falling outside the acceptable range, such as improper handling of the measurement. Page 80 of the description, second paragraph gives examples of these additional features. If the patient had originally input that the sample value was a fasting glucose sample, although they had eaten three slices of pizza before collecting the sample, the device might allow the patient to explain the discrepancy and, if they could not, ask them

questions such as "have you had any recent meals" or "did you clean/remove all sugar or food substances on your fingers before collecting a sample". However, these additional features and the relevant examples do not have any impact on the assessment of inventive step. Namely, the alleged technical effect is still conditional on mental activities of the patient in a broken technical chain. Therefore it follows that the additional features of claim 1 of these requests do not contribute to inventive step (Article 56 EPC).

3. Admissibility of auxiliary requests 4 and 5

According to Article 12(4) RPBA 2007, the board has discretion to hold inadmissible requests which could have been presented in the examination proceedings. In the present case, oral proceedings were held before the examining division, during which the appellants filed new auxiliary requests, namely auxiliary requests 2 and 3 at hand. Even though they could still have filed further auxiliary requests, the appellants decided not to. Further auxiliary requests 4 and 5 were filed for the first time with the statement setting out the grounds of appeal. The board in its preliminary opinion informed the appellants that under these circumstances it was minded not to admit them.

The appellants accepted at the oral proceedings that the additional features of these further auxiliary requests would not have any bearing on the assessment of inventive step.

Therefore the board saw no reason to change its preliminary opinion and did not admit auxiliary requests 4 and 5.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

K. Götz-Wein A. Ritzka

Decision electronically authenticated