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Datasheet for the decision of 7 July 2023

Case Number: T 0647/21 - 3.5.05

Application Number: 11807644.7

Publication Number: 2659407

IPC: G06F19/00

Language of the proceedings: EN

Title of invention:
METHODS OF SELECTING DIABETES THERAPY REGIMENS

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

Headword:
Protocol complexity and patient proficieny levels/ROCHE

Relevant legal provisions:
EPC Art. 84, 56
RPBA 2020 Art. 11, 12(4)

Keyword:
Claims - clarity (yes)
Remittal - (no) - fundamental deficiency in first-instance proceedings (no)
Inventive step - (no)
Amendment to case - request - admissibly raised and maintained (no) - amendment admitted (no)

Decisions cited:
T 0752/19, T 1713/20, T 0335/21

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Case Number: T 0647/21 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 7 July 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 30 November 2020 refusing European patent application No. 11807644.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	K. Kerber-Zubrzycka
Members:	E. Konak
	P. Tabery

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 I to V did not meet the requirements of Articles 84 and 56 EPC in view of the following document:

D1: WO 01/52727 A1

II. With their statement setting out the grounds of appeal, the appellants re-filed the main request and auxiliary requests I to V, on which the contested decision was based, and filed new auxiliary requests VI and VII. They requested that the decision under appeal be set aside and that a patent be granted on the basis of one of these requests.

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, although the main request and auxiliary requests I to V met the requirements of Article 84 EPC, they did not meet the requirements of Article 56 EPC. The board also informed the appellants that it was minded not to admit auxiliary requests VI and VII into the appeal proceedings.

IV. 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 on the basis of the main request or one of auxiliary requests I to VII, all requests as filed with the statement setting out the grounds of appeal. Furthermore, the appellants

requested that the case be remitted to the examining division if the board found that the requirements of Article 84 EPC were met.

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

"A method of assessing a diabetes treatment protocol implemented in a diabetes software by utilizing a processor comprising:

determining a protocol complexity level corresponding to a degree of difficulty of completing the diabetes treatment protocol by utilizing the processor;

and the diabetes treatment protocol comprises one or more tasks, and some procedures for performing the tasks of the diabetes treatment protocol,

and a complexity of the diabetes treatment protocol depends on one of the factors associates with the diabetes treatment protocol selected from the group of a frequency of insulin administration, a frequency of biomarker collection, a complexity of biomarker collection, a time of day of biomarker collection, or combinations thereof;

determining a patient proficiency level corresponding to a skill set of the patient in conducting the diabetes treatment protocol by utilizing the processor;

wherein the patient proficiency level is manually set or calculated by a processor programmed with calculation instructions for the patient proficiency level,

comparing the protocol complexity level to the patient proficiency level, wherein the comparison is performed by the processor; and

providing an output based on the comparison, and instructing the patient via a display unit to commence the diabetes treatment protocol using the procedures if the patient proficiency level is at or above the

protocol complexity level and the procedures are deemed sufficient for the patient to perform the diabetes treatment protocol."

Claim 1 of auxiliary requests I, II and III reads as follows:

"A method of assessing a diabetes treatment protocol by utilizing a processor of a collection device comprising:

determining a protocol complexity level corresponding to a degree of difficulty of completing the diabetes treatment protocol by utilizing calculation instructions programmed into the processor,

selecting a calculation methodology for the protocol complexity level utilizing the processor, wherein

the processor selects the calculation methodology appropriate for the diabetes treatment protocol by executing the programmed calculation instructions, wherein

the selected calculation methodology utilizes

predefined protocol complexity values associated with known diabetes treatment protocols, task complexity values which are assigned to one or more tasks of the diabetes treatment protocol, or combinations thereof;

determining a patient proficiency level corresponding to a skill set of the patient in conducting the diabetes treatment protocol by utilizing calculation instructions programmed into the processor

selecting a calculation methodology for the patient proficiency level via the processor, wherein

the processor selects the calculation methodology appropriate for the diabetes treatment protocol by executing the programmed calculation instructions, wherein

the selected calculation methodology utilizes

predefined patient proficiency levels,

prior patient proficiency levels calculated based on stored data of previously performed treatment protocol or any tasks of the treatment protocol, or combinations thereof, or

contextualized data associated with a biomarker reading, or

wherein the patient proficiency level is computed based on stored data comprising a comparison of requested estimated values and measured values or

the patient proficiency level is computed based on stored data comprising a calculation of the progress of treatment during the previously performed treatment protocol or any tasks of the treatment protocol or

the patient proficiency level is computed based on stored data whereby the previously performed treatment protocol comprising a protocol which prompts the patient to answer treatment related questions or

the patient proficiency level is computed based on the patient adherence level, wherein the patent proficiency level is computed from the previously performed treatment protocol or any tasks of the treatment protocol, or

the patient proficiency level is computed from a combination of patient adherence levels, predefined patient proficiency levels, patient sophistication levels, patient preferences, or combinations thereof or

wherein the patient proficiency level is determined based on a patient's answers to a survey, a patient's prior or current diabetes treatment regimen, or combinations thereof,

comparing the protocol complexity level to the patient proficiency level, wherein the comparison is performed by the processor; and

providing an output based on the comparison via a display unit of the collection device, wherein the

output comprises instructing the patient to perform the tasks of the diabetes treatment protocol if the patient proficiency level is equal to or above the protocol complexity level of the diabetes treatment protocol."

Claim 1 of auxiliary request IV reads as follows:

"A method of assessing a diabetes treatment protocol by utilizing a processor of a collection device comprising:

determining a protocol complexity level corresponding to a degree of difficulty of completing the diabetes treatment protocol by utilizing calculation instructions programmed into the processor, wherein the complexity level depends on at least one of a frequency of insulin administration, a frequency of biomarker collection, a time of day of biomarker collection, a risk of adverse events associated with each task in the diabetes treatment protocol and combinations thereof and a duration of the diabetes treatment protocol,

selecting a calculation methodology for the protocol complexity level utilizing the processor, wherein

the processor selects the calculation methodology appropriate for the diabetes treatment protocol by executing the programmed calculation instructions, wherein

the selected calculation methodology utilizes

predefined protocol complexity values associated with known diabetes treatment protocols, task complexity values which are assigned to one or more tasks of the diabetes treatment protocol, or combinations thereof;

determining a patient proficiency level corresponding to a skill set of the patient in conducting the diabetes treatment protocol by utilizing calculation instructions programmed into the processor

selecting a calculation methodology for the patient proficiency level via the processor, wherein

the processor selects the calculation methodology appropriate for the diabetes treatment protocol by executing the programmed calculation instructions, wherein

the selected calculation methodology utilizes

predefined patient proficiency levels,

prior patient proficiency levels calculated based on

stored data of previously performed treatment protocol or any tasks of the treatment protocol, or combinations thereof, or

contextualized data associated with a biomarker reading, or

wherein the patient proficiency level is computed based on stored data comprising a comparison of requested estimated values and measured values or

the patient proficiency level is computed based on stored data comprising a calculation of the progress of treatment during the previously performed treatment protocol or any tasks of the treatment protocol or

the patient proficiency level is computed based on stored data whereby the previously performed treatment protocol comprising a protocol which prompts the patient to answer treatment related questions or

the patient proficiency level is computed based on the patient adherence level, wherein the patent proficiency level is computed from the previously performed treatment protocol or any tasks of the treatment protocol, or

the patient proficiency level is computed from a combination of patient adherence levels, predefined patient proficiency levels, patient sophistication levels, patient preferences, or combinations thereof or

wherein the patient proficiency level is determined based on a patient's answers to a survey, a patient's

prior or current diabetes treatment regimen, or combinations thereof,

comparing the protocol complexity level to the patient proficiency level, wherein the comparison is performed by the processor; and

providing an output based on the comparison via a display unit of the collection device, wherein the output comprises instructing the patient to perform the tasks of the diabetes treatment protocol if the patient proficiency level is equal to or above the protocol complexity level of the diabetes treatment protocol."

Claim 1 of auxiliary request V reads as follows:

"A method of assessing a diabetes treatment protocol by utilizing a processor of a collection device comprising:

determining a protocol complexity level corresponding to a degree of difficulty of completing the diabetes treatment protocol by utilizing calculation instructions programmed into the processor, wherein the complexity level depends on at least one of a frequency of insulin administration, a frequency of biomarker collection, a time of day of biomarker collection, a risk of adverse events associated with each task in the diabetes treatment protocol and combinations thereof and a duration of the diabetes treatment protocol,

selecting a calculation methodology for the protocol complexity level utilizing the processor, wherein

the processor selects the calculation methodology appropriate for the diabetes treatment protocol by executing the programmed calculation instructions, wherein

the selected calculation methodology utilizes

predefined protocol complexity values associated with known diabetes treatment protocols, task complexity

values which are assigned to one or more tasks of the diabetes treatment protocol, or combinations thereof;

determining a patient proficiency level corresponding to a skill set of the patient in conducting the diabetes treatment protocol by utilizing calculation instructions programmed into the processor

selecting a calculation methodology for the patient proficiency level via the processor, wherein

the processor selects the calculation methodology appropriate for the diabetes treatment protocol by executing the programmed calculation instructions, wherein

the selected calculation methodology utilizes

predefined patient proficiency levels,

prior patient proficiency levels calculated based on

stored data of previously performed treatment protocol or any tasks of the treatment protocol, or combinations thereof, or

contextualized data associated with a biomarker reading,

wherein contextualized data are documented and interrelated conditions that exist or will occur surrounding a collection of a specific biomarker measurement, wherein the data include information about at least one of food or exercises or

wherein the patient proficiency level is computed based on stored data comprising a comparison of requested estimated values and measured values or

the patient proficiency level is computed based on stored data comprising a calculation of the progress of treatment during the previously performed treatment protocol or any tasks of the treatment protocol or

the patient proficiency level is computed based on stored data whereby the previously performed treatment protocol comprising a protocol which prompts the patient to answer treatment related questions or

the patient proficiency level is computed based on the patient adherence level, wherein the patent proficiency level is computed from the previously performed treatment protocol or any tasks of the treatment protocol, or

the patient proficiency level is computed from a combination of patient adherence levels, predefined patient proficiency levels, patient sophistication levels, patient preferences, or combinations thereof or

wherein the patient proficiency level is determined based on a patient's answers to a survey, a patient's prior or current diabetes treatment regimen, or combinations thereof,

wherein the patient sophistication is evaluated by comparing patient estimate of their biomarker reading in comparison to measured biomarker reading after a patient action,

comparing the protocol complexity level to the patient proficiency level, wherein the comparison is performed by the processor; and

providing an output based on the comparison via a display unit of the collection device, wherein the output comprises instructing the patient to perform the tasks of the diabetes treatment protocol if the patient proficiency level is equal to or above the protocol complexity level of the diabetes treatment protocol."

Claim 1 of auxiliary request VI reads as follows:

"A method of assessing a diabetes treatment protocol by utilizing a processor of a collection device comprising:
determining a protocol complexity level corresponding to a degree of difficulty of completing the diabetes treatment protocol by utilizing calculation instructions programmed into the processor, wherein the

complexity level depends on at least one of a frequency of insulin administration, a frequency of biomarker collection, a time of day of biomarker collection, a risk of adverse events associated with each task in the diabetes treatment protocol and combinations thereof and a duration of the diabetes treatment protocol, selecting a calculation methodology for the protocol complexity level utilizing the processor, wherein the processor selects the calculation methodology appropriate for the diabetes treatment protocol by executing the programmed calculation instructions, wherein the selected calculation methodology utilizes predefined protocol complexity values associated with known diabetes treatment protocols, task complexity values which are assigned to one or more tasks of the diabetes treatment protocol, or combinations thereof; determining a patient proficiency level corresponding to a skill set of the patient in conducting the diabetes treatment protocol by utilizing calculation instructions programmed into the processor selecting a calculation methodology for the patient proficiency level via the processor, wherein the processor selects the calculation methodology appropriate for the diabetes treatment protocol by executing the programmed calculation instructions, wherein the selected calculation methodology utilizes predefined patient proficiency levels,
or
contextualized data associated with a biomarker reading,
wherein contextualized data are documented and interrelated conditions that exist or will occur surrounding a collection of a specific biomarker measurement, wherein the data include information about at least one of food or exercises or

wherein the patient proficiency level is computed based on stored data comprising a comparison of requested estimated values and measured values or
the patient proficiency level is computed based on stored data comprising a calculation of the progress of treatment during the previously performed treatment protocol or any tasks of the treatment protocol or
the patient proficiency level is computed based on stored data whereby the previously performed treatment protocol comprising a protocol which prompts the patient to answer treatment related questions or
the patient proficiency level is computed based on the patient adherence level, wherein the patent proficiency level is computed from the previously performed treatment protocol or any tasks of the treatment protocol, or
the patient proficiency level is computed from a combination of patient adherence levels and predefined patient proficiency levels or
wherein the patient proficiency level is determined based on a patient's prior or current diabetes treatment regimen,
comparing the protocol complexity level to the patient proficiency level, wherein the comparison is performed by the processor; and
providing an output based on the comparison via a display unit of the collection device, wherein the output comprises instructing the patient to perform the tasks of the diabetes treatment protocol if the patient proficiency level is equal to or above the protocol complexity level of the diabetes treatment protocol."

Claim 1 of auxiliary request VII reads as follows:

"A method of assessing a diabetes treatment protocol by utilizing a processor of a collection device comprising:
determining a protocol complexity level corresponding to a degree of difficulty of completing the diabetes treatment protocol by utilizing calculation instructions programmed into the processor, wherein the complexity level depends on at least one of a frequency of insulin administration, a frequency of biomarker collection, a time of day of biomarker collection, a risk of adverse events associated with each task in the diabetes treatment protocol and combinations thereof and a duration of the diabetes treatment protocol,
selecting a calculation methodology for the protocol complexity level utilizing the processor, wherein the processor selects the calculation methodology appropriate for the diabetes treatment protocol by executing the programmed calculation instructions, wherein the selected calculation methodology utilizes predefined protocol complexity values associated with known diabetes treatment protocols, task complexity values which are assigned to one or more tasks of the diabetes treatment protocol, or combinations thereof;
determining a patient proficiency level corresponding to a skill set of the patient in conducting the diabetes treatment protocol by utilizing calculation instructions programmed into the processor
selecting a calculation methodology for the patient proficiency level via the processor, wherein the processor selects the calculation methodology appropriate for the diabetes treatment protocol by executing the programmed calculation instructions, wherein the selected calculation methodology utilizes predefined patient proficiency levels,
or

the patient proficiency level is computed based on stored data comprising a calculation of the progress of treatment during the previously performed treatment protocol
comparing the protocol complexity level to the patient proficiency level, wherein the comparison is performed by the processor; and
providing an output based on the comparison via a display unit of the collection device, wherein the output comprises instructing the patient to perform the tasks of the diabetes treatment protocol if the patient proficiency level is equal to or above the protocol complexity level of the diabetes treatment protocol."

Reasons for the Decision

1. Main request and auxiliary requests I to V - Article 84 EPC

The examining division objected that claim 1 of the main request and auxiliary requests I to V was unclear, as the features of "determining a protocol complexity level" and "determining a patient proficiency level" were defined in terms of the result to be achieved; however, the disputed terms "protocol complexity level" and "patient proficiency level" are defined in claim 1 of the requests as the degree of difficulty of a diabetes treatment protocol for a patient and the patient's skill level in conducting the diabetes treatment protocol. The board is not convinced that simply assigning two numbers to these two levels would involve any difficulty for the skilled person in order

to justify an objection that they were defined in terms of the result to be achieved.

2. Request for remittal to the examining division

2.1 The appellants requested that the case be remitted to the examining division if the board found that the requirements of Article 84 EPC were met.

2.2 In accordance with Article 11 RPBA 2020, the board must not remit a case to the department whose decision was appealed for further prosecution unless special reasons present themselves for doing so. As a rule, fundamental deficiencies apparent in the proceedings before that department constitute such special reasons.

2.3 In the case at hand, also referring to T 1713/20, point 1.3 of the Reasons, the appellants argued that the inventive-step objections in the contested decision were not sufficiently reasoned, contrary to Rule 111(2) EPC, which was a fundamental deficiency in examination proceedings. The appellants noted that, as the clarity objections in the contested decision were not upheld by the board, the inventive-step objections, which the examining division raised on the basis of its clarity objections, were also incorrect. More importantly, the examining division had not properly followed the problem-solution approach, which requires the closest prior art to be identified, distinguishing features and their technical effect to be identified, and requires it to be assessed whether the skilled person starting from the closest prior art and confronted with an objective technical problem would have arrived at the claimed subject-matter. The applicants argued that, in particular, the list of distinguishing features in point 13.3 of the contested decision did not correspond

to any actual feature which was claimed and no reasons were given as to why the distinguishing features did not contribute to the technical character of the invention.

2.4 The board does not agree. The fact that the clarity objections in the contested decision were not upheld by the board has no bearing on whether or not the inventive-step objection in the contested decision was sufficiently reasoned. From the structure of the inventive-step objection in the contested decision, it is sufficiently clear that the examining division essentially found all the steps of the method in claim 1 of the main request to be novel over D1 and summarised them in point 13.3 in view of their clarity objections, which the division repeatedly refers to in points 13.4 to 13.7 of the decision. It is also sufficiently clear that the examining division could not identify any technical contribution in view of the same clarity objections. Therefore, the case at hand is not comparable to T 1713/20, in which the reader was left completely in the dark as to why the examining division concluded that the subject-matter of claim 1 of the main request lacked an inventive step (see T 1713/20, point 1.3.6 of the Reasons).

2.5 Therefore, there are no special reasons for a remittal within the meaning of Article 11 RPBA 2020, and the request for remittal cannot be allowed.

3. Main request and auxiliary requests I to V - Article 56 EPC

3.1 D1 discloses a PDA with a medical device and diabetes software, which can be used as a suitable starting point for assessing inventive step. All the steps of

the method in claim 1 of the main request are novel over D1.

3.2 Although they come to different conclusions, both the appellants and the examining division based their assessment of inventive step on the premise that the technical effect achieved (from the examining division's perspective "allegedly achieved") by the distinguishing features of claim 1 of the main request was that of improving the safety of diabetes treatment. The application as filed refers instead to improved patient adherence to a treatment protocol as the achieved effect; however, the appellants argued that increased patient adherence to a treatment protocol improved the safety of diabetes treatment, which involved significant health risks. As elaborated upon in paragraph [0007] of the description, the success of a diabetes treatment protocol was dependent on the patient's adherence to the diabetes treatment protocol. Adherence may be prevented when the diabetes treatment protocol or the tasks of the diabetes treatment protocol are too complex for the patient. A patient may lack the required skill set to perform tasks of the diabetes treatment protocol, such as collecting biomarker readings. Moreover, the patient may be unaware that they lack the required skill set to perform the diabetes treatment protocol.

3.3 Accordingly, claim 1 of the main request tells ("instructing" in the language of the claims) the patient to commence a diabetes treatment protocol only if they are skilled enough to perform it; however, giving a patient a specific treatment protocol or telling them to commence a treatment protocol are intellectual exercises devoid of technical character (see also T 0335/21, points 1.2 and 1.3 of the

Reasons). An instruction to the patient with respect to a treatment protocol does not provide any technical effect. The argument that it improved the safety of treatment by increased patient adherence is instead nothing but an example of a broken technical chain (see T 0752/19, point 2.5 of the Reasons).

Therefore, the method in claim 1 of the main request does not have any technical character beyond its implementation using a processor.

3.4 Claim 1 of auxiliary requests I to V gives additional details of the calculation of the "protocol complexity level" and the "patient proficiency level". The way these parameters are calculated is immaterial for the technical character of the claimed method and does not change the assessment of inventive step.

3.5 Therefore, the subject-matter of claim 1 of the main request and of auxiliary requests I to V does not involve an inventive step (Article 56 EPC).

4. Auxiliary requests VI to VII

4.1 In view of the primary object of the appeal proceedings 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 2020). Any part of an appellant's appeal case which does not meet this requirement is to be regarded as an amendment and may be admitted only at the discretion of the board (Article 12(4) RPBA 2020).

In the case at hand, the contested decision is not based on auxiliary requests VI and VII. Therefore,

these requests are amendments within the meaning of Article 12(2) and (4) RPBA 2020, and thus can only be admitted at the discretion of the board.

4.2 The appellants argued that, if the board were not to remit the case in spite of the procedural violation in the examination proceedings but to decide based on inventive step with a different reasoning than that of the examining division, the appellants should be given a chance to respond to the new line of reasoning provided by the board. Auxiliary requests VI and VII were suitable for overcoming the inventive-step objection raised by the board. Furthermore, the amendments were not complex, in particular since they consisted of the deletion of alternatives restricting the claimed subject-matter to clearly technical alternatives for determining the patient proficiency level.

The board is not convinced by these arguments. The application at hand was refused *inter alia* for lack of inventive step. When the contested decision is based on a lack of inventive step, it goes without saying that the appeal involves a review and correction of the reasoning given for that objection. A corrected reasoning for inventive step does not give appellants *carte blanche* to file amendments. With regard to the amendments in the case at hand, they are not suitable for overcoming the outstanding inventive-step objections, which do not depend on how the patient proficiency level is determined.

4.3 Therefore, the board does not admit auxiliary requests VI and VII into the appeal proceedings.

5. Since there is no allowable request, the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

K. Götz-Wein K. Kerber-Zubrzycka

Decision electronically authenticated