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Datasheet for the decision of 9 July 2018

Case Number: T 0005/15 - 3.5.05

Application Number: 05791269.3

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Language of the proceedings: EN

Title of invention:
System and method for dynamically adjusting patient therapy

Applicant:
CareFusion 303, Inc.

Headword:
Medical control loop/CAREFUSION

Relevant legal provisions:
EPC Art. 123(2)
RPBA Art. 13(1)

Keyword:
Added subject-matter - main, first to third auxiliary requests (yes)
Admission of fourth and fifth auxiliary requests filed during oral proceedings - (no)

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Case Number: T 0005/15 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 9 July 2018

Appellant: (Applicant)	CareFusion 303, Inc. 3750 Torrey View Court San Diego, CA 92130 (US)
Representative:	Richards, John Ladas & Parry LLP Temple Chambers 3-7 Temple Avenue London EC4Y 0DA (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 2 May 2014 refusing European patent application No. 05791269.3 pursuant to Article 97(2) EPC**

Composition of the Board:

Chair	A. Ritzka
Members:	K. Bengi-Akyuerek
	F. Blumer

Summary of Facts and Submissions

I. The appeal is against the decision of the examining division to refuse the present European patent application for lack of inventive step (Article 56 EPC) with respect to the claims of a main request and an auxiliary request, having regard to the combined disclosures of

D6: M.M. Shabot et al.: "Wireless Clinical Alerts for Critical Medication, Laboratory and Physiologic Data", Proceedings of IEEE Conference on System Sciences 2000, pp. 1533-1538, January 2000, and

D7: US-A-2004/0128162.

II. With its statement setting out the grounds of appeal, the appellant re-filed the claims of the main request and the auxiliary request underlying the appealed decision. It requested that the examining division's decision be set aside and that a patent be granted on the basis of either of those claim requests.

III. In a communication under Rule 100(2) EPC dated 10 November 2017, the board gave its preliminary opinion on the appeal. In particular, it raised objections under Articles 123(2), 84 and 83 EPC and pointed out that the claimed subject-matter appeared to relate to the mere computer-based automation of a human activity by means of commonplace technical means such as were known from D7 or D6 (Article 56 EPC).

IV. By letter of reply dated 22 January 2018, the appellant filed amended claims according to second and third auxiliary requests along with counter-arguments to the objections raised in the board's communication under

Rule 100(2) EPC.

V. In a communication annexed to the summons to oral proceedings pursuant to Article 15(1) RPBA, the board indicated that it maintained its objections with regard to the main and first auxiliary requests and that the second and third auxiliary requests likewise did not appear to be allowable under Articles 123(2) and/or 56 EPC.

VI. In a letter of reply, the appellant submitted counter-arguments to some of the objections raised in the board's communication under Article 15(1) RPBA.

VII. Oral proceedings were held on 9 July 2018, during which the appellant filed amended claims according to two further auxiliary requests (fourth and fifth auxiliary requests). The admissibility and allowability of all the claim requests on file were discussed.

The appellant's final request was that the decision under appeal be set aside and that a patent be granted on the basis of the main request or the first auxiliary request, both as filed with the statement setting out the grounds of appeal dated 11 September 2014, or on the basis of the second or third auxiliary request, both as filed with the letter dated 22 January 2018, or on the basis of the fourth or fifth auxiliary request, both as filed during oral proceedings before the board.

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

VIII. Independent claim 15 of the **main request** reads as follows:

"A method of managing medication delivery to a patient, comprising:

communicating information between medication delivery devices (75, 195);

monitoring information communicated between the medication delivery devices (75, 195) for medication delivery parameters entered for a specific patient;

comparing the entered medication delivery parameters with a database (90) of institutionally determined rules related to medications to be delivered to patients in an institution;

identifying instances when the entered medication delivery parameters violate at least one rule of the database (90) of institutionally determined rules; and

communicating an alert to a care giver that the entered medication parameters violate the at least one rule

the method being characterized in that it comprises:

evaluating the physiological response of the patient to the delivery of the medication; and

automatically modifying the at least one rule as a function of the evaluation of the physiological response."

Independent claim 15 of the **first auxiliary request** reads as follows (amendments compared to claim 1 of the main request indicated by the board):

"A method of managing medication delivery to a patient, comprising:

communicating information between medication delivery devices (75, 195);

monitoring information communicated between the medication delivery devices (75, 195) for medication delivery parameters entered for a specific patient;

comparing the entered medication delivery parameters with a database (90) of institutionally determined rules related to medications to be delivered to patients in an institution;

identifying instances when the entered medication delivery parameters violate at least one rule of the database (90) of institutionally determined rules; and

communicating an alert to a care giver that the entered medication parameters violate the at least one rule related to medications to be delivered;

the method being characterized in that it comprises:

evaluating the physiological response of the patient to the delivery of the medication; and

automatically modifying the at least one rule related to medications to be delivered as a function of the evaluation of the physiological response."

Independent claim 15 of the **second auxiliary request** reads as follows (amendments compared to claim 1 of the main request indicated by the board):

"A method of managing medication delivery to a patient by a computer implemented therapy management system, comprising:

communicating information between medication delivery devices (75, 195);

monitoring information communicated between the medication delivery devices (75, 195) for medication delivery parameters entered for a specific patient;

comparing the entered medication delivery parameters with a database (90) of institutionally determined rules related to medications to be delivered to patients in an institution;

identifying instances when the entered medication delivery parameters violate at least one rule of the

database (90) of institutionally determined rules; and

communicating an alert to a care giver that the entered medication parameters violate the at least one rule,

the method being characterized in that it comprises:

performing an ongoing computation of an effect-site concentration of a medication being delivered to the patient;

evaluating the physiological response of the patient to the delivery of the medication; and

automatically modifying ~~the~~ at least one dosing and effect-site limit ~~rule~~ as a function of the evaluations of the physiological response and the effect-site concentration to provide closed-loop control of a therapy to the patient."

Independent claim 14 of the **third auxiliary request** reads as follows (amendments compared to claim 1 of the second auxiliary request indicated by the board):

"A method of managing medication delivery to a patient by a computer implemented therapy management system, comprising:

communicating information between medication delivery devices (75, 195);

monitoring information communicated between the medication delivery devices (75, 195) for medication delivery parameters entered for a specific patient;

comparing the entered medication delivery parameters with a database (90) of institutionally determined rules related to medications to be delivered to patients in an institution;

identifying instances when the entered medication delivery parameters violate at least one rule of the database (90) of institutionally determined rules; and

communicating an alert to a care giver that the entered medication parameters violate the at least one rule,

the method being characterized in that it comprises:

performing an ongoing computation of an effect-site concentration of a medication being delivered to the patient;

evaluating the physiological response of the patient to the delivery of the medication by evaluating the effect-site concentration of the delivered medication and calculating a pharmacodynamics (PD) concentration-response curve for the patient based on measurements of arterial blood pressure for the specific patient and the computation of the effect-site concentration of the medication being delivered to the patient;

determining a response sensitivity for the specific patient based on the PD concentration-response curve;

generating a recommendation for adjusting a dosing therapy associated with the medication based on the response sensitivity;

and

automatically modifying at least one dosing and effect-site limit as a function of the evaluations of the physiological response and the effect-site concentration to provide closed loop control of a therapy to the patient."

Independent claim 15 of the **fourth auxiliary request** reads as follows (amendments compared to claim 1 of the second auxiliary request indicated by the board):

"A method of managing medication delivery to a patient by a computer implemented therapy management system, comprising:

communicating information between medication delivery devices (75, 195);

monitoring information communicated between the medication delivery devices (75, 195) for medication delivery parameters entered for a specific patient;

comparing the entered medication delivery parameters with a database (90) of institutionally determined rules related to medications to be delivered to patients in an institution;

identifying instances when the entered medication delivery parameters violate at least one rule of the database (90) of institutionally determined rules; and

communicating an alert to a care giver that the entered medication parameters violate the at least one rule,

the method being characterized in that it comprises:

performing an ongoing comparison ~~computation~~ of an effect-site concentration of a medication being delivered to the patient with institutionally defined limits;

evaluating the physiological response of the patient to the delivery of the medication;
and

automatically modifying at least one dosing and effect-site limit as a function of ~~the~~ past and present evaluations of the relationship between physiological response and the effect-site concentration to provide closed-loop control of a therapy to the patient."

Independent claim 14 of the **fifth auxiliary request** reads as follows (amendments compared to claim 1 of the fourth auxiliary request indicated by the board):

"A method of managing medication delivery to a patient by a computer implemented therapy management

system, comprising:

communicating information between medication delivery devices (75, 195);

monitoring information communicated between the medication delivery devices (75, 195) for medication delivery parameters entered for a specific patient;

comparing the entered medication delivery parameters with a database (90) of institutionally determined rules related to medications to be delivered to patients in an institution;

identifying instances when the entered medication delivery parameters violate at least one rule of the database (90) of institutionally determined rules; and

communicating an alert to a care giver that the entered medication parameters violate the at least one rule,

the method being characterized in that it comprises:

performing an ongoing comparison of an effect-site concentration of a medication being delivered to the patient with institutionally defined limits;

evaluating the physiological response of the patient to the delivery of the medication;

determining a response sensitivity for the specific patient based on the PD concentration-response curve;

generating a recommendation for adjusting a dosing therapy associated with the medication based on the response sensitivity; and

automatically modifying at least one dosing and effect-site limit as a function of past and present evaluations of the relationship between physiological response and the effect-site concentration to provide closed-loop control of a therapy to the patient."

Reasons for the Decision

1. MAIN REQUEST

Independent claim 15 of the main request comprises the following limiting features (as labelled by the board):

A method of managing medication delivery to a patient, comprising the steps of:

A) communicating information between medication delivery devices;
B) monitoring information communicated between the medication delivery devices for medication delivery parameters entered for a specific patient;
C) comparing the entered medication delivery parameters with a database of institutionally determined rules related to medications to be delivered to patients in an institution;
D) identifying instances when the entered medication delivery parameters violate at least one rule of the database of institutionally determined rules;
E) communicating an alert to a care giver that the entered medication delivery parameters violate the at least one rule;
F) evaluating the physiological response of the patient to the delivery of the medication;
G) automatically modifying the at least one rule as a function of the evaluation of the physiological response.

1.1 *Added subject-matter (Article 123(2) EPC)*

The board holds that claim 15 of the main request is not allowable under Article 123(2) EPC, for the

following reasons:

1.1.1 Features A) to E) of present claim 1 are evidently based on the embodiment related to comparative checks as regards "site-defined rules" according to Figure 11 (see page 48, line 13 to page 49, line 21; Fig. 11, box 630, as originally filed).

1.1.2 Features F) and G) obviously relate to the automatic updating of data to be compared (cf. page 44, lines 9-12 of the original application). However, the present application as filed teaches specifically that "institutionally determined dosing and effect-site limits" (rather than "institutionally determined rules") are to be automatically modified by the therapy management system following a pharmacodynamic (PD) evaluation of the patient's physiological responses to the respective drug concentration (cf. page 44, lines 1-12).

1.1.3 The board concludes that feature G) is not supported by the original application in combination with features C) to E), since they refer to "institutionally determined *rules*" in general and not to "institutionally determined *dosing* and *effect-site limits*" being automatically modified by the therapy management system as originally taught. As a consequence, independent claim 15 comprises an inadmissible extension of the application's original content.

1.1.4 The appellant argued that the skilled person would understand that the institutionally determined rules and limits were interchangeable. However, the board notes that general rules cannot necessarily be said to correspond to or include "dosing and effect-site

limits" in the context of the present application as filed. Thus, this argument must fail.

1.2 In view of the above, the main request is not allowable under Article 123(2) EPC.

2. FIRST AUXILIARY REQUEST

2.1 Given that claim 15 as it stands likewise includes feature G), the objection and reasoning under Article 123(2) EPC with regard to the main request in point 1.1 above also apply *mutatis mutandis* to this claim.

2.2 Accordingly, the first auxiliary request is likewise not allowable under Article 123(2) EPC.

3. SECOND AND THIRD AUXILIARY REQUESTS

Independent method claim 15 of the second and third auxiliary requests differs from claim 15 of the main request essentially in that its method steps are to be performed by a "computer-implemented therapy management system" and that it now specifies *inter alia* the steps of

G') automatically modifying at least one dosing and effect-site limit as a function of the evaluations of the physiological response and the effect-site concentration to provide closed-loop control of a therapy to the patient;

H) performing an ongoing computation of an effect-site concentration of a medication being delivered to the patient.

3.1 *Added subject-matter (Article 123(2) EPC)*

3.1.1 As to feature G'), the board notes that the relevant teaching of the application as originally filed indicates that institutionally determined dosing and effect-site limits may be automatically modified as a function of present and past pharmacodynamic evaluations as well as other patient-specific factors (cf. page 44, lines 9-12). Furthermore, the original application teaches that pharmacodynamic evaluations describe the relationship between the physiological response and the effect-site drug concentration (cf. page 44, lines 1-3), i.e. it specifies that it is the relationship between the patient's physiological response and the drug concentration at the patient's effect site that is to be evaluated. Thus, feature G') amounts to an inadmissible intermediate generalisation of the present application's original teaching.

3.1.2 As to added feature H), it is apparent to the board that the relevant teaching of the original application states that the ongoing computation performed relates to a comparison between effect-site concentrations and institutionally defined effect-site limits to indeed provide alerts to a care giver (cf. page 42, line 30 to page 43, line 4). Hence, feature H) likewise gives rise to an inadmissible intermediate generalisation of the present application's original content.

3.1.3 The appellant did not comment on the above objections under Article 123(2) EPC in its written reply to the board's communication under Article 15(1) RPBA (cf. point VI above) and during the oral proceedings before the board.

3.2 In conclusion, the second and third auxiliary requests are likewise not allowable under Article 123(2) EPC.

4. FOURTH AND FIFTH AUXILIARY REQUESTS

The independent method claims of the fourth and fifth auxiliary requests (i.e. claim 15 and claim 14 respectively) differ from those of the second and third auxiliary requests essentially in that they now include *inter alia* the steps of (emphasis added)

G'') automatically modifying at least one dosing and effect-site limit as a function of past and present evaluations of the relationship between the physiological response and the effect-site concentration to provide closed-loop control of a therapy to the patient;

H') performing an ongoing comparison of an effect-site concentration of a medication being delivered to the patient with institutionally defined limits.

4.1 *Admissibility under Article 13(1) RPBA*

4.1.1 The claims of the fourth and fifth auxiliary requests were filed during the oral proceedings before the board, i.e. at a very late stage in the overall proceedings. The appellant argued that they were submitted with the aim of overcoming the objections under Article 123(2) EPC and that they did not give rise to further objections.

4.1.2 In appeal proceedings, the admissibility of claim amendments filed after a party has submitted its statement setting out the grounds of appeal is principally governed by Article 13 RPBA. Pursuant to

Article 13(1) RPBA, a board's discretion in admitting any amendment to a party's case "shall be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy".

4.1.3 As regards the *procedural* aspects of the fourth and fifth auxiliary requests, the board establishes from the file that the independent method claims of the fourth and fifth auxiliary requests, including new features taken from the application's description as filed (cf. page 42, last line to page 43, line 27), were submitted for the very first time at the oral proceedings before the board. They were thus submitted at a very late stage in the proceedings, during which the appellant had had ample opportunity to file a potentially allowable set of claims, e.g. in response to the board's communications under Rule 100(2) EPC and Article 15(1) RPBA (see points III and V above). In particular, the appellant deliberately chose not to comment on the objections under Article 123(2) EPC in relation to feature G') prior to the oral proceedings before the board.

Furthermore, these auxiliary requests do not converge with the higher-ranking third auxiliary request, as the feature "evaluating the physiological response of the patient to the delivery of the medication by evaluating the effect-site concentration of the delivered medication and calculating a pharmacodynamics (PD) concentration-response curve for the patient based on measurements of arterial blood pressure for the specific patient and the computation of the effect-site concentration of the medication being delivered to the patient" has been replaced by "evaluating the physiological response of the patient to the delivery

of the medication" (see point VIII above). This amendment however adds complexity to the case in the sense that it makes it necessary to further examine whether or not the amended feature gives rise to new objections and does not address the objections raised under Article 123(2) EPC in relation to feature G').

4.1.4 In addition, as regards the *substantive* aspects of the present auxiliary requests, it is apparent to the board that amended feature G'') is not clearly allowable at least under Article 123(2) EPC. This is because it is not specified that the institutionally determined dosing and effect-site limits are to be automatically modified as a function not only of the pharmacodynamic evaluations of the relationship between the patient's physiological response and the effect-site concentration but also of other patient-specific data (see point 3.1.1 above). Hence, feature G'') apparently amounts to an intermediate generalisation of the application's original content and, consequently, does not overcome the objections raised in the board's communication under Article 15(1) RPBA with respect to feature G').

4.2 In view of the above, the board decided not to admit the fourth and fifth auxiliary requests into the appeal proceedings under Article 13(1) RPBA.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

M. H. A. Patin A. Ritzka

Decision electronically authenticated