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Datasheet for the decision of 21 July 2015

Case Number: T 0957/12 - 3.5.05

Application Number: 04706992.7

Publication Number: 1593079

IPC: G06F19/00

Language of the proceedings: EN

Title of invention:
SYSTEM AND METHOD FOR VERIFYING MEDICAL DEVICE OPERATIONAL PARAMETERS

Applicant:
Baxter International Inc.

Headword:
Remote verification of medical device settings/BAXTER

Relevant legal provisions:
EPC 1973 Art. 56

Keyword:
Inventive step - (no)

Decisions cited:

Catchword:

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Case Number: T 0957/12 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 21 July 2015

Appellant: (Applicant)	Baxter International Inc. One Baxter Parkway, DF3-2E Deerfield, Illinois 60015-4633 (US)
Representative:	Potter Clarkson LLP The Belgrave Centre Talbot Street Nottingham, NG1 5GG (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 6 December 2011 refusing European patent application No. 04706992.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman	A. Ritzka
Members:	P. Cretaine
	G. Weiss

Summary of Facts and Submissions

I. The appeal is against the decision of the examining division, announced in oral proceedings and posted on 6 December 2012, to refuse European patent application No. 04706992.7 on the grounds of lack of inventive step, having regard to the disclosure of

D2: WO 02/36044,

with respect to a main request and on the grounds of added matter (Article 123(2) EPC) with respect to eight auxiliary requests. A ninth and a tenth auxiliary requests filed during the oral proceedings were not admitted in the procedure under Rules 116(1) and 137(3) EPC.

II. Notice of appeal was received on 7 February 2012 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 12 April 2012. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of a main request or any of first to eighth auxiliary requests filed with the statement setting out the grounds of appeal. The main request and the first to fifth auxiliary requests corresponded to the main request, the third auxiliary request, the fourth auxiliary request, the fifth auxiliary request, the ninth auxiliary request, and the tenth auxiliary request, respectively, on which the decision was based. Oral proceedings were requested should the main request not be allowed. Furthermore, the appellant commented on several procedural violations that he believed to have occurred during the examination procedure. No request for reimbursement of the appeal fee was made.

III. A summons to oral proceedings scheduled for 27 January 2015 was issued on 22 September 2014. In an annex to this summons, the board gave its preliminary opinion on the appeal pursuant to Article 15(1) RPBA. An objection of lack of essential features under Article 84 EPC 1973 was raised with respect to all the requests on file. Objections of lack of inventive step under Article 56 EPC 1973 were raised with respect to all the requests on file, having regard to the disclosure of **D2** or, alternatively of

D1: US 2002/0038392, cited in examination.

By way of illustration of the common general knowledge in the field of programming techniques, the board also cited:

D4: S. Mitchell, "Designing Active Server Pages", Chapter 5 - Form Reuse, pp. 104-137, O'Reilly & Associates, 2000, ISBN 0-596-00044-8, and

D5: E. Herrmann, "Teach Yourself CGI Programming with Perl in a Week", pp. 91-118, 200-204, 363-375 and 450-455, Sams.net Publishing, 1996, ISBN: 1-57521-009-6.

The board also expressed the preliminary opinion that, in its view, no substantial procedural violation had occurred in examination.

IV. In a communication dated 22 December 2014, the board announced that the oral proceedings had been rescheduled for 21 July 2015.

V. With a letter dated 19 June 2015, the appellant filed a main request and first to eighth auxiliary requests to

replace the main request and first to eighth auxiliary requests previously on file. The claims of the main request and of the first and second auxiliary requests were identical to the claims of the previous sixth, seventh and eighth auxiliary requests, respectively.

VI. Oral proceedings were held on 21 July 2015. The appellant's final requests were that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed with letter dated 19 June 2015 or, in the alternative, on the basis of one of the first to eight auxiliary requests filed with the same letter.

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

VII. Claim 1 of the **main request** reads as follows :

"A system for comparing medical device settings to orders within a healthcare system,
comprising:
a medical device having a communication interface for transmitting data relating to operational parameters of the medical device; and
a first computer having
a communication interface for receiving the data relating to the medical device's operational parameters and for receiving data relating to a medication order,
a processor for comparing at least one of the operational parameters sent from the medical device to at least a portion of the medication order, wherein if the processor is unable to conduct a comparison of the at least one operational parameter to the at least a portion of the medication order, the processor requests

additional data and conducts a comparison, using the additional data, of the at least one operational parameter to the at least a portion of the medication order, and
a transmitter in communication with the first computer for transmitting a comparison result signal of the comparison results to a remote computer."

Claim 1 of the **first auxiliary request** reads as follows:

"A system for comparing medical device settings to orders within a healthcare system comprising:
a medical device having a communication interface for transmitting data relating to operational parameters of the medical device; and
a first computer having
a communication interface for receiving the data relating to the medical device's operational parameters and for receiving data relating to a medication order,
a processor for comparing at least one of the operational parameters sent from the medical device to at least a portion of the medication order, and
a transmitter in communication with the first computer for transmitting a comparison result signal of the comparison results to a remote computer,
wherein if the comparison result signal indicates a mismatch between the medical device's operational parameters and the medication order, the remote computer displays (i) an option to operate the medical device using the medical device's operational parameters and (ii) an option to reprogram the medical device and conduct another comparison."

Claim 1 of the **second auxiliary request** reads as follows:

"A system for comparing medical device settings to orders within a healthcare system, comprising:
a medical device having a communication interface for transmitting data relating to operational parameters of the medical device; and
a first computer having
a communication interface for receiving the data relating to the medical device's operational parameters and for receiving data relating to a medication order,
a processor for comparing at least one of the operational parameters sent from the medical device to at least a portion of the medication order and
a transmitter in communication with the first computer for transmitting a comparison result signal of the comparison results to a remote computer,
wherein the processor checks whether the data relating to the medical device's operational parameters has been programmed into the medical device within a predetermined time, and if the data relating to the medical device's operational parameters has not been programmed into the medical device within the predetermined time, the processor requests programming of new data relating to the medical device's operational parameters before conducting the comparison."

Claim 1 of the **third auxiliary request**, claim 1 of the **fourth auxiliary request**, and claim 1 of the **fifth auxiliary request** add to claim 1 of the main request, claim 1 of the first auxiliary request, and claim 1 of the second auxiliary request, respectively, after the wording "data relating to operational parameters of the medical device" the feature "which data have been programmed into the device", and after the wording "comparing...to at least a portion of the medication

order" the feature "upon request by a remote computer". Further, the wording "comparison results to the remote computer" replaces the wording "comparison results to a remote computer" in those claims.

Claim 1 of the **sixth auxiliary request**, claim 1 of the **seventh auxiliary request**, and claim 1 of the **eight auxiliary request** add to claim 1 of the main request, claim 1 of the first auxiliary request, and claim 1 of the second auxiliary request, respectively, after the wording "data relating to operational parameters of the medical device" the feature "which data have been programmed into the device by a remote computer", and after the wording "comparing...to at least a portion of the medication order" the feature "upon request by the remote computer". Further, the wording "comparison results to the remote computer" replaces the wording "comparison results to a remote computer" in those claims.

Reasons for the Decision

1. Main request

1.1 D2 discloses (see in particular page 9, lines 24 to 30; page 16, line 25 to page 17, line 12; page 23, lines 10 to 19; Figure 1), according to the essential features of claim 1, a system for comparing medical device settings ("IV pump characteristics indicative of the actual delivery of medication to the patient") to orders ("doctor's orders") within a healthcare system ("hospital"), comprising:
a medical device ("IV pump 10") having a communication interface for transmitting data relating to operational

parameters of the medical device ("transmitter 45"); and
a first computer ("HIMS 60") having
a communication interface for receiving the data relating to the medical device's operational parameters and for receiving data relating to a medication order ("receiver 61"),
a processor for comparing at least one of the operational parameters sent from the medical device to at least a portion of the medication order ("CPU 57"), and
a transmitter in communication with the first computer for transmitting a comparison result signal of the comparison results to a remote computer (see page 17, lines 6 to 9)."

1.2 The differences between the subject-matter of claim 1 and the disclosure of D2 are thus that the claimed system provides that, if the processor is unable to conduct a comparison of the at least one operational parameter to at least a portion of the medication order, the processor requests additional data and conducts a comparison, using the additional data, of the at least one operational parameter to at least a portion of the medication order.

This distinguishing feature addresses the problem of incomplete and/or incorrect data entry. This problem is however a generally known one in computing systems performing calculations on received data. In the board's view, the proposed solution does not involve more than a conventional measure falling within the routine competence of the skilled person and whose implementation is merely based on the application of conventional programming techniques forming part of the skilled person's common knowledge, as exemplified by

the disclosures of D4 (see the paragraphs "A Primer on Form use" on pages 106 and 107 and the paragraph "Form validation" on pages 111 to 116) or D5 (see pages 116 to 117: Chapter "Summary"; Figure 7.2 and the associated text on pages 200 to 204; Figure 11.6 and the associated text on pages 363 to 375; first paragraph on page 455).

1.3 The appellant argued at the oral proceedings that D4 and D5 relate to general computing issues only and not specifically to healthcare systems. The board is not convinced by this argument since the above-mentioned distinguishing features merely represent basic redundancy and check functions of a computing system. The skilled person would implement these functions in any system, regardless of the information conveyed by the treated data.

1.4 In conclusion, the main request is not allowable under Article 56 EPC 1973, having regard to the disclosure of D2 and the common general knowledge of the skilled person, as illustrated by D4 or D5.

2. First auxiliary request

In addition to the features already disclosed in D2, as listed in paragraph 1.1 above, claim 1 of this request further specifies that if the comparison result signal indicates a mismatch between the medical device’s operational parameters and the medication order, the remote computer displays (i) an option to operate the medical device using the medical device’s operational parameters and (ii) an option to reprogram the medical device and conduct another comparison.

The technical effect of this feature is that in the event of a comparison mismatch a clinician is able to reprogram the medical device from the remote computer. The objective technical problem can thus be formulated as how to improve the flexibility and ergonomy of the healthcare system.

The skilled person trying to solve this problem would come across document D1, which relates to a clinician device acting with a medical device ("bag 20"), performing a comparison between operational parameters programmed into the medical device ("dispensed delivery information") and a medication order ("prescription for the patient"), and generating a visual alarm in the event of mismatches on a remote computer ("terminal 610") linked to the medical device (see in particular paragraphs [0102] and [0253] to [0271] and Figure 31). Paragraph [0263] states in particular that a physician is able to modify the operational parameters of the medical device using the remote computer ("terminal 610") linked to the medical device, which amounts to a reprogramming of the medical device through the remote computer. By applying this teaching of D1 to the system of D2, the skilled person would arrive at the subject-matter of claim 1 without the exercise of inventive skill.

The first auxiliary request is thus not allowable under Article 56 EPC 1973, having regard to the disclosure of D2 in combination with D1.

3. Second auxiliary request

In addition to the features already disclosed in D2, as listed in paragraph 1.1 above, claim 1 of this request further states that the processor checks whether the

data relating to the medical device’s operational parameters has been programmed into the medical device within a predetermined time, and if this is not the case, the processor requests the programming of new data relating to the medical device’s operational parameters before conducting the comparison.

These additional features address the problem of how to avoid the use of "stale" operational parameters. This problem is however already known from D1 in the context of a computer-based medication delivery system (see paragraph [0254]: "to avoid delivery of medicant pursuant to a stale order"). The solution proposed by D1 (see paragraphs [0264] to [0267]) is to determine whether the medical device's operational parameters ("dispensed delivery information from tag") have been programmed into the medical device within a predetermined time ("pump processor 104 determines if the dispended time is within a threshold time period of the current time"). If not, the physician is requested to verify the validity of the programmed medical device's operational parameters ("the physician should take steps to verify that the tag information is still valid") and program new data, if necessary ("perform process 700 in Figure 43"). D1 further discloses in paragraph [0268] that this process can be performed by the controller 260, i.e. by the computer which also performs the comparison between the medical device's operational parameters and the medication order. By applying this teaching of D1 to the system of D2, the skilled person would arrive at the subject-matter of claim 1 without the exercise of inventive skill.
The second auxiliary request is thus not allowable under Article 56 EPC 1973, having regard to the disclosure of D2 in combination with D1.

3.1 Third auxiliary request

Claim 1 adds in substance to claim 1 of the main request the features that:
- the operational parameters have been programmed into the device, and that
- the comparison is performed upon request by the remote computer to which the results of the comparison are transmitted.

D2 teaches that the IV pump comprises a receiver for receiving instructions for entry into the IV pump controls (see page 10, lines 1 to 6). This amounts to a programming of the operational parameters of the pump.

D2 further discloses that the IV pump comprises a communication interface and the HIMS are connected through a bi-directional link (see for instance page 9, lines 6 to 14 for the link from the IV pump to the HMIS and from page 9, line 30 to page 10, line 6 for the link from the HIMS to the IV pump). Moreover, D2 teaches that, additionally to a continuous monitoring of the IV pump by HIMS, any event that changes the state of the pump, for instance the activation of an alarm, may also trigger the comparison performed by the HMIS (see page 15, lines 22 to 30). The interface of the IV pump (see Figure 2) can thus be considered as a remote computer which may request the HIMS to perform the comparison.

Transmitting the comparison results back to the interface of the IV pump represents an obvious measure that the skilled person would readily contemplate, without the exercise of inventive skill.

The third auxiliary request is thus not allowable under Article 56 EPC 1973, having regard to the disclosure of D2 and the common general knowledge of the skilled person, as illustrated by D4 or D5.

4. Fourth auxiliary request

Claim 1 adds in substance to claim 1 of the first auxiliary request the features that:
- the operational parameters have been programmed into the device, and that
- the comparison is performed upon request by the remote computer to which the results of the comparison are transmitted.

These features are however either already disclosed in, or easily derivable from, D2, as stated in paragraph 3 above.

The fourth auxiliary request is thus not allowable under Article 56 EPC 1973, having regard to the disclosure of D2 in combination with D1.

5. Fifth auxiliary request

Claim 1 adds in substance to claim 1 of the second auxiliary request the features that:
- the operational parameters have been programmed into the device, and that
- the comparison is performed upon request by the remote computer to which the results of the comparison are transmitted.

These features are however either already disclosed in, or easily derivable from, D2, as stated in paragraph 3 above.

The fifth auxiliary request is thus not allowable under Article 56 EPC 1973, having regard to the disclosure of D2 in combination with D1.

6. Sixth auxiliary request

Claim 1 adds in substance to claim 1 of the third auxiliary request the feature that the programming of the operational parameters in the medical device is performed by the remote computer.

D2 teaches that the receiver at the IV pump is capable of receiving instructions for entry into the IV pump controls (see page 10, lines 5 to 6). The interface of the IV pump, comprising this receiver, can thus be considered as a computer which programs the operational parameters in the IV pump. Therefore the above-mentioned added feature is already disclosed in D2.

The sixth auxiliary request is thus not allowable under Article 56 EPC 1973, having regard to the disclosure of D2 and the common general knowledge of the skilled person, as illustrated by D4 or D5.

7. Seventh auxiliary request

Claim 1 adds in substance to claim 1 of the fourth auxiliary request the feature that the programming of the operational parameters in the medical device is performed by the remote computer.
This feature is however already known from D2 (see paragraph 6 above).

The seventh auxiliary request is thus not allowable under Article 56 EPC 1973, having regard to the disclosure of D2 in combination with D1.

8. Eight auxiliary request

Claim 1 adds in substance to claim 1 of the fifth auxiliary request the feature that the programming of the operational parameters in the medical device is performed by the remote computer.

This feature is however already known from D2 (see paragraph 6 above).

The eight auxiliary request is thus not allowable under Article 56 EPC 1973, having regard to the disclosure of D2 in combination with D1.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

K. Götz-Wein A. Ritzka

Decision electronically authenticated