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Datasheet for the decision of 18 November 2009

Case Number: T 1929/06 - 3.5.05

Application Number: 03747604.1

Publication Number: 1500031

IPC: G06F 19/00

Language of the proceedings: EN

Title of invention:
System and method for identifying data streams associated with medical equipment

Applicant:
Baxter International Inc.

Opponent:
-

Headword:
Identifying data streams/BAXTER INTERNATIONAL

Relevant legal provisions:
EPC Art. 52(1), 56, 84, 123(2)

Relevant legal provisions (EPC 1973):
EPC Art. 106, 107, 108

Keyword:
"Added subject-matter (main request - yes)"
"Inventive step (1st to 4th auxiliary request - no)"

Decisions cited:
J 0010/07, T 0464/94, T 0305/87

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1929/06 - 3.5.05

D E C I S I O N
of the Technical Board of Appeal 3.5.05
of 18 November 2009

Appellant: Baxter International Inc.
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Representative: Probert, Gareth David
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 27 July 2006 refusing European patent application No. 03747604.1 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: D. H. Rees
Members: A. Ritzka
F. Blumer

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dispatched 27 July 2006, refusing the European patent application No. 03747604.1 for the reasons that claim 1 of the main request lacked novelty and claim 1 of the auxiliary request did not involve an inventive step having regard to the disclosure of

D1: WO 01/88828 A.

II. Notice of appeal was filed on 29 September 2006. The appeal fee was paid on the same day. The statement of grounds of appeal was submitted on 29 November 2006. The appellant requested that the decision under appeal be set aside and that the patent be granted based on claims 1 to 15 of the main request or auxiliary request 1 (claims labelled "1st auxiliary request"), both requests being filed with the statement setting out the grounds of appeal. An auxiliary request for oral proceedings was made.

III. The Board issued an invitation to oral proceedings accompanied by a communication. In the communication the board expressed the preliminary view that claim 1 of the main request and auxiliary request 1 did not appear to comply with the provisions of Article 84 EPC, that claim 1 of the main request did not appear to comply with the provisions of Article 123(2) EPC and that the subject-matter of claim 1 of the main request and auxiliary request 1 did not appear to be novel having regard to the disclosure of document D1. Even if claim 1 of auxiliary request 1 was considered to be novel due to a different interpretation of the term

"medical device equipment identifier", it would not appear to involve an inventive step having regard to the disclosure of document D1.

IV. With its letter of 12 October 2009, in response to the communication, the appellant filed auxiliary requests 2 to 4 (claims 1 to 13 labelled "2nd auxiliary request", claims 1 to 12 labelled "3rd auxiliary request" and claims 1 to 11 and 14 [sic] labelled "4th auxiliary request") and presented arguments that claim 1 of the main request and auxiliary request 1 was clear and that claim 1 of the main request did not include added subject-matter. As to the lack of novelty the appellant referred to its reasons given in the grounds of appeal.

V. At the oral proceedings which took place as scheduled on 18 November 2009 the appellant filed amended claims of auxiliary requests 1 to 4. On the basis of these requests the case was discussed with the appellant. After deliberation the board announced its decision.

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

"A patient care apparatus (100) comprising:

a personnel identifier (112a, 116a) having a data output comprising personnel information;

a medical device (120) having a data output comprising medical treatment information;

a wireless device (120e) coupled to the data output of the medical device (120) and the data output of the personnel identifier (112a, 116a), the wireless device having a radio frequency (RF) output;

a medical device tag (120d) associated with the medical device (120) and comprising information to

uniquely identify the medical device (120), the information provided upon request by an electronic device (118), and. [sic]

a data stream identifier (204) having an identifier output attached to the medical treatment information, and comprising the personnel information."

Claim 1 of auxiliary request 1 reads as follows:

" 1. A patient care apparatus (100) comprising:

a personnel identifier (112a, 116a) comprising data in a device readable format,

medication (124) having a medication label identifier (124a) comprising data in a device readable format,

a medical device (120) for administration of the medication (124) to a patient (112), the medical device (120) being capable of generating a plurality of data streams which include medical treatment information,

a data stream identifier (204) coupled to the medical device (120), capable of attaching a unique data tag to the data streams,

a medical device identifier (206) coupled to the medical device (120), the medical device identifier (206) being capable of transmitting a unique device tag to identify the medical device (120) upon request to an external computer (104, 108),

a medical device equipment identifier (120d) coupled to the medical device (120) comprising data in a device readable format,

a first wireless device (120e) coupled to the data output of the medical device (120), the first wireless device (120e) having an RF output,

a second wireless device (118) capable of reading the personnel identifier data, the medication label data and the medical device equipment data, the second wireless device (118) having an RF output, the second wireless device (118) being capable of transmitting the personnel identifier data, the medication label data and the medical device label data to an external computer (104,108),

an external computer (104, 108) capable of requesting the device tag from the medical device identifier (206) and being capable of transmitting operating parameters directly to the medical device (120) in response to receiving the personnel identifier data, the medication label data and the medical device label data."

Claim 1 of auxiliary request 2 differs from claim 1 of auxiliary request 1 in replacing "apparatus" by "system" and replacing the personnel identifier by a patient identifier and a clinician identifier, either of them being read and transmitted by the second wireless device and received by the external computer.

Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 2 in specifying that the data stream identifier is secured to the medical device.

Claim 1 of auxiliary request 4 adds to claim 1 of auxiliary request 2 that the patient care system further comprises a bridge configured to attach the information to uniquely identify the medical device to the data stream, the bridge configured to provide the information to uniquely identify the medical device to the external computer.

Reasons for the Decision

1. *Admissibility*

The appeal complies with the provisions of Articles 106 to 108 EPC 1973, which are applicable according to J 10/07, point 1 (see Facts and Submissions, point II above). Thus, it is admissible.

2. *Main request*

Claim 1 of the main request adds to claim 1 as originally filed inter alia that the data stream identifier comprises the personnel information.

It is not clear to what "comprising the personnel information" relates. The application as filed does not provide a basis for this feature.

The appellant submitted in its letter of 12 October 2009 that page 13, lines 14 to 27 of the application as originally filed, provided a basis for this feature.

The cited passage discloses how the clinician identifies his/herself [sic], the patient, the medication and the medical device. The medical device communicates with the medication management module according to different options. Any communication from the medical device will be recognized as originating from the medical device due to the data stream identification system which assists the clinician in administering and verifying the medical treatment. The

data stream identification system may result in downloading of operating parameters to the medical device. The clinician may provide a visual verification of the labelled medication and may scan machine readable information for entering it to the wireless device and the medical device.

The board considers that this passage discloses a number of embodiment details that are not necessarily related to each other, but none that provide a basis for this feature of claim 1.

The appellant did not present further arguments on this issue.

Thus claim 1 does not comply with the provisions of Article 123(2) EPC.

3. *Auxiliary request 1*

3.1 Interpretation

Without prejudice to the question whether claim 1 fulfils the clarity requirements of Article 84 EPC, the further analysis is based on the following interpretations (the appellant having indicated a willingness to amend the requests to overcome any clarity objections):

The medical device identifier and the medical device equipment identifier being listed as separate features are interpreted as features that might be implemented either separately or as a common component with multiple functionality.

The data output coupled to the first wireless device is interpreted to be an interface at which the data stream is available.

The external computer mentioned three times as "an external computer" is interpreted as one and the same external computer.

Various devices are said to be capable of a given functionality. These capabilities are interpreted to be limiting in the sense that the devices are adapted to provide the respective functionality.

3.2 Novelty and inventive step

The appellant argued that the subject-matter of claim 1 differed from D1 in that the external computer transmits operating parameters directly to the medical device in response to receiving the personnel identifier data, the medication label data and the medical device label data, whereas D1 would teach the skilled person to implement a system where a nurse station read the patient identifier, the medication identifier and the medical device equipment identifier, sent them to a central computer for validation, received the operating parameters and activated the medical device using these operating parameters, i.e. where the operating parameters were sent indirectly from the central computer via the nurse station.

D1 (see page 30, line 1 to page 33, line 15) discloses an embodiment of a care management system comprising a communication system that interconnects various care

facility information systems, such as a hospital information system corresponding to the external computer of claim 1, a pharmacy information system and a physician order entry system via suitable interfaces. The communication system includes a connection to a wireless transmitter/receiver through a suitable interface. The wireless transmitter/receiver is configured to send messages to a nurse station and a patient specific asset.

The patient specific asset may be connected to a wireless transmitter/receiver that communicates with the various care facility systems through the communication system, (see page 30, line 29 to page 31, line 3), corresponding to the first wireless device.

The nurse station is connected to a transmitter/ receiver and may include a bar code reader, (see page 30, lines 18 to 26), the combination of theses devices corresponding to the second wireless device of claim 1.

Medical transaction carrier information is transmitted from the care facility information systems directly to a patient specific asset, i.e. a medical device, located at a patient's bedside, (see page 30, lines 1 to 4), the medical transaction carrier taking the form of a formatted electronic message, (see page 31, lines 20 to 24).

The patient specific asset analyses medical transaction information transmitted to the patient specific asset by the transmitter/receiver of the communication system, instructing the patient specific asset to carry out the

medical order contained within the medical transaction information, (see page 31, lines 4 to 15).

Each patient may be identified by a wristband including patient specific information encoded in a barcode which may be read with a bar code reader at the same time that the medical transaction carrier is transmitting its information to the patient specific asset, thus ensuring that the right patient is receiving the right medication, (see page 32, lines 12 to 23).

The medication may equally be validated in real-time using a bar code applied to the medication or some form of active detection using a transmitter/receiver or smart chip or computer embedded in the label of the medication or located on the medication container, (see page 32, lines 24 to 30).

The medical transaction carrier may store and transport a wide variety of information, e.g. a patient's unique ID, a nurse's unique ID, specific medication prescribed, an identification of the specific patient specific asset assigned to a specific patient, the time of medication delivery, a current unique transaction ID identifying the current transaction of information between the medical transaction carrier and the patient specific asset, or the originator of the information such as the hospital information system or the pharmacy information system, (see page 33, lines 3 to 10).

D1 does not explicitly disclose that an external computer transmits operating parameters directly to the medical device in response to receiving the personnel identifier data, the medication label data and the

medical device label data. These parameters could be transmitted from the nurse station. Therefore, the subject-matter of claim 1 is novel.

According to page 23, lines 14 to 16 of the application as published, sending the operating parameters for the medical device directly to the medical device (assuming the various verifications are achieved) has the effect, in bypassing computers at the remote location, of eliminating a potential source of errors in administering medication to a patient. This implies that the problem underlying claim 1 is to provide a patient care apparatus adapted to provide the right medication to the right patient in the right dose at the right time and via the right route avoiding potential errors.

However, the application is silent about the kind of errors that are eliminated when bypassing computers at the remote location.

The appellant submitted that such potential errors may be due to congestion problems of computers at the remote location, e.g. the nurse station, and to data corruption during transmission. The board considers that congestion problems may occur at any computer in a system comprising interconnected computers. The board is not convinced that congestion problems are more likely to occur at the remote nurse station than at the central external computer.

Moreover, data corruption may occur at any data transmission. In the validation process several data transmissions are needed to compare the patient's ID,

clinician's ID, medication identification and the medical device equipment identification to information stored at central databases of the clinical information system. Moreover, the instruction message including the operating parameters has to be generated and transmitted to the medical device. The board considers that a similar number of data transmissions is needed when the computer at the nurse station and the central external computer performs the validation and message generation and that, thus, the specific kind of computer, i.e. the computer at the nurse station or the central external computer, which performs the validation and generates the instruction does not affect the likeliness of data corruption.

The appellant argued further that the validation process would only be performed in real-time if it took place at the central external computer. This argument does not convince the board, since in the system disclosed in D1 the validation of the patient's ID and the medication identification may be performed at the same time as the medical transaction carrier is transmitted, without specifying which computer performs the validation (see page 32, lines 12 to 30). Thus, even if the validation takes place at the computer at the nurse, i.e. remote, station, real-time validation can be provided.

Even if the specific medication regime for a patient was modified after the computer checked the information stored in the central databases of the clinical information system, the behaviour of the system would be equal regardless whether the computer at the remote

location or the central external computer performs the validation and transmits the operating parameters.

Therefore, the board considers that the potential errors discussed by the appellant affect the system disclosed in D1 and the system as claimed in a similar way. The board is not convinced that the alleged benefits of the application (see application as published, page 23, lines 11 to 18) differentiate the claimed system over the system disclosed in D1. The technical problem mentioned above is not solved. The subject-matter of claim 1 is thus considered to be an obvious alternative to the subject-matter disclosed in D1.

The subject-matter of claim 1 does not involve an inventive step (Article 56 EPC).

Thus, the claimed subject-matter does not comply with the provisions of Article 52(1) EPC.

3.3 Additional comment

The appellant referred to the decisions T 464/94 and T 305/87. T 464/94 concerns the question whether a document may be prejudicial to novelty on the basis of probability. T 305/87 concerns the combination of different parts within a prior art document in the assessment of novelty.

The board notes that these decisions are not relevant in the present case since the claims were found to be novel.

4. *Auxiliary requests 2 and 3*

The amendments of claims of auxiliary requests 2 and 3 were made to overcome the clarity objections made in the communication of the board. They do not add inventive matter. Thus, the findings with respect to inventive step presented in point 3.2 above apply similarly.

5. *Auxiliary request 4*

Claim 1 of auxiliary request 4 has been amended based on claim 1 of auxiliary request 2 so that claim 1 also refers to the presence of a bridge configured to attach the information to uniquely identify the medical device to the data stream, the bridge configured to provide the information to uniquely identify the medical device to the external computer.

The appellant did not present any arguments that claim 1 involved an inventive step.

At the priority date of the application, it was common practice in wireless communications and in network communications in general that a device which transmits a data stream attaches information to uniquely identify itself, i.e. a source address, to the data stream and can provide the information to uniquely identify itself (its address) upon request. E.g. in the GSM system a mobile station identifies itself in a paging response to a mobile switching centre in reaction to a paging request from the mobile switching centre. It lay within the routine competence of a skilled person to provide a device, e.g. a bridge, configured to attach the

information to uniquely identify the medical device to the data stream, the bridge being configured to provide the information to uniquely identify the medical device to the external computer.

The subject-matter of claim 1 does not involve an inventive step.

Thus, the claimed subject-matter does not comply with the provisions of Article 52(1) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

K. Götz D. H. Rees