Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 12 December 2023

Case Number: T 3124/19 - 3.4.03

Application Number: 11827387.9

Publication Number: 2619723

IPC: G06Q50/22, G06Q10/06

Language of the proceedings: EN

Title of invention:
AUTOMATIC ASSOCIATION OF MEDICAL ELEMENTS

Applicant:
Carefusion 303 Inc.

Headword:
Automatic association of medical elements/CAREFUSION

Relevant legal provisions:
EPC Art. 52(1), 53(c), 56, 97(1), 111(1), 123(2)
RPBA 2020 Art. 13(1), 13(2)

Keyword:

Exceptions to patentability - method for treatment by therapy (no)
Amendment to appeal case - amendment overcomes issues raised (yes)
Amendments - intermediate generalisation - after amendment (no)
Inventive step - after amendment - (yes)

Decisions cited:

G 0001/07

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 3124/19 - 3.4.03

D E C I S I O N
of Technical Board of Appeal 3.4.03
of 12 December 2023

Appellant: (Applicant)	Carefusion 303 Inc. 3750 Torrey View Court San Diego, California 92130 (US)
Representative:	Epping - Hermann - Fischer Patentanwaltsgesellschaft mbH Postfach 20 07 34 80007 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 4 July 2019 refusing European patent application No. 11827387.9 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	T. Häusser
Members:	M. Stenger
	E. Mille

Summary of Facts and Submissions

I. The appeal concerns the decision of the examining division to refuse European patent application no. 11 827 387.

II. In the contested decision the examining division, referring to D1 (US 2008/189783 A1) and D2 (US 2004/019464 A1), set out that the claims of the then main request and of the then first to third auxiliary requests lacked an inventive step. In addition, it expressed doubts as to the allowability of the aspect of selecting a medication with respect to Article 53(c) EPC. The examining division further set out that some of the former auxiliary requests did not fulfil the requirements of Article 123(2) EPC.

III. In a communication under Article 15(1) RPBA 2020 sent in preparation of the oral proceedings, the board made comments *inter alia* concerning non-compliance of the former auxiliary requests with the requirements of Article 123(2) EPC.

IV. At the end of the oral proceedings before the board, the appellant requested that the contested decision be set aside and that a patent be granted on the basis of the request submitted during these oral proceedings, comprising the following application documents:

Claims: 1 to 13 of the main request submitted during the oral proceedings before the board at 14:35 hours;

Description: pages 1, 1a, 2-15 submitted during the oral proceedings before the board at 14:35 hours;

Drawings: sheets 1/8 to 8/8 as published.

V. Independent method claim 1 of the sole request has the following wording (labeling **a)**, **b)**, ... added by the board):

a) A method of associating a plurality of objects, the method comprising the steps of:
b) determining, by use of a real-time locating system (RTLS), objects that are within a physical space;
c) automatically creating, by a processor associated with the RTLS, at least one association between the objects determined by the RTLS to be within the physical space, wherein the objects include medications, a patient, and a medical device;

d) wherein said determining comprises, by the processor:
d1) determining that a patient is within the physical space; and
d2) determining that a medical device is within the physical space; and
d3) determining that more than one medications are within the physical space;

e) wherein said automatically creating at least one association comprises, by the processor:
e1) automatically creating an association between the medical device and the patient;
e2) automatically providing, by the processor to the medical device, based on detecting that the more than one medications are within the physical space with the medical device and the patient, a list of the medications determined to be within the physical space with the medical device and the patient;

e3) presenting the list of the medications on a display of the medical device;
e4) selecting, by the caregiver using the medical device, a specific medication of the list;
e5) receiving, by the processor, the selected medication from the medical device;
e6) automatically confirming, by the processor, that the selected medication has been ordered for the patient; and
e7) automatically downloading, by the processor to the medical device, based on receiving the selection of the selected medication and confirming that the selected medication has been ordered for the patient, one or more operating parameters for configuring the medical device to administer the medication from a database remote from the medical device.

VI. Independent system claim 8 of the sole request has the following wording (labeling **a')**, **b')**, ... added by the board):

a') A system comprising:
b') a RTLS transceiver configured to define a physical space and identify objects comprising RTLS tags that are within the physical space; and
c') a processor coupled to the RTLS transceiver, the processor configured to receive the identification of the tagged objects and, upon verifying that the objects are within the physical space, automatically create at least one association between the identified objects, wherein the objects include at least one of a caregiver, a patient, a medication, and a medical device;
f') the system further comprising a database coupled to the processor, the database configured to store

data, wherein the processor is further configured to store associations of objects in the database;

d') wherein the processor is further configured to:
d3') determine that more than one medications moved to within the physical space with a patient and a medical device detected by the RTLS;

e2') automatically provide to the medical device, based on detecting that the more than one medications are within the physical space with the medical device and the patient, a list of the medications determined to be within the physical space with the medical device and the patient;
e3') wherein the medical device is configured to present the list of the medications on a display of the medical device, and
e4') is configured to receive a selection for selecting, by the caregiver using the medical device, a specific medication of the list;
e') wherein the processor is further configured to:
e5') receive the selected medication from the medical device;
e6') automatically confirm that the patient has a prescription for the selected medication; and
e7') automatically download to the medical device, based on receiving the selection of the selected medication and confirming that the selected medication has been ordered for the patient, one or more operating parameters for configuring the medical device to administer the medication from a database remote from the medical device.

VII. The appellant argued essentially that the effected amendments had a basis in the original application documents and that the claimed subject-matter involved

an inventive step allowing a more efficient medication administration.

Reasons for the Decision

1. The invention

The application and the invention it relates to provide an improved automated process to ensure the "five rights" of medication administration (right patient, right time, right medication, right route of administration, right dose) in a hospital (see paragraph [0002] of the description). In particular, the time-consuming steps of manually scanning bar codes to identify, e.g., the patient, the caregiver and the medication can be eliminated using a real-time locating system (paragraphs [0003] to [0006].

2. The relevant prior art

D2 discloses a patient care system. Although not explicitly mentioned as such, ensuring the "five rights" of medication administration is one of the aims of D2 (see paragraph [0055]). The disclosed system involves identifiers of clinicians, patients, medications and medical devices (see paragraph [0052]). The embodiments described in detail use bar code scanning for identification purposes, but D2 also refers to the use of RFID (see paragraphs [0022] and [0066]), that is to a real-time locating system.

D1 relates to unlocking access to a medical device based on the presence of a caregiver with a corresponding permission level. It is recorded which caregiver gave which commands to the medical device

(paragraphs [0076] to [0078]). Furthermore, a patient ID may be displayed by the medical device (paragraph [0079]). D1 thus discloses that the co-location of the medical device, the caregiver and the patient is determined and recorded. Therefore, D1 discloses an automatic association of the medical device, the caregiver and the patient. However, D1 does not mention the automatic identification of medications or the "five rights" of medication administration.

3. Admission of the sole request

The sole request was filed during oral proceedings before the board in reaction to the objections under Article 123(2) EPC first raised by the board in its communication preparing the oral proceedings and discussed during the oral proceedings. The board therefore held that there were exceptional circumstances justified with cogent reasons by the appellant according to Article 13(2) RPBA. The amendments further resolved the issues raised by the board (see Article 13(1) RPBA). The board thus decided to admit the request.

4. Amendments - Article 123(2) EPC

4.1 Claim 1 is based on original claims 1 and 2 as well as on paragraphs [31] and [35] of the original description.

Features **a'), b'), c')** and **f')** of claim 8 are based on original claims 16 and 17. The other features of claim 8 correspond to features of claim 1 and are based on paragraphs [31] and [35] of the original description.

4.2 Claims 2, 3, 5, 6 and 7 correspond to original claims 3, 4, 7, 8 and 10, respectively. Claims 9, 10, 12 and 13 are based on original claims 19, 21, 24 and 26, respectively. Claims 4 and 11 are based on paragraph [35] as filed.

4.3 The board notes that the skilled person would understand from paragraphs [31] and [35] of the original description that, in case that more than one medications are detected to be within the physical space, a list of these is presented on a display of the medical device for selection by the caregiver using the same device that displays the list. The medication selected in that manner is then received by the processor.

No other way of receiving the selected medication is disclosed in the original application. The aspects that the list is presented on the medical device and that the caregiver selects a medication using the (i.e. the same) medical device were not included in the auxiliary requests underlying the contested decision. As mentioned in the board's communication preparing the oral proceedings and discussed during the oral proceedings, this absence constituted an intermediate generalisation and contravened the requirements of Article 123(2) EPC. This issue was resolved by the amendments of the sole request filed during oral proceedings.

5. Inventive step - Article 56 EPC

5.1 Closest prior art

It follows from the above (see section 2.) that D2 has the same aim as the present application and shares most

of the technical features therewith. D2 is therefore considered to represent the closest prior art.

5.2 Disclosure of D2

D2 discloses, at the treatment location, the identification of a clinician, a patient, a medication and a medical device (see [0052]). This is done in the detailed embodiments by bar code scanning, but can also be done using RFID (see [0022] and [0066]). That is, D2 discloses, in the wording of claim 1, "determining, by use of a real-time locating system (RTLS), objects that are within a physical space" (namely, the treatment location), and therefore feature **b)**. Since the identifications mentioned in paragraph [0052] of D2 include a patient and a medical device, D2 also discloses features **d)**, **d1)** and **d2)**.

The identifications of the clinician, the patient, the medication and the medical device are then used in a data stream identification system 410 with a computer (and thus a processor) 400 to verify that the right medication is provided to the right patient in the right dose at the right time, and via the right route (i.e. using the right medical device), as disclosed in paragraph [0055] and Figure 4. That is, the computer checks whether the clinician, the patient, the medication and the medical device correspond to what is called in the application the "five rights" of medication administration. This implies that the combination (or "association") of the clinician, the patient, the medication and the medical device identified is checked to be correct (see also Figure 5 and the corresponding paragraphs [0066] to [0075]). Therefore, in the wording of claim 1, D2 discloses "automatically creating, by a processor associated with

the RTLS, at least one association between the objects determined by the RTLS to be within the physical space, wherein the objects include medications, a patient, and a medical device", that is feature **c)**. Feature **a)** is formulated more generally than feature **c)** and is therefore also disclosed. In addition, since the identifications of the medical device and the patient are checked *in association*, D2 also discloses feature **e)** and **e1)**.

More particularly, the system of D2 determines whether the medical treatment, which includes the identified medication, has been previously associated with the patient (see paragraphs [0069] and [0070]), that is, in the wording of claim 1, the system is "automatically confirming, by the processor, that the selected medication has been ordered for the patient". D2 thus discloses feature **e6)**.

Finally, D2 also discloses automatically downloading of operating parameters to the medical device (see paragraph [0076]) and thus feature **e7)**.

5.3 Distinguishing features

The subject-matter of claim 1 thus differs from D2 by how a particular medication is selected according to features **e2)**, **e3)**, **e4)** and **e5)** when more than one medication is detected according to feature **d3)**.

5.4 Technical effect / objective technical problem

When RFID is used to identify objects, more than one object of the same type may in the range of the system and consequently be detected. This may, in principle, also happen in a hospital where medications are to be detected by RFID. The technical effect of the distinguishing features is thus that the clinician/

caregiver is enabled to choose the correct medication in such a situation. The objective technical problem might then be formulated as how to improve the system of D2 such that the "five rights" are still ensured in the presence of a plurality of medications.

5.5 Obviousness

5.5.1 In its detailed embodiments, D2 refers to bar code scanning. With this technology, a plurality of medications present at the treatment location would not be a problem, because only one of them would be bar code scanned by the clinician. When the bar code scanning referred to in the detailed embodiments of D2 is to be replaced by its alternative RFID suggested in paragraphs [0022] and [0066] of D2, the skilled person would normally consider to use an RFID system with a similar range as bar code scanning, that is a few centimetres (using e.g. an NFC system). In that case, the above-mentioned problem would not arise, either.

It is thus likely that the skilled person, starting from D2, would not come across the issue addressed by the distinguishing features.
The skilled person, starting from D2, would thus probably not even consider that the above-mentioned problem needs to be solved.

5.5.2 The board is aware that the medical device 120 of D2 can include a keypad 120b, a display 120c, an antenna 120e for radio technology transmission and/or reception and a bar code reader 120f (see Figure 1 and paragraph [0021]). That is, the medical device 120 can comprise technical features such that the skilled person **could** in principle implement claimed features **d3)** and **e2)** to **e5)** in the system of D2.

However, according to D2, the objects, in particular the medications, are identified using the digital assistant 118 of the clinician (see, e.g., paragraphs [0016], [0051] in combination with [0052] and [0069]). The skilled person, when trying to solve the objective technical problem defined above starting from D2, would thus use the digital assistant 118 and not the medical device 120 of D2 to detect one of the plurality of medications. Moreover, as stated above, the skilled person would be inclined to use near field RFID technology for the detection. The skilled person **would** therefore not arrive at the solution defined in claim 1.

5.5.3 The board thus concludes that the skilled person, starting from D2, would first of all not be aware that the objective technical problem defined above was to be solved at all. Further, even if it was aware of that problem and tried to solve it, it would arrive at a different solution than the one presented in claim 1.

Therefore, the subject-matter of claim 1 of the main request is inventive in view of D2 and the common general knowledge. Since D1 does not refer to medications at all, it has no relevance for the assessment of inventive step.

The board is thus of the opinion that the subject-matter of method claim 1, the corresponding system claim 8 and dependent claims 2-7 and 9-13 of the sole request involves an inventive step under Articles 52(1) and 56 EPC in view of the prior art available.

6. Exceptions to patentability - Article 53(c) EPC

The examining division expressed "considerable doubt" as to whether the step of selecting a medication constituted medical treatment and thus formed a barrier to patentability.

The board is of the opinion that selecting a medication for a patient can have a therapeutic effect only if the selection is performed taking into account the kind of illness to be treated, in the sense that a medication is selected that has, for that kind of illness, a known, beneficial effect on the body of the patient. In the present case, however, the kind of illness does not play a role. Instead, the purpose of the claimed selection step is to make sure that a medication is administered that was previously chosen as appropriate, in a step preceding and therefore not being part of the claimed method.

That is, in the present case, the step of selecting a medication only concerns operating the medical device such that human handling errors are avoided. It has no functional link to the effects of the (unclaimed kind of) medication on the body of the patient (see section 4.3.2 of the Reasons for the Decision of decision G1/07).

The board therefore believes that in the present case, the step of selecting a medication (features **e4)** and **e4')**) does not form a barrier to patentability of the independent claims, contrary to the remark of the examining division.

7. Summary

The sole request complies with the requirements of both Article 123(2) EPC and Articles 52(1) and 56 EPC. The remark made by the examining division with respect to Article 53(c) EPC does not apply. Hence, a patent is to be granted on the basis of that request (Articles 97(1) and 111(1) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division with the order to grant a patent in the following version:

Claims: 1 to 13 of the main request submitted during the oral proceedings before the board at 14:35 hours;

Description: pages 1, 1a, 2-15 submitted during the oral proceedings before the board at 14:35 hours;

Drawings: sheets 1/8 to 8/8 as published.

The Registrar: The Chairman:

T. Buschek T. Häusser

Decision electronically authenticated