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Datasheet for the decision of 21 December 2015

Case Number: T 0823/11 - 3.5.07

Application Number: 96915827.8

Publication Number: 0846293

IPC: G06F17/00, G06G7/48, G06F19/00

Language of the proceedings: EN

Title of invention:
System and method for collecting data and managing patient care

Applicant:
CareFusion 303, Inc.

Headword:
Managing patient care/CAREFUSION

Relevant legal provisions:
EPC Art. 56
EPC R. 103(1)(a), 111(2)
RPBA Art. 11, 12(4)

Keyword:
Substantial procedural violation -
excessive length of proceedings (yes) -
appealed decision sufficiently reasoned (no)
Inventive step - main request (no) - auxiliary request (yes)
Exercise of discretion by the first instance not to admit auxiliary request filed in oral proceedings - overruled
Reimbursement of appeal fee - (yes)

Decisions cited:
G 0007/93, T 0278/00, T 0315/03
Kristiansen and Tyvik AS v. Norway, European Court of Human Rights Application no. 25498/08

Catchword:
see points 2 to 5 of the reasons

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Case Number: T 0823/11 - 3.5.07

D E C I S I O N
of Technical Board of Appeal 3.5.07
of 21 December 2015

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 30 September 2010 refusing European patent application No. 96915827.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	R. Moufang
Members:	P. San-Bento Furtado
	M. Rognoni

Summary of Facts and Submissions

I. The appeal lies from the decision of the Examining Division posted on 30 September 2010 to refuse European patent application No. 96915827.8, which was filed as international application PCT/US96/06944 published as WO 96/36923.

The decision was issued against "Cardinal Health 303, Inc.". A change of the applicant's name to "CareFusion 303, Inc." was registered by the EPO with effect on 4 November 2010. The appeal was filed on 30 November 2010 by the applicant under its new name.

II. The present application, which concerns the configuration of a clinical device in a patient care management system, was filed on 15 May 1996 and entered the European phase on 15 December 1997. The supplementary European search report was completed on 18 February 1999.

During the proceedings the applicant sent two reminders, with letters dated 22 March 2004 and 4 September 2006, pointing out that a long time had passed since the last action by the EPO and enquiring about the further prosecution of the case.

The first communication of 7 June 2004 referred to documents D1 (US-A-4 847 764, published on 11 July 1989) and D2 (US-A-5 401 059, published on 28 March 1995) and raised objections under Rule 29(2) and Articles 52(1) and 56 EPC 1973. The claimed invention was considered to lack inventive step over the disclosure of document D1 in column 2, line 65 to column 6, line 2 and Figure 1. Later two further communications were sent out by the Examining Division

on 18 March 2005 and 13 November 2006. The applicant replied to all these communications, amending the claims once, and each time presenting its counter-arguments. The last reply letter was dated 10 August 2007.

The applicant was summoned to oral proceedings with a communication of 8 March 2010, which contained the preliminary opinion of the Examining Division. It reacted to this communication with the submission of a main request and an auxiliary request. After a telephone conversation with the first examiner on 11 June 2010, in which clarity deficiencies were discussed, the applicant replaced both requests with a single main request. At the oral proceedings before the Examining Division, the appellant submitted an auxiliary request.

III. The application was refused for lack of inventive step, Articles 52(1) and 56 EPC, of the subject-matter of the independent claim of the main request. The Examining Division invoked the common general knowledge and the prior art disclosed by document D1.

The Examining Division did not admit the auxiliary request submitted at the oral proceedings. In its decision, the Division also mentioned that the dependent claims of the main request appeared to lack inventive step. In an *obiter dictum* it expressed the opinion that the claimed system was not clearly defined.

IV. The reasons given in the decision under appeal can be summarised as follows:

Under "SUMMARY OF FACTS AND SUBMISSIONS" the Examining Division explained that the late-filed auxiliary request, submitted during the oral proceedings, was not admitted into the procedure because it did not *prima facie* overcome the previously raised objection of lack of inventive step.

Regarding the reason for refusal of the main request, the Examining Division argued that, insofar as the claims could be understood, it appeared that the technical contribution of the present application was the avoidance of errors when programming a clinical device, obtained via an automatic inputting of data and checks. It then stated:

"Now, the entering of data in a digital system not manually in order to avoid human errors is, in effect, the obvious known way to solve the posed problem since the introduction of the coded data reading devices, in particular bar code reader, derived from the common knowledge, while the checks (comparisons between stored and entered data) which are also obvious measures for a skilled person are furthermore suggested in the prior art.

For example D1: US-A-4 847 764 (HALVORSON JERRY L) 11 July 1989 (1989-07-11), discloses a system for dispensing drugs in health care institutions, see in particular lines 48 - 55 of col. 4 of this document."

In an *obiter dictum* the Examining Division said that the presence of the two processors did not appear to play any role in the working of the claimed system and that the "unessential presence" of those features in the claim introduced ambiguity. The results of the comparisons were independent of the location where they took place.

V. In the statement of grounds of appeal, the appellant requested that the decision be set aside and a patent be granted on the basis of the claims of the main request or, alternatively, of the auxiliary request (titled "Subsidiary Request"), both requests filed with the grounds of appeal and corresponding exactly to the requests on file at the time of the decision.

VI. The appellant was invited to oral proceedings before the Board. In a subsequent communication sent in advance of the oral proceedings, the Board expressed the preliminary view that none of the appellant's requests was allowable.

The Board cited two further documents, D3 and D4:
D3: EP 0 595 474, published on 4 May 1994;
D4: US 4 857 716, published on 15 August 1989.

Document D3 had been cited in the supplementary European search report and document D4 had been cited in the International Search Report issued by the United States Patent and Trademark Office as ISA/US.

The Board considered in particular that the subject-matter of claim 1 of the main request did not appear to be inventive in view of document D1 and the common general knowledge. The Board raised concerns with respect to the inventive step of the subject-matter of the auxiliary request over the disclosure of documents D1 and D3. The Board furthermore discussed issues related to clarity and added subject-matter and explained why also document D4 appeared to be relevant for the question of inventive step.

VII. With a letter of reply, the appellant withdrew its request for oral proceedings and requested that a decision be taken based on the file as it stood.

VIII. Oral proceedings were held on 6 October 2015 in the absence of the appellant. At the end of the oral proceedings, the chairman announced that the Board's decision would be given in writing.

IX. The appellant's final request was that the contested decision be set aside and that a patent be granted on the basis of the claims of the main request or, alternatively, of the auxiliary request, both requests resubmitted with the statement of grounds of appeal.

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

"A patient care management system comprising:

a first programmable computer (80) for processing and storing patient and clinical device configuration data;

a second programmable computer (45) for verifying, monitoring and recording medical treatment provided to the patient;

first input means, comprising a bar code reader (90) operatively connected to the first programmable computer (80) for input of data comprising patient data to the first programmable computer;

second input means operatively connected to the second programmable computer (45) for input of data comprising patient data and clinical device configuration data to the second programmable computer (45); the second programmable computer (45) storing said data comprising patient data and clinical device configuration data input by the second input means;

a clinical device (92) operatively connected to the first programmable computer (80) for delivering medication to the patient;

communication means (50) for operatively connecting the first programmable computer (80) to the second programmable computer (45), wherein the data comprising patient data input into the first input means (90) is communicated to the second programmable computer (45) by the communication means; and

wherein the second programmable computer (45):

verifies the data comprising patient data input into the first input means (90) with the stored patient data; and

when the verification is complete, automatically communicates clinical device configuration data to the first programmable computer (80) to configure the clinical device (92)."

XI. Claim 1 of the auxiliary request differs from claim 1 of the main request in that:

(i) in the first listed feature, the text "storing patient and clinical device configuration data" has been replaced by "storing patient identity, medication and clinical device configuration data",

(ii) the text "data comprising patient data" has been replaced by "patient identity and medication data" in the first four occurrences of that text,

(iii) the last part of the claim after "wherein the second programmable computer(45):" has been amended to

"compares the patient identity and medication data input into the first input means (90) with the stored patient identity and medication data and verifies that the medication identified by the medication data input into the first input

means (90) is the correct medication for the patient identified by the patient identity data input into the first input means (90); and

when the verification is complete, automatically communicates clinical device configuration data to the first programmable computer (80) to configure the clinical device (92); wherein the clinical device comprises an infusion pump, and wherein communicating clinical device configuration data to the first programmable computer (80) to configure the clinical device comprise[s] downloading appropriate configuration parameters for the infusion into the first programmable computer (80) and then into the infusion pump (92)."

XII. The appellant's essential arguments, insofar as relevant for the present decision, can be summarised as follows.

Regarding the objections of lack of clarity of the Examining Division, the appellant argued that the first and second computers were a bedside CPU and a remote computer, respectively. Having a single server and connecting the hardware to it directly would necessitate a rather complex system having proper interfaces with each different connected hardware. Besides, since the hardware was remote from the single server, it would be difficult to check whether the hardware communicated properly with the server. Therefore, the two computers had a technical effect.

The invention made sure that no medication was delivered by mistake to a patient, for example because of name similarities. It avoided mistakes by the nurse when programming the device.

None of the documents D1 or D2 disclosed "configuring directly a clinical device assigned to the patient from a computer after the drug/patient verification has been made".

The invention went against a technical prejudice in the field of providing care, according to which the manual input of configuration data by a professional was necessary to add a security level to the configuration of the clinical device.

Reasons for the Decision

Admissibility of appeal

1. The appeal complies with the provisions referred to in Rule 101 EPC and is therefore admissible.

Procedural violations

2. It follows from the summary of the first-instance proceedings (see section II above) that their length was affected by unacceptable delays, in particular the delay of more than five years between the supplementary European search report dated 18 February 1999 and the Examining Division's first communication of 7 June 2004, and the delay of more than two years between the applicant's reply of 10 August 2007 to the third communication of the Examining Division and the summons to oral proceedings dispatched on 8 March 2010. These delays were pointed out in letters from the

appellant who *inter alia* repeatedly enquired about the further prosecution of the case.

In the opinion of the Board, the delays cannot be justified by the particular circumstances of the case. The duration of the first-instance proceedings of more than twelve years after entry into the European phase must be regarded as excessive. According to decision T 315/03, even a shorter delay of ten years in a much more complex opposition case amounted to a procedural violation (points 15.5 and 15.6 of decision T 315/03 which was published only in an abbreviated form in OJ EPO 2006, 15). The Board in that case found that such a delay was not "within a reasonable time" and therefore infringed Article 6(1) of the European Convention on Human Rights (ECHR).

The Board's considerations in the present case are also in line with a judgment in the case of Kristiansen and Tyvik AS v. Norway before the European Court of Human Rights (decision of 2 May 2013 in application No. 25498/08), in which the examination and (administrative) appeal proceedings of a patent application at the Norwegian Industrial Property Office took a total of eighteen years before the final decision was issued in a second appeal (which the appellant apparently did not challenge before the Norwegian courts). The initial examination proceedings up to the refusal of the application by the first instance in that case took nearly eleven years (see points 4 to 16). Taking into account the duration of patent protection of twenty years, the European Court of Human Rights found "the length of the administrative proceedings before the patent authorities" in that case to be excessive because it "in effect rendered meaningless any exercise by them [the applicants] of

their right of access to a court" (see points 53 to 58 of the decision). Although the Court recognised that the intransigent attitude of the applicant had contributed to the length of the proceedings (points 54 and 56), it reiterated that "in civil length cases examined under Article 6 § 1, the period to be taken into consideration does not necessarily start when the competent tribunal was seized but may also encompass the prior administrative phase" (point 57).

The conclusions of that decision apply all the more to the present case since, in contrast to the case underlying that decision, the proceedings of the first instance in the present case were not affected by any unusual behaviour on the side of the applicant. It is simply not acceptable that under these circumstances the first instance refusal decision was taken more than fourteen years after the filing date and more than twelve and a half years after the entry into the regional phase despite the appellant's repeated attempts to achieve an acceleration of the proceedings.

3. A further issue concerns the reasoning given in the examination proceedings. According to Rule 71(2) EPC any communication under Article 94(3) EPC must contain a reasoned statement covering, where appropriate, all the grounds against the grant of the European patent. These provisions, or the corresponding provisions of the EPC 1973 in force during part of the first-instance proceedings in the present case, have been interpreted by the established jurisprudence as implying that the applicants have to be informed, for each EPC requirement deemed not to be met, of the legal and factual reasons why it was considered not to be met (Case Law of the Boards of Appeal of the EPO, 7th edition 2013, IV.B.2.3.2).

3.1 In the present case, the inventive step argumentation of the first communication simply referred to the abstract and a passage extending over three columns of document D1 (see also section II above). It did not discuss individual features of claim 1 or their correspondence to features disclosed in document D1, and did not identify the differences to the prior art.

The second very short communication simply stated that the data received from the central computer in the system of document D1 included identification data which was checked, and that the check was the crucial feature of the characterising portion of the claim. The third communication did not add any relevant argument, simply stating that two points needed to be clarified "in order to evaluate the technical contribution", and that "an assessment of the technical contribution (or 'inventive step') [...] can be conducted only after the problem solved is clearly fixed in the arguments produced by the applicant and this in order to make them valid".

The communication accompanying the summons to oral proceedings raised objections for lack of clarity of claim 1. The claim did not "respect the distinction between processors and memory (storage) location" and the two processors did not play any role. It was stated that, assuming document D1 as the closest prior art, the feature mentioning the existence of two processors should be included in the characterising part, contrary to the claim wording at the time. Regarding inventive step, the Examining Division argued that the technical contribution of the invention was the avoidance of "errors when programming a clinical device" and that the solution could be derived from the common

knowledge. The communication mentioned for the first time that the dependent claims lacked inventive step, but did not include any reasoning.

In the opinion of the Board, the reasoning in those communications was insufficient. The communications did not clearly identify the closest prior art and the distinguishing features of the invention. None of the communications analyses the individual features of the claim or adequately addresses the arguments of the appellant.

4. Regarding the decision itself, the Board notes that Rule 111(2) EPC stipulates that decisions of the EPO open to appeal should be reasoned. According to the established jurisprudence of the Boards of Appeal, in order to fulfil the requirements of Rule 111(2) EPC, a decision should contain, in logical sequence, those arguments which justify its tenor.

As further explained in T 278/00, OJ EPO 2003, 546 (see point 2): "the conclusions drawn from the facts and evidence must be made clear. Therefore all the facts, evidence and arguments which are essential to the decision must be discussed in detail in the decision including all the decisive considerations in respect of the factual and legal aspects of the case". That decision also explains that the reasoned decision is required to enable the appellants, and the board of appeal in case of an appeal, to examine whether the decision could be considered to be justified or not (see also Case Law of the Boards of Appeal of the EPO, 7th edition 2013, III.K.4.2).

4.1 The decision's argumentation with respect to inventive step, essentially that reproduced in section IV above,

does not discuss the individual features of the claim. It is not clear what the closest prior art is, whether it is the common knowledge of the skilled person or the disclosure of document D1, and what distinguishes the invention from the prior art. The decision simply refers to column 4, lines 48 to 55 of document D1, which discloses the automatic checking of a patient's medication order by the system. Even though this passage is definitely very relevant, the reasoning does not indicate how the features disclosed in it correspond to claimed features. Some features of the claim, for example the particular configuration of interconnected devices of the patient care management system and the way they interact, are not disclosed in that passage of document D1 and are not further discussed in the decision.

The minutes of oral proceedings provide a more complete argumentation on inventive step, explaining where each of four possible distinguishing features is disclosed in either document D2 or in a specific passage of document D1. However, this reasoning was not taken over in the decision.

4.2 The decision of the Examining Division not to admit the auxiliary request is only briefly mentioned in point 7 of the facts and submissions of the written decision, but not in its reasons. According to that passage, the request did not *prima facie* overcome the previously raised objection for lack of inventive step (see section IV above). This reasoning is confusing and insufficient. It exclusively mentions Articles 52(1) and 56 EPC, which however cannot serve alone as the legal basis for not admitting a request.

4.3 Finally, the Board notes that the decision does not treat the arguments of the appellant.

5. The Board hence concludes that the duration of the first-instance proceedings was excessive, the written reasoning given in the communications was inadequate, and the contested decision is insufficiently reasoned within the meaning of Rule 111(2) EPC. These deficiencies amount to substantial procedural violations.

6. According to Article 11 RPBA, a Board shall remit a case to the department of first instance (without substantive examination) if fundamental deficiencies are apparent in the first instance proceedings, unless special reasons present themselves for doing otherwise.

The excessive duration of the examination proceedings in the present case qualifies as such a special reason. Consequently, the Board found that remitting the case directly for formal reasons would be inappropriate.

The invention

7. The application relates to a patient care management system for automating administration of medication to patients in a health-care institution.

8. The care management system shown in Figure 1 is "configured as a local area network with a file server 45 to which are connected a pharmacy computer 60, a nursing station 70, and bedside CPUs 80" (see page 6, lines 22 to 24 of the international publication).

9. A particular mode of operation of the care management system of the invention is described on page 18, line 10, to page 20, line 26. Each patient wears a wristband with a bar code representing his name and other information. The physician prepares an order for administration of a particular medication regime and gives it to the health-care institution's pharmacy, where the necessary medication is packaged in a container labeled, in the example using a bar code, with the patient's name, drug name and other treatment parameters. On page 19, lines 5 to 7, it is also stated: "The existence of this medication order is made available by the hospital's pharmacy information system 20 and is stored by the file server 45".

The medication is then delivered to the appropriate unit for administering to the patient. In order to administer the medication, a caregiver, e.g. a nurse, carries the drug container to the appropriate patient, and reads both bar codes of the patient and the drug container using a bar code reader attached to the bedside computer (also referred to as "bedside CPU 80" in the application, see e.g. page 19, lines 10 to 13). The drug container may also include the identification of both the drug and the patient (page 11, lines 15 to 20, page 18, line 30 to page 19, line 3). Other data may have to be entered for the verification process.

The obtained data is analysed by the medication administration module, which records the therapeutic regimen information for the patient and "verifies that the right medication is being given to the right patient in the right dose by the right route and at the right time". If a discrepancy is detected an alert is sounded (page 19, line 28 to page 20, line 10).

10. In the embodiment described on page 20, lines 11 to 26, the medication is to be delivered using an infusion pump attached to the bedside computer. In that case, "the care management system automatically downloads information consisting of the appropriate configuration parameters for the infusion from the pharmacy CPU 60 through the local area network 50 into the bedside CPU 80 and then into the infusion pump 92, 94 when the verification function of the medical administration management module 110 is complete". This eliminates one potential source of inaccuracy and the need for the caregiver to manually enter the parameters.

11. The following passage on page 20, line 27 to page 21, line 16, states that once the infusion pump is configured, the caregiver starts the infusion by pressing the appropriate control on the infusion pump. This may cause a signal to be transmitted from the pump to the bedside computer which is then logged by the clinical monitoring and event history module and entered by the medical administration management module into the patient's medical administration record.

Main request

12. Claim 1 of the main request is directed to a patient care management system comprising two computers in a communication network.

The first computer, named "first programmable computer (80)" in the claim, is to be understood as a bedside computer or "bedside CPU 80". According to the description on page 8, lines 29 to 31, each private room, semi-private room, or ward area has at least one bedside computer for monitoring and treating one or more patients. The first computer is connected to input

means comprising a bar code reader and to a clinical device for delivering medication to a patient.

According to the claim, the second computer is configured to receive and store data comprising patient data and clinical device configuration data. It is furthermore configured to verify the patient data received from the first computer with stored patient data and to automatically communicate configuration data to the first computer to configure the clinical device.

The claim assigns to the "second programmable computer" the reference sign 45, which is described in the application as the central file server connected to the network and storing information from the pharmacy information system (see, for example, page 7, lines 25 to 31, and page 19, lines 5 to 7). According to the passage on page 20, lines 11 to 26, the configuration parameters for the clinical device, an infusion pump, are downloaded from the "pharmacy CPU 60". In the light of this, the Board interprets the feature "second programmable computer" as also encompassing the "pharmacy CPU" with reference sign 60.

13. Claim 1 of the main request covers a broader subject-matter than that described on page 20, lines 11 to 26, in that the claimed clinical device is not limited to an infusion pump. The Board therefore assumes that it was the intention of the applicant to cover general clinical devices and interprets the feature accordingly.

14. In the grounds for appeal the appellant maintained that the verification step allowed "the second programmable computer to identify with certainty a patient and match

the identified patient with the patients in the database entered by the pharmacist" and that the downloading step allowed "configuring directly the clinical device assigned to the patient from the second computer, rather than having someone such as a nurse configure the device from the bedside" (see page 6 of the grounds of appeal).

The Board agrees that the second computer verifies the data and controls the device. However, the statements of the appellant imply a narrower interpretation of the claim than is derivable from its concrete wording. In particular, the claim does not state that the clinical device configuration data communicated to configure the device is somehow related to the patient. The claim therefore covers any configuration of the device.

Inventive step

15. Document D1 discloses a system for dispensing drugs in health-care institutions for avoiding medication errors, reducing staffing needs, as well as providing automatic functionality concerning inventory control, billing, patient profiles, medication administration reports, hourly patient medication requirements report, daily evaluation of medication due to discontinue, drug-interaction and allergy warnings (column 2, lines 39 to 53).

16. The system includes a central computer and dispensers, or dispenser stations, located at nursing stations. In one disclosed embodiment, the dispenser is operatively connected to the central computer ("computer system" in the wording of the claims of D1) and has "a software controllable, electrical interface that may receive data from the central computer" (column 3, lines 15 to

63, claim 1, column 24, lines 16 to 42). Each dispenser station includes a station terminal operatively connected to the central computer and a dispensing cabinet (see claim 1, column 24). A dispenser contains a plurality of medications that may be automatically dispensed to authorized personnel on demand. No medications are dispensed without verification and authorization (column 4, lines 28 to 32; claims 1 and 3). Medication orders are entered into the central computer via the pharmacy terminals (column 4, lines 38 to 46; claim 1, column 24, lines 37 to 42).

Therefore, document D1 discloses a patient care management system similar to that of the claimed invention and used for the same purpose. From the above explanation it follows that the system of document D1 includes first and second computers connected by communicating means, each including input means, and that the first computer (terminal of a dispensing station) is connected to a clinical device (dispenser or dispensing cabinet) for delivering medication to a patient as in the claimed invention. The second computer in D1 (central computer or computer system) records medical treatments.

In the Board's opinion, the dispenser or dispensing cabinet of document D1 is a clinical device for "delivering medication to the patient" within the meaning of the claim. As explained in point 13 above, the clinical device of the claim is not limited to an infusion pump. The dispensing cabinet of document D1 is used to dispense medication in a clinical environment for the purpose of delivering a specific dispensed medication to a corresponding patient. Since the dispensed medication has to be carried to the patient, the dispenser is not used to administer the medication

directly to the patient in the same way an infusion pump does. However, in the Board's view the claim is not limited to such a "direct delivery" of medication.

17. In order to deliver medication to a patient using the patient care management system of document D1, a nurse requests the medication at the terminal of the dispensing station for the specified patient. The computer system reads the stored patient order data for the specified patient, determines the medication scheduled to be administered and verifies the medication dispensing request with the medication data for the specified patient (claim 1, feature (b) of the software means, column 24, lines 62 to 68). If the verification is positive, the dispensing cabinet is actuated to dispense the scheduled medication (see claim 1, column 24, line 62 to column 25, line 18, and claim 3, column 25, lines 40 to 53, and column 5, line 35 to column 6, line 2). It is clear from claim 1 of D1 that the computer system is responsible for the verification and for controlling the dispensing cabinet. It therefore sends device configuration data to the terminal to configure the clinical device, in this case the dispensing cabinet.

18. In the grounds for appeal the appellant argued that the verification of the system of document D1 identified medication duplication or potentially dangerous drug interactions, but that document D1 did not "disclose or suggest any means for making sure that no medication was delivered by mistake to a patient".

The Board notes that, due to human intervention necessary in both cases (see sections 9 to 11 above), none of the systems can fully ensure that medication is not delivered by mistake. Moreover, for the reasons

given in point 14 above, the system as defined in claim 1 of the main request does not necessarily have that effect mentioned by the appellant.

The Board nevertheless recognises that the system as described in the application sends the appropriate configuration for the patient and contributes to avoid false medication. However, the same is done by the system of document D1 by verifying the medication orders for a specific patient before dispensing the medication and stopping the dispenser cabinet from delivering medication if the result of the verification is negative (claims 1 and 3). This objective is explicitly mentioned in column 2, lines 39 to 53, as well as column 12, lines 45 to 54 of document D1.

19. The system of claim 1 of the main request therefore differs from that of document D1 in that
- the input means of the first programmable computer comprises a bar code reader.

20. Bar code readers allow a more efficient and reliable way of inputting data. The distinguishing feature hence solves the problem of facilitating the input of patient data into the patient care management system.

21. In the opinion of the Board, the claimed solution was obvious for the skilled person at the priority date of the present application.

At that time it was standard practice to use bar codes to identify patients in hospitals and other health-care institutions, as acknowledged in the application on page 10, line 30, to page 11, line 4. It was well known that bar code readers allowed a faster and more reliable way of entering the patient identification

than previous solutions, for example using a keyboard. Furthermore, such a use of bar codes is described in document D4 in the context of a patient identification and verification system (see abstract and Figures 2 to 4).

It would thus be obvious for the skilled person to change the input means of the system of document D1 to the commonly known bar code readers in order to improve input of data in the system of document D1.

22. Consequently, the subject-matter of independent claim 1 of the main request does not involve an inventive step (Articles 52(1) and 56 EPC).

Auxiliary Request

23. The subject-matter of independent claim 1 of the auxiliary request differs from that of the main request essentially in that
- the feature "data comprising patient data" has been amended to "patient identity and medication data" (see amendments (i) and (ii), section XI above),
- the second programmable computer verifies that the medication data input is the correct medication for the patient (amendments (i) to (iii)), and
- the clinical device comprises an infusion pump (amendments (iii)).

Admission of the request

24. The Examining Division did not admit the auxiliary request into the proceedings.

According to Article 12(4) RPBA the Board has the power to hold inadmissible requests which were not admitted in the first-instance proceedings. Article 12(4) RPBA is therefore applicable with respect to the auxiliary request in the present case.

The general principles for exercising the discretion to allow amendments are established in the case law (see G 7/93, OJ EPO 1994, 775). In considering whether to overrule the way in which a first instance department has exercised its discretion, the Board should assess whether the Examining Division exercised its discretion taking into account the right principles and in a reasonable way. This assessment presupposes a comprehensible reasoning of the decision not to admit a request.

25. However, in the present case the rejection of the auxiliary request was not properly reasoned in the written decision, as explained in point 4.2 above. It can only be deduced from the decision that the Examining Division did not admit the request because it did not consider it to be clearly allowable due to lack of inventive step of its subject-matter.

26. In the Board's view, the reasoning given by the Examining Division in its communications before the oral proceedings was incomplete and almost unintelligible (see also point 3.1 above). The communications did not unambiguously identify the closest prior art and the distinguishing features. None of the communications analysed the individual features of the claim or treated the arguments of the appellant. The clarity objections were rather vague. Under these circumstances, it could not be assumed that the applicant had fully understood the objections raised

before the oral proceedings and was in a position to file allowable claims in advance of the hearing.

At the oral proceedings the appellant heard for the first time the more complete argumentation on inventive step, including a discussion of individual features.

The auxiliary request submitted at the oral proceedings was a reaction to this new reasoning and, as stated in the minutes, was considered by the Examining Division to fulfil the requirements of Article 123(2) EPC. Furthermore, it represented a clear improvement over the main request with respect to clarity and restricted the subject-matter of the claim. In the opinion of the Board, given the circumstances of the case, the applicant had the right to have this request admitted, and the complete reasoning regarding inventive step presented, discussed and afterwards included in the written decision.

27. In the exercise of its discretion under Article 12(4) RPBA, the Board therefore decides to admit the auxiliary request into the appeal proceedings.

Inventive step

28. As explained for the main request, document D1 discloses most of those features of claim 1 of the auxiliary request which correspond to features of the main request.

In the opinion of the Board, document D1 also describes some of the additional features relating to the input and verification of patient and medication data, in claim 1, column 24, line 62 to column 25, line 18, and claim 3, column 25, lines 40 to 53, as well as

column 5, line 35 to column 6, line 2. These passages disclose that not only the patient data, but also medication data, medication history and prescriptions, are checked before dispensing medication, and that it is verified whether the identified medication is the correct one for the patient (see also points 15 to 18 above). Document D1 also mentions, on column 4, lines 64 to 67, that the system schedules other medications not stocked in the cabinet, such as intravenous medications that will be needed by patients at a dispensing station.

29. The subject-matter of claim 1 of the auxiliary request differs from the embodiment of document D1 discussed above in that

(a) the input means of the first programmable computer, the first input means, comprises a bar code reader;

(b) the first input means is used for inputting medication data as well; and

(c) the clinical device comprises an infusion pump.

30. The claimed invention therefore solves, starting from the hospital system of document D1, the problem of further automating the delivery of medication.

31. Document D3 discloses a programmable infusion pump. It also describes a data transfer system for allowing monitoring of pump operation and pump reprogramming from a remote location (abstract, column 1, lines 5 to 13).

However, document D3 does not disclose using the infusion pump in a hospital environment, connecting it to a hospital information system, or having it automatically programmed on the basis of data stored in

an information system. Besides, none of the computers of the hospital information system of document D1 controls the direct administration of medication to a patient. The Board is therefore not convinced that the skilled person would consider the teaching of document D3 when trying to solve the problem of further automating the system of document D1.

32. Since none of the other prior art documents cited in the proceedings in the present case, documents D2 and D4, suggests such a usage of an infusion pump controlled by a hospital information system for direct and automatic administration of medication to a patient, the Board concludes that the subject-matter of claim 1 is inventive over that prior art.

Remittal to Examining Division

33. Taking into consideration the above reasons, the Board decides to remit the case for further prosecution on the basis of the auxiliary request.

Given the excessively long duration of the examination proceedings, the Examining Division should expedite its final examination of the remitted case.

Reimbursement of the appeal fee

34. According to Rule 103(1)(a) EPC the appeal fee must be reimbursed in full "where the Board of Appeal deems an appeal to be allowable, if such reimbursement is equitable by reason of a substantial procedural violation".

For the reasons given above, the contested decision is to be set aside. The appeal is therefore allowable within the meaning of Rule 103(1)(a) EPC.

According to the established case law, the failure to provide adequate reasoning in a decision in accordance with Rule 111(2) EPC is to be considered a substantial procedural violation justifying the reimbursement of the appeal fee (see Case Law of the Boards of Appeal of the EPO, IV.E.8.3.4). Similarly, long delays occurring in first instance proceedings can amount to a substantial procedural violation (see e.g. Case Law of the Boards of Appeal of the EPO, IV.E.8.3.6). In particular, it has been held that a delay of ten years in first instance opposition proceedings was beyond question a procedural violation (T 315/03, points 15.5 and 15.6).

In line with that jurisprudence, and taking into account the particulars of the present case, the Board finds that the duration of more than twelve years of the first-instance proceedings and the insufficient reasoning in the written proceedings as well as in the decision amounted to procedural violations and affected the entire procedure (see points 3, 4 and 24 to 26 above). The Board therefore concludes that substantial procedural violations have taken place.

The Board is also convinced that the appeal was caused by the deficient treatment of the case in the first-instance proceedings (see points 3, 4 and 24 to 26 of this decision) and that thus the reimbursement of the appeal fee is equitable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of the auxiliary request.

3. The appeal fee is to be reimbursed.

The Registrar: The Chairman:

I. Aperribay R. Moufang

Decision electronically authenticated