Case Number: T 0609/09 - 3.5.05
Application Number: 00943124.8
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Language of the proceedings: EN
Title of invention: Telemedical expert service provision for intensive care units
Applicant: Visicu, Inc.
Headword: Telemedical expert service provision/VISICU
Relevant legal provisions: EPC Art. 52(1), 56, 84, 123(2)
Keyword: "Clarity - (yes, after amendment)"
"Extension of subject-matter - (no, after amendment)"
"Inventive step - (yes, after amendment)"

Decisions cited:
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Catchword:
-
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DECISION
of the Technical Board of Appeal 3.5.05
of 22 January 2013

Appellant: Visicu, Inc.
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Decision under appeal: Decision of the Examining Division of the European Patent Office posted 10 November 2008 refusing European patent application No. 00943124.8 pursuant to Article 97(2) EPC.

Composition of the Board:
Chair: A. Ritzka
Members: P. Corcoran
F. Blumer
Summary of Facts and Submissions

I. The present appeal is against the decision of the examining division to refuse the European patent application no. 00 943 124.8, published as international application no. WO 00/79466 A2. The decision was announced during oral proceedings on 29 October 2008 and the written reasons were dispatched on 10 November 2008.

II. The decision under appeal was based on a main request and five auxiliary requests filed with the letter of 29 September 2008. In the decision it was found that the independent claims of the main request did not involve an inventive step in the light of the following document:


III. Notice of appeal was received at the EPO on 19 December 2008 with the appropriate fee being paid on the same date. A statement setting out the grounds of appeal was received at the EPO on 9 March 2009. With the statement setting out the grounds of appeal the appellant filed a new main request comprising claims 1 to 18 and an auxiliary request.
IV. In a communication accompanying a summons to oral proceedings to be held on 22 January 2013, the board gave its preliminary opinion that the appellant's requests were not allowable.

In particular, the board expressed reservations as to whether the independent claims of the main request complied with the requirements of Articles 84 and 123(2) EPC. The board further noted that it had not been convinced by the appellant's submissions that the subject-matter of said independent claims involved an inventive step over D1.

In its discussion of D1, the board also referred, *inter alia*, to the following document which is an article co-authored by Brian Rosenfeld and Michael Breslow, the inventors designated with respect to the present application:


V. The board's communication additionally made reference to the prior art pertaining to patient monitoring systems acknowledged in the first paragraph of the introductory section of D1. The following document, *inter alia*, was cited by the board of its own motion as an example of a patient monitoring system for an intensive care unit:

The board noted that the disclosure of D12 appeared to be prejudicial to the novelty or at least the inventive step of the independent claims of the main request.

In its discussion of D12, the board referred, inter alia, to the following document:


D10 is a textbook extract cited as evidence of the common general knowledge of the skilled person in relation to local and wide area networks.

VI. The board's communication also expressed the preliminary opinion that the independent claims of the auxiliary request were not allowable for reasons substantially similar to those set forth in relation to the main request.

VII. With a letter of reply dated 20 December 2012, the appellant filed a new main request and four auxiliary requests.

VIII. Oral proceedings were held as scheduled on 22 January 2013. During the oral proceedings the appellant submitted an amended main request.
IX. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request (claims 1 to 13) filed during oral proceedings before the board or, subsidiarily, on the basis of any of the four auxiliary requests filed with the letter of 20 December 2012.

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

"A system for providing continuous, expert network health care services to a plurality of patients in a plurality of intensive care units from a remote location, the system comprising:

a wide area network;

a plurality of intensive care units comprising patient monitoring equipment for collecting physiological variable data of the patients at predetermined time intervals and means for transmitting the collected physiological variable data to a remote command center by the wide area network;

wherein the remote command center is connected to the wide area network and comprises:

a database for storing patient data of the plurality of patients, the patient data including the collected physiological variable data; and

a computerized patient care management system arranged for:
receiving and storing in the database the collected physiological variable data of the patients, transmitted from the plurality of intensive care units;

constantly monitoring the database for each individual patient and applying rules to the physiological variable data of each patient to automate detection of problems before a condition reaches a crisis state, wherein by means of the rules changes in the physiological variable data over time are detected using thresholds applied to the physiological variable data, the detected changes being indicative of preconfigured alarming conditions,

wherein the rules comprise at least one rule providing a threshold adapted to the respective patient and/or at least one rule which is responsive to simultaneous changes of at least two physiological variables of a patient indicative of an alarming condition; and

providing an alarm to an intensivist at the remote command center, if a change of the physiological variable data indicative of a preconfigured alarming condition is detected based on the rules; and

wherein the remote command center provides continuous intensivist monitoring of the plurality of intensive care units."
Claim 8 seeks protection for a method corresponding to the system of claim 1.

Claim 13 seeks protection for a remote command center corresponding to the remote command center of the system of claim 1.

XI. Insofar as they are relevant to the present decision, the written and oral submissions made with respect to the main request by the appellant during the present appeal proceedings, may be summarised as follows:

(i) The invention as defined in claim 1 of the main request relates to a system comprising a command center, which is connected to multiple intensive care units at various locations remote from the command center. The connection between the command center/remote location and the ICUs is via a wide-area network as disclosed on p.8 1.1-8 of the published application. The remote command center includes a patient care management system which provides automated monitoring of the plurality of ICUs such that a single intensivist can manage the care of a large number of patients.

(ii) The patient care management system of the remote command center of claim 1 comprises a centralised alarm generating function which is defined by the following feature group:

"constantly monitoring the database for each individual patient and applying rules to the physiological variable data of each patient to automate detection of problems before a
condition reaches a crisis state, wherein by means of the rules changes in the physiological variable data over time are detected using thresholds applied to the physiological variable data, the detected changes being indicative of preconfigured alarming conditions,

wherein the rules comprise at least one rule providing a threshold adapted to the respective patient and/or at least one rule which is responsive to simultaneous changes of at least two physiological variables of a patient indicative of an alarming condition; and

providing an alarm to an intensivist at the remote command center, if a change of the physiological variable data indicative of a preconfigured alarming condition is detected based on the rules."

(iii) The alarm generating function is responsible for automatically generating alarms on the basis of a continuous evaluation of patient-specific physiological variable data collected using patient monitoring equipment. Claim 1 specifies that the patient care management system is arranged for "constantly monitoring the database for each individual patient and applying rules to the physiological variable data of each patient" which means that each time a new physiological variable value is stored in the database, the rules are applied to the data including the new value in order to determine whether an alarming condition is fulfilled.
(iv) The rules use thresholds to determine changes in the physiological variable data which are indicative of alarming conditions. The claim refers to two specific families of rules. One family uses thresholds which are adapted to the respective patient whose physiological variable data is being evaluated using the rules. A further family of rules looks for simultaneous changes in multiple physiological variables. Such rules are based on associations between simultaneous changes in multiple physiological variables and adverse clinical events. The rules are implemented such that alarms are generated before a condition reaches a crisis state.

(v) The claim features defining the alarm generating function find support in the passages of the description relating to the vital signs monitoring system and smart alarms system as disclosed respectively on p.26 l.14 - p.27 l.3 and p.30 l.28 - p.31 l.29 of the published application. On this basis, the amendments to claim 1 of the main request are compliant with the requirements of Articles 84 EPC 1973 and 123(2) EPC.

(vi) D1 discloses a system in which remote monitoring clients, i.e. PCs with conventional web browser software, can access the local network of an intensive care unit through the Internet as depicted in Fig. 1 of D1. D1 thus discloses a system allowing a remote site to connect to a monitoring server of a single ICU rather than a command center connected to a plurality of ICUs as specified in claim 1 of the main request. The
remote site of D1 does not have a database for persistently storing patient data nor does it include a system for analysing physiological variable data acquired from the patients and generating alarms based on such an analysis.

(vii) D7 refers to the provision of ICU care by remote intensivists using "telemedical methodologies" to provide patient monitoring. However, it does not provide any specific technical teaching in this regard and it neither discloses nor suggests a system having a central alarming function within the meaning of claim 1.

(viii) D12 discloses a system in which ICU stations comprising bedside monitors equipped with a front-end computer are connected to a central control station via a local area network in the form of an Ethernet network (D12: p.157, left-hand col., last line - right-hand col., third line). D12 does not disclose that patient monitoring equipment is connected to a central station/command center via a wide-area network.

(ix) The system of D12 allows for "the formulation of diagnoses and therapeutic suggestions" which is done by the central station using the information received from the local stations (cf. D12: 4.3 Heuristic handling, p.158-159). However, the task of formulation of diagnosis and therapeutic suggestions is a significantly different task than the generation of alarms based on changes in physiological variable data.
(x) In the system of D12, the task of alarm generation is allocated to the local stations, i.e. the bedside monitor and the front-end computer connected to it, (cf. D12: p.161, left-hand col., in particular item 5):

"PATRICIA 's Deterministic Module is located in the local station (Fig. 8). Its main element is a control procedure that guides the execution of the following tasks:

...  
5. Warning the server module about possible non-inferential alarm or pre-alarm situations (i.e. those numerical values that are beyond or near the thresholds established)."

The alarm messages coming from a local station are transmitted to the central server and displayed together with "inferential alarms" generated in the central server (cf. D12: p.161, right-hand column, last sentence).

(xi) D12 does not provide a further explanation of the term "inferential alarms" and, in particular does not disclose that such alarms are generated by continuously monitoring physiological data of a patient as recited in claim 1 of the main request. Rather, these alarms appear to be closely related to the diagnosis and therapeutic suggestions generated in the central station. Typically, such diagnosis is done once on the basis of a collection of information and this seems to apply to the inferential alarms. Otherwise, there would be no difference between the inferential alarms generated in the central station and the non-inferential alarms generated in the local station.
(xii) Thus, D12 does not disclose a central alarm generating function corresponding to that of claim 1. Rather, it teaches the skilled person to implement the alarming functions in the local stations at each intensive care unit and to forward the locally generated alarms to the central station.

(xiii) The effect achieved by the central alarm generating function of claim 1 of the main request is an improved standardisation of ICU patient care (cf. published application p.7 1.15-19). From a technical point of view, the provision of a central alarm generating function means that the data processing associated with alarm generation is carried out in a standardised and consistent manner for all patients.

(xiv) The skilled person attempting to achieve an improved standardisation of ICU patient care in the system of D12 would try to ensure that the local stations were standardised but he would have no discernible motivation to migrate the alarm generating functionality of the local stations to the central station. Thus starting from D12, the subject-matter of claim 1 can only be arrived at using hindsight.

XII. At the end of the oral proceedings the chair announced the board's decision.
Reasons for the Decision

1. The appeal is admissible. The board also finds that the appeal is allowable for the reasons which follow.

Main request

2. Claim 1

2.1 Claim 1 of the main request is directed towards a system for providing continuous, expert network health care services to a plurality of patients in a plurality of intensive care units from a remote location. The claimed system comprises a wide area network, a plurality of intensive care units (ICUs) comprising patient monitoring equipment and a remote command center connected to the wide area network.

2.2 The claim defines an arrangement according to which the physiological variable data of the patients are collected at predetermined time intervals by the patient monitoring equipment at the ICUs and are transmitted to the remote command center via the wide area network.

2.3 The remote command center comprises a database and a computerized patient care management system which automates the detection of problems relating to a patient's clinical condition and it includes an alarm generating function (cf. Facts and Submissions, item XI(ii)-(iv) above) for generating an alarm which is provided to an intensivist at the remote command center.
3. **Articles 84 and 123(2) EPC**

3.1 Having regard to the appellant's submissions concerning support for the amendments to claim 1 of the main request (cf. Facts and Submissions, item XI (i) and (v) above), the board is satisfied that the aforementioned amendments, in particular those relating to the alarm generating function, are supported by the description and provide a definition of the matter for which protection is sought which complies with the requirements of Article 84 EPC.

3.2 As the passages of the description providing support for the aforementioned amendments, form part of the originally filed application documents, the board is also satisfied that the requirements of Article 123(2) EPC are complied with.

4. **Determination of closest prior art**

4.1 D1, which was cited as the closest prior art in the decision under appeal, discloses a remote patient monitoring service via the World Wide Web (WWW) according to which a bedside monitoring server collects patient-specific physiological variable data and transmits this data through the Internet to a monitoring client at a remote site in real-time (D1: p.929, first paragraph).

4.2 The monitoring client at the remote site of D1 is a computer provided with an Internet connection which is used to receive and present a data stream provided by an ICU system. In this way, a physician at a remote site may observe a stream of vital sign data generated
by an ICU monitoring system using conventional Web browser software (cf. D1: Abstract; p.928, right-hand col., first paragraph).

4.3 The board judges that it is implicit in the disclosure of D1 that the data stream provided to the remote site is only stored in a transient form, i.e. only for as long as it is required for display purposes.

4.4 D1 is thus essentially concerned with displaying a transient stream of ICU data to a physician at a remote location whereas the present application is concerned with providing a physician at a remote location with computerised patient care management facilities including the persistent storage of patient-specific physiological variable data in a database and the automated rule-based analysis of this data to detect situations in which an alarm is to be generated and provided to a physician at the remote site.

4.5 There is no disclosure or suggestion in D1 to the effect that the remote site is provided with database facilities to support the persistent storage of the ICU data or that it is to be provided with a computerised patient care management system to perform automated analysis of this data. For this reason, the board judges that D1 is too remote from the subject-matter of the present application to provide a realistic starting point for an inventive step objection.

4.6 D12, which the board introduced into the proceedings pursuant to Article 114(1) EPC, discloses a patient monitoring system having a hardware infrastructure which includes a plurality of ICUs comprising patient
monitoring equipment ("local bedside monitoring equipment") and a remote command center ("central control station") connected to the local ICUs by way of a network (cf. D12: Abstract; 4. Methods and materials, in particular first paragraph thereof).

4.7 In view of the foregoing, the board concludes that the system of D12, both in terms of its hardware infrastructure and its intended function, is substantially closer to the subject-matter of claim 1 than the system of D1. Consequently, D12 is judged to represent the closest available prior art to the invention according to said claim 1.

5. Differences over D12

5.1 The board concurs with the appellant's submissions to the effect that claim 1 of the main request is distinguished from the disclosure of D12 in the following respects:

(i) Claim 1 specifies that a wide area network (WAN) is used to connect the remote command center to the patient monitoring equipment in the ICUs whereas in D12 a local area network (LAN) in the form of an Ethernet network is used to connect the ICU stations and the central monitoring station (cf. Facts and Submissions, item XI(viii) above).

(ii) The remote command center of claim 1 is provided with a computerised patient care management system which includes an alarm generation function whereby a rule-based analysis of the
patient-specific physiological variable data provided by the ICU monitoring equipment is performed centrally at the remote command center. D12 discloses that such alarms are generated locally at an ICU station from where they are forwarded to the central station (cf. Facts and Submissions, item XI(xii) above).

5.2 With respect to the difference identified under 5.1(i) above, the board judges that although the system of D12 relies on a local area network (LAN) in the form of an Ethernet network to connect the ICU stations and the central monitoring station, the replacement of the LAN by a WAN as specified in claim 1 merely results in an extension of the geographical area covered by the system and would not require the exercise of inventive skill.

In this regard it is noted that, D12 makes an explicit reference to "telemedicine" which, in the board's judgement, is a direct hint to extend the geographical area covered by the system (cf. D12: 6. Discussion, p.162, left-hand col., item 3.). At the claimed priority date, it was generally known in the context of supporting interconnection over larger geographical areas to use WANs to overcome the traditional distance limitations of LANs (cf. D10: section 6.1.1).

6. Inventive step

6.1 With respect to the difference identified under 5.1(ii) above, the board judges that the feature group of claim 1 defining the central alarm generation function (cf. Facts and Submissions, item XI(ii) above) provides an
inventive contribution to the claimed subject-matter for the reasons which follow.

6.2 Although D12 discloses the persistent storage of patient-specific physiological data at the central station in the form of a "historic repository" (cf. D12: paragraph bridging pp. 157 and 158), it does not contain any hint or suggestion to the effect that this repository should be used to provide a central alarm generating function as specified in claim 1.

6.3 According to D12, the bedside monitoring equipment receives data relating to the physiological variables of the patient in the form of signals and incorporates alarm facilities triggered when specified thresholds on the signals have been crossed (cf. D12: p.157, right-hand col., l.4-19). Extra facilities such as dynamic modification of the alarm thresholds and analysis of trends are provided by a front-end computer connected to the physiological monitor at the local station.

6.4 D12 further states that one of the tasks of the software executing on the local station, i.e. the so-called "Deterministic Module", is to forward locally generated alarms indicative of numerical values that are beyond or near the established thresholds to the server at the central station (cf. 5. Application of client-server architecture to the clinical problem, in particular p.161, left-hand col., item 5). The software executing on the central station, i.e. the so-called "Server Module", is arranged to display alarm messages coming from local stations (cf. D12: p.161, last paragraph).
6.5 D12 mentions that the Server Module includes an expert system having an inference engine, i.e. the so-called "Heuristic Module", which may generate information including "inferential alarms" (cf. D12: 4.3 Heuristic handling, p.158; p.161, last paragraph). However, D12 provides no further information about this type of alarm. In the given context, the board judges that the term "inferential alarms" must be interpreted as denoting some kind of additional information generated by the inference engine in response to requests from local stations (cf. D12: p.161, left-hand col., item 7). Based on this interpretation, the board concurs with the appellant's submissions to the effect that the aforementioned "inferential alarms" cannot be considered as alarms of the type specified in claim 1 (cf. Facts and Submissions, item XI(xi) above).

6.6 Insofar as D12 discloses alarms of the type specified in claim 1, it teaches that such alarms are generated locally at ICU stations and then forwarded to the central station which is arranged to display the corresponding alarm messages. It provides no hint or suggestion to the effect that these alarms can or should be generated centrally by monitoring a central database of physiological variable data and by applying rules to said data as specified in claim 1.

6.7 Inasmuch as claim 1 requires the physiological variable data monitoring and associated alarm generation to be performed in one central location within the system and thus in substantially the same manner for all patients, the board accepts the appellant's submissions to the effect that generating alarms in a centralised manner according to claim 1 of the main request achieves the
effect of standardising the data processing relating to ICU patient care (cf. Facts and Submissions, item XI(xiii) above).

6.8 The board further concurs with the appellant's submissions to the effect that, starting from D12, the skilled person attempting to achieve a standardisation of the data processing would try to ensure that the local stations were standardised and he would have no discernible motivation to migrate the alarm generating functionality of the local stations to the central station (cf. Facts and Submissions, item XI(xiv) above).

6.9 For the sake of completeness, the document D7 to which the board referred in its communication, is briefly considered. Although D7 refers in general terms to the provision of ICU care by remote intensivists using "telemedical methodologies", said document contains no specific details as to how the technical infrastructure to provide remote ICU management should be configured. In the board's judgement, D7 neither teaches nor suggests providing a centralised alarm generating function as specified in claim 1 of the main request.

6.10 Although, from a technical point of view, the modifications to the disclosure of D12 required to arrive at the subject-matter of claim 1 of the main request could arguably have been carried out by the skilled person without undue difficulty, the question of obviousness has to be decided, not by considering what the skilled person could hypothetically have done but rather what he would have done.
6.11 In the absence of any clearly identifiable motivation to migrate the alarm generating function of the local stations of D12 to the central station, the board judges that the skilled person starting from D12 would not have arrived at the claimed invention without the use of hindsight.

Conclusions

7. In view of the foregoing, the board concludes that the subject-matter of claim 1 of the main request involves an inventive step over D12. A similar finding applies to the further independent claims of the request.

8. Having regard to its findings concerning the main request, it is not necessary for the board to consider the appellant's auxiliary requests.
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 with the order to grant a patent on the basis of the main request (claims 1 to 13) as filed during the oral proceedings before the board and a description yet to be adapted.

The Registrar: The Chair:

K. Götz A. Ritzka