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Datasheet for the decision of 2 September 2008

Case Number: T 1814/07 - 3.5.05

Application Number: 00650198.5

Publication Number: 1102200

IPC: G06F 19/00

Language of the proceedings: EN

Title of invention:
Automated collection and analysis patient care system and method for ordering and prioritizing multiple health disorders to identify an index disorder

Applicant:
Cardiac Intelligence Corporation

Opponent:
-

Headword:
Index disorder/CARDIAC INTELLIGENCE CORP.

Relevant legal provisions:
EPC Art. 52(2), 53(c)

Relevant legal provisions (EPC 1973):
EPC Art. 56, 106, 107, 108

Keyword:
"Inventive step (all requests - no)"

Decisions cited:
G 0001/04, J 0010/07, T 0208/84, T 0258/03, T 0641/00, T 0926/01, T 0511/98, T 1241/04

Catchword:
In the assessment as to inventive step of a system or device for medical treatment or diagnosis all features and steps that

contribute to the technical caracter of the system or device as a whole must be taken into account, even if, taken out of the context of the system or device, they would fall under the exception of Article 53(c) EPC (see point 3).

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Case Number: T 1814/07 - 3.5.05

D E C I S I O N
of the Technical Board of Appeal 3.5.05
of 2 September 2008

Appellant: Cardiac Intelligence Corporation
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 13 June 2007 refusing European application No. 00650198.5 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: D. H. Rees
Members: A. Ritzka
G. Weiss

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dispatched 13 June 2007, refusing the European patent application No. 00650198.5 for the reasons that the independent claims of the main request did not comply with the requirements of Article 123(2) EPC and that the subject-matter of claim 1 of the first, second and third auxiliary requests did not involve an inventive step.

II. Notice of appeal was filed on the 23 August 2007. The appeal fee was paid on the same day. The statement of grounds of appeal was submitted on 22 October 2007 with letter of 19 October 2007. The appellant requested that the appealed decision be set aside and that the patent be granted based on claims 1 to 30 of the main request or claims 1 to 28 of the first auxiliary request or the second auxiliary request, all requests being filed with the statement setting out the grounds of appeal. Further, it was requested that the application be "returned to the examining division to appoint oral proceedings in this matter". An auxiliary request for oral proceedings was also made.

III. The Board issued an invitation to oral proceedings accompanied by a communication. In the communication the board cited the following documents:

D1: EP 0 531 889 A2;

D2: W. J. Long et al, "Differential diagnosis generation from causal network with probabilities", Computers in Cardiology, 1988, Proceedings, Washington, DC, USA 25-28 September

1988, IEEE Comput. Soc. Pr., ISBN: 0-8186-1949-X, pages 185 to 188;

D3: WO 99/46718;

D4: US 5,113,869.

IV. The board expressed the preliminary view that the claims of all the requests did not comply with the provisions of Articles 84 EPC 1973 and 123(2) EPC, that the claimed subject-matter as a whole was considered as having technical character, that the subject-matter of claim 15 and the claims depending on claim 15 of the main request and claim 14 and the claims depending on claim 14 of the auxiliary requests appeared to be a diagnostic method excepted from patentability under Article 53(c) EPC, and made observations on novelty and inventive step having regard to the disclosure of documents D1, D2, D3 and D4.

V. With its letter of 31 July 2008, in response to the communication, the appellant filed claims 1 to 30 of a new main request, claims 1 to 30 of a new first auxiliary request and announced as second auxiliary request a set of requests with claims corresponding to the claims of the main or first auxiliary request with claims 15 to 30 being deleted, as third auxiliary request a set of requests with claims corresponding to the claims of the main, first auxiliary or second auxiliary request with claim 1 including the features of claim 2 and claim 2 being deleted and as fourth auxiliary request a set of requests with claims corresponding to the claims of the main, first auxiliary or second auxiliary request with claim 1 including the features of claim 11 and claim 11 being deleted.

VI. Oral proceedings took place as scheduled on 2 September 2008. The case was discussed with the appellant's representative who stated that, in his view, objections with respect to lack of clarity and added subject-matter could be overcome by appropriate amendments and that the main issue at stake was inventive step. Moreover, D1, D2 and D3 disclosed instantaneous methods of diagnosis whereas the application was directed to a longer term diagnosis. The final requests were the requests filed with letter of 31 July 2008. After deliberation the board announced its decision.

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

"An automated system for providing medical health care services to a remote patient, comprising:

an interface adapted to periodically retrieve recorded measures from a patient medical device (12, 26) for a remote patient and providing feedback to the remote patient, wherein the recorded measures relate to patient information (11) and are recorded by the patient medical device on a substantially continuous basis;

a database (17) storing a plurality of monitoring sets (27) which each comprise the recorded measures (24b, 25b) or derived measures calculable from the recorded measures;

a diagnostic module (126) to determine patient well being, comprising:

a comparison module (206) determining a patient status change by comparing at least one stored or derived measure from each of the monitoring sets to at least one other stored or derived measure with both

stored or derived measures relating to the same type of patient information;

an analysis module (207) corroborating the patient status change against available qualitative measures, ordering each patient status change in temporal sequence from least recent to most recent and evaluating a plurality of health disorder candidates categorized by quantifiable physiological measures of pathophysiologies indicative of each respective health disorder, and

identifying the health disorder candidate with the pathophysiology most closely matching those patient status changes which occurred substantially least recently as the index disorder; and

a feedback module (128) determining whether any changes to interventive measures are appropriate and to provide feedback and any such changes to the remote patient from the diagnostic module through the interface pending retrieval of further recorded measures."

Claim 1 of the first auxiliary request adds to claim 1 of the main request that the automated system comprises a patient medical device for a remote patient recording measures relating to patient information on a substantially continuous basis.

Claim 1 of both sets of claims of the second auxiliary request is identical to claim 1 of the main request and claim 1 of the first auxiliary request, respectively.

Claim 1 of the third auxiliary request set adds to claim 1 of the main request, the first auxiliary request and the second auxiliary requests that the

automated system further comprises an adjustable time window defined for each type of patient information and that the composition module compares the at least one stored measure to the at least one other stored measure which was recorded within the adjustable time window.

Claim 1 of the fourth auxiliary request set adds to claim 1 of the main request, the first auxiliary request and the second auxiliary request set that the automated system further comprises a set of stickiness indicators for each type of patient information, each stickiness indicator corresponding to a temporal limit related to a program of patient diagnosis or treatment, that the comparison module compares a time span occurring between each patient status change for each stored measure to the stickiness indicator relating to the same type of patient information as the stored measure being compared and that the analysis module determines a revised programme of patient diagnosis or treatment responsive to each patients status change occurring subsequent to a time span exceeding the stickiness indicator.

Since the decision is based on an assessment of claim 1 of all requests, further independent claims need not be cited.

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 0010/07, point 1 (see Facts and Submissions, point II above). Thus, it is admissible.

2. *Interpretation*

Claim 1 of all requests refers to an interface adapted for periodically retrieving recorded measures from a patient medical device. The term "interface" is interpreted as the interface between the medical device and the part of the automated system comprising the database, the diagnostic module and the feedback module, i.e. a computer interface.

The "available qualitative measures" mentioned in the context of the analysis module are understood to be the semi-quantitative measures disclosed at column 8, lines 52 to 55 of the application as published and the non-device quantitative measures disclosed at column 9, lines 22 to 27, also referred to as quality of life measures.

"Recording measures on a substantially continuous basis" is understood as recording measures over a period of time or regularly, in contrast to instantaneously, i.e. relating to a single point in time.

"Providing feedback and any such changes" is understood to relate to feedback comprising information about the index disorder and recommended change of medication, but not comprising change of control parameters of the patient medical device as might be possible for e.g. a pacemaker.

The addition "pending retrieval of further recorded measures" does not appear to be originally disclosed or supported by the description and, therefore, is not taken into consideration.

The appellant agreed to limit the claims to these interpretations if necessary for the board to come to a positive decision.

3. *General remark*

The decision of the department of first instance was based on the assumption that claim 1 related to an automated technical system which comprises as the essential element the implementation of an abstract algorithm which could be performed mentally by a physician in his diagnostic finding process to identify an index disorder in order to determine patient well-being, which algorithm as such was lacking any technical character. All medical aspects of the claim were then simply discounted in the assessment of inventive step. This approach is inappropriate for medical systems.

As the subject-matter of claim 1 includes various clearly technical features (e.g. interface, retrieving recorded measures from a patient medical device, database, composition module, feedback module), the subject-matter as a whole is considered as having technical character, in accordance with established case law, see e.g. T 0258/03 and T 0641/00. It is therefore not excluded from patentability by Articles 52(2) and (3) EPC.

Claim 1 of all the requests is directed to an automated system for providing medical health care services to a remote patient. Medical health care services comprise therapeutic and diagnostic services. Being a product, the system is also not excluded from patentability by Article 53(c) EPC.

The board notes that the Enlarged Board stated in decision G 0001/04 that a diagnostic method comprises features relating to the diagnosis for curative purposes *strictu sensu* representing the deductive medical or veterinary decision phase as a purely intellectual exercise, which is characterized as "non-technical" (Reasons, point 5.3), the preceding steps which are constitutive for making that diagnosis, and the specific interactions with the human or animal body which occur when carrying those out among these preceding steps which are of a technical nature.

The present board considers that in a system for providing medical health care services, e.g. diagnosis, the assessment of means and components for performing individual steps of the diagnosis method as to patentability may be influenced by the nature of the step. Moreover, in accordance with the established case law, see e.g. the VICOM decision T 0208/84, if a method which is not per se "technical" e.g. a mathematical method, is used in a technical process, and this process is carried out on a physical entity by some technical means implementing the method and provides as its result a change in that entity, it contributes to the technical character of the invention as a whole. Thus this feature must be taken into account when assessing inventive step (T 0641/00, T 0258/03). In the

present context, even steps of a diagnosis method not having a technical nature may cause a technical effect in an automated system implementing the diagnosis method. Therefore the board judges that assessing inventive step of an automated system for providing medical health care services calls for a different analysis than automated business related inventions.

Medical engineering as a field is not included in the recitations of Article 52(2) EPC, nor is there any reason to consider it a "non-technical" art as a whole. The solution of a medical problem, e.g. how to determine a new diagnosis or treatment, cannot therefore be equated with e.g. the solution of a business problem.

This is in line with the decisions T 0926/01, T 0511/98 and T 1241/04, which held that a pacemaker or a heart function analysis device, i.e. a medical device, differing from the most relevant prior art document in a different operation motivated by physiological considerations and quite possibly implemented simply by adapting a computer program may involve an inventive step.

It is to be noted however that the board does not conclude that in every claim directed to a device for medical diagnosis or treatment all the features must necessarily be considered when assessing inventive step. It is conceivable for example that in a particular case the only difference compared with the prior art could be the intellectual method used to arrive at the diagnosis *strictu sensu* and that this difference had no technical effect on the functioning of the device or on

the diagnosis or treatment. In this case it is possible that the different intellectual method might not be taken into account in accessing the question of inventive step, in accordance with the case law for computer implemented inventions. However, it is not necessary to decide whether this is the case for the present requests and hence the question is strictly hypothetical.

In the present case claim 1 of all requests does not involve an inventive step for the following reasons.

4. *Inventive step*

4.1 Main request and first auxiliary request

With respect to claim 1 of the main request, claim 1 of the first auxiliary request is further limited by explicitly claiming the medical device recording measures which are retrieved through the interface specified in both claims. The explicit presence of the medical device in the system does not alter the analysis with respect to inventive step. Thus, the following analysis applies to claim 1 of the main request and the first auxiliary request equally.

According to D2 many diseases, e.g. cardiovascular diseases, develop from a primary cause through a causal chain which may have a dozen steps to observed symptoms and findings. See page 185, left column first paragraph.

D2 discloses a program for assisting in a diagnosis of diseases that cause symptoms of heart failure using a

knowledge-based network. The nodes in the knowledge-based network represent causes or physiological states. The causes have a prior probability without being caused by another node within the model. The physiologic state nodes have some probability of being caused by another node within the model. Based on these possibilities the most likely path from the hypothesis nodes to the finding is determined. See page 185, right column fourth paragraph to page 186, right column third paragraph.

It is stated that the system lacks a mechanism to use the time relations among causes and findings. An improvement is expected from extending the model to represent multiple causal chains with the same pathological nodes at different times. See page 188, point 6 "Discussion". Thus, D2 discloses an automated system for providing diagnosis, i.e. medical health care services, to a remote patient. The skilled person would understand that the causes correspond to health disorder candidates categorised by quantifiable physiological measures of pathophysiologies indicative of each respective health disorder and that findings correspond to qualitative measures. D2 gives an indication to consider the time relations among causes and findings, corresponding to ordering each patient status change in temporal sequence from least recent to most recent. The primary cause corresponds to the index disorder and, as a primary cause, occurs first.

Starting from D2, which is considered to be the most relevant prior art document, the problem underlying claim 1 is seen to be to provide a facility for finding

an index disorder. The skilled person faced with this problem is a medical engineer.

D3 discloses a system for monitoring, diagnosing and treating medical conditions of remotely located patients. This system comprises a central data processing system configured to communicate with and receive data from a plurality of respective patient monitoring systems. Patient monitoring systems are capable of receiving and storing patient data. The central data processing system may be configured to obtain patient data from each patient monitoring system, to analyse the obtained patient data, and to identify medical conditions requiring medical attention. For identifying emergency medical conditions, treatment information and altered monitoring instructions may be automatically communicated to the respective patient monitoring system. See page 4, line 30 to page 5, line 27. Thus, D3 discloses an architecture comprising a diagnostic module to determine patient well-being, patient medical devices which are linked to the diagnostic module by an interface adapted to retrieve recorded measures from the patient medical device and a feedback module determining whether any changes to interventive measures are appropriate and providing feedback and any changes to the remote patient.

The portable patient monitors serve as primary means for collecting data from a patient. The data may comprise data from blood, breath or bodily fluids and data on health status, compliance to medical regime, and psychological data, see page 16, lines 15 to 29. Data from blood, breath or bodily fluids are understood

to be measures recorded by a patient medical device, whereas data on health status, compliance to medical regime and psychological data correspond to available qualitative measures.

Data obtained from the portable patient monitor is stored within a physician access centre server database for later analysis and retrieval, see page 28, lines 25 to 28. Data transmission takes place at a given frequency, e.g. every 12 hours, 3 days or every week, see page 29, line 14 to line 24, i.e. the recorded measures are periodically retrieved.

D3 further indicates that for any given chronic disease, there may be a relationship between different medical conditions that a patient may have, see page 33, lines 9 to 11.

Moreover, D3 states that statistical analyses may optionally be performed on published prescriptions that utilise patient analysis, multiple regression, time series and other types of analysis that compare current patient data sets to earlier data and to data of other appropriate patients, see page 49, line 27 to page 50, line 2.

The skilled person faced with the problem underlying claim 1 would understand that the architecture disclosed in D3 is suitable for an automated system for finding an index disorder and would consult D3. The skilled person would understand that data sets of a portable patient monitor may be stored and retrieved later for comparison with current patient data sets.

The appellant argued that the main objective of D3 was trying to minimize the amount of work for medical staff as therapists in charge of care for patients suffering from chronic diseases as diabetes. Therefore the method was essentially taking an instantaneous measure of the patients health. Data was only stored for the practitioner. The statistical analysis mentioned at pages 49 and 50 of D3 were only performed for a blind actuarial review of changes and did not teach looking at individual patients over time.

Even if the comparison in D3 is performed on the basis of a different motivation, as assumed by the appellant, the skilled person would understand that storing data and comparing them later to current patient data is possible and would be an appropriate solution to considering the time relations among causes and findings suggested by D2. Thus, the automated system of claim 1 of the main request and claim 1 of the first auxiliary request does not involve an inventive step.

The appellant's argument that the skilled person would not consider extending the method of D2 to an analysis representing multiple causal chains at different times, since the calculation time in the method would be too long, does not convince the board. Firstly, D2 addresses the objective of calculation time complying with the constraints of an interactive environment and thus teaches the skilled person to search for an effective calculation. Secondly, no arguments or evidence were presented or can be seen that the system of claim 1 would determine the index disorder in a shorter calculation time. In fact, as claim 1 neither limits the number of measures of the monitoring sets to

be compared to measures recorded by the medical device nor specifies how the comparison is executed, claim 1 encompasses embodiments in which the comparison step needs a long calculation time.

4.2 Second auxiliary request

The arguments presented with respect to the main request and the first auxiliary request in point 4.1 above apply to the subject-matter of claim 1 of both sets of claims of the second auxiliary request.

4.3 Third auxiliary request

D2 recommends using the time relations among causes and findings, referring to examples in which findings change within a characteristic time constant, see page 188, point 6 "Discussion". The skilled person would understand that a comparison module might make use of this characteristic time constant for determining a patient status change in comparing stored measures which were recorded within an adjustable time window.

Moreover, in the field of signal and data processing it is common general knowledge to take into consideration only signals and data which were recorded within a given adjustable time window in order to detect changes that occur at a smaller time constant than an overlaying trend. The skilled person in the present case is a medical engineer, who is therefore aware of data and signal processing.

Thus, the additional features of claim 1 of the third auxiliary request set do not add any inventive matter to claim 1 of the main request and the first auxiliary request.

Claim 1 does not involve an inventive step.

4.4 Fourth auxiliary request

The stickiness indicators claimed as an additional feature in claim 1 of the fourth auxiliary request set correspond to a temporal limit related to a program of patient diagnosis for treatment. The comparison module compares the time span occurring between each patient status change for each stored measure to the stickiness indicator relating to the same type of patient information as the stored measure being compared and the analysis module determines a revised program of patient diagnoses or treatment responsive to each patient status change occurring subsequent to a time span exceeding the stickiness indicator. Accordingly, the program of patient diagnosis or treatment is only revised if the time span exceeds the stickiness indicator. This avoids frequent changes of the program and results in a revision of the program following a long term trend. It corresponds to a hysteresis which is common general knowledge in the field of signal and data processing.

The skilled person in the present case is a medical engineer, who is therefore aware of data and signal processing. It lies within the usual professional activity of this skilled person to ignore changes detected within a time span shorter than a

predetermined value, i.e. a stickiness indicator, and to take into consideration only changes occurring subsequent to a time span exceeding the stickiness indicator. The subject-matter of claim 1 of the fourth auxiliary request therefore does not involve an inventive step.

4.5 There being no further requests the appeal has to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

K. Götz D. H. Rees