# PATENTAMTS

# OFFICE

BESCHWERDEKAMMERN BOARDS OF APPEAL OF CHAMBRES DE RECOURS DES EUROPÄISCHEN THE EUROPEAN PATENT DE L'OFFICE EUROPEEN DES BREVETS

#### Internal distribution code:

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

## Datasheet for the decision of 24 November 2011

T 0515/08 - 3.5.05 Case Number:

Application Number: 00650193.6

Publication Number: 1102196

G06F 19/00 IPC:

Language of the proceedings: EN

### Title of invention:

Automated collection and analysis patient care system and method for diagnosing and monitoring congestive heart failure and outcomes thereof

## Applicant:

Cardiac Intelligence Corporation

#### Headword:

Automated patient care system/CARDIAC INTELLIGENCE CORPORATION

## Relevant legal provisions:

EPC Art. 123(2)

RPBA Art. 12(2), 13(1)

#### Relevant legal provisions (EPC 1973):

EPC Art. 84

### Keyword:

- "Admission into proceedings main request, first and third auxiliary requests (no)"
- "Clarity and support by the description second auxiliary request (no)"
- "Extension of subject-matter second auxiliary request (yes)"

#### Decisions cited:

## Catchword:

cf. Reasons, points 4 (in particular 4.3 to 4.5) and 6 (in particular 6.2 to 6.3).



Europäisches Patentamt

European Patent Office

Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Case Number: T 0515/08 - 3.5.05

DECISION

of the Technical Board of Appeal 3.5.05 of 24 November 2011

OI 24 NOVEMBEL ZUII

Appellant: Cardiac Intelligence Corporation

2518 Constance Drive West

Seattle

Washington 98199-3017 (US)

Representative: Asmussen, Arnold

Vossius & Partner POB 86 07 67

81634 München (DE)

Decision under appeal: Decision of the Examining Division of the

European Patent Office posted 13 November 2007

refusing European patent application

No. 00650193.6 pursuant to Article 97(1) EPC

1973.

Composition of the Board:

Chair: A. Ritzka
Members: P. Corcoran

T. Karamanli

- 1 - T 0515/08

## Summary of Facts and Submissions

- I. This appeal is against the decision of the examining division to refuse the European patent application No. 00 650 193.6, publication No. EP 1 102 196. The decision was announced in oral proceedings held on 16 October 2007 and written reasons were dispatched on 13 November 2007.
- II. The decision under appeal was based on a main request comprising a set of claims 1 to 24 and an auxiliary request comprising a set of claims 1 to 22, both of said requests having been filed with the letter dated 14 September 2007.
- III. Claim 1 of the main request on which the decision under appeal was based reads as follows:

"An automated system (10) for remotely managing congestive heart failure and outcomes thereof, comprising:

an interface periodically retrieving recorded measures (24b, 25b) relating to patient (11) information recorded by the patient medical device (12, 26) on a substantially continuous basis and directly providing feedback for the patient;

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

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

a comparison module (130) determining a patient status change by comparing at least one recorded or derived measure from each of the monitoring sets to - 2 - T 0515/08

at least one other recorded or derived measure with both recorded or derived measures relating to the same type of patient information; and

an analysis module (131) testing each patient status change for one of an onset, a progression, a regression, and a status quo of congestive heart failure against an indicator threshold (129) corresponding to the same type of patient information as the recorded measures which were compared, the indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology indicative of congestive heart failure; and

a feedback module (128) for determining whether any changes to interventive measures are appropriate."

IV. According to said decision, the subject-matter of claim 1 of the main request did not involve an inventive step. In particular, the examining division took the view that the diagnostic analysis process underlying the invention was an intellectual activity closely analogous to the non-inventions listed under Article 52(a) and (c) EPC and was not, as such, an invention in the sense of Article 52(1) EPC. The assessment of inventive step was therefore to be carried out, not from the point of view of a medical expert, but from the point of view of a computer expert, as the appropriate person skilled in the art, having knowledge of the relevant medical-related aspects of the diagnostic method.

For the purpose of assessing inventive step, the examining division took the closest prior art to be a general purpose computer comprising a database for the

- 3 - T 0515/08

storage of information and an interface adapted to exchange information with a medical device. Such a system was said to form part of the common general knowledge at the claimed priority date of the application and no specific documents were cited in this regard.

According to the decision, claim 1 defined technical subject-matter which distinguished the invention from the aforementioned closest prior art only in terms of the diagnostic analysis and feedback processes and the associated data. The underlying technical problem was identified as the implementation of the diagnostic analysis algorithm and the provision of feedback on a computer system. On this basis it was found that the claimed solution did not go beyond a mere automation of constraints imposed by the diagnostic analysis and feedback related aspects which were obvious to a skilled person in the field of data processing.

V. Claim 1 of the auxiliary request on which the decision under appeal was based differed from the above-cited claim 1 of the main request by the following additional features which were derived from dependent claim 6 of the main request (which corresponds to dependent claim 6 as originally filed):

"the system further comprising:

a set of stickiness indicators (133) for each type of patient information, each stickiness indicator corresponding to a temporal limit related to a program of patient diagnosis or treatment;

the comparison module (130) comparing a time span occurring between each patient status change for each recorded measure to the stickiness indicator

- 4 - T 0515/08

relating to the same type of patient information as the recorded measure being compared; and

the analysis module (131) determining a revised program of patient diagnosis or treatment responsive to each patient status change occurring subsequent to a time span exceeding the stickiness indicator".

- VI. According to the decision under appeal, substantially the same reasoning as given for claim 1 of the main request also held for claim 1 of the auxiliary request. With respect to the auxiliary request it was stated that the additional restriction relating to the definition of a set of stickiness indicators was based on non-technical considerations and that the technical implementation of such indicators was obvious to the skilled person in the field of data processing. The further restriction of the comparison and analysis modules considering the stickiness indicators was said to be a direct and, thus obvious, consequence of defining stickiness indicators.
- VII. Notice of appeal was received at the EPO on 21 December 2007 with the appropriate fee being paid on the same date. A written statement setting out the grounds of appeal was received at the EPO on 10 March 2008.
- VIII. In the written statement setting out the grounds of appeal the appellant submitted inter alia that the basis used for assessing inventive step was inappropriate and that the examining division had not applied a reasonable test for obviousness to the claims of the present application. More particularly, the appellant disputed the identification of the closest

- 5 - T 0515/08

prior art and the formulation of the underlying technical problem by the examining division.

The appellant further submitted that the application could be considered as directed to a problem invention which gave rise to patentable subject-matter in spite of the fact that the claimed solution appeared retrospectively trivial and in itself obvious in its subsequent implementation.

In conclusion, the appellant requested only that the decision of the examining division be reversed and that a patent be granted "on the basis of the main request of the decision appealed".

- IX. In a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) accompanying a summons to oral proceedings to be held on 24 November 2011, the board gave its preliminary opinion that the appeal was not allowable. Objections were noted *inter alia* under Article 84 EPC 1973 and Articles 123(2) and 52(1) EPC.
  - (i) With reference to Article 84 EPC 1973, the board objected inter alia to the following features of claim 1 of the appellant's request:
     "an interface periodically retrieving recorded measures (24b, 25b) relating to patient information recorded by the patient (11) medical device (12, 26) on a substantially continuous basis and directly providing feedback for the patient";

"a feedback module (128) for determining whether any changes to interventive measures are appropriate".

- (ii) In relation to the "interface" feature of claim 1, the board submitted inter alia that, in the given context, the technical limitation implied by the generic term "interface" was unclear.

  It was further noted in this regard that although the application disclosed the periodic retrieval of telemetered signals stored in a medical device, the board could not identify any disclosure to the effect that such retrieval was performed via an interface which was also adapted to directly provide feedback for a patient as recited in claim 1. Hence, the board expressed doubts as to whether the specification of the "interface" feature of claim 1 was properly supported by the description.
- (iii) In relation to the "feedback module" feature of claim 1, the board noted that according to [0032] of the published application, the feedback module determined whether any changes to interventive measures were appropriate based on threshold stickiness ("hysteresis") as described with reference to Fig. 16. In the absence of any limitation in claim 1 to the effect that the determination required a consideration of threshold stickiness, the specification of the feedback module in said claim appeared to represent an intermediate generalisation which was not supported by the description.

- 7 - T 0515/08

- (iv) It was further noted that the technical limitations implied by the expression "determining whether any changes to interventive measures are appropriate" were not evident from the given context. Likewise, the basis on which the feedback module performed the determination did not appear to be specified in the claim nor was it apparent from the claim wording what the consequences of the determination were, in particular which technical effects if any were associated with it.
- (v) The appellant was advised that claim wording which lacked support in the application documents as originally filed was also subject to objection under Article 123(2) EPC.
- (vi) In addition to the aforementioned objections, the board also expressed a preliminary opinion with respect to the question of inventive step. In the board's view, the claim 1 of the sole request then on file sought protection for a data processing system for automating the collection and analysis of patient data in order to diagnose and monitor a specific medical disorder, viz. congestive heart failure (cf. published application: [0008]). Referring to D1 (WO 99/46718 A), the board noted that it considered said document to represent the most appropriate starting point for assessing the inventive step of the claimed subject-matter. D1 disclosed "a system for monitoring, diagnosing and treating medical conditions of remotely located patients with various chronic illnesses" (cf. D1: p.14 1.13-17; Fig. 1) which appeared to comprise substantially the same technical means as

the system of claim 1 and to differ only in respect of the medical domain in which the system was intended to be used. Insofar as the modifications required to adapt the system of D1 to arrive at the subject matter of claim 1 involved technical considerations, said modifications appeared to lie within the routine competence of the skilled person and, thus, not to involve the exercise of inventive skill.

- X. With a letter of reply dated 24 October 2011, the appellant filed a new main request and auxiliary requests 1 and 2. Claim 1 of auxiliary request 2 comprised the features of the originally filed dependent claim 6.
- XI. During the oral proceedings held as scheduled on 24 November 2011, the appellant filed a new main request which replaced the main request filed with the letter of 24 October 2011. The appellant also filed a new first auxiliary request and maintained the auxiliary requests filed with the letter of 24 October 2011 as second and third auxiliary requests.
- XII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed during oral proceedings or, subsidiarily, on the basis of the first auxiliary request filed during oral proceedings or on the basis of the second and third auxiliary requests which had initially been filed as first and second auxiliary requests with the letter of 24 October 2011.

- 9 - T 0515/08

- XIII. Claim 1 of the main request reads as follows:
  "An automated system (10) for remotely managing congestive heart failure and outcomes thereof, comprising:
  - interface devices (13, 14, 18, 21, 22) periodically retrieving recorded measures (24b, 25b) relating to patient information recorded by the patient medical device (12, 26) on a substantially continuous basis and directly providing feedback for the patient;
  - a database module (125) storing a plurality of monitoring sets (27) which each comprise the recorded measures and derived measures (24b, 25b), which were derived from the recorded measures (24b, 25b);
  - a diagnostic module (126) to determine patient well being, comprising:
    - a comparison module (130) determining a patient status change by comparing at least one recorded or derived measure from each of the monitoring sets to at least one other recorded or derived measure, wherein both recorded or derived measures relate to the same type of patient information;
    - an analysis module (131) testing each patient status change for one of an onset, a progression, a regression, and a status quo of congestive heart failure against an indicator threshold (129) corresponding to the same type of patient information as the recorded measures which were compared, the indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology indicative of congestive heart failure; and
    - a quality of life module (132) determining a change in patient status by comparing at least one recorded quality of life measure (25b) to at least

- 10 - T 0515/08

one other corresponding recorded quality of life measure (25a); and

- a feedback module (128) providing automated feedback to the patient from the diagnostic module (126) for determining whether any changes for managing congestive heart failure are appropriate."
- XIV. Claim 1 of the first auxiliary request reads as follows: "An automated system (10) for remotely managing congestive heart failure and outcomes thereof, comprising:
  - interface devices (13, 14, 18, 21, 22) periodically retrieving recorded measures (24b, 25b) relating to patient information recorded by the patient medical device (12, 26) on a substantially continuous basis and directly providing feedback for the patient;
  - a database module (125) storing a plurality of monitoring sets (27) which each comprise the recorded measures and derived measures (24b, 25b), which were derived from the recorded measures (24b, 25b);
  - a diagnostic module (126) to determine patient well being, comprising:
    - a comparison module (130) determining a patient status change by comparing at least one recorded or derived measure from each of the monitoring sets to at least one other recorded or derived measure, wherein both recorded or derived measures relate to the same type of patient information;
    - an analysis module (131) testing each patient status change for one of an onset, a progression, a regression, and a status quo of congestive heart failure against an indicator threshold (129) corresponding to the same type of patient information as the recorded measures which were

- 11 - T 0515/08

compared, the indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology indicative of congestive heart failure; and

- a quality of life module (132) determining a change in patient status by comparing at least one recorded quality of life measure (25b) to at least one other corresponding recorded quality of life measure (25a); and
- a set of stickiness indicators (133) for each type of patient information, each stickiness indicator corresponding to a temporal limit related to a program of patient diagnosis or treatment, wherein the comparison module (130) compares a time span occurring between each patient status change for each recorded measure to the stickiness indicator relating to the same type of patient information as the recorded measure being compared; and wherein the analysis module (131) determines a revised program of patient diagnosis or treatment responsive to each patient status change occurring subsequent to a time span exceeding the stickiness indicator; and
- a feedback module (128) providing automated feedback to the patient based, in part, on a patient status indicator (127) generated by the diagnostic module (126), and determining whether any changes to interventive measures in the form of a revised treatment program are appropriate based on threshold stickiness."

- 12 - T 0515/08

XV. Claim 1 of the second auxiliary request reads as follows:

"An automated system (10) for remotely managing congestive heart failure and outcomes thereof, comprising:

- an interface (13, 14, 18, 21, 22) periodically retrieving recorded measures (24b, 25b) relating to patient information recorded by the patient medical device (12, 26) on a substantially continuous basis and directly providing feedback for the patient;
- a database module (125) storing a plurality of monitoring sets (27) which each comprise the recorded measures and derived measures (24b, 25b), which were derived from the recorded measures (24b, 25b);
- a diagnostic module (126) to determine patient well being, comprising:
  - a comparison module (130) determining a patient status change by comparing at least one recorded or derived measure from each of the monitoring sets to at least one other recorded or derived measure, wherein both recorded or derived measures relate to the same type of patient information;
  - an analysis module (131) testing each patient status change for one of an onset, a progression, a regression, and a status quo of congestive heart failure against an indicator threshold (129) corresponding to the same type of patient information as the recorded measures which were compared, the indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology indicative of congestive heart failure; and
  - a quality of life module (132); and
- a feedback module (128)."

- 13 - T 0515/08

- XVI. Claim 1 of the third auxiliary request reads as follows: "An automated system (10) for remotely managing congestive heart failure and outcomes thereof, comprising:
  - an interface (13, 14, 18, 21, 22) periodically retrieving recorded measures (24b, 25b) relating to patient information recorded by the patient medical device (12, 26) on a substantially continuous basis and directly providing feedback for the patient;
  - a database module (125) storing a plurality of monitoring sets (27) which each comprise the recorded measures and derived measures (24b, 25b), which were derived from the recorded measures (24b, 25b);
  - a diagnostic module (126) to determine patient well being, comprising:
    - a comparison module (130) determining a patient status change by comparing at least one recorded or derived measure from each of the monitoring sets to at least one other recorded or derived measure, wherein both recorded or derived measures relate to the same type of patient information;
    - an analysis module (131) testing each patient status change for one of an onset, a progression, a regression, and a status quo of congestive heart failure against an indicator threshold (129) corresponding to the same type of patient information as the recorded measures which were compared, the indicator threshold corresponding to a quantifiable physiological measure of a pathophysiology indicative of congestive heart failure; and
    - a quality of life module (132);
  - a feedback module (128); and

- 14 - T 0515/08

- a set of stickiness indicators (133) for each type of patient information, each stickiness indicator corresponding to a temporal limit related to a program of patient diagnosis or treatment, wherein the comparison module (130) compares a time span occurring between each patient status change for each recorded measure to the stickiness indicator relating to the same type of patient information as the recorded measure being compared; and wherein the analysis module (131) determines a revised program of patient diagnosis or treatment responsive to each patient status change occurring subsequent to a time span exceeding the stickiness indicator."
- XVII. In response to the board's observations in writing and during oral proceedings the appellant made oral submissions which are summarised as follows:
  - (i) With respect to the main request, it was submitted that the filed amendments to the claims were an honest attempt to overcome the objections raised by the board and the main request should therefore be admitted into proceedings. The definition of the feedback module provided in claim 1 of the request was supported by [0032] of the published application. The expression "changes for managing congestive heart failure" had been used instead of the expression "changes to interventive measures" used in the cited paragraph of the description because the board had raised objections against the latter expression in its communication. According to the appellant, the newly-introduced expression "changes for managing congestive heart failure" was intended to be substantially

- 15 - T 0515/08

synonymous with the expression "changes to interventive measures" used in the description.

- (ii) With respect to the first auxiliary request, it was submitted that claim 1 of said request was a combination of claims 1 and 5 of the main request and that the features recited in claim 5 of the main request were substantially identical to those of the originally filed dependent claim 6. It was true that claim 1 of the auxiliary request, on which the decision under appeal was also based, already comprised the features of the originally filed dependent claim 6 but was not mentioned or dealt with in the statement of grounds of appeal. However, in response to the board's objections raised in its communication with regard to the request then on file, the features of the originally filed dependent claim 6 were introduced in claim 1 of the second auxiliary request filed with letter of 24 October 2011. The definition of the feedback module in said claim, and in particular the expression "changes to interventive measures in the form of a revised treatment program" was supported by [0032] and [0056] to [0058] of the published application.
- (iii) With respect to the second auxiliary request, which had initially been filed as a first auxiliary request with the letter of 24 October 2011, the appellant referred to the written submissions contained in said letter according to which claim 1 of the present second auxiliary request corresponded to claim 1 of the main request filed with said letter which, in turn,

- 16 - T 0515/08

corresponded to claim 1 of the main request on which the decision under appeal was based with amendments intended to take account of the objections under Article 84 EPC 1973 raised in the board's communication.

- (iv) With respect to the third auxiliary request, which had initially been filed as a second auxiliary request with the letter of 24 October 2011, the appellant referred to the submissions made during oral proceedings on the admission into proceedings of the first auxiliary request and to the written submissions contained in said letter according to which claim 1 of the present third auxiliary request essentially corresponded to claim 1 of the first auxiliary request on which the decision under appeal was based but included the same amendments as claim 1 of the main request filed with said letter (cf. preceding items (ii) and (iii)).
- XVIII. At the end of the oral proceedings the chair announced the board's decision.

- 17 - T 0515/08

#### Reasons for the Decision

- 1. The appeal is admissible. However, the board finds that the appeal is not allowable for the reasons given below.
- 2. Admission of the requests into appeal proceedings
  Article 13(1) RPBA

According to Article 12(2) RPBA, the statement of grounds of appeal shall contain a party's complete case and specify expressly all the facts, arguments and evidence relied on. Article 13(1) RPBA stipulates that any amendment to a party's case after it has filed its grounds of appeal may be admitted and considered at the board's discretion. It further provides that the discretion should be exercised in view of, inter alia, the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

- 3. Main request Admission into proceedings
- 3.1 Claim 1 of the main request defines the feedback module in the following terms: "a feedback module (128) providing automated feedback to the patient from the diagnostic module (126) for determining whether any changes for managing congestive heart failure are appropriate".

In its communication, the board raised objections against the definition of the feedback module according to a previous version of said claim, i.e. claim 1 of the request on which the appeal was initially based. In particular, the expression "changes to interventive

- 18 - T 0515/08

measures" as used in said previous version of the claim was objected to (cf. Facts and Submissions, items IX(i) and IX(iii) above).

- In response to the board's objections and the discussion during the oral proceedings in this regard, claim 1 of the main request was amended during oral proceedings by introducing the expression "changes for managing congestive heart failure". In the board's judgement, this newly-introduced expression is even broader than the previous formulation "changes to interventive measures" and, moreover, has no literal basis in the description. Hence, this amendment to claim 1 of the main request gives rise to fresh clarity and support objections.
- 3.3 Furthermore, even if the expression "changes for managing congestive heart failure" were to be interpreted as being effectively synonymous with "changes to interventive measures" as submitted by the appellant during oral proceedings, the amendments to the feedback module feature of claim 1 fail to address the objections under Article 84 EPC 1973 and Article 123(2) EPC concerning an unsupported intermediate generalisation which were raised in the board's communication with respect to the aforementioned previous version of the claim (cf. Facts and Submissions, item IX(iii) and IX(v) above).
- 3.4 In view of the foregoing and having regard to the late stage of the proceedings at which the aforementioned amendments were filed, the board, exercising its discretion under Article 13(1) RPBA, decided not to admit the main request to the proceedings.

- 19 - T 0515/08

- 4. Admission of the first auxiliary request
- 4.1 Claim 1 of the first auxiliary request, differs from the corresponding claim of the main request in that it comprises an additional feature of "a set of stickiness indicators" which includes a specification to the effect that the analysis module determines a revised program of patient diagnosis or treatment responsive to each patient status change occurring subsequent to a time span exceeding the stickiness indicator and in that the wording used to define the feedback module feature of the claim has been amended as follows: "a feedback module (128) providing automated feedback to the patient based, in part, on a patient status indicator (127) generated by the diagnostic module (126), and determining whether any changes to interventive measures in the form of a revised treatment program are appropriate based on threshold stickiness."
- 4.2 In the board's judgement, the subject-matter of claim 1 of the first auxiliary request relating to the use of "stickiness indicators" results from the incorporation into said claim of the features of dependent claim 6 as originally filed which were also present in claim 1 of the auxiliary request on which the decision under appeal was based (cf. Facts and Submissions, item V. above).
- 4.3 In the written statement setting out the grounds of the appeal, however, the appellant only requested that the decision of the examining division be reversed and that a patent be granted "on the basis of the main request

- 20 - T 0515/08

of the decision appealed" (cf. Facts and Submissions, item VIII. above).

- 4.4 It is noted in this regard that Article 12(2) RPBA prescribes that the written statement setting out the grounds of appeal shall contain the appellant's complete case. The written statement filed in the present case included no identifiable mention of the auxiliary request on which the decision under appeal was based, neither did it include any substantive submissions in response to the examining division's findings pertaining to this request (cf. Facts and Submissions, item VI. above).
- The written statement thus contained no indication that 4.5 the appellant intended to pursue the subject-matter defined by claim 1 of said auxiliary request during the appeal proceedings. The board takes the view that if the appellant had intended to pursue this subjectmatter during the appeal proceedings, whether in its original form or in an amended version thereof, then having regard to the need for procedural economy this intention should have been expressed in the written statement setting out the grounds of appeal. However, it was only with the letter dated 24 October 2011 and, therefore, at a late stage of the appeal proceedings that the appellant filed claim 1 of auxiliary request 2 which comprised the features of the originally filed dependent claim 6. The present first auxiliary request was filed only at the oral proceedings and thus at a even later stage of proceedings.
- 4.6 Moreover, the amendments to claim 1 of the request raise fresh issues in relation to the questions of

- 21 - T 0515/08

support by the description (Article 84 EPC 1973) and the extension of subject-matter (Article 123(2) EPC), in particular due to the inclusion of the aforementioned specification relating to the analysis module (cf. point 4.1 above) in combination with the specification of the feedback module.

According to [0032] of the published application, it is the feedback module rather than the analysis module which determines whether any changes to interventive measures are appropriate based on threshold stickiness. The description does not contain any clearly identifiable support for the aforementioned claim specification of an analysis module which determines a revised program of patient diagnosis or treatment responsive to each patient status change occurring subsequent to a time span exceeding the stickiness indicator.

Whereas dependent claim 6 as originally filed contains a substantially identical specification relating to the analysis module, neither said claim 6 nor the independent claim 1 on which it depends further include the feature of a feedback module as recited in claim 1 of the present first auxiliary request.

Hence, the application documents as originally filed provide no clearly identifiable basis for the overall combination of features according to claim 1 of the first auxiliary request, in particular the combination of an analysis module which determines a revised program of patient diagnosis or treatment and a feedback module which determines whether any changes to

- 22 - T 0515/08

interventive measures in the form of a revised treatment program are appropriate.

- 4.7 In view of the foregoing, the board, exercising its discretion under Article 13(1) RPBA, decided not to admit the first auxiliary request to the proceedings.
- 5. Admission of the second auxiliary request

Having regard to the fact that the second auxiliary request was submitted prior to oral proceedings and merely contains amendments to the wording of the independent claims aimed at addressing the clarity and support objections set forth in the board's communication, the board, exercising its discretion under Article 13(1) RPBA, decided to admit this request to the proceedings.

- 6. Admission of the third auxiliary request
- 6.1 Claim 1 of the third auxiliary request includes the feature of "a set of stickiness indicators" and further comprises a specification to the effect that "the analysis module (131) determines a revised program of patient diagnosis or treatment responsive to each patient status change occurring subsequent to a time span exceeding the stickiness indicator".
- 6.2 As in the case of claim 1 of the first auxiliary request (cf. point 4.2 above), the board finds that claim 1 of the third auxiliary request likewise incorporates the features of dependent claim 6 as originally filed which were also present in claim 1 of the auxiliary request on which the decision under

- 23 - T 0515/08

appeal was based (cf. Facts and Submissions, item V. above).

- 6.3 Although the third auxiliary request was submitted somewhat earlier than the first auxiliary request, it was nevertheless filed at a relatively late stage in the appeal proceedings, i.e. after a summons to oral proceedings had been issued. Referring to the observations made under points 4.3 to 4.5 above with respect to the first auxiliary request, the board judges that, under the given circumstances, the third auxiliary request also represents a belated attempt to pursue the aforementioned subject-matter.
- 6.4 Moreover, the amendments to claim 1 of the request raise fresh issues in relation to the questions of clarity and support by the description (Article 84 EPC 1973).

Although the claim wording to the effect that the analysis module determines a revised program of patient diagnosis or treatment is found in claim 6 as originally filed, this specification does not appear to be consistent with [0032] of the description according to which it is the feedback module rather than the analysis module that determines whether any changes to interventive measures are appropriate based on threshold stickiness (cf. published application: p.8, 1.25-27).

It is further noted with respect to the "quality of life module" and "feedback module" features of said claim, that the claim merely states that these modules are comprised within the system but fails to provide

- 24 - T 0515/08

any meaningful specification of their technical function and their technical relationship to the other system components.

- 6.5 In view of the foregoing, the board, exercising its discretion under Article 13(1) RPBA, decided not to admit the third auxiliary request to the proceedings.
- 7. Allowability of the second auxiliary request

The board decided to admit this request to the proceedings (cf. point 5. above). However, the request is found not to comply with the requirements of the EPC for the reasons which follow.

- 7.1 In the board's judgement, the generic term "interface" used in claim 1 of the second auxiliary request is to be construed as denoting a system boundary across which some exchange of data takes place. However, the term does not define the technical means by which such exchange of data takes place. For this reason, the board finds that, in the given context, the technical limitation implied by the generic term "interface" is unclear.
- 7.2 The board further finds that the "interface" feature of claim 1 lacks support by the description because there is no direct and unambiguous disclosure to the effect that the specified functionality, i.e. the periodic retrieval of telemetered signals and the provision of feedback for a patient, is performed through a single "interface" as implied by the wording of the claim.

- 25 - T 0515/08

- 7.3 Paragraph [0005] of the published application, cited by the appellant as providing support for the disputed feature merely refers to an interrogator "or similar interfacing device" (emphasis added by the board) which is used to periodically retrieve telemetered data. The cited paragraph additionally states that the telemetered data is analysed in an automated fashion and that feedback is provided to the patient. There is, however, no disclosure to the effect that the feedback is provided via the same "interface" which is used to periodically retrieve the telemetered data.
- 7.4 In this regard, the board further refers to [0017] of the description which states that feedback can be provided in the form of an automated voice mail message to a telephone through "a telephone <u>interface device</u>" (emphasis added by the board).
- 7.5 On this basis, the board concludes that whereas the description discloses the periodic retrieval of telemetered data and the provision of feedback to a patient, each of these functions is performed using a separate and distinct interface device. The description contains no direct and unambiguous disclosure of "an interface" which performs both of the aforementioned functions as implied by the wording of claim 1 of the request.
- 7.6 With respect to the "quality of life module" and "feedback module" recited in claim 1, the claim merely states that these modules are comprised within the system without providing any meaningful specification of their technical function and their technical relationship to the other system components. For this

- 26 - T 0515/08

reason, the board finds that the definition of these claim features fails to comply with the clarity requirements of Article 84 EPC 1973.

- 7.7 Referring to the "interface" feature of claim 1 (cf. 7.1 and 7.2 above), the board further notes that, in addition to the lack of support by the description, no basis for this feature can be found in the originally filed claims. In the board's judgement, there is no direct and unambiguous disclosure of said feature in the originally filed application documents and for this reason it is found that its introduction into claim 1 of the request also infringes Article 123(2) EPC.
- 7.8 In view of the foregoing deficiencies in claim 1, the board concludes that the second auxiliary request is not allowable.

#### Conclusions

- 8. Having regard to the above findings, it is not necessary to give further consideration to the other issues raised in the board's communication (cf. Facts and Submissions, item IX(vi) above).
- 9. In the absence of an allowable request the appeal must be dismissed.

# Order

# For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:

K. Götz

A. Ritzka