BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS 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

D E C I S I O N
of 18 July 2001

Case Number: T 0321/99 - 3.2.2

Application Number: 92915643.8

Publication Number: 0548336

IPC: A61M 1/16

Language of the proceedings: EN

Title of invention:
Method of monitoring a dialysis unit

Patentee:
HOSPAL LTD.

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 56, 84, 123

Keyword:
"Inventive step (yes, after amendments)"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0321/99 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 18 July 2001

Appellant: (Opponent)
Fresenius Medical Care Deutschland GmbH
Gluckensteinweg
D-61350 Bad Homburg (DE)

Representative:
Laufhütte, Dieter, Dr.-Ing.
Lorenz-Seidler-Gossel
Widenmayerstrasse 23
D-80538 München (DE)

Respondent: (Proprietor of the patent)
HOSPAL LTD.
Dornacherstrasse 8
CH-4008 Basel (CH)

Representative:
Lejeune, Daniel
Hospal Service Brevets
61, avenue Tony Garnier
FR-69007 Lyon (FR)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 4 February 1999 concerning maintenance of European patent No. 0 548 336 in amended form.**

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noël
R. T. Menapace

Summary of Facts and Submissions

I. Upon opposition by the appellant against the grant of European patent No. 0 548 336, the Opposition Division decided by interlocutory decision dated 4 February 1999 to maintain the patent in amended form.

II. The appellant lodged an appeal against this decision on 23 March 1999. Its statement of grounds, received on 31 May 1999 was accompanied by two new documents D8 and D9, in addition to documents D1 to D7 already on file.

III. Documents considered for the present appeal:

D5: CMS 08 Handbuch, 4. Ausgabe 1988, Teil 1, bzw, Teil 1.1, EDV-Nr: 643 497, Fresenius AG, D-6370 Oberursel.

D8: HDCOMP Version 1.1, 2. Auflage 2/1988 Modellrechnungen zur Kinetik von Natrium und Wasser bei der Hömodialyse, pages 1-30, Fresunius AG, D6380 Bad Homburg.

D7: "Gebrauchsanweisung Blutzellseparator AS104", Sofware version 4.4, Fresenius AG 6/12.90 (GA), pages 0-1 to 2-114.

D9: "Microprocessor based universal dialysis calculator for individualization of artificial kidney therapy" by S. Stiller et. al., Medinfo 80, pages 534 to 538.

IV. Oral proceedings were held on 18 July 2001, at the end of which the requests were as follows:

The appellant requested that the decision under appeal be set aside and that the European patent be revoked.

The respondent (patentee) requested that the decision under appeal be set aside and that the patent be maintained in amended form with claims 1 to 10 and the description as submitted at the oral proceedings and the figures as granted.

V. Claim 1 as filed at the oral proceedings reads as follows (identifying letters (a) to (g) introduced by the Board for ease of reference):

"1. A method of monitoring a dialysis unit, characterized in that it comprises the stages of:
(a) acquiring (11, 12) and storing (19) set values for a plurality of parameters (Q_{inf}, Q_b and Q_{UF}) relating to the treatment to be carried out, the parameters including the infusion rate (Q_{inf}) of a solution containing bicarbonate (HCO_3^-),
(b) calculating (20) a clinical prescription of the concentration in blood of bicarbonate $[HCO_3^-]_b$, which will result from a treatment based on the stored values of the parameters, the prescription being calculated using a mathematical model of the relationship between the treatment parameters (Q_{inf}, Q_b and Q_{UF}) and the prescription $[HCO_3^-]_b$,
(c) comparing during the treatment the set values of the parameters with the initially stored set values of the parameters,
(d) determining (31) suggested values (Q_{infs}) for one of the parameters so as to maintain the prescription $[HCO_3^-]_b$ unchanged,
(e) if any variation is detected between the set values of the one parameter and the initially stored

set value of the parameter, determining any change in the prescription resulting from the change in the set values of the parameter,
(f) generating (36) an alarm signal when a variation in the prescription is detected, and
(g) displaying (36) the suggested value."

VI. The parties argued as follows:

(i) The appellant:

- Documents D5 and D8 which are linked by cross references can be regarded as one single state of the art. D5 discloses a computer programmed control system (CMS 08) for controlling the parameters of a dialysis unit using a mathematical model and a specific software (HDCOMP) as disclosed in D8. The system controls the variation in time of a plurality of parameters, of which the ultrafiltration rate and, optionally, the electrolytic concentration of bicarbonate. Parameter profiles may be changed during the treatment and displayed.

  Document D8 further explains how the computer-modelling-system can actually control the variations of e.g. Na-concentration within a predetermined range. In the present patent, the term "unchanged" allows for some flexibility in the variation of the prescription as well.

- Document D9 discloses a microprocessor system programmed to calculate the plasma concentration (including bicarbonate) and to predict the solute exchange during dialysis, so as to provide the

physician with all information of interest for an individualized dialysis therapy. The calculation may be repeated after the change of parameters. It is, therefore, close at hand for a person skilled in the art, to maintain the bicarbonate concentration unchanged, if necessary.

- Document D7 is concerned with the neighbouring field of blood separation by centrifugation and also for therapeutical purposes. Automatic control is achieved by coupling parameters (flow rate of pumps) in order to maintain a prescription (sedimentation rate) at a constant value and to give an alarm whenever the variations fall outside of predetermined limits.

- Therefore, the subject-matter of claim 1 is suggested by the disclosures of documents D5/D8 and D9, D7 in combination.

(ii) The respondent:

- The bicarbonate concentration referred to in document D5 relates to the dialysis fluid, and not, as in the present patent, to an infusion fluid administered to the patient in the course of the process of "acetate free" treatment. The control system is intended to control the time profile of parameters in the case of a modification of the set values, but is unable to predict the conditions which are dangerous for the patient or to prevent situations of potential risk. The mathematical model is not based on a relationship between the parameters and a prescription, so that the computer programm is

unable to restore the original prescription of the physician on the basis of modified set values of the parameters.

- Document D9 discloses the use of a programmed microcomputer for analysing the solute exchanges during the treatment. But possible variations of the prescription are not taken into account, so that the control system presents the same risks for the patient as those recited in the patent's background.

- Document D7 is concerned with the separation of blood by centrifugation, a technical field far remote to the specific acetate free dialysis method. Therefore, the means provided therein to maintain the sedimentation rate constant are not usable in the method according to the invention.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

The amendments applied to claim 1 during the appeal proceedings are not open to objections. In particular, the specification that the treatment parameters include the infusion rate (Q_{inf}) of a solution containing bicarbonate (HCO_3^-) (feature (a)), is supported by the original description (see page 1, lines 15 to 21; page 3, lines 21 to 30) and implies in itself that the treatment is of "acetate free" type.

The specification that the prescription is the concentration in blood of bicarbonate $[HCO_3^-]_b$ and is calculated using a mathematical model of the relationship between the treatment parameters and the prescription (feature (b)) is also based on the application as filed (see page 1, lines 23 to 35; page 4, lines 3 to 11 and the original claim 3).

The specification of determining suggested values (Q_{infs}) for one of the parameters so as to maintain the prescription unchanged (feature (d)) results from the incorporation of original claim 2 and is more specifically supported by page 4, lines 32 to page 5, line 6 of the description as filed.

Dependent claims 2 to 10 are renumbered to take account of the incorporation of claim 2 into claim 1 and the term "variable" is replaced by "prescription" by reason of consistency, since "the variable" is in fact "the prescription" (cf. page 1, line 34), in other words the desired bicarbonataemia in the blood (page 1, line 27).

Therefore, the amendments are clear and do not extend the subject-matter of the patent beyond the content of the application as filed, in conformity with Article 84 and 123(2) EPC.

With respect to the version of claim 1 as granted, the amendments are made by way of additional features only. Therefore the scope of protection is restricted, in conformity with Article 123(3) EPC.

3. *Inventive step*

3.1 Document D8 discloses a software-package (HDCOMP) for

controlling the various parameters of a dialysis apparatus of the type CMS-08 (Computer-Modelling-System 08) on the basis of mathematical models. Since the operating instructions described in document D5 are specifically concerned with the dialysis system CMS-08 in connection with the programm HDCOMP (see e.g. pages 2.1-5; 2.3-1; 3.2-1; 3.2-12), documents D5 and D8 in combination can be considered as one single state of the art.

Document D5 discloses the control of parameters of a dialysis system by means of a computer and mathematical models (pages 1.2-1 and 2.2-1). As shown on Figure 2.1 (page 2.4-3), the computer controls the flow rate of ultrafiltration through the dialyser on the basis of predetermined time profiles of at least three electrolytic concentrations, one of which is bicarbonate (pages 1.2-1 and 2.2-1). These profiles can be modified during the dialysis treatment. These concentrations, however, all concern dialysis fluids in the dialyser and not blood values.

Differently, according to the patent in suit, the fluid to be controlled is not a dialysis fluid but an infusion fluid containing bicarbonate within the context of a specific dialysis treatment said "acetate free". In this specific treatment, bicarbonate is not present in the dialysis fluid. Instead it is administered to the patient through an infusion pack at a variable flow rate the control of which is determinant to provide the desired bicarbonataemia in the blood with sufficient stability. The subject-matter of claim 1, therefore, already differs from the disclosure of document D5 in that one essential parameter to be controlled includes the infusion rate

(Q_{inf}) of a solution containing bicarbonate (feature (a)).

Further, the invention requires that, before starting the dialysis on the basis of the initial set parameters, a prescription of the concentration in blood of bicarbonate $[HCO_3^-]_b$ is calculated (step 20, Figure 2) using a stored mathematical model of the relationship between the treatment parameters set by the operator and the prescription of the doctor (feature (b)). During the dialysis, in case of variations of the parameters with respect to their initial values (feature (c)), a new value of one parameter (Q_{inf}) is calculated (step 31) as a function of the previously calculated bicarbonataemia (prescription) and of the current values of the other parameters, and this new value is suggested (Q_{infs}) to the operator (feature (d)). In this way, it is possible to maintain the prescription unchanged and to avoid situations which place the patient at risk, as it is set out in the present patent (column 1, lines 22 to 41).

In contrast thereto, in document D5 the system controls different machine parameters with respect to a predetermined profile, without taking account of the modifications of the patient's state during the dialysis. The known system does not comprise any control of the bicarbonate concentration in the blood of the patient during dialysis. According to document D8, the software determines the evolution with time of, for example, the sodium (Na) concentration in the plasma by comparing measured values with mathematical model predictions (cf. pages 12 and 13). However, the model predictions are not based on a

relationship between the patient parameters and a prescription by the physician. Therefore, the patient parameters monitored in D8 (pages 18 to 19) do not include the bicarbonate concentration in blood and the controlled values are subject to fluctuations within predetermined limits (page 20). In contrast thereto, in the invention the prescription is maintained unchanged. This is the reason why the prescription is incorporated in the calculation of the suggested value of the parameter to be changed (Q_{uifs}).

For these reasons, the subject-matter of claim 1 is not disclosed nor suggested by the teaching of documents D5/D8.

3.2 The other documents referred to at the oral proceedings do not suggest the above-mentioned essential features of the invention, either.

In document D9, a microprocessor system is programmed to quantitatively predict solute exchange during artificial kidney therapy. This computer from the plasma concentrations (including bicarbonate) at the beginning of the dialysis session and the dialysis parameters, calculates the plasma concentrations and the eliminated quantities as a function of time, to provide all the information of interest to the supervising physician. Although the calculation may be repeated after the change of some parameters, only the appropriate dialysis time is derived. The generation rate of bicarbonate is given by the transformation rate of metabolized acetate. Clearly, the dialysis method is not "acetate free" and the bicarbonate concentration in blood is not maintained unchanged.

Document D7 discloses operating instructions for blood separation by centrifugation. Apart from belonging to the general medical field of blood treatment (page 2-6), blood separation has nothing in common with a dialysis procedure. Although the operating parameters may be set initially and then changed during the treatment (page 2-12), none of them is calculated on the basis of the others as it is the case in the present patent. Further, automatic control is achieved by means of a microprocessor and an appropriate software by coupling some parameters (here the flow rate of pumps) so as to maintain the sedimentation conditions constant (pages 2-113 and 2-114). Even though an analogy could be generally seen in the coupling of some parameters so as to maintain one condition unchanged (here the sedimentation rate), such analogy alone is insufficient to prompt the skilled person towards the dialysis monitoring method according to the invention, which comprises the specific steps as claimed.

3.3 From the foregoing, it results that the subject-matter of claim 1 is not obvious to a person skilled in the art, in accordance with Article 56 EPC. Therefore, claims 2 to 10 which depend thereon, are also acceptable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent in amended form with claims 1 to 10 and the description as submitted at the oral proceedings and the figures as granted.

The Registrar: The Chairman:

V. Commare W. D. Weiß