

Internal distribution code:

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

D E C I S I O N
of 22 October 2002

Case Number: T 0579/99 - 3.2.2

Application Number: 92925219.5

Publication Number: 0567633

IPC: A61M 1/16

Language of the proceedings: EN

Title of invention:

Hemodialysis Conductivity Servo-Proportioning System

Patentee:

BAXTER INTERNATIONAL INC.

Opponent:

Fresenius Medical Care Deutschland GmbH

Headword:

-

Relevant legal provisions:

EPC Art. 54, 56

Keyword:

"Novelty and inventive step (no)"

Decisions cited:

-

Catchword:

-



Case Number: T 0579/99 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 22 October 2002

Appellant: BAXTER INTERNATIONAL INC.
(Proprietor of the patent) One Baxter Parkway
Deerfield, IL 60015 (US)

Representative: Dee, Ian Mark
Eric Potter Clarkson
Park View House
58 The Ropewalk
Nottingham NG1 5DD (GB)

Respondent: Fresenius Medical Care
(Opponent) Deutschland GmbH
Gluckensteinweg 5
D-61350 Bad Homburg v.d.H. (DE)

Representative: Luderschmidt, Schüler & Partner GbR
Patentanwälte
Postfach 3929
D-65029 Wiesbaden (DE)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 25 March 1999
revoking European patent No. 0 567 633 pursuant
to Article 102(1) EPC.

Composition of the Board:

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

Summary of Facts and Submissions

I. By decision of 25 March 1999 the Opposition Division revoked European patent No. 0 567 633 on the grounds of lack of inventive step vis-à-vis the state of the art represented, in particular, by documents:

D1: EP-A-0 443 324

D2: "Dialysetechnik", Dieter Schleipfer, Gesellschaft für angewandte Medizintechnik m.b.H. & Co. KG, 4. Auflage 1988, pages 188, 190.

D6: as D2 above, with additional pages 104, 156, 162, 182, 184, 190, 192, 214 and 216.

II. The appellant (patentee) lodged an appeal against this decision on 26 May 1999. Its statement of grounds was filed on 26 July 1999.

III. With its grounds of appeal, with its letter of 20 September 2002, and at the oral proceedings which were held on 22 October 2002, the appellant successively submitted various versions of amended claims.

IV. At the end of the oral proceedings the final requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of claims 1 to 20 as submitted at the oral proceedings (main request) or on the basis of the set of claims 1 to 20 filed under the heading "second auxiliary request" on 20 September 2002 (now sole

auxiliary request).

The respondent requested that the appeal be dismissed.

V. The independent method and apparatus claims read as follows (identifying letters (a) to (g) introduced by the Board for ease of reference):

Main request:

"1. A method of controlling mixing dialysate concentrate and water to give a dialysate in a hemodialysis machine, characterised by:

- (a) determining the concentrations of individual concentrate components making up the dialysate concentrate;
- (b) selecting a desired final Na or a desired final Na and Bicarb concentration in the dialysate;
- (c) calculating the mixing ratio of the dialysate concentrate and water which is necessary to obtain the desired final concentration for the Na or Na and Bicarb in the dialysate;
- (d) calculating from the concentrate component concentrations, the conductivity of the dialysate formed by the concentrate components and water;
- (e) combining said concentrate components with said water to form said dialysate;
- (f) sensing the conductivity of said dialysate and comparing said sensed conductivity with said calculated conductivity; and
- (g) controlling the proportions of said concentrate components and said water in accordance with said comparison to obtain said calculated dialysate conductivity."

"11. Apparatus for mixing dialysate concentrate and water to give a dialysate in a hemodialysis machine, characterised by:

means for determining the concentrations of individual concentrate components making up the dialysate concentrate;

means for selecting a desired final Na or a desired final Na and Bicarb concentration in the dialysate;

means for calculating the mixing ratio of the dialysate concentrate and water which is necessary to obtain the desired final concentration for the Na or Na and Bicarb in the dialysate;

means (14,16) for calculating from the concentrate component concentrations, the conductivity of the dialysate formed by the concentrate components and water;

means (44,48,54,58) for combining said concentrate components with said water to form said dialysate;

means (14,16) for sensing the conductivity of said dialysate and means (14,62) for comparing said sensed conductivity with said calculated conductivity; and

means (16) for controlling the proportions of said concentrate components and said water in accordance with said comparison to obtain said calculated dialysate conductivity."

Auxiliary request:

The method claim 1 differs from claim 1 according to the main request by the addition of the following step (before feature (a)):

"entering the final nominal diluted concentrations of the individual concentrate components making up the

dialysate concentrate that are provided by the manufacturer;"

and by amending feature (a), which now reads:

"determining from the final nominal diluted concentrations the actual concentrations of the individual concentrate components making up the dialysate concentrate;"

The apparatus claim 11 differs from claim 11 according to the main request by the same amendments as before, however with the addition of the terms "means for" before each step.

VI. The parties presented the following arguments:

(i) The appellant:

Claim 1 according to the main request differs from the state of the art in that the desired conductivity of the dialysis solution is calculated from the concentrations of the individual components and this conductivity value is then used as set value in the control unit of the proportioning system. The prior art documents are using nominal diluted concentrations provided by the manufacturer but none of them suggests to calculate the desired conductivity of the dialysate from the concentrate component concentrations. The subject-matter of claim 1 is, therefore, novel and involves an inventive step over the prior art.

Claim 1 according to the auxiliary request differs from the main request by the additional features of determining the actual concentrations of the individual

concentrate components from the final nominal diluted concentrations provided by the manufacturer. The actual values are, in fact, derived from the nominal values by application of a multiplication or a division factor. These features are not disclosed by the prior art either.

(ii) The respondent:

Claim 1 according to the main request lacks novelty vis-à-vis the teaching of document D1 or that of document D6 (together with document D2). In particular, the textbook D6 which corresponds to the background reported in the application as filed, addresses the same problem as in the present patent and discloses the same solution which consists, essentially, in correcting the desired conductivity of the dialysis solution (set value) in case of variations in the component concentrations. Calculation of the conductivity of a ionic solution from the respective conductivities of its individual ion species belongs to the general knowledge of a person skilled in the art.

The features added in claim 1 according to the auxiliary request do not add any inventive step since the actual concentrations are directly derived from the nominal concentrations. These features do also not change the control function of the proportioning system upon which the invention is based. Apart from document D6 which suggests to adjust the desired conductivity of the dialysate in relation to any change in the concentrate components, document FR-A-2 504 817 cited in the patent in suit discloses a logic control unit for calculating the desired conductivity of the final solution from the set conductivity values of the

concentrate components. The claimed subject-matter is, therefore, obvious.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

The question of whether there are any formal objections to the current version of the claims need not be answered since all main claims (main and auxiliary requests) are anyway unallowable on other grounds, as set out hereinafter.

3. *Novelty*

3.1 Documents D2 and D6 form together one state of the art, which is henceforth simply referred to as document D6. D6 is considered as the closest prior art document and represents the general knowledge of a person skilled in the field of dialysis at the filing date of the patent in suit. In accordance with the background part reported in columns 1 and 2 of the patent, document D6 relates to a conductivity-based servo-proportioning system for hemodialysis machines (cf. page 188, Figure 7.3.1.4 and text referred to) including a source of incoming water, a source of dialysate concentrate or concentrates which are introduced into the water with a predetermined concentration by means of proportioning pumps, one of which is controlled by a controller receiving the sensed conductivity values of the dialysate to be compared with a predetermined set conductivity value ("Sollwert").

Bicarbonate dialysis is achieved in document D6 by sequentially proportioning two concentrates and water into a single solution (cf. page 162), the first acidified mixture being obtained by continuously proportioning 1 part of concentrate with 34 parts of water. The bicarbonate and acidified concentrates are available in different concentrations to allow the dialysate solution to be adapted to an individual patient (cf. Table 6.5.2, page 156). If a change of concentration is desired in the final solution or if the concentration differs from the nominal value, the volumetric mixing ratios are varied correspondingly (cf. page 184, section 7.3.1.2, last paragraph and page 188, section 7.3.1.4, first paragraph).

In order to mix concentrates by volume accurately, as further reported in the background part of the present patent (column 2, lines 19 to 28), prior art servo-proportioning systems were developed to achieve the desired concentrations through feedback controls based upon nominal conductivity values provided by the concentrate manufacturer (concentrations labels). Such a system is disclosed, for example, by document D6, according to which the set values ("Sollwert") are predetermined (cf. page 188, left column, last two paragraphs and right column, first paragraph).

Like the present patent, document D6 faces the problem (cf. page 188, right column, third paragraph) that the set value of the conductivity, which normally can be determined when the volume ratio of the concentrate on to water is correct, changes in relation to the ionic composition of the concentrate solution, which is adjusted in accordance to the patient's need. The variations of conductivity of the dialysis solution can

reach 10% or more with respect to the desired value, which corresponds to the error of ±5% mentioned in the patent (column 2, lines 28 to 36).

This is the reason why in document D6 (cf. paragraph bridging pages 188 and 190 and page 214, right column, penultimate paragraph), the proportioning system is initially set to the nominal values forming the concentrate solution and then the set value is adjusted in accordance with any modification or change occurring in the concentrate components used in the solution.

With respect to document D6, the subject-matter of claim 1 differs in that the set conductivity value of the dialysate formed by the concentrate components and water is calculated from the concentrations of the single components in the concentrate (feature (d)), whereas in document D6 the set conductivity value is predetermined and then corrected when necessary. The further differentiating features in claim 1 are unavoidable consequences of the said feature (d), since in the absence of a "calculated conductivity" in document D6, there is also no possibility of further comparing it with the sensed conductivity (feature (f)) and, also, the result of this comparison cannot be taken over in the subsequent control operation (feature (g)).

Consequently, the subject-matter of claim 1 is novel over D6.

- 3.2 Document D1 discloses (cf. Figure 1) a system for the in line preparation of a dialysis fluid, whereby a first mixing fluid is prepared in a mixing vessel 21 supplied with water 3, 17 and different concentrates in

powder form placed into cartridges 27 to 29. The first mixing fluid may be made from a liquid-based concentrate supplied from a vessel 31. Mixing is performed by recirculating the fluids through a recirculation circuit 20 until the appropriate concentration and the desired conductivity are attained, which process is controlled by a conductivity meter 23 (cf. column 2, lines 10 to 21 and column 5, lines 28 to 38 and 50 to 57). The so-called "partially prepared solution" is then mixed (mixing point 44, Figure 2) with a second liquid concentrate obtained by dissolving a further concentrate in powder form with water in a vessel 5 connected in parallel thereto. The conductivity of the resulting mixing solution can be measured before (46) and/or after (47) the addition of the partially prepared solution mentioned above. If measured only after it, the partially prepared solution is added by means of an accurately metering dosage pump (not shown, but of the same type as pump 48, so that the proportioning ratio of the mixing fluid may be calculated (cf. column 3, lines 8 to 16). A similar mixing operation is performed with a third liquid concentrate obtained from a further powder concentrate in vessel 32 (Figure 3). The in line prepared dialysis solution is sensed at each mixing stage by conductivity meters 49 and 38 provided for controlling dosage pumps 48 and 40, respectively.

Again, calculating the conductivity of the dialysate solution from the various concentrate component concentrations is not disclosed. Therefore, the subject-matter of claim 1 is also novel over document D1.

4. *Inventive step*

- 4.1 The appellant is in agreement with the Board that the claims 1 according to the main and auxiliary requests have substantially the same scope. The Board finds it, therefore, appropriate to investigate only the auxiliary request which is formulated in clearer terms and is more complete than the main request, since the first two features of the auxiliary request specify that the **actual** concentrations of the individual concentrate components are determined from the final **nominal** diluted concentrations provided by the manufacturer.
- 4.2 As stated in document D6 (cf. page 214, right column, first paragraph and page 216, left column, first paragraph), a mere conductivity measurement of the dialysis solution does not exactly define the composition of the solution, although the contributions to the global conductivity of the individual chemical components are known (cf. page 214, Table 8.1.3). Only a quantitative analysis of the solution by a laboratory or the selective measurement of a specific ion can accurately inform about the correct composition of the solution and the actual concentrations of the individual components.

The patent specification is silent about how the actual concentrations are determined, starting from the nominal values. The description is confined to state that the system calculates the actual conductivity contributions of the individual components to determine the conductivity set points (cf. column 2, lines 46 to 50; column 3, lines 39 to 42 and column 4, lines 35 to 38). The term "actual concentration" used in claim 1 is misleading since - as admitted by the appellant - no

measurement or analysis is performed to determine the actual values of the individual concentrate components. These values are calculated from the nominal values according to the specification of the manufacturer by application of a multiplication factor to take account of the dilution. Therefore no correction of any error is made at this stage. The only correction results from the control function of the proportioning system, which is of a conventional type.

As a consequence, the additional step of determining the actual concentrations of the individual concentrate components does not provide any inventive contribution over the state of the art since this is already implied in the proportioning system disclosed by document D6.

- 4.3 It is general knowledge that the conductivity of a liquid solution can be easily calculated from the conductivity contributions of its individual components (cf. for instance D6, page 214). An obvious alternative is, therefore, to take advantage of the control unit necessarily present in any control system in order to calculate the conductivity of the concentrate solution from the actual values of its components instead of using the nominal values supplied by the manufacturer.

Such an alternative is further disclosed by document FR-A-2 504 817 cited in the description of the patent in suit. As shown in Figure 1, the conductivities of the intermediate solutions obtained first by mixing bicarbonate with water and then with an acidified sodium-based solution, are controlled by conductivity sensors 40, 56 and 60, respectively. According to Figure 2, a logic unit 78 is provided for adjusting the level of the desired conductivity values and is

supplied with set conductivity values for the bicarbonate (selector 80) and the sodium (selector 82), which desired values are then controlled by sensors 40 and 56, respectively. The conductivity of the final solution, which is sensed by sensor 60, is then applied to a conductivity control and monitoring unit 83 (Figure 2), one output of which controls the pumps 52, 54, so as to regulate the proportioning ratio of the mixture and, hence, the desired conductivity of the final dialysis solution (cf. page 8, lines 25 to 33). The set values of the final solution are represented by signals E_cFC_r and E_sFC_r (c for control and s for survey). These signals are generated and calculated in the logic unit 78 from the desired conductivities 80, 82 of the intermediate mixtures (cf. page 9, lines 4 to 6), i.e. from the concentrations of the individual components (cf. page 9, lines 13 to 20), which can be modified during the dialysis treatment.

Consequently, document FR-A-2 504 817 clearly suggests that the conductivity of the dialysate can be calculated from the concentrate component concentrations, in conformity with the essential feature (d) as claimed.

- 4.4 It results therefrom that the subject-matter of claim 1 (both requests) does not involve an inventive step with respect to the combination of documents D6 and FR above. Therefore, the requirements of Article 52(1) in conjunction with Article 56 EPC are not met.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß