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Datasheet for the decision of 2 July 2014

Case Number: T 0968/09 - 3.2.02

Application Number: 01984310.1

Publication Number: 1207923

IPC: A61M1/16, B01D61/32, G06F19/00

Language of the proceedings: EN

Title of invention:
DIALYSIS MACHINE COMPRISING A DEVICE FOR SETTING UP A DIALYSIS TREATMENT

Patent Proprietor:
Gambro Dasco, S.p.A.

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 100(a)

Keyword:
Inventive step - (yes)

Decisions cited:

Catchword:

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Case Number: T 0968/09 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 2 July 2014

Appellant: (Opponent)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Herrmann, Uwe Lorenz - Seidler - Gossel Widenmayerstrasse 23 80538 München (DE)
Respondent: (Patent Proprietor)	Gambro Dasco, S.p.A. Via Modenese, 30 41036 Medolla (IT)
Representative:	Lang, Johannes Bardehle Pagenberg Partnerschaft mbB Patentanwälte, Rechtsanwälte Prinzregentenplatz 7 81675 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 13 February 2009 concerning maintenance of the European Patent No. 1207923 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	P. L. P. Weber
	M. Stern

Summary of Facts and Submissions

I. The appeal by the opponent is against the interlocutory decision of the opposition division that, taking account of the amendments according to the main request made during the opposition proceedings, the patent and the invention to which it related met the requirements of the EPC.

II. Claim 1 (combination of claims 1 and 2 of the patent as granted) as considered allowable by the opposition division reads as follows:

"A dialysis machine (1) comprising:
- an extracorporeal blood circuit (4) for the circulation of blood in a first compartment of a dialyzer (5) having a first and second compartments separated by a semipermeable membrane (7),
- a dialysate circuit (3) for conveying a dialysate in the second compartment of the dialyzer (5), the dialysate having a defined concentration of salts which is correlated to the electrical conductivity (C) of the dialysate,
- an apparatus (2) for varying the concentration of salts in the dialysate during the dialysis treatment,
- an ultrafiltration pump (9) with variable delivery (Q) for extracting plasma water from the blood circulated in the extracorporeal blood circuit (4) and causing a weight loss (TWL) during the dialysis treatment, and
- a device for setting up a dialysis treatment including a microprocessor (11), a data input (12,13) and a screen (13),

said microprocessor being programmed for:

- receiving impositions of boundary conditions (Uo, TWL, DT; Co, Cf, DT; Co, CS, DT) of a dialysis treatment adapted to a specific patient;
- determining a first function (U(t)) of a first quantity (U) characterizing the dialysis treatment as a function of time (t), the first function (U(t)) satisfying the conditions (Uo, TWL, DT) of the dialysis treatment and corresponding to a curve having a defined shape; said microprocessor is also programmed for:
- receiving in its memory constants (M, N) determined experimentally,
- determining a second function (C(t)) of a second quantity (C) characterizing the dialysis treatment, stipulating that:
o the second function (C(t)) is a function of time (t) and is correlated with the first function (U(t)) by means of said constants (M, N),
o the second function (C(t)) corresponds to a curve having a shape of the same kind as the shape of the first curve,

characterised in that the first quantity is the weight loss (U) in unit time, which is correlated to the delivery (Q) of the ultrafiltration pump (9), and wherein the second quantity is the conductivity (C) of the dialysate."

III. The notice of appeal was filed on 16 April 2009 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 22 June 2009.

IV. Oral proceedings were held on 2 July 2014.

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

The respondent requested that the appeal be dismissed.

V. The following document is cited in the decision:

D1: EP-B-0668793.

VI. The arguments of the appellant can be summarised as follows:

The presently claimed features of the dialysis machine did not produce any different effect from that of the state-of-the-art dialysis machine. In particular, an increased efficiency in the setting up of the machine for a specific patient, as submitted by the respondent, could not be recognised. Since the mathematical relationship claimed did not bring acceptable results over the whole range claimed, its effect could not be considered a difference over that obtained in D1. So for that reason alone the subject-matter of claim 1 could not involve any inventive step.

In any case, profiling the ultrafiltration rates first, rather than the sodium concentration as in D1, was a simple alternative.

Furthermore, since in relation to figure 39 and the mirror sodium function described in D1 it was specifically mentioned on page 43 that the mirror profile had been scaled to fit within the UF current rate limits, it was self-evident that the machine of D1 also worked with a calculator and thus used constants to transform the sodium concentration (or conductivity) curve into an ultrafiltration curve. The use of such constants for the mirror transformation could thus in any case not be claimed to be a difference between claim 1 and D1.

The subject-matter of claim 1 was also not inventive because in D1 it was implicit that the described setting up procedure starting with the sodium concentration curve and mirroring it to an ultrafiltration curve could be started from the ultrafiltration curve to obtain the sodium concentration curve by mirroring, as was understandable e.g. from figure 11 on which a "program Na" button and a "program UF" button appeared. An inversion of the programming sequence, even with the use of the mirroring function, could therefore not be inventive.

VII. The arguments of the respondent can be summarised as follows:

The invention of D1 was basically the use of touch screens to graphically introduce data for setting up the machine more easily than in the prior art. What was described in D1 was the transformation of a sodium concentration variation profile into an ultrafiltration rate profile by graphically transposing the first curve. But the obtained curve had to be adjusted, at least to the target ultrafiltration goal as was mentioned on pages 31 and 43. According to the invention, in contrast, not only was the ultrafiltration profile set up first, but there was a mathematical relationship or correlation over the experimentally determined constants (M, N) between the ultrafiltration profile and the mirrored conductivity profile, so that the latter was obtained automatically and required no or very little adjustment to be usable.

In D1 the adjustment to obtain the desired total weight loss (TWL), which was the main boundary condition for a treatment session, had always to be made, because D1 did not provide the operator with a profile for use.

With the machine according to the invention, in standard situations a profile for use not needing any adjustment was obtained and, if not, then the experimentally determined constants (M, N) linked with the patient had to be adapted to improve the correlation. It was hindsight to consider that in D1 such constants were used, since touch screens were used in D1 for tracing the curves.

Therefore the subject-matter of claim 1 was inventive.

Reasons for the Decision

1. The appeal is admissible.

2. The invention concerns a dialysis machine. More specifically it concerns features for setting up the dialysis machine for the treatment of a specific patient. For setting up such patient-specific dialysis treatment sessions, different sets of data for different parameters (weight loss, conductivity, duration of the treatment) have to be entered into the machine. In the prior art, some machines required the introduction of a value, for each time interval, of a histogram for each parameter, other machines required the introduction of an initial value, a final value and a duration for each parameter.

   [0010]: "*The aim of the present invention is to provide a dialysis machine that does not have the disadvantages of the prior art and, in particular, is accurate,* *increases the efficiency of the treatment and at the same time can be implemented easily and quickly. This aim is reached by a machine according to claim 1. [0011] According to the present invention, once the function of the first quantity has been set, the function of the second quantity is determined automatically, greatly reducing the time for setting up the dialysis treatment."*

According to the way described in the patent specification, for setting up the machine according to the claim, the operator enters the parameters or boundary conditions for the ultrafiltration, namely the total weight loss (TWL), the dialysis time (DT), and the maximum weight loss (U_0). Then, by selecting PC (progressive curve) mode, the operator gets several predefined functions U(t,P) of the weight loss per time unit, P being a parameter which characterises the shape of the curve (straight line, hyperbolas or parabolas). The operator gets different curves which all fulfil the boundary conditions TWL, DT and U_0 for the given patient, so that the operator can select the shape most suitable for that patient (figure 3).

The same could generally be done for setting up the conductivity variation profile. However, according to the claimed variant ([0045] onwards) the curve for the conductivity is obtained automatically with a "mirroring" function using constants M, N (determined experimentally and entered into the microprocessor). [0053]: "*In other words, the "MIRRORING" operation is able to supply a curve that is acceptable in itself, or a base curve that is close to the acceptable curve and can be altered for adapting the curve to the therapeutic requirements."*

Thus, the present invention concerns a dialysis machine comprising means which allow the operator to enter ultrafiltration parameters, select an ultrafiltration profile and, by mirroring that first profile, obtain a workable profile for the conductivity.

3. The only objection to be examined is one of lack of inventive step based on document D1.

3.1 D1 is a detailed document on how a dialysis machine is built and how the different functions such a machine has to fulfil are carried out. At several places in the document indications are given as to how the treatment parameters are entered. Also in this document the aim of the invention is to facilitate the setting up of the dialysis machine and the entering of all the necessary data, in particular for the parameters varying over the treatment time.
[0058]: "*Some parameters are not susceptible to representation by a single number displayed in a parameter window. Exemplary are parameters that are programmed to change over time (so-called profiled parameters). In this class are the sodium concentration of the dialysate solution, the bicarbonate concentration of the dialysate solution, kT/V, and the ultrafiltration rate.*"
[0059]: "(...), *such profiled parameters are selectably displayed in the form of bar graphs on the display screen. (...)*"

[0060]: "*The use of bar graphs to display profiled parameters is known in the art. The prior art fails, however, to provide a convenient manner by which data characterizing the profile curve may be entered into the machine. Typically, such data entry has been* *accomplished through a keypad on which data for each discrete time period is entered.(...)"*

Basically, for the introduction of such data, the solution proposed in D1 is to use touch screens instead of keyboards ([0050]: "*In the preferred embodiment, a touch screen user interface is employed.*") which allow an easier introduction of the data for each parameter. For the parameters varying over treatment time the histogram of the variation curve can be traced on the touch screen.

[0061]: "*According to the present invention, in contrast, profiled parameters are entered by simply tracing the desired profile curve on the touch screen.*"

[0066]: "*The user then traces the desired profile curve on the touch screen, and the computer virtually simultaneously displays a series of bars corresponding to the traced curve.*"

Another option disclosed in D1, but not relevant for the present case, is to enter data by use of a data card ([0077]).

The document then describes how the profile of the sodium concentration is entered into the machine.

Later on, under the title "UF profiling", it describes how the variation curve of the ultrafiltration rate is profiled. This profiling can be done as for the sodium concentration profiling ([0227]: "*The UF profiling feature according to the present invention provides the operator with a method for programming a UF profile that can vary over time during a dialysis treatment to achieve a target UF removal volume. This feature is* *similar to variable sodium and variable bicarbonate features discussed hereinabove.*") or in a different manner, as explained in Appendices A and B.

According to these appendices, first the treatment time and the target UF are entered (page 28, lines 19, 20: "*The minimum initial entry prior to UF profiling will be the treatment time and target UF*".). Then, when the profile is entered manually, it can be entered segment by segment (of a histogram) (Page 28, line 51 to page 29, line 4: "*Each time segment will have a marker which graphically indicates the removal rate for that segment. While the graph is unlocked, touching a location on the graph between the maximum and minimum UF rates will cause the marker for that segment to move to the location of the touch.*") or the shape of the profile can be drawn on the screen (page 30, lines 9 and 10: "*Manual Method: By touching the graph at various points within the UF rate and treatment time limits, the user can "draw" a profile for the entire treatment.*").

Once the profile shape has been established, it has to be adjusted so that the target ultrafiltration is reached. This is done by actuating the VERIFY button and then a button named ADJUST PROFILE (page 30, line 30: "*ADJUST PROFILE - Automatically shifts graph up or down to meet target UF (...)*"). In other words, only after this latter function has been activated will the so-called profiled ultrafiltration meet the desired target ultrafiltration for the particular treatment to be carried out.

Instead of the manual introduction of the UF profile, another function, relevant for the present case, can be used which will "copy" the shape of the sodium concentration profile into the UF profile screen. It is called the MIRROR SODIUM function, as explained on page 31, lines 45 to 52:

"*When the MIRROR SODIUM button is touched, the UF graph will be set to approximately the same XY coordinates as the Na profile, with no shifting to accommodate target UF goal. The operator will be required to verify and adjust the profile as needed.*
The profile templates are intended to function as the name implies, as templates or basic shapes only. The operator will be required to verify and adjust the profile as needed."

The MIRROR SODIUM function is further explained in Appendix B when discussing figure 39, starting on page 43, line 26:
"*In FIG. 39, the operator has touched the MIRROR SODIUM PROFILE button, which causes a profile to appear on the graph which resembles the Sodium profile, and causes the VERIFY button to appear.*

The Mirror Sodium feature is similar to Recall Profile, in that an unadjusted profile is made available to the operator.

To determine the mirror profile, the Sodium profile is scaled to the current UF rate limits. The sodium profile illustrated in FIG. 39 actually started at the extreme upper left hand corner of the Sodium graph, and extended to the lower right hand corner (the Sodium profile is allowed to exceed the treatment time limit).

The mirrored profile has been scaled to fit within the UF rate limits which caused the upper left corner of the mirror profile to start at UF rate 3.50 L. The *lower right corner has been truncated, due to the required minimum UF rate beyond the treatment time*."

3.2 In the Board's view, from the above understanding of the ways the dialysis machines according to the invention and according to D1 function it follows that there are two main differences between the claimed dialysis machine and that disclosed in D1, namely that i) the machine according to claim 1 receives imposition of boundary conditions and determines the curve for the the weight loss as a function of time while in the embodiment disclosed in D1 the sodium concentration variation curve is first entered into the machine, and ii) in the machine according to claim 1 the curve for the conductivity of the dialysate as a function of time is determined automatically as it is correlated with the curve for the weight loss through experimentally determined constants (M, N) received in the microprocessor memory of the machine.

3.3 The technical effect of these differences is that the dialysis machine according to the invention is set up more rapidly and more efficiently than in the prior art.

The reasons for that are the following. It is well known, and accepted by the parties, that the main parameter or main boundary condition for setting a dialysis treatment for a specific patient is the total weight the patient should have lost after the dialysis session. This value is also introduced into the machine according to D1 (page 28, lines 19 and 20: "*The minimum initial entry prior to UF profiling will be the treatment time and target UF*"). Starting with the setting up of the ultrafiltration curve, in accordance with the invention, ensures right from the start of the setting up procedure that this main boundary condition (TWL) for the patient is guaranteed. This is not the case for the embodiment of the machine described in D1, where the sodium concentration profile (or conductivity profile) is entered first and the ultrafiltration profile "created" starting from that conductivity profile. So the TWL condition is not fixed right from the start but has to be adjusted a posteriori, precisely to fulfil this essential condition. This is expressed in the paragraph of page 31 quoted above: "*When the MIRROR SODIUM button is touched, the UF graph will be set to approximately the same XY coordinates as the Na profile, with no shifting to accommodate target UF goal. The operator will be required to verify and adjust the profile as needed.*" (emphasis added), and confirmed in relation with figure 39 on page 43: "*The Mirror Sodium feature is similar to Recall Profile, in that an unadjusted profile is made available to the operator.*"(emphasis added). In other words, the UF profile "created" in the machine according to D1 is from a simple graphical copying and will always have to be adjusted to comply with the TWL condition for the patient.

Further, as according to the invention the "transformation" of the UF profile into a conductivity profile is done mathematically on the basis of experimentally determined constants (M, N), the conductivity profile obtained is not simply a "graphically" similar curve which always needs adjustment as in D1, but a curve potentially respecting the boundary conditions for conductivity for a given patient, or in other words a potentially ready-to-use profile.

The appellant submitted that also in the embodiment described in D1 the UF profile obtained with the mirror sodium function was scaled to the current UF limits, as mentioned on page 43 of the description in relation to figure 39, so that also in this machine a mathematical experimental relationship existed between the UF values and the sodium concentration values, including some constants.

The Board does not share this opinion. Further down on the same page 43, it is mentioned that "*the mirror profile has been scaled to fit within the UF rate limits which caused the upper left of the profile to start at a UF rate of 3.50 L.*" In the context of the embodiment of D1, and taking into account the general way the machine functions as explained in more detail above, the Board takes the view that the only conclusion which can be drawn from the explanations given in relation to figure 39, is that after or during the "graphical" transformation or transportation of the sodium concentration profile into a UF profile, the latter is set to start at a UF rate of 3.50 litres/hour as this is the maximum tolerable for most patients. But this still means neither that the curve starts at a value which is acceptable for the specific patient to be treated, nor that the specific TWL for that patient is achieved, in contrast to what happens in the machine according to the invention, in which these boundary conditions are taken into consideration right from the start when setting up the UF profile.

The Board does not dispute that a mathematical relationship may exist between the values used. However, as implicit from the explanations given above about the content of D1, there is no indication in D1 that such a mathematical relationship is used in the machine of D1 to set the UF profile starting from the sodium concentration profile. The transformation operated in D1 is a purely "graphical" one.

The appellant also submitted that the mathematical relationship claimed did not produce acceptable results over the whole range claimed and therefore its effect could not be considered a difference over that obtained in D1.

The Board cannot share this opinion. The claim does not exclude adjustments and the exclusion of any adjustment was also not the aim of the invention. In the opinion of the Board, as explained above, what is important is that with the features of claim 1, in particular with the experimentally determined constants (M, N), it is much more likely that the operator gets a ready-to-use conductivity profile. For that feature to be a difference over D1, it is not necessary that the obtained profile <u>always</u> be such a ready-to-use profile. As explained above, in D1 an adjustment of the profile obtained with the mirror sodium function is always required, in particular to meet the UF boundary conditions. In addition it should be noted that according to the invention, if a result is not that expected, the constants can be determined again in order to obtain a better result the next time the same patient has to be connected to the machine.

3.4 The objective problem can thus be seen as one of improving the setting up procedure of the dialysis machine when it has to be prepared for the treatment session of a particular patient.

3.5 Starting from D1, the subject-matter of claim 1 is inventive. First of all, from the above it appears that the author of D1 did not recognise that it would be advantageous to establish the ultrafiltration profile first, and the present Board does not see why the person skilled in the art wishing to improve the setting up procedure of the machine according to D1 would invert the order of creation of the profiles and use a mathematical relationship to create the second profile. Nothing in D1 points towards such a solution. On the contrary, in the machine according to D1, even though the TWL is introduced into the machine, the sodium concentration profile is established first. The Board does not see for which objective reason the person skilled in the art would be prompted by D1 to change that order. In addition, even if he thought of changing the order, the MIRROR function, if applicable, would still not use any experimentally established mathematical relationship to create the second curve.

The appellant submitted that according to the setting up screen shown in figure 11 of D1 on which a button "program Na" and a button "program UF" can be seen, the operator setting up the machine could start either by programming the sodium concentration profile or by programming the ultrafiltration profile. Basically these were simple alternatives.

Although these buttons do indeed appear on that setting up screen, nowhere in D1 is it explained that the same functionalities would be available when starting with the ultrafiltration programming rather than with the sodium concentration programming. In the absence of more detailed information it can only be assumed that the normal situation of the machine of D1 is implemented, namely that the operator can trace the curve on the touch screen and then run different check functions to get the best possible curve. In particular, whether the mirroring function, which is that of interest for the present case, would be available and how it would work when starting with the ultrafiltration programming is not described. Even if the person skilled in the art thought of also implementing the mirror function when starting with the ultrafiltration programming, there would be no objective reason why he would do it differently from the way it is done when starting with the sodium concentration programming, namely as a "graphical" copying.

The appellant further submitted that the subject-matter as claimed would not produce any technical effect different from those obtained with the prior art and, therefore, would not be inventive.

As explained above, there are differences between the state of the art according to D1 and the claimed subject-matter and these differences produce technical effects, so that this argument of the appellant does not succeed.

3.6 For the reasons set out above, the subject-matter of claim 1 involves an inventive step, so that the ground of opposition of lack of inventive step pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated