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D E C I S I O N
of 15 February 2005

Case Number: T 0110/02 - 3.2.2

Application Number: 94420030.2

Publication Number: 0611228

IPC: A61M 1/16

Language of the proceedings: EN

Title of invention:
Technique for extracorporeal treatment of blood

Patentee:
Hospal Industrie

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 56

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

Decisions cited:
-

Catchword:
-

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Case Number: T 0110/02 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 15 February 2005

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 5 December 2001 rejecting the opposition filed against European patent No. 0611228 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: T. K. H. Kriner
Members: M. G. Noel
U. J. Tronser

Summary of Facts and Submissions

I. Following an opposition filed by the appellant (opponent) against European patent No. 0 611 228, the opposition division decided on 5 December 2001 to reject the opposition.

In the decision, the opposition division held that the grounds for opposition cited by the appellant (Article 100(a) EPC) did not prejudice the maintenance of the patent as granted.

II. The appellant lodged an appeal, received at the EPO on 24 January 2002, against the first instance's decision. The appeal fee was paid at the same date, and the statement setting out the grounds of appeal was filed on 15 April 2002.

III. Oral proceedings were held on 15 February 2005. At the end of the oral proceedings the requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the European patent No. 0 611 228 be revoked.

The respondent requested that the appeal be dismissed and that the patent be maintained on the basis of claims 1 to 10 according to the main request submitted during oral proceedings or on the basis of claim 1 according to the auxiliary requests 1 to 3 submitted with the letter dated 12 January 2005 and claims 2 to 10 as granted.

IV. At the oral proceedings the discussion was focused on the following prior art documents:

D3: EP-A1-0 373 455, already considered during the opposition proceedings, and

D6: FR-A-2 397 197

D7: US-A-4 670 007, both submitted by the appellant with its statement of grounds for appeal.

V. Claim 1 according to the main request reads as follows:

"An apparatus for a plurality of extracorporeal treatments of blood in a filtration unit (40) having a primary chamber (44) and a secondary chamber (46) separated by a semi-permeable membrane (42), the primary chamber (44) being connectable to an extracorporeal blood primary circuit (34, 35), the apparatus comprising:

blood pumping means (52) for controlling the flow of blood through the primary circuit (34, 35);

anticoagulant fluid pumping means (62) for controlling the flow of an anticoagulant fluid from an anticoagulant fluid container (64) connectable to the primary circuit (34, 35);

collection fluid means (84) for controlling the flow of a collection fluid to a collection fluid container (86) connectable to an outlet of the secondary chamber (46) of the filtration unit (40);

first gravimetric scale means (92) operative for providing weight information relative to the amount of the fluid collected in the collection fluid container (86);

secondary fluid pumping means (78) for controlling the flow of a secondary fluid from a secondary fluid container (76) connectable to an inlet of the secondary chamber (46) of the filtration unit (40);

second gravimetric scale means (90) operative for providing weight information relative to the amount of the fluid supplied from the secondary fluid container (76);

replacement fluid pumping means (66) for controlling the flow of a replacement fluid from a replacement fluid container (68) connectable to the primary circuit (34, 35);

third gravimetric scale means (72) operative for providing weight information relative to the amount of the fluid supplied from the replacement fluid container (68);

memory means (123) for storing a plurality of treatment protocols, each defining a variety of treatment information corresponding to a specific treatment;

control means (122) connected to the memory means (123) for receiving information about a treatment protocol to be performed, and corresponding flow rate information, and weight information from the first, second and third gravimetric scale means (72, 90, 92) and for regulating

the flow rate of the collection fluid, the replacement fluid, the secondary fluid, the anticoagulant and the blood by controlling the collection fluid pumping means (84), the replacement fluid pumping means (66), the secondary fluid pumping means (78), the anticoagulant pumping means (62) and the blood pumping means (52), and for discontinuing operation of at least one of the pumping means (52, 62, 66, 78, 84) upon occurrence of an alarm condition."

VI. The parties argued as follows:

(i) the appellant

General features recited in claim 1 (main request) such as "memory means", "control means" and "treatment protocols" were vague and indefinite and, as such, allowed for a broad interpretation of similar features in the prior art documents. In particular, the control means as claimed were confined to receiving an information about a treatment protocol, and not to the parameters constituting said protocol.

Document D6 disclosed an apparatus for a plurality of extracorporeal treatments of blood comprising practically all features listed in claim 1 according to the main request, including different fluid pumping means and a gravimetric scale means for providing a weight information to a control means, so as to control the flow rate of a fluid pumping means. According to an alternative embodiment, the common scale means supporting the three fluid containers could be replaced by

individual electronic balances ("pesons"). In that case, three weight informations were available for controlling corresponding pumping means. Also the apparatus was said to be "polyvalent" and could be programmed ("programmé") for a treatment to be performed, which also implied the presence of processing means and associated memory means. Therefore, given the functional wordings of claim 1, its subject-matter was rendered obvious by the teaching of D6, implemented by the general knowledge of a person skilled in the art.

Also the combination of D6 with document D7 deprived the subject-matter of claim 1 of any inventive step, since D7 provided for accurate flow rate control of a peristaltic pump, as a function of weight reduction of the fluid in a container, to be infused to a patient by the pump, with the view to replace expensive volumetric infusion pumps previously used and to improve the accuracy of the flow control when using peristaltic pumps. Since D6 made use of peristaltic pumps, the skilled person would be prompted to adopt in each line of fluid the more accurate flow control system proposed by D7, in order to carry out the alternative embodiment of D6, based on a plurality of individual balances.

Document D3 disclosed an apparatus for continuously performing a plurality of treatments by using four modular monitors, each dedicated to a fluid, supplied to or withdrawn from the patient through a peristaltic pump. The flow rate of the different fluids was measured by a volumetric

measuring chamber under the control of a microprocessor which measured the time actually taken by the fluid for filling or emptying the measuring chamber and which then actuated the pump in dependence of the error between the actual time and a set value. The processor was not represented but necessarily implied some conventional memory and control means. Again, the skilled person would be incited to replace the various volumetric measuring chambers disclosed in D3 by more accurate control means based on weight measurements of the fluids in their respective containers, as suggested by D7. Therefore, the subject-matter of claim 1 lacked an inventive step also vis-à-vis the combination of D3 and D7.

(ii) The respondent

The features relating to the memory means, the control means and the treatment protocols, as well as their inter-relationship were perfectly and clearly defined in the description of the patent in relation to the drawings, which all served to interpret the claimed features. In particular, the treatment protocols were formed of a number of parameters and set values defining a specific treatment, all stored in the memory means of the control computer.

In document D6 the scale means were only outputting a signal of the total weight of three containers but not of the individual weight of each container. The alternative embodiment with the use of equivalent electronic balances

("pesons") did not necessarily mean that the weight signals were used separately to control the flow rate of each fluid. D6 failed in that several interpretations were possible in this respect. It only aimed at providing a fluid equilibrium or balance without having to know their individual weights.

In document D3 accurate control of the flow rate in each line of fluid was achieved by means of volumetric measuring chambers and a microprocessor for sensing the time taken by the fluid for flowing out of or into said chambers. However, the apparatus did not use any scale means, and the processor was merely used to sense times and to control the pumps. There was no mention of any treatment parameters stored in a memory.

Document D7 disclosed accurate fluid flow control based on the measure of weight of a container and applied to an intravenous infusion system. However, there was no suggestion that the flow control principle described therein should be incorporated into a more sophisticated dialysis machine for automatically performing and monitoring a plurality of predefined treatments. Moreover, even by combining the teaching of D7 with either of documents D3 or D6, the skilled person would not arrive at the subject-matter of claim 1, since none of them disclosed the storing of a plurality of treatment protocols made available to the operator by selecting one treatment or changing it during its performance if necessary.

Reasons for the Decision

1. The appeal raised by the opponent is admissible.

2. *Amendments*

Claim 1 according to the main request submitted by the respondent (proprietor) during oral proceedings differs from the version as granted by the deletion, in the last group of features, of the terms "at least one" before the features related to the various gravimetric scale means, the various fluids and the various pumping means. The deletion of the corresponding alternatives represents a restriction in the scope of the claimed subject-matter which is also supported by the application as filed.

The amendments to the description (column 3 and 4) adapt the description to the amended claim 1, in conformity with the requirements of Article 84 and Rule 27(1)(c) EPC.

The requirements of Article 123(2) and (3) EPC are, therefore, met.

3. *Inventive step (main request of the respondent (proprietor))*

At the oral proceedings the inventive step of claim 1 according to the main request was contested by the appellant, on the basis of document D6 alone or in

combination with document D7 or on the basis of document D3 in combination with document D7.

3.1 Document D6 alone

3.1.1 D6 is considered by the Board as the closest prior art document in view of most structural and functional similarities with the present patent. In particular, in contrast to document D3, D6 discloses an apparatus having scale means for weighing treatment fluids, the output weight information of which is used to control fluid pumping means. More specifically, following the same terminology as in claim 1 in suit, D6 discloses (see Figure 1):

- an apparatus for a plurality of extracorporeal treatments of blood in a filtration unit 3 having a primary chamber 6 connectable to an extracorporeal primary circuit 1 and a secondary chamber 24 separated by a membrane 4;

- the apparatus comprising blood pumping means 2 for controlling the flow of blood through the primary circuit;

- collection fluid pumping means 26 for controlling the flow of a collection fluid to a collection fluid container 29 connectable to an outlet of the secondary chamber of the filtration unit 3;

- secondary fluid pumping means 22 for controlling the flow of a secondary fluid from a secondary fluid container 15 connectable to an inlet of the secondary chamber of the filtration unit 3;

– replacement fluid pumping means 20 for controlling the flow of a replacement fluid from a replacement fluid container 18 connectable to the primary circuit 1;

– gravimetric scale means 35, 36 operative for providing weight information relative to the fluids contained in the previous fluid containers; and

– control means 37 for receiving weight information from the gravimetric scale means and for regulating the flow rate of the collection fluid by controlling the collection fluid pumping means 26, and for generating an alarm condition.

3.1.2 The subject-matter of claim 1 (of the respondent's main request) differs from the teaching of document D6 in that the apparatus comprises:

(a) anticoagulant fluid pumping means for controlling the flow of an anticoagulant fluid from an anticoagulant fluid container connectable to the primary circuit;

(b) three gravimetric scale means for providing separate weight informations relative to the amount of fluid collected in either of the fluid containers.

(c) memory means for storing a plurality of treatment protocols, each defining a variety of treatment information corresponding to a specific treatment.

(d) control means connected to the memory means for receiving information about a treatment protocol to be performed and weight information from all gravimetric scale means for regulating the flow rates of the different fluids involved in the treatment by controlling the corresponding pumping means.

With respect to feature (b), the scale means according to D6 measure the sum of the weights of the three containers, not the weight of each container taken separately. As a matter of fact, there is no need to know the weight of the individual containers. What counts in document D6 is that an equilibrium be maintained by the balance arm 36, whereby the total weight of all fluid containers is maintained unchanged so as to equilibrate the amounts of fluids going into and out of the patient via the filtration unit (cf. page 3, lines 11 to 16; page 5, lines 11 to 15 and page 6, lines 5 to 7). According to an alternative embodiment (cf. page 6, lines 24 to 28) the scale means 35 can be replaced by an equivalent weighing system using individual electronic balances ("pesons"). However, as stated in the precited paragraph the replacement system is equivalent in that it continues to maintain constant the total weight of the three containers. Thus even if individual weight information were made available for each fluid only their sum would be used to maintain a balanced condition. Any other use of the weight information is not envisaged in D6.

The "treatment protocols" cited in feature (c) mean all the parameters defining a specific treatment, such as those recited in column 18, lines 30 to 40 of the contested patent, and which are all stored in the memory 123 of the control processor 102 (figure 3a and column 17, lines 4 to 11). The different blood treatments to be performed are principally UF (Ultrafiltration), HF (Hemofiltration), HD (Hemodialysis) and HDF (Hemodiafiltration) (cf. column 1, lines 33 to 55 and column 15, lines 55 to 57). These treatment protocols can be either selected by the operator before starting the treatment or modified during its performance (column 10, lines 38 to 43; column 18, lines 28 to 35 and lines 51 to 57).

Document D6 does not disclose any processor nor any memory means capable of storing a treatment protocol within the meaning of the patent in suit. Although D6 enables different treatments to be performed ("polyvalence", page 5, line 36) such as HD, HF or HDF, the apparatus is relatively simple, as it comprises only an electronic regulating device 37 mechanically connected to the balance arm 36. The operator sets manually the flow rates of the dialysis pump 22 (secondary fluid) and the substitution pump 20 (replacement fluid) and imposes a predetermined weight loss to the patient by setting the pump 32. All these setting values are not memorized. The term "programmé" mentioned on page 5, line 38 is merely concerned with the way of performing the treatment in relation to time (continuously or sequentially) but does not

refer to a computer program for automatically performing the steps of a treatment protocol such as illustrated in the present patent by the flow chart of Figure 4 (see also column 17, lines 50 to 53).

Since in D6 the control means are restricted to a simple regulating device 37 for controlling the flow rate of the collection fluid pumping means 26 in order to maintain the total weight of the different fluid containers, document D6 does also not disclose the control means defined in feature (d).

3.1.3 A person skilled in the art who is looking for an improved apparatus for automatically performing and monitoring a plurality of extracorporeal blood treatments based each upon a treatment protocol selected by the operator, in accordance with the technical problem stated in the present patent (see column 1, lines 1 to 7 and column 3, lines 36 to 43) and starting from the teaching of document D6, will not be prompted towards the combination of features according to the subject-matter of claim 1 in suit, in view of all the discrepancies referred to in the above section 2.1.2 and because a similar problem is not addressed in this document.

In particular the fluid flow control involved in D6 is of a different nature and does not require accurate control of the flow of each fluid. Only the balance of fluids is of importance. The absence of any processor means associated with memory means for storing various treatment protocols as well as the absence of

individual weight sensing means for weighing each fluid container render this document inappropriate and insufficient in view of the numerous modifications which would then be necessary to arrive at the claimed subject-matter, even when taking account of the general knowledge of a person skilled in the art.

3.2 Combination of documents D6 and D7

Document D7 discloses a fluid dispensing system for controlling the rate of delivery of a fluid administrated to a patient through an intravenous infusion set. It comprises a fluid container 3, a weight sensing device 2 for continuously detecting the loss of weight of fluid in the container an a rotary peristaltic pump 7 controlled by a processing unit 30. Prior to the infusion process, the delivery rate is set on a control panel 10 by an operator and the flow rate of the pump is controlled so as to correspond to the selected flow rate. As the reduction of weight in the container is detected within a predetermined time, the control processor determines the actual rate of delivery, compares it with the required delivery rate selected by the operator, and corrects the speed of the pump accordingly. The function of the weight sensing device, therefore, is to provide data for repeated calibration of the pump to ensure that the actual performance accurately corresponds to the required delivery rate (cf. column 5, lines 29 to 33).

Although document D7 clearly discloses accurate control of the rate of a fluid flowing out of a container as a function of the variation of weight of the container, a control principle already acknowledged as known in the

background part of this document (cf. column 2, lines 53 to 61), the dispensing system is restricted to controllably infusing only one fluid. Moreover, in the control diagram illustrated in figure 3, the function of the memory 31 is restricted to storing the main operating program of the processing unit 30 and the memory 32 to storing both the selected delivery rate and the total volume delivered (cf. column 5, lines 62 to 68; column 7, lines 13 to 16 and column 8, lines 60 to column 9, line 2).

Therefore, D7 does not suggest applying the known control principle to a more ambitious and sophisticated apparatus comprising a plurality of treatment fluids to be controlled simultaneously within the frame of a preselected treatment protocol, by means of a multi-functional, automated dialysis machine. Since memory means for storing treatment protocols are not present in the dispensing system of D7, the incorporation of said system into the multi-treatments apparatus of D6 would not allow to arrive at the subject-matter of claim 1. Furthermore, the skilled person would not even think to fit each container in D6 with a weighing device for performing flow control of each corresponding peristaltic pump since accurate flow control on each fluid is not sought in D6 and is even unnecessary. It is sufficient to control the flow rate of the extraction pump 26 to restore the balance of fluids. The combination of documents D6 and D7, therefore, appears to be the result of an ex-post-facto analysis, which would not lead the skilled person in an obvious way to the subject-matter of claim 1 of the respondent's main request.

3.3 Combination of documents D3 and D7

Document D3 discloses a modular apparatus which, like the present patent, is suitable for performing different extracorporeal treatments such as HD or HDF. Each monitoring module is dedicated to one of the fluids involved in the treatment: FM for the filtration (collection) fluid; DFM for the dialysis (secondary) fluid; SM for the substitution (replacement) fluid and BM for the blood. In figure 1 for example, the four modules are arranged together to realize a hemofiltration machine.

In document D3 the problem set is principally to accurately determine the amount of fluids flowing through the various modules for achieving, despite of the use of imprecise peristaltic pumps, the exact balance of fluids flowing from and into the patient (cf. column 2, lines 15 to 23 and column 3, lines 21 to 26). The solution proposed in D3 consists in providing for each monitoring module a volumetric measuring chamber, including high and low level sensors, associated with a valve and a control pump. The actual volumetric flow rate is calculated by a microprocessor (not shown) measuring the time necessary for filling up or emptying said measuring chamber, the volume of which is known. The microprocessor then controls the speed of the corresponding pump so that the measured actual time equals the preset time corresponding to the desired speed.

However, the multi-treatments apparatus disclosed in D3 does not have any memory means for storing predefined treatment protocols and the function of the

microprocessor is confined to measuring times for calculating flow rates of the fluids through the pumps and for controlling the same. Therefore, to perform a given treatment, the modules have to be arranged in a specific configuration but different treatments cannot be programmed in advance. Neither is it possible to change the configuration during a treatment. Such a machine is then just able to run one treatment at a time.

Moreover, the apparatus of D3 does not use any scale means and the pumps are controlled in a different way compared to the patent in suit. Thus, even if in D3 as in the present patent the flow rates may be accurately controlled on each fluid, this is achieved in both documents with completely different means: by measuring the time for emptying a measuring chamber in D3 and by measuring the variation of weight of fluid in a container in the present patent.

Although document D7 discloses a fluid flow control based upon measurements of the absolute weight of fluid in a container, the skilled person had no reason to replace the volumetric measuring chambers proposed in D3 by the weight sensing means disclosed in D7. Even though in both documents peristaltic pumps are criticized in that they are suffering from lack of precision in the control of fluid delivery rate, the solution proposed in D3 to overcome this drawback is satisfactorily and needs not be changed. Therefore, the improbable combination of documents D3 and D7 also appears as the result of an ex-post-facto reasoning. Finally, as for the previous combination (cf. above section 3.2), the present combination of documents

still would be insufficient to arrive at the claimed subject-matter, given the fundamental lack of memory means connected to control means for storing the various parameters corresponding to different treatment protocols.

3.4 It results from the foregoing that the subject-matter of claim 1 according to the main request of the respondent involves an inventive step within the meaning of Article 56 EPC. As a consequence, claims 2 to 20 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 on the basis of the claims 1 to 10 according to the main request submitted during the oral proceedings, description columns 1 to 32 submitted at the oral proceedings, and Figures 1 to 4 as granted.

The Registrar: The Chairman:

V. Commare T. Kriner