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D E C I S I O N
of 4 August 2004

Case Number: T 0321/03 - 3.2.2

Application Number: 92921805.5

Publication Number: 0607301

IPC: A61M 1/16

Language of the proceedings: EN

Title of invention:
Hemofiltration System

Patentee:
CHILDREN'S HOSPITAL MEDICAL CENTER

Opponent:
HOSPAL INDUSTRIE

Headword:
-

Relevant legal provisions:
EPC Art. 52, 56

Keyword:
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0321/03 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 4 August 2004

Appellant: (Opponent)	HOSPAL INDUSTRIE 7, avenue Lionel Terray, B.P. 126 F-69883 Meyzieu Cedex (FR)
Representative:	Altenburg, Udo, Dipl.-Phys. Patent- und Rechtsanwälte Bardehle, Pagenberg, Dost Altenburg, Geissler Postfach 86 06 20 D-81633 München (DE)
Respondent: (Proprietor of the patent)	CHILDREN'S HOSPITAL MEDICAL CENTER 3333 Burnet Avenue Cincinnati Ohio 45229-3039 (US)
Representative:	Findlay, Alice Rosemary Lloyd Wise Commonwealth House 1-19 New Oxford Street London WC1A 1LW (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted 20 December 2002 concerning maintenance of European patent No. 0607301 in amended form.**

Composition of the Board:

Chairman: T. Kriner
Members: D. Valle
E. J. Dufrasne

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received at the EPO on 18 February 2003, against the decision of the opposition division, posted on 20 December 2002, on the rejection of the opposition against the patent No. 92 921 805.5. The appeal fee was paid simultaneously and the statement setting out the grounds of appeal was filed on 28 April 2003.

II. The opposition was filed against the patent as a whole and based on Article 100(a) EPC in conjunction with Article 52(1) and 56 EPC.

The Opposition Division held that the grounds for opposition did not prejudice the maintenance of the patent in amended form having regard in particular to the following documents:

- D1: Sartorius Hemoprocessor® 400 20 - Operating Instructions, 9/1984
- D6: US-A-4 778 450.

III. In addition to these documents, the following further documents played a role in the appeal proceedings:

- D3: US-A-4 204 957
- D11: US-A-4 728 433
- D12: US-A-4 769 132
- D13: Intensivbehandlung, Zeitschrift für Diagnostik, Therapie und Pflege, Jahrgang 15, 3. Quartal 1990, Heft 3, Seite 110, "An automatic system for fluid balance in

continuous hemofiltration with very high precision".

Documents D3, D11 and D12 are cited and evaluated in the description of the patent in suit, document D13 was submitted by the appellant with letter of 28 April 2003 (statement of grounds).

IV. The appellant (opponent) requested with letter dated 28 June 2004 that the decision under appeal be set aside and the patent be revoked in its entirety. He further communicated with the same letter that he will not attend the oral proceedings, which he subsidiarily requested with letter of 18 February 2003, and he will make no further oral or written submissions in support of the appeal.

V. The respondent requested with letter of 3 June 2004 that the patent be maintained as amended according to the decision under appeal or that the patent be maintained according to two auxiliary requests filed with the same letter. Oral proceedings were requested on an auxiliary basis.

VI. With its communication dated 30 June 2004 the board informed the parties that the oral proceedings fixed for 5 July 2004 were cancelled.

VII. Independent claims 1 and 5 in the form as confirmed by the decision under appeal reads as follows:

"1. A continuous hemofiltration system (10) for removal of fluid from the blood of a patient, comprising hemofiltration means (24), means (16) for pumping blood

from a patient through the hemofiltration means (24) and back to the patient, a first reservoir (50) for maintaining a supply of infusate (52), first pumping means (60) for pumping the infusate (52) from the first reservoir (50), a second reservoir (74) for receiving drained fluid (76) from the hemofiltration means (24), second pumping means (66) for pumping the drained fluid (76) from the hemofiltration means (24) to the second reservoir (74), first weighing means (54) and second weighing means (78) for monitoring the weight of the infusate (52) and drained fluid (76) and generating weight data signals correlated thereto, and control means (12) operably connected to the blood pumping means (16) and to each of the first and second pumping means (60, 66) and the first and second weighing means (54, 78), the control means (12) comprising a computer for operating the first and second pumping means (60, 66), wherein the control means (12) receives the weight data signals generated by the weighting means (54, 78) and determines from the weight data signals the weight of infusate and drained fluid in the first and second reservoirs (50, 74) respectively and wherein the blood pumping means (16) is responsive to control signals generated by the control means to vary the flow rate of the blood through the hemofiltration means (24), characterized in that the first pumping means (60) is for pumping the infusate (52) from the first reservoir (50) to the hemofiltration means; in that the control means computer is programmed to operate the first and second pumping means (60, 66) only when the blood pumping means (16) is operating, in that the control means (12) determines the weight of the infusate and the drained fluid in the first and second reservoirs (50, 74) at regular intervals, compares those

determined weights to corresponding predetermined computer weights, and, in response to said comparison, generates control signals to adjust automatically as necessary on an ongoing basis during hemofiltration the rates of pumping of the infusate and drained fluid whereby a preselected amount of fluid is removed from the blood over a preselected time period.

5. A continuous hemofiltration system (10) for removal of fluid from the blood of a patient, comprising hemofiltration means (24), means (16) for pumping blood from a patient through the hemofiltration means (24) and back to the patient, a first reservoir (50) for maintaining a supply of infusate (52), first pumping means (60) for pumping the infusate (52) from the first reservoir (50) to the patient, a second reservoir (74) for receiving drained fluid (76) from the hemofiltration means (24), second pumping means (66) for pumping the drained fluid (76) from the hemofiltration means (24) to the second reservoir (74), first (54) and second weighing means (78) for monitoring the weight of the infusate (52) and drained fluid (76) and generating weight data signals correlated thereto, and control means (12) operably connected to the blood pumping means (16) and to each of the first and second pumping means (60, 66) and the first and second weighing means (54, 78), the control means (12) comprising a computer for operating the first and second pumping means (60, 66), wherein the control means (12) receives the weight data signals generated by the weighting means (54, 78) and determines from the weight data signals the weight of infusate and drained fluid in the first and second reservoirs (50, 74) respectively and wherein the blood

pumping means (16) is responsive to control signals generated by the control means to vary the flow rate of the blood through the hemofiltration means (24) characterized in that the control means computer is programmed to operate the first and second pumping means (60, 66) only when the blood pumping means (16) is operating, and in that the control means (12) determines the weight of the infusate and the drained fluid in the first and second reservoirs (50, 74) at regular intervals, compares those determined weights to corresponding predetermined computed weights, and, in response to said comparison, generates control signals to adjust automatically as necessary on an ongoing basis during hemofiltration the rates of pumping of the infusate and drained fluid whereby a preselected amount of fluid is removed from the blood over a preselected time period."

Independent claim 5 differs essentially from claim 1 by the feature that the first pumping means (60) is for pumping the infusate (52) from the first reservoir (50) to the patient instead of to the hemofiltration means.

VIII. The appellant argued as follows. The subject-matter of claim 5 lacks novelty over D1. The teaching of D1, D3, D11 or D12 per se made the subject-matter of the claims 1 and 5 obvious. Furthermore, the subject-matter of claims 1 and 5 was suggested by a combination of the teaching of D3 and D6, D1 and D6 or D13 and D6.

IX. The respondent pointed out that the issues already dealt with in the previous decision on the case T 357/98 could not be reexamined in the present procedure. Furthermore, no combination of the teaching

of the cited documents could lead in an obvious way to the claimed invention.

Reasons for the Decision

1. The appeal is admissible.

2. *Case history*

The patent in suit was the subject of a previous decision of the board of appeal bearing the number T 375/98. This decision stated that the subject-matter of the present claims was novel over the disclosure of each of D1 and D3, and was based on an inventive step when considering the same documents D1 or D3 alone or in combination. The board therefore did not consider these questions again, being "res judicata" (see case Law of the Boards of Appeal of the EPO, 4th edition 2001, English version, VII.D.10.1, pages 536, 537).

3. *Inventive step*

3.1 D11 discloses the same features as D12, as far as the inventive step of the claim is concerned (see section 3.2).

3.2 D12 discloses a continuous hemofiltration system for removal of fluid from the blood of a patient, comprising hemofiltration means (5), means (13) for pumping blood from a patient through the hemofiltration means and back to the patient, a first reservoir (2) for maintaining a supply of infusate, first pumping means (8) for pumping the infusate from the first

reservoir to the hemofiltration means, a second reservoir (3) for receiving drained fluid from the hemofiltration means, second pumping means (11) for pumping the drained fluid from the hemofiltration means to the second reservoir.

Starting from D12 the object to be achieved by the invention according to the patent in suit may be regarded as to achieve an ideal or nearly ideal fluid removal and replacement and therefore to improve the accuracy of the hemofiltration procedure (see description, column 5, lines 28 to 37).

This object is achieved by the provision of first weighing means and second weighing means for monitoring the weight of the infusate and drained fluid and generating weight data signals correlated thereto, and control means operably connected to the blood pumping means and to each of the first and second pumping means and the first and second weighing means, the control means comprising a computer for operating the first and second pumping means, wherein the control means receives the weight data signals generated by the weighting means and determines from the weight data signals the weight of infusate and drained fluid in the first and second reservoirs respectively and wherein the blood pumping means is responsive to control signals generated by the control means to vary the flow rate of the blood through the hemofiltration means, the control means computer being programmed to operate the first and second pumping means only when the blood pumping means is operating, the control means determining the weight of the infusate and the drained fluid in the first and second reservoirs at regular

intervals, comparing those determined weights to corresponding predetermined computer weights, and, in response to said comparison, generating control signals to adjust automatically as necessary on an ongoing basis during hemofiltration the rates of pumping of the infusate and drained fluid whereby a preselected amount of fluid is removed from the blood over a preselected time period.

D12 does not contain any hint which would have lead the skilled person in an obvious way to the claimed invention, since it uses the difference of weight between drained fluid and infusate as control parameter and it does not measure directly the weight of the infusate and of the drained fluid.

Claim 5 achieves the same object, with the difference that the first pumping means is for pumping the infusate from the first reservoir to the patient instead of to the hemofiltration means. This feature is also not disclosed in D12.

3.3 D3 discloses a continuous hemofiltration system for removal of fluid from the blood of a patient, comprising hemofiltration means (3), means (2) for pumping blood from a patient through the hemofiltration means and back to the patient, a first reservoir (9) for maintaining a supply of infusate, first pumping means (11) for pumping the infusate from the first reservoir, a second reservoir (7) for receiving drained fluid from the hemofiltration means, second pumping means (6) for pumping the drained fluid from the hemofiltration means to the second reservoir, first weighing means (10) and second weighing means (8) for

monitoring the weight of the infusate (substituate) and drained fluid (filtrate) and generating weight data signals correlated thereto, and control means (see Figure 2) operably connected to each of the first and second pumping means and the first and second weighing means, the control means comprising a computer for operating the first and second pumping means, wherein the control means receives the weight data signals generated by the weighing means, and the control means determines from the weight data signals the weight of the infusate and the drained fluid in the first and second reservoir.

Moreover, with respect to claim 5, D3 additionally discloses that the first pumping means is for pumping the infusate from the first reservoir to the patient.

The subject-matter of claim 1 differs from that which is disclosed in D3 in that:

the control means is operably connected to the blood pumping means, the blood pumping means is responsive to control signals generated by the control means to vary the flow rate of the blood through the hemofiltration means, the first pumping means is for pumping the infusate from the first reservoir to the hemofiltration means, the control means computer is programmed to operate the first and second pumping means only when the blood pumping means is operating, the control means determines the weight of the infusate and the drained fluid in the first and second reservoirs at regular intervals, compares those determined weights to corresponding predetermined computer weights, and, in response to said comparison, generates control signals

to adjust automatically as necessary on an ongoing basis during hemofiltration the rates of pumping of the infusate and drained fluid whereby a preselected amount of fluid is removed from the blood over a preselected time period.

Therefore, starting from D3, the object to be achieved by the patent in suit again may be regarded as to achieve an ideal or nearly ideal fluid removal and replacement and therefore to improve the accuracy of the hemofiltration procedure (see description, column 5, lines 28 to 37).

D6 refers to a fluid flow control system, particularly for use in controlling the draining of fluid (infusate) from a reservoir intravenously into a patient (column 1, lines 15 to 19). Document D6 discloses a control means which determines the weight of the infusate (see Figure 1; 111, 12, 121), compares the determined weight to corresponding predetermined computer weights (13, 121, 141), and generates a control signal (131) to adjust automatically, as necessary, on an ongoing basis during operation the rate of pumping of the infusate (see description, column 2, lines 1 to 66).

D6 therefore teaches the use of a weight based control system. However it does not suggest the characterizing features of claim 1.

In analogy D6 does not disclose the characterizing features of claim 5 either.

Accordingly, a combination of D3 and D6 does not lead in an obvious way to the subject-matter of claims 1 and 5.

3.4 In the previous decision of the board of appeal T 375/98, it has already been decided (see section 2 of the reasons for the decision) that D1 does not disclose any of the features of the characterizing portion of claim 1.

Consequently, D1 does not disclose any of the features of the characterizing portion of claim 5 either.

Since D6 is not suitable to suggest the characterizing features of claim 1 and claim 5 (see section 3.3 above), a combination of documents D1 and D6 cannot lead the skilled person in an obvious way to the subject-matter of claims 1 and 5.

3.5 D13 (see Figure 1 at page 168, and page 167) is less relevant than D3 (see section 3.3) since it does not disclose control means operating the filtrate pumping means.

Subsequently, a combination of the teaching of D13 and D6 can not lead to the invention as claimed in claims 1 and 5 in an obvious way.

4. With respect to the above findings the board concludes that the subject-matter of the present claims 1 and 5 of the patent in suit involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Vottner T. Kriner