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 E C I S I O N
of 14 March 2001

Case Number: T 0375/98 - 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. 54, 56

Keyword:
"Admissibility of late filed documents (yes)"
"Remittal to the first instance for further prosecution (yes)"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0375/98 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 14 March 2001

Appelllant: (Opponent)
HOSPAL INDUSTRIE
7, avenue Lionel Terray, B.P. 126
FR-69883 Meuzieu cedex (FR)

Representative:
Altenburg, Udo, Dipl.-Phys.
Patent- und Rechtsanwälte
Bardehle, Pagenberg, Dost, Altenburg,
Geissler, Isenbruck
Postfach 86 06 20
DE-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, Tregear & Co.
Commonwealth House
1-19 New Oxford Street
London WC1A 1LW (UK)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 3 March 1998 concerning maintenance of the European patent No 0 607 301 in amended form.**

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
J. C. M. De Preter

Summary of Facts and Submissions

I. The opponent filed an appeal against the decision of the opposition division of 3 March 1998 to maintain the patent in amended form.

II. The patent was opposed on the grounds of lack of novelty and inventive step.

III. The following documents are relevant for the decision:

(a) filed during the opposition proceedings:

D1: Sartorius Hemoprocessor 400 20 - operating instructions, 9/1984;

D3: US-A-4 204 957

D5: US-A-4 776 837

(b) filed together with the statement of grounds:

D6: US-A-4 778 450;

D8: Drukker..., Replacement of renal function by dialysis, page 432;

D9: Brochure RP6 HP, dialyzer with RP AN 69 membrane;

D10: M. De Paepe..., Evaluation of hemofiltration with different AN 69 membrane devices using a discontinuous flow-single needle system, pages 87 to 91.

IV. Following a request from both parties oral proceedings have been held on 14 March 2001. 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 the patent be revoked.

The respondent (patentee) requested that the decision under appeal be set aside and the patent be maintained in amended form with claims 1 to 5 filed on 12 March 2001 (main request) or to remit the case to the opposition division for further prosecution (auxiliary request).

V. Claim 1, as filed on 12 March 2001 reads as follows (the features of the characterizing part have been individuated with letters for later easier reference):

"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

a) 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,

b) 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,

c) compares those determined weights to corresponding predetermined computer weights, and,

d) 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".

VI. The appellant argued as follows.

The pressure alarms disclosed on page 21 of document D1 caused the immediate stop of all pumps. In particular, the venous pressure alarm mentioned under number 2 became active when the pressure fell below a set value. The stop of the blood pump resulted in a complete pressure drop, so that the first and second pump (drain and infusate pumps) could be operated only when the operation of the blood pumping means met the requirements of feature a) of claim 1. The measure of determining the weight at regular intervals as required by feature b) of claim 1 was a banal feature common to all digital equipments. The system disclosed in document D1 was also adapted to compare the measured weight values of the infusate with the set values to be reached at the end of the treatment, see page 15; a continuous measurement of the infusate flow was equally maintained by the apparatus of document D1 (see page 18, Filtratfluß), as in feature c) of claim 1. According to page 5 of document D1, all monitoring and control functions were governed by a microprocessor which - like all digitally operating means - determined the values at regular intervals, so that also feature d) of claim 1 was essentially known from document D1.

Regarding the inventive step, the problem to be solved by the patent in suit was to improve the accuracy in the delivery of the infusate and in the drain of fluid waste. A weight control system as suggested by the patent in suit was known from document D3 cited in the description of the patent in suit.

Document D6 was relevant in assessing the inventive

step of claim 1 because it disclosed the central idea of the invention of using a completely weight-based control system in order to improve accuracy, see column 1, from line 34, column 2, from line 26.

The respondent argued as follows:

Since in the system according document D1 the various pumps were controlled by pressure signals, a certain time delay between a stop of the blood pump and its repercussion on the venal pressure was unavoidable. During this delay period the drain and infusate pumps would still operate and therefore the condition of the feature (a) of claim 1 that the other pumps operate only when the blood pump operates was not met.

The control system according to document D1 was based on the principle to continually check whether set end values for the weight of the infusate and of the drained fluid had been reached, whereas according to claim 1 also intermediate set values were compared. Therefore also features b) and c) of claim 1 were not disclosed by document D1.

The problem of the invention was to achieve a level of accuracy which could make the apparatus suitable also for use with infants and premature babies. The lack of accuracy inherent to the apparatus according to document D1 could have been overcome in several ways all of which were different from the one suggested by the patent in suit. The pressure control could have been conceived like in document D5, column 6, from line 11, or the system itself could have been changed from a pressure-based to a flow- or a weight-based control system. The implementation of the weight-based

control system could also have been carried out in different ways. For example document D3 suggested to control only the infusate pump. That all meant that there was more than one known solution to the problem of improving the accuracy of the apparatus, but there was no document that hinted at the one suggested by the patent in suit.

The teaching of document D6 was of no relevance for the patent in suit because there was nothing in document D6 which would prompt a skilled person to change the known pressure-based control of document D1 to the weight-based control of the patent in suit. Document D6 was only concerned with an intravenous supply system which was not described to be a part of a hemofiltration system. There was also no hint to use a weight-driven control for the infusate and the drained fluid pumps. Even if the skilled person learned from document D6 to replace the indirect end point control of the infusate pump of document D1 with the direct continuous control of document D6 he would do that for only one pump. Furthermore, the features of claim 1 which now were contested on the basis of document D6 were contained also in the original version of claim 1. That meant that there existed no justification for the late filing of document D6.

Reasons for the Decision

1. The appeal is admissible

2. Novelty and inventive step having regard to the documents of the state of the art filed during the opposition proceedings.

It is undisputed that the nearest document of the state of the art filed during the opposition proceedings is represented by document D1 which discloses all the features of the precharacterizing part of claim 1.

Claim 1 distinguishes therefrom by its characterizing part.

The device according to document D1 discloses pumping means for the infusate (substitution solution) which does not pump the infusate to the hemofiltration means but to an air detector. Furthermore no computer is provided which directly operates the pumping means by comparing the weight of the drained fluid and of the infusate at regular intervals with set values and by generation of control signals to adjust on an ongoing basis the pumping rates. Document D1 discloses a traditional pressure-based control system. The ongoing control which is provided by the device of document D1 is that of the transmembrane pressure (TMP). In operation the system monitors the TMP and adjusts the drained fluid pump to keep the TMP constant. A weight control is also provided for the weight loss and the infusate so that when the actual values match the set end values the procedure is ended. The weight control is therefore merely an end point control.

Contrary to the contention of the appellant, the device according to document D1 does not disclose a control warranting that the infusate and drain pumps operate only when the blood pump operates. Document D1 discloses a control system where - when the blood pump stops - an alarm is triggered which then initiates the other pumps to stop. This chain of command transmission necessarily implies a delayed stop of the blood pump

which is avoided in the system according to the patent in suit where the computer warrants that the other pumps can only operate when the blood pump runs.

There is no explicit disclosure in document D1 of a weight determination at regular intervals. The digitally operating means (microprocessor) of document D1 does not compare the weights at regular intervals. The formulation of feature c) of claim 1 implies that the measured values are compared with a sequence of intermediate values stored in the computer and not merely with end point values. There is nothing to justify the assertion that document D1 discloses an automatic adjustment on an ongoing basis of the rates of pumping; furthermore there is no indication in document D1 that the removal of a preselected amount of fluid should be done over a preselected time period (feature d)).

Starting from the teaching of document D1 the problem to be solved derives from the observation that by using high permeability membranes the pressure control system becomes less reliable because normal changes in blood pressure are sufficient for varying the fluid withdrawal rate in such a manner as to be intolerable by the patient (see document US-A-4 769 131, cited in the description of the patent in suit, column 1, from line 55). The purpose of the invention is therefore to create a more accurate and reliable hemofiltration system, see description of the patent in suit, column 1, from line 50.

This purpose has been attained by the apparatus according to the patent in suit by a totally weight driven, ongoing control system according to the

characterizing part of claim 1. With the system according to the patent in suit TMP fluctuations as caused, for example by the presence of air bubbles, have no effect on the quantity of drained fluid.

No combination of the documents of the prior art submitted during the opposition proceedings can lead in an obvious way to the invention. Document D3 discloses a system to supply a quantity of substitute fluid to the purified blood which is a constant proportion of the filtrate withdrawn from the blood and therefore does not disclose pump control signals generated upon comparison of the weight of infusate and drained fluid with predetermined computer weights like the characterizing part of claim 1.

Accordingly the subject-matter of claim 1 is novel and inventive having regard to the documents cited during the opposition proceedings.

3. The new documents filed during the appeal proceedings.

The new document D6 has been filed by the appellant with the statement of grounds as direct reaction to the decision under appeal.

The Board considers document D6 being relevant to such an extent that it could have possibly influenced the Opposition Division in its decision.

The further late filed documents D8, D9 and D10 have been also filed together with the statement of grounds as direct reaction to the appealed decision, in particular to argue against the definition of the problem in the appealed decision.

Accordingly documents D6, D8, D9 and D10 should be considered in the procedure.

4. Following a corresponding request from the respondent (patentee), the Board finds it appropriate to remit the case to the first instance for further prosecution in order to grant the patentee two levels of jurisdiction.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition division for further prosecution.

The Registrar: The Chairman:

V. Commare W. D. Weiß