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**Datasheet for the decision
of 7 June 2019**

Case Number: T 0635/17 - 3.2.02

Application Number: 10015768.4

Publication Number: 2319554

IPC: A61M1/34, A61M1/36

Language of the proceedings: EN

Title of invention:

Extracorporeal blood treatment machine

Patent Proprietor:

Gambro Lundia AB

Opponent:

B. Braun Melsungen AG

Headword:

Relevant legal provisions:

EPC Art. 100(a)

Keyword:

Inventive step - (yes)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 0635/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 7 June 2019

Appellant:
(Opponent)

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(Patent Proprietor)

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 5 January 2017
rejecting the opposition filed against European
patent No. 2319554 pursuant to Article 101(2)
EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. The appeal of the opponent is against the decision of the Opposition Division dated 5 January 2017 to reject the opposition.

In the decision, the subject-matter of claim 1 was considered novel and inventive in view of the cited prior art.

- II. Notice of appeal was filed 15 March 2017. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 15 May 2017.

- III. Oral proceedings were held on 7 June 2019.

The appellant/opponent requested that the decision under appeal be set aside and that the patent be revoked.

The respondent/patent proprietor requested that the appeal be dismissed.

- IV. The following documents are cited in the present decision:

E3: EP-A-0532432

E22: WO-A-01/76661

E25: "Pre-dilution haemofiltration - the Sardinian multicentre studies: present and future" Paolo Altieri *et al.*, *Nephrol Dial Transplant* (2000) 15 [Suppl 2]: 55-59

E26: "Mixed predilution and postdilution online hemodiafiltration compared with the traditional infusion modes" Luciano A. Pedrini *et al.*, *Kidney International*, Vol.58 (2000), pp. 2155-2165

V. Claim 1 of the patent as granted reads as follows
(feature numbering introduced by the appellant/
opponent):

M1 - Extracorporeal blood treatment machine comprising:
M2 - at least one filtration unit (2);
M3 - a blood circuit (3) having at least one inlet line
(3a) leading to the filtration unit and one outlet line
(3b) from the filtration unit;
M4 - a fluid circuit (4) having at least one inlet line
(4a) leading to the filtration unit and one outlet line
(4b) from the filtration unit,
M5 - the inlet line (4a) of the fluid circuit (4)
comprising at least one infusion branch (8) connected
to the blood circuit (3);
M6 - at least one infusion line (6) connected to the
blood circuit (3);
M7 - at least one primary fluid container (5) connected
so as to supply the inlet line (4a) of the fluid
circuit (4);
M8 - at least one auxiliary fluid container (7) for
supplying said infusion line (6),
characterized in that
M9 - the infusion line (6) further comprises at least a
pre-infusion branch (23) connected to the inlet line
(3a) of the blood circuit (3) and
M10 - a post-infusion branch (24) connected to the
outlet line (3b) of the blood circuit,
M11 - said infusion line (6) further comprising first
selecting means (25) for determining the percentage of
flow within the post-infusion branch (24) and the pre-
infusion branch (23).

VI. The arguments of the appellant/opponent relevant for
the decision can be summarised as follows:

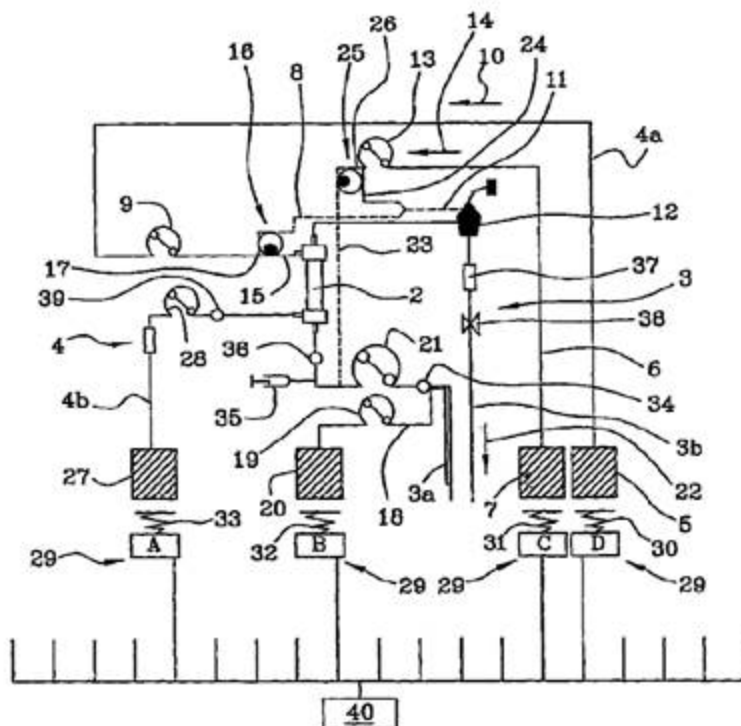
Only features M9 and M11 were not disclosed by E3. The person skilled in the art would have considered the teaching of E22 and arrived at the subject-matter of claim 1 without inventive step, either to solve the objective problem mentioned by the respondent/patent proprietor or to avoid "caking" the filter membrane. The person skilled in the art would have been all the more likely to do so since in E3 the information needed on how to avoid caking was not present, and E22 specifically referred to it. E22 described how the infusion line could be subdivided into a pre-infusion branch and post-infusion branch to allow its connection either to the blood inlet or outlet line of the blood circuit whereby a selection means allowed determining to which branch the fluid had to flow. E22, thus, would have directly led the person skilled in the art to the subject-matter of claim 1. If needed, the person skilled in the art would have adapted the control means of E3 in a routine manner. Moreover, the fact that the embodiments disclosed in E3 all concerned the infusion of bicarbonate was of no relevance since it was clearly expressed in that document that other substances could be infused instead, and in this case the dialysis fluid comprised bicarbonate. Furthermore, E25 and E26 demonstrated that before the priority date it was known to pre-dilute with a bicarbonate solution and to use pre-dilution to avoid caking of the filter, which demonstrated that the person skilled in the art would have had no reason to avoid pre-dilution with such a solution.

Therefore, the subject-matter of claim 1 was not inventive and the patent had to be revoked.

VII. The arguments of the respondent/patent proprietor correspond essentially to those underlying the decision.

Reasons for the Decision

1. The appeal is admissible.
2. The invention concerns an extracorporeal blood treatment machine for intensive therapy ([0002], [0014], [0016], etc.), hence, suitable for carrying out several types of extracorporeal blood treatments (i.e. ultrafiltration, hemofiltration, haemodialysis, hemodiafiltration). The present invention concentrates on the double connection of infusion line (6) with the blood circuit before and after the filter (11, 23, 24) with selecting means (25), allowing some versatility in intensive care machines with small bags of fluids ([0144] to [0151]).



3. Inventive step

The appellant/opponent raised a lack of inventive step objection based on a combination of E3 with E22. E25 and E26 were cited to support the objection.

4. Document E3

This document describes a treatment device for use with patients needing intensive care (column 1, lines 1 to 6; column 2, lines 15 to 24). The fact that bags of fluids are used (instead of online preparation) is a further indication that the device is for intensive care. In the embodiments described in this document, the objective is to better control the dosing of bicarbonate for patients suffering from acidosis (an acidification of the blood) to return back to the normal acid-base equilibrium. This is done by using a separate container containing a sterile solution of sodium bicarbonate and a separate infusion line connected to the blood line returning to the patient. This allows controlling precisely the quantity of bicarbonate introduced into the blood returning to the patient after having passed the filter or exchanger to achieve the desired concentration. To be able to precisely control the quantity of bicarbonate injected into the patient, the method described in E3 requires the use of a bicarbonate-free dialysate (column 3, lines 50 to 56).

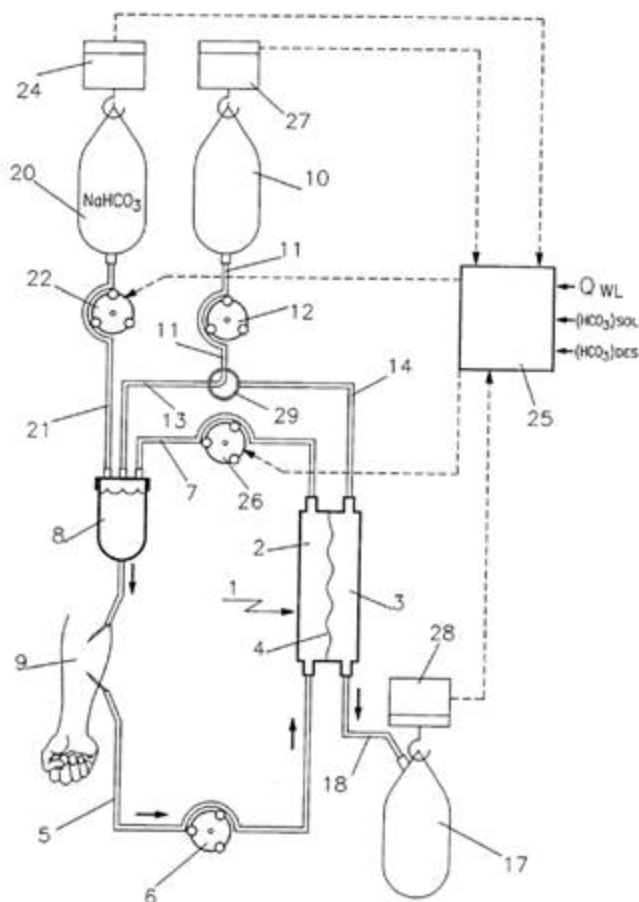


Fig. 2

This device comprises:

- at least one filtration unit (1)
- a blood circuit (5,6,7,8) having at least one inlet line (5) leading to the filtration unit (1) and one outlet line (7) from the filtration unit
- a fluid circuit (10,11,12,14,18) having at least one inlet line (14) leading to the filtration unit (1) and one outlet line (18) from the filtration unit
- the inlet line (14) of the fluid circuit comprising at least one infusion branch (13) connected to the blood circuit
- at least one infusion line (20,21,22) connected to the blood circuit

- at least one primary fluid container (10) connected so as to supply the inlet line (14) of the fluid circuit
- at least one auxiliary fluid container (20) for supplying said infusion line (21)

Therefore, the features of the first part of claim 1 are disclosed by E3. This was not disputed by the parties.

The infusion line (21) also comprises a post-infusion branch connected to the outlet line (7) of the blood circuit. As can be seen in Figure 2, the infusion line (21) is connected to the bubble trap (8), itself being connected to the patient.

5. Differentiating features

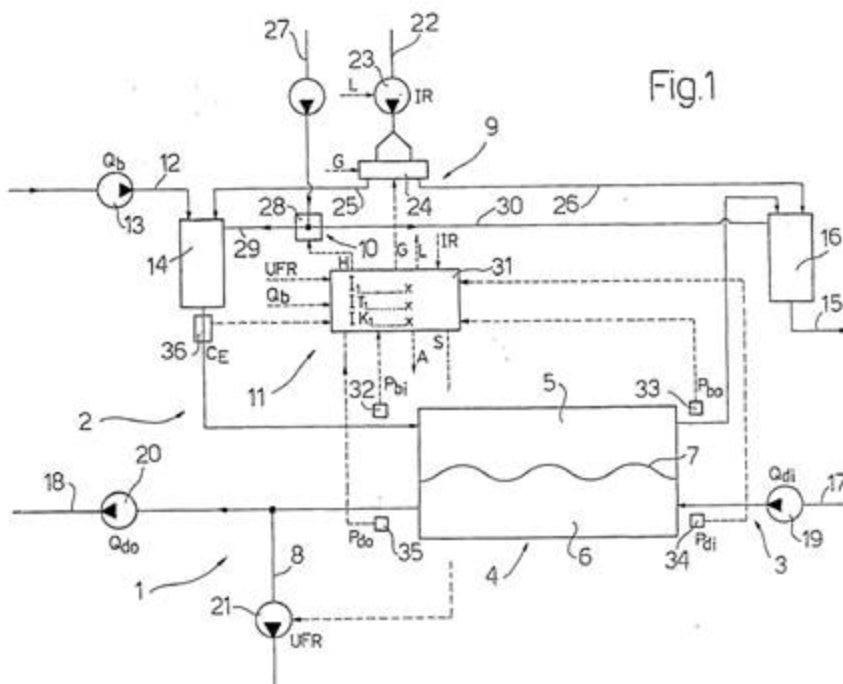
The treatment device according to E3 does not comprise any pre-infusion branch connected to the inlet line (5) of the blood circuit, nor does the infusion line (21) comprise first selecting means for determining the percentage of flow within the post-infusion branch (21) and the pre-infusion branch.

6. Objective problem and inventive step

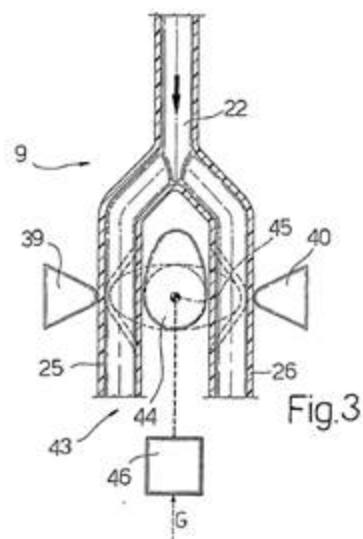
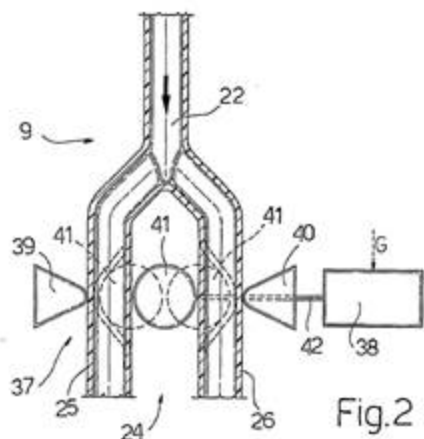
According to the appellant/opponent, the person skilled in the art would have considered the teaching of E22 and arrived at the subject-matter of claim 1 without inventive step, either to solve the objective problem mentioned by the respondent/patent proprietor to *provide a blood treatment machine particularly suitable for intensive care having the ability to offer therapy flexibility and exchange relatively high fluid volumes while maintaining a reasonable number of containers, or*

to avoid caking of the filter membrane. E22 described how the infusion line could be subdivided into a pre- and post-infusion branch to allow its connection either to the blood inlet or outlet line of the blood circuit whereby a selection means allowed determining to which branch the fluid had to flow. Not only was the versatility of the device increased, but the problem of caking directly addressed in E22 would have given the person skilled in the art a direct hint to the solution presented in that document. The person skilled in the art would have been even more likely to combine the teaching of E22 with that of E3 since in the latter there was no information on how to avoid caking of the filter.

E22 describes a dialysis machine for patients which do not need intensive care comprising a filter (4), an extracorporeal blood circuit (2) and a dialysis liquid circuit (3), itself comprising an ultrafiltration line (8) in which a high ultrafiltration flow rate may be activated (pump 21). When the ultrafiltration flow rate is high and leads to a weight loss greater than that prescribed, the excessive loss of plasma water must be compensated by a sterile solution. This is done with an infusion line (9) subdivided into a main line (22), which forks into a pre-dilution branch (25) and a post-dilution branch (26) as can be seen in Figure 1 below.



The advantages and disadvantages of the pre-dilution and post-dilution techniques are known and explained on page 2, line 15, to page 3, line 3, of E22. In essence, post-dilution allows a more efficient treatment but increases the risk of caking the filter, whereas pre-dilution avoids caking and increases the ultrafiltration efficiency, but the treatment is less efficient. The idea developed in this document is to sequentially use one or the other of these dilution alternatives to avoid the drawbacks of both, in particular, filter caking in the post-dilution technique. The sequence is determined by a control means depending on a characteristic value correlated with the concentration of the blood and/or the filtration efficiency of the filter. The control means control movable members (41, 44) to either open or close alternatively one of the pre- or post-dilution branches (page 9, lines 19 to 22; page 12, lines 25 to 27).



As mentioned above, the appellant/opponent considered that in view of the teaching of E22, it would have been obvious to enhance the infusion line (21) of the treatment device according to E3 with valve means and an additional branch connected to the blood inlet line (5).

The Board does not share this view for several reasons. First, it is doubtful that the person skilled in the art wishing to solve a problem in a dialysis machine for intensive care would have sought a solution in a normal dialysis machine as intensive care patients are often too weak to bear normal treatment conditions. But, in any case, the person skilled in the art would not have combined the teachings of E3 and E22. Connecting the line infusing bicarbonate to the blood inlet line would have gone against the very teaching of E3. It would have meant introducing a quantity of bicarbonate into the blood before the blood is filtered, thus, before some of the bicarbonate might have been filtered out again. Hence, it would have been impossible to know the exact concentration of bicarbonate present in the blood when it was reinjected

into the patient, which, however, was the very aim pursued in E3, namely, to accurately adjust the concentration of bicarbonate in the blood to improve the acid/base balance. Moreover, applying the teaching of E22 would have meant alternating post- and pre-dilution, which, from the point of view of knowing the exact concentration of bicarbonate present in the blood, would have made the situation even worse.

The appellant/opponent considered that it would have been a routine measure to adapt the control means to that new situation.

The control means described in E3 are based on weighing the liquid quantities and determining flow rates, in particular, of the infusion pump (22), to achieve the desired concentration of bicarbonate in the blood returned to the patient. It is not clear in which obvious way the control means would have to be adapted to take account a loss of bicarbonate through the filter in case of pre-dilution and nevertheless achieve the desired concentration since, moreover, the permeability of the filter changes over time. The post-dilution seems to be the best solution to achieve the goal desired in E3.

The appellant/opponent further considered that the disclosure of E3 was not limited to the injection of a bicarbonate solution as explained column 8, lines 35 to 45. In case of the infusion of another medicine, the problem with the dosage of bicarbonate would have been solved since, as mentioned in that paragraph, the bicarbonate would have been present in the dialysis liquid in container (10) instead.

The Board does not share this view. As explained in the last paragraph of the description mentioned by the appellant/opponent, the medicine to be injected into the patient would, in the same way as with bicarbonate, have been accurately quantified using the same control means (and formulas) as described for the dosing of bicarbonate. Hence, in the Board's opinion, if the person skilled in the art had wished to achieve a desired precise concentration of this medicine in the blood of the patient, it would not have foreseen an injection of this medicine into the blood before filtration because after the filtration it would have been impossible to know the exact concentration of that medicine in the blood going back to the patient, as already explained in relation to bicarbonate. Hence, there is a fundamental incompatibility between the teaching of E3 and E22.

Documents E25 and E26 do not change this finding. While it was known that a pre-dilution with sterile solution could prevent clotting of blood in the filter, how would this common knowledge have been applied in the treatment device according to E3? In the Board's opinion, if such a pre-dilution were desired in the apparatus according to E3, a separate line leading from a sterile solution of container (10) to the blood inlet line (5) could be used so that the medicine or bicarbonate could still be accurately determined and infused after the filter with the benefit of a proper dosing. By the same token, while it may be possible or even desirable in some instances to pre-dilute the blood with a bicarbonate solution, the question is whether the person skilled in the art starting from the treatment devices according to E3 would have contemplated pre-diluting the blood in this way. It was

explained above why the Board considers that this would not have been the case.

Hence, neither do these documents help to demonstrate why the combination of E3 with E22 would have been obvious for the person skilled in the art as alleged by the appellant/opponent.

Moreover, the valve means in E22 are not for determining the percentage of flow within the post- and pre-infusion branches (as required by the last feature of claim 1) since they are only foreseen for either opening or closing the respective branch alternatively (Figures 2, 3, page 9, lines 19 to 22, page 12, lines 25 to 27). Thus, even in the case of combining the teaching of E3 with E22, this feature would still not have been satisfied. The more general statement in that respect on page 3, lines 22 and 23, cannot change this finding since this statement has to be read and understood in light of the teaching of E3 as whole, which shows that a continuous variation was never envisaged.

For the reasons above, the subject-matter of claim 1 is inventive.

7. Hence, the ground for opposition of lack of inventive step pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated