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**Datasheet for the decision
of 18 November 2021**

Case Number: T 0295/17 - 3.2.02

Application Number: 04812617.1

Publication Number: 1699505

IPC: A61M1/34, A61M1/36

Language of the proceedings: EN

Title of invention:

MEDICAL FLUID THERAPY FLOW CONTROL SYSTEMS

Patent Proprietors:

Baxter International Inc.
Baxter Healthcare S.A.

Opponent:

Fresenius Medical Care AG & Co. KGaA

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 83, 84, 123(2)

Keyword:

Novelty - (yes)
Inventive step - (yes)
Sufficiency of disclosure - (yes)
Claims - clarity (yes)
Amendments - added subject-matter (no)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

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Case Number: T 0295/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 18 November 2021

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
1 December 2016 concerning maintenance of the
European Patent No. 1699505 in amended form.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: S. Böttcher
 C. Schmidt

Summary of Facts and Submissions

- I. Both the patent proprietors and the opponent filed an appeal against the decision of the Opposition Division to maintain the European patent No. 1 699 505 on the basis of auxiliary request 1.
- II. The patent proprietors withdrew their appeal on 15 September 2021.
- III. Oral proceedings before the Board were held on 18 November 2021.
- IV. The (remaining) appellant (opponent) requests that the decision under appeal be set aside and that the patent be revoked.
- V. The respondent (patent proprietors) requests as a main request that the appeal be dismissed.
- VI. Claim 1 of auxiliary request 1 (maintained by the opposition division) reads as follows:

"A medical fluid system (10) comprising:
a medical fluid flow path (20) having a medical fluid supply (12), a first pump (14) operable to pump medical fluid from the supply to an extracorporeal circuit (70) and a second pump (42) operable to pump fluid from a blood filtering device (44);
an apparatus (58, 120) operable to isolate the blood filtering device from the rest of the medical fluid flow path;
a branch (102) located downstream from the first pump;
a first branch line (106) communicating fluidly with:
(i) the branch, (ii) a first clamping device (116)

operable to selectively allow and block flow through the first branch line and (iii) a first point (79) in the extracorporeal circuit located upstream from the blood filtering device so that the medical fluid can be fed into the extracorporeal circuit sufficiently upstream of the blood filtering device to perform a blood rinse back procedure;

a second branch line (104) communicating fluidly with:

(i) the branch, (ii) a second clamping device (114) operable to selectively allow and block flow through the second branch line and (iii) a second point in the extracorporeal circuit located downstream from the blood filtering device; and

a control scheme operable to (i) selectively open at a given point in time at least one of the first and second clamping devices (ii) selectively and concurrently command (a) the isolating apparatus to isolate the blood filtering device and (b) the first pump to deliver a volume of the medical fluid to the extracorporeal circuit to perform the blood rinse back procedure."

VII. In the present decision, reference is made to the following documents:

D1: DE 42 40 681 A1

D4: US 5 366 630

D6: WO 03/047656

VIII. The arguments by the appellant can be summarised as follows:

Added subject-matter

Claim 1 included features of claims 1, 6, 14 and 21 as originally filed. Claims 1 and 14 were independent

claims relating to different aspects. The two aspects defined in claims 1 to 13, concerning the pre- and postdilution, and in claims 14 to 38, concerning the bolus and rinseback functions, were presented in the application as originally filed as separate teachings that could not be combined (page 5, 1st paragraph). None of dependent claims 2 to 13 or 15 to 38 referred back to any of the claims of the other aspect.

Furthermore, claims 1 and 14 as originally filed could not be combined due to contradictions between them. The arrangement defined in claim 1 was configured for pre- and postdilution in hemofiltration clearance modes, and did not require a medical fluid flow path for delivering fluid to the blood filtering device. Hence, the provision of an apparatus for isolating the blood filtering device from the medical fluid flow path as defined in claim 14 was incompatible with the device of claim 1.

Also in the description the two aspects were presented as separate aspects (page 5, 1st paragraph, the headings on page 11 and on page 16).

Furthermore, the description as originally filed did not provide a basis for the general definitions in claim 1 either. Claim 1 included a selection of the features disclosed in Figure 1, and the omission of other features, which were essential for the rinseback procedure, constituted an unallowable intermediate generalisation. In detail, the following features were concerned:

- Controllable pinch clamps were necessary to avoid the use of an extra pump (page 5, 2nd and 3rd paragraph; page 6, 1st paragraph).

- A two-way isolate valve was necessary to perform the "special fluid delivery functions", including the rinseback (page 6, last paragraph). Instead, the claim only mentioned an isolating apparatus.
- The penultimate paragraph on page 7 stated that the rinseback procedure was performed using several valves and TMP alarm limits, that the fluid was balanced through the match flow equalizer, and that the fluid was delivered to the arterial access line prior to the arterial drip chamber. Since these features were not presented as optional features, their omission constituted an unallowable intermediate generalisation.
- The location at which the rinseback solution is delivered to the extracorporeal circuit was not specified in claim 1, although it was essential for the rinseback procedure.
- The purge valve 122 mentioned on page 20, 2nd paragraph, was also essential for the rinseback procedure.
- The Y-connector connecting the pre-and postdilution lines and the check valves 110 and 112 disclosed in Figure 1 were essential features.

For these reasons, claim 1 did not meet the requirements of Article 123(2) EPC.

Moreover, in the statement of ground of appeal the appellant argued that, since the features of originally filed claim 6 had been included in claim 1, new undisclosed claim dependencies had been created.

Clarity

The features which were introduced in claim 1 of auxiliary request 1 lacked clarity.

From the wording "apparatus operable to isolate the blood filtering device from the rest of the medical fluid flow path" it was not clear whether the device was thermally, electrically or locally isolated from the rest of the flow path. Furthermore, if a fluidic isolation was meant, it was not clear how to perform the blood rinseback through the blood filter in the isolated state.

Moreover, it was not clear, what was meant by "the rest of the medical fluid flow path".

It was also not clear whether the control features following the bullet points (i) and (ii) should be performed simultaneously, alternatively or both, and what was meant by "selectively and concurrently".

Furthermore, the term "operable" was unclear with regard to the reference to "manually or automatically" in paragraph [0063] of the patent. In detail, it was not clear how the control scheme was operable to manually perform the claimed actions "at a given point in time".

Sufficiency of disclosure

The invention was not sufficiently disclosed since the person skilled in the art was not taught where to locate the first point to be able to feed the medical fluid into the extracorporeal circuit sufficiently upstream of the blood filtering device to perform a

blood rinseback procedure, in which all the blood remaining in the system had to be pushed back to the patient.

Furthermore, claim 1 required that it was possible to isolate the blood filtering device, i.e. the whole device and not only the dialysate side, and to simultaneously perform the blood rinseback procedure, wherein medical fluid was delivered to the extracorporeal circuit and fed through the blood side of the device. Since this was not feasible, the invention was not sufficiently disclosed to be carried out by the person skilled in the art.

Novelty over D1 and D4

The term "operable" used in the context of the control scheme defined in claim 1 could not mean "programmed to". It had rather to be understood as "suitable for". This was clear from paragraph [0063] of the patent stating that the control scheme was also configured for manual operation. In contrast to an automatic operation, a manual operation could not be programmed.

D4 disclosed in Figure 2 a medical fluid system comprising all the features of claim 1 of auxiliary request 1, in particular a control scheme operable to (i) selectively open at a given point in time at least one of the first and second clamping devices (18, 19), (ii) selectively and concurrently command (a) the isolating apparatus (30, 17, 6) to isolate the blood filtering device and (b) the first pump to deliver a volume of the medical fluid to the extracorporeal circuit to perform the blood rinse back procedure.

Therefore, the subject-matter of claim 1 was

anticipated by D4, as the control unit disclosed therein was suitable to control the clamps 17 and 30 as well as the pump 6 to isolate the blood filtering device. The control unit was also suitable to open the valve 18, such that fluid from bag 11 could be delivered by pump 13 to the extracorporeal circuit to perform a blood rinseback procedure.

D1 disclosed in Figure 2 a medical fluid system comprising all the features of claim 1 of auxiliary request 1. In particular, the pump 32 could be regarded as an apparatus for isolating the blood filtering device from the rest of the fluid flow path. Figure 2 also showed a control unit which could be programmed to control the pump 32, such that the dialyzer 12 was isolated. The control unit was also suitable to (i) selectively open at a given point in time at least one of the first (48 or 50) and second clamping devices, (ii) selectively and concurrently command (a) the isolating apparatus (32) to isolate the blood filtering device and (b) the first pump (84) to deliver a volume of the medical fluid to the extracorporeal circuit to perform the blood rinse back procedure (via 90, 46, 44 and 52).

Hence, the subject-matter of claim 1 lacked novelty over D4 and D1.

Inventive step starting from D1

By means of stopping the pumps 28 and 32, the dialyzer 12 could be isolated from the rest of the fluid flow path. Since the rinseback was performed after the blood treatment was finished, the person skilled in the art would preferably stop the balancing system during the blood rinseback for economic reasons. Hence, a control

scheme according to claim 1 was obvious to the person skilled in the art.

Alternatively, clamp 104 could be regarded as the isolating apparatus. It would be obvious for the person skilled in the art to close this clamp when performing the rinseback.

Moreover, the decision of the opposition division was flawed since it would be obvious to the person skilled in the art to omit bag 46 and deliver the medical fluid directly to the extracorporeal circuit. The person skilled in the art was prompted by the further prior art to dispense with the bag, if it was not intended to perform a dialysis treatment without anticoagulation.

Inventive step starting from D4

The distinguishing feature of claim 1 was a control unit (= control scheme) adapted for controlling the first pump.

The problem to be solved by this feature could be regarded as to automate the control of pump 13.

The person skilled in the art would use control unit 24 of D4 to control the pump without exercising an inventive step. Hence, the subject-matter of claim 1 was not inventive.

Inventive step starting from D6

D6 disclosed a medical fluid system (Figure 1) from which the subject-matter of claim 1 differed in that it comprised a control scheme operable to (i) selectively open at a given point in time at least one of the first

and second clamping devices (ii) selectively and concurrently command (a) the isolating apparatus to isolate the blood filtering device and (b) the first pump to deliver a volume of the medical fluid to the extracorporeal circuit to perform the blood rinse back procedure.

In D6, clamps 35, 36 and valves 26, 27 had to be operated manually in order to perform these functions. Therefore, the problem to be solved was to automate the functions of the control scheme.

Since D6 already disclosed the automatic control of several components of the system, it would be obvious to the person skilled in the art to provide an automatic control scheme for the claimed functions. In order to avoid unnecessary fluid consumption, the person skilled in the art would evidently choose to command the isolating apparatus (clamps 26, 27) to isolate the dialyzer during the rinseback.

It followed that the subject-matter of claim 1 lacked an inventive step over D6 in combination with the common general knowledge.

IX. The arguments by the respondent can be summarised as follows:

Added subject-matter

Viewing the disclosure of the specification as a whole, and in particular claims 1, 6, 14 and 21 and pages 20 and 21 of the description, the subject-matter of the claims was clearly and unambiguously derivable. Basis could also be found in Figure 1, although not each and every feature disclosed in this figure was present in

the claims.

The person skilled in the art would understand that the feature "apparatus operable to isolate the blood filtering device" was disclosed in general terms in the application as filed.

Original claims 1 and 14 were not mutually exclusive. There was rather an overlap between these two claims, which had the underlying technical features in common. Furthermore, original claim 6 introduced the rinseback function as a concept which was further defined in claim 14. Hence, the rinseback feature was disclosed in general terms as a preferred part of the disclosure.

Moreover, original claim 1 did not relate exclusively to hemofiltration treatment, and original claim 14 did not relate exclusively to hemodialysis or hemodiafiltration.

In respect of the dependent claims at the oral proceedings reference was made to the written submissions.

Clarity

Since the blood filtering device normally had medical fluid flowing through it, it was clear that the term "isolate" meant that the fluid flow was stopped in order to perform the rinseback procedure. Hence, there was no ambiguity about what was meant by "isolate" in the context of the claims.

The sentence in paragraph [0063] referred to by the appellant concerned the initiation of the bolus function, which could be done manually. This passage

did not suggest that the operation of the control scheme was done manually.

Sufficiency of disclosure

It was not required by the specification that the blood rinseback procedure resulted in all the blood being returned to the patient.

The patent did not teach the blood filtering device had to be isolated completely from all fluid flow, and this was also not required from claim 1. It was rather indicated in claim 1 that, whilst the dialysate side of the blood filtering device was isolated from the rest of the circuit, the medical fluid was used to flush out the blood from the extracorporeal circuit on the blood side of the blood filtering device.

Therefore, the invention was sufficiently disclosed to be carried out by the person skilled in the art.

Novelty

The claimed medical fluid system comprised a control scheme that had to be operable to perform certain functions with the components of the medical fluid system. Neither D4 nor D1 disclosed such a control scheme to perform the blood rinseback procedure.

Thus, the subject-matter of claim 1 was novel.

Inventive step in view of D1

The skilled person would not modify the system of D1 to arrive at the subject-matter of claim 1. In particular, the person skilled in the art would not dispense of the

bag of anticoagulant.

Furthermore, the dialyzer was already isolated by the bag 46 and the filter 86 (Figure 2). The valve 104 did not isolate the dialyzer.

Contrary to the system of D1, the invention provided pre-and postdilution and rinseback with the same lines.

Inventive step in view of D4

The claimed invention differed from D4 not only in that the controller controlled the first pump, but also in that the control scheme was operable to command the isolation apparatus and the first pump to perform a blood rinseback procedure. Even if automation of the control of the pump was obvious (as argued by the appellant), such a control scheme was not suggested by D4.

Inventive step in view of D6

Since D6 was silent about blood rinseback, the mere automation of the control functions would not result in the subject-matter of the invention as claimed in claim 1. Without any motivation to provide a control scheme for the purpose of providing a blood rinseback procedure, the person skilled in the art would not have modified the system of D6 as suggested by the appellant.

Hence, the subject-matter of claim 1 involved an inventive step.

Reasons for the Decision

1. The invention relates to a medical fluid system for a hemodialysis, hemofiltration or hemodiafiltration system. The fluid system is capable of performing pre- and postdilution clearance modes (page 2, 2nd paragraph of the A2 pamphlet) by infusing substitution fluid into the arterial blood line or the venous blood line, respectively.

According to claim 1 of auxiliary request 1, the medical fluid system comprises a flow path having a fluid supply (e.g. a dialysate generation unit) and two pumps (14, 42), and a branch (102) located downstream from the first pump (14) (Figure 1). The first pump is operable to pump medical fluid from the supply to the extracorporeal circuit and the second pump is operable to pump medical fluid from the blood filtering device. A first branch line extends from the branch via a first clamping device to a first point in the extracorporeal circuit. The first point is located upstream of the filtering device (44) so that the medical fluid can be fed into the extracorporeal circuit sufficiently upstream of the filtering device (predilution) to perform a blood rinseback procedure. A second branch line extends from the branch via a second clamping device to a second point in the extracorporeal circuit. This point is located downstream from the filtering device (postdilution). The system further comprises an apparatus (58, 120) operable to isolate the blood filtering device from the rest of the medical fluid flow path, and a control scheme operable to selectively open at least one of the clamping devices and operable to selectively and concurrently command (a) the isolating apparatus to isolate the blood filtering device and (b) the first pump to deliver a volume of

the medical fluid to the extracorporeal circuit to perform the blood rinseback procedure, i.e. to return blood which remains in the extracorporeal circuit at the end of the treatment to the patient.

2. Added subject-matter

2.1 Claim 1 is a combination of claims 1, 6, 14 and part of 21 as originally filed.

Claim 1 as originally filed relates to the pre- and postdilution clearance mode, and claim 14 relates to the special delivery functions, such as prime, bolus and blood rinseback. These modes are described as "one aspect of the present invention" (page 5, 2nd paragraph, to page 6 last but one paragraph) and "another aspect of the present invention" (page 6, last paragraph, to page 8, 2nd paragraph) in the general part of the description under the heading "Summary of the invention".

Contrary to the appellant, the Board holds that the combination of the two aspects as defined in claim 1 can be directly and unambiguously derived from the application as originally filed. Although claims 1 and 14 as originally filed are independent claims, they both comprise the features "medical fluid flow path", "medical fluid supply", "first pump" and "second pump". It is clear, in particular from dependent claims 6 and 36, that the system of the first "aspect" can be used for a blood rinseback procedure and that the system of the second "aspect" can be used for pre- and postdilution.

Furthermore, although pre- and postdilution is often performed in connection with hemofiltration treatment,

claim 1 is not limited to a system for performing hemofiltration. Likewise, claim 14 does not exclusively relate to a hemodialysis or hemodiafiltration system. Hence, the Board cannot determine any contradictions between these claims.

Moreover, Figure 1 shows an embodiment in which both aspects are combined in one system. In particular, Figure 1 discloses features relating to the first aspect, e.g. the branch lines for the pre- and postdilution, and the isolating valves 58, 120 for the bolus injection. This figure is referred to in the description of the two aspects (page 5, 2nd paragraph, to page 8, 2nd paragraph).

2.2 The Board does not agree with the appellant that the omission of some of the features of the detailed description of the embodiment of Figure 1 constitutes an unallowable intermediate generalisation. In detail:

- The use of an extra pump can be avoided irrespective of the presence of controllable pinch clamp valves in the substitution lines. These clamps are provided for controlling the amount of substitution fluid, rather than the pre- and postdilution function as such.

- The type of isolating apparatus is irrelevant to the function of stopping flow to the dialyzer to perform the rinseback procedure.

- The valve configuration, including the purge valve 122, and the flow equalizer and the TMP alarm limits mentioned in the penultimate paragraph on page 7 are used to balance the post dialyzer fluid with the fluid flowing to the patient. However, these components are not essential for the rinseback procedure as such.

- The exact location at which the rinseback solution is delivered to the extracorporeal circuit is not essential since blood can be returned from any point of the arterial line. Depending on the location of the delivery, the amount of blood returned will be more or less.

- The type of connector connecting the pre- and postdilution lines is irrelevant to the function of branching the lines. Furthermore, the check valves 110 and 112, which prevent blood from flowing back into the dialysate flow path, are not essential for the pre- and postdilution function as such.

2.3 Hence, claim 1 meets the requirements of Article 123(2) EPC.

2.4 In the communication dated 17 August 2021, point 4, the Board stated that they shared the view of the opposition division (points 2.3.1 and 2.3.4 of the decision) that the dependent claims complied with Article 123(2) EPC. No counter argument was provided in this respect, so that the Board does not see any reason to depart from said view.

3. Clarity

3.1 With regard to the feature "isolate", it is clear from the context of the claim, which relates to a medical flow path for supplying dialysate to a blood filtering device, that "isolate" can only mean fluidically isolate, such that no fluid flows through the dialysate side of the filter/dialyzer. This is also in agreement with the description (see A publication, page 17, 2nd paragraph, and page 20, 2nd paragraph) stating that

valves 58 and 120 isolate the filter from the remainder of the dialysate flow path (which is the medical fluid flow path referred to in claim 1). Furthermore, the person skilled in the art would understand that the "rest" of the medical fluid flow path is the part on the opposite side of the isolating apparatus.

Since only the flow through the dialysate side of the blood filtering device is impeded, it is possible to perform the blood rinseback procedure, wherein medical fluid is delivered to the extracorporeal circuit and fed through the blood side of the device, without hindrance.

3.2 As to the feature concerning the control scheme, since there is no "or" in the claim between the operation modes it is clear that both operation modes have to be programmed, i.e. the control scheme has to be operable to selectively open one of the clamps and the control scheme has to be operable to command both the isolating apparatus and the pump in order to perform the blood rinseback mode.

From paragraph [0063] it cannot be concluded that the functions of the control scheme are performed manually. The passage rather states that the procedure to deliver a bolus volume may be started either manually or automatically, i.e. that the control scheme is programmed to start on receipt of an operator input or a signal from a sensor (page 6, last paragraph). Hence, the term "operable" is not unclear.

3.3 Hence, in the Board's view, claim 1 does not lack clarity.

4. Sufficiency of disclosure

The Board holds that the invention is sufficiently disclosed to be carried out by the person skilled in the art.

The blood rinseback procedure does not require that all of the blood remaining in the system has to be returned to the patient, as alleged by the appellant. The passages referred to by the appellant (page 4, 1st paragraph, page 20, 1st and 2nd paragraphs) do not support this allegation. The person skilled in the art would be able to select a location for the first point which is sufficiently upstream of the blood filtering device to return as much of the blood as possible.

Since it is clear that the blood side of the filter is not part of the "medical fluid path" and the isolating apparatus only prevents fluid from flowing through the dialysate side of the filter/dialyzer, the person skilled in the art would have no difficulties to perform the blood rinseback procedure, during which blood and fluid is passed through the blood side of the filter/dialyzer.

5. Novelty over D4 and D1

5.1 D4 discloses a medical fluid system for a hemodialysis treatment (Figure 2). Via branch lines 15 and 16, comprising clamps 18 and 19, it is possible to perform pre- and postdilution. The predilution branch line 15 can be used for a blood rinseback procedure, wherein substitution liquid from container 11 is delivered to the extracorporeal circuit via bubble trap 8, although such a rinseback procedure is not mentioned in D4. The system of D4 also comprises a clamp 17 for isolating

the dialyzer 1 from the rest of the flow path.

However, D4 does not disclose a control scheme operable to "selectively and concurrently command (a) the isolating apparatus to isolate the filtering device and (b) the first pump to deliver a volume of the medical fluid to the extracorporeal circuit to perform the blood rinseback procedure".

Contrary to the opponent, the Board considers that "control scheme" does not merely mean "a control unit that could be operated" to execute certain commands. "Control scheme" rather means that the commands are actually programmed in the control unit of the system. Evidently, this cannot be derived from D4.

5.2 D1 also discloses a medical fluid system for a hemodialysis treatment. In the embodiment of Figure 2, the system comprises pre- and postdilution lines 102, 98 branching from the filter 86 (column 8, lines 13 to 27). From the dialysis liquid line 22 fluid can be branched off and fed via pump 84 to the extracorporeal circuit.

As the treatment is performed without anticoagulation, it is necessary to regularly flush the extracorporeal circuit lines to remove any blood clots. For this purpose, the system of D1 comprises a bag 46 which is filled with substitution liquid from the dialysis fluid circuit 20 via pump 84, filter 86 and line 90 (column 6, line 66, to column 7, line 9). The liquid in this bag can be fed as flushing liquid via line 44 and pump 50 to the arterial line upstream of the blood pump 42 to flush the extracorporeal circuit. This is done several times during the hemodialysis treatment. After each flushing cycle, the bag is re-filled from the

dialysis fluid circuit (column 7, lines 41 to 66). A final flushing cycle is performed after the termination of the treatment to return the blood to the patient, i.e. in the final cycle a rinseback procedure is performed (column 8, lines 8 to 12).

Furthermore, contrary to the present invention, the rinseback liquid is not delivered by the substitution pump 84 (which corresponds to the first pump as defined in the claim), but by the separate pump 50. In fact, during the flushing cycles, the pump 84 does not work at all.

D1 also discloses a control unit 58 that might be suitable to command the pumps and clamps of the system to deliver fluid or to allow and block fluid flow through the lines of the system. However, D1 does not disclose the particular control scheme of claim 1 which is operable to "selectively and concurrently command (a) the isolating apparatus to isolate the filtering device and (b) the first pump to deliver a volume of the medical fluid to the extracorporeal circuit to perform the blood rinseback procedure".

5.3 Hence, the subject-matter of claim 1 is novel over D1 and D4.

6. Inventive step

6.1 Since D1 relates to a blood rinseback procedure, it can be regarded as the closest prior art.

However, as mentioned above, the rinseback procedure of claim 1 differs from the one in D1 in that the blood filtering device is isolated from the dialysis fluid flow path and in that the first pump is commanded to

deliver the medical fluid directly from the dialysis fluid flow path to the extracorporeal circuit.

By isolation of the blood filtering device during the rinseback procedure, it is possible to branch off a defined volume of the dialysis fluid from the dialysis fluid circuit which is then delivered by the first pump via the pre-dilution line to the extracorporeal circuit. This has the effect that the rinseback and the pre- and postdilution can be performed with the same lines and with the same pump. Thus, the objective technical problem solved by this can be regarded as to provide an alternative rinseback procedure that uses the existing equipment.

The Board does not agree with the appellant that it would be obvious to the person skilled in the art to isolate the dialyzer of D1 during the rinseback, either by stopping the pumps 32 and 28 or by closing the valve 104. In D1, when the flushing or the rinseback is performed, there is no fluidic connection between the dialysis fluid circuit 20 and the substitution liquid bag 46 since the pump 84 is stopped after the bag has been filled.

It would also not be obvious to omit the bag 46 from the system of D1 since the bag is an essential component of the anticoagulation-free dialysis treatment. Hence, it would have required a complete redesign of the system of D1 to arrive at the subject-matter of claim 1. This would not have been contemplated by the person skilled in the art.

6.2 D4 does not mention any rinseback procedure. Hence, the person skilled in the art is not prompted by D4 to provide a control scheme for a rinseback procedure as

defined in claim 1.

The appellant's argument cannot be convincing since it is based on the incorrect assumption that the subject-matter of claim 1 differs from the system of D4 only in that the first pump could be controlled by the control unit.

6.3 Similar to D4, D6 discloses a medical fluid system for a hemodialysis treatment (Figure 1). Via branch lines 17, 17c and 17d comprising clamps 35 and 36 it is possible to perform pre- and postdilution.

As in D4, a blood rinseback procedure is not mentioned in D6. Hence, the person skilled in the art is not prompted by D6 to provide a control scheme for a rinseback procedure as defined in claim 1.

The Board does not agree with the appellant that the problem to be solved was merely to automate the control of the pumps and clamps. Therefore, the appellant's argument cannot be considered convincing.

6.4 It follows that the subject-matter of claim 1 involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated