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Datasheet for the decision of 21 July 2020

Case Number: T 0404/16 - 3.2.02

Application Number: 06838361.1

Publication Number: 2001532

IPC: A61M1/36

Language of the proceedings: EN

Title of invention:
CITRATE ANTICOAGULATION SYSTEM FOR EXTRACORPOREAL BLOOD TREATMENTS

Patent Proprietor:
Nikkiso Co., Ltd.

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 56, 84, 100(b), 100(c)
RPBA Art. 12(4)

Keyword:

Grounds for opposition - insufficiency of disclosure (no)
added subject-matter (no)
Claims - clarity (yes)
Late-filed evidence - admitted (yes)
Inventive step - (yes)

Decisions cited:

T 2562/18, G 0003/14

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0404/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 21 July 2020

Respondent: (Patent Proprietor)	Nikkiso Co., Ltd. Yebisu Garden Place Tower 20-3, Ebisu 4-chome Shibuya-ku Tokyo 150-6022 (JP)
Representative:	Grosse Schumacher Knauer von Hirschhausen Patent- und Rechtsanwälte Nymphenburger Strasse 14 80335 München (DE)
Appellant: (Opponent)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Herrmann, Uwe Lorenz Seidler Gossel Rechtsanwälte Patentanwälte Partnerschaft mbB Widenmayerstraße 23 80538 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 18 December 2015 concerning the maintenance of European Patent No. 2001532 in amended form**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	D. Ceccarelli
	Y. Podbielski

Summary of Facts and Submissions

I. The opponent has appealed against the Opposition Division's decision, posted on 18 December 2015, that, account being taken of the amendments according to auxiliary request 5 then on file, European patent No. 2 001 532 and the invention to which it related met the requirements of the EPC.

The patent proprietor appealed but has subsequently withdrawn its appeal.

The patent is derived from the parent application of European patent application No. 11 153 847.6, which is the object of appeal case T 2562/18.

II. At the end of the oral proceedings, which took place on 21 July 2020, the requests were as follows:

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

The respondent requested that the appeal be dismissed.

III. The following documents are mentioned in the present decision:

D1: WO-A-2005/039671
D2: US-A-2005/0011823
D3: US-A-2004/0129638
D4: DE-A-41 14 908
D5: "Dialysef!Bel - Plädoyer für die individuelle Dialyse", pages 401 to 406, G Schönweiß, abakiss Verlag Bad Kissingen, 1996

D6: "Blutreinigungsverfahren - Technik und Klinik", pages 473 to 495, HE Franz and WH Hörl, Georg Thieme Verlag Stuttgart-New York, 1997

D7: DE-A-196 54 746

D8: "Gebrauchsanweisung Automatischer Akutbilanzmonitor AQUARIUS - Für Platinum Software Version 4", Edwards Lifesciences, May 2004

IV. **Claims 1, 4 and 6** of the request held allowable by the Opposition Division read as follows:

"1. A hemofiltration system comprising:
an access line (1) configured to carry blood from a patient's blood stream;
a first pump (14) configured to pump the blood through the access line (1);
a second pump (24) for introducing an anticoagulant solution into the blood traveling through the access line (1);
a filter (60) for filtering the blood traveling through the access line (1);
a third pump (23) for introducing a substitution fluid into the blood;
a fourth pump (16) for introducing a calcium and magnesium solution into the blood;
a return line (2) configured to carry blood back to the patient's blood stream; and
a processing unit (72) for controlling a flow rate for the first pump (14), the second pump (24), the third pump (23), and the fourth pump (16);
wherein the fourth pump (16) is coupled to the return line (2) and
the third pump (23) is coupled to the access line (1), **characterized in that** the hemofiltration system further comprising:

a fifth pump (50) for introducing the substitution fluid into the blood traveling through the return line (2),
wherein when one pump halts for any reason, the other pumps also stop pumping, wherein the stops of blood pump (14) and anticoagulant pump (24) are delayed after the other pumps have stopped."

"4. The hemofiltration system of any of the preceding claims, further comprising:
a filtrate line coupled to the filter (60) and configured to carry a filtrate from the filter (60)."

"6. The hemofiltration system of claim 4 or 5, further comprising:
a reservoir (9) to collect the filtrate traveling through the filtrate line;
a measuring scale to weigh the filtrate collected in the reservoir (9);
wherein the processing unit (72) computes the amount of substitution fluid introduced in the blood from the weight measured by the scale,
wherein the processing unit (72) controls the flow rate of the third pump (23) and the fourth pump (16) to introduce the computed amount of substitution fluid to the blood."

Claims 2, 3, 5 and 7 are further dependent claims.

V. The appellant's arguments, where relevant to the present decision, may be summarised as follows:

Sufficiency of disclosure

In the written procedure the appellant argued that the invention of claim 6 was not sufficiently disclosed.

The feature of claim 6 "wherein a processing unit computes the amount of substitution fluid introduced in the blood from the weight measured by the scale" was not sufficiently disclosed. According to the patent, the scale measured the weight of filtrate in a container. From this measure it was impossible to compute the amount of the substitution fluid already introduced in the blood, as required by the claim.

The feature of claim 6 "wherein the processing unit controls the flow rate of the third pump and the fourth pump to introduce the computed amount of substitution fluid to the blood" was not sufficiently disclosed either. According to claim 1 the fourth pump was used to deliver a calcium and magnesium solution, and not the substitution fluid. Hence, contrary to the claim wording, the control of this pump could not have an influence on the introduction of the substitution fluid.

Added subject-matter

In the written procedure the appellant also submitted that there was no basis in the application as filed for the features of claim 1 "wherein the fourth pump (16) is coupled to the return line (2) and the third pump (23) is coupled to the access line (1)" and "a fifth pump (50) for introducing the substitution fluid into the blood traveling through the return line (2)". Figures 3 and 4, and claim 4 of the application as filed disclosed that, when a fifth pump was present, the third pump was coupled to the access line between the first pump and the filter. The passage in paragraph [0051] of the application as filed which recited "in one embodiment, the predilution line is connected to

the access line 1 pre-blood pump 14" did not refer to embodiments comprising a fifth pump. Hence all the embodiments with a fifth pump disclosed in the application as filed comprised a third pump between the first pump and the filter. The omission of this last feature added subject-matter.

Clarity

The feature "when one pump halts for any reason, stopping the pumping of the other pumps, wherein the stops of blood pump (14) and anticoagulant pump (24) are delayed after the other pumps have stopped" in claim 1 was unclear, since the person skilled in the art was left in doubt whether the term "of the other pumps" referred to all the other pumps mentioned in the claim or to all the other pumps of any hemofiltration system falling within the scope of the claim.

Inventive step

The subject-matter of claim 1 did not involve an inventive step starting from D1 as closest prior art. In the written procedure the appellant also argued that the claimed system was obvious starting from D2, D3, D7 or D8.

The feature of claim 1 "wherein when one pump halts for any reason, the other pumps also stop pumping, wherein the stops of blood pump (14) and anticoagulant pump (24) are delayed after the other pumps have stopped" was a mere method feature, which was not limiting for the claimed subject-matter, directed to a system. In the written procedure the appellant had submitted that for this reason the claimed subject-matter was not novel.

If it was considered that this feature limited the scope of the claim, its subject-matter was not inventive starting from D1 or D2. Each of D1 and D2 disclosed all the other features of claim 1.

The distinguishing feature solved the problem of increasing the safety of the blood treatment performed by the claimed system.

D1 itself suggested that the blood pump and the anticoagulant pump should be regulated together (page 5, lines 16 to 22, page 6, lines 22 to 27, and claim 46).

D3 (paragraphs [0009] and [0013]), D4 (Figure, column 1, lines 45 to 47, and column 2, line 65 to column 3, line 2) and D7 (Figure and last paragraph of the description) disclosed that calcium played an important role for the coagulation of blood and that in a blood treatment system a solution containing calcium and magnesium should be introduced after the blood filter of the system.

D5 and D6 disclosed hemofiltration systems in which a substitution fluid containing calcium and magnesium was introduced after the hemofilter (D5, pages 401 and 402, and D6, table 37.4 on page 478).

D8 was an instruction manual of a blood treatment system which had been made available to the public before the priority date of the patent. It was highly relevant and should be admitted into the proceedings. According to page 29, point 3.6, the actuation of a button "Behandlung Start/Stop" interrupted a blood treatment by stopping a filtration pump, a pre-dilution

pump and a post-dilution pump, while a blood pump continued running. Since page 30 disclosed that for the stopping of an anticoagulant pump the option "Spritzenwechsel" was foreseen, implicitly the anticoagulant pump continued running together with the blood pump upon actuation of the button "Behandlung Start/Stop". Hence, D8 disclosed the distinguishing feature.

It followed that the person skilled in the art would arrive at the subject-matter of claim 1 in an obvious way starting from D1 or D2, in combination with each other, the common general knowledge, D3, D4, D5, D6, D7 and/or D8.

Similarly, the subject-matter of claim 1 was not inventive starting from the combination of D3 or D7 with D1 or D2, in view of the teaching of D2, D3, D4 or D8.

The subject-matter of claim 1 was not inventive either, when the person skilled in the art started from D8. This document disclosed all the claimed features except the fourth pump for introducing a solution containing calcium and magnesium into the blood. This distinguishing feature, however, was taught by each of D1 to D7.

VI. The respondent's arguments, where relevant to the present decision, may be summarised as follows:

Sufficiency of disclosure

Considering the disclosure of the patent as a whole with a mind willing to understand, the person skilled in the art would interpret the feature of claim 6

"wherein a processing unit computes the amount of substitution fluid introduced in the blood from the weight measured by the scale" to refer to the fluid to be introduced in the blood, and not to the fluid already introduced. This latter alternative would make no technical sense.

As regards the feature of claim 6 "wherein the processing unit controls the flow rate of the third pump and the fourth pump to introduce the computed amount of substitution fluid to the blood", the application as filed (paragraph [0047]) explained that the flow through the third pump, which was a substitution fluid pump, and through the fourth pump, which was a calcium/magnesium pump, were adjusted precisely to each other.

It followed that the subject-matter of claim 6 was sufficiently disclosed.

Added subject-matter

The feature of claim 1 "wherein the fourth pump (16) is coupled to the return line (2) and the third pump (23) is coupled to the access line (1)" was based on claim 4 and paragraph [0051] of the application as filed.

Clarity

The term "of the other pumps" in claim 1 was clear. The person skilled in the art would understand it to mean all the pumps of any hemofiltration system according to the claim definition, except the pump that had stopped for any reason.

Inventive step

The feature of claim 1 "wherein when one pump halts for any reason, the other pumps also stop pumping, wherein the stops of blood pump (14) and anticoagulant pump (24) are delayed after the other pumps have stopped" was a limiting functional feature, which was not disclosed in any of D1 to D8 relied upon by the appellant. D8 should not be admitted into the proceedings under Article 12(4) RPBA, as it had been filed late without any justification.

The distinguishing feature favorably allowed the return line and the return catheter of the claimed hemofiltration system to fill with blood containing citrate and avoid clotting. It solved the problem of providing an improved safety when in use.

It followed that the subject-matter of claim 1 was inventive.

Reasons for the Decision

1. The invention

The invention relates to a hemofiltration system, in particular for performing a Continuous Renal-Replacement Therapy (CRRT), indicated for critically ill patients (paragraphs [0003] to [0011] of the patent).

CRRT is a kind of slow and continuous dialysis therapy, which is better tolerated than the traditional dialysis as it does not involve sudden changes in the blood which may cause cardiovascular instability. Continuous

Veno-Venous Hemofiltration (CVVH), Continuous Arterio-Venous Hemofiltration (CAVH), Continuous Veno-Arterial Hemofiltration (CVAH), Continuous-VenoVenous-Hemo-DiaFiltration (CVVHD or CVVHDF) and Continuous-Arterio-VenousHemo-DiaFiltration (CAVHD or CAVHDF), mentioned in paragraphs [0003] and [0004] of the patent are all special kinds of CRRT.

A system according to claim 1 is schematically depicted in Figures 3 and 4 reproduced below.

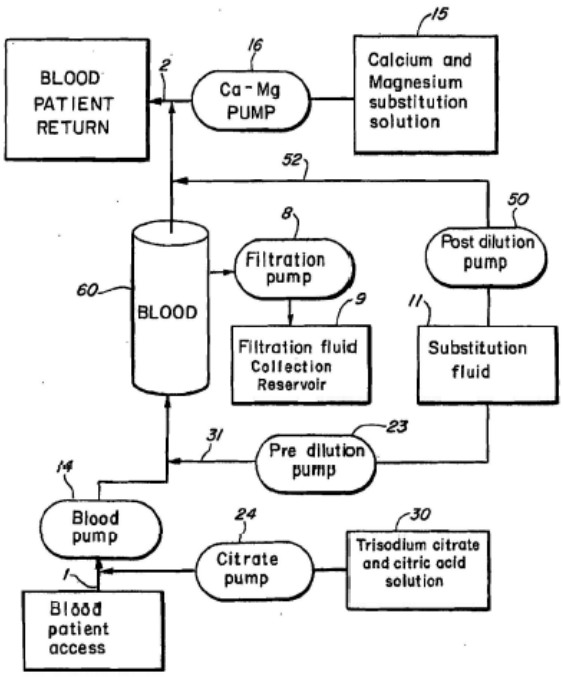


FIG. 3

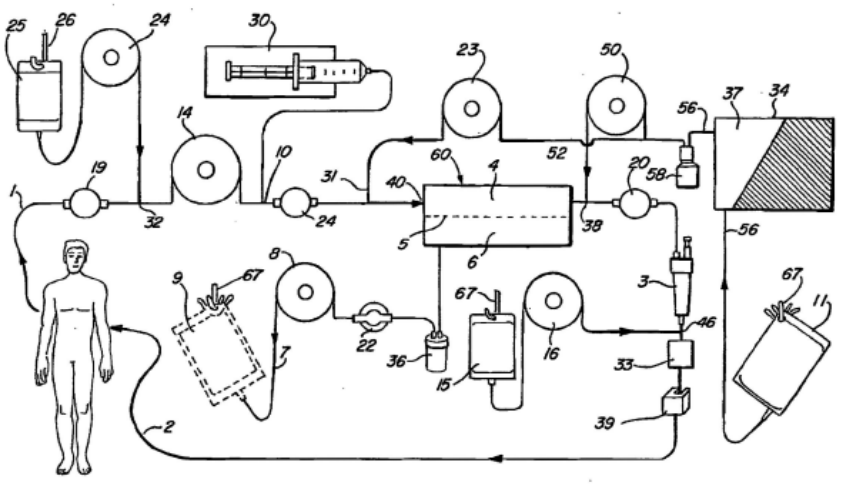


FIG. 4

The hemofiltration system comprises an access line (1) for carrying blood from the patient to a blood filter (60), a return line (2) for carrying blood from the blood filter (60) back to the patient, a first pump (14) for pumping blood through the access line, a second pump (24) for introducing an anticoagulant solution into the blood traveling through the access line, a third pump (23) for introducing substitution fluid into the blood, a fourth pump (16) for introducing a calcium and magnesium solution into the blood, a fifth pump (50) for introducing substitution fluid into the blood travelling through the return line, and a processing unit for controlling the flow rates of the first to fourth pumps. When one pump halts for any reason, the other pumps also stop pumping, wherein the stops of the blood pump and the anticoagulant pump are delayed after the other pumps have stopped.

According to the patent (paragraph [0054]) this is done to fill the return line with blood containing anticoagulant, to avoid the risk of clotting inside

this line when the blood is not circulating.

2. Main request - sufficiency of disclosure

2.1 The appellant argued that the feature of claim 6 "wherein the processing unit (72) computes the amount of substitution fluid introduced in the blood from the weight measured by the scale" was not sufficiently disclosed, in essence because it would be impossible to compute the amount of the fluid already introduced in the blood. However, what the processing unit has to compute according to the claim is not the substitution fluid already introduced, but the fluid to be introduced. As indicated by the Board in the communication of 17 March 2020, this is clearly derivable from the subsequent passage of the claim "wherein the processing unit (72) controls the flow rate of the third pump (23) and the fourth pump (16) **to introduce the computed amount of substitution fluid** to the blood" (emphasis added). How this is done is clearly disclosed in paragraphs [0046], [0056] and [0057] of the patent.

2.2 As regards the feature of claim 6 according to which the processing unit controls the third pump and the fourth pump to introduce the computed amount of substitution fluid into the blood, the Board notes that the fifth pump - and not the fourth pump - is defined as a further pump for pumping substitution fluid in the preceding claims. However, this may result, at most, in a clarity problem which was already present in the claims as granted. The Board has no power to examine such a potential lack of clarity in opposition appeal proceedings (G 3/14, Order). How the processing unit controls the flow rates of the third, fourth and fifth pump is explained in detail in paragraphs [0056] and

[0057] of the patent.

2.3 In conclusion, the subject-matter of claim 6 is sufficiently disclosed. Hence, the ground for opposition under Article 100(b) EPC does not prejudice the maintenance of the patent on the basis of the claims found allowable by the Opposition Division.

3. Added subject-matter

3.1 The appellant argued that the feature of claim 1 "wherein the fourth pump (16) is coupled to the return line (2) and the third pump (23) is coupled to the access line (1)", which was derived from claim 4 as originally filed, added subject-matter because claim 4 additionally defined that the third pump was coupled to the access line between the first pump and the filter.

However, as correctly noted by the Opposition Division in the impugned decision (point 3 of the "grounds for the decision"), according to page 22, lines 13 to 15, of the application as filed "in one embodiment, the pre-dilution line 31 is connected to the access line l pre-blood pump 14". It means that, according to this passage, the third pump can be coupled to the access line in any position, either before or after the blood pump.

3.2 The appellant's argument that the passage on page 22, lines 13 to 15, did not concern a system additionally comprising a fifth pump is not accepted. First, the passage belongs to the detailed descriptions of Figures 3 and 4, which include a fifth pump, and mentions the reference signs appearing in those figures. Moreover, the presence of a fifth pump for introducing substitution fluid in the return line as

stipulated by the claim is obviously in no technical relationship with the exact position of the third pump in the access line.

3.3 In conclusion, the subject-matter of claim 1 does not extend beyond the content of the application as filed. It follows that the ground for opposition under Article 100(c) EPC does not prejudice the maintenance of the patent on the basis of the claims found allowable by the Opposition Division.

4. Clarity

The appellant argued that the feature of claim 1 "when one pump halts for any reason, the other pumps also stop pumping, wherein the stops of blood pump (14) and anticoagulant pump (24) are delayed after the other pumps have stopped" was unclear. The person skilled in the art was left in doubt whether the term "of the other pumps" referred to all the other pumps mentioned in the claim or to all the other pumps of any hemofiltration system falling within the scope of the claim.

The Board notes that the patent as a whole teaches that the claimed stopping of the pumps is intended to handle a situation of malfunction of the hemofiltration system, by stopping the treatment. The term "of the other pumps" can therefore only refer to all the pumps of a hemofiltration system falling within the scope of the claim, except the pump which has already stopped, irrespective of whether all these pumps have explicitly been mentioned in the claim. This makes technical sense, since letting one pump run when the blood pump has already stopped may dangerously change the composition of the blood present in the system. Hence,

in a situation of malfunction, all the pumps of the hemofiltration system have to stop. This construction of the claim is consistent with the description, paragraph [0054], which specifically concerns the feature objected to, explains that in such a system the infusion of all fluids are regulated and controlled together and goes on to explain that "when one pump halts for any reason, the stops of blood pump 14 and anticoagulant pump 24 are preferably delayed by, for example, about 10 seconds after the other pumps have already stopped".

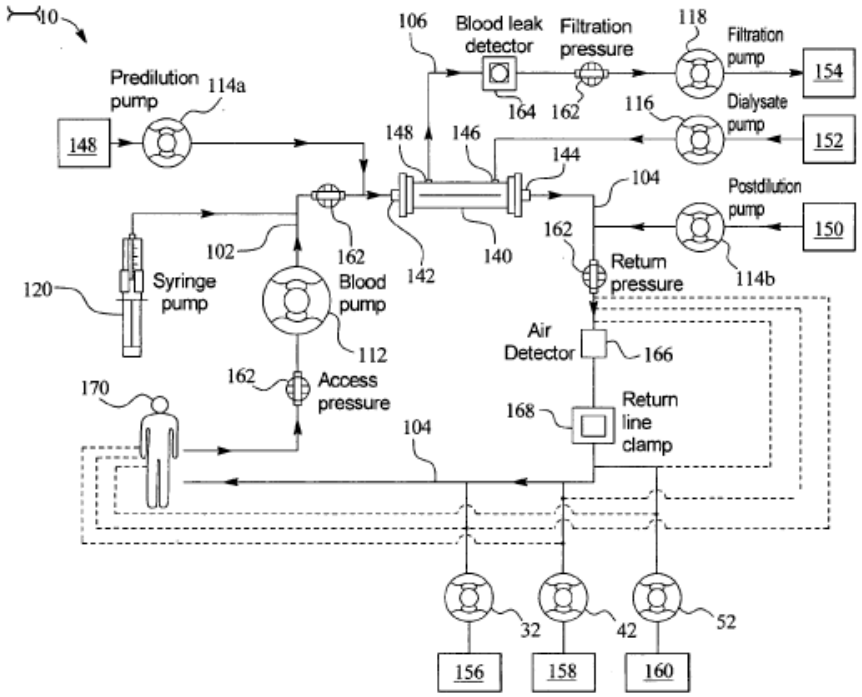
It follows that claim 1 meets the requirements of clarity (Article 84 EPC).

5. Inventive step

5.1 The appellant argued against inventive step of the subject-matter of claim 1, starting from D1 or D2.

5.1.1 D1 concerns a system that can be employed for performing hemofiltration in the context of CRRT (page 8, lines 16 to 30). Such a system is schematically depicted in Figure 3 reproduced below.

FIG. 3



D1 discloses an access line (102) with a blood pump (112), an anticoagulant pump (120), a blood filter (140), a return line (104), a pump (32) suitable for introducing a calcium solution into the blood, a substitution pump (114a) for introducing substitution fluid from a supply of substitution fluid into the blood traveling through the access line, and a substitution pump (114b) for introducing substitution fluid from a supply of substitution fluid into the blood traveling through the return line (page 14, line 22 to page 15, line 11). These elements are controlled by a processing unit (70, Figure 2).

5.1.2 D2 concerns a system that can be employed for performing hemofiltration in intensive therapy (paragraphs [0002] and [0010]). Such a system is schematically depicted in Figure 1 reproduced below.

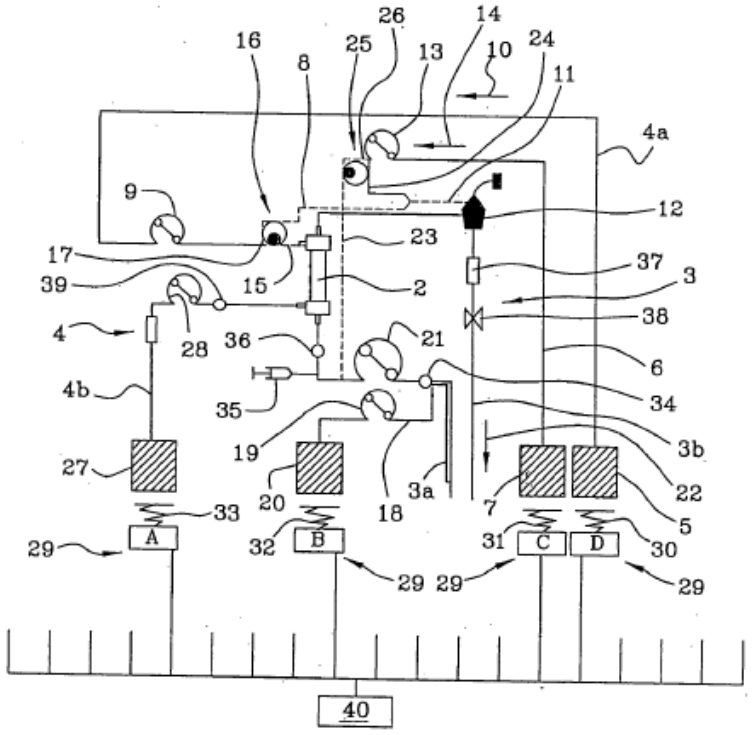


FIG 1

D2 discloses an access line (3a) with a blood pump (21), an anticoagulant syringe (35) for introducing an anticoagulant into the blood, a blood filter (2), a return line (3b), a pump (9) suitable for introducing a calcium solution into the blood (paragraphs [0149] to [0151]), a pump (19) for introducing substitution fluid from a supply of substitution fluid into the blood traveling through the access line (paragraphs [0046] and [0047]) and a further pump (13) for introducing substitution fluid from a supply of substitution fluid into the blood traveling through the return line (paragraph [0075]). These elements are controlled by a processing unit (40, paragraph [0105]).

5.1.3 Neither D1 nor D2 disclose that when one pump halts for any reason, the other pumps also stop pumping, wherein the stops of blood pump and anticoagulant pump are delayed after the other pumps have stopped.

This feature is a functional feature, which prescribes what the claimed system must be capable of doing under a certain condition of use. Hence, it has a limiting effect on the scope of the claim.

As the respondent submitted, the patent (paragraph [0054]) explains that this distinguishing feature allows to fill the return line with blood containing anticoagulant, to avoid the risk of clotting inside this line when the blood is not circulating.

This solves the objective technical problem of increasing the safety of a patient under treatment, in case the treatment is continued after the stop of all pumps, for instance in case of a malfunction.

5.1.4 Although D1 discloses that the blood pump and the anticoagulant pump should be regulated together, as noted by the appellant, this concerns a condition of normal use, not the situation wherein the pumps stop as in case of a malfunction. Consequently D1 does not address the objective technical problem mentioned above.

5.1.5 The appellant also pointed to D3 to D7. Although these documents may teach the administration of a solution containing calcium and magnesium and its effects in connection with blood treatment systems employing citrate as an anticoagulant, as argued by the appellant, they do not do it in relation to the objective technical problem. Moreover, the claimed solution to that problem is not taught by these documents, since none of them discloses said distinguishing features.

The appellant's reference to the common general

knowledge is of little relevance, since no proof was provided that the distinguishing feature had commonly been implemented for the solution of the objective technical problem.

5.1.6 The appellant also referred to D8. This document was filed with the statement of grounds of appeal and is directed against the subject-matter of an independent claim which was present in requests only filed by the proprietor one month before the oral proceedings before the Opposition Division (auxiliary requests 4 and 5 at that time). Those requests were not allowed by the Opposition Division, which allowed a further request comprising that claim as the only independent claim during the oral proceedings. Under these circumstances the Board made use of its discretion under Article 12(4) RPBA 2007 and admitted D8 into the proceedings.

D8 concerns a system for CRRT, in particular hemofiltration, comprising, inter alia, a blood pump and an anticoagulant pump (page 9). On page 29, referred to by the appellant, it is explained that pressing a button "Behandlung Start/Stop" activates a function of the system in which a pre-dilution pump, a post-dilution pump and a filtrate pump are stopped while the blood pump continues working. On page 30, also referred to by the appellant, it is disclosed that a syringe containing an anticoagulant can be replaced activating a further function of the system. This implies an interruption of the administration of the anticoagulant. However, there is no disclosure in D8 that these functions are in any relation to each other. In particular, there is no disclosure in D8 that the anticoagulant delivery can only be interrupted by activating the function of the syringe replacement.

Moreover, there is no disclosure either that when the function "Behandlung Start/Stop" is activated, the anticoagulant syringe continues delivering anticoagulant. The appellant's argument that it would be implicit or obvious for the person skilled in the art to continue the delivery of anticoagulant is not convincing. Since the blood pump continues running when the function "Behandlung Start/Stop" is activated, the delivery of anticoagulant is of no technical importance. Hence, D8 does not disclose the distinguishing feature of claim 1. It does not address the objective technical problem either.

5.1.7 It follows that starting from D1 or D2, in combination with each other, the common general knowledge, D3, D4, D5, D6, D7 and/or D8 the person skilled in the art would not arrive at the subject-matter of claim 1 in an obvious way.

5.2 The appellant also argued starting from D3, D7 or D8. However, as explained, these documents do not disclose the distinguishing feature identified above. That feature is not disclosed in relation to the objective technical problem by any of the cited prior art, either. Hence, the person skilled in the art would not arrive at the subject-matter of claim 1 in an obvious way starting from any of these documents.

5.3 In conclusion, the subject-matter of claim 1 - and a fortiori of dependent claims 2 to 7 - of the request found allowable by the Opposition Division involves an inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated