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Datasheet for the decision of 21 July 2020

Case Number: T 2562/18 - 3.2.02

Application Number: 11153847.6

Publication Number: 2324871

IPC: A61M1/36

Language of the proceedings: EN

Title of invention:
Citrate anticoagulation system for extracorporeal blood treatments

Patent Proprietor:
Nikkiso Co., Ltd.

Opponents:
B. Braun Avitum AG
Fresenius Medical Care AG & Co. KGaA

Headword:

Relevant legal provisions:
EPC Art. 54(1), 54(2), 56, 76(1), 84, 100(b), 123(2)

Keyword:

Grounds for opposition - insufficiency of disclosure (no)
Novelty - main request (no) - auxiliary request 2 (yes)
Claims - clarity - auxiliary requests 1 and 2 (yes)
Amendments - extension beyond the content of the original application and the parent application as filed - auxiliary request 1 (yes) - auxiliary request 2 (no)
Inventive step - auxiliary request 2 (yes)

Decisions cited:

T 0404/16

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2562/18 - 3.2.02

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

Appellant: (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 1)	B. Braun Avitum AG Schwarzenberger Weg 73-79 34212 Melsungen (DE)
Representative:	Winter, Brandl, Fürniss, Hübner, Röss, Kaiser, Polte - Partnerschaft mbB Patent- und Rechtsanwaltskanzlei Alois-Steinecker-Straße 22 85354 Freising (DE)
Appellant: (Opponent 2)	Fresenius Medical Care AG & Co. KGaA 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 September 2018 concerning the maintenance of European Patent No. 2324871 in amended form

Composition of the Board:

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

Summary of Facts and Submissions

I. The patent proprietor and the opponents have appealed against the Opposition Division's decision, posted on on 18 September 2018, that, account being taken of the amendments according to auxiliary request 1 then on file, European patent No. 2 324 871 and the invention to which it related met the requirements of the EPC.

The patent is derived from a divisional application of European patent application No. 06 838 361.1 ("the parent application"), which is the object of appeal case T 404/16. It was opposed on the grounds of added subject-matter, insufficient disclosure, exception to patentability, lack of novelty and lack of inventive step.

II. Oral proceedings took place on 21 July 2020.

The appellant/patent proprietor ("the proprietor") requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request filed on 13 September 2017 or, as an auxiliary measure, on the basis of one of auxiliary requests 1 to 5 filed with letter dated 16 May 2019.

The appellants/opponents ("the opponents") requested that the decision under appeal be set aside and the patent be revoked.

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

D2: WO-A-2004/069311
D2a: US-A-2005/0011823
D10: US-A-5,910,252
D11: US-A-2005/0085760
D11a: WO-A-2005/039671
D31: US-A-4,500,309
D32: "Gebrauchsanweisung Automatischer Akutbilanzmonitor AQUARIUS - Für Platinum Software Version 4", Edwards Lifesciences, May 2004

IV. **Claims 1, 7 and 9 of the main request** read as follows:

"1. A machine-readable storage medium embodying instructions that may be performed by one or more processors, the instructions comprising:

instructions for pumping blood from a patient's blood stream into an access line (1);
instructions for introducing an anticoagulant solution into the pumped blood;
instructions for filtering the pumped blood;
instructions for delivering the pumped blood from the filtering step to a return line (2);
instructions for returning the blood back to the patient's blood stream;
instructions for introducing a calcium solution into the filtered blood traveling through the return line (2), wherein the calcium solution includes magnesium
characterized by
instructions for introducing a substitution fluid from a supply of substitution fluid (11) into the

pumped blood traveling through the access line (1) using a first pump (23) coupled to the access line (1);
instructions for introducing the substitution fluid from the supply of substitution fluid (11) into the filtered blood traveling through the return line (2) using a second pump (50) coupled to the return line (2)."

"7. The machine-readable storage medium according to any one of the preceding claims, further comprising:

instructions for detecting air bubbles from the blood introduced with the substitution fluid; and instructions for removing air bubbles from the blood before it is returned into the patient's blood stream."

"9. The machine-readable storage medium according to any one of the preceding claims, wherein the substitution fluid is a dialysis solution."

Claim 1 of auxiliary request 1 reads as follows (amendments over claim 1 of the main request highlighted by the Board):

"A machine-readable storage medium embodying instructions that may be performed by one or more processors, the instructions comprising:

instructions for pumping blood from a patient's blood stream into an access line (1) by the driving force of a blood pump (14);
instructions for introducing an anticoagulant solution into the pumped blood by an anticoagulant pump (24);

instructions for filtering the pumped blood;
instructions for delivering the pumped blood from the filtering step to a return line (2);
instructions for returning the blood back to the patient's blood stream;
instructions for introducing a calcium solution into the filtered blood traveling through the return line (2), wherein the calcium solution includes magnesium
characterized by
instructions for introducing a substitution fluid from a supply of substitution fluid (11) into the pumped blood traveling through the access line (1) using a first pump (23) coupled to the access line (1);
instructions for introducing the substitution fluid from the supply of substitution fluid (11) into the filtered blood traveling through the return line (2) using a second pump (50) coupled to the return line (2);
instructions for, 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."

Claim 1 of auxiliary request 2 reads as follows (amendments over claim 1 of auxiliary request 1 highlighted by the Board):

"A machine-readable storage medium embodying instructions that may be performed by one or more processors, the instructions comprising:

instructions for controlling a blood pump (14), a filtrate pump (8), a first post-dilution pump (50),

a pre-dilution pump (23), a dialysate pump, an anticoagulant pump (24) and a second post-dilution pump (16);
instructions for pumping blood from a patient's blood stream into an access line (1) by the driving force of ~~a~~ the blood pump (14);
instructions for introducing an anticoagulant solution into the pumped blood by ~~an~~ the anticoagulant pump (24);
instructions for filtering the pumped blood;
instructions for delivering the pumped blood from the filtering step to a return line (2);
instructions for returning the blood back to the patient's blood stream;
instructions for introducing a calcium solution into the filtered blood traveling through the return line (2) by the second post-dilution pump (16), wherein the calcium solution includes magnesium
characterized by
instructions for introducing a substitution fluid from a supply of substitution fluid (11) into the pumped blood traveling through the access line (1) using ~~a first pump~~ the pre-dilution pump (23) coupled to the access line (1);
instructions for introducing the substitution fluid from the supply of substitution fluid (11) into the filtered blood traveling through the return line (2) using ~~a second pump~~ the first post-dilution pump (50) coupled to the return line (2);
instructions for, 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."

Claims 2 to 9 are dependent claims. Claims 7 and 9 read as claims 7 and 9 of the main request.

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

Main request - Sufficiency of disclosure

Claim 1 of the main request was directed to a storage medium embodying instructions for performing method steps involving the conveyance of fluids in a blood treatment machine. The patent disclosed the technical means employed for carrying out those method steps. In particular, the steps of filtering the pumped blood, delivering the pumped blood to the return line and returning the blood back to the patient's blood stream were carried out by the cooperation of appropriately regulated pumps of the machine. The claimed instructions contained specific information about the respective method steps. In particular, they contained information about the fluid to be conveyed. How to formulate the specific instructions for conveying the specific fluids, taking into account their nature, such that the instruction could suitably be employed in an algorithm for an electronic control unit of the blood treatment machine, was within the competence of the person skilled in the art of software development.

Claim 7 did not require that air bubbles were differentiated with regard to their origin. Air bubbles introduced with the substitution fluid were detected and removed. If air bubbles having other origins were present, they would also be detected and removed.

Claim 9 defined the nature of a fluid to be conveyed in the blood treatment machine. How to formulate specific

instructions for suitably conveying this fluid was within the competence of the person skilled in the art of software development.

Main request - novelty

The subject-matter of claim 1 of the main request was novel over D2/D2a and D11/D11a.

These documents did not disclose the administration of a calcium solution including magnesium. The presence or absence of magnesium in the calcium solution had a direct impact on the electrolyte balance of the patient. The presence of magnesium compensated for a part of the magnesium removed in the filtration fluid and allowed to fully restore the patient's electrolyte balance to a physiological state. Instructions for adding calcium solution containing magnesium had to contain very specific information about the solution that was conveyed. Hence, they were different from those needed if the calcium solution did not contain magnesium.

D2/D2a and D11/D11a did not disclose either that the two pumps for introducing substitution fluid pumped from the same fluid supply, as specified in claim 1. Introducing fluid with two pumps from a single supply required different instructions which had to take into account the properties of the supply, such as the quantity of fluid present in the supply.

Auxiliary request 1 - added subject-matter

In claim 1, the feature "instructions for, 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" was based on paragraph [0056] of the application as filed. The claim had to be understood to imply that the calcium solution was delivered by a pump, as shown in particular in Figures 3 and 4 of the patent. The patent did not teach that the calcium solution could be delivered by any means other than a pump. Even if such a pump were not implied by the claim wording, the person skilled in the art would understand the claim wording to mean that the supply of calcium solution was stopped when one pump of the blood treatment machine stopped for any reason.

In the written proceedings the following arguments were also raised:

A basis for claiming a machine readable storage medium was present in paragraph [0067] of the parent application and paragraph [0068] of the application as filed.

The general definition of substitution fluid administered from the same supply in claim 1, without specifying that the fluid did not include calcium and magnesium ions, did not amount to an unallowable intermediate generalisation. Claims 2 and 3 of the application as filed generally disclosed a substitution fluid without specifying its nature. Whether this fluid was taken from one single supply had no technical relationship with the ion content of the fluid.

The features regarding pre- and post-dilution were not disclosed only in connection with hemofiltration in the application as filed. There was no strict separation between hemofiltration and other blood treatments, as derivable in particular from paragraphs [0043], and

[0051] of the application as filed. Accordingly, paragraph [0055] of the application as filed disclosed that the pre- and post-dilution were the same dialysate - i.e. dialysis - solution, which could be employed for any of the disclosed blood treatments, including hemofiltration. It followed that claim 1 and claim 9 did not contain any added subject-matter in this respect.

Auxiliary request 2 - Novelty and inventive step

D2/D2a and D11/D11a did not disclose that when one pump halted for any reason the blood pump and the anticoagulant pump were stopped with a delay after the other pumps had already stopped. D10, D31 and D32 did not show this feature either.

By providing that all other pumps stop, but the stops of the blood pump and the anticoagulant pump are delayed, the return line and the return catheter were allowed to fill with blood containing citrate. This avoided clotting, as explained in paragraph [0056] of the application as filed. In turn, this addressed the objective technical problem on increasing patient safety.

It followed that the subject-matter of claim 1 of auxiliary request 2 was novel and inventive.

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

Main request - Sufficiency of disclosure

The invention as defined in claims 1 and 9 was not sufficiently disclosed, since it was not possible to

provide instructions in a storage medium which, alone, made it possible to deliver a specific solution. It was not disclosed how, on the basis of the instructions, the machine for carrying them out could recognise the nature of the solution to be administered. Providing such instructions went beyond the normal competence of the person skilled in the art.

The patent did not disclose the specific technical means employed for carrying out the instructions for filtering the pumped blood, delivering it to a return line and returning it to the patient. These steps were simply a result of a method of treatment carried out by a blood treatment machine, and did not involve any individual technical means for receiving those instructions. It was therefore not possible to put the instructions into practice.

The subject-matter of claim 7 was not sufficiently disclosed either. In particular, it was not disclosed how the origin of the air bubbles present in the blood could be determined. Moreover, the air trap for removing air bubbles disclosed in the patent functioned without any control by an electronic unit. It was therefore not possible to put into practice the instructions defined in claim 7.

Main request - novelty

The subject-matter of claim 1 of the main request was not novel over D2/D2a and D11/D11a.

Each of these documents disclosed the administration of an electrolyte solution which could contain calcium and/or magnesium. The instructions for operating a pump intended to deliver such a solution did not depend on

the specific nature of the solution, in particular whether the electrolyte solution contained magnesium in addition to calcium or not. The pump could not recognise the solution pumped.

D2/D2a and D11/D11a also disclosed instructions for introducing substitution fluid into the blood travelling through the access line and into the blood travelling through the return line. It was irrelevant, as far as the nature of the instructions was concerned, whether the substitution fluid was drawn from a single container or from two distinct containers.

Auxiliary request 1 - added subject-matter

The feature "instructions for, 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" had been extracted from paragraph [0055] of the parent application as filed. However, this paragraph contained other features omitted from the claim, such as the features that all pumps were controlled together and that all pumps had to run if the blood pump was running. Hence, a further unallowable intermediate generalisation was present.

According to claim 1 the administration of the calcium solution, which was not necessarily performed by a pump, did not have to stop before the stop of the blood pump and the anticoagulant pump. However, the parent application as filed taught that this was the case in order to avoid clotting during the halting of the blood pump (paragraph [0055] of the parent application as filed). Omitting this feature in claim 1 amounted to an unallowable intermediate generalisation.

In the written procedure the opponents also raised the following points:

The term "storage medium" employed in paragraph [0067] of the parent application as filed was in relation to the specific embodiments. Its introduction into claim 1 amounted to an unallowable intermediate generalisation.

The parent application as filed taught (paragraph [0048]) that the substitution fluid did not include calcium and magnesium ions. Omitting this information in claim 1 amounted to an unallowable intermediate generalisation.

The embodiments depicted in Figures 3 and 4 of the parent application as filed were hemofiltration devices. Omitting this definition in claim 1 was not allowable, since the subject-matter of the claim extended to other blood treatment devices. Such a generalisation had no basis in the parent application as filed.

The features recited in claim 9 were based on paragraph [0054] of the parent application as filed, which related to a dialysis system. Such a system had nothing to do with the hemofiltration devices of the embodiments of Figures 3 and 4, on which the claimed machine-readable medium was based. Hence, there was no basis for the combination of the features recited in claim 9 with those of claim 1. Moreover, only some of the features of the combination disclosed in paragraph [0054] had been claimed. This amounted to a further unallowable generalisation.

Auxiliary request 2 - Novelty and inventive step

D2/D2a and D11/D11a anticipated all the features of claim 1 of auxiliary request 2 except the last feature concerning the stopping of the pumps when one pump halted for any reason. This last feature concerned the handling of malfunctions, and was in no technical relation to the other features of the claim, which generally concerned the layout of a blood treatment system. In such a case it was the established case law that the combination of more documents could prejudice the novelty of the claim. D10, column 17, lines 21 to 30 and column 19, lines 52 to 62 disclosed a condition of malfunction of a blood treatment system in which the pumps were stopped as claimed. Even if those passages did not explicitly mention the stop of an anticoagulant pump, while the blood pump was still running, this was implicit for the person skilled in the art. The combination of the teaching of D10 with the disclosure of D2/D2a or D11/D11a deprived the subject-matter of claim 1 of novelty.

The combination of D2/D2a or D11/D11a with D10 and/or D31 rendered obvious the subject-matter of claim 1 in view of the problem of ensuring the safety of the patient when one pump stopped working. D31 additionally taught that in a blood treatment system an anticoagulant pump containing citrate should be shut down after a period of time following the shut down of the blood pump (column 5, lines 30 to 42) in order to full the return line with blood and anticoagulant to avoid the risk of clotting.

In the written procedure the opponents also submitted the following arguments:

Also the combination of D2/D2a or D11/D11a with D32 rendered obvious the subject-matter of claim 1. According to page 29, point 3.6, of D32 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, D32 disclosed the distinguishing feature of claim 1 with respect to D2/D2a or D11/D11a.

The subject-matter of claim 1 of auxiliary request 2 was not inventive when starting from D32. This document disclosed all the claim features except the administration of a calcium solution containing magnesium by the means of a pump. The administration by a pump of such an electrolyte solution was however known from several documents of the state of the art and did not involve an inventive step in view of the problem of optimising the electrolyte balance in the patient's blood.

Reasons for the Decision

1. The invention

The invention relates to a machine-readable storage medium embodying instructions relating to a blood treatment therapy.

Such a therapy could be a Continuous Renal-Replacement Therapy (CRRT), indicated for critically ill patients. 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.

The instructions defined in claim 1 of the main request may be carried out, according to the patent, by an extracorporeal blood treatment system as schematically depicted in Figures 3 and 4 reproduced below.

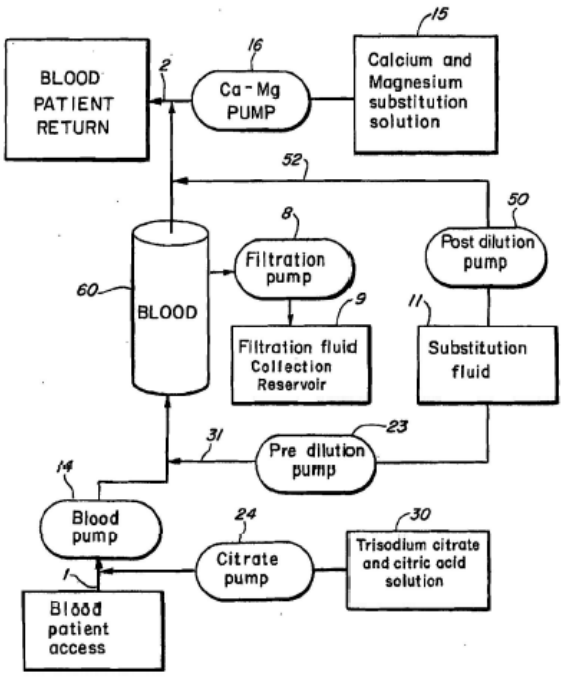


FIG. 3

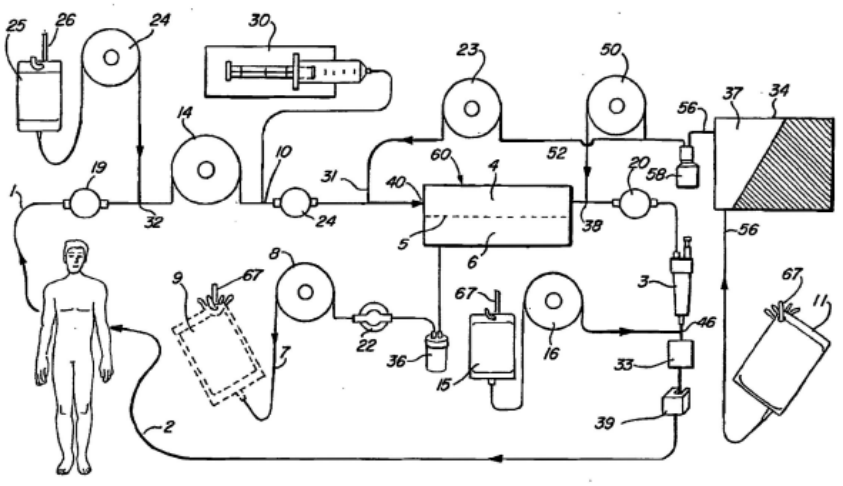


FIG. 4

The instructions comprise instructions for pumping blood from a patient into an access line (access line 1, by means of blood pump 14), introducing an anticoagulant solution into the blood (at inlet port 32, by means of anticoagulant pump 24), filtering the blood (in artificial kidney 60), delivering the blood to a return line (return line 2, from artificial kidney 60) and then back to the patient, introducing a calcium solution including magnesium into the filtered blood traveling through the return line (at connection 46, by means of second post-dilution pump 16), introducing a substitution fluid into the blood using a first pump coupled to the access line (via pre-dilution line 31, by means of pre-dilution pump 23), and introducing the substitution fluid into the blood also using a second pump coupled to the return line (via post-dilution line 52, by means of first post-dilution pump 50).

The introduction of the substitution fluid and the calcium solution are intended to supplement the blood in order to compensate the loss of liquid and other constituents due to the filtration process and possibly to promote that process (substitution fluid introduced

in the access line). Controlling the administration of all these fluids is important so as not to have those sudden changes in the patient's blood, which make traditional dialysis not suitable for critically ill patients.

Claim 1 of auxiliary request 2 additionally specifies, in particular, that the anticoagulant solution and the calcium solution are to be introduced by respective pumps, and defines instructions for, when one pump halts for any reason, stopping the pumping of the other pumps, wherein the stops of the blood pump and the anticoagulant pump are delayed after the other pumps have stopped.

According to the patent (paragraph [0055]) 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 Claim 1 of the patent as granted is directed to a storage medium embodying instructions for performing certain method steps to be carried out by an electronically controlled blood treatment system.

2.2 What the claim requires is the suitability of such instructions for carrying out the respective method steps by means of a blood treatment system appropriately set up for this purpose. In other terms, there is no claim requirement that the instructions should enable the system to distinguish between possible fluids to be conveyed. Still, when the conveyance of a certain fluid is referred to, the instructions should enable the conveyance of this

specific fluid in view of the technical purpose of the blood treatment system, i.e. the performance of a suitable treatment of a patient. For example, the instructions for introducing an anticoagulant solution into the pumped blood should enable the introduction of such a solution from a source, the source being present in the system, at a time and at a flow rate which make it effective in the treatment without putting at risk the patient's health. These time and flow rate are well known to the person skilled in the art from the common general knowledge.

2.3 As the proprietor submitted, the patent discloses the technical means of an electronically controlled blood treatment system adapted to carry out the method steps defined in claim 1 on the basis of appropriate software instructions. These are, in particular, the pumps of the system as depicted in Figures 3 and 4. The opponents' argument that for some instructions - i.e. for filtering the pumped blood, delivering it to a return line and returning it to the patient - this was not the case is not convincing. It can be accepted that the patent may not disclose a single physical entity, such as a dedicated pump, for carrying out each of the claimed instructions. Still, each instruction may be carried out by the blood treatment system as a whole, in certain cases by the cooperation of more than one element of the system. For example, the delivery of blood to a return line with a system as depicted in Figure 3 will depend on the flow rates of blood pump 14, pre-dilution pump 23 and filtration pump 8, which can be controlled by specific instructions.

2.4 Hence, the Board concludes that the person skilled in the art can readily formulate the instructions for the respective purposes as defined in claim 1 on the basis

of the disclosure of the patent (in particular paragraphs [0058] to [0062]) and the common general knowledge.

2.5 For the same reasons, also the instructions defined in claim 9 can readily be formulated by the person skilled in the art.

2.6 As far as claim 7 is concerned, the opponents argued that the removal of air by the means of air traps 3 (Figure 4) worked without any control from a CPU. However, the patent additionally teaches that air can be removed with the aid of an air bubble detector (33) controlled by a monitoring system (paragraph [0052]). This amounts to a disclosure of a technical means adapted to carry out the method step defined in claim 7, on the basis of appropriate software instructions.

The opponents further argued that the patent did not disclose how to distinguish between air bubbles introduced with the substitution fluid and air bubbles of another origin. However, claim 7 simply defines instructions for detecting air bubbles introduced with the substitution fluid, without distinguishing the origin of the bubbles. Detecting all air bubbles (as taught in the patent) will inevitably detect the air bubbles introduced with the substitution fluid.

2.7 It follows that the ground for opposition of insufficient disclosure (Article 100(b) EPC) does not prejudice the maintenance of the patent on the basis of the main request.

3. Main request - novelty

The opponents argued on the basis of documents D2, D2a, D11 and D11a. D2 and D2a belong to the same patent family and have the same technical content. The same applies to D11 and D11a. For ease of reference the Board will only refer to D2a and D11 in the following.

3.1 D2a 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.

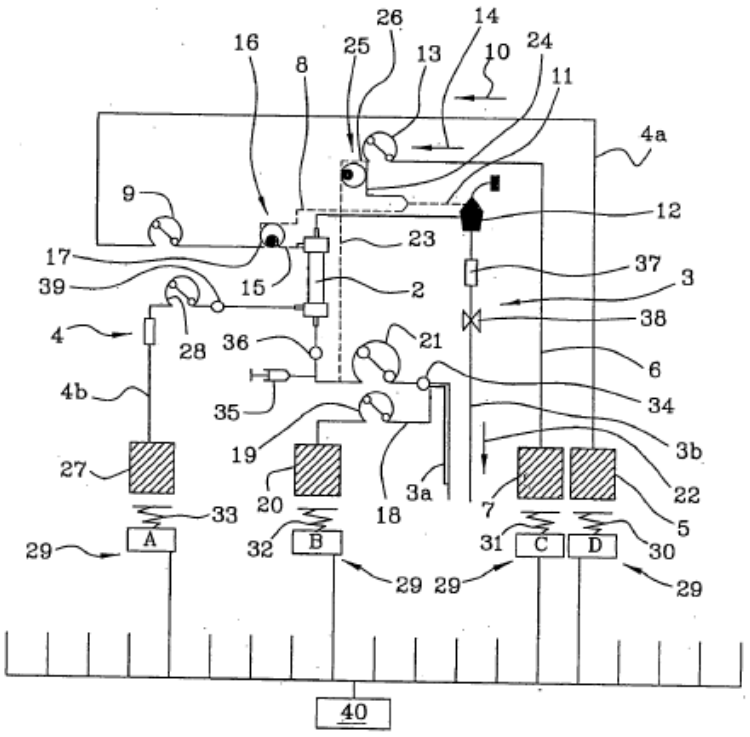


FIG 1

D2a 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 another 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]). It follows that the system of D2a must comprise a machine readable medium (RAM or ROM) comprising suitable instructions for the processing unit.

The proprietor argued that D2a did not disclose the administration of a calcium solution including magnesium. The Board agrees. D2a generally discloses the administration of an electrolyte solution containing "suitable substances (for instance calcium) for recovering the ion balance in the blood" when citrates are used as anticoagulants (paragraph [0149]).

However, claim 1 merely requires instructions suitable for introducing a generically defined "calcium solution including magnesium". In the absence of a more precise definition of the solution, for example the respective concentrations of calcium and magnesium, the Board concludes that instructions for introducing an electrolyte solution of the kind mentioned in D2a at times and at a flow rate which make the administration effective in the treatment without putting at risk the patient's health will also be suitable for administering, for the same purpose, an electrolyte solution according to the definition of claim 1. As a matter of fact, the description of the patent does not describe either how the claimed instruction could possibly differ from an instruction for introducing a

calcium solution as known from D2a.

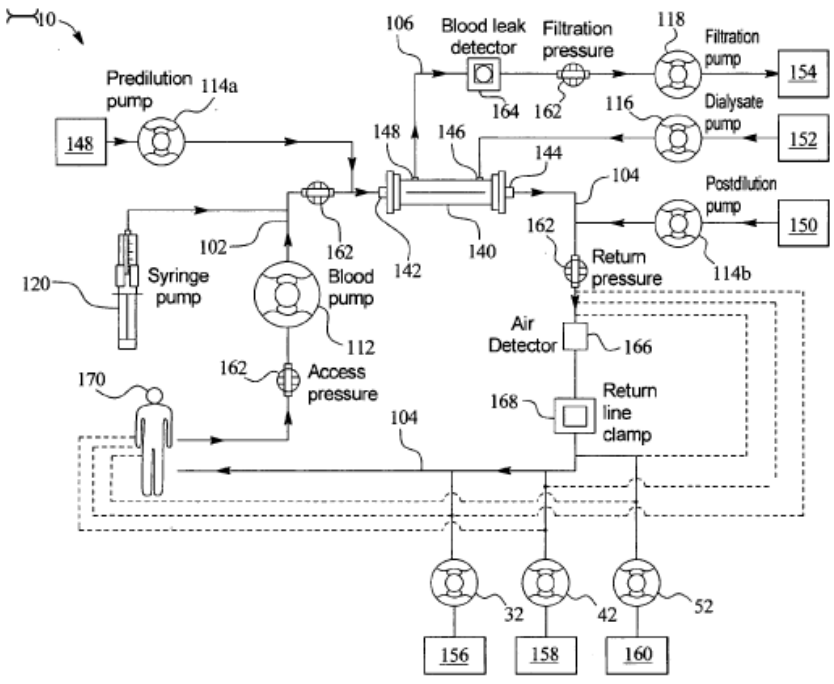
The proprietor also argued that D2a did not disclose two pumps for introducing substitution fluid which pumped from the same fluid supply.

However, this is irrelevant as far as the nature of the instructions suitable for introducing the substitution fluid are concerned. The time and the flow rate of the administration do not depend on where the fluid comes from, but are only related to the administration means, in particular pumps 19 and 13 of D2a.

The Board therefore concludes that D2a discloses all the features of claim 1 of the main request.

3.2 D11 concerns a system that can be employed for performing hemofiltration in the context of CRRT (paragraph [0035]). Such a system is schematically depicted in Figure 3 reproduced below.

FIG. 3



D11 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 an electrolyte solution into the blood (paragraph [0058]), a substitution pump (114a) for introducing substitution fluid from a supply of substitution fluid into the blood traveling through the access line (paragraph [0056]), and a substitution pump (114b) for introducing substitution fluid from another supply of substitution fluid into the blood traveling through the return line (paragraphs [0055] and [0056]).

These elements are controlled by a processing unit (70, Figure 2). It follows that the system of D11 must comprise a machine readable medium (RAM or ROM) comprising suitable instructions for the processing unit.

Pump 32 is suitable for administering a calcium and magnesium solution into the blood: paragraph [0018] discloses that infusions of calcium and magnesium (specific electrolyte solutions) can be administered, and paragraph [0058], discloses that pump 32, coupled to supply 156, can be used to administer, inter alia, electrolyte solutions.

Contrary to the proprietor's view, for the same reasons as those given with respect to D2a, D11 also anticipates instructions suitable for introducing a generically defined calcium solution including magnesium into the filtered blood traveling through the return line as required by claim 1.

For the reasons explained in view of D2a the fact that D11 does not disclose two pumps introducing

substitution fluid which pump from the same fluid supply does not represent a differentiating feature either.

It follows that the subject-matter of claim 1 of the main request also lacks novelty in view of D11.

3.3 As a consequence, the patent cannot be maintained on the basis of the main request for lack of novelty (Article 54(1) and (2) EPC).

4. Auxiliary request 1 - added subject-matter

Claim 1 of auxiliary request 1 is based mainly on claim 1 of the original application and claim 34 of the parent application as filed, in combination with page 17, lines 18 to 29, of the original application and paragraph [0055] of the parent application as filed as regards the feature "instructions for, 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".

4.1 The definition of the machine-readable medium being a "storage medium" is based on paragraph [0067] of the parent application and page 21, lines 4 to 16 of the original application as filed. These passages expressly refer to "the methods or algorithms described in connection with the embodiments disclosed herein". Hence they constitute a general disclosure for all the embodiments of the invention. It follows that the opponents' argument regarding an alleged intermediate generalisation in this respect is without merit.

4.2 A basis for the definition that the substitution fluid introduced before and after the blood filter is the same fluid is provided by claims 2 and 3 of the original application and claims 35 and 36 of the parent application as filed, and by Figure 3 of the parent and the original application as filed. The Board does not accept the opponents' argument that it should be specified that this substitution fluid does not contain calcium and magnesium ions. Those claims of the original application and the parent application as filed did not specify it either. The presence or absence of calcium and magnesium ions in the substitution fluids is in no technical relation to issue of whether one or more of such fluids is used.

4.3 The opponents' argument concerning the absence of the definition that the instructions are for carrying out hemofiltration is not convincing for similar reasons. Claim 1 of the original application and claim 34 of the parent application as filed did not require it either. The use of a single substitution fluid or the specific instructions concerning the stopping of the pumps cannot make this definition necessary, from a technical point of view.

4.4 The additional features of claim 9 are based on paragraph [0054] of the parent application and page 17, lines 15 to 17 of the original application as filed. Contrary to the opponents' submissions, these passages are not specific to dialysis devices, but concern the nature of the substitution fluids, and the pumps and tubing employed in any of the disclosed blood treatment systems. There is thus no inextricable link between the specific nature of the fluids mentioned in these passages and the means for their administration. Hence, the opponents' objection of added subject-matter

directed to claim 9 is not convincing.

4.5 However, the introduction of the feature "instructions for, 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 of auxiliary request 1 is problematic.

The opponents argued that it constituted an unallowable intermediate generalisation, in particular because claim 1 did not specify that all pumps were controlled together, that when the blood pump run all other pumps had to be activated, and that the administration of the solution containing calcium and magnesium had to stop before the stop of the blood pump and the anticoagulant pump.

As regards the allegedly omitted feature that all pumps are controlled together, this is implied by the claim on a technical reading of it. The claimed instructions, when implemented, result in the stop of all the pumps. This implies their control.

Claim 1 of the original application and claim 34 of the parent application as filed did not prescribe that when the blood pump runs all other pumps have to be activated. Moreover, this feature is clearly not inextricably linked with the claimed delay of the stop of the anticoagulant pump and the blood pump, which is for preventing clogging of the return line when the system stops (paragraph [0055] of the parent application and page 17, lines 18 to 29 of the original application as filed). It follows that its omission does not add subject-matter.

However, as the opponents argued, the omission of the feature that the administration of the solution containing calcium and magnesium should stop before the stop of the blood pump and the anticoagulant pump is not allowable. If that administration is not stopped the prevention of the risk of clogging the return line, which is what the claimed instructions aim at, is not achieved: free calcium ions, which play an important role in the coagulation of blood and which are bound by the anticoagulant, would be re-introduced into the blood. Hence, the original application and the parent application as filed inextricably link the omitted feature with the claimed instructions of stopping the pumps. In contrast, claim 1 of auxiliary request 1 conveys the information that the stopping of the administration of the solution containing calcium and magnesium is merely optional.

The proprietor's argument that claim 1 of auxiliary request 1 had to be understood to imply that the administration of the solution containing calcium and magnesium should stop before the stop of the blood pump and the anticoagulant pump is not convincing. The claim does simply not state that such administration is performed by means of a pump. Moreover, a pump is not the only possible technical means for performing that administration. The solution could be delivered from an infusion bag by gravity or from a reservoir under pressure, whereby the flow rate could be controlled by a regulating valve, for example. Hence, stopping the pumps does not necessarily result in stopping the administration of the solution containing calcium and magnesium.

4.6 For this reason the subject-matter of claim 1 of auxiliary request 1 extends beyond the content of the

original application and the parent application as filed, in contravention of Articles 76(1) and 123(2) EPC.

Hence, the patent cannot be maintained on the basis of auxiliary request 1.

5. Auxiliary request 2 - Article 123(2), 83 and 84 EPC

In claim 1 of auxiliary request 2 it is expressly mentioned that the calcium solution including magnesium is administered by a pump, i.e. the second post-dilution pump. Hence, the claimed instructions for stopping all the pumps of the system imply that the administration of this solution stops before the stop of the blood pump and the anticoagulant pump. This overcomes the non-compliance with Articles 76(1) and 123(2) EPC explained above.

For the reasons given in the analysis of the main request made above, auxiliary request 2 also meets the requirements of sufficiency of disclosure.

6. Auxiliary request 2 - Novelty and inventive step

It is common ground that D2/D2a and D11/D11a do not disclose instructions for, when one pump halts for any reason, stopping the pumping of the other pumps, wherein the stops of blood pump and anticoagulant pump are delayed after the other pumps have stopped.

6.1 The opponents argued that since this distinguishing feature concerned a technical problem which was different from the problem addressed by the other claim features a combination of more documents could prejudice the novelty of the claim.

It is the established jurisprudence that, in the assessment of novelty, the claimed invention should be compared with the prior art to see whether the invention differs from it. If it does, no matter for which reason, the invention is novel. In the comparison it is not permissible to combine separate items of prior art together. A claimed subject-matter would lack novelty only if a "clear and unmistakable teaching" of a combination of the claimed features could be found in a prior art disclosure (Case Law of the Boards of Appeal of the European Patent Office, Ninth Edition, July 2019, I.C.4.2 and I.C.5.1).

It follows that the opponents' objection of lack of novelty based on the combination of separate documents (D2/D2a or D11/D11a with D10) is without merit.

6.2 The opponents argued against inventive step starting from D2/D2a or D11/D11a, in combination with one or more of D10, D31 and D32.

D2/D2a and D11/D11a do not disclose instructions for, when one pump halts for any reason, stopping the pumping of the other pumps, wherein the stops of blood pump and anticoagulant pump are delayed after the other pumps have stopped.

As the proprietor submitted, the patent (paragraph [0055]) 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.

6.2.1 D10 (column 17, lines 25 to 30) discloses a "safe state" of an extracorporeal blood treatment apparatus in which all pumps of the apparatus are stopped. Column 19, lines 52 to 57, discloses that a control processor puts the apparatus in the "safe state" if a pump is malfunctioning. According to column 19, lines 57 to 64, if the malfunction is detected "the operator may choose [...] to disconnect the patient with or without returning treated blood to the patient". The opponents argued that this implied that the blood pump had to run longer than the other pumps before being eventually stopped so as to reach the "safe state". Even if this were accepted, there is no disclosure in D10, either explicit or implicit, that the anticoagulant pump should continue running together with the blood pump. The Board notes that D10 is silent about any risk of blood clotting for the purpose of returning the treated blood to the patient before disconnection. This risk is not implicit either, since during that operation the blood would circulate normally in the blood treatment apparatus. It follows that D10 does not disclose the distinguishing feature. It is not concerned with the objective technical problem either.

6.2.2 D31 concerns a system for performing hemodialysis employing citrate as an anticoagulant (column 3, lines 5 to 12). In column 4, lines 57 to 68, D31 teaches that the system should be monitored to ensure that citrate and calcium ions are being added during the hemodialysis operation and that the blood pump should be monitored with the dialyser for determining if and when the blood is bypassing the dialyser. Column 5,

lines 30 to 42, mentioned by the opponents, concerns this last situation. It discloses:

> "the calcium ion pump should be shut down immediately whereas the blood pump should be shut down only after a delay of, e.g., 3 minutes. This permits sufficient time to adjust the dialyzer apparatus without shutting the entire apparatus [...] down. This for the reason that bypass operations are relatively common, and a patient would be in no danger for a short period while attempts are made to put the dialyzer apparatus back on stream. In addition, the citrate pump should be shut down after a period of time following shut down of the blood pump, e.g., 4 minutes after monitoring of a bypass condition in the dialyzer".

Hence, D31 does not disclose instructions for, when one pump halts for any reason, stopping the pumping of the other pumps. In fact, it suggests that the bypass condition is relatively common and should be solved without the need of a complete stop of the system. Moreover, D31 does not teach to fill the return line with blood containing anticoagulant in order to solve the objective technical problem, but simply to purge it altogether by leaving the anticoagulant pump in operation after the blood pump has stopped. It follows that D31 does also not suggest that the objective technical problem should be addressed as it is done by the claimed invention.

6.2.3 D32 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 opponents, 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 opponents, 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 D32 that these functions are in any relation to each other. In particular, there is simply no disclosure in D32 that the anticoagulant delivery can only be interrupted by activating the function of the syringe replacement or that when the function "Behandlung Start/Stop" is activated the anticoagulant syringe continues delivering anticoagulant. Hence, D32 does not disclose the distinguishing feature of claim 1 of auxiliary request 2. It does not address the objective technical problem either.

6.2.4 Since none of D10, D31 and D32 teaches the distinguishing feature for the solution of the objective technical problem, their combination with D2/D2a or D11/D11a does not render obvious the subject-matter of claim 1.

6.3 The opponents also argued against inventive step of claim 1 of auxiliary request 2 starting from D32, under the assumption that this document disclosed all the claim features except the administration of a calcium solution containing magnesium by the means of a pump, and that this feature was rendered obvious by several other documents of the state of the art.

However, as explained above, D32 does not disclose the claimed instructions for stopping the pumps either.

It follows that the objection starting from D32 is without merit for this reason alone.

6.4 In conclusion, the subject-matter of claim 1 of auxiliary request 2 - and a fortiori of dependent claims 2 to 9 - is novel (Article 54(1) and (2) EPC) and inventive (Article 56 EPC).

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 with the order to maintain the patent as amended in the following version:

   - claims: 1-9 according to auxiliary request 2 filed with letter dated 16 May 2019;

   - description: pages 2, 4-7, 9 of the patent specification, and pages 3 and 8 filed during the oral proceedings before the Opposition Division on 2 July 2018;

   - drawings: Figures 1-6 of the patent specification.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated