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Datasheet for the decision of 15 March 2024

Case Number: T 0187/22 - 3.2.02

Application Number: 15833016.7

Publication Number: 3184130

IPC: A61M1/36, A61M1/10, A61M1/14, A61M1/16

Language of the proceedings: EN

Title of invention:
BLOOD CIRCULATION SYSTEM

Patent Proprietor:
Senko Medical Instrument Mfg. Co., Ltd.

Opponent:
Fresenius Medical Care AG

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 100(a), 100(b)
RPBA 2020 Art. 12(2), 12(6), 13(1), 15(1)

Keyword:

Primary object of appeal proceedings to review decision
Late-filed evidence - should have been submitted in first-instance proceedings (yes) - admitted (no)
Late-filed objection - should have been submitted in first-instance proceedings (yes) - admitted (no)
Grounds for opposition - insufficiency of disclosure (no)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0187/22 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 15 March 2024

Appellant: (Opponent)	Fresenius Medical Care AG Else-Kröner-Str. 1 61352 Bad Homburg (DE)
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Respondent: (Patent Proprietor)	Senko Medical Instrument Mfg. Co., Ltd. 23-13, Hongo 3-chome, Bunkyo-ku, Tokyo 113-0033 (JP)
Representative:	Potter Clarkson Chapel Quarter Mount Street Nottingham NG1 6HQ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 3 December 2021 rejecting the opposition filed against European patent No. 3184130 pursuant to Article 101(2) EPC**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	D. Ceccarelli
	C. Schmidt

Summary of Facts and Submissions

I. The opponent appealed against the Opposition Division's decision to reject the opposition against the European patent.

II. The Board summoned the parties to oral proceedings and issued a communication under Article 15(1) RPBA with a preliminary opinion. Oral proceedings took place on 15 March 2024.

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

The respondent requested that the appeal be dismissed (i.e. that the patent be maintained as granted - main request) or that the patent be maintained on the basis of one of the first to third auxiliary requests, filed on 13 July 2021, the fourth auxiliary request, filed with the reply to the statement of grounds of appeal on 9 August 2022, or the fifth to seventh auxiliary requests, filed on 4 August 2020.

III. The following documents are mentioned in this decision:

D1: EP 2 519 282 B1
D2: WO 2011/079941 A1
D3: WO 80/02376 A1
D4: WO 92/02264 A1
D7: WO 2014/121164 A1
D11: WO 2013/025826 A1
D13: DE 37 20 667 A1
D14: US 2007/0158247 A1
D15: EP 2 044 965 A2

IV. Claim 1 of the main request reads as follows:

"A blood circulation system (100) that can be connected to a human body, and is configured to transfer removed blood to the human body via a blood transfer pump (120), the system comprising:
the blood transfer pump;
a blood removal line (101) configured to allow removed blood to flow to the blood transfer pump;
a blood transfer line (104) configured to transfer blood, which is sent from the blood transfer pump, to the human body;
blood removal rate measurement means (111) that is provided in the blood removal line; and
a control unit (140),
wherein, according to a blood removal rate parameter measured by the blood removal rate measurement means, the control unit is configured to control a blood transfer rate of the blood transfer pump such that the transfer rate of blood flowing through the blood transfer line is in a specific range with respect to the removal rate of blood flowing through the blood removal line."

Claims 2 to 8 are dependent claims.

V. The appellant's arguments, where relevant to this decision, can be summarised as follows.

Claim interpretation

The Opposition Division had interpreted claim 1 of the main request in a very restrictive, unjustified way. According to established case law, the claims should be interpreted in the broadest technically sensible way and the description should not be used to unduly

restrict their scope.

With regard to the configuration of the control unit, the claim wording merely specified that the blood transfer rate was controlled in consideration of any one parameter measured by the blood removal rate measurement means. The claim did not prescribe that the control had to depend directly on this parameter, nor did it exclude the possibility that further calculations could be carried out. The control was defined only as a result to be achieved. The blood removal rate had to be in a specific range with respect to the blood transfer rate at a certain time of operation of the claimed system. The range did not have to be maintained under all normal operating conditions of the system. The range could be any range as the absolute values of the blood transfer rate and the blood removal rate were not specified. This included stopping the blood transfer pump altogether. Moreover, the control could be performed by acting on further pumps and valves other than the blood transfer pump, as is typically done in dialysis machines and even foreseen through the use of reservoir 102 and clamper 122A in Figure 5 of the patent in suit.

In addition, the claim wording did not prescribe that the blood removal line and the blood transfer line should be separate. In the claim and the description (paragraph [0104]) these lines were merely defined by their function. The person skilled in the art was aware of single-needle methods in extracorporeal blood treatments, as shown in D4.

Sufficiency of disclosure

The invention as defined in claim 1 of the main request

was not disclosed over its whole scope because the claim did not define a reservoir in the system. Without a reservoir the person skilled in the art was not taught how the "specific range" of the transfer rate of blood flowing through the blood transfer line with respect to the removal rate of blood could be different from 1:1. This was because blood was incompressible and the fluid conduits had to withstand pressure.

Admissibility of D13 to D15 and of a novelty attack based on D3

The Opposition Division had provided a preliminary view, in two separate communications, according to which D3 was novelty-destroying for the subject-matter of claim 1 of the main request. Surprisingly, at the oral proceedings at first instance, the Opposition Division then came to a different conclusion. This constituted exceptional circumstances justifying the admittance into the appeal proceedings of D13 to D15, filed with the statement of grounds of appeal. Moreover, introducing these documents had no negative impact on procedural economy since the respondent had had enough time to study them and present detailed arguments concerning their content.

D13 to D15 were also *prima facie* relevant as each of them disclosed all the features of claim 1 of the main request. D13 disclosed a control unit configured as defined in claim 1 of the main request in column 13, lines 45 to 66. D14 disclosed such a control unit in paragraph [0027]. D15 disclosed such a control unit in paragraph [0013].

An embodiment of the invention according to D3, in which dialysed or oxygenated blood could be introduced

into the patient by a pump (P1 in Figure 3) through a flow meter (FM2 in Figure 3), described on page 20, was novelty-destroying for the subject-matter of claim 1 of the main request. This embodiment would work without the need for the pump P3 in Figure 3. The objection based on this embodiment, presented for the first time during the oral proceedings before the Board, had to be admitted since D3 was part of the proceedings and the objection was *prima facie* relevant.

Novelty

The subject-matter of claim 1 of the main request lacked novelty over each of D1, D2, D3 and D4.

D1 and D2 disclosed a blood circulation system as claimed, comprising a control unit configured to control a blood transfer rate of a blood transfer pump such that the transfer rate of blood flowing through a blood transfer line is in a specific range with respect to the removal rate of blood flowing through a blood removal line. Such a control unit was the central control unit 15 depicted in Figure 1 of these documents and described in paragraphs [0036] to [0038] of D1 and page 9 of D2. The control unit controlled the blood transfer pump such that the pump made blood circulate at a predetermined flow rate. This meant that blood circulated at a constant flow rate through arterial line 6 to dialyser 1 and then to the patient through venous line 6. This implied a specific range of 1:1 of the blood rates as claimed. Moreover, the blood pump could be stopped, which also implied a specific range of 1:1 since both blood rates would amount to 0.

D3 also disclosed a blood circulation system as claimed, comprising a control unit configured to

control a blood transfer rate of a blood transfer pump such that the transfer rate of blood flowing through a blood transfer line is in a specific range with respect to the removal rate of blood flowing through a blood removal line. Fluid line 47 could be considered the blood transfer line according to the claim wording. In that case the pumping rate of pump P1, controlled by controller C1 (Figure 3), determined both blood rates as claimed when the ultrafiltration rate determined by pump P3 was kept at a desired rate (page 23, last paragraph) or when no ultrafiltration was performed. This was because the flow rate of the blood flowing through the blood transfer line was the difference between the flow rate of the blood withdrawn from the patient and the ultrafiltration rate. Moreover, the fluid line between pump P1 and pressure sensor PS1 in Figure 3 could be considered the blood transfer line according to the claim wording. In that case pump P3 had no influence on the flow rate through the blood transfer line at all.

D4 also disclosed a blood circulation system as claimed, comprising a control unit configured to control a blood transfer rate of a blood transfer pump such that the transfer rate of blood flowing through a blood transfer line is in a specific range with respect to the removal rate of blood flowing through a blood removal line. D4 disclosed a flow rate control system (claim 1) which controlled a blood pump 26 (Figure 1). According to feature (g) of claim 1 of D4 a steady state should be reached, in which the blood removal rate and the blood transfer rate were synchronised, i.e. kept at the same value. The specific range would then be 1:1. Moreover, the blood pump could be stopped (page 7, lines 28 to 32), which also implied a specific range of 1:1 since both blood rates would amount to 0.

Inventive step

The subject-matter of claim 1 of the main request was not inventive when starting from D3 in combination with the common general knowledge, D1, D2, D4, D7 or D11.

If it were considered that D3 did not disclose a control unit configured to control a blood transfer rate of a blood transfer pump such that the transfer rate of blood flowing through a blood transfer line is in a specific range with respect to the removal rate of blood flowing through a blood removal line, this feature would have been obvious to the person skilled in the art. For reasons of patient safety the blood had to be circulated in a stable and controlled way. The person skilled in the art would have made sure that the blood circulation system disclosed in D3 worked in this way, which implied setting the blood removal rate and blood transfer rate in a co-ordinated way. These rates would necessarily be in some specific range with respect to one another. It would have been a simple programming task to change the settings of the control unit such that the ratio of the blood transfer rate and blood removal rate was maintained throughout the normal functioning of the blood circulation system. No structural modifications to the system would have been necessary. Moreover, the distinguishing feature was known from D1, D2, D4, D7 and D11. D7 disclosed a control unit (paragraph [0228], claim 38 and Figure 1) that controlled a blood pump so as to obtain synchronised blood removal and blood transfer rates in the range of 50 to 600 ml/min. D11 disclosed a control unit which controlled a blood pump such that a blood transfer rate and a blood removal rate were in a defined range (paragraphs [0014], [0018] and [0072],

and Figures 37, 38 and 40).

The subject-matter of claim 1 of the main request was not inventive when starting from D1, D2 or D4, in combination with D3, D7 or D11.

If it were considered that D1, D2 and D4 did not disclose a control unit configured to control a blood transfer rate of a blood transfer pump such that the transfer rate of blood flowing through a blood transfer line is in a specific range with respect to the removal rate of blood flowing through a blood removal line, the person skilled in the art would have implemented this distinguishing feature in the blood circulation systems disclosed in these documents. On the basis of the teaching of D3, D7 and D11, which all disclosed the distinguishing feature, the person skilled in the art would have implemented the distinguishing feature to ensure patient safety by keeping the blood transfer rate and the blood removal rate in a predetermined range.

VI. The respondent's arguments, where relevant to this decision, can be summarised as follows.

Claim interpretation

Claim 1 of the main request specified that "the control unit is configured to control a blood transfer rate of the blood transfer pump such that the blood transfer rate is in a specific range with respect to the blood removal rate". This meant that although the claim did not exclude the possibility of the blood circulation system including other components (e.g. regulators, clampers or the like), it was necessary for the blood transfer pump alone to be able to control the ratio of

the blood rates at every point during operation of the system. This implied that the characteristics of the blood circulation system, possibly including other elements such as a reservoir and a clamper, were known and taken into account by the control unit. Paragraph [0019] of the patent, which set out the object of the invention during operation of the blood circulation system, confirmed this interpretation.

Sufficiency of disclosure

The patent disclosed a configuration of a blood circulation system with no reservoir (paragraph [0101]), in which the blood removal line was directly connected to the blood transfer pump and the blood transfer line was also directly connected to the blood transfer pump. The ratio of the blood removal rate to the blood transfer rate was 1:1, which did not contradict the last clause of claim 1 of the main request.

Admissibility of D13 to D15 and of a novelty attack based on D3

The Opposition Division's preliminary opinion was not a final decision. Even if the preliminary opinion had been favourable to one of the parties to the opposition proceedings, both parties should have taken the required actions seriously because the opinion could have been reversed in the final decision. It had been entirely the appellant's choice to believe that a preliminary opinion favourable to the appellant would be maintained in the final decision and to decide not to submit D13 to D15 at first instance. These documents had been filed late. Moreover, they were not novelty-destroying for the subject-matter of claim 1 of the

main request. They should not be admitted into the appeal proceedings.

The appellant's new objection based on page 20 of D3 was not submitted until the oral proceedings before the Board, without any apparent reasons for doing so. This objection should not be admitted into the appeal proceedings.

Novelty

D1 and D2 disclosed (Figure 1 of both documents) a flow sensor 21 which measured the flow rate of a centrifugal pump 9, and a control unit which controlled the pump such that the flow rate measured by the sensor matched a target flow rate set by a doctor or an operator. This control mode focused on the relationship between the blood flow rate and the target flow rate, not on the relationship between the blood removal rate and the blood transfer rate. Therefore, neither D1 nor D2 disclosed the feature of claim 1 of the main request according to which "the blood transfer rate is controlled to be in the specific range with respect to the blood removal rate". Even if the "specific range" was broadly defined, the control configuration relevant to this range should not be ignored, and thus it should not be accepted that the blood removal rate and the blood transfer rate could be arbitrary values without any restrictions.

D3 disclosed an ultrafiltration system with an ultrafiltration pump P3 and a blood pump P1 (Figure 3). A controller either maintained or changed a desired rate of ultrafiltration (page 23, lines 24 to 26) on the basis of readings of two pressure sensors. The controller had to control both pumps P3 and P1 to

generate a desired pressure difference between a blood compartment 43 and the dialysate compartment 44. D3 did not disclose a system in which the pump P1 could alone control the transfer rate of blood flowing through a line 47. Hence, D3 did not disclose a configuration as defined in claim 1 of the main request, in which the blood transfer pump alone could control the flow rate of blood flowing through the blood transfer line.

D4 disclosed a "withdrawal control curve" and a "reinfusion control curve" which were not related to each other. Hence it did not disclose controlling a blood transfer rate and a blood removal rate such that they are kept in a specific range with respect to each other.

Inventive step

The subject-matter of claim 1 of the main request was inventive when starting from D3. This document did not disclose a control unit configured to control a blood transfer pump such that the blood transfer rate is in a specific range with respect to the blood removal rate. The problem solved by the distinguishing feature was to keep the blood circulation stable. The system according to D3 did not make it possible to control the ultrafiltration rate by controlling pump P1 alone. The person skilled in the art would not have received any teaching from the common general knowledge, or from D1, D2, D4, D7 or D11, to make this possible either. None of these documents disclosed the distinguishing feature. D7 disclosed a control based on two different pumps 302 and 303 (Figure 1). D11 disclosed controlling a pump to increase the diameter of a vein by adjusting a Wall Share Stress (WSS) acting on the blood vessel wall (Figure 36A). It was not concerned with

controlling the blood transfer rate on the basis of the blood removal rate.

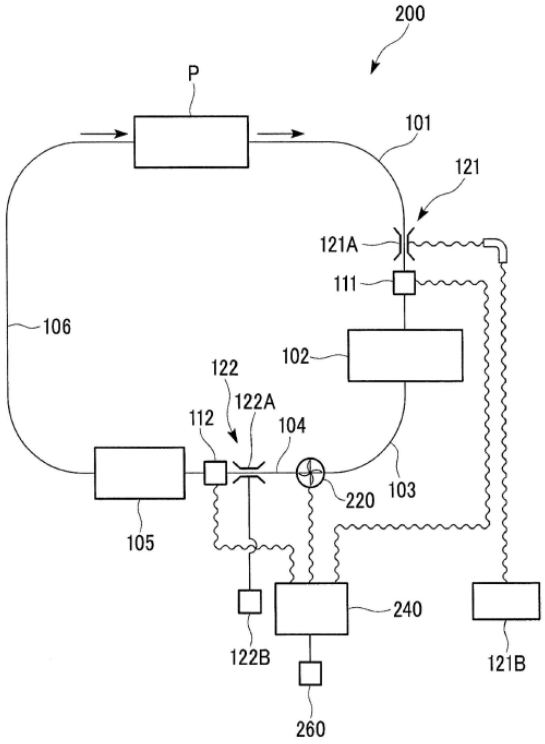
The subject-matter of claim 1 of the main request was also inventive when starting from D1/D2 or D4.

D1 and D4 did not disclose a control unit configured to control a blood transfer rate of a blood transfer pump such that the transfer rate of blood flowing through a blood transfer line is in a specific range with respect to the removal rate of blood flowing through a blood removal line. The problem solved by the distinguishing feature was to keep the blood circulation stable. The purpose of D1 was to detect cannula displacement, nipping or kinking of blood lines, or leakage. The purpose of D4 was to mitigate the frequency or severity of occlusive interruptions. There was nothing in these documents which would prompt the skilled person to modify the described systems and arrive at the claimed invention. D3, D7 and D11 did not disclose the distinguishing feature either.

Reasons for the Decision

1. The patent

The invention as defined in claim 1 of the main request relates to a blood circulation system configured to transfer removed blood to the human body via a blood transfer pump. Such a system can be an artificial heart and lung apparatus used when a heart has to be stopped, for example during cardiac surgery. An embodiment of the claimed system is schematically depicted in Figure 5 of the patent, reproduced below.



The claimed system (200) comprises the blood transfer pump (220), a blood removal line (101), a blood transfer line (104, 106), a measurement means (111) and a control unit (240).

The blood removed from a patient is directed to the pump via the blood removal line and then re-infused into the patient via the blood transfer line. Before being re-infused into the patient the blood may be treated, for example by having it pass through an artificial lung for discharging carbon dioxide from the blood and adding oxygen to it.

The measurement means is in the blood removal line, for measuring a blood removal rate parameter.

The control unit is configured to control a blood transfer rate of the blood transfer pump on the basis of the measured blood removal rate parameter, such that

the transfer rate of blood flowing through the blood transfer line is in a specific range with respect to the removal rate of blood flowing through the blood removal line.

This makes it possible to transfer to the patient the same amount of blood as is removed, i.e. to stably circulate blood at a suitable flow rate even if the blood removal rate changes (paragraphs [0022] and [0023] of the patent), which is of importance for maintaining the health of the patient connected to a heart and lung apparatus.

2. Claim interpretation

An important matter of dispute is the interpretation of the wording of claim 1 of the main request. The appellant argued that the Opposition Division had interpreted the claim in a very restrictive, unjustified way.

The Board considers that the interpretation of the claim wording should remain in the context of the invention as set out by the patent as a whole, including the description.

2.1 Claim 1 of the main request defines the control unit as being configured to control the blood transfer rate of the blood transfer pump according to the blood removal rate parameter measured by the blood removal rate measurement means such that the transfer rate of blood flowing through the blood transfer line is in a specific range with respect to the removal rate of blood flowing through the blood removal line.

For the person skilled in the art this feature means

that the control unit, in all normal operating conditions of the blood circulation system, has to keep the flow rates within a specific range and does so by acting on the blood transfer pump according to the blood removal rate parameter. In other words, when a variation of the blood removal rate parameter is detected, the control unit sends a control signal to the blood transfer pump so that the flow rate of blood flowing through the blood transfer line remains in a specific range with respect to the flow rate of blood flowing through the blood removal line. The blood removal rate parameter and the extent of the range are not specified in the claim. Still, the range should be a normal operating range of the blood circulation system when the blood transfer pump is controlled according to the measured blood removal rate parameter. Moreover, the control of the blood transfer pump does not rule out the presence of other elements of the system (such as reservoir 102 and clamper 122A in Figure 5 of the patent). Still, it must be performed on the blood transfer pump according to the measured blood removal rate parameter, possibly taking into account the known effects that this parameter will have on the other elements of the system. This interpretation, which is derived from a plain technical reading of the claim wording, is not contradicted but supported by the description of the patent (paragraphs [0090], [0093], [0127] and [0130], with Figures 3, 4, 7 and 8).

2.2 Claim 1 of the main request also defines a blood removal line and a blood transfer line. It follows that, for the person skilled in the art, the claimed blood circulation system must comprise two separate and individually identifiable lines: the blood removal line for directing the blood from the human body to the blood transfer pump and the blood transfer line for

directing the blood from the pump to the human body. This interpretation, which is derived from a plain technical reading of the claim wording, is not contradicted but supported by the description of the patent (paragraphs [0058], [0061], [0068], [0071] and [0106], with Figures 1 and 5).

3. Sufficiency of disclosure

The appellant argued that the invention as defined in claim 1 of the main request was not disclosed over its whole scope because the claim did not define a reservoir in the system. Without a reservoir, the "specific range" of the transfer rate of blood flowing through the blood transfer line with respect to the removal rate of blood was limited to 1:1.

This objection is not convincing. The requirement of sufficiency of disclosure has to be assessed with regard to the description. It needs to be assessed whether the description allows the person skilled in the art to put the claimed invention into practice.

From the description the person skilled in the art learns that a reservoir for the blood in the system may prevent the occurrence of excessive negative pressure while the blood transfer rate is being adjusted with respect to the blood removal rate as claimed (paragraph [0101]). This is because if the two flow rates do not coincide, blood can be directed to or removed from the reservoir. If no excessive negative pressure builds up, for example when the "specific range" is 1:1, the person skilled in the art knows that no reservoir is needed (hinted at in paragraph [0101]). Hence, the description teaches how to put the invention into practice over its whole scope, which may involve

providing a reservoir.

This, as such, is enough for sufficiency of disclosure. The fact that the reservoir is described as a means to put the invention into practice does not mean that the reservoir must be claimed to fulfil the requirements of sufficiency of disclosure. The person skilled in the art may devise alternative mechanical arrangements for the same purpose, such as a compliant bypass circuit.

In conclusion, the person skilled in the art is taught how to put the invention as defined in claim 1 of the main request into practice over the whole scope. This may be done by using a reservoir. However, the reservoir does not have to be claimed.

Hence, the ground for opposition of insufficient disclosure (Article 100(b) EPC) does not prejudice the maintenance of the patent according to the main request.

4. Admissibility of D13 to D15 and of a novelty attack based on D3

4.1 D13 to D15 were submitted by the appellant with the statement of grounds of appeal.

Under Article 12(2) RPBA the primary object of the appeal proceedings is to review the decision under appeal in a judicial manner. As a consequence, a party's appeal must be directed to the requests, facts, objections, arguments and evidence on which the decision under appeal was based. The Board must not admit evidence which should have been submitted in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify its

admittance (Article 12(6) RPBA).

4.1.1 The Board cannot see any reason why D13 to D15 were not submitted until the appeal proceedings, to support objections against the patent as granted.

The fact that the Opposition Division had a preliminary view favourable to the appellant is not decisive in this respect. As the respondent pointed out, a preliminary opinion of the Opposition Division, for the very reason that it is preliminary, could be reversed in the final decision. The appellant's deliberate choice to rely on this opinion and not to file further evidence at first instance cannot justify, as such, admitting further evidence only in the appeal proceedings.

4.1.2 Moreover, D13 to D15 are *prima facie* of no particular relevance to the assessment of novelty and inventive step.

D13 discloses a haemodialysis and haemofiltration system. As shown in Figure 1, the system comprises a blood transfer pump (43), a blood removal line (42), a blood transfer line (48a and 48b) and a blood rate measurement means. The blood rate measurement means could be in the form of a speedometer measuring the driving speed of the pump (column 10, lines 44 to 54), as pointed to by the appellant. Contrary to what is required by claim 1 of the main request, the blood rate measurement means disclosed in D13 appears to be not in the blood removal line configured to allow removed blood to flow to the blood transfer pump, but in the blood transfer pump itself. Moreover, D13 discloses such control of the blood pump as to maintain the measured blood flow at a prescribed value (column 13,

lines 45 to 66 pointed to by the appellant). As will be explained below, such a disclosure does not amount to a control unit which is configured to control a blood transfer rate of a blood transfer pump, according to a measured blood removal rate parameter, such that the transfer rate of blood flowing through the blood transfer line is in a specific range with respect to the removal rate of blood flowing through the blood removal line.

D14 discloses a haemodialysis system. As shown in Figure 1, the system comprises a blood transfer pump (26), a blood removal line (20), a blood transfer line (12 and 24) and a blood rate measurement means (34). The blood rate measurement means is a flow sensor in the blood removal line (paragraph [0018]). Paragraph [0027] pointed to by the appellant discloses controlling the blood pump on the basis of the measurements of the flow sensor in the blood removal line. However, there is no disclosure that this control maintains the transfer rate of blood flowing through the blood transfer line in a specific range with respect to the removal rate of blood flowing through the blood removal line. In fact, the same paragraph discloses also controlling the dialysate pump on the basis of various inputs and preprogrammed set parameters for performing a dialysis treatment. In conclusion, D14 does not appear to go beyond the disclosure of D3, as will be explained below.

D15 discloses an extracorporeal blood treatment device. As shown in Figure 1, the device comprises a blood transfer pump in the form of a pulsating membrane pump (paragraph [0011]), a blood removal line and a blood transfer line (Figures 5 and 6, and paragraph [0008]). The device further comprises a blood removal rate

measurement means in the blood removal line (fluid sensor 65 in Figures 5 and 6). It also comprises a control device for controlling the pulsating membrane pump in accordance with measurements of the blood removal rate measurement means (paragraph [0013], for example). The membrane pump makes the blood circulate from the patient through the blood removal line into a pumping chamber (during a vacuum phase of the pump, Figure 5) and subsequently from the pumping chamber through the blood transfer line back into the patient (during the pressuring phase of the pump, Figure 6). According to paragraph [0048] of D15, signals from a sensor are generally compared with one or more preselected conditions and then used to drive the pump, which is analogous to what is disclosed in D14.

4.1.3 For these reasons D13 to D15 are not admitted into the appeal proceedings in accordance with Article 12(6) RPBA.

4.2 During the oral proceedings before the Board, the appellant presented, for the first time, an objection of lack of novelty on the basis of an embodiment of the invention according to D3 (described on page 20 of this document), in which dialysed or oxygenated blood could be introduced into the patient by a pump (P1 in Figure 3) through a flow meter (FM2 in Figure 3). This is an amendment to the appellant's case made after notification of the communication under Article 15(1) RPBA.

Under Article 13(2) RPBA any such amendment must, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the appellant.

The Board cannot see any exceptional circumstances for such an amendment to the appellant's case, which is concerned with the patent as granted. Neither D3 being part of the proceedings, nor the alleged relevance of the objection can amount to such circumstances. The objection is based on a document already on file, so it could and should have been raised before, especially if relevant in the appellant's view.

For these reasons the appellant's objection based on page 20 of D3 is not admitted into the appeal proceedings in accordance with Article 13(2) RPBA.

5. Novelty

The appellant argued that the subject-matter of claim 1 of the main request lacked novelty over each of D1, D2, D3 and D4.

5.1 D1 and D2, which belong to the same patent family and have the same technical content, concern blood treatment apparatuses, e.g. haemodialysis apparatuses (paragraph [0030] of D1 and page 7, third paragraph of D2), and focus on the monitoring of an access site on a patient. The flow rate of blood in a venous line (transfer line) and/or an arterial line (removal line) is measured and monitored to recognise problems at the access sites, such as the dislodgement of an access cannula (paragraph [0018] of D1). A control unit checks whether a measured flow rate matches a prescribed flow rate under given operational conditions of a pump for circulating blood in the apparatus. If the rates do not match, it may be established that there are problems with the access site and a signal may be generated (paragraph [0038] of D1 and page 9, third paragraph of D2). The signal may cause the pump to stop (paragraph

[0024] of D1 and paragraph bridging pages 5 and 6 of D2).

D1 and D2 do not disclose a control unit which is configured to control a blood transfer rate of a blood transfer pump, according to a measured blood removal rate parameter, such that the transfer rate of blood flowing through the blood transfer line is in a specific range with respect to the removal rate of blood flowing through the blood removal line.

Merely checking whether a measured blood removal rate matches a prescribed flow rate does not mean acting on the pump to keep the flow rates within a specific range. Stopping blood flow if anomalies at the access site are detected does not mean that the control unit keeps the flow rates within a specific range in all normal operating conditions of the blood circulation system. In fact, the stopping of the blood flow relates to a situation in which the system is malfunctioning.

5.2 D3 discloses a haemodialysis system with a blood pump (pump P1, Figure 3) connected to a blood removal line (line 11, Figure 3) and a blood transfer line (line 47, Figure 3). The pumping rate of the blood pump can be controlled by a controller on the basis of measurements of various sensors (page 41, second meter FM1, Figure 3).

D3 does not disclose a control unit which is configured to control a blood transfer rate of a blood transfer pump, according to a measured blood removal rate parameter, such that the transfer rate of blood flowing through the blood transfer line is in a specific range with respect to the removal rate of blood flowing through the blood removal line.

It is irrelevant whether the flow rates may be kept in a specific range by keeping the speed of pump P1 constant on the basis of the measurements of the sensors (page 17, second paragraph) under some conditions, such as when the dialysate pump (P3, Figure 3 and page 24, second paragraph) is driven at a constant speed. This does not amount to a disclosure of a control unit configured to keep the flow rates in a specific range in all normal operating conditions of the blood circulation system by acting on the blood transfer pump according to the blood removal rate parameter. The operation of the dialysate pump influences the flow rate in blood transfer line 47. Even if it were accepted that the control unit is configured to maintain the transfer rate of blood flowing through the blood transfer line in a specific range with respect to the removal rate of blood flowing through the blood removal line, this control is implemented not by acting on the blood transfer pump according to the blood removal rate parameter, but by acting on both the blood transfer pump and the dialysate pump (which influence each other) without considering the blood removal rate parameter.

The appellant's argument that the fluid line between pump P1 and pressure sensor PS1 in Figure 3 of D3 could be considered the blood transfer line according to the claim wording is not accepted because that fluid line is not configured to transfer blood, which is sent from the blood transfer pump, to the human body as required by claim 1 of the main request. That fluid line ends before dialysis canister 42 (Figure 3), where blood is treated, and does not reach the human body.

5.3 D4 discloses a plasmapheresis apparatus in which the blood flow rate is controlled and optimised by adapting it to the individual donor undergoing treatment (page 1, lines 5 to 11). The apparatus comprises a blood transfer pump (blood pump 26, Figure 1) connected to a phlebotomy needle through a blood line, a flow rate sensor (12, Figure 1) in the blood line (claim 1) and a flow rate control system (claim 1). The blood line is used for alternately withdrawing and infusing blood (page 13, second paragraph). The flow rate control system controls the blood pump on the basis of measurements made by the flow rate sensor (claim 1).

D4 does not disclose a control unit which is configured to control a blood transfer rate of a blood transfer pump, according to a measured blood removal rate parameter, such that the transfer rate of blood flowing through the blood transfer line is in a specific range with respect to the removal rate of blood flowing through the blood removal line.

As explained by the Board in the communication under Article 15(1) RPBA, D4 does not actually disclose a blood removal line for directing the blood from the human body to the blood transfer pump and a blood transfer line for directing the blood from the pump to the human body that are separate and individually identifiable. Consequently, it cannot disclose a control unit for keeping blood flow rates in such separate lines in a specific range.

5.4 It follows that the subject-matter of claim 1 of the main request is novel (Article 54(1) and (2) EPC) over each of D1, D2, D3 and D4 by virtue of a control unit which is configured to control a blood transfer rate of a blood transfer pump, according to a measured blood

removal rate parameter, such that the transfer rate of blood flowing through the blood transfer line is in a specific range with respect to the removal rate of blood flowing through the blood removal line.

As a consequence, the ground for opposition of lack of novelty (Article 100(a) EPC) does not prejudice the maintenance of the patent according to the main request.

6. Inventive step

The appellant argued that the subject-matter of claim 1 of the main request was not inventive when starting from any of D1 to D4.

As explained in the novelty analysis, none of the documents used as the starting point in the inventive step attacks discloses a control unit which is configured to control a blood transfer rate of a blood transfer pump, according to a measured blood removal rate parameter, such that the transfer rate of blood flowing through the blood transfer line is in a specific range with respect to the removal rate of blood flowing through the blood removal line.

The technical effect of the distinguishing feature is to effectively make sure that blood is stably circulated at a suitable flow rate in a blood circulation system even if the blood removal rate changes. If the system is a heart and lung apparatus, this is of particular importance (paragraphs [0022] and [0023] of the patent). Hence, the objective technical problem is to ensure the safety of a treatment given to a patient connected to the claimed blood circulation system.

None of the documents cited by the appellant in the inventive step objections discloses the distinguishing feature.

As regards D1 to D4, this has been shown above. D7 and D11 do not disclose the distinguishing feature either. They disclose further haemodialysis and haemofiltration systems in which blood circulation in the blood circuit can be controlled and set to a desired flow rate (paragraph [0228] of D7 and paragraph [0018] of D11). The control is not done by acting on a blood transfer rate of a blood transfer pump according to a measured blood removal rate parameter such that the transfer rate of blood flowing through a blood transfer line is in a specific range with respect to the removal rate of blood flowing through a blood removal line.

Hence, the person skilled in the art would not have arrived at the subject-matter of claim 1 of the main request in an obvious way through any combination of the cited documents. The appellant's argument that in view of the technical problem the person skilled in the art would have made sure that the blood circulation system disclosed in D3 featured setting the blood removal rate and blood transfer rate in a co-ordinated way is not convincing either. Such setting does not imply controlling the blood transfer rate of the blood transfer pump according to a measured blood removal rate parameter as claimed; it may take place using other control algorithms, in accordance with other parameters. This is especially so in a dialysis system according to D3, which features a number of pumps and flow regulators (Figure 3).

In conclusion, the appellant's inventive step

objections (Article 56 EPC) are not persuasive. Hence, the ground for opposition of lack of inventive step (Article 100(a) EPC) does not prejudice the maintenance of the patent according to the main request.

7. As none of the grounds for opposition invoked by the appellant prejudice the maintenance of the patent in accordance with the main request, the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated