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Datasheet for the decision of 13 May 2022

Case Number: T 1816/17 - 3.2.02

Application Number: 10796396.9

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Language of the proceedings: EN

Title of invention:
CONTROLLING AN APPARATUS FOR FLUID TRANSFER TO AND/OR FROM A SUBJECT

Patent Proprietor:
Gambro Lundia AB

Opponent:
Fresenius Medical Care AG & Co. KGaA

Headword:

Relevant legal provisions:
EPC Art. 54, 56
RPBA 2020 Art. 13(2)
RPBA Art. 12(4)

Keyword:
Novelty - (yes)
Inventive step - (yes)
Amendment after summons - taken into account (no)
Late-filed facts - admitted (no)

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G 0010/91, G 0001/95, G 0007/95, T 1042/18, T 0597/07, T 0131/01, T 0635/06

Catchword:

Europäisches Patentamt
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Case Number: T 1816/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 13 May 2022

Appellant: (Opponent)	Fresenius Medical Care AG & Co. KGaA Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Bobbert & Partner Patentanwälte PartmbB Postfach 1252 85422 Erding (DE)
Respondent: (Patent Proprietor)	Gambro Lundia AB P.O. Box 10101 220 10 Lund (SE)
Representative:	J A Kemp LLP 80 Turnmill Street London EC1M 5QU (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 19 June 2017 rejecting the opposition filed against European patent No. 2519276 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Böttcher
	Y. Podbielski

Summary of Facts and Submissions

I. The opponent filed an appeal against the decision of the Opposition Division to reject the opposition against European patent No. 2 519 276.

II. Oral proceedings before the Board were held on 13 May 2022.

III. The appellant (opponent) requested that the decision be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed and the patent be maintained as granted, or that the patent be maintained on the basis of one of auxiliary requests 1 to 4 filed with the reply to the statement of grounds of appeal on 9 March 2018.

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

"A control system in an apparatus (200) for extra-corporeal blood treatment, wherein said apparatus comprises an extracorporeal blood circuit (20) and a connection system (C) for connecting the extracorporeal blood circuit (20) to the vascular system of a patient, wherein the extracorporeal blood circuit (20) comprises a blood processing device (6), and at least one pumping device (3), said control system being operable in a blood treatment mode, wherein the blood treatment mode involves operating said at least one pumping device (3) to pump blood from the vascular system via the connection system (C) through the blood processing device (6) and back to the vascular system via the connection system (C), said control system comprising:

an input (28) for obtaining measurement data from at least one energy transfer sensor (40) arranged to sense a transfer of energy between the patient and the connection system (C) or between the patient and the extracorporeal blood circuit (20), and
a signal processor (29) connected to the input (28), characterized in that the control system is operable to switch between a pre-treatment mode and the blood treatment mode, wherein the signal processor (29) is configured to, in the pre-treatment, mode, process the measurement data for detecting a connection of the extracorporeal blood circuit (20) to the vascular system of the patient, said connection being detected by identifying a characteristic change in the measurement data, and, upon such identification, take a dedicated action for controlling the operation of the apparatus."

Claim 18 of the main request reads as follows.

"A computer-readable medium comprising computer instructions which, when executed by a processor, cause the processor to perform a method for controlling an apparatus (200) for extracorporeal blood treatment, wherein said apparatus (200) comprises an extracorporeal blood circuit (20) and a connection system (C) for connecting the extracorporeal blood circuit (20) to the vascular system of a patient, wherein the extracorporeal blood circuit (20) comprises a blood processing device (6), and at least one pumping device (3), wherein said apparatus (200) is operable in a blood treatment mode, wherein the blood treatment mode involves operating said at least one pumping device (3) to pump blood from the vascular system via the connection system (C) through the blood processing device (6) and back to the vascular system via the

connection system (C), said method comprising:

obtaining measurement data from at least one energy transfer sensor (40) which is arranged to sense a transfer of energy between the patient and the connection system (C) or between the patient and the extracorporeal blood circuit (20),
said method being characterized by:

while operating the apparatus (200) in a pre-treatment mode, processing the measurement data for detecting a connection of extracorporeal blood circuit (20) to the vascular system of the patient, said connection being detected by identifying a characteristic change in the measurement data, and upon such identification, causing a dedicated action for controlling the operation of the apparatus to be taken."

V. The arguments of the appellant may be summarized as follows.

Main request - novelty over D1

D1 disclosed the features of the preamble of claim 1 and the feature that the control system was operable to switch between a pre-treatment mode and the blood treatment mode (paragraphs [0030] to [0032], [0039] and [0041], Figure 1). In the pre-treatment mode, the signal processor was configured to process the measurement data of the sensors 19a and 19b for detecting a connection of the extracorporeal circuit to the vascular system of the patient (paragraphs [0039] and [0041]).

The connection was detected by identifying a characteristic change in the measurement data, namely,

in that a desired signal transmitted from the transmitter 18 was received (paragraph [0039]). Such a desired signal could only be received when a connection was established. Hence, the transition from a non-desired signal to a desired signal represented the characteristic change in the measurement data.

D1 disclosed also that the signal processor was configured to take a dedicated action for controlling the operation of the apparatus (paragraph [0041]). The dedicated action was the starting of the blood treatment while the transmitted and sensed signals were monitored by the controller.

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

Main request - novelty over D7

D7 disclosed a control system of an extracorporeal blood treatment apparatus comprising all the features of claim 1 (paragraphs [0006], [0014], [0030], [0031], [0036], [0041], [0045] and [0046], Figure 1). In particular, the blood detectors 11, 12 could be regarded as energy transfer sensors. The movement of blood which was detected by these detectors inherently involved a transfer of energy from the patient's heart as the energy source. A connection was detected by identifying a blood column at the detector at a time t, while previously the detectors did not detect blood. Hence, the blood detectors were used to detect a connection, and not the bubble detectors, as held by the examining division. The dedicated action was the automatic start of the treatment mentioned in paragraph [0046].

Moreover, paragraph [0014] did not refer to the detection of bubbles to trigger the blood detection.

Hence, the subject-matter of claim 1 lacked novelty over D7.

Main request - novelty over D17

D17 disclosed a control system extracorporeal blood treatment apparatus comprising all the features of claim 1 (paragraphs [0052] to [0055], [0149], Figure 1). In particular, it was mentioned in the last sentence of paragraph [0149] that the judgement (i.e. the judgement mentioned in the previous sentences of the paragraph, concerning the connection of the vascular cannula to the patient) could be used for the interlock of the operation of the dialysis device. The interlock required an interaction such as the display of a certain information or a request for confirmation by the user. These actions could be seen as dedicated actions in the sense of claim 1.

Main request - novelty over D26

As could be derived from the abstract, from page 8, lines 22 to 36; page 8, line 38 to page 9, line 1; page 9, lines 7 to 8; page 12, lines 8 to 10 and 37 to 39; page 13, lines 4 to 5; page 22, lines 12 to 15; and figures 2, 4 and 16a, D26 disclosed the features of claim 1 of the main request. In particular, the shut off of the alarm after a heart beat component is discovered (page 13, lines 4 to 5) could be regarded as the dedicated action.

D26 implicitly disclosed that the processing of the measurement data for detecting a connection was done in

the pre-treatment mode, when the extracorporeal circuit was primed with blood. From the last paragraph on page 22 of D26 the person skilled in the art could derive that monitoring the integrity of the flow circuit was vital in all stages of the treatment. Pre-treatment was not excluded by this.

Hence, the subject-matter of claim 1 lacked novelty over D26.

Main request - inventive step in view of the common general knowledge

Blood treatment devices comprising a control system and pressure sensors that were configured to sense a transfer of energy between the patient and the extracorporeal circuit were known from any of D1, D2, D3, D4, D5, D7, D9 and D22.

In the prior art, the steps of connecting the patient to the system, checking whether a blood column entered the arterial blood line and switching from the pre-treatment mode to the blood treatment mode if a connection was detected were done by a dialysis nurse. This could be proven by the hearing of a witness.

The subject-matter of claim 1 merely represented an automation of these manually performed steps.

Such an automation could not be regarded as involving an inventive step since it was common practice in the prior art to allocate critical steps to the machine and to safeguard their execution via alarm functions. For instance, D7 disclosed that the evaluation of the connection conditions was not only done by the nurse but also by the device (paragraphs [0036], [0037],

[0045], [0046]).

Consequently, the subject-matter of claim 1 did not involve an inventive step.

Main request - inventive step in view of D11 in combination with D17 or D7

D11 related to the evaluation of the connection between the patient and the extracorporeal blood circuit. While it was not mentioned whether this evaluation was done during the pre-treatment mode or the blood treatment mode, it was clear to the person skilled in the art that the treatment could not be started unless an adequate connection between the patient and the machine was established.

D17 disclosed that the monitoring of the blood access, in particular during pre-treatment, was advantageous (paragraph [0149]). It was a matter of routine for the person skilled in the art to configure the signal processor to take a dedicated action upon detection of a connection. Moreover, a dedicated action was disclosed in paragraph [0149] of D17. It was therefore obvious for the person skilled in the art to monitor the connection also during pre-treatment.

D7 also related to the evaluation of the connection between the patient and the dialysis device during pre-treatment. In paragraph [0046] it was suggested to use this evaluation for an automated begin of the treatment. This could be regarded as a dedicated action. Hence, a combination of D11 and D7 resulted in the subject-matter of the claim.

Consequently, the subject-matter of claim 1 did not

involve an inventive step over a combination of D11 with D17 or D7.

Main request - inventive step in view of D10 in combination with D17

D10 also related to monitoring the blood vessel access by permanently sensing the pressure in the extracorporeal circuit during blood treatment.

D17 disclosed that the monitoring of the blood access, in particular during pre-treatment, was advantageous (paragraph [0149]). It was a matter of routine for the person skilled in the art to configure the signal processor to take a dedicated action upon detection of a connection. Moreover, a dedicated action was disclosed in paragraph [0149] of D17.

Consequently, the subject-matter of claim 1 did not involve an inventive step over a combination of D10 with D17.

Main request - inventive step in view of D7 in combination with any of D5, D17, D1, D14 or D11

In addition to the bubble sensors and blood detectors, the device of D7 included a pressure sensor. Since the person skilled in the art knew from D5 (Figure 3), D17 (Figures), D14 (page 362, right column, under the heading "Venous pressure monitor") and D11 (Figures 6 and 7) that pressure sensors could be used to monitor the connection between the patient and the system, he would consider using the pressure sensor of D7 for this purpose while maintaining the bubble sensors.

Furthermore, the person skilled in the art was taught

by D1 that an acoustic sensor could be used to detect a connection. Hence, it was obvious for the person skilled in the art to use such a sensor in the device of D7.

Consequently, the subject-matter of claim 1 did not involve an inventive step over a combination of D7 with any of D5, D17, D1, D14 and D11.

Main request - inventive step in view of D4 in combination with D17

D4 related to checking the connection of a syringe pump to an extracorporeal circuit. Starting from this teaching and in view of the teaching of D17 it was obvious for the person skilled in the art to apply this check also to the connection between the patient and the extracorporeal circuit in order to enhance the safety of the patient or reduce the workload of the nurse. It was also self-evident for the person skilled in the art to configure the signal processor to take a dedicated action upon detection of a connection.

Consequently, the subject-matter of claim 1 did not involve an inventive step over a combination of D4 with D17.

Main request - inventive step in view of D17 in combination with the common general knowledge or any of D7, D14 and D1

D17 disclosed the subject-matter of claim 1 except the feature that the signal processor was configured to take a dedicated action upon detection of a connection. This distinguishing feature amounted to shifting of a procedural step, that was previously performed by the

nurse, to the controller.

Therefore, the objective technical problem was to enhance the safety for the patient and to reduce the workload of the nursing staff.

To solve this problem, it was obvious for the person skilled in the art to provide for an automation according to the distinguishing feature, in particular since it was mentioned in paragraph [0149] of D17 that the detection of the connection could be used for the interlock of the operation of the dialysis device.

For this purpose, D7 suggested an automatic transition from priming to treatment (paragraph [0005]) or the use of electromagnetic valves as clamp devices (paragraph [0035]). The dedicated action could be seen in automatically starting the treatment or in opening the clamps.

D14 related to automation of dialysis treatment. Since in D14 the terms "automatic", "automatically" and "semi-automatic" were used 8 times on 12 pages, and since D14 mentioned the advantages of automatic devices and functions, a combination of D17 with D14 would have led to the subject-matter of claim 1.

D1 disclosed that the treatment was begun, when the signals from the sensor were as desired (paragraph [0041]). In the abstract, it was mentioned that the treatment could not be started unless the acoustic signal was within a certain range. This could be regarded as a dedicated action.

Hence, the subject-matter of claim 1 was also rendered obvious by a combination of D17 with the common general

knowledge or any of D7, D14 and D1.

Admittance of the inventive step-objections in view of D17 in combination with D22, in view of D1 in combination with common general knowledge or with any of D1, D7, D17 and D26

It was requested to admit these objections. In particular, the objections starting from D1 should be admitted since this document was previously used for attacking novelty. Both lack of novelty and lack of inventive step were grounds of opposition. Based on case law of the Boards of Appeal concerning fresh grounds of opposition (e.g. decisions T 597/07, T 131/01 and T 635/06) there was no need to substantiate the objection of lack of inventive step based on a document which was the basis for an objection of lack of novelty.

Admittance of the inventive step-objections in view of D7 in combination with itself and in view of D26 in combination with common general knowledge or with any of D7 and D17

It was requested to admit these objections.

Main request - claim 18

All the objections and comments made with regard to claim 1 applied accordingly to claim 18.

VI. The arguments of the patent proprietor may be summarized as follows.

Main request - novelty over D1

D1 did not disclose that a characteristic change in the measurement data was identified during pre-treatment. Paragraph [0039] merely disclosed that the transmitter and sensor were tested without any identification of a change. This was done after the caregiver had confirmed the connection of the patient with the machine. Thus, the purpose of the testing was not to detect an access connection at that time.

Furthermore, it was not disclosed that a dedicated action was taken upon any such identification. The transition from the pre-treatment mode to the blood treatment mode was carried out solely by the operator.

Main request - novelty over D7

In D7, the step of detecting a connection was carried out exclusively by the air bubble detectors. The blood detectors were only used after an air bubble was detected to determine whether there was a bad connection or no connection at all.

Furthermore, the blood detectors were simply arranged to determine the colour of the fluid at the detector location. The movement of the blood was caused by the blood pump. This could not be regarded a transfer of energy between the patient and the machine. Neither was the connection detected by identifying a characteristic change in the measurement data from the blood detectors. D7 rather disclosed that the signal from the blood detectors was read out for one time only to discern whether the connection was bad or missed.

The bubble detectors could not be regarded as energy transfer sensors either.

Paragraph [0014] of D7 did not disclose that the blood detectors were used on their own to detect a connection.

Main request - novelty over D17

In D17, the detection of a patient's heartbeat was used during the blood treatment to ascertain whether the needle had become disconnected.

Paragraph [0149] did not disclose that the controller was actually programmed to identify the patient's heartbeat and to judge from this identification that a connection was present. Furthermore, it could not be derived from the last sentence of this paragraph that a dedicated action was taken by the controller upon this identification. Neither was it disclosed that the interlock referred to some kind of transition between the pre-treatment mode and the blood treatment mode.

Contrary to the appellant's view, merely displaying an indication of the patient connection did not represent a dedicated action regarding the operation of the apparatus.

Main request - novelty over D26

The monitoring of the heart signals described in Figure 4 of D26 took place during the blood treatment mode. D26 did not mention any monitoring in the pre-treatment mode. In particular, D26 did not refer to a signal processor that was configured to, in the pre-treatment mode, process the measurement data for detecting a connection of the circuit to the patient. Furthermore, D26 did not disclose a control system that was operable to switch between a pre-treatment mode and a blood

treatment mode.

Figure 16a referred to by the appellant showed a closed loop for circulating priming fluid. However, this priming took place before the patient was connected. There was no transfer of energy from a patient to the machine at this stage.

The subject-matter of claim was thus novel over D26.

Main request - inventive step in view of the common general knowledge

The invention did not represent a mere automation of steps that were previously performed manually by a dialysis nurse. In particular, such an automation would not result in the monitoring of the transfer of energy between the patient and the device and in the detection of a connection by identifying a characteristic change in the energy transfer data. The invention according to claim 1 provided a different technical solution to the problem of verifying the correct connection that was, in the prior art, solved by the presence of the nurse.

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

Main request - inventive step in view of D11 in combination with D17 or D7

Since neither D11 nor D17 disclosed taking any dedicated action upon detection of a connection between the patient and the system in the pre-treatment mode, a combination of these documents would not result in the subject-matter of claim 1.

D11 related to a system for identifying a disconnection based on monitoring the arterial and venous pressure. D7 used an air bubble detector for detecting a connection. It was not apparent how or why these different approaches would be combined.

Hence, the subject-matter of claim 1 did not lack an inventive step in view of a combination of D11 with D17 or D7.

Main request - inventive step in view of D10 in combination with D17

D10 did not disclose monitoring for a connection in the pre-treatment mode and taking a dedicated action upon detection of a connection.

Since D17 did not disclose these features either, a combination of these documents would not result in the subject-matter of claim 1.

Hence, the subject-matter of claim 1 did not lack an inventive step in view of a combination of D10 with D17

Main request - inventive step in view of D7 in combination with any of D5, D17, D1, D14 or D11

D7 could be considered the most promising starting point for the person skilled in the art. The device of D7 lacked an energy transfer sensor and lacked the detection of a connection based on the identification of a characteristic change in the signal of the sensor. Since D7 taught that the bubble sensor was an essential component for detecting the connection to enable the safe automation of the transition from the pre-treatment phase to the treatment phase, the person

skilled in the art would not replace the bubble sensor with an energy transfer sensor to detect a connection.

Furthermore, such a replacement would require switching the manner of operation of the sensor from a detection of a connection based on the absence of a bubble for a predetermined time to an identification of a characteristic change in the signal. It would thus be necessary to completely redesign the controller, and this would not be obvious for the person skilled in the art.

Inventive step in view of D4 in combination with D17

D4 did not disclose that the controller was configured to detect a connection between a patient and a machine based on a transfer of energy in the pre-treatment mode and to take a dedicated action upon the detection of a connection.

Since D17 did not disclose these features either, a combination of D4 with D17 would not yield the present invention.

Hence, the subject-matter of claim 1 did not lack an inventive step in view of a combination of D4 with D17

Main request - inventive step in view of D17 in combination with the common general knowledge or any of D7, D14 and D1

Paragraph [0149] of D17 referred to the use of the measured frequency components caused by the patient's heartbeat to judge that the cannula is correctly attached before starting the dialysis treatment. However, D17 did not disclose a controller adapted or

programmed to take any dedicated action for controlling the apparatus based on the detected connection. The last sentence of paragraph [0149], suggesting that the judgement could be used for the interlock of the operation of the device, could not be regarded as a disclosure of a dedicated action taken by the controller during pre-treatment.

The distinguishing feature of taking a dedicated action was more than a mere automation. It was rather a different technical solution.

D7 disclosed a different technology to the heartbeat detection of D17, namely, to evaluate whether the connection was good by means of an air bubble sensor. A combination of D17 with D7 would result in replacing the heart beat measurement by an air bubble detection. In paragraph [0046], D7 also referred to the close interrelation between the detection of a good connection by the air bubble sensor and the automation of the process from the priming treatment to the hemodialysis treatment. The person skilled in the art would not be prompted to disregard this link and apply only the feature relating to the automation of the process to the device of D17.

The general references to automatic machines in D14 would not have motivated the person skilled in the art to modify the device of D17.

D1 did not disclose to take a dedicated action in the pre-treatment mode if a connection was detected. Thus, the combination of D17 with D1 would not result in the subject-matter of claim 1.

Hence, the subject-matter of claim 1 did not lack an

inventive step in view of a combination of D17 with the common general knowledge or any of D7, D14 and D1.

Admittance of the inventive step-objections in view of D17 in combination with D22, in view of D1 in combination with common general knowledge or with any of D1, D7, D17 and D26 and in view of D26 in combination with common general knowledge or with any of D7 and D17

These objections, which were not substantiated prior to the oral proceedings before the Board, should not be admitted since the appellant did not provide cogent reasons that there were exceptional circumstances justifying the amendment to their appeal case. In respect of the objections starting from D1 the case law relating to fresh grounds of opposition was not relevant but rather Article 13(2) RPBA was to be considered. There was no reason why these new objections had been made at such a late stage in the proceedings, in particular as the main request was based on the claims a granted.

Admittance of the inventive step-objections in view of D7 in combination with itself

This objection was raised for the first time in the appeal proceedings and should thus not be admitted.

Reasons for the Decision

1. Subject-matter of the invention

The present invention relates to a control system in an apparatus for extracorporeal blood treatment.

As noted in paragraph [0020] of the patent, the operation of the machine may be conceptually divided into two temporal phases: "pre-treatment" and "blood treatment". During the blood treatment mode, blood is extracted from the patient, processed, and returned to the patient. The pre-treatment mode is typically characterised by various set up steps, such as priming of the tubing to displace air in the tubing by blood or saline. As the pre-treatment mode does not involve returning blood to the patient, all or a large part of the safety functions of the controller are typically disabled (paragraph [0021] of the patent).

The claimed control system is configured to carry out a procedure schematically shown in an embodiment in Figure 3. The procedure of Figure 3 is carried out in the pre-treatment mode.
While in the pre-treatment mode, the signal processor receives measurement data from an energy transfer sensor that is arranged to sense the transfer of energy between the patient and the connection system or the extracorporeal blood circuit. This measurement data is processed to identify a characteristic change in the measurement data. Upon such identification, a connection of the extracorporeal blood circuit to the vascular system of the patient is detected and the controller thereafter takes a dedicated action for controlling the operation of the apparatus.

Since claim 1 requires the detection of a characteristic change in the measurement data, it is implicit that the measurement data has to be obtained and processed over a certain period of time, rather than only once. The change in the measurement data indicates that a connection between the patient and the connecting system or the extracorporeal circuit is established.

As noted in paragraph [0034] of the patent, the characteristic change may be a step change in the pressure (encircled at 400 in Figure 4 of the patent) or pulsations originating from the patient's heartbeat (encircled at 402 in Figure 4 of the patent). Further, the "dedicated action for controlling the operation of the apparatus" may be the unlocking of the possibility for entering the blood treatment mode, the automatic entering of the blood treatment mode or the activating of security functions.

Thus, according to the invention, the machine is able to assist in the transition from the pre-treatment mode to the blood treatment mode. This assistance may take the form of preventing entry into the blood treatment mode until the connection is positively detected in the pre-treatment mode or it may take the form of activating the safety functions only once a positive connection is detected.

Claim 18 relates to a computer-readable medium comprising computer instructions which cause a processor to perform the corresponding method for controlling an apparatus for extracorporeal blood treatment.

2. Main request - novelty over D1

It is undisputed that D1 discloses the features of the preamble of claim 1. The acoustic sensors 19a, 19b and 19c (Figure 1 and paragraphs [0027], [0036]) can be regarded as the energy transfer sensor. This sensor is used to detect a disconnection of the access needle during the blood treatment mode by measuring the signal difference between the acoustic transmitter 18 (i.e. the sensor 19a located next to the transmitter) and the sensor 19c (paragraph [0038]).

In paragraph [0039], referred to by the appellant, an initial set-up procedure is described, i.e. the transmitter and the sensors are tested to ensure that the desired signal and amplitude are transmitted and received. This is necessary to be able to attribute a further signal loss to a disconnection.

Hence, in D1, there is no disclosure of detecting a connection by identifying a characteristic change in the measurement data during pre-treatment. Rather, during pre-treatment, the signal of the transmitter is received only once the connection has already been established, for testing (and possibly calibration) purposes. The one-off transmission of a signal that is "as desired" (paragraph [0041]) cannot be regarded as a characteristic change in the measurement data.

A periodic detection of the transmitter signal is disclosed in D1 only during treatment to determine an access disconnect (paragraph [0041]).

Accordingly, D1 does not disclose to take, in the pretreatment mode, a dedicated action for controlling the operation of the apparatus upon the identification

of a characteristic change in the measurement data.

The subject-matter of claim 1 is therefore novel over D1.

3. Main request - novelty over D7

D7 discloses an extracorporeal blood treatment device comprising an air bubble detection device (9, 10) and a blood detector (11, 12) in each of the arterial blood line and the venous blood line (paragraph [0029], Figure 1). The detectors are used in a procedure for evaluating the connection condition of the arterial and venous needles.

The device comprises a signal processor which is configured to, in the pre-treatment mode, process the measurement data of the blood detectors for detecting a connection of the extracorporeal blood circuit to the vascular system of the patient (paragraph [0036]). In detail (paragraph [0042]), the blood detectors are used, after a bubble has been detected by the air bubble detectors, to evaluate whether the connection was bad (blood detected) or missing (no blood detected). A bad connection can be considered to be a connection.

However, the connection is not detected by identifying a characteristic change in the measurement data. Rather, in D7 the data of the blood detectors is read out only once, and only in the case the bubble detectors detects a bubble (Figure 5). Hence, there is no identification of a blood column at the blood detector at a time t prior to which the detectors did not detect blood.

From paragraph [0014], referred to by the appellant, it cannot be derived that the blood detectors are used on their own for identifying a connection.

Moreover, D7 does not disclose to take a dedicated action upon detection of the bad connection. The automation of the process from the priming to the dialysis treatment mentioned in paragraph [0046] can only be performed if the connection is evaluated as "good", which is done on the basis of the air bubble detector.

Hence, the subject-matter of claim 1 is novel over D7.

4. Main request - novelty over D17

D17 discloses a dialysis device comprising an artery pressure sensor 5 and a venous pressure sensor 9 in the extracorporeal blood circuit (Figure 1). The data of the arterial pressure sensor is used to identify a frequency component caused by the patient's heartbeat (paragraph [0054]). This can be used, before the treatment starts, to detect a connection of the vascular needle to the patient (paragraph [149], first two sentences). Hence, D17 discloses all the features of the signal processor of claim 1, except the last one, namely, that the signal processor is configured to take a dedicated action for controlling the operation of the apparatus, upon the identification of a connection during pre-treatment.

However, the last sentence of paragraph [0149] does not imply that the signal processor is configured to take a dedicated action for controlling the operation of the apparatus in the pretreatment mode, upon this identification. Irrespective of which action might be

involved in the "interlock of the operation of the dialysis device", it cannot be derived directly and unambiguously that such an action is taken by the controller and upon detection of a connection during pre-treatment.

Hence, the subject-matter of claim 1 is novel over D17.

5. Main request - novelty over D26

The disclosure of D26 is similar to that of D17. The presence of a signal component originating from the patient's heart in a blood pressure signal is monitored. Absence of such a signal component is taken as an indication of a failure in the integrity of the blood circuit 20, and prompts the device 25 to activate an alarm and/or stop the blood flow by stopping the blood pump 3 (page 8, lines 35 to 38, Figures 1 and 2). It is also mentioned to shut off the alarm once the heart beat signal, i.e. the connection, is discovered again (page 13, lines 4 to 5). However, this is done during blood treatment, not during pre-treatment.

The priming process described on page 22, lines 12 to 15, is performed by pumping a priming fluid through the flow circuit. This is done before the patient is connected, i.e. in a pre-treatment mode, but it does not involve monitoring of the vascular access. A priming with blood, as referred to by the appellant, is neither explicitly nor implicitly mentioned in D26. As to the last paragraph on page 22, it concerned a general statement on the applicability of monitoring the integrity of the flow circuit but did not directly and unambiguously disclose its application to the pre-treatment mode. Hence, D26 does not disclose that the heartbeat detection can be used to detect the

establishment of a connection in a pre-treatment mode.

Hence, the subject-matter of claim 1 is novel over D26.

6. Main request - inventive step in view of D17 in combination with the common general knowledge or any of D7, D14 and D1

D17 is primarily directed to measurement of the pulse and blood pressure during the extracorporeal dialysis and does not disclose that the signal processor is actually programmed to take, when a connection is detected, a dedicated action for controlling the operation of the apparatus, and that this is done in the pre-treatment mode.

The distinguishing feature cannot be regarded as a automation of a step that was previously carried out manually by the nurse. In fact, there are several tasks that are usually performed by the nurse before and after the connection of the patient to the extracorporeal circuit has been established. However, the nurse does not take on a regular basis one specific dedicated action for controlling the operation of the apparatus upon identification of the connection. Hence, the combination of D17 with the common general knowledge of the person skilled in the art would not lead to the claimed invention.

D7 uses a different approach to evaluate the connection conditions, which does not involve detection of a connection based on identifying a characteristic change in the measurement data of an energy transfer sensor. A combination of D17 with D7 would result in replacing the heart beat measurement by an air bubble detection. In paragraph [0046], D7 also refers to the close

interrelation between the detection of a good connection by the air bubble sensor and the automation of the process from the priming treatment to the hemodialysis treatment. The person skilled in the art would not be prompted to disregard this link and apply only the feature relating to the automation of the process to the device of D17.

The general references to automation in dialysis machines in D14 would not have motivated the person skilled in the art to modify the device of D17.

D1 does not disclose to take a dedicated action in the pre-treatment mode if a connection is detected. Thus, the combination of D17 with D1 would not result in the subject-matter of claim 1.

Hence, the subject-matter of claim 1 does not lack an inventive step in view of a combination of D17 with the common general knowledge or any of D7, D14 and D1.

7. Main request - inventive step in view of the common general knowledge

7.1 The Board noted the various offers of witness evidence in support of the skilled person's common general knowledge (pages 29-31 and 58 of the grounds of appeal). However, it was not clear in support of which specific facts the witnesses were to provide evidence. A witness can only provide proof of facts that lie within the realm of their own experience (e.g. a nurse may be able to provide evidence of what she did on a particular date with a particular blood treatment apparatus). No such facts have been relied on, nor is it clear what lies within the realm of the witnesses' experiences, and the Board saw no reason to call any of

the witnesses on the basis of the offer of witness evidence made in the grounds of appeal. The Board wishes to add that common general knowledge is usually effectively proven by way of handbooks and the like.

7.2 The subject-matter of claim 1 does not represent a "mere automation" of a procedure previously carried out by a nurse, since it concerns the detection of the connection by identifying a characteristic change in the measurement data of an energy transfer sensor. However, a dialysis nurse checks whether a connection is established by visually inspecting the blood entering the extracorporeal circuit. There appears to be no evidence that before the priority date the nurse used an energy transfer sensor, as in the present invention, for this purpose. Hence, the subject-matter of claim 1 concerns a different technical solution, and not a mere automation of manual steps. This view, expressed by the Board in the communication of 14 March 2022, has not been disputed by the appellant.

Therefore, the subject-matter of claim 1 is not rendered obvious by the common general knowledge.

8. Main request - inventive step in view of D11 in combination with D17 or D7

D11 relates to a system for identifying a disconnection based on monitoring the arterial and venous pressure during blood treatment. A characteristic change in the measurement data of the pressure sensors is an indication of a disconnection, which triggers an alarm (paragraphs [0039] and [0044]). However, D11 does not disclose the use of a characteristic change in the measurement data for the detection of a connection during pre-treatment, and a dedicated action which is

taken upon such detection.

Since neither D7 nor D17 disclose both said features, a combination of D11 with D7 or D17 would not result in a device according to claim 1.

Hence, the subject-matter of claim 1 involves an inventive step in view of a combination of D11 with D17 or D7.

9. Main request - inventive step in view of D10 in combination with D17

D10 is similar to D11 and also relates to a system for identifying a disconnection based on monitoring the arterial and venous pressure during blood treatment. A characteristic change in the measurement data of the pressure sensors is an indication of a disconnection, which triggers an alarm (paragraph [0054]). However, D10 does not disclose the use of a characteristic change in the measurement data for the detection of a connection during pre-treatment, and a dedicated action which is taken upon such detection.

Since the latter feature is not disclosed in D17 either, a combination of D10 with D17 would not result in a device according to claim 1.

10. Main request - inventive step in view of D7, alone or in combination with any of D5, D17, D1, D14 or D11

In D7, the blood detectors are used to determine whether a (bad or no) connection of the patient to the circuit is present, once the bubble detectors detect bubbles. However, neither the bubble detectors nor the blood detectors are monitored to identify a

characteristic change in the measurement data.

The person skilled in the art would not be motivated, by D7 itself or by any of documents D5, D17, D14, D11 and D1, to modify the connection detection of D7 by using a the pressure sensor disclosed in any of D5, D17, D14 and D11 or the acoustic sensor of D1.

11. Main request - inventive step in view of D4 in combination with D17

D4 relates to monitoring the correct coupling of a syringe to the extracorporeal circuit during treatment (page 13, last paragraph). D4 does not disclose the detection of a connection between a patient and the extracorporeal circuit during pre-treatment, and the taking of a dedicated action when the connection is detected.

Since D17 does not disclose the latter feature either, a combination of D4 with D17 would not result in the present invention.

12. Admittance of the inventive step-objections in view of D1 in combination with common general knowledge or with any of D1,D7, D17 and D26

These objections were not substantiated by the appellant prior to the notification of the summons to the oral proceedings before the Board. This substantiation is considered to represent an amendment to the party's appeal case, which shall not be taken into account unless there are exceptional circumstances which have been justified with cogent reasons (Article 13(2) RPBA).

The appellant argued that they were entitled to raise the objection of lack of inventive step at a late stage of the proceedings as this was permitted by case law, in particular decisions T 597/07, T 131/01 and T 635/06. According to these decisions there was no need to substantiate in the notice of opposition an objection of lack of inventive step, provided it was based on a document which was the basis for an objection of lack of novelty.

The above-mentioned decisions do not concern the Rules of Procedure of the Boards of Appeal and were written against the background of opinion G 10/91 and decisions G 1/95 and G 7/95, where the Enlarged Board had set limits on the examination of fresh grounds for opposition in appeal proceedings. The decisions of the technical boards focused on the issue whether the boards were prevented from examining an objection for lack of substantiation in the notice of opposition. That issue as well as the limits imposed by the Enlarged Board are separate and independent from the articles of the Rules of Procedure which concern the criteria for the admittance of late-filed submissions in the appeal proceedings (see also T 1042/18, Reasons 4.3-4.5). It is thus clear that the decisions relied on by the appellant cannot take precedence over the application of Article 13(2) RPBA.

Since the appellant did not provide cogent reasons and the Board did not see any exceptional circumstances, it decided not to admit these objections.

13. Admittance of the inventive step-objections in view of D17 in combination with D22, D26 in combination with common general knowledge or with any of D7 and D17

In its communication the Board pointed out that these objections had not been previously substantiated. The appellant did not dispute this view and merely provided, in the submission dated 13 April 2022, some arguments in respect of the substance of the objection in view of D26 alone.

The objections in view of D17 in combination with D22 and in view of D26 in combination any of D7 and D17 are disregarded on the basis of Article 12(4) RPBA 2007, since they do not comply with the requirements of Article 12(2) RPBA 2007, referred to by Article 12(4) RPBA 2007.

As to the objection in view of D26 alone its late substantiation is an amendment of the appellant's case after notification of the summons. Since no exceptional circumstance that would justify the admittance of said amendment have been brought forward, this objection is disregarded on the basis of Article 13(2) RPBA 2020.

14. Main request - claim 18

The above considerations apply accordingly to claim 18. The subject-matter of this claim is therefore novel and involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated