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Datasheet for the decision of 26 May 2021

Case Number: T 2165/16 - 3.2.02

Application Number: 03736434.6

Publication Number: 1480713

IPC: A61M1/36, A61M1/34

Language of the proceedings: EN

Title of invention:
APPARATUS FOR AN EXTRACORPOREAL TREATMENT DEVICE TO CONTROL BLOOD WITHDRAWAL AND INFUSION

Patent Proprietor:
Gambro Lundia AB

Opponent:
Fresenius Medical Care AG & Co. KGaA

Headword:

Relevant legal provisions:
EPC Art. 100(a), 100(b), 100(c)
RPBA 2007 Art. 12(4)
RPBA 2020 Art. 12(2), 13(1), 13(2), 25(2)

Keyword:

Grounds for opposition - added subject-matter (no) - insufficiency of disclosure (no) - lack of novelty (no) - lack of inventive step (no)
Amendment to case - reasons for submitting amendment in appeal proceedings (no) - amendment admitted (no)
Amendment after summons - exceptional circumstances (no) - cogent reasons (no) - taken into account (no)

Decisions cited:

T 0775/90

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 2165/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 26 May 2021

Appellant: (Opponent)	Fresenius Medical Care AG & Co. KGaA Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Nordmeyer, Philipp Werner df-mp Dörries Frank-Molnia & Pohlman Patentanwälte Rechtsanwälte PartG mbB Theatinerstraße 16 80333 München (DE)
Respondent: (Patent Proprietor)	Gambro Lundia AB P.O. Box 10101 220 10 Lund (SE)
Representative:	J A Kemp LLP 14 South Square Gray's Inn London WC1R 5JJ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 21 July 2016 rejecting the opposition filed against European patent No. 1480713 pursuant to Article 101(2) EPC**

Composition of the Board:

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

Summary of Facts and Submissions

I. The opponent has appealed against the Opposition Division's decision to reject the opposition against European patent No. 1 480 713. The decision was posted on 21 July 2016.

The patent was opposed on the grounds of insufficient disclosure, added subject-matter, lack of novelty and lack of inventive step.

II. Oral proceedings took place on 26 May 2021 by videoconference.

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

The respondent (patent proprietor) requested that the appeal be dismissed so that the patent is maintained as granted (main request) or, as an auxiliary measure, that the patent be maintained on the basis of one of auxiliary requests 1 to 11 filed with the reply to the grounds of appeal dated 4 April 2017.

III. The following documents are mentioned in this decision:

E1: WO-A-02/35979
E2: WO-A-01/08723
E4: EP-A-0 829 265
E5: EP-A-1 110 566
E6: DE-T-3687453
E8: EP-A-0 834 329
E12: US application No. 09/703,702
E13: "Integra - operator manual", 28 June 1994
E19: "Apheresestandard", Deutsche Arbeitsgemeinschaft

Klinische Nephrologie
E20: US-A-5,980,481

IV. Claim 1 of the patent as granted reads as follows:

"A device for controlling ultrafiltration of blood comprising: an extracorporeal circuit (107), means (102, 113) for withdrawing blood from a blood vessel in a patient into the extracorporeal circuit (107), a blood filter (108) in the circuit for filtering liquid ultrafiltrate from the blood, means (113, 103) for infusing the filtered blood into the patient, and a controller (702, 705) which is configured to monitor a withdrawal pressure (109) and/or infusion pressure (110) in the extracorporeal circuit in order to detect an occlusion which at least partially blocks the withdrawal or infusion of the blood, which controller (702, 705) in response to the detection of the occlusion is configured to automatically reduce blood flow through the circuit, which is configured to detect an alleviation of the occlusion, and which is configured to automatically increase the blood flow after the occlusion has been alleviated, **characterised in that** the device has an ultrafiltrate pump (114), wherein the controller (702, 705) is configured to reduce the speed of the ultrafiltrate pump (114) to reduce the ultrafiltrate flow, and **in that**
the controller (702, 705) is configured to automatically reduce the ultrafiltrate flow in response to the detection of the occlusion, and is configured to automatically increase the ultrafiltrate flow after the occlusion has been alleviated."

Claims 2 to 4 are dependent claims.

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

Admittance of documents

E19 and E20 had been filed as a proof of the common general knowledge that apheresis and ultrafiltration belonged to the same technical field and were based on the use of similar filters. These documents should be admitted into the proceedings.

Novelty

The subject-matter of claim 1 of the patent as granted lacked novelty over each of E1, E5 and E8.

The invention as defined in claim 1 of the patent as granted had been disclosed in E12, which was an application of the same applicant, filed earlier than the application from which the priority was claimed. It followed that the priority claim of the patent was not valid.

E12 disclosed a device for controlling ultrafiltration of blood with a blood pump and an ultrafiltrate pump. It literally disclosed that the ultrafiltrate pump was stopped when an occlusion occurred (page 43, second paragraph). The occlusion could be detected by monitoring the outlet pressure at the blood pump outlet. After the occlusion had been alleviated the blood pump and the ultrafiltrate pump were restarted (Figure 8 and page 34, lines 9 to 18). Whether the pumps were restarted simultaneously was not relevant, as the claim 1 of the patent as granted did not require it.

Although the ultrafiltrate pump was controlled on the basis of the blood flow, this flow was adjusted depending on levels of pressure measured by pressure sensors, which levels were indicative of an occlusion (Figure 5 and pages 30 to 33). In other terms, when an occlusion occurred the pressure target in the withdrawal and infusion lines was reduced. This led to a reduction of the blood flow. When the blood flow fell below a given threshold, the ultrafiltrate pump was stopped. Thus, the ultrafiltrate flow was reduced automatically in response to the detection of an occlusion. It was irrelevant whether the ultrafiltrate pump would also be stopped if the reduction of the blood flow was not caused by an occlusion. Claim 1 of the patent as granted was not limited in this respect.

Since the priority claim of the patent was not valid E1 belonged to the state of the art. E1 had the same content as E12. Since E12 anticipated the subject-matter of claim 1 of the patent as granted, the same held true for E1.

Both E5 and E8 disclosed a device for controlling ultrafiltration of blood. These documents concerned apheresis devices for separating plasma from blood. The device disclosed in the patent did the same, as described in paragraphs [0002], [0034] and [0046]. With an ultrafiltration treatment not only water was removed from blood, but also some blood components which could pass through the filter used for this purpose. Even a filter with the pore size disclosed in paragraph [0048] of the patent in relation to a preferred embodiment would not exclude the passage of molecules other than water and salts, such as small proteins. Thus the patent did not teach that some technical difference between extraction of plasma (as described in E5

and E8) and ultrafiltration was intended. In particular, the filters employed had to be considered the same in the absence of any specific definition in claim 1 of the patent as granted. It followed that apheresis and ultrafiltration, which both involved the separation of plasma water from blood, were performed using identical devices with the same structural features.

Inventive step

The subject-matter of claim 1 of the patent as granted was not inventive when starting from E4, E5 or E13.

E4 disclosed a device for controlling ultrafiltration of blood with all the claimed features except that the controller was configured to automatically reduce the ultrafiltrate flow in response to the detection of an occlusion, and to automatically increase the ultrafiltrate flow after the occlusion had been alleviated.

The distinguishing features avoided an excessive removal of fluid from the blood when a reduced blood flow passed through the device. Thus, the objective technical problem was to obtain an ultrafiltration device with which a defined removal of fluid from the patient blood could be achieved.

To solve the objective technical problem the person skilled in the art would have turned to E2, which concerned the same technical considerations and disclosed that the ultrafiltration rate had to be coupled with the blood flow to increase the efficiency of the treatment and avoid caking of the blood filter (page 2, lines 12 to 18). More specifically, E2 taught

that if the pressure in the blood withdrawal line was outside a desired range the ultrafiltrate flow was adjusted accordingly to bring the pressure back within the range (page 9, lines 1 to 11).

To solve the same problem the person skilled in the art would have also considered the teaching of E5 and E6, which taught to control all the pumps of an apheresis device on the basis of the pressure level in the withdrawal or the infusion lines. In apheresis devices the same technical considerations applied with respect to the control of the pumps. These considerations were not directly dependent on the particular therapeutic application, as even explicitly mentioned in E5 (paragraphs [0007] and [0012]).

The person skilled in the art would have combined E4 with E2 also to solve the objective technical problem of increasing the efficiency of the ultrafiltration device of E4, in particular trying to avoid filter caking (page 1, from line 31). The teaching of E2 aimed at having safe conditions continuously during dialysis by avoiding filter caking and at the same time increasing efficiency by keeping the ultrafiltration rate as high as the conditions of the filter permitted (page 3, line 26 to page 4 line 36).

The objection starting from E5 could be presented only after the Board's finding that E5 did not deprive the subject-matter of claim 1 of novelty. It should be admitted into the appeal proceedings.

E13 also disclosed a device for controlling ultrafiltration of blood. If the pressure in an arterial line was below a defined value an alarm was detected, which resulted in the stop of the blood pumps

of the device and the reduction to a minimum of the speed of the ultrafiltration pump.

Normal functioning conditions with higher flow rates were resumed if an override button was pressed by an operator after a check of the device (page 207).

The only distinguishing feature of the subject-matter of claim 1 over E13 was that the increase of the flow rates of the pumps took place automatically.

Automatising the process of restarting pumps and resuming normal operating conditions, which was carried out manually according to E13, would have been obvious like every other automatisation, as already found for example in T 775/90. Such an automatisation would not have represented any risk for the patient. Moreover, E13 itself hinted at the possibility that the alarm condition could be resolved after 10 seconds without the intervention of an operator (Note on page 207 and page 156, disclosing that the operator intervention was required to merely remove the cause of the alarm, obviously only if needed).

Extension of subject-matter

In the impugned decision the Opposition Division had concluded that the subject-matter of claim 1 of the patent as granted was based on method claims 26 and 28 as filed. These method claims did not disclose the process of the detection of an occlusion by a controller configured to monitor a withdrawal pressure and/or infusion pressure. Method claim 20 as filed, which generally disclosed the detection of a withdrawal pressure or infusion pressure crossing a predetermined threshold value, was dependent on claim 1 and related

to a different embodiment. It could not be combined with claims 26 and 28. All the embodiments disclosed in the application as filed comprised pressure sensors for the controller to monitor the withdrawal and the infusion pressure. Nowhere was it disclosed that such sensors could be optional for the concrete device as defined in claim 1 of the patent as granted to work. Since claim 1 of the patent as granted did not define any pressure sensors, an unallowable intermediate generalisation had been introduced, which extended the claimed subject-matter beyond the content of the application as filed.

Claims 20, 26 and 28 of the application as filed could not provide a basis for all the features of claim 1 of the patent as granted, which included the controller configured to monitor a withdrawal pressure and/or infusion pressure to detect an occlusion. A combination of features of the description with these claims could not provide such a basis either: while claim 26 as filed mentioned an ultrafiltration blood circuit and claim 1 of the patent as granted defined an extracorporeal circuit, it was not derivable from the application as filed how these circuits differed. It followed that a basis for the subject-matter of claim 1 of the patent as granted could only be looked for in the original description alone. However, the description only disclosed specific embodiments with many more features such as the controller which, upon the detection of an occlusion, prompted the patient to move his arm or his body to alleviate the occlusion (page 12, last paragraph). The omission of all these features was a further unallowable intermediate generalisation.

Claim 20 as filed specifically defined that the

detection of an occlusion was performed by detecting a withdrawal pressure or infusion pressure crossing a predetermined threshold value. The requirement of crossing a predetermined threshold, which was consistently taught and not presented as optional in the application as filed (pages 6, 7 and 12 and Figures 3 and 8), had been omitted in claim 1 of the patent as granted. Moreover, neither claim 20 as filed nor the description disclosed that the controller could monitor both the withdrawal pressure and the infusion pressure to detect an occlusion, which was a possibility according to claim 1 of the patent as granted.

In any case the embodiment according to claims 1 and 20, described on pages 6, 7 and 12 of the application as filed, was solely concerned with the control of the blood flow. There was no disclosure of controlling the ultrafiltration. Page 58, lines 4 to 11 disclosed controlling the ultrafiltration based on the control of the blood flow. There was no mention of monitoring the withdrawal pressure or the infusion pressure. More generally, in the application as filed there was no disclosure of a direct dependency of the ultrafiltrate flow on the detection of an occlusion, as could be derived from the two-part form introduced in claim 1 of the patent as granted.

A further unallowable extension of subject-matter had been introduced by the change of claim category from method to device claims. The structural and functional features of the device according to claim 1 of patent as granted were not disclosed in an exhaustive way in the method claims of the application as filed. The controller was mentioned in a single method step of claim 26, according to which it automatically reduced

blood flow and ultrafiltrate flow through the circuit in response to the detection of an occlusion. Claim 26 did not specify, for example, that the detection of the occlusion or the increase of the blood flow and the ultrafiltrate flow after the occlusion had been alleviated were performed by the same controller which automatically reduced the blood flow and the ultrafiltrate flow or even that the detection of the occlusion was performed by a controller at all.

Sufficiency of disclosure

As disclosed in the description (paragraphs [0009] and [0017]), the object of the invention as defined in claim 1 of the patent as granted was to distinguish between small problems such as a partial occlusion which could be resolved automatically or by the patient and bigger problems such as a total occlusion which required consideration by the medical personnel. However, claim 1 of the patent as granted did not differentiate between partial and total occlusions. It provided no specific thresholds for pressure levels indicating such occlusions or even any occlusion within the meaning of the claim. It followed that with most of the embodiments encompassed by claim 1 of the patent as granted the object of the invention could not be reached. Thus, the invention was not sufficiently disclosed over its whole scope.

A claim interpretation according to which every detected occlusion should lead to a reduction of the blood flow and the ultrafiltrate flow was against the precise wording of the claim and was therefore not allowable. Such an interpretation could at most relate to an alternative embodiment, as defined in claim 22 as filed.

The patent did not disclose how an occlusion could be detected by monitoring the withdrawal pressure and/or infusion pressure. A change in pressure could have a number of different causes, for example the use of anticoagulants.

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

Admittance of documents

E19 and E20 should not be admitted into the proceedings. The Opposition Division had correctly decided not to admit E19. E20 represented an amendment to the appellant's case after the filing of the grounds of appeal. There was no reason why E20 could not have been filed earlier. Moreover, the filing was detrimental to procedural efficiency.

Novelty

Neither E12 nor E1 disclosed a controller configured to automatically reduce the ultrafiltrate flow in response to the detection of an occlusion or configured to automatically increase the ultrafiltrate flow after the occlusion had been alleviated. E12 and E1 disclosed controlling ultrafiltration based on a blood flow threshold of 40 ml/min. It followed that the priority claim of the patent was valid and that E1 was not novelty-destroying for the subject-matter of claim 1 of the patent as granted.

Neither E5 nor E8 disclosed a device for controlling ultrafiltration of blood. The filters used in ultrafiltration devices such as those disclosed in the

patent were quite specific types of filters, which were not disclosed in E5 or E8, concerned with separation of blood components. In this context plasma water, mentioned in paragraph [0034] of the patent, was not plasma.

Inventive step

E4 concerned a multi-purpose blood treatment machine, with no special focus on ultrafiltration. Upon the detection of critical conditions, all of the pumps of the machine were stopped and the machine was put into a "safe state". E4 did not disclose a controller being configured to automatically reduce the ultrafiltrate flow in response to the detection of an occlusion, and to automatically increase the ultrafiltrate flow after the occlusion had been alleviated as defined in claim 1 of the patent as granted.

The distinguishing feature of the claim addressed the problem of improving the efficiency, without compromising safety.

E2 did not address this problem. E2 taught to change the ultrafiltration rate of an ultrafiltration device on the basis of the blood flow rate, to maximise the ultrafiltration but still prevent filter caking. E2 taught changes to the ultrafiltration rate that applied to a steady state and were generally uncoupled to the detection or alleviation of an occlusion. Hence it did not disclose the distinguishing feature.

More generally, E2 and E4 had no links with one another. While E4 was about priming a general device, E2 was about controlling a filter in a dialysis method using post-dilution substitution, which was especially

prone to filter caking.

E5 and E6 would not have been considered by the person skilled in the art, since these documents did not concern ultrafiltration.

The appellant's objection starting from E5 had been presented after the notification of the summons to oral proceedings. There were no exceptional circumstances justified with cogent reasons for this late amendment of the appellant's case. The objection should not be admitted into the proceedings.

E13 disclosed a device for controlling ultrafiltration of blood. An improper pressure measurement triggered an alarm condition which caused the blood pump and ultrafiltrate pump to be stopped. Normal operation with a restart of the pumps would be resumed after a check by an operator who had to manually press an "override" key. According to E13 the alarm condition could not be resolved automatically, as it belonged to a class requiring operator intervention (page 156).

Thus, E13 did not disclose a controller configured to automatically increase the blood flow and the ultrafiltrate flow after an occlusion had been alleviated.

The actions of the operator checking needles and tubes and pressing the override key could not be easily automated. The invention as defined in claim 1 of the patent as granted was different. It involved a control algorithm that rendered the presence of an operator unnecessary by pre-emptively avoiding an alarm situation.

Extension of subject-matter

The subject-matter of claim 1 of the patent as granted was generally based on claims 26 and 28 of the application as filed. These claims were directed to a method for controlling ultrafiltration of blood performed using a controller. Claiming a device for controlling ultrafiltration and specifying features of the controller, as in claim 1 of the patent as granted, did not change the level of generality of the claims as filed.

Claims 20 and 21 as filed disclosed the general step of detecting the withdrawal and infusion pressures. The prompting of the patient to move to alleviate an occlusion, defined in claim 1 as filed on which claims 20 and 21 depended, was merely a preferable feature with no inextricable link with the slowing of the blood and ultrafiltrate pumps upon detection of an occlusion and the increasing of the speed of these pumps when the occlusion had been alleviated. Pressure sensors were not essential to the definition of the invention.

Claim 1 of the patent as granted inherently required that the monitored withdrawal and/or infusion pressures exceeded certain limit values, as the monitoring was done to detect an occlusion. Moreover, Figures 3 and 6 of the application as filed showed that these values were not a single threshold, as they could depend on the blood flow. Figures 2 and 4, and page 28 as filed disclosed the monitoring of both the withdrawal and infusion pressures.

Sufficiency of disclosure

The patent described in detail how to carry out the

invention as defined in claim 1. Figures 8 and 9 and paragraphs [0123] to [0133] disclosed an example of how an occlusion could be identified by using certain algorithms. Paragraphs [0053] to [0122] disclosed the algorithms in detail. Paragraphs [0157] to [0159] taught how to reduce and increase the ultrafiltrate flow rates.

Claim 1 did not mention minor difficulties or more serious problems but rather monitoring the pressure to "detect an occlusion which at least partially blocks the withdrawal or infusion of the blood". It was the pressure change that signalled the presence of an occlusion, and this was what defined the claimed "occlusion". The possible use of anticoagulants was irrelevant in this respect. Claim 1 then specified that the detection of the occlusion caused a reduction in the blood flow rate and a reduction in the ultrafiltrate flow rate. Claim 1 was quite clear in teaching that the same reaction was provoked whether the occlusion was "minor" or "more serious". The reduction of the flow rates was done so as to give the flow a time period to recover. If the flow indeed did recover, the flow rates were increased again.

Reasons for the Decision

1. The invention

The invention relates to a device for controlling ultrafiltration of blood.

Such a device withdraws blood from a patient, treats it in an extracorporeal blood circuit and then returns it to the patient's body. According to the patent the

ultrafiltration, designed for the extraction of plasma water from the blood, can be used for the treatment of patients with congestive heart failure. This is a chronic progressive condition in which fluid builds up around the heart and causes it to pump inefficiently.

A treatment session for removing this fluid typically lasts 4 to 8 hours (paragraph [0139] of the patent).

A device according to claim 1 of the patent as granted is depicted in Figures 1 and 2 reproduced below.

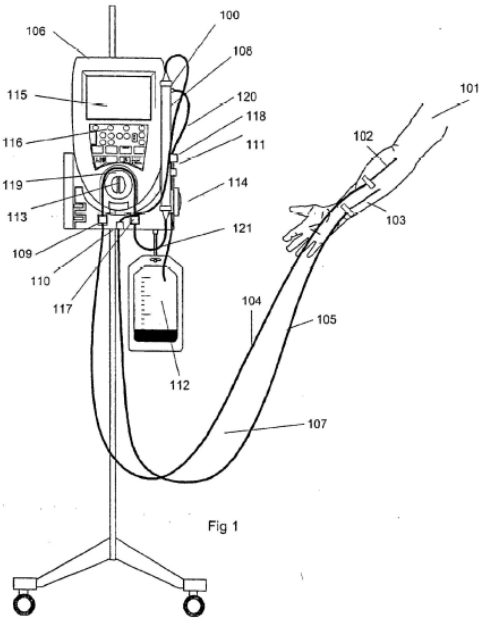

Fig 1

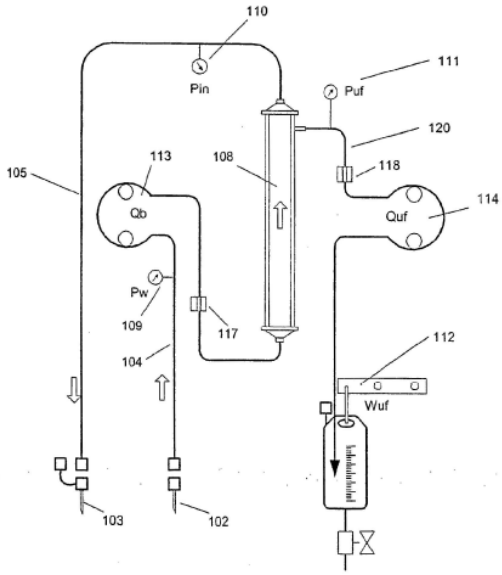

Fig. 2

The device comprises an extracorporeal circuit (107), means (needle 102 and blood pump 113) for withdrawing blood from a blood vessel in a patient into the extracorporeal circuit, a blood filter (108) in the circuit for filtering liquid ultrafiltrate from the blood, an ultrafiltrate pump (114) and means (blood pump 113 and needle 103) for infusing the filtered blood back into the patient. The device further comprises a controller which is configured to monitor a

withdrawal pressure and/or infusion pressure (using pressure sensors 109 and 110) in the extracorporeal circuit in order to detect an occlusion which at least partially blocks the withdrawal or infusion of the blood.

Sudden pressure changes in the blood circuit indicate an occlusion. Occlusions may be caused by minor problems that can be safely and easily solved or more serious problems that require a nurse or other medical professional to attend to the patient and the blood circuit.

In response to the detection of the occlusion the controller is configured to automatically reduce blood flow through the circuit, to detect if an alleviation of the occlusion occurs, and to automatically increase the blood flow after the occlusion has been alleviated. In doing so the controller attempts to solve the problems which have caused the occlusion and, if successful, resumes the ultrafiltration treatment. Since the treatment does not have to be stopped after every episode of occlusion, the comfort of the patient and the medical personnel is increased.

The controller is also configured to reduce the speed of the ultrafiltrate pump to automatically reduce the ultrafiltrate flow in response to the detection of the occlusion, and to automatically increase the ultrafiltrate flow after the occlusion has been alleviated. This avoids the risk of clogging the filter, which would be present if the ultrafiltrate pump continued at its normal speed while the flow of blood through the filter was reduced (paragraphs [0092] and [0093] of the patent).

2. Admittance of documents

The respondent argued that E19 and E20 should not be admitted into the appeal proceedings.

E19 was filed for the first time in the first-instance proceedings after the expiry of the opposition period and was not admitted by the Opposition Division (point 5.2 of the Reasons of the impugned decision).

Under Article 12(4) RPBA 2007, which applies by virtue of Article 25(2) RPBA 2020, the admission of evidence which was not admitted in the first instance proceedings is at the Board's discretion. The appellant did not explain why E19 could not have been filed earlier. Furthermore, it did not explain why the Opposition Division's decision not to admit this document should be overturned. In view of these circumstances, the Board decides not to admit E19 into the appeal proceedings under Article 12(4) RPBA 2007.

E20 was filed in the appeal proceedings after the filing of the grounds of appeal. This filing constitutes an amendment to the appellant's case. Under Article 13(1) RPBA 2020, the amendment is subject to the party's justification and may be admitted only at the discretion of the Board.

The Board notes that the appellant did not provide any reasons why E20 could not have been filed earlier. The issue of whether a device for apheresis can anticipate an ultrafiltration device is one that was already discussed during the opposition proceedings. Even if the appellant's filing of E20 had been intended as a reaction to the non-admission of E19 by the Opposition Division, it could and should have been done with the

statement of grounds of appeal. In view of these circumstances, the Board decides not to admit E20 into the appeal proceedings under Article 13(1) RPBA 2020.

3. Novelty

3.1 The appellant argued that the subject-matter of claim 1 of the patent as granted lacked novelty over E1, which belonged to the state of the art because the priority claim of the patent was not valid.

Thus, the Board has to consider whether the priority claim of the patent is valid, in view of the appellant's arguments.

The patent claims priority of 14 February 2002 from US patent application No. 73855. However, the appellant argued that the same invention had been disclosed in E12, which was an earlier application of the same applicant. If this were the case, US patent application No. 73855 would not be "the first application" disclosing the same invention as the patent in suit within the meaning of Article 87(1) EPC. It would follow that under this article no right of priority could be enjoyed from US patent application No. 73855 for that invention.

The Opposition Division concluded that the priority claim was valid, since E12 did not disclose a controller configured to automatically reduce the ultrafiltrate flow in response to the detection of the occlusion, and automatically increase the ultrafiltrate flow after the occlusion had been alleviated (point 4.2 of the Reasons of the impugned decision).

As the Opposition Division noted, the disclosure

content of E12 is identical to parts of the disclosure of the patent in suit. In particular, E12 has Figures 1 to 9, which are identical to Figures 1 to 9 of the patent in suit. It is common ground that E12 discloses a device for controlling ultrafiltration of blood with the features of the preamble of claim 1 of the patent in suit.

The Board notes that the claim feature of the controller configured to automatically reduce the ultrafiltrate flow in response to the detection of the occlusion, and automatically increase the ultrafiltrate flow after the occlusion had been alleviated implies a specific control algorithm of the controller for acting on the ultrafiltrate flow. This feature is disclosed in detail in relation to Figures 10 to 13 of the patent, which figures are missing in E12.

According to E12 (page 33, last paragraph, to page 34, second paragraph) the ultrafiltrate pump may be stopped when the blood pump flow is less than 40 ml/min. While E12 discloses that the ultrafiltrate pump may be stopped together with the blood pump in response to certain pressure values indicative of an occlusion (page 43, second paragraph) and that the blood pump and the ultrafiltrate pump may be automatically restarted when the occlusion has been alleviated (Figure 8 and page 34, lines 9 to 18), the control of the ultrafiltrate pump is dependent on the blood pump flow, not necessarily on the withdrawal pressure and/or infusion pressure. Hence, a control algorithm different from the one defined in claim 1 of the patent as granted is used. Whether under certain conditions the different control algorithms may produce the same results in terms of stopping or restarting the pumps, as argued by the appellant, is irrelevant. It remains

that the controller disclosed in E12 is not configured to automatically reduce the ultrafiltrate flow in response to the detection of the occlusion on the basis of the monitoring of a withdrawal pressure and/or infusion pressure in the extracorporeal circuit, and to automatically increase the ultrafiltrate flow after the occlusion has been alleviated, as required by claim 1 of the patent as granted.

In conclusion, the invention as defined in claim 1 of the patent as granted is not anticipated by E12, which cannot be "the first application" within the meaning of Article 87(1) EPC. As a consequence, the appellant's objection to the validity of the priority claim of the patent does not succeed.

It is common ground that the disclosure content of E1 is practically identical to that of E12. Thus, E1 cannot deprive the subject-matter of claim 1 of the patent as granted of novelty (Article 54 EPC).

3.2 The appellant also argued that the subject-matter of claim 1 of the patent as granted lacked novelty over each of E5 and E8.

3.2.1 E5 discloses a device for apheresis, to separate various blood components such as red blood cells, white blood cells, platelets, plasma. For separating the blood components an apheresis device may employ a centrifuge, in accordance with the embodiment described in detail in E5, or other separation devices, for example membrane-based (page 2, lines 44 to 47 of E5).

An ultrafiltration device (also known as aquapheresis device) is for removing almost exclusively excess salt and water from the blood. Specific filters must be used

for this purpose. Although it may be accepted, as the appellant argued, that some other blood components could still pass through these filters it remains that, without an explicit disclosure in E5, the apheresis device of this document is not for controlling ultrafiltration of blood and the membrane filters of the apheresis device cannot amount to a direct and unambiguous disclosure of a "blood filter for filtering liquid ultrafiltrate from the blood" as recited in claim 1 of the patent as granted.

The appellant's arguments with reference to paragraphs [0002], [0034] and [0046] of the patent, which allegedly equated ultrafiltration to apheresis, are not convincing. Plasma water, mentioned in paragraph [0034], is not plasma, as also the respondent pointed out. In paragraph [0002] ultrafiltration and apheresis are listed as distinct blood treatment procedures. In paragraph [0046] they are considered equivalent only in relation to the quantity of blood which a peripheral vein can continuously supply.

In conclusion E5 discloses neither a device for controlling ultrafiltration of blood nor a blood filter for filtering liquid ultrafiltrate from the blood, as defined in claim 1 of the patent as granted. Thus the subject-matter of the claim is novel (Article 54 EPC) over E5.

3.2.2 E8 is concerned with a method of controlling a blood pump of a blood treatment system. An exemplary method is applied to a treatment in which plasma is separated from a blood sample and freed of cholesterol (page 3, lines 21 to 23).

Although E8 generally mentions that the method can be

applied to "any blood treating methods including adsorptive removal, plasma exchange, double filtration and artificial dialysis" (page 8, lines 12 to 14), it remains that no specific disclosure of ultrafiltration or a blood filter for filtering liquid ultrafiltrate from the blood is present in E8.

For the same reasons as those given above in relation to E5, the subject-matter of claim 1 of the patent as granted is novel (Article 54 EPC) over E8.

3.3 In conclusion, the ground for opposition of lack of novelty under Article 100(a) EPC raised by the appellant does not prejudice the maintenance of the patent as granted.

4. Inventive step

4.1 The appellant argued that the subject-matter of claim 1 of the patent as granted lacked an inventive step when starting from E4.

E4 discloses a universal blood treatment device with an extracorporeal blood circuit and a controller for monitoring several alarm conditions of the device (column 22, lines 5 to 14). The device is suitable for performing ultrafiltration (column 1, lines 33 to 37). The alarm conditions are monitored by the means of pressure sensors (column 22, lines 25 to 41). As disclosed in column 29, line 54, to column 30, line 32, upon detection of certain anomalous pressure conditions in the extracorporeal blood circuit the controller is configured to automatically reduce blood flow through the circuit and automatically increase the blood flow if the condition is deemed corrected.

It is common ground that E4 does not disclose a controller configured to automatically reduce the ultrafiltrate flow in response to the detection of an occlusion, and automatically increase the ultrafiltrate flow after the occlusion has been alleviated.

According to the patent (paragraph [0151]), such a configuration of the controller has the technical effect of avoiding the risk of clogging of the blood filter, while trying and continue the ultrafiltration treatment without any undue interruption.

The Board shares the respondent's view that the objective technical problem concerns the improvement of the efficiency of the ultrafiltration treatment, without compromising safety.

The problem formulated by the appellant, i.e. to obtain an ultrafiltration device with which a defined removal of fluid from the patient blood can be achieved, is not acceptable, since it is in no relation to the technical effect of the distinguishing feature as explained in the patent and contains a hint to the solution: a predetermined fluid removal rate inherently means the same control of the blood and the ultrafiltrate pump.

4.1.1 E2, referred to by the appellant in combination with E4, concerns a dialysis machine which may perform ultrafiltration as part of the dialysis treatment (paragraph bridging pages 1 and 2). It aims at controlling the transmembrane pressure of the dialysis filter for optimising the dialysis treatment (page 4, lines 20 to 36), in particular avoiding filter caking (page 2, lines 5 to 18).

The Board accepts that E2 discloses to control the

ultrafiltrate flow rate depending on the blood flow rate in the dialysis machine in order to improve the efficiency of the dialysis treatment. However, as the respondent submitted, the control concerns a steady functioning state and is done by monitoring the haematocrit value in the infusion line (page 7, lines 3 to 16) with the aim to keep it within an acceptable range. E2 does not deal with the detection of or the reaction to an occlusion in the extracorporeal circuit of the dialysis machine. Hence, it does not disclose the distinguishing feature. Even if the person skilled in the art had considered E2 for solving the objective technical problem, he or she would have implemented a control of the ultrafiltration in the device of E4 during the normal functioning condition, because this is the teaching of E2. Hence, the subject-matter of claim 1 of the patent as granted would not be arrived at.

It follows that the subject-matter of claim 1 the patent as granted is inventive when starting from E4 in combination with E2.

4.1.2 E5 and E6, referred to by the appellant in combination with E4, are not concerned with ultrafiltration but relate to apheresis devices. Consequently, these documents do not address the problem of improving an ultrafiltration treatment. For this reason alone the person skilled in the art would not have considered them for solving the objective technical problem defined above. Whether the same technical considerations may apply with respect to the control of the pumps of E4, E5 and E6 is irrelevant, since the person skilled in the art would not have considered E5 or E6 in combination with E4.

Hence, the subject-matter of claim 1 the patent as granted is inventive when starting from E4 in combination with E5 or E6.

4.2 The appellant argued that the subject-matter of claim 1 of the patent as granted lacked an inventive step when starting from E5.

This objection was raised for the first time during the oral proceedings and constitutes and amendment to the appellant's case. Under Article 13(2) RPBA 2020, any amendment to a party's appeal case made after notification of a summons to oral proceedings is, in principle, not to be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

The appellant's argument that the objection could only be presented after the Board's conclusion that E5 did not deprive the subject-matter of claim 1 of the patent as granted of novelty does not constitute such cogent reasons justifying exceptional circumstances. As also the respondent submitted, whether E5 was novelty destroying for the subject-matter of claim 1 of the patent as granted has always been a matter of dispute between the parties. Moreover, the Opposition Division did not consider E5 novelty-destroying in the impugned decision.

Hence, the appellant could have raised an objection of lack of inventive step starting from E5 well before the oral proceedings.

In view of these circumstances, under Article 13(2) RPBA 2020 the Board does not admit the objection of lack of inventive step starting from E5 into the appeal

proceedings.

4.3 The appellant argued that the subject-matter of claim 1 of the patent as granted lacked an inventive step when starting from E13.

E13 is an operator manual of a dialysis machine which may perform ultrafiltration as a part of the dialysis treatment (point 1.2.5). It comprises a blood pump and an ultrafiltrate pump. As the appellant pointed out, E13 discloses several alarm conditions under point 8 (from page 155). An alarm condition may be recognised when a certain pressure condition is detected in the blood circuit (page 207 , "Min Art Pressure") . Upon the detection of this condition the blood pump is stopped and the ultrafiltrate pump is slowed down to a minimum speed. After the disappearance of the alarm condition normal operation may be resumed and the pumps are restarted.

According to page 207 ("Suggested Action") an override key may be pressed to restart the pumps. The appellant argued that E13 hinted at the possibility (pages 156 and 207) that the alarm condition could be resolved after 10 seconds without the intervention of an operator.

While the "Note" on page 207 reads "the effect is automatically resolved (the pump restarts) 10 seconds after the disappearance of the alarm", page 156 expressly states that alarms of kind "A", to which the alarm condition "Min Art Pressure" belongs (page 162), require operator intervention to remove the cause. An optional intervention (only if needed) as suggested by the appellant, is neither expressly mentioned not objectively implied by the disclosure of E13. This

seems to mean that "the disappearance of the alarm" mentioned on page 207 must be dependent on the operator intervention.

In any case, the disclosure of E13 concerning the resumption of the normal operation is at least ambiguous. Hence, E13 does not anticipate a controller configured to automatically increase the ultrafiltrate flow after the occlusion has been alleviated, as defined in claim 1 of the patent as granted.

This distinguishing feature addresses the objective technical problem of improving the efficiency of the ultrafiltration treatment, without compromising safety.

The Board does not share the appellant's view that it would be obvious to automate the restarting of the pumps in E13.

El3 does not disclose a mere temporal sequence of manual operations necessarily following one another, which could easily be automated. Instead, it teaches a user check to establish whether a certain automatic safety measure is to be abandoned or not. Hence, the situation is different from that underlying decision T 775/90, mentioned by the appellant.

Doing away with the user check would not result in a mere automation of a certain sequential procedure, but rather in the abandonment of a safety measure which is expressly taught by El3. The person skilled in the art would not have abandoned this safety measure without any express suggestion in this respect.

As the respondent submitted, the invention as defined in claim 1 of the patent as granted is different, as it

involves a control algorithm that may render the presence of an operator unnecessary by pre-emptively avoiding an alarm situation.

Hence, the subject-matter of claim 1 the patent as granted is inventive when starting from E13.

4.4 In conclusion, the ground for opposition of lack of inventive step under Article 100(a) EPC raised by the appellant does not prejudice the maintenance of the patent as granted.

5. Extension of subject-matter

The subject-matter of claim 1 is generally based on claims 26 and 28, claim 20, Figures 2, 3, 4 and 6, page 5, central paragraph, the paragraph bridging pages 6 and 7, page 28 and page 58, lines 4 to 11, of the application as filed.

The appellant argued that claim 20 as filed, referred to for a basis of the feature of the controller "configured to monitor a withdrawal pressure (109) and/or infusion pressure (110) in the extracorporeal circuit in order to detect an occlusion", could not be combined with claims 26 and 28 as these claims were not dependent on one another, and claim 20 related to a different embodiment.

The Board does not share this view. Claim 20, which depends on claim 1 as filed, generally relates to the detection of an occlusion in a blood circuit and to prompting a patient to move to alleviate the occlusion. Claims 26 and 28 also relate to the detection of an occlusion, but then concern the control of ultrafiltrate flow when an occlusion occurs and is

subsequently alleviated. The fact that claim 1 refers to an extracorporeal blood circuit and claim 26 to an ultrafiltration blood circuit is a merely literal difference, in view of the application as a whole which discloses one and the same blood circuit. The different aspects of these claims as filed are implemented in the same embodiment generally depicted in Figures 1 and 2, which comprises a controller for both prompting the patient to move and adjusting the ultrafiltrate flow (the description of the embodiment of the invention in the application as filed consistently refers to a single controller, for example on page 5, central paragraph).

The question which arises is therefore whether the application as filed inextricably links the aspect of prompting the patient to move when an occlusion is detected and the aspect of the specific control of the ultrafiltrate pump when an occlusion is detected. The answer to this question is no, since there is no express disclosure in this respect and since the two aspect are technically independent: one aspect relates to a possibility of alleviating the occlusion and the other relates to the correct functioning of the device defined in claim 1 of the patent as granted while an occlusion occurs.

The Board therefore concludes that the disclosure of claim 20 concerning the detection of the occlusion by detecting a withdrawal or infusion pressure can be combined, at its level of generality, with the disclosure of the method of controlling ultrafiltration of blood as defined in claims 26 and 28 as filed.

As a consequence, the appellant's objections directed to intermediate generalisations occurring because of

the omission of the pressure sensors or other features disclosed in the detailed description of the specific embodiment of the invention do not succeed. These features were not present in claims 26, 28 or 20 as filed, which generalise the teaching of the application as to the definition of the invention.

The appellant's argument that the device as defined in claim 1 of the patent as granted could not monitor the pressure without pressure sensors is without relevance. The claimed invention is not directed to a specific way of measuring pressure, but to the general monitoring of pressure signals. How these pressure signals are obtained is not crucial. Moreover, a signal representative of the pressure to be monitored could well come from sensors external to the claimed device.

The appellant's argument that claim 1 of the patent as granted omitted the definition of the withdrawal pressure or infusion pressure crossing a predetermined threshold value for the detection of the occlusion is not convincing either. As the respondent submitted, claim 1 of the patent as granted inherently requires that the monitored withdrawal and/or infusion pressures exceed certain limit values, as otherwise it would not be technically possible to establish whether an occlusion has occurred by monitoring those pressures. Moreover, Figures 3 and 6 of the application as filed disclose that these values are not fixed but depend on the blood flow. Hence, they do not have to be "a predetermined threshold value" in view of the application as a whole.

As the respondent also pointed out, Figures 2 and 4, and page 28 of the application as filed disclose the monitoring of both the withdrawal and infusion

pressures, which is a possibility according to claim 1 of the patent as granted. In Figure 2 pressure sensors on the withdrawal line and on the infusion line are shown. On page 28, with reference to Figure 4, control algorithms for withdrawal and infusion occlusion are disclosed.

A literal basis for the direct dependency of the ultrafiltrate flow on the detection of an occlusion, i.e. for the controller configured to automatically reduce the ultrafiltrate flow in response to the detection of the occlusion and to automatically increase the ultrafiltrate flow after the occlusion has been alleviated is provided in claim 26 as filed which explicitly discloses: "in response to the detection of the occlusion controller automatically reducing blood flow and reducing ultrafiltrate flow through the circuit" and "automatically increasing the blood flow and ultrafiltrate flow after the occlusion has been alleviated".

As regards the change of claim category from method claims in the application as filed to a device claim in the patent as granted, the Board observes that such a change does not necessarily introduce, per se, added subject-matter.

Method claims 26 and 28 as filed define method steps for controlling ultrafiltration of blood using an ultrafiltration blood circuit having a controller. Claiming a device for controlling ultrafiltration with a controller having means for performing those steps - in terms of functional features at the same level of generality as the original method steps - does not add matter. The appellant's argument that claim 26 as filed did not specify that the method steps were performed

using one and the same controller is not convincing, as it ignores the description as filed, which consistently teaches the presence of one and the same controller responsible for the control of ultrafiltration of blood (for example page 5, central paragraph).

In conclusion, the ground for opposition under Article 100(c) EPC raised by the appellant does not prejudice the maintenance of the patent as granted.

6. Sufficiency of disclosure

The Board notes that the requirement of sufficiency of disclosure, on which the ground for opposition according to Article 100(b) EPC is based, concerns the patent as a whole, not only the claim wording.

The description and drawings of the patent provide a detailed disclosure of the control procedure implemented for fulfilling the functional features of the controller defined in claim 1 of the patent as granted. As the respondent submitted, Figures 8 and 9 and paragraphs [0123] to [0133] disclose an example of how an occlusion could be identified by using certain algorithms. Paragraphs [0053] to [0122] disclose these algorithms in detail. Paragraphs [0157] to [0159] teach how to reduce and increase the ultrafiltrate flow rates according to the claim.

The appellant's argument that the object of the invention was to distinguish between small and bigger problems is taken out of the context of the claim, which generalises the teaching of the description. The claim is directed to the detection of an occlusion and the reaction to such a detection by the controller of the device for controlling ultrafiltration of blood.

According to the plain claim wording every detected occlusion "which at least partially blocks the withdrawal or infusion of the blood" (when the withdrawal or infusion pressures are outside a certain normal operation range, as shown in Figures 3 and 6) results in a reduction of the blood flow and the ultrafiltrate flow. Depending on what will happen to the occlusion after the controller has reacted to its detection, i.e. whether the occlusion may be alleviated without the intervention of medical personnel, the occlusion may then be classified as minor or major. In other terms, the invention as defined in claim 1 of the patent as granted does not require to distinguish between a partial and a total occlusion. It does not even require to establish why the withdrawal pressure or infusion pressure are outside the normal operation range, e.g. possibly due to the use of anticoagulants. When the withdrawal and/or the infusion pressure are outside the normal operation range the controller detects an occlusion and automatically reduces blood flow. As is clear from the description, if the detected occlusion cannot be alleviated it is recognised as more severe and an alarm may be activated. The claim does not explicitly recite this possibility, but does not exclude it either.

In conclusion, the ground for opposition under Article 100(b) EPC raised by the appellant does not prejudice the maintenance of the patent as granted.

7. Since none of the grounds for opposition raised by the appellant prejudice the maintenance of the patent as granted, the Opposition Division's decision to reject the opposition was correct.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated