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Datasheet for the decision of 24 September 2024

Case Number: T 2119/22 - 3.2.02

Application Number: 18210730.0

Publication Number: 3495006

IPC: A61M1/36

Language of the proceedings: EN

Title of invention:
PNEUMATIC MANIFOLD FOR A DIALYSIS SYSTEM

Patent Proprietor:
Mozarc Medical US LLC

Opponent:
B. Braun Avitum AG

Headword:

Relevant legal provisions:
EPC Art. 56, 84, 111(2), 123(2)
RPBA Art. 11 (2007)
Guidelines for examination F-IV.4.14, F-IV.4.14.1
CA/3/19 concerning the revision of the RPBA

Keyword:

Claims - clarity (yes)
Amendments - extension beyond the content of the application as filed (no)
Inventive step - (yes)
Appeal decision - remittal to the department of first instance (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

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Case Number: T 2119/22 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 24 September 2024

Appellant: (Opponent)	B. Braun Avitum AG Schwarzenberger Weg 73-79 34212 Melsungen (DE)
Representative:	Winter, Brandl - Partnerschaft mbB Alois-Steinecker-Straße 22 85354 Freising (DE)
Respondent: (Patent Proprietor)	Mozarc Medical US LLC 710 Medtronic Parkway Minneapolis, MN 55431 (US)
Representative:	Maschio & Soames IP Ltd 30 Carlton Crescent Southampton SO15 2EW (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 11 July 2022 rejecting the opposition filed against European patent No. 3495006 pursuant to Article 101(2) EPC**

Composition of the Board:

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

Summary of Facts and Submissions

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

II. Oral proceedings took place by videoconference on 24 September 2024. At the end of the oral proceedings, the parties' requests were as follows:

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

The respondent requested that the patent be maintained on the basis of the second auxiliary request as filed with the reply to the appellant's statement setting out its grounds of appeal, dated 24 March 2023.

III. The following document is mentioned in this decision:

D1: EP 2 883 558 A1

IV. Claim 1 of the second auxiliary request reads as follows:

"A pneumatic manifold (101), comprising:

an internal conduit (102);

a first fluid line (121) fluidly connected to the internal conduit (102); the first fluid line (121) fluidly connectable to a venous drip chamber (125) in an extracorporeal circuit of a dialysis system;

a second fluid line (120) fluidly connected to the internal conduit (102); the second fluid line (120) fluidly connectable to an arterial drip chamber (123) in the extracorporeal circuit of the dialysis system;

a venous valve (104) fluidly connecting the first fluid line (121) to the internal conduit (102);

an arterial valve (103) fluidly connecting the second fluid line (120) to the internal conduit (102);

a negative valve (106) fluidly connecting the internal conduit (102) to an outlet (109);

a positive valve (105) fluidly connecting the internal conduit (102) to an inlet (110);

the inlet (110) and outlet (109) fluidly connected by a third fluid line containing a pump (108);

a line clamp valve (107); the line clamp valve (107) fluidly connecting the internal conduit (102) and a second outlet; the second outlet fluidly connectable to a line clamp (137) in the extracorporeal circuit; and

a controller selectively activating or deactivating the venous valve (104), arterial valve (103), positive valve (105), and negative valve (106); the controller controlling a fluid level in the venous drip chamber (125) and arterial drip chamber (123) by activating or deactivating the valves."

Claims 2 to 9 are dependent claims.

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

Clarity

Claim 1 of the second auxiliary request defined a pneumatic manifold with an inlet and an outlet connected by a third fluid line containing a pump. The claim wording left the reader in doubt as to whether the pump was part of the claimed subject-matter. According to the Guidelines for Examination in the European Patent Office, F-IV.4.14.1, a claim directed to a combination of entities should be adapted appropriately to reflect this. Moreover, according to paragraph [0081] of the description the pump was optional. Hence, claim 1 of the second auxiliary request was unclear. In any case, if the claim was understood as being directed to a combination of a pneumatic manifold and a pump, the description was not in conformity with the claim and the request had to be refused for this reason alone.

Remittal for the adaptation of the description was not appropriate in view of Article 11 RPBA. The respondent had a duty to file a request that was allowable in its entirety.

Extension of subject-matter

The application as filed (Figures 1 and 2A to 2E) disclosed a third fluid line with a pump outside a pneumatic manifold. Moreover, there was no claim in the application as filed directed to the combination of the third fluid line including a pump and the pneumatic

manifold assembly. There were no other statements suggesting that the patent sought protection for the combination of the third fluid line including a pump and the pneumatic manifold assembly. Hence, the second auxiliary request presented the person skilled in the art with unexpected claims. For these reasons, claim 1 of the second auxiliary request included added subject-matter.

Inventive step

Claim 1 of the second auxiliary request did not include a line clamp. The term "line clamp valve" had to be interpreted simply as a valve, since any valve could be connected to a line clamp.

Starting from the pneumatic manifold disclosed in D1, providing a further pneumatic valve and a further outlet was a mere matter of design, if electromagnetic valve V2 of D1 was not considered to anticipate these features itself. The line clamp valve as defined in the claim did not provide the technical effect of allowing the actuation of a further component of the extracorporeal circuit using the same pneumatic manifold and the same pump. The claim did not specify that the controller activated or deactivated the "line clamp valve". On the contrary, the line clamp valve had been claimed without any functional relation to, and fully isolated from, the other elements of the claim. It followed that the claimed line clamp valve fluidly connecting the internal conduit of the pneumatic manifold to a further outlet only had the technical effect of providing an alternative way of controlling a line clamp valve, which as such was already known. Many kinds of valves with various actuation mechanisms were part of common general knowledge, as was shown in

several documents. In conclusion, the subject-matter of claim 1 of the second auxiliary request was not inventive.

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

Clarity

Claim 1 of the second auxiliary request defined a pneumatic manifold with an inlet and an outlet connected by a third fluid line containing a pump. Hence, the pump was part of the claimed subject-matter.

If the description was not in conformity with the claims, it would be appropriate to remit the case to the Opposition Division for the adaptation of the description.

Extension of subject-matter

Claim 1 of the second auxiliary request did not include added subject-matter. It was based on the combination of claim 1 and claim 2 of the patent as granted.

Inventive step

Claim 1 of the second auxiliary request introduced the requirement for a line clamp valve in the manifold system. It specified that the line clamp valve fluidly connected the internal conduit of the manifold with a second outlet; and that the second outlet was fluidly connectable to a line clamp.

D1 illustrated line clamps V1, V2 and V3 in the extracorporeal circuit, which were not connected to the

manifold disclosed in this document.

The line clamp valve and line clamp provided a mechanism for the removal of gas from the extracorporeal circuit connectable to the manifold.

None of the prior-art documents cited by the appellant disclosed a line clamp valve as claimed. Hence, the subject-matter of claim 1 of the second auxiliary request was inventive.

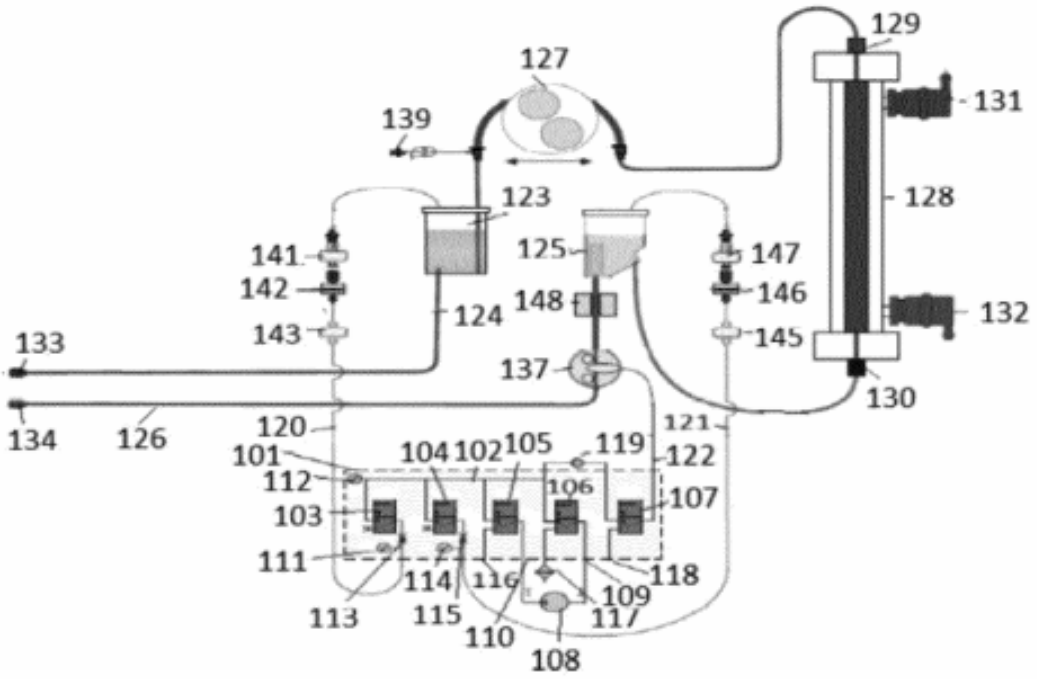
Reasons for the Decision

1. The subject-matter of the patent

The patent relates to a pneumatic manifold for controlling a fluid level in an arterial and a venous drip chamber of a dialysis system.

In such a system, venous and arterial drip chambers are used to separate air bubbles from a patient's blood before the blood enters a dialyser or is returned to the patient. The effective removal of air bubbles usually requires specific fluid levels in the drip chambers. The claimed invention provides a means for actively controlling and keeping constant the fluid levels, which may be affected by changes in the treatment parameters of a dialysis session (paragraph [0003] of the patent).

A pneumatic manifold according to claim 1 of the second auxiliary request is schematically depicted in Figure 1 of the patent, which is reproduced below.



The manifold comprises an internal conduit (102), a first fluid line (121) fluidly connected to the internal conduit and fluidly connectable to a venous drip chamber (125) in an extracorporeal circuit of a dialysis system, and a second fluid line (120) fluidly connected to the internal conduit and fluidly connectable to an arterial drip chamber (123) in the extracorporeal circuit of the dialysis system. The fluid connections make it possible to adjust the fluid levels in the drip chambers by modifying the air pressure in the internal conduit, and also, as a consequence, in the drip chambers.

The manifold further comprises a venous valve (104) fluidly connecting the first fluid line to the internal conduit, and an arterial valve (103) fluidly connecting the second fluid line to the internal conduit. Operation of the valves may selectively connect one, both or neither of the drip chambers to the internal conduit, to selectively adjust the fluid levels in the

drip chambers.

The manifold further comprises a negative valve (106) fluidly connecting the internal conduit to an outlet (109), and a positive valve (105) fluidly connecting the internal conduit to an inlet (110). The inlet and outlet are fluidly connected by a third fluid line containing a pump (108). When operating these valves, the pressure within the internal conduit may be increased or lowered by the pump. The pump sucks air from the internal conduit if the negative valve is open and the positive valve is closed, and pumps air into the internal conduit if the negative valve is closed and the positive valve is open. The qualifiers "negative" and "positive" indicate the position of the valves with respect to the pumping direction of the pump (which inherently is unidirectional).

The pneumatic manifold further comprises a controller selectively activating or deactivating the venous valve, the arterial valve, the positive valve and the negative valve for controlling the fluid level in the venous drip chamber and the arterial drip chamber (as explained above).

The pneumatic manifold further comprises a line clamp valve (107) fluidly connecting the internal conduit and a second outlet fluidly connectable to a line clamp (137) in the extracorporeal circuit. Actuation of the line clamp valve may cause clamping of a fluid line in the extracorporeal circuit.

Figures 2A to 2E of the patent illustrate the valve statuses needed to perform the level adjustments.

2. Clarity

2.1 The appellant argued that by specifying that the inlet and the outlet are fluidly connected by a third fluid line containing a pump, claim 1 of the second auxiliary request lacked clarity.

In the appellant's view, it was not clear whether the third fluid line and the pump were part of the claimed subject-matter.

The Board does not consider there to be any lack of clarity. According to claim 1, the inlet and outlet, which belong to the claimed pneumatic manifold, are connected to the third fluid line. The third fluid line contains a pump. It follows, without ambiguity, that the third fluid line with the pump is part of the claimed subject-matter.

The appellant referred to the Guidelines for Examination in the European Patent Office, F-IV.4.14.1, and argued that a claim directed to a combination of entities had to reflect this.

In this respect, the Board first of all notes that, according to the Guidelines themselves, the Guidelines do not constitute legal provisions. For the ultimate authority on practice at the EPO it is necessary to refer firstly to the EPC itself, including the Implementing Regulations, and secondly to the interpretation of the EPC by the Boards of Appeal and the Enlarged Board of Appeal (Guidelines, General Part, 3, March 2022 version). The Boards of Appeal are not bound by the Guidelines (Article 23(3) EPC). Article 20(2) RPBA therefore only requires that if, in a decision, a Board gives a different interpretation of

the Convention from that provided in the Guidelines for Examination, it must state its grounds for doing so if it considers that the decision will be more readily understood in the light of such grounds.

Here, the passage of the Guidelines cited by the appellant is to be read together with F-IV.4.14, concerning definitions by reference to another entity which may not be part of the claimed subject-matter. The key part of this passage of the Guidelines is "only if the claim is directed without any doubt to a combination of the first and second entities, the features of the other entity are limiting for the subject-matter of the claim".

F-IV.4.14.1 adds that "once it has been established if a claim is directed to either one entity or to a combination of entities, the wording of the claim must be adapted appropriately to reflect it". In the current case, the claim wording is directed, without ambiguity, to a pneumatic manifold assembly comprising a third fluid line containing a pump.

Hence, there is no contradiction with the Guidelines, and claim 1 of the second auxiliary request meets the requirements of clarity (Article 84 EPC).

2.2 The appellant argued that some passages of the description presented the pump as optional.

The Board agrees that the description has not been adapted to the claims of the second auxiliary request.

However, the adaptation of the description is a task that can be performed by the Opposition Division after a claim request has been found allowable. In such a

case it may be appropriate for the Board to remit the case to the Opposition Division (Article 111(2) EPC) with an order to maintain the patent on the basis of this request and a description to be adapted thereto.

Article 11 RPBA, referred to by the appellant, "does not apply to cases that are remitted with an order by the Board [...] to maintain a patent in amended form, with or without the description to be adapted" ("Table setting out the amendments to the RPBA and the explanatory remarks", section VI of document CA/3/19 concerning the revision of the RPBA).

3. Extension of subject-matter

The appellant also argued that the application as filed did not disclose that the third fluid line was within the claimed pneumatic manifold. However, claim 1 of the second auxiliary request does not require this. It merely defines the third fluid line connecting the inlet and the outlet, as shown in Figures 1 and 2A to 2E of the application as filed. It does not state that the third fluid line should be within the claimed pneumatic manifold.

The appellant argued that the application as filed did not contain a claim nor any other statements suggesting that the patent was seeking protection for the combination of the third fluid line including a pump and the pneumatic manifold assembly. This argument is not convincing. For the purposes of added subject-matter, it has to be established whether the European patent has been amended in such a way that it contains subject-matter which extends beyond the content of the application as filed (Article 123(2) EPC). The application as filed is to be considered in its

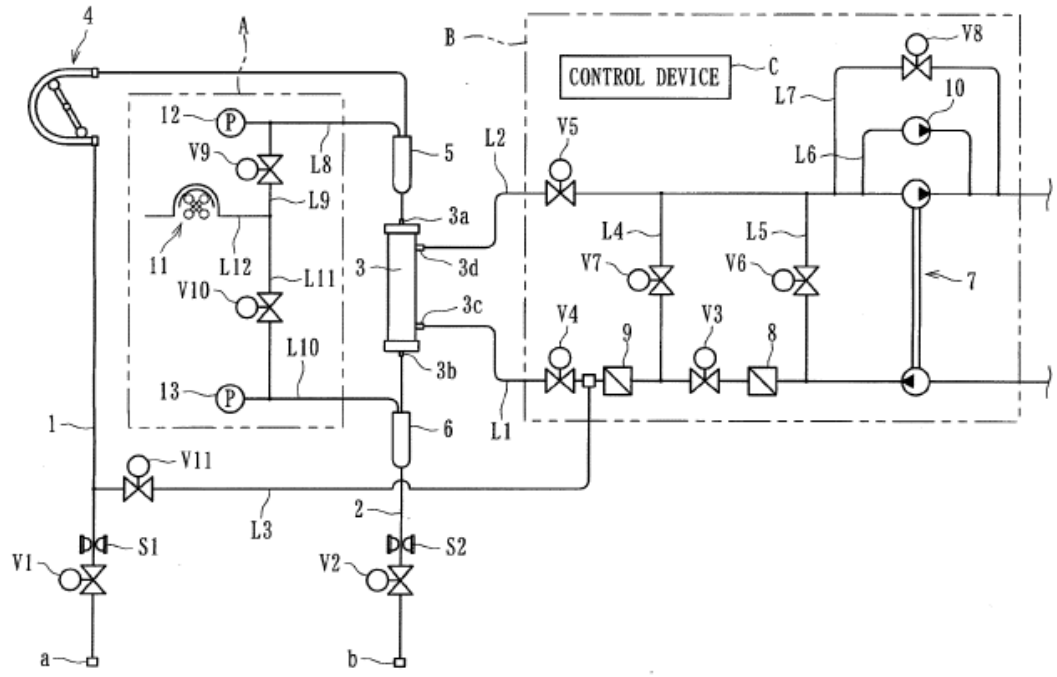
entirety. As explained, Figures 1 and 2A to 2E of the application as filed, for example, disclose a third fluid line including a pump, together with a pneumatic manifold assembly.

In conclusion, the appellant's objections of added subject-matter (Article 123(2) EPC) do not prejudice the maintenance of the patent on the basis of the second auxiliary request.

4. Inventive step

The appellant argued that the subject-matter of claim 1 of the second auxiliary request was not inventive when starting from D1.

D1 discloses a dialysis system schematically depicted in Figure 1, which is reproduced below.



The dialysis system comprises a pneumatic manifold in the form of a liquid level adjustment device (A) (which

can be externally attached to a dialysis device B, paragraph [0041]), for controlling a fluid level in an arterial (5) and a venous (6) drip chamber. The liquid level adjustment device comprises an internal conduit (communication lines L9 and Lll), a first fluid line (Ll0) fluidly connected to the internal conduit and fluidly connectable to a venous drip chamber in an extracorporeal circuit of a dialysis system, and a second fluid line (L8) fluidly connected to the internal conduit and fluidly connectable to an arterial drip chamber in the extracorporeal circuit of the dialysis system. The liquid level adjustment device further comprises a venous valve (Vl0) fluidly connecting the first fluid line to the internal conduit, an arterial valve (V9) fluidly connecting the second fluid line to the internal conduit and a third fluid line (L12) containing a bidirectional pump (11, paragraph [0045]) and provided with an inlet/outlet ("distal end" of release line L12, paragraphs [0046] and [0047]). A control device (C, paragraphs [0033] and [0047]) may operate the valves and selectively connect one, both or neither of the drip chambers to the internal conduit and the third fluid line, to selectively adjust the fluid levels in the drip chambers.

A line clamp valve which fluidly connects the internal conduit and a second outlet, the second outlet being fluidly connectable to a line clamp in the extracorporeal circuit, is a distinguishing feature over D1.

Valve V2 in the extracorporeal circuit of the dialysis system of D1, which was referred to by the appellant, is located downstream of venous drip chamber 6 and has the same function as the line clamp mentioned in

claim 1 of the second auxiliary request (paragraph [0064] of D1). However, it is not connected to the internal conduit and a second outlet, as required by the claim. It cannot be actuated by pump 11.

The Board agrees with the appellant that the term "line clamp valve" does not include the line clamp and should simply be interpreted as a (further) valve. However, the presence of such a further valve as claimed, connected to the internal conduit, has the technical effect of allowing the actuation of a further component of the extracorporeal circuit using the same pneumatic manifold and the same pump. The reference to the possible connection to a line clamp in the extracorporeal circuit plays no role in establishing this technical effect, which is achieved by the distinguishing feature as claimed. This technical effect depends solely on the connection of an outlet to the internal conduit through the line clamp valve, not on the presence of a controller for activating or deactivating the "line clamp valve", as argued by the appellant.

This solves the objective technical problem of having a simple and compact actuation device for controlling multiple components of a dialysis system. The appellant's argument that the objective technical problem was merely an alternative to the actuation of valve V2 of D1 cannot be accepted, as it disregards the technical effect of the distinguishing feature.

None of the prior-art documents on file disclose the distinguishing feature identified above for the solution of the objective technical problem. Although many kind of valves with various actuation mechanisms belong to common general knowledge, as argued by the

appellant with reference to the prior-art documents, this does not render obvious the specific arrangement of the valve connected to the internal conduit in view of the objective technical problem. Common general knowledge gives no hint in this respect.

Hence, the appellant's objection of a lack of inventive step (Article 56 EPC) does not prejudice the maintenance of the patent on the basis of the second auxiliary request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of the claims of the second auxiliary request as filed with the reply to the appellant's statement setting out its grounds of appeal, dated 24 March 2023, and a description to be adapted thereto.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated