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**Datasheet for the decision
of 1 April 2021**

Case Number: T 2427/16 - 3.2.02

Application Number: 04810470.7

Publication Number: 1684825

IPC: A61M1/16, A61M1/34, B01D61/58

Language of the proceedings: EN

Title of invention:
HIGH CONVECTION HOME HEMODIALYSIS/HEMOFILTRATION AND SORBENT
SYSTEM

Patent Proprietor:
Baxter International Inc.
Baxter Healthcare S.A.

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 56
RPBA Art. 12(4)

Keyword:

Inventive step - main request and first to fifth auxiliary requests (no) - new fifth auxiliary request (yes)
Late-filed evidence - not admitted in first instance proceedings

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 2427/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 1 April 2021

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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
24 August 2016 concerning maintenance of the
European Patent No. 1684825 in amended form.

Composition of the Board:

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

Summary of Facts and Submissions

- I. Both the opponent and the patent proprietor lodged an appeal against the interlocutory decision of the Opposition Division, dispatched on 24 August 2016, that, account being taken of the amendments according to the fifth auxiliary request valid at that time, European patent No. EP 1 684 825 and the invention to which it related met the requirements of the EPC.
- II. Oral proceedings took place on 1 April 2021.
- III. Appellant 1 (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request filed with the grounds of appeal dated 30 December 2016 or one of auxiliary requests 1 to 8 filed with the same letter or the new fifth auxiliary request filed during the oral proceedings before the Board. They also requested that document D35 not be admitted into the proceedings.
- IV. Appellant 2 (opponent) requested that the decision under appeal be set aside and that the patent be revoked. They also requested that D35 be admitted into the proceedings.
- V. The following documents are referred to in this decision:

D2: US 5,660,722

D4: P 44 24 693.5

D5: Abstract of JP 11319080 A

D13: US 3,946,731

D35: JP11-394 A and machine translation thereof

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

"A medical fluid therapy system (10, 110, 210) comprising:
a blood line (50) configured and arranged to be coupled to a patient;
a pump (48) connected to the blood line;
a first dialyzer portion (20) in communication with the blood line and positioned to receive blood from the patient;
a second dialyzer portion (30) positioned to receive blood from the first dialyzer portion;
a therapy fluid line (60) connected to a therapy fluid source (14, 16, 18, 112) and in fluid communication with the first and second dialyzer portions; and
a variable flow restriction (40) in communication with the therapy fluid line between the first and second dialyzer portions,
characterised in that: the variable flow restriction (40) is a pneumatically operated variable orifice valve for varying the fluid flow resistance of the flow restriction to selectively increase/decrease backpressure of the therapy fluid in one of the first and second dialyzer portions and in that the first dialyzer portion (20) and second dialyzer portion (30) are housed separately."

VII. Claim 1 of the first auxiliary request differs from claim 1 of the main request in that the flow restriction is defined as an "automatic" pneumatically operated variable orifice valve.

VIII. Claim 1 of the second auxiliary request differs from claim 1 of the first auxiliary request in that the

following feature has been added:

the first dialyzer portion (20) and the second dialyzer portion (30) "are in fluid communication with one another via a section of the therapy fluid line with which the pneumatically operated variable orifice valve communicates".

- IX. Claim 1 of the third auxiliary request differs from claim 1 of the first auxiliary request in that the variable orifice valve is further defined as to be capable of varying the flow resistance "on receipt from a controller of a pneumatic signal at a controlled pressure".
- X. Claim 1 of the fourth auxiliary request combines the amendments of the second and third auxiliary requests.
- XI. Claim 1 of the fifth auxiliary request differs from claim 1 of the first auxiliary request in that the following feature has been added:
"and in that the system further comprises a disposable cassette that includes the flow restriction (40) or both of the first and second dialyzer portions (20,30)".
- XII. Claim 1 of the new fifth auxiliary request differs from claim 1 of the fifth auxiliary request in that the term "or" in the last line has been replaced with "and".
- XIII. The arguments of the patent proprietor, as far as relevant for the present decision, can be summarized as follows:

Admittance of D35

The Opposition Division had decided correctly not to

admit D35 into the opposition proceedings for the reasons given at point 1 of the decision.

D35 was not prima facie relevant to novelty, since it disclosed only a single dialyzer and not separately housed dialyzer portions.

Main request - inventive step

Although D4 disclosed a medical fluid therapy system comprising a variable orifice valve (Figure 1), it expressed a strong preference for using a pump arranged in the fluid line between the dialyzers to create the pressure difference (page 5, third paragraph). In fact, in D2, which claimed priority from D4, the embodiment comprising the pneumatically operated valve was omitted. The use of a pneumatically operated valve would be more complex, and thus be inconsistent with the objective of D4 to provide a simpler apparatus (page 3, third paragraph).

The pneumatically operated variable orifice valve allowed for more sophisticated treatments, as mentioned in paragraph [0008] of the patent.

D13 did not teach the utility of a pneumatically operated variable orifice valve as a means to control fluid flow resistance between first and second dialyzers. Hence, it would not have been obvious for the person skilled in the art to modify the system described in D4 by using a pneumatically operated variable orifice valve as a flow restrictor.

First to fourth auxiliary requests - inventive step

For the same reasons as presented for the main request,

claim 1 of the first to fourth auxiliary requests involved an inventive step.

Fifth auxiliary request - inventive step

D4 did not disclose or suggest a pneumatically operated variable orifice valve or a disposable cassette.

There was a significant prejudice against including a pneumatically operated variable orifice valve in the system of D4. Therefore, D4 was not suitable as a starting point for assessing inventive step.

D13 did not disclose two dialyzer portions and so could not motivate the person skilled in the art to incorporate the two dialyzers in a disposable cassette.

D13 also did not disclose or suggest the utility of a pneumatically operated variable orifice valve as a means to control fluid flow resistance between two dialyzers. D13 rather taught to use a pump to control dialysis fluid flow. Hence, the teaching of D13 did not motivate the person skilled in the art to modify the device of D4 by using a pneumatically operated variable orifice valve as a flow restrictor.

The subject-matter of claim 1 therefore involved an inventive step over the combination of D4 and D13.

New fifth auxiliary request

The new fifth auxiliary request was filed as a reaction on the Board's conclusion that the subject-matter of claim 1 of the fifth auxiliary request lacked an inventive step. The objection was overcome by replacing

the "or" in the last feature with "and".

- XIV. The arguments of the opponent, as far as relevant for the present decision, can be summarized as follows:

Admittance of D35

D35 was already part of the opposition proceedings since it was a translation of a document of which the abstract was already filed as D5.

D35 was *prima facie* highly relevant since it anticipated the subject-matter of claim 1. The Opposition Division construed the expression "housed separately" too narrowly.

Main request - inventive step

Figure 1 of D4 disclosed a medical fluid therapy system from which the subject-matter of claim 1 only differed in that the variable orifice valve was pneumatically operated.

The patent did not mention any advantage to be achieved with the use of pneumatically operated valves.

Adjustable valves, i.e. variable orifice valves, that were pneumatically operated were known from D13 (column 12, lines 22 to 26). It was further mentioned in column 11, lines 17 to 20, that such valves provided positive pressure differences. This was also the purpose of the valve in the contested patent.

Hence, it would have been obvious for the person skilled in the art to select a pneumatically actuated valve for the system of D4. The subject-matter of claim

1 did therefore not involve an inventive step.

First to fourth auxiliary requests - inventive step

The additional features of the claims of the first to fourth auxiliary requests were also disclosed in D4. Consequently, the argumentation as to lack of inventive step applied also to these requests.

Fifth auxiliary request - inventive step

D4 disclosed all features of claim 1 except for the following:

- the variable orifice valve being pneumatically operated,
- the system further comprising a disposable cassette that includes the flow restriction or both of the first and second dialyzer portions.

It was already argued that the feature "pneumatically operated" was obvious for the person skilled in the art.

The objective technical problem to be solved by the provision of a cassette including the flow restriction or the dialyzers could be seen as to simplify the setting up of the blood therapy system.

Pneumatic systems with adjustable valves were known from D13. Together with further components of the system, the valves were arranged on a cassette (Figure 8). It was mentioned in D13 that such a cassette could be produced with low cost such that the system could be disposed after use (column 12, lines 22 to 37).

The provision of a cassette including a pneumatically operated valve was therefore obvious for the person skilled in the art.

The fact that in D13 the dialysate flow was controlled by a pump, rather than by a valve, was irrelevant since D4 already disclosed the control of the dialysate flow by the flow control valve 76. The distinguishing feature only concerned the arrangement of the valve 76 on a cassette.

Hence, the subject-matter of claim 1 lacked an inventive step in view of D4 in combination with D13.

New fifth auxiliary request

There were no objections against the new fifth auxiliary request.

Reasons for the Decision

1. Subject-matter of the invention

The invention relates to a dialysis system (Figure 1) comprising two high flux dialyzers which are arranged in series to combine both diffusion and convection transport from the patient, as described on page 2, line 12, to page 3, line 4, of the A2-publication.

The system comprises a variable flow restriction 40 in communication with the therapy fluid line between the first and second dialyzer portions 20, 30. The flow restriction 40 is a pneumatically operated variable orifice valve. The restriction provides a positive pressure in the first dialyzer that drives a significant amount of the dialysate through the membranes of the first dialyzer 20 and directly into the blood flowing on the inside of the membranes. This backfiltered dialysate is then ultrafiltered from the blood in the second dialyzer, thereby causing a convective transport of toxins from the patient.

The system further comprises a disposable cassette including the flow restriction and both of the first and second dialyzer portions.

2. Admittance of D35

2.1 The Board does not accept the opponent's argument that D35 was already part of the proceedings in view of the filing of D5, because the content of D35 goes clearly beyond that of D5, which is merely an abstract. As D35 was filed late, the opposition division had discretion not to admit it.

2.2 A Board should only overrule the way in which a department of first instance has exercised its discretion if the Board concludes that it has done so according to the wrong principles, or without taking into account the right principles, or in an unreasonable way. The Opposition Division decided not to admit D35 into the proceedings, since it saw no good reason why the document had not been filed earlier in the proceedings, and since it considered D35 to be not

prima facie relevant (point 1 of the Reasons for the Decision). The Board sees no basis for overruling this decision. Whilst the opponent challenges the Opposition Division's finding that D35 is not prima facie relevant, the Board does not see that the Opposition Division's exercise of discretion resulting in this finding suffered from any of the shortcomings described above. In fact, the Board agrees with the Opposition Division that D35 is not prima facie relevant, since the dialyzer portions are not housed separately (see drawing).

2.3 Consequently, the Board decided not to admit D35 into the appeal proceedings.

3. Main request - inventive step

3.1 It is undisputed by the parties that D4 discloses in Figure 1 a medical fluid therapy system from which the subject-matter of claim 1 differs in that the variable orifice valve ("Drossel 76" in D4) is pneumatically operated. It is not mentioned in D4 how the valve is operated.

3.2 Despite the preference in D4 for a pump for increasing/decreasing backpressure of the dialysate, the embodiment of Figure 1 is an adequate piece of prior art and can be regarded as a starting point for assessing inventive step.

3.3 It is noted that the patent in suit does not mention which technical problem could be solved by the use of a pneumatically operated valve. Thus, the Board agrees with the Opposition Division that, starting from the system of Figure 1 of D4, the objective technical problem was to choose a way of operating the flow

restriction of D4 among the possible alternatives (point 3.2.4 of the decision).

The problem mentioned by the patent proprietor, namely, to facilitate a more sophisticated treatment, relates to the valve being a variable orifice valve for varying the fluid flow resistance, rather than to the valve being pneumatically operated. It is noted that this problem is already solved in D4 (page 11, second paragraph).

3.4 D13 discloses a hemodialysis system having a number of valves (V_1 to V_{15} in Figures 1 and 2), some of which are adjustable (e.g. V_2 , V_3 , V_4). The adjustable valves are formed by a duct 44 overlying a duct 26a (through which the treatment fluid passes), and pressurizing duct 44 by liquid or gas (i.e. pneumatically). By varying the extend of pressurization, the duct 26a will be closed off to a corresponding degree (column 11, line 57, to column 12, line 6, and column 12, lines 22 to 26; Figures 4a and 4b). Hence, D13 discloses pneumatically operated variable orifice valves which are used to provide pressure differences in the system (column 11, lines 17 to 20). In view of this teaching, it would have been obvious for the person skilled in the art to select a pneumatically operated valve in the system of D4, thereby arriving at the subject-matter of claim 1.

3.5 The Board does not concur with the patent proprietor that the selection of a pneumatically operated valve would render the system in D4 more complex. Pneumatic actuation of a variable orifice valve can be considered equally complex as other ways of actuating such a valve, e.g. hydraulically, as also mentioned in D13, or mechanically, as in the embodiment of Figure 32 of the

present patent.

3.6 Consequently, the subject-matter of claim 1 of the main request lacks an inventive step.

4. First to fourth auxiliary requests - inventive step

4.1 D4 discloses a controllable flow control valve 76 that cooperates with a device for monitoring the pressure difference to adjust the flow through the dialyzer membranes (page 11, second paragraph). This implies that the valve, when realised as a pneumatically operated valve, is an automatic valve which varies the fluid flow through the restriction on receipt of a pneumatic signal from a controller at a controlled pressure. Furthermore, the dialyzers 12 and 60 are in fluid communication with one another via a section of the dialysate line in which the valve 76 is arranged (Figure 1). Thus, the additional features of the claims of the first to fourth auxiliary requests are also known from D4.

4.2 Therefore, the above-mentioned reasoning as to lack of inventive step also applies to the first to fourth auxiliary requests.

5. Fifth auxiliary request - inventive step

5.1 It is undisputed by the parties that D4 does not disclose a disposable cassette, and even less a cassette including the flow restriction or the dialyzers.

5.2 Nevertheless, as already mentioned in point 3.2, the embodiment of Figure 1 of D4, including a variable orifice valve between the two dialyzers, can be

regarded as an appropriate starting point for assessing inventive step.

Although the prior art does not teach to use a variable orifice valve for controlling fluid flow of dialysate within a cassette, the person skilled in the art would not have any reason to disregard this embodiment and to start instead from the embodiments of Figures 2 to 4, using a pump for controlling the dialysate flow.

- 5.3 It is noted that claim 1 comprises two distinguishing features which are not functionally interdependent. That the first feature, the valve being pneumatically operated, is obvious in the light of the prior art, has already been established in connection with the main request.

The Board considers the first alternative of the second feature, the system comprising a disposable cassette that includes the flow restriction, to be obvious, too.

- 5.4 It is stated in paragraph [0054] of the patent that a disposable cassette including at least a portion of the dialysate flow path provides a space efficient apparatus for handling the dialysate flow portions of the pumps and valves. Any advantages which could be achieved by including the flow restriction in the cassette are not mentioned.

The Board agrees with the opponent that the objective technical problem to be solved can be regarded as to render the setting up of the treatment system easier and more efficient.

- 5.5 In order to solve this problem the person skilled in the art would take D13 into consideration. This

document discloses a hemodialysis system wherein "flexible ducting and pumps operable by pneumatic pressure are constructed of disposable flexible tubing and/or disposable flexible plastic sheets sealed together in appropriate patterns", i.e. in the form of a disposable cassette (column 4, lines 41 to 46, Figure 8 and column 12, lines 22 to 37). By this, an automated equipment is developed allowing for more efficiency in the treatment set up (column 1, lines 37 to 54).

It is noted that, as pointed out by appellant 2, the cassette of D13 also includes pneumatically operated variable orifice valves, in the form of overlying ducts one of which is pressurized by gas (column 11, line 68, to column 12, line 5).

Hence, in view of this teaching, it would be obvious for the person skilled in the art to provide the system of D4 with a disposable cassette including the flow restriction. Consequently, the alternative of the subject-matter of claim 1 in which the cassette includes the flow restriction does not involve an inventive step.

6. New fifth auxiliary request

Appellant 2 did not argue against the new fifth auxiliary request. The Board does not see any reason to object to this request either. Due to the replacement of the term "or" with "and" in the feature concerning the disposable, the objection as to lack of inventive step raised against claim 1 of the 5th auxiliary request has been overcome.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:

Claims 1-22 of the new fifth auxiliary request filed during the oral proceedings on 1 April 2021;

Description:

- pages 2, 3, 11, 12, 14, 15, 17, 18, 21-24, 27-30 and 35 filed during the oral proceedings on 14 July 2016
- pages 4, 7, 9, 10, 13, 16, 19, 20, 25, 26, 31-34 of the patent specification
- pages 5, 6 and 8 filed during the oral proceedings on 1 April 2021;

Figures 1-45 of the patent specification.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated