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Datasheet for the decision of 11 March 2021

Case Number: T 0949/16 - 3.2.02

Application Number: 10005282.8

Publication Number: 2388030

IPC: A61M1/16, A61M1/36

Language of the proceedings: EN

Title of invention:
Kidney substitution device to automate blood sampling procedure in a kidney substitution treatment machine

Patent Proprietor:
B. Braun Avitum AG

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC R. 99(2)
EPC Art. 54, 56, 83, 84, 123(2), 123(3)
RPBA Art. 12(4)

Keyword:
Admissibility of appeal - appeal sufficiently substantiated (yes)
Novelty - (yes)
Inventive step - (yes)
Sufficiency of disclosure - (yes)
Claims - clarity (yes)
Amendments - added subject-matter (no) - broadening of claim (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0949/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 11 March 2021

Appellant: (Opponent)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Herrmann, Uwe Lorenz Seidler Gossel Rechtsanwälte Patentanwälte Partnerschaft mbB Widenmayerstraße 23 80538 München (DE)
Respondent: (Patent Proprietor)	B. Braun Avitum AG Schwarzenberger Weg 73-79 34212 Melsungen (DE)
Representative:	Winter, Brandl - Partnerschaft mbB Alois-Steinecker-Straße 22 85354 Freising (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 15 February 2016 concerning maintenance of the European Patent No. 2388030 in amended form.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Böttcher
	C. Schmidt

Summary of Facts and Submissions

I. The opponent lodged an appeal against the interlocutory decision of the Opposition Division, dispatched on 15 February 2016, that, account being taken of the amendments according to auxiliary request 5 valid at that time, European patent No. EP 2 388 030 and the invention to which it related met the requirements of the EPC.

II. Oral proceedings took place on 11 March 2021.

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

The respondent (patent proprietor) requested that the appeal be rejected as inadmissible or, alternatively, be dismissed, i.e. that the patent be maintained as confirmed by the contested decision (main request) or on the basis of one of auxiliary requests 1 to 3, all filed with letter dated 9 January 2017.

They further requested not to admit the appellant's objections as to inventive step starting from documents D1, D2 and D5.

IV. The following documents are referred to by the parties:

D1: US 4,662,208
D2: DE 34 16956 A1
D3: 2006 Updates Clinical Practice Guidelines and Recommendations; Guideline 3: Methods for post-dialysis blood sampling, pages 31 to 35
D4: US 4,127,111

D5: EP 1 029 554 B1

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

"A kidney substitution treatment device
wherein the device has an extracorporeal blood system (4) which is connected with a blood chamber (3a) of a dialyzer (3), which is divided by a semi-permeable membrane (2) into the blood chamber (3a) and a dialyzing fluid chamber (3b) and wherein the device has a dialyzing fluid system (11, 12) which is connected to the dialyzing fluid chamber (3b) of the dialyzer (3) wherein the extracorporeal blood system (4) has a pump (19), at least one valve (23,20) which divides the extracorporeal blood system (4) from at least one blood sampling chambers (21,22)
characterized in that
the device has a user interface (18) which communicates with a control unit (17) wherein the user interface (18) has actuating means to trigger a routine of actions which is stored on a storage device which communicates with the control unit (17) wherein that routine comprises:
a) an order to turn off the dialysate flow through the dialyzer (3) or to reduce the dialysate flow through the dialyzer (3) to a minimum which is allowed by the dialysis centre policy and
b) an order to decrease the blood flow to a range between 0 and 150 ml/min and
c) an order to run the device with the dialysate flow through the dialyzer (3) defined in paragraph a) and a blood flow defined in paragraph b) for a pre-defined time by timer and
d) an order to generate a signal or a message that a blood sample may be taken from an arterial sampling port or that the arterial line can be disconnected and

that the blood sample may be taken when the pre-defined time of paragraph c) has lapsed."

VI. The arguments of the appellant, as far as relevant for the decision, can be summarised as follows:

Admissibility of the appeal

The statement of grounds of appeal referred to all the issues in which the opposition division decided to the disadvantage of the appellant. The reasoning of the Opposition Division was even explicitly addressed (e.g. page 5, paragraph 3).

According to Article 12(2)a) RPBA, it was not necessary to attach documents D1 to D5 to the statement of grounds of appeal since these documents were already filed during the opposition proceedings.

Main request - added subject-matter

The introduction of the feature "by timer" in claim 1 constituted an unallowable intermediate generalisation since a timer was disclosed in the description as originally filed (paragraphs [0049] and [0050]) only in connection with specific method steps.

Main request - extension of protection

The omission of the feature "generate a signal or a message that the device is ready for further actions" led to a broadening of the scope of claim 1. Due to the omission of this feature, the feature "a blood sample may be taken from an arterial sampling port..." no longer defined the kidney substitution treatment device, as in claim 1 as granted, but the signal or

message in order d). Hence, the scope of protection was extended, contrary to the requirements of Article 123(3) EPC.

Main request - clarity

The parameter "minimum which is allowed by the dialysis centre policy" was not a characteristic of the device, but had to be specified by the dialysis centre. Hence, the device was defined by reference to an unknown and variable parameter. Therefore, claim 1 lacked clarity.

Main request - sufficiency of disclosure

The invention was not sufficiently disclosed to be carried out by the person skilled in the art since it could not be deduced whether the blood sampling chamber and the arterial sampling port are parts of the same component or otherwise related.

Main request - inventive step

Admittance of the objections as to inventive step starting from D1, D2 and D5

The documents D1, D2 and D5 were already submitted in the opposition proceedings and the argumentation based on these documents did not represent new facts or evidence. Hence, pursuant to Article 12(4) RPBA 2007, the objections put forward with the statement of grounds of appeal were to be admitted.

D1 or D2 in combination with D3

Both D1 and D2 disclosed all the features of claim 1 apart from the orders a) to d). In particular, the

device of D1 evidently had to be connected to a power supply. The plugging in or out of the power supply could be regarded as an actuating means to trigger the routine of actions.

The objective technical problem to be solved was to provide a standardized method for taking blood samples to reliably determine dialysis adequacy. The orders a) to d) were known from D3. In particular, the stopping of the blood pump could be regarded as a signal that a blood sample may be taken. Hence, the subject-matter of claim 1 lacked an inventive step in view of a combination of D1 or D2 with D3.

D5 in combination with D1 or D2 and D3

The subject-matter of claim 1 lacked an inventive step in view of this combination for the reasons given in the notice of opposition (pages 15 and 16).

D3 in combination with the common general knowledge or D4 or D1 or D2

D3 disclosed the features a) to d) of claim 1. In particular, the stopping of the pump after 15 seconds mentioned in Table 6 could be regarded as a signal that a blood sample may be taken.

Starting from D3 the objective technical problem was to avoid human errors in performing the procedure depicted in Table 6. This problem was solved by an automation of the orders a) to d).

D4 suggested to take a blood sample automatically. Furthermore, methods of automatically taking blood samples belonged to the common general knowledge of the

person skilled in the art. Hence, it was obvious for the person skilled in the art to provide a blood sampling routine stored on a storage device which communicated with a control unit, and which routine could be triggered by a user acting on a user interface.

The mere automation of functions previously performed by human operators was in line with the general trend in technology and could thus not be considered inventive. Furthermore, it was known from D3 that an accurate BUN (blood urea nitrogen) measurement, including a proper timing, was essential for obtaining a reliable Kt/V value (page 33, the first paragraph below Table 6).

It followed that the subject-matter of claim 1 lacked an inventive step over D3 in combination with the common general knowledge, or over D3 in combination with D4 and the common general knowledge, or over D3 in combination with D4 and D1 or D2 and the common general knowledge.

D4 in combination with D3

D4 related to an automatic blood sampling system for connection with an extracorporeal blood circuit. The system comprised a control unit for controlling the automated blood sampling, which control unit, at least implicitly, included a storage means and a user interface.

Starting from D4 the objective technical problem was to provide a standardised probe sampling method for reliably determining the dialysis adequacy.

D3 related to this problem and provided the solution by reference to the orders a) to d) in Table 6.

Hence, the subject-matter of claim 1 lacked an inventive step in view of a combination of D4 with D3 and the common general knowledge.

VII. The arguments of the respondent, as far as relevant for the decision, can be summarised as follows:

Admissibility of the appeal

The statement of grounds of appeal did not include a link to the contested decision. The appellant merely repeated the submissions made in the opposition proceedings. The documents D1 to D5 were not identified.

Thus, the appeal should be considered inadmissible.

Main request - added subject-matter

The introduction of the feature "by timer" did not add subject-matter since this feature was implicit in the statement "for a pre-defined time".

Main request - extension of protection

Claim 1 of the main request did not involve an extension of protection. It was clear from claim 1 as granted that the features "a blood sample may be taken from an arterial sampling port" and "the arterial line can be disconnected and that the blood sample may be taken" were meant as the "further actions".

Hence, since the broad term "further actions" had been

replaced with the reference to two specific actions, the scope of protection had rather been limited.

Main request - clarity

Claim 1 did not require that a specific "minimum which is allowed by the dialysis centre policy" is stored in the control unit. It was rather specified that the claimed routine comprised an order to reduce the dialysate flow to this minimum. This minimum value could be entered by a user of the system. Hence, the scope of the claim was not limited to a routine using a specific pre-set minimum value.

Hence, claim 1 did not lack clarity.

Main request - sufficiency of disclosure

The invention was sufficiently disclosed to be carried out by the person skilled in the art, irrespective of the question whether the blood sampling chamber and the arterial sampling port are parts of the same component.

Main request - inventive step

Admittance of the objections as to inventive step starting from D1, D2 and D5

The argumentation as to inventive step based on D1, D2 and D5 should not be admitted into the proceedings since it should have been brought forward in the oral proceedings before the opposition division.

D1 or D2 in combination with D3

Neither D1 nor D2 disclosed a user interface to trigger

a routine comprising, in particular, an order to generate a message or a signal that a blood sample may be taken. Hence, none of the combinations of one of these documents with D3 could render the subject-matter of claim 1 obvious.

D5 in combination with D1 or D2 and D3

D5 was even less relevant than documents D1 and D2. Hence, the subject-matter of claim 1 was inventive over D5 in combination with D1 or D2 and D3.

D3 in combination with the common general knowledge and/or D4, or D1 or D2

D3 (Table 6) related to a guidance for manually performing the blood sampling and could therefore not be regarded as the closest prior art for improving a kidney substitution treatment device.

The problem to be solved by the present invention was to increase the safety of the kidney substitution device when the known steps required for taking the blood sample were performed.

The available prior art did not disclose or render obvious to provide a routine according to claim 1 in order to obtain an accurate post-dialysis sample.

D3 related to the steps that had to be performed before the blood sample could be taken. On the contrary, D4 suggested to improve the actual taking of the blood sample by providing an automatic blood sampling system. Hence, D4 did not relate to the preparatory steps that were necessary to obtain an accurate blood sample. Hence, D4 could not render the subject-matter of claim

1 obvious.

The invention as claimed could not be regarded as a mere automation of the steps mentioned in Table 6 of D3. In particular, such an automation would not include to generate a message or a signal that a blood sample may be taken. The stopping of the pump after 15 seconds referred to in D3 could not be regarded as a generation of such a signal.

D1 and D2 disclosed to set the dialysate flow of the device on the basis of an analysis of a blood or dialysing liquid probe (column 3, lines 41 to 47 of D1). Hence, these documents taught away from the present invention. A combination of D3 with D1 or D2 could not render the subject-matter of claim 1 obvious.

Consequently, the subject-matter of claim 1 was inventive.

D4 in combination with D3

D4 did not relate to a kidney substitution treatment device and it did not disclose a user interface as defined in the claim. The feature to generate a signal or message for the user that a blood sample may be taken was also not disclosed in D4.

The argumentation of the appellant was speculative and based on hindsight.

The subject-matter of claim 1 did not lack an inventive step in view of D4 in combination with D3.

Reasons for the Decision

1. Admissibility of the appeal

The Board holds that the appeal is admissible. In the statement setting out the grounds of appeal the appellant referred to all the issues dealt with in the decision. In three passages (page 5, paragraph 3; page 13, last paragraph; and page 14, paragraph 4) they explicitly addressed the reasoning of the Opposition Division.

As to the identity of documents D1-D5, the Board has no doubts that they are the same documents D1-D5 referred to in the appealed decision.

2. Main request - added subject-matter

The Board agrees with the appellant that a timer is explicitly disclosed in the description only in connection with a specific time period (15 seconds) and an order to decrease the blood flow to a specific flow rate (100 ml/min) (paragraphs [0049] and [0050]). However, in the Board's view, these features are not inextricably linked with the measurement of the "pre-defined time" disclosed in originally filed claim 1 being made by a timer. Thus, the inclusion in claim 1 of the feature "by timer" without reference to the specific time period and the specific flow rate does not constitute an unallowable intermediate generalisation.

The amendments made to claim 1 therefore meet the requirements of Article 123(2) EPC.

3. Main request - extension of protection

The Board does not share the appellant's view that the omission of the wording "generate a signal or a message that the device is ready for further actions", which was comprised in claim 1 as granted, leads to a broadening of the scope of claim 1. The omitted wording defined merely the signal or message, without adding any further limitation on the device.

The wording "generate a signal or a message that a blood sample may be taken..." in present claim 1 further limits said signal or message, since it defines more specifically the further actions that may be carried out on receipt of the signal. Hence, no extension of protection resulted from the omission of said wording.

Thus, the amendments made to claim 1 meet the requirements of Article 123(3) EPC.

4. Main request - sufficiency of disclosure

The invention is sufficiently disclosed since the description clearly indicates at least one way enabling the person skilled in the art to carry out the invention (paragraphs [0039] to [0051], Figure 1). Whether the blood sampling chamber and the arterial sampling port are parts of the same component or not, is irrelevant in this regard.

5. Main request - clarity

The Board acknowledges that the parameter "minimum which is allowed by the dialysis centre policy", added to claim 1 during the opposition proceedings, is not a

characteristic of the device. However, the claim does not lack clarity because of this parameter. The feature means that the claimed routine has to comprise an order to reduce the dialysate flow to a certain preset value, namely, the minimum allowed by the policy of the dialysis centre in which the treatment is performed. It is clear that each dialysis centre has its own policy, i.e. that the minimum value may differ from one dialysis centre to the other. Hence, the feature has to be understood in that the routine must be configured to be run with a minimum value to be entered by the user.

Therefore, claim 1 meets the requirements of Article 84 EPC.

6. Main request - inventive step

6.1 Objections starting from D1, D2 and D5

With the statement of grounds of appeal the appellant submitted new objections as to inventive step starting from Dl, D2 and D5. These objections, which comprised factual elements which were not part of the opposition proceedings, were not subject of the contested decision. The appellant did not provide any reasons as to why they were submitted for the first time in appeal.

Moreover, it is noted that none of Dl and D2 discloses a user interface to trigger a routine comprising, in particular, an order to generate a message or a signal that a blood sample may be taken. Hence, none of the combinations of one of these documents with D3 seems to render prima facie the subject-matter of claim 1 obvious.

In respect of the attack starting from D5, the appellant merely refers to pages 15 and 16 of the notice of opposition, which, however, do not refer to claim 1 as maintained by the opposition division. Hence, the Board considers this objection not substantiated.

In view of these considerations the Board decided not to admit the objections starting from D1, D2 and D5 (Article 12(4) RPBA 2007).

6.2 D4 in combination with D3

D4 does not relate to a kidney substitution treatment device, but to an automatic blood sampling system for connection with an extracorporeal blood circuit (column 1, lines 7 to 10). Hence, D4 does not disclose a dialyzer and a dialyzing fluid system.

The blood sampling system of D4 has a pump 10 and at least one valve dividing the extracorporeal blood system from a blood sampling chamber (Fig. 2). D4 mentions a control unit 42 (column 4, line 35), but neither a user interface nor a storage device. Furthermore, D4 does not disclose the routine defined in claim 1. In particular, D4 does not disclose a routine comprising an order to generate a signal or message that the device is ready for a blood sample being taken by the user. Rather, in D4 the blood sample is taken automatically.

Starting from D4, which does not relate to dialysis, the person skilled in the art, without the knowledge of the present invention, would not have attempted to provide a standardised probe sampling method for reliably determining the dialysis adequacy. Therefore,

the teaching of Table 6 of D3 (page 33), which relates to the guidelines of the NKF (National Kidney Foundation) for post-dialysis blood sampling, does not motivate the person skilled in the art to implement a user interface in the automatic sampling device of D4 for triggering a routine that generates a message or signal that a blood sample may be taken after a certain time has lapsed.

Hence, the subject-matter of claim 1 involves an inventive step in view of D4 in combination with D3.

6.3 D3 in combination with D4 and/or with the common general knowledge, or D1 or D2

The appellant alleges that the subject-matter of claim 1 constituted a mere automation of the instructions for the manual blood sampling given in Table 6 of D3, in order to solve the problem of avoiding human errors. According to the appellant, such an automation did not involve an inventive step since methods of taking blood samples automatically as, for instance, described in D4, were generally known to the person skilled in the art.

The Board does not agree with this view. Claim 1 requires a routine that, after some preparatory steps have been performed and a certain time has lapsed, generates a signal or message that the device is ready for taking a blood sample. Upon receiving this message, the user can perform the blood sampling manually. D4 does not teach or render obvious to generate such a message or signal. In D4, the whole blood sampling process is performed automatically.

Furthermore, an automation of the steps described in

Table 6 of D3 would not include an order "to generate a signal or a message that a blood sample may be taken...". Table 6 discloses that the blood flow should be decreased for 15 seconds (A.2.). After that, the user should proceed to obtain the sample. Thus, a routine implementing the steps of Table 6 would be finished after order c) of claim 1, to allow the user to perform the manual step of obtaining the sample. An order to generate a signal or a message that the device is ready such that a blood sample may be taken would not be included in such a routine. The lapse of the 15 seconds, even if it is indicated by a sound, cannot be regarded as such a signal since it does not involve any information on how the user should proceed.

D1 and D2 disclose an apparatus for taking and analyzing blood or dialysis fluid probes (D1: abstract; D2: page 36, lines 17 to 21, page 39, line 31 to page 40, line 15). However, none of these documents suggest an order to generate a signal or message that the device is ready for taking the sample.

Hence, a combination of D3 and the common general knowledge and/or D4, or D1 or D2 cannot render the subject-matter of claim 1 obvious.

7. The patent as maintained by the Opposition Division, and the invention to which it relates are found to meet the requirements of the EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated