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Datasheet for the decision of 2 October 2013

Case Number: T 0435/10 - 3.2.02

Application Number: 02733094.3

Publication Number: 1395314

IPC: A61M 1/36

Language of the proceedings: EN

Title of invention:
Dialysis machine having a device for sensing the detachment of the venous needle from a patient during an extracorporeal blood treatment

Patent Proprietor:
Gambro Lundia AB

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 56, 100(a)

Keyword:
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0435/10 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 2 October 2013

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 23 December 2009 rejecting the opposition filed against European patent No. 1395314 pursuant to Article 101(2) EPC.

Composition of the Board:

Chairman: E. Dufrasne
Members: P. L. P. Weber
D. Ceccarelli

Summary of Facts and Submissions

I. The opponent's appeal is against the decision of the Opposition Division posted on 23 December 2009 to reject the opposition.

The notice of appeal was filed on 1 March 2010 and the appeal fee paid on the same date.
The statement setting out the grounds of appeal was filed on 28 April 2010.

II. Independent claims 1 and 2 of the patent as granted read as follow:

"*1. Dialysis machine comprising:*
an extracorporeal blood circuit (2) provided with a venous branch (10) connected to a venous needle (13) for accessing the cardiovascular system of a patient (P); and
a device for sensing the detachment of the venous needle (13) from the patient (P) during an extracorporeal blood treatment, characterized in that said device (14) comprises:
an electrical line (21, 22, 23) external to the extracorporeal circuit (2), to form, in combination with a portion of the venous branch (10) and the patient (P), an electrical circuit (37) extending along a closed-loop path (P1), said electrical line (21, 22, 23) comprising a first and a second branch (22, 23) and a voltage source (21) located between the first and the second branch (22, 23), the first branch (22) being in use connected to the venous branch (10) and the second branch (23) being in use connected to the earth;

a sensor (17) interacting with the electrical line (21, 22, 23) to detect a signal correlated with the current flowing in said electrical circuit (37), said sensor (17) being located in the first branch (22) or in the second branch (23); and
means (15) of processing said signal for sensing the opening of said electrical circuit (37).

2. Dialysis machine comprising:
an extracorporeal blood circuit (2) provided with a venous branch (10) connected to a venous needle (13) for accessing the cardiovascular system of a patient (P), said patient being isolated from the earth; and
a device for sensing the detachment of the venous needle (13) from the patient (P) during an extracorporeal blood treatment, characterized in that said device (14) comprises:
an electrical line (21, 22, 23) external to the extracorporeal circuit (2), to form, in combination with a portion of the venous branch (10) and the patient (P), an electrical circuit (37) extending along a closed-loop path (P1), said electrical line (21, 22, 23) comprising a first and a second branch (22, 23) and a voltage source (21) located between the first and the second branch (22, 23), the first branch (22) being in use connected to the venous branch (10) and the second branch (23) being in use connected directly to the patient (P);
a sensor (17) interacting with the electrical line (21, 22, 23) to detect a signal correlated with the current flowing in said electrical circuit (37), said sensor (17) being located in the first branch (22) or in the second branch (23); and

means (15) of processing said signal for sensing the opening of said electrical circuit (37)."

III. Oral proceedings were held on 2 October 2013.

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

The respondent requested that the appeal be dismissed, or in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of the first auxiliary request filed with letter dated 20 August 2013.

IV. The following documents are cited in the decision:

D1 : WO-A-99/12588
D2 : WO-A-99/29356
Two extracts from Wikipedia, one in German and one in English, respectively entitled "Zentralvenenkatheter" and "central venous catheter".

V. The appellant's arguments can be summarised as follows:

The Wikipedia extracts were only filed as evidence for the fact that one of the uses of central venous catheters is in kidney replacement therapy. They should therefore be admitted into the proceedings.

Starting from D1 as the closest prior art, the person skilled in the art, having the problem of reducing the impedance of the circuit in the device according to D1 would apply the teaching of D2 and come to the subject-matter of claim 2.

D2 discloses a device for detecting the detachment of a central venous catheter (central venous catheters are used in dialysis) with a circuit involving the patient and having a very low impedance. Although the embodiment according to Figure 1 shows a perfusion of fluid to a patient with one catheter entry into the patient and one electrode 10 on the skin of the patient, it is mentioned on page 4, lines 24 to 26, that the electrode 10 on the skin could be replaced by a second catheter, exactly as is the case in dialysis treatment. Additionally, this document mentions the application of its teaching in heart surgery in which blood circulation is maintained by an external pump. In such a case there are necessarily a blood extraction needle or catheter and a blood returning needle or catheter exactly as in a dialysis treatment device. For these reasons it is immediately apparent to the person skilled in the art that the teaching of D2 is applicable in a dialysis machine in order to detect disconnection of the venous needle.

Therefore, the subject-matter of claim 2 is not inventive.

The subject-matter of claim 1, representing an obvious alternative, in that the patient is connected through earth instead of being connected directly, is not inventive either.

VI. The respondent's arguments can be summarised as follows:

There is no evidence on file that the information in the Wikipedia extracts was available on the priority date so these documents should not be admitted into the proceedings.

The subject-matter of claims 1 and 2 is inventive for two reasons: D1 teaches away from D2, and even if D2 were considered, the combination of D1 and D2 would not lead to the subject-matter of the claims.

D1 mentions the difficulties linked with the dropper, the diameter of the tube, or other parameters influencing the conductivity. Hence, if the intensity of the current to be used in the prior art device according to D1 becomes a problem, D1 itself draws the attention of the person skilled in the art to these parameters worth trying to improve. Hence, the person skilled in the art would not seek for solutions elsewhere.

In any case document D2 shows neither a voltage source between the first and the second lines nor a sensor as required by claim 2. Hence, a combination with D1 cannot lead to the subject-matter of claim 2, and even less to that of claim 1.

Therefore the subject-matter of claims 1 and 2 is inventive.

Reasons for the Decision

1. The appeal is admissible.

2. Admissibility into the proceedings of the Wikipedia extracts

At the end of each of the English and the German versions a date in 2009 is mentioned as the date of the last changes made to the document. This means that the documents were not available to the public in this form before the priority date of the present patent. Moreover, there is no evidence on file that the extracts were available at all on internet at the priority date.

Therefore, the Board decided to not introduce these documents into the proceedings.

Novelty and inventive step

3. Novelty is not disputed by the appellant.

4. The parties agree that D1 is the closest prior art.

Since claim 1 and claim 2 are directed to a dialysis machine, and D1 describes a dialysis machine whereas D2 does not, the Board likewise has no doubt that D1 is the closest prior art.

This document discloses a dialysis machine comprising a means for detecting the detachment of any of the two needles from the patient (page 8, lines 2 to 4). In the described embodiment a current is generated flowing

through the whole extracorporeal blood circuit. An alternative current is induced on the venous side (Erregerspule 18) which generates a magnetic field on the arterial side (Induktionspule 20) and a difference of potential (voltage) at the induction coil. This voltage is measured and compared to a threshold value (page 7, last paragraph to page 8, second paragraph). When one of the needles is detached no current circulates any more and the voltage drops.

5. The differentiating features over claim 2 are those in the characterising portion of the claim, namely that "*the device for sensing the detachment of the venous needle comprises:*
an electrical line (21, 22, 23) external to the extracorporeal circuit (2), to form, in combination with a portion of the venous branch (10) and the patient (P), an electrical circuit (37) extending along a closed-loop path (P1), said electrical line (21, 22, 23) comprising a first and a second branch (22, 23) and a voltage source (21) located between the first and the second branch (22, 23), the first branch (22) being in use connected to the venous branch (10) and the second branch (23) being in use connected directly to the patient (P);
a sensor (17) interacting with the electrical line (21, 22, 23) to detect a signal correlated with the current flowing in said electrical circuit (37), said sensor (17) being located in the first branch (22) or in the second branch (23); and
means (15) of processing said signal for sensing the opening of said electrical circuit (37)."

This is not disputed by the parties.

6. The appellant considers that the objective problem was to reduce the impedance of the circuit in order to avoid the use of strong currents as is necessary in the device according to D1, and according to the appellant, the teaching of D2 would lead the person skilled in the art directly to the subject-matter of claim 2. The subject-matter of claim 1 would be a simple obvious alternative.

7. Compared with the device according to D1, in the device according to the invention the idea is to use only a part of the venous branch combined with a part of the patient, so that the current necessary for reliable detection can be much lower because the impedance of the patient's body is much lower than that of the peristaltic pump and the dropper. Thus the relevant current for the detection, thus, does not flow through these high-impedance elements.

Hence, concerning the technical effects and the objective problem, the Board cannot agree with the appellant's formulation of the objective problem since it already includes or suggests part of the solution, the reduction of impedance. The Board rather shares the analysis of the Opposition Division on page 4 of its decision.

"4c. The technical effect of these features is to allow a reliable detection of the detachment of the venous needle by using lower currents than it would be necessary to use if elements presenting high impedance, such as pumps or droppers, where included in the electrical circuit, such as is the case in D1.

4d. The problem solved is therefore considered to be to increase at the same time safety for the patient and reliability of the detachment detection."

This analysis of the effects and the objective problem is in line with the drawbacks of the state of the art exposed in paragraphs [0007], [0008], [0009] of the patent.

8. Document D2 discloses a means for detecting air bubbles, kinks and cuts in a fluid delivery line leading to a central venous catheter connected to a patient, e.g. for perfusion. The means can also detect detachment of the catheter. Three electrodes are placed at three different places: one at a place (Q) close to the outlet of the reservoir containing the fluid to be delivered to the patient, one at a point (P) close to the place where the catheter enters the patient, and one somewhere else (R) on the patient (e.g. on its skin). By circulating a current between the electrodes and measuring the resistance between Q and P or between P and R, it is possible to deduce problems in the lines. For instance, if the catheter is detached from the patient the resistance between P and R will increase dramatically. Increase of resistance between Q and P is an indication of another kind of problem between the reservoir and the patient (page 3, lines 27 to 34), such as the presence of bubbles, kinks or the like.

9. The Board considers that D1 leads the person skilled in the art away from D2. In the construction according to D1 the current has to flow through the whole extracorporeal blood circuit of the dialysis machine,

in particular through the peristaltic pump 6 and through the dropper 8. Concerning the current to be used, it is mentioned in D1 (page 4, second complete paragraph) that the amplitude and frequency of the alternative current have to be selected so as not to harm the patient or its blood, but nevertheless so as to be able to obtain reliable detection of the detachment. On page 7, last paragraph, it is mentioned that the alternative current to be induced in the blood is dependent on the conductivity of blood, the diameter of the tube and other parameters. It is further explained on page 8, last paragraph, that a special dropper 8 has to be built into the extracorporeal blood circuit in order to guarantee continuous conductivity.

Thus, the problem of conductivity in the extracorporeal blood circuit and the parameters influencing it are largely addressed in this document. In other words, D1 not only proposes a device allowing detection of needle detachment, but already mentions potential improvements. Hence, all these passages in D1 lead, invite or even teach the person skilled in the art to try and find ways to improve the conductivity of the dropper or the peristaltic pump or to improve any of the other parameters influencing the conductivity in the extracorporeal blood circuit, and not to look anywhere else in the hope of finding another solution.

The Board therefore does not see why the person skilled in the art would as an obvious step even seek for a solution to the problem not involving the extracorporeal blood circuit of the dialysis machine.

For this reason alone, the Board considers that subject-matter of claim 2 is inventive.

10. The appellant tries to establish a link between D2 and dialysis because

- on page 1, lines 35 and 36, central venous catheters are mentioned, which according to the appellant are used in kidney replacement therapy,
- on page 4, lines 24 to 26, it is specifically mentioned that the skin electrode 10 could be replaced by a second catheter,
- on page 7, last paragraph, it is mentioned that the detecting device may be used in heart surgery, when an external pump is used to maintain blood flow.

In the Board's opinion these arguments are not convincing.

The device described in D1 allows for the detection of the detachment of both the venous needle and/or the arterial needle since the detachment of any of these needles will interrupt the current flowing through the blood in the extracorporeal blood circuit and will, thus, be detected. The Board considers that there is no reason why the person skilled in the art would consider abandoning the possibility of detecting both the venous and the arterial needle detachments, because both are important for the survival of the patient.

At best D2 discloses a rather general teaching for catheters used for delivering fluids from a reservoir to a patient. This general teaching is, as mentioned above, to use three electrodes to circulate a current in the part going from the fluid reservoir to the

patient and in part of the patient to monitor changes in the resistance between the electrodes and so be able to detect air bubbles, kinks, cuts and possibly detachment. However, there is no information in D2 relating to a device for detecting both the detachment of the venous needle and the arterial needle in an extracorporeal blood circuit as in the device according to D1. When mentioning the possible use in heart surgery, D2 refers only to the advantage of the recognising the presence of bubbles, which is not the problem solved by the present invention. Also on page 1 when catheters are mentioned, and on page 4 when a possible second catheter is cited, it is in the broadest sense, not specifically for detecting the detachment of a needle of an extracorporeal blood circuit during dialysis treatment.

Hence, D2 does not address the problem of increasing safety for the patient, it does not mention any application in a device for dialysis treatment, and finally it does not disclose in detail any embodiment encompassing detection of the detachment of a venous connection and an arterial connection with a patient.

In other words, the Board considers that the person skilled in the art would not consult such a document in the expectation of finding a solution to the problem in the dialysis machine according to D1, or more precisely in the extracorporeal blood circuit of the dialysis machine according to D1. The Board sees no reason as to why the person skilled in the art wanting to improve the dialysis machine of D1 would accept no longer being able to detect the detachment of both needles when this is possible in that device. On the contrary, it rather

seems normal that the person skilled in the art would do everything possible to keep this advantage of the device according to D1 and, thus, try and improve the shortcomings of the device according to D1, and disregard D2.

11. For the above reasons, the subject-matter of claim 2 is inventive.

Since the subject-matter of claim 1 is additionally distinguished from D1 in that the patient is in the detecting circuit through earth instead of being connected directly, the subject-matter of claim 1 is inventive at least for the same reasons.

Therefore, the ground for opposition of lack of inventive step under Article 100(a) EPC does not hold.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne