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**Datasheet for the decision
of 22 March 2011**

Case Number: T 0536/09 - 3.2.02

Application Number: 01900572.7

Publication Number: 1161271

IPC: A61M 1/36

Language of the proceedings: EN

Title of invention:

Method for emptying a blood circuit of an apparatus for the extracorporeal treatment of blood

Patentee:

GAMBRO HOSPAL (Schweiz) AG

Opponent:

Fresenius Medical Care Deutschland GmbH

Headword:

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Relevant legal provisions:

EPC Art. 111, 84, 123(2)

Relevant legal provisions (EPC 1973):

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Keyword:

"Extension of subject-matter (no)"
"Clarity (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 0536/09 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.02
of 22 March 2011

Appellant: GAMBRO HOSPAL (Schweiz) AG
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 14 January 2009
revoking European patent No. 1161271 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: M. Noël
Members: P. L. P. Weber
A. Pignatelli

Summary of Facts and Submissions

- I. The appeal by the patentee is against the decision of the Opposition Division dated 14 January 2009 to revoke European patent EP-B-1 161 271.
- II. During the oral proceedings held on 3 December 2008 before the Opposition Division the appellant filed a new main request and two new auxiliary requests. The Opposition Division considered that due to prima facie objections under Articles 84 and 123(2) EPC, none of the requests could be admitted into the proceedings at that late stage and that consequently the patent had to be revoked.
- III. Notice of appeal was filed on 2 March 2009 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 7 May 2009.
- IV. The respondent (opponent) withdrew its opposition on 11 January 2011.
- V. The appellant requests that:
- 1 - The decision of the Opposition Division be set aside;
 - 2 - The case be remitted to the Opposition Division for further prosecution on the basis of one of the sets of claims filed as the main request, first auxiliary request or second auxiliary request, all with the statement setting out the grounds of appeal;
 - 3 - Oral proceedings be arranged, should the Board of Appeal be minded not to set aside the contested

decision and/or not to remit the case back to the Opposition Division.

VI. The arguments of the appellant can be summarized as follows:

From the amendments made to claim 1 according to the main request, it was clear that the claimed method concerned emptying a blood circuit in view of discarding it after a blood treatment session was over. The request did not include such substantial amendments as to justify the Opposition Division's decision not to admit it into the proceedings.

Over the granted version three amendments were introduced into claim 1 namely:

The first amendment "in view of discarding the blood circuit" appeared several times in the originally filed application documents, see for instance corresponding passages in the patent specification column 2, lines 40 to 43 ; column 2, lines 2 to 20 or column 5, line 53 to column 6, line 1, where it was made clear that the method was part of the same process of ending a treatment or session whose ultimate step was to discard altogether the dialyser and the arterial and venous pipes connected thereto.

The second amendment "saline solution and residual blood" was also disclosed in the originally filed application documents, see for instance patent specification column 5, lines 19 to 21: *"According to the invention, in order to empty the blood circuit 9, which is then full of saline solution and residual*

blood, the venous pipe is disconnected from the patient..."

In addition it was clear in the following claimed feature that the liquid contained in the closed loop circuit consisted of saline solution and residual blood since the word "liquid" was preceded by the article "the" referring to the liquid in the preceding line.

The third amendment "so as to empty the blood circuit" was not objected to by the Opposition Division and was clearly disclosed in the application as filed, see for instance corresponding passages in the patent specification column 5, lines 53 to 56: "*The blood pump is run so as to circulate the saline solution until the transfer of the solution through the membrane 7 is completed.*".

Therefore Claim 1 according to the main request fulfilled the requirements of Articles 84 and 123(2) EPC.

The first and second auxiliary requests should have been admitted for the same reasons.

VII. Claim 1 of the main request as filed during the oral proceedings of 3 December 2008 reads as follows:

"1. Method for emptying a blood circuit of an apparatus for the extracorporeal treatment of blood, in view of discarding the blood circuit after interrupting a treatment session, the apparatus comprising:

- a blood treatment device (4) having a first and a second compartments (5, 6) separated from one another by a semi permeable membrane (7),

- an arterial pipe (8) having a first end connected to an inlet of the first compartment (5) and a second end,
- a venous pipe (9) having a first end connected to an outlet of the first compartment (5) and a second end,
- connection means (28, 29; 32) for connecting the second end of the arterial pipe (8) and the second end of the venous pipe (9) to the vascular system of a patient,
- a fresh dialysis liquid supply pipe (20) connected to an inlet of the second compartment (6),

the method comprising the steps of:

- .closing on itself a blood circuit (2) comprising the arterial pipe (8), the first compartment (5) of the blood treatment apparatus (4) and the venous pipe (9) in order to form a closed loop circuit, after the arterial and venous pipes (8, 9) have been disconnected from the vascular system of the patient, the blood circuit containing saline solution and residual blood;
- .transferring the liquid contained in the closed loop circuit into the used liquid circuit (6, 21), so as to empty the blood circuit (2); and
- .draining the liquid transferred into the used liquid circuit (6, 21) using the drain pipe (21)."

VIII. Claim 1 of the main request as filed with the statement of the grounds of appeal reads as follows:

"1. Method for emptying a blood circuit of an apparatus for the extracorporeal treatment of blood, in view of discarding the blood circuit after interrupting a treatment session, the apparatus comprising:

- a blood treatment device (4) having a first and a second compartments (5, 6) separated from one another by a semi permeable membrane (7),

- an arterial pipe (8) having a first end connected to an inlet of the first compartment (5) and a second end,
- a venous pipe (9) having a first end connected to an outlet of the first compartment (5) and a second end,
- connection means (28, 29; 32) for connecting the second end of the arterial pipe (8) and the second end of the venous pipe (9) to the vascular system of a patient,
- a used liquid circuit (6, 21) having a drain pipe (21) connected to an outlet of the second compartment (6), the method comprising the steps of:
 - .closing on itself a blood circuit (2) comprising the arterial pipe (8), the first compartment (5) of the blood treatment apparatus (4) and the venous pipe (9) in order to form a closed loop circuit, after the arterial and venous pipes (8, 9) have been disconnected from the vascular system of the patient, the blood circuit containing saline solution and residual blood;
 - .transferring the liquid contained in the closed loop circuit into the used liquid circuit (6, 21), so as to empty the blood circuit (2); and
 - .draining the liquid transferred into the used liquid circuit (6, 21) using the drain pipe (21)."

Reasons for the Decision

1. The appeal is admissible.
2. Admissibility of main request.
 - 2.1 Claim 1 of present main request is different from claim 1 of the main request as filed at the oral

proceedings of 3 December 2008 in that a feature has been replaced.

The amendment concerned is the replacement of the last feature of the first part of the claim "*a fresh dialysis liquid supply pipe (20) connected to an inlet of the second compartment (6)*" by the feature "*a used liquid circuit (6, 21) having a drain pipe (21) connected to an outlet of the second compartment (6)*".

The main request filed with the statement setting out the grounds of appeal being a new request, the Board will only deal with the formal admissibility of this new request and not with the question raised by the appellant whether the Opposition Division properly exercised its discretionary power when refusing to admit the former main request into the proceedings.

- 2.2 The main request has been filed with the statement of the grounds of appeal in accordance with Article 12(2) RPBA.

The replacement feature was in originally filed claim 1, and in the granted claim 1. It is therefore not objectionable under Article 84 or 123 EPC.

Compared with claim 1 as granted, the wording of claim 1 according to the main request has been amended by the addition of three new terms:

- i) "*in view of discarding the blood circuit*" has been inserted at the beginning of the claim;
- ii) "*saline solution and residual blood*" replaces the word "liquid" in the third last feature;

iii) "*so as to empty the blood circuit (2)*" has been added in the second last feature.

These amendments clearly limit the claimed subject-matter so that the requirements of Rule 80 EPC are fulfilled.

Therefore the main request is admitted into the appeal proceedings.

3. Compliance with Articles 84 and 123(2) EPC.

As the above mentioned amendments were found by the Opposition Division *prima facie* to contravene Articles 84 and 123(2) EPC, the Board will examine these objections before remitting the case to the first instance for further prosecution, as requested by the appellant.

3.1 Concerning feature i) the Opposition Division considered that it constituted an intermediate generalisation because the passage cited by the patentee, col.5, line 59 to col.6, line 1, specified that "*...the dialyser, the arterial and venous pipes and the flexible bag can be discarded.*", and that there would thus not be any disclosure that the blood circuit could be discarded without the bag being discarded as well.

The Board cannot agree with the Opposition Division as it was clear from the outset what the invention was about, namely to empty the blood circuit in order to make it less dangerous and less costly to discard. This can already be read in paragraph [0008] which explains

the way in which the dialysis process is ended : "*Once disconnected from the dialysis liquid circuit, the dialyzer together with the arterial and venous pipes are discarded in a special container for contaminated waste since the residual blood contained in the blood circuit could be contaminated.*". Thus what is discarded is clearly the blood circuit. The fact that the bag 27 is or may also be discarded, as mentioned in col.6, line 1, does not mean that the primary aim of the invention was not to discard the blood circuit.

The Board can therefore not see any infringement of Article 123(2) EPC in feature i).

- 3.2 In relation to amendment ii) the Opposition Division considered that the added wording did not fulfil the requirement of Article 84 EPC for two reasons: first, because it was not clear whether the liquid in the following clause was meant to be the saline solution with residual blood previously mentioned in the claim, and secondly, because the term residual was considered to be unclear per se because it was considered impossible to know how much blood was meant by this relative term "residual".

Concerning the second argument, it appears to be overstated in the context of the present invention. As a matter of fact, the invention is about emptying the blood circuit of a dialysis system (see paragraph [0011]). In this context it is clearly explained how the treatment is stopped (see paragraph [0008]), namely by introducing a saline solution into the blood circuit before stopping the pumps definitively when the interface between blood and saline solution reaches the

venous needle. It is therefore clear that when both needles are disconnected from the patient, the blood circuit is mainly filled with saline solution but there remains some blood in it, the quantity of which depends on the precise moment when the pumps are stopped and will probably depend on the operator.

In addition, the invention being about emptying the blood circuit, the quantity of blood remaining in the circuit has no influence on the emptying phase per se. The argument of the Opposition Division that it is not clear how much "residual" is meant to be, is therefore artificial in the context of a dialysis method. And in any case it is artificial in the context of emptying a tube.

In the Board's opinion the first argument is no better since the clause immediately following the one at issue begins with "*transferring the liquid contained in the closed loop circuit,*" (emphasis added), so that there can be no doubt about which liquid is meant.

The Board therefore cannot see any objection under Article 84 EPC in relation to this feature.

- 3.3 The amendment iii) has not been objected to, either by the opponent or by the Opposition Division, and the Board cannot see any objection to this amendment either.
- 3.4 Hence, in the Board's judgement the main request fulfils the requirements of Articles 84 and 123(2) EPC.
4. Since the other grounds of opposition have not yet been decided upon by the Opposition Division, remittal of the case to the department of first instance for

further prosecution pursuant to Article 111(1) EPC, as requested by the appellant, is justified.

5. Since the case is remitted no oral proceedings are to be held.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution on the basis of the set of claims according to the main request as filed on 7 May 2009 with the statement setting out the grounds of appeal.

The Registrar:

The Chairman:

D. Sauter

M. Noël