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**Datasheet for the decision
of 20 November 2017**

Case Number: T 0458/13 - 3.2.02

Application Number: 05781502.9

Publication Number: 1815878

IPC: A61M1/14

Language of the proceedings: EN

Title of invention:
BLOOD PURIFYING DEVICE

Patent Proprietor:
NIKKISO COMPANY, LTD.

Opponents:
Fresenius Medical Care Deutschland GmbH
B. Braun Avitum AG

Headword:

Relevant legal provisions:
EPC Art. 84, 54, 56

Keyword:

Main request - clarity (no)

Auxiliary request 1 - combination of claims of the patent as
granted - lack of clarity no ground for opposition

Novelty - auxiliary request 1 (yes)

Inventive step - auxiliary request 1 (yes)

Decisions cited:

G 0003/14

Catchword:



Beschwerdekammern
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Chambres de recours

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Case Number: T 0458/13 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 20 November 2017

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Decision under appeal:

Interlocutory decision of the Opposition
Division of the European Patent Office posted on
3 January 2013 concerning the maintenance of
European patent No. 1815878 in amended form.

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
 M. Stern

Summary of Facts and Submissions

- I. The patent proprietor and the opponents have all appealed the Opposition Division's decision, dispatched on 3 January 2013, that, taking into account the amendments according to the second auxiliary request made by the patent proprietor during the opposition proceedings, European patent No. 1 815 878 and the invention to which it related met the requirements of the EPC.

The patent was opposed on the grounds of lack of novelty and inventive step. The main request was found to contravene Articles 84 and 123(2) EPC; the first auxiliary request was found to lack novelty.

- II. The appellant patent proprietor (hereinafter "the proprietor") filed notice of appeal, received on 4 March 2013. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 3 May 2013.

The appellant opponent 1 (hereinafter "opponent 1") filed notice of appeal, received on 1 March 2013. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 13 May 2013.

The appellant opponent 2 (hereinafter "opponent 2") filed notice of appeal, received on 19 February 2013. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 8 May 2013.

- III. All parties filed further written submissions.

IV. Oral proceedings took place on 20 November 2017.

The proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the main request and auxiliary requests 1 and 2, filed with letter dated 2 May 2013, and auxiliary request 3, filed with letter dated 27 September 2013.

Opponents 1 and 2 requested that the decision under appeal be set aside and that the patent be revoked.

V. The following documents are mentioned in the present decision:

D7: "Operating Instructions 2008 BSS BEDSIDE STATION", Fresenius AG, Revision Date 4/91;

D8: "Dialysegerät Dialog Gebrauchsanweisung", B.Braun Melsungen AG, Ausgabe 4/96;

D9: "Dialysegerät Dialog und Dialog ONLINE Gebrauchsanweisung", B.Braun Medizintechnologie GmbH, Version 12/2002.

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

"A blood purification device comprising:

a blood circuit (1) having an arterial blood circuit (1a) and a venous blood circuit (1b) to circulate extracorporeally blood collected from the patient;

a blood pump (3) provided for said arterial blood circuit (1a);

a blood purification means (2), connected between said arterial blood circuit (1a) and said venous blood

circuit (1b), for purifying the blood flowing in said blood circuit (1).

a venous blood pressure measuring means (5) for measuring the pressure of a patient's blood flowing in said venous blood circuit (1b);

a venous blood pressure monitoring means (12) for activating an alarm by comparing a predetermined alarm-threshold with pressure measured or pressure predicted to be measured, as a base value, by the venous blood pressure measuring means (5);

wherein said venous blood pressure monitoring means (12) updates said predetermined alarm-threshold at a predetermined period of time,

characterized in that

a time interval to update the alarm-threshold by said venous blood pressure monitoring means is determined."

Compared with claim 1 of the main request, claim 1 of **auxiliary request 1** comprises the following additional wording at its end:

"in accordance with changes in the pressure measured or the pressure predicted to be measured by said venous blood pressure measuring means;

wherein said time interval is set shorter when the pressure change is large than when the pressure change is moderate".

VII. The proprietor's arguments may be summarised as follows:

Main request - clarity (Article 84 EPC)

Claim 1 of the main request, in its preamble, defined a "predetermined period of time" at which the alarm-threshold was updated. The characterising portion introduced a "time interval to update the alarm-threshold", which was "determined". Both the "period of time" and the "time interval" designated the time between two points in time at which the alarm-threshold was updated, but they had different meanings. On a technically reasonable reading of the claim, the feature introduced in the characterising portion had to provide an additional teaching. More particularly, while according to the preamble of the claim the times between any two consecutive updates of the alarm-threshold could be predetermined, the characterising portion specifically excluded that it was so for all of these times. Rather, a single time interval, separately from the other time intervals, was determined. In other words, in view of the disclosure of the patent as a whole, the characterising portion of the claim, which excluded the situation in which all the times between any two consecutive updates of the alarm-threshold were predetermined, implied an adaptive adjustment of these times. It followed that the subject-matter of claim 1 of the main request was clear.

Auxiliary request 1 - clarity (Article 84 EPC)

Claim 1 of auxiliary request 1 was the combination of claims 1 and 2 of the patent as granted. In line with the case law, objections based on Article 84 EPC should not be allowed.

*Auxiliary request 1 - novelty and inventive step
(Articles 54 and 56 EPC)*

Claim 1 of auxiliary request 1 defined a device in which the time intervals to update the alarm-threshold were adaptively set and determined before the respective updates took place.

D8 disclosed fixed time intervals and was completely silent about a potential dependence of the time intervals on the pressure measured or the pressure predicted to be measured by a venous blood pressure measuring means. D7 and D9 were no more relevant than D8 since, in particular, they did not disclose such a dependence either.

Starting from D8 as the closest prior art, the adaptive system according to claim 1 of auxiliary request 1 provided a more effective control of false alarms and the patient's conditions. In D8 a different adaptation of the alarm-threshold of the venous pressure during blood purification treatment was presented, although the general variation of that pressure over time, on which the invention according to claim 1 of auxiliary request 1 was based, was known. There was no teaching in the prior art that adaptation of the alarm-threshold should take place as claimed. Therefore, starting from D8, the skilled person would not arrive at the claimed subject-matter in an obvious way. The same applied starting from D7 or D9.

It followed that the subject-matter of claim 1 of auxiliary request 1 was novel and involved an inventive step.

VIII. The arguments of opponents 1 and 2 may be summarised as follows:

Main request - clarity (Article 84 EPC)

Claim 1 of the main request lacked clarity. More particularly, it was not clear whether the "predetermined period of time" defined in the preamble and the "time interval" defined in the characterising portion meant the same parameter. If they did not, their relationship to each other was not derivable. Moreover, it was not clear which technical features of the claimed device could perform the method step defined in the characterising portion of the claim.

Auxiliary request 1 - clarity (Article 84 EPC)

Although clarity was not a ground for opposition, it remained that the subject-matter of claim 1 of auxiliary request 1 was not clear. In the claim several relative terms were employed, and method steps were defined, without specifying which technical features of the claimed device could perform them.

Auxiliary request 1 - novelty and inventive step (Articles 54 and 56 EPC)

Claim 1 of auxiliary request 1 did not prescribe that the time interval defined in the characterising portion had to be predetermined, i.e. should be known before the respective update of the alarm-threshold took place. Nothing in the claim excluded that the time interval could be determined after the update itself had taken place.

D8 disclosed a blood purification device comprising all

the features of claim 1 of auxiliary request 1. More particularly, it disclosed a device providing automatic adaptation of the alarm-threshold of the venous pressure during blood purification treatment. According to chapter 3.18, the venous pressure was measured for a period of 5 minutes. It was only if its average value during that period exceeded a certain limit that the alarm-threshold was updated. It followed that the minimum time between two updates was 5 minutes, but could be longer if the pressure change was moderate. This anticipated the characterising portion of the claim. Since D7 and D9 provided a similar disclosure, they too were novelty-destroying for the subject-matter of claim 1 of auxiliary request 1.

On the assumption that claim 1 of auxiliary request 1 was limited to a device that updated the alarm-threshold at time intervals that were adaptively set and determined before the respective updates took place, this presetting of the time intervals would be the only distinguishing feature over D8. The technical effect of such a distinguishing feature was to reliably reduce false alarm situations. However, the device of D8 also provided an adaptation of the alarm-threshold of the venous pressure during blood purification treatment which reliably reduced false alarm situations. In this respect, there was no evidence that the claimed invention was better or worse. It followed that the objective technical problem solved by the distinguishing feature could only be finding an alternative to the adaptation of D8.

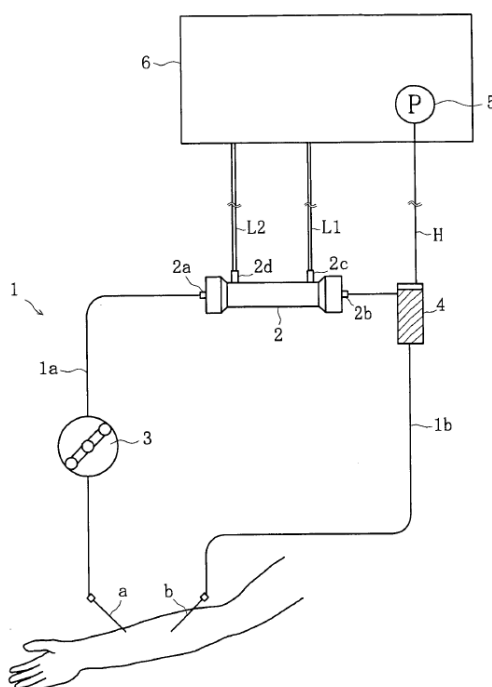
The general variation of venous pressure during blood purification treatment performed by the claimed device, as illustrated in figure 4 of the patent, was known. D8 provided for adaptation of the alarm-threshold

depending on pressure, i.e. the Y-axis in figure 4, whereas the subject-matter of claim 1 of auxiliary request 1 simply prescribed that the adaptation had to be dependent on time, i.e. the X-axis in figure 4. Ultimately, the result of both ways of adapting the alarm-threshold was the same. Changing from one way to the other was obvious for the skilled person.

Reasons for the Decision

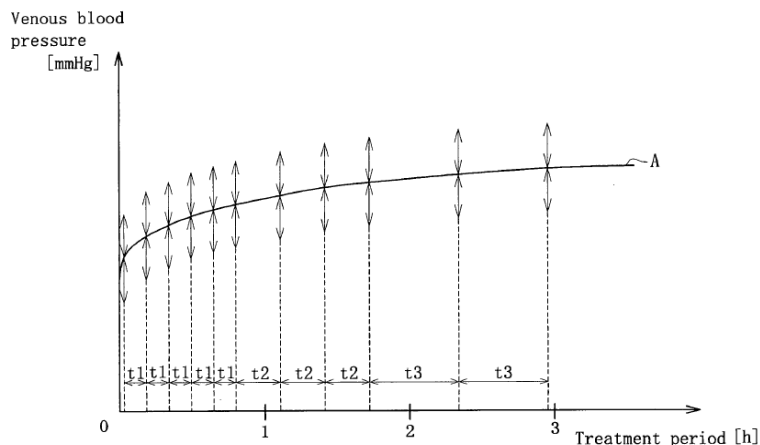
1. The proprietor's appeal is admissible.
2. The invention

The invention relates to a blood purification device, for example a dialysis system of the kind schematically depicted in figure 1 of the patent as reproduced below.



During blood purification treatment, the blood purification device according to the invention collects blood from a patient and conveys it, via an arterial blood circuit (1a), to a blood purification means (2) by means of a blood pump (3). In a dialysis system the blood purification means is a dialyser. From the blood purification means the blood is directed to a venous blood circuit (1b) and then back into the patient. The venous blood circuit is provided with a venous blood pressure measuring means (5), connected to a pressure monitoring means. The pressure monitoring means activates an alarm if the measured pressure lies outside a predetermined alarm-threshold range. During the treatment, the alarm-threshold is updated after determined time intervals. In claim 1 of auxiliary request 1 it is specified that the time interval "is set shorter when the pressure change is large than when the pressure change is moderate".

The normal venous blood pressure is expected to change at a varying speed during the treatment. According to the patent, the removal of water from blood during dialysis causes a continuous increase in venous blood pressure at a decreasing speed (paragraph [0032]), as shown in figure 4 reproduced below.



In view of this change, according to the patent, the claimed setting of the time intervals to update the alarm-threshold aims at avoiding false alarms and more accurately detecting abnormalities in the treatment (paragraph [0015]).

3. Main request - clarity (Article 84 EPC)

Claim 1 of the main request, in its preamble, defines a predetermined "period of time" at which the alarm-threshold is updated, whereas in the characterising portion a "time interval" to update the alarm-threshold, which is determined, is introduced.

Since two different denominations are used, two different time parameters may be meant in the claim. On this assumption the relationship between these two parameters is unclear. Specifying two predetermined (or determined) different times to update an alarm-threshold makes no sense if it is not defined how these times or their determination differ and when the one or the other is employed for the update.

Another interpretation may be that, although two different denominations are used, the predetermined "period of time" and the "time interval" to be determined designate the same parameter, since both relate to an update of the alarm-threshold. On this assumption it is not clear what the characterising portion of the claim is supposed to define. Specifying that a predetermined time is determined makes no technical sense if there is no explanation of how the determination is made.

The proprietor argued that, although both the "period

of time" and the "time interval" designated the time between two instants at which the alarm-threshold was updated, they had a clearly different meaning. More particularly, in view of the disclosure of the patent as a whole, the feature in the characterising portion had to introduce a further limitation, i.e. an adaptive adjustment of the time between those two instants.

The Board does not share this conclusion. More particularly, even in view of the description, no necessary link between the mere definition of a time interval which is determined and an adaptive adjustment of that time interval can be established, since the claim is totally silent about any criterion according to which the adaptation should be performed. Moreover, the Board notes that Article 84 EPC prescribes that the claims are to define in a clear way the matter for which protection is sought. Whether one particular interpretation could be arrived at exclusively with the help of the description is not the appropriate standard with which to assess compliance.

For these reasons it is concluded that the main request is not allowable for lack of compliance with Article 84 EPC.

It follows that other objections to the main request need not be considered by the Board.

4. Auxiliary request 1 - clarity (Article 84 EPC)

Claim 1 of auxiliary request 1 is the combination of claims 1 and 2 of the patent as granted.

The question of the extent to which amendments in opposition proceedings may be examined for compliance

with Article 84 EPC, considering that lack of clarity is not a ground for opposition and in view of previous jurisprudence of the boards of appeal, was dealt with by the Enlarged Board of Appeal in decision G 3/14, in which it was concluded that "in considering whether, for the purposes of Article 101(3) EPC, a patent as amended meets the requirements of the EPC, the claims of the patent may be examined for compliance with the requirements of Article 84 EPC only when, and then only to the extent that the amendment introduces non-compliance with Article 84 EPC" (Order).

In the present case, the subject-matter of claim 1 of auxiliary request 1 was already present as claim 2 of the patent as granted. It follows that it cannot, itself, introduce any non-compliance with Article 84 EPC that was not already present in the patent as granted.

Hence, in particular in view of G 3/14, the objection under Article 84 EPC raised by the opponents cannot be examined by the Board.

5. Auxiliary request 1 - novelty and inventive step (Articles 54 and 56 EPC)

5.1 In view of the different ways in which the parties construe the subject-matter of claim 1 of auxiliary request 1, the first issue to be considered by the Board is the interpretation of the claim.

The claim defines a predetermined "period of time" at which the venous blood pressure monitoring means updates the alarm-threshold, and a "time interval" to update the alarm-threshold, which is determined and then set in a certain way. Both these times relate to

the update of the alarm-threshold. Moreover, they are both defined as being predetermined: explicitly as regards the "period of time" and implicitly by specifying that the time interval is determined and then set, as far as the "time interval" is concerned. This leads to the conclusion that the "period of time" and the "time interval", despite the different denominations, designate the same predetermined time parameter, which has to be adaptively set based on the pressure change measured or predicted to be measured, during operation of the blood purification device. This interpretation is in accordance with the disclosure of the patent as a whole, in particular the embodiment described in paragraphs [0036] to [0039] with reference to figure 4. For example, paragraph [0037] reads:

"Venous blood pressure monitoring means 12 updates the alarm-threshold based on the pressure measured by venous blood pressure sensor 5 every predetermined time interval. The time interval is variable in accordance with variation of the pressure and the time interval when the variation is radical is set as shorter than the time interval when the variation is moderate."

It follows that the Board shares the proprietor's view that claim 1 of auxiliary request 1 prescribes, in particular, that the venous blood pressure monitoring means of the claimed device, in use, updates the alarm-threshold at time intervals which are adaptively set and determined before the respective updates take place.

5.2 The opponents' novelty objections based on D8 must fail in view of the above claim interpretation.

It is common ground that D8 discloses a blood

purification device comprising all the features of the preamble of claim 1. Moreover, D8 discloses that the device, in use, adaptively sets an alarm-threshold for the venous blood pressure depending on the average of the pressure actually measured over the previous five-minute period of time (chapter 3.18). If this average meets certain conditions, the alarm-threshold is updated; if not, no update is carried out. Hence, the time interval between two successive updates is not set and determined before the second update takes place, as required by claim 1 of auxiliary request 1, but is only known once this latter update has taken place.

For this reason, the subject-matter of claim 1 is novel over D8.

- 5.3 Presetting the time interval to update the alarm-threshold of the venous blood pressure, depending on the pressure change measured or predicted to be measured as claimed, clearly allows false alarm situations to be reliably reduced over a device which does not perform any adaptive update of that alarm-threshold. The Board agrees with the opponents that the way of adapting the alarm-threshold as disclosed in D8 provides a similar advantage, to a certain extent. Nevertheless, by presetting the time intervals depending on the specified changes in the pressure measured or predicted to be measured, with the device according to the invention as defined in claim 1 of auxiliary request 1 the venous blood pressure does not have to be continuously measured and its average continuously calculated when the change in pressure is (or is predicted to be) small. At the same time, closer monitoring of the pressure conditions when larger changes are measured, or predicted, is possible.

It follows that the problem solved by the distinguishing feature over D8 is not simply finding an alternative, but rather providing a more effective control of false alarms and patient conditions, as argued by the proprietor.

It is common ground that the general variation of the venous pressure during blood purification treatment over time, as illustrated in figure 4 of the patent, was known at the time the device of D8 was devised. Nevertheless, in D8 a different adaptation of the alarm-threshold is disclosed, and no teaching towards the specific adaptation as claimed is present. The Board therefore concludes that the skilled person, starting from D8, would not arrive at the subject-matter of claim 1 of auxiliary request 1 in an obvious way. The opponents' argument that adaptation of the alarm-threshold depending on either of the variables of the axes of figure 4 of the patent was equivalent and that changing from the one to the other was obvious is a mere allegation, based, in the Board's view, on an *ex post facto* analysis.

It follows that the subject-matter of claim 1 of auxiliary request 1 is inventive over D8.

- 5.4 D7 and D9 also concern blood purification devices of the kind defined in the preamble of claim 1 of auxiliary request 1 which, in use, adaptively update an alarm-threshold for the venous blood pressure. It is undisputed that their disclosure is similar to that of D8. In particular, they do not disclose that the time interval between two successive updates is set and determined before the second update takes place. They also provide no teaching towards the specific

adaptation claimed.

For the same reasons as explained in relation to D8, their disclosure does not deprive the subject-matter of claim 1 of auxiliary request 1 of either novelty or inventive step.

In these circumstances it is not necessary for the Board to establish whether they are comprised in the state of the art for the patent in suit, which was disputed by the proprietor.

5.5 In conclusion the subject-matter of claim 1 of auxiliary request 1 and, consequently, of its dependent claims 2 and 3 is novel and inventive according to Articles 54(1) and (2) and 56 EPC.

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 with the order to maintain the patent on the basis of:
 - claims 1 to 3 of auxiliary request 1 filed with letter dated 2 May 2013;
 - adapted description, columns 1 and 2 as filed during the first-instance oral proceedings on 10 October 2012, columns 3 and 4 as filed during the oral proceedings on 20 November 2017 and columns 5 to 10 of the patent as granted;
 - the figures of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated