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**Datasheet for the decision
of 21 February 2020**

Case Number: T 1191/15 - 3.2.02

Application Number: 10004110.2

Publication Number: 2377563

IPC: A61M1/16

Language of the proceedings: EN

Title of invention:

Dialysis apparatus

Patent Proprietor:

Gambro Lundia AB

Opponent:

Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:

EPC Art. 83, 123(3)

RPBA 2020 Art. 13(1)

Keyword:

Sufficiency of disclosure - (no)

Amendments - broadening of claim (yes)

Late-filed auxiliary requests - admitted (yes)

Decisions cited:

Catchword:



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Case Number: T 1191/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 21 February 2020

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
16 April 2015 concerning maintenance of the
European Patent No. 2377563 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. Both the patent proprietor (appellant I) and the opponent (appellant II) lodged an appeal against the interlocutory decision of the Opposition Division, dispatched on 16 April 2015, that, account being taken of the amendments according to the auxiliary request valid at that time, European patent No. EP 2 377 563 and the invention to which it related met the requirements of the EPC.

II. Oral proceedings took place on 21 February 2020.

Appellant I requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the following requests: the main request filed on 21 January 2020, the main request filed on 26 August 2015, the first auxiliary request filed on 21 January 2020, the first auxiliary request filed on 12 January 2016, the second auxiliary request filed on 21 January 2020, the second auxiliary request filed on 12 January 2016, the third auxiliary request filed on 21 January 2020 or the third auxiliary request filed on 12 January 2016.

Appellant II requested that the decision under appeal be set aside and that the patent be revoked.

Appellant II also requested that neither the first nor third auxiliary request filed on 12 January 2016 nor any of the requests filed on 21 January 2020 be admitted into the proceedings.

III. Claim 1 of the main request filed on 21 January 2020 reads as follows:

"Dialysis apparatus comprising:

- a blood treatment unit (5) comprising a dialysate chamber (13) and a blood chamber (12) separated by a semipermeable membrane (14);

- a dialysate circuit (32) comprising a supply line (2) and a discharge line (6) connected to said blood treatment unit (5), respectively, upstream and downstream of said dialysate chamber (13);

- a preparation device (33) for preparing a dialysate containing a substance, said substance being present in the blood too, said preparation device (33) comprising regulating means (38) for regulating the concentration of said substance in the dialysate, said preparation device (33) being connected to said supply line (2);

- a blood circuit (8) configured to circulate extracorporeal blood through said blood chamber (12);

- control means (19) for determining a value representative of the concentration of said substance in the blood in said blood circuit (8), characterized by comprising control means (19) programmed for driving said regulating means (38) as a function of the determined value representative of the substance concentration in the blood such that the substance concentration in the dialysate tends towards the substance concentration in the blood,

wherein said control means (19) is programmed for driving said regulating means such that the concentration of said substance in the dialysate tends towards:

- (i) the determined concentration of said substance in

the blood if the determined concentration of said substance in the blood is greater than a minimum threshold;

(ii) the minimum threshold if the determined concentration of said substance in the blood is less than the minimum threshold;

and/or wherein said control means (19) is programmed for driving said regulating means such that the concentration of said substance in the dialysate tends towards:

(i) the determined concentration of said substance in the blood if the determined concentration of said substance in the blood is less than a maximum threshold;

(iii) the maximum threshold if the determined concentration of said substance in the blood is greater than the maximum threshold."

IV. Claim 1 of the main request filed on 26 August 2015 differs from claim 1 of the main request filed on 21 January 2020 in that the last point of the list of features reads as follows (differences emphasised):

"- control means (19) for determining a value representative of the concentration of said substance in the blood in said blood circuit (8), characterized by comprising control means (19) programmed for driving said regulating means (38) as a function of the determined value representative of the substance concentration in the blood such that the substance concentration in the dialysate tends towards ~~the substance concentration in the blood,~~

~~wherein said control means (19) is programmed for driving said regulating means such that the concentration of said substance in the dialysate tends towards:~~

(i) the determined concentration of said substance in the blood if the determined concentration of said substance in the blood is greater than a minimum threshold;

(ii) the minimum threshold if the determined concentration of said substance in the blood is less than the minimum threshold;

and/or wherein said control means (19) is programmed for driving said regulating means (38) as a function of the determined value representative of the substance concentration in the blood such that the concentration of said substance in the dialysate tends towards:

(i) the determined concentration of said substance in the blood if the determined concentration of said substance in the blood is less than a maximum threshold;

(iii) the maximum threshold if the determined concentration of said substance in the blood is greater than the maximum threshold."

V. Claim 1 of auxiliary request 1 filed on 21 January 2020 and of auxiliary request 1 filed on 12 January 2016 differs from claim 1 of the respective main request filed on 21 January 2020 and the main request filed on filed on 26 August 2015 in that the "or" alternative in

the last point of the list of features has been deleted.

VI. Claim 1 of auxiliary request 2 filed on 21 January 2020 and of auxiliary request 2 filed on 12 January 2016 differs from claim 1 of the respective main request filed on 21 January 2020 and the main request filed on 26 August 2015 in that the control means comprises also the following features:

"- means (34, 35) for determining the conductivity of the dialysate upstream and downstream of said dialysate chamber (13);

- means for calculating the sodium concentration of the blood from at least two conductivity values determined respectively upstream and downstream of said blood treatment unit (5) in at least two successively prepared dialysates with different concentrations of sodium;"

VII. Claim 1 of auxiliary request 3 filed on 21 January 2020 and of auxiliary request 3 filed on 12 January 2016 is a combination of claim 1 of auxiliary request 1 and 2 filed respectively on 21 January 2020 and on 12 January 2016.

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

Admittance of requests

The submission of the requests filed on 21 January 2020 was a reaction to the preliminary opinion of the Board stating that the previous requests did not meet the requirements of Article 123(3) EPC. The amendments made did not raise any complex issue and did not shift the

discussion on novelty and inventive step.

The first and third auxiliary requests filed on 12 January 2016 were submitted with the reply to the opponent's appeal, hence at the earliest stage in the appeal proceedings.

Thus, all these requests should be admitted into the proceedings.

Main request filed on 21 January 2020 - sufficiency of disclosure

The control means comprised different program blocks. The first program block was programmed for driving the pump such that the concentration of a substance in the dialysate tended towards its concentration in the blood. In addition, a further program block was programmed for driving the pump such that the concentration of the substance in the dialysate tended towards its concentration in the blood if the concentration in the blood was greater than a minimum threshold and/or lower than a maximum threshold and towards the minimum or the maximum threshold if the concentration in the blood was less or greater than the minimum or maximum threshold. The skilled person had sufficient information from the patent as a whole to program these program blocks.

It was not mentioned in the claim that the concentration of the substance in the dialysate always tended towards its concentration in the blood.

Hence, the program included coexisting conditions and was not contradictory. The invention was therefore sufficiently disclosed.

*Main request filed on 26 August 2015 - Article 123(3)
EPC*

During the opposition procedure, claim 1 of the patent as granted was amended to delete the explicit requirement that the control means were programmed so that the substance concentration in the dialysate tended towards the concentration in the blood and to further include the features of granted claims 4 and 5. Hence, according to claim 1 of the main request filed on 26 August 2015 the control unit was additionally programmed to drive the regulating means according to the instructions following the if-statement. By this, claim 1 had been further limited since it now included the specific condition under which the control unit was configured to run the routine defined in the claim as granted.

The claim as granted was open as to the conditions under which the substance concentration in the blood should tend towards the substance concentration in the blood. This meant that the routine of claim 1 as granted did not have to be followed in each and every case. Claim 1 of the patent as granted did not include a limitation as to when the routine had to be followed.

Hence, claim 1 was not broadened by the introduction of the features of claims 4 and 5.

Auxiliary requests

The auxiliary requests filed on 21 January 2020 and 12 January 2016 satisfied the requirements of Articles 83 and 123(3) EPC for the same reasons as explained in connection with the respective main requests of

21 January 2020 and 26 August 2015.

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

Admittance of requests

The requests filed on 21 January 2020 did not constitute a reaction on the communication of the Board because the objection under Article 123(3) EPC was not overcome.

In claim 1 of the first and third auxiliary requests filed on 12 January 2016 the "and/or"-conjunction was replaced with "and". These claims were not presented in the opposition procedure and should therefore be considered as late filed.

Thus, these requests should not be admitted into the proceedings.

Main request filed on 21 January 2020 - sufficiency of disclosure

Claim 1 required that the substance concentration in the dialysate always tended towards the concentration in the blood. At the same time, claim 1 required that the substance concentration in the dialysate only tended towards the substance concentration in the blood if the concentration in the blood was above a minimum threshold and/or below a maximum threshold. Due to these two contradictory requirements the invention could not be carried out by the skilled person.

Main request filed on 26 August 2015 - Article 123(3) EPC

Claim 1 as granted included the feature that the control means was programmed for driving the regulating means such that the concentration of a substance in the dialysate tended towards the concentration of the substance in the blood. The skilled person would understand that only embodiments fulfilling this requirement fell under the scope of the patent.

However, claim 1 of the main request of 26 August 2015 did not comprise this feature any more. Hence, it also encompassed embodiments in which the concentration of a substance in the dialysate did not tend towards the concentration of the substance in the blood but to a minimum or maximum threshold.

The fact that the features concerning the if-statements were included in claims 4 and 5 as granted was irrelevant in that respect, since the teaching of these claims was contradictory to the teaching of claim 1 as granted. In other words, in the amended claim the algorithm of claim 1 as granted was replaced with a different algorithm, namely the algorithm of claims 4 and 5 of the patent as granted.

Thus, the patent was amended in such a way as to extend the protection it conferred.

Auxiliary requests

For the reasons set out above the auxiliary requests of 21 January 2020 and 12 January 2016 did also not comply with the requirements of Articles 83 and 123(3) EPC, respectively.

Reasons for the Decision

1. The invention according to claim 1 of the patent as granted relates to a dialysis apparatus comprising a blood treatment unit, a dialysate circuit connected to the dialysate chamber of the blood treatment unit and a blood circuit connected to the blood chamber of the blood treatment unit, and a dialysate preparation device connected to the dialysate circuit and comprising regulating means for regulating the concentration of a substance in the dialysate. The substance has to be a substance that is present in the blood, too, for instance sodium.

The apparatus further comprises control means for determining a value representative of the concentration of said substance in the blood in said blood circuit, and control means programmed for driving said regulating means as a function of the determined value representative of the substance concentration in the blood such that the substance concentration in the dialysate tends towards the substance concentration in the blood.

2. Admittance of the first and third auxiliary requests filed on 12 January 2016 and of the requests filed on 21 January 2020

- 2.1 The first and third auxiliary requests filed on 12 January 2016 were submitted with the appellant I's reply to the statement of grounds of appellant II. While the Board retains a discretion not to admit requests which could have been presented in the first-instance proceedings, under Article 12(4) RPBA 2007 (applicable under the provision of Art. 25(2) RPBA

2020), the boards have consistently applied this provision in the sense that only those requests which should have been filed in the first instance proceedings are not admitted. In the case before it, the Board does not consider that appellant I should have filed these requests in the opposition proceedings already and considers them to be a fair attempt to address the objections raised by appellant II in appeal. The Board thus admitted these requests into the appeal proceedings.

- 2.2 The requests filed on 21 January 2020 are amendments to the appellant I's case, the admission of which is at the Board's discretion under Article 13(1) RPBA 2020 and Article 13 RPBA 2007 (applicable under the provision of Article 25(3) RPBA 2020). The discretion is to be exercised in view of, inter alia, the complexity of new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

Compared with the corresponding previous requests, the only amendment in the modified requests was the introduction of the feature of claim 1 of the patent as granted that "the control means is programmed for driving the regulating means such that the concentration of a substance in the dialysate tends towards the concentration of the substance in the blood". By this amendment, appellant I addressed in a straightforward way the issue of non-compliance of claim 1 of the previous requests with Article 123(3) EPC, which was raised in the preliminary opinion of the Board. The Board therefore admitted these requests into the appeal proceedings.

3. Main request filed on 21 January 2020 - sufficiency of disclosure

Claim 1 of this request is based on a combination of claims 1, 4 and 5 of the patent as granted.

The Board does not concur with appellant I that the program block including the if-statement (originally defined in claims 4 and 5 as granted) is an additional program block as the claim wording does not suggest this. In the context of present claim 1, the instruction following the if-statement in claim 1 rather represents an alternative to the preceding instruction that the substance concentration in the dialysate should tend towards the substance concentration in the blood. Although the term "always" is not mentioned in the claim, the skilled person would understand that these instructions have to be followed in any case.

As pointed out by appellant II, the combination of claims 1, 4 and 5 as granted rather includes contradictory instructions as to how the substance concentration in the dialysate should be controlled in the case the concentration of the substance in the blood is below the minimum threshold or above the maximum threshold. In that case, the substance concentration in the dialysate should on the one hand tend towards the substance concentration in the blood and on the other hand to the respective threshold. Since the skilled person does not know which instruction is to be followed first, they cannot program the control means as defined in claim 1. Hence, the skilled person is not able to put the invention into practice, contrary to the requirements of Article

83 EPC.

4. Main request filed on 26 August 2015 - Article 123(3) EPC

Claim 1 of the main request filed on 26 August 2015 is not precisely based on a combination of granted claims 1, 4 and 5 since the statement of claim 1 of the patent as granted that the "control means is programmed for driving said regulating means as a function of the determined value representative of the substance concentration in the blood such that the substance concentration in the dialysate tends towards the substance concentration in the blood" has been deleted.

In other words, the controller in claim 1 of the patent as granted regulates the pump such that the substance concentration in the dialysate always tends to the substance concentration in the blood, whereas the controller of claim 1 of the main request filed on 26 August 2015 regulates the pump such that the substance concentration in the dialysate tends to the substance concentration in the blood only under certain conditions (i.e. only when the substance concentration in the dialysate is between the minimum and the maximum threshold).

Hence, the algorithm of claim 1 as granted has been replaced with a different, alternative algorithm in claim 1 of the main request. Now the scope of the claim encompasses embodiments that were not encompassed by claim 1 as granted, namely embodiments wherein the control means is programmed to regulate the substance concentration in the dialysate such that it tends to the minimum or maximum threshold. By this the claim has been amended in such a way as to extend the protection

conferred upon grant.

The Board does not share the appellant I's position that claim 1 of the patent as granted was "open" in the sense that the routine regulating the pump such that the substance concentration in the dialysate tended to the substance concentration in the blood did not have to be followed in each and every case. It cannot be derived from claim 1 as granted that this routine should be followed only under certain conditions.

Hence, the amendment made does not limit the scope of protection of claim 1 as granted but leads to an extension of the protection conferred, in contravention of the provisions of Article 123(3) EPC.

5. Auxiliary requests

Claim 1 of the first to third auxiliary requests filed on 21 January 2020 comprise the same contradictory instructions as claim 1 of the main request filed on the same day. Hence, for the reasons mentioned under point 3, none of these auxiliary requests is allowable.

Since claim 1 of the first to third auxiliary requests filed on 12 January 2016 also includes the amendment leading to the extension of protection discussed above in connection with the main request of 26 August 2015, none of these auxiliary requests is allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated