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Datasheet for the decision of 2 February 2016

Case Number: T 0336/11 - 3.2.02

Application Number: 00114654.7

Publication Number: 1175917

IPC: A61M1/34, A61M1/16

Language of the proceedings: EN

Title of invention:
Hemodialysis apparatus

Patent Proprietor:
Fresenius Medical Care Deutschland GmbH

Opponent:
Gambro Lundia AB

Headword:

Relevant legal provisions:
EPC Art. 123(2), 84, 83, 54, 56, 114(2), 128(4)
EPC R. 144(d)
RPBA Art. 13(1)

Keyword:
Admissibility of objections filed late due to representative's illness (yes)
Added subject-matter (no)
Sufficiency of disclosure and clarity (yes)
Novelty and inventive step (yes)

Decisions cited:

Catchword:

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Case Number: T 0336/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 2 February 2016

Appellant: (Patent Proprietor)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg v.d.H. (DE)
Representative:	Laufhütte, Dieter Lorenz Seidler Gossel Rechtsanwälte Patentanwälte Partnerschaft mbB Widenmayerstraße 23 80538 München (DE)
Appellant: (Opponent)	Gambro Lundia AB Magistratsvägen 16 22643 Lund (SE)
Representative:	Roberts, Mark Peter J A Kemp 14 South Square Gray's Inn London WC1R 5JJ (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 16 December 2010 concerning maintenance of the European Patent No. 1175917 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	M. Stern
	C. Körber

Summary of Facts and Submissions

I. Appeals were lodged by the patent proprietor and the opponent against the interlocutory decision of the Opposition Division, posted on 16 December 2010, concerning maintenance of the European Patent 1 175 917 in amended form. In the decision under appeal, the Opposition Division held that the main request did not satisfy the requirements of Article 123(2) EPC, whereas auxiliary request I did satisfy the requirements of the EPC, in particular those regarding added subject-matter and novelty.

II. The appellant/patent proprietor (hereinafter "the patent proprietor") filed a notice of appeal on 9 February 2011, paying the appeal fee the same day. A statement setting out the grounds of appeal was received on 21 April 2011. It requested that the patent be maintained on the basis of the same main request and auxiliary request I as those underlying the appealed decision or, alternatively, on that of a further auxiliary request II.

III. The appellant/opponent (hereinafter "the opponent") filed a notice of appeal on 14 February 2011, paying the appeal fee the same day. A statement setting out the grounds of appeal was received on 26 April 2011.

IV. The patent proprietor filed its reply to the statement of grounds of appeal by the opponent in due time on 19 September 2011.

V. The opponent filed its reply to the statement of grounds of appeal by the patent proprietor on 10 November 2011. The reply was signed by the representative then in charge, Mr Lejeune, who passed away shortly thereafter,

on 24 December 2011. In an ensuing letter dated 23 March 2012, the opponent's new representative, Mr Roberts, filed further submissions which were said to complete the opponent's previous reply prepared by Mr Lejeune at a time when the latter was already terminally ill.

VI. In a letter dated 29 June 2012, the patent proprietor requested that opponent's second reply dated 23 March 2012 be not admitted.

VII. Several further letters ensued in which the parties presented their arguments concerning the admissibility of the opponent's submissions and commented on the objections. Annexes attached to the opponent's letters dated 23 March 2012 and 19 September 2012, and the annex attached to the patent proprietor's letter dated 29 June 2012, were requested to be excluded from file inspection.

VIII. The following documents are relevant for the present decision:

D1: WO-A-01/32 238
D2: WO-A-01/76 661
D3: US-A-5 366 630
D7: L. Pedrini and V. De Cristofaro: "Hemofiltration with sumultaneous pre- and post-dilution (pre-post-HDF)", EDTA/ERA Congress Madrid, 1999.

IX. Oral proceedings were held on 2 February 2016.

The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or, in the alternative, of

one of auxiliary requests I and II, all filed with letter dated 21 April 2011.

The opponent requested that the decision under appeal be set aside and that the patent be revoked. During oral proceedings, the opponent withdrew its earlier request that the case be remitted to the Opposition Division for further prosecution if the main request was found to meet the requirements of Article 123(2) EPC.

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

"A hemodialysis and/or hemofiltration apparatus with an extracorporeal circuit (10) for receiving blood to be purified as well as with a hemodialyzer and/or hemofilter (20) communicating with the blood circuit (10), wherein upstream and downstream of the hemodialyzer and/or hemofilter (20) the blood circuit (10) has at least one supply line (12, 14), respectively, for supplying a substitution fluid, characterized in that
the apparatus further comprises measuring devices for recording the transmembrane pressure and/or hematocrit (HKT) and/or blood density, the measuring devices being connected to a control unit (100) for controlling one or several of the transmembrane pressure and/or hematocrit (HKT) and/or blood density, wherein the control unit (100) is designed such that the control is carried out by means (13, 15) of both of the infusion rates ($Q_s$pre, $Q_s$post) of the substitution fluid, wherein the infusion rate of the substitution fluid supplied upstream of the hemodialyser and/or the hemofilter is increased relative to the infusion rate supplied downstream of the hemodialyser and/or the hemofilter with increasing transmembrane pressure and/or increasing blood density and/or increasing hematocrit value of the blood."

XI. The arguments of the patent proprietor relevant for the present decision are summarised as follows:

- Admissibility of the objections raised with letter dated 23 March 2012

Whilst there were no objections concerning the admissibility of the opponent's reply dated 10 November 2011 (even though it had been filed after the time limit set), the additional reply dated 23 March 2012 should not be admitted into the appeal proceedings under Article 114(2) EPC. Several of the objections raised therein, in particular against the main request, had not been presented in the first-instance proceedings, such as objections under Articles 83, 84 and 56 EPC and the novelty objections based on D1 and D3. These objections considerably increased the complexity of the appeal. The opponent should have known as early as 2010 that Mr Lejeune was very ill. According to the declaration of Mr Terpin dated 25 February 2013 and filed on 28 February 2013 by the patent proprietor, Mr Lejeune had appeared to be in poor health during meetings held in May 2010. At least when the opponent finally realised in October 2011 that Mr Lejeune was severely ill, its duty of care required it to reassign his duties to other staff. According to established jurisprudence of the boards, in particular decisions T 1401/05, T 324/90, J 41/92 and T 525/91, large firms - like the opponent - were expected to have a functioning system of deputisation in case of illness.

The annex to the letter dated 29 June 2012 should be excluded from file inspection as it mainly concerned the medical condition and illness of Mr Lejeune.

- Regarding the requirements of Articles 123(2), 84, 83, 54 and 56 EPC, the arguments of the patent proprietor are essentially those on which the Reasons below are based.

XII. The arguments of the opponent relevant for the present decision are summarised as follows:

- *Admissibility of the objections raised with letter dated 23 March 2012*

Nobody in a position of authority at the opponent company had any knowledge of Mr Lejeune's terminal illness or reduced work capacity until early December 2011. This was convincingly shown by two declarations, one by Mr McIntyre dated 27 February 2013 and filed on 28 February 2013, the other by Mr Onshage dated and filed on 28 February 2013. This evidence was more probative than the proprietor's, which had no personal knowledge of any of the facts or events surrounding Mr Lejeune's illness. The decision to admit the second reply dated 23 March 2012 was a discretionary one under Article 114(2) EPC and Article 13(1) RPBA, rather than a decision based on the criterion of "all due care" under Article 122(1) EPC. Given the exceptional situation that the opponent's representative was fatally ill, the supplementary reply was admissible.

The three medical documents annexed to the letter dated 23 March 2012, and the annex to the letter dated 19 September 2012, should be excluded from file inspection as they were mainly concerned with the medical condition and illness of Mr Lejeune.

- *Article 123(2) EPC*

The parameter "blood density" was mentioned in the original application in method claims 2 and 3 and in paragraphs [0021] and [0022] only in the context of the method of the invention, but not in connection with the disclosed apparatus. In particular, there was no disclosure at all of an apparatus including blood density sensors. These were not necessary to carry out the method of the invention since blood density could be controlled by a human operator.

Original claims 9 and 10, as well as original paragraphs [0033] to [0035], gave a more detailed definition of the broadly defined "measuring devices for recording the hematocrit" and "measuring devices for recording the transmembrane pressure". Hence, these features in claim 1 constituted unallowable intermediate generalisations.

There was no disclosure of a machine that was programmed to autonomously increase the pre-dilution substitution fluid flow relative to post-dilution flow in response to measured increases in the transmembrane pressure, blood density or hematocrit. There was also no disclosure that "both" these infusion rates were varied by the control unit.

- *Articles 84 and 83 EPC*

Claim 1 did not clearly define which infusion rates were meant by "both" infusion rates, in particular since "the infusion rates" did not have a clearly defined antecedent. Moreover, the definition that the control of both infusion rates was such that the infusion rate of pre-dilution fluid was increased "relative to" the

infusion rate of post-dilution fluid did not clearly specify which one of a total of five conceivable possibilities of control was meant.

Not one example of such control was given in the patent, and it was therefore impossible to implement the invention without undue burden. There was also not a single example showing where in the blood circuit the blood density should be measured. It was not known how to change the substitution fluid flow in response to any particular change in blood density. No relationship was disclosed between the transmembrane pressure or the hematocrit value and the pre-dilution fluid flow.

- *Novelty*

D1 disclosed varying the amount of pre-dilution as a function of measuring the transmembrane pressure. In particular, D1 disclosed at lines 18 to 31 of page 12 that if the transmembrane pressure value increased, the post-dilution pump 8' was stopped while the pre-dilution pump 8 continued to operate. This corresponded to increasing the infusion rate supplied upstream of the hemofilter relative to that supplied downstream.

D2 disclosed calculating the transmembrane pressure and adjusting the amount of pre-dilution flow relative to post-dilution in accordance with the transmembrane pressure. It was clear to the skilled person that the pre-dilution and post-dilution flows were adjusted in a direction that would stabilise the transmembrane pressure, rather than making it unstable. Thus, the general idea of increasing the pre-dilution flow in response to an increase in transmembrane pressure was not novel over D2, when read with the common general knowledge of the skilled person.

D3 disclosed from lines 4 to 47 of column 5 the opening and closing of valves 17 and 19 in response to the transmembrane pressure. In particular, when the transmembrane pressure rose above TMP_1, pre-infusion was kept constant at zero whereas post-infusion was decreased from a certain value to zero. This corresponded to the claimed increase in pre-dilution relative to post-dilution, which encompassed the amount of pre-dilution being kept at zero and the amount of post-dilution being reduced.

- *Inventive step*

Document D7 was the closest prior art. It disclosed avoiding excessive transmembrane pressure and optimising the ratio of pre- and post-dilution. It was furthermore part of the skilled person's common general knowledge that a higher transmembrane pressure was an indication of the filter becoming clogged. Hence, the idea of increasing pre-dilution, in particular the ratio of pre- to post-dilution, in response to a higher transmembrane pressure was obvious.

Reasons for the Decision

1. The appeals are admissible.

2. Admissibility of the objections raised by the opponent on 23 March 2012

2.1 Whilst the patent proprietor had no admissibility objections to the opponent's reply dated 10 November 2011 (even though it had been filed after the time limit set), it requested the additional reply dated

23 March 2012 not to be admitted under Article 114(2) EPC. The content of the additional reply was said to go considerably further than just completing the first reply. In the additional reply the opponent presented for the first time objections under Articles 83, 84 and 56 EPC, and raised a novelty objection not just on the basis of D2, but for the first time also on that of D1 and D3. Several of these new objections had not even been presented in the first-instance proceedings. The new objections were said to considerably increase the complexity of the appeal.

2.2 It is an undisputed fact that the opponent's reply dated 10 November 2011 had been prepared by the former representative of the opponent, Mr Lejeune, shortly before his death on 24 December 2011, and at a time when he was already terminally ill. Mr Lejeune himself alluded in a second letter dated also 10 November 2011 to reasons of "force majeure" which had made it difficult for him to file the opponent's reply within the time limit set. He also indicated that he was absolutely opposed to these "strictly confidential" reasons being divulged to anyone (the EPO did not get to know these reasons either).

2.3 The patent proprietor considered, instead, that given Mr Lejeune's severe illness, the opponent's duty of care required it to reassign his duties to other staff within the company.

The opponent produced evidence showing that in fact nobody in a position of authority at the company knew that Mr Lejeune was terminally ill or that his ability to represent Gambro was impaired. Mr Lejeune was based in Meyzieu, France, and reported to Mr McIntyre, Chief Legal Counsel of the Gambro group, based in Denver,

Colorado. In a declaration, Mr McIntyre stated that the first time he knew about the terminal state of Mr Lejeune was in early December 2011, after he was admitted to hospital for what was to be the last time. Although he knew that during 2010 Mr Lejeune had been treated for some sort of illness, he did not know what the extent or seriousness of that illness was, or that it was hampering him in performing his duties.

In another declaration, Mr Onshage, Vice President of Intellectual Property of Gambro based in Lund, Sweden, who also reported to Mr McIntyre, stated that he first found out that Mr Lejeune had a terminal illness on 8 December 2011. Mr Lejeune had never told him that he had been signed off sick by his doctor or that he was ill. It was then in January 2012 that the present representative, Mr Roberts, was engaged to act as professional representative for the opponent on this case. A proper response to the patent proprietor's appeal was then filed on 23 March 2012.

2.4 In the Board's opinion, these declarations are convincing evidence that until just a few weeks before Mr Lejeune's death the opponent was unaware of his secretly kept terminal health condition preventing him from representing the opponent properly. Moreover, the described circumstances are considered by the Board to be sufficiently exceptional and serious to justify admitting the additional supplementary reply filed on 23 March 2012, only about three months after Mr Lejeune's hospitalisation and his death on 24 December 2012. The fact that Mr Terpin's declaration states that Mr Lejeune appeared to be in very poor health at meetings held in May 2010 does not mean that the opponent's duty of care required it to reassign his duties at that point in time.

The Board also dismisses the analogy drawn by the patent proprietor between the present case and several decisions concerning requests for re-establishment of rights under Article 122 EPC. These decisions relate to the scope and meaning of "all due care" in Article 122(1) EPC, whereas the present case is concerned with a request over which the Board has discretion under Article 114(2) EPC and Article 13(1) RPBA.

2.5 The patent proprietor is in principle right in observing that with its additional reply the opponent raised objections against the main request which had not been presented even in the first-instance proceedings, notably objections under Articles 83, 84 and 56 EPC as well as a new objection of lack of novelty (based on D3). However, the Board follows the view expressed by the opponent that these new objections were introduced into the appeal proceedings as a fall-back position if the Board did not confirm the decision by the Opposition Division not to allow the main request under Article 123(2) EPC. Furthermore, the Board considers that none of the new objections involves particular complexity and that their filing about four years before the oral proceedings certainly allowed the patent proprietor and the Board enough time to prepare the case.

2.6 In view of the exceptional circumstances indicated above, the Board, exercising its discretion under Article 13(1) RPBA, finds it justified to consider the submission dated 23 March 2012 as completing the opponent's reply to the statement of grounds of appeal of the patent proprietor - and thus as completing the opponent's case within the meaning of Article 12(2)

RPBA. Therefore, all the objections raised with this submission are admitted into the proceedings.

3. *Documents excluded from file inspection*

During the written appeal proceedings, both parties enclosed annexes to some of their letters which they requested to be excluded from file inspection pursuant to Article 128(4) and Rule 144(d) EPC. The annexes in question are three medical documents attached to the opponent's letter dated 23 March 2012, and the annex to the opponent's letter dated 19 September 2012, and the annex to the patent proprietor's letter dated 29 June 2012. The requests for excluding the annexes from file inspection were mainly motivated by the fact that they concerned the medical condition and illness of Mr Lejeune and were therefore considered to be prejudicial to the legitimate personal interests of a natural person. The Board agrees with the parties' view.

Hence, and in accordance with Article 1(2)(a) of the decision of the President of the EPO dated 12 July 2007 concerning documents excluded from file inspection (OJ EPO 2007, Special edition No. 3, 125), the Board decides to exclude the aforementioned annexes from file inspection.

4. *Article 123(2) EPC*

The Board considers that the apparatus defined in claim 1 of the main request is based on claims 7 and 8 in combination with paragraphs [0021], [0022] and [0038] of the application as originally filed. The reasons are the following.

4.1 The apparatus of original independent claim 7 relates, in essence, to an apparatus with an extracorporeal blood circuit with a hemodialyser and/or hemofilter having supply lines for supplying a substitution fluid upstream as well as downstream of the hemodialyser and/or hemofilter and a control unit for controlling one or several operational and/or blood parameters.

4.2 Original dependent claim 8 defines the apparatus as further comprising "measuring devices (that) are connected to the control unit for recording the operational and/or blood parameters". Original claim 8 does not specify what the "operational and/or blood parameters" are. However, paragraph [0021] of the original application mentions that, in the context of the invention, the "operational and/or blood parameters are the transmembrane pressure, the blood density and/or the hematocrit value". It is hence evident that these are the "operational and/or blood parameters" measured by the measuring devices of original claim 8.

The opponent argued that while the original disclosure explicitly disclosed measuring devices for recording the transmembrane pressure or the hematocrit value (for example in original claims 9 and 10, or in the embodiment of Figure 1), there was no disclosure of such measuring devices for recording the blood density. Although the method of original claims 1 and 2 included the control of blood density, this control could be achieved manually by a human operator, without any need for a measuring device for recording blood density.

It is true that the original application does not explicitly mention a blood density sensor delivering data to the control unit. However, the Board finds it contrived to interpret the original application in such

a way that control of the apparatus on the basis of blood density data could also be carried out manually by the operator, particularly since the control based on the other two parameters (transmembrane pressure and hematocrit) is specifically and solely disclosed as being carried out using sensors. Moreover, since the control mechanism is disclosed in paragraph [0022] in connection with all three control parameters on an entirely symmetric basis, and since it is undisputed that for two of them (the transmembrane pressure and the hematocrit) the control is performed using sensors, it is artificial to posit that for the third one, the blood density, the control should be any different, let alone manual. In addition, paragraph [0039] makes it clear that the invention's objective of keeping the blood purification of the hemodialyser or hemofilter constant is achieved by using both the claimed method and the claimed apparatus.

Hence, the claimed feature of "measuring devices for recording the blood density" is directly and unambiguously derivable from the original application.

4.3 As indicated above, original claim 8 defines that "measuring devices are connected to the control unit for recording the operational and/or blood parameters", whilst paragraph [0021] mentions that, in the context of the invention, the "operational and/or blood parameters" are "the trans-membrane pressure ... and/or the hematocrit value". The Board sees this as providing a direct and unambiguous basis for the definition of the features of claim 1 of "measuring devices for recording the transmembrane pressure" and "measuring devices for recording the hematocrit". It is hence irrelevant that these measuring devices are defined in more detail in original dependent claims 9 and 10, or in paragraphs

[0033] to [0035], as argued by the opponent in support of its assertion that the claimed features mentioned were unallowable intermediate generalisations.

4.4 Original claim 8 also defines the measuring devices as being connected to the control unit for recording the aforementioned parameters, whilst paragraph [0022] discloses that the control based on these parameters is such that "the infusion rate of the substitution fluid supplied upstream of the hemodialyser and/or the hemofilter is increased relative to the infusion rate supplied downstream of the hemodialyser and/or the hemofilter with increasing transmembrane pressure and/or increasing blood density and/or increasing hematocrit value of the blood", as defined in claim 1. Moreover, paragraph [0038] explicitly discloses that "both" these infusion rates are varied by the control unit.

4.5 The Board therefore concludes that the subject-matter of claim 1 of the main request complies with Article 123(2) EPC.

5. Articles 84 and 83 EPC

5.1 It is true that in the expression "both of the infusion rates" in claim 1 of the main request, "the infusion rates" lacks a defined antecedent. However, the definition given thereafter makes it clear that the two infusion rates referred to are that of the substitution solution supplied upstream (pre-dilution) and that of the substitution solution supplied downstream (post-dilution) of the hemodialyser and/or the hemofilter.

There is, moreover, no valid reason to argue that there is a lack of clarity because several control possibilities may be encompassed by the definition that

the control of both infusion rates is such that the infusion rate of pre-dilution is increased "relative to" the infusion rate of post-dilution fluid.

It follows that claim 1 of the main request complies with Article 84 EPC.

5.2 The opponent questioned sufficiency of disclosure on the grounds that the patent did not explain how the substitution fluid flow should be changed in response to any particular change in blood density, transmembrane pressure or hematocrit value, or where along the circuit the blood density should be measured.

The Board considers, however, that claim 1 already contains sufficient teaching to enable the skilled person to carry out the fluid control. It clearly states that the relation of pre- and post-dilution infusion rates should be increased upon detection of an increase in the transmembrane pressure, blood density or hematocrit values. Moreover, an example of this fluid control is provided in paragraph [0038] with reference to Figure 1 of the patent.

The positions of the transmembrane pressure and hematocrit sensors also are indicated in the fluid circuit of Figure 1. Although this figure does not show the positions of blood density sensors on the blood circuit, the skilled person relying on common general knowledge will be able to readily find suitable positions for these sensors, as it is known that blood density is correlated with hematocrit.

The Board consequently does not agree with the opponent's view that implementing the patent's overall

teaching would involve an undue burden. Thus, the requirements of Article 83 EPC are met.

6. Novelty

6.1 Document D1 concerns a blood treatment apparatus in which the fluid flow rate of the pre-dilution fluid (7') and the post-dilution fluid (7'') can be adapted as a function of the measured transmembrane pressure (page 5, line 31 to page 6, line 7; page 6, line 22 to page 7, line 12). In particular, D1 discloses on page 12, lines 18 to 31 that when the measured transmembrane pressure exceeds a certain limit, a blood filter cleaning procedure is to be carried out which consists in *stopping* the post-dilution pump 8' while the pre-dilution pump 8 circulates a physiological solution to clean the blood filter.

Since the post-dilution pump is stopped altogether, the downstream infusion rate is zero, i.e. there is simply no "infusion rate *supplied* downstream of the hemodialyser and/or the hemofilter" [emphasis added] as required by claim 1. Therefore the Board considers that this procedure of D1 does not fall under the terms of the claim.

As a consequence, the subject-matter of claim 1 of the main request is novel over D1.

6.2 D2 discloses an extracorporeal blood circuit in which a substitution liquid is infused either upstream or downstream of the blood filter. Based on the detected transmembrane pressure (TMP), either the pre-dilution pipe 25 or the post-dilution pipe 26 is opened (page 4, lines 5 to 13; page 12, lines 12 to 16) in a temporal sequence of intervals. The alternate, cyclical opening

and closing of the pre-dilution and post-dilution pipes implies that there is no control of *both* infusion rates "*supplied*" upstream and downstream, respectively, of the hemodialyser or the hemofilter, as defined in claim 1. D2 does not disclose either that the control is such that the upstream fluid *is increased* relative to the infusion rate supplied downstream with *increasing* transmembrane pressure.

Since D2 does not anticipate the claimed subject-matter, there is no need for the Board to decide on the validity of the priority date of D2, which was questioned by the patent proprietor.

6.3 D3 discloses an extracorporeal blood circuit in which pre- and post-dilution flow regimes may be varied according to the transmembrane pressure measured. In particular, in column 5, lines 10 to 20, clamps 17 and 18 are closed and clamp 19 is kept open. This corresponds to post-dilution infusion taking place (hemofiltration mode). When the transmembrane pressure rises above a certain value (TMP_1), as explained in column 5, lines 27 to 40, the control unit causes clamp 19 to close while clamp 17 is opened, with clamp 18 remaining closed (hemodiafiltration mode). Since in both regimes clamp 18 is kept closed, the pre-infusion rate is zero.

With no substitution fluid being supplied upstream, D3 fails to anticipate the claimed control in which "substitution fluid supplied upstream ... is increased relative to the infusion rate supplied downstream ...".

6.4 The Board therefore comes to the conclusion that the subject-matter of claim 1 of the main request is novel, thus fulfilling the requirements of Article 54 EPC.

7. *Inventive step*

7.1 Document D7 (which is cited on paragraph [0014] of the patent) was identified by the opponent as the closest prior art. D7 is a conference abstract reporting on effects of simultaneous pre- and post-dilution infusion. In the last paragraph, D7 presents the conclusion that to avoid excessively high transmembrane pressure, the ratio of pre- and post-dilution needs to be optimised.

7.2 In the light of this teaching, it appears reasonable to assume, as the opponent did, that an increasing transmembrane pressure would lead the skilled person to infer that the membrane filter was becoming clogged, and that to avoid such clogging it would be obvious to increase the pre-dilution.

7.3 However, D7 provides no teaching or suggestion regarding an automated apparatus which is controlled to prevent the clogging of the membrane filter. In particular, it would not be obvious for the skilled person (without any knowledge of the patent) to devise an apparatus which has measuring devices for recording the transmembrane pressure and a control unit acting on both the pre- and post-dilution infusion rates to increase the pre-dilution infusion rate relative to the post-dilution infusion rate upon detection of an increasing transmembrane pressure.

7.4 The Board therefore concludes that the subject-matter of claim 1 of the main request involves an inventive step within the meaning of Article 56 EPC.

8. Since the objections raised do not prejudice the maintenance of the patent on the basis of the main

request, there is no need for the Board to consider the auxiliary requests.

Order

For these reasons it is decided that:

1. The appeal of the opponent is dismissed.

2. The decision under appeal is set aside.

3. The case is remitted to the department of first instance with the order to maintain the patent on the basis of:

   - claims 1 to 5 of the main request filed with letter dated 21 April 2011;

   - adapted description, columns 1 to 7, filed during oral proceedings; and

   - figure 1 of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated