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Datasheet for the decision of 21 August 2018

Case Number: T 1118/13 - 3.2.02

Application Number: 05762877.8

Publication Number: 1898973

IPC: A61M1/34

Language of the proceedings: EN

Title of invention:
Apparatus for testing a filter

Patent Proprietor:
Gambro Lundia AB

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 123(2), 84, 54, 56
RPBA Art. 13(1)

Keyword:
Admissibility of modified claims (yes)
Added subject-matter (no)
Clarity (yes)
Novelty (yes)
Inventive step (yes)
Admissibility of a further objection (no)

Decisions cited:
T 0410/96, T 0096/12

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 1118/13 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 21 August 2018

Appellant: (Opponent)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
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Representative:	Ponzellini, Gianmarco PGA S.P.A., Milano Succursale di Lugano Viale Castagnola, 21c 6900 Lugano (CH)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 13 March 2013 concerning maintenance of the European Patent No. 1898973 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	M. Stern
	P. L. P. Weber

Summary of Facts and Submissions

I. The opponent lodged an appeal against the decision, posted on 13 March 2013, concerning the maintenance of European patent No. 1 898 973 in amended form.

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

D1: EP-A-0 763 367
D4: EP-A-0 407 737
D6: EP-A-1 300 167
D7: DE-T2-695 34 830
D8: Hämodialyse, Technik und Anwendung, Günther Meyer, Wolfgang Pabst Verlag, 1994, pages 34 and 35
D9: DE-C2-28 38 414.

III. Notice of appeal was filed on 13 May 2013, and the fee for appeal was paid the same day. A statement setting out the grounds of appeal was received on 11 July 2013.

IV. Summonses to attend oral proceedings were issued on 26 April 2018.

V. By letter dated 19 July 2018, the appellant expanded on its objections to the claims held allowable by the Opposition Division, introducing *inter alia* a new objection regarding lack of inventive step based on D6 as the closest prior art.

VI. By letter dated 20 July 2018, the respondent filed auxiliary requests for the event that the patent was not maintained with the claims held allowable by the Opposition Division.

VII. In its letter dated 10 August 2018, the appellant requested that the late-filed auxiliary requests not be admitted or the case remitted to the Opposition Division. As a precaution, objections to the auxiliary requests were submitted.

VIII. Oral proceedings were held on 21 August 2018.

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the "main request modified" filed during the oral proceedings. All other requests were withdrawn.

IX. Claim 1 of the "main request modified" reads as follows:

"1. An apparatus for testing a filter, comprising:

a source (2) of a fluid for an extracorporeal blood treatment;

a supply line connected to the source (2);

a blood treatment device (8) having a semipermeable membrane (9) which separates a fluid chamber (10) connected to the supply line from a blood chamber (11) connected to an extracorporeal blood circuit;

a drainage line which connects the fluid chamber (10) with a discharge (18) of a used treatment fluid;

a filter (4) having a semipermeable membrane (5) which separates a first chamber (6) from a second chamber (7), the first chamber (6) having at least a first fluid port (6a) connected to the supply line, the second chamber (7) having at least a second fluid port (7a) connected to the supply line;

means (17, 19) for generating a pressure gradient between the first chamber (6) and the second chamber (7);

means (Pl; P2) for monitoring the pressure in at least one of the first chamber (6) and of the second chamber (7);

a controller connected to the means for generating the pressure gradient and to the means for monitoring the pressure,

and being programmed to carry out a process for testing the filter (4) comprising the following steps of:

providing the filter (4) with the semipermeable membrane (5) wet;

generating the pressure gradient between the first chamber (6, 15) and the second chamber (7, 16);

monitoring the pressure in at least one of the first chamber (6, 15) and of the second chamber (7, 16);

characterized in that the means for generating a pressure gradient between the first chamber and the second chamber are means (19) for generating, in the first chamber (6), a pressure above atmospheric

pressure, and means (17) for generating, in the second chamber (7), a pressure below atmospheric pressure,

that the controller is connected to the means (19) for generating in the first chamber (6), the pressure above atmospheric pressure and to the means (17) for generating, in the second chamber (7), the pressure below atmospheric pressure,

and that the means for monitoring the pressure are means (Pl,P2) for monitoring the pressure in the first chamber (6) and in the second chamber (7)."

X. The parties referred to the following numbering of claimed features:

1.0 An apparatus for testing a filter, comprising:

...

1.7 means (17, 19) for generating a pressure gradient between the first chamber (6) and the second chamber (7);

1.8 means (P1; P2) for monitoring the pressure in at least one of the first chamber (6) and of the second chamber (7);

1.9 a controller connected to the means for generating the pressure gradient and to the means for monitoring the pressure, and being programmed to carry out a process for testing the filter (4) comprising the following steps of:

1.9.1 generating the pressure gradient between the first chamber (6, 15) and the second chamber (7, 16);

1.9.2 monitoring the pressure in at least one of the first chamber (6, 15) and of the second chamber (7, 16);

1.7.1 characterized in that the means for generating a pressure gradient between the first chamber and the second chamber are

1.10 means (19) for generating, in the first chamber (6), a pressure above atmospheric pressure, and

1.11 means (17) for generating, in the second chamber (7), a pressure below atmospheric pressure

1.8.1 and that the means for monitoring the pressure are means for monitoring the pressure in the first chamber and in the second chamber,

1.9.3 that the controller is connected to the means for generating in the first chamber the pressure above atmospheric pressure and

1.9.4 to the means for generating in the second chamber the pressure below atmospheric pressure.

XI. The arguments of the appellant which are relevant for the present decision may be summarised as follows:

- Admissibility of the "main request modified"

The "main request modified" had been filed at a very late stage – during the oral proceedings – but no fundamentally new aspects had been presented at the oral proceedings. The objection under Article 123(2) EPC, based on the omission in claim 1 of the former

main request of the step of providing a **wet** membrane, had been submitted as early as in the statement of grounds of appeal. Moreover, the request gave rise to new objections under Article 84 EPC. Therefore, the new request should not be admitted.

- Article 123(2) EPC

The use of the word "are" in feature 1.7.1, in lieu of "comprising" as in original claim 12, added subject-matter that extended beyond the content of the original application. According to original claim 12, it was sufficient that means for generating an underpressure in the second chamber and means for generating an overpressure in the first chamber were provided in order to generate a gradient. Likewise, there was no disclosure for the interpretation of features 1.9.3 and 1.9.4 as given in the impugned decision.

- Article 84 EPC

It was unclear in claim 1 how the controller could be programmed to carry out the step of providing the filter with the semipermeable membrane wet since the wetting could not be carried out by the controller.

When reading features 1.8, 1.8.1 and 1.9.2 in combination it was unclear whether in the first and second chambers there was just one or several pressures, and whether it was sufficient to just measure one of these pressures. In feature 1.8, the expression "means for monitoring the pressure in at least one of the first and of the second chamber" had no precedent, so that the use of the definite article was unclear.

Moreover, features 1.9.3 and 1.9.4 were not clear and concise since they seemed to repeat the definition of feature 1.9. They also lacked clarity because they defined the connection of the apparatus controller to other components without defining the purpose of this connection.

- Novelty

As to novelty, it was decisive to answer the question whether pumps 13 and 17 in Figure 1 of D6 and pumps 12 and 37 in Figure 2 of D6 were means for generating in the second chamber a pressure below atmospheric pressure. Any pump was suitable to generate a pressure below atmospheric pressure if it was controlled in a corresponding manner.

In the embodiment of Figure 1 of D6, pumps 13 and 17 were placed immediately downstream from the dialyser 1 and the second chamber 23 of dialysate filter 21. Hence, the pumps were effective in creating a depression not only on the dialyser 1, but also on said second chamber 23. The skilled person applying common general knowledge, as evidenced by D8 and D9, would know that, depending on the type of dialyser used, the depression for creating a pressure gradient in the blood circuit in the dialyser could well be an absolute depression, i.e. a pressure below atmospheric pressure. Consequently, normal ultrafiltration methods, particularly when using low-flux dialysers, would require a pressure below atmospheric pressure. This pressure would also be present further upstream, in the second chamber 23 of dialysate filter 21, since the connecting tubing 9b and valve 31 were devised with negligible flow resistance.

In the embodiment of Figure 2 of D6, pumps 12 and 37 provided alternative paths for pumping fluid out of the second chamber 23 of dialysate filter 21. Fluid was provided to the first chamber 22 of dialysate filter 21 by pump 26, which thereby recirculated the fluid through the recirculation circuit 25. From paragraph [0051] it was directly and unambiguously inferable that pumps 12 and 37, operating in combination with the recirculation pump 26, were suitable for generating a pressure below atmospheric pressure in the second chamber 23. This was possible by adjusting the reference pressure for the control of the recirculation pump 26, as disclosed in paragraph [0049].

- *Inventive step*

The apparatus of Figure 1 of D1 was disclosed as suitable for testing the integrity of dialysate filter membranes 17 and 36. The test was carried out by eliminating the fluid from the second chamber using pumps 23 and 25. These pumps were therefore suitable for generating a pressure below atmospheric pressure in each of the second chambers 15 and 37 when pumping out the fluid from drainage line 7 (Figure 1). Therefore, feature 1.11 was present in the apparatus of D1. Claim 1 differed from this known apparatus solely in that D1 did not explicitly mention a pressure sensor in the dialysate circuit which would then be suitable to measure the pressure in the second chamber of filter 16. However, in view of the teaching of the patent, there was no technical effect involved in providing this differentiating feature. In fact, feature 1.9.2 defined monitoring of the pressure, *inter alia*, in just one of the first and second chambers. A feature without any technical effect could not be considered in the formulation of the objective

technical problem. The technical problem could be seen as providing pressure-monitoring capability of the dialysate circuit. However, such a pressure monitor was well known to the skilled person from his common general knowledge, and he would consequently provide it without exercising inventiveness. The pressure sensor would necessarily be suitable too for measuring the pressure in the second chamber of the filter.

Alternatively, the agglomeration of features given by claim 1 was obvious from the combination of D1 and D4. D4 disclosed an integrity test of the dialyser membrane (column 8, line 22 to column 9, line 3), in which an overpressure was generated on one side of the dialyser membrane using an air pump, whilst an underpressure was generated by an underpressure pump on the other side of the dialyser membrane. The underpressure pump was controlled by pressure sensor 66 (column 8, lines 27 to 30). The test was performed on the dialyser membrane in an analogous way to the test on the dialysate membrane described in paragraphs [0058] to [0060] of the patent.

- Admissibility of a further objection

The further objection of lack of inventive step was based on D6 as the closest prior art in combination with the skilled person's common general knowledge. It did not go considerably further than what D6 disclosed. Instead of considering what was directly and unambiguously disclosed in D6, the objection concentrated on what the skilled person would have obviously inferred from D6. Therefore, the new objection introduced no further complexity into the case and should be admitted.

XII. The arguments of the respondent that are relevant for the present decision are essentially those on which the reasons set out below are based.

Reasons for the Decision

1. The appeal is admissible.

2. *The invention*

The invention relates to an apparatus for testing a filter by generating a transmembrane pressure across the dialysate filter membrane by creating an overpressure above atmospheric pressure on one side of the filter membrane and a depression below atmospheric pressure on the opposite side (paragraph [0016] and claim 1 of the patent).

3. *Admissibility of the "main request modified"*

3.1 Claim 1 of the "main request modified" is an amended claim which was filed during the oral proceedings after the Board had presented its opinion that the request held allowable by the Opposition Division (the former main request) did not satisfy the requirements of Article 123(2) EPC since the omission of the process step of providing the filter with a **wet** semipermeable membrane was unallowable.

3.2 The appellant requested the Board not to admit this new request, arguing that it had been filed at a very late stage in the proceedings, and yet no fundamentally new aspects had been presented at the oral proceedings. Moreover, the request gave rise to new objections under Article 84 EPC.

3.3 Under Article 12(2) RPBA, each party should present its complete case in the statement of grounds of appeal or the reply thereto. Thereafter, the admissibility of any amendment to a party's case is left to the Board's discretion in accordance with Article 13(1) RPBA. This discretion must be exercised in view of, *inter alia*, the complexity of the new subject-matter, the current state of the proceedings and the need for procedural economy.

3.4 On the one hand, the appellant is right to point out that it had presented its objection under Article 123(2) EPC based on the omission of the step of providing a **wet** membrane as early as in its statement of grounds of appeal. There was, moreover, no justification for the respondent's filing the amended request at such a very late stage rather than with its reply to the statement of grounds of appeal.

On the other hand, however, the amendment introduced to remedy the deficiency objected to was a mere slight change to the claim which involved no undue complexity which the appellant or the Board could not properly deal with at the oral proceedings. Moreover, the Board was unable to identify, *prima facie*, any lack of clarity arising from the amendment introduced, contrary to what the appellant argued. Furthermore, the amendment did not affect in any way the objections regarding novelty and inventive step, since the feature added to claim 1 was also disclosed in each of the documents cited. In other words, the respondent's late-filed request did not adversely affect the appellant by requiring a last-minute change to its case.

3.5 The Board consequently admitted the "main request modified", exercising its discretion under Article 13(1) RPBA.

4. *Article 123(2) EPC*

4.1 Claim 1 of the "main request modified" effectively remedies the objection that, in claim 1 of the request held allowable by the Opposition Division (former main request), the step of original claim 1 (to which original independent claim 11 refers) of providing the filter with a **wet** semipermeable membrane had been omitted. The appellant did not actually object under Article 123(2) EPC to the newly introduced features.

4.2 However, it did raise an objection to the definition that *"the means for generating a pressure gradient between the first chamber and the second chamber **are** means for generating, in the first chamber, a pressure above atmospheric pressure, and means for generating, in the second chamber, a pressure below atmospheric pressure"* [emphasis added by the Board] (features 1.7.1, 1.10 and 1.11; point X above).

These features are, however, present in original claim 12, albeit using the word "comprise" in lieu of the highlighted word "are".

Original claim 12 already indicates that the means for generating a pressure gradient between both chambers comprises both the means (19) for generating in the first chamber a pressure above atmospheric pressure and the means (17) for generating in the second chamber a pressure below atmospheric pressure. The pressure gradient between both chambers involves nothing more than the pressure difference between the two chambers.

Hence, the means for generating the pressure gradient between both chambers involves nothing more than the means for generating the pressure in the first chamber and the means for generating the pressure in the second chamber. This is what current claim 1 now recites, without adding any new subject-matter.

4.3 An objection to the definition of features 1.9.3 and 1.9.4 was raised too, i.e. to the expression "*the controller is connected to the means for generating in the first chamber the pressure above atmospheric pressure and to the means for generating in the second chamber the pressure below atmospheric pressure*".

In original independent claim 11, the controller was defined as being connected to the means for generating the pressure gradient between both chambers. In principle, it would be technically feasible that only one of the pressure-generating means was controlled by the apparatus controller, while the other pressure-generating means was set manually, for example. However, original paragraph [0070], in particular page 14, lines 4 to 15, discloses an example in which both a pump maintaining an overpressure in the first chamber and a pump maintaining a depression in the second chamber are controlled by a control unit. This example therefore lends support to claiming the controller as connected to both pressure-generating means.

4.4 It follows that claim 1 satisfies the requirements of Article 123(2) EPC.

5. *Article 84 EPC*

5.1 The appellant argued that in claim 1 it was unclear how the controller could be programmed to carry out the step of providing the filter with the semipermeable membrane wet, since wetting could not be carried out by the controller. In the Board's view, however, there seems to be no doubt that the controller may control, for example, the fluid pumps in such a way that the filter (4) is wetted, as disclosed in paragraph [0045] of the patent.

5.2 Contrary to the appellant's view, the Board finds that features 1.8.1 and 1.9.2 do not cause any ambiguity regarding the number of chambers in which the pressure is monitored. Feature 1.8.1 defines that the means for monitoring the pressure are means (suitable) for monitoring the pressure in the first chamber and in the second chamber. In feature 1.9.2, the controller is defined as being programmed to carry out the step of monitoring the pressure in at least one of the first and second chambers. There is hence no contradiction or ambiguity in defining that the monitoring means are suitable for measuring the pressure in both chambers, whilst the process involves the pressure monitoring step in only one of them.

The appellant also objected that, in feature 1.8, the expression *"means for monitoring the pressure in at least one of the first and of the second chamber"* had no precedent, so that the use of the definite article was unclear. Since the feature objected to follows the feature defining the means for generating a pressure gradient between these chambers (feature 1.7), the skilled person will understand that the pressure in at least one of these chambers monitored by the means for

monitoring is the pressure in the chambers created by the means for generating a pressure gradient.

5.3 The Board considers, moreover, that there is no contradiction in reciting in the preamble of claim 1 *"a controller connected to the means for generating the pressure gradient"* (feature 1.9) and then giving more detail on this connection in the characterising portion of the claim by defining it as a connection *"to the means for generating, in the first chamber, the pressure above atmospheric pressure and to the means for generating, in the second chamber, the pressure below atmospheric pressure"* (features 1.9.3 and 1.9.4). The skilled person will immediately recognise that, in accordance with common claim-drafting practice, feature 1.9 is defined in broader terms in the preamble of claim 1 and then in more detail in features 1.9.3 and 1.9.4 in the claim's characterising portion. The fact that the purpose of the connection of the controller to the pressure-generating means in both chambers is not explicitly defined in the claim is not in itself a reason for considering that the claim lacks clarity, as argued by the appellant. Moreover, the skilled person will immediately recognise that the connection of the apparatus controller to components of the apparatus is for the purpose of controlling those components.

5.4 The Board therefore concludes that claim 1 satisfies the clarity requirements of Article 84 EPC.

6. *Novelty*

6.1 The appellant raised novelty objections, referring to documents D6 and D7, the latter being the translation of the patent issued from D6. However, since D7 was

published on 19 October 2006 – and so after the international filing date, 1 July 2005, of the application of the patent in suit – it is not comprised in the state of the art under Article 54(2) EPC.

6.2 Document D6 discloses an apparatus for testing a dialysate filter 21 by generating transmembrane pressure across a semipermeable wet filter membrane 24 separating a first chamber 22 from a second chamber 23 connected to the supply line of a dialysate for extracorporeal blood treatment (paragraphs [0039] and [0045]).

6.3 It was disputed by the parties whether the apparatus of D6 anticipated the claimed "means for generating, in the second chamber, a pressure below atmospheric pressure" (feature 1.11; point X above).

6.4 Firstly, the parties disagreed on the meaning or interpretation of this definition. The respondent considered that "means for" the stated purpose or function should be understood, according to decisions T 410/96 and T 96/12, as being means specifically adapted for that purpose or function. The Board notes, however, that the "means plus function" considered in these decisions were construed in the context of data processing or a computer program – for example for the controller of blood processing apparatus in decision T 96/12 (by the present Board in a different composition; point 4 of the Reasons). It was in this context that it was held that an unprogrammed, or differently programmed, controller would be considered to be unsuitable for carrying out the specified functions.

In the present case, however, the claimed "means for generating, in the second chamber, a pressure below atmospheric pressure" are claimed as a separate and distinct feature from the claimed controller and refer to pressure-generating means, such as pump 17 (paragraph [0070], first sentence), claimed for generating a pressure within a certain pressure range in the second chamber, namely below atmospheric pressure. As indicated in the example of paragraph [0070], the control unit controls the pump 17 so as to keep the pressure under atmospheric pressure. Hence, the pump alone is suitable for achieving this purpose. This interpretation is in accordance with the long-standing EPO practice that a formulation such as "apparatus for" is to be interpreted as meaning an apparatus which is *suitable for* the stated use. Accordingly, any prior art apparatus which is disclosed as comprising the claimed structural features, and can thus reasonably be used for the stated purpose, will then take away the novelty of the claimed apparatus. This is irrespective of whether or not the prior art mentions the stated use or purpose or whether the stated use is obvious or not (Case Law of the Boards of Appeal, 8th edition 2016, I.C.8.1.5).

The Board therefore construes the claimed "means for generating, in the second chamber, a pressure below atmospheric pressure" (feature 1.11) as means *suitable for* generating, in the second chamber, a pressure below atmospheric pressure.

6.5 In the embodiment of Figure 1 of D6, pumps 13 and 17 are operative downstream from the dialyser 1, while pump 12 is operative upstream from the dialyser 1 and the first chamber 22 of dialysate filter 21 which filters the dialysate. Although a certain depression is

created by the ultrafiltration system (pump 17) downstream from the dialyser and within the dialysate chamber 3 of the dialyser, this depression remains confined to the dialyser and does not necessarily extend to the second chamber 23 of dialysate filter 21. Rather, the dialyser is well known to be formed by thousands of very narrow hollow fibers such that dialysate flow needs to be pushed in order to flow through the dialysate compartment interstices. Thus, in order for dialysate coming from dialysate filter 21 to flow through and against the resistance of the dialyser interstices, pump 12 has to create an overpressure region in line 9b. Consequently, there is no depression created in the second chamber 23.

6.6 The appellant argued that the skilled person applying common general knowledge, as evidenced by D8 and D9, would know that, depending on the type of dialyser used in Figure 1 of D6, the depression for creating a pressure gradient in the blood circuit in the dialyser could well be an absolute depression, i.e. a pressure below atmospheric pressure. Consequently, normal ultrafiltration methods, particularly when using low-flux dialysers, would require a pressure below atmospheric pressure. This pressure would also be present further upstream, in the second chamber 23 of dialysate filter 21, since the connecting tubing 9b and valve 31 were devised with negligible flow resistance.

In the Board's view, however, since D6 does not directly and unambiguously disclose further constructional details related to the dialyser or the elements connecting it to the dialysate filter, the suitability of pump 17 for generating, in the second chamber 23, a pressure below atmospheric pressure is not clearly established.

6.7 For the embodiment shown in Figure 2, D6 discusses the pressure which is applied to a second dialysate filter 33, placed downstream from dialysate filter 21. Paragraphs [0049] and [0051] explain that the pressure in chamber 35 of the second filter is positive or at most zero relative to atmospheric pressure. Having a positive or zero pressure in chamber 35 implies that there needs to be an even more positive pressure in the first chamber 34 (to overcome the pressure drop across the second semipermeable membrane 36), and thus in the second chamber 23 of dialysate filter 21. It cannot be directly and unambiguously inferred from D6 that either of pumps 12 or 37 would be suitable for generating, in the second chamber 23, a pressure below atmospheric pressure, as argued by the appellant.

6.8 The Board therefore concludes that the embodiments of Figures 1 and 2 do not comprise "means for generating, in the second chamber, a pressure below atmospheric pressure" (feature 1.11).

6.9 As a consequence, the subject-matter of claim 1 is novel with regard to document D6 within the meaning of Article 54 EPC.

7. *Inventive step*

7.1 Document D1, which is considered to be the closest prior art, discloses an extracorporeal blood treatment device and a method for testing the integrity of the dialysate filters of that device (column 6, line 28, to column 7, line 29). For the test, air is pumped by air pump 42 into the dialysate system, in particular into chamber 18 (corresponding to the "first chamber" of the claim) of filter 16, whereby the pressure build-up

expels dialysate through the filter membrane 17 into chamber 15 (corresponding to the "second chamber" of the claim). Simultaneously, air is pumped into chamber 34 of the second filter 35 too. The dialysate flows from the second chambers 15 and 37 into drainage line 7 (column 7, lines 9 to 16). Once a certain overpressure in the first chambers (18 and 34) has been reached, air pump 42 is switched off. Pressure sensor 54 monitors the pressure drop in the first chambers (18 and 34) within a predetermined time period in order to check the integrity of filter membranes 17 and 36 (column 7, lines 20 to 23). No pressure-monitoring means are disclosed for monitoring the pressure in the second chamber (15 or 37). Consequently, the means for monitoring the pressure as "means for monitoring the pressure in the first chamber *and in the second chamber*", as claimed in feature 1.8.1 (point X above), are not present in the device of D1. This has not been disputed.

7.2 There is, moreover, no explicit disclosure in D1 that the pressure in the second chambers (15 and 37) is below atmospheric pressure. The appellant argued that the ultrafiltration pump 25 was suitable for generating such an underpressure below atmospheric pressure when pumping out the fluid from the drainage line 7 (Figure 1). Therefore, according to the appellant, feature 1.11 is present in D1.

The Board notes, however, that the ultrafiltration pump 25 is clearly not used during the integrity test phase. Moreover, not even during dialysis treatment is this pump, or pump 23, disclosed to generate a pressure under atmospheric pressure in the dialysate filters, since, if this was the case, fluid degassing and bubble generation in the dialysis circuit would negatively

affect the fluid balance and air bubbles could remain trapped in the dialyser, thereby reducing filtration efficiency. Hence, the "means for generating, in the second chamber, a pressure below atmospheric pressure" claimed in feature 1.11 and a controller being connected "to the means for generating in the second chamber the pressure below atmospheric pressure", as claimed in feature 1.9.4, are further differentiating features of the apparatus of claim 1.

7.3 In view of the latter differentiating features, the objective technical problem to be solved by the apparatus of claim 1 consists in providing an alternative reliable integrity test for the dialysate filter membranes.

7.4 D1 indicates that prior-art membrane testing methods used a pressure depression below atmospheric pressure in a filter chamber (column 1, line 43 to column 2, line 15). Whilst D1 recognises the basic usefulness of such tests, a different approach underlies its invention which avoids such a depression below atmospheric pressure and uses overpressure in a filter chamber instead (column 2, lines 10 to 15 and 28 to 43). In particular, D1 describes that the generation of an overpressure, typically of up to 4 bars, is particularly advantageous in that it allows the detection of smaller membrane leakages (it increases the sensitivity by 3 to 4 times over a test with underpressure) and in that it may be built up faster than the generation of a vacuum (column 2, line 54, to column 3, line 20).

Consequently, the person skilled in the art, departing from the invention proposed in D1, would not take a

step backwards by retaining, at least partially, features on which D1 has set out to improve.

The apparatus of claim 1 is consequently not rendered obvious to the skilled person by the teaching of document D1 itself.

7.5 The combination of the teachings of D1 and D4 does not render the claimed apparatus obvious either for the following reasons.

D1 discloses (column 7, lines 37 to 39) that the testing method is applicable for testing the membrane not only of a dialysate filter, but of a dialyser too. Hence, the skilled person, departing from the apparatus of D1 and looking for an alternative reliable integrity test for dialysate filter membranes, may consider the teaching of document D4 as it discloses an integrity test of the dialyser membrane (column 3, lines 2 to 6). In the test disclosed in column 8, line 22, to column 9, line 3 of D4, an overpressure is generated in chamber 18 on one side of the dialyser membrane 14 using an air pump 138, whilst an underpressure is generated by pump 70 in the fluid-filled chamber 16 on the other side of the dialyser membrane. The underpressure pump 70 is controlled by means of the pressure sensor 66 (column 8, lines 27 to 30). The test in D4 is performed on the dialyser membrane in an analogous way to the test on the dialysate membrane described in paragraphs [0058] to [0060] of the patent.

However, there is firstly no convincing reason for the skilled person to consider implementing the testing method of D4 in the device of D1 since the method of D4 has the same disadvantage of working with underpressure, which, as indicated above, D1

specifically sets out to avoid. Moreover, it would not be evident for the skilled person how to modify the dialysate filter testing apparatus of D1 in the light of the teaching of D4, which concerns a dialyser filter testing apparatus. Since the tests described in these documents are applied to different components - dialysate filters in D1, dialyser filter in D4 - the corresponding circuits according to D1 and D4 are not compatible.

The apparatus of claim 1 is consequently not rendered obvious by combining the teachings of D1 and D4.

7.6 Consequently, the Board considers that the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC.

8. *Admissibility of a further objection*

8.1 The appellant introduced, about one month before the oral proceedings, a new objection regarding lack of inventive step, based on document D6 as the closest prior art.

8.2 This is consequently an amendment to the appellant's case as presented in its statement of grounds of appeal, and as such its admissibility is left to the Board's discretion under Article 13(1) RPBA, as was indicated above under point 3.3.

8.3 The new objection of lack of inventive step was based on D6 as the closest prior art in combination with the skilled person's common general knowledge. The appellant argued that it did not go considerably further than what D6 disclosed, which had been considered for assessing novelty. Rather than

considering what was directly and unambiguously disclosed in D6, the newly introduced objection concentrated on what the skilled person would have obviously inferred from D6. The new objection therefore introduced no additional complexity into the case.

8.4 Whilst the appellant may be right on this particular point, no justification was given for filing this new objection at such a very late stage of the proceedings, rather than with the statement of grounds of appeal. Moreover, the new objection may require the respondent to formulate new auxiliary requests during the oral proceedings, and these, in turn, may require the appellant to introduce further objections based on further documents. Such a development in the proceedings is plausible and realistic considering that the respondent had pre-emptively already filed auxiliary requests about one month before the oral proceedings to which the appellant responded about ten days before the oral proceedings, raising entirely new objections based on new documents. Such issues could not reasonably be expected to be dealt with without adjournment of the oral proceedings or remittal of the case to the Opposition Division.

8.5 The Board therefore considers that, in view of the current state of the proceedings and the need for procedural economy, the new objection is not admitted into the proceedings pursuant to Article 13(1) RPBA.

9. In summary, none of the aforementioned objections prejudices the maintenance of the patent on the basis of the "main request modified".

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 5 of the "main request modified" filed during oral proceedings;

   - description: pages 2, 3 and 5 to 9 of the patent as granted and page 4 filed during oral proceedings; and

   - figure pages 1/8 to 8/8 of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated