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Datasheet for the decision of 5 September 2019

Case Number: T 2169/14 - 3.2.02

Application Number: 10170545.7

Publication Number: 2281591

IPC: A61M1/16

Language of the proceedings: EN

Title of invention:
Wearable artificial kidney with regeneration system

Patent Proprietor:
Bellco S.r.l.

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 83, 54, 56

Keyword:
Novelty - main request (no); first auxiliary request (yes)
Inventive step - first auxiliary request (yes)
Sufficiency of disclosure - first auxiliary request (yes)

Decisions cited:
T 2196/14

Catchword:

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Case Number: T 2169/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 5 September 2019

Appellant: (Patent Proprietor)	Bellco S.r.l. Via Camurana 1 Mirandola (IT)
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Appellant: (Opponent)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Nordmeyer, Philipp Werner df-mp Dörries Frank-Molnia & Pohlman Patentanwälte Rechtsanwälte PartG mbB Theatinerstraße 16 80333 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 18 September 2014 concerning maintenance of the European Patent No. 2281591 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	M. Stern
	S. Böttcher

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 18 September 2014 concerning the maintenance of European patent No. 2 281 591 in amended form.

II. The appellant/patent proprietor (hereinafter "the patent proprietor") filed notice of appeal on 21 November 2014, paying the appeal fee the same day. A statement setting out the grounds of appeal was received on 28 January 2015.

III. The appellant/opponent (hereinafter "the opponent") filed notice of appeal on 18 November 2014, paying the appeal fee the same day. A statement setting out the grounds of appeal was received on 28 January 2015.

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

D1: WO-A-2010/144189
D2: US-A-3 669 880
D5: WO-A-2005/044339
D7: US-A-2003/0098270
D18: R.W. Baker, "Membrane Technology and Applications", 2nd Edition, 2004, pages 275 to 300

V. Oral proceedings were held on 5 September 2019, simultaneously with the oral proceedings in the similar case underlying decision T 2196/14.

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

of the first to twelfth auxiliary requests filed with letter dated 2 August 2019.

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

VI. Independent claims 1 and 2 of the **main request** (patent as granted) read as follows:

"1. A dialysis circuit (1; 11) of a wearable artificial kidney comprising a dialysis filter (2), an inlet line (5) to feed a dialysis solution into said filter (2), an outlet line (6) to remove the dialysis solution from said filter (2) connected to said inlet line (5), an arterial line (3) which is responsible for transporting blood from a patient (P) to the filter (2), a venous line (4) which is responsible for transporting blood from the filter (2) to the patient (P), a plurality of pumps (3a, 5a, 6a) adapted for circulation both of the blood and of the dialysis solution and a purification unit (7) adapted to perform filtration of the dialysis solution coming from said outlet line (6) and directed toward said inlet line (5); said dialysis circuit being characterized in that said purification unit (7) comprises a filtration device (8) included in the group composed of a nanofiltration filtration device or a microfiltration filtration device, and adsorption means (14; 34) arranged downstream of said filtration device (13; 33) and adapted to retain the molecules not stopped by said filtration device (13; 33)."

"2. A haemofiltration circuit (21; 31) of a wearable artificial kidney comprising a haemofilter (22), an arterial line (23) which is responsible for transporting blood from a patient (P) to the

haemofilter (22), a venous line (24) which is responsible for transporting blood from the haemofilter (2) to the patient (P), an ultrafiltrate line (25) extending from the haemofilter, a reinfusion line (26) adapted to reinfuse purified plasma water into said arterial line (23) and/or into said venous line (24) and connected to said ultrafiltrate line (25), a plurality of pumps (23a, 25a) adapted for circulation both of blood and of plasma water and a purification unit (27) adapted to perform filtration of the plasma water coming from said ultraflftrate line (25) and directed toward said reinfusion line (26); said haemofiltration circuit being characterized in that said purification unit (27) comprises a filtration device (28) included in the group composed of a nanofiltration filtration device or a microfiltration filtration device, and adsorption means (14; 34) arranged downstream of said filtration device (13; 33) and adapted to retain the molecules not stopped by said filtration device (13; 33)."

VII. Claim 1 of the **first auxiliary request** corresponds to claim 1 of the main request adding the following feature at the end of the claim:

> "...; the plurality of pumps (3a, 5a, 6a) comprise a first pump (3a) attached to the arterial line (3) to guarantee movement of blood and a pair of pumps (5a, 6a) attached respectively to the inlet line (5) and to the outlet line (6) of the dialysis solution."

Independent claim 2 of the **first auxiliary request** corresponds to independent claim 2 of the main request adding the following feature at the end of the claim:

"...; the purification unit comprising a device (26a) for elimination of plasma water and for checking the patient's weight reduction."

Claim 3 is a dependent claim.

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

Main request

The subject-matter of claims 1 and 2 of the main request was novel. D1 did not disclose all features of claims 1 and 2 in a single embodiment, so that to compose all the features of claims 1 and 2 it was necessary to pick up different elements from different embodiments and/or lists of different alternatives concerning, for instance, the type of filtration membrane or the kind of treatment as illustrated in Figures 3A to 3D. A document should not be treated as something in the nature of a reservoir from which features pertaining to separate embodiments may be drawn to artificially create a particular embodiment. Consequently, D1 did not provide a clear and unmistakable teaching of the specific combination of features of the claimed subject-matter, as required by several decisions cited in support of this requirement.

First Auxiliary request

The arguments raised against the first auxiliary request which are relevant for the present decision are those on which the reasons set out below are based.

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

Main request

The subject-matter of claims 1 and 2 of the main request lacked novelty over document D1. The arguments are essentially those on which the reasons set out below are based.

First Auxiliary request

- *Sufficiency of disclosure*

The claims require the adsorption means to be adapted to retain *the* molecules which are not stopped by the filtration device. This definition meant that *all* molecules which were not stopped by the filter were stopped by the adsorption means, for example also water molecules, so that no fluid flow at all would result downstream of the purification unit. This meant that no fluid flow at all would be present. This constituted, however, a non-functional embodiment. The claims were not discussed and enabled over their whole width and should therefore be limited to the workable embodiments disclosed in the patent, for example in paragraphs [0025] and [0035].

- *Novelty*

The subject-matter of claim 1 lacked novelty over D1. Paragraph [0045] of D1 disclosed that dialysis fluid from dialyser 202 was sent to dialysis treatment device 100 for treatment/urea removal, and the treated fluid was then returned to dialyser 202. This anticipated the two claimed pumps attached, respectively, to the inlet line and to the outlet line of the dialysis solution. Paragraph [0045] disclosed

moreover the claimed blood pump attached to the arterial line.

D1 anticipated, moreover, the subject-matter of claim 2. Paragraph [0046] of D1 disclosed that replacement fluid was pumped into the blood of the patient and that a net volume of fluid was taken out of the patient as ultrafiltrate to remove excess water that the patient had accumulated between treatments. It was hence implicit that, in order to carry out the haemofiltration treatment safely, the amount of liquid supplied to and extracted from the patient were monitored. This had to be done by monitoring the patient's weight reduction.

D5 destroyed the novelty of the subject-matter of claims 1 and 2. Figure 9 showed a sorbent-based regeneration system 610 with a number of filtration devices and an adsorption means. In particular, filters 626 and 630 were disclosed to be microfilters, and cartridge 222 was disclosed to have the multilayer arrangement of D2. It comprised layers 25, 26, 27 as adsorption means arranged downstream of filter cloth 24. Since both filters 24 and 28 were depicted in Figure 2 with the same hatching, it was clear that both were the same filters. Filter cloth 28 had pores small enough to retain zirconium phosphate particles in the form of fine granules. D7 disclosed that fine granules of zirconium phosphate had sizes in the micrometer range between about 20 and about 100 micrometres (paragraph [0029]). It was moreover known to the skilled person that fine particles which could be as fine as dust were in the micrometer range. This range could not be precisely defined. The range of sizes up to 10 microns disclosed in D18 gave merely a rough idea of the orders of magnitude covered by the expression

"microfilter". Therefore filter cloth 24 had to be considered as a microfilter.

- *Inventive step*

The subject-matter of claim 1 lacked an inventive step when starting from D5, or alternatively from D2, as the closest prior art, for the following reasons.

D5 as the closest prior art disclosed or at least suggested to devise sorbent cartridge 222 of D5 following the disclosure of D2. The objective technical problem consisted in providing an improved dialysate regeneration system. Faced with this problem, the skilled person would have improved the filtering characteristics of filter cloths 24 and 28 of D2 in cartridge 222 in D5 by providing a filter cloth with pore sizes which ensure that all particles were retained between the filter cloths. In other words, the skilled person would have provided filter cloth 24 as a microfilter in order to achieve this result.

Moreover, the arrangement of Figure 9 of D5 (comprising comprising adsorption means in form of cartridge 222 and, downstream therefrom, microfilter 626) would have the same effect as if these elements were in the opposite arrangement with respect to the flow of spent dialysis fluid. It was of no relevance whether the adsorber was placed upstream or downstream of the filter because it would adsorb only the specific molecules for which it was designed and would not adsorb the other molecules stopped by the filter for which it was not designed. As there was no technical effect attributed to the specific arrangement claimed, the objective technical problem was to provide an alternative arrangement to the one shown in Figure 9 of

D5. As there were only two possible arrangements with respect to the order of the adsorption means and the microfilter, that is, arranging the adsorption means either upstream or downstream of the microfilter, it would have been obvious to the skilled person to choose any of these.

The claimed subject-matter differed from D2 only in that a pair of pumps was attached, respectively, to the inlet line and to the outlet line of the dialysis solution. D2 only had a gear pump 12 in the outlet line 10. However, the provision of a second pump in the inlet line had no technical effect and was not something that could involve an inventive step. Moreover, using a second pump in the regeneration circuit, or an even greater number of pumps, was known from D5 to help improve the flow through the circuit.

Reasons for the Decision

1. The appeals are admissible.

2. The invention

Claim 1 relates to a dialysis circuit (11) (depicted in Figure 2) comprising, in essence, a dialysis filter (2), an inlet line (5) to feed a dialysis solution into the dialysis filter, an outlet line (6) to remove the dialysis solution form said dialysis filter, and a purification unit (12) adapted to perform filtration of the dialysis solution, the purification unit comprising a microfiltration or nanofiltration device (13) and, downstream therefrom, adsorption means (14) adapted to retain molecules not stopped by the microfiltration or nanofiltration device (13). As

explained in paragraph [0025] of the patent, the adsorption device is useful for removing toxins not stopped by the microfiltration or nanofiltration device.

Independent claim 2 relates to a haemofiltration circuit (31) (depicted in Figure 4) comprising, in essence, a reinfusion line (26) to reinfuse purified plasma water into the arterial line (23) and/or the venous line (24) of a haemofilter (22), and a purification unit (32) comprising a microfiltration or nanofiltration device (33) and, downstream therefrom, adsorption means (34) adapted to retain molecules not stopped by the microfiltration or nanofiltration device (33).

3. Main request - novelty

3.1 Document D1, which constitutes prior art according to Article 54(3) EPC, discloses a dialysis circuit (dialysis treatment device 100 depicted in Figure 2 and described in paragraphs [0037] to [0039]) comprising a purification unit (filter 110) adapted to perform filtration of a dialysis solution, the purification unit comprising a nanofiltration device (nanofiltration membrane 114; paragraph [0039]) and, downstream therefrom, adsorption means (ion exchange sorbent 116; paragraph [0039]). It is implicit that the adsorption means can only stop those molecules which have not been stopped by the nanofiltration membrane (114). As explained in paragraphs [0044] and [0045], circuit 100 may be used, inter alia, in the haemodialysis device depicted in Figure 3B comprising a dialyser (202). In paragraph [0024], last full sentence, it is disclosed that the dialysis treatment devices disclosed in D1 (one of which is circuit 100 of

Figure 2) are part of a wearable artificial kidney with which a patient may move freely during dialysis. Moreover, claims 5 and 12 of D1 define the dialysis treatment device within a cartridge for a wearable kidney.

3.2 The patent proprietor argued that D1 did not disclose all the features of claim 1 in a single embodiment, so that to compose all the features of claim 1 it was necessary to pick up different elements from different embodiments and/or lists of different alternatives. A document should not be treated as something in the nature of a reservoir from which features pertaining to separate embodiments may be drawn to artificially create a particular embodiment. Consequently, D1 did not provide a clear and unmistakable teaching of the specific combination of features of the claimed subject-matter.

The Board does not accept this argument. As explained in detail above, the claimed subject-matter is anticipated by a single embodiment, i.e. the dialysis treatment device (100) depicted in Figure 2 and described in paragraphs [0037] to [0039]. Further details of this dialysis treatment device are presented in paragraphs [0044], [0045] and [0024]. The disclosure of the different features of the claimed subject-matter is thus direct and unambiguous and does not involve a random selection of features as argued by the patent proprietor.

3.3 The Board therefore concludes that the subject-matter of claim 1 lacks novelty within the meaning of Article 54(1) and (3) EPC.

3.4 D1 discloses, moreover, in paragraph [0046], that the aforementioned dialysis treatment device (100) may also be used in a haemofiltration device as depicted in Figure 3C. In that paragraph, on page 9, lines 5 to 6, D1 explains that after purification of the treated fluid in circuit 100, the resulting fluid is pumped into the blood stream of the patient. This implies that there is a pump to reinfuse the purified plasma water. Moreover, for blood to be pumped through haemofilter 203 (Figure 3C; paragraph [0046]), a further pump for circulation of blood needs to be provided.

It follows that also the subject-matter of independent claim 2 lacks novelty within the meaning of Article 54(1) and (3) EPC.

4. First auxiliary request

4.1 Article 83 EPC

4.1.1 The claims require the adsorption means to be adapted to retain *the* molecules which are not stopped by the filtration device.

4.1.2 The opponent interpreted this definition to mean that *all* molecules which were not stopped by the filter were stopped by the adsorption means, for example also water molecules, so that no fluid flow at all would result downstream of the purification unit. This meant that no fluid flow at all would be present. This constituted, however, a non-functional embodiment. The claims were not discussed and enabled over their whole width and should therefore be limited to the workable embodiments disclosed in the patent, for example in paragraphs [0025] and [0035].

4.1.3 The Board considers that the aforementioned interpretation of the claimed feature is obviously distorted, thus leading to the aforementioned manifestly technically meaningless embodiment. It is technically evident that the claimed feature should be read to mean that the adsorption means retains molecules - certainly not *all* the molecules - which were not stopped by the filtration device. In fact, paragraphs [0025] and [0035] of the patent make it clear that the filtration device is only capable of stopping a portion of the toxic molecules and the adsorption device must then be used to remove the toxins not stopped by the filter. There is obviously no need for the claims to be limited just because a manifestly technically meaningless embodiment is construed to fall under the wording of the claims. It is a different matter (not related to the requirements of sufficiency of disclosure of the patent as a whole), that a clearer formulation of the claims would have prevented such distorted interpretation.

4.1.4 The Board therefore considers that the patent is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, in accordance with Article 83 EPC.

4.2 Novelty over D1

4.2.1 The subject-matter of claim 1 of the first auxiliary request has been further limited by reciting, inter alia, "a pair of pumps attached respectively to the inlet line and to the outlet line of the dialysis solution". The opponent pointed to paragraph [0045] of D1 disclosing that the dialysis fluid is sent from dialyser 202 to dialysis treatment device 100 for

treatment/urea removal, and the treated fluid is then returned to dialyser 202. This could only be achieved by providing a pump in the inlet line and another in the outlet line.

Contrary to the view of the opponent, this circulation of dialysis fluid through the dialysis treatment device is in principle achievable by a single pump. That this is feasible is evidenced by D2, Figure 1, where the dialysis fluid is circulated through the dialysis treatment device (22) using a single pump (12) on the outlet line (10) of the dialysis fluid (column 1, line 73 to column 2, line 3). The opponent did not in fact give reasons for its assertion that two pumps were needed, one attached to the inlet line and the other to the outlet line of the dialysis solution, as recited in claim 1.

It follows that the subject-matter of claim 1 of the first auxiliary request is novel over D1.

4.2.2 The subject-matter of claim 2 of the first auxiliary request has been further limited by reciting "the purification unit comprising a device for elimination of plasma water and for checking the patient's weight reduction". The opponent referred to the haemofiltration treatment described in paragraph [0046] of D1, particularly the last two sentences of that paragraph, disclosing that replacement fluid was pumped into the blood of the patient and that a net volume of fluid was taken out of the patient as ultrafiltrate to remove excess water that the patient had accumulated between treatments. It was hence implicit that, in order to carry out the haemofiltration treatment safely, the amount of liquid supplied to and extracted

from the patient were monitored. This had to be done by monitoring the patient's weight reduction.

It may be assumed that a safe haemofiltration treatment normally requires that the volume of fluid supplied to and extracted from the patient is monitored. However, the monitoring of the patient's weight reduction, as defined in claim 2, relates to the monitoring of a different parameter which may be determined from the subtraction of the two mentioned volumes. This alternative parameter monitoring is, however, not disclosed in document D1.

It follows that the subject-matter of claim 2 of the first auxiliary request is novel over D1.

4.3 Novelty over D5

4.3.1 Document D5 discloses a dialysis system which is portable and usable by a patient while he travels (page 6, lines 8 to 15). In the embodiment of Figure 9, blood pump 48 is shown to be attached to the arterial line. Page 36, lines 14 and 15 discloses a pump on the inlet line and another pump on the outlet line of the dialysis solution. The dialysis solution passes through a sorbent cartridge 222 to remove waste products from the spent dialysis fluid (page 36, lines 22 to 25), which then passes through microfilter 626 (page 37, lines 8 to 13) and through an additional microfilter 630 (page 37, lines 20 to 22). This disclosure does not anticipate the subject-matter of claims 1 and 2 requiring the adsorption means to be arranged *downstream* of the microfiltration device.

4.3.2 D5 discloses that sorbent cartridge 222 may be "similar" to the cartridges described in D2, the

disclosure of which it incorporates by reference (page 30, lines 18 to 22). Even if, for the sake of argument, it was assumed that D5 disclosed cartridge 222 comprising all features of Figure 2 of D2, such a disclosure would not anticipate adsorption means arranged downstream of a microfiltration device as defined in claims 1 and 2, for the following reasons.

4.3.3 D2 discloses a cartridge or zirconium phosphate column 22 comprising a sheet 24 of filter cloth which covers layer 25 consisting of a mixture of finely divided urease and diatomaceous earth such that the filter cloth 24 keeps the incoming dialysis fluid flow from breaking up the top surface of the layer 25. D2 states that layers 25 and 26 can be fine enough to be called dust (column 2, lines 24 and 25). A layer 27 of zirconium phosphate in fine particle form is located downstream of layer 26 of diatomaceous earth. Another filter cloth 28 is located between layer 27 of zirconium phosphate and flow director device 29 (column 2, lines 16 to 29).

The opponent equated layers 25, 26, 27 to "adsorption means" arranged downstream of filter cloth 24, which was equated to a "microfiltration device". Filter cloth 24 was said to be identical to filter cloth 28 since both filters were depicted in Figure 2 with the same hatching. Filter cloth 28 had pores that were small enough to retain zirconium phosphate particles in the form of fine granules. D7 disclosed that fine granules of zirconium phosphate had sizes in the micrometer range between about 20 and about 100 micrometres (paragraph [0029]).

The Board considers that the opponent's line of argument does not prove that filter cloth 24 is disclosed to be a microfilter. First, the type of hatching of different layers of filters in a schematic figure allows no definite conclusion about the physical properties of the filters depicted. Hence, the filtering properties of filter 24 do not have to be the same as those of filter 28. Second, filter cloth 24 does not retain the particles of zirconium phosphate 27 (as filter 28 does), but covers layer 25 consisting of a mixture of finely divided urease and diatomaceous earth "dust-like" particles to keep the incoming dialysis fluid flow from breaking up the top surface of layer 25. D2 provides no further information as to the size of the "dust-like" particles of layer 25 or the cohesion of the particles on the surface of that layer which the flow of dialysis fluid should not disrupt when covered by filter cloth 24. It is hence not possible to infer directly and unambiguously from D2 the size of the particles which filter cloth 24 retains. Neither is it possible to infer this from the knowledge of the particle sizes of the zirconium phosphate layer 27 disclosed in D7, which is an entirely different material from that of layer 25. Thus, filter cloth 24 is not disclosed to be a microfilter as claimed.

It may be true, as stated by the opponent, that the exact range of particle sizes which a "microfilter" retains cannot be precisely ascertained. However, it seems to be common general knowledge, as evidenced by D18, page 275, first sentence, that a microfilter retains particles with diameters in an (approximate) range between 0.1 to 10 microns.

Thus, D2 does not disclose that filter cloth 24 is a "microfiltration device" (let alone a "nanofiltration device"), as defined in claim 1 and 2. As a consequence, D5, even in combination with the teaching of D2, fails to disclose adsorption means arranged downstream of a microfiltration (or nanofiltration) device.

4.3.4 Hence, the subject-matter of claims 1 and 2 of the first auxiliary request is novel over document D5.

4.4 Inventive step

4.4.1 D5 is considered to constitute the closest prior art. On page 30, lines 18 to 22 it is suggested that the sorbent cartridge 222 may be similar to the multilayer arrangement of Figure 2 of D2. It is hence obvious for the skilled person to follow this suggestion to combine D5 and D2 in this way.

4.4.2 As mentioned above, the subject-matter of claim 1 differs from the combined teaching of D5 and D2 in that it provides adsorption means arranged downstream of a microfiltration (or nanofiltration) device.

4.4.3 The opponent considered that the objective technical problem consisted in providing an improved dialysate regeneration system. Faced with this problem, the skilled person would have improved the filtering characteristics of filter cloths 24 and 28 of D2 in cartridge 222 in D5 by providing a filter cloth with pore sizes which ensure that all particles were retained between the filter cloths. In other words, the skilled person would have provided filter cloth 24 as a microfilter in order to achieve this result.

4.4.4 As explained above, D2 provides filter cloth 24 to cover layer 25 of finely divided urease and diatomaceous earth to prevent the incoming flow from breaking up the top surface of the layer. Nothing is disclosed in D2 concerning the specific size of the particles to be retained, nor has the opponent provided any evidence in this respect. It is also not at all obvious that the skilled person would be inclined to choose a very tightly knit filter cloth if this is not needed for the purpose disclosed, since such a fine filter would unnecessarily hinder the flow of dialysis fluid. D2 does not disclose or suggest any further specific function associated with filter cloth 24. Hence, the skilled person would have not readily devised filter cloth 24 as a microfiltration device, or a fortiori, as a nanofiltration device.

4.4.5 The technical effect achieved by the claimed microfiltration or nanofiltration device in the context of the present invention is to retain at least a portion of the toxic substances and the dissolved salts (sodium, potassium, calcium, etc.) present in the plasma water, with the downstream adsorption device removing toxins not stopped by the filtration device (paragraphs [0024] and [0025] of the patent).

4.4.6 Therefore, the combination of D5 and D2 does not render obvious the subject-matter of claim 1 of the first auxiliary request.

4.4.7 The opponent argued, moreover, that the arrangement of Figure 9 of D5 - comprising adsorption means in the form of cartridge 222 and, downstream therefrom, microfilter 626 - would have the same effect as if these elements were in the opposite arrangement with respect to the flow of spent dialysis fluid. It was of

no relevance whether the adsorber was placed upstream or downstream of the filter because it would adsorb only the specific molecules for which it was designed and would not adsorb the other molecules stopped by the filter for which it was not designed. As there was no technical effect attributed to the specific arrangement claimed, the objective technical problem was to provide an alternative arrangement to the one shown in Figure 9 of D5. As there were only two possible arrangements with respect to the order of the adsorption means and the microfilter, that is, arranging the adsorption means either upstream or downstream of the microfilter, it would have been obvious to the skilled person to choose any of these.

This argument does not convince the Board either. There is indeed a relevant technical difference between positioning the adsorber upstream or downstream of the filter. In the first case (the adsorber upstream of the filter), disclosed in Figure 9 of D5, the dialysis fluid containing all types of toxic substances passes through the adsorber first, which in such conditions tends to work poorly in blocking the molecules that need to be adsorbed. Moreover, as correctly held in the impugned decision, filter 626 is positioned downstream of fluid reservoir 612 and heater 58, so that filter 626 would be useful to remove bacteria and pyrogens introduced by these elements into the dialysis fluid circuit. For this reason, the person skilled in the art would not be inclined to exchange the relative positions of sorbent cartridge 222 and filter 626. In the second case (the adsorber downstream of the filter), which is claimed, a good part of the toxic substances are stopped by the filter and a fluid with only a low content of toxic substances reaches the

adsorption means. In such a condition, the adsorption means work better and achieve better results.

4.4.8 Hence, the subject-matter of claim 1 is not rendered obvious when departing from D5 as the closest prior art.

4.4.9 For the reasons explained above, it is not obvious to devise filter cloth 24 of D2 as a microfiltration device, or a fortiori, as a nanofiltration device. Hence, the objection that the claimed subject-matter would be obvious when starting from D2 as closest prior art fails too.

4.4.10 It follows that the subject-matter of claim 1 of the first auxiliary request satisfies the requirements of an inventive step within the meaning of Article 56 EPC. This applies a fortiori to the preferred embodiment defined in claim 3. No objections under Article 56 EPC were raised against independent claim 2.

4.4.11 There were no further objections raised against the first auxiliary request. In particular, the opponent's request not to admit the third auxiliary request filed with the statement of grounds of appeal, corresponding to the present first auxiliary request, was withdrawn at the oral proceedings.

4.5 As a consequence, none of the raised objections precludes the maintenance of the patent on the basis of the first auxiliary request.

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 the first auxiliary request filed with letter dated 2 August 2019;

   - pages 2 and 3 of the adapted description filed on 26 June 2014; and

   - Figures 1 to 4 of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated