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Datasheet for the decision of 24 October 2022

Case Number: T 1022/19 - 3.2.02

Application Number: 09767267.9

Publication Number: 2318071

IPC: A61M1/28

Language of the proceedings: EN

Title of invention:
DIALYSIS SYSTEM HAVING AUTOMATED EFFLUENT SAMPLING AND PERITONEAL EQUILIBRATION TEST

Patent Proprietor:
Baxter International Inc.
Baxter Healthcare SA

Opponent:
Fresenius Medical Care AG & Co. KGaA

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 83, 123(2)
RPBA 2020 Art. 13(2)

Keyword:
Novelty - (yes)
Inventive step - (yes)
Sufficiency of disclosure - (yes)
Amendments - allowable (yes)
Amendment after summons - taken into account (no)

Decisions cited:
T 0574/17

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

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Case Number: T 1022/19 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 24 October 2022

Appellant: (Opponent)	Fresenius Medical Care AG & Co. KGaA Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Herrmann, Uwe Lorenz Seidler Gossel Rechtsanwälte Patentanwälte Partnerschaft mbB Widenmayerstraße 23 80538 München (DE)
Respondent: (Patent Proprietor 1)	Baxter International Inc. One Baxter Parkway, DF2-2W Deerfield, IL 60015-4633 (US)
Respondent: (Patent Proprietor 2)	Baxter Healthcare SA Thurgauerstrasse 130 8152 Glattpark (Opfikon) (CH)
Representative:	Potter Clarkson The Belgrave Centre Talbot Street Nottingham NG1 5GG (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 14 February 2019 rejecting the opposition filed against European patent No. 2318071 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Böttcher
	N. Obrovski

Summary of Facts and Submissions

I. The opponent filed an appeal against the decision of the opposition division to reject the opposition against the patent No. 2 318 071.

II. Oral proceedings before the board took place on 24 October 2022.

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

The respondent (patent proprietor) requested that the appeal be dismissed and that the patent be maintained as granted or, alternatively, on the basis of one of the first to fifth auxiliary requests filed with the reply to the statement of grounds of appeal.

IV. Claim 1 of the main request reads as follows.

"A dialysis system (10) comprising:

at least one dialysis fluid pump actuator; and a disposable cassette (50) including at least one pump chamber (62) operable with the at least one pump actuator, the disposable cassette further including a plurality of fluid ports (56) configured to be connected fluidly to a plurality of fluid containers (66a, 66b, 66c, 66d, 68, 70);
characterised in that it further comprises
a processor programmed to cause the at least one pump actuator to operate the at least one pumping chamber to collect an effluent dialysis fluid sample by pumping a first number of pump strokes to a drain/drain container (68) followed by a second number of pump strokes to a

sample container (70)."

V. The following documents are referred to in this decision.

D1 EP 0 815 882 A2
D2 US 5,670,057
D3 WO 03/063929 A1
D4 WO 99/06082 A1
D5 Patient Guidelines til PDC test - procedure til CAPD, Gambro 2006

VI. The arguments of the appellant may be summarized as follows.

Main request - Added subject-matter

In the application documents as originally filed it was not disclosed that both the first and the second number of pump strokes were used to collect an effluent dialysis fluid sample, as defined in claim 1.

Furthermore, according to claim 1 the pump actuator operated the at least one pumping chamber, whereas in claim 10 of the application as originally filed the pump actuator operated with the pumping chamber. The direct actuation as defined in claim 1 could not be derived from the original application documents. Claim 10 as originally filed, on which claim 1 was based, included the wording "to operate with the...". This could not be equated with "to operate the...".

Therefore, claim 1 did not meet the requirements of Article 123(2) EPC.

Sufficiency of disclosure

Claim 1 defined that the sample of dialysis solution was collected by pumping both a first number of pump strokes to a drain and a second number of pump strokes to a sample container. However, the person skilled in the art was not able to reproduce this teaching.

Furthermore, the claim covered embodiments with only one pump chamber and without any valves for controlling fluid flow. However, with such an arrangement it was not possible to selectively pump the effluent dialysate flow into the drain and into the sample container. Hence, in such an embodiment, it was technically nonsensical to program the processor in such a manner as defined in claim 1.

Hence, the invention was not sufficiently disclosed over its whole scope to be carried out by the person skilled in the art.

Novelty

D1 disclosed a dialysis system according to claim 1 having, in particular, two pump actuators PA1 and PA2 operating two pump chambers P1, P2, (column 13, lines 27 to 35; Figures 8 and 13) and a processor (controller 16, column 5, lines 38 to 41).

Claim 1 did not require that the amount or duration of the operation of the pump chambers was defined in the program of the processor. Hence, any processor programmed to control a pump actuator fell under the scope of claim 1. Therefore, its subject-matter lacked novelty over D1.

Inventive step starting from D1

D1 disclosed a dialysis system comprising the features of the preamble of claim 1 (column 13, lines 27 to 36; Figures 1, 3, 8A, 8B, 12A, 13 and 14A). Furthermore, the system of D1 comprised a processor programmed to cause the pump actuator to operate the pumping chamber by pumping single pump strokes (column 14, lines 50 to 57, column 29, lines 20 to 24; column 40, lines 25 to 31).

D1 further disclosed that a volume of spent dialysate was diverted into the inspection bag during the first drain cycle, i.e. not at the beginning of the drain cycle (column 7, lines 3 to 17). Since it was mentioned in D1 that the sample should be inspected for cloudy effluent as a sign of peritonitis (column 7, lines 15 to 17), it was obvious for the person skilled in the art that the sample should be taken only after a first number of pump strokes had been pumped into the drain.

Furthermore, claim 1 did not require that the first number of pump strokes was pumped exclusively to the drain and the second number was pumped exclusively to the sample container.

Hence, D1 disclosed that a first number of pump strokes was used to pump the dialysis fluid to a drain and afterwards a second number of pump strokes was used to pump the fluid at least partly to a sample container. The subject-matter of claim 1 differed from this only in that the processor was programmed to control the pump actuator correspondingly.

Starting from D1, the objective technical problem to be solved was to render the probe sampling easier and more secure.

- in combination with D3

The solution to this problem, i.e. the automation of the sampling process, was obvious in view of D3.

D3 disclosed a peritoneal dialysis system with an automatic sampling system. To collect a fluid sample, a certain quantity of fluid was directed exclusively to a specific sampling container (page 7, lines 22 to 33) This was done during the drain cycle at predetermined times (page 7, lines 35 to 37). These predetermined times corresponded to a certain number of pump strokes.

The person skilled in the art would implement this teaching in the system of D1, thereby arriving at a system according to claim 1.

- in combination with the common general knowledge

The programming of the processor according to claim 1 represented merely an automation of the manual sampling process of D1. This was also obvious in view of the common general knowledge since the person skilled in the art would generally aim to automate a manually performed process.

Hence, the subject-matter of claim 1 was not inventive in view of D1 in combination with the common general knowledge.

- in combination with D2

The solution to the above-mentioned problem was also obvious in view of D2 disclosing a method and device for performing an automatic Peritoneal Equilibrium Test

(PET). After one minute of draining a sample was taken automatically from the T-connection (column 7, lines 22 to 28, Figure 2). Hence, the person skilled in the art was taught to automate the sampling process and to take the sample only after part of the dialysis fluid was pumped to the drain.

Such an arrangement would fall under the scope of claim 1 as, during a first number of pump strokes, dialysis fluid was delivered exclusively to the drain and, during a second number of pump strokes, the fluid was delivered at least partly to the sample container.

Thus, the combination of D1 with D2 would result in a system according to claim 1.

- *in combination with D4*

D4 disclosed an automatic sampling after detecting that the effluent was cloudy, i.e. after directing a certain volume of dialysis fluid to the drain (paragraph bridging pages 19 and 20). Hence, during a first number of pump strokes, dialysis fluid was delivered exclusively to the drain and, during a second number of pump strokes, the fluid was delivered at least partly to the sample container. This teaching would prompt the person skilled in the art to program the processor of D1 such as to pump dialysis fluid to the drain as long as the fluid was not cloudy, and to open the clamp in the branch line 28A to pump at least one pump stroke to the sample container.

Thus, the combination of D1 with D4 would result in a system according to claim 1.

- *in combination with D5 and the common general*

knowledge

D5 described a system for manually performing a PDC test. It was mentioned that a certain volume of fluid was discarded before the sample was taken from a bag of drained dialysis fluid (page 5, step 10). It was obvious for the person skilled in the art to automate this procedure and to apply this teaching to the system of D1 by programming the processor to perform this sampling after a certain volume of fluid had been conveyed to the drain.

Claim 1 did not require that the drain container and the sample container were separate containers. An embodiment having only one container in which both the draining fluid and the sample fluid were pumped would also fall under the scope of the claim.

Thus, the combination of D1 with D5 and the common general knowledge would result in a system according to claim 1.

Consequently, the subject-matter of claim 1 lacked an inventive step.

Admittance of the inventive step-objection starting from D4 in combination with D5

D4 was highly relevant since it disclosed that a sample was automatically pumped exclusively to the sample container. In view of its *prima facie* relevance, this objection should be admitted even in the absence of any further exceptional circumstances.

VII. The arguments of the respondent may be summarized as follows.

Added subject-matter

When claim 1 was construed properly, it was clear that only the second number of pump strokes was used for collecting the sample in the sample container and that the first number of pump strokes was used to pump spent dialysis solution to a drain before collecting the sample. This was disclosed in claim 10 as originally filed.

The terms "to operate with the at least one pumping chamber" and "to operate the at least one pumping chamber" were used interchangeably throughout the application as filed. Indeed, claims 1 and 6 as originally filed used the latter.

Hence, there was clear support in the application as filed for "a processor programmed to cause the at least one pump actuator to operate the at least one pumping chamber".

For these reasons claim 1 complied with Article 123(2) EPC.

Sufficiency of disclosure

It was clear that only the second number of pump strokes was used for collecting the sample in the sample container and that the first number of pump strokes was used to pump spent dialysis solution to a drain before collecting the sample. Thus, there was no volume pumped by either the first number of pump strokes or the second number of pump strokes that ended

up going to the drain and also to the sample container.

Therefore, when claim 1 was construed correctly by a mind willing to understand, it was clear that the skilled person would have had no difficulty implementing the invention.

The fact that claim 1 covered dialysis systems with single and multiple pump chambers and dialysis systems that had valves as well as those that did not, did not give rise to an insufficiency problem.

Even with a single pump chamber one could collect the effluent dialysate fluid as claimed without having valves, for example by using an automated clamping system with a clamp arranged on tubing leading to the drain and on tubing leading to the sample container.

In conclusion, the requirements of Article 83 EPC were met.

Novelty

Granted claim 1 required a specifically programmed processor, namely one that was programmed to cause the at least one pump actuator to operate the at least one pumping chamber to collect an effluent dialysis fluid sample by pumping a first number of pump strokes to a drain/drain container followed by a second number of pump strokes to a sample container.

The processor in D1 was simply programmed to cause a pump actuator to operate a pumping chamber until the drain cycle was completed. Furthermore, the teaching at column 7, lines 7 to 17 of D1 did not make it clear whether the step of diverting a volume of spent

dialysate to the inspection bag took place right at the beginning of a drain cycle or after a certain amount of fluid had been drained. In any case, there were no separately programmed pumping operations as required by claim 1.

Thus, the subject-matter of claim 1 did not lack novelty over D1.

Inventive step starting from D1

D1 disclosed a peritoneal dialysis system comprising the features of the preamble of claim 1 and a processor that was programmed to control the pump actuators to operate the pumping chambers.

However, D1 did not disclose that its controller was "programmed to cause the at least one pump actuator to operate the at least one pumping chamber to collect an effluent dialysis fluid sample by pumping a first number of pump strokes to a drain/drain container followed by a second number of pump strokes to a sample container". In D1, manual operation of the clamps shown in Figure 3 controlled when effluent was sent to a drain and when a sample was collected.

The wording "during the first drain cycle" (column 7, lines 13 to 17) did not exclude that the sample was collected right at the beginning of the first drain cycle before any spent dialysate was sent to the drain.

Furthermore, it was clear from the wording of claim 1 that the first number of pump strokes was used to pump effluent dialysis fluid to a drain and not to a sample container and the second number of pump strokes was used to pump effluent dialysis fluid to a sample

container and not to a drain. Thus, the effluent dialysis fluid was pumped to a particular destination to the exclusion of the other depending on whether it was the first number of pump strokes or the second.

- in combination with D3

D3 disclosed a peritoneal dialysis system with an automated sampling system which was able to automatically sample dialysate contained in the peritoneal cavity of the patient at specific time intervals (page 2, lines 7 to 16).

If the person skilled in the art was motivated to replace the drain tube 28A depicted in Figure 3 of D1 with the automatic sampling system of D3, he would not arrive at a dialysis system as claimed, as D3 did not teach or suggest to control the pump to pump a first number of pump strokes exclusively to a drain followed by a second number of pump strokes exclusively to a sample container as required by claim 1. In D3, as in D1, the sampling could take place right at the beginning of the drain cycle. Furthermore, D3 was silent on the basis on which the predetermined time was defined.

- in combination with the common general knowledge

Any automation of the procedure taught in D1 would not lead the person skilled in the art to arrive at a dialysis system as defined in claim 1. If the skilled person was motivated to automate what was described at column 7, lines 13 to 15 of D1, he would replace the manually operated clamps shown in Figure 3 of D1 with some form of automated clamping system which provided for automatic opening and closing of the drain tube 28

and the branch tube 28A. He certainly would not reprogram the software on the system controller so as to "cause the at least one pump actuator to operate the at least one pumping chamber to collect an effluent dialysis fluid sample by pumping a first number of pump strokes to a drain/drain container followed by a second number of pump strokes to a sample container".

- in combination with D2

D2 disclosed an apparatus for automatically sampling dialysis fluid as it dwells in the peritoneal cavity after which the patient is drained (Abstract; col. 3, lines 1 to 6, 23 to 26 and col. 4, lines 17 to 29).

If the person skilled in the art turned to D2 for assistance in developing an improved system, he would, at best, merely replace the manually operable clamps shown in Figure 3 of D1 with an automated clamping system as taught in D2. He would not reprogram the software on the system controller so as to "cause the at least one pump actuator to operate the at least one pumping chamber to collect an effluent dialysis fluid sample by pumping a first number of pump strokes to a drain followed by a second number of pump strokes to a sample container" as required by granted claim 1.

- in combination with D4

D4 disclosed an automated peritoneal dialysis system comprising an effluent detector and a sample collection port 6 from which a fluid line led to a sample container 30 (page 19, second complete paragraph and Fig. 9). If the effluent detector detected that the spent dialysate was cloudy during a drain cycle, the system automatically opened sample collection port 6

and sent a sample of the cloudy spent dialysate to the sample container.

If the person skilled in the art was motivated to modify the system of D1 in light of the teaching of D4, he would not arrive at a dialysis system as presently claimed, as the resulting 'combined' system would simply remove a sample by selective operation of the occlusion chamber (Figure 9 of D4) on detection of a cloudy effluent dialysate by the effluent detector. Thus, the resulting system would not have a processor as claimed which was programmed to sample spent dialysate automatically by "causing the at least one pump actuator to operate the at least one pumping chamber to collect an effluent dialysis fluid sample by pumping a first number of pump strokes to a drain followed by a second number of pump strokes to a sample container".

- in combination with D5 and the common general knowledge

D5 described a system for taking samples from a bag of collected spent dialysate for PDC testing. At Step 10 on page 5, the first 300 ml of spent dialysate was discarded and then samples were collected. It would not be obvious to automate this procedure and to combine the thus automated sampling with the system of D1 to arrive at a peritoneal dialysis system as presently claimed since the bag system shown in D5 had been disconnected from the dialysis system after completion of the drain cycle.

Hence, the subject-matter of claim 1 was inventive over the above-mentioned combinations of documents.

Admittance of the inventive step-objection starting from D4 in combination with D5

The objection was submitted for the first time at oral proceedings before the board. Since there were no exceptional circumstances justifying the late submission, this objection should not be taken into account.

Reasons for the Decision

1. Summary of the invention

The invention relates to a system for automated peritoneal dialysis.

Usually, prior to prescribing a peritoneal dialysis treatment, a peritoneal equilibration test (PET) is performed to assess the peritoneal membrane transport function (i.e. how fast or slow the solutes pass from the blood into the dialysis fluid). A typical PET regime requires to take numerous solution samples over the course of four to five hours. The system according to the present invention collects effluent samples automatically from either a particular drain cycle or from an aggregate of drained solution, without the need for the patient to perform an extra clamping or pouring step. To do so, the system ratiometrically delivers part of the drain volume (a first number of pump strokes) to the drain bag and another part (a second number of pump strokes) to the sample bag. If the ratiometric pumping continues to the end of therapy, a sample is provided that is representative over the

entire drain.

2. Added subject-matter

Claim 1 defines a system configured to collect an effluent dialysis fluid sample by pumping a first number of pump strokes to the drain/drain container followed by a second number of pump strokes to the sample container. The claim thus defines two consecutive steps which are necessary to obtain a representative sample, although the sample itself is collected only by the second step. This is disclosed in the application documents as originally filed, e.g. in claims 1 and 10.

The wording of the claim does not mean that both the first and second number of pump strokes are used "to collect an effluent dialysis fluid sample", as alleged by the appellant.

Furthermore, the wording "to operate with the..." and "to operate the..." are used interchangeably in the original application documents. In fact, claim 1 as originally filed defines "a processor programmed to cause the at least one pump actuator to operate the at least one pumping chamber...".

Hence, the amendments made to claim 1 meet the requirements of Article 123(2) EPC.

3. Sufficiency of disclosure

Since claim 1 does not teach to use both the first and second number of pump strokes to collect an effluent dialysis fluid sample, the appellant's objection to this effect is moot.

Furthermore, the person skilled in the art is able to manufacture the dialysis system as claimed, i.e. having a processor that is programmed to cause a pump actuator to operate a pumping chamber to pump a first number of strokes followed by a second number of strokes, even if the dialysis system has only one pump chamber. The person skilled in the art would know that in this case the appropriate hardware (controllable valves or clamps) had to be provided in order to actually convey the pumped fluid to the respective container by the first and the second number of strokes.

Hence, the patent as whole, either alone or together with the common general knowledge of the person skilled in the art, discloses the subject matter of claim 1 in a sufficiently clear and complete manner to allow it to be carried out by the person skilled in the art.

4. Novelty

Claim 1 requires that the processor is programmed to cause a pump actuator to operate a pumping chamber to pump a first number of strokes followed by a second number of strokes. Hence, at least two numbers of pump strokes have to be defined in the program. In this regard, the board does not concur with the appellant that any programming of a processor would fall under the scope of the claim.

It is undisputed that D1 discloses a dialysis system having the features of the preamble of claim 1 (column 13, lines 27 to 36; Figures 1, 3, 8A, 8B, 12A, 13 and 14A). In addition, D1 discloses a processor programmed to cause the pump actuator to operate the pumping chamber by pumping single pump strokes (column 14,

lines 50 to 57, column 29, lines 20 to 24; column 40, lines 25 to 31).

However, D1 does not disclose that the processor is programmed to pump a first number of pump strokes to a drain or drain container followed by a second number of pump strokes to a sample container. D1 rather discloses, on column 7, lines 13 to 15, that "the patient can divert a volume (about 25 ml) of spent dialysate through branch 28A into the inspection bag during the first drain cycle". Hence, a sample is taken manually somewhen during the drain cycle, without any programming of the processor.

Consequently, the subject-matter of claim 1 is novel over D1.

5. Inventive step

5.1 Claim interpretation and closest prior art

From the wording of claim 1 it is clear that the first number of pump strokes is used to pump effluent dialysis fluid to a drain and not to a sample container and the second number of pump strokes is used to pump effluent dialysis fluid to a sample container and not to a drain. Otherwise it would not make sense to distinguish between a first number of pump strokes and a second number of pump strokes.

It is undisputed that D1 can be considered to represent the closest prior art to the subject-matter of claim 1.

However, in D1 the sample is collected by manually opening the clamp in the branch 28A, while the drain tube remains open. Hence, during sample collection, the

effluent dialysis fluid is pumped both to the inspection bag and to the drain (column 7, lines 7 to 15). Contrary to the appellant's view, D1 does not disclose that the sample is taken only after a certain amount of effluent is pumped into the drain.

Hence, D1 does not disclose that the processor is programmed to pump a first number of pump strokes to a drain or drain container followed by a second number of pump strokes to a sample container. Contrary to the appellant's view, D1 does not disclose that the manual collection of the sample is performed only after a certain amount of fluid has been pumped to the drain and that during the collection of the sample the fluid is exclusively pumped to the sample container.

5.2 Combination with D3

D3 discloses an automatic sampling system to be used with a peritoneal dialysis system. The sampling system comprises controllable valves (page 4, lines 23 to 26, Figure 1) which are used to direct a quantity of fluid exclusively to a specific sampling container (page 7, lines 22 to 33).

In D3, the fluid is pumped by peristaltic pumps (page 7, lines 13 to 25). Hence, the system of D3 does not comprise a pumping chamber operated by a pump operator performing single pump strokes. The peristaltic pumps of D3 rather operate continuously during the drain cycle.

Furthermore, although D3 mentions that a sample can be taken at predetermined times (page 7, lines 35 to 36), it is not disclosed on which basis the times are predetermined. In any case, D3 does not teach or

suggest that the sample should only be taken after a certain, predefined amount of fluid has been sent to the drain.

Hence, D3 does not prompt the person skilled in the art to program the processor of the system of D1 to pump a first number of pump strokes to a drain or drain container followed by a second number of pump strokes to a sample container.

5.3 Combination with the common general knowledge

The appellant's objection is based on the assumption that the invention merely represents an automation of the sample collection procedure described at column 7, lines 13 to 15 of D1, and that such automation would be obvious.

However, since D1 does not disclose or suggest to first pump a certain quantity of fluid to the drain and then to pump a second quantity of fluid exclusively and completely to the sample collector, and to do this only after a certain amount of fluid has been pumped to the drain, a mere automation of the sampling process of D1 would not result in the processor being programmed as defined in claim 1.

5.4 Combination with D2

D2 relates to an apparatus for automatically sampling dialysis fluid from a peritoneal cavity. A sample is taken from a T-connection in a gravity drain line after one minute of draining by using an automated clamping system (column 4, lines 19 to 23, column 7, lines 22 to 28). Thus, applying the teaching of D2 to the system of D1 would result in providing a controllable clamp in

the branch line 28A and programming the processor to automatically open the clamp to allow effluent to flow to the sample container one minute after the start of the drain cycle.

However, contrary to the appellant's view, such an arrangement does not fall under the scope of claim 1. Claim 1 requires that during the first number of pump strokes the effluent dialysis fluid is pumped exclusively to the drain, and that during the second number of pump strokes the effluent dialysis fluid is pumped exclusively to the sample container. Hence, the programming of the processor would have to include the definition of two numbers of pump strokes. Since D2 does not teach or suggest such a programming, the disclosure of D1 in combination with the teaching of D2 does not result in a dialysis system as claimed.

5.5 Combination with D4

D4 discloses to take a sample from effluent dialysate if it is detected that the effluent is cloudy. This is done by automatically opening a sample collection port and sending a sample of the spent dialysate to a sample container (page 19, last paragraph, to page 20, first paragraph).

Thus, applying the teaching of D4 to the system of D1 would result in the provision of a controllable clamp in the branch line 28A and an effluent detector in the drain line, and in programming the processor to automatically open the clamp to allow effluent to flow to the sample container after the start of the drain cycle after detecting that the effluent is cloudy.

However, contrary to the appellant's view, claim 1

requires that during the first number of pump strokes, the effluent dialysis fluid is pumped exclusively to the drain and during the second number of pump strokes, the effluent dialysis fluid is pumped exclusively to the sample container, irrespective of whether the effluent is cloudy or not. Hence, the program of the processor must include the definition of two numbers of pump strokes. Since D4 does not teach or suggest such a programming, the disclosure of D1 in combination with the teaching of D4 does not result in a dialysis system as claimed.

5.6 Combination with D5 and the common general knowledge

D5 discloses an instruction to manually take a sample of dialysate which has already been collected in a drain bag. It is mentioned that a certain volume of fluid is discarded before the sample is taken (page 5, point 10.). If the person skilled in the art applied this teaching to the system of D1, he would provide a drain bag and program the processor to automatically take a sample from the drain bag after completion of the drain cycle. Evidently, this would not result in a programming as defined in claim 1.

Furthermore, contrary to the appellant's view, it is clear from the patent as a whole that the drain container and the sample container are two separate entities.

5.7 Since none of the prior art documents referred to by the appellant renders the claimed programming of the processor obvious, the subject-matter of claim 1 involves an inventive step.

6. Admittance of the inventive step-objection starting from D4 in combination with D5

During the oral proceedings the appellant raised a new inventive step objection based on a combination of D4 with D5. This submission represents an amendment to the appellant's appeal case made after notification of the summons to oral proceedings. Pursuant to Article 13(2) RPBA, it shall not be taken into account unless there are exceptional circumstances which have been justified with cogent reasons. The appellant only alleged that this objection was *prima facie* relevant (see in that regard T 574/17, Reasons 2.3.3), and did otherwise not argue that there were any exceptional circumstances. Hence, the objection was not admitted into the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated