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Datasheet for the decision of 17 March 2026

Case Number: T 1967/23 - 3.2.02

Application Number: 19151374.6

Publication Number: 3501566

IPC: A61M1/16, A61L2/04, C02F1/02

Language of the proceedings: EN

Title of invention:
EQUIPMENT WITH THERMAL DISINFECTION

Patent Proprietor:
Gambro Lundia AB

Opponents:
Bauer, Clemens
Fresenius Medical Care AG

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 76(1), 83
RPBA 2020 Art. 12(4), 13(2)

Keyword:
Novelty - (yes)
Inventive step - (yes)
Divisional application - added subject-matter (no)
Sufficiency of disclosure - (yes)
Amendment to case - amendment admitted (yes)
Amendment after summons - taken into account (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1967/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 17 March 2026

Appellant: (Patent Proprietor)	Gambro Lundia AB Magistratsvägen 16 226 43 Lund (SE)
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Appellant: (Opponent 2)	Fresenius Medical Care AG Else-Kröner-Str. 1 61352 Bad Homburg (DE)
Representative:	Lorenz Seidler Gossel Part. mbB Widenmayerstr. 23 80538 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted/ electronically transmitted on 2 November 2023 concerning maintenance of the European Patent No. 3501566 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. Both opponents and the patent proprietor filed an appeal against the interlocutory decision of the opposition division that the patent was to be maintained on the basis of auxiliary request 2 (filed as auxiliary request 3 on 9 January 2023).

II. Oral proceedings before the Board took place on 17 March 2026 by videoconference. Opponent 1 had announced in their letter dated 10 March 2026 that they would not attend the oral proceedings.

III. The appellant-patent proprietor ("patent proprietor") requested that the decision be set aside and that the patent be maintained on the basis of the main request or auxiliary request 1 filed with the statement of grounds of appeal, or that the patent be maintained on the basis of auxiliary request 2 held by the opposition division to comply with the requirements of the Convention, or that the patent be maintained on the basis of auxiliary request 3 filed with the reply to the opponents' statements of grounds of appeal.

The appellant-opponent 1 ("opponent 1") and appellant-opponent 2 ("opponent 2") requested that the decision be set aside and the patent be revoked.

Opponent 2 also requested that the main request, auxiliary request 1 and auxiliary request 3 not be admitted into the appeal proceedings.

IV. Claim 1 of the main request reads as follows (with the feature numbering added by the Board according to the table on pages 6 and 7 of the patent proprietor's

statement of grounds of appeal).

1.0 "Dialysis apparatus comprising a fluid path,
1.1 said fluid path at least partly consisting of a fluid path with a need for regular thermal disinfection (480, 422),
1.1.1 the fluid path to be disinfected being the treatment fluid path of the dialysis apparatus, the dialysis apparatus further comprising:
1.2 an inlet (428) adapted to receive fluid;
1.3 an actuator (442, 430) configured to control the flow of the fluid from the inlet to a connector (481),
1.4 the connector being configured to connect to the fluid path with a need for regular disinfection;
1.5 a temperature sensor (450) configured to measure the temperature of the fluid in the fluid path;
1.6 a control unit (460) connected to the actuator and the temperature sensor,
1.6.1 the control unit being configured to control the fluid flow by means of the actuator, and to read the temperature measured by the temperature sensor;
wherein
1.6.2 the control unit is configured to receive and/or retrieve information representing a set disinfection dose; and
1.6.3 the control unit is configured to start the disinfection of the fluid path to be disinfected by controlling the actuator to enable fluid from the inlet to flow to the connector and further into the fluid path with a need for regular disinfection; and
1.5.1 the temperature sensor (450) is located at a location of the fluid path which experiences the lowest, or one of the lowest, temperatures

during thermal disinfection; and

1.6.4 the control unit is configured to repeatedly: read the temperature as measured by the temperature sensor during disinfection,

1.6.5 calculate an achieved disinfection dose based on the read temperature, and

1.6.6 compare the achieved disinfection dose with the set disinfection dose,
until the achieved disinfection dose equals or exceeds the set disinfection dose,

1.6.7 and the control unit is further configured to discontinue an ongoing disinfection if the achieved disinfection dose equals or exceeds the set disinfection dose."

V. The following documents are referred to in this decision

D1 DE 196 55 227 B4
D2 WO 96/25214
D3 DE 2934167 A1
D4 WO 00/57935 A1
D7 Rosenberg, U. "Thermal disinfection-The A_0-concept and the Biological Background"; Zentralsterilisation, vol. 11 (2003)
D8 BS EN ISO 15883-1:2009; Washer-disinfectors (published 31 October 2009)
D10 US 2010/0263687 A1
D11 BS ISO 23500:2011; "Guidance for preparation and quality management of fluids for haemodialysis and related therapies" (published 15 May 2011)
D15 AU 768 128 B2 (the page numbers given below for D15 are those of the page headings)
D22 DE 10 2011 051 241 A1
D23 EP 1 824 373 B1
D25 "Bonnes pratiques d'hygiène en hémodialyse",

Hygiènes, Revue Officielle de la Société Française d'Hygiène Hospitalière, volume XIII, No. 2 (2005)

D26 JP 2009-133096

VI. The arguments of the patent proprietor can be summarized as follows.

Admittance of the main request

The new main request was filed to address the opposition division's position that the subject-matter of claim 1 of the former main request (claims as granted) lacked novelty in view of D23. It was filed with the statement of grounds of appeal, i.e. at the earliest stage of the appeal proceedings.

Claim 1 of the main request included a convergent restriction of the subject-matter of former auxiliary request 1 by which a discussion on the issue of novelty in view of D23 could be avoided. The factual and legal framework did not change at all as the same issues would have to be discussed.

Hence, the main request should be admitted into the appeal proceedings.

Main request - added subject-matter

The parent application (page 18, lines 9 to 12) taught the person skilled in the art that the sensor had to measure the lowest or one of the lowest temperatures in the fluid path. This was supported by the description of the alternative embodiment mentioned on page 19, lines 4 to 14, and the description of Figure 5 on page

20, lines 5 to 10. Furthermore, the parent application disclosed in connection with the water system of the embodiment of Figure 1 that the temperature sensor was preferably placed at a location of the fluid system which experienced the lowest or one of the lowest temperatures during thermal disinfection (page 11, lines 30 to 32, and page 12, lines 24 to 29). Hence, the person skilled in the art would understand that the positioning of the temperature sensor at a location where the lowest or one of the lowest temperatures occurred was a feature of the disinfection process which was not associated with any specifically described embodiment, but was used in the context of a process which used the lowest measured temperatures to determine the disinfection dose achieved and stopped the disinfection when a set disinfection dose was reached.

Hence, the inclusion of feature 1.5.1 in claim 1 did not infringe the requirements of Article 76(1) EPC.

Main request - sufficiency of disclosure

In view of the detailed embodiments described by reference to Figures 1, 3 and 4 at least one way was clearly indicated by which the invention could be carried out by a person skilled in the art.

The person skilled in the art would be aware that the water was at its lowest temperature after having travelled the longest distance in the circuit, e.g. before being discharged into the drain (as in Figure 4). The person skilled in the art would also be aware that the returning water about to re-enter the heater would have lost heat since leaving the heater, so in this case the described location upstream of the heater

experienced the lowest, or one of the lowest, temperatures.

Hence, the feature "a location which experiences the lowest or one of the lowest temperatures during thermal disinfection" defined a very limited range of temperature sensor locations which were considered to be suitable for the calculation of a reliable achieved disinfection dose.

Therefore, it would not be technically difficult or unduly burdensome for a person skilled in the art to determine the location of the fluid path that experiences the lowest, or one of the lowest, temperatures during thermal disinfection and to locate the temperature sensor accordingly.

The variables of the circuit and of the disinfection process which would, according to both opponents, affect the temperature distribution in the system could influence the temperature value but not the point where the lowest temperature was reached. Even in the case of a more complex fluid circuit the technician could always identify a suitable temperature sensor location by simply identifying the very few most promising locations during a particular disinfection process and testing their temperature once. This very simple procedure allowed the correct location to be identified without any effort.

In the open circuit configuration described in relation to Figure 4, a location upstream of the heating unit could not be considered by the person skilled in the art to be a location of the fluid path of the thermal disinfection process, since at that location the water had not yet been heated at all.

It was not necessary for the patent in suit to provide a method of measurement to determine a suitable location for the temperature sensor as this location could be determined by routine testing.

The parameter "the lowest temperature or one of the lowest temperatures" defined a limited range of temperature sensor locations that could be considered suitable for calculating a reliably achieved disinfection dose.

Hence, the invention as claimed in the patent as granted was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Main request - novelty in view of D1/D2

Feature 1.5.1 of claim 1 was not disclosed in D2.

There was no explicit mention of placing one of the thermistors at the point in the circuit that experienced the lowest temperature in the fluid path.

Thermistor 293 provided on line 236a was not placed at the location which experienced one of the lowest temperatures during thermal disinfection. During disinfection, hot water entered into the blood circuit via the dialyzer 404. The water was then moved by the blood pump downwards into the arterial line of the blood circuit. At the end of the arterial line the water entered the dialysis module at port 499, flowed via valve V20, crossed thermistor 293 and re-entered into the blood circuit and the venous line at port 497 (Figures 6 and 27B). From port 497 the water flowed via

bubble trap 472 back to the dialyzer, where it was mixed with fresh hot water. The circuit portion experiencing the lowest temperature in the circuit was certainly the area of the connection between the venous return line and the upper part of the dialyzer. However, this was not where the thermistor 273 was located.

Furthermore, features 1.6.5-1.6.7 were not disclosed in D2.

In the dialysis apparatus disclosed in D2, disinfection was achieved by circulating hot water at a sufficiently high temperature through the fluid path to be disinfected for a sufficiently long time, e.g. "at least an hour at 80 degrees C" (page 77, lines 13 to 17). In D2 the control unit simply started a disinfection cycle that had to continue for one hour. If during the one hour a T<80°C was measured the hot water disinfection was either repeated entirely, or aborted (page 82, lines 2-14).

In D2 the temperature was simply measured, but never used for determining any achieved disinfection dose by calculation. There was no comparison in D2 between an achieved disinfection dose and the set disinfection dose and the ongoing disinfection was not discontinued based on the comparison if the achieved disinfection dose equalled or exceeded the set disinfection dose. Rather, D2 taught to stop disinfection after a predetermined period of time (namely, one hour) when the thermistors did not report a sensed temperature of less than 80°C during this period of time. D2 also failed to disclose that features 1.6.5 and 1.6.6 were repeatedly performed.

D1 was part of the same patent family as D2 and both documents claimed the same US priority. D2 contained all and more of the information contained in D1. Consequently, (at least) the differences between the subject-matter of claim 1 of the main request with respect to D2 were also differences with respect to D1.

Hence, the subject-matter of claim 1 was novel in view of D2 and in view of D1.

Main request - novelty in view of D15

D15 disclosed a system for producing and dispensing a sterilized medical fluid, for example for use in peritoneal dialysis. As shown in Figure 1, the system comprised a heating unit 80, 511 for sterilizing a medical fluid as water, and a fluid path formed by a second pipe 2 and a sterilizable connector 90, from which, in practice, sterilized fluid could be dispensed, for example into the peritoneum of a patient or to a container (page 10, lines 23 to 25).

D15 disclosed two sterilizing values F01 and F02, which could be considered as disinfection doses. D15 also defined two thresholds, F0min1 and F0min2, corresponding to the sterility of the liquid and of the sterility of the fluid path, respectively. An adequate sterilization of the fluid path could thus be considered to have been achieved if the calculated values of F01 and F02 were greater than these thresholds. The control unit simply "validated" that this criterion was met by checking that the temperature read was at least equal to a minimum threshold temperature T2 during an uninterrupted time period.

D15 did not disclose that F01 and F02 were calculated

and compared with F0min1 and F0min2 to decide when to stop the disinfection process. Rather, the minimum temperature which was needed to validate the disinfection process could only be determined after the disinfection process had ended.

Further, D15 failed to disclose that the steps disclosed in features 1.6.5, 1.6.6 and 1.6.7 were repeatedly performed until the achieved disinfection dose equalled or exceeded the set disinfection dose.

In the example described on page 28 of D15, the control unit only calculated a suitable treatment duration on the basis of the temperature measured by the sensor 67, but did not calculate an "achieved disinfection dose" in order to decide on this basis whether the treatment should be stopped.

Thus, the subject-matter of claim 1 of the main request was novel over D15.

Main request - inventive step starting from D1/D2

The combination of measuring the lowest temperatures and using them to calculate the achieved disinfection dose had the effect of guaranteeing that the entire fluid path had been properly disinfected. Furthermore, since the disinfection treatment was discontinued when the portion of the fluid path had reached its minimum disinfection dose, the disinfection procedure time was minimized. Since all measured temperatures (in a proper temperature range) were considered, the control unit took into account all temperature contribution in achieving the disinfection dose. This allowed to even more minimize the time to disinfect the fluid path of the dialysis apparatus.

An objective technical problem could be formulated as: "to provide a water system with enhanced disinfection procedure allowing to reduce energy consumption and at the same time increasing available time to treatment for the patients".

This technical problem was not addressed in D2. D2 was directed to provide a home dialysis machine that should allow for more frequent short dialysis treatments (page 8, lines 10-17). The issue of increasing the available time to treatment was not relevant at all. The person skilled in the art would not be motivated to change the working disinfection procedure as implemented in D2.

D2 failed to acknowledge that positioning a temperature sensor in the location experiencing the lowest temperature had any relevance. Further, there was no pointer or suggestion to calculate any disinfection dose, particularly based on the measured temperature. There was no indication or even a need to interrupt the disinfection early.

The standard disclosed in D11 suggested monitoring the lowest temperature in the pure water fluid distribution system. Even if the skilled person reverted to D11, at most they might place a sensor in the water preparation module.

D3, D7, D8, D10 and D23 dealt with steam or moist sterilization of items in a dish washer, rather than with disinfection of a fluid path. The person skilled in the art would not revert to any of D3, D7, D8, D10 or D23 to improve the apparatus of D2.

In D25, the A_0 method was used to change to another time/temperature-couple, but not to terminate the disinfection process when a set disinfection dose was achieved. Hence, the combination of D2 with D25 did not result in an apparatus according to claim 1.

The subject-matter of claim 1 of the main request was inventive over document D2.

The arguments as to inventive step made in respect of D2 also applied to document D1.

Main request - inventive step starting from D15

The comparison of the disinfection dose achieved with a set disinfection dose corresponding to complete disinfection of the fluid circuit had the technical effect of allowing the disinfection process to be terminated at the earliest possible time as soon as a sufficient disinfection dose had been delivered to the fluid circuit. This reduced energy consumption and time needed for the disinfection process.

The objective technical problem might be formulated as "how to provide a dialysis apparatus with improved, reliable and efficient disinfection process of the treatment fluid path".

The person skilled in the art would not be prompted to modify the teaching of D15 in the direction of reducing the time to sterilize the fluid path. D15 needed to sterilize both liquid and tubing, and sterility of the liquid to be injected into the patient was crucial. D15 set a high threshold of the sterilization and the person skilled in the art would not envisage reducing it by reducing the time to treatment.

D3 and D23 dealt with washer-disinfectors for the sterilisation of items (e.g. urine containers, scalpels and other medical items). The field was very far away from the dialysis field of the device according to D15. Both the apparatuses of D3 and D23 used steam/boiling water to sterilize the items. However, D15 (page 27, lines 1-11) indicated that boiling water in the fluid lines would hamper validation of the sterilization process. Therefore, the person skilled in the art was taught away from the combination with D3 or D23 that used steam to sterilize. Furthermore, D3 addressed the problem of avoiding damage of the items to be sterilized. The person skilled in the art would not revert to D3 to improve the apparatus of D15.

Inventive step starting from D26

D26 related to a dialysis system comprising both a purified water manufacturing apparatus 10 and a dialysis apparatus 20.

The system included a hot water circulation feature (e.g., lines 43 and 46) which allowed disinfection of the fluid paths within both the purified water production device and the dialysis apparatus. The control unit 17 of the system calculated in advance a treatment time for disinfection based on a temperature of the hot water in the tank 14. There was no temperature sensor located at a location of the fluid path (i.e. the dialysis fluid path of the patient monitoring device 24 or 25) which experienced the lowest or one of the lowest temperatures during thermal disinfection. Furthermore, there was no disclosure of a repeated calculation of an achieved disinfection dose based on the temperature read.

D26 failed to disclose at least features 1.5.1 and 1.6.4 to 1.6.7 of claim 1 of the main request.

As to feature 1.5.1, as in D26 the temperature reading was necessary only in advance of the disinfection process (to determine the preselected disinfection time), the person skilled in the art would not be prompted to locate the temperature sensor at a location of the fluid path where the lowest temperature during the disinfection process was experienced.

Other documents, such as D15, did not disclose the missing features identified above. Therefore, even a combination of D26 with any other document could not render the subject matter of claim 1 obvious. The subject-matter of claim 1 of the main request involved an inventive step.

Admittance of inventive step objection starting from D15 in combination with D25 as well as with D8

This objection had been raised for the first time during the oral proceedings before the Board. It represented an amendment of opponent 2's appeal case which, according to Article 13(2) EPC, required exceptional circumstances which had been justified with cogent reasons to be taken into account. As no such reasons had been put forward by opponent 2, this objection should not be admitted into the appeal proceedings.

VII. The arguments of opponent 1 can be summarized as follows.

Main request - added subject-matter

Feature 1.5.1 of claim 1 could not be derived directly and unambiguously from the parent application as originally filed.

The passage at page 11, lines 28 to 34, described the sensor location in a water treatment system and did not support feature 1.5.1 where a temperature sensor was located in the dialysis apparatus itself.

From the passages at page 18, lines 9 to 12, at page 18, lines 12 to 18, and at page 19, lines 6 to 14 it could not be derived that the temperature sensor could be located at any other location of the dialysis apparatus as long as it could be ensured that this was the location with the lowest temperature. The disclosed locations were rather specifically selected for the particular embodiment.

Hence, the subject-matter of claim 1 extended beyond the content of the parent application as filed, contrary to the requirements of Article 76(1) EPC.

Main request - sufficiency of disclosure

The patent did not disclose the placement of the temperature sensor according to feature 1.5.1 clearly and completely enough for the person skilled in the art to determine an achieved disinfection based on a read temperature, at least not over the entire scope of protection that was claimed.

The single embodiment described in paragraph [0052] did not address the possible variations in length, diameter, branching, and material of the fluid paths, as well as the rate and pattern of fluid flow as well

as the possible fluctuations of the temperatures over time, or the use of multiple heating elements or heat exchangers, nor did it provide guidance on adapting the temperature sensor's placement to different system configurations or disinfection protocols.

The claim language did not exclude a location of the temperature sensor upstream of the heating unit of Figure 4. However, the temperature measured at this location could not be used to calculate the achieved disinfection rate.

The requirement for the temperature sensor to be located at a location of the fluid path which experienced "the lowest, or one of the lowest, temperatures during thermal disinfection" introduced a significant ambiguity as the patent did not specify how many such points experiencing "one of the lowest" temperatures might exist within the system or how close to the "lowest" temperature these points had to be to remain within the scope of the claim.

Hence, the requirements of Article 83 EPC were not met.

Main request - novelty in view of D2

D2 disclosed all the features of claim 1 of the main request, in particular the feature "calculating an achieved disinfection dose based on the read temperature". In D2, the elapsed time at a temperature greater than 80°C was a quantity which depended directly on the measured temperature as disclosed in the paragraph bridging pages 77 and 78. The increase in elapsed time had to be regarded as an achieved disinfection dose. The target time of one hour constituted a set disinfection dose. The control unit

continuously compared the elapsed time with the target time until the target time was met or exceeded. Hence, D2 disclosed features 1.6.5 to 1.6.7 of claim 1.

D2 also disclosed feature 1.5.1 of claim 1. It was stated on page 39, lines 4 to 8, of D2 that thermistor 293 monitored the temperature of the fluid returning from the extracorporeal circuit during the hot water disinfection cycle. Hence, the thermistor was located at the end of the fluid path. While the exact flow pattern during the disinfection sequence in D2 might be unclear, there was no disclosure in D2 that during disinfection hot water moved from the venous to the arterial line. Hence, the thermistor 293 was inherently placed at a position which experienced the lowest temperature of the fluid path to be disinfected.

Thus, the subject-matter of claim 1 lacked novelty in view of D2.

Main request - novelty in view of D15

D15 described a dialysis apparatus with a temperature sensor 67 positioned at the end of the sterilised fluid path. Hence, it disclosed feature 1.5.1.

D2 further disclosed a disinfection process during which the achieved disinfection doses F01 and F02 were calculated and compared to the set disinfection doses F0min1 and F0min2, respectively. Although D15 disclosed the possibility of using preprogrammed sterilisation values, it also disclosed, in the paragraph bridging pages 25 and 26, a sterilisation involving a real time adjustment of the sterilisation parameters, including the duration of the steps, to ensure that the effective sterilisation dose was greater than the set dose

F0min2. Hence, D15 disclosed the feature of claim 1 that the control unit discontinued disinfection when the achieved dose equalled the set dose. The validation of the sterilisation process performed by the control unit based on the actual operating conditions was then performed in addition to the adjustment of the sterilisation parameters. Hence, D15 also disclosed features 1.6.5 to 1.6.7 of claim 1.

Thus, the subject-matter of claim 1 lacked novelty in view of D15.

Main request - inventive step starting from D2

If D2 did not disclose features 1.6.5 to 1.6.7, the subject-matter of claim 1 would lack inventive step.

The technical problem solved by claim 1 might be formulated as how to achieve a more precise measurement of the delivered disinfection dose.

When seeking to solve this technical problem, the person skilled in the art would be led to consult the standard ISO 15883 (D8) which taught the so-called A_0 method (Annex B and pages 59 to 60) which was the exact same A_0 method adopted in the detailed description of the patent in dispute. The integration of this method in D2 was not only technically feasible but also practically inevitable for enhancing disinfection precision in a dialysis apparatus, thus leading directly to the subject-matter of claim 1 without involving an inventive step.

Feature 1.5.1 was present in D8 as well (paragraph 5.1.2.6). Hence, if this feature was considered not to be disclosed in D2, the subject-matter of claim 1 still

would lack inventive step.

Main request - inventive step starting from D26

D26 disclosed all the features of claim 1, except for feature 1.5.1.

The technical effect of placing the temperature sensor at the lowest temperature point in the fluid path was to ensure that the entire fluid path to be disinfected received the temperature that was used for controlling the disinfection. The technical problem solved by claim 1 could therefore be formulated as "How to ensure adequate thermal disinfection of the entire fluid path".

To solve this problem the person skilled in the art would consult the standard set out in D11 and the guidelines referred to in D25. D11 taught that during disinfection the temperature of the water should be recorded at a point farthest from the water heater (paragraph 7.4.3.3). D25 indicated that the temperature sensors used to monitor the disinfection using the A0 method should be positioned at "the critical points of the circuit" (paragraphs 111-2.3.). Moving the sensor from the purified water tank to the end of the fluid path in D26 would be obvious for the person skilled in the art and did not require significant modifications to the existing system.

Therefore, the subject-matter of claim 1 did not involve an inventive step starting from D26.

VIII. The arguments of opponent 2 can be summarized as follows.

Admittance of the main request

The main request should not be admitted in the appeal proceedings as the patent proprietor could and should have filed this request during the opposition proceedings.

The new main request did not enhance procedural economy as it required a discussion on the question of novelty over document D2 which had not been addressed in the contested decision. This was in clear conflict with the main purpose of the appeal proceedings, which was to check whether the contested decision was correct or not. Therefore, the new main request introduced a fresh case.

Main request - added subject-matter

The passage on page 11, lines 30 to 35 related to a water treatment unit rather than a dialysis apparatus. Therefore, this passage could not provide original disclosure for feature 1.5.1. In the context of a dialysis apparatus, the parent application disclosed several specific embodiments each involving a specific location of the temperature sensor (page 18, lines 9 to 12; page 19, lines 11 to 14). The experienced temperature was mentioned in these passages only as a consequence of the disclosed specific positions of the sensor.

Furthermore, lines 12 to 18 on page 18 did not disclose that alternative locations of the temperature sensor in the fluid path were possible. This passage related to locations which did not experience the lowest temperature and were therefore not covered by claim 1.

Moreover, feature 1.5.1 was not disclosed in combination with feature 1.1 if the term "treatment fluid path" was regarded as limiting the fluid path with a need for disinfection to a specific fluid path of the dialysis machine.

Hence, claim 1 did not meet the requirements of Article 76(1) EPC.

Main request - sufficiency of disclosure

Feature 1.5.1 was not described in the patent in dispute in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

The invention was not sufficiently disclosed over the entire scope that was claimed. The patent only indicated a specific location of the temperature sensor for two specific, extremely simple fluid path configurations.

The patent did not take into account that real fluid paths exhibited a temperature variation and changing fluid flow rates during the disinfection process (as mentioned in D22, paragraphs [0019] and [0020]) which influenced the placement of the sensors. As described in document D4, the insulation properties of the various elements of the fluid paths would equally play a role regarding their temperature behaviour during disinfection.

The patent in dispute did not provide, for a realistic fluid flow path of a real dialysis machine as for example shown in D2, sufficient information as to the position of the temperature sensor as required by feature 1.5.1. A point farthest from the water heater

could not be identified in all cases as the point where the lowest temperature would occur.

Main request - novelty in view of D2

D2 related to a dialysis apparatus having a fluid path with a need for regular thermal disinfection.

During the disinfect sequence, the entire machine was disinfected with hot water at a high-level disinfection temperature for a sufficient period of time to disinfect the machine, for example at least one hour at 80°C (page 77, lines 13 to 15).

This elapsed time with a certain disinfection temperature was the basis of the A_0-method used in the embodiment of the patent in dispute (where the disinfection dose or total lethality was expressed as the equivalent time at a temperature of 80°C). The elapsed time since the temperature was at least 80°C had to be regarded at least as a minimum achieved disinfection dose. The accumulation of the time (as long as the thermistors reported temperatures greater than 80°C) had to be regarded as a repeated calculation of this minimum achieved disinfection dose. This accumulated time was then compared to the predetermined disinfection time of one hour, and the disinfection process was stopped once the one hour was exceeded. Such a calculation was further disclosed on page 74, lines 16 to 22, specifying that after a temporary power interruption the heat cycle might be merely continued or lengthened instead of being re-run. Continuation of the heat cycle necessarily required a calculation of the times elapsed before and after the power interruption and a summation of these times.

Hence, D2 disclosed features 1.6.5 to 1.6.7 of claim 1.

As to feature 1.5.1, lines 13 - 19 on page 77 of document D2 indicated that in the disinfect sequence, the entire machine including the water treatment module 24, the dialysate preparation module 26 and the extracorporeal circuit module 28 were disinfected with hot water.

Even though not specifically described in D2, it could be derived that thermistor 104 was placed close to the water outlet 111 within the water treatment circuit 24 (Figure 5). During disinfection of the dialysate preparation module the thermistor 424 was positioned at a position experiencing the lowest or one of the lowest temperatures within the fluid path, namely, between the dialyzer 404 and tank 202 (page 81, lines 13 to 15).

As indicated in lines 6 to 8 on page 39, thermistor 293 monitored the temperature of the fluid returning from the extracorporeal circuit during the hot water disinfection cycle. As mentioned in lines 3 to 8 on page 102 (in connection with lines 6 to 10 on page 70), during backfiltration, the flow of dialysate would be split in the dialyzer such that half of the dialysate would flow through the arterial line and the other half of the dialysate would flow in parallel through the venous line. According to the disclosure on page 103, lines 15 to 17, and page 82, lines 7 and 8, the hot water circulation steps corresponded to the rinse steps. Since during the rinse mode, the fluid would flow from the extracorporeal circuit via thermistor 293, valve V14 and valve V21 to the tank 202 (page 104, lines 11 to 13), the flow would be the same in the disinfection mode. Hence, the thermistor was inherently positioned at a position experiencing the lowest or at

least one of the lowest temperatures within the fluid path. Therefore, D2 also disclosed feature 1.5.1.

Consequently, the subject-matter of claim 1 lacked novelty in view of D2.

Main request - novelty in view of D1

D1 was a parallel patent document to D2 and contained the same disclosure regarding the constitution of the dialysis machine and the thermal disinfection thereof. However, D1 did not contain the specific disclosure with respect to the disinfect sequence (section A on pages 79 to 83 of D2).

As to feature 1.5.1, D1 indicated in paragraph [0075] that lines 236a and 236b provided fluid paths for disinfection water, such that the disinfection water could leave the extracorporeal circuit via thermistor 293 and valve V14. Further, the last sentence in this paragraph indicated that the thermistor 293 would monitor the temperature of the fluid returning from the extracorporeal circuit 400 during the hot water disinfection cycle. Hence, thermistor 293 was inherently placed with respect to the extracorporeal circuit at the position farthest from the heater and therefore at a position that would likely receive the lowest or one of the lowest temperatures during the corresponding disinfection cycle.

D1 also disclosed features 1.6.5 to 1.6.7, as it contained the same general disclosure regarding the control of disinfection as D2 (paragraphs [0031], [0055], [0097] and [0087]).

Hence, the subject-matter of claim 1 lacked novelty in

view of D1.

Main request - novelty in view of D15

D15 related to a device for sterilizing and dispensing a liquid for medical use, which could be used for peritoneal dialysis. The device comprised a main circuit (dialysate circuit) which had to be sterilized.

The control unit of D15 was configured to repeatedly read the temperature as measured by the temperature sensor 67 during the disinfection. The sensor 67 was arranged downstream of the main circuit to be sterilized (page 23, lines 3 to 8). Hence, feature 1.5.1 was disclosed in D15.

The control unit was further configured to repeatedly calculate an achieved disinfection dose F02 based on the read temperature and to compare the achieved disinfection dose with a threshold value F0min2.

As described in the paragraph bridging pages 25 to 26, in an alternative mode of operation, the flow rate of the pump and the heating supplied by the heating means might be adapted to each other, such that there was no preprogrammed temperature of the disinfection fluid for which the duration of the disinfection sequence could be set. Further, D15 explicitly described in the second paragraph on page 18 that in this operating mode, the control unit regularly adjusted the flow rate of the first pump 40 and/or the temperature of the heating liquid in order to ensure the sterility of the liquid flowing through the main circuit. Therefore, in D15, the temperature of the liquid would vary during the disinfection sequence.

The general teaching of D15 encompassed a continuous validation of the sterility of the liquid flowing through the main circuit (paragraph bridging pages 22 to 23). D15 further disclosed that the validation of the sterilization of the main circuit was performed in parallel to the validation of the sterilization of the liquid, and therefore continuously during the initial phase of sterilizing the device (paragraph bridging pages 23 and 24).

Hence, the only interpretation consistent with the disclosure of document D15 was that the control unit repeatedly calculated F02 based on the read temperature, compared it with the threshold F0min2, and discontinued the initial phase of sterilizing the device once the calculated value equalled or exceeded this threshold.

Consequently, D15 at least implicitly disclosed features 1.6.5 to 1.6.7 of claim 1.

Therefore, the subject-matter of claim 1 lacked novelty in view of D15.

Main request - inventive step starting from D2

Feature 1.5.1 did not synergistically interact with features 1.6.5 - 1.6.7, but solved a different, unrelated partial problem.

As to feature 1.5.1, D11, the relevant standard for disinfecting dialysis machines, taught that the temperature sensor for monitoring disinfection should be positioned at a position of the fluid path that experienced the lowest temperature during disinfection (page 22, section 7.4.3.3). Simply adding such a

requirement already recited in the relevant standard into the claim wording could not contribute to inventive step. Furthermore, D2 already indicated that the temperature during disinfection should be monitored by "strategically placed thermistors" (page 79, line 2), and therefore equally recognized the importance of the position of the thermistors.

As to features 1.6.5 to 1.6.7, the difference between a control based on elapsed time above 80°C as in D2, and a control based on the comparison between the achieved disinfection dose and the set disinfection dose (i.e. the A_0 method, as described in the present patent) only resided in the fact that the A_0 method would take into account that the real temperature would be slightly above 80°C in a control as in D2 rather than exactly at 80°C.

Hence, the object of the patent in dispute when starting from D2 would have been to minimize the disinfection time at any price and even at the expense of losing redundancy and safety.

When starting from this object, employing the A_0 method instead of elapsed time above 80°C in D2 would have been obvious, in particular since D2 already indicated that higher temperatures allowed shorter disinfection times, such that it was evident that the difference between the temperature threshold of 80°C and the real temperature meant that the disinfection time was at least slightly longer than absolutely required by the threshold.

Based on the object defined above, the person skilled in the art would naturally be looking for a method that quantified the disinfection effect achieved by

different disinfection temperatures, and would immediately find the A_0 method as one of the standard approaches to calculate disinfection dose as described in D3, D7, D8, D10, D15, D23 and D25.

D3 (page 3, 1st paragraph), D10 (paragraph [0070]) and D23 (paragraph [0017]) suggested to use the A_0 method to reduce energy consumption and disinfection time.

D7 (introduction, page 119) and D8 (pages 11 and 59) disclosed that the A_0 method was a general concept whenever disinfection was performed by moist heat.

D15 (paragraph bridging pages 18 and 19) and D25 (section III.2.3.3) provided another motivation to use a measure for the disinfection dose that summed over the cumulative disinfection effects during the process.

D2 showed that a value (accumulated time above the temperature threshold) was compared to a set value (disinfection time) and once the value reached the set disinfection time, disinfection was discontinued. Hence, the teaching of D2 did not have to be changed at all when implementing the assessment of the disinfection dose according to the A_0 method, because the accumulated time over 80°C as used in D2 only had to be replaced by the A_0 value, but otherwise exactly the same control logic as in D2 could be used.

Therefore, the subject-matter of claim 1 did not involve an inventive step in view of D2.

The same reasoning applied when starting from D1.

Main request - inventive step starting from D15

The problem to be solved by the distinguishing features 1.6.5 to 1.6.7 could be regarded as to reduce the time and energy needed for the sterilisation.

D15 contained a very strong hint towards an operation where the achieved disinfection dose was calculated by the formula mentioned in the paragraph bridging pages 18 and 19 based on the variable temperature until it exceeded the set disinfection dose, because this calculation and comparison was explicitly disclosed with respect to the validation. When using this formula, it was also evident that a control according to the main request was required, i.e. that the achieved disinfection calculated in this way was compared to the set disinfection dose and the disinfection stopped once the set disinfection had been achieved.

Hence, it was obvious for the person skilled in the art to modify the control unit of D15 to implement features 1.6.5 to 1.6.7.

Furthermore, starting from D15, a control unit having features 1.6.5 to 1.6.7 was rendered obvious by D3 disclosing that the summation of the individual lethality effects at different temperatures would help to reduce the sterilization time (page 3, 1st paragraph, and page 4, 1st paragraph).

The same teaching was disclosed in D8 (page 60, 6th paragraph), D10 (paragraph [0070]) and D23 (paragraph [0017]).

Thus, the subject-matter of claim 1 did not involve an inventive step in view of D15 alone as well as in combination with D3, D8, D10 or D23.

Inventive step starting from D26

D26 disclosed a dialysis apparatus having a fluid path with a need for regular thermal disinfection (Figure 1).

D26 used the temperature of the hot water for controlling the time required for the disinfection cycle. It was implicit that this temperature was repeatedly measured during the cycle and that the reference treatment time had to be continuously calculated due to temperature changes. The reference treatment time defined as a treatment time at a predetermined temperature of for example 80° C of D26 corresponded to a set disinfection dose. The thermal disinfection was controlled such that the hot water was circulated for this equivalent treatment time, and the disinfection was discontinued once the achieved disinfection dose equalled or exceeded the set disinfection dose (paragraphs [0050] and [0054]).

Hence, as features 1.6.4 and 1.6.7 were at least implicitly disclosed in D26, the subject-matter of claim 1 differed from the disclosure of D26 only in feature 1.5.1. In D26, the temperature sensor was arranged to sense the temperature of the water in the water tank of the heater.

The effect of feature 1.5.1 was to ensure that the entire fluid path to be disinfected received the temperature that was used for controlling the disinfection. The object of this feature when starting from D26 therefore would have been to ensure that the entire fluid path received at least the set disinfection dose.

To implement feature 1.5.1 in the apparatus of D26 was obvious for the person skilled in the art since it only defined the location of the temperature sensor recommended by the relevant standard for controlling thermal disinfection (D11, paragraphs 7.4.3.3 and B. 3.4.4).

Even if features 1.6.4 to 1.6.7 were not disclosed in D26, these features would not render the subject-matter of claim 1 inventive. These features would have the technical effect of allowing a more exact determination of the disinfection dose, thereby reducing the time required for disinfection. The implementation of features 1.6.4 to 1.6.7 in the apparatus of D26 would follow from a straightforward application of the general knowledge of the person skilled in the art with respect to thermal disinfection and the A_0 method, in particular in case of varying temperatures. Furthermore, D7 (page 119), D8 (pages 11, 59 and 60), D10 (paragraph [0070]) or D23 (paragraph [0017]), which related to the assessment of disinfection with varying temperatures and applications of the A_0 method, rendered the implementation of features 1.6.4 to 1.6.7 obvious.

Hence, the subject-matter of claim 1 lacked an inventive step in view of D26.

Reasons for the Decision

1. Subject-matter of the patent

The patent as granted relates to a medical equipment

(according to the new main request: a dialysis apparatus) with a fluid path which at least partly needs to be disinfected at regular intervals.

In thermal disinfection, hot water is made to flow (or circulate) through the fluid path to be disinfected for a certain time period. The desired disinfection dose depends on the temperature of the hot water and the time period of the disinfection process. In essence, the higher the temperature is above a certain threshold, the shorter the time necessary for a defined disinfection dose (see paragraphs [0023] to [0032] of the patent). The temperature is typically measured downstream of the fluid path to be disinfected at a location which experiences the lowest or one of the lowest temperatures during thermal disinfection. Thus, if the measured temperature at this location is high enough to achieve a certain (minimum) disinfection dose, it can be considered that this disinfection dose is also achieved in the remainder of the fluid path.

The apparatus of claim 1 (see Figure 4 of the patent) includes i.a. an inlet 428, an actuator (442, 430), a temperature sensor (450) and a control unit (460). The temperature sensor is "located at a location of the fluid path which experiences the lowest, or one of the lowest, temperatures during thermal disinfection". According to the description of the patent (paragraph [0052]), the temperature sensor is located in the vicinity of the outlet 429. The control unit is configured to receive and/or retrieve information representing a set disinfection dose and to start the disinfection by controlling the actuator to enable water to flow into the fluid path at the inlet 428. The water is either heated in the heating unit 410 (not part of the claimed subject-matter), or it has been

heated before entering the dialysis apparatus.

The control unit is further configured to read the temperature as measured by the temperature sensor 450, to calculate an achieved disinfection dose based on the read temperature. The disinfection doses are summed up to determine the achieved disinfection dose, which is then compared to the set disinfection dose. The disinfection is stopped as soon as the achieved disinfection dose equals or exceeds the set disinfection dose.

An achieved disinfection dose is a measure of the degree of disinfection achieved, i.e. of the overall lethality of the disinfection carried out. In accordance with the so-called A_0 concept, involved in particular in standard ISO 15883-1:2006 (paragraphs [0028] and [0054] of the patent; see also D8, Annex B in this respect), this dose is expressed as the equivalent exposure time at a specified temperature to achieve a given disinfection effect, for example by formula 1 of paragraph [0028]. As mentioned in paragraph [0029] of the patent, a certain disinfection dose can be achieved by 10 min at 80°C, by 1 min at 90°C or by 100 min at 70°C.

By stopping the disinfection as soon as a set disinfection dose has been achieved, time and energy can be saved (paragraph [0055] of the patent).

2. Admittance of the main request

2.1 The main request has been filed with the proprietor's statement of grounds. It thus constitutes an amendment and its admittance is subject to the Board's discretion (Article 12(4) RPBA).

2.2 Claim 1 of the main request corresponds to a combination of claims 1, 13 and 14 as granted. It differs from auxiliary request 1 before the opposition division in that claim 13 has been incorporated into claim 1. Rather than claiming a medical equipment, claim 1 is directed to a dialysis apparatus. The amendment is not a complex one.

2.3 The new main request supports an interpretation of claim 1 that would exclude a dishwasher. It was filed as a response to the opposition division's finding that the subject-matter of claim 1 of the patent as granted, and of the then auxiliary request 1, was not novel in view of D23, a document directed to thermal hygienic effects in dishwashers.

2.4 According to opponent 2 the main request introduced a fresh case, in particular as the non-existence of this request during the opposition proceedings meant that the opposition division had effectively been prevented from deciding on the issue of novelty in view of D2.

The Board does not agree. The arguments of the parties regarding novelty in view of D2 were exchanged during the opposition proceedings (at least with regard to the patent as granted). D2 is thus well-known to the parties. Furthermore, the amendment made to claim 1 mirrors the claim interpretation of the patent proprietor during the opposition proceedings according to which the claimed invention was not directed to a dishwasher.

2.5 The new main request addresses (and solves) the novelty issue in view of D23 and enhances procedural economy as the number of issues to be discussed is reduced

(compared to the former main request).

2.6 The main request is therefore admitted into the proceedings.

3. Main request - added subject-matter

3.1 The patent is based on a divisional application of the parent application WO 2014/082855.

Independent claim 1 of the patent differs from independent claim 5 of the parent application as originally filed inter alia in that feature 1.5.1 ("the temperature sensor is located at a location of the fluid path which experiences the lowest, or one of the lowest, temperatures during thermal disinfection") has been introduced in the claim. The opponents argued that this feature was not originally disclosed in combination with the dialysis apparatus and its fluid path (features 1.0 and 1.1).

3.2 It is true that the two embodiments of Figure 4 and of the first paragraph of page 19, both disclosing a dialysis apparatus, disclose the sensor located in specific positions. However, the person skilled in the art, taking into account its common general knowledge, understands that in the embodiment of Figure 4 (see page 19, lines 11-14) and in the alternative mentioned on page 18, lines 12 to 18, the temperature sensor is located at two respective locations which are merely exemplary for the general requirement that the sensor "normally" has to be located at the location with the lowest or one of the lowest temperatures (page 18, lines 11 to 12).

3.3 Furthermore, the passage on page 11, lines 27 to 32, mentioning the location with the lowest temperature as a preferred location of the temperature sensor, also provides support for feature 1.5.1 in a dialysis apparatus as claimed in claim 1. Although this passage relates to the embodiment of Figures 1 and 3, i.e. a water system 100 comprising a water treatment unit 110 through which water circulates during disinfection of the dialysis apparatus 130, 131 and 132, the person skilled in the art understands that, if the sensor is located in the dialysis apparatus itself as required by claim 1, the preferred location would still be the one with the lowest temperature.

3.4 Hence, feature 1.5.1 can be derived from the parent application as a general requirement of the location of the temperature sensor.

3.5 Contrary to opponent 2's view, the combination of feature 1.5.1 with feature 1.1 is disclosed in connection with the embodiment of Figure 4, irrespective of how the term "treatment fluid path" is interpreted.

3.6 Consequently, claim 1 of the main request meets the requirements of Article 76(1) EPC.

4. Main request - sufficiency of disclosure

4.1 The Board recognises that, as argued by the opponents, the fluid topology of the water system between the inlet and the outlet and the thermal properties of the various components of the system are not defined in claim 1. Moreover, the way in which the flow and heating of the water are controlled by the control unit, as well as the number and type of devices

connected to the fluid path, are not defined either. All these unspecified parameters will have an influence on the temperature profile in the fluid path.

4.2 Nevertheless, contrary to the opponents' view, using the guidance provided in the patent, common general knowledge and possibly routine testing, a person skilled in the art would be able, for a given dialysis apparatus falling within claim 1, to determine without undue burden the location of the sensor in the fluid path which experiences the lowest, or one of the lowest, temperatures during thermal disinfection as required by feature 1.5.1.

4.3 Indeed, the person skilled in the art would be aware that, in the absence of further heating and due to the inevitable heat losses, after leaving the heating unit or after entering the dialysis apparatus, the heated water will normally be at its lowest temperature after having travelled the longest path in the circuit. This is explicitly illustrated in the patent for two embodiments in which the heated water is either discharged into a drain (as in Figure 4) or reintroduced into the circuit to form a loop in which it circulates (as in the alternative embodiment mentioned in paragraph [0053]). In the first case, the patent explains that the water will be at its lowest temperature just before it is discharged into the drain (paragraph [0052] of the patent). In the second case, this location will be at the end of the circuit (paragraph [0053]), where the water is about to mix with the heated water from the heater or the inlet.

4.4 For more complex water systems covered by the claim, the person skilled in the art would have no difficulty, in particular on the basis of this general principle

and routine testing, in identifying a limited number of potential appropriate sensor locations which could then be tested without any undue burden.

4.5 As to the alleged ambiguity of the expression "one of the lowest" temperatures, this could at most be a lack of clarity, which is not a ground of opposition.

4.6 Hence, the invention as claimed in claim 1 of the main request is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

5. Main request - novelty in view of D2

5.1 In the dialysis apparatus disclosed in D2, disinfection is achieved by circulating hot water at a sufficiently high temperature through the fluid path to be disinfected for a sufficiently long time, e.g. "at least an hour at 80 degrees C" (page 77, lines 13 to 17). The temperature and circulation time are determined or selected in advance to ensure a high level of disinfection (page 78, line 18, to page 79, line 3).

In practice, the control unit starts the disinfection by initiating a disinfection cycle for one hour. During this period, the temperature of the circulating water is monitored, and if any of the temperature sensors located in the fluid system report a temperature below 80°C the water is heated further and the complete disinfection cycle is repeated; alternatively, thermal disinfection is aborted and an alarm is activated or a different chemical disinfection mode is entered (page 82, lines 2-14).

5.2 The opponents consider that the accumulated or elapsed time with a temperature above 80°C since the beginning of the disinfection process could be regarded as the achieved disinfection dose and that the target time of one hour was the set disinfection dose. The increase in elapsed time (i.e. the repeated calculation of the achieved disinfection dose) was "based on the read temperature" as the elapsed time was only increased when the temperature was above 80°C, and the elapsed time was repeatedly compared with the target time of one hour until it equalled the target time.

5.3 The Board does not share the opponents' view. The elapsed time of D2 is in no way related to the efficiency of the disinfection. In fact, each time the measured temperature falls below 80°C, the elapsed time is deleted, and any disinfection dose already achieved is disregarded. Then, the disinfection process is started again from the beginning. Hence, the measurement of the elapsed time in D2 is different from the A_0 method used in the embodiment of the patent in dispute. Indeed the elapsed time with a temperature above 80°C since the beginning of the disinfection process cannot represent the achieved disinfection dose based on the read temperature.

5.4 Furthermore, in D2, only the elapsed time at any temperature above 80°C is considered, without taking into account how much the temperature actually is above 80°C. It is noted that any higher temperature (e.g. 85°C) contributes in a significantly higher amount to the achieved disinfection dose. This effect is completely neglected in D2. Thus, if anything, the elapsed time could only represent a minimum disinfection dose, as acknowledged by opponent 2.

5.5 Hence, D2 does not disclose that the control unit is configured to repeatedly calculate an achieved disinfection dose based on the read temperature, and compare the achieved disinfection dose with the set disinfection dose until the achieved disinfection dose equals or exceeds the set disinfection dose, and then to discontinue the disinfection (features 1.6.5 to 1.6.7).

5.6 D2 also does not disclose a temperature sensor that is located at a location of the fluid path which experiences the lowest or one of the lowest temperatures during thermal disinfection.

There is no explicit disclosure of a temperature sensor located at such a location in D2, in particular for thermistors 104 and 424.

5.7 As pointed out by both opponents, it is mentioned on page 39, lines 4 to 8, that the thermistor 293 shown on Figure 6 monitors the temperature of the fluid returning from the extracorporeal circuit during the hot water disinfection cycle. However, the description of the disinfection sequence on pages 79 to 83 does not provide any details on how the hot water circulates through the extracorporeal circuit. In particular, there is no disclosure on where the hot water enters and where it leaves the extracorporeal circuit. Hence, contrary to the opponents' view, it cannot be derived directly and unambiguously from D2 that the thermistor 293 is inherently placed at a location of the fluid path which experiences the lowest or one of the lowest temperatures during disinfection. The same holds true for the thermistors 104 and 424.

5.8 D2 does not disclose features 1.5.1 and 1.6.5 to 1.6.7 of claim 1. The subject-matter of claim 1 is therefore novel in view of D2.

6. Main request - novelty in view of D1

6.1 D1 is part of the same patent family as D2, but contains less information than D2. Hence, the conclusions made in respect of D2 also apply to D1.

6.2 In particular, from the disclosure that thermistor 293 will monitor the temperature of the fluid returning from the extracorporeal circuit 400 during the hot water disinfection cycle (paragraph [0075]) it cannot be concluded that D1 directly and unambiguously discloses that the thermistor 293 is located at a position that would experience the lowest or one of the lowest temperatures during the disinfection cycle.

6.3 Opponent 2's argument concerning features 1.6.5 to 1.6.7 are also based on the assumption that the elapsed time at a disinfection temperature of more than 80°C can be considered the achieved disinfection dose. As detailed above, this is not convincing. Like D2, D1 rather fails to disclose features 1.6.5 to 1.6.7 of claim 1.

6.4 The subject-matter of claim 1 is therefore novel over document D1.

7. Main request - novelty in view of D15

7.1 D15 relates to a device for sterilizing and dispensing a liquid for medical use, which can be used for peritoneal dialysis (Figure 1). To ensure the sterility of the dispensed liquid, the system is configured to

first sterilise the fluid circuit with sterilised water in an initial sterilisation phase before producing sterilised medical liquid in a second standby production phase.

D15 discloses two "sterilizing values" F01 and F02 for characterising the sterilisation of the liquid and the circuit, respectively, achieved during the first and second phases. F01 and F02 are calculated from a measured temperature and then compared with a "set sterilizing value" or "threshold value" F0min1 and F0min2 (claims 2 and 26; page 17, penultimate paragraph; page 23, first full paragraph). These values can be regarded to represent achieved disinfection doses and set disinfection doses, respectively.

7.2 D15 does not disclose that the comparison of F01 and F02 with F0min1 and F0min2 would serve as a criterion for the control unit to discontinue the ongoing sterilisation as defined in feature 1.6.7. In D15, the sterilizing values F01 and F02 are the disinfection doses that are achieved after the sterilisation processes of the circuit and the liquid are terminated. These values are compared with the set sterilizing value to validate the sterilization, i.e. to classify the sterilization as adequate. This validation process can be performed at regular intervals, as pointed out by opponent 2. However, the values F01 and F02 are not used as a trigger to stop the disinfection process once the thresholds F0min1 and F0min2 are reached.

7.3 Both opponents referred to the paragraph bridging pages 25 and 26 relating to adjusting the sterilisation parameters to ensure that the effective sterilisation dose was greater than the set dose. Opponent 2 further referred to the second paragraph on page 18 of D15,

mentioning that operating parameters such as the flow rate may be varied during the sterilisation process of the liquid, and that the other parameters relevant for the sterilizing value, e.g. the temperature of the heating fluid, have to be adjusted accordingly, such that the calculated value of the sterilizing value is always greater than the set value.

However, also in connection with varying operation parameters, D15 is silent on using the comparison between F0l and F0minl to discontinue the sterilisation of the liquid. This is consistent with the fact that the liquid must be continuously sterilised during all operating phases of the device as stated in the paragraph bridging pages 22 and 23. In such a permanent state, there is indeed no need to discontinue the sterilisation of the liquid. Therefore, this disclosure does not anticipate feature 1.6.7.

7.4 The subject-matter of claim 1 is novel, as D15 does not disclose feature 1.6.7.

8. Main request - inventive step starting from D2/D1

8.1 Opponent 1 considered the objective technical problem solved by the distinguishing features 1.6.5 to 1.6.7 concerning the control unit to be how to achieve a more precise/exact measurement of the disinfection dose.

8.2 However, D2 does not disclose any measurement of the achieved disinfection dose at any time of the process. Hence, the objective technical problem cannot relate to determining a more exact value of this disinfection dose as it would comprise a pointer to the claimed solution.

8.3 The distinguishing features rather solve the objective technical problem of reducing time and energy consumption of the disinfection process while increasing available time for treatment of the patients, as acknowledged by opponent 2.

8.4 However, contrary to opponent 2's view, the person skilled in the art would not be prompted to replace the accumulated time with the disinfection dose or A_0 value. D2 discloses a working sterilisation system for the apparatus which is used at home and only by one patient. After the disinfect sequence has been performed, the apparatus is left in the idle state until the next dialysis session begins (page 78, lines 8 to 10). Hence, time constraints are not relevant in the sterilisation process of D2.

As correctly acknowledged by opponent 2, the calculation of the achieved disinfection dose based on the measured temperature allows to take into account that, during the disinfection process, the real temperature of the water in D2 is not exactly at 80°C but above that value. The temperature interval between the minimum temperature of 80°C and the real temperature contributes to the disinfection dose and allows to reduce the time needed to achieve the set disinfection dose. D2 mentions that a higher minimum temperature allows to set a shorter disinfection time (page 78, line 22). However, D2 does not teach or suggest to take the contribution of temperatures above the minimum value into account and to use this contribution to reduce the disinfection time.

8.5 Contrary to opponent 2's view, the person skilled in the art would not be prompted by any of D3, D7, D8, D10, D15, D23 or D25 to implement the A_0 concept in the

apparatus of D2.

In D3, D7, D8, D10 and D23 the purpose of the use of the A_0 concept is to reduce the disinfection time to avoid damage of the items to be treated, in particular during steam disinfection of items in a dishwasher.

Although D15 mentions that the sterilizing value can be determined as a sum of cumulative sterilizing effects during a sterilizing treatment (paragraph bridging pages 18 and 19), it explicitly teaches away from using the canonical formula on page 19 in a sterilization process of liquid which is flowing in a flow path (page 19, second paragraph). Hence, contrary to opponent 2's view, this disclosure does not prompt the person skilled in the art to modify the control unit of D2.

D25 proposes to use the A_0 concept as described in D8 to change to another disinfection time/temperature couple rather than to terminate the disinfection process as soon as a set disinfection dose has been reached.

8.6 Hence, already the distinguishing features 1.6.5 to 1.6.7 provide for an inventive step when starting from D2.

8.7 The same conclusions apply to the inventive step objection starting from D1.

9. Main request - inventive step starting from D15

9.1 According to opponent 2, the person skilled in the art, faced with the technical problem of reducing the disinfection time and in view of their common general knowledge, would obviously have modified the control

unit of D15 so as to discontinue the ongoing sterilisation based on the comparison of the values F01 and F02 with the set values F0min1 and F0min2.

9.2 The Board does not share this view. In fact, reducing the time to sterilize the fluid path does not matter in D15. Therefore, the person skilled in the art would not be prompted to modify the apparatus of D15. Even if the person skilled in the art sought, in view of their common general knowledge, to shorten the initial sterilisation treatment in D15 they would not have used the achieved disinfection dose as a trigger to stop the sterilisation. They would rather have programmed the control unit to select the duration of the sterilisation so as to obtain calculated values of F02 as close as possible to the set value F0min2 and not just "greater than" this value. However, this modification would not have led the person skilled in the art to the subject-matter of claim 1.

9.3 Nor would the prior art D3, D8, D10 or D23 have led the person skilled in the art starting from D15 towards the claimed solution. As mentioned above, D15 mentions that the sterilizing value can be determined as a sum of cumulative sterilizing effects during a sterilizing treatment (paragraph bridging pages 18 and 19). However, as mentioned in the second paragraph on page 19, the control unit of D15 does not use the canonical formula, but rather teaches away from applying it to the sterilisation treatment of liquid in a fluid path.

9.4 Hence, the person skilled in the art would not be prompted by any of D3, D8, D10 or D23 to implement the A_0 concept in the apparatus of D15.

This is all the more true given that in D3, D8, D10 and

D23 the purpose of the use of the A_0 concept is to reduce the disinfection time to avoid damage of the items to be treated, in particular during steam disinfection of items in a dishwasher.

9.5 Thus, the subject-matter of claim 1 involves an inventive step in view of D15.

9.6 Admittance of the objection based on a combination with D25 and D8

During the oral proceedings before the Board opponent 2 raised for the first time an objection of lack of inventive step starting from D15 in combination with D25 and D8.

With reference to Article 13(2) RPBA the patent proprietor requested that this objection not be admitted into the appeal proceedings. According to this Article, any amendment to a party's appeal case will, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

Opponent 2 did not put forward any exceptional circumstances that would justify the late submission of the new objection.

The objection is therefore not admitted into the proceedings.

10. Main request - inventive step starting from D26

10.1 D26 relates to a dialysis system comprising a purified water manufacturing apparatus 10 that is responsible for producing the purified water required for a

dialysis apparatus 20 (Figure 1). Both the purified water manufacturing apparatus 10 and the dialysis apparatus 20 can be disinfected by hot water treatment (paragraphs [0049] and [0054]).

10.2 D26 does not disclose features 1.6.4 to 1.6.7. As can be derived from paragraph [0050], the calculation of the disinfection time is done in advance of the hot water treatment and is based on the water temperature in the water tank, i.e. the higher the temperature is, the lower the necessary disinfection time can be. Hence, D26 does not disclose that the temperature of the hot water is measured and the achieved disinfection dose is calculated repeatedly during the disinfection process and that the disinfection process is stopped once the achieved disinfection dose equals or exceeds a set disinfection dose.

10.3 Furthermore, as agreed by both opponents, in D26 the temperature sensor is not located at a location of the fluid path which experiences the lowest temperature or one of the lowest temperatures. It is arranged to sense the temperature of the water in the water tank of the heater (paragraph [0017]).

10.4 These distinguishing features render the subject-matter of claim 1 inventive. They allow to achieve a complete disinfection in a shorter time, as the disinfection is stopped as soon as a sufficient disinfection dose has been delivered to the fluid path.

10.5 Opponent 2 argued that the implementation of features 1.6.4 to 1.6.7 would be obvious for the person skilled in the art.

These features would have the technical effect of

allowing a more exact determination of the disinfection dose, thereby reducing the time required for disinfection. The implementation of features 1.6.4 to 1.6.7 in the apparatus of D26 would follow from a straightforward application of the general knowledge of the person skilled in the art with respect to thermal disinfection and the A_0 method, in particular in case of varying temperatures.

10.6 However, without the benefit of hindsight, the person skilled in the art would have had no motivation to implement these features in D26. D26 does not teach to calculate any achieved disinfection dose during the disinfection process. In D26, the temperature is only measured in advance to determine the equivalent disinfection time from the reference time on the basis of the A_0 concept. The aim is to maintain the same dose of disinfection applied with the reference time at the reference temperature of 80°C (paragraph [0050]). The disinfection process is then carried out until the calculated disinfection time has elapsed. Hence, the issue of varying temperatures of the water in the water tank is already addressed by adjusting the necessary disinfection time. In order to reduce the disinfection time, the person skilled in the art, when starting from D26, would rather increase the temperature of the water.

10.7 As to the proposed combination of document D26 with any of documents D7, D8, D10 and D23, arguments identical to those brought forward with regard to the combination of documents D2 or D15 and the same secondary references apply.

10.8 Furthermore, contrary to opponent 1's and opponent 2's view, even considering the common general knowledge as exemplified by D11 and D25, it is not obvious to locate the temperature sensor at a location of the fluid path where the lowest temperature is experienced. In D26, it is essential to measure the actual temperature of the hot water to be used for the disinfection in advance in order to determine the equivalent disinfection time. Thus, the person skilled in the art would not move the temperature sensor from the purified water tank to the end of the fluid path to be disinfected.

10.9 Hence, the subject-matter of claim 1 does not lack an inventive step starting from D26.

11. Conclusion

None of the grounds of opposition prejudices the maintenance of the patent according to the main request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent with the following claims and a description to be adapted thereto:

Claims 1-13 of the main request filed with the patent proprietor's statement of grounds of appeal.

The Registrar: The Chairman:

G. Magouliotis M. Alvazzi Delfrate

Decision electronically authenticated