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Datasheet for the decision of 7 May 2024

Case Number: T 1590/21 - 3.2.02

Application Number: 13794846.9

Publication Number: 2925383

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

Language of the proceedings: EN

Title of invention:
SYSTEMS, APPARATUS, EQUIPMENT WITH THERMAL DISINFECTION AND THERMAL DISINFECTION METHODS

Patent Proprietor:
Gambro Lundia AB

Opponent:
Bauer, Clemens

Relevant legal provisions:
EPC Art. 54, 56, 83, 123(2)
RPBA 2020 Art. 12(6), 13(1), 13(2)

Keyword:

Amendments - added subject-matter (no)
Sufficiency of disclosure - (yes)
Late-filed evidence - should have been submitted in first-instance proceedings (yes) - admitted (no)
Novelty - (yes)
Inventive step - (yes)
Amendment after summons - exceptional circumstances (no) - taken into account (no)

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Case Number: T 1590/21 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 7 May 2024

Appellant: (Patent Proprietor)	Gambro Lundia AB P.O. Box 10101 220 10 Lund (SE)
Representative:	Ponzellini, Gian-Marco PGA S.p.A., Milano Succursale di Lugano Via Castagnola 21C 6900 Lugano (CH)
Appellant: (Opponent)	Bauer, Clemens Schlehbuschstr. 28 80997 München (DE)
Representative:	Müller Schupfner & Partner Patent- und Rechtsanwaltspartnerschaft mbB (Muc) Bavariaring 11 80336 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 July 2021 concerning maintenance of the European Patent No. 2925383 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. Both the opponent and the patent proprietor appealed against the opposition division's interlocutory decision finding that the contested patent as amended in accordance with auxiliary request 1 filed during the oral proceedings before the opposition division met the requirements of the EPC.

II. In its decision, the opposition division held, *inter alia*, that the invention of the patent as granted was sufficiently disclosed and that the subject-matter of claims 1 and 12 as granted did not contain added subject-matter and was novel in view of documents D2 and D8, but not in view of document D16.

D2, D8 and D16 are the following documents:

D2 WO 96/25214 A1
D8 "*Washer-disinfectors, Part 1: General requirements, terms and definitions and tests*" (ISO 15883-1:2006), BSI 2009
D16 AU 768 128 B2 (the page numbers given below for D16 are those of the page headings)

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

IV. The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, as an auxiliary measure, that the patent be maintained as amended on the basis of one of the first to third auxiliary requests filed with the proprietor's statement of grounds of appeal, auxiliary request 1 underlying the decision under

appeal, or one of the fourth to sixth auxiliary requests filed with the proprietor's letter of 19 April 2022.

V. Oral proceedings were held before the Board on 7 May 2024, at the end of which the present decision was announced.

VI. Claims 1 and 12 as granted (hereinafter "claim 1" and "claim 12") read as follows (feature numbering as used in the decision under appeal, and amendments to claims 1 and 10 as originally filed, respectively, highlighted by the Board):

Claim 1:

1.0 "*A Water System for providing water to at least one connected device through a fluid path and being able to disinfect the fluid path by means of thermal disinfection, the Water System comprising:*

1.1 *an inlet (111, 301) for receiving water to the Water System;*

1.2 *a heating unit (115, 325) configured to heat water within the Water System;*

1.3 *a filter unit (122, 314) configured to filter water within the Water System in order to provide filtered water to an outlet (112, 302);*

1.4 *an actuator (117, 122, 324, 333) configured to control the flow of the water from the heating unit to the outlet;*

1.5 *a fluid path (121) connected to the outlet, the fluid path comprising at least one connector (150, 151, 152) configured to connect to at least one device to which water is provided by the Water System;*

1.6 *a temperature sensor (118, 358) located at the fluid path and configured to measure the temperature of a fluid in the fluid path;*

1.7 *a control unit (119, 329) connected to the heating unit, the actuator and the temperature sensor,*

1.7.1 *the control unit being configured to control the flow of water by means of the actuator,*

1.7.2 *to control the heating of water by the heating unit, and*

1.7.3 *to read the temperature as measured by the temperature sensor;*
~~*characterized in that*~~

1.7.4 *the control unit is configured to start the disinfection of the fluid path by controlling the heating unit to heat water and*

1.7.5 *controlling the actuator to enable heated water to flow to the outlet and further into the fluid path; and*

1.6.1 *wherein the temperature sensor (118, 358) is located at a location of the fluid path which experiences the lowest, or one of the lowest, temperatures during thermal disinfection or in the proximity thereof; and*

1.7.6 *the control unit is configured to read the temperature as measured by the temperature sensor during the disinfection, and*

1.7.7 *to calculate an achieved disinfection dose based on the read temperature, and*

1.7.8 *to compare the achieved disinfection dose with information representing a set disinfection dose, and*

1.7.9 *to discontinue the disinfection if the achieved disinfection dose equals or exceeds the set disinfection dose.*"

Claim 12:

12.0 "*A method for performing thermal disinfection of a fluid path, the method comprising the steps of:*

12.1 *i) receiving at an inlet a fluid to be used during disinfection of the fluid path to be disinfected;*

12.2 *ii) heating the fluid received from the inlet;*

12.3 *iii) setting a disinfection dose;*

12.4 *iv) starting the thermal disinfection by controlling an actuator thereby enable heated fluid from the heating unit to flow into the fluid path to be disinfected;*

12.5 *v) measuring the temperature of the fluid in the fluid path at a location of the fluid path which experiences the lowest, or one of the lowest, temperatures during thermal disinfection or in the proximity thereof;*

12.6 *vi) calculating an achieved disinfection dose based on the measured temperature;*

12.7 *vii) comparing the achieved disinfection dose with the set disinfection dose; and*

12.8 *viii) discontinuing the disinfection if the achieved disinfection dose equals or exceeds the set disinfection dose.*"

VII. Reference is also made to the following documents:

D3 DE 29 34 167 A1

D17 R. F. Bliem and W. G. Nowak, "*Assessment of the Inaccuracy Inherent in the F_0 and A_0 Concepts of Microbial Inactivation*" including "*Part 1: F_0 concept*", Die Pharmazeutische Industrie 67(7):

819-822 (2005) and "*Part 2: A_0 concept*", Die Pharmazeutische Industrie 67(8):966-968 (2005)

D18 "*Bonnes pratiques d'hygiène en hémodialyse*", Hygiènes, Revue Officielle de la Société Française d'Hygiène Hospitalière, volume XIII, No. 2 (2005)

D19 EP 1 824 373 B1

D19' US 2009/0183753 A1

VIII. The opponent's arguments, where relevant to the present decision, can be summarised as follows:

Added subject-matter

Both claims 1 and 12 contained added subject-matter. By defining that the temperature sensor was located at a location of the "fluid path" which experienced the lowest, or one of the lowest, temperatures and not at a corresponding location of the broader "fluid system" as disclosed on page 11, lines 30-32 of the original description, features 1.6.1 and 12.5 introduced a limitation which was not supported by the application as originally filed.

Sufficiency of disclosure

The invention as claimed in the patent as granted was insufficiently disclosed. For the majority of water systems covered by the patent, a person skilled in the art would not be able to determine without undue burden the location of the fluid path that experienced the lowest, or one of the lowest, temperatures during thermal disinfection as required by features 1.6.1 and 12.5. The water systems might indeed have complex topologies and unspecified thermal properties, and might involve complex disinfection programmes. In

addition, the number of devices connected, which was not specified in the claims, had an important and unpredictable influence on where the lowest temperature in the fluid path occurred.

Admittance of D19 and D19'

D19 and its English equivalent D19' should be admitted because they were *prima facie* novelty-destroying for claims 1 and 12 (see in particular paragraph [0046]). The opponent had not been aware of these documents until D19 was cited by a third party acting as an opponent in opposition proceedings relating to a patent of the same family as the patent in suit. The opponent then filed them as soon as their high relevance in the present case became apparent. These documents could not surprise the proprietor, because it had been involved in the other opposition proceedings and was therefore also aware of the existence of D19.

Novelty in view of D2, D8 and D16

The subject-matter of claims 1 and 12 was not novel in view of D2, D8 and D16. All these documents disclosed, *inter alia*, features 1.7.7 to 1.7.9 and 12.6 to 12.8.

In the system of D2, the ongoing disinfection was stopped after a predetermined period of time, one hour, had elapsed without the temperature sensors having reported a temperature below a minimum threshold temperature, 80°C, during that period of time (page 77, lines 11-17). This necessarily involved calculating the time that had elapsed since the sensors had last measured a temperature below 80°C and comparing it with the set duration of one hour. This elapsed time amounted to an achieved disinfection dose. Moreover, it

was calculated based on the measured temperature since the process of accumulating time by adding each second that the temperature remained above 80°C to the elapsed time was an arithmetic operation, and the measured temperature dictated whether this accumulation should continue.

The instructions and methods disclosed in D8 were not limited to test scenarios but included methods for controlling the operation of a washer-disinfector. These methods involved the term A_0 (see Annex B), which was an achieved disinfection dose calculated based on the measured temperature. In addition, the claim language also covered a validation method where the functionality of the control unit to calculate an achieved disinfection dose and compare it with a set disinfection dose was used to verify that the system met predefined criteria under test conditions, as it would control the disinfection process during normal operation.

The "sterilizing values" F01 and F02 disclosed in D16 for characterising the sterilisation of the liquid and the circuit, respectively, represented achieved disinfection doses which were explicitly calculated by the control unit based on the measured temperature and then compared with respective threshold values F0min1 and F0min2 (claims 2 and 26).

In order to ensure adequate sterilisation of the circuit and the liquid, D16 disclosed that, *inter alia*, the duration of the sterilisation could be "adjusted" by the control unit - which necessarily involved discontinuing the sterilisation at a suitable point, determined by the control unit - so as to give achieved values F01 and F02 greater than F0min1 and

F0min2 (paragraph bridging pages 25 and 26). This involved calculating the expected outcome of the sterilisation process, i.e. the achieved F01 and F02, in real time before the ongoing process ended, and using this calculation to set the operational parameters, including when to end the process.

In fact, the claim language did not require the steps of calculating, comparing and discontinuing to occur simultaneously with or as part of the active control of the disinfection process. Thus it did not preclude a control strategy that used predictive calculations to determine the duration of the process upfront, before the start of the disinfection. Nor did it exclude that these steps were merely part of a separate validation of the disinfection, regardless of when they were executed in the process timeline.

Furthermore, as detailed in point III.2.3 on page 6 of the opponent's reply, adjusting the flow rate to ensure that F01 remained greater than F0min1 amounted, in view of the mathematical formulae on page 19 of D16, to discontinuing the sterilisation treatment applied to an infinitesimal volume of fluid as soon as F01 had reached or exceeded F0min1.

Inventive step starting from D16

If features 1.7.7-1.7.9 and 12.5-12.8 were to be interpreted as defining real-time control of the disinfection in which the moment of termination was determined on the fly, and were to be considered as undisclosed in D16, these features would in any event not render the subject-matter of claims 1 and 12 inventive over this document.

Prompted by the common general knowledge - e.g. as reflected in D3, which emphasised the need to stop sterilisation once the desired lethal effect had been achieved (paragraphs [0006] and [0009]) - the person skilled in the art would obviously have sought to minimise the duration of the sterilisation in D16. To this end, it would have been obvious to use as the criterion for stopping the sterilisation the same criterion as that checked by the validation means, namely whether the achieved disinfection dose F0 had reached or exceeded the minimum acceptable threshold F0min. Since the temperature in D16 was already measured in real time during the sterilisation, this would have required only a minor and obvious modification of the control logic within the control unit. The person skilled in the art would therefore have arrived at the subject-matter of claims 1 and 12 without an inventive step.

Inventive step starting from D2

The subject-matter of claims 1 and 12 also lacked an inventive step starting from D2. Indeed, the person skilled in the art starting from this document and seeking to shorten the disinfection time and reduce energy consumption during the disinfection process would naturally have consulted D18, which suggested applying the A_0 concept to the thermal disinfection of hydraulic circuits of dialysis machines (first sentence of second full paragraph of column 2 of page 120), referring in this respect to the EN ISO 15883 standard described in D8. By implementing this concept in the system of D2 as explained in D8 (sections B.2 and B.3 of Annex B), the person skilled in the art would have arrived at the subject-matter of claims 1 and 12 without an inventive step.

In its letter of 19 March 2024 (see point III), the opponent raised another inventive-step objection to claims 1 and 12 starting from D2, arguing that it would have been a straightforward and logical progression for the person skilled in the art starting from this document to consider quantifying the disinfection efficacy in terms of dose. Indeed, the concept of calculating a disinfection dose based on the temperature was well known in the art. In particular, D17 suggested adopting the A_0 concept for the hydraulic circuit of dialysis machines, i.e. the A_0 concept described in D8. Based on that teaching, the person skilled in the art would obviously have implemented a real-time control method based on that concept within the water system of D2. The opponent, which did not dispute that this objection was an amendment of its appeal case, did not give any reason why it had not been raised earlier.

IX. The proprietor's arguments, where relevant to the present decision, can be summarised as follows:

Added subject-matter

Claims 1 and 12 did not contain added subject-matter. Features 1.6.1 and 12.5 were supported by the original disclosure because the person skilled in the art would have understood that the terms "fluid system" and "fluid path" were used interchangeably in the original application.

Sufficiency of disclosure

The invention was sufficiently disclosed. A person skilled in the art using the guidance provided in the

description, common general knowledge and possibly routine testing would be able to determine without undue burden the location of the fluid path which experienced the lowest, or one of the lowest, temperatures during the thermal disinfection.

Admittance of D19 and D19'

D19 and D19' should not be admitted under Article 13(1) RPBA. The opponent had not provided any acceptable reasons for submitting these documents so late. Moreover, admitting them would be contrary to the principle of procedural economy, and in any event these documents were not *prima facie* relevant.

Novelty in view of D2, D8 and D16

The subject-matter of claims 1 and 12 was novel in view of D2, D8 and D16, all of which failed to disclose at least some of features 1.7.7-1.7.9 and 12.5-12.8.

In the system of D2, temperature was simply measured but was never used to calculate an achieved disinfection dose based on the measured temperature and to stop the disinfection depending on the comparison of this achieved disinfection dose with a set disinfection dose.

D8 was part of an ISO standard which specified general performance requirements for washer-disinfectors used to disinfect medical devices. D8 did not disclose a method for operating a washer-disinfector, but at most a method for testing its compliance with the standard. Conducting such a test might involve calculating an achieved disinfection dose and comparing it with an expected minimum set dose, but only to check whether

the requirements of the standard were met and the test was passed or not. D8 did not disclose that disinfection was stopped whenever the achieved disinfection dose equalled or exceeded the set dose, as required by features 1.7.9 and 12.8.

D16 only disclosed specific measures to "validate" the sterilisation treatments carried out in the different phases of functioning of the device. Even assuming that the disclosed "sterilizing values" were actually calculated, this was only to check, in particular retrospectively, whether a minimum acceptable value had been exceeded, and not to stop the sterilisation process once this minimum value had been reached. D16 instead disclosed that the duration of the preliminary sterilisation phase and the temperature of the heated water were selected in advance so as to achieve at least the minimum acceptable "sterilizing value". Therefore D16 did not disclose at least features 1.7.9 and 12.8.

Inventive step starting from D2 or D16

The subject-matter of claims 1 and 12 involved an inventive step starting from either D2 or D16. Indeed, the reduction of the duration of the disinfection, and thus the increase of the time available for treating the patients, allowed by features 1.7.9 and 12.8 was irrelevant for the dialysis machines of D2 and D16, which were intended for use in a home environment where there was plenty of time to disinfect the machine without adverse effects and where the quality of the disinfection was much more important than its duration. Starting from D2 or D16, there was therefore no motivation for the person skilled in the art to reduce the duration of the disinfection.

Moreover, even if they had wanted to do so, they would simply have programmed a shorter predefined duration of the sterilisation using, accordingly, a higher temperature of the sterilisation liquid to achieve the same quality of sterilisation.

The new inventive-step objection raised in the opponent's letter of 19 March 2024 was an amendment of its appeal case and should not be admitted under Article 13(2) RPBA.

Reasons for the Decision

1. Subject-matter of the contested patent

1.1 The contested patent relates to a water system for supplying filtered water through a fluid path to a device such as a dialysis machine, the water system being capable of disinfecting the fluid path by means of thermal disinfection. The patent also relates to a method of performing thermal disinfection of a fluid path. The system and method are defined in independent claims 1 and 12.

1.2 An embodiment of the claimed system (100) is shown in Figure 1, reproduced hereinafter. It comprises an inlet (111) for receiving water, a heating unit (115) for heating the water, a filter unit (114) for filtering the water, an actuator, such as a pump (122), for controlling the flow of the water from the heating unit to an outlet (112), and a fluid path (121) for conveying the heated water from the outlet to one or more connected devices, such as a plurality of dialysis apparatuses (130-132).

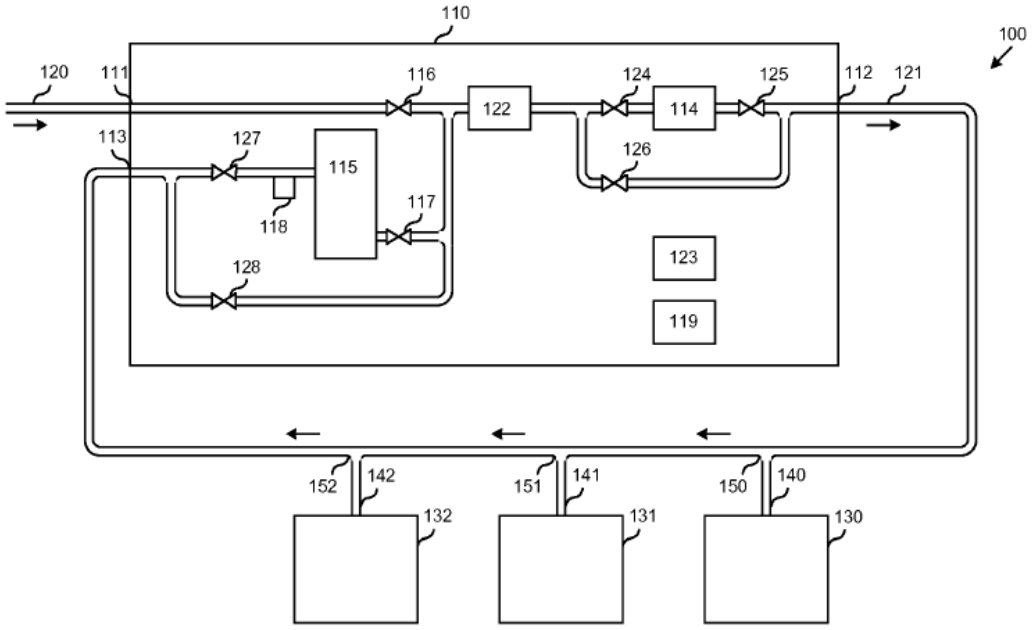

Fig 1

The claimed system further comprises a temperature sensor (118) located at a location of the fluid path which experiences the lowest, or one of the lowest, temperatures during thermal disinfection or in the proximity thereof (paragraph [0036]), and a control unit (119) for controlling the pump and various valves (122-128) also comprised in the system.

The control unit is configured to calculate an achieved disinfection dose based on the temperature measured by the temperature sensor, compare the achieved disinfection dose with a set disinfection dose, and discontinue the disinfection if the achieved disinfection dose equals or exceeds the set disinfection dose (features 1.7.7 to 1.7.9).

An achieved disinfection dose is a measure of the degree of disinfection achieved, i.e. of the overall lethality of the disinfection carried out (paragraphs

[0029] and [0030]). In accordance with the so-called A_0 method, involved in particular in standard ISO 15883-1:2009 (paragraph [0029]; 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 the formula of paragraph [0030].

This way of controlling the system prevents an unnecessary waste of energy and terminates the disinfection process more quickly, thereby reducing the time during which patients cannot be treated due to the disinfection process taking place (paragraphs [0018] and [0038]).

1.3 The method defined in claim 12 comprises substantially corresponding steps.

2. Added subject-matter

2.1 It is common ground that claims 1 and 12 are based on claims 1 and 10 as originally filed, respectively, with the additional feature that 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, or in the proximity thereof (features 1.6.1 and 12.5).

2.2 The opponent objected that this additional feature was not disclosed in the application as filed, with the original description instead disclosing on page 11, lines 30-32 that the temperature sensor 118 was located at a corresponding location of the "fluid system" and was configured to measure the temperature of the water in the "fluid system". According to the opponent, the "fluid system" was broader than and included the

claimed "fluid path", which was limited to the pipe loop arrangement 121 in the embodiments described (page 9, lines 8-12). It followed that claims 1 and 12 contained a limitation on the optimal location of the sensor which extended beyond the content of the application as filed, and thus infringed Article 123(2) EPC.

2.3 The Board disagrees. The application as filed as a whole generally relates to a system and a method aiming at disinfecting a "fluid path" by means of thermal disinfection. To this end, both the original description (see, for example, the "Summary" section on pages 3 and 4) and the original claim 1 consistently disclose a temperature sensor "located at the fluid path" and configured to measure the temperature of the fluid "in the fluid path". Disinfection of the fluid path is then monitored and controlled on the basis of this temperature measured in the fluid path.

Reading in this context the passage cited by the opponent, which does indeed refer to the "fluid system" but undisputedly refers to an embodiment in accordance with the invention, the person skilled in the art would understand that the terms "fluid system" and "fluid path" are used interchangeably, as argued by the proprietor. Indeed, the person skilled in the art would recognise that it is the lowest temperature of the fluid in the fluid path to be disinfected that is relevant for monitoring and controlling the disinfection of the fluid path, and not the lowest temperature elsewhere.

As also argued by the proprietor, this understanding is further supported by the description of the other embodiment shown in Figure 4, according to which the

first temperature sensor 450 is explicitly configured to measure the lowest, or one of the lowest, temperatures of both the "fluid path" (page 18, lines 9-12) and the "fluid system" (page 20, lines 6-8).

Therefore the person skilled in the art would not necessarily limit the "fluid path" to be disinfected in the embodiment of Figure 1 to the only pipe loop arrangement 121 as claimed by the opponent. This is irrespective of the use of the reference sign 121 to refer to the fluid path in claim 1, since the reference signs do not limit the claim (Rule 43(7) EPC).

It is also irrelevant that granted dependent claim 8 specifies that the fluid path to be disinfected ends at a return inlet. It is true that, in this case, the fluid path to be disinfected extends between the outlet and the return inlet, which in the embodiment of Figure 1 corresponds to the pipe loop arrangement 121. However, this limitation is not defined in claim 1. In any event, it defines a preferred embodiment which is also disclosed in the original application, with the last paragraph of page 11 of the original description disclosing that the temperature sensor, while being located at a location of the fluid system - or fluid path, as discussed above - which experiences the lowest, or one of the lowest, temperatures, may be located "at the end of the fluid loop", hence in the fluid loop.

It follows that, contrary to the opponent's view, features 1.6.1 and 12.5 do not present the person skilled in the art with new information that was not originally disclosed in the application as filed.

Claims 1 and 12 therefore do not contain any added subject-matter, as required by Article 123(2) EPC.

3. Sufficiency of disclosure

3.1 As argued by the opponent, claims 1 and 12 leave many characteristics of the water system and the fluid path unspecified, such as the fluid topology of the water system between the inlet and the outlet, that of the fluid path connected to the outlet, and the thermal properties of the various components of the system. 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. The Board recognises that all these unspecified parameters will have an influence on the temperature profile in the fluid path.

3.2 Nevertheless, contrary to the opponent's 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 water system falling within claims 1 and 12, to determine without undue burden the location of the fluid path which experiences the lowest, or one of the lowest, temperatures during thermal disinfection as required by features 1.6.1 and 12.5.

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 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 general classes of water systems in which the heated water is either discharged into a

drain (as in Figure 4) or re-introduced into the circuit to form a loop in which it circulates (as in Figures 1 and 3). 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 [0053] of the patent). In the second case, this location will normally be at the point of re-injection where the water is about to re-enter the heating unit (paragraph [0054]).

For more complex water systems covered by the claims, the person skilled in the art would have no difficulty, in particular on the basis of this general principle, in identifying a limited number of potential appropriate sensor locations which could then be tested without any undue burden.

3.3 The Board therefore agrees with the proprietor that the invention as claimed in the patent as granted is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

4. Admittance of D19 and D19'

4.1 D19 and D19' were filed by the opponent for the first time in the appeal proceedings with its submission of 25 November 2022 (erroneously referred to therein as D18 and D18'), thus after the opponent had filed its statement of grounds of appeal and its reply to the proprietor's statement of grounds of appeal.

These documents therefore constitute an amendment of the opponent's appeal case which, as such, under Article 13(1) RPBA may only be admitted at the discretion of the Board. Moreover, under Article 12(6)

RPBA, a board must not admit objections or evidence which should have been submitted in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify their admittance. The legal consequence in Article 12(6) RPBA ("shall not admit") being stricter than the legal consequence in Article 13(1) RPBA ("may be admitted only at the discretion of the Board"), Article 12(6) RPBA - which by virtue of Article 13(1), second sentence, RPBA *mutatis mutandis* is also applicable after the filing of the statement of grounds of appeal and reply - can be considered a *lex specialis* not only to Article 12(4) RPBA, but also to Article 13(1) RPBA.

4.2 Contrary to the opponent's view, the fact that the opponent had not earlier been aware of these documents and their alleged relevance to the present case as novelty-destroying documents cannot justify their submission at that stage of the proceedings. In particular, the opponent did not present any reason which had objectively prevented it from becoming aware of these documents and their alleged relevance already in the opposition proceedings. Rather, it seems that a more complete prior-art search would have led to D19 and D19' already in the opposition proceedings. Hence both documents and the novelty objections based on them could and should have been filed in the opposition proceedings, in addition to the other novelty objections to the granted claims raised in the notice of opposition. This applies irrespective of whether or not the opponent was subjectively aware of D19 and D19' at that time.

4.3 For completeness, the Board notes that D19 and D19' are not *prima facie* relevant either. As argued by the proprietor, it is doubtful whether the cleaning

chamber 102 of the system 100 shown in Figure 2, which the opponent has identified as a part of the "fluid path" to be disinfected defined in claims 1 and 12 (features 1.0 and 12.0), can be considered to be thermally disinfected since this chamber is configured to receive residues of human excreta from the containers placed therein (paragraph [0043]). Furthermore, the person skilled in the art would not consider the nozzles 108, 110, 112 of the system 100 to be devices connected to the water system which, according to the wording of claim 1, are not part of the claimed system. Admitting D19 and D19' would also require detailed examination of several new issues. As argued by the proprietor, this would be contrary to the principle of procedural economy.

4.4 For these reasons, the Board decided not to admit D19 and D19' under Article 13(1) RPBA in conjunction with Article 12(6) RPBA.

5. Novelty

5.1 The Board agrees with the proprietor that the subject-matter of claims 1 and 12 is novel in view of D2, D8 and D16, at least for the reason that none of these documents discloses a system or method comprising all of features 1.7.7 to 1.7.9 and 12.5 to 12.8.

5.2 Novelty in view of D2

5.2.1 In the dialysis machine 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 11-17). 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 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).

5.2.2 The Board agrees with the proprietor that this does not directly and unambiguously disclose features 1.7.7 to 1.7.9 and 12.6 to 12.8. In D2, the water temperature is indeed only measured to determine whether the current disinfection cycle needs to be restarted; the person skilled in the art would not consider that it is used to calculate an achieved disinfection dose and to stop the disinfection depending on the comparison of this achieved disinfection dose with a set disinfection dose.

5.2.3 The opponent argued that terminating the disinfection after one hour, provided that the measured temperature had remained above 80°C during that period, involved both calculating the time that had elapsed since the sensors had last measured a temperature below 80°C and comparing it with the set duration of one hour. According to the opponent, that elapsed time constituted an achieved disinfection dose calculated based on the measured temperature, since the process of accumulating time by adding each second that the temperature remained above 80°C to the elapsed time was

an arithmetical operation, and the measured temperature dictated whether that accumulation should continue.

This is not convincing. The person skilled in the art would understand from the wording of claims 1 and 12 that the "achieved disinfection dose" in features 1.7.7 and 12.6 refers to the disinfection dose achieved since the start of the disinfection in accordance with features 1.7.4 and 12.4. Even assuming that the control unit in D2 calculates the time elapsed since the sensors last measured a temperature below 80°C, as argued by the opponent, this elapsed time would fall back to zero at each start of a new cycle resulting from the measurement of a temperature below 80°C, thereby "forgetting", i.e. disregarding, any disinfection dose achieved during the previous cycle(s) of the overall disinfection process. This elapsed time cannot therefore anticipate an achieved disinfection dose according to features 1.7.7 and 12.6.

5.3 Novelty in view of D8

5.3.1 D8 relates to an ISO standard specifying general requirements and tests applicable to washer-disinfectors (see title).

5.3.2 The Board agrees with the proprietor that D8 does not disclose a water system which is operated, or a method of operating such a system, in which disinfection is discontinued depending on the result of the comparison of an achieved disinfection dose with a set disinfection dose, as required by features 1.7.9 and 12.8.

As argued by the proprietor, the person skilled in the art would indeed understand that this comparison

represents a condition which, once realised, causes the termination of the disinfection previously started by the control unit in accordance with features 1.7.4 and 12.4. This is reflected in the use of the conjunction "if" in features 1.7.9 and 12.8, which establishes a causal link between the criterion on the achieved disinfection dose and the termination of the disinfection. D8 is silent on such a causal link.

5.3.3 In particular, it is true that by referring to the criterion "if [...] the equivalent lethality (A_0, see Annex B), is achieved" in point 4.3.1.1 on page 10, where A_0 does indeed correspond to an achieved disinfection dose similar to that used in the contested patent (see paragraphs [0029] and [0030]), D8 discloses a criterion similar to that defined by the 'if' clause in features 1.7.9 and 12.7.

However, this passage of D8, which specifies a condition at which a washer-disinfector "when tested" can be said to meet the expected requirements for thermal disinfection, refers only to the testing of a washer-disinfector (see also point 5.12.6 on page 21: "For a method of testing, see the appropriate part of ISO 15883"). Conducting such a test may actually involve calculating an achieved disinfection dose such as the A_0 value and comparing it with an expected minimum dose, but this is only to check whether the standard disinfection requirements are met and the test is passed or not. D8 does not disclose that this criterion could also be used to control, namely to discontinue, the disinfection carried out by the system during normal operation.

5.3.4 The opponent's further argument that the wording of claims 1 and 12 would actually cover the operation of a

water system under test conditions, where the functionality of the control unit for calculating an achieved disinfection dose and comparing it with a set disinfection dose is used to verify whether the system meets this criterion under test conditions, is not convincing since it ignores the causal link required by features 1.7.9 and 12.8 as discussed above.

The Board points out that, for the same reason, the fact that the criterion on A_0 may be met when the disinfection is stopped (which is necessarily the case for a washer-disinfector meeting the standard disinfection requirements defined in D8, otherwise the washer-disinfector would not pass the disinfection test) cannot *per se* anticipate features 1.7.9 and 12.8.

5.4 Novelty in view of D16

5.4.1 D16 discloses a system for producing and dispensing a sterilised medical liquid, for example for use in 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.

5.4.2 D16 discloses two "sterilizing values" F01 and F02 for characterising the sterilisation of the liquid and the circuit, respectively, achieved during these phases. F01 and F02 are both calculated from a measured temperature and then compared with respective "set sterilizing values" or "threshold values" F0min1 and F0min2 (see for example: claims 2 and 26, which define "calculation means" and "means for comparing" for this purpose; page 17, penultimate paragraph; page 23, first

full paragraph). The Board agrees with the opponent that F01, F02 and F0min1, F0min2 respectively represent achieved disinfection doses and set disinfection doses as defined in features 1.7.7, 1.7.8 and 12.6, 12.7.

However, in agreement with the proprietor, the Board finds no direct and unambiguous disclosure in D16 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 features 1.7.9 and 12.8.

5.4.3 Although D16 discloses that F01 and F02 can be calculated "at any moment" and "[t]hroughout all the operation phases of the device" (page 2, last two paragraphs), their comparison with F0min1 and F0min2 is described only as having the function of "validating" the sterilisation treatment applied to the liquid and to the circuit, namely by "checking" that F01 and F02 are greater than F0min1 and F0min2 (paragraph bridging pages 23 and 24) - in which case the sterilisation would be classed as adequate. The Board notes that the "calculation means" and "means for comparing" of claim 2 are indeed part of "validation means" which are distinct from other control means for controlling the operation of the system. Contrary to the opponent's view, D16 does not disclose that the sterilisation is discontinued if one of the calculated F0 reaches the set value F0min. In the absence of such a causal link, the "validation" disclosed in D16 cannot anticipate features 1.7.9 and 12.8 (see point 5.3.4 above).

In fact, D16 discloses on page 23 that the validation of the initial sterilisation of the circuit "can be made simply by the control unit by checking that, during an uninterrupted interval at least equal to t2,

the temperature of the liquid measured by the temperature sensor has constantly been above T2". This indicates that F02 may not even need to be calculated and compared with F0min2, but that the control unit may simply "validate" that this criterion is met by a method similar to that used in D2, provided that t2 and T2 are chosen to satisfy the definition of F0min2 given on page 23. For similar considerations as discussed for D2 in section 5.2 above, this cannot anticipate features 1.7.9 and 12.8 either.

5.4.4 The opponent also referred to the passage bridging pages 25 and 26 which discloses that the duration of the initial sterilisation phase, instead of being "adjusted to [a] preprogrammed value[]", can also be "adjusted [...] such that the sterilizing value for the sterilization treatment applied to the water and to the circuit is greater than the first and the second set value F0minl, F0min2" (see also claim 4: "controlling the pumping means (..) so that" F02 is greater than F0min2). According to the opponent, this necessarily involves stopping the sterilisation in the initial phase at a suitable point, to be determined by the control unit, so as to obtain achieved values F01 and F02 greater than F01min and F02min. The Board agrees.

However, the Board does not accept the opponent's argument that this necessarily means that the control unit calculates in real time the values F01 and F02 achieved by the ongoing sterilisation and decides to stop the sterilisation if F01 and F02 reach the set values F0min1 and F0min2. On the contrary, as explained for the example described in the following paragraph on page 26, the control unit calculates and selects ("is chosen such that") - thus in advance of the sterilisation phase - on the basis of the measured

temperature an appropriate duration of the initial sterilisation treatment applied to the fluid path, in order to achieve an F02 which is ultimately greater than the set F0min2. This is based on the fact that a given sterilisation value can be achieved using different pairs of duration and temperature. As discussed in points 5.3.2 and 5.3.4 above, this is not what is required by features 1.7.9 and 12.8, which define a causal link between the comparison of the achieved disinfection dose with the set dose and the termination of the disinfection.

5.4.5 In a further line of argument, the opponent submitted that adjusting the flow rate to ensure that F01 remained greater than F0min1, as also disclosed in the paragraph bridging pages 25 and 26, could also be seen, in the light of the mathematical formulae on page 19 of D16, as discontinuing the sterilisation treatment applied to an infinitesimal volume of fluid once F01 had reached or exceeded F01min. This argument is not convincing. Even if one were to accept this interpretation of the formulae of D19, which the Board considers to be far-fetched and artificial, the person skilled in the art would not consider the step of discontinuing the sterilisation treatment applied to an infinitesimal volume of fluid as anticipating the step of "discontinuing the disinfection" previously started by the control unit in accordance with features 1.7.4 and 12.4.

5.4.6 With regard to the second standby production phase of the water system, D16 discloses on page 17, last two paragraphs that F01 is calculated and compared with F0min1 "at regular intervals" in order to validate the sterilisation of the liquid and, if necessary, to adjust the pump flow rate and/or the heating

temperature on the fly so that F0 is always greater than F0min1 (page 18, second paragraph). However, D16 is again silent on using the comparison between F01 and F0min1 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 (paragraph bridging pages 22 and 23). In such a permanent state, there is indeed no need to discontinue the sterilisation of the liquid. This disclosure therefore does not anticipate features 1.7.9 and 12.8 either.

6. Inventive step starting from D2 or D16

6.1 It is common ground that features 1.7.9 and 12.8, in combination with features 1.7.7, 1.7.8 and 12.6, 12.7, prevent the unnecessary continuation of the disinfection when the set disinfection dose has been reached. The objective technical problem to be solved starting from either D2 or D16 can therefore be formulated as how to minimise the duration of the disinfection while still achieving the set disinfection level. This in turn leads to a reduction in energy consumption and an increase in the time available for patient treatment, as explained in paragraphs [0018] and [0038].

6.2 Even assuming that the person skilled in the art starting from D16 or D2 would have considered this technical problem, which is disputed by the proprietor, they would not have arrived at the subject-matter of claims 1 and 12 in an obvious manner, as explained below. The Board therefore concludes that, contrary to the opponent's view, the subject-matter of claims 1 and 12 involves an inventive step starting from D16 or D2.

6.3 Starting from D16

According to the opponent, the person skilled in the art starting from D16 and faced with the technical problem above would obviously have used as the criterion for stopping the sterilisation the same criterion as that checked by the validation means. In other words, they would have modified the control unit in D16 so as to discontinue the ongoing sterilisation based on the comparison of the values F01 and F02 with the set values F0min1 and F0min2.

This does not convince the Board. Without the benefit of hindsight, the person skilled in the art would have had no motivation to implement such a feature in D16. This is because, as discussed above with regard to novelty, D16 already discloses that the control unit selects the duration of the sterilisation in advance and in an *ad hoc* manner in order to obtain, in the end, calculated values of F01 and F02 which are "greater than" the set values F0min1 and F0min2 (page 26, first paragraph). In view of this, the person skilled in the art seeking to shorten the initial sterilisation treatment in D16 would simply have programmed the control unit to select the duration of the sterilisation so as to obtain calculated values of F01 and F02 as close as possible to the set values F0min1 and F0min2 and not just "greater than" them.

Alternatively, as also argued by the proprietor, the person skilled in the art would have chosen a shorter sterilisation duration using a correspondingly higher temperature of the sterilising liquid, taking advantage of the fact that a given sterilisation value can be

achieved with different pairs of duration and temperature.

However, none of these modifications would have led the person skilled in the art to the subject-matter of claims 1 and 12.

6.4 Starting from D2

6.4.1 The opponent also argued that the person skilled in the art starting from D2 and faced with the above technical problem would, prompted by D18, have implemented the A_0 concept described in D8 in the system of D2.

This does not convince the Board either. As discussed above for the inventive-step objection starting from D16, the person skilled in the art would simply have chosen a shorter sterilisation duration with a correspondingly higher temperature of the sterilising liquid. This is also explicitly suggested on page 78, lines 18-21 of D2. This would not have led the person skilled in the art to the subject-matter of claims 1 and 12 either.

6.4.2 In its letter of 19 March 2024, the opponent also raised a further inventive-step objection to claims 1 and 12 starting from D2 in combination with common general knowledge, in particular as reflected in D17.

Although the opponent acknowledged that this objection constituted an amendment to its appeal case under Article 13(2) RPBA, it did not allege any exceptional circumstances which might have justified the admittance of this objection at this late stage of the appeal proceedings. Consequently, the Board decided not to admit this objection.

7. Conclusion

It follows from the foregoing that none of the opponent's objections taken into account on appeal prejudice maintenance of the contested patent as granted.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is maintained as granted.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated