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Datasheet for the decision of 16 September 2024

Case Number: T 0479/22 - 3.2.02

Application Number: 17168783.3

Publication Number: 3219340

IPC: A61M1/16, A61M1/28

Language of the proceedings: EN

Title of invention:
PERITONEAL DIALYSIS OPTIMIZED USING A PATIENT HAND-HELD SCANNING DEVICE

Patent Proprietors:
Baxter International Inc.
Baxter Healthcare S.A.

Opponent:
Fresenius Medical Care AG & Co. KGaA

Relevant legal provisions:
EPC Art. 54(2), 76(1), 84, 108, 111(1)
EPC R. 117
RPBA 2020 Art. 11, 12(2), 12(3), 12(4), 12(6)

Keyword:

Admissibility of appeal - appeal sufficiently substantiated (yes)
Auxiliary request 3 - not admitted in first-instance - circumstances of appeal case justify admittance (yes)
Added subject-matter (main request - yes) (auxiliary request 3 - no)
Taking of evidence - hearing by video-conference
Public prior use - availability to the public (yes)
Remittal - special reasons for remittal (yes)

Decisions cited:

G 0007/93, T 2292/14

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Case Number: T 0479/22 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 16 September 2024

Appellant: (Patent Proprietor 1)	Baxter International Inc. One Baxter Parkway Deerfield, IL 60015 (US)
Appellant: (Patent Proprietor 2)	Baxter Healthcare S.A. Thurgauerstrasse 130 8152 Glattpark (Opfikon) (CH)
Representative:	Schweizer, Christiane K&L Gates LLP Friedrichstraße 110 A 10117 Berlin (DE)
Respondent: (Opponent)	Fresenius Medical Care AG & Co. KGaA Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
Representative:	Nordmeyer, Philipp Werner df-mp Dörries Frank-Molnia & Pohlman Patentanwälte Rechtsanwälte PartG mbB Theatinerstraße 16 80333 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 22 December 2021 revoking European patent No. 3219340 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	C. Schmidt
	D. Ceccarelli
	N. Obrovski

Summary of Facts and Submissions

I. The contested patent was opposed on the grounds of Article 100(a), (b) and (c) EPC.

II. The patent proprietors (the appellants) filed an appeal against the opposition division's decision to revoke the patent on the ground, *inter alia*, that claim 1 as granted and claim 1 of auxiliary requests 1 and 2 contained added subject-matter in breach of Article 76(1) EPC.

A further request, auxiliary request 3, was submitted by the appellants during the oral proceedings before the opposition division but was not admitted because it was considered *prima facie* to also contain added subject-matter in breach of Article 76(1) EPC.

In addition, the opposition division found the two public prior uses alleged by the opponent (the respondent), relating respectively to the "sleep·safe" dialysis machine and the "PatientOnLine" (POL) software, to be proven. With regard to the latter, two witnesses, Mr Guido Neyer and Ms Claudia Wolfers, were heard and a CD was inspected during the oral proceedings, which were held by videoconference. The opposition division concluded in its decision that the two following documents belonged to the state of the art under Article 54(2) EPC:

D1''' "sleep·safe Gebrauchsanweisung, Software-Version 1.0, Art. Nr. 677 804 1", "Stand 2/10.00", 2nd edn. of October 2000, Fresenius Medical Care

D6 "PatientOnLine User Manual", Release 4.2, Fresenius Medical Care

III. The Board provided a preliminary opinion on the appeal in its communication under Article 15(1) RPBA.

IV. At the end of the oral proceedings held before the Board on 16 September 2024, the parties' final requests were as follows.

(a) The appellants requested that the decision under appeal be set aside and that the contested patent be maintained as granted (main request) or in amended form on the basis of auxiliary request 3 submitted at the oral proceedings before the opposition division.

(b) The respondent requested that the appeal be rejected as inadmissible or that it be dismissed.

In addition, the appellants and the respondent requested that, in the event of the decision under appeal being set aside, the case be remitted to the opposition division for further prosecution, in particular for consideration of the other grounds for opposition under Article 100(a) and (b) EPC.

V. **Claim 1 as granted (main request**) reads as follows (with the feature numbering introduced in the decision under appeal):

1.0 "*A handheld personal communication apparatus (30a, 30b, 30c, 60, 90) for dialysis comprising:*

1.1 *a reader (38, 42, 92, 94) configured to perform at least one of*

1.1.1 *(i) read a marking (18) displayed on a dialysis fluid container (16) to acquire data concerning at least one of*

1.1.1.1 *a dialysis fluid type or*

1.1.1.2 *a dialysis fluid volume from the marking, or*

1.1.2 *(ii) receive a patient weight signal from a weight scale (20);*

1.2 *a processor (44, 98) configured to use the at least one of*

1.2.1 *the dialysis fluid type,*

1.2.2 *the dialysis fluid volume, or*

1.2.3 *the patient weight signal*

1.2.4 *to determine a dialysis dwell time for at least one cycle of a dialysis therapy for a patient,*

1.3 *the dialysis dwell time corresponding to a time to achieve at least one of*

1.3.1 *(a) a specified ultrafiltrate level for the at least one cycle,*

1.3.2 *(b) a urea removal level for the at least one cycle, or*

1.3.3 *(c) a creatinine removal level for the at least one cycle; and*

1.4 *an output interface (48, 62, 102) configured to provide an indication to the patient of a completion of the dialysis dwell time.*"

VI. **Claim 1 of auxiliary request 3** reads as follows (with similar feature numbering and the amendments relative to claim 1 as granted highlighted by the Board):

1.0 "*A handheld personal communication apparatus (30a, 30b, 30c, 60, 90) for peritoneal dialysis comprising:*

1.1 *a reader (38, 42, 92, 94) configured to perform ~~at least one of~~*

1.1.1 *(i) read a marking (18) displayed on a dialysis fluid container (16) to acquire data concerning ~~at least one of~~*

1.1.1.1 *a dialysis fluid type or*

1.1.1.2 *a dialysis fluid volume from the marking~~, or~~ and*

1.1.2 *(ii) receive a patient weight signal from a weight scale (20);*

1.2 *a processor (44, 98) configured to use ~~the at least one of~~*

1.2.1 *the dialysis fluid type,*

1.2.2 *the dialysis fluid volume, ~~or~~ and*

1.2.3 *the patient weight signal*

1.2.4 *to determine an optimal dialysis dwell time for at least one cycle of a dialysis therapy for a patient,*

1.3 *~~the~~ said dialysis dwell time corresponding to a time to achieve ~~at least one of~~*

1.3.1 *~~(a)~~ a maximum specified ultrafiltrate level for the at least one cycle,*

1.3.2 *~~(b)~~ a maximum urea removal level for the at least one cycle, or*

1.3.3 *~~(c)~~ a maximum creatinine removal level for the at least one cycle; and*

1.4 *an output interface (48, 62, 102) configured to provide an indication to the patient of a completion of the dialysis dwell time,*

1.5 *wherein the reader (38, 42, 92, 94) includes at least one of*
(i) a barcode scanner, the marking displayed on the dialysis fluid container being a barcode,
(ii) a radio frequency identification ("RFID") reader, the marking displayed on the dialysis fluid container being an RFID tag,
(iii) a camera of a smart phone, or
(iv) a wireless receiver to wirelessly receive the patient weight signal from the weight scale;

1.6 *and wherein the handheld personal communication apparatus (30a, 30b, 30c, 60, 90) is a smart phone.*"

VII. The contested patent was granted from a divisional application of an earlier European application published in the PCT phase under WO 2011/046797 A1 (the parent application), the content of which is relevant for the assessment of added subject-matter under Article 76(1) EPC.

VIII. This decision also refers to the following documents:

D3i Affidavit of Mr Clemens Jung, 2 January 2015

D3j Affidavits of:
Ms Elke Oberdorf, 10 January 2015
Ms Marianne Merten, 12 January 2015
Ms Brigitte Zweschper, 15 January 2015

D6a Affidavit of Mr Guido Neyer, 28 February 2019
D6c "Varel_Biernat" file, "PatientOnLine registration data sheet"
D6d Affidavit of Ms Claudia Wolfers, 28 February 2019

IX. The **appellants' arguments** relevant for the present decision can be summarised as follows.

Admissibility of the appeal; substantiation of the main request and auxiliary request 3

The appellants did not comment on the admissibility of the appeal. In point 3.1 of their statement of grounds of appeal, they explained why, in their view, claim 1 as granted, and in particular feature 1.1, complied with Article 76(1) EPC. In point 3.4, they argued why the submission of auxiliary request 3 during the oral proceedings before the opposition division had been a *bona fide* attempt to overcome the added-matter objections previously discussed for the higher-ranking requests and why auxiliary request 3 should be admitted on appeal.

Main request - added subject-matter

Claim 1 as granted did not contain added subject-matter, *inter alia,* because it did not limit the parameters used to determine the dialysis dwell time to one or more values obtained from the reader. This was consistent with what was disclosed in the parent application, in particular in paragraph [0014], which described a list of possible parameters that could be used to determine the dwell time. In that list, which was written in American English style, the final "and" did not mean that all the listed parameters had to be

used all together. Rather, each of these parameters was optional. This was also reflected in the terms "alternatively" and "additionally" in paragraph [0016], which clearly described optional requirements. The embodiments referred to by the respondent were only specific embodiments of the invention. Therefore, feature 1.1 complied with Article 76(1) EPC.

Auxiliary request 3 - added subject-matter and clarity

Auxiliary request 3 should be admitted into the proceedings. Claim 1 of this request *prima facie* overcame all the added-matter objections raised against claim 1 as granted, as well as those raised against the higher-ranking auxiliary requests which had been withdrawn. Feature 1.5 merely further specified certain forms of the reader which was defined in general terms in features 1.1 to 1.1.2. Furthermore, the person skilled in the art would have understood that the camera in feature 1.5(iii) was clearly the camera of the smartphone of feature 1.6. Auxiliary request 3 therefore *prima facie* complied with Articles 76(1) and 84 EPC.

Public availability of D1'''

In deciding that D1''' was prior art, the opposition division had not applied the correct standard that a public prior use had to be based on facts and evidence and had to be proven up to the hilt, with absolute conviction, and not simply on a balance of probabilities. Although the opposition division referred to T 2292/14, its decision in the current case was based on two mere unproven assumptions, namely that "as a matter of principle, electronic and medical devices are delivered to customers with operation

instructions or manuals" and that "there is no reason to believe that the document may not have been delivered with the product after that date. No such document, which is specifically addressed to the users of the product, is prepared just to be kept internally" (point 5 on pages 12-13 of the decision). Consequently, the alleged prior use was not sufficiently proven and D1''' should not be considered to belong to the state of the art.l

Public availability of D6

It was not proved up to the hilt that D6 had been made publicly available before the priority date of the contested patent.

Firstly, the CD offered for inspection by the respondent in support of the public availability of D6 should not have been admitted by the opposition division. It had been filed after the expiry of the opposition period, i.e. late. It should therefore not be admitted on appeal.

Secondly, the inspection of the CD and the hearing of the two witnesses offered by the respondent had been carried out by videoconference, a format which was incompatible with the high degree of complexity of the case and which cast doubt on the probative value of the evidence taken. The appellants' requests to inspect the CD in person or to receive a copy of it prior to the virtual inspection had been refused by the opposition division, with the result that the appellants never had the opportunity to physically inspect the CD themselves.

Thirdly, the alleged prior use itself was subject to serious doubts which neither the inspection of the CD nor the hearing of the witnesses could resolve. It was unclear whether the inspected CD - which, according to the respondent, was the only one retrieved that was still readable - was identical to the CD actually used to install the software at the hospital in 2007. The virtual inspection of the CD's contents had been limited to certain files, and many of these files were inoperable. In particular, the setup installation file could not be executed. It was therefore uncertain whether the POL software had been successfully installed on a computer at the hospital in 2007 - or whether it could ever have been installed - or whether the manual allegedly stored on the CD and copied onto the computer as part of the installation could have been read. In any event, D6 and the CD inspected had different version numbers, 4.2 and 4.2.0.1, suggesting that D6 was different from the manual allegedly provided with the installation in 2007. Although the appellants did not challenge the credibility of the witnesses, the latter were unable to convincingly corroborate the facts alleged by the respondent. None of them could prove or recall the actual events of the alleged installation without the assistance of a counsel of the respondent, especially for the drafting of the affidavits.

As a result, D6 should not be considered to belong to the state of the art.

X. The **respondent's arguments** relevant for the present decision can be summarised as follows.

Admissibility of the appeal; substantiation of the main request and auxiliary request 3

The appellants' statement of grounds of appeal was not substantiated, and the appeal should therefore be rejected as inadmissible.

Main request - added subject-matter

Claim 1 as granted contained added subject-matter in breach of Article 76(1) EPC.

Feature 1.1 was based on an inadmissible intermediate generalisation of the original disclosure. This feature failed to specify that the reader included an optical scanner, an output device, a processor and a memory as originally disclosed in paragraph [0016] of the parent application.

The expression "at least one [...] or" in features 1.2 to 1.2.3 meant that the processor could possibly be configured to determine a dialysis dwell time, *inter alia*, based only on the patient weight signal. This was also an inadmissible generalisation of the parent application, which consistently disclosed that the dwell time was determined at least based on some information about the solution type and/or volume obtained from the dialysis fluid container used to perform the dialysis treatment.

Auxiliary request 3

Auxiliary request 3, which had only been submitted during the oral proceedings before the opposition division and was not admitted at that time, should not be admitted on appeal pursuant to Article 12(6) RPBA.

Indeed, it followed from the expression "at least one of [...] or" in feature 1.5 of claim 1 of that request that the claimed reader could well comprise only one of the alternatives (i) to (iv), hence, for example, no camera or wireless receiver for receiving a patient weight signal. However, no such reader was disclosed in the parent application, which instead consistently disclosed - as was actually also defined in feature 1.1 of claim 1 - that the reader had to be configured both to read a marking and to receive a patient weight signal. Similarly, a "smart phone" including such a reader, as further defined by feature 1.6, was not disclosed in the parent application, which instead disclosed that a "smart phone" included at least a camera for reading a barcode and a wireless transceiver for receiving a patient weight signal (paragraph [0063]). Moreover, as features 1.5(iii) and 1.6 both referred to "a smart phone", claim 1 also covered an apparatus comprising two different smartphones, this also going beyond the content of the parent application. Claim 1 of auxiliary request 3 thus *prima facie* contained added subject-matter. The opposition division had therefore correctly exercised its discretion in deciding not to admit auxiliary request 3.

Furthermore, the reference to two smartphones in features 1.5 (iii) and 1.6 also rendered claim 1 of auxiliary request 3 *prima facie* unclear.

Therefore, there was no reason for the Board to overturn the opposition division's decision not to admit auxiliary request 3, and this request in any event did not comply with Article 76(1) and 84 EPC.

Public availability of D1'''

There was no reason for the Board to depart from the conclusion reached in the earlier decision T 2292/14 that D1''' belonged to the state of the art since the facts and circumstances of the alleged public prior use were the same. The statements made by the opposition division in the decision under appeal, to which the appellants referred, were merely additional explanations which only further supported that conclusion.

Public availability of D6

It had not been inappropriate to conduct the taking of evidence on the public prior use of the POL software by videoconference.

The fact that the POL software, version 4.2, had been successfully installed in a German hospital in 2007, using an installation CD which was identical to the inspected CD and which had been left at the hospital after installation, had been clearly established as stated by the witnesses in their affidavits, confirmed by their hearings and further corroborated by the evidence produced. The examination of the manual contained on the CD inspected had shown that it was identical to D6, which had the same version number 4.2. This proved that D6 had been made publicly available in connection with the installation of the POL software in that hospital in 2007. The doubts raised by the appellants were not convincing.

Therefore, D6 should be considered to belong to the state of the art.

Reasons for the Decision

1. The subject-matter of the contested patent

1.1 Like haemodialysis, peritoneal dialysis is a therapy commonly used to treat a patient's loss of kidney function (paragraphs [0002] and [0003] of the contested patent). Peritoneal dialysis uses a dialysate that is infused through an implanted catheter and left in the patient's peritoneal cavity for a period of time, called the dwell time. There, the dialysate comes into contact with the peritoneal membrane, through which wastes, toxins and water from the bloodstream are transferred to the dialysate by diffusion and osmosis. After the dwell time, the dialysate, together with the substances transferred to it, is drained from the peritoneal cavity and disposed of (paragraph [0004]).

The contested patent relates to an apparatus for assisting a patient in managing a peritoneal dialysis therapy, such as continuous ambulatory peritoneal dialysis, in which the patient performs the fill, dwell and drain cycles manually at home (paragraph [0005]).

1.2 An example embodiment of an apparatus according to claim 1 as granted is shown in Figure 1A reproduced below (see the corresponding parts of the description, in particular paragraphs [0033] to [0042]). The apparatus (30a) (which may also take the form of a smartphone, see paragraph [0058]) comprises a reader (38, 42) configured to read a marking, such as a barcode (18), displayed on a dialysis fluid container (16) to acquire data on the fluid contained in that container, such as its type and/or its volume. The

reader can also wirelessly receive a patient weight signal from a weight scale (20).

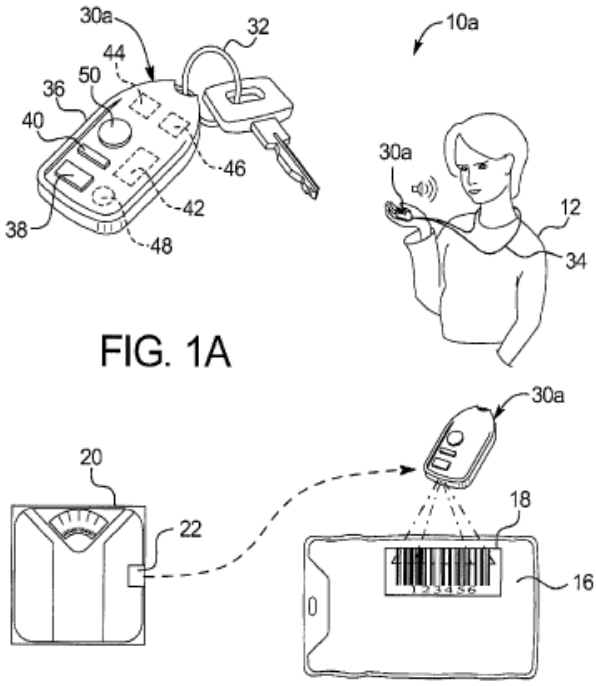

FIG. 1A

Using the data acquired by the reader, a processor (44) determines an optimum dialysis dwell time, for example the time required to achieve a maximum level of ultrafiltration or a maximum level of urea or creatinine removal, and an output interface (48) provides an indication to the patient of the completion of the dwell time, for example in the form of a countdown (paragraph [0042]).

2. Admissibility of the appeal; substantiation of the main request and auxiliary request 3

The Board considers the appeal admissible and the appellant's appeal case for the main request and auxiliary request 3 sufficiently substantiated, as required by Rule 99(2) EPC. The last paragraph of page 10 of the statement of grounds contains sufficient

reasoning as to why the contested decision should be set aside. This applies regardless of whether the arguments presented in support of these requests, especially in section 3 of the statement of grounds of appeal, are persuasive or not.

This view was expressed in the Board's communication under Article 15(1) RPBA. The parties did not present any arguments at the oral proceedings before the Board but referred to their written submissions.

3. Main request - added subject-matter

Claim 1 as granted contains added subject-matter in breach of Article 76(1) EPC.

Features 1.2 to 1.2.3 define that the dialysis dwell time is determined via the processor using "at least one of the dialysis fluid type, the dialysis fluid volume, or the patient weight signal" (emphasis added by the Board) acquired or received by the reader. The same expression "at least one of [...] or [...]" is used in the definition of the reader in features 1.1 to 1.1.2 to specify the data which can be acquired or received by the reader.

It is true, as submitted by the appellants, that claim 1 as granted does not limit the parameters used to determine the dialysis dwell time to one or more values obtained from the reader. However, it follows from the use of the expression "at least one of [...] or [...]" that the determination of the dialysis dwell time carried out by the claimed processor can, according to one alternative, be based solely on the patient weight signal, i.e. without using any

information on the type or volume of the dialysis fluid.

As argued by the respondent and held by the opposition division (see points 1.2.1 to 1.2.3 on pages 16 to 18 of the decision under appeal), such an alternative is not disclosed in the parent application. While, contrary to the opposition division's view, the type and the volume of the dialysis fluid are not necessarily both required to determine the dwell time (see for example the alternative "or" in paragraph [0016]: "The barcode identifies the solution type [...] and/or the solution volume"), the parent application consistently discloses that the dwell time is determined using at least some information obtained from the dialysis fluid container used to perform the dialysis treatment (see paragraph [0016]: "The wireless receiver of the portable reader also receives the patient's pre-therapy weight" (emphasis added); see also paragraphs [0014], [0016], [0017], [0019], [0020], [0045], [0048] to [0051], which are also discussed in point 1.2.1 on pages 16 to 18 of the decision under appeal).

The omission of this requirement from features 1.1 to 1.1.2 and 1.2 to 1.2.3 of claim 1 as granted therefore constitutes an inadmissible intermediate generalisation of the original disclosure in breach of Article 76(1) EPC.

The main request is therefore not allowable.

4. Auxiliary request 3

4.1 Admittance

4.1.1 Auxiliary request 3 was submitted for the first time during the oral proceedings before the opposition division. The opposition division did not admit it on the ground that it *prima facie* infringed Article 76(1) EPC.

4.1.2 Pursuant to Article 12(6) RPBA, a board must not admit a request which was not admitted in the proceedings leading to the decision under appeal unless, *inter alia*, the circumstances of the appeal case justify its admittance. In the current case, the Board considered that such circumstances justifying the admittance of auxiliary request 3 existed.

Indeed, the amendments made to claim 1 of auxiliary request 3 compared to claim 1 as granted are not complex and are easily understandable, and, as explained below, claim 1 of auxiliary request 3 appeared *prima facie* to comply with Articles 76(1) EPC and 84 EPC.

Due to the amendments of features 1.1 to 1.1.2, 1.2 to 1.2.3 and 1.3 to 1.3.3, discussed in detail in points 4.2.1 and 4.2.3 below, auxiliary request 3 appeared *prima facie* to overcome all those objections under Article 76(1) EPC which had been raised against the main request and the higher-ranking auxiliary requests 1 and 2 discussed in the decision under appeal and which the Board had found convincing (see point 3. above for the main request and the relevant sections of the Board's communication under Article 15(1) RPBA for auxiliary requests 1 and 2). This was not disputed by the respondent.

Moreover, as discussed in detail in point 4.2.2 below, the other objection under Article 76(1) EPC raised by

the respondent against the term "reader" in feature 1.1 of claim 1 as granted, which is also contained in claim 1 of auxiliary request 3, was unconvincing.

In addition, as also discussed in detail in points 4.2.4 and 4.3 below, the additional objections under Articles 76(1) and 84 EPC raised by the respondent specifically against features 1.5 and 1.6 were *prima facie* unconvincing.

For these reasons, the Board decided to admit auxiliary request 3.

4.2 Added subject-matter

4.2.1 Compared to claim 1 as granted, features 1.1 to 1.1.2 and features 1.2 to 1.2.3 of claim 1 of auxiliary request 3 specify that not only the patient weight signal but also the dialysis fluid type and the dialysis fluid volume are acquired or received by the reader and then used by the processor to determine the dialysis dwell time, as supported, *inter alia*, by paragraph [0016] ("The barcode identifies the solution type [...] and/or the solution volume. The wireless receiver of the portable reader also receives the patient's pre-therapy weight from a weigh scale"). As stated above, this immediately overcomes the added-matter objection to claim 1 as granted set out in point 3. above. This was not disputed by the respondent.

4.2.2 The respondent had also objected that claim 1 as granted was based on an inadmissible intermediate generalisation in that feature 1.1 did not specify that the "reader" included an optical scanner, an output device, a processor and a memory as originally

disclosed in paragraph [0016] of the parent application. This objection, which also concerns claim 1 of auxiliary request 3, is not convincing.

The term "portable reader" in paragraph [0016] refers to a handheld personal communication apparatus as a whole, on the same footing as the handheld apparatus claimed in feature 1.0, and not to a subcomponent of it, such as the "reader" of feature 1.1.

Paragraph [0016] of the parent application expressly discloses that the marking from which the portable reader can obtain information about the fluid container may "for example be a barcode or [an] RFID tag", thus implying that the handheld apparatus does not necessarily comprise an optical scanner but may instead include, for example, an RFID reader. Therefore, the omission of an optical scanner in feature 1.1 does not infringe Article 76(1) EPC.

The other features that the respondent claimed were improperly omitted from claim 1 as granted are in fact explicitly or implicitly defined in the claim. Feature 1.4 explicitly defines that the claimed handheld apparatus comprises an "output interface", i.e. an output device, and at least some kind of memory must necessarily be implicitly associated with the processor of feature 1.2 to enable it to determine the dialysis dwell time, in line with the description of the "portable reader" in paragraph [0016].

4.2.3 Amended features 1.3 to 1.3.3 provide that the processor is configured to determine an "optimal" dialysis dwell time corresponding to a time to achieve a "maximum" specified ultrafiltrate level, a "maximum" urea removal level "or" a "maximum" creatinine removal

level. As mentioned above, this immediately resolves the concerns and objections of the Board set out in points 5.4 and 7.1 of the communication under Article 15(1) RPBA. This was also not disputed by the respondent.

4.2.4 The Board is also not convinced by the respondent's other objections under Article 76(1) EPC against features 1.5 and 1.6.

The respondent argued that, due to the expression "at least one of [...] or" in feature 1.5, claim 1 of auxiliary request 3 covered, *inter alia*, a reader which had no barcode scanner or camera or which had no wireless receiver. According to the respondent, this went beyond the original disclosure because the parent application instead consistently disclosed - as in fact was defined in features 1.1 to 1.1.2 of claim 1 - that the reader had to be configured both to read a marking and to receive a patient weight scale.

This objection is not convincing. As argued by the appellants, feature 1.5 merely further specifies possible embodiments of the reader already defined in general terms in features 1.1 to 1.1.2 as being configured both to read a marking and to receive a patient weight scale, with the various alternatives (i) to (iv) defined in feature 1.5 only constituting optional additional features of that reader. These options are all supported by the parent application. Alternatives (i), (ii) and (iv) are consistently described throughout the parent application (see for example the above-mentioned paragraph [0016]). Alternative (iii) is supported by paragraph [0063], which discloses - as is further defined in feature 1.6 of claim 1 - that in one embodiment the handheld

apparatus could be embodied in a smartphone having a camera.

Similarly, the respondent objected that a "smart phone", as defined in feature 1.6, including such a reader was not disclosed in the parent application if that reader comprised one of alternatives (i) or (ii) of feature 1.5. This was because, according to the respondent, paragraph [0063] of the parent application only disclosed a smartphone with a camera and a wireless receiver for receiving a patient weight signal but not a smartphone with a barcode scanner or an RFID reader.

This objection is not convincing either. As argued by the appellants, the disclosure of paragraph [0063] must be read in the context of the application as a whole, and the person skilled in the art would therefore understand that the smartphone disclosed in paragraph [0063] may also comprise other features generally disclosed for the reader in the parent application, including a barcode scanner or an RFID reader as specified in alternatives (i) and (ii). Indeed, the system disclosed in paragraph [0063] is explicitly described as "including many of the features" of the systems previously disclosed in the parent application.

The respondent's further added-matter objection based on the argument that features 1.5 (iii) and 1.6 could be understood to refer to two different smartphones - a configuration about which the parent application is effectively silent - is also not convincing. As argued by the appellants, this argument makes no technical sense in the context of the claim. On the contrary, it would be clear to the person skilled in the art that the camera in alternative (iii) of feature 1.5 is the

camera of the smartphone mentioned in feature 1.6, meaning that both features refer to the same and only smartphone.

4.3 Clarity

The clarity objection raised by the respondent against features 1.5 and 1.6 that it was unclear whether the smartphones referred to in features 1.5 (iii) and 1.6 were two different smartphones or the same smartphone also does not convince the Board for the same reasons as given in the paragraph above for the corresponding added-matter objection.

5. Public availability of D1'''

5.1 D1''' is an operating instruction manual for a dialysis machine called "sleep·safe" sold by the respondent.

5.2 In the decision under appeal, the opposition division endorsed the conclusion reached by the current Board (in a different composition) in T 2292/14 (see points 5 and 3.3.1 of the Reasons for that decision) that D1''' was made available to the public during a training course on the "sleep·safe" dialysis machine which took place on 4 January 2002. That conclusion was based, *inter alia*, on affidavits D3i and D3j, which were again submitted as evidence in the opposition proceedings which led to the decision under appeal.

5.3 The current Board, like the opposition division, sees no reason to depart from that conclusion since the alleged facts and circumstances of the public prior use invoked by the respondent are the same.

The appellants objected that the statements made by the opposition division in point 5 on pages 12-13 of the decision under appeal that "as a matter of principle, electronic and medical devices are delivered to customers with operation instructions or manuals" and that "there is no reason to believe that the document may not have been delivered with the product after that date" were mere unproven assumptions. According to the appellants, this indicated that the opposition division, in reaching its conclusion as to the prior use of the "sleep·safe" dialysis machine, had relied on a mere "balance of probabilities" standard of proof, rather than the "up to the hilt" standard of proof that should have been applied.

This argument is not convincing. The passages of the decision quoted by the appellants merely corroborate the sworn statement in D3i that the "sleep·safe" dialysis machine was delivered together with a copy of D1''' and support the opposition division's reasoning. In any event, they do not affect the conclusion drawn in T 2292/14 on the public availability of D1'''.

The Board therefore concludes, as did the opposition division in the decision under appeal, that D1''' was made publicly available before the earliest priority date claimed by the patent in suit in the current case. D1''' therefore belongs to the state of the art for assessing the novelty and inventive step of the subject-matter claimed in the contested patent.

6. Public availability of D6

6.1 D6 is a user manual for the "PatientOnLine" (POL) software sold by the respondent which enables the creation and management of prescriptions for the

"sleep·safe" dialysis machine. D6a and D6d are affidavits stating that D6 was made publicly available during the installation of this software in a hospital in June 2007. In relation to this alleged prior use, the authors of the affidavits were heard as witnesses and a CD, presented by the respondent as an original installation CD of the POL software and allegedly containing a copy of D6, was inspected during the oral proceedings before the opposition division, which were held by videoconference.

6.2 Admittance of the CD

Objecting that the CD had been late filed, the appellants argued that it should not have been admitted by the opposition division and requested that it not be admitted on appeal.

The inspected CD was filed after the expiry of the opposition period. However, as noted by the opposition division (see point 2 on page 10 of the decision under appeal), the respondent did not submit it as evidence of a new set of facts but to support the alleged prior use of the POL software and in accordance with the opposition division's order to take evidence of 21 January 2021, according to which evidence was to be taken on this prior use, *inter alia,* "by inspecting an original installation CD of the POL software in the version 4.2" (see page 2). This prior use had already been invoked in the notice of opposition (see point VI.3 on page 16). In such a situation, the opposition division had no discretion not to admit the CD into the opposition proceedings. In any case, its decision to admit it did not suffer from an error in the use of discretion as set out in G 7/93, point 2.6 of the Reasons.

While this is without prejudice to the Board's power to review the exercise of discretion by the opposition position, the Board does not have any discretionary power of its own under Article 12(4) RPBA not to admit the CD into the appeal proceedings as it forms part of the evidence on which the decision under appeal is based within the meaning of Article 12(2) RPBA.

For these reasons, the Board decided to take into account the evidence obtained from the inspection of the CD in the appeal proceedings.

6.3 Taking of evidence by videoconference

The appellants also objected that it had been inappropriate to inspect the CD and to hear the two witnesses in oral proceedings held by videoconference. In their view, this format of oral proceedings was incompatible with the high degree of complexity of the case. Rather, the opposition division should have granted their request to take evidence in person on the premises of the EPO and, as this was not possible during the pandemic, to postpone the oral proceedings until in-person oral proceedings were allowed again.

The Board disagrees. The fact that taking of evidence may be conducted by videoconference is expressly mentioned in Rule 117 EPC. It is also immaterial that the appellants themselves did not have physical access to the inspected CD. The inspection of the CD did not concern its haptic feel, texture or handling experience, but only its content - in particular the file "PatientOnLine User Manual" with which D6 was alleged to be identical - and the fact that the inspection of the CD was carried out by videoconference

did not prejudice the proper inspection of that content. The inspection was carried out by a member of the opposition division, assisted by a technician who presented the CD to the camera. The minutes also show that the parties were able to follow the inspection in real time during the videoconference and that the content of the CD, including some of its directories, was displayed to the videoconference participants. Moreover, all the pages of the user manual requested by the parties and the opposition division, as well as the contents of several other files, were also displayed, with corresponding screenshots being included in the minutes. The fact that some of the files were corrupted and therefore could not be opened is not related to the format of the oral proceedings.

The Board also sees no reason to consider that the hearings of the two witnesses by the opposition division were compromised by holding the oral proceedings by videoconference. The minutes of both hearings show that precautions were taken to ensure that the witnesses were alone in front of the camera and that they had no document in front of them from which to read their statements.

Furthermore, according to point 13 of the minutes, the parties were provided with the draft minutes of the taking of evidence and were given the opportunity to comment on them already during the oral proceedings. None of the parties made any comments at that time, except to note that page 7 was present twice. Moreover, the appellants never complained that their right to be heard was violated by the fact that the oral proceedings were held by videoconference.

The Board therefore concludes that conducting the taking of evidence by videoconference was not inappropriate and did not diminish the probative value of the evidence taken.

6.4 Availability to the public of D6

6.4.1 D6a and D6d are affidavits, i.e. statements sworn under oath, which should be given a high probative value, unless other evidence casts doubt on them. The fact that the affidavits may have been written by someone else, e.g. the respondent's representative, is immaterial since by signing them the authors endorse the statements made in the affidavits.

6.4.2 In D6a, Mr Neyer stated that, in June 2007, he had installed the POL software, version 4.2, on a computer at the St. Johannes Hospital, Varel (Germany), using an installation CD, without a confidentiality agreement, and that, as part of the installation, the corresponding user manual which was on the installation CD had been automatically copied onto the computer for later consultation by users of the software. Moreover, as Mr Neyer also explained in his testimony, the CD used for the installation remained in the hospital in any event after the installation. It was therefore possible for a user to consult the user manual contained on the CD.

In D6d, Ms Wolfers stated that she had given a public training session on the POL software, version 4.2, at the hospital in June 2007. This did require the installation of this software at the hospital. Mr Neyer and Ms Wolfers both confirmed their written statements during their hearings as witnesses.

Both witnesses precisely identified the version of the POL software installed at the hospital to be version 4.2. This is also supported by the screenshots provided in D6a and by D6c.

The CD inspected is not the installation CD actually used to install the POL software at the hospital since the latter was left there after installation. However, according to Mr Neyer's sworn declaration, both CDs are identical. The Board sees no reason to doubt that the user manuals present on the two CDs are also identical.

D6, which was attached to D6a, is alleged to be a copy of the user manual contained on the installation CD and copied onto the hospital's computer. The comparison of pages 2-3, 11, 28, 31-33, 95-97, 124, 126, 129, 146, 174-176, 178, 179, 182-186, 195, 200, 219, 220, 223, 224, 228, 291, 295 and 296 of D6 with the corresponding pages of the user manual contained on the CD inspected indeed revealed that these pages are identical (see last paragraph of page 6 of the minutes of the inspection). This was admitted by the appellants at the oral proceedings before the opposition division (see page 14 of the decision, fourth bullet). Furthermore, both user manuals have the same version number 4.2 as the POL software installed at the hospital, and the inspection of the CD showed that the file "PatientOnLine User Manual" corresponding to the user manual on the CD was last modified in May 2007 (see page 6 of the minutes of the inspection), which is consistent with the date of the alleged installation at the hospital in June 2007.

The Board is satisfied that this evidence is sufficient to establish that D6 was made available to the public in June 2007, i.e. before the earliest priority date of

the contested patent. D6 therefore belongs to the state of the art for assessing the novelty and inventive step of the subject-matter claimed in the patent.

6.4.3 The alleged inconsistencies and doubts raised by the appellant are not convincing.

It is irrelevant that the CD inspected was not the CD actually used to install the POL software at the hospital since Mr Neyer testified that the POL software, in its version 4.2, had been installed at the hospital using an installation CD identical to the CD inspected. It is also irrelevant that the setup installation file contained on the inspected CD could not be executed during the inspection. Given the age of the CD, it is not surprising that some of the files may be damaged.

It is also irrelevant that the inspected CD bears the version number 4.2.0.1 and not 4.2. Both witnesses precisely identified the version of the software installed at the hospital as version 4.2, which is also the version number indicated on D6. This is consistent with Mr Neyer's explanations that the suffix 0.1 was merely an internal designation and did not indicate any difference in the functionality of the POL software.

Furthermore, the fact that the events in question took place a long time ago could easily explain some imprecisions in the witnesses' testimonies, without calling into question the overall credibility of their statements. The appellants also explicitly mentioned that they did not question the witnesses' credibility.

7. Remittal to the opposition division

It follows from the foregoing that while the ground for opposition under Article 100(c) EPC prejudices the maintenance of the contested patent as granted, the patent amended according to auxiliary request 3 complies with Article 76(1) and 84 EPC. The decision under appeal is therefore to be set aside.

However, the decision under appeal did not deal with the other grounds for opposition under Article 100(a) and (b) EPC also invoked by the respondent.

In view of the primary object of the appeal proceedings, which is to review the decision under appeal in a judicial manner (Article 12(2) RPBA), the Board, in agreement with all the parties, considers that there are special reasons under Article 11 RPBA for remitting the case to the opposition division for further prosecution under Article 111(1) EPC, in particular for consideration of the other grounds for opposition under Article 100(a) and (b) EPC.

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 for further prosecution.

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated