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Datasheet for the decision of 16 September 2024

Case Number: T 1604/22 - 3.2.02

Application Number: 09790207.6

Publication Number: 2320971

IPC: A61M1/28, G06F19/00

Language of the proceedings: EN

Title of invention:
DIALYSIS SYSTEM AND MACHINE HAVING THERAPY PRESCRIPTION RECALL

Patent Proprietors:
Baxter International Inc.
Baxter Healthcare SA

Opponent:
Fresenius Medical Care AG

Relevant legal provisions:
EPC Art. 54(2), 111(1), 123(2)
EPC R. 117
RPBA 2020 Art. 11, 12(2), 12(4)

Keyword:
Added subject-matter (main request - 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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Beschwerdekammern

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Case Number: T 1604/22 - 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 SA Thurgauerstrasse 130 8152 Glattpark (Opfikon) (CH)
Representative:	K&L Gates LLP Friedrichstraße 110 A 10117 Berlin (DE)
Respondent: (Opponent)	Fresenius Medical Care AG Else-Kröner-Str. 1 61352 Bad Homburg (DE)
Representative:	Behr, Wolfgang Lorenz Seidler Gossel Rechtsanwälte Patentanwälte Partnerschaft mbB Widenmayerstraße 23 80538 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 20 April 2022 revoking European patent No. 2320971 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.

In its decision, the opposition division held that the ground for opposition under Article 100(c) EPC prejudiced the maintenance of the patent as granted because independent claims 1 and 8 as granted contained added subject-matter in breach of Article 123(2) EPC. The opposition division did not address the compliance of the dependent claims as granted with Article 123(2) EPC in the decision.

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 parties made the following requests in their written submissions on appeal.

(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 one of the auxiliary requests 1 to 6 on which the decision was based.

(b) The respondent requested that the appeal be dismissed.

IV. In its communication under Article 15(1) RPBA, the Board expressed the preliminary view that independent claims 1 and 8 as granted did not contain added subject-matter and that if this view were confirmed at the oral proceedings before the Board, the Board would be inclined to remit the case to the opposition division for further prosecution.

V. During the oral proceedings held before the Board on 16 September 2024, after the Chairman announced that the Board had come to the conclusion that independent claims 1 and 8 as granted did not contain added subject-matter, the parties made the following additional requests.

(a) The appellants requested that the case be remitted to the opposition division for further prosecution.

(b) The respondent requested that its further objections under Article 123(2) EPC to the dependent claims as granted and its novelty

objection in view of D6 to claim 1 as granted be also dealt with by the Board during the ongoing oral proceedings.

VI. At the end of the oral proceedings, the present decision was announced.

VII. **Independent claims 1 and 8 as granted (main request)** read as follows (with the feature numbering introduced in the decision under appeal and the amendments relative to claims 1 and 9 as originally filed, respectively, highlighted by the Board):

Claim 1 as granted:

1 *"An automated peritoneal dialysis ("APD") machine (104) comprising:*

1.1 *at least one pump;*

1.2 *a logic implementer*

1.2.1 *storing a plurality of therapy prescriptions by which to operate the at least one pump,*

1.2.2 *including prescriptions that specify different amounts of ultrafiltration ("UF"),*

1.2.3 *each therapy prescription pre-approved for a particular patient; and*

1.3 *an input device*

1.3.1 *operating with the logic implementer to allow the patient to select one of the therapy prescriptions for a particular therapy."*

Claim 8 as granted:

8 *"A ~~An automated peritoneal~~ dialysis ~~("APD")~~ system (10) comprising:*

8.1 *an automated peritoneal dialysis ("APD") machine (104);*

8.2 *a logic implementer*

8.2.1 *storing a plurality of therapy prescriptions by which to operate the ~~APD~~ dialysis machine,*

8.2.2 *including prescriptions that specify different amounts of ultrafiltration ("UF"),*

8.2.3 *each therapy prescription pre-approved for a particular patient treated by the ~~APD~~ dialysis machine; and*

8.3 *an input device*

8.3.1 *operating with the logic implementer to allow a doctor/clinician to select or approve one of the therapy prescriptions to be run on the ~~APD~~ dialysis machine.*"

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.

Claims 1 and 8 as granted - added subject-matter

Claims 1 and 8 as granted did not contain added subject-matter.

a) The person skilled in the art would understand the word "specify" in features 1.2.2 and 8.2.2 in its ordinary meaning of "define", i.e. that the therapy prescriptions stored in the claimed logic implementer included prescriptions that "defined" different amounts of ultrafiltration (UF). This was consistent with what the application as filed disclosed, for example in Figure 7A, which showed a list of possible therapy prescriptions that could be selected for storage in the logic implementer and that specified, i.e. defined, the predicted amounts of UF indicated in the column "24 hr UF (L)". Therefore, the word "specify", although not used literally in the application as filed, did not add subject-matter.

b) Furthermore, the person skilled in the art would infer from the application as filed as a whole that although the three levels of UF "low", "standard" and "high" were the most commonly used in practice, the therapy prescriptions stored in the logic implementer could in fact include any two or more prescriptions specifying, i.e. defining, different arbitrary amounts of UF, which a clinician could freely choose to ultimately provide the best personalised treatment for each individual patient in accordance with their lifestyle and daily routine. Therefore, features 1.2.2 and 8.2.2 were not based on an inadmissible intermediate generalisation.

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 3 on page 15 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.

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.

Remittal to the opposition division

In view of the primary purpose of the appeal proceedings, which was to obtain a judicial review of the contested decision, the case should be remitted to the opposition division for consideration of the further objections raised by the respondent which had not been dealt with in the decision.

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

Claims 1 and 8 as granted - added subject-matter

Independent claims 1 and 8 as granted contained added subject-matter in breach of Article 123(2) EPC.

a) Firstly, the application as filed did not implicitly or explicitly disclose that the therapy prescriptions stored in the logic implementer could "specify" an amount of UF as claimed in features 1.2.2 and 8.2.2.

In the application as filed, a "therapy prescription by which to operate the dialysis machine" was in practice a data set defining a dialysis treatment by defining the basic "therapy parameters" used to control the dialysis machine to carry out that treatment, such as the dialysate used, the fill volume and the dwell time (see e.g. paragraph [0002]).

The amount of UF, on the other hand, was not part of this data set but was rather the (desired) result of the treatment carried out on a patient. This was

because, unlike in haemodialysis, the amount of UF in peritoneal dialysis could not be directly controlled but only resulted from the exchange of substances between the dialysate and the patient's abdominal cavity during the patient's actual treatment. Accordingly, the amount of UF was not an intrinsic property of a therapy prescription or of the logic implementer storing that prescription. This was expressly reflected in the application as filed, which described the amount of UF as a "therapy result" (paragraph [0108]) and not as a "therapy parameter" on the basis of which the dialysis machine could be controlled. It followed that a therapy prescription did not include any information on the amount of UF and therefore could not "specify" an amount of UF.

For the same reason, the "standard UF prescription", "low UF prescription" and "high UF prescription" disclosed in the application as filed (see for example paragraphs [0108] to [0115]) could not be considered, even implicitly, to "specify" respective standard, low and high amounts of UF. Rather, the application as filed disclosed only that these prescriptions were selected for storage in the logic implementer and named as such on the basis of their predicted amount of UF. However, again, it did not disclose that these therapy prescriptions defined or in any way included the corresponding amounts of UF.

b) Secondly, even if it were considered that the application as filed disclosed that a therapy prescription could "specify" an amount of UF, features 1.2.2 and 8.2.2 would still infringe Article 123(2) EPC.

Indeed, features 1.2.2 and 8.2.2 only required that the plurality of prescriptions stored in the logic implementer included at least two prescriptions specifying different amounts of UF, i.e. possibly only two prescriptions with two amounts of UF differing from each other only by an arbitrarily small amount. In contrast, the application as filed consistently disclosed that the therapy prescriptions stored in the logic implementer had to include at least a "standard UF prescription", a "low UF prescription" and a "high UF prescription" (see for example paragraphs [0006], [0010], [0011], [0020], [0028], [0029] and [0066]). In addition, the corresponding standard, low and high amounts of UF could not be chosen arbitrarily but had to be sufficiently far apart from each other from a clinical point of view so that these prescriptions could be assigned to three different categories based on their respective amounts of UF. The omission of these requirements in features 1.2.2 and 8.2. resulted in an inadmissible intermediate generalisation.

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.

Remittal to the opposition division

The respondent's further added-matter objections under Article 123(2) EPC to the dependent claims as granted and the novelty objection in view of D6 to claim 1 as granted should be dealt with by the Board in the ongoing oral proceedings. Remittal of the case to the opposition division for further prosecution without the Board having first decided on these objections would unnecessarily delay the proceedings significantly and would be contrary to the *ratio legis* of Article 11 RPBA. According to this provision, the Board must not remit a case for further prosecution to the department whose decision was appealed unless there were special

reasons for doing so. Special reasons were not present in the case at hand.

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 volume of 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]).

1.2 The contested patent relates to an automated peritoneal dialysis machine, or a dialysis system comprising such a dialysis machine, comprising a logic implementer storing a plurality of therapy prescriptions by which to operate the dialysis machine, each therapy prescription pre-approved for a particular patient to be treated by the dialysis machine, and an input device operating with the logic implementer to allow the patient or a doctor/clinician to select one of the therapy prescriptions to be run by the dialysis machine. The dialysis machine and the dialysis system are respectively defined in independent claims 1 and 8.

Claims 1 and 8 stipulate that the plurality of therapy prescriptions stored in the logic implementer include

"prescriptions that specify different amounts of ultrafiltration" (features 1.2.2 and 8.2.2). The amount of ultrafiltration (UF) is the amount of fluid that should be removed from the patient's body during a dialysis treatment to return the patient to their target or base weight. As described in paragraph [0022], the prescriptions may include, for example, a "low UF prescription" adapted for days when the patient has lost large amounts of body fluid, for example through sweat after heavy exercise; a "high UF prescription" for days when the patient has consumed more liquids than usual; and a "standard UF prescription" for all other normal days. This allows the patient to select and run a pre-approved prescription that is tailored to their daily activities and lifestyle.

2. Main request - claims 1 and 8 as granted - added subject-matter (Article 123(2) EPC)

2.1 It is common ground that independent claims 1 and 8 as granted correspond respectively to claims 1 and 9 as filed with the addition of features 1.2.2 and 8.2.2, according to which the therapy prescriptions stored in the logic implementer "includ[e] prescriptions that specify different amounts of ultrafiltration ('UF')". These additional features are not themselves literally disclosed in the application as filed.

2.2 The respondent objected to the word "specify" and argued that the application as filed did not disclose that a therapy prescription stored in the logic implementer could "specify" an amount of UF.

The Board disagrees.

The Board recognises that, as argued by the respondent, the amount of UF in peritoneal dialysis - unlike, for example, the dwell time or the fill volume - is not a parameter that can be used directly to control the peritoneal dialysis machine and thus the dialysis treatment applied to the patient. This is because the amount of UF in peritoneal dialysis cannot be directly adjusted but results from the exchange of substances between the dialysate and the patient's abdominal cavity during the patient's actual treatment, which itself can be only indirectly and partially controlled. It follows that the amount of UF associated with a therapy prescription can indeed only be estimated in advance using appropriate simulation models or quantified during the actual dialysis treatment of the patient. This is expressly acknowledged in the application as filed, where the amount of UF is described as a "therapy result" (paragraphs [0108] to [0113]) and not as a "therapy parameter" (paragraph [0002]). The contested patent, whose specification is largely identical to the original description, is also based on the same understanding of the amount of UF. This was also not disputed by the appellants.

Accordingly, the person skilled in the art, who is familiar with peritoneal dialysis, would understand that, in the context of the contested patent, features 1.2.2 and 8.2.2, by referring to a therapy prescription that "specifies" a certain amount of UF, simply refer to a therapy prescription which is expected, when administered to a patient by running it on the dialysis machine, to result in that amount of UF, for example as determined by appropriate simulation.

As submitted by the appellants, this is no different from what the application as filed consistently discloses for the various therapy prescriptions associated with a particular predicted amount of UF for storage in the logic implementer. For example, the person skilled in the art would, with the same understanding, consider that the various candidate prescriptions listed in the table shown in Figure 7A "specify" the predicted amounts of UF indicated in the "24 hr UF (L)" column. Similarly, the three prescriptions selected as "standard UF regimen", "higher UF prescription" and "low UF prescription" as disclosed in paragraphs [0112] to [0115] respectively "specify" a standard UF, a high(er) UF and a low(er) UF.

It follows that, contrary to the respondent's argument, the word "specify" in features 1.2.2 and 8.2.2, although not used literally in the application as filed, does not itself add subject-matter.

2.3 The respondent also objected that features 1.2.2 and 8.2.2 were based on an inadmissible intermediate generalisation because they only required a minimum of two prescriptions specifying two different amounts of UF. Moreover, in the absence of any further requirement, these two amounts could be arbitrarily close to each other. However, by contrast, as the respondent argued, the application as filed consistently disclosed that the therapy prescriptions stored in the logic implementer included at least a "standard UF prescription", a "low UF prescription" and a "high UF prescription", associated with three clinically different amounts of UF which could not be chosen arbitrarily.

This objection is not convincing either.

As argued by the appellants, the person skilled in the art would understand from the application as filed as a whole that these three levels of UF "standard", "low" and "high" to which the respondent referred correspond only to an exemplary set of prescriptions that can be stored in the logic implementer to ultimately enable a patient to select and perform a dialysis treatment that better suits their daily activities. This is explicitly mentioned in paragraph [0020] ("One set of prescriptions can include for example: (i) a standard UF prescription; (ii) a high UF prescription; and (iii) a low UF prescription"; emphasis added by the Board). This set of three therapy prescriptions, specifying not only a typical amount of UF but also a lower and a higher amount of UF, indeed offers good flexibility to the patient and may well be the most commonly used choice in practice.

However, the person skilled in the art would also recognise that this flexibility is not necessarily achieved with exactly three such prescriptions. While more prescriptions specifying a larger number of different amounts of UF (such as five prescriptions, see paragraph [0029]) obviously offer even greater flexibility, the person skilled in the art would also understand from the application as filed that, conversely, the purported flexibility is already achieved with only two prescriptions specifying two different amounts of UF, the description as filed indeed generally disclosing that "a certain number of" (paragraph [0006]), "multiple" (paragraph [0010]) and "a few" (paragraph [0019]) therapy prescriptions, each specifying a different amount of UF, can be selected for storage in the logic implementer. The fact that

features 1.2.2 and 8.2.2 only require "prescriptions that specify different amounts of UF", i.e. at least two of such prescriptions, does therefore not extend beyond the original disclosure.

With respect to the selection of the different amounts of UF specified by the prescriptions stored in the logic implementer, the application as filed consistently discloses that this choice is left to the full discretion of the doctor or clinician in consultation with the patient (see for example paragraph [0019]: "The clinician and patient then agree on a few of the paired down prescription possibilities to be stored as prescriptions on the patient's APD machine"). Therefore, the fact that features 1.2.2 and 8.2.2 do not contain any requirement as to the extent to which the different amounts of UF must differ does not result in added subject-matter either.

It follows that features 1.2.2 and 8.2.2 are not based on an inadmissible intermediate generalisation, contrary to the respondent's view.

3. The Board therefore concludes that, contrary to the opposition division's finding in the decision under appeal, claims 1 and 8 as granted do not contain added subject-matter in breach of Article 123(2) EPC. The contested decision is therefore to be set aside.

4. Public availability of D1'''

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

4.2 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.

4.3 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 3 on page 15 of the decision under appeal, first paragraph, 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.

5. Public availability of D6

5.1 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.

5.2 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 13 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 4. b) on page 21). 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.

5.3 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.

5.4 Availability to the public of D6

5.4.1 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.

5.4.2 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 17 of the decision, second 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 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.

5.4.3 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.

6. Remittal to the opposition division

6.1 The decision under appeal did not deal with the further objections under Article 123(2) EPC raised by the respondent in the notice of opposition against dependent claims 4, 6, 7, 10 to 15 (see section 6.b) on pages 34 to 36). Since the features defined in these dependent claims are not related to features 1.2.2 and 8.2.2 discussed above in connection with independent claims 1 and 8 but concern other aspects of the claimed dialysis machine and system, the assessment of whether these dependent claims comply with Article 123(2) EPC in the current appeal proceedings would open a completely new discussion. This would also require the Board to decide on these issues for the first time in the absence of a corresponding decision by the opposition division.

The same applies to the other grounds for opposition under Article 100(a) and (b) EPC, including the question of the novelty of claims 1 and 8 as granted in view of D6, which were also raised by the respondent in

the opposition proceedings but not dealt with in the decision under appeal.

In view of the primary purpose of the appeal proceedings, which is to review the decision under appeal in a judicial manner (Article 12(2) RPBA), the Board therefore considers, in line with its preliminary view set out in the communication under Article 15(1) RPBA and contrary to the respondent's argument, 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.

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