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Datasheet for the decision of 2 February 2024

T 2651/19 - 3.2.02 Case Number:

Application Number: 10771589.8

Publication Number: 2488227

A61M1/16, A61M1/28 IPC:

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, 84, 123(2) RPBA Art. 12(4) (2007)

Keyword:

Novelty - main request (no)

Late-filed request - auxiliary request 1 - admitted in firstinstance proceedings (no) - admitted (no)

Amendments - auxiliary request 2 - added subject-matter (yes)

Decisions cited:

G 0010/91



Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 2651/19 - 3.2.02

DECISION
of Technical Board of Appeal 3.2.02
of 2 February 2024

Appellant: Baxter International Inc.

(Patent Proprietor 1)

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Deerfield, IL 60015 (US)

Appellant: Baxter Healthcare S.A. Thurgauerstrasse 130

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Respondent: Fresenius Medical Care AG & Co. KGaA

(Opponent) Else-Kröner-Strasse 1 61352 Bad Homburg (DE)

Representative: Nordmeyer, Philipp Werner

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Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 23 July 2019 revoking European patent No. 2488227 pursuant to

Article 101(3)(b) EPC.

Composition of the Board:

Chairman M. Alvazzi Delfrate Members: S. Dennler

C. Schmidt

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Summary of Facts and Submissions

- I. The patent proprietors filed an appeal against the decision of the opposition division to revoke the contested patent on the grounds that none of the requests admitted in the opposition proceedings met the requirements of the EPC. The opposition division held, inter alia, that the subject-matter of claim 1 as granted was not novel in view of the following document:
 - extract from the QuickMark software publisher's
 website taken on 5 June 2009
 (www.quickmark.com.tw/En/basic/hotnews.asp),
 retrieved via the Wayback Machine

and that claim 1 of auxiliary request 2, submitted by the patent proprietors during the oral proceedings and admitted by the opposition division, contained added subject-matter. Another request submitted by the patent proprietors during the oral proceedings, auxiliary request 1, was not admitted by the opposition division as claim 1 of that request was considered to be *prima facie* unclear.

- II. The appellants (patent proprietors) requested that the decision under appeal be set aside and that the contested patent be maintained as granted (main request) or, alternatively, in amended form on the basis of the auxiliary request 1 or 2 submitted at the oral proceedings before the opposition division.
- III. The respondent (opponent) requested that the appeal be dismissed.

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IV. Claim 1 of the **main request** (claim 1 as granted) reads as follows:

"A dialysis system (10a to 10d, 110a, 110b) comprising:

a portable device (30a to 30c, 90) configured to be carried by a patient (12) such that the patient can hold the device (30a to 30c, 90) next to a marking (18) displayed on a dialysis fluid container (16) and configured to read the marking (18), the device (30a to 30c, 90) obtaining data concerning at least one of a dialysis fluid type and a dialysis fluid volume from the marking (18); the device (30a to 30c, 90) further configured to transfer the data to a computer (52, 120); and wherein the computer (52, 120) is configured to use the data to track therapy progress of the patient (12)."

V. Claim 1 of auxiliary request 1 reads as follows (with the amendments compared to claim 1 as granted highlighted by the Board):

"A dialysis system (10a to 10d, 110a, 110b) comprising:

a portable device (30a to 30c, 90) configured to be carried by a patient (12) such that the patient can hold the device (30a to 30c, 90) next to a marking (18) displayed on a dialysis fluid container (16) and configured to read the marking (18), the marking (18) is then read by the portable device (30a to 30c, 90), the device (30a to 30c, 90) obtaining data concerning at least one of a dialysis fluid type and a dialysis fluid volume from the marking (18);

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the device (30a to 30c, 90) further configured to transfers the data to a computer (52, 120); and wherein the computer (52, 120) is configured to uses the data to track therapy progress of the patient (12)."

VI. Claim 1 of auxiliary request 2 reads as follows (with the amendments compared to claim 1 as originally filed highlighted by the Board):

"A dialysis system (10a to 10d, 110a, 110b) comprising:

a portable device (30a to 30c, 90) configured to be carried by a patient (12) such that the patient can hold the device (30a to 30c, 90) next to and to read a marking (18) displayed on a dialysis fluid container (16) and configured to read the marking (18), the device (30a to 30c, 90) obtaining data concerning at least one of a dialysis fluid type and a dialysis fluid volume from the marking (18); the device (30a to 30c, 90) further configured to transfer the data to a computer (52, 120); and wherein the computer (52, 120) is configured to use the data to track therapy progress of the patient (12); wherein the dialysis system further comprises

a server computer (120) in communication with the portable device (30a to 30c, 90), the portable device (30a to 30c, 90) further configured to send supply usage data to the server computer (120);

a doctor/clinician computer (52) in communication with the server computer (120), the doctor/clinician computer (52) configured to send a

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therapy prescription for the patient to the server computer (120); and

<u>a supply warehouse computer (116) in</u> communication with the server computer (120),

wherein the portable device (30a to 30c, 90), server computer (120), doctor/clinician computer (52) and supply warehouse computer (116) are linked such that the server computer (120) can issue a supply order for the patient to the supply warehouse computer (116), the supply order taking into account the therapy prescription and the supply usage data."

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

Main request - novelty in view of E16

The subject-matter of claim 1 as granted was novel over E16.

Firstly, it was the opposition division that raised the novelty objection in view of E16, not the respondent, which had submitted E16 in the opposition proceedings only for an inventive-step objection. However, the opposition division was not entitled to raise this objection because opposition proceedings were not an opportunity for the opposition division to re-examine a patent in detail on its own initiative.

Secondly, this novelty objection was, in any event, unfounded. E16 was very remote and did not relate to any medical aspect. In particular, it did not disclose a dialysis system, let alone a dialysis system

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according to claim 1 as granted comprising a portable device, a computer and all the claimed functionality which limited that structure. In accordance with the interpretation of the expression "configured to" accepted in the field of computer-implemented inventions, the claimed portable device and the claimed computer were not merely suitable for carrying out the functions following this expression but were adapted to carry them out. Therefore, the features including and following the expressions "configured to" limited the claimed subject-matter and could not be ignored in assessing the novelty of claim 1.

Auxiliary request 1 - admittance

The opposition division's decision not to admit auxiliary request 1 on the ground that claim 1 of that request was unclear was incorrect, and this request should be admitted on appeal. Claim 1 of auxiliary request 1 was clear.

The opposition division's finding that it was unclear contradicted the opposition division's earlier finding that the invention as claimed in claim 1 as granted was sufficiently disclosed. Indeed, it was from the point of view of the same person skilled in the art that both Articles 83 and 84 EPC were assessed.

Claim 1 of auxiliary request 1 had been reworded so that all features introduced by the expression "configured to" were instead positively ("actively") recited. These amendments did not change the meaning of claim 1 in any way. As in claim 1 as granted, the functional language imposed clear limitations on the portable device and the computer that would not otherwise have existed.

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Auxiliary request 2 - added subject-matter

Claim 1 of auxiliary request 2 did not contain any added subject-matter. This claim was essentially a combination of original claims 1 and 22. Although these claims had been drafted as independent claims, their combination was fully supported by the application as originally filed, including paragraphs [0023], [0024] and [0067] to [0070] of the original description and Figure 5. The computer first mentioned in claim 1 represented a class of computers with which the portable device was generally configured to communicate and which encompassed the other three computers defined later in the claim. The respondent's objection against this was based on a deliberate linguistic misunderstanding.

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

Main request - novelty in view of E16

The subject-matter of claim 1 as granted was not novel in view of E16. It was immaterial that this novelty objection had been raised by the opposition division on its own motion.

Claim 1 as granted did not require the claimed "dialysis system" to comprise any component for performing a dialysis treatment, such as a dialysis machine or a dialysis fluid container, or a computer. Rather, the claimed system was limited to a portable device suitable for being held by a patient next to a marking displayed on a dialysis fluid container and being configured to read data from that marking and transfer it to a computer. The nature of the data

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obtained from the marking and the steps performed by the computer with that data, i.e. the use of the data to track the patient's therapy progress, were irrelevant because they did not limit the subjectmatter of claim 1. The patent itself (paragraphs [0059] and [0060]) stated that the claimed invention could be carried out by an iPhone running the appropriate software, for example, the QuickMark software.

E16 disclosed just that configuration (see page 1). Such a portable device was configured to read a barcode, decode it, append the decoded barcode data to the end of a URL and access it via the smartphone's browser (see page 2) and thus transfer it to a remote computer. This device was also clearly suitable for reading a barcode displayed on a dialysis fluid container. E16 was therefore novelty-destroying.

Auxiliary request 1 - admittance

Claim 1 of auxiliary request 1, which was directed not to a method but to a system, defined that system by reference to the manner in which it was to be used ("carried by a patient", "is then read", "further transfers" and "uses that data"). The intended technical limitations were not clear to the person skilled in the art. Claim 1 was therefore prima facie not clear, and auxiliary request 1 should not be admitted in the appeal proceedings.

Auxiliary request 2 - added subject-matter

Claim 1 of auxiliary request 2 contained added subjectmatter. Compared to claim 1 as granted, this claim explicitly defined three computers as part of the claimed dialysis system (a server computer, a doctor/ - 8 - T 2651/19

clinician computer and a supply warehouse computer) with which the claimed portable device was somehow "linked" and "further" configured to communicate. However, claim 1 of auxiliary request 2 did not require that the computer first mentioned in the claim, to which the portable device was configured to transfer the data obtained from the marking as defined in granted claim 1, be one of these three computers or even be part of the claimed dialysis system. It followed that the portable device according to claim 1 of auxiliary request 2 was in fact configured to interact with four different computers. This configuration of the portable device was not disclosed in the application as originally filed.

Reasons for the Decision

1. The subject-matter of the contested patent

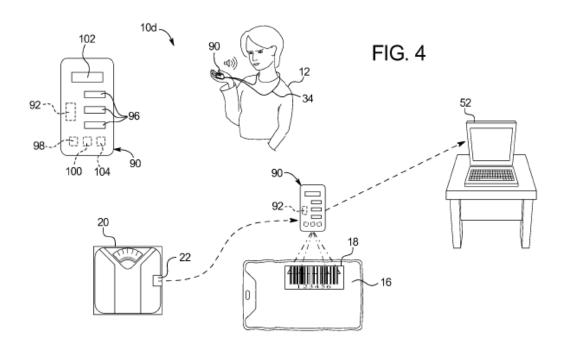
Like haemodialysis, peritoneal dialysis is a therapy commonly used to treat a patient's loss of kidney function (paragraph [0003]). Peritoneal dialysis uses a dialysate which is infused through an implanted catheter and left dwelling in the patient's peritoneal cavity for a period of time. There, the dialysate contacts the peritoneal membrane, through which waste, 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 a system for assisting the patient in managing a peritoneal dialysis therapy, such as continuous ambulatory peritoneal dialysis (paragraph [0015]), in which the patient performs the

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fill, dwell and drain cycles manually at home (paragraph [0005]).

1.2 An example embodiment of a system according to claim 1 as granted is shown in Figure 4 reproduced below.



The system comprises a portable device (90), which can be a smartphone (paragraph [0059]). When the device is held by the patient (12) next to a marking, such as a barcode (18), displayed on a dialysis fluid container (16), the device is configured to read the marking and thus obtain data concerning at least one of a dialysis fluid type and a dialysis fluid volume corresponding to that container. The device then transfers the obtained data to a computer (52) configured to use the data to track the therapy progress of the patient. This computer can be, for example, a doctor's computer (see granted claim 6) or a server computer configured to automatically order a solution bag for delivery to the patient (see granted claim 16).

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2. Main request - novelty in view of E16

- 2.1 The Board agrees with the respondent that the subjectmatter of claim 1 as granted is not novel in view of E16.
- 2.1.1 Contrary to the appellant's argument, it follows from the wording of claim 1 as granted that neither the dialysis fluid container nor the computer, although both referred to in the claim, is part of the claimed "dialysis system". Rather, the subject-matter of claim 1 as granted is limited to a "dialysis system" comprising a "portable device" "configured" in a particular way. One or more computers are positively defined as part of the system, but only in dependent claims 21 and 22 as granted (see, for example, claim 21: "The dialysis system [...] which includes a computer").
- 2.1.2 As regards the expression "configured", in agreement with the appellant, the Board recognises that in the field of computer-implemented inventions this expression must generally be interpreted as meaning "adapted" to carry out the steps or functions defined after the expression and not merely as meaning "suitable" for carrying them out.

Given that the portable device is "configured to transfer the data to a computer" and, in particular, that it can be a smartphone running appropriate software, as disclosed in paragraphs [0059] and [0060] of the contested patent, this interpretation does apply, as argued by the appellant, to the claimed portable device, which must therefore be adapted, i.e. programmed, to read a marking, obtain data from that marking and transfer that data to a computer.

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This interpretation also applies, of course, to the computer to which the portable device transfers the data. However, since that computer does not form part of the claimed system, as mentioned above, the configuration of the computer and the steps performed by that computer with the data (namely, the use of the data to track the patient's therapy progress) have no bearing on the claimed system and do not limit it.

On the other hand, the feature according to which the portable device is "configured to be carried by a patient (12) such that the patient can hold the device (30a to 30c, 90) next to a marking (18) displayed on a dialysis fluid container (16)" does not relate to the portable device being programmed in a particular way but merely reflects the fact that the device is portable and suitable, *inter alia*, to be held by a patient for reading a marking displayed on a dialysis fluid container.

- 2.1.3 The Board agrees with the respondent that the feature according to which the data obtained from the marking "concern[s] at least one of dialysis fluid type and a dialysis fluid volume" does not limit the claimed system. This feature is not technical and merely associates arbitrary cognitive content with the marking. This cognitive content is irrelevant for the portable device, which is only configured to obtain data from the marking and transfer it to a computer.
- 2.1.4 The Board shares the respondent's view that the term "dialysis system" in the contested patent does not have to include a component for performing a dialysis treatment, such as a dialysis machine - or, as mentioned above, a dialysis fluid container - but is only a system suitable for use in connection with

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dialysis, such as a system for optimising a dialysis therapy, as consistently disclosed throughout the patent (see, for example, paragraph [0015] of the patent). In claim 1 as granted, the claimed "dialysis system" can therefore be limited to the sole "portable device" defined in the claim, suitable for reading a marking displayed on a dialysis fluid container.

2.1.5 As considered by the opposition division in the contested decision and submitted again by the respondent on appeal, E16 discloses that an iPhone running the QuickMark software is configured to read a barcode, decode it and transfer the decoded barcode data to a remote computer, for example, by appending it to the end of a URL and accessing this URL via the smartphone's browser (see pages 1 and 2).

An iPhone configured in this way is also clearly suitable for reading a barcode displayed on a dialysis fluid container and as such can itself be regarded as a "dialysis system" (see point 2.1.4 above). The fact that, as argued by the appellant, E16 does not deal with any medical aspect, in particular dialysis, does not prevent the iPhone running the QuickMark software from being suitable for that use and is therefore irrelevant.

It follows that the portable device disclosed in E16 anticipates the subject-matter of claim 1 as granted interpreted as discussed above. As submitted by the respondent, an iPhone running the QuickMark software amounts to the portable device described in paragraphs [0059] and [0060] of the contested patent.

2.2 Contrary to the appellant's view, it is immaterial that this novelty objection was first raised by the

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opposition division and that E16 was originally filed by the respondent in the different context of an inventive-step objection.

Although it is true, as submitted by the appellant, that an opposition division should not undertake a complete re-examination of an opposed patent on its own motion, an opposition division is not prevented from examining the patentability of the subject-matter of the patent if facts come to its notice which, prima facie, wholly or partially prejudice the maintenance of the patent (see, for example, G 10/91, point 2 of the Order). In the current case, the opposition division's view that E16 was prima facie relevant for novelty is clearly justified in point 3 of the decision under appeal.

3. Auxiliary request 1 - admittance

- Auxiliary request 1 was filed by the appellant during the oral proceedings before the opposition division to overcome the novelty objection raised in view of E16. At that late stage of the proceedings, the admittance of this request was at the opposition division's discretion. Exercising this discretion, the opposition division decided not to admit auxiliary request 1, considering that claim 1 of this request was prima facie unclear, as explained in point 5.1 of the decision under appeal.
- 3.2 Under Article 12(4) RPBA (which applies in this case by virtue of the transitional provisions of Article 25(2) RPBA 2020), a board has the power to hold inadmissible requests not admitted in the first-instance proceedings. Moreover, a board should only overrule the way in which a department of first instance exercised

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its discretion not to admit a request if the board comes to the conclusion that this was done according to the wrong principles or in an unreasonable way or if the circumstances of the appeal case justify its admittance.

In the case at hand, the Board sees no reason to doubt that the opposition division exercised its discretion in accordance with the proper principles and in a reasonable way. There is no inconsistency in the opposition division's findings that claim 1 was unclear and at the same time that the invention of the contested patent was sufficiently disclosed. Clarity of the claims and sufficiency of the disclosure are two different requirements of the EPC to be assessed separately and according to different criteria.

Consequently, there is no reason for the Board to overrule the opposition division's decision not to admit auxiliary request 1.

- 3.3 In any event, the Board shares the view that claim 1 of this request, which defines the system by reference to the manner in which it is to be used ("carried by a patient", "is then read", "further transfers" and "uses that data") instead of defining it in terms of its technical features, is prima facie not clear.
- 3.4 The Board therefore decides not to take auxiliary request 1 into account in the appeal proceedings.

4. Auxiliary request 2 - added subject-matter

4.1 The Board agrees with the respondent that claim 1 of auxiliary request 2 contains added subject-matter, contrary to Article 123(2) EPC.

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- 4.2 Compared to claim 1 as granted, claim 1 of auxiliary request 2 explicitly defines three computers as being comprised in the claimed dialysis system ("wherein the dialysis system further comprises a server computer (120) [...] a doctor/clinician computer (52) [...] and a supply warehouse computer (116)") to which the portable device is "linked".
- As submitted by the respondent, claim 1 does not specify that the first computer mentioned in the claim, to which the portable device is configured to "transfer the data" obtained from the marking, is one of these three computers.

The Board does not accept the appellant's argument that this is necessarily so and that the person skilled in the art would implicitly understand the claim in this way. No such link can be inferred from the plain wording of claim 1. This applies irrespective of the fact that the portable device is claimed to be "linked" to these three computers. Rather, as submitted by the respondent, claim 1 of auxiliary request 2 states that the portable device is "further configured to send supply usage data to the server computer" (emphasis added by the Board). The term "further" implies that this function of the portable device is in fact different from its first function of "transfer[ring] the data [obtained from the marking] to a computer" defined earlier in the claim.

4.4 The Board therefore agrees with the respondent that the portable device in claim 1 of auxiliary request 2, in addition to being "linked" to the three computers of the claimed system, can be configured to send data to an additional, different fourth computer.

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4.5 It is common ground that the application as originally filed, in particular the paragraphs of the original description cited by the appellant, does not disclose such a configuration involving four different computers.

The fact that claim 1 of auxiliary request 2 essentially corresponds to the combination of original independent claims 1 and 22 is irrelevant. Original claim 22 mentions only three computers to which the portable device is "linked" but does not mention an additional, different computer with which the portable device would additionally communicate. Admittedly, original claims 6 and 16, which depend on original claim 1 - the wording of which has been substantially retained in claim 1 of auxiliary request 2 - explicitly state that the computer referred to in claim 1 is a doctor/clinician computer or a server computer. However, such an explicit relationship between the computers is not defined in claim 1 of auxiliary request 2.

4.6 For these reasons, the Board agrees with the respondent that claim 1 of auxiliary request 2 presents new information to the person skilled in the art which was not originally disclosed, in breach of Article 123(2) EPC.

5. Conclusion

It follows from the foregoing that none of the appellants' requests taken into account by the Board in the appeal proceedings meets the requirements of the EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated