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**Datasheet for the decision
of 10 March 2011**

Case Number: T 0547/08 - 3.2.02

Application Number: 97938177.9

Publication Number: 0959980

IPC: A61M 1/16

Language of the proceedings: EN

Title of invention:

Dialysis machines with touch screen user interface

Patentee:

HHD LLC

Opponent:

Fresenius Medical Care Deutschland GmbH

Headword:

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Relevant legal provisions:

EPC Art. 56, 64(1), 69(1), 112(1), 123(2)(3)

Relevant legal provisions (EPC 1973):

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Keyword:

"Extension of scope of protection (no)"

"Inventive step (yes)"

"Referral to Enlarged Board of Appeal (no)"

Decisions cited:

G 0002/88, G 0003/98, T 0352/04, T 0867/05

Catchword:

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Case Number: T 0547/08 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 10 March 2011

Appellant: Fresenius Medical Care Deutschland GmbH
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
14 February 2008 concerning maintenance of the
European patent No. 0959980 in amended form.

Composition of the Board:

Chairman: M. Noël
Members: C. Körber
A. Pignatelli

Summary of Facts and Submissions

- I. On 14 February 2008 the Opposition Division posted its interlocutory decision concerning maintenance of European patent No. 0 959 980 in amended form.
- II. An appeal was lodged against this decision by the opponent by notice received on 13 March 2008, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 13 June 2008.
- III. By communication of 27 December 2010, the Board forwarded its provisional opinion to the parties.
- IV. Oral proceedings were held on 10 March 2011, at the end of which the requests of the parties were as follows:
- The appellant (opponent) requested that the impugned decision be set aside and that the patent be revoked. He further requested that the two questions posed on page 11 of his letter dated 9 February 2011 be referred to the Enlarged Board of Appeal.
- The respondent (patentee) requested that the appeal be dismissed.
- V. The following documents are of importance for the present decision:

D1: DE-A-195 00 529
D5: EP-A-0 321 754
D6: US-A-5 472 614

D11: WO-A-94/11093

D13: US-A-5 326 476.

VI. The independent claims of the patent in the form as maintained by the Opposition Division read as follows:

"1. A system for controlling the operation of a dialysis machine (10), comprising, in combination: a user interface (12) comprising:
(1) a touch screen (14) displaying messages and information as to said machine (10) to a user and permitting said user to touch said touch screen (14) to select at least one parametric value pertinent to operation of said machine (10) or pertinent to a treatment by said machine (10); and
(2) at least one hard key (16) off of said touch screen (14), said touch screen (14) prompting said user to press said hard key (16) to signify that the selection of said at least one parametric value by said user has been completed; and
a control system (100) within said machine (10) for controlling operation of said machine (10) and responsive to said touch screen (14) and said at least one hard key (16), said control system (100) comprising a host microprocessor (110) and a safety microprocessor (116) operatively connected to each other so as to enable an exchange of information related to said at least one selected parametric value,
wherein pressing of said hard key (16) causes said host (110) and safety (116) microprocessors to undergo a verification routine whereby said selected parametric value is checked for appropriateness for a patient connected to said machine (10) so as to prevent changes to said parameter potentially harmful to said patient."

"15. A method of controlling a dialysis machine (10) having a user interface (12) and a central computer system (100) to control the operation of said dialysis machine (10), said user interface (12) having a touch screen (14) enabling a patient, by touching the touch screen (14), to select parametric values and accomplish entry of said selected parametric values in a process of changing a parametric value pertinent to operation of said machine (10) or pertinent to a dialysis treatment of a patient connected to said machine, the method comprising:

providing said user interface with at least one hard key (16;18);

connecting said hard key (16;18) to said central computer system (100); and

after said user has selected said parametric value and entered said selected parametric value by touching the touch screen (14), prompting said user of said machine (10) to press said hard key (16;18) to confirm the entry of said parametric value, so that a failure in said touch screen (14) to respond to touching of the touch screen (14) to confirm parametric value changes may be avoided."

"22. A dialysis machine comprising a user interface (12) and screen display apparatus that promotes ease of use of said user interface (12) by a user operating said machine (10) without immediate supervision by trained professional medical personnel, comprising:

(a) a touch screen (14);

(b) a screen display for such touch screen (14), said display arranged in at least two portions extending

across said display, said at least two portions comprising:

- (1) a first portion displaying instruction and status information to a user of said machine (10); and
- (2) a second portion (72) adjacent to said first portion on said display and displaying a plurality of icons, each of said icons associated with a specific functional activity associated either with said machine (10) or a treatment session of said machine (10); and
- (c) at least one hard key (16; 18) associated with said display, said first portion of said screen display prompting said user to press said at least one hard key (16;18) in a process of confirming entry of information into said machine (10)."

Claims 2 to 14, 16 to 21 and 23 to 29 are dependent claims.

VII. The appellant's relevant arguments are summarised as follows:

Claim 22 as granted was directed to a user interface per se. The term "for a dialysis machine" merely implied its suitability for a dialysis machine and did not exclude the user interface being usable for other devices. The term "for" was not limiting and did not imply that the dialysis machine formed part of the claimed subject-matter. Claim 22 as maintained by the Opposition Division, on the other hand, was directed to a dialysis machine comprising a user interface. Consequently, an "aliud" was claimed and the scope of protection as afforded by the amended claim was shifted and extended in breach of Article 123(3) EPC. A dialysis machine as now claimed was not within the

scope of protection as defined by claim 22 as granted and could also not have been claimed by means of a claim dependent therefrom. According to T 352/04 and T 867/05, a shift to a more complex aliud which was not encompassed by the claims as granted was not allowable under Article 123(3) EPC.

As a result of the amendment to claim 22 the rights of the patentee to sue third parties for indirect infringement had changed. The scope of protection had been broadened since parties who could not be sued for contributory infringement on the basis of the claims as granted could be sued on the basis of the claims as upheld in the opposition proceedings. When assessing the requirements of Article 123(3) EPC, the scope of protection had to be determined according to Article 69(1) EPC and its Protocol, as ruled in G 2/88. It followed that the legal certainty of third parties had to be taken into consideration in this respect. Necessarily, this also implied infringement issues.

In the event that the present Board were to decide otherwise on this issue, the following questions should be referred to the Enlarged Board of Appeal:

1. Which criteria should be applied when deciding whether a change to a patent claim in opposition proceedings from a first physical entity results in a more complex physical entity which qualifies as an aliud and thus constitutes a violation of Article 123(3) EPC?
2. Is it consistent with the safeguarding of legal certainty for third parties as required by the Protocol

on the Interpretation of Article 69 EPC if, in at least one designated Contracting State, that change to the claim confers rights on the patent proprietor for the first time which did not exist for the claim as granted?

D13 was particularly relevant for the assessment of inventive step since it related to a dialysis machine with a user interface comprising a touch screen and explicitly referred to the problem of touch screen failure in columns 307/308 and disclosed a "verify button" prompting the user to confirm the entry of information into the machine. A double verification routine was also disclosed in the first paragraph of page 10 of D11. Claim 22 in suit differed from D13 and D11 only in that it required the user to be prompted to press a **hard** key. The problem to be solved by this feature was to achieve a clearer and better perceptible design of the user interface. This was exactly the problem addressed in D1 (paragraph bridging columns 1 and 2), which also disclosed the solution as claimed by means of a confirmation switch ("Quittierschalter 22"). The obviousness of this feature was further apparent from the fact that the inventors of D1 started from a device without a touch screen, but decided not to incorporate into the touch screen the entire communication and interaction with the user. Instead, they deliberately retained certain hard keys (21, 22), i.e. keys not to be operated via the touch screen. Accordingly, the subject-matter of claim 22 was obvious from D11/D13 in view of D1, which documents were clearly combinable since respirators and dialysis machines could be found side by side in a hospital environment.

Even though directed to a respirator, D1 could also be regarded as the closest prior art since it comprised all features of claim 22 with the exception that the user interface was part of a dialysis machine. In particular, D1 disclosed in column 2, lines 26 to 31, the crucial feature of prompting the user to press a key in order to confirm the entry of information. For the skilled person it was obvious to incorporate a user interface known from a respirator into a neighbouring medical device such as a dialysis machine.

VIII. The respondent's relevant arguments are summarised as follows:

Claim 22 as upheld had been clearly restricted by including the dialysis machine as an additional technical feature, being of the same category (apparatus) as the user interface. According to G 2/88, the appellant's arguments relating to contributory infringement should be ignored. Such matters related to the rights conferred on the patentee by national law of the Contracting States per Article 64(1) EPC. As clearly ruled in G 2/88, this issue was not to be considered when deciding about the requirements of Article 123(3) EPC. Accordingly, there was no need to refer the questions posed by the appellant to the Enlarged Board of Appeal.

When starting from documents D11/D13, which both disclosed "verification buttons" appearing on the touch screen and prompting the user to confirm the entry of changed parameter values via the touch screen, there was no motivation whatsoever for the skilled person to

consider the possibility of prompting the user to press a separate hard key, the presence of which was not even envisaged in D11/D13. The problem to be solved by the distinguishing feature was to improve the safety of operation, in particular by an untrained user such as the patient himself. D1 was not combinable with D11/D13 since D1 related to a different technical field, namely a respirator which was generally operated by trained medical personnel, the patient being unconscious.

Since D1 did not relate to a dialysis machine, it could not be considered as closest prior art with respect to the subject-matter of claim 22. Moreover, it failed to address the problem underlying the claimed invention. The touch screen disclosed in D1 did not display any instruction information to the user and did not prompt the user to press a hard key to confirm the selection of a parametric value. Any assumption that a skilled person would seek to incorporate the respirator user interface disclosed in D1 into a conventional dialysis machine would be based on hindsight.

Reasons for the Decision

1. The appeal is admissible.
2. The feature denotation of claim 22 proposed by the respondent as given below in bold will be used in the following:

(P) A dialysis machine comprising a user interface (12) and screen display apparatus that promotes ease of use of said user interface (12) by a user operating said

machine (10) without immediate supervision by trained professional medical personnel, comprising:

(Q) (a) a touch screen (14);

(R) (b) a screen display for such touch screen (14), said display arranged in at least two portions extending across said display, said at least two portions comprising:

(S) (1) a first portion displaying instruction and status information to a user of said machine (10); and

(T) (2) a second portion (72) adjacent to said first portion on said display and displaying a plurality of icons, each of said icons associated with a specific functional activity associated either with said machine (10) or a treatment session of said machine (10); and

(U) (c) at least one hard key (16; 18) associated with said display, said first portion of said screen display prompting said user to press said at least one hard key (16;18) in a process of confirming entry of information into said machine (10).

3. Amendments

3.1 Basis

Claim 1 corresponds to original claim 1 as published under WO-A-98/35747. Independent claim 15 is based on claim 8 (with alternative (a) deleted). Independent claim 22 is based on claim 15. The Board is satisfied that the requirements of Article 123(2) EPC are met.

3.2 Scope of protection

Claim 22 as granted was directed to a user interface (12) and screen display apparatus for a dialysis

machine (10) that promotes ease of use of said user interface (12) by a user operating said machine (10) without immediate supervision by trained professional medical personnel, comprising features Q to U. Claim 22 as maintained by the Opposition Division, on the other hand, is directed to a dialysis machine comprising a user interface (12) and screen display apparatus that promotes ease of use of said user interface (12) by a user operating said machine (10) without immediate supervision by trained professional medical personnel, comprising features Q to U. Accordingly, the scope of protection has been changed from "a user interface and screen display apparatus" per se [suitable] for a dialysis machine, i.e. a device A for a device B, to "a dialysis machine comprising a user interface and screen display apparatus", i.e. a combination of the two devices B and A. The remaining claimed features, Q to U, are identical in both cases. In the Board's view, the scope of the claim as maintained has been restricted vis-à-vis that of the claim as granted since the subject-matter upheld explicitly comprises the dialysis machine as an additional feature, instead of mere suitability of the user interface and screen display apparatus for a dialysis machine.

The appellant's arguments relating to the rights of the patent proprietor to sue for indirect or contributory infringement are not relevant to the issue of extension of scope of protection under Article 123(3) EPC. According to G 2/88 (OJ 1990, 93; see Reasons 3.3) a distinction is to be made between the protection conferred by a patent as determined by the claims according to Article 69(1) EPC and the rights conferred on the patent owner in the designated Contracting States

according to Article 64 EPC. According to G 2/88 the rights conferred on the proprietor of a European patent under Article 64(1) EPC "*are the legal rights which the law of a designated Contracting State may confer upon the proprietor, for example, as regards what acts of third parties constitute infringement of the patent, and as regards the remedies which are available in respect of any infringement*". In G 2/88 it is clearly ruled that it is not necessary to consider the national laws of the Contracting States in relation to infringement and that this issue is not relevant when deciding upon admissibility of an amendment under Article 123(3) EPC (see Reasons 3.3).

With respect to the question of extension of scope of protection under Article 123(3) EPC, it is rather appropriate to take into account that the protection conferred by a patent is determined by the terms of the claims, and in particular by the categories of the claims and their technical features, in accordance with Article 69(1) EPC and its Protocol (G 2/88, loc. cit.). According to the latter, Article 69 should be interpreted as a compromise between a fair protection for the patentee and a reasonable degree of legal certainty for third parties. The description and drawings may be employed to a certain extent to interpret the claims, rather than only for the purpose of resolving a possible ambiguity in the wording of the claims.

In the present case, the wording of granted claim 22 is not directed to a user interface and screen display apparatus per se, being suitable for many kinds of devices other than dialysis machines. On the contrary,

the expression "for a dialysis machine" is already to be regarded as a limiting technical feature. Moreover, the technical features S, T and U relating to the user interface and screen display apparatus are defined with reference to the dialysis machine and are closely related to its functional interaction therewith. In the description and drawings, the user interface and screen display apparatus is always presented in combination and interaction with the dialysis machine (see, for instance, Figure 1 and paragraph [0022] of the patent specification). Its protection in combination with a dialysis machine was clearly intended, even at the very beginning when the application was filed (see original claim 8).

The decisions cited by the appellant to support his line of argument are not applicable to the present situation. The case underlying T 352/04 relates to a change from a substance to a combination of the substance and a device, which was regarded as a change of the claim category. In the present case, however, there is no such change of category. T 867/05 relates to a change from "*a membrane material for use in dialysis ...*", i.e. a substance A for use in a method X, to "*an artificial kidney in which there is used a membrane material...*", i.e. a combination of a device B and the substance A, which is also a situation quite different from the present case.

Therefore, the appellant's argument that the scope of protection has been shifted to an "*aliud*", i.e. from a user interface and screen display apparatus to a dialysis machine, thus being in breach of Article 123(3) EPC, is not accepted by the Board.

Accordingly, the Board is satisfied that the scope of protection has not been extended and that claim 22 as maintained by the Opposition Division complies with the requirements of Article 123(3) EPC.

4. Referral to the Enlarged Board

Under Article 112(1) EPC a board shall refer a question to the Enlarged Board if it appears necessary in order to ensure a uniform application of the law or if a point of law of fundamental importance arises. Neither pre-condition is fulfilled for either of the two questions (1) and (2) proposed for referral by the appellant (see point VII above). The case law referred to above is not contradictory and not applicable to the present case, which concerns only devices and their technical features.

A change from a (granted) claim, directed to a first physical entity, to a second, more complex physical entity (an "aliud") in opposition proceedings is a common and usual procedure entirely in line with the requirements of Article 123(3) EPC: adding one or more limiting technical features to a claimed device naturally renders the claimed entity more complex and results in a restriction rather than an extension of scope. Accordingly, question (1) is not of "fundamental importance".

Question (2) is not relevant either since the Board considers that the rights of the patentee have not been extended by the modification. As a consequence, the

legal certainty of third parties is sufficiently safeguarded.

Moreover, the admissibility of a referral under Article 112(1)(a) presupposes that an answer to the question is necessary for the referring board to be able to decide on the appeal (cf. G 3/98, OJ 2001, 62; Reasons 1). This is not the case here where the two questions are not relevant for deciding on the specific situation under consideration. A purely theoretical interest in clarifying points of law is no justification for a referral. Consequently, the request for referral to the Enlarged Board is rejected under Article 112(1)(a) EPC.

5. Inventive step

- 5.1 Document D13 as closest prior art discloses a dialysis machine comprising those features of claim 22 (which appears to be the broadest independent claim) which are acknowledged in paragraph [0004] of the specification of the patent in suit.

There is no indication in D13 that the machine is designed to be operated by a user without immediate supervision by trained professional medical personnel. After the user has entered a new value of a parameter via the touch screen display of D13, a "verify button" (see for instance the dashed box shown at the lower right of the drawing in columns 667/668) appears on the screen and prompts the user to confirm the changed value by touching this virtual "verify button" on the screen. This verification is said to serve as a protection against random touches or failures of the

touch screen (see columns 307/308, sixth to last paragraph).

5.1.1 Accordingly, the subject-matter of claim 22 is distinguished over D13 by the first portion of the screen display prompting the user to press the at least one **hard** key in a process of confirming entry of information into the machine.

5.1.2 The technical advantage achieved by the distinguishing feature is that in case of a defective touch screen, the computer system is still able to independently receive the correct information from the touch screen (see paragraph [0005] of the specification). Accordingly, the objective technical problem is to improve the operational safety of the system, especially when it is operated by a user without immediate supervision by trained professional personnel, such as the patient himself (cf. paragraphs [0009] and [0011] of the specification).

5.1.3 None of the cited prior art documents gives a hint towards a screen display prompting a user to press a hard key for the stated purpose.

D1 relates to a respirator which is used not by a patient (who is normally unconscious) but rather by skilled medical professionals. The mere fact that respirators may be located side by side with dialysis machines in a hospital environment or treatment centre does not imply that the teachings relating to these two kinds of device are necessarily combinable.

Accordingly, the skilled person starting from D13 and attempting to solve the above-mentioned problem would

not necessarily consider the teaching of D1, which furthermore fails to give any hint towards the above-mentioned problem. However, even if the teaching of D1 were combined with that of D13, the subject-matter of claim 22 would not be rendered obvious. D1 discloses a hard key ("Quittiertaster 22") for verification of a parameter which may be changed and adjusted by turning a knob or dial 21 (paragraph bridging columns 4 and 5) or by using hard keys (column 2, lines 29 to 40), but there is no indication whatsoever of any **prompting**, in particular not from the screen display, to press the **hard** key 22. Once the dial 21 has been adjusted as desired, it can simply be pressed in order to confirm the revised setting. Accordingly, even a combination of the teachings of both documents, D13 and D1, does not lead to the subject-matter of claim 22. Even if touch screen prompting for verification purposes and parameter entry via a hard key separate from a touch screen are both routinely known, this does not render obvious the functional combination of touch screen display prompting the user to press the at least one hard key in a process of confirming entry of information into the machine as claimed.

- 5.2 The inventiveness of the subject-matter of claim 22 has also been challenged starting from D11. D13 is the patent resulting from the US-application that is the priority document of D11. The teaching of D11 does not go beyond that of D13 (however, the problem of touch screen failure is not addressed in D11). Accordingly, the distinguishing feature over D11 and the underlying objective technical problem are the same as that mentioned above with respect to D13, and inventiveness is given for the same reasons as already explained.

Further, the Board cannot follow the appellant's argument that the distinguishing feature merely results in a clearer arrangement which is easier to use, which is the objective mentioned in D1 (paragraph bridging columns 1 and 2). The fact that D1 seems to start from a respirator without touch screen (as defined in the preamble of claim 1 of D1), but nevertheless teaches (see characterising portion) not to use a touch screen only for the entire communication with the user, but to explicitly retain certain hard keys (Eingabeelement 21, Quittierschalter 22), also does not render obvious a screen display prompting the user to press the at least one hard key for confirming entry of information into the machine.

5.3 As D1 does not deal with a dialysis machine and does not aim at the same objective as the patent in suit, this document does not constitute the closest prior art. Claim 22 is furthermore distinguished over D1 in that there is no display of **instruction** information to the user as required by feature S and, moreover, no prompting at all as defined in feature U.

5.3.1 The first input sector 23 as shown in Figure 2 of D1 merely shows various parameters and associated values, e.g. oxygen concentration O_2 231, respiratory gas flow V 232, etc. The first input sector 23 does not though display instruction information to a user as required by claim 22. The first output sector 25 displays quantities that vary over time, such as respiration pressure or respiratory flow. Again, the first output sector 25 does not display instruction information to a user as required by claim 22. Furthermore, neither the

first input sector 23 nor the first output sector 25 of D1 (i.e. the alleged first portion of the screen as claimed in claim 22) prompts a trained professional medical operator to press a hard key. This shows that the respirator as disclosed in D1 is intended to be used by trained professional medical personnel and not by a patient. D1 does not operate by getting a user to vary a parameter using the touch screen and then getting him to confirm that the change is correct using a hard key. Instead, D1 simply teaches that various parameters which may be altered are displayed only on the touch screen and that the varying of a selected parameter is done by turning the dial 21 and then confirmed by pressing it, yet without any prompting. This is a quick and easy solution which is quite appropriate for artificial respiration, where the speed of response of the user is crucial.

- 5.3.2 The appellant regarded the subject-matter of claim 22 as being obvious from D1 in view of the general knowledge of the skilled person who would routinely incorporate the user interface of a respirator known from D1 into a dialysis machine. However, since the further distinguishing features of display of instruction information and prompting were not taken into account, this line of argumentation must fail. Both features contribute to solving the problem of designing the user interface such that it is easy to use by a person who is not a technically trained medical professional such as the patient himself, who needs more guidance (by means of instructions and prompting) than a professional user. The fact that the **hard** key is to be pressed in response to prompting is further advantageous in case of defects in the touch

screen as mentioned above. Since D1 is entirely silent with respect to these features and the above-mentioned objective technical problem to be solved, the subject-matter of claim 22 is not obvious from D1 in combination with common technical knowledge.

5.3.3 Even taking into account the teaching of D11/D13, the skilled person would not arrive at the subject-matter of claim 22 since both documents fail to disclose or suggest the touch screen display prompting the user to press a hard key for entry confirmation, as mentioned above. The first paragraph of page 10 of D11 and columns 307/308 and 667/668 of D13 merely describe touch screen prompting of the user to press a (virtual) key or "verify button" appearing **on that touch screen**, and there is no obvious reason why the skilled person should deviate from this simple and coherent concept and consider prompting the user to press a hard key. Accordingly, D1 in combination with these documents does not render the claimed invention obvious, either.

5.4 Documents D5 and D6 have not been cited against claim 22 and are of interest only in that they both disclose dialysis machines comprising safety microprocessors and verification routines as defined in claim 1. However, they fail to disclose or suggest any prompting as defined in feature U of claim 22 and the advantages associated therewith. Accordingly, their teaching likewise does not render the claimed invention obvious.

5.5 From the above it follows that the subject-matter of claim 22 involves an inventive step within the meaning of Article 56 EPC.

Since claims 1 and 15 are more restricted in that they define further technical features, but yet both also comprise the above-mentioned decisive feature of the touch screen prompting the user to press the hard key for the purpose of confirming entry or completion of selection of the parametric value, the above reasoning and conclusion apply to the subject-matter of these independent claims as well. Consequently, it is not necessary here to discuss any further arguments regarding inventiveness relating to the additional features comprised in claims 1 and 15. The subject-matter of these claims also involves an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

2. The request for the questions posed on page 11 of the appellant's letter of 9 February 2011 to be referred to the Enlarged Board of Appeal is refused.

The Registrar:

The Chairman:

D. Sauter

M. Noël