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Datasheet for the decision of 22 June 2007

Case Number: T 0936/05 - 3.2.02

Application Number: 97903075.6

Publication Number: 0837708

IPC: A61M 5/172

Language of the proceedings: EN

Title of invention:
Medical Infusion Pump

Patentee:
Baxter International Inc.

Opponent:
Fresenius AG

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 56

Keyword:
"Inventive step (no, all requests)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0936/05 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 22 June 2007

Appellant: (Patent Proprietor)
Baxter International Inc.
One Baxter Parkway
Deerfield, Illinois 60015 (US)

Representative:
Dee, Ian Mark
Eric Potter Clarkson LLP
Park View House
58 The Ropewalk
Nottingham NG1 5DD (GB)

Respondent: (Opponent)
Fresenius AG
Else-Kröner-Straße 23
D-61352 Bad Homburg (DE)

Representative:
Laufhütte, Dieter
Lorenz-Seidler-Gossel
Widenmayerstraße 23
D-80538 München (DE)

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 18 may 2005 revoking European Patent No. 0837708 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: S. Chowdhury
Members: D. Valle
M. Vogel

Summary of Facts and Submissions

I. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division to revoke European patent No. 0 837 708. The decision was dispatched on 18 May 2005.

The appeal was received on 22 July 2005 and the fee for the appeal was paid on the same day. The statement setting out the grounds of appeal was received on 27 September 2005.

The opposition was filed against the whole patent and based on Article 100(a) EPC (lack of inventive step) of the claimed subject-matter. The opposition division decided that the subject-matter of claim 1 then on file did not involve an inventive step, and revoked the patent, accordingly.

II. The following documents were considered in the opposition procedure:

Dl: US-A-4 756 706
D2: US-A-5 247 434
D3: JP-A-06277283 and its English translation (D3a).

III. Oral proceedings were held on 22 June 2007.

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or on the basis of claims of the first, second, third, fourth, or fifth auxiliary request filed on 21 May 2007.

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

IV. Claim 1 of the main request reads as follows:

"An infusion pump [10] comprising: a main body portion [14]; a main display [23] contained on the main body portion for displaying user interface information; at least one pump module [16] removably secured to the main body portion and adapted to receive a tube, the pump module having means for applying pumping action to the tube; an auxiliary display [29] contained on the pump module for displaying supplemental user interface information; and microprocessor means contained in the main body portion for generating user interface information on the display areas; and wherein the user interface information includes a plurality of sets of configuration parameters such that a user can select which of the plurality of sets of configuration parameters to configure the pump; and characterised in that the pump further comprises means for generating a plurality of icons as user interface information on the main display and in that the status of a ramp infusion operation that is determined by entered configuration parameters can be displayed on the main display by means of a ramp status icon (140) that is continually updated with the operation of the pump."

Claims 2 to 18 are dependent claims.

Auxiliary requests

Claim 1 of the first auxiliary request is identical with claim 1 of the main request except that it includes the word "pictorial" before "icons" in the characterising part of the claim.

Claim 1 of the second auxiliary request reads as follows:

"An infusion pump [10] comprising: a main body portion [14]; a main display [23] contained on the main body portion for displaying user interface information; at least one pump module [16] removably secured to the main body portion and adapted to receive a tube, the pump module having means for applying pumping action to the tube; an auxiliary display [29] contained on the pump module for displaying supplemental user interface information; and microprocessor means contained in the main body portion for generating user interface information on the display areas; characterised in that the user interface information includes a plurality of sets of configuration parameters, each set being customised to a particular clinical application, such that a user can select which of the plurality of sets of configuration parameters to configure the pump; and in that the pump further comprises means for generating a plurality of icons as user interface information on the main display and in that the status of a ramp infusion operation that is determined by entered configuration parameters can be displayed on the main display by means of a ramp status icon (140) that is continually updated with the operation of the pump."

Claim 1 of the third auxiliary request specifies that the particular clinical application in claim 1 of the second auxiliary request is selected from the group consisting of general floor, paediatrics, neonatal intensive care, critical care and home care.

Claim 1 of the fourth auxiliary request includes the additional features: "means (25, 44, 46, 50) for entering values related to a beneficial agent to be infused into a patient and means responsive to the entered values for calculating an infusion profile of the beneficial agent, wherein a graphical representation of the calculated infusion profile is included as user interface information, the graphical representation including the infusion remaining" added to the end of claim 1 of the second auxiliary request.

Claim 1 of the fifth auxiliary request includes the additional features: "means (25, 44, 46, 50) for entering values related to a beneficial agent to be infused into a patient and means responsive to the entered values for calculating an infusion profile of the beneficial agent, wherein a graphical representation of the calculated infusion profile is included as user interface information, the graphical representation including the infusion remaining" added to the end of claim 1 of the third auxiliary request.

V. The parties argued as follows:

Appellant

The word "icon" had a special meaning in the art; it meant a pictorial representation which conveyed

information to a user, as confirmed by the usage of this term in the patent. The numerical keyboard of document D1 could not be called in icon. This, first characterising feature of claim 1 should be assessed for inventive step, accordingly. There was no teaching or suggestion in D1 to modify the pump thereof by including means for generation a plurality of icons as user interface information on the main display. The use of icons enabled the user to easily see the status of the pump and react more quickly if problems arose.

There was no information in the available state of the art regarding the claimed configuration parameters in the broad sense as intended by the application, nor regarding the provision of a plurality of clinical sets which could be simply selected, for example, by a knob.

D2 was not relevant since it related to hemodialysis apparatus and the only parameters displayed graphically in D2 had nothing to do with the control of an infusion process. D2 involved displaying past and future treatment which was not equivalent to continuous updating.

The updating of the infusion profile in D3 was periodic or incremental and not continuous, and this document also did not suggest means for generating a plurality of icons as user interface information.

The second characterising feature of the claim, the ramp status icon which was continually updated with the operation of the pump, was not disclosed or suggested in the prior art. D2 disclosed a graph used for programming the pump, which was not continually updated

with the operation of the pump. D3a did not disclose continual updating in the sense of presenting an up-to-date graphic in a real time manner.

Auxiliary requests: None of the prior art documents taught or suggested an infusion pump in which a user could select from a plurality of sets of clinically specific configuration parameters as user interface information. Different clinical applications for an infusion pump required dedicated pumps, whereas according to the auxiliary requests a single pump could be adapted very simply to multiple clinical settings, which could be selected by a knob, thus providing flexibility and safety and minimising errors.

Thus, starting from the closest prior art document D1, the person skilled in the art would not be led to the claimed invention even upon combining D2 and D3.

Respondent

Some of the features in the characterising part of claim 1 were known from D1 and should be in the preamble thereof, accordingly. In particular, D1 disclosed the use of icons and also taught continually updating the displayed information.

In any case, the person skilled in the art would design a user-friendly apparatus and use icon displays which were known to convey information simply, as disclosed in D3, for example. D3 also taught the display of a ramp icon, and D1 that this could be updated continually, so that claim 1 of the main request and

the first auxiliary request did not involve an inventive step.

The second and third auxiliary requests related to a technical problem which was different to that of the main request and the first auxiliary request. This problem (arising from the use of a pump in different clinical applications) was known from D1 (column 1, lines 21 ff), which also suggested the solution to this problem (column 8, line 41 ff), as did paragraph 0015 of D3a.

The new features of the fourth and fifth auxiliary requests either did not add anything new or were also implicit in D3.

Reasons for the decision

1. The appeal is admissible.

2. The question of novelty is not an issue in the present proceedings.

3. *Inventive step – general considerations*

The appellant's arguments are based on a particular construction of the expression "configuration parameters", and on advantages of the features of the claims, for which there is no basis in the patent in suit or in the application as originally filed. For example, the appellant stated that "configuration parameters" would include an alarm setting and other settings depicted in Figure 25a of the patent.

However, the patent in suit does not define this term or restrict it in any sense, so that ordinary parameters such as flow volume, flow rate, etc may also be considered to be "configuration parameters" for the infusion pump, and a group of these parameters, such as a particular flow volume and a particular flow rate may be considered to comprise a set of configuration parameters.

For example, D3a teaches that a delivery pattern for the infusion comprising the infusion flow amount, the infusion scheduled amount, infused amount, etc. may be established (see page 12 of D3a, paragraph 0023). These parameters may be considered to be configuration parameters, and the delivery pattern may be considered to be a set of configuration parameters for the pump.

Similarly, the appellant argued that multiple clinical settings which could be selected by a knob, thus providing flexibility and safety and minimising errors, for which there is no basis in the patent.

4. *Inventive step - main request and first auxiliary request*

4.1 According to the appellant D1 is the closest prior art document, and the apparatus of claim 1 includes two sets of features not disclosed in D1, as follows:

(i) the pump further comprises means for generating a plurality of icons as user interface information on the main display, and

(ii) the status of a ramp infusion operation that is determined by entered configuration parameters can be displayed on the main display by means of a ramp status icon (140) that is continually updated with the operation of the pump.

4.2 These sets of features are not technically linked and may be inspected for inventive step independently of each other, accordingly.

4.3 The technical problem to be solved by feature i) is to provide a simple graphic representation of an infusion operation (see the grounds of appeal, page 8, first paragraph).

However, D3a shows that it was known to graphically represent a liquid delivery pattern in an infusion system so as to provide a simple way of grasping the shape of the delivery pattern (see Abstract, and paragraphs 25 and 49). The graphical representation in Figure 5 of D3 may be considered to be an iconic representation (as is the graphical representation of Figure 22 of the patent, which is termed a ramp delivery icon). Therefore, feature i) concerns the same problem as addressed in D3a and employs the same solution, which does not involve an inventive step.

4.4 Document D1 teaches that the desired function, e.g. volume, time, rate, etc. or a special function (i.e. configuration parameters) may be entered by using the numerical keypad 218, and the entered values made to appear in a status line 216 (column 8, lines 4 to 13 and Figure 7), and also that the values of these

parameters may be updated continuously (column 8, lines 27 to 33) for display.

One known "special function" is the delivery pattern of the infusion flow in the form of a ramp function (see Figure 5 of D3a). If desired this ramp function may also be displayed as a graphical representation (or icon) in D1 in the same manner that the other functions are displayed. There is no invention in selecting this function as the special function, or in displaying the status of the infusion operation by means of a ramp status icon which is updated with the operation of the pump, because D1 teaches that once a function is selected it may be displayed and continually updated.

4.5 For these reasons neither of the features i) and ii) involves an inventive step, and the main request and the first auxiliary request are not allowable.

5. *Second and third auxiliary requests*

5.1 The expression "a particular clinical application" is not considered to have a special meaning in the context since every clinical application of an infusion apparatus to a patient may be considered to be "a particular clinical application". In practice every infusion apparatus would be customised to a particular patient in that the infusion rate, flow volume, etc. would be selected to suit that patient. Therefore, the content of claim 1 of the second auxiliary request does not go beyond claim 1 of the main request in this respect.

Claim 1 of the third auxiliary request specifies what is meant by a particular clinical application, and includes commonplace applications such as general floor and paediatrics. It cannot be inventive to customise an infusion apparatus for such well-known applications.

5.2 According to D3a (paragraph 0049) a plurality of delivery patterns (which may be considered to be a plurality of sets of configuration parameters, see point 3, above) is stored in the storage section so that the optimum delivery pattern may be quickly selected according to the type of medicine fluid and the conditions of the patient.

Given that, in the absence of a limiting definition of "configuration parameters" claim 1 is to be interpreted broadly, this part of D3a is a disclosure of "user interface information which includes a plurality of sets of configuration parameters, each set being customised to a particular clinical application, such that a user can select which of the plurality of sets of configuration parameters to configure the pump". Therefore, these features of claim 1 of the second and third auxiliary requests are known from D3a.

5.3 For these reasons the main claims of the second and third auxiliary requests do not involve an inventive step.

6. *Fourth and fifth auxiliary requests*

The final parts of claim 1 of these requests also relate to known and/or redundant features. It may be assumed that every infusion fluid contains a beneficial

agent. D3 shows that a graphical representation of a calculated infusion profile may be presented, the graphical representation including the infusion remaining (Figure 5). It is also noted that the description is silent as to the technical merits of these features.

The claims of these requests are also devoid of an inventive step, accordingly.

ORDER

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar The Chairman

V. Commare S. S. Chowdhury