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Datasheet for the decision of 9 May 2007

Case Number: T 0588/04 - 3.2.05

Application Number: 93924322.6

Publication Number: 0649316

IPC: A61M 5/172

Language of the proceedings: EN

Title of invention:
An infusion pump with an electronically loadable drug library

Patentees:
THE GENERAL HOSPITAL CORPORATION, et al

Opponents:
TERUMO CORPORATION
Fresenius Medical Care Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 54, 84, 111(1), 123(2)
RPBA Art. 10b(3)

Keyword:
"late filed requests (admitted)"
"clarity (yes)"
"added subject-matter (no)"
"novelty (yes)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0588/04 - 3.2.05

D E C I S I O N
of the Technical Board of Appeal 3.2.05
of 9 May 2007

Appellants: THE GENERAL HOSPITAL CORPORATION
(Patent proprietors:) 55 Fruit Street
Boston, MA 02114 (US)

Baxter, International Inc.
Deerfield, IL 60015 (US)

(Representative:) Molnia, David
Dörries Frank-Molnia Pohlman,
Triftstraße 13
D-80538 München (DE)

Respondent: TERUMO CORPORATION
(Opponent 01) No. 44-1, Hatagaya 2-chome
Shibuya-ku
Tokyo 151-0072 (JP)

Representative: Harrison, David Christopher
Mewburn Ellis LLP
York House
23 Kingsway
GB-London WC2B 6HP (GB)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 25 February 2004 revoking European Patent No. 0649316 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: W. Zellhuber
Members: P. Michel
E. Lachacinski

Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal against the decision of the Opposition Division revoking European Patent no. 0 649 316.

The Opposition Division held that the subject-matter of claim 1 of a main request lacked novelty. An auxiliary request was not admitted.

II. Oral proceedings were held before the Board of Appeal on 9 May 2007.

III. The appellant requested that the decision under appeal be set aside and that the patent in suit be maintained on the basis of the following documents submitted at the oral proceedings:
claims 1 to 5 submitted as main request; or
alternatively the sets of claims constituting auxiliary requests 1 to 5.

The respondent (opponent 01) requested that the appeal be dismissed and that the requests filed on 6 April 2007 should not be admitted into the proceedings.

Former opponent 02 (Fresenius Medical Care Deutschland GmbH) informed the Board on 17 March 2005 that their opposition was withdrawn.

IV. The following document is referred to in the present decision:

D6: "Recommendations for Specifications and Operator Interface Design for New Medical Infusion Pumps", Bazaral and Petre, Biomedical Instrumentation & Technology, September/October 1992, pages 364 to 370

V. Claim 1 of the main request of the appellant reads as follows:

"1. A drug infusion pump (10) for use with a container (28) containing a particular drug, said pump comprising:
a drive mechanism (37, 53) which during operation causes the particular drug to be delivered to a patient from the container;
a programmable controller (40) controlling the drive mechanism;
a memory (48) inside the pump, wherein said memory (48) is electronically loadable and stores a customized drug library (59, 96);
input circuitry (12, 50) through which the memory (48) can be electronically loaded with said customized drug library, said customized drug library containing a plurality of drug entries, there being associated with each drug entry a set of associated drug delivery parameters and/or drug delivery protocols for configuring the drug infusion pump, wherein the drug delivery parameters and/or drug delivery protocols include minimum and maximum drug delivery rates and/or minimum and maximum drug dosages;
a user interface (12) enabling a user to program the programmable controller, said user interface comprising:

means for enabling (12) a user to select a drug entry from the electronically loaded customized drug library;
means for enabling (12) a user to select a drug delivery rate and/or drug dosage; and
means for configuring (12) the programmable controller with the set of drug delivery parameters associated with the selected drug entry; and
means for alerting (14, 40, 45) the user if a selected drug delivery rate is outside of a range from a minimum to a maximum drug delivery rate for the selected drug and/or if a selected drug dosage is outside of a range from a minimum to a maximum drug dosage for the selected drug entry."

VI. The appellant argued substantially as follows in the written and oral procedure:

The requests filed on 6 April 2007 were amended in response to the provisional opinion of the Board. The complexity of the amendments is not such as to prevent the respondent from dealing with the issues.

The feature of claim 1 of the main request according to which "the drug delivery parameters and/or drug delivery protocols include minimum and maximum drug delivery rates and/or minimum and maximum drug dosages" is disclosed in the application as filed at page 5, lines 9 to 16. As stated at line 11, the drug delivery parameters are selected from the listed parameters and do not necessarily include them all.

The features of claim 1 of the main request according to which there are provided "means for enabling (12) a user to select a drug delivery rate and/or drug dosage"

and "means for alerting (14, 40, 45) the user if a selected drug delivery rate is outside of a range from a minimum to a maximum drug delivery rate for the selected drug and/or if a selected drug dosage is outside of a range from a minimum to a maximum drug dosage for the selected drug entry" are disclosed in the application as filed at page 48, lines 4 to 19. It is clear that the concept underlying this passage is the reduction of errors in data entry.

The amendments to claim 1 of the main request thus comply with the requirements of Article 123(2) EPC.

Document D6 includes a memory in the form of a ROM which cannot be altered by the user. Whilst the footnote at page 367 refers to updating, this would be carried out by the manufacturer who would replace the ROM. There is thus no necessity for input circuitry.

Document D6 also does not disclose an alerting function as required by claim 1. The figure at the bottom of the right hand column of page 368 merely shows a display of information which is obtained when a "GET INFO" button is pushed.

The subject-matter of claim 1 of the main request is thus new.

VII. Respondent I argued substantially as follows in the written and oral procedure:

The requests filed by the appellant on 6 April 2007, which were only received by the respondent on 23 April 2007, should not be admitted. The filing of

the requests raises serious issues for the first time in the proceedings. The appellant should not have waited until the issue of the preliminary opinion to file the amended requests. The requirements of Articles 10a and 10b of the Rules of Procedure of the Boards of Appeal are not met.

The passage in the application as filed at page 5, lines 9 to 16 not only refers to maxima and minima, but also default values as well as parameters relating to bolus size. There is no basis for a selection among these parameters. Neither is there any disclosure of only drug delivery rates or dosages.

The paragraph in the application as filed at page 48, lines 4 to 19, is very specific and it is not possible to extract the broad concept as specified in claim 1 from this passage. In particular, there is no importance attached to the alert feature.

Claim 1 of the main request thus includes features which were not disclosed in the application as filed.

The term "select" as used in claim 1 of the main request in connection with the drug delivery rate and/or drug dosage is not clear, since it is not specified from what the selection is made. The term "enter" would be more appropriate. It is further not clear to what the terms "a selected drug delivery rate" and "a selected drug dosage" refer.

The claim further includes impossible combinations of features in which drug delivery rates or drug dosages

are omitted from the drug delivery parameters and protocols.

Claim 1 of the main request is thus not clear.

Document D6 discloses all the features of claim 1 of the main request. In particular, the presence of a loadable memory implies the presence of input circuitry.

The figure at the bottom of the right hand column of page 368 shows means for alerting the user as defined in the last four lines of claim 1.

The subject-matter of claim 1 of the main request is thus not new.

Reasons for the Decision

1. *Admissibility of the requests of the Appellant*

The requests filed by the appellant on 6 April 2007 are regarded as being intended to deal with issues raised by the Board in the annex to the summons to oral proceedings. In accordance with the indication given in the annex, the requests were filed more than one month before the date set for oral proceedings.

Unfortunately, the amended requests were only received by the respondent on 23 April 2007. However, in the Board's judgement, the issues raised by the new sets of claims were such that the respondent could be reasonably expected to deal with them in the period of a little over two weeks which were available before the

oral proceedings. Accordingly, the conditions set out in Article 10b(3) of the Rules of Procedure of the Boards of Appeal are satisfied.

The Board accordingly considers it appropriate to exercise their discretion to admit the amended requests into the proceedings.

2. *Main Request*

2.1 Amendments

The feature of claim 1 according to which "the drug delivery parameters and/or drug delivery protocols include minimum and maximum drug delivery rates and/or minimum and maximum drug dosages" is disclosed in the application as filed at page 5, lines 10 to 16. Whilst this passage also refers to a default drug delivery rate and dose, as well as parameters relating to bolus size and rate, it is noted that lines 11 and 12 refer to information selected from the disclosed parameters. In addition, the parameters not specified in claim 1 are not relevant to the claimed invention, which is concerned with the provision of means for alerting the user if a drug delivery rate or dosage is selected outside preset limits.

The features of claim 1 specifying "means for enabling (12) a user to select a drug delivery rate and/or drug dosage" and "means for alerting (14, 40, 45) the user if a selected drug delivery rate is outside of a range from a minimum to a maximum drug delivery rate for the selected drug and/or if a selected drug dosage is outside of a range from a minimum to a maximum drug

dosage for the selected drug entry" are disclosed in the application as filed at page 48, lines 4 to 19. Whilst this passage discloses these features in more specific terms than those used in the claim, the person skilled in the art would recognise that the passage refers to an arrangement for alerting the user if a drug delivery rate and/or drug dosage is selected which is outside specified maximum and minimum values.

The amendments to claim 1 accordingly satisfy the requirements of Article 123(2) EPC.

2.2 Clarity

It is not reasonable to construe claim 1 as including within its scope combinations of features which would not function. Thus, in the case of a user selecting a particular drug delivery rate, and the means for alerting the user serving to alert the user if the selected rate were above the maximum or below the minimum rate, the drug delivery parameters would include minimum and maximum drug delivery rates. Similarly, in the case of a selected drug dosage, and the means for alerting the user serving to alert the user if the selected dosage were above the maximum or below the minimum dosage, the drug delivery protocols would include maximum and minimum drug dosages.

In addition, the reference to "selecting" a drug delivery rate and/or dosage should be understood as entering or specifying a drug delivery rate and/or dosage, and not selecting from among a limited number of alternatives.

Claim 1 is thus clear.

2.3 Novelty

Document D6 does not disclose a means for alerting the user as specified in the final limb of claim 1. Claim 1 is construed as requiring that, the drug infusion pump is such that, in use of the pump, if a selected drug delivery rate is outside of a range from a minimum to a maximum drug delivery rate for the selected drug and/or if a selected drug dosage is outside of a range from a minimum to a maximum drug dosage for the selected drug entry, the user will be alerted by the means for alerting the user.

In the arrangement described in document D6 in the right hand column of page 368, the display shown at the bottom of the column will only be obtained when the user pushes a button referred to as the "GET INFO" button, as described immediately above the figure. The user is thus not alerted; rather, the user must positively act in order to obtain the information regarding the therapeutic functions of ranges of drug delivery rates.

3. The opposition division has not had the opportunity of considering the question of whether or not the subject-matter of claim 1 involves an inventive step. The Board considers it to be appropriate in these circumstances, in order to permit the issue to be considered at two instances, to remit the case to the opposition division for further prosecution in accordance with Article 111(1) EPC (second sentence, second alternative).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

D. Meyfarth W. Zellhuber