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Datasheet for the decision of 13 November 2012

Case Number: T 0986/08 - 3.2.02

Application Number: 93924322.6

Publication Number: 649316

IPC: A61M 5/172, A61M 1/00, A61M 5/00, A61N 1/30, G06F 15/00

Language of the proceedings: EN

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

Patent Proprietors:
THE GENERAL HOSPITAL CORPORATION and BAXTER INTERNATIONAL INC.

Opponent:
TERUMO CORPORATION

Headword:
-

Relevant legal provisions:
EPC Art. 54(1)(2), 56, 114(2)

Keyword:
"Res judicata"
"Admissibility of evidence (yes)"
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
T 0502/98, T 0588/04

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0986/08 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 13 November 2012

Appellant: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 5 March 2008 concerning maintenance of European patent No. 649316 in amended form.

Composition of the Board:

Chairman: E. Dufrasne
Members: C. Körber
P. L. P. Weber

Summary of Facts and Submissions

I. On 5 March 2008 the Opposition Division posted its interlocutory decision concerning maintenance of European patent No. 649316 in amended form according to the patent proprietors' main request against objections of lack of novelty and inventive step, following a remittal ordered in decision T 588/04. The Opposition Division declined to admit document D11 into the proceedings.

II. An appeal was lodged against this decision by opponent O1, by notice received on 14 May 2008 with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 14 July 2008. Opponent O2 had withdrawn its opposition by letter dated 17 March 2005.

III. By communication of 23 April 2012, the Board summoned the parties to oral proceedings and forwarded its provisional opinion to the parties.

IV. Oral proceedings were held on 13 November 2012.

The final requests of the parties were as follows:

The appellant (opponent O1) requested that the decision under appeal be set aside and that the patent be revoked.

The respondents (patent proprietors) requested that the appeal be dismissed.

V. The following documents are of importance for the present decision:

D1: US-A-5 088 981;

D6: M. Bazaral and J. Petre "Recommendations for specifications and operator interface design for new medical infusion pumps", Biomedical Instrumentation & Technology, September/October 1992, pages 364 to 370;

D9: US-A-4 741 732;

D11: JP-A-63-238870 (English translation submitted with appellant's letter of 13 February 2008).

VI. Claim 1 of the main request reads as follows (with the feature denotation used in the previous opposition and appeal proceedings added in square brackets):

"[G] A drug infusion pump (10) for use with a container (28) containing a particular drug, said pump comprising:
[H] a drive mechanism (37, 53) which during operation causes the particular drug to be delivered to a patient from the container;
[I] a programmable controller (40) controlling the drive mechanism;
[J] a memory (48) inside the pump, wherein said memory (48) is electronically loadable and stores a customized drug library (59, 96);
[K] 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,
[P] wherein the drug delivery parameters and/or drug delivery protocols include minimum and maximum drug delivery rates and/or minimum and maximum drug dosages;
[L] a user interface (12) enabling a user to program the programmable controller, said user interface comprising:
[M] means for enabling (12) a user to select a drug entry from the electronically loaded customized drug library;
[Q] means for enabling (12) a user to select a drug delivery rate and/or drug dosage; and
[N] means for configuring (12) the programmable controller with the set of drug delivery parameters associated with the selected drug entry; and
[R] 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."

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

D11 was filed in direct response to the very late amendment of the claims by the patentees, which introduced into claim 1 subject-matter never previously present in the claims. Accordingly, D11 was not "late filed", as shown by decision T 502/98. D11 should therefore have been admitted by the Opposition Division.

D11 was novelty-destroying for claim 1. In Figure 4, items 4-D, 4-E and 4-F showed the permitted ranges, step rates and bolus amounts for each of three preset insulin

concentrations. These preset data sets, respectively relating to three different insulin concentrations, in the memory of Dl1 constituted a "customized drug library" within the meaning of feature J of claim 1. The library was "customized" in that the rates were selected for a particular patient in mind, or for a particular practice of a hospital, or for some other reason relating to the intended user (who was a customer, in a general sense). In the patent in suit "customized" had no special meaning. Furthermore, paragraph [0136] of the patent in suit mentioned that, in the case of drug entries having identical names and concentrations but differing assigned modes, the drug is displayed as one drug entry. Accordingly, a "drug entry" could consist of the specification of different concentrations or modes for one and the same drug. Moreover, it was mentioned in the paragraph bridging pages 16 and 17 of D11 that the application of its invention was not limited to the injection of insulin, and that its pump could be applied for injection of various infusions. Accordingly the teaching of D11 was not limited to insulin as the only drug entry.

Figure 4 of D11 showed that the data in the memory for each of the three insulin concentrations included an infusion rate range and also a bolus amount range. Each of these ranges had a minimum and a maximum value. Accordingly, feature P of claim 1 was also anticipated by D11.

Figure 4 of D11 included the note "If the bolus infusion amount reaches or exceeds 25.5 U, the bolus amount display becomes [25.5 U]". This display of [25.5 U], visible to the user, constituted means for alerting the

user that a selected drug dosage (the bolus amount) was outside of a range from a minimum to a maximum drug dosage for the selected drug entry (the selected concentration of insulin). This message given to the user in Dl1, indicating that the selected bolus amount was out of range, was just as much an "alert" as the signals described in the paragraphs in the patent in suit on which feature R of claim 1 was based. The relevant paragraph [0147] in the patent did not make much sense, but referred to a signal such as "DOSE [or RATE] > nnn" and also to a beep and a signal such as "VERIFY > nnn". Accordingly, the alert disclosed in D11 was no different from what constituted an alert according to the patent in suit.

No difference could be seen over D11 with respect to the ranges defined in claim 1, since the claim failed to specify them as therapeutic ranges.

Claim 1 was further anticipated by document D1 for the reasons the appellant had already presented in the opposition proceedings. In particular, feature R was disclosed by the fact that D1 referred to "assistive programs" providing the user with information such as "accepted drug dosage ranges" (second paragraph of column 7). The purpose of such programs was to prevent erroneous entries by a user, implying that the computer had to alert the user in some way if a value outside of the acceptable range was entered.

Claim 1 lacked inventive step when starting from Dl, Dl1 or D6.

The only feature absent from D6 was R. This was a simple alert feature, warning the user that a selected drug delivery rate or dosage was outside a stored range. Such an obvious feature of a drug delivery system, which aimed to minimise the risk of overdosing a patient, could not provide inventive step over D6. Nothing could be more routine and obviously desirable for a medical professional than to include a simple alert function to indicate a risk of overdose in the pump of D6, particularly in view of the fact that at page 370 a clear hint was already given towards incorporating alarms in the infusion pump. Actually, no documentary evidence was needed that in 1992 medical professionals appreciated the need to provide an alert in an infusion pump to warn of overdose. In any case, evidence that an overdose prevention alert was in the mind of someone designing a pump was provided by D9 at the top of column 11. The alert with respect to patient concentration was even more sophisticated than that according to feature R of claim 1. D6 already provided the user with information as to the appropriate range of the drug delivery rate. There was no inhibition or technical difficulty in programming an alert when a value out of the range was selected.

Claim 1 was further not inventive when starting from D11. Since D11 already disclosed that the user was alerted if the parameters were beyond the maximum of the ranges, it could not be inventive to also alert the user below the minimum. If D11 was considered not to disclose means for alerting as defined in feature R, the inclusion of such means was obvious for the same reasons as given with respect to D6. Increasing the number of

drug entries to more than one would not give rise to an inventive step.

D1 also disclosed all features of claim 1 except the means for alerting as defined in feature R. The objective technical problem was reduction of the risk of administering an undesirable dosage of drug. It was common general knowledge that there were undesirable dosage amounts and delivery rates specifically associated with specific drugs, for example to avoid overdosing or the administration of ineffective quantities of drug. Dl (column 7, lines 4 to 17) clearly taught that it was desirable to enter error-free information. From Dl and common general knowledge, the skilled person would be aware of the need to find a way of avoiding errors when selecting values for use with such infusion pumps, in particular to avoid entering dosage values outside an acceptable range for that drug (and other related important input values familiar to the skilled person, such as delivery rates). In view of this, the skilled person would have found in the teaching of documents D6, D9 and D11 known systems for alerting a user of an infusion pump that an entered value was outside an acceptable range for dosage amount and dosage rate.

VIII. The respondents' arguments are summarised as follows:

The novelty of the subject-matter of claim 1 over D1 to D10 had already been confirmed by decision T 588/04, and accordingly was res judicata and should not be reopened.

The Opposition Division had properly exercised its discretionary power when it did not admit document D11

into the proceedings. D11 was not prima facie relevant and had been filed only about one month before the second oral proceedings before the Opposition Division, and thus not as soon as possible after the previous Board's decision.

D11 was not novelty-destroying. It only dealt with the infusion of insulin and thus failed to disclose a drug library as defined in feature J of claim 1. Furthermore, there was no disclosure of input circuitry (feature K) for loading a program into the pump. Consequently, feature P was also not known from D11. The display of "[25.5U]" mentioned in Figure 4 of D11 could not be equated with means for alerting (feature R), but was rather a result of hardware limitation of the display not being capable of displaying more than 256 steps (8 bits). Moreover, the display of "[25.5U]" occurred when the bolus amount was equal to or greater than 25.5U, which was different from the conditions specified in feature R.

Document D6 had to be regarded as closest prior art for the assessment of inventive step. However, the drug library of the pump disclosed in D6 was not customizable by a user or a specific hospital. On the contrary, it was explicitly stated at page 369 that the corresponding database was not user-alterable and that hospital-specific menus were not desired. The alarms mentioned at page 370 related to infusion errors and could not be equated with means for alerting as defined in feature R of claim 1. The problem solved by the distinguishing features over D6 was to provide a smarter and more error-proof pump. The solution according to claim 1 was not obvious from common general knowledge or when taking

into account the teaching of D9. The passage bridging columns 9 and 10 of D9 clearly related to ranges of patient concentration, which was different from and not comparable to the delivery rate or dosage of a drug which was to be delivered by the infusion pump to the patient.

D11 was more remote and gave no incentive towards including a customized drug library. Moreover, since the bolus injection was done manually and only if desired, i.e. intentionally, there was no need at all for providing means for alerting.

D1 was also more remote since it was not possible for the user to select a drug entry from the customized drug library stored in the logic unit. Furthermore, there was no hint towards alerting the user as required by feature R of claim 1.

Reasons for the Decision

1. The appeal is admissible.

2. Res judicata

The present set of claims is identical to that of the main request on which the Board ruled in its previous decision T 588/04. Since claim 1 was held to meet the requirements of Articles 123(2) and 84 EPC (Reasons, points 2.1 and 2.2), this finding is res judicata.

In its previous decision (Reasons, point 2.3), the Board further held that the subject-matter of claim 1 was

novel since document D6 failed to disclose feature R and the case was remitted to the department of first instance for further prosecution with respect to inventive step. Since the claims have remained unchanged since then, the issue of novelty over the documents in the proceedings at that time, i.e. documents D1 to D10, is res judicata, as correctly stated in point 2 of the Reasons of the impugned decision. For this reason, the appellant's novelty objection vis-à-vis document D1 is not allowable.

3. Admissibility of D11

Claim 1 comprises amendments taken from the description of the patent in suit which have no counterpart in the set of claims of the patent as granted. It was filed by the (present) respondents-proprietors relatively shortly before the oral proceedings in the first appeal. Accordingly, the (present) appellant-opponent could not have foreseen these amendments. It may be agreed that within the two weeks that remained before the oral proceedings, the (present) appellant-opponent did not have sufficient opportunity to carry out prior-art searches and to investigate the technical content of the claim. Consequently, the filing of D11 represents a reaction to the filing of amended claims in the first appeal, and its filing during the opposition proceedings following remittal is justified and "in due time", in line with decision T 502/98 (Reasons, points 1.5 and 1.6). It follows that the Opposition Division did not correctly exercise its discretionary power in not admitting D11 pursuant Article 114(2) EPC, which only applies to facts and evidence filed late. Since D11 was filed in reaction to the amended claim 1 and before the

time limit set in the communication of 30 July 2007 annexed to the summons to the (second) oral proceedings before the Opposition Division, it is further considered that the respondents-proprietors had sufficient opportunity to consider its teaching. Accordingly, the discretionary decision of the Opposition Division is overruled and D11 is admitted into the present appeal proceedings.

4. Novelty

Since document D11 is admitted into the present proceedings and was not the subject of the decision of the previous Board, the issue of novelty vis-à-vis D11 has to be ascertained by the Board in the present appeal.

In feature K of claim 1 of the patent in suit the term "customized drug library" previously introduced in feature J is further defined as "containing a plurality of drug entries". This definition is also used in paragraph [0012] of the specification. An example of a "drug entry" is given in paragraph [0064] and Figure 8, viz. "alfentan", i.e. a particular type or name of drug. Accordingly, each "drug entry" is to be understood as relating to a particular type of drug. The "drug library" in the patent in suit is to be understood as corresponding to a list of names of different drugs. This also becomes evident from paragraphs [0132] and [0133] where it is stated that the list of drugs in the customized drug library is organised alphabetically so that the user can select the respective drug name from it.

Document D11 deals with only one particular type of drug, namely insulin. Accordingly, in the Board's view, it does not disclose a customized drug **library** containing a **plurality** of drug entries. The fact that in the paragraph bridging pages 16 and 17 of D11 it is mentioned that the application of its invention is not limited to the injection of insulin, and that its pump can be used to inject various infusions cannot be read as disclosing a "drug library" as claimed.

The Board also does not accept the appellant's interpretation that the term "drug entry" could be understood as relating to the specification of different concentrations or infusion rates for one and the same drug as shown in items 4-D and 4-E of Figure 4 of D11. Feature K of claim 1 makes a clear distinction between a "drug entry" and "drug delivery parameters" associated therewith, and the concentrations and infusion rates shown in Figure 4 of D11 are to be understood as forming part of the "drug delivery parameters". This understanding is not changed by the cited statement in paragraph [0136] of the patent in suit, which merely relates to the fact that under certain circumstances similar drug entries may be grouped together and displayed as one drug entry.

Accordingly, D11 fails to disclose a "drug library" (let alone a customized drug library) as mentioned in features J, K and M of claim 1.

Furthermore, items 4-E and 4-F of Figure 4 of D11 do not disclose that the drug delivery parameters and/or drug delivery protocols include **minimum** drug delivery rates and/or **minimum** drug dosages as defined in feature P. The

lower limit value of the ranges indicated in these items of Figure 4 is always either "0.0" or "0.00", which corresponds to no infusion at all. The terms "minimum drug delivery rates" and "minimum drug dosages" in the claim, however, clearly imply that the drug is to be administered, yet with a minimal rate or dosage. From paragraph [0097] of the patent in suit it is explicitly clear that the minima and maxima are to define the **therapeutic** range of the drug. Accordingly, the fact that D11 mentions a lower limit value of 0.0 does not anticipate minimum drug delivery rates and/or minimum drug dosages in a therapeutic sense.

Lastly, even if the display of "[25.5U]" when the bolus infusion is greater than or equal to 25.5U, as stated in item 4-G of Figure 4 of D11, is regarded as "means for alerting the user", this display does not alert the user under the conditions specified in feature R of claim 1, namely "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". Firstly, item 4-G refers to the "bolus amount" which is to be distinguished from the parameters "drug delivery rate" or "drug dosage" mentioned in feature R of the claim. In the patent in suit, "bolus size" is clearly defined as a drug delivery parameter additional to and different from "drug delivery rate" or "drug dosage", as can be seen, for instance, from claim 5 of the patent as granted. Secondly, the definition "outside of a range" in feature R requires that the alerting takes place not only when the value of the respective parameter is above the maximum value of the range, but also when it is below

the minimum value. In this latter respect, D11 is, of course, entirely silent since values below the lower limit value of 0.0 are technically meaningless.

Accordingly, the subject-matter of claim 1 is novel over D11 within the meaning of Article 54(1) and (2) EPC.

5. Inventive step

5.1 D6 as starting point

As decided by the Board in its previous decision T 588/04, the subject-matter of claim 1 is distinguished from document D6 by feature R. In the present appeal, the Board is of the opinion that D6 is to be regarded as closest prior art. This is in line with point 3.3 of the Reasons of the impugned decision, where it is stated that both parties agreed that D6 represents the closest prior art (among the documents admitted into the proceedings at that time, viz. D1 to D10). D6 is furthermore closer to the invention than D11, since D6 clearly discloses a drug infusion pump with a drug library (according to the displays relating to steps 3 and 4 depicted at page 367). In contrast to what is stated in the second paragraph of point 3.3 of the impugned decision, the Board is of the opinion that this drug library is "customized" in view of the statement in the footnote marked by an asterisk at page 367, which reads: "The database would be assembled by the manufacturer, presumably in collaboration with a hospital. Included would be all drugs infused in sample ICUs and wards. ... occasional database updates can include drugs that later become common." Accordingly, the database representing the drug library is adapted to

the specific requirements of the hospital, ICU or ward and therefore "customized". The Board is aware that paragraphs [0026] to [0028] of the patent in suit indicate that the customizing can be done by the users, i.e. the clinicians at a particular hospital, but the wording of the claim leaves it entirely open where the customization takes place and by whom it is performed. Accordingly, a drug library customized by the manufacturer as disclosed in D6 also falls under the wording of the claim. Under these circumstances the statement in D6 at page 369 that the database is stored in a memory that is "not user-alterable" is of no relevance since that database or drug library is already "customized" (by the manufacturer).

The technical advantage of the means for alerting as defined in feature R is that the user is made aware if the drug delivery rate and/or drug dosage selected is outside of the respective ranges.

The objective technical problem underlying the invention is to provide a drug infusion pump that is safer and simpler to use, particularly in a clinical environment with a large community of users.

In the second paragraph of page 370, D6 gives a general hint towards "named" alarms specific to the type of drug or infusion. This is, however, quite different from alerting the user under the particular conditions specified in feature R of claim 1. There is no indication or suggestion in D6 that the user, pushing the "GET INFO" button shown at page 368, is to be alerted when selecting a drug delivery rate outside of the ranges indicated in the appearing display shown at

the bottom right of page 368. When activating the GET INFO function, the user is already provided with a display of the supportive information relevant for the selected drug, allowing him or her to check or adjust the selected drug delivery rate against the displayed ranges. The alerting means as defined in feature R is simpler in that it does not require the user to intentionally activate a display and to compare the selected rate with a number of ranges shown in the display. This is particularly advantageous in a busy clinical environment.

In view of the circumstances indicated above, it cannot be said that the solution according to feature R is within the common general knowledge of the skilled person.

Feature R is also not obvious when taking into account the teaching of D9. The cited passage of this document at column 10, line 67, to column 11, line 5, mainly deals with the parameter "patient concentration", i.e. the concentration of the drug in the plasma of a patient, which is to be kept within an acceptable range for each drug, stored in an EPROM module 108. The paragraph bridging columns 10 and 11 discloses means for alerting the user if values outside these patient concentrations are entered. However, as correctly stated in the impugned decision (Reasons, point 3.8), the parameter "patient concentration" is quite different from and not comparable to the delivery rate or dosage of a drug which is to be delivered by the infusion pump to the patient. Accordingly, the teaching of D9 does not render obvious the invention according to claim 1.

5.2 D11 as starting point

The appellant has further contested inventive step when starting from document D11. However, as explained above in point 3, D11 is more remote from the invention than D6, since it fails to disclose further features in addition to feature R and gives no hint whatsoever towards means for alerting. Accordingly, the subject-matter of claim 1 cannot be rendered obvious by D11 in view of common general knowledge or D9, for the same reasons as indicated in point 4.1 above.

5.3 D1 as starting point

Document D1 discloses a customized drug library residing in data base 22, which is used for simulation and verification purposes in programming unit 13. After successful verification it is electronically loaded into logic cartridge 18 in the delivery unit 14. Since this can be done for four channels (Figure 3), it can be said that a customized drug library containing four entries is also present in the memory inside the pump (feature J). However, the user is not able to select a drug entry from these entries, as required by feature M. This was also observed by the Board in the previous appeal in point 6 of its preliminary opinion attached to the summons to oral proceedings dated 22 February 2007. Furthermore, D1 is silent regarding feature R. Contrary to the appellant's view, the fact that D1 refers to "assistive programs" providing the user with information such as "accepted drug dosage ranges" (second paragraph of column 7) cannot be seen as giving an indication or suggestion of means for alerting as defined in feature R. Accordingly, the subject-matter of claim 1 cannot be

rendered obvious by D1 in view of common general knowledge or D9, for the same reasons as indicated in point 4.1 above.

5.4 Since none of the documents cited against claim 1 gives a hint towards feature R and the advantages achieved thereby, none of their combinations renders obvious the subject-matter of claim 1. The Board is satisfied that its subject-matter is based on an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne