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File No.: T 0696/92 - 3.2.2
Application No.: 84 901 878.3
Publication No.: 0 149 618
Classification: A61M 5/00
Title of invention: Differential occlusion sensing method and apparatus

D E C I S I O N
of 27 July 1993

Applicant:
Proprietor of the patent: Baxter International Inc.
Opponent: Fresenius AG

Headword:

EPC: Art. 54(1), (2)

Keyword: "Novelty (no)"

Headnote
Catchwords



Case Number: T 0696/92 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 27 July 1993

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Decision under appeal: Decision of the Opposition Division of the
European Patent Office dated 8 May 1992, notified
on 4 June 1992, rejecting the opposition filed
against European patent No. 0 149 618 pursuant to
Article 102(2) EPC.

Composition of the Board:

Chairman: G. Szabo
Members: P. Dropmann
J. Van Moer

Summary of Facts and Submissions

- I. European patent No. 0 149 618 was granted on 20 June 1990 on the basis of European patent application No. 84 901 878.3 filed on 16 April 1984.

The independent Claims 1 and 6 read as follows (the subdivision of Claim 1 has been suggested by the Board for the sake of convenience):

Claim 1:

- A: "A method of sensing and monitoring downline fluid pressure changes in a fluid infusion system
- B: in which a positive fluid flow is provided through a tubing (16),
- C: comprising sensing the initial operating location of a wall portion of the tubing,
- D: monitoring the location of the wall portion by sensing movement thereof from the initial location,
- E: feeding sensed information to a control means (28),
- F: storing in the control means the information sensed at the initial location,
- G: comparing in the control means the monitoring information with the stored information and
- H: setting an alarm when movement of said wall portion from the initial location is sensed,
characterised in that
- I: the location of a single wall portion of the tubing is sensed
- J: so that the information sensed at the initial location represents the initial fluid pressure in the tubing,
- K: in that the control means is provided with a predetermined value representing permitted pressure deviation from said initial fluid pressure,

L: and in that said alarm is set when the monitoring information represents a fluid pressure in excess of said permitted deviation."

Claim 6:

"An apparatus for sensing and monitoring downline fluid pressure changes in the tubing (16) of a fluid infusion system comprising sensing means (12) adapted to be coupled to the fluid tubing for monitoring the location of a wall portion thereof by sensing movement of the portion from an initial operating location, means for setting an alarm in response to such movement, control means (26,28) including means for receiving information from said sensing means (12) during initial operation of the infusion system, means for storing said initially sensed information, means for comparing monitoring information from the sensing means during operation with said initially sensed information and means for setting the alarm when movement from the initial location is sensed, *characterised in that* the sensing means is arranged to sense and monitor the location of a single wall portion of tubing so that the information sensed at the initial location represents the initial fluid pressure in the tubing, in that the control means holds a predetermined value representing permitted pressure deviation from said initial fluid pressure, and in that the control means operates to set the alarm when the monitoring information represents a fluid pressure which exceeds said permitted deviation."

II. An opposition was filed against this patent on the grounds of lack of novelty and inventive step (Article 100(a) EPC).

- III. By its decision taken at the oral proceedings on 8 May 1992 and notified on 4 June 1992, the Opposition Division rejected the opposition.
- IV. On 30 July 1992, a Notice of Appeal was filed against the decision by the Opponent. The appeal fee was paid on the same date. The Statement of Grounds was received on 9 September 1992.
- V. In a communication dated 16 July 1993 and transmitted by telefax, the Board introduced document WO-A-82/00590 (D9) into the proceedings. This document belongs to the same applicant as the contested patent and was published before the priority date of this patent. It corresponds to document US-A-4 394 862 which was cited as an X,P-category document in the international search report. The parties were invited to give comments on document D9 either before or during the oral proceedings arranged for 27 July 1993.
- V. In a reply to the communication, filed by telefax on 22 July 1993, the Respondent withdrew its request for oral proceedings and informed the Appellant and the Board that it intended not to be represented at the hearing.

Furthermore, the Respondent presented its comments on document D9 arguing that there was a difference between the subject-matter of the patent in suit and the prior art known from D9. The D9 system did not allow for variations in wall thickness and inside diameter of the tube, in tubing material and in temperature. The claimed method and apparatus overcame this problem and allowed for these differences in the tubing properties by sensing the initial location of the tubing portion and monitoring deviation from that initial location. The

method of Claim 1 and apparatus of Claim 6, therefore, were both novel and involved an inventive step over D9.

VI. Oral proceedings were held on 27 July 1993. At these proceedings, the Appellant argued that all of the features of Claims 1 and 6 were known from document D9. The claimed method and apparatus thus lacked novelty. Even if there was a difference between the claimed subject-matter and the prior art, it would not involve an inventive step.

VIII. The Appellant requested that the decision under appeal be set aside and the patent be revoked in its entirety.

The Respondent requested dismissal of the appeal and maintenance of the patent either without amendment or, as an auxiliary request, on the basis of amended Claims 1 and 6, which differ from the claims as granted only in that the word "downline" was moved from the prior art portion to the characterising portion.

Reasons for the Appeal

1. The appeal is admissible.
2. *Novelty (Claim 1)*
 - 2.1 Using the terminology of Claim 1 of the contested patent, document D9 discloses a method of sensing and monitoring downline fluid pressure changes (cf. pages 9 to 11, Claims 1 to 3 and Figures 5 and 6, in particular page 9, lines 13 to 28) in a fluid infusion system in which a positive fluid flow is provided through a tubing 18 by a pump assembly 23 (cf. features A and B of Claim 1.)

2.2 The prior art method comprises sensing the operating location of a wall portion of the tubing (cf. page 9, lines 21 to 28 and feature C of Claim 1). Page 11, lines 1 to 9 states that, in operation, the voltage level at the non-inverting input of differential amplifier 90 is a function of the downline pressure as applied by the sidewall of tubing 18 to the transducer 81. It further states that by adjusting potentiometer 91 the voltage level at the inverting input of amplifier 90 is set so that the output of the differential amplifier as applied to voltage comparator 94 is at a predetermined reference level when the downline pressure is at a **nominal** level.

This adjustment using the balance adjust potentiometer 91 is necessarily made at the beginning of the infusion after a steady state has been reached, because the said reference level serves as a basic value for the following monitoring step (cf. page 11, lines 9 to 11: "**As the pressure increases**, the output of differential amplifier 90 rises above the **reference level**, ..."). Since, in the method according to Claim 1 of the patent, the initial location of the tubing may also be sensed a set time period after initiation of the infusion (cf. column 2, lines 24 to 26 and Claim 2 of the patent in suit), it is to be assumed that the said step of sensing the operating location in the prior art method corresponds to the step of sensing the **initial** operating location specified in Claim 1, feature C, of the patent.

2.3 As already indicated in the preceding paragraph, the prior art method also comprises the step of monitoring the location of the wall portion by sensing the movement thereof from the initial location (cf. feature D of Claim 1). The sensed information is fed to the pressure monitor circuit 83 which, together with the pump control circuits 84, has the same function as the control means of the claimed method (cf. feature E of Claim 1).

Step F of Claim 1 of the contested patent that the information sensed at the initial location is stored in the control means corresponds to the setting of the voltage level at the inverting input of amplifier 90 by adjusting potentiometer 91 as disclosed in document D9. Comparing the monitoring information with the stored information (cf. feature G of claim 1) takes place in the differential amplifier 90.

As to feature H of Claim 1 that an alarm is set when movement of the wall portion from the initial location is sensed, reference is made to feature L which will be discussed hereinafter at the end of point 2.4.

- 2.4 In further correspondence with the method according to Claim 1, features I and J of the contested patent, it is known from document D9 that the location of a single wall portion of the tubing is sensed so that the information sensed at the initial location represents the initial fluid pressure in the tubing (cf. page 9, lines 26 to 28 and the preceding statements under point 2.2 above concerning the sensing of the initial location).

D9 furthermore discloses that the control means 83, 84 is provided with a predetermined value (upper limit voltage source comprising potentiometer 96 determining the maximum pressure reference level) representing the permitted pressure deviation from said initial fluid pressure (cf. feature K of Claim 1 and document D9, page 9, lines 28 to 32; page 10, lines 29 to 34; and page 11, lines 9 to 13 and 19 to 27). In this context, it is relevant that the alarm limit in the claimed method can also include a maximum operating pressure for the system (cf. patent specification, column 4, lines 5 to 8). Finally, it is also known from D9 that an alarm is set in the same manner as in the claimed method, i.e.

when the monitoring information represents a fluid pressure in excess of said permitted deviation (cf. feature L of Claim 1 and document D9, page 9, lines 28 to 34 and page 11, lines 9 to 18).

- 2.5 In the light of the state of the art set out in points 2.1 to 2.4 above, the Board can see no difference between the subject-matter of Claim 1 and the method known from document D9.

In particular, the Board cannot accept the Respondent's argument that the D9 system did not allow for variations in wall thickness and inside diameter of the tube, in tubing material and in temperature. Since, as stated under point 2.2 above, in the known method the adjustment using the balance adjust potentiometer 91 is to be carried out at the beginning of the infusion or shortly afterwards and since the initial location or pressure is thus sensed and stored similarly to the claimed method, variations in the tubing thickness, diameter, material and temperature are eliminated in the known method just as much as in the claimed method.

Furthermore, contrary to the Respondent's statement, D9 does not teach "that the potentiometer 96 is set to the nominal value, i.e. the expected value". Potentiometer 96 is rather set to a predetermined upper limit (maximum pressure reference level) which represents the permitted pressure deviation from the initial pressure.

- 2.6 Hence, the method according to Claim 1 lacks novelty and thus does not meet the requirements of Articles 52(1) and 54(1), (2) EPC.

3. Claim 6 is directed to an apparatus and defines the structural means necessary to carry out the method of Claim 1. Since these means are known from document D9

(cf. point 2 above), the apparatus according to Claim 6 also lacks novelty.

4. Claims 1 and 6 of the auxiliary request differ from granted Claims 1 and 6 only in that the term "downline" indicating the location of the fluid pressure measurement has been transferred from the preamble to the characterising portion. This amendment, however, does not introduce novelty into the subject-matter of the claims, since said location is the same in the state of the art. Thus, the lack of novelty objection raised against Claims 1 and 6 as granted also applies to the corresponding claims of the auxiliary request.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.


The Registrar:


S. Fabiani

The Chairman:


G. Szabo

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