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D E C I S I O N
of 21 October 2003

Case Number: T 0234/01 - 3.2.2

Application Number: 96200504.7

Publication Number: 0718008

IPC: A61M 39/28

Language of the proceedings: EN

Title of invention:

IV pump safety apparatus with a non-obstructive clamp sensor

Patentee:

BAXTER INTERNATIONAL INC.

Opponent:

FRESENIUS AG

Headword:

-

Relevant legal provisions:

EPC Art. 56, 123

Keyword:

"Inventive step (yes, after amendments)"

Decisions cited:

-

Catchword:

-



Case Number: T 0234/01 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 21 October 2003

(Opponent)

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Respondent:

(Proprietor of the patent)

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Decision under appeal:

Decision of the Opposition Division of the
European Patent Office posted 22 December 2000
rejecting the opposition filed against European
patent No. 0718008 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noël
U. J. Tronser

Summary of Facts and Submissions

I. Following an opposition filed by the appellant against European patent No. 0718008, the Opposition Division decided on 22 December 2000 to reject the opposition and hence to maintain the patent as granted after having considered the state of the art represented by:

D1: US-A-4 689 043

D2a: EP-A1-0 319 279, and

D3: US-A-5 017 192.

II. The reasons of the Opposition Division were that starting from document D3 which disclosed a mechanically operated sensor, the skilled person which was looking for an alternative or a safer sensor would not have inevitably turned to a non-obstructive sensor, even though such sensor *per se* was well known in the art and used in other arrangements such as that disclosed in document D2a.

III. The appellant lodged an appeal on 20 February 2001 against the first instance's decision and filed a statement of grounds on 20 April 2001.

IV. Oral proceedings were held on 21 October 2003, at the end of which the requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be revoked;

The respondent requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of claims 1 to 7 and the description columns 1 to 4 as submitted at the oral proceedings; description columns 5 to 14 and Figures 1 to 14 as granted (main request); or on the basis of the claims according to the first to third auxiliary requests submitted at the oral proceedings.

V. Claim 1 according to the main request reads as follows:

"A pump provided with an I.V. tube activator, the pump having a clamp receiving area (62) and the activator comprising a slide clamp (109,109') for receiving an I.V. tube (26) in an operative position, the clamp comprising a regulating aperture (110, 110') having an occluding slot (111, 111') and a non-occluding passage (112, 112') and being selectively movable in said operative position between an occluding position, when the I.V. tube is located in the occluding slot and the clamp collapses an outer wall of the I.V. tube to occlude its flow lumen (124), and a non-occluding position, when the I.V. tube is located in the non-occluding passage and the clamp does not collapse the outer wall of the I.V. tube so as not to occlude the flow lumen (124), characterised by means (81) in the clamp receiving area for selectively moving the clamp from the occluding position to the non-occluding position, and

by safety means for preventing an inadvertent free flow condition, the safety means comprising:

a non-obstructive sensor (85) within the clamp receiving area (62), the non-obstructive sensor being in a first state in response to the presence of the

clamp in a predetermined position in the clamp receiving area and a second state in response to the absence of the clamp from the predetermined position; and

means operatively associated with the non-obstructive sensor for disabling the pump (20) in response to the non-obstructive sensor being in the second state."

VI. The parties submitted the following arguments:

(i) the appellant:

- The replacement in the first characterising feature of claim 1 of the expression "between ... and" by the expression "from ... to", results in an extension of the protection contrary to Article 123(3) EPC.

- With respect to document D1 which discloses all the features of the preamble of claim 1, the problem underlying the present patent was to provide correct positioning of the slide clamp within its receiving area. Document D2a discloses the use of a non-obstructive sensor for determining the proper position of a cassette containing a fluid onto a main pump unit. Though the position of the clamp is not directly sensed, the clamp is opened only when the cassette is properly installed and latched into place. Further, a control system is provided for controlling the operation of the fluid pump in response to the detected signal. Therefore, the subject-matter of

claim 1 is suggested by the combination of documents D1 and D2a.

- Also in document D3 there is disclosed a slidable clamp movable between an occluding and a non-occluding position. Since the relevant question at issue relates to the fluid flow condition within the tubing (open or restricted) and not to the location of the tubing within the clamp, the differences, if any, with respect to the features of the preamble of claim 1 are only of a formal nature. Further, document D3 discloses a mechanically operated sensor for detecting the positions of the slidable clamp within its receiving area and the corresponding fluid flow conditions. But since the movement of the clamp is not really hindered by the proximity switch, said sensor can be called "non-obstructive". Therefore, claim 1 is also suggested by the combination of documents D1 and D3.

(ii) the respondent:

- Document D1 discloses a pump safety apparatus according to the precharacterising features of claim 1. But no sensor is provided for detecting the slide clamp in a predetermined position. Moreover, the sliding movement of the clamp is generated by operating the handle in the direction opposite to the movement of the clamp as claimed, i.e. from the occluding to the non-occluding position.

- The optical sensor disclosed in document D2a does not sense the position of the clamp but that of a cassette through a complex mechanical linkage. The sensor is not, therefore, non-obstructive within the meaning of the present patent. Moreover, the sensed signal does not stop the pump unit.

- In document D3 the non-occluding (open) position of the tubing is obtained without moving the clamp in the operative position and the position of the clamp is sensed by a mechanically operated sensor. Therefore, the skilled person would not have arrived at the claimed invention even when considering all these documents in combination.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

Claim 1 according to the main request is based on features taken from the original claim 1 and features from passages of the description as filed, relating to the sensor: page 4, lines 12 to 28; page 12, lines 24 to 30 and page 18, lines 14 to 26. With respect to the version as granted, the amendments to claim 1 consist in transferring one feature from the preamble to the characterising portion and in adding to the preamble some specific features such as: "the clamp comprising a regulating aperture (110, 110') having an occluding slot (111,111') and a non-occluding passage (112,

112')"; "when the I.V. tube is located in the occluding slot"; "when the I.V. tube is located in the non-occluding passage". These features are fairly supported by the original claim 2 and by the description as originally filed, in particular page 19, lines 2 to 7 and page 16, lines 16 to 21.

Further, the first characterising feature was amended by replacing the expression "between ... and" by "from ... to" so as to read: "means (81) in the clamp receiving area for selectively moving the clamp from the occluding position to the non-occluding position". This amendment is in line with the operating of the device as set out in the patent in suit (cf. column 12, lines 36 to 47; Figure 4d) and represents a restriction of the protection if compared with the version as granted. The requirements of Article 123(2) and (3) are, therefore, met.

3. *Inventive step*

3.1 Document D1 represents the closest prior art. It discloses the precharacterising features of claim 1, in particular a pump provided with a I.V. tube activator (Figure 2), the pump having a clamp receiving area and the activator comprising a slide clamp 32 for receiving an I.V. tube 12 in an operative position, the clamp comprising a regulating aperture having an occluding slot 50 and a non-occluding passage 48 (Figure 3A). The clamp is selectively movable in said operative position between an occluding position (Figure 4), when the tube is located in the occluding slot and the clamp collapses an outer wall of the tube to occlude its flow lumen, and a non-occluding position (Figure 5), when

the tube is located in the non-occluding passage and the clamp does not collapse the outer wall of the tube as not to occlude the flow lumen.

In document D1, as the door is closed, a handle 72 is actuated (Figures 7A to 7D) to move the slidable clamp from its occluding position (tube constricted; Figure 4) to its non-occluding position (tube open; Figure 5) and reciprocally. However, this actuator is mounted outside of the pump housing, in contrast to the inner pushing means 81 according to the invention, located in the clamp receiving area, for selectively moving the clamp from the occluding to the non-occluding position. Further, the pump apparatus according to D1 has no sensor capable of detecting a predetermined position of the clamp and thus no associated means for stopping the pump in response thereto.

Therefore, the subject-matter of claim 1 differs from the disclosure of document D1 by its characterising features.

- 3.2 Starting from the teaching of D1, as recited in the introductory part of the patent specification, the problem underlying the present invention is to provide safety means to prevent inadvertent free flow condition prior to loading or after removal of the tube from the pump, as well as inadvertent occlusion of a loaded tube. In other words the I.V. tube must be brought safely and at the right stage of the infusion process either in a closed (obstructed) or in an opened condition.

This problem is solved by the combination of the characterising features, in particular by the provision of internal pushing means within the clamp receiving area for moving the clamp and allowing fluid flow when the clamp is into place and correctly positioned in its receiving area, and by the provision of a non-obstructive sensor for sensing the position of the clamp and for producing a stop signal whenever the clamp is incorrectly located or absent from its receiving area.

- 3.3 Document D3 discloses a free flow prevention system for an infusion pump, in which clamp-opening means (wedge 22) are located in a clamp receiving area for causing the operative condition to change from an occluding position (tubing closed; Figure 2) to a non-occluding position (tubing open; Figure 3) by separating the arms of a flexible clamp 20, however without slidebly moving the clamp itself.

Therefore, document D3 does not disclose the first characterising feature of claim 1, i.e. means for selectively moving the clamp between the two positions of interest. It results also therefrom that in order to open the lumen of the tubing for allowing free flow, the position of the tubing within the clamp does not change from the narrow occluding slot 30 to the wide non-occluding passage 28, but remains into place at the bottom of the slot, contrary to the situation in the present invention.

When the clamp is brought into the operative position of Figure 3, a sensor 50 formed by a proximity switch 52 and actuated by a linkage 54 causes the pump to

operate. Conversely (Figure 2), the pump is electrically disabled when the clamp is removed from the pump or not fully inserted. It results therefrom that the sensor is not "non-obstructive " within the meaning of the present patent, i.e. having no mechanical linkage (cf. column 3, lines 36 to 38). Therefore, D3 does not disclose a non-obstructive sensor, either.

3.4 The use of optical sensors for sensing the proper positioning of a disposable cassette containing a fluid onto a pump unit or for identifying the particular cassette installed by means of identifying indicia, is known from document D2a (cf. from column 50, line 18 to column 52, line 30). In particular, an optical light sensor 682, 684 (Figure 105) detects the position of a slide lock 560 attached to a slide latch 240, this latter element having the function of a slidable clamp (Figures 27 and 44) for controlling the flow of fluid through the outlet tubing of the pump. This slide latch 240 is itself slidably mounted onto the cassette 100 between guiding elements 124, 126 (Figure 4). However, said sensor is not located within the clamp receiving area and therefore does not detect the presence of the clamp in a predetermined position. Moreover, the signal generated by the sensor ("latch closed signal"; column 52, lines 15 to 16) indicates that the slide lock 560 is in the closed position and that the cassette is properly installed. Document D2a does not disclose, however, that an incorrect positioning or the absence of the slide latch has a consequence for the operation of the pump. Therefore, document D2a does not suggest the use of an optical, non-obstructive, sensor in the meaning and functioning of the sensor as claimed.

Consequently, the invention resides in the specific combination of all the features claimed such that even by a simultaneous consideration of the three documents mentioned above the skilled person would not have arrived at the claimed arrangement.

- 3.5 From the foregoing it results that the subject-matter of claim 1 according to the main request involves an inventive step within the meaning of Article 56 EPC. The dependent claims can also stand.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to maintain the patent in amended form according to the main request on the basis of claims 1 to 7 and description columns 1 to 4 as submitted at the oral proceedings, description columns 5 to 14 and Figures 1 to 14 as granted.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß