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Datasheet for the decision of 12 October 2006

Case Number: T 0636/05 - 3.2.02

Application Number: 96912464.3

Publication Number: 0900106

IPC: A61M 39/28

Language of the proceedings: EN

Title of invention:
Pinch clip occluder for infusion sets

Patentee:
Zevex, Inc.

Opponent:
Fresenius AG

Headword:
-

Relevant legal provisions:
EPC Art. 100(b), 123(2)

Keyword:
"Sufficiency of disclosure (no) - main request and auxiliary request 5"
"Extension of the subject-matter (yes) - auxiliary requests 1 to 4"

Decisions cited:
-

Catchword:
-

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Case Number: T 0636/05 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 12 October 2006

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 17 March 2005 revoking European patent No. 0900106 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: D. Valle
M. Vogel

Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal on 12 May 2005 against the decision of the opposition division posted on 17 March 2005 to revoke the European patent No. 96 912 464.3. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 15 July 2005.

II. The patent had been opposed on the basis of Article 100(a) EPC (lack of inventive step) and 100(b) EPC (insufficient disclosure).

The opposition division held that the amended claims filed during the opposition proceedings did not meet the requirements of Article 84 EPC (main, first and second auxiliary request) or 123(3) EPC (third and fourth auxiliary request then on file).

III. Oral proceedings were held on 12 October 2006.

At the end of the oral proceedings the appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or, in the alternative, of the auxiliary requests 1 to 4 all filed with the letter of 15 July 2005, or on the basis of the fifth auxiliary request filed during the oral proceedings.

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

IV. Claim 1 of the main request reads as follows (amendments with respect to the granted version are underlined):

"Apparatus for selectively controlling flow through one or more tubes (250, 250a, 250b) of an infusion delivery set, the apparatus comprising:
a pump housing (300) having:
- pumping means disposed therein
- at least one channel (310, 314) disposed therein for receiving a tube (250, 250a, 250b) of the delivery set,
- a cover means (330) for holding the tube (250, 250a, 250b) of the delivery set within the pump housing (300), the cover means (330) having an open position wherein the delivery set can be removed from the at least one channel (310, 314), and a closed position, wherein the delivery set cannot be removed from the at least one channel (310, 314), and
- a void formed therein for receiving an occluder means (200),
- an occluder means (200) nestable within the void in the pump housing (300), the occluder means (200) comprising;
- an occluder housing (204) having an open first end (208, 222) and an open second end (212, 274) and a passage (218) therethrough extending from the open first end (208, 222) to the open second end (212, 274) for receiving the tube (250, 250a, 250b) of the delivery set;
- flow restriction means (230) disposed at least partially within the occluder housing (204) and moveable between a first position in which the flow restriction means (230) occludes flow through the tube (250, 250a, 250b) of the delivery set and

a second position in which the flow restriction means (230) does not occlude flow through the tube (250, 250a, 250b); and

- biasing means (260) disposed adjacent the occluder housing (204) and the flow restriction means (230) for biasing the flow restricting means (230) into the first position;

- the cover means (330) being configured to contact and move the flow restriction means (230) into the second position when the cover means (330) is moved into the closed position,

characterised in that

at least one channel (310, 314) formed by the pump housing (300) defines a passage, and wherein a passage (218) of the occluder means (200) is in alignment with the passage of the pump housing (300) when the occluder means (200) is nested in the pump housing (300) and wherein the apparatus comprises means for precluding flow through the delivery set when the passage (218) of the occluder means (200) is not in alignment with the passage of the pump housing (300)."

Claim 1 of the main request has been essentially amended by deleting the reference numbers pertaining to Figures 1 to 4 and partially correcting the reference numbers pertaining Figures 5, 5a and 6. Furthermore the term "pump" has been added to the term "housing" in the paragraph referring to the cover means and the term "occluder" has been added to the term "housing" in the paragraphs referring to the flow restriction means and the biasing means.

Claim 1 of the first auxiliary request reads as follows (amendments with respect to the main request are underscored):

"Apparatus for selectively controlling flow through one or more tubes (250, 250a, 250b) of an infusion delivery set, the apparatus comprising:
a pump housing (300) having:
- pumping means disposed therein
- at least one channel (310, 314) disposed therein for receiving a tube (250, 250a, 250b) of the delivery set,
- a cover means (330) for holding the tube (250, 250a, 250b) of the delivery set within the pump housing (300), the cover means (330) having an open position wherein the delivery set can be removed from the at least one channel (310, 314), and a closed position, wherein the delivery set cannot be removed from the at least one channel (310, 314), and
- a void formed therein for receiving an occluder means (200),
- an occluder means (200) nestable within the void in the pump housing (300), the occluder means (200) comprising;

- an occluder housing (204) having an open first end (208, 222) and an open second end (212, 274) and a passage (218) therethrough extending from the open first end (208, 222) to the open second end (212, 274) for receiving the tube (250, 250a, 250b) of the delivery set;
- flow restriction means (230) disposed at least partially within the occluder housing (204) and moveable between a first position in which the flow restriction means (230) occludes flow through the tube (250, 250a, 250b) of the delivery set and

a second position in which the flow restriction means (230) does not occlude flow through the tube (250, 250a, 250b); and

- biasing means (260) disposed adjacent the occluder housing (204) and the flow restriction means (230) for biasing the flow restricting means (230) into the first position; and

- the cover means (330) being configured to contact and move the flow restriction means (230) into the second position when the cover means (330) is moved into the closed position,

characterised in that

at least one channel (310, 314) formed by the pump housing (300) defines a passage, and wherein a passage (218) of the occluder means (200) is in alignment with the passage of the pump housing (300) when the occluder means (200) is nested in the pump housing (300) and wherein the apparatus comprises means for precluding flow through the delivery set when the occluder means (200) and delivery set tube (250, 250a, 250b) are not properly loaded wherein the passage (218) of the occluder means (200) is not in alignment with the passage of the pump housing (300) such that if the delivery set and occluder means (200) are not properly loaded, the cover (330) is unable to close and the flow restriction means (230) is not moved into the second position thereby allow flow through the delivery set."

Claim 1 of the second auxiliary request differs from claim 1 of the first auxiliary request by the addition of the features:

", and wherein the void in the pump housing (300) is disposed along a channel (310, 314) of the pump housing

(300) to maintain alignment of the occluder means (200) within the pump housing (300)."

at the end of the claim.

Claim 1 of the third auxiliary request differs from claim 1 of the first auxiliary request by the addition of the features:

", and whereby if the delivery set and occluder means (200) are properly loaded the cover (330) is able to close and thereby move the flow restriction means (230) into the second position such that a passage (234) through the flow restriction means (230) is in alignment with the passage (218) through the occluder housing (204) to thereby allow flow through the delivery set."

at the end of the claim.

Claim 1 of the fourth auxiliary request differs from claim 1 of the main request by the addition of the underlined features to the characterising portion of the claim.

"characterised in that
- at least one channel (310, 314) formed by the pump housing (300) defines an elongate passage, and wherein a passage (218) of the occluder means (200) is in alignment with the passage of the pump housing (300) when the occluder means (200) is nested in the pump housing (300), wherein the flow restriction means (230) has a passage (234) disposed therethrough such that the passage (234) through the flow restriction means (230)

is not aligned with the passage (218) in the occluder housing (204) when the flow restriction means (230) is in the first position and the passage (234) through the flow restriction means (230) is aligned with the passage (218) in the occluder housing (204) when the flow restriction means (230) is in the second position, and wherein the apparatus comprises means for precluding flow through the delivery set when the occluder means (200) and delivery set tube (250, 250a, 250b) are not properly loaded wherein the passage (218) of the occluder means (200) is not in alignment with the passage of the pump housing (300) and wherein closing the cover (330) overcomes the bias of the flow restriction means (230) and thereby allows flow through the delivery set."

Claim 1 of the fifth auxiliary request differs from claim 1 of the main request by the addition of the features:

"the means comprising a plunger disposed in the occluder housing so that a plunger passage and the occluder housing passage through which the delivery set extends are out of alignment and thereby prevent fluid flow through the housing unless an external force is applied to the plunger."

V. The appellant argued essentially as follows:

The patent in suit did not disclose separate means for precluding flow through the delivery set when the passage of the occluder means was not in alignment with the passage of the pump housing. However, it was clear for the skilled person that this means was defined by

the interaction of the explicitly claimed elements of the apparatus. If for example the tube of the delivery set was not properly loaded in the channels 310 and 314, it was not possible to close the cover 330 (see column 7, lines 45 to 51). As a consequence the plunger 230 could not be forced downwardly and would continue to preclude flow through the delivery set. It was obvious that in the case where the passage of the occluder means was not in alignment with the passage of the pump housing the cover could also not move the plunger with the same result of precluding flow as described above. Hence the invention was feasible.

The additional features of the auxiliary submissions were disclosed in the passage of the patent specification starting from line 45 of column 7 or were directly derivable from the whole description, in particular from that portion concerning Figure 6.

VI. The respondent contested the statements of the appellant and argued essentially as follows:

The invention was not disclosed in a manner sufficiently clear and complete to be carried out by a skilled person.

Nowhere in the patent specification was described the means which could preclude flow when the passage of the occluder means was not in alignment with the passage of the pump housing. A slight misalignment of the two passages, such as that caused by the presence of small particles of material on the bottom of the occluder casing, or a lateral misalignment did not necessarily prevent the closing of the cover.

Contrary to the assertion of the appellant the additional features of claim 1 of all the auxiliary requests were not disclosed in the originally filed application.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request and auxiliary request 5*

Claim 1 of the main request and of the auxiliary request 5 contain in the characterising portion the feature that the apparatus comprises means for precluding flow through the delivery set when the passage of the occluder means is not in alignment with the passage of the pump housing.

This feature was disclosed in the originally filed claim 6 (see WO-A-96/30679). However, neither the description nor the drawings or the claims of the patent in suit contain any relevant information on the design of this means. The passage in column 7, lines 45 to 55, cited by the appellant, does not refer to a situation where the passage of the occluder means is not in alignment with the pump housing, but to the situation where the tube of the delivery set is not properly loaded in the channels of the pump housing. Since it is also not immediately clear how the preclusion means can be designed either, the invention is not disclosed in the patent in a manner sufficiently

clear and complete for it to be carried out by a person skilled in the art as required by Article 100(b) EPC.

The appellant's argumentation according to which the invention was feasible, since it was obvious that the contested means were formed by the claimed elements of the apparatus, in particular the cover (330), the plunger (230) and the occluder housing (204) which interacted to perform the claimed function, is not convincing.

Certainly, there could be misalignments between the passage of the occluder means and the passage of the pump housing which would result in a situation where the occluder housing protrudes out of the pump housing so that the cover is prevented from operating the plunger. However not all misalignment positions would produce such an effect. In particular those misalignments cited by the respondent would not result in a preclusion of flow through the delivery set. Consequently the patent in suit does not comprise a teaching how to design means which are suitable for precluding flow through the delivery set in all situations where the passage of the occluder means is not in alignment with the passage of the pump housing.

3. *Auxiliary requests*

Claim 1 of all auxiliary requests 1 to 4 contains in the characterising portion the feature according to which the apparatus comprises means for precluding flow through the delivery set when the occluder means (200) and delivery set tube (250, 250a, 250b) are not properly loaded.

However, this feature is not disclosed in the originally filed application. In particular the passage of the description cited by the appellant (column 7, from line 45) does not disclose a precluding means which operates when the occluder means and delivery set tube are not properly loaded, but merely means operating when only the delivery set tube is not properly loaded.

Accordingly the auxiliary requests 1 to 4 do not comply with Article 123 (2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar: The Chairman:

V. Commare T. Kriner