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**Datasheet for the decision
of 28 May 2009**

Case Number: T 0648/06 - 3.2.02

Application Number: 02004309.7

Publication Number: 1210960

IPC: A61M 39/26

Language of the proceedings: EN

Title of invention:

Needleless valve for use in intravenous infusion

Applicant:

Richmond, Frank

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 123(2), 56

Relevant legal provisions (EPC 1973):

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Keyword:

"Main request: admissible (no)"

"1st, 2nd, 4th, 6th requests: extension (yes)"

"3rd, 5th, 7th requests: inventive step (no)"

Decisions cited:

-

Catchword:

-



Case Number: T 0648/06 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.02
of 28 May 2009

Appellant: Richmond, Frank
205A Grant Street
Harvard
IL 60053 (US)

Representative: HOFFMANN EITLE
Patent- und Rechtsanwälte
Arabellastraße 4
D-81925 München (DE)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 12 December 2005
refusing European application No. 02004309.7
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: M. Noël
Members: P. L. P. Weber
M. J. Vogel

Summary of Facts and Submissions

I. The present appeal is against the decision of the examining division dated 12 December 2005 to refuse European patent application number 02004309.7.

A notice of appeal was filed on 17 February 2006 and the appeal fee paid on the same day. A statement setting out the grounds of appeal was filed on 12 April 2006.

II. The following documents play a role in the appeal proceedings:

D3 : US-A-4838875

D5 : US-A-4683916

D6 : US-A-5190067

D7 : WO-A-9300956

III. In its decision the examining division considered that the claimed subject-matter lacked an inventive step over the combination of D3 and D5.

IV. With the statement setting out the grounds of appeal, the appellant filed three sets of claims and presented arguments in support of their patentability.

V. In an annex to the summons to oral proceedings dated 27 February 2009, the Board made formal objections to the claims, in particular to the use of the term "valve member". Additionally, the board expressed the provisional opinion that the subject-matter of claim 1 of any requests did not seem inventive at least over the combinations of D3 with D5 or of D7 with D6.

- VI. With its letter of 23 April 2009, the appellant filed new auxiliary requests 1 to 6 to be substituted for the previous ones and presented arguments restricted to the requirements of Article 123(2) EPC and Article 84 EPC.
- VII. With its letter of 22 May 2009 the appellant filed again a new main request and renumbered the former requests as 1st to 7th auxiliary requests respectively.
- VIII. Oral proceedings were held on 28 May 2009, at the end of which the appellant requested that the decision under appeal be set aside and that a patent be granted either on the basis of claims 1 to 7 as filed on 22 May 2009 (main request) or as an auxiliary measure on the basis of the claims according to any of the 1st to 7th auxiliary requests as presented with letter of 22 May 2009, or as a further auxiliary measure on the basis of the same requests with the method claims being deleted
- IX. The arguments of the appellant can be summarised as follows:

The reason for this late filing of the main request was that the representative was not able to join Mr Richmond (the applicant) earlier.

While it was recognised that the term "valve member" did not appear in the originally filed description, the applicant had a right to a certain generalisation, in particular of the term "valve disc" used restrictively in the description of the specific embodiments of the invention. This generalisation was supported by originally filed claim 13 (which corresponds to

originally filed claim 1 of the parent application) which did not mention any valve disc but did mention an open position and a closed position of the valve, thus implicitly requiring the presence of an element or member within the valve for performing the above operations. The term "valve member", therefore, was nothing other than a common means used to put the operation of the valve into practice.

The universal valve disclosed in document D7, was of a totally different type of construction. The tip of the syringe was not for pushing against an intermediate valve element, as required by claim 1, but directly against a unique piston-like element through which fluid was either flowing or not. This valve was used to withdraw fluid (medicament) from a vial (fig.4) and then, in a different operation, to inject this medicament into an infusion bag or into an infusion line linked to the patient (fig.5). The skilled person therefore would have no reason to adopt the valve disclosed in D5, which was foreseen for connection in an infusion line only as can be understood for instance from column 3, lines 37 to 40 of that document.

Additionally there was no indication in D7 that the same valve means could be used indifferently to either take out fluid or inject fluid. The skilled person would not be prompted to take out a fluid sample from a defective infusion bag. Should this be the case, he would rather simply throw the bag away and take a new one.

X. The different claims 1 according to the various requests read as follows:

Main request:

"In combination:

(i) a medical device comprising a container for containing medicament and provided with at least one normally-closed reflux valve, the valve being openable for introducing medicament into or dispensing medicament from the container, the or each reflux valve comprising:

a valve body (46) having a distal end and a proximal end, the body defining a fluid passageway providing two-way fluid communication through the body, via the proximal end, to the interior of the container, the valve having a first, closed, position wherein said fluid communication is not established and a second, open, position wherein said fluid communication is permitted; and

a valve element (52) disposed in the passageway for displacement within the passageway to change the valve between its first and second positions, the valve element having an engagement surface (54); and

(ii) a spikeless/needleless connector connected to, or for connection to, said reflux valve for contacting the engagement surface (64) and displacing the valve element, to cause the valve to change to the second position."

First auxiliary request

"In combination:

(i) a medical device comprising a container for containing medicament and provided with at least one normally-closed reflux valve, the valve being openable for introducing medicament into or dispensing medicament from the container, the or each reflux valve comprising:

 a valve body (46) having a distal end and a proximal end, the body defining a fluid passageway providing two-way fluid communication through the body, via the proximal end, to the interior of the container;

 a valve member (54) disposed in the body, the valve member being biased to a first, closed, position wherein said fluid communication is not established, the member being moveable to a second, open, position wherein said fluid communication is permitted; and

 a valve element (62) disposed in the passageway for direct contact with the valve member for displacement within the passageway, the valve element having an engagement surface (64); and

(ii) a spikeless/needleless connector connected to, or for connection to, said reflux valve for contacting the engagement surface (64) and displacing the valve element, to cause the valve member to move to the second position."

Second auxiliary request

"In combination:

(i) a medical device comprising a container for containing medicament and provided with at least one

normally-closed reflux valve, the valve being openable for introducing medicament into or dispensing medicament from the container, the or each reflux valve comprising

a valve body (46) having a distal end and a proximal end, the body defining a fluid passageway for providing two-way fluid flow through the body, via the proximal end, to the interior of the container;

a valve member (54) disposed in the fluid passageway and biased to a first, closed, position wherein the valve member blocks fluid flow through the fluid passageway, the valve member being moveable to a second, open, position wherein said fluid flow is permitted;

and

a valve element (G2) disposed in the passageway for direct contact with the valve member and for reciprocal displacement within the passageway, the valve element having an engagement surface (64); and

(ii) a spikeless/needleless connector connected to, or for connection to, said reflux valve so as to contact the engagement surface (64) and displace the valve element within the passageway against the valve member, to cause the valve member to move to the second position."

Third auxiliary request

"In combination;

(i) a medical device comprising a container for containing medicament and provided with at least one normally-closed reflux valve, the valve being openable for introducing medicament into or dispensing medicament from the container, the or each reflux valve comprising

a valve body (46) having a distal end and a proximal end, the body defining a fluid passageway for providing two- way fluid flow through the body, via the proximal end, to the interior of the container;

a resilient valve disc (54) disposed in the fluid passageway and biased to a first, closed, position wherein the valve disc blocks fluid flow through the fluid passageway, the valve disc being moveable to a second, open, position wherein said fluid flow is permitted; and

a valve element (62) disposed in the passageway for direct contact with the valve disc and for reciprocal displacement within the passageway, the valve element having an engagement surface (64),; and

(ii) a spikeless/needleless connector connected to, or for connection to, said reflux valve so as to contact the engagement surface (64) and displace the valve element within the passageway against the valve member, to cause the valve disc to move to the second position."

Fourth auxiliary request

"In combination:

(i) a medical device comprising a container for containing medicament and provided with at least one normally-closed reflux valve, the valve being openable for introducing medicament into or dispensing medicament from the container, the or each reflux valve comprising;

a valve body (46) having a distal end and a proximal end, the body defining a fluid passageway for providing two- way fluid flow through the body, via the proximal end, to the interior of the container;

a valve member (54) disposed in the fluid passageway and biased to a first, closed, position wherein the valve member blocks fluid flow through the fluid passageway, the valve member being moveable to a second, open, position wherein said fluid flow is permitted; and

a valve element (62) disposed in the passageway for direct contact with the valve member and for reciprocal displacement within the passageway, the valve element having an engagement surface (64); and

(ii) a spikeless/needleless connector connected to, or for connection to, said reflux valve so as to contact the

engagement surface (64) and displace the valve element within the passageway against the valve member, to cause the valve member to move to the second position and thereby allow medicament to be introduced into or dispensed from the container through the connector and the fluid passageway in the valve body."

Fifth auxiliary request

"In combination:

(i) a medical device comprising a container for containing medicament and provided with at least one normally-closed reflux valve, the valve being openable for introducing medicament into or dispensing medicament from the container, the or each reflux valve comprising:

a valve body (46) having a distal end and a proximal end, the body defining a fluid passageway for providing two-way fluid flow through the body, via the proximal end, to the interior of the container;

a resilient valve disc (54) disposed in the fluid passageway and biased to a first, closed, position wherein the valve disc blocks fluid flow through the fluid passageway, the valve disc being moveable to a second, open, position wherein said fluid flow is permitted; and

a valve element (62) disposed in the passageway for direct contact with the valve disc and for reciprocal displacement within the passageway, the valve element having an engagement surface (64); and

(ii) a spikeless/needleless, connector connected to, or for connection to, said reflux valve so as to contact the engagement surface (64) and displace the valve element within the passageway against the valve member, to cause the valve disc to move to the second position and thereby allow medicament to be introduced into or dispensed from the container through the connector and the fluid passageway in the valve body."

Sixth auxiliary request

"In combination

(i) a medical device comprising a container for containing medicament and provided with at least one normally-closed reflux valve, the container having a port to which a said reflux valve is connected and the valve being openable for introducing medicament into or dispensing medicament from the container, the or each reflux valve comprising:

a valve body (46) having a distal end and a proximal end, the body defining a fluid passageway for providing two-way fluid flow through the body, via the proximal end, to the interior of the container;

a valve member (54) disposed in the fluid passageway and biased to a first, closed, position wherein the valve member blocks fluid flow through the fluid passageway, the valve member being moveable to a second, open, position wherein said fluid flow is permitted; and

a valve element (62) disposed in the passageway for direct contact with the valve member and for reciprocal displacement within the passageway, the valve element having an engagement surface (64); and

(ii) a spikeless/needleless connector connected to, or for connection to, said reflux valve so as to contact the engagement surface (64) and displace the valve element within the passageway against the valve member, to cause the valve member to move to the second position."

Seventh auxiliary request

"In combination:

(i) a medical device comprising a container for containing medicament and provided with at least one normally-closed reflux valve, the container having a port to which a said reflux valve is connected and the valve being openable for introducing medicament into or dispensing medicament from the container, the or each reflux valve comprising:

a valve body (46) having a distal end and a proximal end, the body defining a fluid passageway for providing two-way fluid flow through the body, via the proximal end, to the interior of the container;

a resilient valve disc (54) disposed in the fluid passageway and biased to a first, closed, position wherein the valve disc blocks fluid flow through the

fluid passageway, the valve disc being moveable to a second, open, position wherein said fluid flow is permitted; and
a valve element (62) disposed in the passageway for direct contact with the valve disc and for reciprocal displacement within the passageway, the valve element having an engagement surface (64); and
(ii) a spikeless/needleless connector connected to, or for connection to said reflux valve so as to contact the engagement surface (64) and displace the valve element within the passageway against the valve member, to cause the valve disc to move to the second position."

Reasons for the Decision

1. The appeal is admissible.
2. *Main request - admissibility*

The Main request was filed very late with the letter of the appellant of 22 May 2009, that is one week before the date of the oral proceedings. Since claim 1 of the main request was amended in a broadening way by omission of an essential feature (valve member) the question arises whether the new combination of features is sufficiently supported and, hence, whether the late-filed request is clearly and immediately admissible or not.

Original claim 13 on which claim 1 of the main request is supposedly be based, does not recite any valve member, and is formed from another combination of

features, than that forming the subject-matter of claim 1 according to the main request. For instance claim 13 requires a male valve element having a skirt disposed in the valve body and an engagement surface extending outwardly beyond the valve body, which are not present in claim 1 of the main request.

It results that *prima facie*, the originally filed claim 13 cannot be a proper basis for the more general feature combination of the present claim 1. Therefore, the Board has decided not to admit the late filed main request into the proceedings, under the provisions of Article 114(2) EPC.

3. *First, second, fourth and sixth auxiliary requests*

Claim 1 according to the first auxiliary request requires a "valve member" to be disposed in the valve body. However, such a valve member has never been defined in the originally filed application documents, where a corresponding "element" is called either valve disc or resilient valve disc, flexible resilient plastic or still silicon rubber disc. Also the figures clearly show axially symmetrically shaped valves having valve discs and nothing else. Any other shape or type of "valve member" are neither described nor derivable.

The appellant submitted that claim 13 was sufficient basis for the introduction of the term "valve member" as claim 13 implicitly required the presence of such a "valve member".

The same objection as against claim 1 according to the main request applies as claim 13 is a particular

combination of features including features which are not in claim 1 according to the first auxiliary request. For instance claim 13 requires a male valve element having a skirt disposed in the valve body and an engagement surface extending outwardly beyond the valve body which is not required by claim 1 according to the first auxiliary request.

Hence claim 1 according to the first auxiliary request contravenes Article 123(2) EPC.

The same as the above applies to claim 1 according to the second, fourth and sixth auxiliary requests, which all contain a feature directed to a "valve member".

4. *Third auxiliary request*

- 4.1 D7 is considered to be the closest prior art as it discloses a needleless valve connected to a bag or a vial provided with medication ports, which enable fluid to be injected or withdrawn from a vial, as shown in Figure 4 or to and from intravenous bottle, intravenous tubing or the like as shown in Figure 5, without the use of a hypodermic needle.

The universal port according to D7 comprises a cylindrical member with an internal bore in which a plunger is axially movable. The plunger itself has a bore extending from one opening at one end of the plunger to several openings on the circumference of the plunger close to its other end. When a tip of a needleless syringe is pushed against the surface having the one opening, the plunger is moved within the cylindrical member so that the openings on the

circumference of the plunger correspond with openings in the cylindrical member. In this way a fluid connection is established between the openings in the cylindrical member and the syringe. In the absence of the tip of the syringe a spring pushes the plunger into a rest position in which the fluid connection is interrupted.

In the terms of claim 1 D7 discloses with reference to Figure 4 a medical device comprising a container 43 for containing medicament and provided with at least one normally-closed reflux valve 10', the valve being openable for introducing medicament into or dispensing medicament from the container, the or each reflux valve comprising a valve body 12 having a distal end and a proximal end 19, the body defining a fluid passageway for providing two-way fluid flow through the body, via the proximal end, to the interior of the container 43; a spikeless/needleless connector 26 connected to, or for connection to, said reflux valve 10'.

- 4.2 The subject-matter of claim 1 differs from D7 in that it additionally comprises a resilient valve disc 54 disposed in the fluid passageway and biased to a first, closed, position wherein the valve disc blocks fluid flow through the fluid passageway, the valve disc being moveable to a second, open, position wherein said fluid flow is permitted; and a valve element 62 disposed in the passageway for direct contact with the valve disc and for reciprocal displacement within the passageway, the valve element having an engagement surface 64; and the needleless connector contacts the engagement surface 64 and displaces the valve element within the

passageway against the valve disc, to cause the valve disc to move to the second position.

In the valve construction according to D7 the tip of the syringe contacts the plunger engagement surface and moves the plunger axially in the bore of the valve body to establish the fluid connection by aligning the bores in the plunger with the ones in the valve body whereas in the construction according to claim 1 the tip of the syringe engages the (intermediate) valve element which pushes on a resilient disc to maintain it away from its resting surface and to establish the fluid connection.

In both cases the same pushing movement of the tip of the syringe produces the same effect namely to open a two-way fluid connection between the syringe and the interior of the container.

With respect to the disclosure of D7, the objective problem can thus be seen in the provision of a two-way valve having an alternative constructional design.

- 4.3 Such an alternative constructional design is however shown in D5. This document discloses a backflow check valve for use with liquid flow and administration apparatus for medical purposes (see column 1, lines 6 to 9) having the same constructional features as those recited in the subject-matter of claim 1.

More specifically, D5 discloses a valve body having a distal end and a proximal end, the body defining a fluid passageway for providing two-way fluid flow through the body a resilient valve disc 50 disposed in the fluid passageway and biased to a first, closed,

position wherein the valve disc blocks fluid flow through the fluid passageway, the valve disc being moveable to a second, open, position wherein said fluid flow is permitted; and a valve element 60 disposed in the passageway for direct contact with the valve disc 50 and for reciprocal displacement within the passageway, the valve element having an engagement surface 62.

This valve element has a ring 62 and legs 64 extending therefrom for contacting the surface 51 of resilient valve disc 50. When it is desired to open the valve, the tip of the needleless syringe is introduced into the valve body and pressed against the ring 62 of the valve element 60 so as to push the latter in the passageway. When advancing in the passageway the legs 64 of valve element 60 push on the surface 51 of valve disc 50 and thus push the valve disc away from its seat which in turn permits fluid flow in both directions.

Therefore the valve according to D5 clearly works in the same way as the valve disclosed in D7 but only differs from it in the way it is constructed.

The skilled man would thus select either one of two valve constructions for the same applications depending on the circumstances and would easily replace some components from one construction to the other so as to arrive at the claimed subject-matter, the more so since it is a constant desire of the skilled man to look for alternative components to the ones used usually.

The appellant's argument that there is no indication in D7 whatsoever that when connected to a vial the valve

is also used to inject medicament or liquid cannot be accepted.

The valve disclosed in D7 is a universal valve which permits fluid flow in both directions. Thus also in the case where the valve is connected to a vial as in the embodiment according to Figure 4 for taking out medicament fluid flow is permitted in both directions.

The appellant submitted that the valve shown in D5 is not suitable for connection to a vial or infusion bag but only for insertion in an infusion line.

D5 describes a check valve in general terms, but specifically and clearly discloses the engagement of the ring portion of the structure by the tip of a syringe (or other injection device) in order to open the valve (see column 2, lines 57 to 64). This is a clear indication that the valve operates in the same way as the one in D7, which are thus interchangeable.

The appellant's argument that a syringe is not a connector in the sense of claim 1 cannot be accepted either as in the application in suit it is also a syringe which is used to be connected to the valve body, see for instance Figure 1 and the corresponding description part.

It results therefrom that the subject-matter of claim 1 according to the third auxiliary request does not involve an inventive step contrary to the requirement of Article 56 EPC 1973.

5. *Fifth and seventh auxiliary requests*

The amendments to claim 1 according to the fifth or seventh auxiliary requests were made to obviate objections of lack of support and clarity raised in the provisional communication of the Board. These amendments, however, do not change anything to the above reasoning based on the lack of inventive step. Therefore, the same conclusion as above applies to the subject-matter of the fifth and seventh auxiliary requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

D. Sauter

M. Noël