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**Datasheet for the decision
of 21 May 2007**

Case Number: T 1133/05 - 3.2.02

Application Number: 99916372.8

Publication Number: 1071487

IPC: A61M 5/315

Language of the proceedings: EN

Title of invention:

Syringe assembly

Applicant:

Becton Dickinson and Company

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step (yes, after amendments)"

Decisions cited:

-

Catchword:

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Case Number: T 1133/05 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 21 May 2007

Appellant: Becton Dickinson and Company
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Franklin Lakes,
New Jersey 07417-1880 (US)

Representative: Ruffles, Graham Keith
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 29 April 2005
refusing European application No. 99916372.8
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: D. Valle
E. Dufrasne

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal on 7 June 2005 against the decision of the examining division posted on 29 April 2005 refusing the European patent application 99916372.8. The fee for the appeal was paid on 8 June 2005 and the statement setting out the grounds for appeal was received on 23 August 2005.

II. The examining division held that the application did not meet the requirement of Art. 52 and 56 EPC (lack of inventive step) having the regard to the teaching of

D2 = US - A - 5 395 339.

Additionally the following document has been considered for the present decision:

D1 = US - A - 3 930 492.

III. Oral proceedings on request of the appellant took place on 21 May 2007.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of:

- claims: 1 to 8 and
- description: pages 1 to 3, 3a, 3b, 4 to 12

as submitted during oral proceedings;

- figures: 1 to 9 as published (WO - A - 99/52578).

IV. Claim 1 reads as follows:

"An I.V. flush syringe assembly (55) comprising:
a syringe barrel (56) having an elongated body (57) defining a chamber (58) for retaining fluid, an open proximal end (59), a distal end (62) and a frusto-conically shaped tip (64) extending from said distal end having a tip passageway (65) therethrough in fluid communication with said chamber, said chamber having a distal end defined by a distal wall (68) through which said passageway passes;
a stopper (70) in fluid-tight engagement inside said barrel;
an elongated rigid plunger rod (73) defining a longitudinal axis and extending proximally from said stopper through said open proximal end of said barrel, a flange (77) at a proximal end of said plunger rod, said flange being shaped and positioned to limit the distal motion of said plunger rod in said barrel by contacting said proximal end of said barrel;
a tip cap (80) releasably connected to said tip for sealing said passageway; and flush solution (82) in said chamber;
characterized in that said chamber has an inside diameter of at least 13.5 mm (0.53 inch), and the length of said chamber (58) is no more than 57 mm (2.25 inches), and said stopper (70) and said plunger rod (73) are dimensioned so that when said plunger rod flange (77) contacts said proximal end of said barrel (56) there is a space between at least a portion of the distal end of said stopper and said distal wall of said barrel."

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

Claim 1 is based on the original claims 1 and 3 and on the description (see page 1, line 8; page 7, line 13; page 11, line 30). Claims 2 to 8 have been renumbered subsequently to the inclusion of the subject matter of claim 3 in claim 1. The description has been adapted to the new independent claim and now includes also an evaluation of D2.

Hence the amendments meet the requirements of Article 123(2) EPC.

3. *Inventive step*

Claim 1 is distinguished from the state of the art disclosed in D2 at least by the characterizing part of the claim, that is in that:

- (a) said chamber has an inside diameter of at least 13.5 mm (0.53 inch),
- (b) the length of said chamber (58) is no more than 57 mm (2.25 inches), and
- (c) said stopper (70) and said plunger rod (73) are dimensioned so that when said plunger rod flange (77) contacts said proximal end of said barrel (56) there is a space between at least a portion of the distal end of said stopper and said distal wall of said barrel.

The purpose of the claimed invention has to be seen in:

feature a: improving the control of the pressure during flush procedures (see description, page 2, lines 20 to 26);

feature b: thoroughly adapting the size (length) of the syringe to the capacity requirements for flushing;

feature c: preventing the stopper from pressing against the distal end wall of the barrel and thereby avoiding a reflux due to the rebound of the elastic stopper (see description, page 8, lines 14 to 17).

The patent application acknowledges that it was known to use conventional hypodermic syringes of 10 ml capacity for flushing (see description, page 2, lines 13, 14 and 23). These syringes have a diameter of 14,5 mm, i.e. in the claimed range of at least 13,5 mm. Accordingly feature a) as such is known. However, this 10 ml syringe has a internal length of the barrel of $10/[\pi(1,45/2)^2] = 6,05$ cm, which is outside the claimed range of no more than 57 mm.

D1 (see Figures 1 and 2 and column 4, lines 11 to 21) discloses a blood sampling assembly comprising a blood sampling container 1 and a holder 13, whereby the container has a plunger 11 with a stopper 12 (corresponding to the plunger rod flange of the invention) engageable with a flange 4 at the proximal end of the barrel and preventing the gasket 3 (= stopper) from being repelled by the distal end of the barrel and thereby preventing air from entering the interior of the blood sampling. However, the arrangement does not concern an I.V. flush syringe

assembly like the invention, and does not deal with the avoidance of reflux of blood into a syringe.

The hints contained in the available state of the art were not sufficient to lead the skilled person in the field of syringe design in an obvious way to the claimed invention.

4. With respect to the above findings, the subject-matter of the independent claim 1 also involves an inventive step.

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 grant a patent on the basis of:
 - claims: 1 to 8 and
 - description: pages 1 to 3, 3a, 3b, 4 to 12as submitted during oral proceedings;
 - figures: 1 to 9 as published (WO - A - 99/52578).

The Registrar:

The Chairman:

V. Commare

T. Kriner