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

**Case Number:** T 0016/08 - 3.2.02

**Application Number:** 93307092.2

**Publication Number:** 0629418

**IPC:** A61M 39/04

**Language of the proceedings:** EN

**Title of invention:**  
Needleless access device

**Patentee:**  
FILTERTEK INC.

**Opponent:**  
Baxter Healthcare Corporation

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 54, 123(2)

**Relevant legal provisions (EPC 1973):**  
EPC Art. 84

**Keyword:**  
"Novelty, clarity (no)"

**Decisions cited:**  
-

**Catchword:**  
-



Case Number: T 0016/08 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 28 April 2009

**Appellant:** FILTERTEK INC.  
(Patent Proprietor) P.O. Box 310  
Hebron,  
Illinois 60034-0310 (US)

**Representative:** Bayliss, Geoffrey Cyril  
Boult Wade Tennant  
Verulam Gardens  
70 Gray's Inn Road  
London WC1X 8BT (GB)

**Respondent:** Baxter Healthcare Corporation  
(Opponent) One Baxter Parkway  
Deerfield, Illinois 60015-4633 (US)

**Representative:** Dee, Ian Mark  
Potter Clarkson LLP  
Park View House  
58 The Ropewalk  
Nottingham NG1 5DD (GB)

**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 2 November 2007  
revoking European patent No. 0629418 pursuant  
to Article 102(1) EPC 1973.

**Composition of the Board:**

**Chairman:** D. Valle  
**Members:** C. Körber  
A. Pignatelli

## Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal on 21 December 2007 against the decision of the opposition division posted on 2 November 2007 to revoke the patent for lack of novelty or of clarity of the requests then on file. The fee for the appeal was paid on the same day and the statement setting out the grounds for appeal was received on 26 February 2008.

II. The following documents are relevant for the present decision:

D2 = US - A - 5 006 114

Exhibit A1 = A technical report for Baxter medical valve assembly finite elements analysis filed by the respondent by telefax of 25 March 2009.

III. Oral proceedings were held on 28 April 2009.

At the end of the oral proceedings the appellant requested that the decision under appeal be set aside or that the patent be maintained on the basis of one of the seven auxiliary requests filed with letter of 26 February 2008.

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

IV. Claim 1 of the main request reads as follows:

"A needleless access device (10, 40, 60, 70, 80, 90, 100) comprising: a housing (12) having an inlet opening (6), an outlet opening (8), and a channel (15)

therethrough; and a moveable piston (18) adjacent said inlet opening (6) inside said channel (15) and biased so that the top surface of the piston (18) is either generally flush with the inlet opening (6) or extends outwardly of the inlet opening (6) to facilitate aseptic treatment of the top surface of the piston (18); characterized in that a wiper seal (25) is formed on the top section of said piston (18) for sealing the inlet opening (26) and wiping the surface of the channel (15) surrounding the piston (18) during actuation and release of the piston (18)."

Claim 1 of the first auxiliary request contains the additional feature:

"[a wiper seal (25) ... for ... wiping the surface of the channel (15) ...] leaving it in a clean state."

Claim 1 of the second auxiliary request contains the following amendments with respect to the main request:

- addition of the feature:

"[a channel (15) ...] defined between the two openings and forming a fluid passageway through the device;"

- deletion of the feature:

"inside said channel"

- addition of the features:

"[biased so that] in the closed state [the top surface of the piston ...]", and:

"except when in the closed state when the top surface of the piston may extend outwardly of the inlet opening, the entire movable piston stays inside the channel".

Claim 1 of the third auxiliary request is made of the features of claim 1 of the first and second auxiliary request.

Claim 1 of the fourth auxiliary request contains the additional feature with respect to the main request:

"a centre support pin (24) is provided in said piston (18) for transmitting force applied at the top of the pin to the bottom of the piston."

Claim 1 of the fifth auxiliary request is made of the features of claim 1 of the first and fourth auxiliary request.

Claim 1 of the sixth auxiliary request is made of the features of claim 1 of the second and fourth auxiliary request.

claim 1 of the seventh auxiliary request is made of the features of claim 1 of the first, second and fourth auxiliary request.

V. The appellant argued essentially as follows:

D2 did not show directly and unambiguously a wiping seal on the top section of the piston whereas D2 explicitly mentions a wiping seal at the bottom of the

piston (column 6, lines 15 to 19 in combination with column 7, lines 20 to 22) in the sense of claim 1 of the main request. Column 7, lines 23 to 28 referred exclusively to the static unloaded state. D2 did not need a wiper seal at the top and the sharp edge which necessarily was present at the inlet of the side channel due to the moulding procedure would destroy a wiper seal anyway. The fluid between the two compression fits of the piston would remain trapped there causing hygienic problems.

The study report (Exhibit A1) was filed too late and the accompanying circumstances around it were not clear. Some values of the parameters taken to perform the study were arbitrary. In particular at page 4 it was not proved that the depth of the standard luer taper was 0.162 inches and that the diameter of the inner walls increased toward the end of the housing. It was further not clear whether the draft used was 1%, 3% or an intermediate value, the dimensions of the spade were not made known by D2 and the distance of the top of the spade from the top of the piston was not according to that of Figure 6 of D2. The position of the side channel was not clear either. The order of magnitude of the spring force of 0.1 lb was not realistic and extremely low and form, dimensions and length of travel of the spring did not correspond to those of the drawings. The study did not mention the kind of fluid to be wiped and the assumption that the force applied to the top of the piston was 0.01 lbs (see page 6) was arbitrary. The pieces of information contained in D2 were not sufficient to carry out a serious test, the study was based on highly schematic and arbitrary assumptions and was therefore unreliable.

The additional feature of claim 1 of the first auxiliary request (leaving it in a clear state) was disclosed on page 6, lines 15 to 16 of the description as filed and introduced in order to exclude lubrication.

The reference to the channel in claim 1 of the second auxiliary request was taken from page 4, lines 31 to 34 and from the figures. The feature concerning the closed state was taken from the figures and it was clear.

The additional feature of claim 1 of the fourth auxiliary request was not known from D2 since D2 did not show a centre support pin for transmitting force applied at the top of the pin to the bottom of the piston. There was simply no surface in the device of D2 which could possibly transmit force to the bottom of the piston.

Claims 1 of the auxiliary requests 3 and 5 to 7 were made of combinations of the features of the requests dealt with above.

VI. The respondent contested the assertions of the appellant and argued in particular that D2 contained a wiping seal at the top, see column 7, lines 5 to 27. The (arguable) presence of a sharp edge at the attachment of the side channel did not destroy the wiper. Fluid will not be trapped between the two compression fits since it could escape through the side channel.

The study report was not filed too late since it had been submitted as a direct reaction to the communication of the board and within the time limit set by the board. The value taken in the study for the taper of the female luer (0.162 inches) was realistic and lay within the range given in column 7, lines 45 to 49 of D2. The draft taken by the study was 1%, see page 7, second paragraph and corresponds to a value disclosed in D2 (column 7, lines 50 - 51). The distance from the top of the spade to the top of the piston and the depth of the attachment of the side channel used in the study, see for example Figure 4, were taken from the preferred embodiments of D2 shown in Figure 4. The value of the spring force was sufficient to cause the reverse travel of the piston and the form of the spring was not essential for evaluating the wiping effect. The choice of a specific fluid was not necessary to assess the deformation of the piston and this was not specified in the claim either.

The new feature of claim 1 of the first auxiliary request was not clear as far as the word "clean" was concerned.

The feature concerning the channel of claim 1 of the second auxiliary request was not originally disclosed since the cited passage at claim 4 referred to a channel in the cap and not between the two openings of the housing. The feature concerning the closed state was not clear.

The additional feature of claim 1 of the fourth auxiliary request was not novel having regard to D2, see also the study report. The feature did not require



that the whole force applied at the top of the piston be transmitted to the bottom; also a partial transmission would fall under the claimed feature.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Novelty of claim 1 of the main request*

D2 discloses a needleless access device (see in particular Figure 4) comprising a housing (20) having an inlet opening (on the surface 64), an outlet opening (in the connector 18), and a channel (see reference number 34 and inside upper part of housing 20) therethrough; and a moveable piston (50) adjacent said inlet opening inside said channel and biased so that the top surface of the piston is generally flush with the inlet opening to facilitate aseptic treatment of the top surface of the piston.

D2 does not explicitly disclose the characterizing part of claim 1, that is:

"that a wiper seal (25) is formed on the top section of said piston (18) for sealing the inlet opening (26) and wiping the surface of the channel (15) surrounding the piston (18) during actuation and release of the piston (18)."

However, the board, after a careful consideration of all the evidence has come to the conclusion that D2 implicitly, but clearly and unambiguously discloses

also the characterizing part of the claim and that the subject-matter of claim 1 of the main request lacks novelty.

It is uncontested that the compression fit on the top of the section of the piston according to D2 seals the inlet opening, see column 7, lines 24 to 33:

"There is approximately 0.005 to 0.008 inches compression fit with the interior of the housing for a distance of approximately 0.05 inches on each end of the piston providing sealing required to prevent leaks; between the larger diameters on each end of the piston the diameter of the piston ranges from 0.001 to 0.003 inches smaller than the piston housing diameter."

The appellant argues that such seal could not wipe the surface of the channel surrounding the piston during actuation and release of the piston because the piston will be deformed during loading by the needless syringe and the seal will not stay in contact with the surface of the channel. The appellant has illustrated this in a drawing called Annex 1 filed with the grounds of appeal and has called it "barrelling effect".

However, the respondent in reply to the objections of the appellant has filed as Exhibit A1 a technical report which convincingly shows that the barrelling effect does not occur for the preferred embodiment of D2. The study is thorough and accurate and takes into account all the relevant parameters which would affect the results, see pages 4 to 6 of the study. The method used to carry out the study, the finite elements method, is of a high standard for performing studies of

stress and deformation of materials, the results are laid down in a clear and detailed way, see pages 11 to 17 of the study and accompanying demonstration on CD.

The appellant contested the reliability of the study submitted by the respondent stressing that D2 did not contain sufficient information to carry out the test and that the test itself was based on arbitrary assumptions. This however is not the view of the board. D2 shows a high level of detail in the information about the form and dimensions of the device and on the choice of materials. Furthermore, the test is accurate and the assumptions on which it is based are valid and reliable. Every test based on a model is necessarily in part based on assumptions. It is the task of the skilled person carrying out the test to carefully choose the assumptions in order to get reliable results. It is the view of the board that in this case this goal has been achieved.

Annex 1, which according to the appellant should show the so-called "barrelling effect" is merely a schematic sketch of a hypothetical behaviour of the device not supported by any evidence at all.

The counter-argument of the sharp-edge at the attachment of the side channel destroying the wiper seal does not convince the board, particularly in view of the fact that a wiper seal is also present at the bottom of the piston in D2.

Furthermore, the argument concerning the trapped fluid between the two compression fits is not convincing either because - as rightly pointed out by the

respondent - such fluid can escape through the side channel.

From the above it follows that the preferred embodiment of D2 shows implicitly, but clearly and unambiguously a wiper seal formed on the top section of the piston for sealing the inlet opening and wiping the surface of the channel surrounding the piston during actuation and release of the piston and that therefore the subject-matter of claim 1 of the main request is not novel (Article 54(1) and (2) EPC).

3. *The auxiliary requests*

The term "clean state" contained in the additional feature of claim 1 of the first auxiliary request is merely qualitative and is not clear per se. The appellant could not cite any passage of the patent in suit which could further specify this term. Accordingly, claim 1 of the first auxiliary request is not clear (Article 84 EPC 1973).

The term "in the closed state" in claim 1 of the second auxiliary request is ambiguous: it can refer to the uppermost position of the piston or to any intermediate positions between that one and the other when the upper part of the piston reaches the enlargement formed by the flow channels (see reference number 28 of figure 3). Accordingly claim 1 of the second auxiliary request is not clear (Article 84 EPC 1973).

Furthermore the feature concerning the channel does not comply with Article 123(2) EPC since it is taken out of

the context, where it is cited especially in combination with the cap (see page 4, lines 31 to 34).

The additional feature of claim 1 of the fourth auxiliary request is not novel (Article 54 EPC). It is evident for the person skilled in the art that in the device of D2, Figure 4, part of the force applied to the top of the piston (50) is transmitted to the enlargement (53) at the top of the pin which, in turn, presses down the lower part of the piston forming a sheath around the stem of the pin and thereby transmits part of the force to the bottom of the piston biasing it against the enlargement at the bottom of the stem of the pin (see also Fig. 12 and 13 of Exhibit A1).

Claims 1 of the auxiliary requests 3 and 5 to 7 contain several combinations of the features objected above and are therefore not allowable as well.

## **Order**

### **For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

D. Sauter

D. Valle