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**Datasheet for the decision  
of 29 July 2010**

**Case Number:** T 1185/08 - 3.2.02

**Application Number:** 04027056.3

**Publication Number:** 1543855

**IPC:** A61M 5/32

**Language of the proceedings:** EN

**Title of invention:**  
Needle safety device

**Applicant:**  
Becton, Dickinson and Company

**Headword:**  
-

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

**Relevant legal provisions (EPC 1973):**  
-

**Keyword:**  
"Extended subject-matter (yes)"  
"Novelty (no)"

**Decisions cited:**  
-

**Catchword:**  
-



Case Number: T 1185/08 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 29 July 2010

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

**Representative:** von Kreisler Selting Werner  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 7 February 2008  
refusing European patent application  
No. 04027056.3 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman:** D. Valle  
**Members:** C. Körber  
M. J. Vogel

## Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal on 4 April 2008 against the decision of the Examining Division posted on 7 February 2008 to refuse the application. The fee for the appeal was paid at the same time and the statement setting out the grounds for appeal was received on 5 June 2008.

II. The following document is relevant for the decision:

D4 = US - A - 4 664 654.

III. Oral proceedings took place on 29 July 2010.

The appellant requested that the decision under appeal be set aside and that a patent be granted in the following version:

- claims 1 to 9 filed on 29 June 2010 (main request), or as an auxiliary measure on the basis of:
- claims 1 to 9 filed as first auxiliary request on 5 June 2008, or on the basis of:
- claims 1 to 8 filed as second auxiliary request on 5 June 2008.

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

"A medical device comprising:  
a piercing element (22) having a piercing end;  
a safety shield (28, 128) releasably held in a proximal position on said medical device where said piercing end (36) of said piercing element (22) is exposed and being movable to a distal position where said piercing end of said piercing element is shielded;

a release actuator (30) movably disposed in said medical device and configured for passively releasing said safety shield (28, 128) from said proximal position in response to use of said medical device; and a lock (74, 68) for locking said safety shield in said distal position;  
characterized by  
a slide back actuator (65, 165) for moving said safety shield (28, 128) from an intermediate position between said proximal and distal positions back toward said proximal position, wherein said safety shield (28, 128) and said slide back actuator (65, 165) are not unitary."

Claim 1 of the first auxiliary request reads as follows:

"A medical device comprising:  
a piercing element (22) having a piercing end;  
a safety shield (28, 128) releasably held in a proximal position on said medical device where said piercing end (36) of said piercing element (22) is exposed and being movable to a distal position where said piercing end of said piercing element is shielded;  
a release actuator (30) movably disposed in said medical device and configured for passively releasing said safety shield (28, 128) from said proximal position in response to use of said medical device; and  
a lock (74, 68) for locking said safety shield in said distal position;  
characterized by  
a slide back actuator (65, 165) for moving said safety shield (28, 128) from an intermediate position between said proximal and distal positions back toward said

proximal position, said slide back actuator (65, 165) projecting from said safety shield (28, 128)"

Claim 1 of the second auxiliary request reads as follows:

"A medical device comprising:  
a piercing element (22) having a piercing end;  
a safety shield (28, 128) releasably held in a proximal position on said medical device where said piercing end (36) of said piercing element (22) is exposed and being movable to a distal position where said piercing end of said piercing element is shielded;  
a release actuator (30) movably disposed in said medical device and configured for passively releasing said safety shield (28, 128) from said proximal position in response to use of said medical device; and  
a lock (74, 68) for locking said safety shield in said distal position;  
characterized by  
a slide back actuator (65, 165) for moving said safety shield (28, 128) from an intermediate position between said proximal and distal positions back toward said proximal position,  
a housing (180), said safety shield (128) being telescoped within said housing (180) and  
an elongate slot (181) formed in said housing (180)  
said slide back actuator (165) projecting through said slot of said housing and being slidably movable with respect to said slot."

V. The appellant argued as follows:

Claim 1 of the main request complied with Article 123 (2) EPC. The sentence: "said safety shield (28, 128) and said slide back actuator (65, 165) are not unitary" was supported by the drawings and by the sentence of the description bridging pages 18 and 19.

Also claim 1 of the first auxiliary request complied with Article 123 (2) EPC. The feature that the slide back actuator projects from the safety shield was supported by the Figures 17, 18 and 28 and by the description, page 15, lines 15 to 17 and the sentence bridging pages 18 and 19.

Claim 1 of the second auxiliary request was novel over the teaching of D4. Figure 3a did not disclose a proximal position as required by the claim but an intermediate position. The proximal position was shown in Figure 3b. Consequently, D4 did not disclose a device configured for passively releasing the safety shield from said proximal position in response to use of the device.

Moreover, Figure 3a represented a situation "prior to puncture", i.e. before use, whereas the release actuator according to claim 1 was configured to release the shield "in response to use of the shield".

## **Reasons for the Decision**

1. The appeal is admissible.

2. Main request

Claim 1 of the main request does not comply with Article 123 (2) EPC since the feature: "said safety shield (28, 128) and said slide back actuator (65, 165) are not unitary" was not disclosed in the application as originally filed.

The argument of the appellant that the contested feature was supported by the drawings and the description can not be accepted. The drawings do not disclose a safety shield and a slide back actuator which are not unitary. The term "unitary" means according to the Oxford English dictionary: "forming a unit with something". In this sense, the two elements (28, 128) and (65, 165) of Figures 4, 17, 18 and 28 respectively form a unit and the drawings contradict the claimed feature. Also the passage of the description cited by the appellant does not support the contested feature since there is written that the safety shield 128 is provided with a slide back actuator 165 that projects through slot 185 in housing 180 and not that the two elements are not unitary. On the contrary, the description, page 13, lines 12 to 14 states that the safety shield includes an elongated slide back actuator.

Accordingly, claim 1 of the main request does not comply with Article 123 (2) EPC.

3. First auxiliary request

Claim 1 of the first auxiliary request does not comply with Article 123 (2) EPC either. The feature: "said

slide back actuator (65, 165) projecting from said safety shield (28, 128)" is not disclosed in the original application. The passage at page 15 of the original description cited by the appellant recites that the slide back actuator extends proximally from the distal end of the safety shield and not that the actuator "projects" in any direction from any position of the safety shield. This is also shown by the Figures 17, 18 and 28. Also the passage bridging pages 18 and 19 of the original description does not support the broad wording of the claim. There it is namely written that the actuator projects through a slot in the housing but not that it projects from the safety shield.

Accordingly, claim 1 of the first auxiliary request comprises an intermediate generalisation which does not comply with Article 123 (2) EPC.

4. Second auxiliary request

D4 discloses a medical device comprising a piercing element having a piercing end; a safety shield (12) releasably held in a proximal position on said medical device where said piercing end of said piercing element is exposed (Figure 3a) and being movable to a distal position where said piercing end of said piercing element is shielded (Figure 2); a release actuator (18) movably disposed in said medical device and configured for passively releasing said safety shield from said proximal position in response to use of said medical device; and a lock (36) for locking said safety shield in said distal position (column 4, lines 16-22); whereby a slide back actuator (24) is further provided,



which is suitable for moving said safety shield from an intermediate position between said proximal and distal positions back toward said proximal position and a housing (28), said safety shield being telescoped within said housing, and an elongate slot (26) formed in said housing said slide back actuator projecting through said slot of said housing and being slidably movable with respect to said slot.

Contrary to the assertion of the appellant, Figure 3a of D4 discloses a proximal position in the sense of the invention. A proximal position is defined by the claim as a position where the piercing end of the piercing element is exposed and that can be clearly seen in the Figure. The general feature "in response to use" fails to define the kind of use and is therefore not suited to establish novelty over D4.

Accordingly, claim 1 of the second auxiliary request is not novel within the meaning of Article 54(1) and (2) EPC.

**Order**

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

The appeal is dismissed.

The Registrar:

The Chairman:

D. Sauter

D. Valle