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# Datasheet for the decision of 31 July 2014

**Case Number:** T 0222/12 - 3.2.02

**Application Number:** 08000914.5

**Publication Number:** 1911486

**IPC:** A61M25/06, A61M5/32

**Language of the proceedings:** EN

**Title of invention:**
Spring clip as needle tip protection for a safety IV catheter

**Patent Proprietor:**
B. Braun Melsungen AG

**Opponent:**
Poly Medicure Limited

**Headword:**

**Relevant legal provisions:**
EPC Art. 100(c)
RPBA Art. 13(1), 13(3)

**Keyword:**
Late-filed request - admitted (yes)
Added subject-matter (yes)

**Decisions cited:**

**Catchword:**

Europäisches Patentamt
European Patent Office
Office européen des brevets

**Beschwerdekammern**
**Boards of Appeal**
**Chambres de recours**

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

**Case Number: T 0222/12 - 3.2.02**

# D E C I S I O N
# of Technical Board of Appeal 3.2.02
# of 31 July 2014

| | |
|---|---|
| **Appellant:** (Patent Proprietor) | B. Braun Melsungen AG<br>Carl-Braun-Strasse 1<br>34212 Melsungen (DE) |
| **Representative:** | Kinkeldey, Daniela<br>Bird & Bird LLP<br>Maximiliansplatz 22<br>80333 München (DE) |
| **Appellant:** (Opponent) | Poly Medicure Limited<br>105, Sector 59<br>HSIDC Industrial Area<br>Faridabad<br>Haryana 121 004 (IN) |
| **Representative:** | Thum, Bernhard<br>Wuesthoff & Wuesthoff<br>Patent- und Rechtsanwälte<br>Schweigerstrasse 2<br>81541 München (DE) |
| **Decision under appeal:** | **Interlocutory decision of the Opposition Division of the European Patent Office posted on 5 December 2011 concerning maintenance of the European Patent No. 1911486 in amended form.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | E. Dufrasne |
| **Members:** | P. L. P. Weber |
| | C. Körber |

## Summary of Facts and Submissions

I. The present appeal proceedings concern the appeals filed by the patent proprietor and the opponent against the decision of the opposition division posted on 5 December 2011 that, in view of the amendments made by the patent proprietor during the opposition proceedings, the patent and the invention to which it related according to the 3rd auxiliary request met the requirements of the EPC.

The notice of appeal of the patent proprietor was filed on 1 February 2012 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 16 April 2012. A main request and auxiliary requests I to V were filed on the same date.

The notice of appeal of the opponent was filed on 3 February 2012 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 11 April 2012.

II. With communication of 15 May 2014 the parties were summoned to oral proceedings. In a communication sent on 26 May 2014, the Board inter alia drew the attention of the parties to possible objections under Article 100(c) EPC with regard to amended passages of the description before grant.

III. On 5 June 2014 the appellant patent proprietor filed auxiliary requests VI to IX.

IV. On 24 June 2014 the appellant patent proprietor filed an amended description and amended drawings as auxiliary requests “A”.

V. On 25 July 2014 the appellant patent proprietor filed copies of some documents of the proceedings before the US patent office making reference to the corresponding parallel patent and concerning the interpretation of the word "unitary".

VI. Oral proceedings were held on 31 July 2014.

The appellant patent proprietor 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 one of auxiliary requests I to VII, all filed during oral proceedings.

The appellant opponent requested that the decision be set aside and that the patent be revoked.

VII. The present patent was granted on the basis of a second divisional application (EP-A-1911486) of a first divisional application (EP-A-1421969) of parent application (WO-A-99/08742).

VIII. The main arguments of the appellant patent proprietor on the issues dealt with in this decision can be summarised as follows:

The auxiliary requests I and III to VII filed during the oral proceedings should be admitted into the proceedings because their subject-matter was already present in the auxiliary requests filed earlier and the amendments to the description and drawings had been made in reply to the communication of the Board.

The aim of the invention was to protect users of intravenous catheters from inadvertent needlestick injuries when the needle was withdrawn from the

catheter hub. The clamping action of the needle guard was not an essential feature to achieve this aim, so it could be absent from the claim.

The person skilled in the art would recognise that when a slot or a bulge was provided on the needle shaft the clamping action was not necessary anyway. Concerning the bulge, this would be particularly clear from the statement in the second paragraph of page 12 of the application as filed.

In auxiliary request I the description paragraph explaining the clamping function had been reintroduced. This overcame the objection of the absence of the clamping function in the claim.

IX. The main arguments of the appellant opponent on the issues dealt with in the decision can be summarised as follows:

Auxiliary requests I and III to VII should not be admitted into the proceedings because they could have been filed earlier and they gave rise to numerous problems of added subject-matter and of extension of the scope of protection.

For divisional applications, a basic principle was that only an invention which was directly and unambiguously disclosed in the parent application could be claimed. This was not the case here, because no transverse segment without a clamping function was disclosed in the earlier application as filed. This clamping function was mentioned in the "Summary of the invention" and described in relation to the embodiments of Figures 1C and 1D and to those of Figures 7D and 7E. It was also shown on the same figures.

In none of the requests was the clamping function of the transverse segment present, so that they all contained added subject-matter.

X. The different versions of claim 1 read as follows (amendments to claim 1 as granted being highlighted by the Board):

Claim 1 according to the main request:

"An IV catheter including:

a tubular catheter (24);
a needle (16) having a needle shaft and a tip, said needle being received within said tubular catheter (24) when in a ready position, the needle comprising a bulge (61) in its shaft;
a catheter hub (26) attached to the proximal end of said tubular catheter (24), said catheter hub having a hollow interior enclosed by an interior wall (36);
said needle being movable from said ready position in which said tip is outside of said catheter hub (26) to a retracted blocking position in which said tip is within the interior of said catheter hub (26),
a **spring clip** needle guard comprising:
a proximal vertical arm (54, 106) engaging with the bulge (61) in the shaft of the needle to prevent the removal of the needle from the needle guard (96, 40);
a distal arm (42, 112) engaged by said needle shaft when said needle is in said ready position;
a section (46) of a transverse segment (50, 98) of said needle guard (96, 40) connecting the proximal vertical arm (54, 106) and the distal arm (42, 112) and being urged by said needle shaft into retaining relation

within said catheter hub (26) when said needle is in the ready position;
said distal arm (42, 112) extending from said transverse segment (98) and engaging the needle spaced from said needle tip when said needle is in said ready position and movable within the interior of said catheter hub to the blocking position distal of said needle tip when said needle is in its retracted position;
the engaging of the needle and the urging of said section of the transverse segment (50, 98) into retaining relation with the catheter hub in the ready position being both achieved by engagement of the distal arm (42, 112) of the needle guard with the needle shaft;
said section (46) of said transverse segment (50, 98) being a curved section in retaining contact with the interior wall (36) of the catheter hub (26), for providing engagement of the needle guard (96,40) when transitioning from the ready position to the blocking position at a fixed longitudinal position within the catheter hub."

Claim 1 according to auxiliary request II:

"An IV catheter including:

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a **unitary spring clip** needle guard comprising:
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Claim 1 according to auxiliary request IV:

"An IV catheter including:

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a **spring clip** needle guard comprising:
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~~a section (46) of~~ a transverse segment (50, 98) of said needle guard (96, 40) connecting the proximal vertical arm (54, 106) and the distal arm (42, 112) ~~and~~, **said transverse segment (50, 98) extending upward and proximally from said distal arm (42, 112) with a section (46) of said transverse segment (50, 98)** being urged by said needle shaft into retaining relation within said catheter hub (26) when said needle is in the ready position;
.
."

Claim 1 according to auxiliary request VI:

"An IV catheter including:

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a **unitary spring clip** needle guard comprising:
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~~a section (46) of~~ a transverse segment (50, 98) of said needle guard (96, 40) connecting the proximal vertical arm (54, 106) and the distal arm (42, 112) ~~and~~**,said transverse segment (50, 98) extending upward and proximally from said distal arm (42, 112) with a section (46) of said transverse segment (50, 98)** being urged by said needle shaft into retaining relation within said catheter hub (26) when said needle is in the ready position;

.

."

Claim 1 of auxiliary requests I, III, V and VII is the same as in the main request and auxiliary requests II, IV and VI respectively. In these requests, by comparison, the figures have been amended by the reintroduction of reference signs "e" and "d" at the same locations as in originally filed Figures 1C, 1D and 7E and 7D and the description has been amended by the insertion of the following paragraph at the end of paragraph [0025] of the patent as granted:

"Simultaneously with the blocking and releasing actions, the spring clip guard 40 becomes securely clamped onto the needle shaft at points d and e, thereby to securely lock the needle guard 40 onto the needle shaft. At this time, the needle 16 and needle guard 40 can be removed together from the catheter hub 26, and the tip of the needle cannot be pushed past the needle guard because it is blocked by the distal arm 42 and lip 44 of the needle guard."

## Reasons for the Decision

1. The appeals are admissible.

*Admissibility of the auxiliary requests*

2. The appellant opponent objected to the admission into the proceedings of auxiliary requests I and III to VII because they were filed too late and were prima facie unallowable because they added subject-matter and/or extended the scope of protection.

The Board decides to admit the said requests into the proceedings pursuant to Article 13(1)(3) RPBA because they were combinations of requests the appellant patent proprietor had already filed with the statement setting out the grounds of appeal, and for this reason not more complex to analyse, and because the amendments made to the description and drawings were considered to be a bona fide attempt to reply more than one month before the oral proceedings to the Board's communication of 26 May 2014 in which possible objections to the description of the patent in suit were addressed. The simple renumbering at the beginning of the oral proceedings was not a substantial change.

*Main request - Added subject-matter*

3. Several features of claim 1 were objected to by the appellant opponent as introducing subject-matter extending beyond the present and/or earlier application as filed. The Board would like to concentrate first on the objection concerning the absence of any clamping function of the transverse segment.

4. Basis for support

The description of the divisional application as filed which led to the patent in suit, the description of the first divisional application as filed as well as the description of the parent application as filed are identical. The same is true for the figures of the different applications as filed.

In the following, unless mentioned otherwise, the Board will refer to the passages of the parent application as published (WO-A-99/08742) when quoting the application as filed, as the parties did.

5. It is undisputed by the appellant patent proprietor that the patent in suit concentrates on the embodiments shown in Figures 1C, 1D, 7D and 7E of the application as filed, with a bulge on the needle shaft.

6. Content of the description and drawings of the application as filed relating to the above-mentioned embodiments.

6.1 The invention is about an intravenous catheter in which, when the insertion needle is withdrawn, a needle guard will automatically protect the needle tip. Basically, in the "ready position" of the needle in the catheter, a distal arm of the needle guard is pushed by the needle shaft into a retaining position in the catheter hub. When the needle is withdrawn from the catheter after placement of the latter, the distal arm of the needle guard is freed, which allows the withdrawal of the needle guard together with the needle from the catheter hub, the needle tip being protected by the said distal arm ("retracted position").

As explicitly mentioned under the title "*Brief description of the drawings*", "*Figs. 1C and 1D are views similar to Figs. 1A and 1B of a possible variation to the embodiment illustrated therein*" (page 6). This is confirmed at the beginning of the second paragraph of page 12: "*The safety IV catheter illustrated in Figs. 1C and 1D is the same as that illustrated in Figs. 1A and 1B, except that the slot 60 in the needle shaft in the latter is replaced in the former by a bulge 61 whose diameter is greater than that of opening 58 in vertical arm 54*." Therefore it is necessary to look at the embodiment of Figures 1A and 1B to fully understand the disclosure of the embodiment of Figures 1C and 1D.

6.2 In the embodiment of Figures 1A and 1B, the spring clip generally has a "lying S" shape, i.e. a distal arm 42 which is vertical in the retracted position, a transverse segment 50 crossing the needle shaft and a vertical arm 54. Transverse segment 50 and vertical arm 54 include aligned openings 56, 58. As long as the needle is in the catheter, i.e. in its ready position, the needle shaft passes through the openings in the vertical arm and the transverse segment and pushes the distal arm on one side of the latter, so that the other side is caused to sit in a groove 48 in the catheter hub. In this way the needle with the needle guard is retained in the catheter hub.

Once the catheter is installed in a blood vessel of the patient, the needle is withdrawn. During withdrawal of the needle, as soon as the needle tip passes the distal point of the distal arm contacting the needle shaft, due to the resiliency of the spring clip needle guard, the distal arm will move into a position in front of the needle tip, thereby protecting the needle tip. As

explained page 11 starting middle of the second paragraph, simultaneously with this releasing of the distal arm, the needle guard becomes clamped onto the needle shaft at two diametrically opposed points "e" and "d" of the opening in the transverse segment thereby to securely lock the needle guard onto the needle shaft. This clamping allows the needle to be removed from the catheter hub together with the needle guard (page 11: "*At this time, the needle 16 and needle guard 40 can be removed together from the catheter hub 26,...*"). Starting last paragraph of page 11, it is explained which role should be played by a slot 60 which may be formed, if desired, in the needle shaft slightly proximal to the needle tip. This slot would be formed slightly distal to the clamping point "e" and would provide additional force to retain the needle guard on the needle in the protected position.

It is in this context that the first sentence of the second paragraph of page 12 (quoted above), stating that in Figures 1C and 1D the slot 60 is replaced by a bulge 61, has to be read. It is further noted that Figure 1D showing the bulge on the needle shaft, and showing the spring clip needle guard in its protected position, still shows the clamping points "e" and "d" as did Figure 1B, which is an additional indication that the author of the application as filed considered both the clamping function and the bulge to be present together.

The way this embodiment functions is also explained in more general terms starting the last sentence of page 4 of the description: "*When the needle is withdrawn from the catheter, the force it had previously exerted on the needle guard is released causing the needle guard to pivot within the catheter hub until it clamps onto*

*the needle shaft. At this time, the distal end wall of the needle guard blocks the distal pointed end tip of the needle. In addition, the spring clip and protected needle onto which it is clamped can be readily and safely removed from the catheter hub. The needle may be provided with a slot or a bulge which cooperates with the needle guard to prevent the inadvertent removal of the needle from the needle guard after their removal from the catheter hub*".(emphasis added).

6.3 In the opinion of the Board, several conclusions can be drawn from the above. Firstly, for this embodiment the clamping function of the spring clip needle guard is essential because it is the clamping of the needle guard on the needle shaft which primarily allows the removal of the needle together with the needle guard from the catheter hub. In other words, the clamping function is essential for the protection of the needle tip, because in the first place it is this clamping action which will prevent the needle guard from falling off the needle shaft when the needle is removed from the catheter. Secondly, in the application as filed no functional distinction is made between the slot and the bulge. Both are presented as equivalent alternative retaining means to prevent further proximal movement of the needle guard on the needle, in addition to the clamping effect of the needle guard. Thirdly, the clamping effect is strong enough to allow the needle guard to be removed from the catheter hub without the help of the slot or the bulge, which are meant to be additional means to maintain the needle guard more securely on the needle shaft once the needle together with the needle guard is outside the catheter hub.

6.4 The embodiment shown in Figures 7A, 7B and 7C, with its variation shown in Figures 7D and 7E, functions in the

same way and does not change the above findings. Under the title "Brief description of the drawings", Figures 7D and 7E are said to show a variation of the embodiment as shown in Figures 7A and 7B (page 7). At the beginning of the first paragraph of page 18, it is indicated that "The safety IV catheter illustrated in Figs. 7D and 7E is the same as that illustrated in Figs. 7A and 7B, except that the slot 60 in the needle shaft in the latter is replaced in the former by a bulge 61 whose diameter is greater than that of opening 58 in vertical arm 54." Hence, here too the bulge is presented as an alternative to the slot in the embodiment according to Figures 7A, 7B and 7C and not as an embodiment in its own right. Compared with the embodiment of Figures 1A and 1B, in this embodiment the opening 56 in the transverse segment is replaced by an elongated slot 100 defining a flexible flap 116 with a locking tab 118 at its distal end. When the needle is removed from the catheter the locking tab slides on the needle shaft until it snaps into the groove or slot 60. Also in relation to this embodiment it is mentioned in the last paragraph of page 17 that "Movement of the spring clip 96 from its protecting or retracted position shown in Fig. 7C is further prevented by the insertion of the locking tab 118 into the needle groove 60,..." Although in the description of this embodiment the word "clamping" does not appear and reference sign "d" denoting one of the clamping points is not shown in the drawings, as rightly pointed out by the appellant patent proprietor, it is mechanically self-evident that the flap 116 with its locking tab 118 is pressed against the needle shaft, which will create nothing other than a clamping action. This clamping action is necessary in order for the locking tab to enter the groove or slot 60 when the tab is positioned above it

and in order to make sure that the locking tab remains in the slot.

7. From the above it follows that claim 1 contains subject-matter extending beyond the present and/or earlier applications as filed, at least since it covers intravenous catheters comprising combinations of a needle and a needle guard without any clamping effect between them.

Hence, this objection under Article 100(c) EPC prejudices the maintenance of the patent as amended according to the main request.

8. The appellant patent proprietor submitted that the clamping action of the needle guard was not an essential feature to protect the needle tip, so that it could be absent from the claim.

The Board does not share this opinion. In the context of the embodiments for which protection is sought with present claim 1, as apparent from the above, the clamping action of the transverse segment is disclosed as the first means for preventing the needle guard from falling off the needle shaft when the needle is taken out of the catheter. The clamping action is also emphasised throughout the general description relating to the embodiments comprising a bulge or slot recited above under point 6.2. In other words, the clamping function is essential for protection against injury, because it makes sure that the element which is there to ensure protection from inadvertent needlestick injury is still present on the needle shaft or tip just after the needle has been taken out of the catheter hub.

9. The appellant patent proprietor further submitted that the person skilled in the art would recognise that when a slot or a bulge was used on the needle shaft the clamping action was not necessary. Concerning the bulge, this was particularly clear from the statement in the second paragraph of page 12 that "If an attempt is made to move the protected needle illustrated in Fig. 1C in the rearward or proximal direction, bulge 61 will engage wall 54 and will thus not be able to pass through opening 58, so as to prevent further proximal movement of the needle and removal of the needle from the needle guard, as defined." The same statement was also present on page 18 in relation to the embodiment of Figures 7D and 7E.

Again, the Board does not share this opinion. This statement is present in the description to explain the role of the bulge when a bulge is used. As explained above, in such a case the application as filed presents the bulge as an alternative to the slot in the same embodiment. Nowhere in the paragraphs of the application as filed describing the embodiments of the Figures 1 or of the Figures 7, or in the general statements corresponding to these figures, is there any suggestion of the idea that the clamping action could be dispensed with when a bulge is used. There is no indication in the application as filed that the author had thought of such an alternative when filing the application. As explained above, not only are the slot and the bulge presented as equivalent, they are also presented as additional to the clamping action. In the opinion of the Board, there is thus no direct and unambiguous disclosure of an embodiment like that presented in Figures 1 and/or 7 with the bulge but without a clamping action of the needle guard.

Whether or not an embodiment with a bulge but without a clamping action of the needle guard would also function is not relevant for the question of assessing what information was made available to the person skilled in the art by the application as filed. Even if this might be an obvious mechanical alternative, without any hint to them in the application as filed, such alternatives cannot be considered to be directly and unambiguously disclosed. In the present case, accepting that such embodiments without a clamping effect of the needle guard were disclosed by the application as filed would even go against what is presented in that same application, according to which when a bulge is present, it is always in combination with the clamping effect of the needle guard.

*Auxiliary request I – Added subject-matter*

10. In auxiliary request I the drawings have been amended by the reintroduction of the reference signs “e” and “d” in Figure 1B, reference sign “e” in Figures 1A, 2A and 2B, and the description has been amended by reintroducing a paragraph explaining the clamping action of the transverse segment.

The Board cannot follow the appellant proprietor’s argument that with the above amendments of the description and drawings, claim 1 can only be read as including the clamping function of the transverse segment. While the transverse segment having a clamping function now described in the description opens a possible interpretation of the claim as including a transverse segment having such a function, this does not change that the other option of the transverse segment not having that function is still covered by the wording of the claim.

Therefore, since no additional feature has been introduced into claim 1 the objections mentioned above remain applicable.

*Auxiliary requests II to VII – Added subject-matter*

11. Since no claim 1 of the other auxiliary requests contains the missing feature of the clamping function associated with the transverse segment, the same objection applies to all of them.

12. The additional information filed with letter of 25 July 2014 does not change the above findings, because that information was filed in relation to a different feature of claim 1.

**Order**

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

1. The decision under appeal is set aside.

2. The appeal of the patent proprietor is dismissed.

3. The patent is revoked.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated