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Datasheet for the decision of 10 May 2017

Case Number: T 1648/15 - 3.2.02

Application Number: 08000915.2

Publication Number: 1911487

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

Opponents:
Poly Medicure Limited
Becton, Dickinson and Company

Headword:

Relevant legal provisions:
EPC Art. 76(1), 100(c), 123(2)
RPBA Art. 13

Keyword:
Divisional application - subject-matter extends beyond content of earlier application (yes)
Late-filed auxiliary request - admitted (no)

Decisions cited:
T 1202/09, T 2613/11, T 0222/12

Catchword:

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Case Number: T 1648/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 10 May 2017

Appellant: (Patent Proprietor)	B. Braun Melsungen AG Carl-Braun-Strasse 1 34212 Melsungen (DE)
Representative:	Kinkeldey, Daniela Bird & Bird LLP Maximiliansplatz 22 80333 München (DE)
Appellant: (Opponent 1)	Poly Medicure Limited Plot No. 104-105 & 115 Sector- 59 HSIDC Industrial Area Ballabgarth Faridabad 121 004 Haryana (IN)
Representative:	Thum, Bernhard Wuesthoff & Wuesthoff Patentanwälte PartG mbB Schweigerstraße 2 81541 München (DE)
Appellant: (Opponent 2)	Becton, Dickinson and Company One Becton Drive Franklin Lakes, New Jersey 07417-1880 (US)
Representative:	Herr, Jochen Baker & McKenzie Theatinerstraße 23 80333 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 July 2015 concerning the maintenance of European Patent No. 1911487 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	P. L. P. Weber
	D. Ceccarelli

Summary of Facts and Submissions

I. The appeals of the patent proprietor and the two opponents are against the decision of the opposition division, posted on 21 July 2015, which found that, account being taken of the amendments as per the (then valid) auxiliary request III made by the patent proprietor, the patent and the invention to which it related met the requirements of the EPC.

II. The patent proprietor filed a notice of appeal on 31 July 2015 and paid the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 25 November 2015.

III. Opponent 01 filed a notice of appeal on 30 July 2015 and paid the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 13 November 2015.

In the statement setting out the grounds of appeal, point V-2.1 is entitled "Lack of the feature regarding the "transverse segment"".

IV. Opponent 02 filed a notice of appeal on 28 September 2015 and paid the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 30 November 2015.

In the statement setting out the grounds of appeal, point 3.1 entitled "Omission of transverse segment", starts in the middle of page 3 and ends in the middle of page 14.

V. The patent in suit is based on a divisional application of parent application EP 04000853 (EP-A-1421969), which

itself is a divisional application of grand-parent application EP 98948843 (EP-A-1003588).

In the examination phase of parent application EP 04000853, this Board took decision T 1202/09 in which it considered that a claim directed to the embodiment of Figures 10A, 10B and 11 fulfilled the requirements of Articles 76(1) and 123(2) EPC.

In the case of application EP 06013843 (EP-A-1702643), also a divisional application of EP04000853 (EP-A-1421969), this Board took decision T 2613/11 to revoke the patent based on that divisional application because of added subject-matter.

In the case of application EP 08000914 (EP-A-1911486), also a divisional application of the same EP 04000853 (EP-A-1421969) this Board took decision T 0222/12 to revoke the patent based on that divisional application because of added subject-matter. Claim 1 was directed to the embodiments of Figures 1C&1D and 7D&7E.

VI. Oral proceedings were held on 10 May 2017.

The appellant/patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, on the basis of one of auxiliary requests I to XVIII, filed with letter dated 25 November 2015 and auxiliary request VII B, filed during oral proceedings, in that order.

The appellant/opponent 01 requested that the decision under appeal be set aside and that the patent be revoked.

The appellant/opponent 02 requested that the decision under appeal be set aside and that the patent be revoked.

VII. Claim 1 of the patent as granted (main request) reads as follows:

"A safety IV catheter comprising:

a) a needle (16) having a needle shaft and a needle tip (18);

b) said needle shaft comprising a bulge (61, 138);

c) a hollow tubular catheter (24) having a proximal end;

d) said hollow tubular catheter (24) is secured to the distal end of a catheter hub (26);

e) said catheter hub (26) having a hub section (30), wherein a chamber (36) is formed in said hub section (30), and having an inner wall;

f) a resilient spring clip needle guard (40, 96, 120) located within said chamber (36) being formed in said hub section (30) of said catheter hub (26) and having a distal arm (42, 112) or distal end walls (130);

g) said needle (16) being received within said hollow tubular catheter (24) when in a ready position, wherein said needle extends through said chamber (36), a passageway (34) and distally beyond said catheter hub (26) and said hollow tubular catheter (24) so that said needle tip (18) extends beyond the tapered distal end of said hollow tubular catheter (24) and said needle

guard (40, 96, 120) located within said hub chamber (36) is adapted to automatically snap or pivot into a retracted position for blocking access to said distal needle tip (18) and preventing further movement of said needle tip (18) when said needle (16) is in its retracted position;

h) said needle guard (40, 96, 120) being adapted to be inserted into said catheter hub (26) and to be urged by said needle shaft into contact with said inner wall of said catheter hub (26) so that the needle guard (40, 96, 120) is retained therein;

i) and a groove (48, 136) or bump (62) being formed in said inner wall of said catheter hub (26) for engaging a lower end (46) or curved section (110) or curved protrusion (128) of said needle guard (40, 96, 120) for retaining said needle guard (40, 96, 120) in said catheter hub (26) in the ready position;

j) said needle shaft of needle (16) being adapted to engage said distal arm (42, 112) or distal end walls (130) of said needle guard (40, 96, 120) when said needle (16) is in its said ready position; and

k) the said catheter hub (26) being configured such that a force exerted by said needle shaft on said needle guard (40, 96, 120) in said catheter hub (26) is released when said needle (16) is retracted causing said needle guard (40, 96, 120) to pivot or snap to the retracted position in which said distal arm (42, 112) or distal end walls (130) block said needle tip (18);

l) and said needle guard (40, 96, 120) further comprising a proximal wall (54, 126) or proximal vertical arm (54, 106) having an opening (58, 134)

adapted to let said shaft of needle (16) freely pass through and axially move;

m) wherein said bulge (61, 138) has a diameter greater than that of said opening (58, 134) of said proximal wall (54, 126) or proximal vertical arm (54, 106).”

VIII. Claim 1 of auxiliary request VII reads as follows (amendments over main request underlined by the Board):

“A safety IV catheter comprising:

a) a needle (16) having a needle shaft and a needle tip (18);

b) said needle shaft comprising a bulge (61, 138);

c) a hollow tubular catheter (24) having a proximal end;

d) said hollow tubular catheter (24) is secured to the distal end of a catheter hub (26);

e) said catheter hub (26) having a hub section (30), wherein a chamber (36) is formed in said hub section (30), and having an inner wall;

f) a resilient spring clip needle guard (40, 96, 120) located within said chamber (36) being formed in said hub section (30) of said catheter hub (26) and having a distal arm (42, 112) or distal end walls (130) and a transverse segment (50) having an opening (56) through which the shaft of the needle (16) is free to pass and axially move;

g) said needle (16) being received within said hollow tubular catheter (24) when in a ready position, wherein said needle extends through said chamber (36), a passageway (34) and distally beyond said catheter hub (26) and said hollow tubular catheter (24) so that said needle tip (18) extends beyond the tapered distal end of said hollow tubular catheter (24) and said needle guard (40, 96, 120) located within said hub chamber (36) is adapted to automatically snap or pivot until it clamps onto the needle shaft into a retracted position for blocking access to said distal needle tip (18) and preventing further movement of said needle tip (18) when said needle (16) is in its retracted position;

h) said needle guard (40, 96, 120) being adapted to be inserted into said catheter hub (26) and to be urged by said needle shaft into contact with said inner wall of said catheter hub (26) so that the needle guard (40, 96, 120) is retained therein;

i) and a groove (48, 136) or bump (62) being formed in said inner wall of said catheter hub (26) for engaging a lower end (46) or curved section (110) or curved protrusion (128) of said needle guard (40, 96, 120) for retaining said needle guard (40, 96, 120) in said catheter hub (26) in the ready position;

j) said needle shaft of needle (16) being adapted to engage said distal arm (42, 112) or distal end walls (130) of said needle guard (40, 96, 120) when said needle (16) is in its said ready position; and

k) the said catheter hub (26) being configured such that a force exerted by said needle shaft on said needle guard (40, 96, 120) in said catheter hub (26) is released when said needle (16) is retracted causing

said needle guard (40, 96, 120) to pivot or snap to the retracted position in which said distal arm (42, 112) or distal end walls (130) block said needle tip (18);

l) and said needle guard (40, 96, 120) further comprising a proximal wall (54, 126) or proximal vertical arm (54, 106) having an opening (58, 134) adapted to let said shaft of needle (16) freely pass through and axially move;

m) wherein said bulge (61, 138) has a diameter greater than that of said opening (58, 134) of said proximal wall (54, 126) or proximal vertical arm (54, 106).”

IX. Claim 1 of auxiliary request VII B reads as follows (amendments over main request underlined by the Board)

“A safety IV catheter comprising:

a) a needle (16) having a needle shaft and a needle tip (18);

b) said needle shaft comprising a bulge (61, 138);

c) a hollow tubular catheter (24) having a proximal end;

d) said hollow tubular catheter (24) is secured to the distal end of a catheter hub (26);

e) said catheter hub (26) having a hub section (30), wherein a chamber (36) is formed in said hub section (30), and having an inner wall;

f) a resilient spring clip needle guard (40, 96, 120) located within said chamber (36) being formed in said

hub section (30) of said catheter hub (26) and having a distal arm (42, 112) or distal end walls (130) and a transverse segment (50) that extends upward and proximally from lower pointed end (46) and terminates at a U-shaped upper end (52) having an opening (56) through which the shaft of the needle (16) is free to pass and axially move or first and second arms (122, 124) respectively joined at their proximal ends in a hinged arrangement (125) to the ends of a rear wall (126);

g) said needle (16) being received within said hollow tubular catheter (24) when in a ready position, wherein said needle extends through said chamber (36), a passageway (34) and distally beyond said catheter hub (26) and said hollow tubular catheter (24) so that said needle tip (18) extends beyond the tapered distal end of said hollow tubular catheter (24) and said needle guard (40, 96, 120) located within said hub chamber (36) is adapted to automatically snap or pivot until it clamps onto the needle shaft into a retracted position for blocking access to said distal needle tip (18) and preventing further movement of said needle tip (18) when said needle (16) is in its retracted position;

h) said needle guard (40, 96, 120) being adapted to be inserted into said catheter hub (26) and to be urged by said needle shaft into contact with said inner wall of said catheter hub (26) so that the needle guard (40, 96, 120) is retained therein;

i) and a groove (48, 136) or bump (62) being formed in said inner wall of said catheter hub (26) for engaging a lower end (46) or curved section (110) or curved protrusion (128) of said needle guard (40, 96, 120) for

retaining said needle guard (40, 96, 120) in said catheter hub (26) in the ready position;

j) said needle shaft of needle (16) being adapted to engage said distal arm (42, 112) or distal end walls (130) of said needle guard (40, 96, 120) when said needle (16) is in its said ready position; and

k) the said catheter hub (26) being configured such that a force exerted by said needle shaft on said needle guard (40, 96, 120) in said catheter hub (26) is released when said needle (16) is retracted causing said needle guard (40, 96, 120) to pivot or snap to the retracted position in which said distal arm (42, 112) or distal end walls (130) block said needle tip (18);

l) and said needle guard (40, 96, 120) further comprising a proximal or the rear wall (54, 126) or proximal vertical arm (54, 106) extending downwards from the U-shaped upper end (52) having an opening (58, 134) adapted to let said shaft of needle (16) freely pass through and axially move;

m) wherein said bulge (61, 138) has a diameter greater than that of said opening (58, 134) of said proximal wall (54, 126) or proximal vertical arm (54, 106).”

X. The arguments of the appellant/patent proprietor relevant for the decision can be summarised as follows:

Main request – added subject-matter

The person skilled in the art was the addressee of the disclosure and he understood from the general description on pages 4 and 5 of the parent application as originally filed that the paramount aim of the

invention was to prevent removal of the needle from the needle guard after use, and that this aim was in particular achieved with the provision of a bulge as expressed in the last sentence of the first paragraph on page 5. These passages as well as the paragraph bridging pages 5 and 6 reciting the use of a tether did not require the presence of any clamping action of the needle guard onto the needle shaft. That was so also when a bulge was present instead of a tether. Also in T 1202/09 the clamping action was not considered essential.

The same was true for the transverse segment which was not even mentioned in the general description of the embodiments. T 0222/12 concentrated on the clamping function of the transverse segment because the latter was mentioned in the claim, which was not the case here. It was moreover inherent from the functional language used in the claim to describe how the device worked, that the distal wall(s) was or were connected to the proximal wall. In any case the clamping action and the transverse segment were two different issues.

Auxiliary request VII – added subject-matter

The clamping function and the transverse segment were added in claim 1 according to this request and the amended wording was based on the application as filed. The connection of the transverse segment to the distal and proximal walls and the association of the clamping function to the transverse segment was implicit as was the case in the description of the application as filed, which did not mention any such direct link between the transverse segment and the clamping function either.

Auxiliary request VII B - admissibility

It was not possible to respond to the diversity of the many objections raised by the appellants/opponents in the appeal proceedings. The importance of the link between the clamping effect and the transverse segment only became apparent during the discussion at the oral proceedings. Moreover, the decision of the Opposition Division concentrated on the absence of the clamping function, not the absence of the transverse segment, so the appellant/patent proprietor had no reason to believe that this point could have become essential.

The structural design of the needle guard was now better defined, so the inherent link between the transverse segment and the clamping function was more readily apparent.

XI. The arguments of the appellants/opponents relevant for the decision are essentially those developed by the Board in the reasons for the decision.

Reasons for the Decision

1. The appeals are admissible.

2. The invention

The invention is about a protection guard for the needle tip of a so-called safety IV catheter, used to administer fluids directly into the patient's vascular system. The catheter is introduced into the vein of the patient with the help of a needle. Once in the vein the needle is withdrawn and the catheter remains in place. The invention is about a protection guard for the

needle tip once the needle is withdrawn from the catheter and catheter hub. The object is to have a protection guard within the hub of the catheter and this protection guard becomes active when the needle is withdrawn.

3. Main request - added subject-matter

The appellants/opponents objected that several features of claim 1 introduced subject-matter extending beyond the present and/or earlier applications as filed. The Board will concentrate on the objection concerning the absence of the clamping function associated with the transverse segment.

3.1 Basis for support

The description of the divisional application as filed (which led to the patent in suit), the description of the parent divisional application as filed as well as the description of the grand-parent application as filed are identical. The same is true for the figures of the different applications as filed. The set of claims as filed are, however, different in each application.

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

3.2 It is undisputed by the appellant/patent proprietor that the patent in suit is meant to concentrate on the embodiments shown in Figures 1C and 1D, 7D and 7E, and

10A and 10B of the application as filed, with a bulge on the needle shaft.

In the embodiments shown in Figures 1C and 1D, 7D and 7E 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 proximal arm 54.

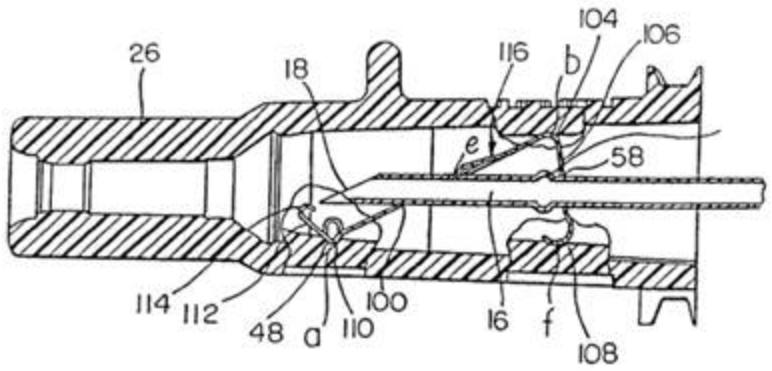

FIG. 7E

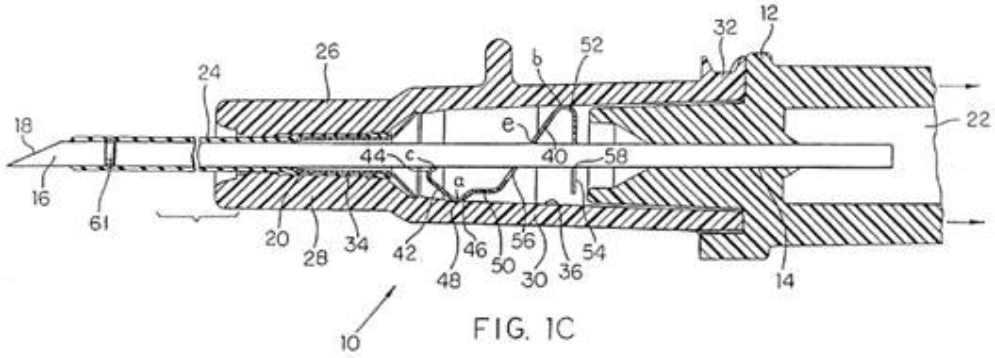

FIG. 1C

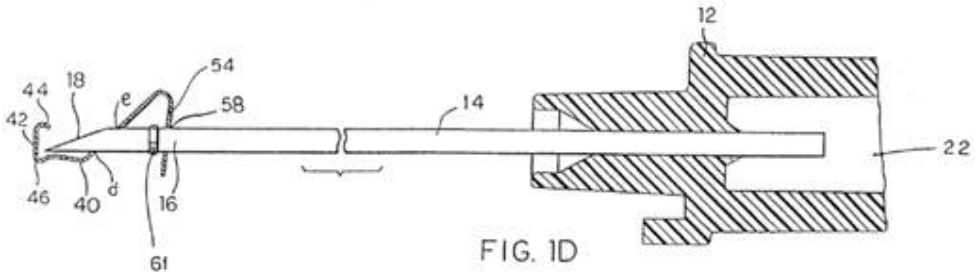

FIG. 1D

In the embodiment according to Figures 10A and 10B the spring clip generally has a "closed X" shape, i.e. two

intersecting arms 122, 124 hinged at a proximal wall 126 and each having a distal wall 130.

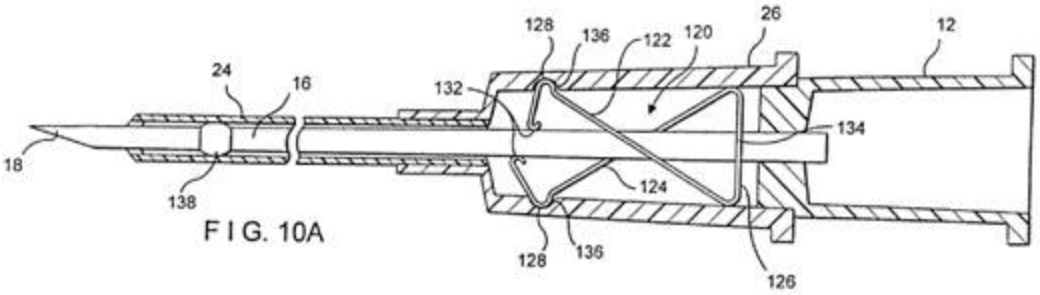

FIG. 10A

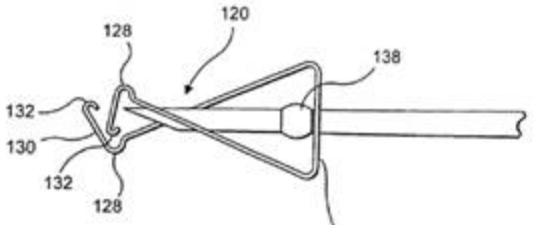

FIG. 10B

In claim 1 not only are the singular and plural used for the number of distal arm or end walls, thus corresponding to the embodiments of Figures 1C, 1D, 7D, 7E and Figures 10A, 10B and 11 respectively, but the very same wording and reference numerals as in the corresponding detailed description of the specific embodiments meant to be covered are used to designate the different elements claimed.

Hence, from its wording it appears that while claim 1 is clearly meant to cover all these embodiments, they are claimed in a side-by-side or juxtaposed way. Moreover, for each embodiment meant to be covered, the wording used is more precise than the wording used in the general presentation of the embodiments in the introductory part of the description, but it is more general than the wording used in the detailed description of each embodiment since only part of the features of those detailed embodiments are recited.

For the above reason claim 1 clearly constitutes a juxtaposition of so-called intermediate generalisations, so the question arises whether these intermediate generalisations are allowable in view of the disclosure of the description and figures of the application as filed.

3.3 The Board will concentrate on the embodiments generally exhibiting a "lying S" shape. These embodiments have extensively been analysed and commented in T 0222/12 under point 6. of the reasons (see point V. above). The present Board concurs with the findings presented there, in particular with the following:

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

6.1 (...)

6.2 (...)

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 starting middle of the second paragraph of page 11, 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. (...)"

The present Board also concurs with the conclusion under point 7. of the reasons for the same decision:

"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."

The appellant/patent proprietor considered that the last sentence of the first paragraph of page 5 of the application as filed:

"*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.*"

and the sentence bridging page 5 and page 6:

"*In a further embodiment of the spring clip catheter guard of the invention, a tether is connected to the needle hub and the spring clip guard to prevent the spring clip guard from being pulled off the protected needle without requiring an excessive clamping force therebetween.*"

would be evidence that the clamping was not necessary in order to protect the needle tip after removal from the catheter hub. The reason for discussing the clamping in T 0222/12 was because the transverse segment was mentioned in the claim, which was not the case here.

The Board does not share this opinion. Concerning the first sentence cited the Board concurs with the findings under point 9. of the reasons for decision T 0222/12, namely that nowhere in the paragraphs of the application as filed describing the claimed "lying S" embodiments, or in the general statements corresponding to the figures showing them, is there any suggestion 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 only presented as additional to the clamping action.

This applies to the first sentence cited by the appellant/patent proprietor: this sentence has to be read in the context of the paragraph as a whole, in which it is first explained that when the needle is

withdrawn from the catheter the needle guard pivots until it clamps onto the needle shaft, and that this allows a safe removal of the needle with its needle guard from the catheter hub. The provision of a bulge is then only presented as an additional measure to prevent inadvertent removal of the needle from the needle guard after their removal from the catheter hub. In other words, the provision of a bulge is presented as a complementary measure useful once the needle with its needle guard are completely out of the catheter, probably assuming that once out of the hub, inadvertence might lead to forces being applied to the needle guard which could overcome the clamping force.

Also the second sentence mentioned by the appellant/ patent proprietor does no more than explain that when a tether is used to prevent the needle guard from being pulled off the protected needle, the clamping force can be less high. Hence, not only is this statement not linked to the claimed "lying S" embodiments, it also confirms, contrary to the appellant/patent proprietor's interpretation, that even when a tether is used a clamping force must nevertheless be present. Once again, the author of the document did not consider that he could dispense with the clamping force.

The fact that the transverse segment was mentioned in the claim examined in T 0222/12 does not play any role in the above analysis. Indeed, what is decisive is that throughout the description of the claimed "lying S" embodiments, the clamping of the needle guard onto the needle shaft is presented as the very first means necessary to make sure that the needle tip can be removed safely from the catheter hub, and that only after that removal the bulge plays an additional safety

role (as also explained in T 0222/12, point 8. of the reasons).

The appellant/patent proprietor further considered that there was no necessary link between the transverse segment and the clamping function, the transverse segment not even being mentioned in the general presentation of the embodiments in the introductory part of the application as filed.

While it is true that in the introductory part of the description the transverse segment is not mentioned, hence, also not in relation to the clamping function, in the context of the patent in suit this does not mean that the transverse segment can be dispensed with in claim 1.

Indeed, as indicated e.g. in T 0222/12, points 6.2, 6.3 of the reasons (cited above), in relation to Figure 1B (which is identical to Figure 1D except for the slot which has been replaced by a bulge) it is explained on page 11 of the application as filed that "*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.*". Points e and d are precisely indicated on the corresponding figures as being the upper and lower points of the hole 56 in the transverse segment. This is a clear teaching that the clamping is primarily taking place at the transverse segment. For the person skilled in the art this means that the material used for the needle guard, the size of the holes 56, 58, the mechanical constraints present must be so chosen as to bring about this clamping. Thus this is a clear link

between the clamping function and the transverse segment.

The fact, mentioned by the appellant/patent proprietor, that in decision T 1202/09 a claim without the clamping feature was allowed does not play any role here, because that claim was only directed to the embodiment of Figure 10 with the "closed X" shape.

Hence, to summarise the above findings, in the context of the embodiments according to Figures 1C, 1D and 7D, 7E covered by the wording of claim 1, the clamping is presented as essential to be able to safely withdraw the needle with the needle guard remaining on it out of the catheter hub, and the only way presented in the application as filed to achieve this clamping is by use of a transverse segment joining the proximal wall to the distal wall. In other words, the clamping is inextricably associated with the transverse segment. No other means are described (or implicit) for allowing such a clamping of the needle guard onto the needle shaft to take place in these embodiments.

At least for the reasons above the Board is of the opinion that this intermediate generalisation is not allowable.

3.4 Hence, the ground for opposition pursuant to Article 100(c) EPC prejudices the maintenance of the patent as granted.

4. Auxiliary requests I to VI suffer the same deficiencies as the main request, which was not disputed by the appellant/patent proprietor, so these requests were not further considered, since they are not allowable for the same reasons.

5. Auxiliary request VII – added subject-matter

Compared to that of main request claim 1 of this request includes further specified features f) and g):

"f) a resilient spring clip needle guard (40, 96, 120) located within said chamber (36) being formed in said hub section (30) of said catheter hub (26) and having a distal arm (42, 112) or distal end walls (130) and a transverse segment (50) having an opening (56) through which the shaft of the needle (16) is free to pass and axially move; (emphasis added)"

In feature g) it has been specified that "needle guard (40, 96, 120) located within said hub chamber (36) is adapted to automatically snap or pivot until it clamps onto the needle shaft into a retracted position for blocking access to said distal needle tip" (emphasis added).

While in feature g) it is indicated that the needle guard is able to clamp onto the needle shaft, not only is it not indicated that this clamping allows the removal of the needle with the needle guard from the catheter hub, above all it does not indicate that this clamping is obtained by the transverse segment.

And although a transverse segment is now present in feature f), it is only presented as an element of the needle guard. The connection, if any, between this transverse segment and the distal and proximal walls respectively is not specified, and consequently not even an implicit link is made between this transverse segment and the clamping effect obtained specifically

with this transverse segment in the embodiments according to Figures 1 and 7.

Hence, for the same reasons as developed in relation with the main request, claim 1 does not fulfil the requirements of Articles 76(1) and 123(2) EPC.

6. Auxiliary requests VIII to XVIII suffer the same deficiencies as auxiliary request VII, which was not disputed by the appellant/patent proprietor, so these requests were not further considered, since they are not allowable for the same reasons.

7. Auxiliary request VIIB – admissibility

This request was filed during the oral proceedings of 10 May 2017.

Compared with the wording of claim 1 according to auxiliary request VII, in claim 1 according to this request feature f) reads as follows:

"a resilient spring clip needle guard (40, 96, 120) located within said chamber (36) being formed in said hub section (30) of said catheter hub (26) and having a distal arm (42, 112) or distal end walls (130) and a transverse segment (50) that extends upward and proximally from lower pointed end (46) and terminates at a U-shaped upper end (52) having an opening (56) through which the shaft of the needle (16) is free to pass and axially move or first and second arms (122, 124) respectively joined at their proximal ends in a hinged arrangement (125) to the ends of a rear wall (126); (emphasis added)

and feature l) reads as follows:

"and said needle guard (40, 96, 120) further comprising a proximal or the rear wall (54, 126) or proximal vertical arm (54, 106) extending downwards from the U-shaped upper end (52) having an opening (58, 134) adapted to let said shaft of needle (16) freely pass through and axially move; (emphasis added)"

Concerning the embodiments according to Figures 1C, 1D and 7D, 7E, the information has now been added that the one (upper) end of the transverse segment is joined to the proximal vertical arm (54, 106) at its U-shaped upper end. This does however still not define that the transverse segment plays a role in the clamping of the needle guard on the needle shaft.
Thus, this request does not *prima facie* solve the problem of added subject-matter discussed above.

Moreover, an objection of added subject-matter linked to the absence in the different versions of claim 1 of the transverse segment and its link to the clamping effect was raised right from the start of the appeal proceedings in the statement of the appellants/ opponents setting out the grounds of appeal, so the appellant/patent proprietor had ample time to deal with this objection.

Consequently the Board decides not to admit auxiliary request VIIB into the proceedings pursuant to Article 13 RPBA.

Order

For these reasons it is decided that:

1. The appeal of the patent proprietor is dismissed.

2. The decision under appeal is set aside.

3. The patent is revoked.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated