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Datasheet for the decision of 5 December 2014

Case Number: T 2613/11 - 3.2.02

Application Number: 06013843.5

Publication Number: 1702643

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:
Terumo Kabushiki Kaisha

Headword:

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

Keyword:
Grounds for opposition - extension of subject-matter (yes)
Late-filed request - admitted (no)

Decisions cited:
T 1202/09

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It can be changed at any time and without notice.

Catchword:

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Case Number: T 2613/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 5 December 2014

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)	Terumo Kabushiki Kaisha 44-1, Hatagaya 2-Chome Shibuya-ku Tokyo 151-0072 (JP)
Representative:	Wegner, Hans Bardehle Pagenberg Partnerschaft mbB Patentanwälte, Rechtsanwälte Postfach 86 06 20 81633 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 October 2011 concerning maintenance of the European Patent No. 1702643 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	P. L. P. Weber
	C. Körber

Summary of Facts and Submissions

I. The patent proprietor and the opponent each filed an appeal against the interlocutory decision of the Opposition Division posted on 21 October 2011 that, account being taken of the amendments according to the second auxiliary request made by the patent proprietor during the opposition proceedings, the patent and the invention to which it related were found to meet the requirements of the EPC.

II. The appellant-patent proprietor filed notice of appeal on 20 December 2011 and paid the appeal fee on the same day. The statement setting out its grounds of appeal was filed on 27 February 2012.

III. The appellant-opponent filed notice of appeal on 22 December 2011 and paid the appeal fee on the same day. The statement setting out its grounds of appeal was filed on 29 February 2012.

In its statement setting out the grounds of appeal the appellant-opponent objected to several features of claim 1 of the patent as granted under Article 100(c) EPC.

IV. Oral proceedings took place on 5 December 2014.

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 X filed with letter dated 4 November 2014 and auxiliary request XI filed during oral proceedings.

Although having been duly summoned by communication dated 7 August 2014, the appellant-opponent was not present, as announced by letter dated 14 October 2014.

In the written proceedings the appellant-opponent had requested that the decision under appeal be set aside and that the patent be revoked.

V. The patent in suit is based on a divisional application (06013843.5) of a first-generation divisional application (04000853.4, basis for decision T 1202/09) of a parent application (98948843.2, E12: WO-A-9908742 being the published version).

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

Claim 1 of the patent as granted

"Segment of increased diameter"

In relation to the embodiment shown in Figures 10A, B and 11 and described in the corresponding passages of the description, the person skilled in the art would understand that what was important was that the needle guard did not fall off the needle. This was the essential function of the bulge in that embodiment as described in the first paragraph of page 19 and the second paragraph of page 20 of E12. The proper bulge shape was not in itself relevant for fulfilling this function.

It was also clear when applying the test for extracting a feature from an embodiment that the specific shape of the increased diameter segment was not important. This bulge shape was not linked to other features of the

embodiment. What mattered was that some element engaged the rear wall of the needle guard. This was essential for preventing the sticking, because it guaranteed that the needle guard could not fall off or be taken from the needle shaft. In this context the position of the increased diameter segment was important and this position was mentioned in claim 1 ("*slightly proximal to the needle tip*").

Nor could it validly be asserted that the needle tip was of a smaller diameter than the portion immediately following it, since the needle shaft's theoretical diameter was identical all along the shaft, also where the biased cut was present to create the tip.

It was not necessary to include in the wording of the claim that the segment of increased diameter had a small enough diameter to be free to move axially along the catheter, because for the person skilled in the art this was inherent for a proper functioning of the device. The same was true for the feature of the bulge being able to pass the distal walls of the needle guard, this compatibility between the shape of the increased diameter segment and the distal walls of the needle guard being also inherent to a good functioning device.

The word “segment” was precise enough and supported implicitly as it was used in its usual meaning, in the present case designating a part of the shaft, i.e. it could not be the whole shaft.

Therefore, the ground for opposition pursuant to Article 100(c) EPC did not prejudice the maintenance of the patent as granted.

Lateness and admissibility of auxiliary request XI

Claim 1 of auxiliary request XI was identical to claim 1 of the patent as granted except that the word "segment" had been replaced by "bulge". This change could not be considered a surprising amendment, since this question of the "bulge" feature was already present in the opponent's statement setting out the grounds of appeal. Furthermore it was not technically complicated to understand.

Moreover in its decision the Opposition Division had considered the feature to be allowable, so that the appellant-patent proprietor had no reason to amend it earlier.

Such a minimal amendment overcoming the objection raised therefore had to be admitted even at such a late stage as during the oral proceedings.

VII. The arguments of the appellant-opponent relevant for the decision can be summarised as follows:

Claim 1 of the patent as granted

"Segment of increased diameter"

Contrary to what the Opposition Division had stated in its decision, it was considered that the general relationship between an increased diameter segment on the needle shaft and the needle tip as claimed in claim 1 was not disclosed in Fig.10A,B or 11. In these figures the increased diameter bulge 138 and the needle tip were only shown together with numerous other functionally related features.

These other features were at least that the increased diameter segment was a bulge, and that this bulge was sufficiently small to allow the needle to move axially along the catheter. Furthermore, there was a relationship between the two distal end walls terminating in a curved lip 132 and the bulge, because the needle guard end walls had to be able to slide over the bulge on the needle shaft when the latter moved from the ready position to the protective position.

Not including these features, the subject-matter of claim 1 of the patent as granted constituted a so-called intermediate generalisation and therefore extended beyond the content of the patent application as filed and beyond the earlier application as filed.

At least for this reason the ground for opposition under Article 100(c) EPC prejudiced the maintenance of the patent as granted, and also on the basis of any of the auxiliary requests, so that the patent had to be revoked.

VIII. The different versions of claim 1 relevant for the decision read as follows (feature identification as in the decision):

Claim 1 of the patent as granted reads as follows:

“1. An intravenous catheter comprising

a) a catheter hub (26) attached to the proximal end of a tubular catheter (24) and having a chamber,

b) a needle (16) having a needle shaft and a needle tip, wherein the needle is provided with an increased diameter, and

c) a needle guard (120) retained in a ready position wholly in the chamber of the catheter hub (26),

d) wherein the needle guard (120) has two resilient arms (122, 124)
d1) which are urged away from each other by said needle shaft in the ready position,
d2) each arm being provided at the distal end with a distal guard wall (130) positioned on the shaft of the needle (16) in the ready position and
d3) wherein the distal guard walls overlap each other in front of the needle tip when the needle guard is in a blocking position,

characterised in that

e) the needle shaft has a segment (138) slightly proximal to the needle tip, the segment (138) being provided with an increased diameter in relation to the needle tip, and

f) the needle guard (120) having a rear wall (126) from which the arms (122, 124) extend in a distal direction wherein the rear wall (126) includes an opening (134) through which the needle shaft passes,

g) wherein the diameter of the increased diameter segment (138) is greater than that of said opening (134), and

h) wherein an inner wall of the chamber of the catheter hub (26) is provided with a retaining means in the form of an annular groove (136) by which the needle guard is retained in the catheter hub in the ready position."

The different claims 1 according to auxiliary requests I to X include several amendments but none of them concerns the feature relevant for the present decision (auxiliary requests V to X filed by the appellant-patent proprietor with letter dated 4 November 2014 correspond to auxiliary requests I to VI filed with the statement setting out its grounds of appeal).

Claim 1 of auxiliary request XI reads as follows (emphasis added by the Board showing the amendments over claim 1 of the patent as granted):

"1. An intravenous catheter comprising

a) a catheter hub (26) attached to the proximal end of a tubular catheter (24) and having a chamber,

b) a needle (16) having a needle shaft and a needle tip, wherein the needle is provided with an increased diameter, and

c) a needle guard (120) retained in a ready position wholly in the chamber of the catheter hub (26),

d) wherein the needle guard (120) has two resilient arms (122, 124)
d1) which are urged away from each other by said needle shaft in the ready position,
d2) each arm being provided at the distal end with a distal guard wall (130) positioned on the shaft of the needle (16) in the ready position and
d3) wherein the distal guard walls overlap each other in front of the needle tip when the needle guard is in a blocking position,

characterised in that

e) the needle shaft has a bulge (138) slightly proximal to the needle tip, the bulge (138) being provided with an increased diameter in relation to the needle tip, and

f) the needle guard (120) having a rear wall (126) from which the arms (122, 124) extend in a distal direction wherein the rear wall (126) includes an opening (134) through which the needle shaft passes,

g) wherein the diameter of the increased diameter bulge (138) is greater than that of said opening (134), and

h) wherein an inner wall of the chamber of the catheter hub (26) is provided with a retaining means in the form of an annular groove (136) by which the needle guard is retained in the catheter hub in the ready position."

Reasons for the Decision

1. Both appeals are admissible.

2. The description and the drawings of the second divisional application as filed (basis of the patent in suit) are identical to the same elements of the first divisional application as filed, which are also identical to the same elements of the parent application as filed. In the decision, the Board will refer to the paragraphs of the description of the published version of the parent application (E12), as did the parties.

3. The patent in suit concentrates on the embodiments disclosed in Figures 10A, 10B and 11 and the

corresponding description parts of the application as filed. This was not disputed by the appellant-patent proprietor.

The embodiment of the intravenous catheter according to these figures basically comprises a catheter hub integral with a tubular catheter meant to be introduced into a vessel of a patient. A needle is associated with the catheter to help introduce it into the patient's vessel. In addition, in the catheter hub a needle guard is positioned having two intersecting arms joined at their proximal ends to the ends of a rear wall having an opening through which the needle shaft passes and having at their distal ends two distal walls extending between the needle shaft and a groove of the catheter hub. Additionally, the needle shaft is provided with a bulge at a position proximal of the needle tip but within the tubular catheter. Once the catheter has been introduced into the vessel of the patient and the needle begins to be withdrawn by the operator, the needle shaft with the bulge moves along the tubular catheter, the bulge passes the distal walls and subsequently, when the needle tip passes the said distal walls, they move from their position in which they were retained in the catheter hub into a position in front of the needle tip, thereby protecting the needle tip and allowing movement of the needle guard in a proximal direction out of the catheter hub together with the needle. In order to prevent the needle guard from falling off the needle shaft a clamping action of the arms on the shaft exists. Furthermore the diameter of the bulge is greater than the diameter of the hole in the rear wall of the needle guard so that the latter cannot move past the bulge and possibly fall off the needle shaft. This is explained on page 6 first complete paragraph and in more detail from page 18

second paragraph up to and including page 20 second paragraph of E12.

4. Main request - Added subject-matter

4.1 Segment of increased diameter

Claim 1 of the patent as granted requires in feature b) that the intravenous catheter comprises a needle (16) provided with an increased diameter. It further requires in feature e) that the needle shaft has a segment (138) slightly proximal to the needle tip, the segment (138) being provided with an increased diameter in relation to the needle tip. Finally it further requires in feature g) that the diameter of the increased diameter segment (138) is greater than that of the opening (134) in the rear wall of the needle guard through which the needle shaft passes.

It follows from the above that claim 1 requires a segment of increased diameter to be present on the needle shaft, the diameter of which is greater than the opening in the rear wall of the needle guard.

As mentioned above, and not disputed by the appellant-patent proprietor, the only potential basis for present claim 1 is the specific embodiment shown in Figures 10A, B and 11 and the corresponding paragraphs of the description. The figures, which are not schematic sketches but close to technical drawings, disclose a very specific embodiment which functions as is, namely when all dimensions, shapes of the different elements present and the relationships between them are respected.

Concerning more particularly the "segment of increased diameter" shown in the figures, it is shown in the shape of a bulge, positioned in the tubular part of the catheter, placed on the shaft at a certain distance from the tip inferior to the distance between the rear wall of the needle guard and its distal walls, to name only some of the immediately apparent elements.

For the shown intravenous catheter to be able to work as desired, once the catheter is in the vessel of the patient the needle must be able to be withdrawn proximally, i.e. the bulge must be able to be moved along the tubular part of the catheter and it must be able to pass the distal walls of the needle guard so that the distal walls can come in front of the needle tip to protect the user from sticking.

This is what is expressed on page 19, in the last sentence of the first paragraph which reads as follows: "*Needle 16 includes an increased diameter bulge 138, which is sufficiently small to allow needle 16 to move axially along catheter 24, but greater in diameter than opening 134 for reasons to be described below*."

Also on page 19, last paragraph which reads as follows: "*When the needle is retracted axially, to the right as viewed in Fig. 10A, within the catheter hub, and moves past the end lip 132 of the needle guard, the radial force previously exerted on arms 122, 124 of needle guard 120 is suddenly released. This causes the distal end walls 130 of the needle guard to be released from their seat in the annular groove 136 and to pivot inwards into the catheter hub until, as seen in Fig. 10B, the end walls 130 overlap one another at a location distally in front of the needle tip, thereby*

to form a barrier that prevents inadvertent contact with, and distal movement of, the needle tip."

It follows from the above that the figures disclose a very specific embodiment but also, except for the precise dimensions, the description of the embodiment does not convey any more general teaching relating to the increased diameter bulge than what is disclosed by the figures.

In the Board's opinion, already because present claim 1 does not recite that the segment of increased diameter is a bulge and does not recite that its diameter must be sufficiently small to allow the needle to move axially along the catheter, its subject-matter extends beyond the content of the application as filed.

4.2 The appellant-patent proprietor submitted that the person skilled in the art would recognise in particular from the sentence in the second paragraph of page 20 ("*If an attempt is made, intentionally or inadvertently, to pull the needle further to the right, as viewed in Fig. 10B, out of the needle guard, the bulge 138 on the needle shaft will come into contact with the end wall 126, and since its diameter is greater than that of opening 134, the end wall 126 will at this point prevent any further axial movement of the needle out of the needle guard.*") that what was essential for the function was the presence of a segment of increased diameter but not the precise shape of the segment.

The Board does not share this opinion. While it is accepted that, for the specific function of blocking the needle shaft against the rear wall of the needle guard, the specific bulge shape is mechanically not

necessary, as explained above this is, however, not the only function the bulge or segment of increased diameter has to fulfil. In particular it must be able to move axially along the catheter, in both directions, when the needle is introduced into the catheter and when it is withdrawn, as explained in the two paragraphs of page 19 and unmistakably understandable from the figures. The only shape disclosed in the application as filed which is able to fulfil all these functions is a bulge shape. The Board notes that also in the paragraph mentioned above by the appellant-patent proprietor reference is made to "its" diameter, i.e. that of the bulge 138 mentioned at the beginning of the sentence.

For the same reason, the argument of the appellant-patent proprietor that the bulge shape could be dispensed with because it had no influence on other features of the embodiment cannot be followed either. Another shape of the segment of increased diameter may have an influence on the shape and/or dimensions of other components of the intravenous catheter which it has to co-operate with in order to have a functioning device; in particular, the tubular part of the catheter and/or the distal walls of the needle guard. Hence, it is not implicit that the device would function with any kind of segment of increased diameter, so that also for this reason the bulge feature cannot be deleted.

According to the appellant-patent proprietor, of course the device had to function and the missing relationship between the segment of increased diameter and the other components of the device would therefore be considered implicit by the person skilled in the art.

In the Board's opinion, for the person skilled in the art the embodiment shown in the relevant figures, with all the features present, constitutes a functioning intravenous catheter. Numerous features of this embodiment were, however, not taken over into claim 1, so that the wording of claim 1 encompasses numerous undisclosed alternative embodiments for which a general support cannot be found. In the Board's opinion, something implicit for the person skilled in the art must be immediately apparent, an immediate and unambiguous consequence of or necessarily implied by what is explicitly disclosed, or belonging to the general knowledge of the person skilled in the art. As soon as the person skilled in the art has to think about a way of carrying out an alternative embodiment, it is no longer directly and unambiguously derivable from the specification. The relevant question is then whether the alternative is obvious or involves an inventive step. Such alternative embodiments can, however, no longer be considered to be implicitly disclosed.

In the present case, the sole potential basis for claim 1 being the specific embodiment of Figures 10A, B and 11 and the corresponding description parts, the above question of implicit disclosure is of fundamental importance. No embodiment has been disclosed in which the segment of increased diameter is of any shape other than a bulge and leads to a functioning device. The same applies for the feature of the segment being axially movable along the catheter. The present wording of claim 1 does not require that this function is present, so that the claim also covers embodiments in which the axial movement of the segment of increased diameter along the catheter would not be possible or would simply be absent, e.g. if the segment of

increased diameter were possibly placed elsewhere along the catheter shaft. A functioning device of such nature has not been disclosed.

Also the presently used word "segment" is not further defined and was not used in the application as filed, so that a precise meaning of this term in relation to the embodiment shown in the mentioned figures cannot be found in the application. While this word normally designates "a part of", in the present case (most probably) a part of the needle shaft, this word does not give any indication as to the axial length of such a segment. Here again no functioning device has explicitly or implicitly been disclosed with a segment of increased diameter having any length and other than a bulge.

4.3 At least for the reasons above, the ground for opposition pursuant to Article 100(c) EPC prejudices the maintenance of the patent as granted.

5. Auxiliary requests I to X

Since none of the claims 1 according to any of these requests comprises the feature of the bulge, they all fail to fulfil the requirements of Article 123(2) EPC and are therefore not allowable. This was not further disputed to by the appellant-patent proprietor.

6. Auxiliary request XI - Admissibility

Auxiliary request XI was filed during the oral proceedings. When compared to claim 1 of the patent as granted, in claim 1 according to this request only the word "segment" has been replaced by the word "bulge". According to the appellant-patent proprietor the filing

of this request was not late and the amendment proposed overcame the objection raised.

In the present case the objection concerning the bulge feature was already present in the statement setting out the grounds of appeal of the appellant – opponent (pages 8 and 9, the objection concerning features b) and e)), beside other objections pursuant to Article 100(c) EPC (point II starting page 7 and the objections against features c) and h)). It follows from the above that the amendment now proposed of the increased diameter feature or bulge feature cannot be considered to be a reaction to an objection raised for the first time during or shortly before oral proceedings. The appellant-patent proprietor knew of the existence of this objection already at the start of the appeal procedure, and thus had ample time to deal with it before the oral proceedings. The Board notes in this context that ten auxiliary requests were filed by the appellant-patent proprietor before the oral proceedings, addressing most of the objections raised by the appellant-opponent, but none of them dealt with the bulge feature.

Therefore there is no obligation under Article 113(1) EPC to give an opportunity to the appellant-patent proprietor to amend its claim during oral proceedings in order to try and overcome the objection raised.

At least in such a case, prima facie allowability, or prima facie overcoming of the objection, plays an important role for deciding on the admissibility of the newly filed request into the appeal proceedings at this late stage, this prima facie overcoming of the objection also being an element of procedural economy within the meaning of Article 13(1) RPBA.

In the present case, only the word "segment" having been amended to "bulge", and the other functions of the bulge still not having been stated in the claim, in particular that the diameter should be sufficiently small to allow the needle to move axially along the catheter, present claim 1 does not prima facie fulfil the requirements of Article 123(2) EPC.

For these reasons, the Board decides not to admit auxiliary request XI into the proceedings pursuant to Article 13(1) RPBA.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The appeal of the appellant-patent proprietor is dismissed.

3. The patent is revoked.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated