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Title of invention:
Catheter instrument

Patent Proprietor:
Vigmed AB

Opponent:
B. Braun Melsungen AG

Relevant legal provisions:
EPC Art. 54(2), 56, 84, 123(2), 123(3)

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Case Number: T 0564/16 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 20 November 2020

Appellant: (Patent Proprietor)	Vigmed AB Garnisonsgatan 10 254 66 Helsingborg (SE)
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Appellant: (Opponent)	B. Braun Melsungen AG Carl-Braun-Str.1 34212 Melsungen (DE)
Representative:	Akers, Noel James N.J. Akers & Co 63 Lemon Street Truro, Cornwall TR1 2PN (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 4 January 2016 concerning maintenance of the European Patent No. 2464408 in amended form.**

Composition of the Board:

Chairwoman	P. Acton
Members:	G. Buchmann
	C. Schmidt

Summary of Facts and Submissions

I. With the decision of 4 January 2016, the opposition division decided to maintain European patent No. 2 464 408 in amended form, based on the then-valid auxiliary request IX.

The opposition division had come to the conclusion that the subject-matter of claim 1 according to the then-valid main request and auxiliary requests I-VIII contravened Article 123(2) EPC.

II. Both parties filed an appeal against this decision.

III. Appellant 1 (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted (main request) or on the basis of one of auxiliary requests 1-10, filed either with the letter dated 2 October 2015 (auxiliary requests 1 - 8) or with the letter setting out the grounds of appeal dated 4 May 2016 (auxiliary requests 9 and 10).

IV. Appellant 2 (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

V. Oral proceedings before the Board took place by video conference on 20 November 2020.

VI. In the present decision, reference is made to the following documents:

D1: US 2005/277879 A1
D3: WO 2005/042080 A1

Document D2 cited during the proceedings is a German version of D1. This decision will not refer to D2, but only to D1.

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

The numbering and also an indication of the disputed additions and ~~deletions~~ (compared to the original claim 1) have been added.

1.1
"A catheter instrument (1000) comprising:
1.2
a catheter hub (200),
1.3
a needle unit (300), and
1.4
a plastic needle tip shielding device (100);
1.5
wherein said needle unit (300) is provided with connecting means (301) for connection to said catheter hub (200),
1.5.1 with connecting means (302) for connection to an external device, and
1.5.2 is fixed around the rear end of a needle (303),
1.5.3 said needle unit (300) further comprising a hollow needle (303) with a needle tip (304),
1.5.4 the hollow needle (301) being provided with an expansion region (305) near the needle tip (304);

1.6
wherein said catheter hub (200) is connected to a catheter (201),
1.6.1 said needle (303) extending longitudinally within

said catheter (201) when said catheter instrument (1000) is in a ready mode and said needle unit (300) is connected to said catheter hub (200);

1.7
wherein said plastic needle tip shielding device (100) is fitted inside the catheter hub (200) and onto said needle (303), when said catheter instrument (1000) is in a ready mode,
1.7.1 said needle tip shielding device (100) comprising: a body with a rear side (106), a front side (107), an outer surface (108) connecting said rear side (106) and said front side (107),
1.7.2 a hole (102) extending from said rear side (106) to said front side (107), through which hole (102) said needle (303) runs;
1.7.3 and a resilient arm (103) extending at an attachment point (105) from said front side (107) of said body,
1.7.4 wherein said resilient arm (103) has a resting state, from which it may be forced by said hollow needle (303);
~~**1.7.5**~~
~~said resilient arm (103) being adapted for clamping the needle tip (304) of the hollow needle (303) extending through said hole (102) in a direction from said rear side (106) to said front side (107), when said resilient arm (103) is in said resting state;~~
~~**1.7.6**~~
~~wherein any straight imaginary line extending longitudinally through said hole (102) in the axial direction of said body coincides with said resilient arm (103), when said resilient arm (103) is in said resting state;~~

1.8
wherein said resilient arm (103) is forced to yield free passage through said hole (102) in an axial direction of said body by said needle (300) when said catheter instrument (1000) is in the ready mode,
1.8.1 such that said resilient arm (103) strives toward its resting state when the hollow needle (303) is withdrawn to a point where the needle tip (304) passes a contact point between the resilient arm (103) and the needle (303),
1.8.2 such that a part of the resilient arm (103) is in front of the needle tip (304);

1.9 and wherein said outer surface (108) of said body of the needle tip shielding device (100) is contacting the inner surface of the catheter hub (200) in a **retaining manner** when said catheter instrument (1000) is in the ready mode.

VIII. **Auxiliary Requests**

(a) **Auxiliary request 10** differs from claim 1 as granted by the following additional features:

1.5.4.1 "expansion region" (part):
"wherein the expansion region (305) is a region on the hollow needle (303) where the effective diameter is larger than elsewhere on the needle in the direction towards the rear of the hollow needle (303)".

1.7.1.1 "needle protruding":
"wherein the hollow needle (303) is further extending through the catheter (201) so that the needle tip (304) is protruding slightly past an opening of the catheter (201) in order to

facilitate penetration of the skin of a patient."

1.7.2.1 "expansion region" (part):
"whereby the increase in the effective diameter of the hollow needle (303) by expansion region (305) has the effect that the expansion region (305) is not movable through the hole (102)".

1.7.5 "clamping":
"wherein said resilient arm (103) is adapted for clamping the needle tip (304) of the hollow needle (303) extending through said hole (102) in a direction from said rear side (106) to said front side (107), when said resilient arm (103) is in said resting state".

1.7.6 "straight imaginary lines":
"wherein any straight imaginary line extending longitudinally through said hole (102) in the axial direction of said body coincides with said resilient arm (103), when said resilient arm (103) is in said resting state".

1.9.1 "protuberances" replacing "in a retaining manner":
"via a catheter hub contact area, wherein movement of the needle tip shielding device (100) relative the catheter hub (200) is restricted by means of at least one protuberance (101), comprising the catheter hub contact area, located on the outer surface (108) of the needle tip shielding device (100)".

1.9.2 "imprint":
"wherein the at least one protuberance (101) is making a corresponding imprint in, and where it

contacts, the inner surface of the catheter hub (200)".

(b) **Auxiliary Requests 1-9**

In each of auxiliary requests 1-9, one or more of the above features have been added, in accordance with the following scheme. Auxiliary requests 8 and 9 include further amendments which are not relevant to the present decision.

Auxiliary request	1	2	3	4	5	6	7	8	9	10
1.5.4.1 and 1.7.2.1 "expansion region"			x	x			x	x	x	x
1.7.1.1 "needle protruding"									x	x
1.7.5 "clamping"					x	x	x	x	x	x
1.7.6 "straight imaginary lines"	x			x		x	x	x	x	x
1.9.1 "protuberances" replacing "in a retaining manner"		x		x			x	x	x	x
1.9.2 "imprint"										x

IX. **The arguments of appellant 1 can be summarised as follows:**

Main Request

Amendments - Article 123(2) EPC

(a) Omission of the "**straight imaginary lines**" (Feature 1.7.6)

This feature could be omitted from the granted claim 1.

The definition of the straight imaginary lines was only necessary in the original claim 1 because that claim referred to the needle tip shielding device without including the needle itself. The subject-matter of claim 1 as granted, however, comprised the complete catheter instrument including the needle, so the same geometry defined by the feature "straight imaginary lines" was now defined by the "part of the arm being in front of the needle tip" in the resting state of the resilient arm. This made the definition using the imaginary lines obsolete. From the description on page 10, lines 23-29 of the application, it was clear that the needle tip was protected in any rotational position of the needle.

Furthermore, the imaginary lines were only mentioned in the context of the embodiment of Fig. 5, and not of that of Fig. 7, which also formed part of the invention. Therefore the feature of the imaginary lines was not essential to the invention and could be omitted.

(b) Omission of the "**clamping**" feature (1.7.5)

This feature could be omitted from the granted claim 1 because it only described the effect of the structural features of the claim. The function described by this feature was still present in the claim due to the definition of the relationship between the arm and the needle.

Appellant 1 also referred to the "three-point test" developed in decision T 331/87 and argued that the result of this test was positive in view of the "clamping" feature.

(c) Introduction of "**retaining manner**" (Feature 1.9)

The application described the connection of the body of the needle tip shielding device to the catheter hub using different types of protuberances (e.g. page 8, lines 30-35; page 15, line 20 - page 16, line 29), or using a frictional connection (page 20, lines 7-17).
The term "in a retaining manner" covered all the embodiments disclosed in the application and was therefore allowable.

It could also be derived from Figures 1-3 that the needle tip shielding device was held in a retaining manner in the catheter hub.

(d) Introduction of an "**expansion region**" (Feature 1.5.4)

Page 9, lines 4-10 formed a basis for this feature.

The expansion region of the needle was independent

of the hole diameter which was a feature of the needle tip shielding device. Furthermore, the question of the expansion region being related to the hole diameter was more a matter of clarity than of added subject-matter.

Admission of Auxiliary Requests 1-8

These auxiliary requests were admissible because the amendments attempted to overcome the objections raised under Article 123(2) EPC.

Allowability of Auxiliary Requests 1-6

Amendments - Article 123(2) EPC

The above arguments concerning the main request were valid for auxiliary requests 1-6 where applicable.

Allowability of Auxiliary Requests 7-9

Amendments - Article 123(2) EPC

In auxiliary requests 7-9, the wording "in a retaining manner" was replaced by Feature 1.9.1.

This amendment was based on page 8, lines 32-35.

The imprints described in line 35 were only an effect caused by the protuberances, not a technical feature of the instrument. Therefore they did not need to be included in the claim.

Allowability of Auxiliary Request 10

Extension of Protection - Article 123(3) EPC

Claim 1 complied with Article 123(3) EPC because the complete phrase "restricting by means of at least one protuberance ... wherein the at least one protuberance (101) is making a corresponding imprint in, and where it contacts, the inner surface of the catheter hub (200)" was not broader than the term "retaining". The term "retaining" included the holding in place by friction and by protuberances/imprints. The protuberances did not allow limited movement of the needle tip shielding device.

Clarity - Article 84 EPC

The feature according to which "the needle tip is protruding slightly past an opening of the catheter in order to facilitate penetration of the skin of the patient" was not unclear to the skilled reader.

The term "in order to facilitate penetration of the skin" was not a result to be achieved but an additional clarification of the claimed subject-matter.

The feature according to which "the resilient arm is adapted for clamping" was clear to a skilled person in view of the technical context.

Novelty over D1 - Article 54(2) EPC

The term "any imaginary straight line" in Feature 1.7.6 meant "whichever imaginary straight line". Therefore the claim defined that the resilient arm must be able to cover every possible imaginary line extending

longitudinally through the hole. This was not disclosed in D1.

Furthermore, D1 did not disclose protuberances on the body of the needle tip shielding device as required by Features 1.9.1 and 1.9.2. The reference sign "48" referred to a jaw, not to a protuberance or a body. D1 did not describe any contact between the body and the inner surface of the catheter hub, let alone any imprint made by the protuberances. Nor did D1 disclose any hardnesses of the materials of the needle tip shielding device and the catheter hub which allowed a conclusion to be drawn in relation to imprints.

Novelty over D3 - Article 54(2) EPC

D3 did not explicitly disclose any material of the needle tip shielding device, but given its geometry in the figures the device must be made from metal instead of plastics material.

The corners of the transverse wall 5c of the needle tip shielding device of D3 (Figure 2) did not represent protuberances extending from an outer surface of the body.

Inventive Step - Article 56 EPC

In D1, the retention of the needle shield was achieved by the obstruction 34. Hence there was no reason to provide a different retention mechanism by protuberances making imprints on the inner surface of the catheter hub. Without hindsight, the skilled person would not modify the device of D1.

When starting from D3, it was not obvious to replace

the corners of the transverse wall of the needle tip shielding device by protuberances on an outer surface of the body.

When starting from D1, there was no reason to replace the retention mechanism present in D1 by the retention mechanism according to D3. Additionally, the corners of the transverse wall did not lead the skilled person to protuberances on an outer surface.

X. **The arguments of appellant 2 can be summarised as follows:**

Main Request

Amendments - Article 123(2) EPC

(a) Omission of the "**straight imaginary lines**" feature (1.7.6)

The omitted "straight imaginary lines" feature could not be replaced by the combination of the needle tip shielding device as originally claimed with the whole of the catheter instrument including the needle as argued by appellant 1. The added feature according to which "said resilient arm 103 strives towards its resting state ... such that a part of the resilient arm is in front of the needle tip 304" was not equivalent to the needle tip being covered by the arm in any rotational position of the needle in relation to the needle tip shielding device, the latter being the technical result of the "straight imaginary lines" feature.

Moreover, the complete and unconditional covering of the needle tip was indeed an essential feature

of the invention.

(b) Omission of the **"clamping"** feature (1.7.5)

The omitted "clamping" feature defined the main function of the device, namely that the needle tip is prevented by the resilient arm from being exposed. Such an essential feature of the invention could not be deleted without contravening Article 123(2) EPC.

(c) Introduction of **"retaining manner"** (Feature 1.9)

The passages of the description which were cited by appellant 1 only described specific embodiments in which the needle tip shielding device was held in place by protuberances on the outer surface of its body. These specific embodiments of the fixation did not provide a basis for the general wording "in a retaining manner". Also, Figures 1-3 which appellant 1 referred to only showed the needle tip shielding device being held by protuberances on the outer surface of the body.

(d) Introduction of an **"expansion region"** (Feature 1.5.4)

This feature represented an intermediate generalisation of the original disclosure because it defined only the expansion region on the needle tip itself without any limitation of its form, size or function. Without including the functional context of the hole 102, this feature contravened Article 123(2) EPC.

Admission of Auxiliary Requests 1-8

Auxiliary requests 1-8 should not be admitted because appellant 1 had not provided any indication as to in what way the amendments therein were in response to any of the grounds of opposition.

Allowability of Auxiliary Requests 1-6

Amendments - Article 123(2) EPC

The arguments concerning the main request were valid for auxiliary requests 1-6 where applicable.

Allowability of Auxiliary Requests 7-9

Amendments - Article 123(2) EPC

Feature 1.9.1 represented an intermediate generalisation of the original disclosure. According to the description, the protuberance cooperated with imprints on the inner surface of the catheter hub. No fixation of the needle tip shielding device without making imprints was disclosed.

Allowability of Auxiliary Request 10

Extension of Protection - Article 123(3) EPC

Claim 1 of auxiliary request 10 contravened Article 123(3) EPC because in the feature according to which "said outer surface (108) of said body of the needle tip shielding device (100) is contacting the inner surface of the catheter hub (200) in a retaining manner" the term "in a retaining manner" had been replaced by "via a catheter hub contact area, wherein

the movement of the needle tip shielding device (100) relative the catheter hub (200) is restricted". This replacement represented a broadening of the scope of claim 1. The term "restrict" was broader than the term "retain", because "restricting" meant "holding while allowing some limited movement", whereas "retaining" meant "holding while not allowing any movement".

Clarity - Article 84 EPC

Claim 1 of auxiliary request 10 lacked clarity because the feature according to which "the needle (304) is protruding slightly past an opening of the catheter" was vague. The skilled person was not able to determine how much of the needle tip was permitted to protrude from the opening in the catheter. Moreover, the subsequent passage according to which the needle protrudes "in order to facilitate penetration of the skin of a patient" was an attempt to define the subject-matter by the result to be achieved. It was not clear under what conditions this result was or was not achieved.

Finally, the feature according to which "said resilient arm is adapted for clamping the needle tip" was unclear as to what structural features of the arm might fulfil this purpose.

Novelty over D1 - Article 54(2) EPC

The subject-matter of claim 1 of auxiliary request 10 was not novel over D1.

Regarding the disputed Feature 1.7.6, "any" meant "one or more" of the imaginary lines. Figure 8a of D1 showed that at least some of the lines extending

longitudinally through the hole of the body coincided with the portion (54) of the resilient arm (48). Therefore, Feature 1.7.6 was disclosed in D1.

Also, the disputed features 1.9.1 and 1.9.2 were disclosed in D1 because Figure 3a showed contact points of the body of the needle tip shielding device on the inside of the catheter hub which were formed by protuberances located on the outer surface of the needle tip shielding device. Since the material of the needle shield had to be relatively rigid in order to provide a stable cover for the needle tip, it was evident that the protrusions shown in Figure 3a produced imprints on the inner surface of the catheter hub. These retained the needle tip shielding device inside the catheter hub.

Novelty over D3 - Article 54(2) EPC

The subject-matter of claim 1 of auxiliary request 10 was not novel over D3.

In particular, the corners of the transverse wall 5c of the needle tip shielding device of D3 represented protuberances which, according to Figure 2 and page 3, last paragraph, made imprints in the inner surface of the catheter hub.

Inventive Step - Article 56 EPC

When starting from D1, the distinguishing features were trivial alternatives which were obvious to the skilled person. Regarding the feature of the protuberances making an imprint on the inner surface of the catheter hub, it was clear that for proper protection of the needle tip the material of the needle tip shielding

device must be relatively rigid. Consequently, the protuberances made from the same material made an imprint on the inner surface of the catheter hub.

When starting from D3, the corners of the transverse wall could be regarded as protuberances because anything that stuck out from a body was a protuberance. Furthermore, the corners of the transverse wall had exactly the same function as the protuberances in the claimed instrument, which made the design of the needle tip shielding device according to claim 1 obvious.

When starting from D1, D3 suggested adapting the instrument of D1 in such a way as to arrive at the subject-matter of claim 1.

Reasons for the Decision

1. **Main Request**

Amendments - Article 123(2) EPC

1.1 Omission of the **"straight imaginary lines"** feature (1.7.6)

Claim 1 as originally filed required that "any straight imaginary line extending longitudinally through said hole 102 in the axial direction of said body coincides with said resilient arm, when said resilient arm is in said resting state" (Feature 1.7.6). This feature has been omitted from claim 1 as granted.

This feature has the meaning that, if a needle is extending coaxially through the hole, its tip (which is normally located at the periphery of the circumference of the needle cross-section) will contact the resilient arm regardless of the rotational orientation of the needle. In order to be allowable under Art. 123 (2) EPC, the amended claim must include this technical correlation because it is essential to the invention that the needle tip be covered in any case.

Claim 1 as granted, in Features 1.8.1 and 1.8.2, defines that "said resilient arm 103 strives towards its resting state [...] such that a part of the resilient arm is in front of the needle tip 304". This means that the needle tip is covered by the resilient arm. However, it does not mean that the needle tip is covered by the arm in any rotational position of the needle in relation to the needle tip shielding device as required by the omitted Feature 1.7.6. In other words, the claim as granted covers needle tip shielding devices having e.g. a short arm which covers the needle tip, if it is oriented in a specific position, but does not cover the needle tip when oriented in an unfavourable position. Such devices were not disclosed by the original application. Hence, features 1.8.1 and 1.8.2 cannot replace the omitted feature 1.7.6 as argued by appellant 1, and claim 1 as granted goes beyond the original disclosure in this respect.

Appellant 1 argued that from the description on page 10, lines 23-29, of the application, it was clear that the needle tip was protected in every rotational position of the needle.

What is described on page 10, lines 23-29, is, however, exactly what is missing from the granted claim, namely

the fact that "the needle tip 304 will always project [...] onto a point of the surface of the resilient arm 103 independent of the degree of rotation of the hollow needle 303 around its longitudinal axis". This feature corresponds to the "imaginary lines" feature of original claim 1. It is, however, not present in the granted claim.

Appellant 1 further argued that the imaginary lines were only mentioned in the context of the embodiment of Figure 5 and not that of Figure 7, which also formed part of the invention. Therefore, the feature of the imaginary lines was not essential to the invention and could be omitted.

Regardless of the question of whether this feature is essential to the embodiment of Figure 7, it is in fact essential to all the other embodiments which are supposed to fall under the claimed invention (see above).

Therefore, the omission of the "imaginary lines" feature (1.7.6) in granted claim 1 contravenes Article 123(2) EPC.

1.2 Omission of the "**clamping**" Feature (1.7.5)

Claim 1 required that "said resilient arm (103) [is] adapted for clamping the needle tip (304) of the hollow needle (303) extending through said hole (102) in a direction from said rear side (106) to said front side (107), when said resilient arm (103) is in said resting state". This feature has been omitted from claim 1 as granted.

This feature defines the main function of the device,

namely that the needle tip is prevented by the resilient arm from being exposed. Contrary to appellant 1's submission, the omitted feature describes not only the effect of the structural features of the claim, but also the functional relationship between the structural components. The structural features describe the geometrical relationship of the needle with the resilient arm. The omitted feature, however, defines that the resilient arm not only covers the needle tip but that it has to clamp it. Since it is possible to conceive of an arm which covers the needle tip without clamping it, the omission of Feature 1.7.5 contravenes Article 123(2) EPC.

Since Feature 1.7.5 represents the main function of the device, it is essential to the invention. In this respect, the "three-point test" referred to by appellant 1 also produces a negative result.

Therefore, the omission of the "clamping" feature (1.7.5) from claim 1 as granted contravenes Article 123(2) EPC.

1.3 Introduction of **"retaining manner"** (Feature 1.9)

The feature according to which "said outer surface 108 of said body of the needle tip shielding device 100 is contacting the inner surface of the catheter hub 200 in a retaining manner when said catheter instrument is in the ready mode" is not disclosed verbatim in the application as originally filed.

The application describes the connection of the body to the catheter hub using protuberances which make imprints in the inner surface of the catheter hub (e.g. page 8, lines 30-35; page 15, line 20 - page 16, line

29), or, alternatively, using a friction connection (page 20, lines 7-17).

These two particular connection mechanisms cannot form a basis for the general term "in a retaining manner".

It may be true that the term "in a retaining manner" encompasses all the connection mechanisms disclosed in the application, but it also encompasses other retaining mechanisms which are not disclosed in the original application. Therefore, it introduces additional subject-matter into the claim.

Appellant 1 argued that Feature 1.9 could be derived from Figures 1-3.

However, all these figures show the specific embodiment including protuberances 101. Therefore, a more generic "retaining manner" cannot be derived from the Figures either.

Therefore, the insertion of Feature 1.9 into claim 1 contravenes Article 123(2) EPC.

1.4 Introduction of an "**expansion region**" (Feature 1.5.4)

The feature according to which "the hollow needle (301) [is] provided with an expansion region (305) near the needle tip (304)" was added to claim 1 prior to grant.

Appellant 1 cited page 9, lines 4-10, of the application as originally filed as a basis for this feature. According to page 9, lines 4-5, "the hollow needle 303 is provided with an expansion region 305 near the needle tip". However, the expansion region is highly functionally linked to the size of the hole 102

in the needle tip shielding device, namely "that this region is not movable through the hole 102" (page 9, lines 9-10). Including only the expansion region in the claim while omitting its relationship with the hole represents an unallowable intermediate generalisation of the disclosed subject-matter.

Contrary to appellant 1's opinion, the expansion region is not independent of the hole diameter, but there is an inextricable link between the expansion region and the diameter of the hole. The only purpose of the expansion region is to be thicker than the diameter of the hole in order to fulfil one of the basic functions of the claimed instrument, namely to retract the needle tip shielding device from the catheter hub. This functional link cannot be ignored without extending the subject-matter of the original application.

Claim 1 as granted also encompasses those expansion regions which have a smaller diameter than the hole. Such embodiments are not disclosed in the application as originally filed. This is, contrary to the appellant 1's argument, not a question of clarity.

Therefore, the insertion of Feature 1.5.4 contravenes Article 123(2) EPC.

2. **Auxiliary Requests 1-8**

Admissibility

Appellant 2 raised an objection based on Rule 80 EPC against the filing of auxiliary requests 1-8 because appellant 1 had not demonstrated that the amendments therein were in response to any of the grounds of opposition.

However, all these requests include amendments which clearly attempt to overcome attacks based on Article 123(2) EPC.

Therefore, these auxiliary requests are admitted into the proceedings.

3. **Allowability of Auxiliary Requests 1-6**

Amendments - Article 123(2) EPC

Auxiliary requests 1-6 contravene Article 123(2) EPC because at least one of the reasons given above for the main request applies to each of these auxiliary requests.

In auxiliary requests 2, 3 and 5, the "imaginary lines" feature is missing. In auxiliary requests 1-4, the "clamping" feature is missing. In auxiliary requests 1, 3, 5 and 6, the feature of the needle tip shielding device contacting the inner surface of the catheter hub in a "retaining manner" (feature 1.9) is present. In auxiliary requests 1, 2, 5 and 6, the "expansion region" of the needle is present only in isolation from the features of the needle tip shielding device.

4. **Auxiliary Requests 7-9**

Amendments - Article 123(2) EPC

In auxiliary requests 7-9, Feature 1.9.1 has been added, according to which the needle tip shielding device is contacting the inner surface of the catheter hub "via a catheter hub contact area, wherein movement of the needle tip shielding device (100) relative the

catheter hub (200) is restricted by means of at least one protuberance (101), comprising the catheter hub contact area, located on the outer surface (108) of the needle tip shielding device (100)".

This feature replaces the words "in a retaining manner".

Appellant 1 cited page 8, lines 32-35, as a basis for this feature. This passage discloses Feature 1.9.1 verbatim. However, the same paragraph from line 35 onwards describes that the protuberances make an imprint in the inner surface of the catheter hub. The retaining function is not achieved by the protuberances alone, but only by them in cooperation with the imprints in the inner surface. This means that there is a functional link between the protuberances and the imprints. Therefore, taking the protuberances in isolation from the description represents an unallowable intermediate generalisation of the disclosed subject-matter. In particular, claim 1 of auxiliary requests 7-9 covers catheter instruments in which the protuberances do not make an imprint, but provide only frictional retention or cooperate with recesses in the inner surface of the catheter hub. Such embodiments, however, are not disclosed in the application as originally filed.

The imprints are not achieved automatically in all cases, but only if the materials of the needle tip shielding device and the catheter hub have hardness values which result in this effect. Therefore, contrary to appellant 1's opinion, the making of the imprints by the protuberances is not an effect caused by the protuberances alone, but only by them in cooperation with the catheter hub.

Therefore, claim 1 of auxiliary requests 7-9 contravenes Article 123(2) EPC.

5. Auxiliary Request 10

5.1 Amendments - Article 123(2) EPC

Appellant 2 did not raise any objection under Article 123(2) EPC to claim 1 of auxiliary request 10.

5.2 Extension of Protection - Article 123(3) EPC

Appellant 2 argued that claim 1 of auxiliary request 10 contravened Article 123(3) EPC because the scope of the claim was broadened by replacing the wording "in a retaining manner" in feature 1.9 by the feature according to which the contact between the shielding device and catheter hub is achieved "via a catheter hub contact area, wherein the movement of the needle tip shielding device (100) relative the catheter hub (200) is restricted by means of at least one protuberance (101), comprising the catheter hub contact area, located on the outer surface (108) of the needle tip shielding device (100), wherein the at least one protuberance (101) is making a corresponding imprint in, and where it contacts, the inner surface of the catheter hub (200)" (features 1.9.1 and 1.9.2).

According to appellant 2, the term "restrict" was broader than the term "retain", because "restricting" meant "holding while allowing some limited movement" whereas "retaining" meant "holding while not allowing any movement". The scope of claim 1 included embodiments where the needle tip shielding device was restricted, but not retained.

The Board notes that, in the claim, the term "in a retaining manner" has not simply been replaced by the term "in a restricting manner", but the term "restricted" is further limited by additional features, namely by the protuberances making imprints in the inner surface of the catheter hub. The effect of the cooperation of the protuberances with the imprints is that the needle tip shielding device is held in the catheter hub without any possibility of limited movement. Even assuming that the distinction between "retaining" and "restricting" as submitted by appellant 2 were correct, Features 1.9.1 and 1.9.2 taken together stipulate that the shielding device is held without allowing any movement thereof. Hence, the scope of claim 1 of auxiliary request 10 has not been extended compared with the scope of claim 1 as granted.

For these reasons, claim 1 of auxiliary request 10 meets the requirements of Article 123(3) EPC.

5.3 **Clarity - Article 84 EPC**

The claim including Feature 1.7.1.1, according to which "the needle (304) is protruding slightly past an opening of the catheter in order to facilitate penetration of the skin of a patient", meets the requirements of Article 84 EPC.

It is noted that it is standard for catheter instruments that the needle protrudes from the distal end of the catheter. In this context, it is clear to the skilled person how far the needle tip should protrude from the catheter to fulfil its purpose. The restriction to the needle protruding only "slightly" does not create any doubt about the subject-matter

claimed.

It is also well known to a skilled person that a protruding needle facilitates the insertion of the catheter tube (which has no sharp tip of its own). Therefore, the feature according to which the penetration of the skin is facilitated is a matter of course as it automatically results from the needle protruding from the opening of the catheter.

Regarding the feature according to which "said resilient arm is adapted for clamping the needle tip", it is noted that the arm being "adapted for" clamping the needle tip is a normal way to specify a structural feature of a claim more closely as being adapted for a certain function. Together with the further features in the context of claim 1, it is clear what features the resilient arm must have, e.g. in terms of material strength or elasticity, in order to meet the definition of the claim.

Therefore, claim 1 of auxiliary request 10 meets the requirements of Article 84 EPC.

5.4 **Novelty - Article 54(2) EPC**

5.4.1 **Novelty over D1**

Document D1 discloses (see Figures 1-3, 8-10)
1.1
A catheter instrument (10) comprising:
1.2
a catheter hub (14),
1.3
a needle unit (18), and
1.4

a plastic needle tip shielding device (40);
1.5
wherein said needle unit (18) is provided with connecting means (30) for connection to said catheter hub,
1.5.1 with connecting means for connection to an external device, and
1.5.2 is fixed around the rear end of a needle (20),
1.5.3 said needle unit (18) further comprising a hollow needle (20) with a needle tip (22),
1.5.4 the hollow needle (20) being provided with an expansion region (flare 23, paragraph [0041]) near the needle tip;
1.5.4.1 wherein the expansion region is a region on the hollow needle where the effective diameter is larger than elsewhere on the needle in the direction towards the rear of the hollow needle (paragraph [0041]),

1.6
wherein said catheter hub is connected to a catheter (26),
1.6.1 said needle extending longitudinally within said catheter when said catheter instrument is in a ready mode and said needle unit is connected to said catheter hub;

1.7
wherein said plastic needle tip shielding device (40) is fitted inside the catheter hub and onto said needle, when said catheter instrument is in a ready mode,
1.7.1 said needle tip shielding device (40) comprising: a body with a rear side, a front side, an outer surface connecting said rear side and said front side,
1.7.1.1 wherein the hollow needle is further extending through the catheter so that the needle tip is protruding slightly past an opening of the catheter in

order to facilitate penetration of the skin of a patient,
1.7.2 a hole (44) extending from said rear side to said front side, through which hole (44) said needle (20) runs;
1.7.2.1 whereby the increase in the effective diameter of the hollow needle by expansion region (23) has the effect that the expansion region is not movable through the hole (paragraph [0043]),
1.7.3 and a resilient arm (48) extending at an attachment point from said front side of said body,
1.7.4 wherein said resilient arm (48) has a resting state, from which it may be forced by said hollow needle (20);
1.7.5 wherein said resilient arm is adapted for clamping the needle tip of the hollow needle extending through said hole in a direction from said rear side to said front side, when said resilient arm is in said resting state,

1.8
wherein said resilient arm (48) is forced to yield free passage through said hole (44) in an axial direction of said body by said needle (20) when said catheter instrument is in the ready mode (Figures 3, 3a, 9),
1.8.1 such that said resilient arm strives toward its resting state when the hollow needle is withdrawn to a point where the needle tip passes a contact point between the resilient arm and the needle,
1.8.2 such that a part (54) of the resilient arm is in front of the needle tip (Figure 8a);

1.9 and wherein said outer surface of said body of the needle tip shielding device is contacting the inner surface of the catheter hub in a retaining manner when said catheter instrument is in the ready mode.

Feature 1.7.6

D1 does not disclose Feature **1.7.6**, according to which "any straight imaginary line extending longitudinally through said hole in the axial direction of said body coincides with said resilient arm, when said resilient arm is in said resting state".

Appellant 2 argued that "any" meant "one or more" of the imaginary lines. Figure 8a of D1 showed that at least some of the lines extending longitudinally through the hole of the body coincided with the portion (54) of the resilient arm (48), which met the definition of Feature 1.7.6.

However, as stated by appellant 2 when discussing the allowability of amendments, "any" does not mean "one or more" but means "whichever" imaginary line. It may be true that in Figure 8a of D1 some of these imaginary axial lines do coincide with the arm 48, but some of them do not.

Features 1.9.1 and 1.9.2

Contrary to appellant 2's opinion, neither of features 1.9.1 and 1.9.2 is disclosed in D1.

Appellant 2 identified "contact points" close to the reference signs 48 in Figure 3a which, however, are not described at all in D1. Corresponding contact points are missing in Figures 8a and 9. The alleged contact in Figure 3a appears rather to be an artefact in the schematic drawings of D1, all the more so since the retention of the needle shield is achieved in all embodiments by the obstructions 34 in connection with

the ends of the arms (paragraphs [0039] and [0043], Figures 3a, 8a, 9). Therefore, it cannot be derived from D1 that there is a catheter hub contact area as identified by appellant 2 which would provide a "restricting" function for the needle tip shielding device by protuberances (Feature 1.9.1).

Since no such contact area is clearly and unambiguously disclosed in D1, this document cannot disclose any imprints in the catheter hub according to Feature 1.9.2 either.

Therefore, the subject-matter of claim 1 of auxiliary request 10 is novel over D1.

5.4.2 **Novelty over D3**

Novelty over D3 was only discussed in writing.

Document D3 discloses (see Figures 1-3)
1.1
A catheter instrument comprising:
1.2
a catheter hub (2),
1.3
a needle unit (3, 4), and
1.4
a ~~plastic~~ needle tip shielding device (spring clip 5);
1.5
wherein said needle unit is provided with connecting means (Figure 1) for connection to said catheter hub,
1.5.1 with connecting means for connection to an external device (Figure 1), and
1.5.2 is fixed around the rear end of a needle (3),
1.5.3 said needle unit further comprising a hollow needle (3) with a needle tip,

1.5.4 the hollow needle (3) being provided with an expansion region (3a) near the needle tip;
1.5.4.1 wherein the expansion region is a region on the hollow needle where the effective diameter is larger than elsewhere on the needle in the direction towards the rear of the hollow needle,

1.6
wherein said catheter hub is connected to a catheter (1),
1.6.1 said needle extending longitudinally within said catheter when said catheter instrument is in a ready mode and said needle unit is connected to said catheter hub (Figure 1);

1.7
wherein said ~~plastic~~ needle tip shielding device (5) is fitted inside the catheter hub and onto said needle, when said catheter instrument is in a ready mode,
1.7.1 said needle tip shielding device (5) comprising: a body (transverse wall 5c having corners, page 2, third paragraph) with a rear side, a front side, an outer surface connecting said rear side and said front side,
1.7.1.1 wherein the hollow needle is further extending through the catheter so that the needle tip is protruding slightly past an opening of the catheter in order to facilitate penetration of the skin of a patient (Figure 1),
1.7.2 a hole (5d) extending from said rear side to said front side, through which hole (5d) said needle (3) runs;
1.7.2.1 whereby the increase in the effective diameter of the hollow needle by expansion region (3a) has the effect that the expansion region is not movable through the hole (page 2, second paragraph),

1.7.3 and a resilient arm (5a, 5b) extending at an attachment point from said front side of said body,
1.7.4 wherein said resilient arm (5a, 5b) has a resting state, from which it may be forced by said hollow needle (Figure 1);
1.7.5 wherein said resilient arm is adapted for clamping the needle tip of the hollow needle extending through said hole in a direction from said rear side to said front side, when said resilient arm is in said resting state (Figure 3), wherein
1.7.6 any straight imaginary line extending longitudinally through said hole in the axial direction of said body coincides with said resilient arm, when said resilient arm is in said resting state (Figure 3),

1.8
wherein said resilient arm is forced to yield free passage through said hole in an axial direction of said body by said needle when said catheter instrument is in the ready mode (Figure 1),
1.8.1 such that said resilient arm strives toward its resting state when the hollow needle is withdrawn to a point where the needle tip passes a contact point between the resilient arm and the needle,
1.8.2 such that a part (5e, 5f) of the resilient arm is in front of the needle tip (Figure 3);

1.9 and wherein said outer surface (corners of the transverse wall 5c) of said body of the needle tip shielding device is contacting the inner surface of the catheter hub in a retaining manner when said catheter instrument is in the ready mode (page 3, first paragraph),
1.9.2 wherein the ~~at least one protuberance is~~ corners of the transverse wall 5c are making a corresponding imprint in, and where it contacts, the inner surface of

the catheter hub (page 2, third paragraph).

As a first difference, D3 does not disclose the needle tip shielding device (spring clip 5) being made from plastics material.

Furthermore, D3 does not disclose features 1.9.1 and 1.9.2 according to which said outer surface of said body of the needle tip shielding device is contacting the inner surface of the catheter hub
[1.9.1] via a catheter hub contact area, wherein movement of the needle tip shielding device relative the catheter hub is restricted by means of at least one protuberance, comprising the catheter hub contact area, located on the outer surface of the needle tip shielding device,
[1.9.2] wherein the at least one protuberance is making a corresponding imprint in, and where it contacts, the inner surface of the catheter hub.

Appellant 2 argued that the corners of the transverse wall 5c of the needle tip shielding device of D3 represented protuberances which, according to Figure 2 and page 3, last paragraph, make imprints into the inner surface of the catheter hub.

However, these corners cannot be regarded as protuberances being located on the outer surface of the needle tip shielding device, because in terms of claim 1 the outer surface of the spring clip is the rectangular rim of the transverse wall 5c which comprises the corners as well. Hence, no protuberances extend from this rectangular rim.

Therefore, the subject-matter of claim 1 of auxiliary

request 10 is novel over D3.

5.5 **Inventive Step - Article 56 EPC**

5.5.1 **Starting from D1, in Combination with the Common General Knowledge**

As stated above, the subject-matter of claim 1 differs from the catheter instrument of D1 in Features 1.7.6, 1.9.1 and 1.9.2.

The protuberances making an imprint on the inner surface of the catheter hub (Features 1.9.1, 1.9.2) have the effect that the needle tip shielding device is held inside the catheter hub during retraction of the needle. In the catheter instrument of D1, this is achieved by the obstruction 34 in connection with the ends of the arms being forced outwardly (paragraphs [0039] and [0043], Figures 3a, 8a, 9).

When starting from D1, the problem to be solved is regarded as the provision of an alternative retention mechanism for the needle tip shielding device.

D1 on its own does not give any indication of an alternative retaining mechanism. The "contact points" which appellant 2 identifies close to the reference signs 48 in Figure 3a are not described, and it is pure speculation that they have any technical function in the device at all. Appellant 2's argument that, for proper protection of the needle, the material of the needle tip shielding device must be relatively rigid, hence inevitably making imprints on the inner surface of the catheter hub, is mere speculation as well.

Therefore, it cannot be regarded either as obvious or

as trivial to provide a protuberance on the outer surface of the needle tip shielding device which makes an imprint on the inner surface of the catheter hub for restricting the movement of the needle tip shielding device.

5.5.2 **Starting from D3, in Combination with the Common General Knowledge**

The subject-matter of claim 1 differs from the catheter instrument of D3 in Features 1.9.1 and 1.9.2. The problem to be solved is regarded as the provision of an alternative solution for the retention of the needle tip shielding device.

Spring clip 5 represents the needle tip shielding device in D3. It is retained by the corners of its transverse wall 5c which are hooked on the inner wall of the catheter hub 2.

In order to arrive at the subject-matter of claim 1, the skilled person would have to change the shape of the transverse wall in order to create an outer surface on which protuberances which are able to interact with the inner wall of the catheter hub may be positioned.

On the one hand, D3 does not give any indication that the skilled person could provide such an alternative solution; on the other hand, the above modifications do not represent a standard design option which could be regarded as obvious.

Appellant 2 argued that the corners of the transverse wall had exactly the same function as the protuberances in the claimed instrument. This, however, underlines that the skilled person would not have had any

motivation to modify the device of D3 only to arrive at a device having the same function.

Therefore, the subject-matter of claim 1 of auxiliary request 10 is not obvious in view of D3 alone.

5.5.3 **Starting from D1, in Combination with D3**

As stated above under point 5.5.1, when starting from D1, the problem to be solved is regarded as the provision of an alternative retention mechanism for the needle tip shielding device.

D3 teaches that an alternative retention mechanism may be provided by a needle tip shielding device having a body formed by a rectangular transverse wall having corners which can hook into the inner surface of the catheter hub. However, as stated above under point 5.4.2, this solution is different from the one stipulated in Features 1.9.1 and 1.9.2.

Hence, even if the skilled person were to apply the teaching of D3 to the device of D1, they would not arrive at the claimed solution.

Therefore, the subject-matter of claim 1 of auxiliary request 10 is not obvious when starting from D1 in combination with D3.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated