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Datasheet for the decision of 10 May 2021

Case Number: T 1771/17 - 3.2.02

Application Number: 11710636.9

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IPC: A61M5/162, A61M5/32, A61M25/06

Language of the proceedings: EN

Title of invention:
TIP PROTECTOR FOR A SAFETY CATHETER

Patent Proprietor:
Smiths Medical ASD, Inc.

Opponent:
Becton, Dickinson and Company

Headword:

Relevant legal provisions:
EPC Art. 54, 123(2)
RPBA 2020 Art. 13(2)

Keyword:
Novelty
Amendments - added subject-matter
Amendment to appeal case - new objection not admitted - claim amendment admitted

Decisions cited:

Catchword:

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Case Number: T 1771/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 10 May 2021

Appellant: (Opponent)	Becton, Dickinson and Company One Becton Drive Franklin Lakes, New Jersey 07417-1880 (US)
Representative:	Herr, Jochen Baker & McKenzie Theatinerstraße 23 80333 München (DE)
Respondent: (Patent Proprietor)	Smiths Medical ASD, Inc. 160 Weymouth Street Rockland, MA 02370 (US)
Representative:	Kotitschke, Ralf Thomas Maiwald Patentanwalts- und Rechtsanwaltsgesellschaft mbH Elisenhof Elisenstraße 3 80335 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 9 June 2017 concerning maintenance of the European Patent No. 2575946 in amended form.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	C. Schmidt

Summary of Facts and Submissions

I. The opponent lodged an appeal against the Opposition Division's decision to maintain the contested patent in amended form.

II. Oral proceedings before the Board were held by videoconference on 10 May 2021.

III. The respondent (proprietor) requested as a main request that the appeal be dismissed and that the patent be maintained in the form allowed by the appealed decision (main request filed with the letter dated 9 October 2015) or, as an auxiliary measure, that the patent be maintained on the basis of the first or second auxiliary request; auxiliary request 2A or 2B; the third auxiliary request; auxiliary request 3A; or one of the fourth to sixth auxiliary requests (with the first to fifth auxiliary requests filed with the letter dated 9 October 2015; auxiliary requests 2A and 3A and the sixth auxiliary request filed with the letter dated 25 January 2017; and auxiliary request 2B filed with the letter dated 7 April 2021).

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

V. Claim 1 of the **main request** reads as follows (feature numbering in bold as used by the parties):

1. *A safety catheter, comprising*
2. *a catheter hub (16) and*
3. *a catheter tube (18)*
3.1 *extending distally thereof;*

4. *a needle hub (20) and*

5. *a needle cannula (22)*

5.1 *extending distally thereof,*

5.2 *the needle cannula (22) having a distal tip (24); and*

6. *a tip protector (30) for shielding the distal tip (24), comprising*

6.1 *an outer member (34) including*

6.1.1 *at least one flexible tab (130) configured to releasably engage with the interior of the catheter hub (16) and to release therefrom on radially inward movement of the flexible tab (130), and*

6.2 *an inner member (32)*

6.2.1 *having a portion (64) to impede radially inward movement of the flexible tab (130) when the inner member portion (64) is disposed axially adjacent the flexible tab (130),*

7. *the needle cannula (22) being received in the inner and outer members (34, 32),*

6.2.2 *the inner member (32) configured to be axially shiftable relative to the outer member (34) between*

6.2.2.1 *a first position wherein the distal tip (24) extends distally of the tip protector (38) and the inner member portion (64) is disposed axially adjacent the flexible tab (130) so as to impede release of the outer member (34), and*

6.2.2.2 *a second position wherein the inner member (32) is axially shifted such that the inner member portion (64) is no longer disposed axially adjacent the flexible tab (130) such that the inner member (32) no longer impedes*

release of the outer member (34) from the catheter hub (16),

6.2.3 *the inner member (32) including a central axis (44) and*
6.2.4 *at least one arm (48a)*

and characterized in that

6.2.4.1 *the arm (48a) is biased radially outwardly relative to the central axis (44),*
and
8. *movement of the arm (48a) is constrained by the outer member (34) when the inner member (32) is in the first position.*

VI. Claim 1 of the **first auxiliary request** differs from claim 1 of the main request by feature 8 being amended as follows (amendments highlighted by the Board):

8. *radial outward movement of the arm (48a) is constrained by the outer member (34) when the inner member (32) is in the first position.*

VII. Claim 1 of the **second auxiliary request** differs from claim 1 of the main request by features 5.2 and 6.2.4.1 being amended as follows (amendments highlighted by the Board):

5.2 *the needle cannula (22) having a shaft (23) with an outer surface (248) and a distal tip (24);*

6.2.4.1 *the arm (48a) is biased radially outwardly relative to the central axis (44) such that an inner surface of the arm (48a) is slightly spaced from the*

outer surface (248) of the needle shaft (23) when the inner member (32) is in the first position,

VIII. Claim 1 of **auxiliary request 2A** differs from claim 1 of the second auxiliary request in that the word "slightly" has been deleted in feature 6.2.4.1.

IX. Claim 1 of **auxiliary request 2B** differs from claim 1 of auxiliary request 2A in that the indefinite article "an" in the expression "an inner surface of the arm" in feature 6.2.4.1 has been replaced by the definite article "the".

X. The following document is relevant to the present decision:
D5: WO 2009/139951 A1

XI. The appellant's arguments, as far as relevant for the present decision, can be summarised as follows.

(a) Main request and first auxiliary request - Novelty over D5

The subject-matter of claim 1 of the main request was not new over D5 even according to the proprietor's own interpretation of the outward bias.

In the configurations shown in Figures 1-3, features 6.2.4.1 and 8 resulted from the "pinching interaction" of the arms 28, 28a with the safety clip contacts 46, 46a (paragraph [0036]) which deformed the arms inwardly and thus made them biased outwardly.

Moreover, the interlock fingers 44 were naturally inwardly biased. Once the inner member had been moved sufficiently in the proximal direction in the

configurations shown in Figures 4-5, the interlock fingers relaxed inwardly and thus exerted an inward pressure onto the distal ends of the arms 28, 28a, causing these arms to be outwardly biased (paragraph [0039]). Features 6.2.4.1 and 8 were therefore also disclosed for those configurations.

The same considerations applied to the first auxiliary request.

(b) Second auxiliary request and auxiliary request 2A - Added subject-matter

From paragraph [0085] of the description as originally filed, it was apparent that the entire inner surface of the arm was slightly spaced from the outer surface of the needle shaft. By contrast, claim 1 referred to "an inner surface" of the arm. The use of the indefinite article "an" suggested that there might be multiple inner surfaces, one of which was spaced from the needle shaft's outer surface whereas other inner surfaces might not be. This constituted new information extending beyond the original disclosure in breach of Article 123(2) EPC.

(c) Auxiliary request 2B

Admittance

Auxiliary request 2B had been filed after notification of the summons to oral proceedings, hence it was late filed. The issue addressed by this request, namely with respect to the wording "an inner surface", had been mentioned already in the first-instance proceedings (point 6 of the Opposition Division's preliminary opinion accompanying the summons to attend oral

proceedings dated 9 September 2016). The respondent could and should have therefore filed this request earlier. However, the respondent did not provide any cogent reasons why it had not.

Moreover, compared to auxiliary request 2, the word "slightly" had been deleted. This omission prima facie introduced a new problem of added subject-matter.

In addition, the amendments in claim 1 raised new issues which could require a further search to be carried out by the appellant and thus that the oral proceedings be adjourned.

Auxiliary request 2B should therefore not be admitted into the proceedings pursuant to Article 13(2) RPBA 2020.

Added subject-matter

In claim 1, the word "slightly" had been omitted from the original disclosure of paragraph [0085] of the description as filed. The requirements of Article 123(2) EPC were therefore still not met by amended claim 1.

Novelty over D5

If auxiliary request 2B were admitted into the proceedings, the appellant should be given the opportunity to raise objections against this request. In particular, the subject-matter of claim 1 was not new over D5.

XII. The respondent's arguments, as far as relevant for the present decision, can be summarised as follows.

(a) Main request and first auxiliary request

D5 disclosed neither feature 6.2.4.1 nor feature 8 of claim 1 of the main request. Hence, the subject-matter of claim 1 was new.

In the configurations shown in Figures 1-3, the elastic arms 28, 28a were indeed moved radially outwardly away from their shielding position (shown in Figure 5) by the needle shaft 12 which interacted with the flaps 30, 30a formed at the free ends of the arms. This made the arms biased inwardly, not outwardly as required by claim 1. At most the arm portions adjacent to the inner member base 36 ("arm shoulders"), but not the whole arms as required by claim 1, were outwardly biased by the interlock fingers 44, 44a.

Radial inward movement of the arms 28, 28a to their shielding position (due to their inward bias) was possible once the needle shaft had been moved proximally far enough and did not block the path of the arms anymore. In the end configuration of Figure 5, there was no stress in the arms, hence no outward bias. By contrast, in the patent in suit, the arm was moved radially inwardly to a shielding position against its outward bias due to a camming interaction with the outer member.

The same considerations applied to the first auxiliary request.

(b) Second auxiliary request and auxiliary request 2A - Added subject-matter

Amended feature 6.2.4.1 of claim 1 of the second auxiliary request was supported by paragraphs [0085] and [0050] of the description as originally filed. The requirements of Article 123(2) EPC were therefore met. The expression "an inner surface" instead of "the inner surface" had been used to avoid a lack of clarity objection due to the lack of an antecedent basis for the inner surface in claim 1. Using indefinite articles was common practice in patent drafting.

(c) Auxiliary request 2B

Admittance

The objection under Article 123(2) EPC with respect to the expression "an inner surface" had been mentioned for the first time by the Board in its preliminary opinion. The respondent had immediately reacted by filing auxiliary request 2B based on auxiliary request 2A already on file. The respondent had no reason to file this request earlier.

The only amendment carried out in auxiliary request 2B compared to auxiliary request 2A was the replacement of the article "an" by "the", which clearly addressed the objection.

The word "slightly" had already been stricken out in auxiliary request 2A. Hence, no new issues were raised by auxiliary request 2B. Auxiliary request 2B was therefore to be admitted into the proceedings.

Added subject-matter

Whether the inner surface of the arm was "slightly" spaced from the outer surface of the needle shaft was

irrelevant, especially in view of the tiny transverse dimensions of the catheter. The omission of the term "slightly" did therefore not contravene Article 123(2) EPC.

Novelty over D5

Apart from the replacement of the article, auxiliary request 2B was identical to auxiliary request 2A previously on file. The appellant had not raised any objection against auxiliary request 2A or any other auxiliary request. The novelty objection raised against auxiliary request 2B was therefore late filed and should have been raised earlier. It should therefore not be admitted into the proceedings.

Reasons for the Decision

1. **The invention**

1.1 The patent in suit relates to a tip protector (30) for a safety catheter (12) including a catheter hub (16) with a catheter tube (18) extending distally from it, and a needle cannula (22) extending through the catheter tube to facilitate intravenous insertion of the catheter tube (Figure 1, paragraph [0016]).

The tip protector is initially positioned substantially within the catheter hub and around the needle cannula. Once the latter has been withdrawn from the catheter hub, the tip protector is released from the catheter hub and shields the distal tip of the needle cannula to prevent accidental needle sticks (paragraph [0002]).

1.2 To this aim, the tip protector comprises an inner member (32) surrounding the needle cannula (22) and an outer member (34) cooperating with the catheter hub (16). The inner member is axially movable relative to the outer member between a first position in which the outer member is secured to the catheter hub by a flexible tab (130) engaging a retention groove formed on the catheter hub's inner surface (Figure 16A reproduced below) and a second position in which the outer member is released when the flexible tab is allowed to move inwardly (Figures 18A-B). The flexible tab's movement is controlled by an arm (48a) of the inner member which impedes radial inward movement of the tab in the first position but not in the second position.

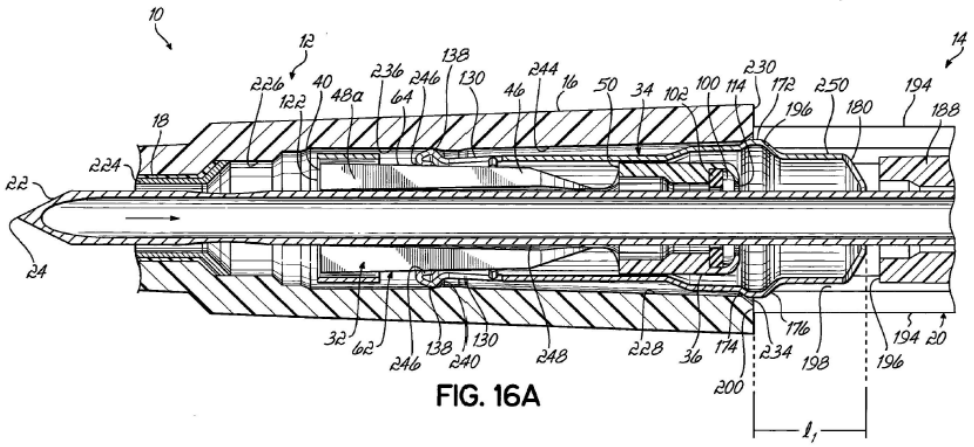


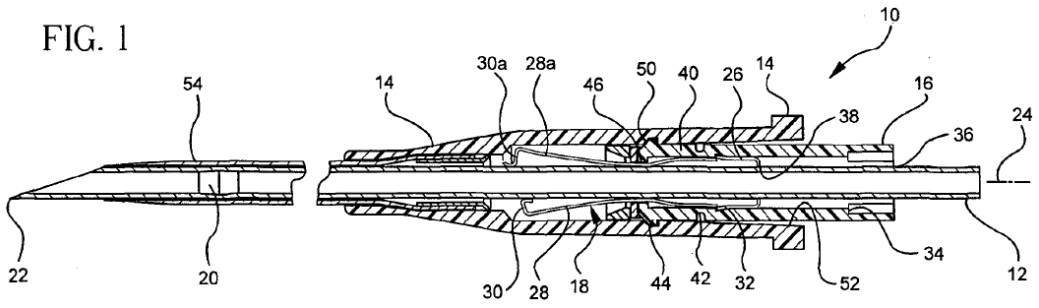
FIG. 16A

1.3 In accordance with the invention, the arm (48a) is "biased radially outwardly" relative to the central axis to avoid frictional forces between the needle shaft and the tip protector as the needle shaft is being withdrawn proximally (paragraphs [0013], [0055]).

2. **Main request - Novelty over D5**

2.1 It is common ground that D5 discloses the following features of claim 1 of the main request (see Figure 1 reproduced below):

FIG. 1



1. *A safety catheter* (10), *comprising*
2. *a catheter hub* (catheter adapter 14; paragraph [0027]) *and*
3. *a catheter tube* (catheter 54; paragraph [0035])
3.1 *extending distally thereof* (Figure 5);
4. *a needle hub* (not shown, but implicit) and
5. *a needle cannula* (needle 12)
5.1 *extending distally thereof* (implicit),
5.2 *the needle cannula* (12) *having a distal tip* (22); *and*
6 *a tip protector* (sleeve 16, safety clip 18) *for shielding the distal tip* (paragraph [0028]), *comprising*
6.1 *an outer member* (sleeve 16) *including*
6.1.1 *at least one flexible tab* (interlock flange 40 comprising an interlock finger 44; paragraphs [0032]-[0033]) *configured to releasably engage with the interior of the catheter hub and to release therefrom on radially inward movement of the flexible tab* (paragraphs [0034], [0036]), *and*
6.2 *an inner member* (safety clip 18; paragraph [0028])
6.2.1 *having a portion* (flexible arm 28a) *to impede radially inward movement of the flexible tab when the inner member portion is disposed axially adjacent the flexible tab* (Figures 1-3; paragraphs [0034], [0036]),
7. *the needle cannula* (12) *being received in the inner and outer member* (Figures 1-5),
6.2.2 *the inner member* (18) *configured to be axially shiftable relative to the outer member* (16) *between*

6.2.2.1 *a first position* (any of the positions shown in Figures 1, 2; paragraphs [0034], [0036]) *wherein the distal tip* (22) *extends distally of the tip protector and the inner member portion* (in particular, distally of arm 28a) *is disposed axially adjacent the flexible tab* (40) *so as to impede release of the outer member* (16), *and*
6.2.2.2 *a second position* (position shown in Figures 4, 5; paragraph [0039]) *wherein the inner member* (18) *is axially shifted such that the inner member portion* (arm 28a) *is no longer disposed axially adjacent the flexible tab* (40) *such that the inner member* (18) *no longer impedes release of the outer member* (16) *from the catheter hub* (14),
6.2.3 *the inner member* (18) *including a central axis* (longitudinal axis) *and*
6.2.4 *at least one arm* (arm 28a).

In dispute between the parties is whether D5 further discloses the remaining features 6.2.4.1 and 8, in particular whether the arm 28a is "biased radially outwardly".

2.2 Outward bias in the context of the patent in suit is described in paragraph [0055]:

"*In one embodiment, the arms 48a, 48b may be configured to be biased generally radially outward relative to central axis 44. For example, the outer member 34 may be configured to constrain the arms 48a, 48b (i.e., but for the outer member 34, the arms 48a, 48b would move further apart from one another).*"

In other terms, *outward* bias may result from an *inward* constraint applied by the outer member on the arm. In the absence of the outer member, the arm would move

radially *outwardly*. This interpretation corresponds to the interpretation defended by the respondent.

As further disclosed in paragraph [0055], outward bias is generated by the application of the inward constraint irrespective of whether the arm engages the needle shaft (lines 20-23: "*in one embodiment, the inner surface 54 of the arms 48a, 48b may be configured to engage the outer surface 248 of the needle shaft 23.*") or not (lines 23-26: "*In an alternative embodiment, however, the inner surface 54 of arms 48a, 48b may be slightly spaced from the outer surface 248 of the needle shaft 23.*").

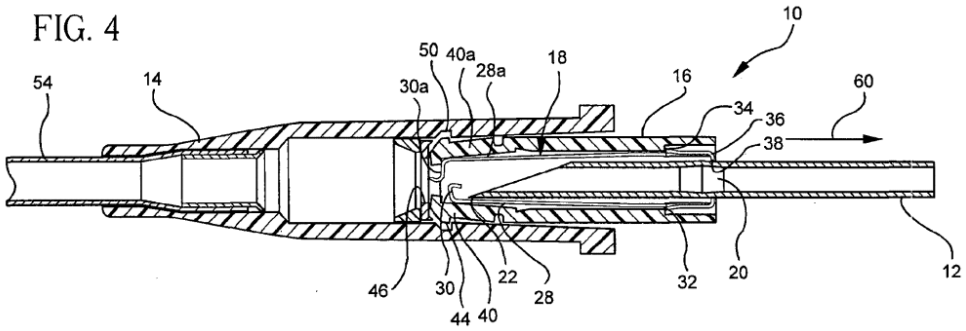
2.3 In the configurations illustrated in Figures 1 and 2 of D5 (which both correspond to the first position defined in claim 1), the arm is engaged by an inward extension of the interlock flange (the safety clip contact 46) in a "pinching interaction" (paragraph [0036]). This enables the interlock flange 40 to be pushed outwardly to lock the sleeve 16 within the catheter adapter. Conversely, the arm is subjected to an inward constraint exerted by the safety clip contact which causes the flexible arm to inward deform from the inner member's base 26. Hence, in the first configuration, the arm is "biased radially outwardly" in the way described above. As the safety clip contact belongs to the outer member, it also results that feature 8 is disclosed.

As mentioned above (see especially the last paragraph of point 2.2), it is irrelevant that the arm engages the needle shaft at its distal flap 30a, contrary to the respondent's argument. Besides, the respondent has conceded that the arm's portion adjacent to the inner member's base was itself outwardly biased. In the

Board's view, this is sufficient to make the arm "radially outwardly biased" as required by claim 1.

2.4 In the configurations illustrated in Figures 4 and 5 (which correspond to the second position defined in claim 1, see Figure 4 reproduced below), the safety clip has translated proximally to such an extent that the interlock flange (numbered 40a in Figure 4) "relaxes inwardly" (paragraph [0039]).

FIG. 4



As consistently shown in Figures 4 and 5, the interlock flange in relaxing engages the arm's distal end. This was not disputed by the respondent. The interlock flange thus exerts an inward constraint on the flexible arm and causes it to be "radially outwardly biased". While this constraint may be smaller than the constraint resulting from the "pinching interaction" with the safety clip contact in the first position, the flexible arm is not in a zero-stress state as argued by the respondent. In this respect, the Board notes that the outward bias described in paragraph [0055] of the patent in suit does not rely on the existence of a minimum inward constraint.

In addition, the fact that the arm's distal end moves radially inwardly once the needle shaft has been moved proximally far enough and does not block the path of the arm anymore (i.e. once the "pinching interaction" ceases to be exerted) is irrelevant. This reflects the shielding function of the arm, as brought forward by

the respondent, but does not preclude the flexible arm in the second position from being subjected to an inward constraint by the interlock flange as discussed above.

2.5 In the configuration illustrated in Figure 3, intermediate between the first and second positions, the same "pinching interaction" takes place between the arm and the safety clip contact as in the first position.

2.6 It results from the above that the arm is "radially outwardly biased" in all of the configurations of the tip protector, as required by feature 6.2.4.1.

The Board therefore concludes that the subject-matter of claim 1 is not new over D5.

3. **First auxiliary request - Novelty over D5**

In the configurations illustrated in Figures 1 and 2 of D5 (which correspond to the first position defined in claim 1) discussed in point 2.3 above, the arm would move radially outwardly in the absence of the safety clip contact. The safety clip contact (which is part of the outer member) therefore constrains *radial outward movement* of the arm.

It follows that feature 8 amended according to the first auxiliary request is also disclosed in D5. The subject-matter of claim 1 of this request is therefore not new over D5. This was not contested by the respondent.

4. **Second auxiliary request and auxiliary request 2A - Added subject-matter**

4.1 Feature 6.2.4.1 in claim 1 of the second auxiliary request has been amended to incorporate the wording "such that an inner surface of the arm (48a) is slightly spaced from the outer surface (248) of the needle shaft (23) when the inner member (32) is in the first position".

Most of this wording finds support in the penultimate sentence of paragraph [0085] of the description as originally filed, as brought forward by the respondent. However, this sentence refers to "the" inner surface of the arm. From the use of the definite article "the", the person skilled in the art would have inferred that the *entire* inner surface of the arm was slightly spaced from the outer surface of the needle shaft. This finding is in line with the effect achieved by this arrangement, namely to reduce the drag force on the needle cannula (last sentence of paragraph [0085]), and cannot be changed by the fact that paragraph [0050], in a different context and without any reference to a spacing from the needle shaft, mentions "an inner surface" of arm 48a.

By contrast, the choice of the articles used in claim 1, which refers to "an" inner surface of the arm but to "the" outer surface of the needle shaft, suggests that multiple inner surfaces of the arm might be defined, one of which is slightly spaced from the needle shaft's outer surface whereas other inner surfaces may not be. In other words, the entire inner surface of the arm may not necessarily be spaced from the needle shaft's outer surface.

Contrary to the respondent's argument, the subject-matter of claim 1 of the second auxiliary request is

therefore not directly and unambiguously derivable from the original disclosure, contrary to the requirements of Article 123(2) EPC.

4.2 Since claim 1 of auxiliary request 2A uses the same combination of articles, the objection also applies to this request.

5. **Auxiliary request 2B**

5.1 *Admittance of the request*

Auxiliary request 2B was filed after the summons had been notified and in reaction to the Board's communication indicating its preliminary opinion that the expression "an inner surface of the arm" in the second auxiliary request appeared to be in breach of Article 123(2) EPC. The admission of this request into the proceedings is therefore subject of Article 13(2) RPBA 2020.

It is irrelevant whether the Opposition Division's preliminary opinion might have referred to this expression, as brought forward by the appellant, because this preliminary opinion was not reflected in the contested decision and is therefore not part of the appeal proceedings. Hence, the objection under Article 123(2) EPC was mentioned as such for the first time in the appeal proceedings in the Board's communication, and the respondent had no reason to file auxiliary request 2B earlier.

Moreover, auxiliary request 2B is based on auxiliary request 2A which was already on file and against which no objection was raised by the appellant in the written procedure. The only amendment carried out consisted in

the replacement of the article "an" by "the", which clearly addressed the objection. The word "slightly" had already been stricken out in auxiliary request 2A. Therefore, no new issues were raised by auxiliary request 2B. Hence, consideration of this request did not require an adjournment of the oral proceedings.

For these reasons, although auxiliary request 2B had been filed after notification of the summons, the Board considered that exceptional circumstances justifying its admission into the proceedings pursuant to Article 13(2) RPBA 2020 were given.

5.2 *Added subject-matter*

With the replacement of the article "an" by "the", amended feature 6.2.4.1 clearly specifies that the entire inner surface of the arm is spaced from the needle shaft's outer surface, as originally disclosed in paragraph [0085] of the description as filed.

It is true that claim 1 does not, contrary to the aforementioned paragraph, explicitly recite that the arm's inner surface is "slightly" spaced from the needle shaft's outer surface. However, this is irrelevant, especially in view of the function achieved by the spacing, namely to reduce the drag force on the needle cannula as it is being pulled proximally (see last sentence of paragraph [0085]). Moreover, given the nature of the device claimed, a safety catheter, any spacing within the internal mechanism of the tip protector is necessarily small. Hence, a "slight" spacing is implicit in the claim. The omission of the term "slightly" does therefore not contravene Article 123(2) EPC.

The Board concludes that auxiliary request 2B meets the requirements of Article 123(2) EPC.

5.3 *Admittance of the appellant's novelty objection over D5*

The appellant raised a novelty objection in view of D5 against claim 1 of auxiliary request 2B. The respondent contested the admittance of this objection.

As indicated in point 5.1 above, claim 1 of auxiliary request 2B differs from claim 1 of auxiliary request 2A only by the replacement of the indefinite article "an" with "the" so that amended feature 6.2.4.1 refers to "the inner surface of the arm" instead of "an inner surface of the arm".

It follows that any novelty objection raised against claim 1 of auxiliary request 2B would apply equally to claim 1 of auxiliary request 2A.

The appellant, which in the written procedure did not raise any objection against auxiliary request 2A (or against the other auxiliary requests on file), did not provide any cogent reasons why the novelty objection raised against auxiliary request 2B had not been raised earlier against auxiliary request 2A.

Consequently, the Board decided not to take into account the appellant's novelty objection against auxiliary request 2B in accordance with Article 13(2) RPBA 2020.

5.4 *Further objections*

The appellant had no further objections against auxiliary request 2B. The Board does not see any reason

against the maintenance of the patent on the basis of this set of claims either.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division with the order to maintain the patent with claims 1 to 33 of auxiliary request 2B filed with the letter dated 7 April 2021, and a description and drawings to be adapted.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated