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**Datasheet for the decision
of 2 August 2022**

Case Number: T 0629/19 - 3.2.02

Application Number: 11760268.0

Publication Number: 2549918

IPC: A61B5/00

Language of the proceedings: EN

Title of invention:

MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING
MEDICAL DEVICES

Patent Proprietor:

Abbott Diabetes Care, Inc.

Opponent:

Dexcom, Inc.

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 83, 84, 123(2)

RPBA Art. 12(4)

Keyword:

Sufficiency of disclosure - (yes)
Amendments - extension beyond the content of the application
as filed (no)
Novelty - (yes)
Inventive step - (yes)
Claims - clarity in view of the description - (yes)
Late-filed facts - objection withdrawn before the opposition
division - admitted (no)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0629/19 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 2 August 2022

Appellant: Abbott Diabetes Care, Inc.
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
13 December 2018 concerning the maintenance of
European Patent No. 2549918 in amended form**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: D. Ceccarelli
W. Sekretaruk

Summary of Facts and Submissions

I. The patent proprietor and the opponent appealed against the Opposition Division's decision that, account being taken of the amendments made by the patent proprietor according to auxiliary request 1 during the opposition proceedings, the European patent and the invention to which it relates met the requirements of the EPC.

The patent was opposed on the grounds of insufficient disclosure, extension of subject-matter, lack of novelty and lack of inventive step.

II. Oral proceedings took place on 2 August 2022.

As the main request, the appellant/patent proprietor ("the proprietor") requested that the decision under appeal be set aside and that the patent be maintained in amended form in the following version:

- claims 1 to 12, filed as auxiliary request 3 on 23 April 2019
- description, pages 2, 3 and 31, filed during oral proceedings on 2 August 2022 (labelled "description - main request") and pages 4 to 30 of the patent specification
- drawings of the patent specification.

As an auxiliary measure, the proprietor requested that the patent be maintained on the basis of one of auxiliary requests 1, 2, 4 or 5, filed on 23 April 2019, and 6 to 9, filed on 5 September 2019.

The appellant/opponent ("the opponent") requested that

the decision under appeal be set aside and that the patent be revoked.

III. The following documents are relevant to this decision:

D1a: US 2009/0124979 A1

D3a: US 2005/0101912 A1

D4: US 7,407,493 B2

D5: US 6,102,896 A

D26: US 2002/0022855 A1

IV. Independent claims 1 and 8 of the main request read as follows.

"1. An apparatus (200) (300) (400) (2400) (2500) (2700) (3700) for inserting a medical device (14) into the skin of a subject, which comprises:

 a sheath (242) (342) (442) (2512) (2708) (3708) defining a distal surface for placement on a skin surface;

 a device support (430) (3702) movable between a proximal position and a distal position that is closer to the skin surface, and adapted to support a medical device;

 a sharp support movable between the proximal position and the distal position that is closer to the skin surface and adapted to support a sharp (224) (324) (424) (2404) (2550) for inserting the medical device under the skin surface and extending through a portion of the device support;

 a handle (302) (402) (2502) (2702) (3702) movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from the proximal position to the distal position to insert the sharp under the skin surface; and

a driver (246) (346) (446) (2406) (2544) for advancing the sharp support towards the proximal position when the sharp support reaches the distal position;
wherein the device support (430) (3702) includes a first engagement member (474) (475) for releasably coupling the device support to the sharp support (428) (434) (436) and a second engagement member (3727) (3732) for engaging the medical device;
and further characterised in that the sheath (242) (342) (442) (2512) (2708) (3708) has at least one biased retention feature (2440) (2518) (2726) (3726);
and

advancing the handle (302) (402) (2502) (2702) (3702) from the proximal position to the distal position comprises applying a minimum force to the handle overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath, and a force applied to the handle moves the sheath into the handle and moves the medical device from the proximal position to the distal position and inserts the sharp under the skin surface."

"8. A method for using a medical device (14) comprising:

providing an apparatus comprising a sheath (242) (342) (442) (2512) (2708) (3708) defining a distal surface, a device support (430) (3702) adapted to support a medical device (14), a sharp support (428) (434) (436) adapted to support a sharp (224) (324) (424) (2404) (2550) extending through a portion of the device support, a handle (302) (402) (2502) (2702) (3702) movable relative to the sheath, and a driver (246) (346) (446) (2406) (2544) for displacing the sharp support;

disposing the distal surface of the sheath on a

skin surface (S);
displacing the handle in a first longitudinal direction such that the sheath moves into the handle;
displacing the sharp support in the first longitudinal direction, the sharp support displacing the sharp and the medical device;
inserting the sharp and the medical device under the skin surface;
releasing the driver; and
displacing the sharp in a second longitudinal direction by the driver;
characterised in that the sheath (242) (342) (442) (2512) (2708) (3708) has at least one biased retention feature (2440) (2518) (2726) (3726); and displacing the handle (302) (402) (2502) (2702) (3702) in the first longitudinal direction comprises applying a minimum force to the handle overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath, and displacing the handle in the first longitudinal direction displaces the device support in the first longitudinal direction and inserts the sharp and the medical device under the skin surface."

Dependent claims 2, 9 and 10 read as follows.

"2. The apparatus of claim 1, wherein the handle and sheath comprise an interlocking configuration (328) (351) which prevents relative movement of the handle with respect to the sheath which is overcome by a force applied to the handle."

"9. The method of claim 8, having one or more of the following:

wherein the first longitudinal direction is from a proximal to distal position, and the second

longitudinal direction is from a distal to proximal position,

wherein the sharp (224) (324) (424) (2404) (2550) is displaced towards the proximal direction when the sharp support (428) (434) (436) reaches the distal position,

wherein the handle (302) (402) (2502) (2702) (3702) is maintained in a distal position when the sharp support is displaced to the proximal position,

wherein displacing the handle in the first longitudinal direction comprises overcoming an interlocking configuration between the handle and the sheath (242) (342) (442) (2512) (2708) (3708) by applying a predetermined force."

"10. The method of claims 8 or 9, wherein delivering the medical device (14) to the subject comprises releasing the medical device from the device support (430) (3702), preferably wherein releasing the medical device from the device support comprises allowing one or more movable arms (3762) (3762') on the device support to displace radially outwardly."

V. The opponent's arguments of relevance to the decision are summarised as follows.

Sufficiency of disclosure

Claim 1 of the main request recited "applying a minimum force to the handle overcome the at least one biased retention feature" and "a force applied to the handle moves the sheath into the handle". The general references to a "minimum force" and a "force" were too vague to enable a person skilled in the art to carry out the claimed invention. There were many types of forces such as a compressive force, a tensile force, a

frictional force, a rotational force etc., but the claim did not specify which kind of force was required for the invention to work. The claim did not specify the direction of application of the force, nor did it quantify it. It was directed to an unreasonable range of non-disclosed options and its subject-matter could not be carried out over its whole scope.

Extension of subject-matter

The feature in claim 1 "a force applied to the handle moves the sheath into the handle and moves the medical device from the proximal position to the distal position and inserts the sharp under the skin surface" included added matter.

Paragraph [00152] of the application as filed disclosed a manual force. However the claim did not specify that the force was a manual one. The person skilled in the art could not derive from this paragraph either that the same force that was transferred to the sharp and/or support structure also moved the handle into the sheath. A mere transfer of force from an actuator did not necessarily lead to insertion of the sharp under the skin surface. Claim 1 made no reference to the coupling between the sharp and/or the support structure, and therefore introduced previously undisclosed possibilities in which no such coupling was present.

Furthermore, claim 1 referred to a minimum force and a separate force for moving the handle. There was no disclosure of such a combination of forces in the application as filed. All mentions of "force" in the application as filed were in the context of a "downward" force. This omission of the definition of a

downward force in claim 1 added subject-matter.

The feature of claim 2 "the handle and sheath comprise an interlocking configuration which prevents relative movement of the handle with respect to the sheath which is overcome by a force on the handle" had not been disclosed in combination with the sheath having at least one biased retention feature, and with the advancement of the handle from the proximal position to the distal position comprising applying a minimum force to the handle to overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath.

Claim 9 included a reference to one or more optional features. However, whilst there was basis for each of the individual features in the application as filed, there was insufficient support for the many combinations of features that the wording "or more" provided. Whilst the Opposition Division had noted that certain passages in the application as filed provided basis for a combination of all of the features listed in claim 9, there was still no support for sub-sets of those features. A similar issue arose for claim 10.

Novelty

The subject-matter of claims 1 and 8 was not novel in view of D1a. This document disclosed an apparatus for inserting a medical device into the skin of a subject with a biased retention feature as claimed in the form of an insertion spring 108, or the combination of a sleeve-engaging feet 198 and an upper surface 154 of a sleeve 106, or a rotational lock described in paragraphs [0074] and [0102].

The term "biased retention feature" was not defined in the patent and should be interpreted broadly to cover any biased feature that has a retaining function. To "overcome" a biased retention feature had to be interpreted as meaning to overcome a force produced by the biased retention feature.

As regards the rotational lock, protrusions 174 were biased retention features of a sheath (sleeve 106). To unlock the rotational lock and then enable advancement of the handle (104, Figure 4), a minimum force was required to let feet 134 pass over protrusions 174. Claims 1 and 8 did not require the force applied to the handle to overcome the biased retention feature to be in the same direction as the longitudinal movement of the handle. In any case, the force needed for unlocking the rotational lock had such a longitudinal component. Moreover, bringing parts away from each other would be within the meaning of the term "overcome", also in view of the embodiment of Figure 81 of the patent, the reference signs of which appeared in claims 1 and 8. This embodiment fell within the scope of claim 1 because there was no mention in the patent that it would be excluded and it even clearly comprised the features defined in claim 2 of the main request.

The subject-matter of claims 1 and 8 was not novel over D3a either. This document disclosed an apparatus for inserting a medical device into the skin of a subject with a biased retention feature as claimed in the form of a spring 150 or the surface of a sheath 140 on which the spring rested, or in the form of hooks of the sheath engaging respective hooks of a handle (Figure 26A).

Inventive step

The subject-matter of claims 1 and 8 was not inventive over the combination of D3a with D5 or D4.

Starting from the device disclosed in D3a, the problem of preventing unwanted actuation or of preventing needle exposure was already solved by the provision of spring 150, the force of which had to be overcome to actuate the device. Furthermore, the patent did not mention any problem solved by the biased retention feature as defined in claims 1 and 8 of the main request.

Hence, the biased retention feature did not solve any technical problem and had to be ignored for the assessment of inventive step.

Even if it was assumed that the claimed biased retention feature addressed the problem of preventing needle exposure, this problem had been solved by the same feature in D5 (biased retention feature in the form of breaking tabs or snap ring 112 in Figure 7A), as explained in column 2, lines 9 to 11 and column 17, lines 52 to 55, and D4 (biased retention feature in the form of circumferential rims 25 and 27 in Figure 2), as explained in column 3, lines 48 to 53.

The person skilled in the art would thus have combined the teaching of D5 or D4 with D3a and would have arrived at the subject-matter of claims 1 and 8 in an obvious way, for example by providing interlocking surfaces below hooks of the handle engaging respective hooks of the sheath.

The subject-matter of claims 1 and 8 was also obvious

starting from D1a in view of common general knowledge. It would have been straightforward for a person skilled in the art to change the relative positioning of the feet 198 so that they would be part of the sleeve and could engage the device support.

The subject-matter of claims 1 and 8 of the main request was also obvious over a combination of D1a and D3a, starting from either document, if the Board agreed that a biased retention feature as defined in these claims was disclosed in one of D1a and D3a.

The subject-matter of claims 1 and 8 of the main request was also obvious in view of the combination of D3a and D26. This objection had been withdrawn at the oral proceedings before the Opposition Division in response to the Opposition Division asserting that it did not want to see any further combinations of documents based on D3a, unless the additional document included both a spring and a further biased retention feature. This assertion had effectively forced the opponent to withdraw the objection, which should be considered by the Board on appeal.

Clarity in view of the description

The description of the patent mentioned embodiments, such as the inserter 2500 depicted in Figure 81, which would have to be deleted if they did not fall under the scope of the claims. Otherwise the clarity of the claim would be compromised (Article 84 EPC). The wording used to describe the invention in claims 1 and 8 (paragraph [0009]) did not by itself remove the ambiguity.

VI. The proprietor's arguments of relevance to the decision are summarised as follows.

Sufficiency of disclosure

The objection of insufficiency against claim 1 of the main request should not have been admitted by the Opposition Division, as it had been presented late. In any case the objection directed to the terms "minimum force" and "force" was a disguised clarity objection. The patent as a whole, and in particular the embodiment disclosed in paragraphs 174 to 188 and Figures 91 to 108, or the embodiment disclosed in paragraphs 189 to 205 and Figures 109 to 134 provided sufficient teaching for the person skilled in the art to carry out the claimed invention.

Extension of subject-matter

The objection of added subject-matter against claim 1 of the main request should not have been admitted by the Opposition Division, as it had been presented late. In any case, claim 1 of the main request was based on claim 1 and paragraph [00152] of the application as filed.

Claim 2 was based on Figure 114 or on Figures 91 to 108 of the application as filed.

Claims 9 and 10 were based on Figures 45 to 50 and 91 to 134 and paragraphs [00198] to [00206] and [00236] to [00265] of the application as filed.

Novelty

The subject-matter of claims 1 and 8 was novel over

D1a.

This document did not disclose a biased retention feature as defined in claims 1 and 8. Spring 108 did not belong to sleeve 106, which had to be considered to be the sheath according to the definition of claims 1 and 8. Surface 154, which belonged to the sheath, was not a biased retention feature. Similarly, protrusions 174 were not biased. Moreover, a force applied to the handle for advancing it played no role in overcoming protrusions 174.

The embodiment of Figure 81 in the patent did not fall under the scope of the claims as it clearly did not comprise a biased retention feature as claimed. The fact that it comprised the features of claim 2 was irrelevant. The features defined in claim 2 were also present in the embodiment depicted in Figures 101 and 102, which was in accordance with the claims.

D3a was also not novelty-destroying for the subject-matter of claims 1 and 8, as it did not disclose a biased retention feature as defined in these claims. Spring 150 did not belong to sheath 140, the surface of this sheath where the spring rested was not biased and the engagement of the hooks on the sheath and the handle was not overcome by a force applied to the handle to advance it.

Inventive step

The subject-matter of claims 1 and 8 was inventive over the combination of D3a with D5 or D4.

Starting from the device disclosed in D3a, the objective technical problem was how to prevent unwanted

actuation.

Neither D4 nor D5 taught a biased retention feature of a sheath in relation to this problem.

The breaking tabs or snap rings coupling a sheath with a handle disclosed in D5 had a different function. They were intended to ensure abrupt advancement of an injection needle. Moreover, in the couplings of D5 the biased retention feature was on the handle and not on the sheath. Also, it would have been technically difficult to implement such couplings in the complex device of D3a. Providing them below the hooks of the handle engaging respective hooks of the sheath would have made the device of D3a fall apart when the breaking tabs or the snap rings were overcome.

The coupling between a needle plate and a sheath disclosed in D4 also had a different function. It was intended to promote rapid insertion of the needle under the skin. Moreover it was the needle plate which deformed (column 4, lines 28 to 31). No biased retention feature was present on the sheath.

The subject-matter of claims 1 and 8 was also inventive starting from D1a in view of common general knowledge. It was mere speculation based on hindsight to allege that the person skilled in the art would have modified D1a to include a biased retention feature as claimed. The person skilled in the art would have had no reason to perform such a complex modification without any specific teaching.

The objection of lack of inventive step on the basis of the combination of D3a and D26 should not be admitted. The opponent had expressly withdrawn this objection

before the Opposition Division. The opponent was not forced to do so, but chose to.

Clarity in view of the description

The description of the patent had been adapted to clarify that the invention was described in claims 1 and 8. Several of the embodiments disclosed in the patent clearly did not fall within the scope of the claims. However, the patent did not state the contrary. The use of the term "embodiment" did not imply that the embodiment had to fall within the scope of the claims. This was also the case with the patent as granted.

Reasons for the Decision

1. The invention

The invention relates to an apparatus (claim 1 of the main request) for inserting a medical device into the skin of a subject and a related method of use (claim 8 of the main request).

Such apparatuses, also known as inserters, are typically used to position an infusion cannula or a subcutaneous sensor under the skin.

An apparatus as claimed is shown in Figures 100 and 101, 103 and 105 of the patent, reproduced below.

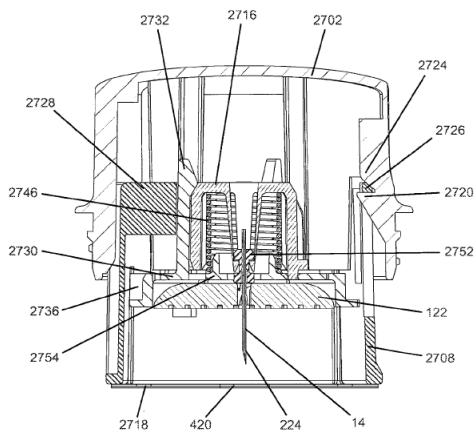


FIG. 100

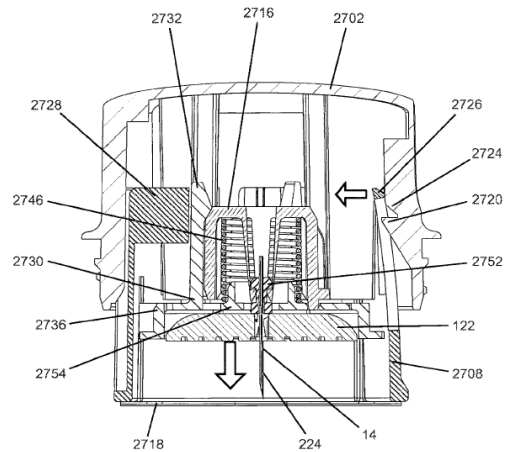


FIG. 101

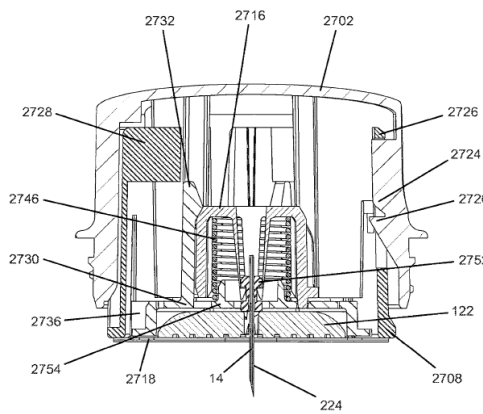


FIG. 103

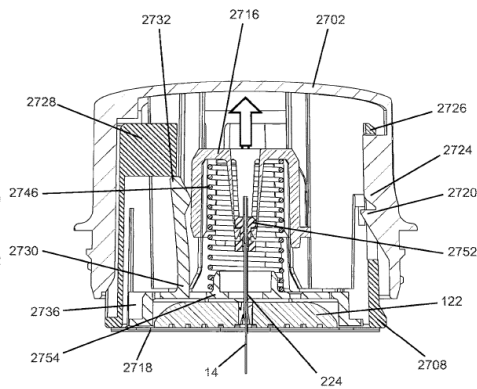


FIG. 105

The claimed apparatus comprises a sheath (2708), a device support (2730, supporting medical device 122), a sharp support (2716 supporting needle 224), a handle (2702) and a driver (spring 2746).

The sheath (generally depicted as cylindrical in the patent) defines a distal surface for placement on a skin surface.

The device support, which is adapted to support the medical device to be inserted, is movable between a proximal position (Figure 100) and a distal position (Figure 103) that is closer to the skin surface. It includes a first engagement member (2732) for

releasably coupling the device support to the sharp support and a second engagement member for engaging the medical device.

The sharp support is adapted to support a sharp extending through a portion of the device support (e.g. an insertion needle) for inserting the medical device under the skin surface. The sharp support is movable between the proximal position and the distal position.

The handle (i.e. housing part of the apparatus which the user may push) is movable between a proximal position and a distal position relative to the sheath and is adapted to urge the device support and the sharp support from the proximal position to the distal position to insert the sharp under the skin surface.

The driver is intended to advance the sharp support towards the proximal position when the sharp support reaches the distal position. This causes the sharp to be extracted from the skin surface (Figure 105).

The sheath has at least one biased retention feature (2726), and advancing the handle (302) (402) (2502) (2702) (3702) from the proximal position to the distal position comprises applying a minimum force to the handle to overcome the at least one biased retention feature (Figure 101) to allow distal movement of the handle relative to the sheath. A force applied to the handle moves the sheath into the handle and moves the medical device from the proximal position to the distal position and inserts the sharp under the skin surface (Figure 103).

2. Sufficiency of disclosure

The opponent argued that the subject-matter of claim 1 of the main request was not sufficiently disclosed.

The proprietor argued that the objection should not be admitted. However, the Opposition Division, making use of its discretionary power, deemed the objection to be *prima facie* relevant, and admitted and considered it in the first-instance proceedings. The Board sees no reason to overturn the discretionary decision of the Opposition Division in this respect.

The opponent argued that the general references to "a minimum force" and "a force" in the claim were too vague. However, sufficiency of disclosure has to be assessed in view of the patent as a whole. The description discloses embodiments of the claimed invention, such as the one described in relation to Figures 91 to 108, from which the person skilled in the art understands how forces applied to the handle can cause the movements as defined in the claim. Establishing the exact direction of application and the intensity of these forces within a technically reasonable field of application relating to the claimed apparatus is within the competence of the person skilled in the art.

Hence, the opponent's objection of insufficient disclosure (Article 83 EPC) has not met with success.

3. Extension of subject-matter

- 3.1 The opponent argued that the feature "a force applied to the handle moves the sheath into the handle and moves the medical device from the proximal position to

the distal position and inserts the sharp under the skin surface" in claim 1 of the main request added subject-matter.

The proprietor argued that the objection should not be admitted. However, the Opposition Division, making use of its discretionary power, deemed the objection to be *prima facie* relevant, and admitted and considered it in the first-instance proceedings. The Board sees no reason to overturn the discretionary decision of the Opposition Division in this respect.

The Opposition Division held that paragraph [00152] of the application as filed provided a basis for the feature objected to.

The Board agrees with the Opposition Division and notes that the plurality of embodiments disclosed in the application as filed also provide a basis for this feature, since they function according to the feature definition.

The opponent's argument that the claim did not specify that the force was a manual one, as mentioned in paragraph [00152] of the application as filed, is not convincing. The claim defines a handle as the element to which the force is applied. A handle is normally controlled by hand, i.e. manually.

The opponent also argued that the person skilled in the art was unable to derive directly and unambiguously from paragraph [00152] that the same force that was transferred to the sharp and/or support structure also moved the handle into the sheath. However, the claim does not require this. It defines effects of a force applied to the handle but does not prescribe that a

force with the same magnitude should be transferred to the elements which are moved. The defined effects of the application of the force to the handle, including the insertion of the sharp under the skin surface, are in accordance with the disclosure of the embodiments in the application as filed.

The opponent's argument that claim 1 made no reference to the coupling between the sharp and/or support structure, as disclosed in paragraph [00152] of the application as filed, is not convincing either. The claim expressly defines a sharp support adapted to support a sharp. This amounts to a definition of the coupling as disclosed in paragraph [00152] of the application as filed.

The opponent also argued that claim 1 referred to a minimum force and a separate force for moving the handle. However, the claim does not state that the minimum force for overcoming the biased retention feature and the force applied to the handle for moving the sheath are two separate forces.

The opponent's argument that all mentions of "force" in the application as filed were in the context of a "downward" force has no merit either. Paragraph [00152] does not specify that the force is a downward force. Moreover, as also pointed out by the Board in the communication accompanying the summons to oral proceedings, paragraphs [00162], [00191], [00203], [00215], [00230], [00244] and [00260] of the application as filed specifically disclose that the sharp may be supported at an oblique angle, which implies an oblique insertion force.

3.2 Claim 2 of the main request defines the additional feature of an interlocking configuration between the handle and the sheath, as also defined in claim 2 as originally filed. Contrary to the opponent's argument, this additional feature was disclosed in combination with the sheath having at least one biased retention feature, and with the advancement of the handle from the proximal position to the distal position comprising applying a minimum force to the handle to overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath, for example in the embodiment of Figures 91 to 108 of the application as filed.

3.3 Claims 9 and 10 of the main request are based on claims 13 to 19 of the application as filed, which all defined optional individual features. The person skilled in the art recognises that these optional features are not incompatible with each other. On the contrary, it is common ground that they are disclosed in combination in several embodiments of the application as filed. The opponent has not pointed to any inextricable links between the optional features either. Hence, grouping these additional features as done in claims 9 and 10 of the main request does not add subject-matter.

3.4 In conclusion, the objections of added subject-matter (Article 123(2) EPC) raised by the opponent do not prejudice the maintenance of the patent on the basis of the main request.

4. Novelty

4.1 The opponent argued that the subject-matter of claims 1 and 8 was not novel in view of D1a.

D1a discloses an insertion device, which is an apparatus for inserting a medical device into the skin of a subject. Figures 1, 7, 14 and 15, reproduced below, illustrate the relevant components of the insertion device.

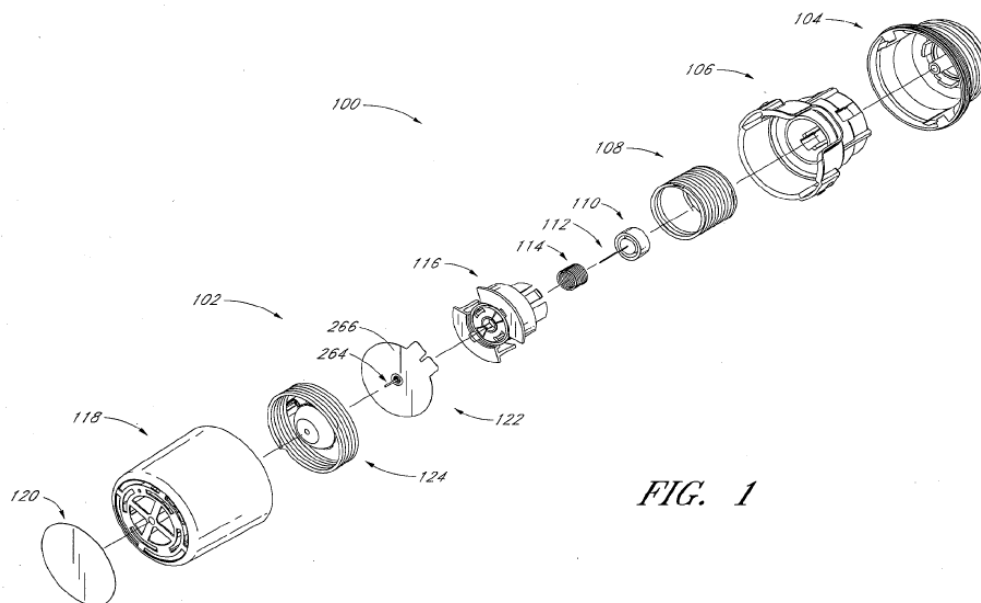


FIG. 1

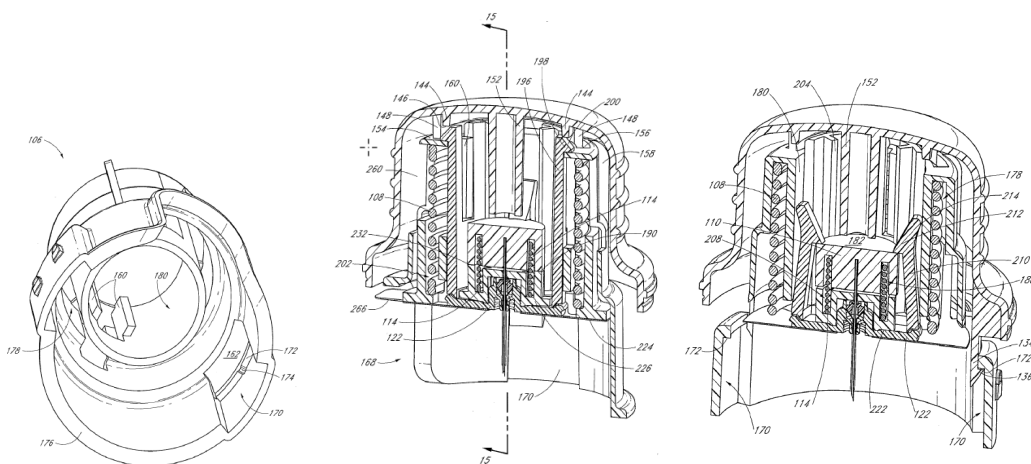


FIG. 7

FIG. 14

FIG. 15

The insertion device comprises a sheath (sleeve 106), a device support (shuttle 116) adapted to support a medical device (infusion set 102), a sharp support (needle hub 110) adapted to support a sharp (needle

112) for inserting the medical device under the skin surface, a handle (actuator 104), movable between a proximal position and a distal position relative to the sheath, and a driver (spring 114).

D1a does not disclose that the sheath has a biased retention feature and advancing the handle from the proximal position to the distal position comprises applying a minimum force to the handle to overcome the biased retention feature to allow distal movement of the handle relative to the sheath.

As the Opposition Division correctly noted in the impugned decision, the expression "the sheath has" in claims 1 and 8 of the main request implies that the biased retention feature is a part of the sheath. This is the normal technical meaning of such an expression, and is in accordance with the detailed description of the embodiments of the invention in the patent.

The Board agrees with the opponent that the term "biased retention feature" should be interpreted broadly to cover any biased feature that has a retaining function. However, this implies that the retaining function must derive from a force applied by the biased retention feature, due to its biased state. Consequently, "to overcome" the biased retention feature means to overcome this force. Therefore the embodiment according to Figure 81 of the patent, which does not have any retention feature of the sheath that applies a force due to its biased state, does not fall within the scope of the claims of the main request. It is irrelevant, in this respect, that the claims comprise reference signs pertaining to this embodiment. Reference signs in a claim have no limiting effect. Moreover, the Board notes that the claims as granted

already comprised these reference signs and others pertaining to embodiments of the patent, such as the one according to Figure 61, which clearly did not fall within the scope of the claims as granted.

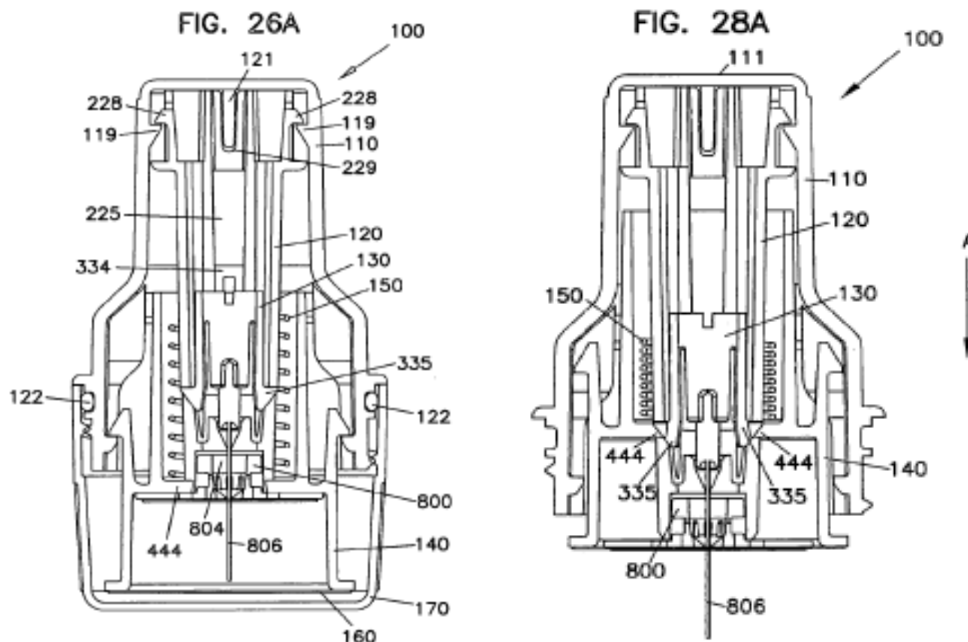
According to D1a, insertion spring 108 and sleeve-engaging feet 198 are not parts of the sheath. Upper surface 154 of sleeve 106 does not apply any biasing force.

As regards the opponent's argument that the rotational lock described in paragraphs [0074] and [0102] of D1a could be considered the biased retention feature as claimed, the Board notes that this rotational lock is realised by the engagement of protrusions 174 of the sheath with feet 134 of the handle. To unlock the insertion device for actuation, a force between the protrusions and the feet has to be overcome by rotating the handle with respect to the sheath. Still, protrusions 174 are stiff elements of the sheath, which do not apply any force due to their biased state within the meaning of claims 1 and 8 of the main request.

- 4.2 The opponent argued that the subject-matter of claims 1 and 8 was not novel in view of D3a.

D3a discloses an apparatus for inserting a medical device into the skin of a subject (as shown in Figures 26A and 28A reproduced below) comprising a sheath (sleeve 140), a device support (cylinder hub 120) adapted to support a medical device (infusion site 800), a sharp support (needle hub 130) adapted to support a sharp (needle within cannula 806) for inserting the medical device under the skin surface, a handle (housing 110), movable between a proximal position and a distal position relative to the sheath,

and a driver (spring 150).



D3a does not disclose that the sheath has a biased retention feature and advancing the handle from the proximal position to the distal position comprises applying a minimum force to the handle to overcome the biased retention feature to allow distal movement of the handle relative to the sheath.

The opponent argued that D3a disclosed a biased retention feature in the form of a spring 150 or the surface of the sheath on which the spring rested, or in the form of hooks of the sheath engaging respective hooks of the handle. However, spring 150 is not a part of the sheath. The surface of the sheath on which spring 150 rests and the hooks of the sheath engaging the hooks of the handle do not apply any biasing force which has to be overcome to allow distal movement of the handle.

4.3 It follows that the opponent's objections of lack of novelty (Article 54(1) and (2) EPC) do not prejudice the maintenance of the patent on the basis of the main request.

5. Inventive step

5.1 The opponent argued that the subject-matter of claims 1 and 8 was not inventive over the combination of D3a with D5 or D4.

As explained above, D3a does not disclose that the sheath has a biased retention feature and advancing the handle from the proximal position to the distal position comprises applying a minimum force to the handle to overcome the biased retention feature to allow distal movement of the handle relative to the sheath.

This feature has the technical effect that, to enable actuation of the apparatus, a certain initial force applied by the biased retention feature has to be overcome. As the opponent argued, in D3a too a certain initial force has to be overcome to enable actuation. However, according to the device of D3a, this force is applied by the driver (spring 150), which has the further function of advancing the sharp support towards a proximal position when the sharp support reaches a distal position (in accordance with claims 1 and 8 of the main request). Providing a dedicated biased retention feature makes it possible to set the initial force to be overcome to enable actuation independently of the force needed for advancing the sharp support.

Hence, the distinguishing feature addresses the objective technical problem of better preventing

unwanted actuation.

Whether or not the patent mentions this problem is irrelevant, as the objective technical problem has to be derivable by the person skilled in the art from the disclosure of the patent as a whole.

D5 discloses an injector device which comprises a handle in the form of plunger section 12 (Figure 1), and a base section 14 supporting an injection device. The handle has snap means 100 in the form of breaking tabs or circumferential snap ring 112 (Figure 7A). D5 discloses that the presence of the snap means is to enable rapid completion of the injection for optimum patient comfort (column 7, lines 24 to 27). The snap means do not address the objective technical problem. Column 2, lines 9 to 11 and column 17, lines 52 to 55 of D5, which mention the problem of preventing needle sticks, do not do so in relation to the snap means. Hence, the person skilled in the art receives no motivation from D5 to provide D3a with snap means on the sheath.

D4 discloses a container for placing a needle under a patient's skin. The container (Figures 1 to 5) includes a handle in the form of cap 1a, a sheath in the form of sleeve 1b and a device support in the form of needle plate 13. The sleeve has a retention feature in the form of circumferential rims 25 and 27 (column 3, lines 48 to 53) which engage the plate. D4 discloses that the presence of circumferential rim 25 is intended to prevent cap 1a from sliding until a force sufficient to overcome the resistance of the rim relative to the cap is exerted against the cap. However, D4 does not disclose that the rims are intended to address the objective technical problem. As the proprietor argued,

they could simply be intended to promote rapid insertion of the needle under the skin. Moreover D4 discloses that it is plate 13 which is deformed when the retention is overcome (column 4, lines 28 to 31). Hence, D4 does not disclose a biased retention feature on the sheath. The person skilled in the art receives no motivation from D4 to provide D3a with the claimed biased retention feature.

Moreover, the provision of a biased retention feature on the sheath (sleeve 140) of D3a, engaging the device support (cylinder hub 120), would require a complex re-design of the device of D3a, which the person skilled in the art would not do without express prompting to do so. Providing interlocking surfaces below hooks of the handle engaging respective hooks of the sheath, as suggested by the opponent, would not be a trivial task. It would require a special design to prevent the handle and the sheath of D3a from falling apart following disengagement between the hooks as a result of the deformation of the handle and the sheath when the interlocking surfaces are overcome.

In conclusion, the combination of D3a with D5 or D4 does not render obvious the subject-matter of claims 1 and 8 of the main request.

5.2 The opponent argued that the subject-matter of claims 1 and 8 was obvious starting from D1a in view of common general knowledge.

D1a does not disclose that the sheath has a biased retention feature and advancing the handle from the proximal position to the distal position comprises applying a minimum force to the handle to overcome the biased retention feature to allow distal movement of

the handle relative to the sheath.

According to D1a the force of a spring (108) can act on the device support (116) to insert the sharp (112) under the skin surface. Overcoming the retention feature (feet 198) in D1a involves acting against the spring responsible for the insertion. Providing a dedicated biased retention feature makes it possible to set the initial force to be overcome to enable actuation independently of the force needed for advancing the sharp support.

Hence, the distinguishing feature addresses the objective technical problem of better preventing unwanted actuation.

The opponent argued that it would have been straightforward for the person skilled in the art to change the relative positioning of feet 198 so that they would be part of the sleeve and could engage the device support. However, according to D3a feet 198 cooperate with displacement members 144 to release the device support (shuttle 116) driven by insertion spring 108. Providing feet 198 on the sleeve would require a complex re-design of the device to maintain the same insertion function. The person skilled in the art would not have done so without express prompting.

Hence the subject-matter of claims 1 and 8 of the main request is not obvious in view of D1a and common general knowledge.

- 5.3 The opponent argued that if the Board agreed that D1a or D3a disclosed a biased retention feature as claimed, the combination of D1a and D3a, starting from either document, would render obvious the subject-matter of

claims 1 and 8 of the main request.

However, as explained in points 4.1 and 4.2 above, neither D1a nor D3a disclose a biased retention feature as claimed. Hence, the combination of D1a and D3a does not need to be considered further.

- 5.4 The opponent argued that the subject-matter of claims 1 and 8 of the main request was also obvious in view of the combination of D3a and D26.

According to the minutes of the oral proceedings before the Opposition Division (page 7), as noted by the proprietor, the opponent withdrew a previously raised objection of lack of inventive step in view of the combination of D3a and D26.

According to Article 12(4) RPBA 2007, which applies by virtue of Article 25(2) RPBA 2020, the Board has the discretion to hold inadmissible facts, evidence or requests which could have been presented in the first instance proceedings.

Admitting the objection based on D3a and D26, which is a statement of fact based on evidence, after its express withdrawal before the Opposition Division would require the Board to conduct an examination of the objection without any decision of the Opposition Division on its merit. This would be against procedural economy and against the primary object of the appeal proceedings which is to review the decision under appeal in a judicial manner (Article 12(2) RPBA 2020).

The opponent's argument that it was forced by the Opposition Division to withdraw the objection is an unsubstantiated assertion. The opponent could and

should have maintained the objection if it had wished to obtain an appealable decision on the matter.

For these reasons, in accordance with Article 12(4) RPBA 2007, the Board does not admit the objection on the basis of D3a in combination with D26 into the appeal proceedings.

5.5 In conclusion, the opponent's objections of lack of inventive step (Article 56 EPC) do not prejudice the maintenance of the patent on the basis of the main request.

6. Clarity in view of the description

The opponent argued that the claims lacked clarity because the description of the patent mentioned embodiments which did not fall under the scope of the claims.

The Board notes that the description contains a clear statement (paragraph [0009]) that the invention is described in claims 1 and 8.

Moreover, the patent as granted generally used the term "embodiment(s)" to describe arrangements which clearly did not fall within the scope of the claims. It did not refer to them as embodiments of the invention. In this respect, the situation has not changed after appeal. The person skilled in the art would have understood from the patent as granted, and still does from the patent as amended according to the main request, that the term "embodiment" in the patent does not imply an arrangement falling within the meaning of the claim.

Hence, the opponent's objection under Article 84 EPC

does not prejudice the maintenance of the patent according to the main request.

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 European patent in amended form in the following version:
 - claims 1 to 12, filed as auxiliary request 3 on 23 April 2019;
 - description, pages 2, 3 and 31 filed during oral proceedings on 2 August 2022 (labelled "description - main request"), and pages 4 to 30 of the patent specification
 - drawings of the patent specification.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated