Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 20 August 2020

Case Number: T 0756/17 - 3.2.08

Application Number: 10709132.4

Publication Number: 2408507

IPC: A61M25/06, A61M5/32

Language of the proceedings: EN

Title of invention:
NEEDLE-TIP SHIELDING MECHANISM

Patent Proprietor:
Becton Dickinson and Company

Opponent:
Smiths Medical ASD, Inc.

Headword:

Relevant legal provisions:
EPC Art. 54(3), 56, 83, 123(2)
RPBA Art. 12(4)
RPBA 2020 Art. 25(2)

Keyword:
Novelty - main request (no) - auxiliary request (yes)
Inventive step - (yes)
Sufficiency of disclosure - (yes)
Amendments - extension beyond the content of the application as filed (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0756/17 - 3.2.08

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

Appellant: (Patent Proprietor)	Becton Dickinson and Company One Becton Drive Franklin Lakes, NJ 07417-1880 (US)
Representative:	Herr, Jochen Baker & McKenzie Theatinerstraße 23 80333 München (DE)
Appellant: (Opponent)	Smiths Medical ASD, Inc. 160 Weymouth Street Rockland MA 02370-1136 (US)
Representative:	Thum, Bernhard Wuesthoff & Wuesthoff Patentanwälte PartG mbB Schweigerstraße 2 81541 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 27 January 2017 concerning maintenance of the European Patent No. 2408507 in amended form.**

Composition of the Board:

Chairwoman	P. Acton
Members:	A. Björklund
	Y. Podbielski

Summary of Facts and Submissions

I. The appeals were filed by the patent proprietor (appellant I) and opponent (appellant II) against the interlocutory decision of the opposition division finding that, on the basis of the auxiliary request VIII (then on file), the patent in suit (hereinafter "the patent") met the requirements of the EPC.

II. Oral proceedings before the Board were held on 20 August 2020.

III. The final requests were as follows:

Appellant I requested that the decision under appeal be set aside and the patent be maintained as granted (main request) or, as an auxiliary measure, that the patent be maintained on the basis of one of auxiliary requests IV to XIV filed with the grounds of appeal on 6 June 2017, or one of auxiliary requests Ia, IIa, IIIa, IXa, Xa, XIa, XIIIa and XIVa filed with the grounds of appeal on 6 June 2017.

Appellant II requested that the decision under appeal be set aside and the patent be revoked. Appellant II also requested that auxiliary requests Ia, IIa, IIIa, XIIIa and XIVa not be admitted into the proceedings.

IV. Independent claims

Claim 1 of the main request (patent as granted), with feature designations as used in the impugned decision reads:

1.1 A needle-tip shielding mechanism (20), comprising:
1.2 an outer housing (80) having an adapter-interlock feature (110);
1.3 an inner housing (60) comprising a needle-feature capture mechanism (96) and
1.4 a needletip [sic] capture mechanism (90),
1.5 a needle (40) that extends into the inner housing (60),
1.6 the needle having a needle feature (50, 52, 54, 56, 58), and
1.7 the inner housing (60) having a first position in which the inner housing (60) biases the adapter-interlock feature (110) radially outward into an engaged position and
1.8 a second position that allows the adapter-interlock feature (110) to move to an unengaged position,
characterized in that
1.9 the inner housing (60) is slidably movable within the outer housing (80).

Claim 1 of auxiliary request Ia differs from claim 1 of the main request in that the tip error in feature 1.4 has been corrected and in that feature 1.10a has been added at the end of the claim. It reads:

"... and wherein the outer housing (80) comprises a sleeve with an inner space (82) that is sized and shaped to allow the inner housing (60) to translate between the first position and the second position within the outer housing."

The claims of the further auxiliary requests are not relevant for the present decision.

V. The following documents are of relevance for the decision:

D1 WO 2009/139951 A1
D2 WO 2009/154824 A1
D3 WO 2010/101740 A1
D4 US 2004/0236288 A1
D7 WO 2006/062983 A1

VI. Appellant I argued essentially the following:

Main request - novelty

D2 did not disclose features 1.7 to 1.9 of claim 1 of the main request.

The wording "biases ... into an engaged position" in Feature 1.7 required an active force acting on and actively pushing of the adapter-interlock feature into an engaged position. This was clear from feature 1.7 itself.

In contrast thereto, as described in paragraph [0031], the inner housing of the needle-tip shielding mechanism of D2 did not actively act on the adapter-interlock feature to force it into an engaged position but merely prevented movement of the interlock feature away from the engaged position. This was not a biasing in the sense of feature 1.7.

In view of paragraph [0056] of the patent, feature 1.8 had to be understood as the second position allowing the adapter-interlock features to autonomously move to the unengaged position since the biasing force was removed.

In the needle-tip shielding mechanism of D2, however, the adapter-interlock remained in the engaged position even when the inner housing had been moved to its proximal, or second, position. This mechanism did therefore not have a second position according to feature 1.8.

Finally, feature 1.9 required that the entire inner housing was completely contained within the perimeter of the outer housing in the first and the second positions. This followed already from the definition of an inner and an outer housing. Furthermore, the term "within" defined that something was within an area or boundary, and did not extend beyond. Contrary to the opposition division's opinion, the skilled person would not understand paragraph [0041] of the patent, which disclosed that "the inner housing can be shorter than the outer housing", to mean that the opposite could also be true, but would rather see the shorter inner housing as required in the same way as it was required that the diameter of the inner housing allowed the inner housing to slide within the outer housing. This understanding of the term "within" was emphasized by paragraph [0007] of the patent which used the term to describe the prior art D4 where, as could be seen in figures 10A to C, the inner housing was completely inside the outer housing and also by paragraph [0014] which described that the outer housing was sized to "slidably receive the inner housing in a manner which allows the inner housing to translate between a distal and a proximal position within the outer housing".

As could be seen in the drawings of D2, the inner housing of that needle-tip shielding mechanism extended beyond the outer housing when the inner housing was in

its proximal or second position. Feature 1.9 was thus not disclosed in D2.

Auxiliary request Ia - admission

Auxiliary request Ia contained amendments addressing the reason for which the opposition division found that claim 1 of auxiliary request I did not comply with the requirements of Article 123(2) EPC.

It was filed at the earliest possible opportunity during the appeal proceedings and should therefore be admitted into the proceedings.

Auxiliary request Ia - extension of subject-matter

Feature 1.10a had a basis in paragraph [0050] of the original application. It was obvious to the skilled person that the distal position was synonymous to the first position and the proximal position was synonymous to the second position.

Auxiliary request Ia - sufficiency of disclosure

The skilled person would not understand the term "translate" as something fundamentally different than "slide". There was no contradiction between these terms and the invention was sufficiently disclosed for it to be carried out by the skilled person.

Auxiliary request Ia - novelty

Feature 1.10a required that the entire inner housing was completely within the outer housing in both the first and the second position.

This distinguished the claimed shielding mechanism from the prior art mechanisms disclosed in D1 to D3, where a part of the inner housing extended beyond the outer housing in either the first or the second position.

Auxiliary request Ia - inventive step

The subject-matter of claim 1 differed from the shielding mechanism in figures 10A to C of D4 not only in feature 1.7, but also in features 1.1 and 1.4 since this mechanism did not actually shield the needle-tip.

Even if assuming that the only difference was feature 1.7, the skilled person would have no reason to change the design of the shielding mechanism of figures 10A to C.

The interlocks of this mechanism were made to grip the luer lock thread on the outside of the catheter hub and the needle gripping mechanism would need to be completely redesigned in order for the shielding mechanism to be positionable inside the catheter hub. In case this was desired, the skilled person would use the shielding mechanism of figures 19A to B of D4 instead of the mechanism of figures 10A to C.

The subject-matter of claim 1 therefore involved an inventive step.

VII. Appellant II argued essentially the following:

Main request - novelty

D2 disclosed not only features 1.1 to 1.6, but also features 1.7 to 1.9 of claim 1 of the main request. Its subject-matter was therefore not novel.

Paragraphs [0058] to [0060] of the patent described that biasing means encompassed any means which held something in a position, e.g. by friction ([0058], line 9). The term "biases" of feature 1.7 thus had to be understood as encompassing an active force as well as a passive blocking of the adapter-interlock in its engaged position.

The inner housing of the needle-tip shielding mechanism of D2 did in its distal position prevent a movement of the adapter-interlock feature from an engaged position. Feature 1.7 was thus disclosed in D2.

Feature 1.8 merely required that the adapter-interlock was allowed to move to an unengaged position when the inner housing was in the second position, but not that it actually did. This feature was thus also disclosed in D2.

Feature 1.9 did not require that the inner housing was entirely within the outer housing in the first and second positions but only defined that the inner housing was slidable within the outer housing. The term "within" thus concerned the relative radial dimensions of the inner and outer housings, rather than the relative axial dimensions. The latter were irrelevant to the question of whether the inner housing extended outside of the outer housing. Paragraph [0064] of the patent described that the manufacturer seated the shielding mechanism "within" the inner lumen of the catheter adapter and as could be seen in figures 4A to 5, this included that the shielding mechanism partly extended outside of the catheter adapter. Finally, paragraph [0007] not only concerned D4, but also D7 and used the term "within" to describe a coupling housing

respectively a needle shield which were partly but not completely within a catheter adapter respectively the coupling housing. Hence, the patent did not give a univocal definition of the term "within".

Since the inner housing of the needle-tip shielding mechanism of D2 was slidable inside the outer housing it was slidably movable within the outer housing and feature 1.9 was disclosed.

Auxiliary request Ia - admission

The request should not be admitted into the proceedings under Article 12(4) RPBA 2007. It was late filed, since appellant I, then patent proprietor, had the chance to file it in response to the outcome of the discussions during the opposition proceedings of whether auxiliary request I fulfilled the requirements of Article 123(2) EPC. Instead, appellant I chose to file other auxiliary requests not addressing the discussed issue.

Auxiliary request Ia - extension of subject-matter

Paragraph [0050] of the original application, disclosed that the inner housing could translate between a distal position and a proximal position.

Feature 1.10a required that the inner housing could translate between a first and a second position. This had no basis in the original application.

Auxiliary request Ia - sufficiency of disclosure

The terms "translate" and "slide" were coupled by an exclusive "or" in paragraph [0014] of the patent. As a result these terms had different technical meanings.

These terms were both used in the claim. Due to the difference in their meaning, the skilled person would not be able to carry out the invention.

Auxiliary request Ia - novelty

Feature 1.10a did not further restrict the claim. It followed that the subject-matter of claim 1 still lacked novelty over the shielding mechanism of D2.

Furthermore, also the needle shielding mechanisms disclosed in D1 and D3 deprived the subject-matter of claim 1 of novelty.

Auxiliary request Ia - inventive step

D4 disclosed in figures 10A to C not only features 1.1 to 1.6 and 1.8 to 1.10a but also feature 1.7 of claim 1. A radial outward direction could namely be understood as a circular movement. The adapter-interlock 158 of D4 did move in a radial direction similarly to the adapter-interlock of the patent, which could be seen as being biased radially outwardly, as required by feature 1.7. Therefore, there were in fact no features distinguishing the subject-matter of claim 1 from the shielding mechanism of D4.

Should the direction of the movement of the adapter-interlock in feature 1.7 be seen as a distinguishing feature, it was a mere kinematic reversal and thus a trivial alternative not involving an inventive step. Moreover, alternative adapter-interlocks moving radially outwardly were known from figures 19A to B of D4 and the skilled person would apply this teaching to

the shielding mechanism in figures 10A to C without involvement of inventive skill.

The subject-matter of claim 1 of auxiliary request Ia did therefore not involve an inventive step.

Reasons for the Decision

1. Main request - novelty

It has not been disputed that figures 1 to 6 of D2 disclose a needle-tip shielding mechanism having features 1.1 to 1.6 of claim 1.

1.1 Appellant I argued that feature 1.7 required an active force from the inner housing which acted on and pushed the adapter-interlock feature of the outer housing into an engaged position. This was clear from the wording of the claim itself.

The outer diameter of the inner housing 22 of the shielding mechanism of D2 was slightly smaller than the inner diameter of the outer housing and merely prevented a movement of the interlock 50 from its form-fit with the catheter adapter, as described in paragraph [0031] of D2. Since there was no active force from the inner housing pushing the interlock into frictional contact with the catheter adapter, feature 1.7 was not disclosed in D2.

However, paragraphs [0058] to [0060] of the patent use the term "biasing means" not only for a spring which constantly exerts a force, but also for friction or detent mechanisms such as protuberances, undercuts or other components which counteract a movement and thus

exert a reactive force only in case of a relative movement.

The term "biases" as used in the patent in general, and feature 1.7 in particular, must therefore be understood as encompassing a reactive force from the inner housing on the adapter-interlock feature which only occurs during, and then counteracts, an attempted or actual movement.

As disclosed in paragraph [0031] in conjunction with figure 5, the inner housing 24 of the shielding mechanism of D2 has a distal, or first, position where it supports the fingers and/or interlock 50 of the outer housing 22 and thus prevents it from disengaging from the interlock mate 52 of the catheter adapter. The inner housing thus provides a force counteracting a movement of the interlocks. This is a first position according to feature 1.7.

1.2 Appellant I argued that in view of paragraph [0056] of the patent, which described that the interlock features were released upon movement of the inner housing, feature 1.8 required that the adapter-interlock feature automatically moved into an unengaged position when the inner housing was in its second position.

However, the literal wording of feature 1.8 is clear and defines that the second position of the inner housing allows the adapter-interlock feature to move to an unengaged position. The skilled person, therefore, has no need to consult the description when interpreting feature 1.8. Moreover, paragraph [0056] of the patent concerns a specific embodiment and does not as such limit the scope of the claim.

In the second position of the inner housing 24 of the shielding mechanism of D2 showed in figure 6, the adapter-interlock feature 50 is allowed to move to an unengaged position. Feature 1.8 is thus disclosed in D2.

1.3 Regarding feature 1.9, appellant I argued that the skilled person would understand the term "slidably movable within" as the entire inner housing being within the boundaries of the outer housing not only during the sliding between the first and second positions but also when it was in these positions. This was underlined by paragraphs [0007], [0014] and [0041] and also by the embodiments showed in the drawings of the patent.

However, as set out by appellant II, while a sliding movement of the inner housing within the outer housing requires that the inner housing has a smaller radial dimension, it is not required that it also has a smaller axial extension. Furthermore, it is not excluded that also a shorter inner housing can slide into positions where it extends out of an outer housing. The skilled person would therefore not understand feature 1.9 alone, or in combination with features 1.7 and 1.8, to require that the entire inner housing is within the boundaries of outer housing when it is in or slides between the first and second positions. They would rather understand that it was required that the inner and outer housings have relative radial dimensions allowing the inner housing to slide within the outer housing.

This interpretation does not change even if the description of the patent is considered. Paragraph [0007] which was added during examination to describe

the prior art does not as such give a definition of the term "within" in the sense of the patent. Anyway, in this paragraph, the term is used to describe various parts of prior art shielding mechanisms in D4 respectively D7. These parts are entirely or only partly contained within another part. Paragraphs [0014] and [0041] concern specific examples of the claimed invention which, again, do not as such limit the scope of the claim. Paragraph [0064] describes how the manufacturer seats the shielding mechanism of the patent within the inner lumen of the catheter adapter, and as can be seen in e.g. figures 4A to 5 of the patent, the shielding mechanism is not entirely contained within the catheter adapter but protrudes slightly. The description and drawings of the patent do, therefore, not give an univocal definition of the term "within" as "entirely within".

Therefore, even if the internal housing 24 of the shielding mechanism of D2 extends proximally beyond the end of outer housing 22 in its second position, it is "slidably movable within" the outer housing in the sense of feature 1.9.

1.4 The subject-matter of claim 1 is therefore not new over the needle-tip shielding mechanism of D2 (Article 54(3) EPC).

2. Auxiliary request Ia

2.1 Admission into the proceedings

The request was filed with the grounds of appeal, at the first opportunity during the appeal proceedings. It contains straightforward amendments addressing the reason why the opposition found that auxiliary request

I did not fulfil the requirements of Article 123(2) EPC.

For these reasons, the request was admitted into the proceedings (Rule 12(4) RPBA 2007, applicable pursuant to Rule 25(2) RPBA 2020).

2.2 Extension of subject-matter

Apart from the definition of the positions of the inner sleeve as "first" and "second" instead of "distal" and "proximal", feature 1.10a has a literal basis in paragraph [0050] of the application as originally filed.

According to appellant II, feature 1.10a extended beyond the content of the application as originally filed due to the different designations of the inner housing's positions.

The positions of the inner housing are designated as "distal" and "proximal" in the description respectively as "first" and "second" in the claims of the application as originally filed. It is self-evident to the skilled person that the designations "distal" and "first" position, and "proximal" and "second" position, respectively, are synonymous. The patent concerns a well known type of needle-tip shielding mechanism in which the inner housing in use is pulled from a first position to a second position upon contact of the needle feature with the needle feature capture mechanism of the inner housing. The first position therefore has to be the distal position and consequently the second position is the proximal position.

Feature 1.10a therefore has a basis in the application as originally filed and the requirements of Article 123(2) EPC are thus fulfilled.

2.3 Sufficiency of disclosure

Appellant II pointed out that in paragraph [0014] of the patent, the terms "translate" and "slide" were described as mutually exclusive alternatives for the movement of the inner housing. Since the terms "slidably movable" and "translatable" of claim 1 had different meanings, the skilled person could not carry out the invention.

In light of the complete disclosure of the patent, the skilled person does not have any reason to see a translation of the inner housing as being something fundamentally different than a slidable movement, but they would rather see the terms as synonymous. Furthermore, the patent shows with more than sufficient detail how the invention can be carried.

The requirements of Article 83 EPC are therefore fulfilled.

2.4 Novelty

According to appellant II, the addition of feature 1.10a did not restrict the scope of the claim, and consequently, the subject-matter of claim 1 still lacked novelty over the needle-tip shielding mechanism of D2 and also over the shielding mechanisms of D1 and D3.

However, the wording of feature 1.10a defines that the outer housing comprises a sleeve with an inner space

which is sized and shaped to allow the inner housing to translate (or slide) between the first position and the second position within the outer housing. This means that the first and second positions have to be located within the outer housing, with the consequence that the inner housing can only translate (slide) between two positions which are positioned (completely) within the outer housing. This leads to the conclusion that the inner housing must also be smaller in axial direction than the inner housing.

This is different from the wording of Feature 1.9 of the main request, which requires that the inner housing is slidably movable within the outer housing. As explained above, this implies that the diameter of the inner housing is smaller than that of the outer housing, however, without specifying any limitation of the axial position of the inner housing.

In the shielding mechanism of D2, the proximal end of the inner housing 24 extends beyond the proximal end of the outer housing 22 when it is in its second position, as can be seen in figure 6. Feature 1.10a is thus not disclosed in D2.

Given the interpretation of feature 1.10a above, none of the documents D1 or D3 disclose feature 1.10a either. When the inner housing 18 of the shielding mechanism of D1 is in its first position, it extends distally beyond the distal end of the outer housing 16, as can be seen in figure 1. Also in the shielding mechanism of D3, the distal end of the inner housing 80 extends beyond the distal end of the outer housing 100 when it is in its first position, as seen in figure 3A.

The subject-matter of claim 1 is therefore new.

2.5 Inventive step starting from D4

Appellant II argued that the shielding mechanism of figures 10A to C of D4 showed features 1.1 to 1.6 and 1.8 to 1.10. The inner housing 55 was able to move between a first position (figure 10 A) to a second position (figure 10B) within the outer housing 10, thereby allowing the adapter-interlock feature 158 to move to an unengaged position.

2.5.1 During the inventive-step discussion, appellant II also put forward that in view of figure 5 of the patent, the radial movement of the interlock could be understood as a rotating movement. The interlock 158 which performed a rotational movement under the bias of the inner housing 55 would thus be biased radially outwardly in the first position of the inner housing. Feature 1.7 was therefore also disclosed in D4.

However, the skilled person reading the entire claim would interpret feature 1.7 as requiring either an active force or - as set out with respect to the main request - a passive blocking which maintains the adapter-interlock feature in an engaged position which is radially outward of its unengaged position.

In contrast thereto, the engaged position of the interlock 158 of the shielding mechanism in figures 10A to C of D4 is radially inward of its unengaged position.

The subject-matter of claim 1 therefore differs from the shielding mechanism in figures 10A to C of D4 at least through feature 1.7.

2.5.2 Appellant II argued that if feature 1.7 was seen as distinguishing the subject-matter of claim 1 from the shielding mechanism in figures 10A to C of D4, the difference of the engaged position being radially outward or inward of the unengaged position was a mere kinematic reversal of the movement of the adapter-interlock mechanism. Moreover, adapter-interlock features which had a radially outward engaged position where known from the embodiment in figures 19A to B of D4. It would thus have been obvious for the skilled person to invert the direction of movement of the interlock of the shielding mechanism in figures 10 thereby arriving at the subject-matter of claim 1 without inventive skill.

Feature 1.7 allows the claimed needle-tip shielding mechanism to be positioned inside a catheter adapter. The problem solved by the distinguishing feature 1.7 is thus to provide an alternative needle-tip shielding mechanism which can be positioned inside a catheter adapter.

It is true that inversing the direction of movement of the adapter-interlock may seem to be trivial. However, the skilled person has no incentive to change the direction of movement of the adapter-interlock of the shielding mechanism of D4. The shielding mechanism in figures 10A to C of D4 is specifically designed to be positioned radially outwardly of a catheter hub and the adapter-interlocks are configured for gripping the luer lock thread of the catheter adapter. Furthermore, the needle gripping mechanism including the plates 28 and 40 and the biasing means 227 would have to be modified substantially in order for the shielding mechanism in figures 10A to C to be downsized enough for it to be positioned inside a catheter adapter. The skilled

person would therefore be dissuaded from changing the direction of movement of the adapter-interlock of the shielding mechanism of D4. The skilled person looking for a shielding mechanism which can be inserted inside a catheter adapter would rather use the complete shielding mechanism of figures 19A to B which is designed to be positioned inside a catheter adapter than try to modify the shielding mechanism in figures 10 A to C such that it could be positioned inside a catheter adapter.

The subject-matter of claim 1 of auxiliary request Ia therefore involves an inventive step.

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 on the basis of

claims 1-13 of auxiliary request Ia filed with letter dated 6 June 2017,
figures 1-9 of the patent specification
and a description to be adapted.

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated