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**Datasheet for the decision
of 1 April 2025**

Case Number: T 0404/23 - 3.2.02

Application Number: 12756031.6

Publication Number: 2736576

IPC: A61M25/06

Language of the proceedings: EN

Title of invention:

NEEDLE TIP PROTECTOR ASSEMBLY FOR SAFETY IV CATHETER ASSEMBLY

Patent Proprietor:

Poly Medicure Limited

Opponent:

B. Braun Melsungen AG

Headword:

Relevant legal provisions:

EPC Art. 100(b), 100(c), 83, 123(2)

RPBA 2020 Art. 12(3), 12(5), 13(1)

EPC R. 106

Keyword:

Grounds for opposition - insufficiency of disclosure (no) -
subject-matter extends beyond content of earlier application
(no)

Statement of grounds of appeal - party's complete appeal case
- reasons set out clearly and concisely (no)

Discretion not to admit submission - requirements of Art.
12(3) RPBA 2020 met (no) - submission admitted (no)

Amendment to appeal case - state of the proceedings

Obligation to raise objections under Rule 106 EPC - objection
raised (yes)

Decisions cited:

G 0003/14, T 0858/22, T 0557/21, T 2117/18, T 0367/20,
T 0321/21

Catchword:



Beschwerdekammern

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Case Number: T 0404/23 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 1 April 2025

Appellant: B. Braun Melsungen AG
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 22 December 2022 rejecting the opposition filed against European patent No. 2736576 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chair M. Alvazzi Delfrate
Members: A. Martinez Möller
N. Obrovski

Summary of Facts and Submissions

I. The appeal is directed against the decision of the opposition division rejecting the opposition against European patent No. 2736576.

II. Oral proceedings before the board took place on 1 April 2025.

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

The appellant further requested that all of the objections raised in the statement of grounds of appeal be admitted into the appeal proceedings.

The appellant also raised objections under Rule 106 EPC in connection with Article 112a(2) (c) and (d) EPC.

The respondent (patent proprietor) requested that the appeal be dismissed. As an auxiliary measure, the respondent requested that the patent be maintained on the basis of one of auxiliary requests 1 to 3 as filed on 25 August 2023.

The respondent further requested that all of the objections raised in the statement of grounds of appeal not be admitted into the appeal proceedings on the basis of Article 12(5) RPBA.

III. Claim 1 of the main request (patent as granted) reads as follows (with feature numbering added in bold by the board).

M1 "A safety IV catheter assembly (10) comprising:

M1.1 a catheter tube (26) having a distal end (30) and a proximal end (28);

M1.2 a catheter hub (24) having a distal end (30) and a proximal end (28);

M1.3 a needle (14) with a needle shaft (16) extending through the catheter hub (24) and the catheter tube (26) having opposite proximal (28) and distal ends (30) defining an axial direction (A),

M1.4 wherein the proximal end (28) is joined to a needle hub (20) and the distal end (30) forms a needle tip (18) and a change in profile (34) is provided between the proximal (28) and distal (30) ends of the needle;

M1.5 a tip protector assembly (12) being arranged movably on the needle (14) in-between the catheter hub (24) and needle hub (20) including:**M1.6** a base portion (42) having a needle passage (22) extending in the axial direction (A) from the proximal end (28) of the base portion (42) to a distal side of the base portion (42);

M1.7 a hollow enclosure (32) formed by the extension of the base portion (42) in a direction generally parallel to the axial direction (A);

M1.8 wherein the distal end (30) of the hollow enclosure (32) has a substantially circular opening (90) allowing the needle (14) to pass there-through;

M1.9 first (46) and second (48) arms made integrally within the hollow enclosure (32) and extending from the distal side of the base portion (42) in an axial direction (A),

M1.10 wherein the region between the first (46) and second (48) arms and the hollow enclosure (32) defines open space (56);

M1.11 at least one tension creating element (68) surrounding partially or completely the first (46) and second (48) arms in a region proximal to the distal ends (30) thereof;

M1.12 at least one stopper element (80) arranged in the base portion (42) having an axial bore (82) with a dimension adapted to the principal outer profile of the said needle; and

M1.13 one or more first locking means (52) to lockingly arrange the tip protector assembly (12) outside the catheter hub (24) in an arrangement engaging with one or more second locking means (54) provided on the catheter hub (24) in its ready position,

M1.14 wherein the first arm (46) is deflected radially outwards by the needle (14) against a restoring force of the tension creating element (68), characterized in that

M1.15 a groove is provided in the inner wall of at least one of the first (46) and second (48) arms extending substantially in the axial direction from the base portion (42), and

M1.16 being capable of acting as a guide groove for the needle shaft (16) and aiding the axial movement of the needle shaft (16) relative to the tip protector assembly (12)."

IV. The following documents are relevant to the present decision.

D1 US 2009/0281499 A1

D2 WO 03/011381 A1

D10 WO 2011/036574 A1

D11 US 2011/0060294 A1

V. The appellant's arguments, where relevant to the present decision, can be summarised as follows.

Admittance of the objections raised in the statement of grounds of appeal

All of the objections raised in the statement of grounds of appeal should be admitted into the appeal proceedings. These objections were raised and maintained in the opposition proceedings.

It had been necessary to re-submit the first-instance submissions in order to maintain them in the appeal proceedings.

At the time of submitting the grounds of appeal, it was not possible to determine which points were particularly relevant to the appeal proceedings. Moreover, under Article 12(4) RPBA, only submissions made for the first time in the appeal proceedings represented an amendment which could be admitted only at the discretion of the board.

The grounds of appeal explicitly distinguished between new submissions, which dealt in particular with the reasoning in the decision under appeal, and the repetition of submissions made in the first-instance proceedings, which had not been duly considered by the opposition division.

By substantiating each of the grounds of opposition that prevented the maintenance of the patent as granted, the statement of grounds of appeal provided reasons why the patent was to be revoked and consequently why the decision was to be set aside. It was only because of the conciseness required by Article 12(3) RPBA that the grounds of appeal omitted a

sentence indicating that the corresponding assessment in the decision under appeal was incorrect.

The submissions in the statement of grounds of appeal were complete, and included an interpretation of the features of claim 1 as required by Article 69 EPC as well as objections according to this claim interpretation. It was not comprehensible why a review of the decision under appeal by the board should represent an undue burden. If, however, such a review were to be considered an undue burden, then this was caused by the insufficient reasoning in the decision under appeal, as the opposition division did not interpret the features of the claim before examining the grounds for opposition, contrary to the requirements of Article 69 EPC.

As far as inventive step is concerned, the opposition division considered many features to be undisclosed in D1 and D2 even though they were evidently disclosed. The decision under appeal misjudged documents D1 and D2 to such an extent that it would have been inappropriate to address its reasoning and to argue why the features that the opposition division considered to be undisclosed were obvious.

In respect of the inventive-step objection starting from D2, the grounds of appeal stated why the constructions of D2 and D10 were similar and why no effort was needed to combine their teachings and provide a shallow groove in a distal end of the arm of D2. Moreover, the decision under appeal was based on an incorrect claim interpretation, and the grounds of appeal also addressed this issue.

The submissions in the letter of 20 October 2023 should also be admitted into the appeal proceedings. A lack of substantiation was raised for the first time in the respondent's reply to the appeal, and the appellant quickly reacted to this with the aforementioned letter of 20 October 2023, long before it received the summons to oral proceedings. It was thus incomprehensible how the submissions contained in the letter of 20 October 2023 could have been filed earlier.

Added subject-matter in respect of features M1.15 and M1.16

Claim 1 comprised added subject-matter.

Prior to assessing whether or not claim 1 comprised added subject-matter, it was necessary to interpret the features of claim 1 to determine what subject-matter was protected by the claim. The participles "extending" and "being" in features M1.15 and M1.16 were linked by the word "and" and had to refer to the same noun. Since a participle referred to the immediately preceding noun, both these participles seemed to refer to the at least one of the first and second arms or to the inner walls of at least one of the arms. If it were assumed that "being capable of [acting as a guide groove]" in feature M1.16 referred to the groove, then "extending" in feature M1.15 also had to refer to the groove.

In paragraph [48] of the application as filed, the participle "extending" referred to the arms or their inner walls, and not to the groove, and the groove acted as guide groove. Therefore, paragraph [48] could not provide a basis for features M1.15 and M1.16.

Sufficiency of disclosure

Features M1.15 and M1.16 of claim 1 could be interpreted in four different ways:

- a) The arms extend in the axial direction from the base portion and act as a guiding groove.
- b) The groove extends in the axial direction from the base portion and acts as a guiding groove.
- c) The arms extend in the axial direction from the base portion and the groove acts as a guiding groove.
- d) The groove extends in the axial direction from the base portion and the arms act as a guiding groove.

Interpretation b) seemed to apply. This was also reflected in the German translation of claim 1 as granted, which had been filed by the proprietor itself.

While it was possible, in principle, to implement an assembly having a groove as defined according to interpretation b), the contested patent did not teach how to do this. The groove was not immediately apparent in Figure 6B. The claimed invention was therefore insufficiently disclosed and Article 100(b) EPC prejudiced the maintenance of the patent as granted.

Objection under Rule 106 EPC

There had been a fundamental violation of the right to be heard in the appeal proceedings (Articles 112a(2)(c) and 113 EPC) because the complete and concise submissions on the lack of inventive step that had been filed with the statement of grounds of appeal had not been admitted into the proceedings without dealing with them in substance.

Moreover, the appellant had requested that the decision under appeal be set aside based on Article 100(a) EPC because the subject-matter of claim 1 lacked inventive step. By not admitting the inventive-step objections, the board had not decided on this request. This resulted in a further fundamental procedural defect within the meaning of Article 112a(2) (d) and Rule 104 EPC.

In T 858/22, the board had decided on the case on the basis of a submission of a lack of inventive step in which the opponent's own problem-solution approach was set out, despite the fact that the problem-solution approach had not been dealt with in detail in the decision under appeal. The board's decision not to admit the inventive-step objections in the present case risked creating divergent case law.

VI. The respondent's arguments, where relevant to the present decision, can be summarised as follows.

Admittance of the objections raised in the statement of grounds of appeal

None of the objections raised in the statement of grounds of appeal should be admitted into the appeal proceedings because they did not comply with Article 12(3) RPBA.

The decision under appeal included detailed reasoning. The appellant had merely repeated its first-instance submissions by copying them verbatim into its statement of grounds of appeal. If the appellant was of the opinion that there were flaws in the decision under appeal, this should have been pointed out in its statement of grounds of appeal, and yet the statement

of grounds of appeal did not discuss any flaws in the decision under appeal. The only part that did refer to the decision under appeal, on pages 21 and 22, did not include a detailed discussion of the alleged deficiencies, and referred to only one aspect which, according to the opposition division, had not been decisive for the outcome.

Added subject-matter

Claim 1 of the patent as granted did not comprise added subject-matter. There was a literal disclosure in paragraph [48] of the application as filed for features M1.15 and M1.16.

Feature M1.15 repeated the indication of feature M1.9 that the arms extended in the axial direction. The question of whether the term "extending" in feature M1.15 and in the first sentence of paragraph [48] of the application as filed referred to the groove or to the arms was at most a question of clarity, not of added subject-matter.

Sufficiency of disclosure

Feature M1.15 was literally disclosed in the first sentence of paragraph [0045] of the specification; there was thus no contradiction between the claims and the description. Figure 6B showed the guiding groove in the second arm 48. The person skilled in the art could therefore carry out the invention by implementing an assembly as shown in Figure 6B. The skilled person could also use generally known methods for providing a groove, and thus was able to carry out the invention.

The alleged ambiguity of features M1.15 and M1.16 related to an issue of clarity, which was not a ground for opposition.

Objection under Rule 106 EPC

The objection under Rule 106 EPC should be dismissed. The statement of grounds of appeal had not been substantiated as required by Article 12(3) RPBA.

Reasons for the Decision

1. Patent
 - 1.1 Safety intravenous (IV) catheter assemblies are used to administer fluid and/or medicine or to take blood from a patient. Handling of these instruments can result in the healthcare worker being accidentally stuck with a needle contaminated with the patient's blood. To prevent this from happening, assemblies have been developed to automatically cover and shield the needle tip after its withdrawal from the patient, but these suffer from problems such as costly manufacturing and insufficient protective function. The patent addresses these issues.
 - 1.2 The claimed invention relates to a safety IV catheter assembly comprising a catheter tube, a catheter hub, a needle and a tip protector assembly. The tip protector assembly comprises a base portion, a hollow enclosure, first and second arms, at least one tension-creating element, at least one stopper element and one or more first locking means. The first and second arms extend from the distal side of the base portion in an axial

direction. A groove is provided in the inner wall of at least one of the first and second arms.

2. Admittance of the objections raised in the statement of grounds of appeal

2.1 First-instance proceedings

2.1.1 The opposition was based on the following grounds for opposition.

(i) Article 100(b) in connection with Article 83 EPC

(ii) Article 100(c) in connection with Article 123(2) EPC and

(iii) Article 100(a) in connection with Article 56 EPC

2.1.2 The notice of opposition comprised, *inter alia*, a section on claim interpretation and the following objections.

(i) insufficient disclosure

(ii) added subject-matter in respect of features M1.3 and M1.14

(iii) added subject-matter in respect of features M1.15 and M1.16

(iv) lack of inventive step starting from D1 in combination with either D10 or D11

(v) lack of inventive step starting from D2 in combination with either D10 or D11

2.1.3 The appellant submitted further arguments on these objections in its written submissions of 19 July 2022 and 17 August 2022.

2.1.4 At the oral proceedings, the opposition division found none of objections (i) to (v) to be convincing for the

reasons set out in sections 11 to 14 of the decision under appeal, and concluded that none of the grounds for opposition raised by the appellant were prejudicial to the maintenance of the patent as granted. The opposition was therefore rejected.

2.2 Content of the statement of grounds of appeal

- 2.2.1 The statement setting out the grounds of appeal consists of sections I to VIII. Except for section I ("Anträge"/Requests), section VIII ("Zusammenfassung"/Summary) and the passage from the last paragraph of page 20 to the end of page 22, the grounds of appeal are limited to a - mostly verbatim - repetition of written submissions made in the first-instance proceedings.
- 2.2.2 In particular, section III of the grounds of appeal, which deals with claim interpretation, is identical to section III of the notice of opposition. With the exception of the passage on pages 20 to 22 referred to above, sections V to VII of the grounds of appeal, which contain all the objections, are also limited to repetitions of written submissions made in the first-instance proceedings. This is also acknowledged in the statement of grounds of appeal itself in relation to each of sections V to VII (see pages 15, 20 and 42: "Es wird darauf hingewiesen, dass die voranstehenden Ausführungen bereits in [...] vorgetragen wurden.)).
- 2.2.3 Hence, with the exception of the passage on pages 20 to 22, the objections raised in the statement of grounds of appeal had already been presented, in the very same manner, in the first-instance proceedings, i.e. before the decision under appeal had been issued.

2.2.4 The passage on pages 20 to 22 provides arguments in relation to objection (iii) and explicitly addresses the reasoning set out in the section of the decision under appeal dealing with that objection. The passage, however, is not relevant for any of the other objections raised in the statement of grounds of appeal.

2.3 Article 12(3) and Article 12(5) RPBA

2.3.1 The respondent argued that a mere repetition of the first-instance arguments, without taking into account the decision under appeal, did not comply with Article 12(3) RPBA and requested that the objections raised in the statement of grounds of appeal not be admitted under Article 12(5) RPBA.

2.3.2 Article 12(3) RPBA reads as follows.

"The statement of grounds of appeal and the reply shall contain a party's complete appeal case. Accordingly, they shall set out clearly and concisely the reasons why it is requested that the decision under appeal be reversed, amended or upheld, and should specify expressly all the requests, facts, objections, arguments and evidence relied on. All documents referred to shall be

(a) attached as annexes insofar as they have not already been filed in the course of the grant, opposition or appeal proceedings or produced by the Office in said proceedings;

(b) filed in any event to the extent that the Board so directs in a particular case."

Article 12(5) RPBA reads as follows.

"The Board has discretion not to admit any part of a submission by a party which does not meet the requirements in paragraph 3."

Article 12(3) RPBA specifies several requirements of the statement of grounds of appeal and reply thereto. The requirement to "set out clearly and concisely the reasons why it is requested that the decision under appeal be reversed, amended or upheld" is commonly understood as the requirement that the statement of grounds of appeal and reply thereto, and in particular the objections and claim requests set out therein, must be substantiated.

Whether or not this requirement of Article 12(3) RPBA is met depends on the specific circumstances of each case.

In the case of an appeal of an opponent against a decision of the opposition division in which an objection was found unconvincing, a mere repetition of the first-instance submissions is normally not sufficient. Rather, an opponent must normally provide arguments why the opposition division's reasoning in the decision under appeal is allegedly incorrect (see T 557/21, Reasons 6.2.3). Arguments which have already been put forward in the opposition proceedings may be included, but must usually be set out in the context of the decision under appeal (see T 2117/18, Reasons 2.2.11).

Article 12(5) RPBA states that the board has discretion not to admit any part of a submission by a party which does not meet the requirements of Article 12(3) RPBA.

Contrary to what was indicated by the appellant, the board's power not to admit a submission under Article 12(5) RPBA does not depend on whether that submission qualifies as an "amendment". Accordingly, the fact that a claim request or objection is not an amendment under Article 12(4) RPBA does not exempt or reduce a party's duty to substantiate it.

When exercising the discretion conferred to the board under Article 12(5) RPBA with regard to the substantiation requirement under Article 12(3), second sentence, RPBA, the extent of substantiation, respectively the lack thereof, is assessed. This involves assessing the extent to which the appellant's case for setting aside the decision can be understood (see T 321/21, Reasons 6.6), taking into account the reasoning in the impugned decision.

- 2.4 Admittance of the inventive-step objections starting from document D1
 - 2.4.1 The inventive-step objections starting from document D1 in combination with D10 or D11 are essentially based on the argument that D1 discloses all of the features of claim 1 except features M1.15 and M1.16 and that the person skilled in the art would modify the assembly of D1 in view of either D10 or D11 and provide a groove in one of the arms of the assembly in order to guide the needle shaft.
 - 2.4.2 The reasoning in point 13.3 of the decision under appeal sets out why other features of claim 1 are not disclosed in D1 and explains why the person skilled in the art would not modify D1 in view of either D10 or D11.

- 2.4.3 In particular, with regard to the objection relying on the combination of D1 and D10, the decision under appeal explains that D1 and D10 would not be combined because the teaching of D10 relating to providing a guiding groove in the locking edge of the arm, if applied to D1, would lead to two undesirable consequences: the needle tip would not be sufficiently covered and the arms would no longer be sufficiently deflected.
- 2.4.4 It is argued in the statement of grounds of appeal that, taking into account the teaching of D10, the person skilled in the art starting from the assembly of D1 would be able, with very little effort, to provide a groove at the distal end of the arm. However, the statement of grounds of appeal does not include any arguments concerning the undesirable consequences of the modification which, according to the decision under appeal, would mean that the person skilled in the art would not even consider the modification.
- 2.4.5 With regard to the objection relying on the combination of D1 and D11, the decision under appeal explains that D1 and D11 would not be combined because the semicircular profile forming a groove in D1 is provided in a plastic, non-resilient arm, and not in a resilient metal arm, and bending the metal arm into a semicircular profile would be cumbersome and remove the required resilience.
- 2.4.6 In the statement of grounds of appeal it is argued that, taking into account the teaching of D11, the person skilled in the art starting from the assembly of D1 would provide a semicircular groove in one of the arms of D1. However, the statement of grounds of appeal does not include any arguments on why the teaching of

D11 would be applied despite the difference of materials and resilience; moreover, it does not provide any arguments on the lack of the required resilience as a result of the modification, i.e. it does not address the two reasons which, according to the decision under appeal, would mean that the person skilled in the art would not even consider the modification.

- 2.4.7 The appellant's submissions on claim interpretation, which are themselves also a mere repetition of first-instance submissions, have no impact on whether the person skilled in the art would modify the assembly of D1 in view of D10 or D11.
- 2.4.8 The appellant further argued that repeating the objections in the same manner as in the first-instance proceedings constituted sufficient reasons as to why the decision under appeal should be reversed. For example, the arguments supporting why claim 1 as granted was not inventive represented a reason to revoke the patent and therefore a reason for setting aside the decision under appeal, showing that the decision was wrong.
- 2.4.9 The Board disagrees. While it is permissible and sometimes even advisable to repeat arguments made in the proceedings before the department of first instance in the statement of grounds of appeal, such arguments must usually be put into the context of the decision under appeal, addressing the reasoning therein (to the extent that it contains such reasoning). Moreover, making the required links to the corresponding parts of the decision under appeal and addressing the reasoning provided therein does not qualify as an amendment under Article 12(2) and (4) RPBA.

- 2.4.10 In failing to do this, by merely repeating in the statement of grounds of appeal the arguments submitted during the opposition proceedings, without taking into account the reasoning in the decision under appeal, the appellant is also misunderstanding the function of the appeal proceedings. This function does not consist in a repetition of the proceedings before the department of first instance. Rather, as stated in Article 12(2) RPBA, the primary object of the appeal proceedings is to review the decision under appeal in a judicial manner.
- 2.4.11 Furthermore, since the objections relied on in the statement of grounds of appeal were found unconvincing in the decision under appeal, a mere repetition of those objections without addressing the reasons of the appealed decision does not allow the board and the respondent to understand why the decision under appeal is allegedly wrong and should therefore be set aside. In its letter dated 13 February 2025, the appellant submitted that this was due to insufficient reasoning and a lack of interpretation of the features of claim 1 in the decision under appeal. The board does not share this view and considers the reasoning in the decision under appeal to be sufficient. Moreover, as stated by the respondent, the appellant should have pointed out any alleged flaws in the reasoning of the decision under appeal in its statement of grounds of appeal, and yet the statement of grounds of appeal does not at all refer to insufficient reasoning, nor to a lack of claim interpretation in the decision under appeal.
- 2.4.12 The appellant further argued that the only thing that was possibly missing from the statement of grounds of appeal, and which had been omitted for the sake of conciseness, was an additional statement indicating

that, on account of the submissions made, the assessment as set out in the corresponding part of the decision under appeal was incorrect.

- 2.4.13 The board notes first of all that such an additional statement is not present in the statement of grounds of appeal. That such a hypothetical statement would have remedied the lack of substantiation seems unlikely, and would in any case have had to be assessed in view of its specific wording and considered in the context of the appealed decision, taking into account the obligation under Article 12(3) RPBA to expressly specify all the facts, objections, arguments and evidence relied on.
- 2.4.14 Furthermore, the obligation under Article 12(3) RPBA to be concise, referred to by the appellant, does not exempt a party from the obligation to set out its reasons why the decision under appeal should be reversed, amended or upheld, taking into account the decision under appeal.
- 2.4.15 It follows that the inventive-step objections starting from document D1 are not substantiated within the meaning of Article 12(3) RPBA. Indeed, the statement of grounds of appeal leaves the reader completely in the dark as to the possible reasons why the appealed decision should be set aside in this respect. Under these circumstances, the board exercised its discretion under Article 12(5) RPBA and decided not to admit these objections into the appeal proceedings.
- 2.5 Admittance of the inventive-step objections starting from document D2

2.5.1 The objections starting from document D2 in combination with D10 or D11 are essentially based on the argument that D2 discloses all of the features of claim 1 except features M1.15 and M1.16 and that the person skilled in the art would modify the assembly of D2 in view of either D10 or D11 and provide a groove in one of the arms of the assembly in order to guide the needle shaft.

2.5.2 The reasoning in point 13.4.1 of the decision under appeal sets out why other features of claim 1 are not disclosed in D2, explains why the assembly of D2 works in a different manner from the assemblies of D10 and D11, and, as far as features M1.15 and M1.16 are concerned, why a person skilled in the art would not be incentivised to form a groove on the inner walls of the arms in D2.

According to the decision under appeal, a groove would weaken the arms and change their resilience, which was needed for the functioning of the device, while not improving the guidance of the needle because the inner walls of the arms in D2 were not in contact with the needle shaft, referring to Figures 9 and 10. The decision under appeal goes on to add that, in D2, guidance of the needle was provided by needle passages 24 and 38, as well as the stopper element, and that providing a groove in the distal end walls 43 would hamper the functioning of the device by reducing their blocking resistance to the needle tip.

2.5.3 With regard to the combination of D2 with D10, it is indicated in the statement of grounds of appeal that, taking into account the teaching of D10, the person skilled in the art starting from the assembly of D2 would be able, with very little effort, to provide a

groove at the distal end of the arm.

Contrary to the appellant's contention at the oral proceedings, this does not explain why the constructions of D2 and D10 are similar. More importantly, the statement of grounds of appeal does not include any arguments on the weakening of the arms and their resilience as a result of the combination, nor any arguments on the absence of contact between the inner walls of the arms and the needle shaft in D2 and thus the inability of such a groove to guide the needle, nor any arguments on the reduction of the blocking resistance to the needle tip.

- 2.5.4 With regard to the combination of D2 with D11, it is indicated in the statement of grounds of appeal that, taking into account the teaching of D11, the person skilled in the art starting from the assembly of D2 would provide a semicircular groove in one of the arms.

However, the statement of grounds of appeal does not address any of the arguments set out in the decision under appeal against the combination of D2 with either D10 or D11.

- 2.5.5 The appellant argued at the oral proceedings before the board that the decision under appeal was based on an incorrect claim interpretation and that the grounds of appeal had addressed this issue. However, the reasons why a person skilled in the art starting from the assembly of D2 (or D1, for that matter) would not consider the combination with D10 or D11 are unrelated to the issues of claim interpretation. Moreover, the appellant's submissions on claim interpretation are also a repetition of its first-instance submissions, and the decision under appeal sets out in point 12.2 of

the Reasons why the opposition division interpreted features M1.15 and M1.16 the way it did.

- 2.5.6 It follows that the inventive-step objections starting from D2 are not substantiated within the meaning of Article 12(3) RPBA. The statement of grounds of appeal leaves the reader completely in the dark as to the possible reasons for setting aside the appealed decision in this respect. Under these circumstances, the board exercised its discretion under Article 12(5) RPBA and decided not to admit these objections into the appeal proceedings.

- 2.6 Admittance of the added-matter objection in respect of features M1.3 and M1.14
 - 2.6.1 This objection is essentially based on the argument that paragraph [76] of the application as filed only discloses these features (in particular the needle shaft in feature M1.3 and the restoring force exerted by the tension creating element in feature M1.14) in combination with further features.

 - 2.6.2 According to the reasoning in point 12.2 of the decision under appeal, a needle with a needle shaft is disclosed throughout the application and a needle shaft is a standard and necessary feature of a needle. It is also stated that support for feature M1.14 can be found in paragraphs [38] and [82] of the application as published, additionally noting that the provision of a restoring force is not inextricably linked to any other feature.

 - 2.6.3 The statement of grounds of appeal does not address this reasoning in the decision under appeal. Moreover, it does not discuss the passages of the application as

filed which were considered to provide support for the disputed features. It is therefore not possible to understand why the assessment of this objection as set out in the decision under appeal is, in the appellant's view, incorrect.

- 2.6.4 This objection is therefore not substantiated within the meaning of Article 12(3) RPBA. Indeed, the statement of grounds of appeal leaves the reader completely in the dark as to the possible reasons for setting aside the appealed decision in this respect. Under these circumstances, the board exercised its discretion under Article 12(5) RPBA and decided not to admit the added-matter objection in respect of features M1.3 and M1.14 into the appeal proceedings.

- 2.7 Admittance of the added-matter objection in respect of features M1.15 and M1.16
 - 2.7.1 The passage on pages 20 to 22 of the statement of grounds of appeal discusses the reasoning in point 12.2 of the decision under appeal and provides arguments as to why this reasoning is allegedly incorrect. The objection is therefore substantiated within the meaning of Article 12(3) RPBA and considered in the appeal proceedings.

- 2.8 Admittance of the objection of insufficient disclosure
 - 2.8.1 This objection is essentially based on the argument that four different interpretations of features M1.15 and M1.16 are possible but only one is disclosed, and on the argument that the groove is not shown or described in any of the embodiments of the specification.

2.8.2 The reasoning in point 11.2 of the decision under appeal states that "the interpretations offered by the opponent are either far-fetched or represent equivalent possible embodiments of the invention" and that Figures 4B and 6B offer sufficient information for the skilled person to be able to form a groove, capable of acting as a guide groove, in the inner wall of at least one of the arms.

2.8.3 As far as the possible interpretations are concerned, the reasoning in point 11.2 of the decision under appeal dismisses them altogether without specifying which interpretation was followed.

If the opposition division considered the groove to extend from the base portion, as seems to be the case according to the later part of the decision under appeal dealing with added subject-matter (see, in particular, the paragraph bridging pages 7 and 8), it is not immediately apparent from the reasoning in point 11.2 why an assembly with such a groove was considered to be sufficiently disclosed.

2.8.4 The degree of substantiation required under Article 12(3) RPBA usually depends on the degree of reasoning in the decision under appeal, which, as explained above, is rather limited in respect of this objection. Moreover, the issue of the interpretation of the claim also played a role in the assessment of the added subject-matter objection that the board decided to take into consideration (see point 2.7.1 above). Under these circumstances, the board exercised its discretion under Article 12(5) RPBA and admitted this objection into the appeal proceedings. The board also exercised its discretion under Article 13(1) RPBA to take into account the appellant's argument regarding sufficiency

of disclosure and Figure 6B on page 3 of its letter dated 20 October 2023.

- 2.9 In summary, the board decided, having exercised its discretion under Article 12(5) RPBA, not to admit the objections of added subject-matter in respect of features M1.3 and M1.14, nor the inventive-step objections starting from D1 or D2. The objection of added subject-matter in respect of features M1.15 and M1.16 and the objection of insufficient disclosure were, on the other hand, taken into account.
- 2.10 Admittance of submissions in the appellant's letter of 20 October 2023
- 2.10.1 Insofar as the appellant's letter of 20 October 2023 concerns objections that were not admitted into the appeal proceedings due to a lack of substantiation, the arguments attempting to provide a substantiation for these objections represent an amendment within the meaning of Article 13(1) RPBA.
- 2.10.2 The appellant argued that it could not have submitted these arguments earlier because the lack of substantiation had only been raised with the reply to the statement of grounds of appeal, and the appellant's letter had addressed this issue at the first opportunity.

This is entirely unconvincing. It is incumbent on an appellant to substantiate its case within the meaning of Article 12(3) RPBA in its statement of grounds of appeal, without waiting for another party or the board to object to a lack of substantiation at a later stage.

2.10.3 Pursuant to Article 13(1) RPBA, and taking into account the state of the proceedings when these arguments were submitted, the board decided not to admit those parts of the appellant's submissions of 20 October 2023 that attempt to provide a substantiation for the objections relied on in the statement of grounds of appeal that were not admitted.

3. Added subject-matter in respect of features M1.15 and M1.16

3.1 The appellant infers from the word "and" linking features M1.15 and M1.16 that the participles "extending" and "being" must refer to the same noun.

However, the word "and" follows a comma and, contrary to the appellant's submission, the board considers that its function is to link the two features and not the two participles.

3.2 Even if a participle usually refers to the nearest noun to prevent confusion, this is not always the case, and the relevant question is not how a linguist would construe the claim, but how the person skilled in the art would. In claim 1, the order of the words alone is insufficient to determine to which noun "extending" and "being" refer. Rather, the meaning of the words and the context provided by the other features of claim 1 and by the patent specification as a whole must also be taken into account.

3.3 In feature M1.16, given the ability to act "as a guide groove", the term "being capable of" undoubtedly refers to the groove mentioned at the beginning of feature M1.15. This interpretation is also confirmed by the second sentence of paragraph [0045] of the patent

specification. The ability of the groove to act as a guide groove is disclosed in paragraph [48] of the application as filed.

3.4 This does not affect whether "extending" in feature M1.15 refers to the groove or to the arms. This is again to be determined taking into account the technical meaning and the overall context. However, for the purpose of deciding whether claim 1 comprises added subject-matter, and contrary to the appellant's submission that it is necessary to construe the claims prior to examining the merits of the case in substance (see the caveat in T 367/20, Reasons 1.3.9: "if decisive for the outcome of the case"), the board does not consider it necessary to determine whether "extending" in feature M1.15 refers to the groove or to the arms: since the wording of feature M1.15 corresponds to the wording of the first sentence of paragraph [48] of the application as filed, whatever noun is modified by "extending" in feature M1.15, the same noun is modified by "extending" in paragraph [48]. Hence, even if the appellant's submission that "extending" in feature M1.15 refers to the groove were to be accepted, it would not result in added subject-matter.

3.5 Consequently, the objection of added subject-matter in connection with features M1.15 and M1.16 is not convincing.

4. Sufficiency of disclosure

4.1 The appellant's submission that there are four possible ways to interpret claim 1 in respect of features M1.15 and M1.16 does not relate to an issue of added subject-matter; it relates to an issue of clarity that cannot

be examined in these appeal proceedings (see the order of G 3/14).

- 4.2 The appellant submitted that the interpretation which appeared to apply was that the groove extended in the axial direction from the base portion and acted as a guiding groove, and that even if it was possible, in principle, to make such a groove, the contested patent did not show how this could be done.

Even if, for the sake of argument, the appellant's interpretation of features M1.15 and M1.16 were to be accepted, there are no apparent reasons, nor have any been put forward by the appellant, why a person skilled in the art, using common general knowledge, would have any technical difficulty in implementing the assembly with a groove extending in the axial direction from the base portion and acting as a guide groove. Therefore, the appellant's objection does not show that there are serious doubts, substantiated by verifiable facts, that a person skilled in the art, using common general knowledge, would be able to carry out the invention. For this reason alone, the objection is not convincing.

Moreover, as stated in the decision under appeal, Figures 4B and 6B of the contested patent provide sufficient information for a person skilled in the art to be able to form a groove (by using a concave shape) in the inner wall of the second arm 48 such that the groove acts as a guide groove. Even though the part of the groove near the base portion is not visible in those Figures, there is no technical difficulty involved in providing the groove extending from the base portion.

4.3 It follows that the objection of insufficient disclosure is not convincing.

5. Objections under Rule 106 EPC

5.1 Regarding a first alleged procedural violation, the appellant essentially argued that there had been a fundamental violation of its right to be heard under Article 113(1) EPC because its allegedly complete, clear and concise objections on a lack of inventive step in the statement of grounds of appeal had not been admitted into the appeal proceedings without dealing with them in substance, even though these objections had already been raised and maintained in the opposition proceedings. This had also violated its right to have the case examined at two instances, and was furthermore not in line with the purpose of the appeal proceedings, which was to review the decision under appeal.

5.2 This is not persuasive. As set out above, the objections in question were not admitted into the appeal proceedings under Article 12(3) and (5) RPBA due to a lack of substantiation, which resulted from the statement of grounds of appeal not addressing the reasoning in the decision under appeal as to why these objections were not convincing. In this regard, the objections in the statement of grounds of appeal were thus not "complete". Not admitting objections which do not address the reasoning in the decision under appeal is also entirely in line with the purpose of the appeal proceedings to review the decision under appeal, as such a review can only be carried out in a meaningful manner if the appellant addresses this reasoning. Furthermore, contrary to Article 12(4) RPBA, it does not matter under Article 12(3) and (5) RPBA whether or

not the objections in question were raised and maintained in the proceedings leading to the decision under appeal. Moreover, according to settled case law, there is no right to have a case examined at two instances. Finally, there is no procedural violation in not fully assessing the merits of an objection when not admitting that objection; otherwise, there would be no point in not admitting it.

5.3 Regarding a second alleged procedural violation, the appellant essentially argued that the board had not decided on its request to set the decision under appeal aside and to revoke the patent on the ground of a lack of inventive step, thereby deciding on the appeal without deciding on a request relevant to that decision within the meaning of Rule 104 (b) EPC.

5.4 This is not persuasive either. By dismissing the appeal, the board decided on the appellant's request that the decision under appeal be set aside and that the patent be revoked. The board also decided on the inventive-step objections by not admitting them.

5.5 Regarding a third alleged procedural violation, the appellant essentially argued that there was a risk of conflicting decisions between the present decision and the decision in T 858/22, as in the latter decision the board had allegedly considered an inventive-step objection which had exclusively been based on a different problem-solution approach from the one applied in the decision under appeal.

5.6 This is not convincing either. Whether or not there are two conflicting decisions on a point of law may matter under Article 112 EPC, but it does not matter under Article 112a EPC. The board further notes that the

facts of the present case and the one underlying T 858/22 are entirely different, and that decision T 858/22 does not even mention Article 12(3) or (5) EPC.

5.7 In view of the above, the board decided to reject the appellant's objections under Rule 106 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated