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Datasheet for the decision of 11 February 2025

Case Number: T 2185/21 - 3.2.02

Application Number: 09707113.8

Publication Number: 2254622

IPC: A61M39/26, A61M5/158, A61M5/142, A61M5/14

Language of the proceedings: EN

Title of invention:
INSERTER ASSEMBLY

Patent Proprietor:
Unomedical A/S

Opponent:
Bock, Dr. Wolfgang

Relevant legal provisions:
EPC Art. 54, 83, 111(1), 123(2)
EPC R. 80
RPBA 2020 Art. 11, 12(4) sentence 1, 12(6), 13(2)

Keyword:

Amendment to case - admissibly raised and maintained (yes)
Amendment occasioned by ground for opposition - (yes)
Amendments - added subject-matter (no)
Sufficiency of disclosure - (yes)
Novelty - (yes)
Remittal - special reasons for remittal (no)
Late-filed objection - should have been submitted in first-instance proceedings (yes)
Amendment after notification of Art. 15(1) RPBA communication - exercise of discretion - taken into account (no)

Decisions cited:

G 0001/10, T 0256/19, T 0123/22, T 0657/11, T 0574/17

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Case Number: T 2185/21 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 11 February 2025

Appellant: (Opponent)	Bock, Dr. Wolfgang Stuntzstrasse 33 81677 München (DE)
Representative:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Respondent: (Patent Proprietor)	Unomedical A/S Birkerød Kongevej 2 3460 Birkerød (DK)
Representative:	D Young & Co LLP 3 Noble Street London EC2V 7BQ (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 17 November 2021 concerning maintenance of the European Patent No. 2254622 in amended form.**

Composition of the Board:

Chairwoman	Y. Podbielski
Members:	A. Martinez Möller
	S. Böttcher

Summary of Facts and Submissions

I. The appeal was filed by the opponent against the decision of the Opposition Division maintaining European patent No. 2254622 on the basis of the then auxiliary request 1.

II. Oral proceedings before the Board took place on 11 February 2025. At the end of the oral proceedings the requests were as follows:

The appellant (opponent) requested that the decision under appeal be set aside and the patent be revoked. The appellant further requested not to admit the respondent's main request (filed as auxiliary request 4 with letter dated 9 August 2022) into the proceedings and to remit the case to the Opposition Division if it was admitted.

The respondent (patent proprietor) requested that the patent be maintained on the basis of the main request.

III. Claim 1 of the main request (filed as auxiliary request 4 with letter dated 9 August 2022) reads as follows, with feature numbering added in bold by the Board:

1 "An assembly comprising an inserter device (10), a penetrating member (7) and a base part (100), where

1.1 - the base part (100) comprises a surface adapted to be attached to a skin surface, a position adapted to receive and/or attach to the penetrating member (7), and means (14) adapted to secure the base part to the inserter device (10),

1.2 - the penetrating member (7) comprises a part to be placed subcutaneously or intramuscularly, a body (24) which is in contact with the inserter device (10) during insertion and with the base part (100) during use, and

1.3 - the inserter device (10) comprises a cavity for receiving the penetrating member (7), means (45) for accelerating the penetrating member (7) and bringing the penetrating member (7) to the receiving position in the base part (100) and means for penetrating the skin of the patient,

1.4 characterized in that the length of the joined assembly (l_{total}) in a dimension horizontal to the skin of the patient when attached to the patients skin before use is larger than the length of the base part (100) (l_2) alone and

1.5 the inserter device (10) is releasable from the base part (100) by applying a force to the inserter device (10) or a part of the inserter device (10) in a direction different from a direction of insertion of the penetrating member (7), wherein the inserter device comprises

3.1 - a moving part (38) comprising guiding means (39) which guiding means (39) restrict the movement of the penetrating member (50) and guide the penetrating member (50) from a first to a second position in a first direction, i.e. the direction of insertion, towards the injection site, and

3.2 - a stationary housing (30) comprising guiding means (32) which guiding means (32) restrict the movement of the moving part (38), and

3.3 - the penetrating member (50) comprises transformation means (52) corresponding to the guiding means (39) of the moving part (38)."

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

D2 WO 2009/001346 A1
D3 WO 2009/001347 A1
D4 WO 2009/001345 A1
D5 US 2007/0282269 Al
D19 US 2008/0208139 A1

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

Main request - admittance and Rule 80 EPC

The main request not only combined claims 1 and 3 as granted, but included a further amendment consisting in the replacement of the term "the insertion device" (present in claim 3 as granted) by "the inserter device". Since clarity was not a ground for opposition and could not be examined for granted claims, this further amendment was not occasioned by a ground for opposition and therefore did not comply with Rule 80 EPC. Consequently, the main request was not admissible. The replacement of "insertion" by "inserter" could not be a correction under Rule 139 EPC because the error was obvious, but not the correction: "an insertion device" or "the inserter device" defined two alternative possible corrections.

Admitting the main request would also be detrimental to the aim of the appeal proceedings to review the first-instance decision in a judicial manner.

Main request - request for remittal

If the main request was admitted, the case should be remitted to the Opposition Division because no decision was taken on that request. The amendments present in the main request were of a fundamental nature and involved issues which had not been discussed at the oral proceedings before the Opposition Division. The primary object of the appeal proceedings was to review the decision under appeal and not to extend the first-instance proceedings.

Main request - Article 123(2) EPC

Feature 1.4 of claim 1 had been amended restricting when the condition relating to the length had to be fulfilled without a corresponding disclosure in the application as filed. The main request therefore contravened Article 123(2) EPC.

The disclosure on page 1, lines 8 to 19 related to the background of the invention, which related to known systems and provided no information with respect to the length measurement of feature 1.4. Page 3, lines 1 to 11 defined the term length, without however disclosing that it was "in a dimension horizontal to the skin of the patient when attached to the patients skin before use" and instead defining further requirements for the arrangement of the components of the assembly. The disclosure on pages 21 and 22 related to the embodiment of Figure 4, which comprised further inextricably linked features and which left open whether "before

use" was restricted to the situation where the assembly was attached to the skin. Before use could refer to any time before the insertion, for example to a situation where the assembly was provided in a sterile packing.

Main request - Article 83 EPC

Claim 1 did not comply with Article 83 EPC. On one hand, the technical effect that was to be achieved by the invention of achieving a relatively stable assembly was not achieved over the whole breadth claimed. On the other hand, the person skilled in the art would not know how to carry out the invention for a force that is not perpendicular to the insertion direction. This latter objection should be admitted if the main request was admitted into the appeal proceedings, because the appellant had had no opportunity to present this objection against this request.

Main request - novelty over any of D2, D3 or D4

D2 anticipated in the embodiment of Figures 21 to 23 the subject-matter of claim 1. The grip portion 712 anticipated a body as required by feature 1.2. The term "in contact" in feature 1.2 did not restrict the subject-matter to direct physical contact but encompassed indirect physical contact via another entity. Moreover, the grip portion 712 could be considered to form part of the inserter device. A body that was part of the penetrating member could also be part of the inserter device.

The disclosure of documents D3 and D4 was similar to the disclosure of D2. Therefore, claim 1 was not novel over D3 and D4 for the same reasons provided in relation to D2.

Main request - admittance of D19

The subject-matter of claim 1 of the main request was not novel over D19. D19 should be admitted because it had been filed at the earliest possible stage of the appeal proceedings and deprived claim 1 of novelty. The filing of D19 was also justified by the change of claim interpretation in the decision under appeal. Admitting the main request and not admitting D19 would mean that the patent was only maintained due to procedural reasons.

Main request - inventive step starting from D2

Starting from D2, it would have been obvious, either in the light of common general knowledge or D5, to arrive at an assembly as claimed including feature 1.2. No technical effect was associated with this feature, which merely defined an alternative penetrating member. The person skilled in the art would have chosen, if it had been deemed necessary, the alternative defined by feature 1.2 in the light of common general knowledge, for example by leaving the grip portion 712 in contact with the base part. D5 disclosed an alternative realisation of a penetrating member with feature 1.2, and the structures of D2 and D5 were similar. It would therefore have been an obvious alternative to use the penetrating member of D5.

Although these objections were raised only at the oral proceedings before the Board, they should be admitted, as otherwise it would have been necessary to file a plurality of inventive-step objections for each possible distinguishing feature.

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

Main request - admittance and Rule 80 EPC

The main request essentially corresponded to auxiliary request 3 filed with the response to the notice of opposition and combined claims 1 and 3 as granted. This request had not been withdrawn in the first-instance proceedings. It was therefore not an amendment within the meaning of Article 12(4) RPBA. The replacement of "the insertion device" by "the inserter device" was made for consistency. It was appropriate and necessary due to the inclusion of claim 3, and without the replacement the appellant could have objected to the claim for lack of clarity. The main request therefore complied with Rule 80 EPC.

Main request - request for remittal

The Opposition Division had decided that then auxiliary request 1 complied with Articles 54, 56, 83 and 123(2) EPC, thus taking a full substantive decision. The appellant-opponent had had opportunity to address the request, and claim 3 as granted had been discussed in the notice of opposition. There were no special reasons for remitting the case to the Opposition Division.

Main request - Article 123(2) EPC

The application as filed taught that the insertion required the assembly to be attached to the skin. Page 1, lines 25 to 26, provided two alternative definitions of the term "before use", and page 3, lines 1 to 4 and page 22, lines 1 to 2 confirmed that it meant before insertion. The person skilled in the art would

understand that the measurement before use "in a direction horizontal to the patients skin" (page 3, lines 1-3) was made with the assembly attached to the skin. This allowed the dimension of the assembly that is horizontal to the skin to be identified and was also apparent from the stable assembly due to the "large contact surface" (page 3, lines 5 to 7). The description of the embodiment of Figure 4, in particular page 22, lines 1 to 16, also confirmed the same understanding.

Main request - Article 83 EPC

The technical effect of achieving a relatively stable assembly mentioned in paragraph [0011] of the specification was not a feature of claim 1. An objection of insufficient disclosure could not legitimately be based on an argument that the patent did not enable a skilled person to achieve a technical effect which was not defined in the claim.

The objection related to forces that are not perpendicular to the insertion direction should not be admitted. The appellant did not give any reasons for submitting it only on appeal. The decision under appeal dealt with sufficiency of disclosure also for the dependent claims, and by not raising the objection in the first-instance proceedings, the appellant had avoided a decision on it.

Main request - novelty over any of D2, D3 or D4

The subject-matter of claim 1 was novel over any of D2, D3 or D4.

D2 did not disclose feature 1.2 "the penetrating member comprising ... a body which is in contact with the inserter device during insertion and with the base part during use". This feature required direct physical contact. The grip portion 712 was part of the penetrating member and not part of the inserter device. D2 did not disclose any contact between the grip portion 712 and the base part during use or at any time. The same reasons applied to D3 and D4.

Main request - admittance of D19

D19 should not be admitted into the proceedings. The Opposition Division maintained the same interpretation of feature 1.5 throughout the first-instance proceedings. There were no "circumstances" within the meaning of Article 12(6) RPBA which justified the admittance of D19. Moreover, the objection of lack of novelty over D19 improperly combined at least three different documents and was not *prima facie* relevant.

Main request - inventive step starting from D2

The objections should not be admitted because there were no exceptional circumstances for submitting them at the oral proceedings before the Board. They were also not convincing because D2 required for its operation a separate body and a significant number of modifications would have to be made to arrive at the invention.

Reasons for the Decision

1. Patent

1.1 The patent deals with devices for the subcutaneous insertion of a penetrating member such as a needle, cannula or sensor.

1.2 Claim 1 is directed to an assembly comprising an inserter device, a penetrating member and a base part.

1.3 The assembly is typically provided with the inserter device secured to the base part and with the penetrating member provided in a cavity of the inserter device. To use it, the assembly is first attached to a skin surface by means of its base part. The inserter device is actuated to subcutaneously insert part of the penetrating member, and then released and removed from the base part. The base part can subsequently be used, for example, for attaching a medical device to the patient's skin.

2. Main request - admittance and Rule 80 EPC

2.1 The appellant puts forward that the respondent's main request is not admissible because it does not comply with Rule 80 EPC.

2.2 The main request was filed as auxiliary request 4 with the reply to the statement of grounds of appeal. As submitted by the respondent, the main request had been filed as twelfth auxiliary request before the Opposition Division on 13 July 2021, i.e. before the final date for making written submissions in

preparation for the oral proceedings as fixed by the Opposition Division under Rule 116 EPC. Except for the deletion of claim 23 as granted, this request essentially corresponds to the third and fourth auxiliary requests filed with the reply to the notice of opposition, which were substantiated when they were filed (see paragraphs 148 to 160 of the letter dated 19 June 2020). This substantiation applies to auxiliary request 12 (see also paragraphs 89 to 90 of the letter dated 13 July 2021). That request was not withdrawn in the first-instance proceedings and there is nothing to suggest that the Opposition Division could have decided not to admit it.

2.3 In view of the above, the main request was admissibly raised and maintained in the first-instance proceedings. Consequently, the main request is not an amendment within the meaning of Article 12(4), first sentence, RPBA and is part of the appeal proceedings.

2.4 The above conclusion applies irrespective of compliance of the request with Rule 80 EPC, which the Board considers to define a substantive requirement relating to the allowability of a request rather than to its admissibility (see e.g. T 256/19, Reasons 4.7, and T 123/22, Reasons 3.7).

2.5 According to Rule 80 EPC, the description, claims and drawings of a European patent may be amended, provided that the amendments are occasioned by a ground for opposition under Article 100 EPC, even if that ground has not been invoked by the opponent.

2.6 It is common ground that amending claim 1 by combining claims 1 and 3 as granted is occasioned by a ground for opposition. Disputed is whether the replacement of the

wording "wherein the insertion device" present in claim 3 as granted by "wherein the inserter device" (emphasis added by the Board) when it was incorporated into claim 1 results in a lack of compliance with Rule 80 EPC.

2.7 According to G 1/10, Reasons 13, where a patent proprietor seeks to amend their patent during opposition or limitation proceedings, such an amendment may remove a perceived error. An amendment with the sole aim of removing a perceived error cannot be said to be occasioned by a ground for opposition, and the error could only be removed by way of a correction pursuant to Rule 139 EPC (see T 657/11, Reasons 3.4). This is not the case here because the amendment in the main request, i.e. the incorporation of claim 3 as granted into claim 1 with the above replacement, does not have the sole aim of removing an error. The Board concludes, concerning this issue which was also discussed during the oral proceedings, that the replacement of "wherein the insertion device" with "wherein the inserter device" forms part of the amendment whereby granted claim 3 was incorporated into claim 1. As stated by the respondent, the replacement was made for the sake of consistency. It follows that the amendment is occasioned by a ground of opposition and therefore complies with Rule 80 EPC. It also follows that there is no need for a formal correction under Rule 139 EPC.

2.8 The Board additionally observes that the appellant submitted that the conditions for a correction pursuant to Rule 139 EPC would not be complied with, arguing that it was obvious that there was an error (no antecedence for "the insertion device") but that "an insertion device" (i.e. a different entity) rather than

"the inserter device" could have been meant. However, as indicated above, the Board does not consider the amendment in question to require a formal correction. In any event, if this argument were to be followed, it would mean that claim 1 without this replacement would allow a claim construction that is no longer possible with the replacement, and therefore that the replacement addresses potential objections such as insufficient disclosure. This would mean that also an amendment directed only to this replacement would be occasioned by a ground for opposition and would therefore comply with Rule 80 EPC.

3. Main request - request for remittal

3.1 Claim 1 of the main request essentially corresponds to claim 3 as granted. Objections to claim 3 as granted were already raised with the notice of opposition.

3.2 The merits of the main request were discussed (as auxiliary request 4) by both parties in their written submissions during the appeal proceedings and also in the Board's communication pursuant to Article 15(1) RPBA. It was only in reply to that communication that the appellant requested that the case be remitted to the Opposition Division for further prosecution if the Board admitted the main request.

3.3 As set out in point 2.3 above, the main request is part of the appeal proceedings without the Board having used any discretion under Article 12(4) RPBA to admit it. Moreover, while it is true that the Opposition Division did not decide on the current main request, it is settled case law that parties do not have a fundamental right to have each matter examined at two instances (see also Case Law of the Boards of Appeal, 10th

edition, 2022, V.A.9.2.1). Article 111(1), second sentence, EPC grants the Board discretion to either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution. According to Article 11 RPBA, a board shall not remit the case for further prosecution "unless special reasons present themselves for doing so". No special reasons are apparent in this case. On the contrary, the parties have had extensive opportunity to discuss the merits of the main request, and have also used this opportunity in their submissions. Therefore, the Board decided not to remit the case to the Opposition Division for further prosecution.

4. Main request - Article 123(2) EPC

4.1 It is disputed whether the application as filed provides disclosure for feature 1.4.

4.2 Claim 1 as originally filed referred to the length of the joined assembly "before use". The application as filed defines the term "before use" on page 2, lines 25 to 26, as "before insertion and e.g. also before the assembly is removed from a sterile packing". Page 22, lines 1 to 2, further discloses "before use i.e. before insertion and possible removal of the inserter housing".

4.3 Claim 1 of the main request specifies that the length is "in a dimension horizontal to the skin of the patient", a wording which reflects how the length of the joined assembly is to be measured as defined on page 3, lines 1 to 3, of the application as filed. The additional wording "when attached to the patient's

skin" limits the relative orientation between the assembly and the skin at which the restriction in claim 1 related to the length measurement is to be fulfilled.

4.4 According to the application as filed, the assembly is removed from the sterile packing and attached to the patient's skin before insertion (see e.g. page 1, lines 8 to 19; page 21, lines 23 to 25). The appellant refers to the last paragraph of page 1 and puts forward that page 1 of the application as filed relates to known systems. However, it is clear from the wording of the first three paragraphs of page 1 that they concern a general teaching of the invention (see e.g. "The invention concerns an assembly ...", line 4; "The assembly comprising the three elements ...", line 12; "The assembly of the present invention ... According to the present invention ...", lines 23 and 24).

4.5 The person skilled in the art, in the context of the application as filed, would thus unambiguously understand that the length measurement "in a dimension horizontal to the patients skin" (page 3, lines 1 to 3) is not in an arbitrary position/orientation of the assembly relative to the skin (e.g. when the assembly is in a sterile packing, as argued by the appellant) but when attached to the skin. This understanding is also supported by page 3, lines 3 to 11, a passage which immediately follows the definition of the term "length" and which refers to the placement of the inserter and the base part at least partially beside each other "before and during insertion" resulting in the assembly's "large contact surface to the patients skin" and the penetrating member not being "pulled away from the in-use position" during removal of the inserter device. This understanding is also consistent

with the disclosure in connection with the embodiment of Figure 4 ("when the mounting pad is adhered to the patient" on page 21, lines 17 to 25, and "length ... before use i.e. before insertion and possible removal of the inserter housing" on page 22, lines 1 to 3).

4.6 It follows that claim 1 does not contain subject-matter which extends beyond the content of the application as filed.

5. Main request - Article 83 EPC

5.1 An objection of insufficient disclosure cannot legitimately be based on an argument that the application would not enable a skilled person to achieve a non-claimed technical effect (see Case Law of the Boards of Appeal, 10th edition, 2022, II.C.3.2). The appellant's objection that the unclaimed technical effect of an increase in stability is not achieved over the whole breadth claimed is thus not convincing.

5.2 The appellant raises a further objection of insufficient disclosure, namely that the person skilled in the art would not know how to carry out the invention for a force that is not perpendicular to the insertion direction. This objection is new and it was not dealt with in the appealed decision. When raising the objection in the statement of grounds of appeal (against the version found to be allowable by the Opposition Division, with claim 1 corresponding to claim 1 as granted), the appellant neither identified the objection as an amendment nor provided reasons for submitting it in the appeal proceedings (see Article 12(4) RPBA).

5.3 The appellant argues that if the main request is admitted into the appeal proceedings, this objection should be admitted too. The Board cannot follow this argument. The main request was admissibly raised and maintained in the first-instance proceedings and is thus part of the appeal proceedings. Its claim 1 corresponds to claim 1 of the third and fourth auxiliary requests filed with the reply to the notice of opposition, and the appellant-opponent had ample opportunity - and also used this opportunity - to raise objections against this request in the first-instance proceedings. Moreover, the new objection of lack of sufficiency was raised against claim 1 as maintained by the Opposition Division (i.e. claim 1 as granted) and is not caused by the amendments in the present main request. Hence, the objection should have been submitted in the first-instance proceedings. The Board therefore decided not to admit the objection under Article 12(6), second sentence, RPBA.

6. Main request - novelty over D2, D3 and D4

6.1 D2 deals with devices for insertion of a cannula into the body. D2 discloses in the embodiment of Figures 21 to 23 an assembly comprising an inserter 90, a penetrating cartridge 711 and a cradle unit 20. According to the novelty objection, these elements correspond respectively to the inserter device, the penetrating member and the base part as defined in claim 1.

6.2 In the embodiment of Figures 21 to 23, a penetrating member 716 (e.g. a sharp needle) having a grip portion 712 pierces the skin and enters the subcutaneous tissue, and along with it a cannula 713 is also inserted. After the cannula 713 is inserted, the

penetrating member 716 is retracted together with the grip portion 712 (see paragraphs [0103] to [0107] of D2).

6.3 It is disputed whether or not the grip portion 712 of D2 anticipates the part of feature 1.2 reading "[the penetrating member comprises] a body which is in contact with the inserter device during insertion and with the base part during use".

6.4 The appellant puts forward that "in contact" in feature 1.2 is not restricted to direct physical contact but should be construed as encompassing indirect physical contact. The Board cannot follow this submission: by stating that two structural elements are "in contact", claim 1 refers to direct physical contact, according to the usual meaning of the term.

6.5 The appellant submits that the grip portion 712 would be part of the inserter device within the meaning of claim 1. The Board does not share this view. Claim 1 presents the penetrating member and the inserter device as two distinct elements comprised in the assembly, meaning that a component/body cannot belong to both elements. According to D2, the grip portion 712 is part of the penetrating cartridge 711 (see e.g. the last sentence of paragraph [0104]; see also the second sentence of paragraph [0069]). Hence, the grip portion 712 is part of the element that in the appellant's objection corresponds to the penetrating member and not to the inserter device. Moreover, if the grip portion 712 were to be regarded as being part of the inserter 90 (i.e. of the inserter device), then it could not be a body within the meaning of feature 1.2 because it would not be comprised in the penetrating member as required by this feature. Also the requirement of

feature 1.2 that the body is "in contact" with the inserter device would make no sense for a body that is part of the inserter device.

6.6 In D2, the grip portion 712 is in contact with the hooks 930 of the inserter 90 during insertion (see Figures 21e to 21g and the last two sentences of paragraph [0104]). However, D2 does not disclose that the grip portion 712 is in contact with the cradle unit 20 at any time, i.e. it is not in contact with the base part during use as required by feature 1.2. Instead, a different part of the penetrating cartridge 711 is disclosed to be in contact with the cradle unit 20, namely the cannula hub 714. The cannula hub 714, which is attached to the cannula 713, is retained within the well 310 of the cradle unit 20 in order to seal the upper opening of the cannula upon insertion, while the grip portion 712 is instead pulled upwards to retract the penetrating member 716 (see Figures 21h and 21i and paragraph [0107]; see also paragraph [0069]).

6.7 Addressing feature 1.2, the appellant also referred in his written submissions to Figure 12c of D2. This figure corresponds to a different embodiment and does not show any contact between the grip portion 712 and the cradle unit 20 either.

6.8 Therefore, D2 does not anticipate that the penetrating member comprises a body which is in contact with the inserter device during insertion and with the base part during use, as required by feature 1.2. It follows that the subject-matter of claim 1 is novel over D2.

6.9 The appellant also raised objections of lack of novelty over D3 (embodiment of Figure 17) and D4 (embodiment of Figures 19a to 19h) without, however, substantiating in

the written submissions in appeal why these documents anticipated feature 1.2. At the oral proceedings, the appellant submitted that similar arguments to those made in respect of D2 applied to D3 and D4 in view of the similarity of their disclosures.

6.10 Compared to D2, documents D3 and D4 provide less detail as to the construction and function of the penetrating cartridge 711. In particular, neither the description nor the relevant figures disclose feature 1.2 because the grip portion 712 (not labelled in the relevant figures of D3 and D4, but visible as the upper component of the penetrating cartridge 711) is never said or shown to be in contact with the cradle unit 20. It follows that the subject-matter of claim 1 is novel over D3 and D4.

7. Main request - admittance of D19

7.1 The appellant justified the filing of D19 with the statement of grounds of appeal with an alleged change of the claim interpretation for feature 1.5 by the Opposition Division and because D19 allegedly deprived claim 1 as maintained by the Opposition Division (i.e. claim 1 as granted) of novelty. The respondent requested that D19 not be admitted into the proceedings.

7.2 The interpretation of feature 1.5 in the appealed decision was already set out in point 2.2.5 of the preliminary opinion of the Opposition Division on 10 November 2020. It cannot therefore justify the filing of new evidence in the appeal proceedings.

7.3 The appellant argued that D19 should be admitted if the main request (filed as auxiliary request 4) was

admitted into the appeal proceedings. As set out in point 5.3 above, the main request was admissibly raised and maintained in the first-instance proceedings and is thus part of the appeal proceedings. The appellant-opponent had ample opportunity to raise objections to this request in the first-instance proceedings. The appellant's contention that D19 destroyed the novelty of claim 1 of the main request and also of claim 1 as granted indicates that D19 and the objections based thereon could have been submitted with the notice of opposition and should in any event have been submitted in the first-instance proceedings. The Board therefore decided not to admit D19 and the objections based thereon pursuant to Article 12(6), second sentence, RPBA.

8. Main request - inventive step starting from D2

8.1 At the oral proceedings before the Board, the appellant submitted that starting from the assembly of D2 feature 1.2 would be obvious in view of any of common general knowledge or D5.

8.2 The appellant supported these objections arguing that the problem solved by feature 1.2 was only to provide an alternative penetrating member (i.e. an alternative to the penetrating cartridge 711) and that it would be an obvious modification to modify the assembly of D2 to anticipate feature 1.2, if deemed necessary, using only common general knowledge. No evidence was submitted in support of such common general knowledge. The appellant also argued that the structures of D2 and D5 were alike, and that the person skilled in the art would have used the penetrating member of D5 in the assembly of D2 without use of inventive skill. The appellant further put forward that there were exceptional

circumstances within the meaning of Article 13(2) RPBA because he could not have known which features of claim 1, if any, would be found not to be disclosed in D2, and it was not reasonable to raise inventive-step objections for each disputed feature.

8.3 The respondent contested the admittance of these objections.

8.4 The Board considered it appropriate in the case before it to exercise its discretion under Article 13(2) RPBA relying also on criteria referred to in Article 13(1) RPBA 2020 (see the explanatory remarks on Article 13(2) RPBA, Supplementary publication 1, OJ EPO 2022, pages 185ff; see also T 574/17, Reasons 2.3). One key criterion is whether the amendment to the party's case is suitable to resolve the issues at stake. This is not the case if the new objection is not *prima facie* relevant.

8.5 In the absence of evidence of the alleged common general knowledge, it is not apparent why the person skilled in the art would have modified D2 to obtain an assembly anticipating feature 1.2. Such a modification would be contrary to the teaching of D2 of having a component (grip portion 712) for transmitting the downward movement and subsequently retracting the penetrating member 716, and another component (cannula hub 714) which is retained within the well 310 after insertion (as explained in paragraph 6.6 above).

8.6 With respect to the combination with D5, in D5 the cannula assembly 230 was considered by the appellant to anticipate the penetrating member of claim 1. The respondent highlighted the differences between D2 and D5, such that these documents would not be combined in

a way to arrive at the claimed invention. In D5, the cannula assembly 230 is retained in the port septum 502 and does not contribute to the retraction of the needle 234 (see Figures 23 to 24 and paragraphs [0084] to [0085] of D5). It is not apparent to the Board how the assembly of D2 could function if its penetrating cartridge 711 - which, as explained above, does contribute to the retraction - were to be replaced by the cannula assembly 230 of D5. The cannula assembly 230 would have to be adapted to allow the hooks 930 of D2 to engage with it in order to move it. Even with this adaptation, the hooks 930 in D2 move first downwards and then upwards, i.e. the cannula assembly 230 would be pulled upwards by the hooks 930 after insertion and thus be retracted (instead of retracting only the needle as done in D2). No cannula would remain inserted and the modified device of D2 would not achieve its intended function. If the retention of the cannula assembly 230 within the well 310 was greater than the upward force of the hooks 930, then the needle (i.e. the penetrating member 716 in D2) would not be retracted, again not achieving the intended function.

8.7 It follows that the objections are not *prima facie* prejudicial to the maintenance of the patent on the basis of the main request and the Board decided not to admit them under Article 13(2) RPBA.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the Opposition Division with the order to maintain the patent on the basis of claims 1 to 21 of the

main request filed as auxiliary request 4 with letter dated 9 August 2022 and a description to be adapted thereto if necessary.

The Registrar: The Chairwoman:

A. Chavinier-Tomsic Y. Podbielski

Decision electronically authenticated