

Internal distribution code:

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

**Datasheet for the decision
of 31 January 2020**

Case Number: T 0209/15 - 3.2.02

Application Number: 06121820.2

Publication Number: 1747789

IPC: A61M5/34

Language of the proceedings: EN

Title of invention:

A needle mount and use of the needle mount for mounting a
needle assembly

Patent Proprietor:

NOVO NORDISK A/S

Opponent:

SANOFI-AVENTIS DEUTSCHLAND GMBH

Headword:

Relevant legal provisions:

EPC Art. 100(a), 100(c)

RPBA Art. 12(4), 13

RPBA 2020 Art. 13(1)

Keyword:

Late filed ground for opposition - admitted (no)
Late filed document - admitted (no)
Discretionary decision - revised (no)
Late filed line of argument of lack of inventive step -
admitted (no)
Late filed line of argument of lack of novelty - admitted (no)
Novelty - (yes)

Decisions cited:

G 0010/91, G 0007/93, T 0190/99, T 0556/02

Catchword:



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 0209/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 31 January 2020

Appellant: SANOFI-AVENTIS DEUTSCHLAND GMBH
(Opponent) Patentabteilung
Industriepark Höchst, Geb. K 801
65926 Frankfurt (DE)

Representative: Weilnau, Carsten
Quermann - Sturm - Weilnau
Patentanwälte Partnerschaft mbB
Unter den Eichen 5
65195 Wiesbaden (DE)

Respondent: NOVO NORDISK A/S
(Patent Proprietor) Novo Allé
2880 Bagsværd (DK)

Representative: Hoffmann Eitle
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München (DE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 17 November
2014 rejecting the opposition filed against
European patent No. 1747789 pursuant to Article
101(2) EPC.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: P. L. P. Weber
A. Jimenez

Summary of Facts and Submissions

- I. The opponent appealed the decision of the Opposition Division dated 17 November 2014 to reject the opposition.

Notice of appeal was filed on 27 January 2015. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was filed on 27 March 2015.

- II. By letter dated 5 November 2019, the Board summoned the parties to oral proceedings. On the same day, a communication pursuant to Article 15(1) RPBA 2007 was issued.

- III. By letter dated 2 December 2019, the appellant/opponent informed the Board of a change of representative.

- IV. By letter dated 18 December 2019, the appellant/opponent raised an objection under the ground for opposition pursuant to Article 100(c) EPC and requested that this ground be introduced into the proceedings and that the objection be examined by the Board. By the same letter, the appellant/opponent filed D14, explaining why it considered this document to be prima facie relevant and why the subject-matter of claim 1 lacked novelty or at least inventive step in view of this document. It further submitted that the subject-matter of claim 1 also lacked novelty in view of D10.

- V. In a letter dated 7 January 2020, the respondent/patent proprietor indicated that it refused to consent to the belated introduction of the new ground for opposition into the proceedings.

VI. Oral proceedings were held on 31 January 2020.

The appellant/opponent requested that the decision under appeal be set aside and that European patent No. 1 747 789 be revoked.

The respondent/patent proprietor requested that the appeal be dismissed or, alternatively, that the patent be maintained:

- on the basis of one of auxiliary requests 1-7 filed by letter dated 12 August 2014 during the opposition proceedings or;
- on the basis of version "A" of the main request or of one of auxiliary requests 1A to 7A filed on 29 July 2015 with the reply to the grounds of appeal or;
- on the basis of version "B" of the main request or of one of auxiliary requests 1B to 7B filed by letter dated 7 January 2020;

with variants A and B of the main request and of the auxiliary requests 1 to 7 having to be considered immediately after the corresponding requests before moving to the next lower-ranking ones.

VII. The documents cited in the present decision are the following:

- D1: US 5273543 A
- D10: DE 20101594 U1
- D11: JP 63-46148 U
- D11': English translation of D11
- D12: JP 63-46148 U1
- D12': English translation of D12

D14: CH 332340 A

VIII. The arguments of the appellant/opponent relevant for the decision can be summarised as follows (for further details, see the corresponding part of the Reasons for the Decision below):

Admission of D11, D12, D11', D12'

The Opposition Division had misused its discretionary power not to admit D11 in that it had wrongly applied the criterion of prima facie relevance. D11 was highly relevant and should have been admitted into the proceedings. D12 and the translations filed confirmed this position.

Admission of the line of argument of lack of inventive step based on the combination of D1 with D10

D10 disclosed a simple alternative fixing means for fixing the needle assembly to the needle mount. Thus, this prima facie highly relevant combination had to be admitted into the proceedings. There were many appeal cases in which the boards had accepted new lines of argument at the start of the appeal proceedings.

Admission of D14

This document was highly relevant in the sense that it prima facie questioned the novelty and inventive step of the subject-matter of claim 1. Furthermore, this document was cited in the patent in suit so it was well known to the respondent/patent proprietor. The latter had even filed auxiliary requests to answer the additional objections raised, which showed that it could deal with it. Moreover, the case law of the

boards of appeal held that relevance should take precedence over the lateness of the filing.

The reason for filing it after the summons was that a change of attorney had taken place, and possibly the former attorney had considered that D1 was sufficient.

Admission of the objection of lack of novelty in view of D10

Since the wording of claim 1 was very general, even the neck of the shampoo container according to D10 comprising threads and grooves had, prima facie, to be considered a novelty-destroying needle mount.

Lack of novelty in view of D1

Litigious features 1.3 and 1.4 were anticipated by D1. In the patent in suit it was only in relation to the description of the specific embodiment that the threads were described to be on the exterior surface of the outer wall. In the more general part of the patent, in particular in paragraphs [0005] and [0009], this was not so. And claim 1 did not define that the threads and the grooves had to be on the same surface. Moreover, in D1, the needle assembly 35 had to be considered a standard needle assembly functioning with a luer-type connection, which was one of the most commonly known connection types in the medical field. In this context, it had to be noted that the wording "for accepting" was very general. In particular, it did not mean that the engagement of the two parts had to be threaded, which was a further reason for considering these features to be anticipated.

IX. The arguments of the respondent/patent proprietor relevant for the decision are essentially those

endorsed by the Board and can be summarised as follows (for further details, see the corresponding part of the Reasons for the Decision below):

Admission into the appeal proceedings of D11, D11', D12, D12', D14 and the objections based on them, of the objection of lack of inventive step in view of D1 combined with D10 and of the lack-of-novelty objection in view of D10

D11 was late-filed and not admitted in the opposition proceedings. The opposition division, which found that this document lacked prima facie relevance, had exercised its discretion according to the correct criteria and in a reasonable way. Hence, D11 should not be admitted into the appeal proceedings either. The same applied to D12, which related to the same invention of D11 and to their translations, since these documents could have been filed already in opposition proceedings and were not prima facie relevant for the same reasons as D11.

The lack-of-inventive-step line of argument based on the combination of D1 with D10, the objection of lack of novelty in view of D10 and document D14 could all have been submitted at an earlier stage, since D10 was already part of the opposition proceedings and D14 was cited in the patent in suit. There was no objective justification for the delay of these submissions. Moreover, neither said objections based on D10 nor document D14 were prima facie relevant. Hence, they should not be admitted into the proceedings either.

Novelty in view of D1

At least features 1.3 and 1.4 were not disclosed in D1. As clear from the context of the claim and the description, the outer wall was provided with threads on its outer surface, so that standard needle hubs could be mounted on it. Hence, a standard needle hub or assembly within the meaning of the patent in suit was a hub with internal threading, which could be threaded onto the outer threading of the needle mount. Thus the threads, contrary to what was disclosed in D1, had to be on the outer surface of the outer wall.

Therefore, the subject-matter of claim 1 was novel in view of D1.

X. Claim 1 of the patent as granted reads as follows (with the addition of feature numbering as proposed by the appellant/opponent in the grounds of appeal):

1. A needle mount (100) comprising;
 - 1.1 A cylindrical outer wall (110)
 - 1.2 having a top end and
 - 1.3 threads (200) disposed on the cylindrical outer wall (110)
 - 1.4 for accepting thereon a standard threaded needle assembly,
 - 1.5 and a plurality of grooves (120) disposed in the cylindrical outer wall (110) beginning at the end of the cylindrical outer wall (11)
 - 1.6 and defining a passageway that is generally parallel to a cylindrical axis (1000) of the cylindrical outer wall (110),
 - 1.7 Characterized in that,
at least one groove (120) of the needle mount (100) further comprises a first portion (130) and a second

portion (150) oriented at an angle to the first portion (130).

Reasons for the Decision

1. The appeal is admissible.
2. The invention

The invention is a needle mount for accepting a needle assembly. To improve the ease of mounting the needle assembly on the needle mount for persons disabled or with poor dexterity (see paragraph [0007]), the invention proposes, on top of a standard threading (allowing a standard threaded needle assembly to be mounted), a way to mount the assembly on the needle mount with a bayonet-connection-type groove, without having to screw it on the threads. An embodiment is shown in Figures 1 and 2 of the patent, which are reproduced below.

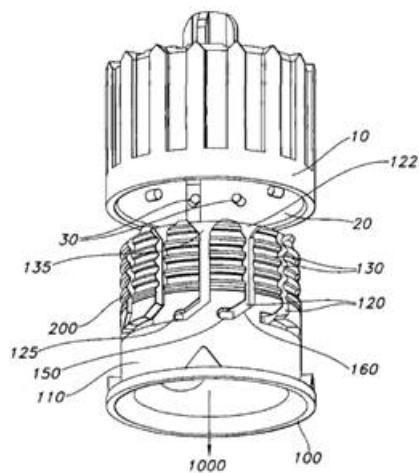


FIG. 1

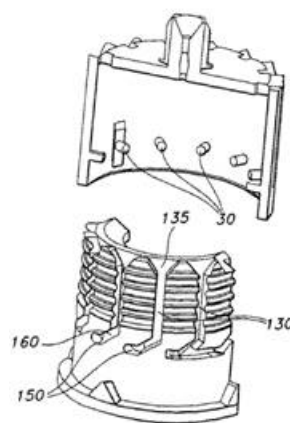


FIG. 2

3. Admission of the ground for opposition according to Article 100(c) EPC into the appeal proceedings

By letter of 18 December 2019, the appellant/opponent raised an objection under the ground for opposition pursuant to Article 100(c) EPC not yet in the appeal proceedings. This ground had not been in the opposition proceedings either. The opposition proceedings had been based only on the grounds for opposition of lack of novelty and lack of inventive step pursuant to Article 100(a) EPC (see facts and submissions of the impugned decision). Thus, the ground for opposition pursuant to Article 100(c) EPC was a new ground in the appeal proceedings within the meaning of G 10/91 (OJ EPO 1993, 420). According to that decision (point 3 of the Opinion), when an appellant/opponent raises a new ground for opposition in the appeal proceedings, the Board can only examine it with the consent of the patentee.

In the present case, in its letter dated 7 January 2020, the respondent/patent proprietor did not approve the introduction of this ground into the appeal proceedings. Therefore, the Board has no power to examine it.

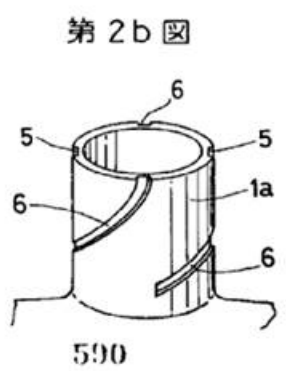
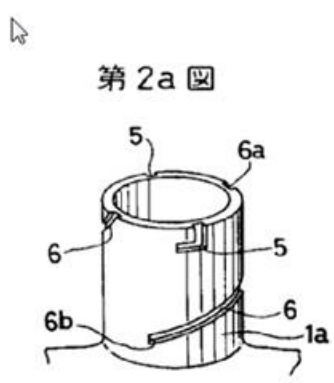
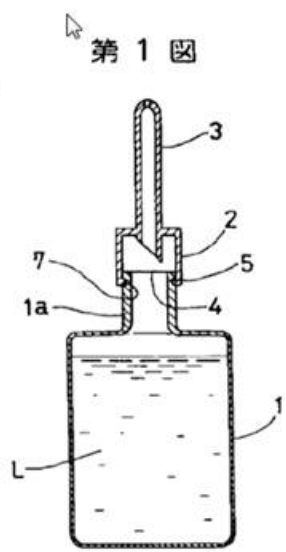
4. Admission into the appeal proceedings of D11, D11', D12, D12', D14 and the objections based on them, of the objection of lack of inventive step in view of D1 combined with D10 and of the lack-of-novelty objection in view of D10

- 4.1 D11 was filed for the first time in the opposition proceedings and was not admitted into them (see points 2 and 3 of the reasons for the impugned decision). D12 (a document relating to the same utility model as D11),

the translations D11' and D12' and the objection of lack of inventive step in view of D1 combined with D10 were all submitted with the statement setting out the grounds of appeal. Given that D12 relates to the same utility model as D11 and that D10 was part of the opposition proceedings (it was admitted by the Opposition Division), there is no doubt that all these new submissions could have been made in the opposition proceedings. Accordingly, on the basis of Article 12(4) RPBA 2007 (which applies to the present case by virtue of the transitional provisions of Article 25(2) RPBA 2020), it is within the power of the Board to hold inadmissible these late submissions, which either could have been presented or were not admitted in the first-instance proceedings.

4.1.1 D11 (the Figures 1, 2a and 2b of which are reproduced hereafter) and D12 are two Japanese documents showing the same technology. D11' and D12' are the English translations of these documents. Therefore, they will be considered together. The parties agreed with this way of proceeding.

The Opposition Division considered that prima facie D11 did not disclose a needle mount and did not disclose threads for accepting a standard threaded needle assembly.



The appellant/opponent considered that the Opposition Division had misused its discretionary power not to admit D11 in that it had wrongly applied the criterion of prima facie relevance. Contrary to the Opposition Division, the appellant/opponent considered that D11 was highly relevant and should have been admitted into the proceedings. According to it, D12 and the translations filed confirmed this position and should be admitted as well.

It is established case law that a board of appeal should only overrule how a first-instance department exercised its discretion if it comes to the conclusion that the first-instance department in its discretionary

decision either did not exercise its discretion in accordance with the right principles or exercised its discretion in an unreasonable way (G7/93, OJ EPO 1994, 775).

More precisely, the appellant/opponent considered that the "cannula 3" disclosed in D11 was a needle-like element. Since claim 1 of the patent in suit did not indicate that the needle claimed was for an injection device, the word "needle" in claim 1 had to be interpreted more generally, and therefore also encompassed needle-like elements.

The Board does not share the opinion of the appellant/opponent and does not see any reason to depart from the finding of the Opposition Division.

As the patent in suit indicates in paragraph [0001], it relates to the field of injection devices. This is mentioned several times, for instance in paragraphs [0002], [0003], [0004] and [0007]. Hence, there cannot be any doubt that, when using the word "needle", the author of the patent meant to designate a typical needle used in such injection devices. The respondent/patent proprietor confirmed this interpretation.

The drawings alone in D11 do not show a typical needle shape for the element 3 extending from the top of the mount 2. This element 3 has a rounded-end shape and not a puncturing tip typical of needles. The reason for the use of such a rounded-end shape is apparent from D12' (the translation of D12 into English), which indicates that the outflow tube 3 is adapted for use in body cavities, such as the anus and the vagina. Quite obviously, no needle within the meaning of the patent

will be used in such a context. Therefore, D11 and D12 do not relate prima facie to a needle mount.

For the reasons above, the Board considers that the Opposition Division did not apply the criterion of prima facie relevance in an unreasonable way. Thus, the Board has no reason to overturn the discretionary decision of the Opposition Division not to admit D11 into the proceedings.

Hence, the Board finds that D11 and D12 lack prima facie relevance and holds them and their translations inadmissible pursuant to Article 12(4) RPBA 2007.

4.2 Documents D1 and D10 were in the first-instance proceedings.

In the statement setting out the grounds of appeal, the appellant/opponent introduced a lack-of-inventive-step line of argument based on the combination of D1 with D10. The appellant/opponent considered that D10 disclosed a simple alternative fixing means for fixing the needle assembly to the needle mount and that therefore this prima facie highly relevant combination should be admitted into the proceedings. It argued that there were many appeal cases in which the boards had accepted new lines of argument at the start of the appeal proceedings.

In the present case, the combination presented in the appeal proceedings not only could have been filed earlier but is also prima facie not relevant.

There is no reason why the appellant/opponent could not have presented this combination in the first-instance

proceedings when D10 was filed, D1 already being in the proceedings at that time.

D1 discloses a safety needle syringe which helps prevent accidental needle sticks (see column 1, lines 5 to 11). The aim of the invention in D1 is to provide a safety syringe in which the user can easily withdraw the needle into the syringe barrel and can easily adapt the type of needle used to the type of use of the syringe (see column 2, lines 27 to 39).

D10 discloses, in the sole described specific embodiment of the claimed container, a container for containing a bigger quantity of shampoo specially conceived for haircut salons (see page 1, first four paragraphs). In such salons, a manual pump has to be connected to the big shampoo container (see page 1, lines 25 to 29) to be able to take individual shampoo portions out of the container. To avoid having to screw the pump adapter onto the neck, the proposal of D10 is to provide the neck not only with a normal threading 3 (used for a corresponding threaded cap when the container is transported), but also with vertical grooves 4 terminating in a bayonet coupling 7 (as can be seen in Figure 1 of D10 reproduced below). In this way, a pump adapter provided with corresponding internal projections can easily be fixed to the neck without any long and cumbersome rotational movement.

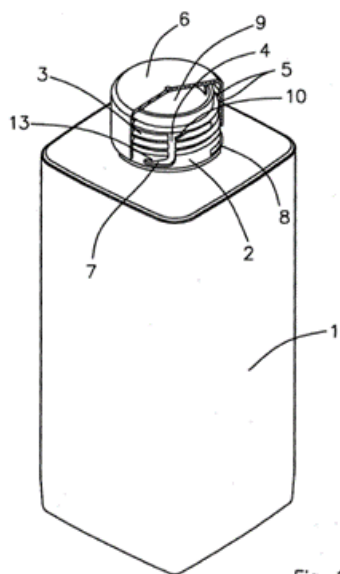


Fig. 1

In the Board's view, it would therefore be prima facie hindsight reasoning to submit that the person skilled in the art working in the medical field wishing to improve the safety syringe of D1 would ever consult container technology, even less so for haircut salons, to find a way to more easily fix a needle assembly to a needle mount of that safety syringe.

Moreover, when starting from D1 (for a more detailed description of its content, see below), such a change would mean a complete redesign of the distal end of the syringe (in particular, the neck 27) and of the needle mount 28, which the Board also considers prima facie not obvious.

The Board therefore decides that this late-filed line of argument of lack of inventive step should be declared inadmissible pursuant to Article 12(4) RPBA 2007.

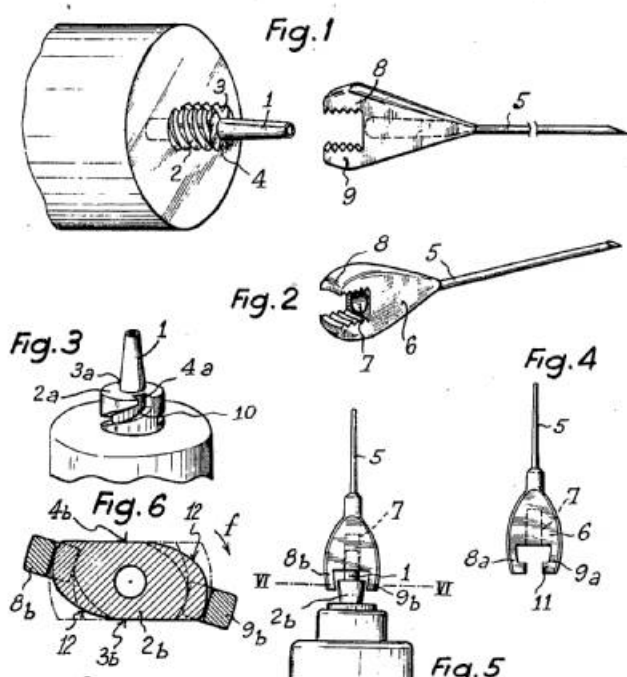
4.3 Both D14 and the objection of lack of novelty in view of D10 were submitted after the statement setting

out the grounds of appeal and after the summons to oral proceedings. Thus, they represent an amendment to the appellant/opponent's case, admission of which is subject to the Board's discretion under both Article 13(1) RPBA 2020 and Article 13 RPBA 2007 (see the transitional provisions of Article 25(3) RPBA 2020, which apply in the present case). According to both articles, the Board's discretion is exercised in view of, *inter alia*, the complexity of the new subject-matter, the current state of the proceedings and the need for procedural economy. Moreover, according to Article 13(1) RPBA 2020, it is subject to the party's justification for the late amendment.

4.3.1 By letter of 18 December 2019, the appellant/opponent filed D14 (Figures 1-6 of which are reproduced hereafter) and explained that this document was highly relevant in the sense that it *prima facie* questioned the novelty and inventive step of the subject-matter of claim 1. The embodiment according to Figure 1 disclosed a needle mount with grooves generally parallel to the axis of the cylindrical wall. Moreover, since the shape of the grooves was not further defined in claim 1 of the patent in suit, it could also be considered that the last partial turn of the threads was the second portion of the groove oriented at an angle to the first portion as defined in feature 1.7. Thus, the novelty of the subject-matter of claim 1 was in doubt. In any case, this feature 1.7 could not be considered inventive in view of the embodiments shown in Figures 3 and 4 of D14, which specifically disclosed grooves with a second portion at an angle. Furthermore, this document was cited in the patent in suit so it was well known to the respondent/patent proprietor. The latter had even filed auxiliary requests to answer the additional objections raised. This showed that it could

deal with it. Moreover, the case law of the boards of appeal held that relevance should take precedence over the lateness of the filing.

The reason for filing it after the summons was that a change of attorney had taken place, and possibly the former attorney had considered that D1 was sufficient.



In the Board's opinion, since this document was mentioned in the patent in suit, there was ample time to file it in due time in the opposition and appeal proceedings, in particular with the notice of opposition or with the statement setting out the grounds of appeal. The change of attorney cannot justify the late filing, such a change being a voluntary choice of the party, not one dictated by an external influence such as a new argument/document/ground submitted by the opposing party or the Board.

Moreover, in any case D14 is not prima facie relevant. Feature 1.7 is not disclosed by D14 - a partial thread of the threading disclosed there not being a

continuation of the groove along the axis. Moreover, there is prima facie also no reason to combine the fixing means by threadings of Figure 1 with the fixing means by grooves disclosed in Figures 3 and 4 of the same document, these fixing means being disclosed as alternative means, and this document not hinting at providing two different fixing means at the same time on the same needle mount.

Hence, for the reasons above, D14 and the objections raised with it are not introduced into the appeal proceedings.

4.3.2 In its letter dated 18 December 2019, the appellant/opponent considered that, since the wording of claim 1 was very general, even the neck of the shampoo container according to D10 comprising threads and grooves (see drawing above) had to be considered a novelty-destroying needle mount.

According to the Board, it is made amply clear in the patent in suit that the invention disclosed concerns needle mounts for mounting a needle to an injection device (see e.g. [0001], [0002] and [0003]). It is therefore not possible that the person skilled in the art reading claim 1 would consider that a shampoo container neck was such a needle mount. Hence, D10 is prima facie not novelty-destroying.

For this reason, and because no reason for the late filing was provided, this objection was not admitted into the appeal proceedings.

5. Novelty in view of D1

D1 (see Figures 2 and 3 here below) discloses a needle mount 28 (movable needle carrier 28) to be attached (by using the distal side of the plunger 47) to the distal end 27 of the syringe 21 by means of grooves 59 in the needle mount and inwardly directed projections 65 in the distal end 27. A needle assembly 35 can then be attached to the needle mount 28. Projections 44 of the needle assembly engage helical groove 45, so that the needle assembly will be tightened on the tapered luer tip 43.

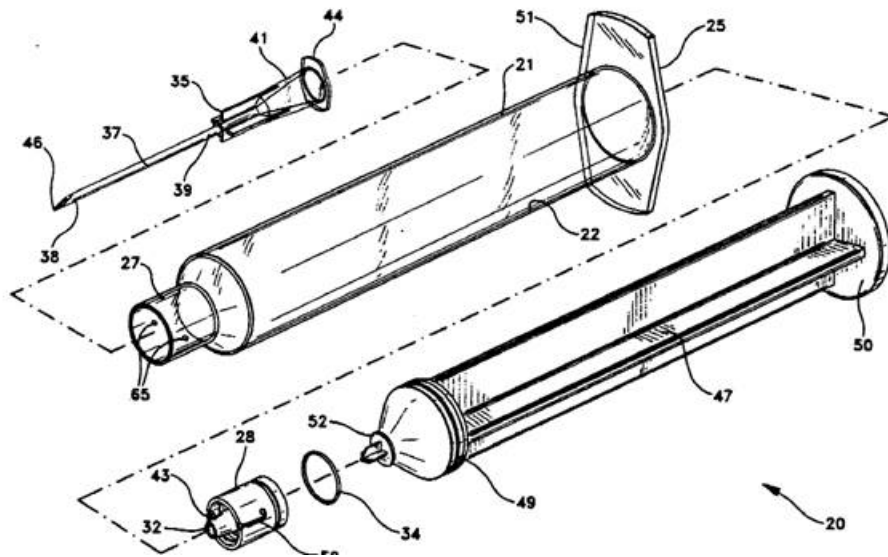
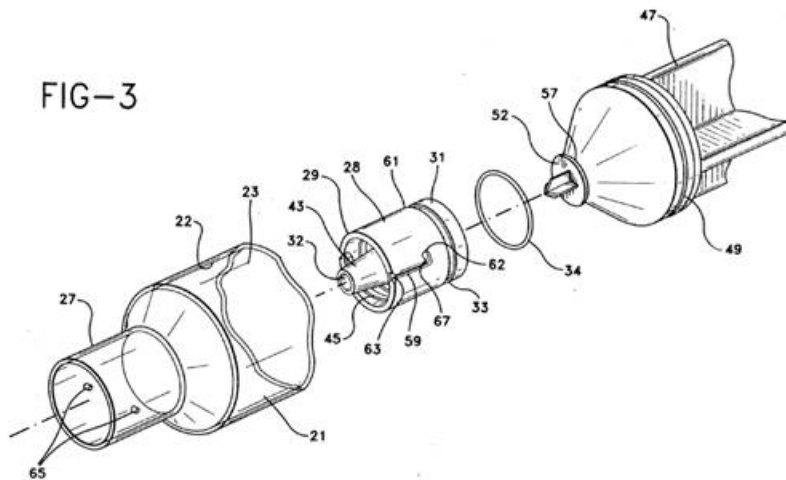


FIG-3



There was agreement between the parties that the disputed features were at least features 1.3 and 1.4. In particular, there was discussion as to the meaning of "outer wall", and in particular whether this had to be read as "outer wall surface" or whether it could more generally designate a wall with an interior and an exterior surface, the threads being on any of the two surfaces. It was further discussed what kind of features were implied by the functional definition "for accepting thereon a standard threaded needle assembly".

The appellant/opponent submitted that it was only in relation to the description of the specific embodiment that the threads were described to be on the exterior surface of the outer wall. In the more general part of the patent, in particular in paragraphs [0005] and [0009], this was not so. Moreover, claim 1 did not define that the threads and the grooves had to be on the same surface. For these reasons, the embodiment disclosed in D1 in which the grooves were on the exterior surface of the outer wall and the threads were on the interior surface of the outer wall anticipated the corresponding feature of claim 1. Moreover, in D1, the needle assembly 35 had to be considered a standard needle assembly functioning with a luer-type connection, which was one of the most commonly known connection types in the medical field. It was even explicitly mentioned in column 4, lines 21 to 35, that the projections 44 of this luer-type connector engaged with the internal groove (thread) 45 of the needle mount. Thus, the functional feature of claim 1 was also anticipated. In this context, it had to be noted that the wording "for accepting" was very general. In particular, it did not mean that the engagement of the two parts had to be threaded. This was a further reason for considering this feature to be anticipated.

The Board does not share the appellant/opponent's opinion. It is established case law that claims should not be read alone but in the context of the patent as a whole with a mind willing to understand (e.g. T 0190/99, point 2.4 of the Reasons; T 0556/02, point 5.3 of the Reasons). Or, in other words, the patent in suit is its own dictionary.

In the present case, it therefore has to be established what is meant by the feature that "threads (are) disposed on the cylindrical outer wall", with the additional functional feature "for accepting thereon a standard threaded needle assembly", in the context of the patent in suit.

In the Board's opinion, paragraph [0017] and the end of paragraph [0020] of the patent in suit give a clear indication in this respect.

Paragraph [0017] reads: *"One advantage of the present invention is that the needle mount, may be equipped with standard threads 200 on its exterior surface (see Fig. 1). The grooves 120 may be cut into the standard threads 200. This allows the needle mount 100 of the present invention to accept not only needle hubs, but also standard, threaded needle-hub assemblies."*

Paragraph [0020], last sentence, reads: *"The embodiment shown in Figures 2-4 also advantageously allows the outer surface of the needle mount to have threads so that standard prior-art needle hubs may be used with the improved needle mount of the present invention."*

As can be seen, these paragraphs define that, if the outer wall is provided with threads on its outer

surface, standard needle hubs can be mounted on it. Hence, a standard needle hub or assembly within the meaning of the patent in suit is a hub with internal threading. Thus, it can be threaded onto the outer threading of the needle mount.

In other words, when the wording of claim 1 requires threads on the cylindrical outer wall for accepting a standard threaded needle assembly, in the context of the patent in suit, this can mean nothing other than that the threads must be on the outer surface of the outer wall (or that, in the context of the patent, the wording "cylindrical outer wall" is equivalent to "cylindrical outer surface") so that a standard needle hub or assembly having internal threads can be mounted on it.

From the above, it follows that the subject-matter of claim 1 is novel in view of D1 since the needle mount according to D1 is not provided with threads disposed on the cylindrical outer wall for accepting a standard threaded needle assembly.

Therefore, the ground for opposition of lack of novelty pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent as granted.

6. Since no other objection of lack of novelty and no other grounds for opposition are to be examined, the appeal has to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated