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**Datasheet for the decision  
of 7 July 2016**

**Case Number:** T 0419/13 - 3.2.02

**Application Number:** 05770366.2

**Publication Number:** 1790372

**IPC:** A61M25/00

**Language of the proceedings:** EN

**Title of invention:**  
Indwelling needle assembly

**Patent Proprietor:**  
Terumo Kabushiki Kaisha

**Opponent:**  
B. Braun Melsungen AG

**Headword:**

**Relevant legal provisions:**  
EPC Art. 83, 123(2), 54, 56

**Keyword:**

Sufficiency of disclosure - (yes)  
Amendments - added subject-matter (no)  
Novelty - (yes)  
Inventive step - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
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Case Number: T 0419/13 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 7 July 2016**

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**Decision under appeal:** **Interlocutory decision of the Opposition**  
**Division of the European Patent Office posted on**  
**6 December 2012 concerning maintenance of the**  
**European Patent No. 1790372 in amended form.**

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** C. Körber  
D. Ceccarelli

## **Summary of Facts and Submissions**

- I. On 6 December 2012 the Opposition Division posted its interlocutory decision concerning maintenance of European patent No. 1790372 in amended form.
- II. An appeal was lodged against this decision by the opponent by notice received on 13 February 2013 with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 12 April 2013.
- III. By communication of 9 March 2016, the Board forwarded its provisional opinion to the parties and summoned them to oral proceedings.
- IV. Oral proceedings were held on 7 July 2016.

The final requests of the parties were as follows:

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

The respondent (patent proprietor) requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of one of the first to fifth auxiliary requests filed with letter dated 18 April 2016.

- V. The following document is of importance for the present decision:

D1: US-A-5 688 253.

VI. Claim 1 of the patent as upheld in the impugned decision reads:

"An indwelling needle assembly (1) comprising:  
an inner needle (4) having a sharp point (41) at a tip thereof;  
an inner needle hub (5) fixed to a base section of said inner needle (4);  
a hollow outer needle (2) into which said inner needle is inserted;  
an outer needle hub (3) fixed to a base section of said outer needle; and  
a tube (7) inserted into said inner needle hub (5) and connected to said base section of said outer needle hub (3) so that an inner cavity (71) of said tube (7) communicates with an inner cavity (21) of said outer needle (2),  
wherein a center axis of said outer needle (2) and a center axis of said tube (7) at a head section of said tube are substantially parallel with each other in the condition where said inner needle (4) is inserted into said outer needle (2)."

Claims 2 to 12 are dependent claims, with claims 4 to 9 and 11 reading as follows:

"4. The indwelling needle assembly as set forth in claim 1, wherein said inner cavity (21) of said outer needle (2) and said inner cavity (71) of said tube (7) communicate with each other through a junction conduit provided in said outer needle hub (3)."

"5. The indwelling needle assembly as set forth in claim 1, further comprising a protector (9) for covering at least the sharp point (41) at the tip of

said inner needle (4) when said inner needle is withdrawn from said outer needle (2)."

"6. The indwelling needle assembly as set forth in claim 5, wherein said protector (9) includes a protector body (91) having an inner needle passage (911) into which said inner needle (4) can be inserted, and shutter means (92) which is displaced between a first posture such that said inner needle (4) can be inserted into said inner needle passage (911) and a second posture to inhibit the passage of said sharp point (41) of said inner needle (4)."

"7. The indwelling needle assembly as set forth in claim 5, further comprising movement restraining means for restraining said inner needle (4) from moving in the direction opposite to said sharp point (41) of said inner needle (4) in relation to said protector (9) in the condition where said protector (9) covers at least said sharp point (41) of said inner needle (4)."

"8. The indwelling needle assembly as set forth in claim 7, wherein said movement restraining means comprises engaging means for engagement between said inner needle (4) and said protector (9)."

"9. The indwelling needle assembly as set forth in claim 8, wherein said inner needle (4) has a section (42) varying in an outside diameter; said protector body (91) has a reduced diameter section (915) where an inside diameter of said inner needle passage (911) is reduced; and said engaging means comprises said section (42) with the varying outside diameter of said inner needle (4) and said reduced diameter section (915)."

"11. The indwelling needle assembly as set forth in claim 1, wherein said inner needle (4) is solid."

VII. The appellant's arguments are summarised as follows:

Sufficiency of disclosure - Article 83 EPC

The claimed invention was not disclosed in a manner sufficiently clear and complete for it to be performed by a person skilled in the art. Claim 4 required the indwelling needle assembly to comprise a so-called junction conduit in the outer needle hub to allow the tube to communicate with the interior of the outer needle. The claims contained no limitations on the shape or configuration of the junction conduit. Thus, the claims embraced any shape or configuration of junction conduit that extended between the bore of the tube and the interior of the outer needle hub. The figures showed a substantially L-shaped conduit 32, described in paragraph [0061] of the specification. However, there was no teaching in the specification regarding how the outer needle hub could be formed with such an L-shaped conduit. Typically, the components of the indwelling needle assembly, such as the outer needle hub, were formed from a suitable polymer by moulding. It could not be seen how the outer needle hub having an L-shaped conduit as shown in the figures could be moulded in the known manner. Accordingly, the outer needle hub had to be prepared using atypical or unusual techniques. However, the specification was wholly silent about the techniques to be used. Furthermore the L-shaped conduit was just one of many shapes and configurations of conduit embraced by the claims, including conduits more complex and convoluted in shape than the conduit shown. Again, there was no teaching as to how such complex and convoluted conduits

could be formed in the outer needle hub. Also, no evidence was provided by the respondent to show that this was within the skilled person's common general knowledge. The respondent had chosen to cast the claimed feature extremely broadly but had failed to discharge the burden of providing sufficient information to enable all the forms of conduit to be manufactured.

Section 3.1 of the impugned decision indicated that the requirements for sufficiency of disclosure were met if only some of the embodiments embraced by the claims were enabled by the specification. That was wrong in law. As stated in the Case Law of the Boards of Appeal, section II.A.1, substantially any embodiment of the invention, as defined in the broadest claim, had to be capable of being realised on the basis of the disclosure. According to section II.A.3(c), it was not allowed for there to be embodiments of the claimed invention that could not be realised by the person skilled in the art. In the present case, the vast and likely innumerable range of embodiments of the junction conduit covered by claim 1 included many that simply could not be made by the person skilled in the art.

Claims 6 to 9 related to embodiments of the assembly, in which a protector was provided. Claim 9 merely referred to the inner needle having a section "varying" in outer diameter, which included the embodiment in which the section of the inner needle "varying" in outer diameter had a smaller diameter than other sections of the inner needle. As shown in Figure 5, the inner needle was provided with a portion close to its sharpened tip having an increased diameter, which engaged with a narrow portion 915 of the passage in the protector body, as the inner needle was withdrawn from



the outer needle. However, there was no teaching as to how such a reduced diameter section of the needle could engage with the passage through the protector body. Rather, the inner needle would pass completely through the protector, thus exposing the sharpened tip of the needle. Again, the respondent had elected to word a claimed feature very broadly without providing any disclosure that would allow all the embodiments covered to be constructed.

Claims 1 and 11 embraced indwelling needle assemblies in which the inner needle was solid. In paragraphs [0002] to [0011] it was described that an essential feature of an indwelling needle assembly was the so-called "flashback" of blood. This function was essential to the proper and safe operation of an indwelling needle assembly. In the case of a solid inner needle, as embraced by claim 1 and recited in claim 11, blood could not flow within the inner needle and flashback could not occur. The groove 44 described in paragraph [0080] was too short to permit a visual check of the blood flow through the (transparent) hub of the inner needle.

Added subject-matter - Article 123(2) EPC

The replacement of the term "different" in original claim 9 by the term "varying" in the expression "the inner needle has a section varying in an outside diameter" had been made in order to clarify the claim, that is to change its meaning. If there was no different meaning, there would have been no reason to amend. Regardless of the different meanings of the words, such a change in meaning resulted in an addition of new subject-matter. In paragraph [0070] of the original application as published, cited by the

respondent in support of this amendment, the term "varied" was used, which was different from "varying".

#### Novelty - Article 54 EPC

The base 30-b with the seal plug 30s gripping the inner needle 51 of D1 anticipated the inner needle hub as defined in claim 1. The respondent's argument that the inner needle of D1 was movable with respect to the base and the hub was thus not fixed to the needle was flawed. The specification of the patent contained no definition of the term "fixed". Certainly, there was nothing to require that the inner needle hub was fixed to the base section of the needle such that the needle could not be moved at all with respect to the inner needle hub. Paragraph [0077] of the patent in suit merely suggested some techniques that could be used, and the example of "fitting" covered the inner needle being loosely fitted inside the inner needle hub.

#### Inventive step - Article 56 EPC

The assembly recited in claim 1 differed from that of D1 by virtue of a single feature, viz. that the tube was inserted into the inner needle hub. Claim 1 was cast very broadly, in particular with respect to the form of the inner needle hub and the extent to which the tube extended into the inner needle hub. As a result, it included embodiments in which the needle hub extended laterally and in which the tube was inserted only a very short distance into the needle hub. In such embodiments, the tube was provided with no significant protection by the inner needle hub and the inner needle hub did not act to shield the tube in any way. Furthermore, in such embodiments, the arrangement of the tube and inner needle hub were at least as bulky as

the device of D1, if not bulkier. This in turn led to the tube being no less of an obstacle to the use of the device than the arrangement of D1. In addition, the tube in such embodiments was liable to be disturbed in use. Accordingly, claim 1 covered many embodiments which simply did not in any way solve the technical problem identified in the impugned decision. The technical problem was simply to provide an alternative arrangement to that of D1. The arrangement defined in claim 1 was just a trivial design modification that provided no technical advantage and would have been obvious to a person skilled in the art. It would be a trivial matter to provide a small collar on the inner needle hub 53, for example with a slit in the collar to allow the tube to be removed, to provide support and/or shielding of the tube. Similarly an extension could be provided at the proximal plate of the plunger 53 for holding the tube 35, as indicated in the modified drawing of Figure 1A submitted during the oral proceedings. Such minor modifications would not involve an inventive step.

VIII. The respondent's arguments are essentially those underlying the reasons for this decision set out below.

### **Reasons for the Decision**

1. The appeal is admissible.
2. Sufficiency of disclosure
  - 2.1 Claim 4

Claim 4 defines a junction conduit provided in the outer needle hub 3 through which conduit the inner cavity 21 of the outer needle 2 and the inner cavity 71

of the tube 7 communicate with each other. This junction conduit is denoted by reference numeral 32 and shown in Figures 2 to 5 as being L-shaped. It is within the skilled person's general technical knowledge to manufacture such an L-shaped conduit in a needle hub (usually formed from a suitable polymer) with conventional techniques used in this field, such as moulding, either with pins or rods being inserted beforehand or by subsequent drilling. Accordingly, it is not necessary that such techniques be described or even mentioned in the specification.

Nor does the Board share the appellant's view that, since claim 4 does not specify any particular shape of the conduit, it could be extremely convoluted and complex and thus impossible to manufacture. This is merely a hypothetical assertion, contrary to the principle that when an insufficiency objection is made the burden of proof generally lies with the opponent (see decisions cited in section in "Case Law of the Boards of Appeal of the EPO" section II.C.8 (7<sup>th</sup> ed. 2013)). Moreover, the skilled person knows which shapes can be made using conventional manufacturing techniques and would thus a priori exclude those that cannot be realised.

## 2.2 Claims 5 to 9

Claim 5 defines a protector for covering at least the sharp point 41 at the tip of the inner needle 4. The protector may have a movement-restraining means and an engaging means for engagement between the inner needle 4 and the protector 9 as further defined in claims 7 and 8. Claim 9 specifies that the engaging means as comprises a section 42 of the inner needle 4 varying in an outside diameter and the protector body 91 with a

reduced diameter section 915. Even though the term "varying" in an outside diameter in principle also covers a reduced outside diameter, as correctly argued by the appellant, the skilled person excludes this interpretation as technically meaningless since it would lead to an artificial construction which would not work. According to the established case law cited in section II.C.4.2 of "Case Law of the Boards of Appeal of the EPO" (7<sup>th</sup> ed. 2013) an invention is in principle sufficiently disclosed if at least one way is clearly indicated enabling the skilled person to carry out the invention. This is the case here as described in paragraphs [0069] and [0070] and [0109] to [0111] of the specification and shown in Figures 2 to 5, wherein the section 42 of the inner needle 4 "varying in an outside diameter" is located between an intermediate outside diameter section 4b and a maximum outside diameter section 4a, thus being a section of **increasing** outside diameter of the inner needle which cannot pass through the reduced diameter part 915 of the protector and consequently becomes engaged therewith, thus preventing the inner needle from coming off from the protector.

### 2.3 Claim 11

Claim 11 is directed to an inner needle 4 which is solid. Such a solid needle is described in paragraph [0067] of the specification and the Board has no doubts that the skilled person could reproduce such a needle. The Board is not able to verify that flashback (or "flush-back" as referred to in paragraphs [0005] et seq. in the section "Background Art") is presented as an essential feature of the claimed invention, allowing a visual check that the inner needle has punctured a blood vessel. Even if that were the case, the

specification does describe in paragraph [0080] an embodiment wherein the solid inner needle has a groove 44 which allows blood to flow through it upon puncture to enhance visual confirmability. It is not necessary that this visual check is of whether blood appears in the (transparent) inner needle hub 5, as argued by the appellant. In paragraph [0080] it is stated that the outer needle hub 3 may also be formed of a transparent material. Accordingly, the visual check may be performed through the outer needle hub, and it is not necessary that blood becomes visible through the inner needle hub 5. It follows that the appellant's argument that the disclosed length of the groove 44 is too short for a visual check is moot.

2.4 Accordingly, the requirements of Article 83 EPC are fulfilled.

3. Added subject-matter

Claim 9 corresponds to claim 9 as originally filed with the wording "said inner needle has a section **differing** in an outside diameter" at the beginning of the claim being replaced by "said inner needle (4) has a section (42) **varying** in an outside diameter" [emphasis added].

The common meaning of "to vary" is to make something different in some attribute or characteristic. Accordingly, the Board cannot see any difference in the technical meaning of the two terms, in agreement with point 4.3 of the impugned decision. The Board is also of the opinion that no such difference in meaning was intended by the amendment. As convincingly explained by the respondent, the amendment was introduced merely to make the claim wording at its beginning consistent with that at its end ("... said engaging means comprises

said section with the varying outside diameter ...") and in paragraph [0070] of the original description as published.

Accordingly, the amendment does not infringe Article 123(2) EPC.

4. Novelty

The appellant regards the base 30-b with the seal plug 30s depicted in Figure 4B of document D1 as anticipating the "inner needle hub (5) fixed to a base section of said inner needle (4)" as defined in claim 1 (with the tube 35 of D1 being inserted in said inner needle hub, as also claimed).

The Board does not share this view, for the following reasons. The catheter 31 of D1 may be regarded as corresponding to the "hollow outer needle" in claim 1. As shown in Figure 3, this catheter has at its base section a hub 32, also referred to as "mounting hub 32" in line 13 of column 8, corresponding to the "outer needle hub (3) fixed to a base section of said outer needle" as claimed. As described in lines 12 to 31 of column 8, the base 30-b with the seal plug 30s depicted in Figure 4B forms part of the hub 32, i.e. the "outer needle hub". In D1, the inner needle (not shown in Figure 4B, but depicted in detail in Figure 5A) is denoted by reference numeral 51. As mentioned in lines 33 to 35 of column 6 and also shown in Figure 5A, a mount 52 is attached to the needle 51 at its proximal end or base section, thus anticipating an "inner needle hub (5) fixed to a base section of said inner needle (4)" as claimed. Under these circumstances, the skilled person reading document D1 would regard the mount 52 as corresponding to the inner needle hub, and not the base

30-b with the seal plug 30s, as argued by the appellant, since these components form part of the outer needle hub 32.

Also, the Board does not follow the appellant's interpretation that the base 30-b, by means of the seal plug 30s, grips the needle 51 when it is inserted therein and thus forms a inner needle hub "fixed" to the inner needle, this inner needle hub not being defined any further in the claim and the term "fixed" not being defined in the specification of the patent in suit. In paragraph [0077] of the patent, it is stated that fixation of the inner needle 4 to the inner needle hub 5 is carried out by "fitting, caulking, fusing, adhesion with an adhesive, etc.", i.e. conventional methods for achieving permanent fixation. Accordingly, the Board also does not accept the appellant's comment about this paragraph to the effect that "fitting" two components together covers a technique where the inner needle is loosely fitted inside the inner needle hub. As stated in lines 29 to 32 of column 8 of D1, the seal plug 30-s serves the important function of sealing the needle withdrawal passage after the catheter sleeve 31 has been inserted into a patient. From the overall disclosure of D1 and in particular its claim 15 it becomes clear that the catheter 31 with the needle 51 positioned therein (Figure 1C) is first inserted into the patient and thereafter the needle 51 is retracted while the catheter 31 remains in the patient (Fig. 2B). This implies a movement of the needle 51 through the catheter hub 32 and the seal plug 30s therein. Accordingly, the needle 51 must be able to slide through the base 30-b with its seal plug 30s, and these two components cannot be regarded as being "fixed" to the needle 51.



It follows that D1 discloses an inner needle hub 52 fixed to a base section of the inner needle 51 and a hollow outer needle 31 into which said inner needle is inserted and an outer needle hub 32 fixed to a base section of said outer needle, but fails to disclose "a tube inserted into said inner needle hub" as claimed. Instead, the tube 35 of D1 is inserted into an extension 34 of the **outer** needle hub 32 as shown in Figures 1C, 3 4A and 4B.

Accordingly, the subject-matter of claim 1 is novel vis-à-vis D1 within the meaning of Article 54 EPC.

5. Inventive step

As explained above in point 4, the subject-matter of claim 1 differs from D1 in that the tube is inserted into the inner rather than the outer needle hub. In its obviousness attack, the appellant also relied on this as being the only missing feature.

The technical effect achieved by the tube being inserted into the inner needle hub (instead of the outer hub as shown in Figure 1A of D1) is that the distal end of the tube is less exposed in proximity to the inner needle hub and does not form an obstacle when the inner needle hub is manipulated by the user (which becomes necessary, for instance, when the inner needle is withdrawn from the outer needle, as also described in point [4] of paragraph [0127] of the patent in suit). Moreover, the overall structure can be made smaller and more compact.

The objective technical problem underlying the distinguishing feature is to improve the operability of

the needle assembly, as also mentioned in paragraphs [0012] and [0014] of the patent in suit.

This problem is credibly solved by the distinguishing feature. The Board does not accept the appellant's argument that claim 1 would include embodiments where the needle hub extends laterally and hence becomes bulkier, and where the tube is inserted only a very short distance into the needle hub and thus not provided with significant protection. These interpretations appear artificial and speculative, in particular in view of the requirement in claim 1 that the centre axis of said outer needle and a centre axis of the tube at a head section of the tube are substantially parallel with each other.

D1 itself does not give any hint towards this problem and its solution. On the contrary, as becomes clear from Figure 1A, the tube 35 is separated from the inner needle 51 and its hub 52 by the guard 60 located between them. Inserting the tube into the inner needle hub would mean removing or substantially modifying the needle guard.

The solution according to claim 1 cannot be regarded as "just a trivial design modification that provides no technical advantage", as argued by the appellant. The Board also does not share the appellant's view that it would be "a trivial matter to provide a small collar on the inner needle hub (53) ... to provide support and/or shielding of the tube", or to provide an extension at the proximal plate of the plunger 53 for holding the tube 35, as indicated in the modified drawing of Figure 1A submitted during the oral proceedings. In the absence of any motivation for the skilled person to do so, this objection is based on hindsight. Moreover, the

proximal plunger 53 of D1 is different from the inner needle hub 52 (into which the tube is inserted according to claim 1) which is connected thereto via cross ridges 53r as shown in Figure 5A.

Accordingly, the subject-matter of claim 1 is inventive over D1 within the meaning of Article 56 EPC.

6. It follows that none of the objections put forward by the appellant prejudices the maintenance of the patent as amended according to the impugned decision.

## Order

### **For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated