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**Datasheet for the decision  
of 8 June 2017**

**Case Number:** T 0126/13 - 3.2.02

**Application Number:** 04013518.8

**Publication Number:** 1464352

**IPC:** A61M5/32

**Language of the proceedings:** EN

**Title of invention:**

Syringe guard

**Patent Proprietor:**

SAFETY SYRINGES, INC.

**Opponent:**

Sanofi-Aventis Deutschland GmbH

**Headword:**

**Relevant legal provisions:**

EPC Art. 76(1), 123(2), 83, 84, 54(1), 54(2), 56

**Keyword:**

Divisional application - added subject-matter (no)

Sufficiency of disclosure - (yes)

Claims - clarity (yes)

Novelty - (yes)

Inventive step - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

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Case Number: T 0126/13 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 8 June 2017**

**Appellant:** Sanofi-Aventis Deutschland GmbH  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
13 November 2012 concerning the maintenance of  
European Patent No. 1464352 in amended form.

**Composition of the Board:**

<b>Chairman</b>	E. Dufrasne
<b>Members:</b>	D. Ceccarelli
	P. L. P. Weber

## **Summary of Facts and Submissions**

- I. The opponent has appealed the Opposition Division's decision, dispatched on 13 November 2012, that, taking into account the amendments according to the then pending first auxiliary request, European patent 1 464 352 and the invention to which it related met the requirements of the EPC.
- II. The patent was opposed on the grounds of lack of novelty and inventive step.
- III. The notice of appeal was received on 9 January 2013. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 13 March 2013.  
  
The appellant raised substantiated objections of lack of novelty and inventive step against claim 1 of the request found allowable by the Opposition Division.
- IV. The respondent replied to the statement of grounds by letter dated 11 July 2013.
- V. The Board summoned the parties to oral proceedings and set out its provisional opinion in a communication dated 10 March 2017.
- VI. Both parties filed further written submissions. In particular, the appellant raised objections of added subject-matter and insufficient disclosure against claim 1 of the request found allowable by the Opposition Division.
- VII. Oral proceedings took place on 8 June 2017.

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

The respondent 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 the first auxiliary request filed with letter dated 11 July 2013.

VIII. The following documents are mentioned in the present decision:

D6: EP-A-0 740 942;

D8: EP-A-0 467 173.

IX. Claim 1 of the request found allowable by the Opposition Division reads as follows:

"A guard (10) for a medical cartridge (90) having a proximal (93) and a distal end (94), for holding a needle (95) extending from the distal end (94), the cartridge having a lip (96) on the proximal end, the guard (10) comprising a rigid body (20) having a cavity (26) adapted to receive the cartridge (90) axially therein through an open proximal end (22) of the body (20), and having a distal end (24) including an opening through which the needle (95) may extend when the cartridge (90) is received within the cavity (26) and a shield (60) slidably attached to the body (20), and having open proximal (62) and distal (63) ends, the shield (60) being slidable between an unguarded and a guarded position with respect to the body, thereby uncovering and covering, respectively, the needle (95) on the cartridge (90) and the guard further comprising cooperating detents (40, 42, 71) on the shield (60) and body (20) for holding the shield (60) in the unguarded

and guarded positions, the guard characterized by:

a finger grip (50) on the proximal end (22) of the body (20), the finger grip comprising a pair of wing-like members (52) generally defining a "T" shape, each wing-like member having a distal surface (54) defining a finger ledge engageable when the shield is in said unguarded position with respect to the body and an outer gripping surface (56) extending proximally from the outer edge (54a) of the finger ledge, the finger grip including a pair of opposed, laterally extending surfaces (55) projecting proximally from the finger ledges (54) between the outer gripping surfaces (55) to define an open proximal end (51) communicating with the cavity (26) for receiving the proximal end (93) of the medical cartridge (90), the laterally extending surfaces having locking detents (58) for substantially permanently retaining the lip (96) on the proximal end (93) of the cartridge (90) received in the cavity (26)."

Claims 2 to 13 are dependent claims.

X. The appellant's arguments may be summarised as follows:

The feature "a pair of wing-like members generally defining a 'T' shape" had been added to the independent claim during the first-instance proceedings. This feature was not disclosed in the originally filed application. In particular, paragraphs [0014] and [0032] of the application as published described a finger grip integrally moulded onto the proximal end of a body, the finger grip comprising the wing-like members. The body and the whole finger grip together - not the wing-like members alone - defined the "T" shape. It followed that the subject-matter of claim 1 of the request found allowable by the Opposition

Division infringed Article 123(2) EPC.

Moreover, it was not apparent - and the patent did not disclose - how wing-like members alone could define a "T" shape. Only the combination of the body and the wing-like members was disclosed as defining a "T" shape. Hence, the subject-matter of the claim was neither sufficiently disclosed to be carried out by a skilled person, nor clear, in contravention of Articles 83 and 84 EPC.

During the oral proceedings the appellant confirmed that its objection of lack of novelty was only based on D6. More particularly, in figures 3, 4 and 5, D6 disclosed a guard for a medical cartridge having a needle, the guard comprising a proximal ring (105) forming the wing-like members, the finger ledges, the outer gripping surfaces and the laterally extending surfaces as defined in claim 1 of the request found allowable by the Opposition Division. This was explained in detail with reference to annotated figures filed during the oral proceedings.

During the oral proceedings the appellant confirmed that its objection of lack of inventive step was only based on the combination of closest-prior-art document D6, and D8. More particularly, if one considered that D6 did not disclose outer gripping surfaces extending from the outer edges of the finger ledges as defined in claim 1 of the request found allowable by the Opposition Division, this distinguishing feature addressed the problem of providing a needle guard which could be easily and safely gripped, in order to more easily and safely protect the needle. D8, which concerned a safety syringe with a shield for concealing a needle after use, disclosed a "boxlike head" (10 in



figures 6, 8 and 9) formed at the proximal end of the syringe. The outer surface of the boxlike head comprised a pair of opposed laterally extending surfaces as claimed. From figure 6, the skilled person realised that the outer surface provided gripping capabilities in the same manner as in the claimed subject-matter. Its implementation in the device of D6 was therefore obvious.

XI. The respondent's arguments may be summarised as follows:

The objections under Articles 123(2), 83 and 84 EPC had been raised late. They should not be admitted into the appeal proceedings without the respondent's approval. That was not given.

The skilled person would construe claim 1 of the request found allowable by the Opposition Division to mean that the finger grip as a whole, to which the wing-like members belonged, defined a "T" shape in combination with the body. Such a construction was clear and was disclosed in paragraph [0032] of the original application. Moreover, the teaching of the patent was sufficient in order for the skilled person to carry out the wing-like members, the finger grip and the body in accordance with this construction.

D6 did not disclose wing-like members as defined in claim 1 of the request found allowable by the Opposition Division. A ring did not provide such members. Even if the parts protruding outwardly from the ring in figures 3, 4 and 5 constituted wing-like members defining respective finger ledges, then the ring still did not comprise outer gripping surfaces extending from the outer edges of the finger ledges.

More particularly, the surfaces identified by the appellant as the outer gripping surfaces did not extend from the outer edge of the finger ledges. It followed that the subject-matter of the claim was novel over D6.

D6 was the closest prior art. The outer gripping surfaces as defined in claim 1 of the request found allowable by the Opposition Division provided advantages for a single-handed operation of the needle guard, including better grip. Neither D6 nor D8 was specifically concerned with the provision of additional grip on surfaces of a needle guard. Hence a combination of D6 and D8 had to be based on an ex post facto analysis. Moreover, if one were to implement the boxlike head disclosed in D8 in the needle guard of D6, that would have to be done at the expense of the specific function of the ring of D6, that is, locking the piston of the safety syringe after use. The skilled person would not do so without exercising inventive skill.

### **Reasons for the Decision**

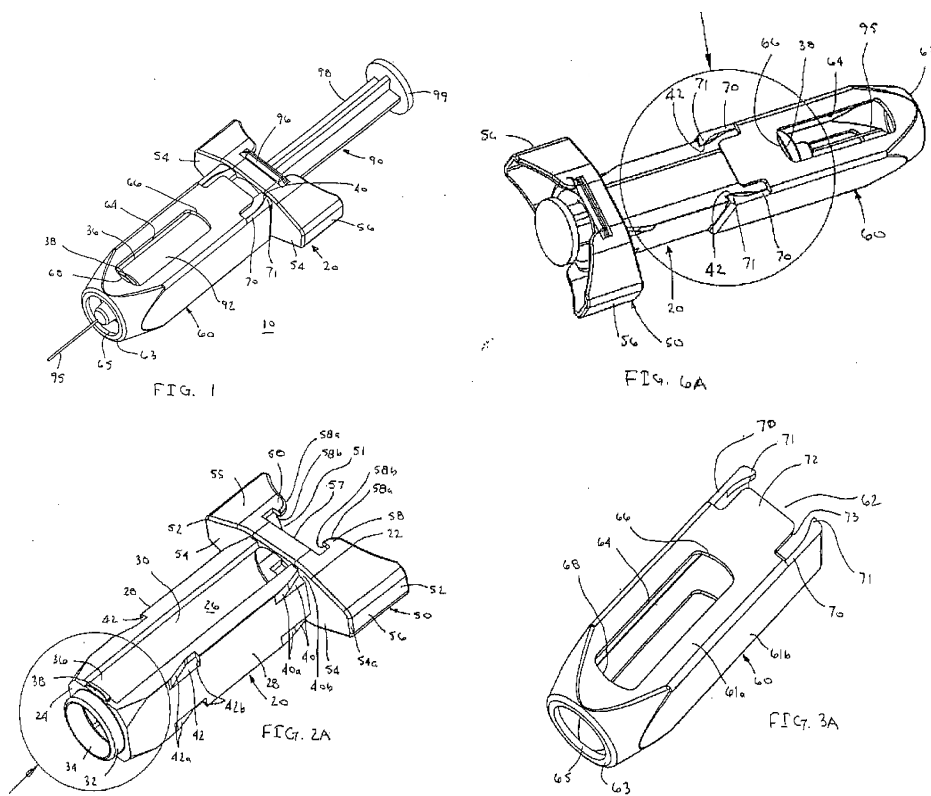
1. The appeal is admissible.
2. The patent in suit is derived from divisional application No. 04013518.8 (published as EP-A-1 464 352) of European patent application No. 98 301 704.7 (published as EP-A-0 864 335).

3. The invention

The invention relates to a guard for a needle of a medical cartridge.

Such guards are commonly used to render a needle inaccessible after a medical injection, in order to avoid needle-stick injuries to the person performing the injection.

Figures 1, 2A, 3A and 6A of the patent illustrate the guard as defined in claim 1 of the request held allowable by the Opposition Division.



The guard comprises a rigid body (20) and a shield (60) individually shown in figures 2A and 3A, respectively. In use the shield is disposed around the rigid body,

while the latter houses a medical cartridge (90) provided with a needle (95). The shield is slidable along the rigid body between an unguarded position (figure 1), in which the needle protrudes from the guard, and a guarded position (figure 6A) in which the shield extends distally from the rigid body, thereby covering the needle of the medical cartridge.

The invention focuses on a finger grip (50) provided on the proximal end of the rigid body. The finger grip comprises a pair of wing-like members (52) having respective distal surfaces (54) and outer gripping surfaces (56), and a pair of laterally extending surfaces (55). The claimed configuration of the finger grip is intended to facilitate the displacement of the shield from the unguarded to the guarded position (as explained in paragraph [0043] of the patent).

4. The patent was opposed only on the grounds of lack of novelty and inventive step. On appeal, the appellant raised objections of added subject-matter (Article 123(2) EPC), lack of clarity (Article 84 EPC) and insufficiency of disclosure (Article 83 EPC), all based on a particular interpretation of the feature of the finger grip "comprising a pair of wing-like members generally defining a 'T' shape", added during the first-instance proceedings.

In the Board's view, the first sentence of paragraph [0032] of the application as originally filed (corresponding to column 8, lines 4 to 7 of the original parent application as published), together with the figures to which it refers, provides a basis for adding this feature to claim 1 of the request found allowable by the Opposition Division.

More particularly, according to this sentence:

*"[...] the finger grip 50 generally comprises a pair of wing-like members 52 molded onto the proximal end 22 of the body 20, thereby generally defining a 'T' shape".*

The appellant argued that, according to this sentence, the body and the whole finger grip together - not the wing-like members alone - defined the "T" shape.

The Board shares this view, but notes that this is also the clear technical meaning that the skilled person would directly and unambiguously derive from the claim wording when reading it with a mind willing to understand. An interpretation according to which the wing-like members alone defined the "T" shape, as put forward by the appellant, might be literally correct but it would make no technical sense in the context of the patent. Generally, two wings of a pair are not perpendicular to each other and the patent does not teach otherwise. Rather, the patent discloses - in a sufficient way - how the wing-like members contribute, together with the body and the finger grip, to providing the "T" shape, for example in figures 1, 2A and 6A.

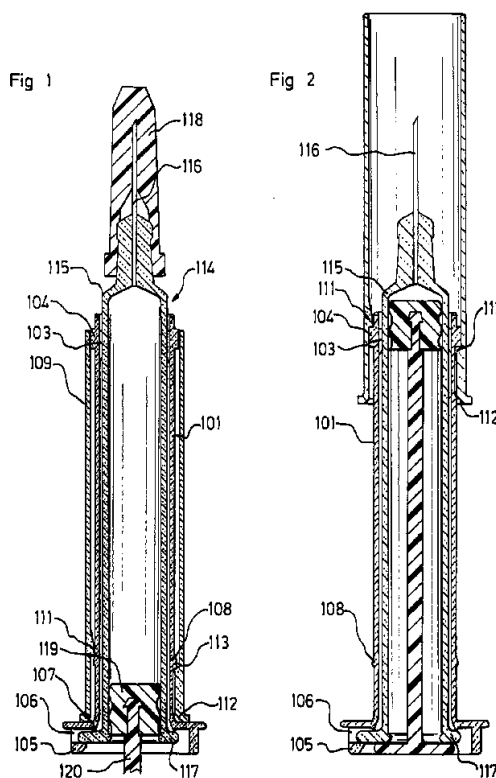
The Board also notes that, in the claim, it is permissible to omit the definition that the wing-like members should be moulded onto the proximal end of the body, as disclosed in the above-mentioned sentence of the application as originally filed. The skilled person recognises that there is no functional link between the "T" shape in itself and the way it is manufactured (here by moulding), so that the way the wing-like members are specifically formed is merely optional for

providing the claimed "T" shape.

For these reasons the Board concludes that the requirements of Articles 123(2), 76(1), 83 and 84 EPC are fulfilled by the amendments made to claim 1 of the request found allowable by the Opposition Division. In view of this conclusion on the substance it is not necessary for the Board to consider the respondent's request not to admit these objections into the appeal proceedings.

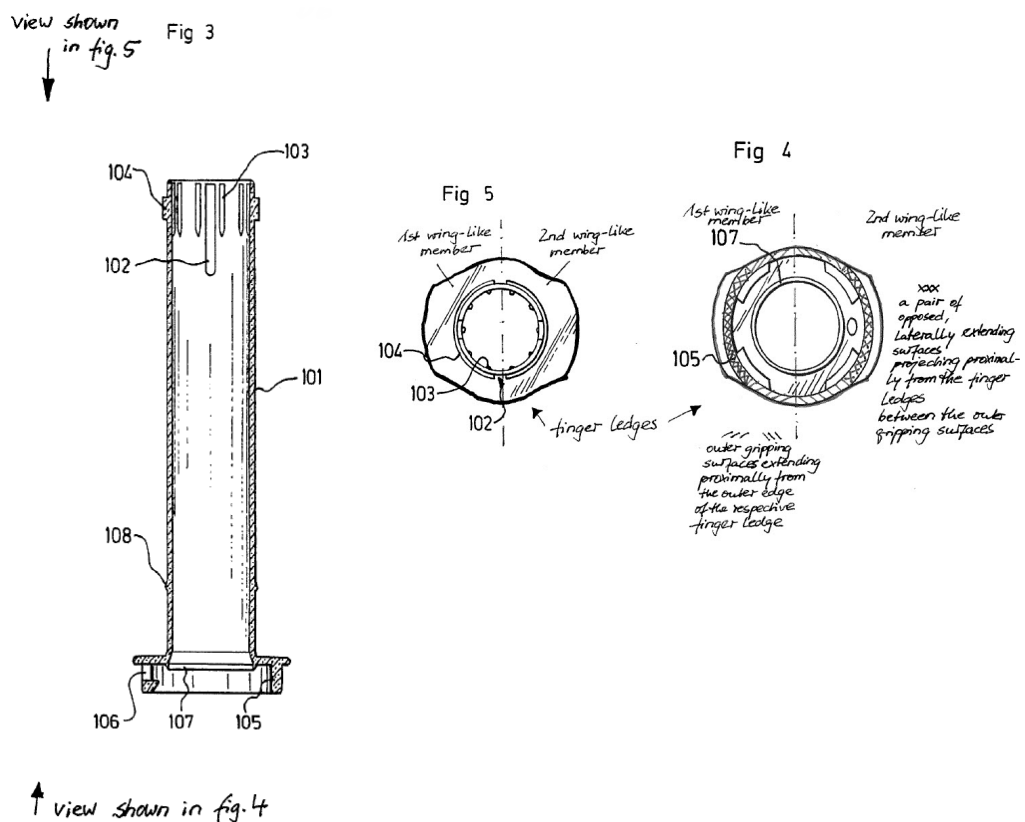
5. The appellant argued that the subject-matter of claim 1 of the request found allowable by the Opposition Division was anticipated by D6.

D6 generally concerns a method of producing a safety syringe by assembling a pre-filled syringe and a needle guard. Such a safety syringe is shown in the assembled state in figures 1 and 2 reproduced below.



More particularly, D6 discloses a guard for a medical cartridge comprising a rigid body (101) and a shield (109) according to the preamble of the claim. This was common ground between the parties.

The appellant argued that the rigid body comprised all the technical features of the characterising portion of the claim, as identified in the annotated figures of D6 filed by the appellant and reproduced below.



In particular, the appellant identified a proximal ring (105) of the rigid body as the claimed finger grip. Radial extensions of the ring constituted the claimed wing-like members defining finger ledges. An external surface of the ring extending in the longitudinal direction of the rigid body built up the outer gripping surfaces and the laterally extending

surfaces as claimed.

The Board notes that, even accepting the appellant's interpretation that the external surface of the ring could be regarded as forming two opposite pairs of surfaces as indicated in the annotated figures, the outer gripping surfaces as thus identified would not extend proximally from **the outer edge** of the respective finger ledges as required by the claim.

Reasonably, the **outer** edges of the finger ledges can only be those edges that are at the longest distance from the centre of the ring, i.e. the edges of the regions of the finger ledges at 3 o'clock and 9 o'clock in figures 4 and 5. However, no outer gripping surfaces as claimed extend from those edges.

At least for this reason D6 does not anticipate the subject-matter of claim 1 of the request found allowable by the Opposition Division.

Consequently, the Board is satisfied that the subject-matter of the claim is novel within the meaning of Article 54(1) and (2) EPC.

6. The appellant further argued that the subject-matter of claim 1 of the request found allowable by the Opposition Division was rendered obvious by the combination of D6 and D8.

There is agreement amongst the parties that D6 is the closest prior art.

As explained above, D6 does not disclose outer gripping surfaces extending proximally from the respective outer edges of the finger ledges as defined in the claim.



This distinguishing feature has the technical effect that, compared with the guard disclosed in D6, the claimed guard has outer gripping surfaces further apart from each other.

The objective technical problem identified by the appellant is the provision of a needle guard which could be easily and safely gripped, in order to more easily and safely protect the needle. In view of the intended use of the claimed guard as explained in paragraph [0043] of the patent, in particular the way the user should hold the outer gripping surfaces with his thumb and ring finger to move the shield in the guarded position, the Board agrees with this formulation of the problem.

D8 concerns a safety syringe with a shield slidable in the longitudinal direction of the syringe body, in order to conceal the needle after use (figures 3 and 4). A "boxlike" head (10) is formed at the proximal end of the syringe body (1). This head comprises two apertures (20) through which clamping tongues (16) of the shield (protective sleeve 12) can pass so as to engage the bottom of the head and keep the shield in a retracted, unguarded position (column 6, line 58 to column 7, line 7). In operation, at the end of an injection a pusher member (19) provided on the syringe plunger releases the engagement between the clamping tongues and the bottom of the head (column 7, lines 39 to 48), so as to permit a displacement of the shield in an extended, guarded position. This displacement is normally obtained automatically with a spring (15, in all embodiments depicted in the figures), although it is also contemplated that the user performs it (column 2, lines 5 to 16).

The specific construction of the "boxlike" head of D8, serving the purpose of retaining and releasing the shield, is totally different from the finger grip of D6. In the guard of D6 the shield is retained in the retracted position by detents provided elsewhere on the rigid body of the guard. D8 does not mention that outer surfaces of the head, possibly corresponding to the outer gripping surfaces as claimed, should be gripped at all during the operation of the safety syringe. It does not even mention any function of those outer surfaces. The appellant's assertion that, with the construction of D8, gripping of those outer surfaces of the head was implied, is not demonstrated either. In particular, figure 6, referred to by the appellant, does not show any such grip.

It follows that D8 would not be considered by the skilled person looking for a solution to the objective technical problem.

Moreover, as the respondent submitted, the specific construction of the proximal ring of D6 has the function of locking the piston of the safety syringe after use. Replacing the proximal ring of the needle guard of D6 with the "boxlike" head disclosed in D8 would imply the loss of this function. That is a price that the skilled person would not be prepared to pay.

The Board therefore concludes that the subject-matter of claim 1 of the request found allowable by the Opposition Division involves an inventive step within the meaning of Article 56 EPC.

7. In conclusion, none of the appellant's objections prejudices the maintenance of the patent according to

the request which the Opposition Division found to meet the requirements of the EPC. The Board has no further objections either.

8. In view of this conclusion, there is no need for the Board to consider the first auxiliary request.

### **Order**

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

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. DufRASne

Decision electronically authenticated