

**Internal distribution code:**

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

**Datasheet for the decision  
of 27 January 2016**

**Case Number:** T 2179/11 - 3.2.02

**Application Number:** 05006983.0

**Publication Number:** 1557191

**IPC:** A61M5/32

**Language of the proceedings:** EN

**Title of invention:**

A safety needle assembly

**Patent Proprietor:**

NOVO NORDISK A/S

**Opponents:**

Sanofi-Aventis Deutschland GmbH  
Ypsomed AG

**Headword:**

**Relevant legal provisions:**

EPC Art. 100(a), 100(b), 100(c), 76(1), 123(2), 83, 54, 56  
RPBA Art. 12(2), 13(1), 13(3)

**Keyword:**

Added subject-matter (no)

Insufficiency of disclosure (no)

Novelty - (yes)

Inventive step - (yes)

Late-filed lines of argument -

amendments after arrangement of oral proceedings,

adjournment of oral proceedings required (yes),

justification for late filing (no),

admitted (no)

**Decisions cited:**

**Catchword:**



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

European Patent  
Office  
D-80298 MUNICH  
GERMANY  
Tel. +49 (0) 89 2399-0  
Fax +49 (0) 89  
2399-4465

Case Number: T 2179/11 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 27 January 2016**

**Appellant:** Sanofi-Aventis Deutschland GmbH  
(Opponent 1) Patent- und Lizenzabteilung  
Industriepark Höchst  
Geb. K 801  
65926 Frankfurt am Main (DE)

**Representative:** Finger, Catrin  
Liedtke & Partner  
Patentanwälte  
Gerhart-Hauptmann-Strasse 10-11  
99096 Erfurt (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)

**Party as of right:** Ypsomed AG  
(Opponent 2) Brunnmattstrasse 6  
3401 Burgdorf (CH)

**Representative:** Gassenhuber, Andreas  
Schwabe, Sandmair, Marx  
Patentanwälte  
Stuntzstrasse 16  
81677 München (DE)

**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
29 July 2011 concerning the maintenance of  
European Patent No. 1557191 in amended form.

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** D. Ceccarelli  
M. Stern

## **Summary of Facts and Submissions**

- I. Opponent 1 has appealed the Opposition Division's decision, dispatched on 29 July 2011, that the patent as amended according to the then pending main request complied with the EPC.
- II. The patent, which is derived from a divisional application of European patent application No. 02 803 754.7 (the parent), was opposed on the grounds of added subject-matter, insufficiency of disclosure, lack of novelty and lack of inventive step.
- III. The notice of appeal was received on 29 September 2011. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 28 November 2011.
- IV. The respondent replied to the statement of grounds of appeal by letter received on 23 March 2012.
- V. The Board summoned the parties to oral proceedings and set out its provisional opinion in a communication dated 28 September 2015.
- VI. Both the appellant and the respondent filed further submissions by respective letters dated 23 December 2015.
- VII. The party as of right, opponent 2, has not filed any requests or arguments in the appeal proceedings.
- VIII. Oral proceedings took place on 27 January 2016 in the absence of the party as of right, opponent 2.

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 one of the first to eighth auxiliary requests filed with letter dated 23 March 2012.

IX. The following documents are referred to in the present decision:

D1: WO-A-01/32255;  
D3: US-A-5,674,203;  
D4: US-A-5,688,241;  
D5: WO-A-01/76665;  
D7: WO-A-93/00122;  
D8: US-A-5,415,645;  
D9: EP-B-1 289 587;  
D10: US-A-5,197,953;  
D11: EP-A-0 724 890.

X. Claim 1 of the request found allowable by the Opposition Division, corresponding to the main request in the appeal proceedings, reads as follows:

"A Safety needle assembly comprising  
a cylindrical housing (1, 40, 103+104) having a top surface (6) and a bottom surface (9, 50), the housing (1, 40, 103+104) having means for mounting the housing (1, 40, 103+104) onto a medical injection device,

A needle cannula (30, 130) mounted in the bottom surface (9, 50), the needle cannula (30, 130) having a distal end located at a distal side of the bottom surface (9, 50),

A shield (2, 43, 102) telescopically movable relatively to the housing (1, 40, 103+104) for movement

between a first distal position where the shield (2, 43, 102) covers the distal end of the needle cannula (30, 130) when the needle assembly is in an unused condition, a proximal position where at least a part of the distal end of the needle cannula (30, 130) is exposed, and a second distal position where the shield (2, 43, 102) is locked in a position covering the distal end of the needle cannula (30, 130) when the needle assembly is in a used condition,

A spring (25, 125) located inside the housing (1, 40, 103+104) urging the shield in the distal direction, and

A locking element (16, 44, 116) provided inside the housing (1, 40, 103+104) and having at least one locking protrusion (17, 49, 117),

the locking element (16, 44, 116) being a separate part, the at least one locking protrusion (17, 49, 117) engaging the housing (1, 40, 103+104) in that the locking protrusion is blocked by a blocking surface (15, 55) provided on an inside surface of the housing to irreversibly lock the shield (2, 43, 102) in the second distal position when the needle assembly is in the used condition, and wherein

the housing (1) is provided with at least one transparent area (20, 120) wherein through the transparent area (20, 120) a coloured part on the shield (2, 43, 102) and/or on the locking element (16, 44, 116) is visible when the needle assembly is in the unused condition indicating that the safety needle assembly is ready for use."

Claim 2 is a dependent claim.

XI. The appellant's arguments, as far as relevant for the present decision, may be summarised as follows:

a) The following features of claim 1 of the main request were not disclosed in the parent application as originally filed:

- A) "a second distal portion where the shield is locked in a position covering the distal end of the needle cannula when the needle assembly is in a used condition";
- B) "the at least one locking protrusion engaging the housing in that the locking protrusion is blocked by a blocking surface provided on an inside surface of the housing to irreversible lock the shield in the second distal position when the needle assembly is in the used condition";
- C) "the housing is provided with at least one transparent area".

Moreover, there was no basis in the parent application as originally filed for the omission in claim 1 of the main request of the following features originally present in claim 1 of the parent:

- D) "the locking element ... [has] at least one outwardly pointing locking protrusion";
- E) "the locking element is [...] provided between the spring and the shield and longitudinal moved simultaneously with the shield relatively to the housing during use".

The arguments concerning features A), B), and E), which were not present in the statement of grounds



of appeal, did not constitute new facts. The subject-matter of claim 1 of the main request involved a number of features in a complex relationship with one another. Presenting new arguments concerning the same claimed features after the summons to oral proceedings had to be possible in order to analyse and further discuss this complex relationship in view of the requirement of non-extension of the subject-matter of the patent beyond the content of the parent application as filed. It followed that the arguments concerning features A), B) and E) should be admitted into the appeal proceedings.

Concerning feature C), the introduction of "at least one transparent area" extended beyond the content of the original and the parent application as filed. The latter only disclosed a "window" which could "either be transparent or simply an opening in the sidewall of the housing" (in particular page 4, line 9). It was inadmissible to replace the specific term "window" by the words "transparent area", since their meaning was different. A window was an opening in a wall, provided with a frame. The newly introduced expression "transparent area" was an unallowable generalisation, as it allowed alternatives other than the disclosed window or simple opening. For example, a transparent, frameless area in the housing or a fully transparent housing of the claimed safety needle assembly would also be encompassed by that expression. Moreover, there would have been no need for the replacement if the terms in question had had the same meaning.

Concerning feature D), doing away with the

definition in claim 1 of the parent application as filed that the locking protrusion was "outwardly pointing" also constituted an inadmissible generalisation. It resulted in claim 1 of the main request covering also embodiments with other than outwardly pointing locking protrusions. However, the direction of the locking protrusion was essential for the invention in order to achieve the claimed technical effect, i.e. the blockage of the shield. From the fact that according to claim 1 of the main request the locking protrusion was blocked by a blocking surface provided on the inside surface of the housing the direction of the locking protrusion could not be inferred, since the latter belonged to another structural element. Also for these reasons claim 1 of the main request contained subject-matter extending beyond the content of the original and the parent application as filed.

- b) The absence of the definition in claim 1 of the main request that the locking protrusion was outwardly pointing rendered the claimed invention insufficiently disclosed over its scope as a whole. The skilled person, from the teaching of the patent, which only described in detail outwardly pointing protrusions, would not know how to carry out protrusions other than outwardly pointing but still satisfying the functional feature of the claim according to which the shield should be blocked.
- c) The subject-matter of claim 1 of the main request lacked novelty over D1 or D9.

D1 disclosed a safety needle assembly comprising

all the features of claim 1 of the main request. In particular, it comprised a cylindrical, multi-part housing including cap 800, outer housing 45, needle holder 260 and inner housing 25 in the figures. The housing had means for mounting it onto a medical injection device, which was in the form of cartridge assembly 300 in the figures. Those means were constituted by the needle holder (260), intended to hold the cartridge assembly (page 11, lines 16 to 17). As a matter of fact, also in the opposed patent, in particular in paragraph [0032], it was stated that a cartridge could fall under the definition of "medical injection device" according to claim 1 of the main request.

D9 also disclosed a safety needle assembly comprising all the features of claim 1 of the main request. In particular, the assembly comprised a safety shield (10 in the figures) having resilient arms (23 in figure 3), each carrying a locking projection (22 in figure 3). Each resilient arm was an integral part of the shield, but separated from it by a gap. It followed that each resilient arm, together with its respective locking projection, fell within the definition of the claimed locking element being a separate part.

- d) The subject-matter of claim 1 of the main request lacked an inventive step over D4 in combination with D3, D7 or D11, or D5 in combination with D3 or D10, or D8 in combination with D3 or D10.

The lines of argument based on D5 in combination with D3 or D10, and D8 in combination with D3 or D10 were not presented in the statement of grounds of appeal, but only subsequently introduced with

letter dated 23 December 2015. On the objection to their admission into the proceedings raised by the respondent in view of Article 13 RPBA the appellant provided no arguments.

Document D11 had been introduced with the statement of grounds of appeal due to a shift in the focus of the invention in the opposition proceedings at first instance. Hence, it should be admitted into the appeal proceedings.

The focus of the invention as defined in claim 1 of the main request was to indicate a used or unused condition of the safety needle assembly.

Starting from D4 as the closest prior art, even conceding that this document failed to disclose a locking element in the form of a separate part as claimed in claim 1 of the main request, the person skilled in the art would find separate locking elements in each of D3, D7 or D11.

D3 was concerned with a safety needle assembly having a visual indicator. Hence it would be considered by the skilled person. Collar 33 in figures 3 to 6 constituted a locking element being a separate part.

D7 was directed to a medical safety needle, and hence would equally be considered by the skilled person. It disclosed a locking element in the form of adapter hub 50 in figure 9.

Similarly, D11 would be considered by the skilled person, as it related to a needle shield assembly having visual indication features. D11 disclosed a

separate locking element in the form of sleeve 46 in figures 4 and 6.

The skilled person, seeking to provide a simplified construction, and noting that the feature of the locking element in the form of a separate part was not essential for the invention focused at indicating a used or unused condition of the safety needle assembly, would therefore combine D4 with one of D3, D7 or D11 without any inventive step.

XII. The respondent's arguments, as far as relevant for the present decision, may be summarised as follows:

- a) As far as the appellant's objection concerning extension of the subject-matter of the patent beyond the content of the parent application as filed was concerned, the lines of argument regarding features A), B), and E) constituted amendments to the appellant's case filed after the statement of grounds of appeal. Their admissibility was at the Board's discretion under Article 13 RPBA. They constituted different attacks on features of claim 1 of the main request which had not been objected to until shortly before the oral proceedings, after those proceedings had been arranged. Such attacks increased the complexity of the case and the respondent could not be expected to deal with them properly without an adjournment of the oral proceedings. In view of Article 13(3) RPBA they should not be admitted.

As regards the introduction of "at least one transparent area", i.e. feature C) objected to by the appellant, the teaching of the parent

application as a whole, in particular page 4, lines 1 to 7 and page 11, lines 24 to 26, was to provide a possibility of visually inspecting through the housing whether the safety needle had been used or not. Hence, the term "window" as used in the parent application as filed was to be interpreted as an "opportunity to observe", equivalent to the expression "transparent area" as introduced in claim 1 of the main request.

Concerning the appellant's objection relating to feature D), i.e. the omission of the definition that the locking protrusion was outwardly pointing in claim 1 of the main request, no subject-matter extending beyond the content of the parent application as filed had been added. The definition in the claim that the protrusion was blocked "by a blocking surface [...] provided on the inside surface of the housing" implied that the protrusion was outwardly pointing within the meaning of the original claim of the parent. Moreover, a protrusion, by definition, always extended outwardly with respect to a surrounding surface. In this respect it had to be noted that, in the description of the parent application as filed, the qualifier "outwardly pointing" had never been employed in connection with the term "protrusion".

It followed that no subject-matter extending beyond the content of the parent application as filed was present in the main request.

- b) The patent disclosed how to carry out a locking protrusion within the meaning of claim 1 of the main request. The description referred to locking

protrusions in general, rather than to outwardly pointing locking protrusions. Moreover, protrusions could not be anything other than outwardly pointing, by definition.

- c) The subject-matter of claim 1 of the main request was novel over the cited prior art.

D1 did not disclose a number of features of claim 1 of the main request. In particular, it failed to disclose a safety needle assembly comprising a cylindrical housing having means for mounting the housing onto a medical injection device. The claim required an express difference between the safety needle assembly and the injection device, which was confirmed by paragraph [0032] of the patent. D1 pertained to a medical injection device as such. The elements identified by the appellant as the housing constituted the housing of the medical injection device, and not of an associated safety needle assembly.

D9 failed to disclose, amongst other features, a locking element being a separate part of the safety needle assembly. Resilient arms 23 identified by the appellant as the locking elements were disclosed as being formed as an integral part of safety shield 10. They could not constitute a separate part within the meaning of claim 1 of the main request.

- d) The subject-matter of claim 1 of the main request involved an inventive step.

The appellant's lines of argument against an inventive step based on D5 in combination with D3

or D10, and D8 in combination with D3 or D10 had not been presented in the statement of grounds of appeal. They constituted an amendment to the appellant's case made after oral proceedings had been arranged. Their admission was subject to the Board's discretion under Article 13(3) RPBA. They should not be admitted as they raised complex issues which the Board and the respondent could not properly deal with without an adjournment of the oral proceedings. With respect to the combination of D5 with D3 and D10, even a proper substantiation was lacking, since the appellant had identified several novel features of the subject-matter of claim 1 of the main request over D5, but had not explained where all of these features were disclosed in D3 or D10.

D11 should not be admitted into the proceedings, as it was not *prima facie* relevant.

As regards the line of argument concerning D4 in combination with D3, D7 or D11, D4 did not represent the closest prior art as it concerned a medical injection device which did not comprise a safety needle assembly of the kind defined in claim 1 of the main request. Moreover, D4 did not disclose a number of features defined in the claim. In particular, the injection device of D4 did not comprise a locking element in the form of a separate part. Providing the device of D4 with a locking element in the form of a separate part was not taught by the cited prior art and would require a number of complex structural modifications. Hence, starting from D4, the subject-matter of claim 1 would not be arrived at in an obvious way.



## **Reasons for the Decision**

1. The appeal is admissible.
2. Although having been duly summoned by communications dated 28 September 2015 and 20 October 2015, the party as of right, opponent 2, was not present at the oral proceedings. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without this party.

3. *The invention*

The invention as defined in claim 1 of the main request relates to a safety needle assembly for a medical injection device, intended to reduce the risk of needle-stick injuries. It comprises a needle cannula with a cylindrical housing to be mounted onto the medical injection device and a shield telescopically movable relative to the housing between a position in which it covers the tip of the needle cannula and a position in which the needle cannula is exposed and an injection can be performed.

According to the invention, when the shield moves from the position in which the needle is exposed to the position in which the needle is covered, a locking element locks the shield irreversibly, such that the needle cannula cannot be exposed a second time. Hence, once the needle cannula has been used, it cannot be accessed any longer and the risk of a needle-stick injury with a contaminated needle cannula is reduced.

More particularly, the invention focuses on the fact that the locking element is a separate part comprising a

locking protrusion to be engaged by the housing and that the housing has a transparent area through which a coloured part of the shield and/or the locking element may be seen when the needle cannula has still not been used.

4. *Main request - extension of subject-matter*

4.1 The application as originally filed and its parent application as originally filed share the technical content of the description, figures and claims of the parent application as originally filed. In particular, the application, although it has claims different from those of its parent, comprises a description section in which the subject-matter defined in the claims of the parent is included as "Examples of the invention" (paragraph [0069]). It follows that, if the subject-matter of the patent is found not to extend beyond the content of the parent application as originally filed, then the same applies with respect to the content of the application as originally filed.

4.2 The subject-matter of claims 1 and 2 is generally derived from claim 1, page 4, lines 5 to 9 and page 9, lines 23 to 31 of the parent application as originally filed.

The appellant has raised objections relating to a number of features of claim 1 of the main request, which allegedly involved an impermissible extension of the subject-matter of the patent.

The objections related to features A), B) and E) as identified above were raised for the first time in the letter dated 23 December 2015, i.e. they were neither presented in the statement of grounds of appeal, nor

submitted before the oral proceedings had been arranged.

Article 12(2) RPBA prescribes that "the statement of grounds of appeal and the reply shall contain a party's complete case". The procedural aspects relating to amendments to the party's case are the subject of Article 13 RPBA.

The appellant has argued that the objections related to features A), B) and E) do not constitute new facts. Whether this is the case or not is irrelevant, as they certainly represent new lines of argument. It follows that they constitute amendments to the appellant's case within the meaning of Article 13 RPBA.

According to Article 13(1) RPBA, such amendments may be admitted into the appeal proceedings at the Board's discretion, to be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy. Article 13(3) RPBA prescribes that amendments sought to be made after oral proceedings have been arranged are not to be admitted if they raise issues which the Board or the respondent cannot reasonably be expected to deal with without adjournment of the oral proceedings.

The Board observes that such amendments were not triggered by any submission of the respondent or communication of the Board. Their late introduction is also not justified by the allegedly complex relationship between the features defined in claim 1, since this relationship has neither changed nor involved a different interpretation at any time during the appeal proceedings.

The Board agrees with the respondent that these amendments introduce complex issues, since they would require a thorough analysis of the features hitherto not objected to and their relation to the remaining features of claim 1 of the main request in view of the disclosure of the parent application as a whole. In particular, the Board would have to accept and consider totally new counter-arguments presented by the respondent for the first time during the oral proceedings. Under these circumstances it could not reasonably be excluded that the Board would have to adjourn the oral proceedings in order to deal with the amendments properly.

For these reasons the Board decides that the objections relating to features A), B) and E) are not admitted into the appeal proceedings pursuant to Article 13(1) and (3) RPBA.

- 4.3 As regards the objection to the feature that the housing is provided with at least one transparent area, i.e. feature C), the appellant correctly argued that the expression "transparent area" was not present in the parent application as originally filed. This expression, in general, may not be equivalent to the term "window".

However, the Board observes that a patent is directed to the skilled person, who reads it with the intention to grasp the technical meaning of its disclosure as a whole. Under some circumstances, that meaning does not strictly correspond to the literal meaning of the terms employed.

In the parent application as filed, the technical purpose of the "window" is clearly explained as the provision of a possibility of viewing a "*part of the shield and/or the locking element*", which "*can also be*

*coloured in a colour indicating that the safety needle assembly is ready for use" (page 4, lines 5 to 7). Further, the "window could be provided [...] such that the user can get a visible indication whether the safety needle assembly has been used or not" (page 11, lines 24 to 26). On the contrary, there is no strict prescription of a particular structural realisation of the window. On page 4, line 9 it is disclosed that "the window can either be transparent or simply an opening in the sidewall of the housing".*

For these reasons the Board accepts the respondent's submission that the term "window" as employed in the parent application as originally filed would be understood by the skilled person as having the technical meaning "opportunity to observe", and not necessarily requiring an opening in a wall, provided with a frame. Based on this interpretation, the expression "transparent area" as present in claim 1 of the main request is considered to have the same technical meaning. Hence, it does not extend beyond the content of the parent application as originally filed.

Whether that expression could encompass a transparent, frameless area in the housing or a fully transparent housing is of no relevance for the assessment whether the skilled person is presented with information extending beyond the content of the parent application as originally filed. Disclosure and scope of a claim are different issues. Finally, it is not the Board's duty to speculate about the respondent's possible intentions during the procedure which led to the grant of the patent in suit, in particular the reasons why the term "window" was amended by replacement with "transparent area", if the amendment is not against the provisions of

the EPC.

4.4 Concerning the objection relating to feature D), i.e. the omission of the qualifier "outwardly pointing" in the definition of the locking protrusion compared with claim 1 of the parent application as originally filed, the Board observes that the claim of the parent did not define with respect to what the protrusion was "outwardly pointing". On the contrary, a clear requirement in the claim was that the protrusion could be "blocked by a blocking surface provided on the inside of the housing". The same requirement is present in claim 1 of the main request. Taking into account that, as the respondent submitted, any protrusion is, by definition, always outwardly pointing with respect to a surrounding area, from a technical point of view the omission of the qualifier "outwardly pointing" from the subject-matter of claim 1 of the main request does not teach anything different from what was taught by the parent application as originally filed.

4.5 For these reasons the Board concludes that the subject-matter of the patent according to the main request does not extend beyond the content of either the application or the parent as originally filed.

It follows that Articles 76(1), 100(c) and 123(2) EPC are no bar to the maintenance of the patent as amended according to the main request.

5. *Main request - sufficiency of disclosure*

In the Board's view, the section "Detailed Description of Embodiment" (paragraphs [0028] to [0069]) in the patent provides a clear and complete structural disclosure of a preferred embodiment enabling the

skilled person to carry out the invention as defined in claim 1 over its whole scope.

The appellant's argument that, based on the teaching of the patent, the skilled person could not carry out a generic locking protrusion, but only "outwardly pointing" locking protrusions, is considered artificial. First of all, as already stated above, a protrusion is, per definition, always outwardly pointing with respect to a surrounding area. More importantly, the invention as defined in claim 1 does not require any generic locking protrusion, but a specific locking protrusion of a separate locking element, to be blocked by a blocking surface provided on an inside surface of the housing. The explanation of an embodiment of such a specific arrangement, from which the skilled person would readily derive other possible embodiments falling within the scope of claim 1 of the main request, is provided for example in connection with figures 9 to 12, paragraphs [0041] to [0047]. Notably, as the respondent observed, in these paragraphs the qualifier "outwardly pointing" is not employed at all.

It is therefore concluded that Articles 83 and 100(b) EPC are also no bar to the maintenance of the patent as amended according to the main request.

6. *Main request - novelty*

6.1 The appellant has argued that the subject-matter of claim 1 of the main request lacked novelty over D1.

D1 discloses a so-called needle assisted jet injector, provided with a needle assembly having a needle guard. The jet injector comprises a force-generating source that, in use, automatically exposes the needle from its

guard and performs the injection. After injection, the needle retracts back into the injector and cannot be exposed a second time.

The most relevant embodiment for the assessment of novelty of the subject-matter of claim 1 of the main request, to which the appellant referred, is described with reference to figures 14A to 33. Figures 28 to 31 illustrate its operation in more detail.

The appellant's interpretation is that this embodiment comprises a multi-part cylindrical housing including inner housing 25, outer housing 45, needle holder 260 and cap 800. Since the housing defined in claim 1 of the main request may also be composed of more than one part according to the patent in suit (for example body 4 and hub 3 in figure 1 and paragraph [0029]), this interpretation can be accepted.

The injector further comprises a needle cannula (480) mounted in a bottom surface of the housing, a shield (540) telescopically movable relative to the housing, a spring (660) urging the shield in the distal direction and a locking element (700) being a separate part. Furthermore, the housing is provided with a transparent area (page 11, lines 27 to 29).

However, D1 does not disclose, in particular, that the housing has means for mounting it onto a medical injector device.

As derivable from figures 14A and 14B, external and internal housings 45 and 25, amongst other elements, constitute components of the jet injector. They cannot be separated from the other elements, for example ram 125 and spring 240, without rendering the jet injector



inoperable. Without protrusions 100 of inner housing 25, for example, it would be impossible to perform an injection (page 11, lines 5 to 15). In other words, in the absence of the housing as identified by the appellant, the remaining elements would not form an injector at all. As a consequence, there is no disclosure that the housing has means for mounting it onto a medical injection device within the meaning of claim 1 of the main request.

The Board does not accept the appellant's argument that cartridge assembly 400 alone could be construed as a medical injection device within the meaning of the claim. Such a cartridge assembly cannot be used to perform an injection if it is not provided with other elements. The patent in suit does not suggest the appellant's construction either. The relevant parts of paragraph [0032] referred to by the appellant read:

*"The needle cannula 30 can either be mounted such that a part of needle cannula 30 projects from the bottom surface 9 in the proximal direction, which is preferred for use with cartridges, or it can be mounted without this so called back needle, which is preferred for hypodermic syringes."*

In the Board's view, this may possibly amount to an explanation that the medical injection device according to D1 can comprise a cartridge or a hypodermic syringe. It is nowhere contemplated that only the cartridge could constitute the medical injection device.

For these reasons the Board concludes that the subject-matter of claim 1 is novel over D1.

6.2 The appellant has also argued that the subject-matter of claim 1 of the main request lacked novelty over D9.

D9, which belongs to the state of the art according to Article 54(3) EPC, relates to a safety needle assembly for mounting onto a syringe (paragraph [0001]) of the kind defined in claim 1 of the main request.

Referring in particular to figures 2 and 3, D9 discloses a safety needle assembly comprising a cylindrical housing (4) with a needle cannula (8 + 9) and means for mounting the housing onto a medical injector device (paragraph [0047]), a shield (10), a spring (21), a locking element (23) with a locking protrusion (22), and a transparent area (32, figure 7 and paragraphs [0059] and [0060]) provided on the shield.

However, locking element 23 is disclosed as being part of shield 10. The appellant argued that there is a gap between a part of the periphery of the locking element and the rest of the shield (figures 1 and 3). Nevertheless, this does not change the fact that the locking element is connected to the rest of the shield and forms, together with the latter, an integral element (figures 1 and 3 and paragraph [0050]). It follows that locking element 23 cannot reasonably be considered a separate element within the meaning of claim 1 of the main request.

As a consequence, the subject-matter of claim 1 of the main request is novel over D9.

6.3 The appellant has not raised any further objections as to lack of novelty. The Board does not see any either. It follows that the subject-matter of claim 1 of the

main request is novel over the cited prior art.

7. *Main request - inventive step*

- 7.1 The appellant has raised objections as to lack of inventive step of the subject-matter of claim 1 of the main request involving several lines of argument based on different combinations of prior-art documents.

The lines of argument based on D5 in combination with D3 or D10, and D8 in combination with D3 or D10 were not presented in the statement of grounds of appeal, but only subsequently introduced by letter dated 23 December 2015, after the oral proceedings had been arranged.

These lines of argument constitute amendments to the appellant's case within the meaning of Article 13 RPBA. As explained in point 4.2 above, pursuant to this article, their admission is at the Board's discretion.

- 7.2 As regards the line of argument based on D8 in combination with D3 or D10, the situation is similar to that concerning the amendments to the appellant's case in relation to extension of subject-matter (point 4.2 above).

In particular, the late introduction of this line of argument cannot be seen as a legitimate reaction to new submissions of the respondent or communications of the Board.

Furthermore, the Board agrees with the respondent that the introduction of this line of argument too would involve complex new issues, since a thorough analysis of new combinations of documents in view of technical

problems not yet considered in the appeal proceedings would be required. In particular, the Board would have to accept and consider totally new counter-arguments presented by the respondent for the first time during the oral proceedings. Under these circumstances it could not reasonably be excluded that the Board would have to adjourn the oral proceedings in order to deal with the new issues properly.

For these reasons the Board decides that the appellant's line of argument based on D8 in combination with D3 or D10 is not admitted into the appeal proceedings pursuant to Article 13(1) and (3) RPBA.

7.3 As far as the line of argument based on D5 in combination with D3 or D10 is concerned, it was the respondent's contention that D5 should be considered the closest prior art (reply to the statement of grounds of appeal). The Board, in the communication accompanying the summons, stated that, compared with D4, D5 appeared "to concern a device closer to that of the claimed invention".

However, as the respondent pointed out, the appellant's line of argument based on D5 in combination with D3 or D10 amounted to an objection without proper substantiation. The appellant identified features of the subject-matter of claim 1 of the main request which were not disclosed in D5, e.g. "the at least one locking protrusion engaging the housing" and "in that the locking protrusion is blocked by a blocking surface provided on an inside surface of the housing", but did not provide any explanation as to whether these features were disclosed in D3 or D10, or why the skilled person, considering D3 and D10, would implement these features in the device of D5 in an obvious way.

Under these circumstances, the Board and the respondent could only have dealt with this objection if further arguments from the appellant had been admitted at the oral proceedings. That could have required an adjournment of the oral proceedings, in order for the respondent to be able to present an adequate reply.

Moreover, the appellant has provided no reasons as to why the line of argument based on D5 in combination with D3 or D10 should be admitted at this late stage of the proceedings.

Therefore, the Board decides that the appellant's line of argument based on D5 in combination with D3 or D10 is not admitted into the appeal proceedings pursuant to Article 13(1) and (3) RPBA.

- 7.4 The only line of argument from the appellant in the appeal proceedings against an inventive step of the subject-matter of claim 1 of the main request is based on D4, considered the closest prior art, in combination with D3, D7 or D11.

D11 was not introduced by the appellant within the opposition period, but together with the statement of grounds of appeal, as a reaction to the findings of the Opposition Division in the impugned decision. The appellant argued that this document taught a feature of claim 1 of the main request which was not disclosed in D4. In the Board's view, its prima facie relevance was convincingly argued. In line with the established jurisprudence of the boards of appeal, there are no reasons why it should not be admitted. As a consequence, D11 is admitted into the appeal proceedings.

D4 relates to a safety needle guard apparatus (10 in figure 1) applied to a needle of an injection device (12 in figure 1). It comprises locking protrusions (52a in figures 1 and 2) on an inner cylinder (26 in figures 1 and 2) of the needle guard, for locking the inner cylinder in a position covering the needle (figure 6c). These locking protrusions together with the inner cylinder form an integral element.

D4 fails to disclose a locking element being a separate part within the meaning of claim 1 of the main request.

It can be accepted, as the appellant argued, that in the devices of each of D3, D7 or D11 separate locking elements are employed.

However, the Board sees no reasons why the skilled person should apply the mechanical structures of any of these documents to the safety needle guard apparatus of D4.

As the respondent submitted, replacing the locking protrusions of the apparatus of D4 or in any case providing it with a separate locking element would require a number of complex structural modifications to that apparatus in order to achieve the same locking function.

The cited prior art does not provide the skilled person with any motivation to do so, in particular certainly not with a view to providing "a simplified construction", as the appellant argued.

It is therefore concluded that, starting from D4 as the closest prior art, the subject-matter of claim 1 of the

main request would not be arrived at in an obvious way.

- 7.5 For these reasons it is concluded that the subject-matter of claim 1 of the main request is inventive over the cited prior art.
8. It is therefore concluded that Articles 54, 56 and 100(a) EPC are also no bar to the maintenance of the patent as amended according to the main request.

## Order

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

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated