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**Datasheet for the decision
of 16 February 2023**

Case Number: T 2133/19 - 3.2.01

Application Number: 09161062.6

Publication Number: 2255842

IPC: A61M5/32

Language of the proceedings: EN

Title of invention:
Needle cover assembly

Patent Proprietor:
SHL Group AB

Opponent:
Sanofi-Aventis Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 83, 84, 52(1), 54, 56, 123(2)

Keyword:

Amendments - added subject-matter (no)

Sufficiency of disclosure - (yes)

Claims - clarity (yes)

Novelty - (yes)

Inventive step - (yes) - non-obvious alternative

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 2133/19 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 16 February 2023

Respondent:

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Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
21 June 2019 concerning maintenance of the
European Patent No. 2255842 in amended form.**

Composition of the Board:

Chairman G. Pricolo
Members: V. Vinci
P. Guntz

Summary of Facts and Submissions

I. The appeal filed by the appellant (opponent) is directed against the interlocutory decision of the opposition division to maintain the European patent No. 2 255 842 in amended form.

In its decision the opposition division held that the ground for opposition under Article 100(c) EPC in combination with Article 123(2) EPC was prejudicial to the maintenance of the patent as granted and decided to maintain the patent in amended form according to the sole auxiliary request underlying the decision under appeal. In particular, the opposition division stated that the subject-matter of independent claim 1 of the auxiliary request met the requirements of Article 84 EPC, was novel in the meaning of Articles 52(1) and 54 EPC and involved an inventive step in the meaning of Articles 52(1) and 56 EPC in view of the following prior art:

D1: WO 2009/040603
D4: WO 2009/019440
D5: WO 2005/070481
D9: WO 98/551 68
D10: WO 2005/115508
D12: US 6575939
D13: WO 2006/106290
D14: WO 2008/094984
D16: WO 2005/044348

II. With the communication according to Article 15(1) RPBA dated 13 April 2022 the Board informed the parties of its preliminary assessment of the case.

Oral proceedings pursuant to Article 116 EPC were held before the Board on 16 February 2023 by videoconference.

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

The respondent (patent proprietor) requested that the appeal be dismissed.

- IV. Independent claim 1 of the patent as maintained by the opposition division reads as follows:

"Needle cover assembly comprising:

a manually operable member (10);

a rigid needle shield RNS (38) provided with an internally arranged resilient cap (40), in turn arranged to house and protect an injection needle (42)

a RNS remover assembly comprising a tubular shaped member (31) surrounding said RNS (38) wherein said tubular shaped member (31) is arranged with at least one grip member (36) capable of gripping said RNS in order to remove said RNS;

said RNS remover assembly further comprising a spinning attachment member (19) having a distal end fixedly attached to said tubular shaped member (31) and a proximal end rotatably attached to said manually operable member (10) such that said manually operable member can be freely turned in relation to said RNS remover assembly but locked to each other in an axial direction (I1) and wherein an annular distal end

surface of said manually operable member (10) is arranged to be in contact with a corresponding proximally directed annular surface of a housing (12) of a medicament delivery device to which said needle cover assembly can be releasably attached;

characterised in that

said surfaces form an interface (14) having a wave or cam shape such that when said manually operable member is turned in relation to said housing the RNS remover assembly is moved in an axial proximal direction without rotation wherein said turning also enables an initial axial movement of the manually operable member in relation to the housing and thus to the injection needle attached to a medicament container due to the wave or cam interface between the manually operable member and the housing."

Reasons for the Decision

1. With their statement of grounds of appeal the appellant (opponent) raised objections under Articles 123(2) and 83 EPC in respect of the patent as maintained by the opposition division. The respondent (patent proprietor) requested to dismiss these objections with the reason that they were not raised in respect to the auxiliary request underlying the decision under appeal during the opposition proceedings, but for the first time with the appeal.
 - 1.1 Irrespective of the assessment of the admissibility issue raised by the respondent (patent proprietor), the Board concludes that the patent in the version allowed by the opposition division complies with the requirements of Articles 123(2) and 83 EPC for the reasons that will be presented below.
 - 1.2 At the oral proceedings and regarding the objections under Articles 123(2) and 83 EPC the parties referred to the arguments presented in writing and did not wish to make any further submission. The Board has thus no reasons to deviate from the assessment of these issues presented with its preliminary opinion dated 14 April 2022 that is hereby confirmed and reads as follows:

Amendments: Article 123(2) EPC

"Cap cover" vs "manually operable member"

2. The appellant (opponent) objected that the term *"manually operable member"* as comprising a wave or cam shaped interface could not be found in the passage on page 4, lines 13-16 of the originally filed description which was indicated by the respondent (patent

proprietor) as basis for the amendments introduced in claim 1. It was put forward that while in the above mentioned passage only the term "*cap cover*" was recited in combination with a wave or cam shaped interface, this term was not present in claim 1 as amended. In the appellant's (opponent's) view this circumstance resulted in an undisclosed combination of selected features, i.e. a manually operable member comprising an interface having a wave or cam shape, and in an unallowable generalisation because, in their view and in the technical context of claim 1, a "*cap cover*" did not technically equate a "*manually operable member*". In fact it was argued that a "*cap cover*" could be interpreted as the entire cap outer surface, while the term "*manually operable member*" could refer only to the region of the cap gripped by the user.

2.1 The Board is not convinced and follows the view of the respondent (patent proprietor) for the following reasons:

Contrary to the appellant's (opponent's) view, the person skilled in the art directly and unambiguously realizes that, despite the different terminology adopted through the originally filed application, the terms "*cap cover*" and "*manually operable member*" are consistently used to indicate one and the same technical feature, namely the element labelled with the reference (10) in figure 2 which is provided with an annular distal end surface "*arranged to be in contact*", i.e. suitable for being in contact, with a corresponding proximally directed annular surface of a housing of a medicament delivery device, thereby forming an interface having a wave or cam shape. Therefore, in accordance with the conclusion of the opposition division presented in respect of the same

issue in the decision under appeal in the context of the discussion of the main request, the use in claim 1 at stake of the term "*manually operable member*" and/or the omission of the term "*cap cover*" does neither result in an unallowable intermediate generalisation nor in undisclosed information as instead alleged by the appellant (opponent).

Omission in claim 1 of the features "*Fit over proximal end*" and "*forming a unit with the housing*"

2.2 The appellant (opponent) referred to page 6, lines 4-8 of the originally filed description and asserted that there was no unambiguous basis for the omission in the last feature of claim 1 of the feature presented in this passage that the manually operable member is "*designed to fit over the proximal end of a medicament delivery device, forming a unit with the housing of the medicament delivery member*", this leading to an unallowable intermediate generalisation of a specific embodiment on which the amendments introduced were based infringing Article 123(2) EPC.

2.3 However, as convincingly pointed out by the respondent (patent proprietor), the wording of the last feature of claim 1 as maintained is fully supported for example by paragraph [0015] of the originally filed application (see A-publication) which does not contain the omitted features objected to by the appellant (opponent). Therefore no unallowable intermediate generalisation arises.

"Housing"

2.4 The appellant (opponent) expressed the view that the description as originally filed did not provide a clear

basis for a claim not covering a needle cover assembly in combination with a housing of a medicament delivery device, i.e. for a needle cover assembly "per se". As according to the wording of claim 1 the housing was not part of the claimed subject-matter (see last feature of the preamble of claim 1) and thus a needle cover assembly was claimed "per se", the appellant (opponent) concluded that an unallowable intermediate generalisation infringing Article 123(2) EPC occurred, in particular in view of the embodiment described on page 4, lines 13-16 of the originally filed description.

- 2.5 The Board agrees with the appellant (opponent) that the subject-matter of claim 1, in view of the wording of the last feature of the preamble stating that the manually operable member *"is arranged to be in contact with a corresponding proximally directed annular surface of a housing"* does not include the housing of a medicament delivery device, but merely covers a needle cover assembly suitable for being used with such a housing. This is not contested by the respondent (patent proprietor). However, the objection raised is unfounded because the wording adopted in claim 1 as maintained and reciting the *"housing"* is fully supported by dependent claim 2 as originally filed and paragraph [0015] of the A-publication. Therefore, no undisclosed information is presented.

Sufficiency of disclosure: Article 83 EPC

3. The appellant (opponent) alleged that, given the inherent friction taking place between the spinning attachment member and the manually operable member, there was no enabling disclosure as to how securely preclude any rotation of the RNS remover assembly

during its movement in a proximal axial direction upon rotation of the manual operable member.

- 3.1 However, the Board concurs with the respondent (patent proprietor) that the person skilled in the art encounters no difficulties in selecting the appropriate materials and dimensions for the involved rotational contact interfaces in such a way to prevent, as required by claim 1, rotation of the RNS remover assembly when the manually operable member is rotated to remove the rigid needle shield RNS (hereinafter referred as RNS) from the needle. Also the objection that there is no information as to how to obtain the axial movement of the RNS remover assembly is unjustified in view of the detailed embodiment described in paragraph [0023] onwards of the patent. The above conclusions are not affected by the fact that the housing and the annular wave or cam-shaped surface associated with it are not covered by the claim.

Clarity: Article 84 EPC

4. The subject-matter of claim 1 of the patent as maintained by the opposition division meets the requirements of Article 84 EPC.
- 4.1 At the oral proceedings the parties referred also in this respect to the arguments presented in writing and did not wish to make any further submission. The Board has thus no reasons to deviate from the positive clarity assessment presented in its preliminary opinion that is hereby confirmed and reads as follows:
- 4.2 The appellant (opponent) maintained the view that, contrary to the assessment of the opposition division,

the negative formulation in the characterizing portion of claim 1 that *"the RNS remover assembly is moved in an axial proximal direction without rotation"*, i.e. the negative expression *"without rotation"*, introduced unclear subject-matter.

4.3 The Board, in agreement with the findings of the opposition division and the view of the respondent (patent proprietor), considers that the objected negative formulation actually results in a clear positive technical limitation the presence of which can be promptly detected when operating a needle cover assembly in conformity with the contested patent.

4.4 Furthermore, the Board agrees with the respondent (patent proprietor) that although the feature reading *"such that when said manually operable member is turned in relation to said housing the RNS remover assembly is moved in an axial proximal direction without rotation"* seems to define the subject-matter for which protection is sought in terms of a result to be achieved, the combination of technical features which achieves this result, i.e. the spinning attachment member connecting the manually operable member with the tubular shaped member, is sufficiently defined in claim 1, in a way that, contrary to the appellant's (opponent's) allegation, no lack of clarity arises.

Novelty: Articles 52(1) and 54 EPC

5. The subject-matter of independent claim 1 of the patent as maintained by the opposition division is novel and as such meets the requirements of Articles 52(1) and 54 EPC as correctly stated in the decision under appeal.

5.1 The appellant (opponent) maintained that, contrary to the assessment of the opposition division, document D5 was prejudicial to novelty of the subject-matter of claim 1. In particular the appellant (opponent) contested the statement of the opposition division that D5 (reference was made to the embodiment in figures 25 and 26) did not directly and unambiguously disclose a needle cover assembly comprising:

(i) a RNS remover assembly comprising a tubular shaped member surrounding the RNS, wherein the distal end of the spinning attachment is fixedly attached to the tubular member,

and

(ii) a manual operable member having an annular distal end surface having a wave or cam shape and forming an interface with the corresponding proximally directed annular surface of the housing such that when said manually operable member is turned in relation to said housing, said turning also enables an initial axial movement of the manually operable member in relation to the housing and thus to the injection needle attached to a medicament container due to the wave or cam interface between the manually operable member and the housing.

5.2 The appellant (opponent) identified the "*nylon sheath (17)*" in figure 26 of D5 as a "*tubular member*" in the meaning of feature (i) above and the "*rubber molding (16)*" arranged therein as the "*rigid needle shield RNS*" recited in claim 1. Based on this interpretation of the technical content of D5 they concluded that, contrary to the assessment of the opposition division, an arrangement according to feature (i) was directly and

unambiguously disclosed in this prior art document.

5.3 However, this interpretation of document D5 cannot be shared for the following reasons:

As convincingly pointed out by the respondent (patent proprietor), the person skilled in the art reading document D5 with a mind willing to understand and in view of their common general knowledge would not identify the "rubber molding (16)", which is inherently not rigid, with the "rigid needle shield RNS" of claim 1. In fact the RNS's functionality in the known needle cover assembly is clearly achieved by the "nylon sheath (17)" which indeed rigidly shields the needle (10) and not by the deformable and thus not rigid "rubber molding (16)" as asserted by the appellant (opponent). This interpretation is supported by the fact that the functionality of the "rubber molding (16)" internally arranged in the "nylon sheath (17)" actually corresponds to that of the "resilient cap (40)" defined in claim 1 as a separate component internally arranged in the "rigid needle shield RNS". Therefore, contrary to the appellant's (opponent's) allegation, no "tubular shaped element" in the meaning of feature (i) is provided in the needle cover assembly disclosed of D5.

5.4 Regarding feature (ii) the appellant (opponent) argued that as the term "housing" did not exclude a housing formed in two pieces, the structure resulting from the combination of the "outer housing (30)" with the "nozzle (11)" in figure 26 of D5 embodied a "housing of a medicament delivery device" in the meaning of claim 1. The appellant (opponent) identified the surface delimiting the recess provided inside the "needle cover (15)" in figure 26 of D5 as "an annular distal end surface of said manually operable member arranged to be

in contact with a corresponding proximally directed annular surface of a housing of a medicament delivery device ..." in the meaning of the last feature of the preamble of claim 1, wherein the corresponding proximally directed annular surface of the housing of the medicament delivery device was provided by the protrusion (11A) of the "nozzle (11)" engaging the recess. In this respect the appellant (opponent) put forward that the contact surface of the recess provided in the "needle cover (15)" and cooperating with the helical protrusion/s (11A) provided on the housing part represented by the "nozzle (11)" resulted in an interface having a wave or cam shape according to the first feature of the characterizing portion of claim 1 and providing the functionality defined therein. The appellant (opponent) thus concluded that, contrary to the assessment of the opposition division, also feature (ii) was disclosed in D5.

5.5 The Board is not convinced for the following reasons:

Even accepting the view of the appellant (opponent) that the housing of the medicament device shown in figure 26 of D5 is formed by the "outer housing (30)" and the "nozzle (11)", the Board cannot see how feature (ii) can be considered directly and unambiguously derivable from this prior art document. Firstly, the Board agrees with the observation of the respondent (patent proprietor) that the single helical recess provided on the inner surface of the manually operable member/needle cover (15) forms an open helical contact surface and not an "annular distal end surface" as required by claim 1. In fact the Board concurs with the respondent (patent proprietor) that the term "annular" is interpreted by a person skilled in the art as indicating a ring-shaped and thus closed surface.

Furthermore, in the context of claim 1, the expression "*distal end surface*" clearly indicates a surface located at the front end/extremity of the manually operable member and facing the housing. This is not the case of the contacting surface defined by the recess (and the protrusion (11A)) shown in figure 26 of D5. In other words, the arrangement defined by feature (ii) results in the interacting contact surfaces forming an interface that, contrary to the constructional solution of D5, is located at the distal end of the manually operable member. Finally, it is at least doubtful that the thread-like interface resulting from the contact between the cooperating helicoidal surfaces of the recess and the protrusion/s (11A) can be considered as being wave or cam-shaped as required by the first feature of the characterizing portion of claim 1.

- 5.6 For the reasons above the Board confirms the conclusion of the opposition division that features (i) and (ii) above are not directly and unambiguously disclosed in document D5 on which the sole novelty attack raised by the appellant (opponent) was based.

Inventive Step: Articles 52(1) and 56 EPC

6. The subject-matter of independent claim 1 of the patent as maintained is not rendered obvious by the available prior art in the meaning of Articles 52(1) and 56 EPC as correctly stated in the decision under appeal.
- 6.1 This conclusion of the opposition division is contested by the appellant (opponent) who presented several inventive step attacks based on documents D5 or D1 as closest prior art.

D5 as closest prior art

- 6.2 There is agreement between the parties that document D5 (see embodiment in figures 25 and 26) can be considered a promising starting point for the invention claimed in the contested patent. In fact this document, beside disclosing in figures 25 and 26 a needle cover assembly functionally and constructionally similar to that defined in claim 1, also addresses the same technical problem underlying the contested patent, namely to provide a needle cover assembly suitable for safely removing the RNS in a simple way without requiring substantial initial force, whereby damage to the needle which may result from accidental application of a twisting load to the RNS upon removal is prevented (compare paragraphs [0011] and [0017] of the patent specification and page 5, line 28 onwards as well as page 25, lines 14-19 of document D5).

"Partial problem approach"

- 6.3 A first point to be decided is whether, as alleged by the appellant (opponent), the "*partial problem approach*" shall be adopted when assessing inventive step of claim 1 as maintained. In this respect the appellant (opponent) essentially argued that features (i) and (ii) were not functionally interrelated in such a way to produce a synergistic effect. It was asserted that the technical effect of feature (i) was to provide a mechanical connection between the manually operable member and the RNS, whereas the technical effect of feature (ii) was to convert the rotation of the manually operable member into an axial movement thereof with consequent easy and safe removal of the RNS connected thereto. In view of the technical problem underlying the contested patent presented above, i.e.

to remove the RNS in a simple way without requiring substantial initial force, it was submitted that only feature (ii) relating to the provision of a cam or wave shaped interface addressed this technical problem, and this in the same way as the helical protrusions (11A) provided on the "nozzle (11)" and the complementary recesses machined on the "needle cover (15)" of the needle cover assembly of D5 did. The appellant (opponent) stressed that the tubular shaped member according to feature (i) did not serve to address this technical problem, but rather to provide, compared to D5, a mere alternative solution for the connection between the manually operable member and the RNS. It was concluded that as there was no evident functional interaction between features (i) and (ii) leading to a combined technical effect different from the sum of the effects of the individual features, these effects had to be discussed independently according to the "*partial problem approach*" when assessing inventive step (reference was made to T389/86).

6.4 The Board does not agree for the following reasons:

As convincingly put forward by the respondent (patent proprietor), all the technical features defining the constructional solution proposed in claim 1 are technically interrelated in the sense that they achieve, in combination, a safe removal of the RNS without requiring substantial initial force wherein, in particular, accidental twisting of the RNS, which might cause damage to the needle, is prevented. The Board has no doubt that the rotation of the manually operable member in relation to the housing and the consequent interaction at the interface thereof which determines the axial movement of the manually operable member cannot prescind, in order to achieve a safe

removal of the RNS, from the presence of the tubular shaped member surrounding the RNS and connecting it, via the spinning attachment member, to the manually operable member. The person skilled in the art recognizes that it is the interaction of all these concatenated features which enables the conversion of the rotation of the manually operable member into an axial movement which is then transmitted to the tubular element and in turn, by means of the spinning attachment member, to the RNS without any twisting load. These features are thus all clearly operationally linked. The omission of any of them would result in the impossibility to remove the RNS according to the functionality defined in claim 1. For the reasons above the Board concurs with the view of the opposition division and the respondent (patent proprietor) that the distinguishing features (i) and (ii) are indeed technically interrelated in the sense that they synergistically interact and contribute to the solution of the technical problem underlying the contested patent, whereby the use of the "*partial problem approach*" invoked by the appellant (opponent) is not justified.

D5 in combination with D4 or D16 in view of common general knowledge or D9, D10 and D12 to D14

- 6.5 The appellant (opponent) alleged that the skilled person, starting from D5 and looking for an alternative connection between the "*floating rivet (35)*" and the "*nylon sheath (17)*" in figure 26 of this known needle cover assembly, would promptly realize that the cylindrical "*retainer (125)*" or the "*shield grip (178)*" of the embodiments in figures 2a and 3a of D4 respectively could be introduced in the assembly of D5 between the "*floating rivet (35)*" and the "*nylon sheath*

(17)" in a way to surround the latter thereby achieving, without any inventive step, an arrangement according to the distinguishing feature (i) identified by the opposition division. In reaction to the objection of the respondent (patent proprietor) that the "*protrusion (125(a))*" of the "*retainer (125)*" were foreseen to grip the "*rubber boot (123)*" and not the RNS as required by claim 1, the appellant (opponent) replied that this modification was explicitly mentioned in D4 (reference was made to page 10, lines 21-22) and fell in any case within customary practice of a person skilled in the art. Therefore, contrary to the view of the opposition division, even if such a modification would be required, it could not prevent the person skilled in the art to modify the needle cover assembly of D5 by introducing an additional tubular member connecting the manually operable member with the RNS as suggested by D4, thereby fulfilling feature (i) of claim 1.

6.6 These arguments are not convincing for the following reasons:

Irrespective of the disputed question of whether the "*retainer (125)*" and the "*shield grip (178)*" in figures 2a and 3a of D4 are essentially cylindrically shaped in the meaning of claim 1, as asserted by the appellant (opponent) or U-shaped, as asserted by the respondent (patent proprietor), the Board does not see why the person skilled in the art should be motivated, in view of D4, to modify the direct connection provided between the "*floating rivet (35)*" and the "*nylon sheath (17)*" (functionally acting as RNS) of document D5 by introducing an additional tubular member in between as required by feature (i). This would firstly require the isolation of the "*retainer (125)*" or the "*shield grip*

(178)" from the specific structural context of the respective embodiments, and then the introduction of this allegedly cylindrical member specifically between the "*floating rivet (35)*" and the RNS of the needle cover assembly of D5, thereby connecting its proximal and distal ends to the "*rivet (35)*" and the "*nylon sheath (17)*" respectively. The Board does not contest that the modifications required may fall within customary practice of a person skilled in the art, but rather that there is no motivation for the person skilled in the art to carry out all the steps presented above which are required to fulfil feature (i) of claim 1.

- 6.7 The same applies to the allegedly obvious step of modifying the connection between the "*nylon sheath (17)*" and the "*needle cover (15)*" of the needle cover assembly in document D5 by introducing the "*metal ring (52)*" shown in figure 3 of document D16. In this regard the Board also concurs with the opposition division and the respondent (patent proprietor) that the cylindrical "*metal ring (52)*" does not surround the RNS as required by claim 1, but a "*rubber needle protector*" (see page 10, lines 17-20 of D16) the functionality of which corresponds to those of the "*resilient cap (40)*" recited in claim 1. The Board, as the opposition division and the respondent (patent proprietor), cannot see any motivation for the person skilled in the art to isolate the "*metal ring (52)*" from the needle cover assembly of D16 and introduce it in the assembly of D5 in a different position, namely in a way to surround the RNS (38) as required by claim 1 (and not to surround the "*resilient cap (40)*" as may be considered obvious by analogy).

- 6.8 Furthermore none of documents D5 (see point 7.5 above), D4 and D16 directly and unambiguously disclose an arrangement according to feature (ii) of claim 1. In this respect the appellant (opponent) argued that it is well known to convert a rotational movement of an element into an axial translational movement by using cooperating wave or cam shaped surfaces as demonstrated by the technical content of any of documents D9, D10 and D12 to D14. It was thus alleged that it would be obvious to replace the thread-like connection embodied by the recess and the cooperating protrusions provided on the *"needle cover (15)"* and on the *"nozzle (11)"* of the needle cover assembly of D5 respectively by such a well known mechanism, thereby fulfilling also feature (ii) of claim 1. The appellant (opponent) also alleged that the use of a thread-like connection between the manually operable member and the housing was presented in D5 as a mere preferred possibility, whereby it could be replaced, without requiring an inventive step, by any equivalent mechanism converting a rotational movement in an axial translational movement, i.e. by the mechanisms disclosed in D9, D10 and D12 to D14.
- 6.9 However, the Board concurs with the respondent (patent proprietor) that the person skilled in the art has no reason to replace the threaded connection successfully adopted in both document D4 and D5 by cam or wave shaped interacting surfaces. The respondent (patent proprietor) also correctly observed in this regard that, contrary to the allegation of the appellant (opponent), the use of a thread-like connection is not disclosed as being optional in the relevant embodiment of D5, figure 26. In addition, in order to meet the arrangement of feature (ii) of claim 1, it would be further necessary to move the location of the interface from the position shown in figure 26 of D5 to the

distal end of the "needle cover (15)" and thus to the proximal end surface of the "outer housing (30)". No hint for this step which implies several constructional modifications can be found either in D5 or D4 which consistently rely on a thread-type mechanism located at a position within the manually operable member. Therefore a modification of the needle cover assembly of D5 in the meaning of feature (ii) is not rendered obvious in view of common general knowledge or of documents D9, D10 and D12 to D14 as instead alleged by the appellant (opponent).

- 6.10 In conclusion, the Board concurs with the opposition division and the respondent (patent proprietor) that the reasoning of the appellant (opponent) goes beyond what the skilled person would have objectively inferred from cited prior art documents without the benefit of hindsight knowledge of the invention. This "ex post facto" approach cannot be adopted for correctly assessing inventive step.

Document D1 as closest prior art

- 6.11 The appellant (opponent) maintained the view that also document D1 could be considered to represent an appropriate starting point to arrive to the subject-matter of claim 1 as maintained. It was explained that this prior art related to a deshielder and addressed the problem of permitting an easy removal of the needle protection cap without requiring the application of a considerable force by the user (reference was made to page 1, lines 28 to 20). Furthermore, it was pointed out that, as clearly shown in figures 26 to 28, the manually operable member of this known assembly embodied by the "cap (26)" is also rotatable mounted with respect to the "housing (300)" of the injection

device. The appellant (opponent) alleged that it was obvious to introduce a mechanism based on wave or cam shaped cooperating surfaces of the kind known from D9, D10 and D12 to D14 at the interface between the manually rotatable "cap 26" and the "housing (300)" in order to convert the rotation of the "cap (26)" into a translational axial movement resulting in the removal of the protection cap/RNS. In the appellant's (opponent's) view this obvious modification would lead to the subject-matter of claim 1 as maintained without any inventive step.

6.12 The Board is not convinced for the following reasons:

The needle cover assembly of document D1 is based on a quite different operational principle according to which removal of the needle protection takes place merely by manually pulling the "cap 26" in an axial direction (see figures 26 to 28). This renders this document less relevant as starting point when compared with D5 as correctly pointed out by the respondent (patent proprietor). A rotation of the "cap 26" with respect to the "sleeve (33)" and thus the "housing (300)" is indeed permitted by the particular mounting adopted (see "grooved pin (37)" engaging the opening provided in the "cap (26)"). However, this rotation does not determine any axial translation of the "cap (26)" with consequent deshielding which is instead achieved by simply axially pulling the "cap (26)" manually. In view of the above the Board, as the opposition division and the respondent (patent proprietor), cannot see why the person skilled in the art, even considering to start from this prior art document for solving the technical problem at stake, should be motivated to basically modify the operation principle adopted therein by introducing cooperating

wave or came shaped surfaces at the interface between the "housing (300)" and the "cap (26)". This step, which would only lead to a more complicated constructional solution, cannot be considered obvious.

6.13 The Board thus concludes that for the reasons above the solution defined in claim 1 represents an alternative to the needle cover assembly of D5 or D1 which is not rendered obvious by the available prior art.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



A. Vottner

G. Pricolo

Decision electronically authenticated