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

Case Number: T 1829/20 - 3.2.01

Application Number: 12733240.1

Publication Number: 2729203

IPC: A61M5/20, A61M5/32

Language of the proceedings: EN

Title of invention:
NEEDLE SHEATH REMOVER ASSEMBLY

Patent Proprietor:
SHL Group AB

Opponent:
Sanofi-Aventis Deutschland GmbH

Headword:

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

Keyword:
Novelty - main request (no) - auxiliary request (yes)
Inventive step - auxiliary request (yes)
Sufficiency of disclosure - (yes)

Decisions cited:

Catchword:



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Case Number: T 1829/20 - 3.2.01

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

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
17 July 2020 concerning maintenance of the
European Patent No. 2729203 in amended form.**

Composition of the Board:

Chairman G. Pricolo
Members: V. Vinci
O. Loizou

Summary of Facts and Submissions

- I. The appeals were filed by both the patent proprietor and the opponent against the interlocutory decision of the opposition division to maintain the European patent N° 2 729 203 in amended form.

The opposition division held that the ground of opposition pursuant to Article 100(a) EPC in combination with Article 54 EPC was prejudicial to the maintenance of the patent as granted and decided to maintain the patent in amended form according to the auxiliary request 1 filed at the oral proceedings. Novelty and inventive step within the meaning of Article 52(1) in combination with Articles 54 and 56 EPC respectively were assessed in view of the following state of the art:

D1: WO 2009/090499 A2
D2: WO 2007/138296 A1
D3: WO 2006/009508 A1
D4: EP 2 468 338 A1
D5: WO 2009/040601 A1
D7: US 6 186 980 B1
D8: US 2003/0181859 A1
D9: WO 2010/007395 A1

- II. With a communication under Article 15(1) RPBA dated 3 August 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 May 2023 by videoconference.

III. The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted (main request) or in the alternative, that the patent be maintained in amended form on the basis of one of auxiliary requests 1 or 2 filed with the statement of grounds of appeal.

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

IV. Independent claim 1 as granted reads as follows (labelling adopted in the decision under appeal added):

1.a *"Needle sheath remover assembly for use in a medicament delivery device, axially elongated in a proximal and a distal direction, comprising*

1.b *a cap (10) comprising second blocking means (17) and biasing means (18), said cap configured to be removably attached to a housing (32) of a medicament delivery device,*

1.c.1 *a sheath grabber (20) comprising second stop means (24) and engaging means (22),*

1.c.2 *said sheath grabber is connected to said cap (10) and configured to be engageable to a needle sheath (42) of a medicament container (46) positioned within said medicament delivery device, characterized in that*

1.d.1 *said cap (10) and said sheath grabber (20) are axially movable in relation to each other and*

1.d.2 *in that said sheath grabber and said cap are configured to interact with each other such that upon*

removal of said cap from the housing, said sheath grabber is capable of engaging and removing said needle sheath, and

1.d.3 in that said cap is coaxially movable relative to the sheath grabber wherein movement of the sheath grabber is restricted by the interaction between the biasing means (18) and the engaging means (22) such that the grabber is biased to engage the sheath (42) and

1.d.4 wherein movement of the cap relative to the sheath grabber is restricted by the interaction between the second blocking means (17) and the second stop means (24)."

Independent claim 1 according to the auxiliary request 1 corresponds to claim 1 of the patent as maintained by the opposition division. This claim 1 is based on claim 1 as granted further limited by introducing the additional features of dependent claim 13 as granted reading:

"the second stop means (24) is positioned at a predetermined distance from the second blocking (17) means when the cap is attached to the device and wherein the second stop means and the second blocking means abuts each other when the cap is coaxially moved in relation to the grabber said predetermined distance such that the cap biases the sheath grabber to move axially."

Reasons for the Decision

APPEAL OF THE PATENT PROPRIETOR

Patent as Granted

Novelty: Articles 52(1) and 54 EPC

1. The subject-matter of claim 1 as granted lacks novelty within the meaning of Articles 52(1) and 54 EPC as correctly assessed by the opposition division.
- 1.1 The appellant (patent proprietor) contested the conclusion of the opposition division that claim 1 as granted lacked novelty over document D3, and in particular that the features labelled 1.b, 1.c.1, 1.c.2 and 1.d.1 to 1.d.4 were directly and unambiguously derivable from this prior art document.
- 1.2 Feature 1.b reads

"a cap (10) comprising second blocking means (17) and biasing means (18), said cap configured to be removably attached to a housing (32) of a medicament delivery device"
- 1.3 The appellant (patent proprietor) referred to figure 5 and to the passage on page 8, lines 1 to 11 of D3 and essentially argued that the tongues (60) and the ledges (62), which the opposition division functionally identified to be the *"second blocking means (17)"* recited in claim 1, were part of the push button (54) and not of the cap as required by claim 1 and this because, in the appellant's (patent proprietor's) view, the cap of the known needle sheath remover assembly consisted of the cylindrical housing (12) only. This

assertion was contested by the appellant (opponent) who instead asserted, based on the same passage of D3 and on the functionality of the known needle sheath remover assembly, that the tongues (60) and the ledges (62) were formed on the cylindrical housing (12) and thus on the cap. The appellant (opponent) further argued that in any event the cap of the assembly of D3 consisted of both the housing (12) and the push button (54) and pointed out that claim 1 as granted did not require the cap (10) to be necessarily embodied in one single piece.

- 1.4 Regarding feature 1.b the Board shares the view of the opposition division supported by the appellant (opponent) for the following reasons:

Irrespective of the disputed question whether the tongues (60) and the ledges (62) are provided on the housing (12) or on the push button (54) of the needle sheath remover assembly of D3, the wording of claim 1 does not indeed contain any limitation to a specific form or structure of the cap implying in particular that the latter must be manufactured in one single piece. In addition the Board, in agreement with the appellant (opponent), is convinced that the person skilled in the art has no reasons to understand the term "*cap*" recited in claim 1 as meaning a covering element mandatorily built up in one piece. In the Board's view the cap of the assembly of D3 consists indeed of two separate elements, namely the housing (12) and the push button (54) closing the housing (12) at its upper end, thereby forming a protection cover or cap in the meaning that the person skilled in the art would generally confer to this term. Therefore, even if as asserted by the appellant (patent proprietor) the tongues (60) and the the ledges (62) were integral with

the button (54) and not with the housing (12) as instead asserted by the appellant (opponent), the cap of the assembly of D3 comprises "*second block means*" in the meaning of feature 1.b of claim 1 as granted, i.e. the tongues (60) and the ledges (62), and this irrespective of whether they are provided on the housing (12) or on the push button (54) that, as explained above, are both parts of the cap of the needle sheath remover assembly according to D3.

1.5 Features 1.c.1, 1.c.2 read

"a sheath grabber (20) comprising second stop means (24) and engaging means (22)", and

"said sheath grabber is connected to said cap (10) and configured to be engageable to a needle sheath (42) of a medicament container (46) positioned within said medicament delivery device"

respectively.

1.6 The appellant (patent proprietor) argued that the protrusions (48) formed on the arms (46) of the sheath grabber (28) of the known needle sheath remover assembly shown in Figure 5, which were identified by the opposition division as the "*second stop means (24)*" recited in feature 1.c.1 of claim 1, did not actually act as a stop means, but rather served as latch elements which engaged the ledges (62) upon securing the needle sheath remover assembly to the medicament delivery device. It was thus asserted that the protrusions (48) functionally were "*engaging means*" and not "*stop means*" as instead required by feature 1.c.1 of claim 1.

1.7 The Board is not convinced and concurs with the appellant (opponent) that as the "*second stop means (24)*" is only functionally defined in claim 1, this feature can also be read in D3 and in particular anticipated by the protrusions (48) of the sheath grabber (28). In fact, as explained by the appellant (opponent) in their reply to the statement of grounds of appeal of the appellant (patent proprietor), the protrusions (48), upon mounting of the needle sheath remover assembly on the medicament delivery device, move past the ledges (62) and engage the corresponding cooperating surfaces provided on the latter, thereby preventing, i.e. stopping the axial relative movement of the sheath grabber (28) with respect to the cap (12,54) in a downward axial direction.

1.8 Regarding feature 1.c.2, the appellant (patent proprietor) argued that the sheath grabber (28) of the needle sheath remover assembly of D3 is slidably arranged inside the housing (12) as confirmed by the passage on page 7, line 13 of the description whereby, contrary to the view of the opposition division, there was no disclosure that the sheath grabber (28) was connected to the cap as required by claim 1.

1.9 However, also in this respect, the Board does not share the interpretation of the appellant (patent proprietor) for the following reasons:

The expression "*connected to*" does not mandatorily imply a fully rigid connection between two elements, at least not to the extent that they are joined together in such a way that no relative movement is permitted. In the present case the sheath grabber (28) is slidably connected to the housing (12), whereby this connection permits relative axial displacement but prevents any

relative movement in the radial direction. Furthermore, as pointed out by the appellant (opponent), at least upon mounting of the needle sheath remover assembly of D3 on the medicament delivery device, the sheath grabber (28) is axially connected with the cap (10,54) by means of the protrusions (48) engaging the ledges (62). Therefore also feature 1.c.2 is directly and unambiguously disclosed in D3.

1.10 Feature 1.d.1 reads:

"said cap (10) and said sheath grabber (20) are axially movable in relation to each other".

1.11 The appellant (patent proprietor) essentially argued that the sheath grabber (28) of the assembly of D3 is not permanently axially movable relative to the cap.

1.12 However, the Board concurs with the argument of the opposition division and the appellant (opponent) that no restriction in the sense of a permanently allowing relative movement is implied by the wording of the claim. Furthermore, as observed by the appellant (opponent), the appellant (patent proprietor) in its statement of grounds of appeal (see page 5, third paragraph) recognized that the sheath grabber (28) of the known needle sheath remover assembly is slidably arranged inside the housing (12) and hence axially movable in relation to the cap as also confirmed by the statement on page 7, line 13 of D3.

1.13 Feature 1.d.2 reads:

"said sheath grabber and said cap are configured to interact with each other such that upon removal of said cap from the housing, said sheath grabber is capable of

engaging and removing said needle sheath".

1.14 The appellant (patent proprietor) maintained that, contrary to the interpretation provided by the opposition division, it was clear from the wording of the claim that the sheath grabber (20) *"is capable of engaging and removing said needle sheath"* only starting from a precise moment, namely only upon removal of the cap from the housing. On the contrary, according to the operation of the remover assembly of D3, engagement with the needle sheath took place already upon mounting and securing the cap onto the injection device, i.e. before and not only upon removal of the cap as instead required by claim 1.

1.15 The Board is not convinced and shares the interpretation of the claim provided by the opposition division and the appellant (opponent) that the presence of the expression *"such that"* determines that the wording of the claim does not exclude that the interaction between the sheath grabber (28) and needle sheath takes place already before removal of the cap as it is the case for the assembly of D3. In fact, the engagement between the sheath grabber (28) and the needle sheath occurring upon mounting of the cap of D3 on the medicament delivery device is still provided/maintained upon removal of the cap whereby, also in the case of the known assembly, the sheath grabber (28), upon removal of the cap, is (still) capable of engaging with the needle sheath and removing it according to the functionality of feature 1.d.2. The alleged limitation that engaging of the sheath needle takes place only concurrently with the removal of the cap cannot be read in claim 1 as granted.

1.16 Feature 1.d.3 reads:

"said cap is coaxially movable relative to the sheath grabber wherein movement of the sheath grabber is restricted by the interaction between the biasing means (18) and the engaging means (22) such that the grabber is biased to engage the sheath (42)".

1.17 Regarding this feature the appellant (patent proprietor) argued that, likewise for the previous feature 1.d.2, the claimed functionality took place also only *"upon removal of the cap"* and not upon mounting of the needle sheath remover assembly on the medicament delivery device as it was the case of D3, and this even though the expression *"upon removal"* was not explicitly recited as objected by the appellant (opponent).

1.18 However, as explained above regarding feature 1.d.2, the alleged limitation that the claimed functionality takes place only upon removal of the cap is not unambiguously expressed in claim 1 as granted whereby, for the same reasons given under point 1.15 above, feature 1.d.3 is disclosed in document D3 either.

1.19 Feature 1.d.4 reads:

"wherein movement of the cap relative to the sheath grabber is restricted by the interaction between the second blocking means (17) and the second stop means (24) such that the cap, the grabber and the sheath can be removed from the device."

1.20 The appellant (patent proprietor) essentially argued that according to D3 the movement restriction did not take place between the cap and the sheath grabber as

recited in claim 1, but rather between the push button (54) and the sheath grabber (28).

1.21 Also these arguments are not convincing because, as stated under point 1.4 above, the push button (54) is part of the cap.

1.22 For the above reasons and irrespective of the assessment of the other novelty attacks as well as the objection raised under 83 EPC by the appellant (opponent), the main request lacks novelty within the meaning of Articles 52(1) and 54 EPC and is thus not allowable as correctly decided by the opposition division.

Auxiliary Request 1

2. The auxiliary request 1 filed with the statement of grounds of appeal of the appellant (patent proprietor) corresponds to the auxiliary request 1 deemed allowable by the opposition division. This decision is contested by the appellant (opponent) with its appeal.

APPEAL OF THE OPPONENT

Patent as maintained in amended form

Article 83 EPC: Sufficiency of Disclosure

3. The patent as maintained meets the requirements of Article 83 EPC as correctly decided by the opposition division.

3.1 The appellant (opponent) contested the conclusion of the opposition division regarding compliance with Article 83 EPC and maintained that the invention as

defined in independent claim 1 and in dependent claim 12 is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Claim 1

3.2 The appellant (opponent) pointed out that feature 1.d.3 of claim 1 of the patent as maintained required that the *"movement of the sheath grabber (20) is restricted by the interaction between the biasing means (18) of the cap and the engaging means (22) of the sheath grabber (20) such that the grabber (20) is biased to engage the needle sheath (42)"*. It was objected that the patent specification is silent as to how the restriction of movement of the sheath grabber (20) resulted in the sheath grabber to be biased to engage the needle sheath (42).

3.3 The Board does not agree for the following reasons:

As correctly observed by the opposition division and the appellant (patent proprietor), it is clear from figures 4A and 4B in combination with paragraphs [0053] and [0057] of the patent description that, as a result of an initial relative axial movement of the cap (10) with respect to the stationary sheath grabber (20), the ramp-shaped biasing means (18) inwardly protruding from the inner surface of the cap comes into contact with the flexible arms (22) of the sheath grabber (20) and pushes them inwardly until they dig into the needle sheath (42) which is thereby engaged by their distal gripping elements and hence ready for removal. The Board, in agreement with the opposition division and the appellant (patent proprietor) has no doubt that the disclosure of the contested patent, in particular the

contents of figures 4A and 4B and the cited paragraphs of the description, deliver sufficient information regarding the meaning of the expression "*movement restriction*" and how this restriction can be realized, i.e. by the interaction between the ramp-shaped biasing means (18) and the engaging means (22), thereby enabling a person skilled in the art to embody the functionality defined by feature 1.d.3 of claim 1 without undue burden.

Claim 12

- 3.4 At the oral proceedings the appellant (opponent) relied regarding the alleged lack of compliance with Article 83 EPC of dependent claim 12 on the arguments presented in writing and did not wish to make any further submission. Consequently, the Board has no reason to deviate from the assessment of this issue as presented in its preliminary opinion that is herewith confirmed and reads as follows:
- 3.5 The appellant (opponent) objected to the expression of claim 12 "*maximum engaging force between the engaging means and the needle sheath*" and argued that the person skilled in the art did not know neither how to determine the resulting "*maximum engaging force*" nor whether a certain remover assembly was working inside or outside the scope of the the invention as claimed.
- 3.6 However, the Board agrees with the conclusion of the opposition division that the contested feature expresses a mere optimized dimensioning of the elements of the assembly which by interacting with each other determine the engaging force at stake. The Board is convinced that the person skilled in the art is able to choose the height of the fins of the ramp-shaped

biasing means (18) and to position them at an appropriate distance from the distal end of the inner tubular member (12) in such a way to obtain the maximum engaging force compatible with the size and the mechanical strength of the constructional elements involved, thereby being able to carry out the invention without undue burden.

Novelty: Articles 52(1) and 54 EPC

4. The subject-matter of claim 1 of the patent as maintained is novel within the meaning of Articles 52(1) and 54 EPC as correctly assessed by the opposition division.

4.1 Claim 1 according to the patent as maintained by the opposition division is based on claim 1 as granted and includes the additional limitation that:

"the second stop means (24) is positioned at a predetermined distance from the second blocking (17) means when the cap is attached to the device and wherein the second stop means and the second blocking means abuts each other when the cap is coaxially moved in relation to the grabber said predetermined distance such that the cap biases the sheath grabber to move axially."

Interpretation of the expression "predetermined distance"

4.2 The appellant (opponent) alleged that the expression *"predetermined distance"* placed no meaningful limitation on the scope of the claim and, as such, should be ignored for the purpose of assessing novelty, whereby claim 1 as maintained lacked novelty over D3

for the same reasons presented in respect of claim 1 as granted.

- 4.3 The Board does not agree and concurs with the opposition division and the appellant (patent proprietor) that the requirement that "*the second stop (24) is positioned at a predetermined distance from the second blocking means when the cap is attached to the device*" introduces a clear and verifiable structural limitation according to which the second stop means and the second blocking means are such that they remain spaced apart when the cap is mounted on the medicament delivery device. In this respect it is irrelevant that the distance is not specified in the claim, but merely defined as being "*predetermined*" as objected by the appellant (opponent).

Novelty in view of D3

- 4.4 The appellant (opponent) contested the view of the opposition division that document D3 did not directly and unambiguously disclose the feature that the second stop means means was positioned at a predetermined distance from the second blocking means when the cap was attached to the device.
- 4.5 The appellant (opponent) referred to Figure 5 of D3 showing a distance between the protrusions (48) of the sheath grabber (28), embodying the "*second stop means*", and the ledges (62), embodying the "*second blocking means*". However, as correctly pointed out by the opposition division and the appellant (patent proprietor), Figure 5 shows the cap of the needle sheath remover assembly of D3 before being attached to the medicament delivery device (see description page 7, line 23 to page 8, line 11), whereas in Figures 8 and

9 which depict the remover assembly in the assembled state, the protrusions (48) and the inwardly extending ledges (62) of the cap are in abutment and hence not positioned at a predetermined distance from each other as required by claim 1 (see also passages on page 8, line 13 onwards and page 9 lines 4 to 11).

4.6 The appellant (opponent) further argued that as 4 protrusions (48) and 4 cooperating ledges (62) were foreseen, it was inevitable that in the mounted state the inherent manufacturing and assembling tolerances resulted in a gap between at least some of them and hence in a "*predetermined distance*" within the meaning of claim 1.

4.7 Also this argument is not convincing for the following reasons:

As pointed out by the appellant (patent proprietor), the presence of inherent manufacturing tolerances inside the device invoked by the appellant (opponent) is a matter of mere speculation not supported by the disclosure of D3 which does not provide any direct and unambiguous teaching in the sense to provide a distance within the meaning of the last feature of claim 1 as maintained. Furthermore, the extent of the gap between a ledge of the cap and the corresponding protrusion of the sheath grabber of D3 in the mounted status which may result from inherent manufacturing and assembling tolerances is a parameter that cannot be controlled and set to a "*predetermined*" value and therefore in any case it could not be considered a "*predetermined distance*" within the meaning of claim 1 as maintained., i.e. a distance that the person skilled in the art could precisely set as they like.

4.8 The appellant (opponent) also alleged that a "*predetermined distance*" within the meaning of claim 1 as maintained was directly and unambiguously derivable from Figure 12 of D3 in combination with the passage on page 8, lines 21-23.

4.9 The Board does not agree:

As convincingly pointed out by the appellant (patent proprietor), Figure 12 represents a situation where the cap has not yet been attached to the medicament delivery device. Therefore, even if such a distance could be directly and unambiguously derived from Figure 12, which is doubtful, it would not relate to a mounted state of the cap.

4.10 In conclusion the disclosure of D3 is not prejudicial to novelty of the subject-matter of claim 1 as maintained as correctly concluded by the opposition division.

Admissibility of the further novelty attacks

5. With its statement of grounds of the appeal the appellant (opponent) raised further novelty attacks in respect of claim 1 as maintained by the opposition division based on documents D1, D2, D4, D5 and D7 to D9. The appellant (patent proprietor) objected the admissibility of these lines of attack for the reason that they had been allegedly submitted for the first time with the statement of grounds of appeal of the appellant (opponent).

6. The Board decided to admit the further novelty attacks in the appeal proceedings essentially for the reason that they had been raised with the notice of opposition

in respect of the subject-matter of independent claim 1 and dependent claim 13 as granted, the additional features of which having been now introduced in claim 1 as maintained. Furthermore, these attacks have never been withdrawn as also confirmed by the statement of the appellant (patent proprietor) in its letter dated 21 October 2020 submitted in response to the request of correction of the minutes of the appellant (opponent) dated 21 September 2020, and by the communication of the opposition division dated 5 November 2020.

Novelty in view of D2

- 6.1 The appellant (opponent) argued that the element (134) in figures 9, 10A and 10B of D2 labelled "*second part of the cap (130)*", contrary to the view of the opposition division, is part of the cap of the known assembly. This interpretation of the disclosure of D2 was contested by the appellant (patent proprietor).
- 6.2 The Board concurs with the opposition division and the appellant (patent proprietor) that the element (134) of the system of D2, rather than being a cap or a part thereof in the meaning that a person skilled in the art commonly confers to this term, functionally acts as a biasing means biasing the sheath grabber (138) into engagement with the boot (118). Furthermore, in view of the above described functionality, the system of D2 does not provide for relative coaxial movement between the cap and the sheath grabber because the latter, namely the arms (138), is integral with the cap.

Novelty in view of D7

- 6.3 The appellant (opponent) argued that the person skilled in the art was aware that a gap between the shoulder

(17) of the cylindrical body (8b) and the bosses (40) of the joining piece (32) shown in Figures 9 and 10 had to be provided in order to avoid, as a result of the unavoidable manufacturing tolerances, that the joining piece (32) could not be fully and securely inserted into the cylindrical body (8b) when the needle sheath remover assembly of D7 is mounted on the medicament delivery device. Reference was made to the passage in column 8, lines 35-36 of D7.

6.4 These arguments are not convincing:

The Board concurs with the appellant (patent proprietor) that document D7 does not directly and unambiguously disclose a gap between the bosses (40) and the shoulder (17). The Board maintains that the allegation of the appellant (opponent) that the bosses (40) and the shoulder (17) of the needle sheath remover assembly of D7 must be purposely arranged spaced away from each other when the cap is attached to the medicament delivery device in order to ensure that the joining piece (32) can be fully and securely inserted into the element (8b), is based on mere speculations not supported by the disclosure of D7.

6.5 Regarding the novelty attacks based on document D1, D4, D5, D8 and D9 the appellant (opponent) relied on the arguments presented in writing and did not wish to make any further submission at the oral proceedings. Consequently, the Board has no reason to deviate from the assessment of these novelty attacks presented in its preliminary opinion that is herewith confirmed and that reads as follows:

Novelty over D1

- 6.6 The Board concurs with the opposition division and with the appellant (patent proprietor) that, contrary to the view of the appellant (opponent), D1 fails to disclose an axial or coaxial movement of the cap with respect to the sheath grabber (see features 1.d.1 and 1.d.3 of claim 1). In this respect the Board follows the view of the opposition division and the appellant (patent proprietor) that the eventual take up of internal axial play due to inherent manufacture tolerances cannot be seen as purposive axial/coaxial movement in the meaning that a person skilled in the art reading the claim with a mind willing to understand and to make technical sense of it would attribute to this expression.

Novelty over D4

- 6.7 Even assuming that the interpretation of document D4 proposed by the appellant (opponent) regarding in particular the elements 1.6 to 1.6.3 in Figures 1A, 2A, 5A and 5B is correct, the Board follows the view of the appellant (patent proprietor) that no distance between the second stop means (protrusion 1.6.3) and the second blocking means (1.6.2) in the meaning of the last feature of claim 1 is provided because the cooperating surfaces thereof are shown in abutment at any time.

Novelty over D5

- 6.8 The Board does not follow the argument of the appellant (opponent) that the portion of the internal thread of the deshielder (33) in Figure 1 of D5 is initially positioned at predetermined distance from a portion of the cooperating external thread provided of the hollow cylindrical sheath 51. In fact, as convincingly argued

by the appellant (patent proprietor), the cooperating surfaces of a threaded connection are manufactured in such a way to avoid any relevant play therebetween. Eventual manufacture tolerances resulting in the presence of a minimal play between the threads cannot equate to the purposive "*predetermined distance*" required by claim 1 as maintained.

Novelty over D8

- 6.9 The Board concurs with the assessment of the opposition division and the view of the appellant (patent proprietor) that the cap and the sheath grabber (see claws 12) of the remover assembly according to D8 are an integral piece and hence there is no relative axial movement therebetween as required by feature 1.d.1. Therefore, contrary to the conclusion of the appellant (opponent), at least for this reason, document D8 is not prejudicial to novelty of claim 1 as maintained.

Novelty over D9

- 6.10 Contrary to the allegation of the appellant (opponent), the Board shares the view of the opposition division and the appellant (patent proprietor) that, as in the case of D1, document D9 does not disclose an axial or coaxial movement of the cap with respect to the grabber, whereby at least for this reason this prior art document is not prejudicial to the novelty of claim 1 as maintained by the opposition division.

Inventive Step: Articles 52(1) and 56 EPC

7. The subject-matter of claim 1 of the patent as maintained is not rendered obvious by the prior art as

correctly stated by the opposition division.

- 7.1 The appellant (opponent) contested this conclusion of the opposition division and submitted two lines of inventive step attack based on documents D3 and D7 as closest state of the art.
- 7.2 The Board observes that, as stated above, neither of D3 and D7 disclose the last feature of claim 1 and in particular that the *"second stop means is positioned at a predetermined distance from the second blocking means when the cap is attached to the device"*
- 7.3 There is agreement that starting from these prior art documents the technical problem underlying the contested patent has to be seen in the provision of an alternative needle sheath remover assembly.

D3 as closest prior art

- 7.4 The appellant (opponent) argued that starting from D3 the inherent manufacture tolerances unavoidably resulted in a *"predetermined distance"* between the second stop means and the second blocking means of the remover assembly of D3 when the cap was attached to the device in the meaning of the last feature of claim 1 which thus lacked inventive step over D3. It was also asserted that for reasons of safety it would be obvious to modify the needle sheath remover assembly of D3 by foreseeing some gap between the protrusions (48) and the ledges (62) in the mounted state because such measure would ensure a secure and stable connection of the remover assembly with the medicament delivery device. Reference was made to the passage of D3, page 3, lines 9 to 12 stressing the safety requirements of

this kind of assemblies.

- 7.5 The arguments of the appellant (opponent) are not convincing:

In agreement with the the opposition division and the appellant (patent proprietor), the Board does not see why the person skilled in the art would modify the construction of the needle sheath remover assembly of D3 in the sense of claim 1, i.e. by providing a gap between the second stop means (48) and the ledges (62) when the cap is mounted on the device. This modification goes indeed against the operating principle underlying the remover assembly of D3 which on the contrary foresees that the second stop means (48) and the ledges (62) are spaced away before mounting the remover on the medicament delivery device and in abutment after they have been assembled. Such a modification would require further constructional changes and adaptation which cannot be considered obvious. Furthermore, contrary to the assertion of the appellant (opponent), the person skilled in the art would certainly not manufacture the device of D3 by deliberately introducing a deviation from the nominal dimensioning resulting in a distance according to the last feature of claim 1.

D7 as closest prior art

- 7.6 Regarding this line of attack the appellant (opponent) alleged that it was obvious to modify the remover assembly disclosed in D7 by introducing a predetermined distance within the meaning of claim 1.
- 7.7 However this allegation has not been convincingly substantiated. The Board agrees with the appellant

(patent proprietor) that, as in the case of D3, there is no obvious hint for the person skilled in the art to arrange the bosses (40) and the shoulder (17) spaced away from each other of a predetermined distance when the cap is mounted on the medicament delivery device as required by the the last feature of claim 1. As convincingly explained by the appellant (patent proprietor), such a modification would negatively affect the precision of the relative positioning of the elements concerned and for this reason would be certainly disregarded by the person skilled in the art.

7.8 The positive assessment of inventive step of the opposition division is thus confirmed.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar:

The Chairman:



A. Vottner

G. Pricolo

Decision electronically authenticated