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Datasheet for the decision of 9 September 2022

Case Number: T 1436/18 - 3.2.01

Application Number: 10771732.4

Publication Number: 2493531

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Language of the proceedings: EN

Title of invention:
Drug delivery devices and method of assembly

Patent Proprietor:
Sanofi-Aventis Deutschland GmbH

Opponent:
Novo Nordisk A/S

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 83
RPBA Art. 12(4)
RPBA 2020 Art. 13(2)

Keyword:

Novelty - main request (no) - auxiliary request 6 (yes)
Auxiliary requests 1-5 filed in appeal - admissibility (no)
Auxiliary request 6 filed in appeal - admissibility (yes)
Inventive step - auxiliary request 6 (yes)
Amendment after summons - taken into account (no)
Sufficiency of disclosure - enabling disclosure (yes)

Decisions cited:

Catchword:

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Office européen des brevets

Beschwerdekammern

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Chambres de recours

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Case Number: T 1436/18 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 9 September 2022

Appellant: (Patent Proprietor)	Sanofi-Aventis Deutschland GmbH Brüningstraße 50 65929 Frankfurt am Main (DE)
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Appellant: (Opponent)	Novo Nordisk A/S Novo Allé 2880 Bagsvaerd (DK)
Representative:	Appelt, Christian W. Boehmert & Boehmert Anwaltspartnerschaft mbB Pettenkoferstrasse 22 80336 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 29 March 2018 concerning maintenance of the European Patent No. 2493531 in amended form.**

Composition of the Board:

Chairman	G. Pricolo
Members:	A. Wagner
	O. Loizou

Summary of Facts and Submissions

I. The appeals by the patent proprietor (appellant 1) and the opponent (appellant 2) are directed against the decision of the opposition division to maintain European patent No. 2493531 in amended form on the basis of the second auxiliary request filed during oral proceedings.

II. In its decision, the opposition division held, inter alia, that the subject-matter of claim 1 of the patent as granted was not new over E6. Auxiliary request 1, filed during oral proceedings before the opposition division, was not admitted into the proceedings as the amendments made did not prima facie fulfil the clear allowability criterion for late filed requests. Auxiliary request 2, objected with regard to Articles 83, 54 and 56 EPC, was found to be allowable.

III. In order to come to these conclusions the opposition division considered, among others, the following documents:

E2: US 6,106,501
E3: W02009/095332 A1
E6: US 4,031,893
E7: US 5,695,472
E11: W02011/039229 A1
E12: W02011/039215 A1
E18: WO 2010/124961 A1
E19: "The Lean Design Guidebook: Everything Your Product Development Team Needs to Slash Manufacturing Cost", by Ronald Mascitelli, Technology Perspectives, 1st edition, 2004, page 168

E20: E20 US-A-5 092 843

IV. Oral proceedings by videoconference were held before the Board on 9 September 2022.

V. The appellant 1 (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted (main request), in the alternative the patent be maintained in amended form on the basis of one of the auxiliary requests 1-10 filed with the statement of grounds of appeal.

The appellant 2 (opponent) requested that the decision under appeal be set aside and the patent be revoked.

VI. The patent as granted (main request) comprises two independent claims: device claim 1 and method claim 6. The feature numbering provided by appellant 2 (opponent) in the statement of grounds of appeal is hereby adopted.

Claim 1 reads as follows:

M1.1 A drug delivery device for dispensing of a dose of a medicinal product, comprising:
M1.2 - a holder (14)
M1.3 for a product-containing cartridge (16), the cartridge (16) having a piston (18) slidably arranged therein in an axial direction, and
M1.4 - a piston rod (12) to be operably engaged with the cartridge's piston (18) for dispensing of a dose of the medicinal product,
characterized in that
M1.5 - at least one spacer (20) selected according to a relative distance between piston (18) and piston rod (12)

M1.6 is disposed between the piston rod (12) and the piston (18) for eliminating axial clearance between piston (18) and piston rod (12).

Claim 6 reads as follows:

M6.1 A method of assembly of a drug delivery device being adapted for dispensing of a dose of a medicinal product, comprising:
M6.2 - determining an axial position of a proximal end face of a piston (18) of a cartridge (16) pre-assembled in a cartridge holder (14),
M6.3 - determining an axial position of a distal end face of a piston rod (12) of a drive mechanism (11) pre-assembled in a housing (l0),
M6.4 - determining or estimating the size of axial clearance between the piston (18) and the piston rod (12) if cartridge holder (14) and housing (10) were assembled,
M6.5 - selecting at least one spacer (20) from a set of differently sized spacers with respect to the determined size of axial clearance and
M6.6 arranging the selected spacer (20) between the piston (18) and the piston rod (12).

In **auxiliary request 1** claim 1 is amended as follows while the method claim remains unchanged (in the following, the board has indicated additions in underlined and deletions in strikethrough).

M1.1 A drug delivery device for dispensing of a dose of a medicinal product, comprising:
M1.2* - a cartridge holder (14)
M1.3* for a product-containing cartridge (16),
- the cartridge disposed in the cartridge holder (14) to build a cartridge holder sub-assembly (15), the

cartridge (16) having a piston (18) slidably arranged therein in an axial direction, and
- a drive mechanism (11) having a piston rod (12), wherein the drive mechanism (11) with its piton rod (12) is disposed in a housing (10) to build a housing sub-assembly (13),
M1.4* - wherein the ~~a~~ piston rod (12) is configured to ~~be~~ operably engage~~d~~ with the cartridge's piston (18) for dispensing of a dose of the medicinal product,
- wherein the cartridge holder (14) and the housing (10) are interconnected and fixed in an interleaved arrangement, wherein an insert portion on a proximal end of the cartridge holder (14) is received in a corresponding receptacle located at a distal end section of the housing (10),
characterized in that
M1.5 - at least one spacer (20) selected according to a relative distance between piston (18) and piston rod (12)
M1.6 is disposed between the piston rod (12) and the piston (18) for eliminating axial clearance between piston (18) and piston rod (12),
M1.7 wherein the at least one spacer (20) is selected from a set of spacers having different axial dimensions and wherein the at least one spacer (20) is selected according to an actually measured and/or determined and/or estimated gap size between piston rod (12) and piston (18) in the device's final assembly configuration.

Auxiliary request 2 is based on auxiliary request 1. Claim 1 is amended by omitting feature M1.7 and by adding before the characterising portion the following feature. The independent method claim remains unchanged.

- wherein the cartridge holder (14) or the housing (10) comprises a bearing acting as a stopper and being adapted to delimit a mutually inserting movement of the housing (10) and cartridge holder (14) and wherein a final assembly configuration of the drug delivery device is defined when a free end of one of the receptacle and the insert portion axially abuts with the bearing of the other one of the receptacle and the insert portion.

Auxiliary request 3 is based on auxiliary request 2 wherein feature M1.7 of auxiliary request 1 is re-introduced in claim 1. The independent method is identical to the method claim as granted.

Auxiliary request 4 is based on auxiliary request 3 wherein claim 1 is amended and the method claim is unchanged. In claim 1, the feature introduced with auxiliary request 2 is amended as follows:

- wherein the cartridge holder (14) or the housing (10) comprises a bearing acting as a stopper and being adapted to delimit a proximally directed ~~mutually~~ inserting movement of the ~~housing (10) and~~ cartridge holder (14) relative to the housing (10) and wherein a final assembly configuration of the drug delivery device is defined when a free end of one of the receptacle and the insert portion axially abuts with the bearing of the other one of the receptacle and the insert portion.

Auxiliary request 5 is based on auxiliary request 4 wherein the following feature is added to claim 1. The method claim is unchanged:

M1.8 wherein the at least one spacer (20) is

individually selected for each combination of pre-configured housing assembly (13) and cartridge holder assembly (15).

Auxiliary request 6 is limited to the method claims as granted. Claim 1 corresponds to claim 6 of the main request.

VII. The appellant's 1 (patent proprietor's) arguments relevant to the present decision may be summarized as follows:

Main request - Article 54 EPC

E6 did not disclose features M1.5 with M1.6 as the spacer 300 did not eliminate an axial clearance to avoid initial priming. Spacer 300 had a different purpose, i.e. to reduce the maximum medicament capacity to a dictated dose being less than the maximum dose (column 3, lines 40 to 45).
As apparent from figure 1, two gaps existed distally and proximally of the spacer caused by the twofold snap fit connection of the spacer (column 4, lines 1 to 9). However, the purpose of features M1.5 and M1.6 was to achieve a clearance-free effective abutment of the piston and the piston rod at the end of a final assembly process. In E6, the final assembly was inevitably accompanied by non-negligible axial gaps.

Auxiliary requests 1 to 5 - admissibility

The auxiliary requests were filed at the earliest stage of the appeal procedure, i.e. with the statement of grounds of appeal. The amendments made were in conformity with Rule 80 EPC and all found a basis in the application as original filed.

Auxiliary request 6 - admissibility

Auxiliary request 6 was filed with the statement of grounds of appeal as a normal and legitimate reaction to the unfounded limitation of the claims forming the basis of the interlocutory decision.
Auxiliary request 6 was limited to the granted method claims 6 to 13 being part of the proceedings from the very beginning.

There was no motivation to file auxiliary request 6 in the first instance proceedings. In the preliminarily opinion of June 2017 in section 9.1.4, the opposition division stated that claim 1 and method claim 6 were not regarded new over E6. Therefore, during oral proceedings before the opposition division, the patent proprietor had the impression that the conclusion announced for claim 1 of the main request with regard to E6 would also concern claim 6, i.e. a non-compliance with the EPC. Only upon receipt of the interlocutory decision, the proprietor became aware that the independent method claim 6 as granted was considered new over E6 (point 26 of the impugned decision).

Auxiliary request 6 - Article 54 EPC

None of the documents E6, E20, E18, E7, E3, E2, E11, E12 took away novelty of the method as claimed in claim 1.
Regarding **E6 and E18**, the opposition division was right in stating under points 26 and 27, that none of the method steps 6.2 to 6.5 were disclosed.

E6 was not about determining or measuring an axial position of an end face or of an axial clearance but disclosed the possibility to change the size of the

medicament chamber by using a spacer 300.
Furthermore E6 disclosed that the spacer pushed the piston forward in the ampoule cylinder (column 3, lines 40 to 45). The axial position of the piston relevant for the axial clearance was only reached after the full assembly of the device.
E20 showed the same arrangement as E6 and referred concerning the spacer to E6 (column 5, line 67 to column 6, line 4).

E18 was directed to the same problem but solved it in a total different way. E18 disclosed several embodiments of spacers (e.g. figures 1, 4, 6, 8, etc.) from which a skilled person could select. However neither the spacer size nor the selection was motivated by the size of axial clearance.
The embodiments of E18 shown in figure 20 and figure 23 disclosed spring-actuated spacers that adapted automatically to the gap size 34. For this method neither a determination of axial positions of end faces nor a selection of one spacer from a set of differently sized spacers with respect to a determined axial clearance was necessary. Here, a single spacer was used for different gap sizes.

A similar but manually adjustable spacer was disclosed in **E7**. Accordingly, E7 at least did not disclose step 6.5 according to which during assembly at least one spacer from a set of different sized spacers had to be selected. E7 disclosed just one spacer for different gap sizes.

Also **E3** disclosed only one rod foot 170 (figures 6 to 10) used as a spacer that automatically adapted to the present gap size during assembly (page 10, lines 27 to 33). The piston rod foot 170 was not selected from a

set of differently sized spacers as defined in step 6.5.

E2, E11 and E12 did not disclose a spacer at all. Flange 10 of E2 (figure 1 with column 2, lines 59 to 63), bearing 14 of E11 (figures 2, 3 with page 16, lines 22 to 27) or pad 26 of E12 (figures 2a, 2b with page 13, lines 1 to 5) did not constitute a spacer. Each of these parts formed part of the driven member which, as a whole, was adjusted to remove the gap between the driven member and the piston.

Auxiliary request 6 - Article 56 EPC

Features M6.4 combined with M6.5 were not disclosed in E3 or in any of the other documents cited by the opponent.
E6 was the only document disclosing a set of differently sized spacers. Therein the different sized spacers were used to adapt the maximum dose to a dictated, smaller dose. Therefore, when starting from E3, the skilled person did not get any hint to use the set of spacers of E6 to eliminate undesired gaps caused by manufacturing tolerances. Even if E3 and E6 were combined, the determination of the size of axial clearance was still missing as in E6, the selected spacer simply pushed the piston as far as necessary into the cartridge (column 3, lines 40 to 45).

The attack starting from E6 was presented for the first time during oral proceedings before the board. The new attack constituted an amendment to the opponent's case and were not to be admitted into the appeal proceedings.

Auxiliary request 6 - Article 83 EPC

The impugned decision, point 12, had to be confirmed. Steps 6.2 and 6.3 were sufficiently disclosed by several examples given in paragraphs [0035, 0036, 0037] and paragraphs [0049, 0050, 0051] of the patent.

The argument of the opponent that claim 1 did not define that M6.2 and M6.3 were used for step M6.4 was a clarity issue. The skilled person would readily understand from the claim itself and the description that nothing else was meant. Otherwise steps M6.2 and M6.3 would be useless.

VIII. The appellant 2 (opponent's) arguments relevant to the present decision may be summarised as follows:

Main request - Article 54 EPC

The device according to claim 1 was disclosed in E6. The feature "selected according to a relative distance..." had no structural limitations for the spacer. In particular, the skilled person could not recognize from the assembled device whether or not the spacer was previously selected on using a relative distance between a piston and the claimed piston rod. Finally, the meaning of "eliminating axial clearance" was defined in the patent in paragraph [0023]: "*By appropriately selecting and arranging a particular distance spacer between piston and piston rod, a substantially clearance-free effective abutment of piston and piston rod can be reached upon final assembly of the drug delivery device*".
E6 disclosed a selection from several differently sized spacers in column 5, lines 9, 19. The spacer 300,

selected according to whatever criteria, at least substantially eliminated an axial distance (figure 1).

Auxiliary requests 1 to 5 - admissibility

None of the auxiliary requests should be admitted into the appeal proceedings. The patent proprietor was given enough time to reflect on its requests during oral proceedings before the opposition division (minutes, point 4). All auxiliary requests could and should have been filed at the first instance proceedings.
New auxiliary request 1 was similar to auxiliary request 1 underlying the impugned decision, which was already not admitted into the proceedings for prima facie lack of novelty. Also auxiliary requests 2 to 5, all comprising an independent device claim could not prima facie overcome the novelty objections raised with regard to claim 1 of the main request.

Auxiliary request 6 - admissibility

The fact that auxiliary request 6 was based on granted claims is irrelevant as it could and should have been filed at the first instance proceedings. Claim 1 was identical to the method claim of auxiliary requests 1 to 3 of the first instance which where withdrawn during first instance oral proceedings (minutes, point 4). Method claim 1 would also be broadening the subject-matter compared to the one discussed before the opposition division with regard to auxiliary request 2.

Auxiliary request 6 - Article 54 EPC

Method claim 6 was not new over E6, E20, E18, E7, E3, E12, E2 and E11.

In **E6**, the disputed method steps M6.2, M6.4 and M6.5 were disclosed in column 5, lines 2 to 11, and feature M6.3 was disclosed in column 4, lines 10 to 15, 26 to 34. To select an appropriate spacer for the dictated dose, the determination of the axial positions of the piston and the piston rod as well as of the axial clearance were mandatory.
Additionally, as method step M6.4 was not formulated as using the results of steps M6.2 and M6.3, feature M6.4 allowed a rough estimation of the size of the axial clearance. In E6, the gap needed to reach the dictated dose had to be estimated to select the proper spacer. The same applied for **E20**.

E18 addressed the same problem as the patent in suit (E18, page 4, lines 21 to 24) and disclosed in the different embodiments a large variety of differently sized spacers 20 (fig. 1), 46 (fig. 4), 54 (fig. 6), 64 (fig. 8), 78 (fig. 12), 90 (fig. 20), 112 (fig. 23) among which one was selected according to step M6.5. Additionally, the wording "different sized spacers" did not require different spacers or their physical presence at the same time. E.g. in figures 23 to 25, adjustment sleeve 114 in combination with adjustment member 112 allowed to define a set of differently sized spacers by selecting their degree of engagement (short, medium, long). The same was valid for the embodiment of figures 20 to 22.
Alternatively, parts 112, 114 (figure 23) could be considered as a set of differently sized spacers, all being selected at once to eliminate the axial clearance between the piston and the piston rod. Such an interpretation would fall under the claim wording "*select at least one spacer*".

In **E7**, figures 1 and 8, the head 334 was supposed to fill the gap between the piston and the piston rod. According to column 4, lines 38 to 40, a gauge was used to indicate the desired position of the head. As the adjustment to the desired position was done manually, steps M6.2, M6.3 and M6.4 were implicit. The different positions of the head 334 with respect to the sleeve 331 could be considered as a set of differently sized spacers according to feature M6.5. As mentioned for E18, "different sized" did not require different spacers or their physical presence at the same time.

Alternatively, as for the spacer of E18, the parts 29, 330 and 334 were considered as a set of different sized spacers, which were all selected to eliminate the gap.

Also the stops 152 and the washer 151 constituted spacers and were selected depending on the axial clearance as disclosed in column 4, lines 41 to 46 and lines 55 to 64.

E3 (figures 6 to 10) disclosed a spacer (piston rod foot 170) selected "*such that the distance between the distal end of the piston rod means an the plunger is minimized preferably to zero*" (abstract and page 10, line 26 to page 11, line 2, with figure 10). The purpose of the spacer was the same as in the patent in suit (E3, page 11, line 2). Similar to E7 or E18, the different axial positions of the piston rod foot 170 corresponded to differently sized spacers among which one is selected for the assembly, see e.g. figures 7 and 8 wherein the foot 170 was shown in two different axial positions.

E12, page 6, lines 24 to 30, explicitly disclosed steps M6.2 to M6.4: "*The position of the cartridge bung* [44]

is then measured. The position of the distal end [at 26] *of the first member* [20] *or, if applicable, the position of the bearing* [66] *within the device mechanism is also measured and the required position of the first member relative to the body* [16] *is calculated, such that when the two sub-assemblies are connected together, there is no gap or excessive pre-load between the end of the first member and the cartridge bung.*"
The spacer was disclosed as pad 26 (figures 2a, 2b), bearing 66 or first member 201 (figures 4a, 4b) and selected according to step 6.5.

In **E2**, the flange 10 (e.g. figures 1 and 2) constituted the spacer as it was clearly disposed between the piston 5 and the threaded rod 39 of the driven member 9 being the piston rod. In column 3, lines 15 to 17, and column 4, lines 60 to 65, it was disclosed that the flange was selected such that axial clearance between piston (18) and piston rod (12) was eliminated.

In **E11**, the bearing 14 was a spacer selected according to feature M6.5. The steps M6.2 to M6.5 were disclosed in figures 2 and 3 with page 6, lines 1 to 12 and page 16, lines 2 to 5. The gap 28 between the piston rod (lead screw 5) and the piston (cartridge bung 6) was eliminated before the device was used for injection.

Auxiliary request 6 - Article 56 EPC

Method claim 1 lacked an inventive step starting from E3 combined with general knowledge as e.g. disclosed in E19, or combined with E7.
If at all, claim 1 differed from E3 in method steps M6.4 and M6.5. As the piston rod foot 170 in E3 had the same purpose as the spacer in the patent in suit, the

problem could be seen in finding an alternative solution. Selecting one spacer out of a set of differently sized spacers to eliminate axial clearance instead of using the piston rod foot 170 was one of few equivalent, straightforward possibilities the skilled person would readily select, see e.g. E19, page 168. E19 showed that tolerances could be relaxed by using slots, spacers, shims, etc. and that this was known in the field long before the priority date.

As argued with regard to novelty, also E7 disclosed an alternative spacer with different size settings from which one was selected or, alternatively, disclosed several spacers 29, 330, 334 (figure 8), all selected with respect to a determined axial clearance between the piston and the piston rod (column 4, lines 38 to 41).
Should the problem be defined as providing a device that avoided axial pressure to the piston during assembling, the skilled person recognized immediately that a spacer that was manually adjusted to the gap size as disclosed in E7 would not axially push the piston. The automatically adjusting spacer 170 of E3 would thus simply be replaced by the spacers 29, 330, 334 known from E7 thereby arriving at the method as claimed.

Also E6 constituted an appropriate starting point. An inventive step attack starting from E6 was presented in the reply to the patent proprietor's statement of grounds of appeal with regard to auxiliary request 9 (point X). No new facts or arguments were thus presented.

Auxiliary request 6 - Article 83 EPC

M6.4 referred to an assembled state while M6.2 and M6.3 referred to a pre-assembled state. Claim 1 did not provide any feature bridging these two states. Moreover claim 1 did not even specify that the results of steps M6.2 and M6.3 were used for step M6.4.
Additionally it was not defined, in particular by reference points, how the respective axial positions of M6.2 and M6.3 could be determined over the whole breadth of the claim.

Reasons for the Decision

1. Main request - Article 54 EPC

1.1 The board confirms the decision of the opposition division that claim 1 as granted lacks novelty over E6.

1.2 The appellant 1 (patent proprietor) disputed features M1.5 and M1.6. The argument of the appellant 1 that in E6, the spacer 300 did not eliminate an axial clearance and was not selected according to the relative distance between the piston and the piston rod is not convincing.

1.3 As brought forward by appellant 2 (opponent) and mentioned in the impugned decision (point 14.1), the patent itself (paragraph [0023]) gives the term "eliminating axial clearance" the meaning of "substantially clearance-free effective abutment". This implies that small gaps as might exist in the device of E6 at both sides of the spacer 300 (figure 1) are not excluded.

1.4 Furthermore the feature "*selected according to a relative distance between piston and piston rod*" in device claim 1 is not identifiable at the assembled device and has no further structural limitations than filling the axial distance between the piston and the piston rod.

1.5 Fact is that the spacer 300 in the assembled state at least substantially eliminates the axial distance between the piston 148 and the piston rod 162 as can be seen in figure 1.

1.6 Hence, the requirements of Article 54 EPC are not met.

2. Auxiliary requests 1 to 5 - Admissibility

2.1 The Board exercised its discretion under Article 12(4) RPBA 2007 to not admit auxiliary requests 1 to 5 (AR1 to AR5), filed with the statement of grounds of appeal, into the appeal proceedings.

2.2 Article 12(4) RPBA 2007 allows not to admit requests in case that they could have been presented or were not admitted in the first instance proceedings.

2.3 **AR 1**

2.3.1 Claim 1 of AR1 on file corresponds to claim 1 of auxiliary request 1 underlying the impugned decision except in that in feature M1.7 all options "measured and/or determined and/or estimated" of granted claim 2 are introduced while in auxiliary request 1 of the opposition proceedings, the options were reduced to "measured".

2.3.2 As argued by the appellant 2 (opponent), claim 1 of AR1 on file is broader than the previous version of auxiliary request 1 which was not admitted by the opposition division because it prima facie lacked novelty (impugned decision, point 21). Consequently the broader wording of claim 1 of AR1 also cannot prima facie overcome the lack of novelty.

2.3.3 Furthermore, the non-admission of the previous auxiliary request 1 was a discretionary decision of the first instance which has to be re-examined by the board only if the wrong criteria have been applied or the discretion has been exercised in an arbitrary manner. This is clearly not the case and was not argued by the appellant 1 (patent proprietor).

2.3.4 The board therefore, considering that
i) no reasons are apparent why the broader auxiliary request was not filed before the opposition division, and additionally
ii) the reasons for not admitting the first auxiliary request in opposition proceedings would also have applied to the broader request as filed now in appeal proceedings,
exercised its discretion not to admit AR1.

2.4 **AR2 to AR5**

2.4.1 AR2 to AR5 are not literally, but in their gist (as explained below) identical to auxiliary request 5 (AR2), auxiliary request 7 (AR3, AR4) and auxiliary request 8 (AR5) which were withdrawn during oral proceedings (minutes, point 4). It is therefore not apparent why the auxiliary requests 5, 7 and 8 were not maintained pending during the opposition proceedings, or, alternatively, why AR2 to AR5 were not filed in the

first instance proceedings, in order to be decided by the opposition division. In fact, it appears that the appellant 1 (proprietor), by filing AR2 to AR5 in appeal, seeks to circumvent the withdrawal of the similar auxiliary requests 5, 7 and 8 filed in opposition proceedings.

2.4.2 In detail, AR2 and AR3 on file substantially correspond to auxiliary requests 5 and 7 of the first instance. Compared to the version of the first instance, the wording of feature M1.4* is amended as follows:
a) The cartridge holder and the housing are not "interconnectable" and "fixable", but "interconnected" and "fixed".
b) It is specified that the insert portion is located "on a proximal end" of the cartridge holder (14) and that the corresponding receptacle is "located at a distal end section" of the housing.
c) The insert portion is "received" and not "axially inserted".
Additionally, the feature introduced with AR2 on file is limited to:
d) the "bearing ~~or an abutment shoulder~~".

2.4.3 However none of these amendments results in a different technical content compared to the version of the claim submitted in the first instance.
The amendments a and b only constitute a formal clarification without any change in the subject-matter.
"Received" - in the context of in insert portion, a receptacle and an axial abutment as defined in the claim - is identical to the wording "axial inserted".
Finally, the term "abutment shoulder" is understood as a specific example of the more generic term "bearing". Thus deleting the wording "or an abutment shoulder" does not change the claimed subject-matter.

2.4.4 AR4 (as AR3) also substantially corresponds to auxiliary request 7 of the first instance. Amendment a to d are the same as for AR3. Additionally, the feature introduced with AR2 is adapted as follows:
e) "*a proximally directed inserting movement of the cartridge holder relative to the housing*".

However, in the context of the claim as a whole, this amendment of the previous wording of auxiliary request 7 "*a mutually inserting movement of the housing and the cartridge holder*" only constitutes a re-formulation of the same technical information.

2.4.5 AR5 is similar to auxiliary request 8 of the first instance. Amendments a to e are the same as discussed before. Furthermore the passage in the characterising portion of auxiliary request 8 "*and to reach a clearance-free effective abutment of the piston and the piston rod upon the final assembly configuration of the drug delivery device*" is deleted in claim 1 of AR5. This passage however only repeats the meaning of "*eliminating axial clearance between piston and piston rod*" in the drug delivery device. By deleting the mentioned passage the claim becomes more concise without changing the content of the claimed subject-matter.

2.4.6 The board concludes that these minor amendments in AR2 to AR5 on file compared to the withdrawn requests are only of formal nature and do not justify the resubmission of subject-matter that could have been presented in the first instance and was not.

2.5 Thus AR1 to AR5 were not admitted into the appeal proceedings.

3. Auxiliary request 6 - Admissibility

3.1 The Board did not make use of its power to hold auxiliary request 6 (AR6) inadmissible (Article 12(4) RPBA 2007).

3.2 As compared to the patent as granted (main request), which includes claims 1 to 5 directed to a device and claims 6 to 13 directed to a method, AR6 only includes the latter method claims renumbered to claims 1 to 8.

3.3 Claim 6 as granted was objected to and discussed between the parties since the beginning of the opposition proceedings. The decision under appeal deals with both the device claim and the method claim as granted. Even if claim 6 during oral proceedings mainly was discussed in amended form (as claim 1 of auxiliary request 2), the reasoning in the impugned decision for novelty and inventive step of the method claim is solely based on features of granted claim 6 (points 26, 27 and 29).

3.4 Furthermore, the board follows the argumentation of the appellant 1 (patent proprietor) that the course of the proceedings gave the impression that claim 6 as granted was not considered new by the opposition division. As the main request was rejected for lack of novelty of claim 1 over E6, claim 6 as granted was not further discussed in connection with the main request. However as the preliminary opinion of the opposition division likewise was negative for claim 6 in view of E6, there was no motivation for the patent proprietor to file an auxiliary request according to AR6 during the first instance oral proceedings. AR6 is thus a legitimate reaction to the decision of the first instance from which it became clear for the first time that claim 6

as granted was considered new by the opposition division.

3.5 Under these circumstances, the Board sees no reason to exercise its discretion pursuant to Article 12(4) RPBA 2007 not to admit AR6 in the appeal proceedings.

4. Auxiliary request 6 - Novelty

4.1 Claim 1 of AR6 meets the requirements of Article 54 EPC. At least feature 6.5 that the at least one spacer is selected from a set of differently sized spacers with respect to the determined size of axial clearance, is not disclosed in any of the documents cited by the appellant 2 (opponent).

4.2 The appellant 2 objected novelty of claim 1 with regard to E6, E20, E3, E7, E18, E12, E2 and E11.
E18, E12 and E11 are documents under Article 54(3) EPC.

4.3 E6, E20

4.3.1 E20 discloses the same arrangement as E6 and refers in view of the spacer to the teaching of E6 (column 5, line 67 to column 6, line 2). The following conclusion for E6 therefore applies mutas mutandis to E20.

4.3.2 For feature 6.5, the appellant 2 (opponent) referred to E6, column 5, lines 2 to 11. Therein E6 discloses a set of differently sized spacers 300 from which at least one spacer is selected. However the selection is made with respect to a dictated medicament dose being less then the maximum medicament capacity (column 3, lines 40 to 50) - not with respect to a determined size of axial clearance between the piston and the piston rod.

4.3.3 The board does not follow the argument of the appellant 2 (opponent) that with the method disclosed in E6 implicitly also a selection with respect to a determined size of axial clearance is disclosed. It is noted that E6 does not deal with the problem of a gap between piston and piston rod that needs to be eliminated. Furthermore, E6, column 3, lines 40 to 45, describes that during assembling the spacer 300 is "*placed between the plunger 162 and the piston 148 to thereby push the piston forward in the ampoule cylinder 136 to change the size of the medicament chamber.*" It follows that the final axial position of the piston 148 relevant for the axial clearance is only reached after the final assembly. Thus the axial clearance can not be determined in a pre-assembled state in which the spacer has to be selected.

4.3.4 Hence, the method of claim 1 is new over E6 and E20.

4.4 **E3, E7, E18**

4.4.1 E3, E7 and E18 all disclose an adjustable spacer.

In E3, the spacer (figures 9 and 10, piston rod foot 170) adapts automatically to the gap size when the cartridge holder 120 is attached to the main body 130. During assembling, the piston rod foot 170 is moved onto the end portion of the piston rod depending the size of the axial clearance (E3, page 10, lines 27 to 34).

In E7, the axial clearance between piston 38 and piston rod 56 is eliminated by manually adjusting the position of the head 334 of multiple-part spacer 29, 330, 334 (figures 1 and 8 with column 4, lines 32 to 41).

In E18, the multiple-part spacer 90, 100 (figure 20) or 112, 114 (figure 23) adapts automatically to the gap

size 34 after a spring 98 (figure 20) or 126 (figure 23) is actuated in the assembled state of the device. None of these documents disclose a set of differently sized spacers from which a selection can be made during assembly.

4.4.2 For all three documents, the appellant 2 (opponent) argued that the different size settings or the different positions of the spacer, as e.g. shown in E3, figures 7 and 8 or in E18, figures 20 to 22, would correspond to a set of different sized spacers from which one is selected according to feature 6.5.

The board does not agree. Claim 1 refers to a method of assembly. During assembly of the device, feature 6.5 requires that a spacer is selected from a set of spacers, i.e. selected at least out of two physically present spacers. However when assembling the device of E3, E7 or E18 such a selection can not be made, as there is only one spacer that is physically available. Additionally in E3, the piston rod foot 170 automatically "determines" (see wording of claim 1 of E3) the gap size so that the selection itself does not depend on a (previously) "*determined size of axial clearance*". The same is valid for the embodiments of the spacer in E18, figures 20 and 23.

4.4.3 For E7 and E18 is was further argued by the appellant 2 (opponent) that the different parts of the multiple-part spacer (in E7, figure 8, parts 29, 330, 334, in E18, figure 20, parts 90, 100, and figure 23, parts 112, 114) each constituted a separate spacer which were all selected with respect to the axial clearance. Such an interpretation would fall under the claim wording "select at least one spacer" of feature 6.5.

The board does not follow this interpretation. In both documents the relevant embodiments show one spacer that comprises several parts to allow a telescopic adjustability. However no selection out of a set of spacers depending on the axial clearance is made. Either the spacer as such - comprising all parts together -, or no spacer is selected during assembling.

4.4.4 For E18 in particular it was also argued that feature 6.5 was disclosed by selecting one spacer out of the large variety of differently sized spacers shown e.g. in figure 1, figure 4, figure 6, figure 8, etc.

The board is not convinced. E18 indeed discloses a variety of differently sized spacer, however this variety presents different alternative embodiments. The selection of a spacer is not motivated by the size of a determined axial clearance. All embodiments are disclosed as being suitable for and used to eliminate same gap sizes. E18 does not include any hint that one embodiment is preferred for larger gaps and another embodiment is preferably used for smaller gaps.

4.4.5 For E7 it was additionally argued that the washer 151 and the first stop 152 could be seen as spacers and were selected depending on the axial clearance. However, the board agrees with the opinion of the opposition division (impugned decision, point 19) that neither the washer 151 nor the stop 152 can be seen as the claimed spacers. Both parts do not eliminate an axial clearance between the piston 38 and the piston rod 56 as they are disposed around the plunger shaft 40 or 330 and not between the piston and the piston rod.

4.5 E2

4.5.1 In E2, the flange 10 (figure 1) allegedly constituted the spacer selected according to feature 6.5.

4.5.2 The board does not agree as the flange 10 is a fixed part of the driven member 9. A possible gap between the flange, i.e. the end face of the piston rod, and the piston 5 is eliminated as disclosed in column 4, lines 60 to 63: "*the new carpules 3 to be inserted are filled in such a manner that the piston 5 is pushed forward a little by the flange 10 during incorporation into the injection device and some liquid is ejected from the needle 7*.".
Thus it is the filling of the capsule that is selected in such a way that the axial clearance between piston and piston rod is eliminated.

4.6 E12, E11

4.6.1 E12 (figures 2a, 2b with page 13, lines 1 to 15) as well as E11 (figures 2, 3 with page 16, lines 22 to 27) disclose clearance elimination by means of axial displacing the piston rod comprising a pad 26 (E12) or a bearing 14 (E11). Contrary to the appellant's (opponent's) argumentation, the pad 26 or bearing 14 does not constitute a spacer selected from a set of spacers according to feature M6.5.

4.6.2 Even if E12 explicitly discloses steps M6.2 and M6.3 (page 6, lines 24 to 30), no spacer from a set of spacers is selected during assembly. The pad or bearing 26, allegedly constituting the claimed spacer, forms part of the piston rod and has the purpose of preventing the transmission of torque to the piston (bung 44) by the piston rod 20, 22 as described on page

4, lines 18 to 25. A set of differently sized spacers is neither disclosed nor necessary as the piston rod as such is movable to eliminate the gap to the piston.

4.6.3 In E11, an axial clearance 28 is eliminated by advancing the piston rod (lead screw 5) until the bearing 14 contacts the piston (bung 6), see figures 2 and 3 with page 16, line 22 to page 17, line 14. Similar to the device disclosed in E12, the bearing 14 is a fixed part of the piston rod having the purpose to prevent the transmission of torque to the piston (bung 6) by the piston rod (lead screw 5), see page 14, lines 2, 3. As for E12, a set of differently sized spacers is neither disclosed nor necessary.

4.6.4 E12 and E11 thus disclose alternative solutions for the same problem as posed in the patent in suit, i.e. to avoid priming (patent in suit, paragraph [0010]; E12, page 2, lines 8 to 11; E11, page 17, lines 30, 31).

5. Auxiliary request 6 - Article 56 EPC

5.1 The method according to claim 1 of auxiliary request 6 involves an inventive step over E3 combined with common general knowledge or combined with E7.

5.2 E3 with general knowledge or with E7

5.2.1 The impugned decision and the appellant 2 (opponent) start from E3 as closest prior art. E3 aims to avoid initial priming (E3, page 3, line 3, 4) as the opposed patent (paragraph [0010]) and discloses an adjustable piston rod foot 170 that automatically adapts to the size of the axial clearance between the piston 144 and the piston rod 160 (figures 7 to 10) during the final

assembling.

5.2.2 The board agrees with the opinion of the appellant 1 (patent proprietor) that at least features M6.4 combined with M6.5 cannot be identified in E3. The self-adjusting spacer of E3 can neither be selected out of a set of differently sized spacers nor with respect to a determined size of axial clearance as the axial clearance between piston and piston rod is not determined at all.
As put forward by the appellant 1 (patent proprietor) the effect of the distinguishing features is that the undesired axial gap between piston and piston rod caused by manufacturing tolerances is closed without moving the piston of the cartridge. The objective technical problem can thus be formulated as finding an alternative solution without applying axial pressure to the piston of the cartridge during final step of assembly.

5.2.3 None of the documents cited by the appellant 2 (opponent) discloses a method including steps M6.4 with M6.5. Even if E19 on page 168 mentions "spacers" to relax tolerances, the skilled person does not get any hint to replace the already available solution of E3 by selecting a spacer out of a set of spacers according to claim 1. E19 does not give any further information than using a spacer which is known by the skilled person and already done in E3. E19 does not give any hint how the axial pressure of the piston during final assembling could be avoided.

5.2.4 E6, also mentioned in relation to common general knowledge, is the only document that discloses the employment of spacers of various sizes. However the spacers according to E6 do not solve the problem of

avoiding axial pressure to the piston as the piston is pushed by the spacer during final assembly (see column 3, lines 40 to 45).
Additionally, it is not obvious to simply replace the foot 170 shown in E3, figure 10, with one spacer out of a set of spacers as disclosed in E6 as the spacers have different purposes. In E3, the spacer 170 closes the gap of manufacturing tolerances; in E6, the spacer 300 is used for reducing the maximum medicament dose to a dictated amount.

5.2.5 The appellant 2 (opponent) further argued that the teaching of E7 would prompt the skilled person to a method according to claim 1 by replacing the piston rod foot 170 by spacer 29, 330, 334 of E7 (figure 8) that can be manually adjusted with respect to a gap size determined in advance (column 4, lines 38 to 41) and thereby avoid pressure to the piston during final assembly.

5.2.6 The board does not agree. Neither E3 nor E7 discloses a set of differently sized spacers from which the skilled person could select (see also points 4.4.2 and 4.4.3 of this decision). Hence even E3 were combined with E7, the skilled person would not arrive at the method as defined in claim 1.

5.3 E6 with general knowledge - Article 13(2) RPBA 2020

5.3.1 The board did not admit the attack starting from E6, submitted for the first time during oral proceedings before the board.

5.3.2 The appellant 2 (opponent) referred to their reply to the statement of grounds of appeal of the patent proprietor, point X, wherein it was stated that the

method claim of auxiliary request 9 "*is at least not based on an inventive step over E6 combined with common general knowledge in the art or with E21 (see, e.g., column 5, line 35-43, Figure 2 and 7 of E21)*".

5.3.3 The board judges that this statement by its very general and vague formulation cannot be regarded as a objection of lack of inventive step which is duly substantiated. The statement indeed does not provide any information allowing the reader to understand appellant's 2 reasoning in substance, not to speak of the complete lack of argumentation using the problem-solution approach. Thus the submission made during oral proceedings amounts to an amendment to the opponent's case such that Article 13(2) RPBA 2020 applies.
As there are no exceptional circumstances which have been justified with cogent reasons by the appellant 2 (opponent), the new attack based on E6 with general knowledge is not admitted into appeal proceedings.

6. Auxiliary request 6 - Article 83 EPC

6.1 The board confirms the impugned decision, point 12.2, that the requirements of Article 83 EPC are met.

6.2 Contrary to the appellant's (opponent's) opinion that the skilled person can not put the claimed method into practice because claim 1 does not provide any bridging features between the pre-assembled and the assembled state and does not define that the results of steps M6.2 and M6.3 were used for step M6.4, the board does not see an insufficient disclosure; rather the appellant's (opponent's) objection raises a clarity issue. From the application as a whole, in particular figures 1, 2 and 5 and e.g. paragraph [0036] of the patent the skilled person readily understands what the

relation between the axial positions determined in the pre-assembled state and the axial clearance in the assembled state is, and that steps M6.2 and M6.3 are used for step M6.4 ("*By measuring the distance between end faces of piston rod and piston with respect to a free end or with respect to an abutment shoulder of insert portion or receptacle of housing or cartridge holder, the axial clearance between piston rod and piston when reaching the final assembly position can be precisely determined.*").

6.3 The appellant further argued that the claimed method was not sufficiently disclosed over its whole breadth because the patent, paragraph [0033], only disclosed one specific way of how to determine the axial positions in step M6.2 and M6.3 (i.e. with reference points) but did not provide additional technical features to generalize the method over the broad claimed range.

The board does not agree. Paragraphs [0031, 0035 to 0038] of the patent, referred to by the appellant 1 (patent proprietor) describe several possibilities of how to determine the axial positions: by reference points in general, by a bearing or abutment shoulder or a free end of the receptacle, by means of a tactile probe or by means of an optical sensor.
It is not necessary to provide a full list of all possibilities of how to determine an axial position of an end face. In particular, it is not apparent which possibilities to determine an axial position would fall under claim 1 which the skilled person is not able to put in practice.

7. Description

The parties agreed that the description as maintained by the opposition division does not need further adaptation to the claims according to AR6.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:

Description:
Paragraphs [0001] to [0055] as filed during oral proceedings before the opposition division dated 20 February 2018.

Claims:
No. 1 to 8 according to auxiliary request 6 filed with the statement of grounds of appeal of the patent proprietor dated 8 August 2018.

Drawings:
Sheet(s): 1/4 to 4/4 of the patent specification.

The Registrar: The Chairman:

A. Vottner G. Pricolo

Decision electronically authenticated