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Datasheet for the decision of 29 November 2022

Case Number: T 3287/19 - 3.2.01

Application Number: 11724422.8

Publication Number: 2579928

IPC: A61M5/315

Language of the proceedings: EN

Title of invention:
DRIVE ASSEMBLY, DRIVE COMPONENT AND DRUG DELIVERY DEVICE

Patent Proprietor:
Sanofi-Aventis Deutschland GmbH

Opponents:
Ypsomed AG
Bandpay & Greuter
Patentree, Lda

Headword:

Relevant legal provisions:
EPC Art. 123(2), 111(1)
RPBA 2020 Art. 11

Keyword:
Amendments - extension beyond the content of the application as filed (yes)
Remittal - special reasons for remittal - (no)

Decisions cited:
T 0727/00, T 1924/18, T 1437/15

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 3287/19 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 29 November 2022

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Respondent: (Opponent 2)	Bandpay & Greuter 30, rue Notre-Dame des Victoires 75002 Paris (FR)
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Respondent: (Opponent 3)	Patentree, Lda Rua Salazares 842 4149-002 Porto (PT)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 9 December 2019 revoking European patent No. 2579928 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The appeal of the patent proprietor lies against the decision of the opposition division to revoke European patent No. 2579928 pursuant to Article 101(3)(b) EPC.

II. In its decision, the opposition division held that the invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, contrary to the requirements of Article 83 EPC.

III. The patent was opposed by three opponents. With letter dated 7 October 2022 opponent 1 withdrew their opposition.

IV. Oral proceedings by videoconference were held before the Board on 29 November 2022. Respondent 2 (opponent 2) did not attend oral proceedings as announced with letter dated 29 October 2022.

V. The appellant (patent proprietor) requested that the decision under appeal to revoke the patent on the basis of Article 83 EPC 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 the auxiliary requests 1 to 5 filed with the grounds of appeal.
Furthermore the appellant requested that the board also decides the main request on Article 83 EPC or at least writes a positive statement in the decision in this respect.
With their letter dated 9 July 2021 the appellant requested remittal to the first instance in case additional reasons, not yet addressed by the opposition

division, were to be discussed in connection with claim 1.

The respondents (opponents 2 and 3) requested that the appeal be dismissed.

VI. Claim 1 of the main request (patent as granted) reads as follows (feature numbering according to the impugned decision):

1.1 A drive assembly for a drug delivery device, the drive assembly comprising:

1.2 a housing (17) having a proximal end (18) and a distal end (19),

1.3 a rotation member (21) being configured to be rotated in a first direction (44) with respect to the housing (17) during setting of a dose of a drug and to be rotated in a second direction (47) with respect to the housing (17) during delivery of the dose, the second direction (47) being opposite to the first direction (44),

1.4 a drive component (20) being configured to follow rotational movement of the rotation member (21) in the second direction (47) during delivery of the dose,

1.5 a stop member (26) being configured to prevent rotational movement of the drive component (20) in the first direction (44) with respect to the housing (17),

1.6 a piston rod (12)

1.6.1 being configured to be displaced in the distal direction for delivering a dose of a drug and being

configured such that rotational movement of the drive component (20) in the second direction is at least partially converted into movement of the piston rod (12) in the distal direction with respect to the housing (17),

1.6.2 wherein the piston rod (12) is a lead-screw,

1.7 the drive component (20) and the rotation member (21) are rotatable around a common rotation axis,

1.8 the drive component (20) comprises a first drive part (71) and a second drive part (72), coupled to each other such that relative rotational movement of the first and second drive parts (71,72) is prevented and relative axial movement is permitted,

1.9 the first drive part (71) is configured for engagement with the rotation member (21) and

1.10 the second drive part (72) is configured for engagement with the stop member (26),

1.11 the stop member (26) is secured against both axial and rotational movements with respect to the housing (17), and

1.12 the stop member (26) is configured to permit rotational movement of the drive component (20) in the second direction (47) with respect to the housing (17), **characterized in that**

1.13 the first drive part (71) is directly engaged with the piston rod (12),

1.14 the rotational movement of the drive component (20) is converted into pure linear movement of the piston rod (12) in the distal direction along the rotation axis,

1.15 the drive component (20) comprises a biasing member (73) for providing a force on the first and second drive parts (71,72) for keeping at least the first part (71) in abutment with the rotational member (12) or the second drive part (72) in abutment with the stop member (26),

1.16 wherein the biasing member (73) forces the first and second drive parts (71,72) apart in opposite axial directions,

1.17 wherein the drive component (20) comprises retaining means to limit the axial separation of the first and second drive parts (71,72), and

1.18 wherein at least one of the first and second drive parts (71,72) comprises a toothing (22, 28) for engagement with one of the rotation member (21) and the stop member (26), respectively.

In claim 1 of **auxiliary request 1** the following feature is added between features 1.17 and 1.18:

"the retaining means being arranged at both the first and second drive parts (71, 72), with the retaining means comprising a first stop face on one of the drive parts arranged for abutment with a second stop face on the other drive part,"

Auxiliary request 2 is based on auxiliary request 1 wherein in claim 1 the following feature is added

after the feature introduced with auxiliary request 1:

"wherein the drive component (20) is provided as a pre-assembled component for assembly with the rotation member (21), the stop member (26) and the housing (17) for building the drive assembly (70) and"

Auxiliary request 3 is based on auxiliary request 2. In claim 1 of auxiliary request 3 feature 1.6.2 of the main request is amended as follows:

"wherein the piston rod (12) is a lead-screw comprising two oppositely disposed engagement tracks (37) on the outside which interrupt a thread (49) and which linearly extend along the axis along which the piston rod (12) is displaceable with respect to the housing and with respect to the drive component (20)"

Auxiliary request 4 is based on auxiliary request 3. In claim 1 of auxiliary request 4 the following feature is added between features 1.10 and 1.11:

"wherein both drive parts (71, 72) are formed as a respective sleeve, with the sleeve of the second drive part (72) partially enclosing the sleeve of the first drive part (71),"

Auxiliary request 5 is based on auxiliary request 2. In claim 1 of auxiliary request 5 feature 1.13 of the main request is amended as follows:

"the first drive part (71) is directly engaged with the piston rod (12) by a splined engagement,"

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

follows:

Added subject-matter

The original disclosure was reflected by the A1-publication WO2011/154483. All features of claim 1 were shown in the embodiment of figures 2 to 5 except feature 1.14 according to which the piston rod moved purely linearly. In the embodiment shown in the figures, the piston rod moved helically.
A skilled person was aware that there were only two alternatives for driving a threaded lead-screw such that axial displacement occurred as was intended in drug delivery devices.
Said second alternative, reflected in feature 1.14, was disclosed on page 4, lines 25 to 29. A drive component comprising a gear teeth mentioned in this passage in the context of the pure linear movement of the piston rod just provided a suitable example but no limitation.

The original application even explicitly disclosed an arrangement with a purely linearly moving rod in the context of the dose member 34. In the paragraph bridging page 4 and 5, it was described that "*the dose member may be secured against rotational movement with respect to the housing*" and that "*the dose member may be splined to the housing*".

Furthermore, the application was directed to a skilled person, who was readily able to kinematically inverse the shown arrangement with a helically moving piston rod to an arrangement with a piston rod moving purely linearly. The two alternatives were a simple exchange of the threaded interface between piston rod 12 and stop member 26 and the splined interface between piston

rod and drive component 20 (page 27, lines 4 to 28). Nothing more needed to be adapted.

The respondent's (opponent's) argument that the simple exchange of interfaces may lead to vibrations of the piston rod during dose setting, were not crucial, as the claim was about a drive assembly, not about the drug delivery device as such. Furthermore the skilled person may simply accept an undesired oscillating movement of the piston rod if the advantages of an embodiment outweighed its minor drawbacks.

If the skilled person wished to avoid the oscillating movement, they would follow the teaching of the original application to use - instead of the toothing 22 at the drive part 71 - another kind of uni-directional friction clutch mechanism (page 7, lines 6 to 13).

Remittal for issues others than Article 100(b) EPC

As the impugned decision only dealt with Article 83 EPC, it was appropriate to remit the case to the first instance for all other outstanding issues, in case the board came to the conclusion that the requirements of Article 83 EPC were met.

Decision with regard to Article 83 EPC

Should the board come to the conclusion that the patent in suit does not meet the requirements of Article 100(c) EPC taken in combination with with Article 123(2) EPC, the patent proprietor would be put in a worse situation than if they had not appealed. The patent proprietor would then be confronted with a further decision revoking the patent based on a second

ground.
Therefore, based on the legal provision of the prohibition of the *reformatio in peius*, and in view of the positive preliminary opinion expressed in the communication under Article 15(1) RPBA by the Board with respect to sufficiency of disclosure, the request to additionally decide the issue regarding Article 83 EPC, or at least to write a positive statement thereon in the decision, e.g. in an obiter dictum, was admissible.

VIII. The respondents' (opponents') arguments relevant to the present decision may be summarised as follows:

Added subject-matter

The combination of feature 1.6, 1.13 and 1.14 was originally not disclosed, even if all features - seen isolated - may find a basis in the original application (WO 2011/154483). Reference was made to T 0727/00. Therein it was held that even if the claimed subject-matter might be conceptually comprised in the application, it was not disclosed in that particular individual form.

In the embodiments shown in the figures 2 to 5, the piston rod was in splined engagement with the first drive part 71 and in threaded engagement with the stop member (page 27, lines 4 to 28). This arrangement was described as improving the dose accuracy by preventing the piston rod from moving during dose setting (page 4, lines 2 to 7). Contrary to the opinion of the appellant (patent proprietor) a simple exchange of these interfaces was originally not disclosed. Such an exchange would result in a device with an undesired functionality because the piston rod would axially move

during dose setting.

The most general disclosure for feature 1.13 could be found on page 3, lines 24 to 29. Therein, the drive component was described as being engaged with the piston rod, but only in such a way that relative rotational movement was prevented but relative axial movement was allowed. This arrangement corresponded to the one shown in figures 2 to 5 wherein the piston rod moved helically.

Furthermore the wording "directly engaged" in feature 1.13 found no literal basis at all in the original application. The only disclosed direct engagement of the first drive part 71 with the piston rod 12 was a splined engagement (page 26, lines 26 to 31 of the A1-publication) which - again - did not result in the pure linear movement of the piston rod as defined in feature 1.14.

The pure linear movement of the piston rod was only mentioned on page 4, lines 25 to 29. This passage proposed that when a pure linear movement was intended, the drive component comprised a gear teeth. Such a gear teeth usually cooperated with a tooth rack but not with a lead screw as claimed in feature 1.6.2.

Finally, the disclosure of a linear moving dose member had no relevance for the question whether a piston rod being a purely linearly moving lead screw was originally disclosed.

Reasons for the Decision

1. Article 100(c) EPC and Article 123(2) EPC - Main request

1.1 The originally filed application does not have a basis for the feature combination 1.6.2, 1.13 and 1.14. A drive component having a first and a second drive part, wherein the first drive part is directly engaged with a lead-screw, such that the lead-screw moves purely linear in the distal direction is originally not disclosed.

1.2 For the examination of the requirements of Article 123(2) EPC reference is made to the A1-publication WO 2011/154483 of the patent in suit.

1.3 Starting from the illustrated embodiment (figures 2 to 5) a lead-screw that moves purely linearly is not implicitly disclosed - contrary to the appellant's (patent proprietor's) opinion.

1.3.1 In the figures, the drive component 20 comprises two drive parts 71, 72, wherein the first drive part 71 and the piston rod 12 (being a lead-screw) are in direct splined engagement. Additionally the lead-screw 12 is in threaded engagement with the stop member 26 which is fixed relative to the housing 17 (page 27, lines 4 to 28). Such an arrangement indisputably leads to a rotating piston rod 12 during dose delivery and a non-moving piston rod during dose setting. During dose setting the drive part 71 axially moves relative to the piston rod because of the splined engagement.

1.3.2 A simple exchange of the interfaces such that the piston rod moves purely linear is in contradiction with

one of the problems posed in the patent in suit (page 4, lines 2 to 6: "*Unintentional proximal movement of the piston rod may result in decreased dose accuracy*").

As pointed out by the respondent (opponent), during dose setting, the first drive part 71 is prevented from rotation but is axially oscillating (see page 29, lines 4 to 13, and figure 3 (double arrow 45) of the original application).
When kinematically inverting the interfaces, during dose setting, a relative axial movement between the drive part 71 and the piston rod 12 - then being in threaded engagement - would not be possible anymore. Thus the piston rod also would, undisputedly, axially oscillate. The axial displacement of the piston rod would correspond to the height of tooth 22 of the drive part (see figure 3).

Contrary to the appellant's (patent proprietor's) opinion such an axial displacement cannot be neglected. According to page 29, line 30, to page 30, line 2, the rotation about one tooth can determine one dose of drug. Thus with an oscillating piston rod during dose setting, an amount of drug corresponding to a single dose increment would be lost and decrease dose accuracy.

1.3.3 Accordingly, a skilled person would not consider such an embodiment with undesired functionality as being implicitly disclosed by figures 2 to 5 of the original application.

1.3.4 It is further noted that even if the skilled person in addition to the exchange of interfaces could replace the illustrated toothing 22 by another type of uni-directional clutch, no basis can be found in the

original application for the combination of all necessary modifications.

1.4 Furthermore, the original application does not mention to simply switch the disclosed arrangement. Instead the patent teaches away from such an exchange and proposes to use a drive component of a different structure, namely a drive component comprising a gear teeth, for the purpose of a purely linearly moving piston rod (page 4, lines 28, 29).
The skilled person would not read the teaching of page 4, lines 25 to 29, together with the illustrated embodiment because it would result in the axial movement of the piston rod 12 during dose setting as described above (point 1.3.2).

1.5 The pure linear movement of the piston rod only is disclosed with a drive component in general, not in combination with a drive component 20 comprising first and second drive parts 71, 72.
The only disclosure for a pure axial movement of the piston rod on page 4, lines 25 to 29 of the A1-publication (paragraph [0016] of the patent in suit) describes that in "*another embodiment, the rotational movement of the drive component is converted into a pure linear movement of the piston rod in the distal direction.*".

1.6 On the other hand, the drive parts 71, 72 are only disclosed in combination with a piston rod that rotates together with the drive component, see e.g. page 3, lines 22 to 29: "*The drive component may be engaged with the piston rod such that relative axial movement between the piston rod and the drive component is allowed and relative rotational movement is prevented. In particular, the drive component, for example at*

least one of the first and second drive parts, may be engaged with the piston rod."

1.7 The fact that a purely linearly moving dose member 34 is disclosed in the paragraph bridging pages 4 and 5, does not change the fact that the original disclosure does not contain a basis for the claimed feature combination.

1.8 Consequently the claimed subject-matter is the result of an artificial combination of cherry-picked features. The requirements of Article 100(c) EPC taken into combination with Article 123(2) EPC are not met.

2. Auxiliary requests 1 to 5

Claim 1 of all auxiliary requests comprises the disputed feature combination and thus contravenes Article 123(2) EPC for the same reasons as claim 1 of the main request.

3. Article 11 RPBA

3.1 The board did not grant the appellant's (patent proprietor's) request to remit the case to the first instance for all issues concerning Article 100(a) and (c) EPC which were not discussed before the opposition division, as no special reasons presented themselves for doing so.

The objections under Articles 100(c) and 123(2) EPC were in the appeal proceedings from the beginning and were raised by the respondents (opponents 2, 3) with their replies to the statement of grounds of appeal. The objection relevant to the present decision concerns the same features as the objection under Article 83

EPC, i.e. a purely linearly moving piston rod being a screw thread directly engaged with the first drive part (features 1.6.2, 1.13 and 1.14).

3.2 Under these circumstances, the board exercised its discretion under Article 111(1), second sentence, to decide on the respondents' (opponents' 2, 3) objections raised under Article 100(c) EPC.

It is the boards' settled case law that parties do not have a fundamental right to have their case examined at two levels of jurisdiction. Accordingly, they have no absolute right to have each and every matter examined at two instances. Article 111(1), second sentence, EPC leaves it instead to the board's discretion to decide on an appeal either by exercising any power conferred on the department of first instance or by remitting the case to that department (Case Law of the BoA of the EPO, 10th edition, V.A.9.2.1).

4. Further issues

4.1 The board dismissed the request of the appellant (patent proprietor) to include additionally a decision about Article 100(b) EPC or at least a positive statement in the decision to reflect the positive preliminary opinion of the board on this issue because there is no legal basis for granting this request. On the contrary, Rule 102 EPC implies that a decision should be reasoned in so far as the issues to be decided are concerned.

4.2 Contrary to the appellant's (patent proprietor's) opinion the prohibition of *reformatio in peius* does not apply. The legal effect of the impugned decision was that the patent was revoked. By confirming the decision

of the first instance, even if on a different ground, the legal effect of the impugned decision remains the same, whereby the situation of the appellant (patent proprietor) is the same as if they had not appealed. The prohibition of *reformatio in peius* relates solely to the legal effect of an impugned decision; it does not apply to individual issues or objections (see e.g. T 1924/18 and T 1437/15).

The appellant's (patent proprietor's) argument that in some national proceedings a revocation for lack of sufficiency before the EPO would be looked at differently than a revocation for added subject-matter is irrelevant because i) the criteria for applying the prohibition of *reformatio in peius* relate to the situation of the appellant in the proceedings before the EPO, ii) a reference to such national proceedings is merely hypothetical, and iii) the present decision would in any effect have no binding effect therein.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Voyé G. Pricolo

Decision electronically authenticated