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**Datasheet for the decision  
of 27 March 2023**

**Case Number:** T 1426/21 - 3.2.01

**Application Number:** 14799430.5

**Publication Number:** 3071264

**IPC:** A61M5/315

**Language of the proceedings:** EN

**Title of invention:**

ASSEMBLY FOR DRUG DELIVERY DEVICE AND DRUG DELIVERY DEVICE  
COMPRISING ONE SUCH ASSEMBLY

**Applicant:**

Sanofi-Aventis Deutschland GmbH

**Headword:**

**Relevant legal provisions:**

EPC Art. 84  
EPC R. 42

**Keyword:**

Claims - clarity (yes)

**Decisions cited:**

T 1444/20

**Catchword:**



**Beschwerdekammern**  
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Case Number: T 1426/21 - 3.2.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.01**  
**of 27 March 2023**

**Appellant:** Sanofi-Aventis Deutschland GmbH  
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**Representative:** Zwicker, Jörk  
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**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 3 March 2021  
refusing European patent application No.  
14799430.5 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** G. Pricolo  
**Members:** S. Mangin  
O. Loizou

## **Summary of Facts and Submissions**

- I. The appeal was filed by the appellant (applicant) against the decision of the examining division to refuse the patent application in suit (hereinafter "the application").
- II. The examining division refused the application on the basis of Article 84 EPC. The examining division held that  
*"the main request and the first and second auxiliary request comprise claim-like clauses on pages 10a to 12, which are different from the set of claims. Therefore, these claim-like clauses imply that the scope of protection may be different to that defined in the claims and hence do not comply with the requirements of Article 84 EPC. Their presence may lead to unclarity as to the actual scope of protection. According to the Guidelines F-IV, 4.4, last paragraph these passages should be deleted. Moreover such clauses do not comply with Rule 42 EPC, given that they do not belong in the description, as explained in decision T 490/90 points 5 and 6"*.
- III. With their statement of grounds of appeal, the appellant requested the appealed decision to be set aside and a patent to be granted on the basis of the main request, based on the EDREXFINAL attached to the appealed decision with pages 10, 10a, 11 and 12 being replaced with pages 10-12a entitled "main request" filed with the statement of grounds of appeal. Alternatively, the appellant requested a patent to be granted on the basis of the first to fourth auxiliary requests based on the EDREXFINAL attached to the appealed decision with the replacement of pages 10,

10a, 11 and 12 with the description pages 10-12a entitled first, second, third and fourth auxiliary request respectively or on the basis of auxiliary request 5 corresponding to the EDREXFINAL attached to the appealed decision (without any modification).

The documents according to the EDREXFINAL are those mentioned in the communication under Rule 71(3) EPC issued on 27 July 2020 (see also page 5, first paragraph of the appealed decision).

- IV. In their communication pursuant Article 15(1) RPBA, the Board indicated that the claim-like clauses in the description of the main request, the first, second and third auxiliary requests were not consistent with the claims which led to the claims being unclear pursuant to Article 84 EPC (i.e. not supported by the description). However the Board indicated that the amendments made to the description of the fourth auxiliary request met the requirements of Article 123(2) EPC and overcame the inconsistencies between the the description and claims and met the requirements of Article 84 EPC.
- V. With letter of 13 March 2023, the appellant made their fourth auxiliary request their main request and renumbered the other requests in the same order as auxiliary request 1 to 5. The appellant further noted that in case the Board regarded the new main request as allowable, the oral proceedings could be cancelled.
- VI. Since the main request request was considered allowable by the Board, the oral proceedings were cancelled, and the Board decided in written proceedings.
- VII. The subject-matter of claim 1 reads:

1. Assembly (1) for a drug delivery device (1) comprising:  
a housing (4);  
a lead screw (22) having a longitudinal axis, a distal end and a proximal end, the lead screw (22) being rotatably fixed during dose setting and dose delivery and axially movable in a distal direction relative to the housing (4), the lead screw (22) further including a thread (33),  
a drive nut (23) threadedly engaged with and screwable along the lead screw thread (33);  
a dial link (25) connected with the drive nut (23) and axially movable and rotatably fixed relative to the drive nut (23), where the dial link (25) comprises a first portion of a feedback ratchet (80, 81), and wherein the assembly is configured such that, during dose setting, the dial link (25) is moved relative to the housing (4) a first axial distance from a home position and the drive nut (23) is moved along the thread (33) a second axial distance and wherein, during dose delivery, the dial link (25) is moved relative to the housing (4) back toward the home position, and the drive nut (23) and therewith the lead screw (22) is advanced axially, and where the assembly comprises a second portion of the feedback ratchet (80, 81), wherein the second portion is arranged and configured to engage the first portion such that, during dose delivery, the contact between said portions generates a feedback signal,  
**characterized in that**  
a) the thread (33) of the lead screw (22) forms the second portion of the feedback ratchet and the first portion of the feedback ratchet comprises a ratchet arm (80, 81) configured to engage the second portion of the

feedback ratchet (80, 81), where in the ratchet arm forms the first portion of the feedback ratchet, or b) the drive nut (23) comprises the second portion of the feedback ratchet (80, 81).

## **Reasons for the Decision**

1. Admissibility of the main request first filed with the statement of grounds of appeal (Request numbered fourth auxiliary request in the statement on grounds of appeal)- Article 12(4) RPBA 2020

The Board exercised its discretion to admit the main request. As noted by the Board in its communication pursuant Article 15(1) RPBA the main request addresses the issues which led to the refusal of the application. Its admission in the appeal proceedings contributes to the procedural economy.

2. Clarity of the main request

- 2.1 Pages 11 and 12 of the description refer to "*aspects*" to which "*the present disclosure may further relate*". In the application as filed (see pages 11 and 12), the "*aspects*" are numbered 1 to 7. As compared to the application as filed, pages 11 and 12 are amended such as to include the features of aspects 2 and 3 (option i), and of aspect 4 (option ii) to aspect 1 and are reproduced below:

*"i) the first portion of the feedback ratchet comprises a ratchet arm configured to engage a section portion of the feedback ratchet comprising the helical threads on the lead screw or ratchet teeth on the drive nut and wherein*

*the ratchet arm is positioned radially inward and engages the threads on the lead screw such that during dose setting and dose delivery the contact between the ratchet arm and the threads generates a feedback signal to the user, or*

*ii) the drive nut comprises a second portion of the feedback ratchet that cooperates with the first portion such that the cooperation generates a feedback signal to the user".*

The remaining "aspects" 5 to 7 have been merely renumbered as aspects 2 to 4.

2.2 Accordingly, the amendments to these pages of the description fulfil the requirements of Article 123(2) EPC. Furthermore the amendments of the description overcome the inconsistencies with claim 1. Claim 1 indeed includes all the features under "aspect" 1. The claims therefore fulfil the requirements of Article 84 EPC.

2.3 According to Article 84 EPC, the claims define the matter for which protection is sought. They shall be clear and concise and be supported by the description. This means that any inconsistencies between the claims and those parts of the description disclosing ways to carry out the invention need to be removed. This understanding of Article 84 EPC is in line with the standard of claim interpretation for national proceedings enshrined in Article 69(1) EPC, which requires that the description also be taken into account when interpreting the claims.

2.4 The passage on page 10-12 of the description situated in the middle of the description (at the end of the "summary" of the invention) although using the term "aspects" and not "claims" may indeed be regarded as



relating to "claim-like clauses". Indeed, the passage is drafted similarly to claims, where dependent aspects depend on previous aspects using language such as "the drug delivery device of aspect 1 where (...)".

- 2.5 The Board notes that the Guidelines 2023, Part F, Chapter IV, 4.4 indicate that *"claim-like clauses must also be deleted or amended to avoid claim-like language prior to grant since they otherwise may lead to unclarity on the subject-matter for which protection is sought"*.

In the present case the "claim-like clauses" do not render the subject-matter for which protection is sought unclear because the text in the description is consistent, and not in contradiction, with the set of claims. Moreover, the Board notes that the "aspects" on pages 11 and 12 cannot be mistaken for claims. It is obvious that they are part of the description and are not part of the claims defining the protection to be sought.

- 2.6 Furthermore Rule 42 EPC defines the content of the description and in particular Rule 42(c) EPC states that *"The description shall disclose the invention, as claimed, in such terms that the technical problem, even if not expressly stated as such, and its solution can be understood, and state any advantageous effects of the invention with reference to the background art"*.

Rule 42 EPC does not rule out claim-like clauses in the description. In the present case, the claim-like clauses disclosed as "aspects" on pages 11 and 12 can be considered as embodiments of the invention defined in terms of technical features. These claim-like clauses do not change or impair the understanding of

the technical problem and the solution defined in the description. Therefore there is no reason to require their deletion.

- 2.7 In this respect, the Board follows decision T1444/20 finding that the "specific embodiments of the invention" drafted as claim-like clauses in the description, which were consistent with the claims did not render the claims unclear pursuant Article 84 EPC and met the requirements of Rule 42 EPC.
3. To conclude, the amendments to the description according to the main request remove the inconsistencies between the claim-clause like embodiments and the claims. The claims are thereby supported by the description pursuant to Article 84 EPC.
4. The contested decision is thus to be set aside. The Board, having no reason to interfere with the finding of the Examining Division that the claims in accordance with the EDREXFINAL attached to the appealed decision meet the requirements of the EPC (i.e. the claims in accordance with the communication under Rule 71(3) EPC dated 27 July 2020), thus concludes that the documents according to the appellant's main request form a suitable basis for the grant of a patent.

## **Order**

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

1. The decision under appeal is set aside.
2. The case is remitted to the examining division with the order to grant a patent in the following version:

Description:

- Pages 1-9 and 13-30 of the EDREXFINAL as attached to the appealed decision.
- Pages 10, 11, 12 and 12a of auxiliary request 4 filed with the statement of grounds of appeal dated 12 July 2021.

Claims:

- No. 1-12 of the EDREXFINAL as attached to the appealed decision.

Drawings:

- Sheets 1/5-5/5 of the EDREXFINAL as attached to the appealed decision.

The Registrar:

The Chairman:



A. Vottner

G. Pricolo

Decision electronically authenticated