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**Datasheet for the decision
of 12 June 2023**

Case Number: T 0100/19 - 3.2.01

Application Number: 10745254.2

Publication Number: 2470241

IPC: A61M5/24, A61M5/31

Language of the proceedings: EN

Title of invention:

HOUSING COMPONENT FOR A DRUG DELIVERY DEVICE

Patent Proprietor:

Sanofi-Aventis Deutschland GmbH

Opponent:

Peterreins, Frank

Headword:

Relevant legal provisions:

EPC Art. 52(1), 54, 56, 123(2)

EPC R. 103(1) (a)

Keyword:

Novelty - main request (no) - auxiliary request (yes)
Inventive step - auxiliary request (yes)
Amendments - added subject-matter (no)
Reimbursement of appeal fee - (no)
Remittal with the order to maintain the patent - (yes)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0100/19 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 12 June 2023

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
26 October 2018 concerning maintenance of the
European Patent No. 2470241 in amended form.**

Composition of the Board:

Chairman G. Pricolo
Members: V. Vinci
S. Fernández de Córdoba

Summary of Facts and Submissions

I. The appeals filed by the appellant (patent proprietor) and the appellant (opponent) are directed against the interlocutory decision of the opposition division to maintain the European patent No. 2 470 241 in amended form.

In its decision the opposition division held that the ground for opposition under Article 100(a) in combination with Article 54 EPC was prejudicial to the maintenance of the patent as granted, that the subject-matter of independent claim 1 according to auxiliary requests 1 and 2 lacked novelty within the meaning of Articles 52(1) and 54 EPC and decided to maintain the patent in amended form according to the auxiliary request 3.

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 prior art:

D2: US 6 235 004 B1
D3: US2009/0048561 A 1
D4: US 5 827 232
D5: WO 2007/01 7052
D6: US 2008/0306446 A 1

With its reply to the statement of grounds of appeal of the appellant (patent proprietor), the appellant (opponent) submitted following non-patent literature:

D9: excerpt from "*Design Guides for Plastics*", Tangram Technology, April 2006

D10: excerpt from *"Part and Maid Design, A Design Guide"*, Lanxess, 2007.

- II. With the communication according to Article 15(1) RPBA dated 8 September 2022 the Board informed the parties of its preliminary assessment of the case.
- III. Oral proceedings pursuant to Article 116 EPC were held before the Board on 12 June 2023 by videoconference.
- IV. The appellant (patent proprietor) requested to set aside the decision under appeal and to maintain the patent as granted (main request) or, in the alternative, according to one of the auxiliary requests 1, 3, 2, 4 to 8 filed with the statement of grounds of appeal.

The appellant (opponent) requested that the decision under appeal be set aside and that the European patent be revoked. The appellant (opponent) further requested that the appeal fee be reimbursed.

- V. Independent claim 1 as granted reads as follows (labelling according to the contested decision):

A 1: *"Housing component of a drug delivery device (10) to accommodate a drive mechanism (11), the drive mechanism (11) being operable to interact with a piston (20) of a cartridge (18) containing a medicinal product to be dispensed by the drug delivery device,*

A2: wherein the housing component comprises at least one radially inwardly extending flange portion (16) to be operably engaged with a piston rod (24) of the drive mechanism (11), characterised in that

A3: *the flange portion (16) is at least partially structurally strengthened by means of an at least partially rippled structure (28) and/or a rippled surface."*

Independent claim 1 of the auxiliary request 1 reads as follows:

"Housing component of a drug delivery device (10) to accommodate a drive mechanism (11), the drive mechanism (11) being operable to interact with a piston (20) of a cartridge (18) containing a medicinal product to be dispensed by the drug delivery device, wherein the housing component is connectable to a cartridge holder (12) by a connection (26) comprising positive or friction-locked interconnecting means and wherein the cartridge holder (12) is configured to receive the cartridge (18), wherein the housing component is substantially cylindrically shaped and comprises at least one radially inwardly extending flange portion (16) to be operably engaged with a piston rod (24) of the drive mechanism (11), wherein the flange portion (16) is integrally formed with the housing component (14), wherein the flange portion (16) comprises an inner annular section (34) and an outer annular section (28), wherein the outer annular section (34) abuts against an inner sidewall of the housing component, wherein the flange portion (16) comprises a through opening (30) to receive the axially displaceable piston rod (24) and wherein the through opening (30) comprises an inner thread (32) to be engaged with an outer thread of the piston rod (24), characterized in that the flange portion (16) is at least partially structurally strengthened and wherein the outer annular section (34) of the flange portion (16) comprises a rippled structure (28) and/or a rippled surface and wherein the

flange portion (16) is structurally strengthened by means of the rippled structure (28) and/or the rippled surface."

Independent claim 1 according to the auxiliary request 3 is based on claim 1, wherein the characterizing portion has been amended to read as follows:

"the flange portion (16) is at least partially structurally strengthened by means of an at least partially rippled structure (28) wherein the rippled structure (28) is formed by radially extending and adjacently interconnected stiffening segments (36)".

Reasons for the Decision

MAIN REQUEST - PATENT AS GRANTED

Novelty: Articles 52(1) and 54 EPC

1. The subject-matter of claim 1 as granted is not novel over the prior art within the meaning of Articles 52(1) and 54 EPC as stated in the decision under appeal.
 - 1.1 With its appeal the appellant (patent proprietor) contested the conclusion of the opposition division that the technical content of document D3 was prejudicial to novelty of claim 1 as granted.
 - 1.2 The appellant (patent proprietor) argued that the term "*housing component*" used in claim 1 implied that the housing of the claimed drug delivery device was built up in a single piece, and that consequently only the housing portion 3 described in paragraph [0033] and

shown in Figure 3 of D3, which was the one accommodating the drive mechanism of the known device, embodied the *"housing component"* in the meaning of claim 1 as granted and not, as asserted by the opposition division and the appellant (opponent), the assembly consisting of the housing portions 2 and 3. Based on this interpretation of D3, the appellant (patent proprietor) pointed out that as the housing portion 3 of the device of D3 was not provided with any radially inwardly extending flange portion, feature A2 and, consequently, feature A3 of claim 1 as granted were not disclosed in this prior art document. The appellant (patent proprietor) further argued that even considering the assembly formed by the housing portions 2 and 3 as a housing component within the meaning of claim 1 as granted, feature A3 was still not fulfilled because D3 only disclosed a catch mechanism 2a comprising elements protruding axially from the upper surface of the alleged flange portion inwardly extending from the housing portion 2, whereby these protruding elements did not technically and functionally equate to the *"rippled structure and/or a rippled surface"* required by claim 1. In support of this interpretation of document D3, the appellant (patent proprietor) pointed out that this prior art document did not describe or imply that protruding elements of the catch mechanism 2a resulted in a strengthening of the flange.

- 1.3 The arguments submitted by the appellant (patent proprietor) are not convincing for the following reasons:
- 1.4 The Board is of the opinion that a *"component"* can also be built up of two or more elements that together achieve a given functionality. It follows that the

term "*component*" in the expression "*housing component*" of claim 1, contrary to the interpretation of the appellant (patent proprietor), does not rule out an housing component formed by a plurality of elements connected to each other as it is the case of the housing of the device of D3 which is indeed made up of the housing portions 2 and 3. Said 2-piece housing component also accommodates the drive mechanism and is provided with an inwardly and radially extending flange portion operably engaged with the piston rod 11 of the drive mechanism. Features A1 and A2 are disclosed in D3. Regarding feature A3, the Board concurs with the opposition division and the appellant (opponent) that the elements axially protruding from the catch mechanism 2a provided on the proximal side of the flange portion and visible in Figures 2 and 3 of D3 embodies indeed a rippled structure, and that the person skilled in the art promptly recognizes that they inherently provide for a strengthening of the flange portion as required by feature A3 which is thus also at least implicitly disclosed in D3.

- 1.5 In view of the above the Board confirms the negative assessment of novelty of claim 1 as granted in view of D3 of the opposition division, whereby the ground for opposition pursuant to Article 100(a) in combination with Article 54 EPC is prejudicial to the maintenance of the patent as granted as correctly stated in the decision under appeal.

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 underlying the decision under appeal and as such is part of the appeal

proceedings (see Article 12(2) RPBA in version 2020 which applies to present appeal in view of Article 25(1) RPBA 2020). The admissibility issue raised by the appellant (opponent) with its reply is thus moot. The Board also observes that at the oral proceedings no further arguments have been presented by the appellant (opponent) against the admissibility of the auxiliary request 1.

2.1 In any event the Board concurs with the opposition division and with the appellant (opponent) that the subject-matter of claim 1 of the auxiliary request 1 lacks novelty within the meaning of Articles 52(1) and 54 EPC in view of document D3.

2.2 This conclusion of the opposition division is contested by the appellant (patent proprietor) with its appeal. The parties at the oral proceedings referred in this respect to the arguments provided in writing and did not make any further submission. The Board has thus no reason to deviate from its preliminary assessment of this issue as set out in the communication according to Article 15(1) RPBA which is herewith confirmed and reads as follow:

2.3 Under discussion is merely whether the feature introduced in claim 1 of the auxiliary request 1 reading *"the outer annular section (28) abuts against an inner sidewall of the housing component"* can be directly and unambiguously derived from document D3.

2.4 The appellant (patent proprietor) drew the attention to the gap provided between the inner and outer cylindrical and coaxial portions of the lower housing portion 2 in which the setting and display element 30 was located (see Figure 3), said gap excluding, in the

appellant's (patent proprietor's) view, the claimed abutment of the outer annular section of the flange portion against the inner sidewall of the housing component.

2.5 However, the flange portion of the device according to D3 is at its outer annular section integrally formed with the housing portion 2, namely with the inner cylindrical surface of the housing portion 2 bridging the shoulder 2c with the flange, whereby also in the case of the housing of D3 the outer annular section of the flange portion can be said to abut against (in the sense that it is connected to and supported by) the inner sidewall of the housing component.

2.6 It follows that claim 1 of the auxiliary request 1 also lacks novelty over D3 as correctly assessed by the opposition division, whereby also this auxiliary request, irrespective of the further issues raised by the appellant (opponent), is not allowable.

AUXILIARY REQUEST 3

3. At the oral proceedings the appellant (patent proprietor) requested to discuss the auxiliary request 3 before the auxiliary request 2 filed with the statement of grounds of appeal. This was not objected by the appellant (opponent). The auxiliary request 3 corresponds to the auxiliary request 2 underlying the decision under appeal and as such, analogous to the auxiliary request 1, is part of the appeal proceedings. The admissibility issue raised by the appellant (opponent) against the auxiliary request 3 with its reply is thus also moot. The Board observes that at the oral proceedings the appellant (opponent) did not present any further argument against the admissibility

of the auxiliary request 3.

Article 123(2) EPC

- 3.1 The auxiliary request 3 meets the requirements of Article 123(2) EPC.
- 3.2 With its statement of grounds of appeal the appellant (opponent) argued that, contrary to the conclusion of the opposition division, the causal technical relationship between the provision of a rippled structure and the strengthening of the flange expressed in feature A3 of claim 1 as granted was not directly and unambiguously disclosed in the application as originally filed. This objection was maintained also in respect to claim 1 according to the auxiliary request 3 which contains the same alleged issue.
- 3.3 However, the Board agrees with the arguments of opposition division that the causal technical relationship expressed in feature A3 of claim 1 is directly and unambiguously derivable from the passage on page 4 of the originally filed description, lines 19-21.
- 3.4 With its statements of grounds of appeal and in reaction to the reasoning of the opposition division in the decision under appeal, the appellant (opponent) further developed the line of arguments presented in support of this objection during the first instance proceedings and alleged that the claimed strengthening of the flange portion according to the characterizing portion of claim 1 was disclosed in the cited passage of the description as filed only in connection with an uneven rippled structure, whereby the omission of the term "uneven" in the characterizing feature of claim 1

of the auxiliary request 3 resulted in an unallowable intermediate generalisation infringing Article 123(2) EPC.

- 3.5 Irrespective of the admissibility issue raised by the appellant (patent proprietor) regarding this allegedly new argument, the reasoning of the appellant (opponent) is not convincing:

The Board, in agreement with the appellant (patent proprietor), considers that the presence of an uneven surface profile is an inherent feature of a "*rippled surface*" which per definition implies a wave-shaped and hence uneven path. The omission of the term "*uneven*" in the characterizing portion of claim 1 does not thus result in any unallowable intermediate generalisation of the passage of the description under discussion.

Novelty: Articles 52(1) an 54 EPC

- 3.6 Contrary to the assessment of the opposition division the subject-matter of claim 1 of the auxiliary request 3 is novel over the cited prior art within the meaning of Articles 52(1) and 54 EPC.
- 3.7 In the appealed decision the opposition division came to the conclusion that the technical content of documents D2, D4, D5 was prejudicial to novelty of the subject-matter claim 1 of the auxiliary request 2, corresponding to claim 1 of the auxiliary request 3 at stake. This conclusion is contested by the appellant (patent proprietor) with its appeal.
- 3.8 Regarding D2 the opposition division essentially argued that this prior art document disclosed in Figure 2 a housing component provided with feature A1 of claim 1

consisting of two cylindrical housing elements 1 and 2, wherein the housing element 2 comprised at least one radially inwardly extending flange 4 operably engaged with the piston rod of the drive mechanism and hence according to feature A2. Furthermore, the opposition division considered the pawl wheel teeth structure 10 provided at the top surface of the flange portion 4 as a rippled structure fulfilling the geometry defined in the characterising portion of the claim and inherently resulting in a strengthening of the flange. This interpretation of document D2 was supported by the appellant (opponent).

3.9 However the reasoning of the opposition division is not convincing for the following reasons:

The Board concurs with the interpretation of the appellant (patent proprietor) that only the tubular housing 1 in Figure 2 of D2 technically and functionally equates to, and thus embodies, the "*housing component*" recited in claim 1. As a matter of fact this is indeed the only housing component accommodating the driving mechanism as required by feature A1. The tubular element 2 is instead according to the description an ampoule holder (see column 5, lines 38-44) which is snapped by a snap lock into the housing component 1 and which does not have the functionality of accommodating the driving mechanism which is fully located within the housing component 1. As the radially inwardly extending flange portion 4 is provided on the ampoule holder 2 and not on the housing component 1, feature A2, and consequently the features of the characterizing portion of claim 1 of the auxiliary request 3, are not disclosed in document D2 and this irrespective of the disputed question of whether the pawl wheel teeth structure 10 inherently

results in a strengthening of the flange 4.

3.10 For the reasons above and contrary to the conclusion of the opposition division, the subject matter of claim 1 of the auxiliary request 3 is novel over D2.

3.11 The appellant (opponent) maintained that the subject-matter of claim 1 of the auxiliary request 3 lacked novelty in view of documents D4, D5 and D6. At the oral proceedings, the parties relied in this respect on the arguments presented in writing and did not make any further submission. Consequently, the Board has no reason to deviate from the assessment of novelty in view of documents D4 to D6 as presented in its preliminary opinion which is herewith confirmed and reads as follows:

3.12 Regarding document D4, the opposition division and the appellant (opponent) identified the nut 34 in Figure 2 with the radially extending flange portion of the housing component recited in claim 1. The Board does not agree because, as convincingly put forward by the appellant (patent proprietor), the nut 34 does not functionally belong to the housing, but is just one of the components of the injection device located therein. Feature A2 and consequently the features of the characterizing portion of claim 1 are thus not directly and unambiguously disclosed in D4. For this reason the objection of lack of novelty raised by the opposition division in respect of D4 is unjustified.

3.13 Regarding document D5, the opposition division and the appellant (opponent) identified the teeth 24 of the housing 26 with the radially inwardly extending flange portion recited in claim 1. However, the Board concurs with the appellant (patent proprietor) that the only

element of the housing of the injection device of D5 which structurally and functionally equates to the claimed flange portion is the transversal segment of the housing 26 in which the thread 30 is provided (see for example Figures 4, 7 and 8). As said inwardly extending flange portion of the housing 26 is not structurally strengthened by means of an at least partially rippled structure, the features of the characterizing portion of claim 1 according to the auxiliary request 3 are not derivable from D5. Furthermore, even considering the teeth 24 as a radially inwardly extending flange portion, the Board cannot see how the provision of a teeth structure can result in a rippled structure with the geometry defined in claim 1 further resulting in a strengthening of the flange.

3.14 The same reasoning and conclusion apply with the same arguments to the housing component of document D6, also cited by the appellant (opponent) against novelty of claim 1, which shows for example in Figures 3, 4 and 6 to 8, 10 and 11 the same structure of the housing component in figure 4 of D5. In any event no rippled surface with the geometry defined in the characterizing portion of claim 1 can be identified.

3.15 It follows that, contrary to the assessment of the opposition division and the view of the appellant (patent proprietor), the subject-matter of claim 1 according to the auxiliary request 3 is novel over the cited prior art.

Inventive Step: Articles 52(1) and 56 EPC

4. The subject-matter of claim 1 of the auxiliary request 3 involves an inventive step within the meaning of

Articles 52(1) and 56 EPC.

5. The Board observes that inventive step of the subject-matter of independent claim 1 of the auxiliary 2 underlying the decision under appeal which corresponds to claim 1 of the auxiliary request 3 at stake has not been decided upon by the opposition division. Arguments in support of lack of inventive step were submitted by the appellant (opponent) under point 5.3.3 of its reply. The appellant (patent proprietor) confirmed at the oral proceedings that the arguments provided with the statement of grounds of appeal in support of the inventive step of claim 1 of the main request also applied to the auxiliary request 3.

5.1 The appellant (opponent) essentially argued that the person skilled in the art starting from any of documents D3 to D6 and aiming to achieve an enhanced stability of the drug delivery device without increasing its dimension and the associated manufacturing costs would obviously consider to add rippled structures according to the characterizing portion of claim 1 thereby arriving without inventive step to the claimed subject-matter. In this respect the appellant (opponent) argued that the specific shape of the ripple structure suggested in claim 1 did not provide any specific technical effect and thus represented, at best, only an arbitrary and obvious choice among well known alternatives for the ripple design. In order to support this allegation reference was made to the non-patent literature D9 and D10 filed with the reply of the appellant (opponent), the admittance of which was contested by the appellant (patent proprietor). The appellant (opponent) also argued that starting from D2 it was obvious for the person skilled in the art looking for an alternative

drug delivery device to move the position of the rippled structure from the flange portion 4 of the ampule holder to an inwardly extending flange portion provided in the housing component. Furthermore, it was objected that the patent did not contain any comparative example demonstrating that the provision of a rippled surface according to claim 1 achieved the claimed strengthening of the flange portion. Finally, the avoidance of radially shrink marks presented by the appellant (patent proprietor) as a bonus effect supporting an inventive contribution over the prior art of the claimed housing component was considered the result of the obvious implementation of an alternative drug delivery device.

5.2 The arguments of the appellant (opponent) are not convincing for the following reasons:

The Board does not see in the cited prior art either a hint to the technical problem addressed by the contested patent nor to the specific design of the rippled structure introduced in claim 1 according to the auxiliary request 3. The Board observes that the person skilled in the art would certainly not replace the catching elements of the retaining mechanism 2a provided on the flange portion of the housing component according to D3 by a rippled surface according to claim 1 because such a modification would disrupt their original functionality as disclosed in paragraph [0038]. Turning to document D4, the housing of the drug delivery device disclosed therein does not comprise a flange portion within the meaning of feature A2 (see point 3.12 above), whereby starting from this prior art document, substantial structural modifications, which as such could not be considered obvious, would be required to achieve the constructional solution

according to claim 1. Starting from document D5 the Board observes that the flange portion of the housing component of the embodiments in Figures 4, 7 and 8 shows already a comparatively large thickness, whereby the person skilled in the art has no motivation to add a rippled surface which would also interfere with the functionality of the adjacent elements. The same applies to document D6.

5.3 In any event, the specific design of the rippled surface recited in claim 1 cannot be considered an arbitrary and obvious choice among well known alternative ripple designs. In this respect the non-patent literature documents D9 and D10, irrespective of the admissibility issue raised by the appellant (patent proprietor), do not provide any support to this allegation of the appellant (opponent), because they merely demonstrate that it belongs to common general knowledge that ribs can be provided, designed and dimensioned in such a way to enhance the stiffness of a moulded component. A rippled surface wherein the rippled structure is formed by radially extending and adjacently interconnected stiffening segments is not disclosed.

5.4 In conclusion the Board is of the opinion that the arguments of the appellant (opponent) are based on considerations that go beyond what the skilled person would have objectively inferred from the cited documents without the benefit of hindsight knowledge of the invention, whereby the subject-matter of claim 1 of the auxiliary request 3 is not rendered obvious by the prior art.

REIMBURSEMENT OF THE APPEAL FEE

6. The appellant (opponent) requested the reimbursement of the appeal fee due to an alleged substantial procedural violation.

6.1 However, according to Rule 103(1)(a) EPC, the precondition for granting the reimbursement of the appeal fee is that the appeal of the party concerned is deemed to be allowable. This is not the case here, because the appeal of the opponent is directed against the maintenance of the patent in amended form according to auxiliary request 3 underlying the contested decision, whilst with the present decision the higher ranking auxiliary request 2 underlying the contested decision (which is auxiliary request 3 in appeal) is allowed. The request of reimbursement of the appeal fee is therefore rejected.

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 with the claims 1 to 12 according to the auxiliary request 3 filed with the statement of grounds of appeal (patent proprietor), the description (pages 2 to 4) filed during the oral proceedings before the Board and figures 1 and 2 of the patent as granted.

The Registrar:

The Chairman:



A. Vottner

G. Pricolo

Decision electronically authenticated