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**Datasheet for the decision
of 15 October 2019**

Case Number: T 0629/16 - 3.2.02

Application Number: 09783840.3

Publication Number: 2346552

IPC: A61M5/315, A61M5/24

Language of the proceedings: EN

Title of invention:

DRUG DELIVERY DEVICE AND METHOD OF MANUFACTURING A DRUG
DELIVERY DEVICE

Patent Proprietor:

Sanofi-Aventis Deutschland GmbH

Opponents:

Bock Wolfgang
Mylan SAS

Headword:

Relevant legal provisions:

EPC Art. 123(2), 84, 56
EPC R. 89
RPBA Art. 12(2), 12(4), 13(1)

Keyword:

Added subject-matter (no)

Lack of clarity (no)

Inventive step (yes)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0629/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 15 October 2019

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Decision under appeal: **Interlocutory decision of the Opposition**
Division of the European Patent Office posted on
4 January 2016 concerning the maintenance of the
European Patent No. 2346552 in amended form.

Composition of the Board:

Chairman E. Dufrasne
Members: M. Stern
 P. L. P. Weber

Summary of Facts and Submissions

- I. Appeals were lodged by the patent proprietor and the opponent against the interlocutory decision of the Opposition Division posted on 4 January 2016 concerning the maintenance of European patent No. 2 346 552 in amended form.
- II. The appellant/patent proprietor (hereinafter "the patent proprietor") filed notice of appeal on 14 March 2016, paying the appeal fee the same day. A statement setting out the grounds of appeal was received on 17 May 2016.
- III. The appellant/opponent (hereinafter "the opponent") filed notice of appeal on 11 March 2016, paying the appeal fee the same day. A statement setting out the grounds of appeal was received on 17 May 2016.
- IV. A notice of intervention was filed on 11 October 2018, the intervener paying the opposition fee the same day.
- V. The following documents are relevant for the present decision:

D1: DE-A-10 2005 032 705

D3: US-A-2004/0035491

D9: Wikipedia excerpt: "Washer (hardware)"
website [https://en.wikipedia.org/wiki/Washer_\(hardware\)](https://en.wikipedia.org/wiki/Washer_(hardware)) on 6 May 2013

D10: "Dubbel Taschenbuch für den Maschinenbau",
W. Beitz and K.-H. Grote, pages 655 - 657, 1997

D11: "Technische Federn, Stanz- und Biegeteile",
Wilhelm Becker GmbH Co. KG 2007

D15: US-A-2001/0039394

D16: US-B-6 585 685

D17: WO-A-2004/062715

D18: Specification for spring washers for general engineering and automobile purposes, metric series, British Standards Institution, BS 4464: 1969

VI. Oral proceedings were held on 15 October 2019.

The appellant/patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of auxiliary request 2 filed with letter dated 4 March 2019.

The appellant/opponent and the intervener requested that the decision under appeal be set aside and that the patent be revoked.

VII. Claim 1 of **auxiliary request 2** (held allowable by the Opposition Division) reads as follows (amendments to claim 1 of the granted patent are highlighted by the Board):

"1. A drug delivery device (5) comprising:
a housing (10) with a proximal end and a distal end,
a cartridge (15) adapted to accommodate a drug,
a cartridge retaining member (45) adapted to retain the cartridge (15), the cartridge retaining member (45) being secured to the housing (10), ~~characterized in that~~ wherein a spring washer (50) is arranged within the housing (10) so as to exert a force on the cartridge (15) and to secure the cartridge (15) against movement with respect to the cartridge retaining member (45), the spring washer (50) being arranged so as to abut the cartridge (15) on a side of the cartridge (15) that faces the proximal end of the housing (10), wherein a sleeve member is fixed to the housing,

characterized in that the spring washer is fixed to the sleeve member on an outer surface of the sleeve member, wherein the spring washer is fixed to the sleeve member by fixing elements of the spring washer, and wherein the fixing elements extend in an axial direction."

Claims 2 to 12 are dependent claims.

VIII. The arguments of the patent proprietor relevant for the present decision can be summarised as follows:

Admissibility of D11 and D17

Documents D11 and D17 should not be admitted. Document D11 had been filed with the statement of grounds of appeal, rather than in opposition proceedings. D11 was an industrial brochure and hence was not evidence of the skilled person's common general knowledge. Moreover, the publication date of D11 was uncertain. Document D17 had been filed by the intervener too late in the appeal proceedings, i.e. after the deadline for filing the notice of intervention. Hence, its consideration was not procedurally efficient. D17 was not prima facie relevant either.

The arguments regarding the objections under Articles 123(2), 84 and 56 EPC which are relevant for the present decision are essentially those on which the reasons set out below are based.

IX. The arguments of the opponent and the intervener relevant for the present decision can be summarised as follows:

As stated during the oral proceedings, the former objection regarding the admissibility of auxiliary request 2 was no longer maintained.

Admissibility of D11 and D17

Since auxiliary request 2 had been filed as late as during the oral proceedings held before the Opposition Division, D11 had been filed as early as possible with the statement of grounds of appeal and was thus an integral part of the opponent's case. D17 should also be admitted as it was highly relevant for the ground of lack of inventive step.

Article 123(2) EPC

The limitations taken from page 8, lines 6 to 11 of the application as filed were presented in combination with several other features mentioned in the description. Since they were not included in the claim, the subject-matter of claim 1 amounted to an unallowable intermediate generalisation. The omitted features included the sleeve member being laser welded to the housing and the cartridge retaining member being secured to the housing by an inner thread. Furthermore, the sleeve member was a sleeve member "of the housing", according to page 3, lines 26 and 27. Moreover, the spring washer was fixed to the sleeve member by a snap-fit fixation according to page 8, lines 11 and 12. Hence, the claimed subject-matter extended beyond the content of the application as filed, contrary to Article 123(2) EPC.

Clarity

Claim 1 was unclear since axially extending fixing elements which ran parallel to the outer surface of the sleeve member could not fix the spring washer to the sleeve member. It would require fixing elements extending in the radial direction to actually achieve a proper engagement with the sleeve member. Moreover, the claimed expression "fixing element of the spring washer" was ambiguous as it did not make clear whether the fixing elements formed part of the spring washer.

Inventive step

The claimed device was novel over the cited prior art but lacked an inventive step when departing from document D1, D15 (or its similar document D3) or D16.

D1 disclosed two embodiments of a drug delivery device depicted in Figures 1 to 3 and in Figure 4, respectively. Furthermore, D1 disclosed in paragraph [0011] that the spring coils could be replaced by a spring washer. It was implicit that such a spring washer needed to be fixed to the housing, and in fact D1 disclosed in paragraphs [0008], [0009] and [0030] positioning devices for the spring, in particular in the form of snap-fit securements. The fixation of a spring washer using a plurality of axially extending fixing elements was conventional in the technical field and well known, for example, from D11 or D16.

Moreover, the embodiment of Figures 1 to 3 of D1 comprised a spring washer as claimed. In particular, the coil spring 10 depicted in Figures 2 and 3 was attached to positioning devices 13 and 14 and had flat

surfaces with a hole, typical for a washer. The upper positioning device 13 was inserted in element 2 which was a "sleeve member" as claimed (Figure 1; paragraph [0019]). Similar spring washers were depicted in Tables 1 and 3 of D18, where the spring washers were made of helically wound flat band springs. The upper positioning device 13 of the spring washer in D1 was a single unitary fixing element which extended axially and completely surrounded the annular outer surface of the insert 2, which was a sleeve member as claimed. Providing a plurality of axially extending fixing elements was not associated with any relevant technical effect capable of supporting an inventive step. The same conclusions could be drawn when starting from the second embodiment of D1 shown in Figure 4.

When departing from D15 or D3, the fixing arrangement of the spring washer recited in claim 1, by which axially extending elements were fixed to an outer surface of a sleeve member which is itself fixed to the housing, would have represented an obvious design choice for the skilled person. It amounted to a standard mechanical engineering design approach which was not associated with any identifiable benefits, let alone any unexpected or surprising technical effects.

In D16, the spring washer (36) was provided with axially extending fixing elements (spring arms 36d). Although the spring arms (36d) were not fixed to a sleeve member as claimed, this would not be advantageous. This would be a foreseeable disadvantageous modification or at least a merely non-functional modification. Hence, the objective technical problem was to provide an alternative fixing arrangement for the spring washer. Faced with this problem, it would have been obvious to modify the

spring washer and housing design so that the spring washer was fixed to the outer surface of a sleeve member, such as housing 28, by the axially extending fixing elements (36d) in Figure 15).

Adaptation of the description

There were no objections against the adapted description filed during the oral proceedings.

Reasons for the Decision

1. The appeals and the intervention are admissible.
2. *The invention*
 - 2.1 The invention relates to a drug delivery device comprising, in essence, a housing (10), a drug cartridge (15), a cartridge retaining member (45) and a spring washer (50) securing the drug cartridge against movement with respect to the cartridge retaining member, the spring washer abutting the drug cartridge on the side of the drug cartridge that faces the proximal end of the housing. The present request, auxiliary request 2, includes further limitations relating to a sleeve member (60) fixed to the housing, the spring washer being fixed to the sleeve member on an outer surface of the sleeve member by fixing elements (52) of the spring washer which extend in an axial direction.

3. *Article 123(2) EPC*

3.1 Claim 1 recites all the features of original claims 1 and 2 adding at the end further limitations defining the fixation of the spring washer to a sleeve member. These additional features have a clear basis on page 8, lines 6 to 11 of the application as filed.

3.2 The objection was raised taht several other features mentioned in the description were not included in the claim and hence that the subject-matter of claim 1 amounted to an unallowable intermediate generalisation.

However, in the context of the fixation of the spring washer to a sleeve member it is of no particular relevance that the sleeve member is described (on page 11, lines 16 and 17) as being laser welded to the housing and that the cartridge retaining member is described (on page 9, lines 14 to 16) as being secured to the housing by an inner thread on the sleeve member. The latter passage makes it clear that the inner thread is disclosed as a merely preferred way of securing the cartridge retaining member to the sleeve member.

Although page 3, lines 26 and 27 includes the expression of a sleeve member "of the housing", it is clear from the description of page 8, lines 6 to 11 and Figure 4 that the sleeve member 60 and the housing 10 are two separate features.

Finally, a snap-fit fixation of the spring washer to the sleeve member is explicitly mentioned on page 8, lines 11 and 12 as being just an example.

3.3 The Board therefore considers that the allegedly omitted features mentioned by the opponent and the

intervener are not inextricably linked to the claimed limitations taken from page 8, lines 6 to 11. Hence, their omission from claim 1 does not lead to an unallowable intermediate generalisation.

- 3.4 As a consequence, claim 1 of auxiliary request 2 satisfies the requirements of Article 123(2) EPC.

4. *Clarity*

- 4.1 It was argued that claim 1 lacked clarity since axially extending fixing elements which ran parallel to the outer surface of the sleeve member could not fix the spring washer to the sleeve member. It would require fixing elements extending in the radial direction to actually achieve a proper engagement with the sleeve member.

In the Board's view, these objections appear artificial and difficult to understand. The wording of the claim does not exclude that a portion of the fixing elements extends in the radial direction. It is moreover conceivable that fixing elements extending exclusively in axial direction are appropriate to fix the spring washer, for example, by clamping. In any case, these objections do not appear to point to a clarity deficiency within the meaning of Article 84 EPC.

- 4.2 The objection was also raised that the expression "fixing element of the spring washer" in claim 1 was ambiguous as it did not make it clear whether the fixing elements formed part of the spring washer.

The patent proprietor referred to Figure 5 and paragraph [0037] of the patent showing that the fixing elements 52 were part of the spring washer 50. Hence,

in the context of this example, the fixing elements were clearly part of the washer.

A claim is not unclear just because it is broader than an example presented in the description. Hence, the expression "fixing element of the spring washer" in claim 1 is not ambiguous for the reason that it may include fixing elements which form part of the spring washer or fixing elements which do not.

4.3 Thus, claim 1 of auxiliary request 2 satisfies the requirement of clarity of Article 84 EPC.

5. *Admissibility of D11 and D17*

5.1 The opponent filed document D11 with its statement of grounds of appeal in reaction to the late insertion into claim 1 of features extracted from the description during the oral proceedings before the Opposition Division.

5.2 In the Board's view, the filing of a new request during the oral proceedings at first instance containing features extracted from the description deprived the opponent of the necessary time to search for further documents. Thus, it is unreasonable to expect, as the patent proprietor did, that D11 should have been presented already in first-instance proceedings (Article 12(4) RPBA). The opponent filed the document at the earliest possible time, i.e. with the statement of grounds of appeal.

Hence, the Board considers D11 to be part of the opponent's case in the appeal proceedings in accordance with Article 12(2) RPBA and not to be excluded pursuant to Article 12(4) RPBA.

5.3 In the course of the appeal proceedings the intervener filed document D17 after the deadline for filing its notice of intervention under Rule 89 EPC, raising an objection of lack of inventive step based on the combination of D1 with D17.

This objection is hence an amendment of the case presented by the intervener in its notice of intervention. Under Article 13(1) RPBA, it is left to the Board's discretion to admit such late-filed evidence and objection. The Board fails, moreover, to see the prima facie relevance of D17 as a secondary document in an objection of lack of inventive step based on D1 as the closest prior art. D17 does not disclose or suggest the features missing from D1. The injection device disclosed in D17 comprises a collar (52 in Figures 2 and 4; paragraph [0032]) which is clearly not a spring washer with fixing elements extending in an axial direction for fixing the spring washer to a sleeve member on an outer surface of the sleeve member.

Under these circumstances, the Board considers that it is not procedurally efficient to take D17 into consideration, and does not admit it into the proceedings (Article 13(1) RPBA).

6. *Inventive step*

Departing from D1

6.1 D1 describes two embodiments of a drug delivery device as depicted in Figures 1 to 3 and Figure 4, respectively. In each of these embodiments, the drug delivery device comprises a housing (Gehäuse 1), a drug

cartridge (Behältnis 5), a cartridge retaining member (Anschlag 4 described in the third sentence of paragraph [0020] is an element separate from the housing 1) and a coil spring (Schraubenfeder 10 or 20; paragraphs [0020 and 0028]) securing the cartridge (5) against movement with respect to the cartridge retaining member (4) (paragraph [0026]), the coil spring (10 or 20) abutting the cartridge on the side of the cartridge that faces the proximal end of the housing (Figures 1 and 4).

According to paragraph [0011], first two sentences, the coil spring 10 in Figure 1 or the coil spring 20 in Figure 4 may be replaced by a spring washer (Tellerfeder). It is implicit that such a spring washer needs to be fixed to the housing, and in fact D1 discloses, in paragraphs [0008] and [0009], positioning devices for the coil spring, in particular in the form of snap-fit securements.

However, D1 does not disclose the fixation of the spring washer (Tellerfeder) to the housing as defined in claim 1, that is, in essence, a sleeve member fixed to the housing, and the spring washer fixed to the sleeve member on an outer surface of the sleeve member by fixing elements of the spring washer which extend in an axial direction.

6.2 As convincingly argued by the patent proprietor, the claimed fixation of the spring washer to the housing has a number of evident technical effects. The fixation of the spring washer by means of fixing elements extending in an axial direction eliminates the need of a substantially radially extending bearing surface for a fixing element in the housing which would necessarily increase the diameter of the entire device. Moreover,

the provision of a plurality of fixing elements in an axial direction allows to rotationally lock the spring washer. Fixing the sleeve member on an outer surface of the sleeve member has the technical effect of reducing the risk of contact between the spring washer, in particular its fixing elements, and any element moving within the sleeve member, such as piston rod 30 in the patent or piston rod 8 in D1. Moreover, by placing the fixing elements on the outer surface of the sleeve member, the fixation is particularly stable with respect to radial forces.

- 6.3 The opponent and the intervener argued that the fixation of a spring washer using a plurality of axially extending fixing elements was conventional and well known in the technical field, for example, from D11 or D16, and that even D1 envisaged similar latched or snap-fit securements (paragraphs [0009] and [0030]).

The Board was not convinced by these arguments.

D11 is a company brochure relating to different types of springs manufactured for car, furniture or electrical companies (page 5, second paragraph)). Such a specific product brochure is by no means evidence of the skilled person's common general knowledge as argued by the opponent and the intervener. The springs disclosed in D11 are devised for technical domains which are remote from the technical field of drug delivery devices to which D1 pertains. There certainly would have been no motivation for the skilled person to choose the item on the upper photograph of page 7, last column, third line of D11, identified by the opponent and the intervener, and to provide the spring washer (Tellerfeder) disclosed in paragraph [0011] of D1 with similar axially extending fixing elements. Even if the

skilled person had been led to do this, he would still not have arrived at the claimed subject-matter, which requires the fixation of the axial fixing elements to the outer surface of a sleeve member which is in turn fixed to the housing.

D16 (as will be discussed under point 6.10 below) and paragraphs [0009] and [0030] of D1 may be concerned with snap-fit securements of springs onto a surface. However, they are not disclosed to be applied on the *outer* surface of a sleeve member which is fixed to a housing as required by claim 1. In fact, paragraph [0030] of D1, which refers to Figure 4, discloses a single axially extending fixing element with a protrusion (Halteeinrichtung 23b) extending radially from it which snaps into the *inner* surface of what may be, arguably, considered as a sleeve (3) attached to the housing (1). As was indicated above under point 6.2, the provision of a plurality of fixing elements in an axial direction allows to rotationally lock the spring washer. Due to the placement of the fixing elements on the outer surface of the sleeve member, the fixation is particularly stable with respect to radial forces.

- 6.4 The opponent and intervener considered, moreover, that the embodiment of a drug delivery device depicted in Figures 1 to 3 of D1 comprised a spring washer as claimed. They argued that the coil spring 10 depicted in Figures 2 and 3 was attached to positioning devices 13 and 14 and had flat surfaces with a hole, which were typical features of a washer. The upper positioning device 13 was inserted in element 2, which was a "sleeve member" as claimed (Figure 1; paragraph [0019]).

However, coil spring 10 and its flat annular positioning devices 13 and 14 cannot be considered to be a spring washer. The coil spring is made of a flat band spring of considerable width (B) helically wound 360° around an axis, with the width (B) of the strip material extending in the *axial* direction (paragraph [0024]; Figure 2). Consequently, the coil spring in D1 differs in a fundamental aspect from the spring washers depicted in Tables 1 and 3 of document D18, which are spring washers made of flat band springs helically wound 360° or even 720° around an axis, but with the width of the strip material extending in the *radial* direction. As a result, the washers in D18 are substantially flat, whilst the spring coil of Figures 2 and 3 of D1 manifestly lacks such substantial flatness. This holds true all the more for the axially more extended coil spring 20 in Figure 4 of D1.

No other conclusion can be drawn in this respect in view of the Wikipedia excerpt on washers D9, where a washer is considered to be a thin plate (typically disk-shaped) with a hole (typically in the middle) (first paragraph of D9), and where examples such as Belleville or conical washers, wave washers and spring lock washers are described (page 3). No further relevant teaching in this respect may be drawn from document D10 either, which merely describes and depicts thin Belleville or conical washers (Figure 6; second paragraph of point 2.2.4).

Therefore, if the skilled person departed from the embodiment of Figures 1 to 3 of D1 or from that of Figure 4 he would not have arrived at a device with a spring washer as claimed.

6.5 The Board therefore concludes that the subject-matter of claim 1 is not rendered obvious when starting from D1 as the closest prior art.

Departing from D15 or D3

6.6 Document D15 discloses a drug delivery device comprising a resilient gasket or wave washer (12) (depicted in Figure 2) which secures a cartridge (3) against movement within the cartridge housing (body 1), the spring washer (12) abutting the cartridge on the side of the cartridge that faces the proximal end of the cartridge housing ((paragraph [0049]); Figure 2). In the embodiment shown in Figure 7 and described in paragraph [0059], the distal end of the housing (1) is devised as a separate screwed retaining cap (39) against which the cartridge (3) is firmly secured by the spring washer (12).

6.7 Regarding the mounting of the spring washer within the housing (1), D15 merely states that the washer (12) is interposed between shoulder 11 and an end face of the cartridge (3) (last sentence in paragraph [0049]; Figure 2). Moreover, nothing in D15, nor in the remaining cited prior art, would have suggested to the skilled person the specific spring washer fixation recited in claim 1, by which axially extending elements are fixed to an outer surface of a sleeve member which is itself fixed to the housing. As explained above under point 6.2, there are clear technical effects associated with this type of fixation.

6.8 Thus, the subject-matter of claim 1 is not rendered obvious when starting from D15 as the closest prior art.

6.9 Document D3 is entirely similar to D15 regarding the aforementioned aspects (paragraph [0042] and Figures 11 and 16 of D3). Hence, when considering D3 as the closest prior art, the same conclusions as for D15 are drawn, *mutatis mutandis*.

Departing from D16

6.10 Document D16 discloses a drug delivery device comprising a housing (12) and a drug cartridge (14 in Figures 1 to 4; column 4, lines 17 to 28) and a cartridge retaining member (latching pairs 20a, 20b in Figures 4 and 15; column 5, lines 1 to 14) which retains the cartridge secured to the housing (12) and which engages latching lugs (14g) of the cartridge, thereby retaining the cartridge (column 4, lines 54 to 62; Figure 4).

The device comprises, moreover, a multi-function spring and guide member (36 in Figures 4, 13 and 15) having an axially through hole (36b in Figure 13) and arcuate spring fingers (36c) which provide an axial reaction force when compressed (column 6, lines 19 to 28). The multi-function spring (36) has therefore the structure of a spring washer which is arranged within the housing exerting a force on the cartridge (14) securing the cartridge against movement with respect to latching lugs (14g). The spring (36) comprises axially extending spring arms (36d) which bias outwardly the latching members (20a/20b) which retain the injection cartridge (14) (column 5, lines 25 to 28; Figure 15). The spring arms (36d) engage the finger pad portions (22a/22b) at their inner surfaces (column 6, lines 28 to 35). When the user depresses the finger pad portions (22a/22b), the used cartridge is urged out of the housing.

Even if the axially extending arms (36d) were identified as axially extending fixing elements, they do not fix the spring (36) on an outer surface of a sleeve member which itself is fixed to the housing, as claimed. Firstly, even if the finger pad portions (22a/22b) were equated to a sleeve member, the spring arms (36d) are fixed onto the inner rather than the outer surface of the finger pad portions. Moreover, the skilled person would certainly not have fixed the freely movable spring arms (36d) onto the outer surface of the housing portion (28) as it would impair the necessary flexibility of the arms for biasing outwardly the latching members (20a/20b).

- 6.11 Thus, the subject-matter of claim 1 is not rendered obvious when starting from D16 as the closest prior art.
- 6.12 The Board therefore comes to the conclusion that claim 1 of auxiliary request 2 satisfies the requirements of an inventive step within the meaning of Article 56 EPC. This applies a fortiori to the preferred embodiments defined in dependent claims 2 to 12.
7. Having regard to the amendments to the granted patent based on auxiliary request 2, an amended description was filed during the oral proceedings before the Board. The parties indicated to have no objections concerning this amended description.
8. Hence, none of the grounds raised prejudices the maintenance of the patent on the basis of auxiliary request 2.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of:
 - claims 1 to 12 of auxiliary request 2 filed with letter dated 4 March 2019;
 - description:
columns 1 to 6 and 9 as filed on 17 November 2015 and columns 7 and 8 and paragraphs [0005], [0007], [0019] and [0037] as filed during the oral proceedings; and
 - Figures 1 to 6 of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated