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**Datasheet for the decision
of 10 March 2022**

Case Number: T 0912/17 - 3.2.02

Application Number: 11741207.2

Publication Number: 2600922

IPC: A61M5/145, A61M5/315

Language of the proceedings: EN

Title of invention:

CARTRIDGE HOLDER AND METHOD FOR ASSEMBLING A CARTRIDGE UNIT
FOR A DRUG DELIVERY DEVICE

Patent Proprietor:

Sanofi-Aventis Deutschland GmbH

Opponent:

Ypsomed AG

Headword:

Relevant legal provisions:

EPC Art. 54

Keyword:

Novelty - (yes)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0912/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 10 March 2022

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
7 February 2017 concerning maintenance of the
European Patent No. 2600922 in amended form.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: S. Böttcher
N. Obrovski

Summary of Facts and Submissions

- I. The patent proprietor filed an appeal against the decision of the opposition division to maintain European patent No. 2 600 922 on the basis of the first auxiliary request then on file.
- II. Oral proceedings before the Board were held on 10 March 2022.
- III. The appellant (patent proprietor) requests that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or one of auxiliary requests 1 to 4, all filed with the statement of grounds of appeal.
- IV. The respondent (opponent) requests that the appeal be dismissed.
- V. Claim 1 of the main request reads as follows.

"A cartridge holder (4) for a drug delivery device, the cartridge holder (4) being adapted for retaining a cartridge (5), and

- the cartridge holder comprising
- a distal end and a proximal end being spaced apart from one another in the direction of an axis, wherein the distal end is the end of the cartridge holder (4) which is or is to be arranged closest to a dispensing end of the drug delivery device,
- an interior (50) which is suitable to receive and retain a cartridge (5) in a cartridge retaining section (47B) of the interior (50), and
- a main part (47) and at least one protrusion (39) which is moveably connected to the main part (47),

wherein the protrusion (39) is arranged to define the radial extension of a subsection (10) of the interior (50), wherein the subsection (10) is arranged at an axial position which is further away from the distal end than the cartridge retaining section (47B), and wherein the protrusion (39) is arranged to vary the radial extension of the subsection (10) when the protrusion (39) is moved with respect to the main part (47), wherein the main part (47) comprises two or more axially extending cut-outs (48),

- a movable part (23) connected to the main part (47), wherein the protrusion (39) is connected to the movable part (23), wherein the movable part (23) is formed between two cut-outs (48),
- an engaging means (15; 37) provided in at least a portion of an outer surface of the movable part (23), wherein the engaging means (15; 37) is adapted and arranged to secure the cartridge holder (4) to a drive unit (3) of the drug delivery device."

Claim 11 of the main request reads as follows.

"A method for securing a cartridge (5) in a cartridge holder (4) for a drug delivery device, comprising the following steps:

- providing the cartridge (5), a bung (17) being retained within the cartridge (5), the bung (17) sealing the cartridge (5) proximally,
- providing the cartridge holder (4), the cartridge holder (4) comprising an interior (50), a distal end and a proximal end being spaced apart from one another in the direction of an axis, wherein the distal end is the end of the cartridge holder (4) which is or is to be arranged closest to a dispensing end of the drug delivery device, and the cartridge holder (4) being provided with at least one protrusion (39) protruding

radially inwardly from the cartridge holder (4) and movably connected to a main part of the cartridge holder, the cartridge holder (4) comprising a movable part (23) connected to the main part (47), wherein the main part (47) comprises two or more axially extending cut-outs (48) and wherein the movable part (23) is formed between two cut-outs (48), wherein the protrusion (39) is connected to the movable part (23) and the cartridge holder (4) comprising an engaging means (15; 37) provided in at least a portion of an outer surface of the movable part (23), wherein the engaging means (15; 37) is adapted and arranged to secure the cartridge holder (4) to a drive unit (3) of the drug delivery device, the protrusion (39) defining the radial extension of a subsection (10) of the interior (50), which subsection (10) is arranged further away from the distal end of the cartridge holder (4) than a cartridge retaining section (47B), the radial extension being smaller than a radial dimension of the cartridge (5) such that the cartridge (5) is prevented from being guided from the proximal end of the cartridge holder (4) into the cartridge retaining section (47B),

- moving the protrusion (39) with respect to main part of the cartridge holder (4) such that the radial extension of the subsection (10) is increased,
- guiding the cartridge (5) past the protrusion (39A) into the cartridge retaining section (47B) of the cartridge holder (4),
- moving the protrusion (39) with respect to the main part of the cartridge holder (4) to decrease the radial extension of the subsection (10) such that the cartridge (5) is secured against proximal displacement with respect to the cartridge holder (4) by mechanical cooperation of the cartridge (5) and the protrusion

(39)."

- VI. In the present decision, reference is made to documents E1 (US 2005/0020979) and E3 (WO-A-95/07672).
- VII. The arguments of the respondent can be summarised as follows.

Novelty in view of E3

In claim 1, the engaging means was defined by reference to a drive unit, which was, however, not part of the claimed subject-matter. Hence, the term "engaging means" had to be understood as "something that can be used to connect the cartridge holder to a drive unit". Claim 1 did not specify the kind of drive unit used. The drive unit could be any mechanical device.

Therefore, the finger grips 70 of the applicator of E3 were objectively suitable to be connected to a drive unit of a drug delivery device.

Furthermore, a drive unit used with a standard syringe similar to that of E3 was known from E1 (Figure 1).

It followed that the subject-matter of claim 1 was anticipated by E3.

- VIII. The arguments of the appellant can be summarised as follows.

Novelty in view of E3

E3 did not disclose the feature "wherein the engaging means is adapted and arranged to secure the cartridge holder to a drive unit of a drug delivery device".

The wing members 70 formed finger grips sized and configured to support the fingers of the person administering the medication. E3 did not mention a drive unit to which the wing members could be secured. Since in E3 there was no need for a machine controlled or measured dispensing of the medicament, connecting the cartridge holder to a drive unit was superfluous and unrealistic.

The finger grips were neither intended nor configured to act as an engaging means adapted and arranged to secure the cartridge holder to a drive unit of a drug delivery device.

The same arguments applied to claim 11.

The subject-matter of claims 1 and 11 was therefore novel.

Reasons for the Decision

1. The invention relates to a cartridge holder for a drug delivery device, for instance, an insulin pen.

The cartridge holder 4 (Figure 3) has a (cylindrical) main part with an opening 42 at the proximal end, into which a cartridge 5 can be inserted. Also at the proximal end, the main part comprises two or more (here four) axially extending cut-outs 48 (Figure 4B) and a movable part 23 between two of these cut-outs. A protrusion 39 is connected to the movable part 23

(Figure 4A). During insertion of the cartridge, the movable part with the protrusion is pushed radially outwardly (in the direction of arrows 21A in Figure 3) such that the cartridge can be guided into the cartridge holder. After the cartridge has passed the protrusion, the movable part moves inwardly again (in the direction of arrows 21B in Figure 4A), and the protrusion secures the cartridge against displacement (Figure 4A).

To dispense the drug, the cartridge unit has to be secured to a drive unit 3 (Figures 2 and 5). For this purpose, the cartridge holder comprises an engaging means (15, 37) which is provided in at least a portion of the outer surface of the movable part and which is adapted and arranged to secure the cartridge holder to the drive unit of the drug delivery device. In the embodiment of Figure 3, the engaging means is a thread 15 that cooperates with a corresponding thread 32 on the drive unit (Figure 6B). In the embodiment of Figure 8C, the cartridge holder is irreleasably secured to the drive unit by a snap fit connection. In this case, the engaging means is a radially outwardly protruding flange 37, which mates with a recess on the drive unit.

2. Main request - novelty in view of E3

It is undisputed that E3 discloses all the features of claim 1 apart from the last one, "wherein the engaging means is adapted and arranged to secure the cartridge holder to a drive unit of a drug delivery device".

The applicator of E3 has wing members 70 which act as finger grips which are engaged by the user's fingers to apply pressure on the plunger 60, thus forcing the medicament out of the cartridge 50 (page 24, lines 1 to

5, Figure 3). The Board agrees with the appellant that the applicator of E3 is intended for manual operation by a hand of the user only, and it is not envisaged or suggested to use the applicator with a drive unit configured to displace the plunger 60.

In any case, there is no evidence on file showing a drive unit that can be secured to the finger grips 70 of the applicator of E3. In E1, which shows a drug delivery device which can be used with a standard syringe (Figure 1), the flange 124 may be considered to have some similarity with the wing members of E3, but it has a different shape to these wing members and, most importantly, it is not used to secure the syringe to the drive unit.

Thus, the wings or finger grips 70 cannot be regarded as an engaging means adapted and arranged to secure the cartridge holder to a drive unit.

The same reasoning applies to independent claim 11.

The subject-matter of claims 1 and 11 is therefore novel over E3.

3. The respondent did not raise further objections against the main request.

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:
 - claims 1-14 according to the main request filed with the statement of grounds of appeal
 - description paragraphs [1]-[5], [8]-[9], [11]-[13] and [17]-[101] of the patent specification and paragraphs [6]-[7], [10] and [14]-[16] filed during the oral proceedings before the Board by email dated 10 March 2022, received at 09.51 hrs
 - drawings of the patent specification

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated