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Datasheet for the decision of 11 January 2019

Case Number: T 0980/14 - 3.2.02

Application Number: 08776083.1

Publication Number: 2173413

IPC: A61M5/20

Language of the proceedings: EN

Title of invention:
INJECTION DEVICE

Patent Proprietor:
Cilag GmbH International

Opponent:
SANOFI-AVENTIS DEUTSCHLAND GMBH

Headword:

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
Novelty - main request (no)
Inventive step - first auxiliary request (yes)

Decisions cited:
T 0169/83, T 0241/88, T 0896/92

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0980/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 11 January 2019

Appellant: (Patent Proprietor)	Cilag GmbH International Gubelstrasse 34 6300 Zug (CH)
Representative:	Tunstall, Christopher Stephen Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent: (Opponent)	SANOFI-AVENTIS DEUTSCHLAND GMBH Patentabteilung Industriepark Höchst, Geb. K 801 65926 Frankfurt (DE)
Representative:	Finger, Catrin Liedtke & Partner Patentanwälte Gerhart-Hauptmann-Strasse 10/11 99096 Erfurt (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 14 February 2014 concerning the maintenance of European patent No. 2173413 in amended form**

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
M. Stern

Summary of Facts and Submissions

I. The patent proprietor has appealed against the Opposition Division's decision, despatched on 14 February 2014, that, taking into consideration the amendments according to the second auxiliary request made by the proprietor during the opposition proceedings, European patent No. 2 173 413 and the invention to which it related met the requirement of the EPC. The subject-matter of claim 1 of the patent as granted was found to lack novelty.

II. Notice of appeal was filed on 24 April 2014. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 24 June 2014.

III. By communication dated 12 October 2018, the Board summoned the parties to oral proceedings and provided its preliminary opinion.

IV. By letter dated 3 December 2018, the respondent announced that it would not take part in the oral proceedings.

V. Oral proceedings took place on 11 January 2019 in the absence of the respondent.

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, on the basis of one of the first to third auxiliary requests, all filed with letter dated 24 June 2014.

The respondent had requested in writing that the appeal be dismissed.

VI. The following documents are mentioned in the present decision:

D2: WO-A-2007/036676;
D4: US-A-2004/0225262;
D7: WO-A-2004/054645;
D8: WO-A-03/097133.

VII. Claim 1 of the patent as granted (main request) reads as follows:

"An injection device (110) comprising:

a housing (112) adapted to receive a syringe (114) having a discharge nozzle (118), the syringe (114) being moveable in the housing (112) along a longitudinal axis from a retracted position in which the discharge nozzle (118) is contained within the housing (112) and an extended position in which the discharge nozzle (118) of the syringe (114) extends from the housing (112) through an exit aperture (128);

an actuator (130);

a drive (129) adapted to be acted upon by the actuator (130) and in turn act upon the syringe (114) to advance it from its retracted position to its extended position and discharge its contents through the discharge nozzle (118); and

a syringe carrier (127) adapted to support the syringe (114) as it is advanced;

characterised by:

a locking mechanism (170) between the syringe carrier (127) and the drive (129) to inhibit movement of the syringe carrier (127) and syringe (114) towards the exit aperture (128)."

Claim 1 of the first auxiliary request reads as follows:

"An injection device (110) comprising:

a housing (112) adapted to receive a syringe (114) having a discharge nozzle (118), the syringe (114) being moveable in the housing (112) along a longitudinal axis from a retracted position in which the discharge nozzle (118) is contained within the housing (112) and an extended position in which the discharge nozzle (118) of the syringe (114) extends from the housing (112) through an exit aperture (128);

an actuator (130);

a drive (129) adapted to be acted upon by the actuator (130) and in turn act upon the syringe (114) to advance it from its retracted position to its extended position and discharge its contents through the discharge nozzle (118);

a syringe carrier (127) adapted to support the syringe (114) as it is advanced;

a return spring that biases the syringe (114) from the extended position to the retracted position, wherein the return spring acts on the syringe via the syringe carrier; and

a locking mechanism (170) between the syringe carrier (127) and the drive (129) to inhibit movement of the syringe carrier (127) and syringe (114) towards the exit aperture (128)."

Claims 2 to 23 are dependent claims.

VIII. The appellant's arguments, where relevant to the present decision, may be summarised as follows:

Main request - novelty

The subject-matter of claim 1 of the main request was novel over D4.

More particularly, D4 did not disclose a locking mechanism between the syringe carrier and the drive to inhibit movement of the syringe carrier and syringe toward the exit aperture as defined in claim 1 of the patent as granted. The engagement of the hook-like proximal ends of the rails coupled to the syringe with the platform attached to the drive of the injector of D4 did not prevent relative movement of the platform with respect to the rails. Paragraph [0050] of D4 made clear that the engagement merely provided a guiding function, not a locking function as required by the claim. Neither could such a locking function be derived from the figures because the shown hooks of the rails could deform or deflect to allow the rails and platform to come apart. Hence, in accordance with decisions T 896/92, T 169/83 and T 241/88, the figures did not disclose the claimed locking mechanism.

Nor did D4 disclose a syringe carrier for supporting the syringe as it was advanced. The mounting element and the rails were not adapted to support the syringe as it was advanced. Instead they themselves were supported by the syringe. Only the plunger spring of the injector - not the rails - was responsible for advancing the syringe. No force was imparted to the syringe via the rails or the mounting element in engagement with the syringe. It followed that those two elements were not responsible for any constraint or movement of the syringe and could not build a syringe carrier as claimed.

First auxiliary request - inventive step

D4 did not disclose any return spring as defined in claim 1 of the first auxiliary request. Implementing a return spring as claimed in the injector of D4 would be difficult whilst also retaining the existing drive system. Hence, the subject-matter of claim 1 of the first auxiliary request would not have been obvious based on D4.

IX. The respondent's arguments, where relevant to the present decision, may be summarised as follows:

Main request - novelty

The subject-matter of claim 1 of the main request lacked novelty over D4. More particularly, Figures 2(a) to 2(c) of D4 unambiguously disclosed a locking mechanism between the syringe carrier and the drive of the injector of D4, built by the hooks of the rails, which held the platform of the drive in fixed relation with the syringe carrier and the syringe. Figure 12 disclosed a syringe carrier in the form of a mounting element that supported the syringe when the plunger of the syringe was moved in a distal direction. The patent was entirely silent on structural features by which the syringe carrier was supported.

First auxiliary request - inventive step

The locking mechanism and the return spring defined in claim 1 of the first auxiliary request provided no synergistic effect but related to different partial problems. The claimed locking mechanism was disclosed in D4, while the claimed return spring was disclosed in D2 (page 5, lines 28 to 32). It followed that the

subject-matter of claim 1 did not make a contribution to the state of the art and did not involve an inventive step. Moreover, a return spring arranged between a housing and a syringe was well known to those skilled in the art, for example from D7 or D8.

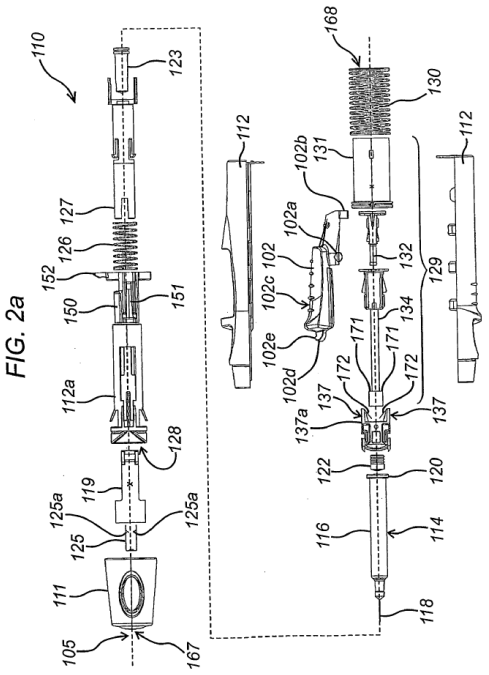
Reasons for the Decision

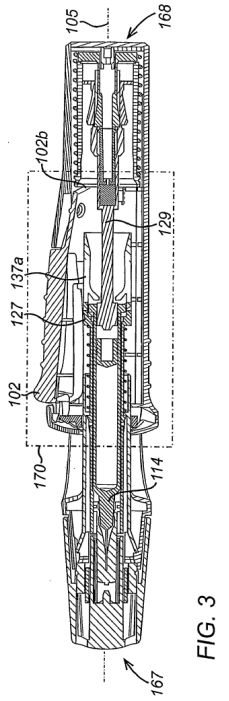
1. The appeal is admissible.

2. Although having been duly summoned in a communication dated 12 October 2018, the respondent was not present at the oral proceedings, as announced by letter dated 3 December 2018. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without the respondent, who is treated as relying only on its written case.

3. The invention

The invention relates to an injection device for automatic injection of medicament. A specific embodiment is shown in exploded view in figure 2a and in sectional view in figure 3, reproduced below.





The injection device comprises a housing (112) within which a syringe (114) with a discharge nozzle (118) is received. In use, the syringe is extended in a position in which the discharge nozzle extends from the housing, and its contents are discharged automatically. According to the specific embodiment disclosed in the description and drawings, the syringe is automatically retracted within the housing after the injection. The subject-matter of claim 1 of the patent as granted, however, is not limited in this respect. In claim 1 according to the first auxiliary request, a return spring (126) is defined, which biases the syringe from the extended position to a retracted position in which the discharge nozzle is contained within the housing.

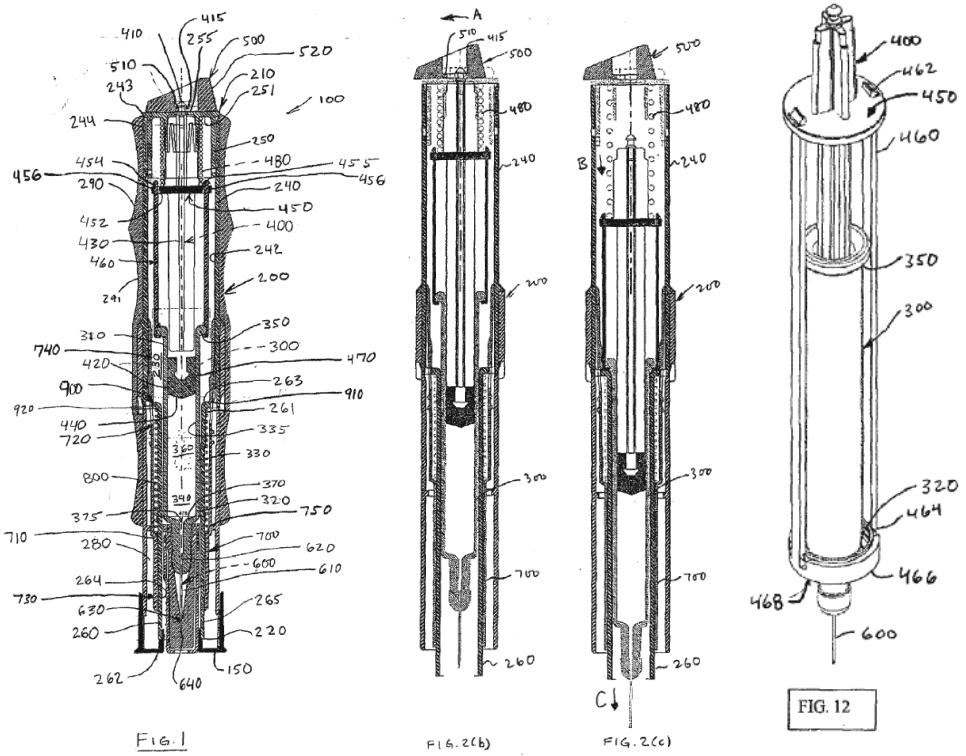
Claim 1 of the patent as granted characterises the invention by a locking mechanism which, when locked, prevents the extension of the syringe. According to the patent, the locking mechanism is for preventing unwanted movement of the syringe when, for preparing

the injection, an axial force is applied to the syringe by removing a needle protecting cap (111) (paragraph [0004] of the patent). Such a movement could damage the syringe, the needle or other components of the injection device.

4. Main request - novelty

4.1 The respondent argued that the subject-matter of claim 1 of the patent as granted lacked novelty over D4.

D4 discloses an automatic injector comprising a syringe and a shroud, the shroud being extendable in order to cover a needle of the syringe at the end of the injection. Figures 1, 2(b), 2(c) and 12, reproduced below, show the main components of the automatic injector. Figure 12 depicts an embodiment which differs in the configuration of mounting element 460 and rails 466.



More specifically, D4 discloses an injection device (100 in the figures) comprising a housing (200) adapted to receive a syringe (300) having a discharge nozzle (needle 600), the syringe being movable in the housing along a longitudinal axis (paragraph [0054], first two sentences) from a retracted position (shown in figure 2(b)) in which the discharge nozzle is contained within the housing and an extended position (shown in figure 2(c)) in which the discharge nozzle of the syringe extends from the housing though an exit aperture; an actuator (spring 480); a drive (platform 450) adapted to be acted upon by the actuator and in turn act upon the syringe (by means of the connection with piston 400 of the syringe) to advance it from its retracted position to its extended position and discharge its contents through the discharge nozzle (paragraph [0054], last sentence); a syringe carrier (mounting element 466 with rails 460 described in paragraph [0056]) adapted to support the syringe as it is advanced (paragraph [0058]); and a locking mechanism (made up by hook-like ends 462 of rails 460 engaged - paragraph [0056] - with respective apertures in platform 450 as best shown in figure 12) between the syringe carrier and the drive to inhibit movement of the syringe carrier and syringe towards the exit aperture.

4.2 The appellant argued that hook-like ends 462 and the apertures in platform 450 were not disclosed as building a locking mechanism preventing relative movement of the platform with respect to the rails.

The Board notes that the claim does not require that the relative movement be prevented but merely inhibited.

Hook-like ends 462 and the apertures in platform 450 are shown in sufficient detail in the figures. Additionally, they are described as being engaged with one another (paragraph [0056]). It follows that the description and the figures together provide the skilled person with a direct and unambiguous disclosure that hook-like ends 462 and the apertures in platform 450 are able to transfer some axial force from the syringe, through mounting element 466 and rails 460, to platform 450 which is held in place by the engagement between proximal end 410 of plunger 400 and element 510 of actuator 500 (paragraph [0061] and figure 1). This force, which would have to be overcome to permit the relative movement of the platform with respect to the rails, clearly inhibits the movement within the meaning of the claim.

Whether a guiding function is also provided is of no relevance in this respect. The appellant's reference to decisions T 896/92, T 169/83 and T 241/88 is of no relevance either since these decisions concern the disclosure content of figures alone.

4.3 The appellant further argued that mounting element 466 and rails 460 were not adapted to support the syringe as it was advanced but instead were themselves supported by the syringe.

The Board notes that rails 460 of mounting element 466 are disclosed as being able "to guide the platform 450 as the plunger 400 travels in a distal direction" (paragraph [0050], fifth sentence). This guiding function, which is transferred to the syringe connected to platform 450, provides a certain constraint to the syringe and is therefore enough for anticipating a generic carrier adapted to support the

syringe, as defined in the claim.

The appellant's argument that no advancing force was imparted to the syringe via the rails or the mounting element is without merit since the transfer of such an advancing force is not required by the claim. More particularly, the Board does not see why such transfer should be implied by the term "carrier".

4.4 It follows that the subject-matter of claim 1 of the main request lacks novelty (Article 54(1) and (2) EPC) over D4 and is therefore not patentable in view of Article 52(1) EPC.

Hence, the patent cannot be maintained as granted.

5. First auxiliary request - inventive step

5.1 Claim 1 of the first auxiliary request, which is based on claim 1 and page 7, lines 22 to 26 of the application as filed, further defines a return spring that biases the syringe from the extended position to the retracted position and acts on the syringe via the syringe carrier.

It is common ground that D4 does not disclose such a spring.

5.2 The claimed return spring contributes to the technical effect of protecting the discharge nozzle of the syringe after the completion of an injection, thereby addressing the problem of preventing injuries for a user with a compact design of the injection device.

D4 provides for protection of the tip of needle 600 at the end of the injection in a different way, i.e. by

means of a shroud (700) which is moved forward to cover the needle in the extended position (shown in figure 2(e)).

5.3 A combination of D4 with a document disclosing a return spring for biasing the syringe from the extended position to the retracted position such as D2 would require a complete redesign of the internal structures of the respective injection devices. Starting from D4, the only document analysed in detail by the respondent in its reply to the statement of grounds, it would have to be considered, for example, that spring 480 continues to act on plunger 400 at the end of the injection. Hence, irrespective of whether such a return spring is disclosed in D2, D7 or D8 or is well known, the skilled person would not combine such a spring with the injection device of D4 in an obvious way.

5.4 It follows that the subject-matter of claim 1 of the first auxiliary request is inventive (Article 56 EPC) over the cited documents of the prior art.

6. The description has been brought into conformity with the claims of the first auxiliary request.

The respondent did not raise any other objections to the first auxiliary request. The Board does not have any either.

7. Hence, the patent can be maintained on the basis of the first auxiliary request, and there is no need for the Board to consider the appellant's lower-ranking requests.

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 23 of the first auxiliary request filed with letter dated 24 June 2014;

   - description: adapted columns 1 and 2 filed during the oral proceedings and columns 3 to 10 of the patent as granted; and

   - figures 1a to 3 of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated