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**Datasheet for the decision
of 14 October 2015**

Case Number: T 0219/12 - 3.2.02
Application Number: 05104734.8
Publication Number: 1728529
IPC: A61M5/315, A61M5/20, A61M5/48,
A61M15/00
Language of the proceedings: EN

Title of invention:
Device for delivering medicament

Patent Proprietor:
SHL Group AB

Opponent:
TecPharma Licensing AG

Headword:

Relevant legal provisions:
EPC Art. 100(c), 123(2), 83, 56
RPBA Art. 12(1), 12(4)

Keyword:
Added subject-matter -
main request (yes), auxiliary request 1 (no)
Sufficiency of disclosure - auxiliary request 1 (yes)
Novelty, fresh ground of opposition introduced in appeal, not
considered
Inventive step - auxiliary request 1 (yes)

Decisions cited:

T 0331/87, G 0010/91

Catchword:



**Beschwerdekammern
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Chambres de recours**

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Case Number: T 0219/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 14 October 2015

Appellant: TecPharma Licensing AG
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 22 November 2011 rejecting the opposition filed against European patent No. 1728529 pursuant to Article 101(2) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The opponent lodged an appeal against the decision posted on 22 November 2011 rejecting the opposition filed against European patent No. 1 728 529. In the decision under appeal, the Opposition Division held that the patent as granted satisfied the requirements of Article 100(a), (b) and (c) EPC.

II. Notice of appeal was filed on 24 January 2012 and the fee for appeal was paid the same day. A statement setting out the grounds of appeal was received on 30 March 2012.

III. The following documents are relevant for the present decision:

D1: WO-A-01/87384

D3: US-B1-6 475 193

D4: WO-A-2006/089436.

IV. Oral proceedings were held on 14 October 2015.

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

The respondent (patent proprietor) requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of auxiliary request 1, filed with letter dated 15 October 2012.

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

"A device (2, 100, 60) for delivery of predetermined doses of liquid medicament, which device is adapted to be in a medicament delivery state and in a medicament non-delivery state, said device comprising:
- a cartridge (10, 103, 69) adapted to contain the liquid medicament and a piston sealingly and slidably arranged in said cartridge, an energy accumulating member (26, 114, 86),
an elongated threaded plunger rod (16, 126, 84) adapted to be arranged in the interior of the device, wherein the proximal end of the plunger rod is adapted to be in contact with the piston, such that, when a first force from said energy accumulating member is applied to the plunger rod when the device is in the medicament delivery state, the plunger rod and the piston moves towards the proximal end of the cartridge with a predetermined distance and expels a predetermined dose of the liquid rnedicament from the cartridge,
characterized in that the device comprises at least one additional rod (200) extending along the longitudinal axis of the device, that is in contact with the plunger rod (16, 126, 84), wherein said at least one additional rod is adapted to provide the plunger rod with a second force that drives the plunger rod towards the proximal end of the cartridge when the at least one additional rod is applied with the second force that drives the at least one additional rod towards the proximal end of the device when said device is in the medicament delivery state."

VI. Claim 1 of **auxiliary request 1** reads as claim 1 of the patent as granted, with the following expression added at the end:

", wherein the first force that is applied to the piston during medicament delivery is set to a predetermined force value."

Claims 2 to 16 of auxiliary request 1 are dependent claims.

VII. The arguments of the appellant-opponent relevant for the present decision are summarised as follows:

(i) Main request - Added subject-matter

The omission of the characterising feature of original claim 1 ("the force that is applied to the piston during medicament delivery is set to a predetermined force value") from claim 1 of the contested patent led to an unallowable intermediate generalisation of the content of the original application. It was prominently explained in the first paragraph of the description and the first paragraph of the "Summary of the invention" of the original application (page 4, paragraph 3) that it was the object of the invention to provide an automatic liquid medicament delivery device which applied a force with a predetermined force value to a piston in order to ensure that a predetermined volume of medicament was expelled from the cartridge. This feature was lacking in the prior art (page 4, paragraph 2). There was no reason for the skilled person to view this prominently presented feature as non-essential. Even if in the last paragraph of page 4 a *further* object was presented, it was clear that the main object of the invention was the former one (mentioned on page 4, third paragraph). The shifting of the objective technical problem during examination proceedings was of no relevance for establishing the

non-essentiality of features of the original disclosure.

(ii) Auxiliary request 1

Admissibility of the request

Auxiliary request 1 should not be admitted since it was filed too late in the sense that the claims could easily have been filed in the first-instance proceedings.

Added subject-matter

Claim 1 defined an energy accumulating member whose accumulated energy, according to original claim 4, was an energy which provided the plunger rod with the predetermined force. As this feature was absent from claim 1, it gave rise to an unallowable intermediate generalisation.

Sufficiency of disclosure

Since two forces acted on the plunger rod, it was unclear how the skilled person could set the predetermined force value to move the plunger rod and the piston a predetermined distance to expel a predetermined dose of the medicament. Moreover, in the embodiment of Figures 16 and 17, the plunger rod (16) was devised as a hollow member through which the second additional rod (200) extended. Consequently, the latter could not have the capability to drive the plunger rod into the cartridge, whereby this embodiment did not fall under the terms of claim 1. Even if the plunger rod was devised as a solid member, as was also mentioned in paragraph [0028], the additional rod would

fail to drive the plunger rod into the cartridge, since the plunger rod was a screw threaded rod.

Novelty

Document D4 was a prima facie highly relevant document regarding the novelty of claim 1, and should therefore be considered.

Inventive step

The claimed device lacked an inventive step in view of D1 as the closest prior art in combination with the skilled person's common general knowledge or, alternatively, in combination with D3. D1 did not disclose the features of the characterising portion related to the additional rod. The skilled person would certainly know that the energy stored in the energy accumulating member, i.e. the torsion rods 14, was causative for plastic creep and deformation. The avoidance of this deformation constituted the objective technical problem to be solved. The skilled person would immediately arrive at the conclusion that the energy stored in the torsion rods of D1 needed to be reduced. It would be immediately clear to the skilled person, from his general knowledge about standard syringes, or from the disclosure of such a syringe from D3, that such energy would then have to be applied to the piston externally with a manually activatable rod. Such energy would also be needed if the piston in the medicament cartridge of D1 got stuck and could not move. Thus, the skilled person would readily arrive at the claimed device as a solution to the posed problem.

VIII. The arguments of the respondent-patent proprietor relevant for the present decision are summarised as follows:

(i) Main request - Added subject-matter

It was allowable under Article 123(2) EPC to leave out from claim 1 the characterising feature of original claim 1. According to established case law, it was allowable to extend the scope of a claim by deleting a technical feature if the original description contained at least one embodiment without this feature. Such embodiments were presented on page 8, last paragraph and on page 20, first paragraph, in which the user could manually apply a force on the distal end of the second rod as an additional force acting on the piston.

The elimination of the feature in question was also allowable when applying the three-point test developed in T 331/87, as the Opposition Division correctly found. The feature in question had not been explained as essential in the original application. In particular, none of the objects of the invention disclosed the alleged essential character of the aforementioned feature.

Claim 1 of the patent included the feature of the additional rod defined in original dependent claim 11, which solved a different problem than that of original claim 1, namely the problem associated with creep in and plastic deformation of the materials of the delivery device (page 3, paragraph 3; page 4, last paragraph). In view of this shifted problem, the characterising feature of original claim 1 was no longer necessary.

(ii) Auxiliary request 1

Admissibility of the request

Auxiliary request 1 should be admitted as it had been filed with the reply to the statement of grounds of appeal, thus at the earliest possible time during the appeal proceedings. Moreover, the same set of claims had already been filed during the first-instance proceedings on 6 August 2009, as auxiliary request 2, in case the Opposition Division did not follow the proprietor's arguments regarding claim 1 of the patent as granted.

Added subject-matter

Claim 1 satisfied the requirements of Article 123(2) EPC since it included the characterising feature of original claim 1. The claim was, moreover, in accordance with the definition of original claim 4 insofar as it stated that the energy in the energy accumulating member was adapted to be transferred to the plunger rod so that the plunger rod was provided with the predetermined force.

Sufficiency of disclosure

The predetermined medicament dose was given by the predetermined distance of the plunger rod and piston moved by the energy accumulating member. The person skilled in the art would recognise from the patent description that once the second additional force is sufficient to overcome the break-loose force, the plunger rod and the piston would move a predetermined distance towards the patient-proximal end of the medicament cartridge, expelling a predetermined dose of

the medicament from the cartridge. Paragraph [0028] not only disclosed an embodiment in which the plunger rod was hollow, as pointed out by the appellant, but also one in which the same was solid. Without undue burden the skilled person would appropriately devise the threaded plunger rod, e.g. with an appropriate pitch, so that it could move towards the cartridge by a force exerted by the additional second rod.

Novelty

The opposition brief did not contain any arguments or evidence regarding lack of novelty. Thus, following G 10/91, novelty based on D4 was a fresh ground of opposition which should not be considered in the appeal proceedings. Since D4 had not been filed earlier during the opposition proceedings and was prior art under Article 54(3) EPC, being thus only relevant for this fresh ground for opposition, it should not be admitted into the proceedings.

Inventive step

The claimed device differed from the closest prior art D1 by the characterising features related to the additional rod for providing the plunger rod with an additional force. The objective technical problem which they solved was to avoid creep and plastic deformation of the plastic materials of the device. This problem was not addressed in any of the documents on file. Nor did any of them disclose the differentiating features. A standard syringe, or a syringe as disclosed in D3, had a manually pushable plunger rod for continuous injection of a liquid medicament, rather than for injection of set doses of the liquid. It was with hindsight that the appellant posited to modify the set-

dose-delivery device of D1 to additionally include a push rod as known for standard syringes or a syringe as in D3.

Reasons for the Decision

1. The appeal is admissible.

2. *Background*

The invention according to claim 1 of the contested patent relates to a device for delivery of predetermined doses of a liquid medicament comprising, in essence, a cartridge containing the medicament with a sliding piston sealing the cartridge, and an elongated plunger rod in contact with the piston. On the elongated plunger rod and the piston two forces are applied. A first force is provided from an energy accumulating member, e.g. a flat spiral spring, with a predetermined force value to ensure that a predetermined volume of medicament is expelled from the cartridge (paragraph [0015] of the patent, or page 4, paragraph 3 of the original application). A second force is provided from an additional rod, allowing the user to manually apply an additional force on the piston (paragraphs [0028] and [0059] of the patent, or page 8, paragraph 3 and page 20, paragraph 1 of the original application), for example, for providing a so-called "break-loose force" on the piston to start its movement from its initial position in the cartridge (paragraph [0095] of the patent, or page 33, paragraph 1 of the original application).

3. *Main request - Article 100(c) EPC*

3.1 Claim 1 of the contested patent is formulated on the basis of claim 1 and dependent claims 4 and 11 of the original application, leaving out, however, the (only) characterising feature of original claim 1, viz. "the force that is applied to the piston during medicament delivery is set to a predetermined force value".

3.2 The appellant raised the objection that the omission of this feature from claim 1 of the granted patent led to an unallowable intermediate generalisation, an objection which the Board follows for the following reasons.

3.3 As prominently explained in the "Summary of the invention" of the original application (page 4, paragraph 3), the object of the invention is to provide an automatic liquid medicament delivery device which applies a force with a predetermined force value to a piston in order to ensure that a predetermined volume of medicament is expelled from the cartridge. It is explicitly mentioned that the cited prior art lacked such means (page 4, paragraph 2).

3.4 Consequently, the device of the invention according to original independent device claim 1 specifies, as its (sole) characterising feature, that "the force that is applied to the piston during medicament delivery is set to a predetermined force value". Also the first paragraph of the original application explains that the device should have this feature. A more detailed explanation of how it works is then provided in the paragraph bridging pages 15 and 16 (and in the similar paragraphs starting on pages 25 and 33).

There is also no explicit or implied indication in the original specification which might have allowed to recognise the possibility of omitting the feature in question from the application.

Thus, the skilled person is left in no doubt about the fact that the aforementioned (sole) characterising feature of original claim 1 is the essence of the invention as originally disclosed. Hence, it does not matter that the original application contains no explicit reference to the feature as an "essential" feature, an aspect which appears to have led the Opposition Division to conclude (in application of the "three-point test" developed in T 331/87) that the removal of the feature from patent claim 1 was allowable (point 2.3 of the Reasons of the impugned decision), a conclusion which the respondent endorsed.

- 3.5 Contrary to a further argument by the respondent, the shifting of the objective technical problem during examination proceedings is also of no relevance for establishing the perceived "non-essential" character of the characterising feature of original claim 1. One of the features of claim 1 of the granted patent is the additional rod defined in original dependent claim 11 which solves the problem associated with creep in and plastic deformation of the materials of the delivery device (page 3, paragraph 3; page 4, last paragraph). As clearly explained on page 4, last paragraph, the solution of this problem is just *another* object of the invention, additional (and not related) to the one previously stated on page 4, of providing the delivery device with means for applying a predetermined force to the piston to ensure that a predetermined volume of medicament is expelled from the cartridge. As indicated above, the latter object is achieved by providing the

delivery device with the feature according to the characterising portion of original claim 1.

- 3.6 The respondent also argued that according to established case law it was allowable to extend the scope of a claim by deleting a technical feature without contravening Article 123(2) EPC if the original description contained at least one embodiment without this feature. It was said that such embodiments were presented on page 8, last paragraph and on page 20, first paragraph, in which the user could manually apply a force on the distal end of the second rod as an additional force acting on the piston.

The respondent seems to be implying that, because in these embodiments the user can manually apply a force on the second rod, the force which the energy accumulating member (spring 26, 114, 86) applies on the piston cannot be set to a predetermined force value. The Board, however, disagrees with this conclusion, since, according to the description, both forces can be applied independently of each other. The cited passages make it clear that the force which is exerted by the second rod on the piston is an *additional* force. It allows the provision of an initial priming of the delivery device, for example as a force corresponding to the "break-loose force" explained under point 2 above, i.e. the minimum force value required for the piston to start its movement (lines 5 to 9 from the bottom of page 16; page 24, paragraph 2; page 2, paragraph 3).

- 3.7 From the foregoing it follows that the omission of the characterising feature of original claim 1 from claim 1 of the contested patent leads to an unallowable

intermediate generalisation of the content of the original application.

3.8 Consequently, the ground for opposition pursuant to Article 100(c) EPC prejudices the maintenance of the patent as granted.

4. *Auxiliary request 1*

4.1 *Admissibility of the request*

The appellant requested not to admit auxiliary request 1 arguing that it had been filed too late. According to the appellant, the claims could easily have been filed in the first-instance proceedings.

It is first noted that the latter assertion is incorrect, since the same claims had actually been filed in the first-instance proceedings (on 6 August 2009), as auxiliary request 2, in case the Opposition Division did not follow the proprietor's arguments concerning claim 1 of the patent as granted.

It is, moreover, noted that the claims of present auxiliary request 1 were filed in the appeal proceedings with the reply to the statement of grounds of appeal, again as a fall-back position in case claim 1 of the patent as granted was found to contravene Article 100(c) EPC. Hence, in accordance with Article 12(1) and (4) RPBA, auxiliary request 1 is to be taken into account by the Board.

The appellant's request not to admit present auxiliary request 1 is consequently rejected.

4.2 *Added subject-matter*

In contrast to the main request, claim 1 of auxiliary request 1 includes the additional limitation that "the first force (from the energy accumulating member) applied to the piston during medicament delivery is set to a predetermined force value". The aforementioned deficiency regarding added subject-matter of claim 1 of the patent has thereby been remedied.

The added expression is, moreover, in accordance with the definition of original claim 4 insofar as it states that the energy in the energy accumulating member is adapted to be transferred to the plunger rod so that the plunger rod is provided with the predetermined force.

Consequently, claim 1 of auxiliary request 1 satisfies the requirements of Article 123(2) EPC.

4.3 *Sufficiency of disclosure*

As already indicated under point 2 above, the patent provides the skilled person with a clear teaching about the two separate forces acting on the plunger rod: a first force provided from an energy accumulating member, e.g. a flat spiral spring, with a predetermined force value to ensure that a predetermined volume of medicament is expelled from the cartridge, and a second force provided from an additional rod, allowing, for example, the user to manually apply an additional force on the piston delivering a "break-loose force" on the piston to start its movement from its initial position in the cartridge (paragraphs [0028], [0059] and [0095]).

Moreover, it would constitute no more than a routine engineering measure for the skilled person to devise the screw threaded solid plunger rod disclosed in paragraph [0028] with the appropriate pitch so that a force exerted on it by the additional rod would allow it to be driven into the cartridge. The appellant's argument that the specific embodiment of Figures 16 and 17 does not allow the skilled person to reproduce the invention is therefore not conclusive.

The disclosure of the patent is therefore sufficient for the skilled person using common general knowledge to put the claimed invention into practice without undue burden.

Consequently, the requirements of Article 83 EPC are fulfilled.

4.4 Admissibility of novelty as new ground for opposition

In the notice of opposition, the grounds for opposition under Article 100(a) EPC had only been substantiated concerning the requirement of inventive step under Article 56 EPC. Apart from a cross in the box corresponding to lack of novelty in EPO opposition Form 2300, the notice of opposition did not contain any indication of facts, evidence and arguments in support of the lack of novelty of the subject-matter of claim 1 of the contested patent. In the absence of any substantiation of the ground of lack of novelty in the notice of opposition, and following established case law (as cited in Case Law of the Boards of Appeal of the EPO, 7th edition 2013, IV.D.3.1), the ground of lack of novelty is regarded as not having been raised.

The appellant raised a novelty objection for the first time in its statement of grounds of appeal. The objection was based on newly cited document D4, which the parties considered to constitute prior art under Article 54(3) EPC.

It follows that the ground of lack of novelty is a fresh ground for opposition, which, according to decision G 10/91 (Reasons, point 18), could be considered in the present appeal proceedings only with the approval of the proprietor. Since the proprietor expressly refused to give that approval, the ground of lack of novelty is not to be considered (irrespective of the prima facie relevance which D4 may have).

4.5 *Inventive step*

4.5.1 It is common ground between the parties that document D1 (cited in the patent in paragraph [0013]) constitutes the closest prior art. The document discloses (page 3, lines 7 to 12) a liquid medicament delivery device for the delivery of predetermined doses of a liquid medicament comprising, in essence, a medicament cartridge (2), a sliding piston (5) within the cartridge, an elongated threaded plunger rod (6) in contact with the piston, and an energy accumulating member (torsion rod 14) as claimed. In particular, the force which the torsion rod (14) applies to the piston (5) is settable to a predetermined force value in order to expel a predetermined dose of the liquid medicament from the cartridge (page 4, lines 7 to 9).

4.5.2 It is also undisputed that D1 does not disclose the features of the characterising portion of claim 1 related to the additional rod for providing the plunger rod with a second force that drives the plunger rod

towards the proximal end of the cartridge (the patent explains in paragraph [0024] that the "proximal end" of the cartridge is the end of the cartridge closest to the patient).

4.5.3 The technical effect of the additional rod is to provide a manually controllable "break-loose force" insuring a correct initiation of the automatic medicament delivery. The additional force exerted by the additional rod allows a reduction of the energy stored in the energy accumulating member which eventually leads to deformation of the plastic material of the delivery device. Hence, the objective technical problem associated with the additional rod consists in avoiding creep in and plastic deformation of the plastic material of the delivery device (as indicated in paragraphs [0019] and [0095] of the patent).

4.5.4 None of the documents on file discloses either said problem or any such *additional* rod for providing the plunger rod with an *additional* force. In particular, document D3 discloses a continuous injecting syringe with a manually pushable plunger rod (abstract; column 4, lines 43 to 48), rather than a device as claimed for injecting set doses of medicament. Thus, D3 does not comprise the claimed "energy accumulating member" applying a force on the plunger rod. It therefore provides no reason to the skilled person for incorporating a rod in addition to the claimed "energy accumulating member".

4.5.5 At oral proceedings, the appellant presented the additional argument that if the piston in the medicament cartridge of D1 were to get stuck and could not move, it would be obvious for the skilled person to push the piston with a manually pushable rod as in a

well-known standard syringe. Such a measure would, moreover, allow the solution of the posed problem of reducing the deformation of the plastic device due to excessive tension produced by the torsion rod(s) in D1 (a plurality of torsion rods is also envisioned in D1; page 4, lines 20 to 23).

The Board is not persuaded by this argument. The device of D1 and a known standard syringe are two different, alternative injection devices, one for injecting preset amounts of a medicament under a preset force from a spring element, the other for continuously injecting a medicament under a manually exerted force. To combine the alternative driving mechanisms of each of these alternative injection devices into one device is not a straight-forward technical measure which the skilled person would implement without knowledge of the present invention. Moreover, D1 already presents the skilled person with an obvious way of increasing the force applied by the piston, namely by increasing the number of torsion rods (page 4, lines 20 to 23).

4.5.6 Consequently, claim 1 of auxiliary request 1 fulfils the requirement of an inventive step within the meaning of Article 56 EPC.

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 16 of auxiliary request 1, filed with letter dated 15 October 2012; and
 - the description and figures of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

E. DufRASne

Decision electronically authenticated