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Case Number: T 0378/16 - 3.2.02

Application Number: 01270353.4

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Title of invention:
AUTO-INJECTOR

Patent Proprietor:
SHL Group AB

Opponents:
De Ros, Alberto
TecPharma Licensing AG

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 83

Keyword:
Novelty - (yes)
Inventive step - (yes)
Sufficiency of disclosure - (yes)

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T 1071/09

Catchword:

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Beschwerdekammern

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Case Number: T 0378/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 29 October 2020

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Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 21 December 2015 rejecting the oppositions filed against European patent No. 1349590 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Böttcher
	Y. Podbielski

Summary of Facts and Submissions

I. The present case concerns the appeal filed by Opponent 1 against the decision of the opposition division posted on 21 December 2015 to reject the oppositions against the European patent EP 1349590.

The appealed decision was taken after the Board had decided, in decision T 1071/09, on the issue of Article 100(c) EPC and had remitted the case to the Opposition Division for further prosecution.

II. Oral proceedings before the Board took place on 29 October 2020.

Although having been duly summoned, the party as of right (opponent 2) was not present as announced by letter dated 18 June 2020. In accordance with Rule 115(2) EPC and Article 15(3) RPBA 2020, the proceedings were continued without this party.

At the end of the oral proceedings the requests were as follows:

The appellant (opponent 1) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the the appeal be dismissed, i.e. that the patent be maintained as granted (main request), or that the patent be maintained on the basis of the auxiliary request filed with letter dated 13 February 2020.

III. In appeal the parties supported their arguments by reference to documents

D3: US 5,478,316 and
D1a: EP -A- 0 824 923.

IV. Claim 1 of the main request reads as follows:

"Device for auto-injection of a dose of medicament, comprising:

- a housing (10) arranged to contain a medicament container (24) therein and comprising a needle cover (18, 20) with a contact part intended to be applied against an injection site,
- spring means (76, 82) capable of, upon activation, pushing the needle past the end (20) of the neatle [sic] cover as well as operating said medicament container to supply the dose of medicament,
- first locking means (46, 58, 62, 78) capable of locking said spring means in a pressurised state,
- first activating means (54, 58) capable of, upon manual operation, releasing said spring means for injection,
- second locking means (56, 68, 70) capable of locking said first activating means,
- second activating means (16, 18, 46) comprising said needle cover, capable of releasing said second locking means when said second activating means is exposed to pressure, characterised in that said second locking means (56, 68, 70) is arranged and designed such that it is prevented from being released if said first activating means (54, 58) is operated before said contact part (18, 20) is exposed to pressure."

V. The arguments of the appellant, as far as relevant for the decision, can be summarised as follows:

Sufficiency of disclosure

The disclosure of the feature "said second locking means is arranged and designed such that it is prevented from being released if said first activating means is operated before said contact part is exposed to pressure", was not sufficiently clear and complete for it to be carried out by a person skilled in the art.

Meaning of the characterising feature

From the above-mentioned feature the person skilled in the art would understand that the push-button was pushed inward, thus activating an internal mechanism which locked the device. If the user were to press the push-button accidentally, when no force was applied to the needle cover, then an internal mechanism should be activated to prevent the device from firing, for as long as the push-button continued to be operated (pressed).

Description of the "two-step" operation in the patent

The "two-step" operation of the device was described in general in paragraph [0011] of the patent. However, the operation was not described in terms of the physical interaction of internal components of the device, but rather in terms of the result to be achieved.

In paragraphs [0021] to [0024], with reference to Figures 6 and 7, the "correct" operation for activating the injector was described, i.e. the operation in which

the two steps were performed in the right order for unlocking the mechanism. However, the skilled person was not provided with a clear teaching as to the "incorrect" operation, i.e. the operation for putting the device in a locked state if pressure was applied to the activator while there was no pressure on needle cover.

The activator 52, which accounted for the locking as described in paragraph [0011], was shown in Figure 5 and described in column 5, lines 10 to 25. However, it was not clear what the "opposite side surfaces" were and in which way they were arranged "somewhat conical inwardly".

The locking mechanism 64 that interacted with the activator could be considered the second locking means according to claim 1. It was shown in Figure 4 and described in column 5, lines 26 to 42. However, it was left open where the "backward facing surfaces" of protrusions 70 were, where the ring of the activator 52 was and which surfaces of the ring and the protrusions were to have the corresponding conicity, in particular since these surfaces did not have any reference numerals.

Furthermore, the description of the components of the device in paragraphs [0019] to [0020] contained multiple inconsistencies in terminology, leaving doubt as to which parts of the drawings corresponded to terms introduced in the description. Consequently, the person skilled in the art was not able to deduce the mechanism based on the disclosure of the patent.

Contradictory statements on enabling embodiments

In paragraph [0020] it was mentioned that the locking mechanism 64 "abuts against" the activator 52. This contradicted the Opposition Division's statement that for a functioning embodiment there had to be a gap between these parts when no pressure was being applied to the push-button of activator 52.

In Figure 1, such a gap was not unambiguously discernible. In fact, a gap was not mentioned at all in the description of the patent. Hence, the disclosure of paragraph [0020] (describing an abutment) was at odds with the only disclosure which would be enabling (requiring a gap).

The teaching of the patent was not sufficiently clear and complete so as to lead the person skilled in the art to a functioning embodiment, which would require a gap.

Color drawings

During the first appeal proceedings the proprietor filed three colored and augmented drawings to "facilitate an easy understanding of the present invention" (page 2 of the grounds of appeal). The following features could be derived from these drawings:

- The protrusions 56 and the end of arms 68 were provided with angled surfaces.

- The angled surfaces were in alignment.

- There was a space between the angled surfaces.

These features were essential for the locking

mechanism. In particular, there had to be a space or gap to release the second locking means when performing the steps in the "correct" order.

However, none of these features was disclosed in the patent in a way that the skilled person could understand. For instance, the elements of the locking mechanism were not denoted with reference numerals in the patent. Moreover, it was stated in paragraph [0020] that the surfaces abutted against each other, i.e. that there was no space or gap.

Since additional, enlarged and coloured drawings were necessary to understand the invention, the disclosure in the patent could not be considered sufficient.

Novelty

From paragraph [0020] of the patent the person skilled in the art learnt that the surfaces of the locking mechanism 64 and activator 52 abut against each other. The person skilled in the art would have concluded that the locking mechanism was prevented from being released by the friction between these surfaces.

D3 disclosed an auto-injector comprising all the features of the preamble of claim 1.

In the device of D3, pressure applied to the push-button 66C caused the member 66B to be pressed onto sleeve projection 28A (the "second locking means" of claim 1). Since a significant force had to be applied to the push-button 66C to overcome coil spring 68, the resulting friction between member 66B and projection 28A was large enough to prevent the sleeve 28 from being moved into the housing.

Hence, D3 disclosed a second locking means (the projection 28A) that was arranged and designed such that it was prevented (by the frictional force between the member 66B and the projection 28A) from being released if the first activating means (the push-button 66C) was operated before the contact part (the end of the sleeve 28) exposed to pressure.

Hence, the subject-matter of claim 1 lacked novelty over D3.

Since the disclosure of D1a corresponded to that of D3, the same arguments applied in view of D1a.

Inventive step

D3 was to be considered the closest prior art. The distinguishing feature, i.e. the characterising feature, provided the effect that activation of the injector in the reverse order was not possible.

The problem to be solved was therefore to ensure that the device was operated in the intended order.

When operating the device of D3 in the intended order, the end of the needle sleeve was first pressed against the injection site. This caused the sleeve to move rearward, thus displacing the projection 28A such that it no longer interfered with member 66B and allowed downward movement of the push-button 66C for starting the injection process.

The person skilled in the art would have derived from this teaching that an improper operation in the reverse order could be avoided by preventing the second locking

means from being released in that case. Nothing else was defined in claim 1. The characterising feature merely stated the intention to prevent the release of the second locking means without giving any structural details of the interaction of elements. The solution to the objective technical problem was therefore obvious for the person skilled in the art.

In order to technically implement the characterising feature of claim 1 in the device of D3, the person skilled in the art could have designed the member 66B as an "F" instead of an "L". The tab 28A would have to be provided with a hole for receiving a pin formed by the middle beam of the "F", thus preventing lateral movement of the tab 28A with respect to the member 66B. This was a straightforward design modification for the person skilled in the art.

Consequently, the subject-matter of claim 1 did not involve an inventive step in view of D3.

VI. The arguments of the respondent, as far as relevant for the decision, can be summarised as follows:

Sufficiency of disclosure

Meaning of the characterising feature

It was disclosed in column 2, lines 53 to 55, of the patent that the locking of the activator 52 was released by pressing the injector against the injection site. In turn, this meant that the locking means was prevented from being released until the contact part was exposed to pressure.

It was further disclosed in column 2, lines 55 to 57,

of the patent that after release of the locking of the activator 52 the button could be pressed to activate the spring-loaded syringe and to inject the medicament. This also meant that before the release the activator was locked and could not be pressed, as was also stated in column 3, lines 1 to 3. Hence, the second locking means had to be designed and arranged such that it was prevented from being released if the first activating means was operated before the contact part was exposed to pressure.

As stated by the Board in the earlier decision T 1071/09 (point 4 of the Reasons), the phrase "is operated" in claim 1 expressed an intention to operate rather than the actual operation of the first activating means.

Description of the "two-step" operation in the patent

The mechanism locking the activator when the push-button was intended to be operated was sufficiently described in paragraph [0020] of the patent. In connection with Figure 6 the person skilled in the art would understand that the conical surfaces of protrusions 56 would abut against the conical surfaces of the protrusions 70 when a force was applied to the push-button. This abutment would prevent the arms 68 from flexing outwardly even if there was pressure on the needle cover. Hence, one specific example for implementing the characterising feature of claim 1 was given in the patent.

Contradictory statements on enabling embodiments

It could be derived from Figure 6 that, when pressure was applied to the contact portion of the needle cover,

the arms 68 could only be lifted from the activator if the conical surfaces of the protrusions were spaced from the conical surfaces of the ring by a gap. This gap was also shown in Figures 7 and 9. Hence, the person skilled in the art would have learnt from this disclosure that a gap had to be present, and that this gap could be closed by pressing the push-button before applying pressure to the contact portion, resulting in an abutment of the conical surfaces.

The disclosure of an abutment of the conical surfaces was not in contradiction to the presence of a gap in the described embodiment.

Color drawings

The color drawings were filed in the first appeal proceedings to support that the claim met the requirements of Article 123(2) EPC. The elements visible in the enlarged drawings were also visible in the figures of the patent (Figures 6, 7 and 9). The person skilled in the art would understand from these figures of the patent that there had to be a gap between the arms 68 and the protrusions 56, without reference to the color drawings.

Novelty

In the device of D3, drive 58 could be released by exerting pressure on sleeve 28 while already pushing on button 66C. Since the projection 28A was not restricted from moving rearward, the engagement between projection 28A and the member 66B could be released at any time, irrespective of whether the push-button 66C was pressed or not. Hence, there was no second locking means that was prevented from being released if the push-button

was operated before the end of the sleeve 28 was exposed to pressure.

In the patent, the backward facing surfaces of the protrusions 70 abutted against the conical surface of the ring/protrusion 56 of the activator. This abutment could not be compared to the friction occurring if two surfaces slid along each other as in D3.

It was not mentioned in D3 that the sleeve 28 could be prevented from being moved by the frictional force between the member 66B and the tab 28A.

The amount of frictional force possibly exerted in D3 on the push-button 66C could not be considered sufficient for preventing movement of the sleeve.

Therefore, D3 did not disclose the characterising feature of claim 1. The subject-matter of claim 1 was therefore novel over D3.

Since the disclosure of D1a corresponded to that of D3, the same arguments applied in view of D1a.

Inventive step

The objective technical problem to be solved with the characterising feature was to prevent accidental misfiring of the injector.

Being faced with this problem, the person skilled in the art would not find any hint or pointer in D3 to modify the injector of D3 to provide a second locking means being arranged and designed such that it was prevented from being released if the first activating means was operated before the contact part was exposed

to pressure.

With the structure of the injector of D3, an unintentional misfiring by operating the device in the reverse order could not be avoided. If the user operated the button 66C first, and placed the injector on the site in a second step, the projection 28A and the member 66B would be disengaged, thus unlocking the push-button.

Such operation in the reverse order was prevented with the invention, as acknowledged by the Board of Appeal in their earlier decision (point 3 of the Reasons). In this context, "operated" meant "intended to operate", in accordance with the earlier decision T 1071/09 (point 4 of the Reasons).

The technical implementation of the characterising feature in the device of D3 was not straightforward for the person skilled in the art. If the member 66B was designed as an "F" and the tab 28A was provided with a hole for the middle bar of the "F", the normal sequence of steps would be prevented, thus leading to a non-working embodiment. The implementation of the characterising feature to obtain a working embodiment rather required a substantial modification of the device of D3.

The features of the characterising part were thus neither disclosed nor suggested by D3. The subject-matter of claim 1 was based on an inventive step.

VII. The party as of right (opponent 2) did not make any submissions in the appeal proceedings.

Reasons for the Decision

1. Subject-matter of the invention

The invention relates to an auto-injection device intended for injection of a dose of medicament. The device comprises a housing having a needle cover with a contact part intended to be applied against an injection site, and an activator which is arranged inside the housing. A locking mechanism is provided between the housing and the activator. In order to activate the injector, a two-step operation is needed. First, the contact part of the needle cover has to be pressed against the injection site. This causes the needle cover to move inside the housing and to release the locking mechanism. Then the activator can be pressed to initiate the injection. This two-step operation prevents misfiring before the injector is placed against the intended injection site (paragraph [0011] of the patent).

If the activator is pushed before the contact part has been pressed against the injection site, the needle cover cannot be moved inside the housing and the locking mechanism cannot be released. This further prevents accidental misfiring of the injector (column 3, lines 8 to 12).

2. Sufficiency of disclosure

The patent discloses the characterising feature "said locking means is arranged and designed such that it is prevented from being released if said first activating means is operated before said contact part is exposed to pressure" sufficiently clear and complete for it to

be carried out by a person skilled in the art.

2.1 Meaning of the characterising feature

As stated by the Board in the earlier decision T 1071/09 (point 3 of the Reasons), the wording of the characterising feature of claim 1 means that "without first a pressure being exerted on the second activation means... it is impossible to release the second locking means". Thus, if the user tries to perform the two steps in the reverse order, the injection is blocked.

This can also be derived from column 2, lines 53 to 57 of the patent, as referred to by the respondent.

Further, in accordance with the earlier decision T 1071/09 (point 4 of the Reasons), the Board considers that the term "is operated" in the characterising feature of claim 1 expresses "an intention to operate rather than the actual operation" of the activating means.

Hence, the Board does not agree with the appellant that the characterising feature implied the actual operation of the activating means.

2.2 Description of the "two-step" operation in the patent

As acknowledged by the appellant, the operation of the injector in the "correct" order, i.e. first the contact portion of the needle cover is pressed on the injection site and then the activator tube 54 is pushed into the housing by a finger, is described in paragraphs [0021] and [0024], with reference to Figures 6 and 7.

According to these passages, pressing the needle cover on the injection site causes the end of the rear extension tube 46 to flex outwardly due to contact with the conical surface 16 of the tubular passage. This lifts the arms 68 of the locking mechanism which rest on the outer surface of the rear extension tube (column 6, lines 24 to 27). After the arms of the locking mechanism are lifted out of the way of the ring 56 of the activator tube, the activator 54 can be pressed to start the injection process.

Hence, the person skilled in the art is taught that by performing the two steps in this "correct" order the locking mechanism will be released to enable the injection.

The locking mechanism 64 itself is described in paragraph [0020] of the patent. The arms 68 of the circular body 66 are provided with protrusions 70, the backward facing surfaces of which are conical. The conical surfaces can be derived from Figures 6 and 7, although they are not provided with reference numerals. In the locked state of the injector, these surfaces abut against the conical surfaces of the ring of the activator tube (column 5, lines 31 to 37). It is clear from Figure 5, that the protrusions 56 (mentioned in column 5, lines 13 to 15) form the ring. From column 5, lines 15 to 18, in connection with Figure 6, it can be derived where the conical "opposite side surfaces" are, namely the surfaces facing the arms 68.

From this description of the locking mechanism, in connection with the disclosure of the two-step operation, the person skilled in the art will understand what happens if the activator is intended to be pushed before the needle cover is pressed to the

injection site. In this case, the abutment between the conical surfaces of the arms 68 and the ring 56 prevents the arms 68 from being lifted, and the activator tube cannot be moved into the housing.

Hence, the patent discloses one way of how to design and arrange the second locking means such that it is prevented from being released if the user intends to perform the two steps in the opposite order, namely, by providing the ring 56 of the activator and the protrusions 70 of the arms 68 with corresponding conical surfaces, which abut against each other in the locked state of the activator. Consequently, contrary to the appellant's view, it is clear from the disclosure of the patent which elements of the mechanism interact in this case.

2.3 Contradictory statements on enabling embodiments

The person skilled in the art would also understand from the disclosure in paragraphs [0020] and [0022] in connection with Figure 6, that the locking mechanism is activated by the user's trial to press the activator without pressing the needle cover to the injection site first. When trying to press the activator, the conical surfaces are caused to abut against each other. This abutment ensures that the rear extension tube cannot be moved backwards to lift the arms of the locking mechanism. As can also be derived from Figure 6, for the rear extension tube 46 to be able to lift the arms in the unlocked state, i.e. when there is no pressure on the activator, there has to be a gap between the protrusions 72 of the arms 68 and the ring 56.

Hence, the teaching of the abutment in the locked state does not contradict the presence of a gap in the

unlocked state. Although the gap is not explicitly mentioned in the description, but only visible in Figure 6, the teaching of the patent is sufficient to enable the person skilled in the art to obtain a functioning embodiment.

2.4 Color drawings

The features shown in the colored drawings, i.e. the conical surfaces and the gap, and their interaction in the two-step operation of the device, can also be derived from the originally filed description and figures of the patent (paragraphs [0019] and [0020]; and Figures 5 to 7 and 9).

As already mentioned above, the teaching of the patent alone, without the colored drawings, is sufficient for the person skilled in the art to put the invention into practice.

3. Novelty

The subject-matter of claim 1 does not lack novelty over D3.

It is not disputed by the parties that D3 discloses the features of the preamble of claim 1.

The injector of D3 has a locking mechanism that prevents the push-button 66 from being inadvertently actuated. For this purpose, the push-button 66 comprises a member 66B which engages a projection 28A of the sleeve 28 enclosing the syringe (column 4, lines 45 to 52; Figures 3 and 19).

The injector of D3 also requires a two-step operation

to commence the injection procedure. As described in column 5, lines 51 to 61, pressing the end of the sleeve 28 against the injection site causes the sleeve to move into the housing. Due to this movement, the sleeve projection 28A is displaced sufficiently such that it no longer interferes with the downward movement of the push-button 66 (Figures 4 and 5). The push-button can then be pressed towards the housing to disengage from the driver 58 and to start the injection.

If the user tries to press the push-button 66 before the sleeve is moved into the housing, the sleeve projection 28A abuts the member 66B and prevents downward movement (column 5, lines 42 to 45). However, this abutment does not exclude lateral movement of the projection 28A if the sleeve is pressed to the injection site in this state. By exerting a sufficient force on the sleeve, while the push-button remains under pressure, it is possible to overcome the frictional force between the member 66B and the projection 28A and to unlock the push-button.

Contrary to the appellant, the Board does not consider the magnitude of the frictional force large enough to prevent the sliding movement of the projection 28A and its disengagement from member 66B. Since, in the locked state, pressing the push-button will not cause any substantial movement thereof, there cannot be any counter-force from the coil spring 68 which would have to be overcome.

Hence, the second locking means, i.e. the projection 28A in D3, is not arranged and designed such that it is prevented from being released if the first activation means, i.e. the push-button 66 in D3, is operated

before the contact part, i.e. the end of the sleeve in D3, is exposed to pressure. Consequently, the characterising feature of claim 1 is not disclosed in D3.

Since it is undisputed that the disclosure of D1a corresponds to that of D3, the same applies in view of D1a.

4. Inventive step

4.1 Both parties agree that D3 can be considered the closest prior art.

4.2 As mentioned before, D3 does not disclose the feature "the second locking means is arranged and designed such that it is prevented from being released if said first activation means is operated before said contact part is exposed to pressure".

4.3 Due to this feature, the two-step operation of first pressing the needle cover to the injection site and then pushing the activator, cannot be performed in the reverse order. Once and as long as pressure is exerted on the activator, i.e. the activator is intended to be operated, the needle cover cannot be moved into the housing to unlock the activator.

The locking mechanism of D3 also requires a two-step operation of pressing the needle cover on the injection site and pressing the push-button. However, with the device of D3, the steps can be performed in the "correct" order but also in the reverse order. If the push-button of D3 is pressed, i.e. intended to be pressed, before the end of the sleeve is exposed to pressure, the locking mechanism can be released by

overcoming the frictional force between the projection 28A and the member 66B.

In contrast, in the present invention, without first a pressure being exerted on the needle cover it is impossible to release the locking mechanism. Hence, the invention provides for a further safety feature by not allowing the two steps to be performed in the reverse order.

The objective technical problem to be solved by the present invention can be regarded as to further reduce the risk of unintentional misfiring (column 3, lines 8 to 12).

Thus, the Board does not concur with the appellant that the objective technical problem is to be considered to prevent the two-step operation in the reverse order.

4.4 Being faced with the above-mentioned problem, the person skilled in the art would not find any pointer in D3 towards modifying the injector of D3 to arrange and design the second locking means such that the two-step operation cannot be performed in the reverse order.

4.5 In D3, no hint can be found that the reverse order of steps could be disadvantageous and should be prevented. Therefore, the Board does not concur with the appellant that it belonged to the normal ability of the person skilled in the art to design and arrange the locking means to prevent the reverse order. Although the locking means is defined in functional terms in claim 1, the characterising feature cannot be regarded obvious.

4.6 Furthermore, to implement the distinguishing feature in the device of D3 would require a significant redesign of the locking mechanism. Providing a pin and a hole to prevent the sliding movement between the projection 28A and the member 66B, as proposed by the appellant, would lead to a non-functional embodiment. The sleeve could not be moved into the housing at all.

Consequently, in the Board's view starting from D3 the technical implementation of the locking means as defined in the characterising part of claim 1 is not straightforward for the person skilled in the art.

4.7 Therefore, the subject-matter of claim 1 involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated