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**Datasheet for the decision
of 17 September 2014**

Case Number: T 1071/09 - 3.2.02

Application Number: 01270353.4

Publication Number: 1349590

IPC: A61M5/20, A61M5/32

Language of the proceedings: EN

Title of invention:

AUTO-INJECTOR

Patent Proprietor:

SHL Group AB

Opponents:

De Ros, Alberto
TecPharma Licensing AG

Headword:

Relevant legal provisions:

EPC Art. 100(c), 111(1)

Keyword:

Grounds for opposition - added subject-matter (no)
Appeal decision -
remittal to the department of first instance (yes)

Decisions cited:

T 0190/99, T 0284/94

Catchword:



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Boards of Appeal
Chambres de recours**

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Case Number: T 1071/09 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 17 September 2014

Appellant:
(Patent Proprietor)

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 20 March 2009
revoking European patent No. 1349590 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	P. L. P. Weber
	C. Körber

Summary of Facts and Submissions

- I. The appeal of the patent proprietor is against the decision of the Opposition Division posted on 20 March 2009 to revoke the patent because it contained subject-matter extending beyond the content of the application as filed.

The notice of appeal was filed on 12 May 2009 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 16 July 2009.

- II. Oral proceedings took place on 17 September 2014.

The appellant (patent proprietor) 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 auxiliary requests 1, 2, 5, 6 and 7 filed with letter dated 16 July 2009 and auxiliary requests 3, 4, 8 and 9 filed with letter dated 30 June 2011, in numerical order.

It also requested remittal of the case to the first instance department for further prosecution if allowability of the claims under Articles 100(c), 123(2) and 123(3) EPC is acknowledged.

The respondent (opponent 01) requested that the appeal be dismissed.

The respondent (opponent 02) requested that the appeal be dismissed.

The respondents (opponents) did not request the Board not to remit the case.

III. The versions of claim 1 of interest for the decision read as follows:

Claim 1 of the application as filed reads as follows:

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

- a housing (10) arranged to contain a medicament container (24) therein and comprising a contact part (18,20) intended to be applied against an injection site,
- a needle cover (18,20) surrounding a needle arranged to the medicament container and extending at least the length of the needle,
- spring means (76,82) capable of, upon activation, pushing the needle past the end (20) of the needle 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,

characterised by a second locking means (56,68,70) capable of locking said first activating means and a second activating means (16,18,46), capable of releasing said second locking means when said contact part is exposed to pressure."

Claim 1 of the patent as granted reads as follows:

"1. 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 neetle [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."

IV. With regard to claim 1 of the patent as granted, two features were objected to under Article 100(c) EPC in the opposition proceedings and dealt with in the decision under appeal:

i) compared to claim 1 of the application as filed the feature that the needle cover is *"surrounding a needle arranged to the medicament container and extending at least the length of the needle"* was deleted,

ii) compared to claim 1 of the application as filed the last feature of claim 1 of the patent as granted *"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" was added.

In the decision under appeal the deletion of feature i) was considered to not add subject-matter whereas feature ii) was considered to add subject-matter which extended beyond the content of the application as filed.

In the appeal proceedings only feature ii) was further addressed by the respondents (opponents).

V. The arguments of the appellant (patent proprietor) can be summarised as follows:

A feature of the claim could not be read in isolation but had to be read in relation to the other features of the claim. Moreover, the wording of the claim had to be read in view of the patent as a whole, in particular taking into account the intended function of a feature. When doing so there was no doubt about the meaning of the features of claim 1 of the patent as granted. In particular, the feature of the characterising portion had to be understood as the misfiring feature explained on page 4 of the application as filed. Therefore, the ground for opposition pursuant to Article 100(c) EPC did not prejudice the maintenance of the patent as granted.

VI. The arguments of the respondents (opponents) can be summarised as follows:

The wording "is operated" in the characterising portion of claim 1 of the patent as granted implied an

effective action on the first activating means. However, there was no disclosure in the application as filed of an embodiment in which the first activating means could be operated before the contact part was exposed to pressure.

The generalisation in the characterising portion of the specific means of the embodiment described in the description of the patent also introduced subject-matter extending beyond the content of the application as filed (T 0284/94).

The use of the word "before" in the characterising portion had a different meaning from "unless" used in the description of the application as filed. If, as according to the description, the first activation means could not be operated unless there was pressure on the contact part, this was more restrictive than the corresponding clause of claim 1, so that also for this reason there was added subject-matter in claim 1.

Lastly, also as a whole the clause introduced by "if" created a different condition from that of the specific embodiment. The always compulsory (and solely described) two-step operation mentioned in the description was not present in the claim, which defined only part of it.

Reasons for the Decision

1. The appeal is admissible.
2. The invention is about an auto-injection device intended for injecting a dose of medicament. It comprises a preloaded compression spring which when

activated acts on a plunger, thereby introducing the needle into the injection site and injecting the dose. The injection device has to be pressed against the skin or injection site in order to be activated. To additionally prevent unintentional firing, the activating button cannot be pressed unless there is pressure exercised on the distal or contact part of the injection device.

Technically, in the main embodiment of the description, as long as there is no pressure exerted on the needle cover (second activation means in the claim), the front extension tube 21 and thus the rear extension tube 46 are not displaced towards the conical surfaces 16 of the end cap, so that the protrusions 70 of the locking mechanism 64 (second locking means) still prevent the activator button 52 (first activation means) from being moved and from releasing the projections 60 of arms 58 (first locking means) which would allow the movement of the needle. Consequently, if anyone tried to operate, e.g. push the activator button 52, without a pressure being exerted on the needle cover, this would not be possible because the locking mechanism 64 would block any movement of the activator button. This corresponds to the aim of the invention, requiring a two-step operation for injection: first the injection device is pressed against the injection site, and only then can the activator button be pressed (see page 3, line 21 to page 4, line 8).

3. Nothing else is expressed in more general terms in claim 1 of the patent as granted. In the first part of claim 1 the second activating means are said to comprise the needle cover and to be capable of releasing the second locking means when the second activating means (comprising the needle cover) is

exposed to pressure. The second locking means are said to be capable of locking the first activating means. The first activating means are said to be capable, upon manual operation, of releasing the spring means for injection or, in other words, of releasing the first locking means which lock the spring means in a pressurised state.

In other words, the same succession of steps as in the described embodiment and which are capable of leading to injection (pressure on the second activating means which releases the second locking means which then allows the manual operation of the first activating means which, when activated, releases the first locking means and thus frees the spring means) are already in the first part of claim 1.

The first part of claim 1 does, however, not precisely express that a manual operation of the first activation means is not possible without first exerting a pressure on the second activation means. The first part of claim 1 leaves other activation options open. In the opinion of the Board, the further limitation as disclosed in the described embodiment is however integrated in the characterising portion of claim 1 stating that *the second locking means 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*. This wording means nothing else than that without first a pressure being exerted on the second activating means (which comprises the needle cover with the contact part as defined in the first part of the claim) it is impossible to release the second locking means and thus to operate the first activating means and, in turn, to fire the injection. Or in other words,

the pressure to be exerted on the second activating means to release the second locking means, as expressed in the last feature of the first part of claim 1, is an absolutely necessary step before the first activating means can be operated. This corresponds exactly to what is described in relation to the specific embodiment and on page 4, lines 5 to 8: *"Further, the "two-step" operation can not be done in the opposite way, i.e. by first pressing the activator and then pressing the injector against the injection site,..."*

4. The respondents (opponents) considered that the wording "is operated" in the characterising portion of claim 1 (*"if said first activating means is operated before said contact part is exposed to pressure"* (emphasis added)) must be understood as meaning that the first activating means is indeed operated, and when doing so there was no disclosure in the application as filed of any embodiment in which the actuation button can actually be operated without the pressure being exerted on the second activation means.

In the opinion of the Board, while it is correct that, strictly speaking, an embodiment in which the activator button 52 (first activation means) can indeed be operated or pushed without the cover being pressed against the injection site has not been described, the above wording of the characterising portion of claim 1 cannot be read in isolation but has to be read together with the other features of the claim, in view of the patent as a whole, and with a mind willing to understand (T 190/99).

In doing so, it is first to be noted that the two last features of the first part of claim 1 require that the device comprises:

- *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.*

This means that the feature of the characterising portion as read by the respondents would be contradictory to the first of these features which requires that the second locking means locks the first activating means, i.e. if the first activating means is locked by the second locking means, it seems contradictory that the same first activating means could be operated, in the sense of moved or pushed as required by the characterising feature (in the interpretation of the respondents (opponents)), without any prior action on the second locking means. Already because of this possible contradiction in the wording of the claim when read as a whole, there is a need for interpretation. Considering the patent as a whole, the Board agrees with the appellant (patent proprietor) and considers that the wording of the characterising portion can only express an intention to operate rather than the actual operation of the first activating means. This is in line with the two-step mode of operation mentioned in the description and not allowing the pressing of the first activation means until the device is pressed against the injection site (*Further, the "two-step" operation can not be done in the opposite way, i.e. by first pressing the activator and then pressing the injector against the injection site, ...*).

Hence, the wording "is operated" in the characterising portion of claim 1 is to be read and understood as "is intended to be operated".

5. The respondents (opponents) further submitted that according to headnote II of T 0284/94 (*Nor is an amendment allowable under Article 123(2) EPC which replaces a disclosed specific feature either by its function or by a more general term and thus incorporates undisclosed equivalents into the content of the application as filed.*) a specific feature could not be replaced by a functional feature and thus also for this reason the characterising portion of claim 1 contained subject-matter extending beyond the application as filed, the specific detailed means of the embodiment having been replaced by the more general feature of the claim.

Here again the Board cannot agree with the respondents (opponents) in view of the general statement already cited: *"Further, the "two-step" operation can not be done in the opposite way, i. e. by first pressing the activator and then pressing the injector against the injection site, thereby further preventing accidental misfiring of the injector."* This sentence does not specify any structural technical means able to fulfil the desired functions.

Consequently, the question whether or not a specific teaching can be generalised does not arise in the present case.

6. The respondents (opponents) also submitted that the wording "before said contact part is exposed to pressure" had a different meaning from "unless said contact part is exposed to pressure" as disclosed on

pages 3 and 4, because the first clause did not define what happened once the contact part had been exposed to pressure while the second defined that it was never possible to actuate the first activating means if no pressure was applied to the contact part.

In the opinion of the Board, as mentioned above, this has to be read in the context of the patent as a whole, in particular taking into account the disclosed intended use of the device. If the second locking means cannot be released before the contact part is exposed to pressure, this must be true any time the actuator is intended to be actuated; it cannot be true only the first time the injector device is intended to be used. In particular, this property has to be present when the injection device is moved to another injection site before being fired, as suggested at the top of page 4 of the application as filed. Thus, should a user change his mind after having pressed the device against a first injection site and then, without performing an injection, decide to move the device to another injection site, the characterising portion of claim 1 must still be valid. In other words, the second locking means must be locked again in order to be able to be released again when pressure is exerted on the contact portion at the second injection site. This is, again, in line with the two-step mode of operation defined on pages 3 and 4. Hence, in the opinion of the Board, the wording "before" cannot mean anything different from "unless" in the context of the present patent.

7. The respondents (opponents) further considered that the condition introduced by "if" in the characterising portion of claim 1 is a different condition from that required by the specific embodiment described in the specification. Whereas in the specific embodiment the

second locking means could only be released and hence the first activating means could only be operated when pressure was applied to the second activating means, the claim now only required that the second locking means was prevented from being released if the first activating means was operated before the second activating means was exposed to pressure. In other words, the necessary condition of always having to expose the second activating means to pressure in order to be able to operate the first activating means was no longer present.

This objection is closely linked to the two others dealt with under points 5 and 7 above. Once again, the wording of the characterising portion of claim 1 has to be read in relation to the other features of claim 1 and in view of the patent as a whole, and when doing so, there is no doubt about the way the feature should be read, as explained above.

8. Therefore, the Board considers that Article 100(c) EPC does not prejudice the maintenance of the patent as granted.

9. Remittal

Since novelty and inventive step have not yet been examined by the Opposition Division, and neither of the respondents (opponents) objected to a remittal, the Board decided to allow the request of the appellant (patent proprietor) and to remit the case to the department of first instance for further prosecution pursuant to Article 111(1) 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 for further prosecution on the basis of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated