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Datasheet for the decision of 15 July 2021

Case Number: T 0586/17 - 3.2.02

Application Number: 10194414.8

Publication Number: 2311510

IPC: A61M5/20, A61M5/24, A61M5/31, A61M5/32

Language of the proceedings: EN

Title of invention:
Automatic injector

Patent Proprietor:
Meridian Medical Technologies, Inc.

Opponents:
ALK-ABELLO A/S
Feldmeier, Jürgen

Headword:

Relevant legal provisions:
EPC Art. 84, 100(b), 123(3)
EPC R. 43(1)

Keyword:

Grounds for opposition - insufficiency of disclosure (yes)
Amendments - extension of the scope of protection of the patent (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Chambres de recours

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Case Number: T 0586/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 15 July 2021

Appellant: (Patent Proprietor)	Meridian Medical Technologies, Inc. 6350 Stevens Forest Road, Suite 301 Columbia, MD 21046 (US)
Representative:	Lavoix 2, place d'Estienne d'Orves 75441 Paris Cedex 09 (FR)
Respondent: (Opponent 1)	ALK-ABELLO A/S Böge Alle 6-8 2970 Hörsholm (DK)
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Respondent: (Opponent 2)	Feldmeier, Jürgen Prüfer & Partner GbR Patentanwälte Sohnckestraße 12 DE-81479 München (DE)
Representative:	Zacco Denmark A/S Arne Jacobsens Allé 15 2300 Copenhagen S (DK)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 20 January 2017 revoking European patent No. 2311510 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	D. Ceccarelli
	C. Schmidt

Summary of Facts and Submissions

I. The patent proprietor has appealed against the Opposition Division's decision to revoke European patent No. 2 311 510. In particular, auxiliary request 4 was refused for insufficient disclosure and auxiliary requests 4a and 4b were refused for extension of the scope of protection with respect to the patent as granted.

II. The Board summoned the parties to oral proceedings.

III. By letter dated 6 July 2021 the respondent/opponent 2 announced that it would not be attending the oral proceedings.

IV. Oral proceedings took place on 15 July 2021 by videoconference without the respondent/opponent 2, who had not filed any substantive requests.

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or on the basis of main request', auxiliary request 1, auxiliary request 1', auxiliary request 2, auxiliary request 2', auxiliary request 3, auxiliary request 3', auxiliary request 4, auxiliary request 4', auxiliary request 4a, auxiliary request 4a', auxiliary request 4b, auxiliary request 4b', auxiliary request 5, auxiliary request 5', auxiliary request 6, auxiliary request 6', filed before the Opposition Division (auxiliary requests without ') and on 15 June 2021 (requests with ').

The appellant further requested that Mr Gordon Row's curriculum vitae filed by the respondent/opponent 1

(hereinafter "the respondent") on 20 February 2015 should be forwarded to it and should not be excluded from public inspection.

The respondent requested that the appeal be dismissed.

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

"An automatic injector (100) comprising:

a housing (110);
a cartridge (160) containing a medicament and including a needle assembly operative to dispense the medicament there through during a medicament dispensing operation, the needle assembly including a needle (162);
a cartridge container (140) disposed within the housing (110) and operative to receive the cartridge (160) therein;
an actuation assembly (130) providing a stored energy source capable of driving the cartridge (160) to permit injection of the medicament into a user; and
a needle cover (150) at least partially received within the housing (110) and positioned between the housing (110) and the cartridge container (140), the needle cover (150) having an opening (152a) formed therein,
characterized in that the force from the stored energy source that drives the cartridge (160) forward is opposed by the cartridge container (140) such that energy released from the stored energy source to drive the cartridge (160) during the medicament dispensing operation is not

transferred to the needle cover (150)."

Claim 1 of auxiliary request 1 is the same as claim 1 of the main request except that the characterising portion reads as follows (amendments highlighted by the Board):

"characterized in that the force from the stored energy source that drives the cartridge (160) forward is opposed by the cartridge container (140) such that energy released from the stored energy source to drive the cartridge (160) ~~during the medicament dispensing operation~~ is not transferred to the needle cover (150) during the medicament dispensing operation."

Claim 1 of auxiliary request 2 is the same as claim 1 of the main request except that the characterising portion reads as follows (amendments highlighted by the Board):

"characterized in that the force from the stored energy source that drives the cartridge (160) forward is opposed by the cartridge container (140) such that ~~energy~~ the force released from the stored energy source to drive the cartridge (160) during the medicament dispensing operation is not transferred to the needle cover (150)."

Claim 1 of auxiliary request 3 is the same as claim 1 of the main request except that the characterising portion reads as follows (amendments highlighted by the Board):

"characterized in that the force from the stored energy source that drives the cartridge (160)

forward is opposed by the front end of the cartridge container (140) such that energy released from the stored energy source to drive the cartridge (160) during the medicament dispensing operation is not transferred to the needle cover (150)."

Claim 1 of auxiliary request 4 is the same as claim 1 of the main request except that the characterising portion reads as follows (amendments highlighted by the Board):

"characterized in that the force from the stored energy source that drives the cartridge (160) forward is opposed by the cartridge container (140) such that energy released from the stored energy source to drive the cartridge (160) during the medicament dispensing operation is not transferred to the needle cover (150), and in that the cartridge (160) further comprises a needle sheath (165) disposed about the needle (162), the needle sheath (165) being compressed between the cartridge container (140) and the cartridge (160) for preventing the energy of the energy source from being directly transferred through the cartridge (160) onto the needle cover (150) during a medicament dispensing operation."

Claim 1 of auxiliary request 4a is the same as claim 1 of auxiliary request 4 except that in the characterising portion, after the first occurrence of the expression "needle cover (150)", the following wording has been added:

"while the medicament is being dispensed through the needle (162)"

Claim 1 of auxiliary request 4b is the same as claim 1 of auxiliary request 4 except that in the characterising portion, after the first occurrence of the expression "needle cover (150)", the following wording has been added:

"after activation"

Claim 1 of auxiliary request 5 is the same as claim 1 of the main request except that the characterising portion reads as follows (amendments highlighted by the Board):

"characterized in that the force from the stored energy source that drives the cartridge (160) forward is opposed by the cartridge container (140) such that energy released from the stored energy source to drive the cartridge (160) during the medicament dispensing operation is not transferred to the needle cover (150), and in that the needle cover (150) has a surface operative to contact the injection site prior to a medicament dispensing operation, the surface being operative to receive a force to activate the automatic injector, and the surface having the opening (152a) to receive the needle (162) there though during the medicament dispensing operation."

Claim 1 of auxiliary request 6 is the same as claim 1 of the main request except that the characterising portion reads as follows (amendments highlighted by the Board):

"characterized in that the force from the stored energy source that drives the cartridge (160) forward is opposed by the front end of the cartridge container (140) such that ~~energy~~ the force released from the stored energy source to drive the cartridge (160) ~~during the medicament dispensing operation~~ is not transferred to the needle cover (150) during the medicament dispensing operation, in that the needle cover (150) has a surface operative to contact the injection site prior to a medicament dispensing operation, the surface being operative to receive a force to activate the automatic injector, and the surface having the opening (152a) to receive the needle (162) there though during the medicament dispensing operation, and in that the cartridge (160) further comprises a needle sheath (165) disposed about the needle (162), the needle sheath (165) being compressed between the cartridge container (140) and the cartridge (160) for preventing the force of the energy source from being directly transferred through the cartridge (160) onto the needle cover (150) during a medicament dispensing operation."

Claim 1 of each of the requests with ' is the same as claim 1 of each of the requests without ' but with the addition of the following wording at the end of the claim:

", the automatic injector further comprising a locking mechanism (156, 240, 243) for selectively holding the needle cover (150) in a first locked retracted position, and a second locked extended position, the locking mechanism (156, 240, 243) located within the housing (110) to protect

against tampering and dirt ingress, and wherein the medicament is rearwardly confined by a plunger (438)"

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

Main request - sufficiency of disclosure

The specific embodiment disclosed in the patent had been manufactured, was operational and could be reproduced without any undue burden by a person skilled in the art.

It was conceded that the feature of claim 1 of the patent as granted "such that energy released from the stored energy source to drive the cartridge (160) during the medicament dispensing operation is not transferred to the needle cover (150)" could lack clarity. However, lack of clarity was not a ground for opposition. Hence, the feature had to be interpreted in the light of the description, with a mind willing to understand the teaching of the patent as a whole.

The Opposition Division and the respondent had misinterpreted the feature under consideration. The expression "the stored energy source to drive the cartridge" should be read as simply designating the energy source. The reference to the medicament dispensing operation did not specify the moment in time when the energy was released to drive the cartridge. This was consistent with the previous occurrences, in the claim, of the expressions "a stored energy source capable of driving the cartridge" and "the force from the stored energy source that drives the cartridge (160) forward", which solely designated the energy

source. The expression "during the medicament dispensing operation" did not qualify the source of energy, but only stressed the moment in time when the claimed cartridge container opposed the force from the energy source.

"The medicament dispensing operation" as defined in the claim could not be interpreted broadly such as to designate the whole operation of the auto-injector, also including the short preparatory phase before injection. Instead, it only designated the phase when medicament was dispensed through the needle.

It was common ground that, according to the only embodiment described in the patent, the energy source transferred energy to the needle cover during the preparatory phase of the injection. Therefore, the broad interpretation of "the medicament dispensing operation", which contradicted the description, had to be ruled out as illogical when interpreting the claim and trying to make technical sense out of its wording.

The patent as granted, especially column 35, lines 25 to 29, taught that the force from the energy source was opposed by the cartridge container during the dispensing of the medicament, which prevented a kick back of the auto-injector. Hence, the interpretation according to which the medicament dispensing operation only designated the phase in which medicament was dispensed was consistent with the embodiment disclosed in the patent. Moreover, the claim wording did not specify that the energy released from the stored energy source was not transferred to the needle cover during the whole medicament dispensing operation.

The references to paragraph [0018] of the patent as

granted made by the Opposition Division and the respondent were of little relevance. The claims of the first parent application of the patent in suit, drafted for the United States, had been copied and pasted to constitute the aforementioned paragraph [0018]. Nothing could be concluded from the wording "injection sequence" or "injection operation" employed in this paragraph. There was at most a clarity and consistency issue.

It followed that the invention as defined in claim 1 of the patent as granted was sufficiently disclosed.

Auxiliary requests 4a and 4b - Article 123(3) EPC

Since the wording of claim 1 of the patent as granted did not specify that the energy released from the stored energy source was not transferred to the needle cover during the whole medicament dispensing operation, the addition, in claim 1 of auxiliary request 4a, that such transfer of energy did not take place while the medicament was being dispensed through the needle did not extend the scope of protection of the patent. The same held true for the feature added to claim 1 of auxiliary request 4b.

Another matter

The respondent had filed a curriculum vitae of a technical expert, Mr Gordon Row, which had been excluded from the public file and had not been sent to the appellant.

For reasons of equal treatment of the parties, the curriculum vitae should be forwarded to the appellant.

It was also requested that the curriculum vitae should not be excluded from public inspection. Even if it contained personal information, members of the public were entitled to make their own assessment whether such information was important for the case.

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

Main request - sufficiency of disclosure

The expression in claim 1 of the patent as granted that "energy released from the stored energy source to drive the cartridge (160) during the medicament dispensing operation" clearly required energy driving the cartridge during the medicament dispensing operation.

This meant, in particular, that the cartridge was moving during the medicament dispensing operation, which movement occurred prior to medicament flowing through the needle according to the disclosed operation of the automatic injector described in paragraph [0054] of the patent.

Also, the various uses of the automatic injector defined in the items in paragraph [0018] of the patent required movement of the cartridge during the medicament dispensing operation. Hence, the appellant's interpretation that the medicament dispensing operation should be read as only including the injection phase when medicament was flowing through the needle was contradicted by the patent.

According to the patent, forward movement of the cartridge took place also when the cartridge container was moving, which resulted in the needle cover being

moved. As such, energy was inevitably transferred to the needle cover during the medicament dispensing operation. Hence, the teaching of the patent did not enable the person skilled in the art to reproduce the claimed invention.

Auxiliary requests 4a and 4b

Auxiliary requests 4a and 4b were not admissible since in the statement of grounds, in particular pages 6 and 7, the appellant had not substantiated why the Opposition Division's decision with respect to these requests had to be set aside. Moreover, they did not comply with the requirements of Article 123(2) and (3) EPC.

Reasons for the Decision

1. The invention

The invention relates to an automatic injector for injecting a medicament into a user.

An automatic injector typically allows a user to self-administer a predetermined dose of a medicament composition subcutaneously or intramuscularly. It may be used in an emergency situation, for example to treat anaphylactic reactions and to administer antidotes for certain poisons, such as chemical nerve agents (paragraph [0004] of the patent).

The automatic injector according to claim 1 of the patent as granted includes a housing, a cartridge containing a medicament and including a needle assembly

with a needle, a cartridge container disposed within the housing, an actuation assembly providing a stored energy source capable of driving the needle to permit injection of the medicament into a user, and a needle cover.

It is a key feature of the claimed invention that the energy released from the stored energy source to drive the needle during the medicament dispensing operation is not transferred to the needle cover. This arrangement is for preventing a kick back effect from occurring. The auto-injector is not pushed away from the injection site during activation, in order to ensure that the proper dose of medicament is administered and that the proper needle extended length or proper needle penetration is maintained (paragraph [0054] of the patent).

2. Despite being duly summoned by communication dated 9 February 2021, the respondent/opponent 2 was not present as announced by letter dated 6 July 2021. In accordance with Rule 115(2) EPC and Article 15(3) RPBA 2020, the Board decided to hold the oral proceedings without this party.

3. Main request - sufficiency of disclosure

3.1 According to the characterising portion of claim 1 of the patent as granted "energy released from the stored energy source to drive the cartridge (160) during the medicament dispensing operation is not transferred to the needle cover (150)".

The plain meaning of this claim feature is that during the medicament dispensing operation the cartridge is driven by energy. This energy, which is released from

the stored energy source, is not transferred to the needle cover.

The previous occurrences of the term "stored energy source" in the claim, referred to by the appellant, do not change this meaning as they do not specify when the energy is transferred, or is not transferred, to the needle cover.

This meaning also makes technical sense. It imposes a functional requirement which the automatic injector according to claim 1 has to fulfil. This functional requirement is that transfer of energy from the stored energy source to the needle cover is excluded while the cartridge is being driven during the medicament delivery operation.

As a consequence, the medicament delivery operation must include the phase during which the cartridge is being driven by energy released from the stored energy source.

The appellant argued that the claim had to be interpreted in the light of the description and that the claim only excluded such transfer of energy to the needle cover during the injection of the medicament into the user.

The Board agrees that the patent discloses that during the injection of the medicament into the user no transfer of energy from the stored energy source to the needle cover takes place. However, it is not acceptable to disregard the plain and technically sensible meaning of a claim feature with the aim of making the claimed invention match the disclosure of the patent.

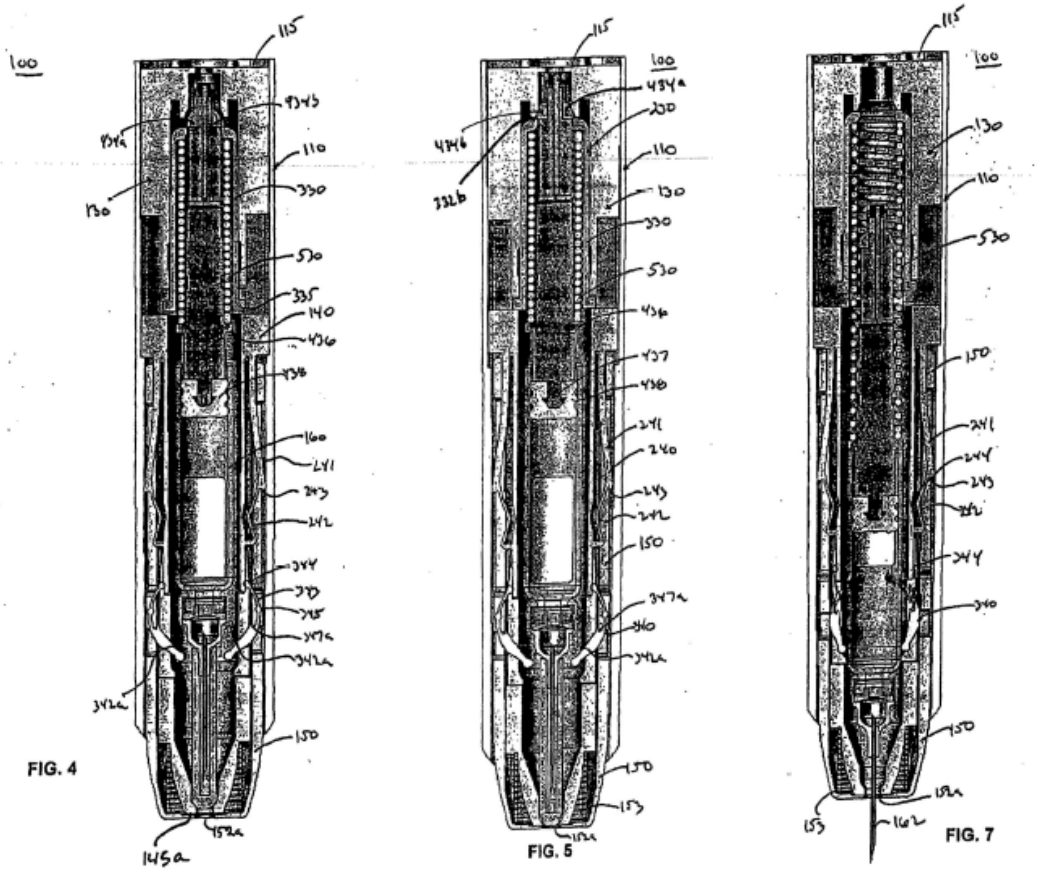
On the contrary, according to Article 84 EPC, the claims must define the matter for which protection is sought. Under Rule 43(1) EPC they must do so in terms of the technical features of the invention. With this aim in mind, it was the proprietor's choice and responsibility to draft the claims in an appropriate manner.

It is then for the Board to assess whether the patent discloses the claimed invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. If not, the patent cannot be maintained (Article 100(b) EPC in conjunction with Article 101(2) EPC).

The Board also notes that the description of the patent does not define the medicament delivery operation as excluding the phase in which the cartridge is being driven by energy released from the stored energy source. On the contrary, paragraph [0018] seems to disclose that this phase is part of the medicament delivery operation. The reasons why this paragraph has been included in the patent are not decisive in this respect.

It has therefore to be established whether the patent sufficiently discloses that transfer of energy from the stored energy source to the needle cover is excluded while the cartridge is being driven during the medicament delivery operation.

3.2 The patent discloses an automatic injector shown in Figures 4, 5 and 7 reproduced below.



This automatic injector includes a housing (110), a cartridge (160) including a needle assembly with a needle (162), a cartridge container (140), an actuation assembly (130) and a needle cover (150). The actuation assembly automatically releases the energy stored in the energy source when the needle cover is pressed against the injection site.

Figure 4 shows a condition before use.

To perform an injection, the user presses the end surface with opening 152a for needle 162 against an injection site.

This causes cartridge container 140 to move rearward within housing 110, such that movement of its ledge at the end opposite to the needle end causes the activation of actuation assembly 130. Figure 5 shows a condition in which the cartridge container has been moved rearward. Following this movement the energy stored in spring 530 is released. This drives cartridge container 140 back forward within housing 110, extends the needle through needle cover 150 and injects medicament into the user (Figure 7).

It is common ground that during the forward movement of cartridge container 140 within housing 110 until the ledge of the cartridge container contacts a retention surface of the housing, energy is also transferred to needle cover 150, which is driven forward together with the cartridge container.

Hence, in the embodiment described in the patent, energy from the stored energy source is transferred to the needle cover while the cartridge is being driven during the medicament delivery operation.

It is irrelevant whether the cartridge is moved forward only for a short time (and therefore energy is transferred to the needle cover only for a short time while the cartridge is being driven) during the medicament dispensing operation, as the claim excludes the energy transfer while the cartridge is being driven.

3.3 Therefore, the person skilled in the art is not provided with a teaching making the reproduction of the claimed invention possible.

As a consequence, the ground for opposition under Article 100(b) EPC prejudices the maintenance of the patent on the basis of the main request.

4. Auxiliary requests 1 to 4, 5, 6, 1' to 4', 5' and 6'

Claim 1 of each of auxiliary requests 1 to 4, 5, 6, 1' to 4', 5' and 6' clearly comprises the same (or a corresponding) problematic feature as claim 1 of the main request. The appellant has not disputed this finding.

It follows that the patent cannot be maintained on the basis of any of these requests either.

5. Auxiliary requests 4a, 4b, 4a' and 4b'

Compared with claim 1 of the patent as granted, claim 1 of each of auxiliary requests 4a, 4b, 4a' and 4b' has been amended with the aim of avoiding the limitation that transfer of energy from the stored energy source to the needle cover is excluded while the cartridge is being driven (during the medicament delivery operation).

As also found by the Opposition Division in the impugned decision, according to these requests the scope of protection of the patent would be extended with respect to the granted version. Automatic injectors in which such transfer of energy may take place would not have fallen within the scope of protection according to the granted version but could be within the scope of auxiliary requests 4a, 4b, 4a' and 4b'.

The appellant's argument that claim 1 of the patent as

granted did not specify that the energy released from the stored energy source was not transferred to the needle cover during the whole medicament dispensing operation is of no relevance. As explained under point 3 above, that claim was specifically limited to automatic injectors in which transfer of energy from a stored energy source to a needle cover was excluded during a certain phase of the medicament delivery operation, i.e. while the cartridge was being driven, not during the whole medicament delivery operation. Still, the amendments of claim 1 of auxiliary requests 4a, 4b, 4a' and 4b' are an attempt to remove this claim limitation.

As a consequence, auxiliary requests 4a, 4b, 4a' and 4b' cannot be allowed, for non-compliance with Article 123(3) EPC.

6. Since the patent cannot be maintained on the basis of any of the pending requests the appeal has to be dismissed.

7. The appellant also requested that Mr Gordon Row's curriculum vitae filed by the respondent on 20 February 2015 should be forwarded to it and should not be excluded from public inspection.

For reasons of transparency and equal treatment of the parties this curriculum vitae is to be forwarded to the appellant.

However, the Board notes that this curriculum vitae is of no relevance for the outcome of the present decision, in particular because there is no need to consider Mr Gordon Row's submissions. There is thus no reason to overrule the Opposition Division's decision

that the curriculum vitae should not be made public, also in view of the fact that it contains personal information.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

2. Mr Gordon Row's curriculum vitae filed on 20 February 2015 has to be forwarded to the appellant.

3. The request that Mr Gordon Row's curriculum vitae should not be excluded from public file inspection is rejected.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated