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Datasheet for the decision of 26 March 2025

Case Number: T 1045/23 - 3.2.01

Application Number: 10155967.2

Publication Number: 2204201

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

Language of the proceedings: EN

Title of invention:
Automatic injector

Patent Proprietor:
Meridian Medical Technologies, Inc.

Opponents:
1.ALK-ABELLO A/S
2.Keilitz Haines & Partner Patentanwälte PartGmbB

Headword:

Relevant legal provisions:
EPC R. 103(4)(c)
EPC Art. 83

Keyword:
Sufficiency of disclosure - (no)
Partial reimbursement of appeal fee - (yes)

Decisions cited:
T 0586/17

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1045/23 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 26 March 2025

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)
Representative:	Inspicos P/S Agern Allé 24 2970 Hørsholm (DK)
Respondent: (Opponent 2)	Keilitz Haines & Partner Patentanwälte PartGmbB Nigerstraße 4 81675 München (DE)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 3 May 2023 revoking European patent No. 2204201 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman G. Pricolo
Members: V. Vinci
O. Loizou

Summary of Facts and Submissions

I. The appeal of the appellant (patent proprietor) lies against the decision of the opposition division to revoke the European patent No. 2 204 201.

In its decision, the Opposition Division found that the ground for opposition raised by the opponent under Article 100(b) EPC was prejudicial to the maintenance of the patent as granted and that none of the auxiliary requests 1 to 63 complied with the requirements of Article 83 EPC. The European patent was thus revoked.

II. With a communication pursuant Article 15(1) RPBA dated 7 January 2025, the Board informed the parties that according to its preliminary assessment of the case, the appeal of the appellant (patent proprietor) was likely to be dismissed and the decision of the opposition division confirmed.

With a letter dated 25 February 2025, the appellant (patent proprietor) confirmed that the statement in their previous letter of 7 February 2025 had to be understood as a withdrawal of the request for oral proceedings scheduled by the Board on 20 May 2025.

The summons to oral proceedings dated 18 June 2024 were thus cancelled and the case decided in writing.

III. The appellant (patent proprietor) requested that the decision of the opposition division be set aside and that the patent be maintained as granted (main request) or, in the alternative, that the patent be maintained according to one of the auxiliary requests 1 to 63 underlying the decision under appeal, or according to

one of the auxiliary requests 64 to 127 filed with the statement of grounds of appeal.

The respondent (opponent 1) requested that the appeal be dismissed.

IV. Independent claim 1 as granted according to the main request reads as follows (labelling of the features according to the appealed decision):

(F1) *An automatic injector comprising:*

(F2) *a housing (110) having a retention step (112) formed on an inner surface of the housing (110);*

(F3) *a cartridge (160) having an opening (161) therein and containing a medicament,*

(F4) *the medicament rearwardly confined by a plunger (438) received through the opening (161),*

(F5) *the cartridge (160) including a needle assembly operative to dispense the medicament there through during a medicament dispensing operation, the needle assembly including a needle (162);*

(F6) *a cartridge container (140) disposed within the housing (110) and operative to receive the cartridge (160) therein,*

(F7) *the cartridge container (140) having a ledge (142) that abuts the retention step (112) of the housing (110) to limit movement of the cartridge container (140) within the housing (110) during a medicament dispensing operation,*

(F8) *the cartridge container (140) having a closed*

front end except for an opening (144) sized to receive the needle (162) there through during a medicament dispensing operation;

(F9) *an actuation assembly (130) providing a stored energy source capable of driving the plunger (438) within the cartridge (160) to dispense the medicament through the needle assembly, the actuation assembly (130) secured to the housing (110);*

(F10) *a needle cover (150) at least partially received within the housing (110),*

(F11) *the needle cover (150) extending beyond the housing (110) and having an enclosed end surface (152) operative to contact an injection site prior to a medicament dispensing operation,*

(F12) *the end surface (152) having an opening (152A) sized to receive the needle (162) there through during a medicament dispensing operation*

(F13) *a locking mechanism for selectively holding the needle cover (150) in a first locked position with respect to the housing (110) and in a second locked position with respect to the housing (110);*

(F14) *a needle cover spring assembly (153) for moving the needle cover (150) from the retracted first locked position to the extended second locked position,*

(F15) *wherein the actuation assembly (130) has an activation force necessary to release the stored energy source and the needle cover spring assembly provides a biasing force wherein the activation force is greater than the biasing force*

(F16) *and wherein the cartridge container is constructed and arranged such that the energy released from the stored energy source of the activation assembly, during dispensing of the medicament, is not transmitted to the needle cover."*

Independent claim 1 of each one of the auxiliary requests 1 to 15 and 32 to 47 contains the identical wording of feature F16 of claim 1 as granted requiring that *"the energy released from the stored energy source of the activation assembly, during dispensing of the medicament is not transmitted to the needle cover.".*

In independent claim 1 of each one of the auxiliary requests 16 to 31 and 48 to 63, the appellant (patent proprietor) chose *"inter alia"* to amend the above mentioned wording of feature F16 of claim 1 as granted as follows (amendment emphasized by the Board):

"the energy released from the stored energy source of the activation assembly, during dispensing of the medicament through the needle assembly is not transmitted to the needle cover.".

The set of claims of the auxiliary requests 64 to 127 are identical to the corresponding set of claims of the main and auxiliary requests 1 to 63. However, in these auxiliary requests paragraph [0016] of the description has been deleted.

Reasons for the Decision

1. The parties did not make any submission in reaction to the communication issued by the Board on 7 January 2025 pursuant Article 15(1) RPBA. The Board has thus no reason to deviate from its preliminary assessment of the case as presented in the above mentioned communication which is hereby confirmed and reads as follows:

MAIN REQUEST - PATENT AS GRANTED

Article 100(b) EPC

2. The ground for opposition pursuant to Article 100(b) in association with Article 83 EPC is prejudicial to the maintenance of the patent as granted as correctly found by the opposition division.

2.1 The appellant (patent proprietor) contested the conclusion of the opposition division that the patent as granted dis not comply with the requirements of Article 83 EPC because no sufficient information was provided to the person skilled in the art as to how to design and realize an injector capable to carry out the functionality required by feature F16 of claim 1, namely an injector in which *"the energy released from the stored energy source of the activation assembly, during dispensing of the medicament is not transmitted to the needle cover."* The appellant (patent proprietor) criticized the view of the opposition division that the skilled person was unable, in view of the information presented in the contested patent description, to decide between a narrow interpretation of the expression *"during dispensing of the medicament"* encompassing only the phase where the medicament flew through the needle and a broad interpretation of the

same expression also including the preparatory phase in which the cartridge was being driven forward by energy released from the energy source. In this respect, the appellant (patent proprietor) referred to T 586/17 relating to similar subject-matter indicated as evidence (D34) in the statement of grounds of appeal wherein, although it was acknowledged by the appellant (patent proprietor) that the wording of claim 1 was different, the board in that case came to the conclusion that claim 1 did not require any interpretation regarding the meaning of the expression *"during dispensing of the medicament"*. The appellant (patent proprietor) pointed out that the person skilled in the art construing the claim in the light of common general knowledge and with a mind willing to understand rather than with a mind desirous of misunderstanding certainly ruled out the broad interpretation suggested by the opposition division and focused on the only technically meaningful reading of the claim as a whole according to which the expression *"during dispensing of the medicament"* designated only the phase where the medicament flew through the needle, thereby excluding the preparatory phase before injection. In their view, this interpretation was consistent with and supported by the wording of preceding feature F5. In the appellant's (patent proprietor's) view, the claimed functionality could be achieved by the person skilled in the art without undue burden by designing the injector according to the only embodiment presented in detail in the contested patent (reference was made to Figures 1 to 7 and to paragraph [0052] in particular), namely by providing a stable abutment between the step (112) of the housing and the ledge (142) when the medicament starts to flow trough the needle. Furthermore, the appellant (patent proprietor) put forward that the arguments of the opposition division

and the respondent (opponent 1), namely that whether the energy released from the stored energy source of the activation assembly during dispensing of the medicament were transmitted to the needle cover or not depended on the force actually applied by the user, were based on unsupported allegations and mere speculations which as such had to be rejected.

2.2 The arguments put forward by the appellant (patent proprietor) are not convincing for the following reasons:

2.3 The Board notes that the opposition division came to the conclusion that the patent as granted did not comply with the requirements of Article 83 EPC irrespectively of the disputed interpretation of the expression *"during dispensing of the medicament"* in feature F16, i.e. of whether this expression should be understood broadly as meaning the whole medicament dispensing operation hence also encompassing the preparatory phase in which the cartridge container (140) moves towards the injection site but no medicament has been delivered yet, or narrowly as indicating only the time span starting from the moment in time when the medicament begins to flow trough the needle.

2.4 It is common ground that according to the only detailed embodiment disclosed in the patent, the energy source transfers energy to the needle cover during the preparatory phase of the injection, i.e. when the injector is pressed onto the injection site by the user. Therefore, if the broader interpretation for the expression *"during dispensing of the medicament"* in feature F16 of claim 1 is adopted, it is undisputed that the patent does not provide sufficient information

as to how to design an injector that achieves the functional requirement expressed by this feature.

2.5 Furthermore, the Board shares the view of the opposition division and the respondent (opponent 1) that even by adopting the narrow interpretation of the expression *"during dispensing of the medicament"* in feature F16 suggested by the appellant (patent proprietor), the patent does not contain sufficient information regarding how to to design and arrange the cartridge container such that the energy released from the spring (530) is not transmitted to the needle cover during dispensing of the medicament as required by claim 1. In fact, the energy generated by the spring (530) is not transmitted to the needle cover only when the ledge (142) and the step (112) of the housing are in stable abutment (see paragraph [0052] of the contested patent). Conversely - as correctly pointed out by the opposition division - if a slight gap between ledge (112) and retention step (142) is still present when the medicament starts to flow through the needle, a transfer of energy necessarily occurs between the actuation assembly (130) and the needle cover (150). This is at least due to the coupling between spring (530), cartridge container (140) and needle cover (150) similarly to the situation taking place during the preparatory phase. The Board thus concurs with the respondent (opponent 1) that the specification fails to disclose how it can be ensured that the ledge (142) and the step (112) reliably stay in mutual and stable abutment starting from the point in time when injection of medicament begins. In fact, even a slight gap remaining between the ledge (142) and the step (112) would prevent the achievement of the result required by feature F16. The Board thus follows the view of the opposition division and the respondent

(opponent 1) that whether the claimed result is achieved or not depends indeed on how the injector is used, i.e. on the magnitude of the force applied by the user, but also on the characteristic of the spring (530) that cannot be selected at will. In fact, the strength of the spring (530) must be mechanically balanced with the mechanical resistance of the materials used to manufacture the other components of the injector. Furthermore, the conclusions put forward in the declarations D5 and D16 supported by the respective videos D6 and D19 as well as the problem of the occurrence of axial oscillations referred to by the respondent (opponent 1) and discussed in document D7 (no prior art but cited as evidence of the technical context) support, in the Board's view, the conclusion of the opposition division that with the embodiment disclosed in the patent energy can be potentially transferred to the needle cover also during the injection phase.

2.6 In view of all the above, the Board confirms the finding of the opposition division that the invention according to the contested patent does not comply with the requirements of Article 83 EPC.

2.7 It follows that, irrespective of the assessment of the further objections raised by the respondent (opponent 1), the main request is not allowable.

AUXILIARY REQUESTS 1 to 127

Article 83 EPC

3. Independent claim 1 of each of the auxiliary requests 1 to 15 and 32 to 47 recites the identical feature F16 of claim 1 as granted. In the auxiliary requests 16 to 31

and 48 to 63, feature F16 of claim 1 as granted has been modified by specifying that dispensing of the medicament takes place "*through the needle assembly*" and this in an attempt to support the narrow interpretation of feature F16 adopted by the appellant (patent proprietor). To the same purpose, paragraph [0016] of the description associated with the auxiliary requests 64 to 127, the admittance of which was contested by the respondent (opponent 1), has been deleted while maintaining the wording of feature F16 identical to the wording of independent claim 1 of the main request and of the corresponding auxiliary requests 1 to 63.

3.1 However, as explained above under point 2.2 and ff. the reasoning of the opposition division in support of the objection of not compliance with the requirements of Article 83 EPC convincingly applies to both the narrow and broader interpretations of feature F16. Therefore, all the auxiliary requests suffer from the same issue raised under Article 83 EPC and are not allowable for the same reasons presented in the decision under appeal in respect to the main request and confirmed by the Board. The question of the admittance into the appeal proceedings of the auxiliary requests 64 to 127 raised by the respondent (opponent 1) can thus be let aside.

RULE 103(4)(c) EPC: PARTIAL REIMBURSEMENT OF THE APPEAL FEE

4. With a letter dated 25 February 2025, the appellant (patent proprietor) confirmed to the Board that the statement in previous letter dated 7 February had to be understood as a withdrawal of the request for oral proceedings. As this request was filed within the time limit set according to Rule 103(4)(c) EPC and no oral

proceedings took place a reimbursement of the appeal fee at 25% is justified.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

H. Jenney G. Pricolo

Decision electronically authenticated