Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 11 April 2024

Case Number: T 0227/22 - 3.2.01

Application Number: 12871394.8

Publication Number: 2825227

IPC: A61M5/20, A61M5/315

Language of the proceedings: EN

Title of invention:
MULTIPLE USE DISPOSABLE INJECTION PEN

Patent Proprietor:
Becton, Dickinson and Company

Opponents:
1.Ypsomed AG
2.Pawlowski, Adam
3.Bandpay & Greuter

Headword:

Relevant legal provisions:
EPC 1973 Art. 100(c), 123(2)

Keyword:
Added subject-matter (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0227/22 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 11 April 2024

Appellant: (Patent Proprietor)	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417-1880 (US)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstrasse 3 81675 München (DE)
Respondent: (Opponent 1)	Ypsomed AG Brunnmattstrasse 6 3401 Burgdorf (CH)
Representative:	SSM Sandmair Patentanwälte Rechtsanwalt Partnerschaft mbB Joseph-Wild-Straße 20 81829 München (DE)
Respondent: (Opponent 2)	Pawlowski, Adam Kancelaria EUPATENT.PL ul. Kilinskiego 185 90-348 Lodz (PL)
Representative:	Inspicos P/S Agern Allé 24 2970 Hørsholm (DK)
Respondent: (Opponent 3)	Bandpay & Greuter 30, rue Notre-Dame des Victoires 75002 Paris (FR)
Representative:	Bandpay & Greuter 11 rue Christophe Colomb 75008 Paris (FR)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 22 November 2021 revoking European patent No. 2825227 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman G. Pricolo
Members: A. Pieracci
O. Loizou

Summary of Facts and Submissions

I. An appeal was filed by the patent proprietor in the prescribed form and within the prescribed time limit against the decision of the opposition division to revoke the European patent No. 2 825 227.

II. In preparation for the oral proceedings the Board communicated its preliminary assessment of the case with a communication pursuant to Article 15(1) RPBA.

III. Oral proceedings before the Board took place on 11 April 2024. At the end of the oral proceedings the decision was announced.

IV. The final requests of the appellant (patent proprietor) are:

> that the decision under appeal be set aside and the patent be maintained in amended form according to the main request filed on 29 June 2020, or in the alternative that the patent be maintained in amended form on the basis of one of auxiliary requests 1 to 19, all requests filed with the statement of grounds of appeal.

V. The final request of respondent 2 (opponent 2) is:

> that the appeal be dismissed.

VI. Respondent 3 (opponent 3) has not filed any submissions in appeal proceedings. Opponent 1 withdrew their opposition and is not a party of these appeal proceedings.

VII. The arguments of the parties are dealt with in detail in the reasons of the decision.

VIII. Claim 1 of the patent as amended according to the main request (features numbering according to the decision of the opposition division), reads as follows:

"1 A medication injection pen, comprising:
1.1 a housing (1);
1.2 a dose set knob (2) rotatable with respect to said housing (1);
1.5 a dose stop member (71) to prevent the setting of a dose that is larger than the remaining amount of medication;
1.3 a brake assembly (36)
1.3.1 disposed in said housing (1) and
1.3.2 having a ratchet member (43); and
1.4 a driver (21) characterized in that said driver (21)
1.4.1 includes at least one external tooth (57) engaging said ratchet member (43), wherein said at least one external tooth (57) extends axially and said ratchet member (43) extends axially;
1.4.2 wherein during dose setting and dose correcting, stopping surfaces (59) of said at least one external tooth (57) of said driver (21) engage stopping surfaces (49) of teeth (46) of ratchet member (43) to substantially prevent said driver (21) from rotating with respect to said dose set knob (2), and
1.4.3 during an injection, said driver (21) moves into locking engagement with said dose set knob (2) thereby overcoming friction between said ratchet member (43) and said driver (21) to allow said driver (21) to rotate with said dose set

knob (2)."

IX. Claim 1 of the patent as amended according to auxiliary requests 1 to 13 also includes the above-mentioned feature 1.4.2 of claim 1 according to the main request.

This feature is amended in claim 1 of auxiliary requests 14 to 16 by replacing "said at least one external tooth" by "said external teeth". In claim 1 of auxiliary request 17 this feature is additionally amended by replacing the term "ratchet member" by "ratchet disk".

In claim 1 of auxiliary requests 18 and 19 this feature - as amended in claim 1 of auxiliary request 17 - is followed by the additional feature "wherein during dose setting, the dose set knob (2) rotates relative to the setback member (9) and therefore also the dose stop member (71), wherein during dose correcting, the sloped surfaces (48, 58) provide for friction between said ratchet disk (43) and said driver (21)".

Reasons for the Decision

1. Added subject-matter of claim 1 of the patent as amended according to the main request (Article 100 c) and 123(2) EPC)

1.1 The patent proprietor (see the statement setting out the grounds of appeal, point 3.2, pages 6 to 8) contests the finding of the opposition division (see the appealed decision, page 13, last paragraph – page 14, fourth paragraph) that contrary to Article 123(2) EPC subject-matter has been added by feature 1.4.2 (see feature analysis in point VIII above) introduced during prosecution of the patent, the feature reading:

"wherein during dose setting and dose correcting, stopping surfaces (59) of said at least one external tooth (57) of said driver (21) engage stopping surfaces (49) of teeth (46) of ratchet member (43) to substantially prevent said driver (21) from rotating with respect to said dose set knob (2)".

This is because, so the opposition division, the prevention of rotation through the stopping surfaces during dose correcting is not to be derived from paragraph [0059] of the original application contrary to the opinion of the patent proprietor.

1.2 The Board cannot follow the arguments of the patent proprietor (see the statement setting out the grounds of appeal, page 7, third and fourth paragraph) that support for feature 1.4.2 is provided in paragraph

[0005] of the application as originally filed, reading:

"The engagement between the ratchet member and the at least one external tooth substantially prevents the driver from rotating with respect to the dose set knob during dose setting and dose correcting"

since stopping surfaces, as required by feature 1.4.2, are not mentioned in this paragraph.

1.3 The Board is also not convinced by the argument of the patent proprietor (see letter dated 12 October 2023, page 2, fourth paragraph) that
"the original disclosure is found in paragraph [0054] (disclosure of the dose set knob and setback member 9), paragraph [0055] (disclosure of the driver 21 and setback member 9), paragraph [0056] (disclosure of the ratchet member 43), paragraphs [0057] and [0058] (disclosure of the dose setting) and paragraph [0059] (disclosure of the dose correction) as well as Figs. 2 (disclosure of relative arrangement of all elements), Fig. 7A and 7B (detailed disclosure of dose set knob 2 and teeth 54), Fig. 10 (disclosure of stopping surface 49), Figs. 11A to 11C (disclosure of ratchet member 43), and Fig. 5A (disclosure of teeth 55)".

This is so because in none of these passages it is to be derived that during dose correcting the stopping surfaces of said at least one external tooth of the driver engage stopping surfaces of teeth of ratchet member to substantially prevent said driver from rotating with respect to said dose set knob.

1.4 The Board is also not convinced by the argument of the patent proprietor (see the statement setting out the

grounds of appeal, page 8, first paragraph) that paragraph [0059] provides support for the claimed feature since it can be derived from this paragraph that

"during operation, a user would first rotate the dose set knob to set a desired dose – clearly "the stopping surfaces" would engage during the dose setting to prevent the driver from rotating. If the user then decides to correct the set dose by rotation in the opposite direction, at the start of the dose correcting, the stopping surfaces are still engaged in the same position and remain engaged in this position. Therefore, the configuration where the stopping surfaces are engaged, as recited in claim 1, results in the friction between the ratchet member and the driver sufficient to preventing the driver from rotating with respect to the dose set knob during dose correcting".

The Board is unable to find in paragraph [0059] of the originally filed application the same information as the one identified by the patent proprietor.

1.5 Paragraph [0059] reads:

"To correct a set dose that may have been set too high, the user rotates back the dose set knob 2 in the opposite direction. Rotation of the dose set knob 2 in this direction is not transferred to the setback member 9 due to the one-way ratchet between the driver 21 (to which the setback member 9 is rotationally fixed) and the ratchet disk 43, as shown in Fig. 3. The friction between the teeth 54 and 55 of the dose set knob 2 and the setback member 9 is not large enough to overcome the friction between the driver flange 56 and the spring-biased ratchet disk 43. Thus, the dose set knob

2 can be rotated back to correct a set dose without causing rotation of the setback member 9 in this direction, although the setback member 9 will move axially due to the engagement of the setback member keys 24 in the driver slots 27. Accordingly, the dose set knob teeth 54 slip past the setback member teeth 55, which is prevented from rotating, to provide a clicking noise during dialing back of the dose, just as during normal dose setting."

It cannot be directly and unambiguously derived from the above paragraph that the "stopping surfaces" remain engaged during dose correcting as maintained by the patent proprietor.
Furthermore, as found by the opposition division (see the appealed decision, page 14, third paragraph), the fact that during dose correcting the stopping surfaces **engage to prevent the driver to rotate** is also not to be derived from this passage. The direction of movement during dose correcting is in the reverse direction with respect to dose setting, in which the "stopping surfaces" engage, therefore the stopping surface cannot interact in the way claimed contrary to what argued by the patent proprietor but, as argued by the opponent, even if in contact they would rather tend to detach.

1.6 The patent proprietor also argued (see the letter dated 6 December 2022, page 3, sixth and seventh paragraphs) that there is no other engagement apart for the one between the stopping surfaces as claimed, so that such engagement should be the one preventing the driver to rotate with respect to the dose set knob mentioned in paragraph [0005]. Furthermore the interaction between the sloped surfaces and the driver does not prevent the rotation but allows for the "dial back" in the reverse direction.

The Board disagrees.

The fact that the interaction between the sloped surfaces and the driver allows the dial back in a reverse direction does not imply an engagement between the stopping surfaces preventing rotation of the driver during dose correcting.

The argument that there is no other form of engagement apart from the one of the stopping surfaces cannot be followed since the sloped surfaces do engage with each other (see the drawings at page 12 and 13 of the letter of the patent proprietor dated 12 October 2023) .

Moreover, as disclosed in paragraph [0059] of the original application and already discussed above, the rotation of the driver during dose correcting is prevented through the fact that the friction between the teeth 54 and 55 of the dose set knob 2 and the setback member 9 is not large enough to overcome the friction between the driver flange 56 and the spring-biased ratchet disk 43 and not because of the engagement of the stopping surfaces.

1.7 The Board does not follow the further argument put forward by the patent proprietor at the oral proceedings that paragraph [0059] does not indicate between which surfaces the friction takes place, so that it cannot be derived that the friction mentioned therein is the one between the sloped surfaces. This is because it is evident to a person skilled in the art that, since the friction between the driver flange 56 and the spring-biased ratchet disk 43 has to prevent rotation of the driver, it has to act against the direction of motion of the driver and thus it can

only be the friction between the sloped surfaces, as also apparent from the drawings submitted by the patent proprietor at page 12 and 13 of their letter of 12 October 2023.

1.8 The arguments of the patent proprietor in relation to the constraints provided by the transverse wall 60 on the movement of the driver, to the spring 41 which forces the ratchet disk 43 against the flange of driver 56 providing the engagement of the teeth 46 and 47 and in relation to the decomposition of the forces presented in the letter dated 12 October 2023 (see the drawings on page 12 and 13 and the related discussion) are not relevant as they do not address the issue of the disclosure of the prevention of the rotation of the driver by the stopping surfaces which is claimed by the contested feature.

1.9 The Board is therefore not convinced by the arguments of the patent proprietor that the opposition division erred in finding that claim 1 according to the main request contains subject-matter extending beyond the content of the application as originally filed.

2. Auxiliary request 1 to 17

The patent proprietor agreed at the oral proceedings that analogous considerations as for the main request apply to auxiliary requests 1 to 17. The Board in fact finds that since Claim 1 of auxiliary requests 1 to 17 comprises the feature of the stopping surfaces preventing rotation of the driver during dose correcting, auxiliary requests 1 to 17 also contain subject-matter extending beyond the content of the application as originally filed and are thus not allowable.

3. Auxiliary requests 18 and 19

3.1 The patent proprietor argued that auxiliary requests 18 and 19, corresponding to auxiliary requests 8 and 9 that were not admitted in the proceedings by the opposition division, should be admitted into the appeal proceedings and that these requests, by indicating that there is friction between the sloped surfaces, clarify the interaction between the stopping surfaces to prevent rotation of the driver.

3.2 The Board is not convinced and rather concurs with the opponent that also the above requests are not allowable for the following reasons.

Although it is correct that in claim 1 of auxiliary requests 18 and 19 the presence of friction between the sloped surfaces is specified by claiming that:

"wherein during dose correcting, the sloped surfaces (48, 58) provide for friction between said ratchet disk (43) and said driver (21)",

such friction is in no way linked in the claim to preventing rotation of the driver during dose correcting, which, as in the previous requests, is instead still linked to the engagement of the stopping surfaces by the feature:

"wherein during dose setting and dose correcting, stopping surfaces (59) of said external teeth (57) of said driver (21) engage stopping surfaces (49) of teeth (46) of ratchet disk (43) to substantially prevent said driver (21) from rotating with respect to said dose set knob (2)".

Therefore also claim 1 of auxiliary requests 18 and 19 includes subject-matter extending beyond the content of the application as originally filed and therefore these requests are thus not allowable.

3.3 In view of the above finding there is no need to address the issue of admittance into the proceedings of auxiliary requests 18 and 19 which was objected by opponent 2.

4. Conclusions

In view of the above findings the appeal cannot be allowed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Vottner G. Pricolo

Decision electronically authenticated