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Datasheet for the decision of 11 July 2017

Case Number: T 0433/12 - 3.2.02

Application Number: 01272097.5

Publication Number: 1349593

IPC: A61M5/24, A61M5/315, A61M5/172, A61M5/145, A61M5/142

Language of the proceedings: EN

Title of invention:
PEN-TYPE INJECTOR HAVING AN ELECTRONIC CONTROL UNIT

Patent Proprietor:
Sanofi-Aventis Deutschland GmbH

Opponent:
TecPharma Licensing AG

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 100(c)
RPBA Art. 12(4)

Keyword:
Fresh ground for opposition - admitted (no)
Document admitted into the proceedings (yes)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:
G 0009/91, G 0010/91, G 0001/95

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

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Case Number: T 0433/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 11 July 2017

Appellant: (Patent Proprietor)	Sanofi-Aventis Deutschland GmbH Brüningstraße 50 65929 Frankfurt am Main (DE)
Representative:	Derry, Paul Stefan Venner Shipley LLP 200 Aldersgate London EC1A 4HD (GB)
Appellant: (Opponent)	TecPharma Licensing AG Brunnmattstrasse 6 3401 Burgdorf (CH)
Representative:	Schwabe - Sandmair - Marx Patentanwälte Rechtsanwalt Partnerschaft mbB Joseph-Wild-Straße 20 81829 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 25 January 2012 concerning maintenance of the European Patent No. 1349593 in amended form.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	P. L. P. Weber
	M. Stern

Summary of Facts and Submissions

I. The appeals of the opponent and patent proprietor have been filed against the decision of the Opposition Division posted on 25 January 2012 and finding that, following the amendments according to the patent proprietor's fourth auxiliary request made during the opposition proceedings, the patent and the invention to which it related met the requirements of the Convention.

II. Although in the notice of opposition the box for the ground for opposition under Article 100(c) EPC was crossed in Form 2300, no argument relating to this ground for opposition was presented in the notice itself. The Opposition Division refused to admit this ground into the proceedings when the opponent wished to do so in the first-instance oral proceedings (point 2.1 of the reasons for the decision).

III. The opponent filed its notice of appeal on 16 February 2012 and paid the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 31 May 2012.

IV. The patent proprietor filed its notice of appeal on 22 March 2012 and paid the appeal fee on the same day. The statement setting out the grounds of appeal was filed on 4 June 2012.

V. Oral proceedings were held on 11 July 2017.

The final requests of the parties at the oral proceedings were the following:

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

The appellant (patent proprietor) requested that the patent be maintained on the basis of the documents found in the impugned decision to meet the requirements of the EPC.

The appellant (patent proprietor) did not agree to the ground for opposition under Article 100(c) EPC being admitted into the appeal proceedings.

The main request (patent as granted) and the first to third auxiliary requests filed with letter dated 4 June 2012 were withdrawn.

The appellant (patent proprietor) requested additionally that document D12 not be admitted into the appeal proceedings.

VI. Documents cited in the appeal proceedings:

Priority document GB 0031466.6
D9: WO-A-01/26710
D12: WO-A-99/07425

VII. Claim 1 of the documents which were found in the impugned decision to meet the requirements of the EPC reads as follows (filed as amended fourth auxiliary request during the oral proceedings, with differences over claim 1 of the granted patent highlighted by the Board):

"An injection device having

a drive mechanism (42) to expel selectively a dose of medicament from a medicament cartridge (40) through a needle unit (22),

an electronic control unit to control the drive mechanism (42),

dose buttons (12, 14) to select a desired dosage, and

a dispense button (18) to generate a dispense button signal to the electronic control unit indicative of the dose to be expelled and

an arm button (16), in which ~~an~~ the arm button (16) causes a first arm button signal to be sent to the electronic control unit to permit the dose to be expelled,

wherein the arm button (16) is linked to a cover detection switch (28) such that the arm button will only function to arm an injector (2) when a cover (6) is not present."

VIII. The appellant (opponent)'s arguments relevant for the decision can be summarised as follows:

The last two features of claim 1 contained added subject-matter, so the ground for opposition pursuant to Article 100(c) EPC prejudiced the maintenance of the patent. There could be no interest in maintaining an invalid patent.

Moreover, in claim 1 it was not clear whether the desired dosage selected with the dose buttons was the same as the dose to be expelled indicated by the

dispense button signal. This lack of clarity even led to insufficiency of disclosure.

Novelty in view of D9

The wording of claim 1 did not require explicitly that the elements listed be separate. The dose buttons of D9 fulfilled two functions: allowing selection of the desired dosage and making the dispense button active.

D12 had been filed with the statement setting out the grounds of appeal and should be admitted into the appeal proceedings.

Novelty in view of D12

The same analysis as above applied here. The presence of an arm button in the claim had to be understood as the presence of an arming function, which was also disclosed in D12 in terms of the cover. The cover could be seen as the arm button of claim 1, since it fulfilled the same function.

Inventive step

The priority of the patent in suit was not validly claimed because the functions of the arm button and dispense button as mentioned in the claim were not disclosed in the priority document.

Having in mind the most general way of reading the features of the claim, further developing the device according to D12 and using his common general knowledge, the person skilled in the art would arrive at the subject-matter of claim 1 in an obvious way.

IX. The appellant (patent proprietor)'s arguments are essentially those underlying the reasons for the present decision as set out below. Concerning the admissibility of D12, it took the view that this document could have been filed earlier. Moreover, if admitted, the appellant (patent proprietor) would not have been able to have any decision based on D12 examined by two instances. Therefore D12 should not be admitted into the proceedings.

Reasons for the Decision

1. The appeals are admissible.

2. The invention

The invention is about a pen-type injector having an electronic control unit, a drive mechanism, an arm button and a dispense button. The dispense button can only be activated once the arm button has been, and the arm button can only be activated when a cover sensor indicates that the cover is no longer present.

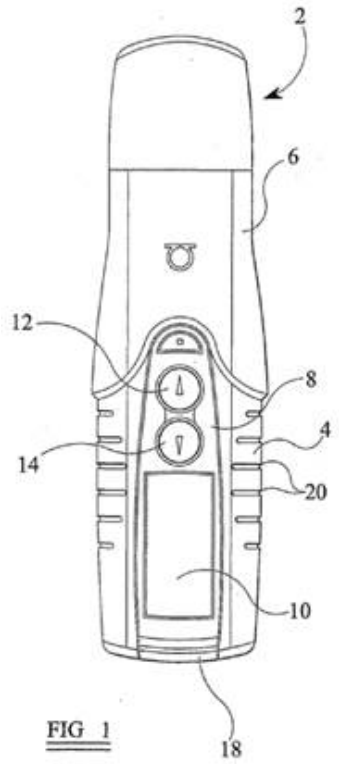


FIG 1

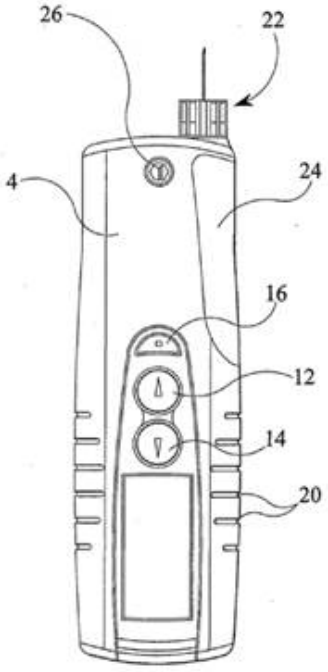


FIG 2

3. Since the appellant (patent proprietor) withdrew its main request (patent as granted) and the first to third auxiliary requests filed with letter dated 4 June 2012, and its final request is equivalent to a request for dismissal of the appeal of the opponent, its appeal appears to be moot and no longer requires a decision.

4. Added subject-matter

In its written submissions in the appeal proceedings the appellant (opponent) argued that the last two features of the claim added subject-matter, so the ground for opposition under Article 100(c) EPC prejudiced the maintenance of the patent.

In its notice of opposition, on Form 2300, the appellant (opponent) had crossed the box indicating that said ground was amongst those regarded as prejudicial to maintenance of the patent. However, no

arguments in support of this ground were presented in the notice of opposition. Subsequently the Opposition Division refused to consider this ground for opposition when the opponent eventually substantiated it in the first-instance oral proceedings (impugned decision, Reasons, point 2.1).

The last two features of the claim were contained in claim 1 of the patent as granted, so they do not constitute amendments which, pursuant to G9/91, Reasons, point 19 (OJ 1993, 408), the Board has the power to examine ex officio for compliance with the requirements of the EPC.

Concerning patents as granted, in G10/91 (OJ 1993, 420, Reasons, point 3) the Enlarged Board of Appeal decided that "*Fresh grounds for opposition may be considered in appeal proceedings only with the approval of the patentee.*"

The appellant (patent proprietor) did not give its approval to a new ground for opposition being admitted into the appeal proceedings.

Hence, it remains to be examined whether crossing the relevant box in Form 2300 and/or the Opposition Division's discretionary decision not to admit this ground for opposition into the first-instance proceedings mean that the ground was present in those proceedings.

In its decision G1/95 (OJ 1996 EPO, 615) the Enlarged Board of Appeal stated the following under Reasons, point 5.3:

"*The Enlarged Board in G 10/91 first used the term "a fresh ground for opposition" in paragraph 18, in the context of considering the proper application of Article 114(1) EPC during opposition appeal proceedings (see paragraph 1.2 above). It is clear that this term is intended to refer to a ground for opposition which was neither raised and substantiated in the notice of opposition, nor introduced into the proceedings by the Opposition Division in application of Article 114(1) EPC and in accordance with the principles set out in paragraph 16 of G 10/91*" (emphasis added by the Board).

In the present case the ground was not substantiated in the notice of opposition and, as explained, was also not introduced into the proceedings by the Opposition Division.

The appellant (opponent) presented no further reasons why this discretionary decision by the Opposition Division should be revised, and the Board does not see any either.

Hence, the ground for opposition according to Article 100(c) EPC was not in the opposition proceedings and the Board has no power to examine it in the appeal proceedings.

5. The appellant (opponent) argued that claim 1 lacked clarity (Article 84 EPC) because it was not clear whether the desired dosage selected with the dose buttons was the same as the dose to be expelled indicated by the dispense button signal. It contended that this lack of clarity even led to insufficiency of disclosure (Article 83 EPC).

The Board shares the opinion of the appellant (patent proprietor) in this respect. The wording used in the claim that the dispense button generates a dispense button signal to the electronic control unit indicative of the dose to be expelled has to be understood, in the context of the patent as a whole, as simply meaning that the dispense button, when activated, sends a binary yes signal to the control unit indicating that the selected dose is to be expelled. Nothing different has been described or suggested in the patent in suit.

Therefore claim 1 complies with Articles 83 and 84 EPC.

6. Admissibility of D12

The appellant (patent proprietor) considered that the appellant (opponent) could have submitted D12 earlier, i.e. during the first-instance proceedings, and that, if it gave rise to any adverse decision, the appellant (patent proprietor) would not have been able to benefit from proceedings before two instances. D12 should therefore not be admitted into the proceedings.

The appellant (opponent) filed D12 together with its statement setting out the grounds of appeal and used it in particular to substantiate a novelty objection. According to Article 12(4) RPBA, everything presented by the parties with the statement setting out the grounds of appeal is to be taken into account by the Board if and to the extent it relates to the case under appeal and the arguments relied on are expressly specified, which is the case here.
While the same paragraph also empowers the Board to hold inadmissible facts, evidence or requests which could have been presented in the first-instance proceedings, the Board considers that this is not

decisive in the present case because the version of the claims found to meet the requirements of the Convention was filed shortly prior to the oral proceedings before the first instance. Moreover, there is no absolute right to have all decisions examined by two instances.

Hence, D12 is admitted into the appeal proceedings pursuant to Article 12(4) RPBA.

7. Novelty

During the oral proceedings the appellant (opponent) limited its novelty objections to one based on D9 and one based on D12.

Moreover, the Board notes that during the examination of novelty both parties have interpreted the feature that the dispense button should generate a dispense button signal to the electronic control unit indicative of the dose to be expelled as being a simple binary signal that either triggers the injection or not.

7.1 Novelty in view of D9

The injection device disclosed in D9 is meant to work in an air-shot mode and in an injection mode. The air-shot mode is to free the injector of any air it might contain before starting an injection. The inventors in this document did not wish to have an additional button for changing from one mode to the other (page 2, lines 24 to 26), so the change of mode is operated differently. The electronic circuit is in air-shot mode until it receives a signal from one of the two dose-setting buttons. At that moment it switches to injection mode (page 6, lines 22 to 25), in which it is possible to set the dose and inject it.

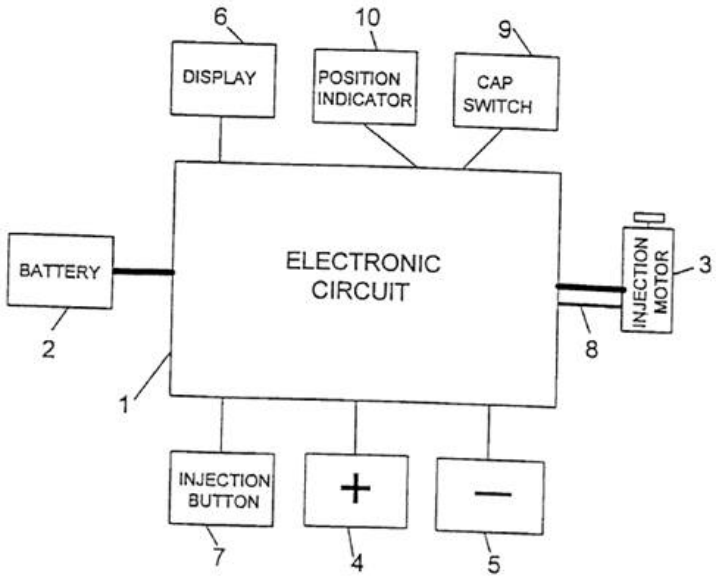


Fig. 1

The appellant (opponent) argued that the dose-setting buttons of D9 had the dual function of allowing selection of the desired dosage and of making the dispense button active and thus permitting the dose to be expelled. The wording of claim 1 did not require that the dose buttons be separate buttons from the arm button.

The Board does not share this opinion. The claim wording lists the items included in the injection device, and this list contains an arm button and dose buttons. The normal way to read such a claim is that the items listed are meant to be different items, unless there is a special reason to do otherwise. The embodiment described in the patent in suit includes an arm button 16 and two dose-setting buttons 12, 14 (separate from the arm button 16), which is in line with the function of the arm button indicated in the description, e.g. in paragraph 28, first sentence: "*The function of the arm button 16 is to make the dispense*

button 18 active". This feature is intended to avoid inadvertently pressing the dispense button e.g. before the dose has been definitively set with the dose-setting buttons. There is no other indication in the patent in suit that the two functions could be integrated in one and the same button(s). Hence, no special reason is apparent from the patent in suit for not regarding the arm button and the dose buttons as separate items.

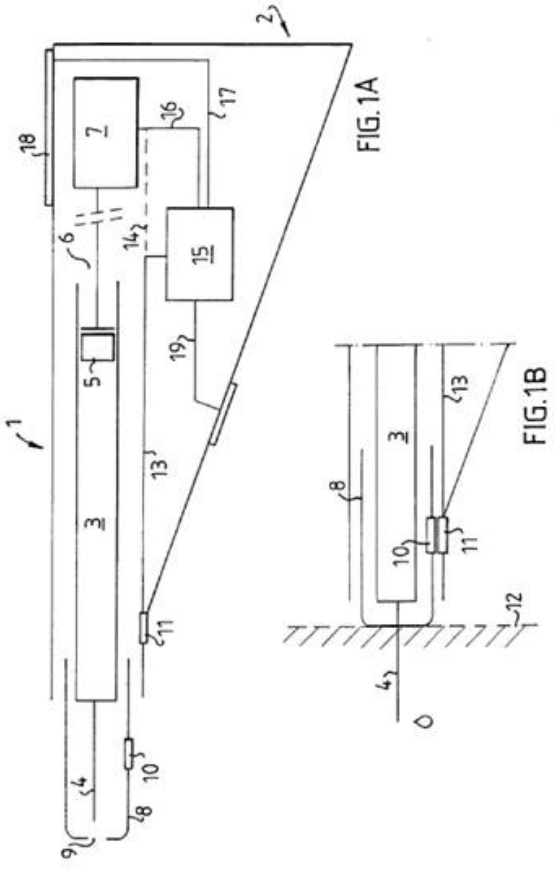
Hence, the device of D9 does not have a distinct arm button, or a safety feature preventing premature firing of the injection. There is no button additional to the dose-setting buttons which needs to be pressed before the injection can be triggered by pressing the delivery button.

At least for the reason given above, the subject-matter of claim 1 is novel over D9.

7.2 Novelty in view of D12

This document describes injection devices used for various kinds of administration, including "*entirely continuous infusion, continuous infusion with varying flow or intermittent infusions or injections with repeated either equal or varying doses*" (page 5, lines 9 to 11). One object of the invention of D12 is to prevent or mitigate the consequences of unintended actions or misuse (page 3, lines 15 and 16). After a general description of the elements constituting the injection device (page 4 to 20), one embodiment of an automated injection device is described more specifically in relation to Figures 1A and 1B. In this embodiment, the cover 8 covering the needle is pushed proximally when the needle penetrates the body of the

patient. Two switch elements 10, 11 co-operate when the cover is sufficiently proximal to indicate to the control unit 15 via an electromagnetic signal that the injection can be triggered. This is explained on page 21, lines 24 to 28: "*The processor 15 may be arranged to directly trigger the control signals upon reception of a proper electromagnetic signal 13, or preferably also await for a manual control button operation signal 19 to thereby treat the proper electromagnetic signal 13 only as an enabling signal before manual triggering takes place.*"



The appellant (opponent) considered that all the features of claim 1 could be read into the device described in D12. In particular, the feature of an arm button in the claim could only be understood as an

arming function which was also present in this embodiment of D12. The cover 8 could anyway be considered as a button in the sense of the patent in suit, since when pressed it also served to make the dispense button active. Moreover, the elements constituting the injection device mentioned in the claim were not specified as necessarily being separate elements, so this document was novelty-destroying.

For a disclosure to be novelty-destroying the claimed features must be directly and unambiguously derivable from that disclosure. In the Board's opinion, several features of claim 1 are not disclosed by D12. While it is indicated on page 21, lines 18 to 23 that the automated device shown can include "*dose setting and monitoring routines*", there is no indication as to how the dose is actually set. More specifically, there is no indication that dose buttons are used for that purpose, as required by claim 1. Furthermore, while it can be deduced from the above-mentioned sentence referring to a "*manual control button operation signal 19*" (emphasis added) and "*manual triggering*" that a dispense button must be present, no arm button is disclosed in D12.

In the device according to D12, cover detection switch 11 detects the retracted position of the cover in order to allow the triggering of the injection, whereas the device claimed requires a cover detection switch to detect the absence of the cover, which will render an arm button active, and pressing the arm button will permit the dose to be expelled by rendering the dispense button active. In other words, in D12 the cover is retracted and not withdrawn, and it is the cover detection switch 11 which renders the dispense

button active, not a separate arm button as required by claim 1 of the patent in suit.

Hence, the subject-matter of claim 1 is novel over D12.

7.3 Therefore, the subject-matter of claim 1 is novel pursuant to Article 54 EPC.

8. Inventive step

During the oral proceedings the appellant (opponent) limited its lines of argument in support of lack of inventive step to the following:
D9 combined with common general knowledge
D12 combined with common general knowledge
D9 combined with D12.

8.1 Validity of the priority of the patent in suit

The international publication date of D9 is 19 April 2001, and the patent in suit has a filing date of 21 December 2001 and a priority date of 22 December 2000. Therefore, D9 will only be prior art under Article 54(2) EPC, and thus usable for assessing inventive step, if the priority claim was not valid.

The appellant (opponent) argued that the priority document did not disclose a signal generated by the dispense button and sent to the control unit; the link could only be mechanical, and nor did the arm button generate a signal to the electronic control unit to permit the dose to be expelled.

The Board does not share this opinion. In the priority document it is mentioned on page 8, line 23 that "*The dispense button 18 allows a user to initiate dispensing*

of the dosage", and on page 6, line 12 that "*The function of the arm button 16 is to make the dose button 18 [meaning, obviously, the dispense button 18] active.*" The functions of these buttons are thus clearly stated.

It is further mentioned on page 5, lines 19 to 21 that "*The injector 2 is provided with an electronic control unit. The electronic control unit is coupled both to the drive mechanism and a user interface. The user interface includes the display panel 10 as well as the user operable buttons (and associated contacts).*"

Hence, the user-operable buttons (including the arm button and the dispense button) have associated contacts, and are part of the user interface which is coupled to the electronic control unit, which itself is also coupled to the drive mechanism. The associated contacts are shown in Figure 3 and mentioned on page 4, lines 9 to 11 (e.g. arm contact 32, dispense contact 19). It follows that the only interpretation which makes technical sense is that the pressing of the arm button or dispense button sends a signal to the control unit corresponding to the explained functions of the respective buttons (these functions being the same as those recited in the claim wording). There is no indication in the priority document as a whole that the arm button and dispense button could have different functions or function in a different way, in particular mechanically.

Therefore the priority of the patent in suit was validly claimed, and document D9 cannot be used in support of an inventive-step objection.

8.2 Inventive step starting from D12

As explained above (point 7.2) D12 does not disclose:

- dose buttons to select a desired dosage
- an arm button causing a first arm button signal to be sent to the electronic control unit to permit the dose to be expelled
- the arm button being linked to a cover detection switch such that the arm button will only function to arm an injector when a cover is not present.

The appellant (opponent) proposed several different ways of reading the claim wording which would lead to fewer differentiating features. In particular, it took the view that there was no indication in the claim wording that the constitutive elements had to be separate. It further argued that the retractable cover had to be seen as an arm button, or that – as the dispense button signal was mentioned in the claim as indicative of the dose – this signal could be a signal for a display.

As already explained above during the discussion of novelty, in the patent in suit as a whole there is no apparent reason why a claim wording including an explicit separate listing of constitutive elements fulfilling separate functions would also have been intended to encompass elements fulfilling several of the separate functions. For the same reason, when the claim wording requires an arm button and a cover, these elements cannot be one and the same. Lastly, the dispense button, as its name indicates, is for triggering the injection, as was accepted and even suggested by the appellant (opponent) during the examination of novelty.

As also already indicated above, one object of the invention described in D12 is to prevent or mitigate the consequences of unintended actions or misuse (page 3, lines 15 and 16). In the device shown in Figures 1A and 1B this is done by using the electromagnetic signal 13 coming from the cover rear position detection switch 11 as an enabling signal before manual triggering can take place. In other words, when the dose is being set, and even after the dose has been set but before the injection needle has been inserted into the patient's body, pressing the dispense button does not have any effect. Pressing the dispense button will only trigger the injection after the electronic control unit has received a signal from switch 11 indicating that the cover is in its retracted position, and thus that the needle is in the body. This device thus excludes inadvertently triggering the injection, e.g. while setting the dose.

Hence, incorporating the differentiating features into the device according to D12 would mean completely redesigning it to integrate a removable cover and an arm button as claimed.

As mentioned by the appellant (patent proprietor), the claimed device requires a removable cover, not a retractable one. The cover detection switch 11 according to D12 would therefore no longer be usable with a removable cover. Even if the person skilled in the art tried to apply the concept of D12 to an injection device having a removable cover, this would at most mean equipping it with a cover detection switch that would send an enabling signal to the electronic control unit when the cover was not present. In the Board’s opinion, there would still be no reason to provide a separate arm button as required by the claim.

Therefore, in the Board's opinion, such an alternative design is not obvious.

8.3 Hence, the subject-matter of claim 1 involves an inventive step pursuant to Article 56 EPC.

Order

For these reasons it is decided that:

The appeal of the opponent is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated