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**Datasheet for the decision
of 8 December 2022**

Case Number: T 1484/18 - 3.2.01

Application Number: 13700569.0

Publication Number: 2806925

IPC: A61M5/315, A61M5/31

Language of the proceedings: EN

Title of invention:

INJECTION DEVICE WITH A SLIDING SCALE

Patent Proprietor:

Novo Nordisk A/S

Opponents:

1. Sanofi-Aventis Deutschland GmbH
2. medmix Switzerland AG

Headword:

Relevant legal provisions:

EPC Art. 83

RPBA 2020 Art. 11, 13(2)

Keyword:

Sufficiency of disclosure - enabling disclosure (no) - main request (no)

Amendment after summons - exceptional circumstances (yes) - taken into account (yes)

Remittal - special reasons for remittal - (yes)

Decisions cited:

G 0001/99, T 1488/08

Catchword:



Beschwerdekammern

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Case Number: T 1484/18 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 8 December 2022

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
20 April 2018 concerning maintenance of the
European Patent No. 2806925 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. The appeal of the opponent 1 lies against the decision of the opposition division concerning the maintenance of the European patent No. 2 806 925 in amended form.
- II. In their decision, the Opposition Division held among others that none of the grounds of opposition raised by the opponents (opponents 1 and 2) under Article 83 EPC and under Article 56 EPC was prejudicial to the maintenance of the patent in amended form according to auxiliary request 2.
- III. Following summons to oral proceedings issued by the board on 12 November 2021, third party observations pursuant to Article 115 EPC were received on 2 August 2022.
- IV. Oral proceedings by videoconference were held before the board on 8 December 2022.

The appellant (opponent 1) requested that the decision under appeal be set aside and the patent be revoked. The opponent 2 did not participate in the appeal proceedings.

The patent proprietor (respondent) requested that the appeal be dismissed (main request) or as an auxiliary measure that the patent be maintained in amended form on the basis of auxiliary request I (filed as auxiliary request IIa during oral proceedings), or one of the auxiliary requests II, III, IV and V (previously stated in their reply as auxiliary requests I, II, III and IV).

V. The main request corresponds to auxiliary request 2 as maintained by the opposition division. Claim 1 of the main request reads as follows (feature analyses as provided in the impugned decision):

1. An injection device for automatic spring driven injection of a liquid drug, comprising:

1.1 a dose setting mechanism by which doses of an individual size can be set by a user, and

1.2 a mechanical dose size display for displaying the size of the set dose,
which injection device further comprises:

1.3 a housing (2) defining an interior space and having a longitudinal window (3),

1.4 a rotatable dose dial button (10) coupled to the dose setting mechanism,

1.5 a rotatable scale drum (20) carrying indicia (22) for indicating the size of the set dose and

1.6 which scale drum (20) is functionally coupled to the dose dial button (10) to rotate when the dose dial button (10) is rotated to set a dose,

1.7 the rotatable scale drum (20) being rotatable within the interior space defined by the housing (2) during dose setting,

1.8 a sliding element (30) coupled to the scale drum (20), and provided with a window (35),

1.9 which sliding element (30) is adapted to slide

axially in relation to the housing (2) during dose setting,

1.10 and through which window (35) the indicia (22) carried by the scale drum (20) is visible such that the longitudinal window (3) and the window (35) in combination with the indicia (22) form the dose size display,

1.11 wherein the rotatable dose dial button (10) is axially retained in relation to the housing (2), and

1.12 wherein the sliding element (30) move axially within the boundaries of the housing (2) when the scale drum (20) is rotated,

characterized in that

1.13 the dose dial button (10) is releasable coupled to scale drum (20).

Claim 1 of **auxiliary request I** differs from claim 1 of the main request in that feature 1.13 is deleted and replaced by the following feature:

"neither the dose dial button (10) nor the scale drum (20) move axially and the scale drum (20) stays within the boundaries of the housing."

Additionally feature 1.11 is repositioned to the preamble between features 1.7 and 1.8 and the characterizing portion starts with feature 1.8.

VI. The appellant's (opponent's) arguments relevant to the present decision may be summarized as follows:

Admission into the appeal proceedings

*- of the ground of opposition based on Article 83 EPC
- of the submissions made with letter dated
16 August 2022*

The objection put forward with the statement of grounds of appeal was directed to the imbalance applied by the opposition division for the level of skills regarding Article 83 EPC and Article 56 EPC respectively. Such an imbalance automatically concerned both sides of the impugned decision: either the level of skills was correct with regard to Article 83 EPC but then it was too low with regard to Article 56 EPC, or the level of skills was correct with regard to Article 56 EPC but then it was too high with regard to Article 83 EPC.

The passage in the statement of grounds of appeal (second paragraph under the title "Reasons:") cited by the respondent (patent proprietor) reflected said objection stating that the patent as maintained "*must fail at last in view of one ground for opposition for systematic reasons.*"

The sentence following this statement did not at all exclude the ground of Article 83 EPC ("*It may be left aside whether the appealed decision has applied appropriate criteria when finding the amended patent to satisfy the sufficiency of disclosure requirement. The crucial flaw of the appealed decision is to apply different criteria to a similar technical situation for declining obviousness.*"). It rather emphasised the main objection of imbalance applied by the opposition division when examining the requirements of Article 83 EPC and Article 56 EPC.

Additionally, point 1.a. of the statement of grounds of appeal obviously referred to point 15.4 of the impugned

decision. The opposition division was of the opinion that the concept of a releasable coupling of granted claim 7, now incorporated in claim 1 of the main request, was well known in the art and that by the exemplary disclosure of a one-way ratchet mechanism in paragraph [0016], no more technical details were needed to be disclosed to enable a skilled person to put the invention into practice. This conclusion was objected in stating that "*the patent falsely proposed a one-way ratchet*" followed by several reasons why a one-way ratchet was not suitable for implementing rotational release of the dial button from the scale drum during dose injection.

Therefore the ground of opposition based on Article 83 EPC was in the appeal proceedings from the beginning. The submissions provided with letter dated 16 August 2022 simply supported and visualized the already invoked objections and arguments and did not constitute any amendments to the appellant's case. Therefore the admission of these submissions could not be put in question.

Sufficiency of disclosure

The opposition division erred when assuming that the exemplary disclosure of a one-way ratchet for a releasable coupling (paragraph [0016] of the patent in suit) was sufficient to enable a skilled person to put the invention into practice.

The one-way ratchet is the sole embodiment of a releasable coupling disclosed in the patent in suit. As acknowledged by the respondent (patent proprietor) the term "releasable" implied a switch between a first and a second state. In a first state the components of the

ratchet were engaged and transferred torque in one direction and did not transfer torque in the opposite direction. In a second state, the components were spatially separated und completely disengaged. Only in such a second state, the dose dial button would be released from the scale drum to allow the function as described in paragraphs [0016, 0031] of the patent, i.e. "*when the set dose is injected, the dial button 10 does not necessarily rotate back with the scale drum 20*". However a one-way ratchet lacked any ability to switch into such a second state.

Furthermore, should the skilled person provide a one-way ratchet in the device as shown in figure 1 of the patent in suit, an axial movement of the dose dial button 10 or the scale drum 20 would be required to release the coupling. However the patent in suit excluded any axial movement of the dose dial button or the scale drum (see feature 1.11 and paragraph [0010]: "*neither the dose dial button nor the scale drum move axially*"). An axial release thus contradicted the teaching of the patent.

The patent in suit was absolute silent about how the switch could be realized. Therefore the skilled person did not get enough information how feature 1.13 could be put in practice to provide the intended function.

*Admission of auxiliary request I - reformatio in peius
- remittal*

Auxiliary request I filed during oral proceedings before the board was not prima facie allowable and should thus not be admitted into the proceedings. In particular the prohibition of *reformatio in peius* applied. By deleting feature 1.13 the scope of the

claim was broadened in comparison to the claim as maintained by the opposition division. This would put the sole appellant (opponent) in a worse position than if they had not appealed.

The fact that auxiliary request I might be based on auxiliary request IV of the opposition proceedings was not a reason to admit auxiliary request I in appeal. Auxiliary request IV was submitted during oral proceedings before the opposition division and its admissibility was never decided.

Should the board admit auxiliary request I into the appeal proceedings, remittal to the first instance was requested. Deleting feature 1.13 and adding the feature "*neither the dose dial button (10) nor the scale drum (20) move axially and the scale drum (20) stays within the boundaries of the housing*" had the consequence that totally different subject-matter had to be discussed.

Third party observations (Article 115 EPC)

The appellant (opponent) did not comment on the third party observations.

VII. The respondent's (patent proprietor's) arguments relevant to the present decision may be summarised as follows:

Admission into the appeal proceedings

- *of the ground of opposition based on Article 83 EPC*
- *of the submissions made with letter dated 16 August 2022*

In the statement of grounds of appeal, the opponent explicitly excluded Article 83 EPC from the appeal

proceedings by stating that *"it may be left aside whether the appealed decision has applied appropriate criteria when finding the amended patent to satisfy the sufficiency of disclosure requirement (A. 83 EPC) or not."* (statement of grounds of appeal, second paragraph under the title "Reasons:"). Thus, the opponent did not challenge the opposition division's findings with respect to sufficiency of disclosure in the impugned decision but only the findings with regard to inventive step.

According to Article 12(3) RPBA 2020, the statement of grounds of appeal shall contain a party's complete appeal case. However, the appellant (opponent) only introduced with letter dated 16 August 2022 objections under Article 83 EPC - thus after receiving the summons to oral proceedings and around four years after filing the statement of grounds of appeal. The opponent therewith opened a completely new case which was not admissible pursuant to Article 13(2) RPBA 2020. Reference was made to T 1488/08, wherein it was held that grounds of appeal which were substantiated only after the reply of the respondent without the submission of any objective reasons, were late filed and not admissible. The same applied in the present case.

Even if the statement of grounds of appeal included Article 83 EPC, at least the submissions made in the appellant's letter dated 16 August 2022 were not admissible because they were late filed. The submissions included new arguments that constituted amendments to the opponent's appeal case. No exceptional circumstances presented themselves which would justify these amendments. No cogent reasons for

the late filing were provided by the appellant (opponent).

Sufficiency of disclosure

The wording in paragraph [0031] "*The connection between the dial button 10 and the scale drum 20*" implied that the device comprised an additional connector. It was one part of the connection that moved axially to the scale drum and to the dial button to switch the disclosed one-way ratchet from a first engaged state to a second disengaged state. A skilled person knew that such a one-way ratchet could easily be decoupled by a lever or button to maintain the dial button in its position when the scale drum rotated back to its initial position. Thus the decision of the opposition division that the skilled person was readily able to provide a suitable releasable coupling was to be confirmed.

Admission of auxiliary request I - reformatio in peius

Should the board come to the final conclusion that the main request was not allowable under Article 83 EPC, the respondent (patent proprietor) would be taken by surprise. It would not have been foreseeable that feature 1.13 could be seen as insufficient disclosed.

Auxiliary request I filed during oral proceedings before the board corresponded to auxiliary request IV of the opposition proceedings wherein the objected feature 1.13 was deleted. As the opposition division held auxiliary request II of the opposition proceedings allowable, there was no need to decide the admissibility of auxiliary request IV at that time. However this request was maintained in appeal as

auxiliary request IV and filed with the reply to the statement of grounds of appeal and was therefore admissible.

As feature 1.13 was found not to be enabling it could not be restrictive and its deletion could not broaden the claimed subject-matter. The legal provision of the prohibition of *reformatio in peius* would thus not be applied.

Reasons for the Decision

1. Admission of the ground of opposition based on Article 83 EPC

1.1 Pursuant to Article 12(1), (2) RPBA, the ground of opposition based on Article 83 EPC is admitted into the appeal proceedings. The Board takes the view that the statement of grounds of appeal can not be read as being limited to Article 56 EPC.

1.2 The respondent (patent proprietor) is of the opinion that in the statement of grounds of appeal, the appellant (opponent) explicitly excluded the ground of insufficiency of disclosure under Article 83 EPC.

1.3 The board does not agree. Contrary to the respondent's (patent proprietor's) opinion the sentence in the statement of grounds of appeal that "*it may be left aside whether the appealed decision has applied appropriate criteria when finding the amended patent to satisfy the sufficiency of disclosure requirement (A. 83 EPC) or not*" cannot be understood as excluding Article 83 EPC from the appeal proceedings. Seen in the context of the whole paragraph it is clear that the

main objection of the appellant (opponent) is that the opposition division allegedly did not apply the same level of competence to the skilled person in the reasoning under Article 83 EPC and under Article 56 EPC (points 15.4 and 21.3 of the impugned decision). The statement of grounds of appeal thus refers to both grounds.

1.4 Furthermore in point 1.a. of the statement of grounds of appeal, the appellant (opponent) obviously disagrees with the opposition division's findings under point 15.4 of the impugned decision:

Contrary to the opposition division's opinion that the exemplary disclosure of a one-way ratchet would be sufficient, the appellant (opponent) argues that such a one-way ratchet could not implement the function as described in paragraph [0016] of the patent in suit. This argument is substantiated at least by stating that "*the one-way ratchet lacks any ability to switch*" and that in an expelling operation, "*the dial button will be dragged backward by the one-way ratchet*", instead of being released from the scale drum.

Thus, as the statement of grounds of appeal includes substantiated arguments, the situation described in T 1488/08, referred to by the respondent (patent proprietor), in which no substantiation for some of the mentioned grounds for opposition was provided in the statement of grounds for appeal, does not apply to this case.

1.5 Hence, the ground of opposition under Article 83 EPC was invoked in the statement of grounds of appeal and is to be taken into consideration.

2. Sufficiency of disclosure

2.1 The patent in suit does not disclose the subject-matter of claim 1 of the main request in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

2.2 It is noted that the board's conclusion is based on the statement of grounds of appeal and the appellant's (opponent's) explanations given during oral proceedings based thereupon. The appellant's (opponent's) submissions filed with letter dated 16 August 2022 were not taken into consideration.

2.3 Claim 1 of the main request incorporates the features of granted claim 7 that requires that "*the dose dial button (10) is releasable coupled to scale drum (20)*" (feature 1.13). Granted claim 7 was objected under Article 83 EPC during opposition proceedings and dealt with in the contested decision under point 15.4. The respondent (patent proprietor) agreed with the opposition division that the concept of a releasable coupling was well known in the art and that the exemplary disclosure of a one-way ratchet (paragraph [0016]) was sufficient to enable a skilled person to put the invention into practice.

2.4 The board does not agree for the following reasons.

2.4.1 The releasable coupling is only mentioned in paragraphs [0016] and [0031] of the patent in suit. Paragraph [0031] of the patent in suit discloses that "*The connection between the dial button 10 and the scale drum 20 can be made through a releasable coupling such that when the set dose is injected, the dial button 10 does not necessarily rotate back with the scale drum*

20.". In the context of a dial button that does not rotate back with the scale drum during dose injection, paragraph [0016] discloses that *"in one embodiment this coupling can be made such that they [the scale drum and the dial button] only rotate together when a dose is set where after the dose dial button remains in its position when the scale drum rotate back to its initial position. Such coupling could be any kind of one-way ratchet mechanism which allows the scale drum to rotate in one direction independently of the dose dial button."*

- 2.4.2 It is undisputed by the parties that to implement a one-way ratchet in such a manner that the dial button 10 does not rotate back with the scale drum 20 during dose injection, at least one of the cooperating components of a one-way ratchet has to be axially moved to get disengaged from the other component of the one-way ratchet.
- 2.4.3 The respondent's (patent proprietor's) argumentation that a skilled person reading the disclosure of the patent would understand that such an axial movement would be necessary and that they would obviously find means to implement it, e.g. by providing a separate connector and an additional lever for moving the connector in and out of engagement, is not convincing.
- 2.4.4 The only hint in the patent about how to realize feature 1.13 is by means of any kind of one-way ratchet mechanism (paragraph [0016]). However this general disclosure of a releasable coupling does not specify how the desired functionality might be obtained, in particular as neither the dial button nor the scale drum moves axially (paragraph [0010] of the patent in suit). As brought forward by the appellant (opponent),

there is no inherent releasable coupling in the sense of an axial disengagement in a one-way ratchet mechanism. Additionally, the patent in suit does not comprise any instruction regarding the provision of a releasable coupling with the intended function in combination with a one-way ratchet. Neither an additional connector nor any kind of lever is mentioned.

- 2.4.5 Therefore the skilled person, armed with the disclosure of the patent and common general knowledge, is not in a position to configure without undue burden an injection device comprising the feature 1.13 of claim 1 of the main request, i.e. a device in which the dose dial button does not rotate back with the scale drum 20 during dose injection by means of a releasable coupling between it and the scale drum.

3. Admission of auxiliary request I

- 3.1 The Board admitted into the appeal proceedings auxiliary request I, filed during oral proceedings before the board.
- 3.2 Article 13(2) RPBA 2020 applies. While in principle, any amendment to a party's appeal case made after notification of a summons to oral proceedings shall not be taken into account, the Board takes the view that there are exceptional circumstances in the present case which justify the admission of the auxiliary request I.
- 3.3 In the statement of grounds of appeal some aspects why a one-way ratchet would not be suitable as a releasable coupling, were raised but worded in such a manner that their intended meaning only became fully clear with the explanations given by the appellant (opponent) during

oral proceedings. In particular the meaning of the argument that a *"one-way ratchet lacks any ability to switch"* and the necessity of such a *"switching"* function to prevent that *"in an expelling operation, [...], the dial button will be dragged backwards by the one-way ratchet"* (see point 1.a. of the statement of grounds of appeal) was fully clarified only during oral proceedings before the board.

3.4 Accordingly, it is fair to say that the respondent (patent proprietor) only became fully aware of the arguments of the appellant (opponent) at the oral proceedings. Under these exceptional circumstances, the Board takes the view that the respondent (patent proprietor) should be given a possibility to react by submitting the new auxiliary request I during oral proceedings.

3.5 Furthermore auxiliary request I is based on auxiliary request IV, filed for the first time during oral proceedings before the opposition division. Even if its admissibility was not decided upon in the first instance proceedings, it was maintained by the respondent (patent proprietor) by filing it again as auxiliary request II with the statement of grounds of appeal. Claim 1 of auxiliary request I filed during oral proceedings differs from claim 1 of the main request essentially by the deletion of feature 1.13 and by the additional amendments made in accordance with auxiliary request II. The latter amendments were thus not surprising for the appellant (opponent).

4. Reformatio in peius

4.1 The appellant (opponent) submitted that the deletion of feature 1.13 in claim 1 of the auxiliary request I was

not allowable in view of the prohibition of the *reformatio in peius*.

- 4.2 By deleting feature 1.13, claim 1 no longer requires a releasable coupling between the dial button and the scale drum as in claim 1 maintained by the opposition division.
- 4.3 It is noted that the amendment is within the limits of Article 123(3) EPC as the deleted feature 1.13 was added only in opposition proceedings.
- 4.4 In principle, an amended claim, which would put the opponent and sole appellant in a worse situation than if it had not appealed, must be rejected. However, G 1/99 (see headnote) allows an exception to this principle in order to meet an objection put forward by the opponent/appellant during the appeal proceedings, in circumstances where the patent as maintained in amended form would otherwise have to be revoked as a direct consequence of an inadmissible amendment held allowable by the opposition division in its interlocutory decision.
- 4.5 In the present case, it is undisputedly not possible to restrict feature 1.13 by introducing one or more originally disclosed limiting features in order to overcome the lack of sufficient disclosure. The board thus takes the view that the deletion of feature 1.13 is the only possibility for the respondent (proprietor) to overcome the deficiency due to the amendment introduced into the version of the patent as maintained by the opposition division but which does not comply with the requirements of the EPC (see G 1/99, point 15).

4.6 Hence the Board considers the amendment made in accordance with auxiliary request I is appropriate and necessary even if, as a result, the situation of the appellant (opponent) is worsened.

5. Remittal

5.1 According to Article 11, first sentence, RPBA 2020, the board remits the case for further prosecution as special reasons present themselves for doing so.

5.2 The opposition division maintained the patent in amended form according to the main request underlying this decision. The reasoning for the maintenance of the patent was based on feature 1.13 added to granted claim 1 during opposition proceedings.

5.3 Feature 1.13 is no longer present in claim 1 of auxiliary request I and the latter is further amended by introducing other features.

5.4 This leads to a substantially different situation as compared to the one underlying the decision under appeal.

5.5 Moreover, the remittal was requested by the appellant (opponent) and not objected to by the respondent (patent proprietor).

5.6 Under these circumstances, the Board considers that there are special reasons in the sense of Article 11 RPBA for remitting the case to the opposition division.

6. Third party observations (Article 115 EPC)

In view of the above, and considering that the third

party's observations only deal with the issue of inventive step of the subject-matter of claim 1 as maintained by the opposition division, they are irrelevant to the present decision such that there is no need to discuss them.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division for further prosecution.

The Registrar:

The Chairman:



A. Vottner

G. Pricolo

Decision electronically authenticated