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Datasheet for the decision of 27 June 2012

Case Number: T 0056/09 - 3.2.02

Application Number: 97939980.5

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Language of the proceedings: EN

Title of invention:
Syringe

Patent Proprietor:
NOVO NORDISK A/S

Opponent:
Aventis Pharma Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (yes)"

Decisions cited:
T 1166/05

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0056/09 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 27 June 2012

Appellant: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 5 November 2008 concerning maintenance of the European patent No. 927058 in amended form.

Composition of the Board:

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

Summary of Facts and Submissions

I. The appeal of the Opponent is against the decision of the Opposition Division posted 5 November 2008 finding that, account being taken of the amendments according to the main request made by the proprietor during the opposition proceedings, the patent and the invention to which it relates meet the requirements of the Convention.

The notice of appeal was filed on 23 December 2008 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 5 March 2009.

II. Oral proceedings took place on 27 June 2012.

The Appellant requested that the decision under appeal be set aside and the patent revoked.

The Respondent requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of one of the first and second auxiliary requests filed with letter dated 16 September 2008.

III. The following documents were cited in the appeal proceedings:

D1 : EP-A-0037696
D2 : WO-A-93/07922
D6 : US-A-4082121
D9 : DE-A-3638984 (filed with the statement setting out the grounds of appeal).

IV. Claim 1 according to the main request (as accepted by the Opposition Division) reads as follows:

"A syringe by which medicine may be apportioned in preset doses from an ampoule, which syringe has
- a dose setting (2, 23) and injection mechanism comprising a dose setting member which comprises an injection button (11) on a carrier rod (13) and may be moved in one direction to preset a dose and in the opposite direction to inject the preset dose, and
- a piston advancing mechanism comprising a piston rod and a piston rod drive,
- the dose setting (2, 23) and injection mechanism being coupled to the piston advancing mechanism through a unidirectional coupling transmitting only movement of the dose setting member in the dose injecting direction to the piston rod drive (17),
in which syringe
- an air shot button (26, 30) is provided,
- the operation of which acts only on the piston advancing mechanism side of the unidirectional coupling to enable influence on the piston advancing mechanism to advance the piston rod a distance corresponding to expulsion of a fixed volume of medicine." (underlining added)

The first and second auxiliary requests do not need to be considered in this decision.

V. For the application in suit the Board has taken a first decision in respect of novelty (T 1166/05), namely that the subject-matter of present claim 1 (some minor clerical changes were introduced during the opposition

proceedings, see underlined elements above) was novel over D1, D2 and D6. The case was then remitted to the first instance department for further prosecution, which led to the impugned decision.

VI. The arguments of the Appellant can be summarised as follows:

The subject-matter according to claim 1 of the main request lacks an inventive step over a combination of, respectively, D1 and D6, D2 and D6, or D6 and the common general knowledge of the person skilled in the art.
According to the former decision of the Board the only feature not disclosed in D1 is the last feature of claim 1, i.e. the operation of the air shot button acts only on the piston advancing mechanism side of the unidirectional coupling to enable influence on the piston advancing mechanism to advance the piston rod a distance corresponding to expulsion of a fixed volume of medicine.

This feature is however known from the syringe according to D6 in which the loading slide 45 pushes the piston 17 downwards to eliminate the dead air within the piston chamber.
In the syringe according to D6 this operation of the loading slide is also performed without having any influence on the dose setting mechanism.

It would be a matter of routine for the person skilled in the art to integrate such a slide into the pen syringe according to D1 and arrive in an obvious way at

the subject-matter of claim 1 according to the main request.

The reasoning starting from D2 is essentially analogous.

Document D9 was filed with the statement setting out the grounds of appeal, so the Respondent had ample time to examine it. It is also prima facie relevant because the only feature of claim 1 not disclosed in D9 is that of the expulsion of a fixed volume of medicine by the air shot mechanism and this feature would be obvious to implement in the syringe of D9, for instance by providing an abutment for limiting the rotation of knob 100, so that the subject-matter of claim 1 is prima facie not inventive over D9.
For these reasons D9 should be admitted into the proceedings.

Because the wording of claim 1 is so vague and general, there are several ways to read the features of claim 1 in the syringe according to D9, but whichever way this is done, all the features apart from the fixed volume expelled by the air shot button are anticipated by D9. In one reading, rings 56 and 65 constitute a dose setting mechanism with a unidirectional coupling to the piston rod 18. There is also an injection button 83 on the carrier rod 18 (the claim wording does not exclude the possibility that the piston rod and the carrier rod are the same element) which can be moved in the direction opposite to the injection direction when the dose is set, and in the other direction when the dose is injected. An air shot button is provided in the form of knob 100.

Hence the only difference is that the air shot button expels a fixed volume of medicine.
However, this feature could be easily implemented by the person skilled in the art by the provision of an abutment limiting the rotation of knob 100, so the subject-matter of claim 1 is not inventive.

For the reasons above, the impugned decision should be set aside and the patent revoked.

VII. The arguments of the Respondent can be summarised as follows:

The syringe disclosed in D6 has no air shot button and therefore cannot render the subject-matter of claim 1 obvious. D6 does not address the technical problem of removing the air before each injection. D6 is about removing air in a different device (which is refilled and does not use ampoules) and solving a different problem, namely refilling without introduction of air.

Even if the person skilled in the art might consider transferring the mechanism with the loading slide 45 into the pen syringe disclosed in D1, how should this be done? The pen syringe of D1 would be much thicker and in fine would not be a pen anymore and the syringe so obtained would still not be the subject-matter of claim 1 because the air could still not be removed between each injection.

Hence D6, whether combined with the prior art according to D1 or according to D2, does not suggest the invention.

D6 could moreover not be a proper starting point for an inventive step reasoning since according to the established case law this cannot be a springboard to the invention. The device according to D6 is a different device without ampoules. Ampoules do not need to be refilled, they are prefilled.
Moreover, the purging mechanism disclosed in D6 is for purging the device of any remaining air before refilling it with liquid. D6 has the same disadvantages as the other prior-art syringes mentioned in the introductory part of the patent in suit.

It is only with hindsight that the Appellant can come to the conclusion that the subject-matter of claim 1 is not inventive.

The same is true for D9.

This document should not be admitted into the appeal proceedings. At least after the first decision of the Board of Appeal the Appellant knew that its line of argument might not be convincing and it had the opportunity to file any new document at that time. The Proprietor is also supposed to file new requests as early as possible so there should be equal treatment between the parties.
In addition, this document is prima facie not relevant because it does not address the problem solved by the invention. On the contrary, the syringe according to D9 has the same disadvantages as those of the prior-art devices mentioned in the introductory part of the description.

In any case, even if admitted into the proceedings this document cannot change the outcome of the examination for inventive step because numerous features of claim 1 are not present in the device according to D9.
Among others, contrary to what is required in claim 1, in the syringe according to D9 the dose setting member does not move when the injection takes place. The piston rod cannot be at the same time the carrier rod of claim 1 and the piston rod of claim 1 when the claim requires two different elements. The unidirectional coupling of the syringe of D9, if there is any, does not transmit movement in the dose injection direction. The air shot mechanism does not expel a fixed volume of medicine.

In other words, there are so many features of claim 1 which are not disclosed by D9 that D9 cannot be a better starting point for an inventive step reasoning than D1.

Hence, the appeal should be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. The invention is about an air shot mechanism for a syringe allowing injection of preset doses from an ampoule, the air shot mechanism being independent of the dose setting system and of the drive system for the dose injection, so that the air shot mechanism can be operated without influencing the set dose.

3. In decision T 1166/05, the Board already decided on novelty (over D1, D2 and D6) so that the only issue to be dealt with in the present appeal is inventive step.

Main request

4. Combination of D1 and D6.

4.1 According to the earlier decision of the Board (T 1166/05, point 3.1 of the reasons):

"D1 discloses a syringe by which medicine may be apportioned in preset doses from an ampoule (2), which syringe has a dose setting and injection mechanism (10, 12, 13, 14) comprising a dose setting member (10) which comprises an injection button (7) on a carrier rod (10), and may be moved in one direction to preset a dose (see in particular page 5, line 20 to page 6, line 22) and in the opposite direction to inject the preset dose, and a piston advancing mechanism comprising a piston rod (14) and a piston rod drive (12), the dose setting and injection mechanism being coupled to the piston advancing mechanism through a unidirectional coupling (12, 13) transmitting only movement of the dose setting member (10) in the dose injecting direction to the piston rod drive, and in which syringe an air shot button (4) is provided to enable an expulsion of a fixed volume of medicine (see page 7, lines 9 to 18).

However, D1 does not disclose that the operation of the air shot button acts only on the piston advancing mechanism side of the unidirectional coupling to enable influence on the piston advancing mechanism to advance the piston (17) rod a distance corresponding to said expulsion of a fixed volume of medicine."

Hence the Board found that the last feature of claim 1 was not disclosed in D1.

In the syringe of D1, the detachable front end portion 4 which can be considered to be an air shot button fulfils its function when a new cartridge or ampoule is inserted. As explained on page 7, lines 9 to 13: "*The front barrel portion 4 is then replaced and as it is brought into its fully secured position it pushes back the body of the syringe 2 into its starting position, expelling a small amount of liquid and/or any air that might be present in the syringe*."
It is further explained at the end of the paragraph that: "*If all the air present in the syringe is not expelled at this stage then the expulsion may be completed with the aid of one or more strokes of the dispenser*."

4.2 In other words, in the syringe of D1, the provision of the distinguishing feature according to the invention, namely of an air shot button capable of advancing the piston rod a distance corresponding to the expulsion of a fixed volume of medicine, would give the patient the possibility to evacuate air and/or liquid through the needle at any time, in particular before the injection of any individual dose, without changing the set dose, in order to make sure that all the air possibly present in the needle is evacuated and the needle is only filled with liquid. In addition it would have the effect of avoiding unnecessary waste of medicine as the volume ejected by the air shot button is fixed.

4.3 Thus, the objective problem can be seen as one of allowing the user of the syringe according to D1, without amending the set dose, to empty the needle of any remaining air, at any time, in particular before the injection of an individual dose, and avoid unnecessary waste of expensive medicine.

4.4 In the opinion of the Board the solution proposed in claim 1 is not obvious.

More particularly, and contrary to the opinion of the Appellant, D6 cannot hint at the solution.

D6 discloses a liquid dispenser with means for automatically purging air therefrom during liquid loading.

The syringe disclosed in D6 can deliver individual doses of liquid by pressing on a knob 25. When pressing on this knob 25 a pawl 27 moving with the latter engages a tooth of a rack 37 forming a unit with the piston 17. When the knob is released it returns to its initial position while the rack and thence the piston remain in the position to which they just have been pushed. Each time knob 25 is depressed, the piston 17 moves within the piston chamber 19, thus discharging a determined amount of liquid.

When the piston comes close to the bottom of the piston chamber and hence the piston chamber 19 is almost empty and has to be refilled, it is possible with the aid of the loading slide 45 abutting a protrusion 53 of rack support slide 39 to urge the piston 17 downwards a maximum amount to an overshoot position to minimise the volume of dead air within the piston chamber 19 before refilling it (column 3, lines 18 to 25).

Then the chamber 19 can be refilled by pulling loading slide 45 upwards. At the beginning of this upwards

movement an additional chamber and piston structure is provided for eliminating air possibly still in the needle. This latter structure is of no interest for the present inventive-step assessment because it concerns the elimination of air during the refilling of the piston chamber 19 and this is not the problem to be solved starting from D1, namely to empty the needle of any remaining air, at any time, in particular before an injection. Moreover in the syringe according to D1 ampoules are used which do not have to be refilled.

According to the Appellant it would be obvious for the person skilled in the art to integrate the mechanism disclosed in D6, allowing the piston to be brought to an overshoot position, into the pen syringe of D1 and thereby arrive at the subject-matter of claim 1.

In the opinion of the Board it is already questionable whether the person skilled in the art having to solve the above-mentioned problem would take into account document D6, as the essential teaching of this document is about the refilling of the syringe without introduction of air, as is already clearly visible from its title: Liquid dispenser with means for automatically purging air therefrom during liquid loading.

But independently of that question, D6 cannot hint at the solution according to claim 1 for the simple reason that, as already stated in T 1166/05 (point 3.2 of the reasons), there is no air shot button or air shot mechanism within the meaning of claim 1 in this device. As a matter of fact there is no mechanism which is able to guarantee that once the piston chamber 19 is full of

liquid and the device is ready for use, or when the piston chamber is partially full after some injections have been made, there is no air in the needle. If, for whatever reason, some air gets into the needle after the filling of the piston chamber and before the first or any subsequent injection, there is no air shot button or system to help to evacuate this air before the injection.

While it is true that in the device according to D6 the loading slide 45 can act on the piston rod independently of the dose setting mechanism, it can only do so when the piston chamber is empty, or, in other words, when no further injection is possible (column 3, lines 18 to 25, Figure 4). This obviously is not an air shot button in the sense of the invention. Even if the person skilled in the art envisaged, in one way or another, to built the relevant mechanism according to D6 into the syringe according to D1, he would not end up with a syringe having the features of claim 1.

5. D2 as closest prior art

As already mentioned in T 1166/05 (point 3.2 of the reasons), *"The syringe disclosed in D2 does not comprise an air shot button. The press button (30) has exclusively the function of easing the mechanism of the dose setting knob (14) (see page 5, line 30, page 7, line 8)."*

As D2 discloses fewer features of claim 1 than D1, and in particular not the essential feature of the air shot button, its combination with the teaching of D6 is even

less likely to render the subject-matter of claim 1 obvious for the person skilled in the art.

6. D6 as closest prior art

The Appellant submitted that the subject-matter of claim 1 was also not inventive over a combination of D6 and the general knowledge of the person skilled in the art.

In the so-called problem-solution approach for assessing inventive step in an objective manner, the first step is to determine the closest prior art, i.e. the most promising starting point or "springboard" towards the invention.

In the present case, as already mentioned in T 1166/05 (point 3.2 of the reasons), "*D2 and D6 disclose less features of claim 1 of the main request than D1".*

More particularly for D6 the Board considered that *"D6 does not refer to a syringe by which medicine may be apportioned in set doses from an ampoule. The syringe according to D6 has a closed piston chamber (19) into which liquid medicine may be drawn and subsequently be injected by a piston (17). Furthermore this syringe does not comprise an air shot button but a system that automatically eliminates any air from the piston chamber when this chamber is filled."*

Hence it is clear that the syringe disclosed in D6 is not of the same type as that claimed, since it is not a syringe by which medicine may be apportioned in set doses from an ampoule, and as already mentioned above

it has fewer features in common with the subject-matter of claim 1 than D1.

Thus, according to established case law, the syringe disclosed in D6 is further away from the subject-matter of claim 1 or the invention than the syringe disclosed in D1.
In other words, D6 is a weaker starting point than D1 for a lack of inventive step reasoning, so since the subject-matter of claim 1 is inventive starting from D1 it is also inventive starting from D6.

7. Admittance of D9

7.1 D9 was filed with the statement setting out the grounds of appeal immediately after the decision of the Opposition Division adversely affecting the Appellant, so that it has been present in the file since the very beginning of the appeal proceedings. The Opposition Division considered the subject-matter of claim 1 to involve an inventive step and the Appellant filed D9 to question this finding. Prima facie this document discloses a syringe of the same type as that claimed since it is a syringe by which medicine may be apportioned in set doses from an ampoule, and this syringe prima facie has an air shot mechanism which can be used before each individual injection (column 10, lines 25 to 32). Thus D9 is prima facie relevant.

7.2 The Respondent considered that the document could have been filed earlier, after the first decision of the Board, after which the Appellant should have known that his case might not be strong enough.

The Board does not share the opinion of the Respondent. The impugned decision was the first decision dealing with the ground of inventive step, so the Appellant had no reason to file this document earlier if he was convinced that the documents on file were strong enough to obtain the revocation of the patent on the basis of a lack of inventive step reasoning.

7.3 For the above reasons the Board decided to admit D9 into the appeal proceedings.

8. Examination of inventive step starting from D9

8.1 D9 discloses a syringe with which medicine may be apportioned in set doses from an ampoule and automatically injected. The syringe structure comprises an ampoule holder 20 slidable in a housing 30 between a distal abutment position in which the needle extends out of the distal end of the housing and a proximal abutment position in which the needle 22 is within the housing, a telescopic piston rod assembly 77, 80 movable between a distal position which corresponds to the position of the piston rod at the end of an injection and a proximal position in which the dose can be set (figure 2) and from which the piston rod assembly is fired in direction of the piston in the ampoule when the patient launches the injection.

When the piston rod assembly is in its rest position at the end of an injection cycle and before a new dose is set, the piston rod can be lengthened in the distal direction by rotating knob 100. Because the ampoule holder is in its distalmost position when the piston

rod assembly is in its rest position, such rotation of knob 100 will displace the piston in the ampoule in the distal direction and eventually lead to a drop of medicine coming out of the distal end of the needle (Column 6, line 67 to Column 7, line 9, Column 10, lines 25 to 35). Thus the patient can evacuate any air from the needle before starting a new injection.

When the piston rod assembly is in the proximal position the dose can be adjusted by first rotating a dose preselecting ring 56 and then rotating a dose setting ring 65 which will lengthen the piston rod in the distal direction by the desired amount (Column 10, lines 36 to 62). When the patient then fires the injection by pressing a clip which will allow movement of the piston rod assembly in the distal direction, a spring under pressure is freed and pushes the piston rod assembly in the distal direction in order for the injection to be performed (Column 11, lines 2 to 19).

8.2 The Appellant submitted that the only difference between the subject-matter of claim 1 and the syringe disclosed in D9 was that in the latter there was no limitation on the quantity of medicine expressed during the air shot operation by the ring 100 and that it would be obvious for the person skilled in the art to provide the ring with some kind of abutment if ever this was desired.

8.3 The Board cannot agree with any of these arguments.

It is true that there is no limitation to the rotation of the knob 100, so that for the air shot no fixed

volume of medicine is defined as required by claim 1. However, this is not the only difference.

The claim requires a dose setting and injection mechanism comprising a dose setting member which may be moved in one direction to preset a dose and in the opposite direction to inject the preset dose. In D9 the ring 65, if it can be considered to be the dose setting member, is rotatable in one direction to preset the dose but does not rotate in the opposite direction to inject the dose. It has no role at all during the injection.

Furthermore, claim 1 requires that the dose setting member comprises an injection button on a carrier rod. Here again the dose setting ring 65 does not have any carrier rod with an injection button on it.

The Appellant considered that the carrier rod of the dose setting member can be the same element as the piston rod of the piston advancing mechanism. In the opinion of the Board this is an incorrect reading of the claim. It is established case law that a person skilled in the art should try to build up rather than tear down, to arrive at an interpretation of the claim which is technically sensible and takes into account the whole disclosure of the patent. In other words, the patent must be construed by a mind willing to understand, not a mind desirous of misunderstanding. In the present case there is no reason whatsoever to consider that for the draughtsman of the patent specification the carrier rod 13 of the dose setting and injection mechanism and the piston rod 14 of the piston advancing mechanism could or should have been

the same element. Throughout the description and drawings these two rods are two separate elements and, fundamentally, two different words are used for them in claim 1.

Furthermore, claim 1 requires that the air shot button acts only on the piston advancing mechanism side of the unidirectional coupling to enable influence on the piston advancing mechanism. This feature must be understood as meaning that the air shot button can only act on the piston rod in one direction, namely in the injection direction. So that even if knob 100 is considered to be an air shot button there is nothing preventing this button from being rotated in the direction opposed to that indicated by arrow 106 in Figure 6 of D9, to move the piston in the opposite direction to the injection direction (Column 8, lines 49 to 52).

8.4 There are thus several structural and functional differences between the subject-matter of claim 1 and the syringe disclosed in D9, so that the Board does not see how this document could come closer to the invention than D1 and lead to any different assessment of inventive step in relation to the subject-matter of claim 1.

8.5 For the sake of completeness the Board notes that even if the fixed volume expelled were the only difference between the subject-matter of claim 1 and the disclosure in D9, the Board does not see why it would be obvious for the person skilled in the art to enhance the syringe disclosed in D9 with a mechanism limiting the expelled medicine to a fixed volume.

Nothing in D9 indicates that such a structural amendment would be obvious. There is no mention in D9 that less than one rotation of the knob 100 would be necessary to perform the air shot, so that there is no obvious way to limit the rotation of the knob by a simple abutment when the abutment must be active only after more than one complete rotation.
Even if the necessary rotation were less than one complete rotation the placing of any abutment limiting the rotation of the knob would have to be flexible because there is no reason why the knob would be in the same rotational position after each injection. It would also have to be somehow disconnectable because the same element 77 is rotated by the knob 100 when performing an air shot and by the ring 65 when setting the dose, and when setting the dose a limitation of the rotation is not acceptable.

In other words the Board does not see why it would be obvious to implement any limitation of the rotation of knob 100 in the device according to D9. Nor has the Appellant given any further details about that.

9. In view of the above, the subject-matter of claim 1 of the main request (as accepted by the Opposition Division), and by the same token that of the dependent claims, involves an inventive step (Article 56 EPC).

Consequently, there is no need to consider the first and second auxiliary requests in the present decision.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne