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**Datasheet for the decision
of 25 November 2015**

Case Number: T 2314/11 - 3.2.02

Application Number: 08002101.7

Publication Number: 1920794

IPC: A61M5/315

Language of the proceedings: EN

Title of invention:

Drive mechanism for drug delivery device

Patent Proprietor:

Sanofi-Aventis Deutschland GmbH

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 76(1), 100(a), 100(c)

Keyword:

subject-
matter extends beyond content of earlier application (no)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:



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Case Number: T 2314/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 25 November 2015

Appellant: Sanofi-Aventis Deutschland GmbH
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Representative: Keil & Schaafhausen
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
7 June 2011 concerning maintenance of the
European Patent No. 1920794 in amended form.

Composition of the Board:

Chairman E. Dufrasne
Members: P. L. P. Weber
D. Ceccarelli

Summary of Facts and Submissions

- I. The appeal by the patent proprietor is against the interlocutory decision of the Opposition Division posted on 7 June 2011 that, taking into consideration the amendments according to the third auxiliary request, the patent and the invention to which it relates fulfil the requirements of the EPC.

The objection to the main, first and second auxiliary requests was that they did not fulfil the requirements of Article 76(1) EPC. The Opposition Division considered that, since the feature "*an internal housing having an external helical thread, which internal housing is provided within a main housing;*" referred to the embodiment of Figure 17, the subject-matter of claim 1 was a non-allowable intermediate generalisation, because many essential features of this embodiment were not taken over into the claim.

- II. The notice of appeal was filed on 22 July 2011 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 6 October 2011.

The appellant requested that the impugned decision be set aside and that the patent be maintained as granted or, in the alternative, on the basis of one of auxiliary requests 1 and 2 filed on 9 February 2011.

- III. The opposition was withdrawn on 8 January 2010.

- IV. The patent in suit was granted on the basis of a divisional application of EP-A-1603611 (parent application). Apart from the first complete paragraph of page 3 of the divisional application as filed, the description and the drawings of the divisional

application as filed are identical to the same elements of the parent application as filed.

V. The patent in suit has been granted with claim 1 of the divisional application as filed, except for the reference signs which have been added.

VI. The following documents are cited in the decision:

D1: WO-A-01/95959

D2: WO-A-01/19434

VII. Claim 1 of the parent application as filed reads as follows:

"1. A drive mechanism for use in a drug delivery device is provided comprising:
a housing having a helical thread, preferably an internal helical thread;
a dose dial sleeve having a helical thread engaged with the helical thread of the said housing;
a drive sleeve releasably connected to the said dose dial sleeve; and
a clutch means located between the dose dial sleeve and the drive sleeve; characterized in that,
a) when the dose dial sleeve and the drive sleeve are coupled, both are allowed to rotate with respect to the housing; and
b) when the dose dial sleeve and the drive sleeve are de-coupled, rotation of the dose dial sleeve with respect to the housing is allowed, whilst rotation of the drive sleeve with respect to the housing is not allowed, whereby axial movement of the drive sleeve is allowed so that a force is transferred in the longitudinal direction to the proximal end of the drug delivery device."

VIII. Claim 1 of the patent as granted reads as follows:

"1. A drive mechanism for use in a drug delivery device is provided comprising:

an internal housing (154) having an external helical thread (150), which internal housing (154) is provided within a main housing (4');

a dose dial sleeve (70') having a helical thread engaged with the helical thread of the said internal housing (154);

a drive sleeve (30') releasably connected to the said dose dial sleeve (70');

and a clutch means (60') located between the dose dial sleeve (70') and the drive sleeve (30'); characterized in that,

a) when the dose dial sleeve (70') and the drive sleeve (30') are coupled, both are allowed to rotate with respect to the internal housing (154); and

b) when the dose dial sleeve (70') and the drive sleeve (30') are de-coupled, rotation of the dose dial sleeve (70') with respect to the internal housing (154) is allowed, whilst rotation of the drive sleeve (30') with respect to the internal housing (154) is not allowed, whereby axial movement of the drive sleeve (30') is allowed so that a force is transferred in the longitudinal direction to the proximal end of the drug delivery device."

IX. The appellant's arguments are essentially those on which the following reasons for this decision are based.

Reasons for the Decision

1. The appeal is admissible.
2. The invention is about a drive mechanism for a drug delivery device with which several individual doses can be delivered to a patient and in which it is possible to correct a set dose due to the presence of a clutch mechanism. Three embodiments are disclosed, whereby the first two function the same way and are mechanically almost identical (first embodiment: Figures 1 to 16, second embodiment: Figure 17) and the third embodiment is constructed differently (Figures 18 to 24).

The patent in suit, based on the divisional application, concentrates on the embodiment of Figure 17 comprising an additional external housing.

3. Requirements of Article 76(1) EPC

In the following analysis, the Board will refer to the parent application as filed, as did the appellant.

As already mentioned above, according to the Opposition Division, because the feature "*an internal housing having an external helical thread, which internal housing is provided within a main housing;*" referred to the embodiment of Figure 17, the subject-matter of claim 1 was a non-allowable intermediate generalisation, as many essential features of this embodiment had not been taken over into the claim.

The Board does not share this opinion.

First of all, it has to be noted that the essential difference in wording between claim 1 of the parent

application as filed and claim 1 of the divisional application as filed is that the first feature of the claim has been amended from "*a housing having a helical thread, preferably an internal helical thread;*" to "*an internal housing having an external helical thread, which internal housing is provided within a main housing;*".

Following the presence of an internal housing in claim 1 of the divisional application as filed, the rest of the claim wording has been adapted to repeat "*internal housing*" instead of "*housing*" where necessary, but the rest of the wording is identical with that of the claim 1 of the parent application as filed.

In the description of the invention (page 2, line 17 onwards), a first drive mechanism is described in general terms. In fact, it corresponds word for word to the wording of claim 1 of the parent application as filed. This general description is followed (page 3, line 14 onwards) by several definitions, including the definitions of "*housing*", "*helical thread*", "*dose dial sleeve*", "*drive sleeve*", etc... Only then are the specific embodiments described.

In the opinion of the Board, this means that claim 1 of the parent application as filed must be read in the light of these definitions. In particular, when the critical feature is read having the definitions in mind, the following can be established:

According to the definition given, the "*helical thread*" can be located on the internal and/or external surface of a component (page 4, lines 17 to 21). Hence, when it is then mentioned in claim 1 of the parent application as filed that the housing is provided with a helical

thread, this means (already in the parent application) that the helical thread can be external or internal. This is confirmed by the rest of the feature wording, "*preferably an internal helical thread*", necessarily meaning that it could also be an external thread.

In other words, the option of the drive mechanism comprising a housing with an external thread was already included in claim 1 of the parent application as filed.

The fact that the second feature of claim 1 of the parent application requires "*a dose dial sleeve having a helical thread engaged with the helical thread of the said housing*" can then only mean that the dose dial sleeve has an internal thread cooperating with the external thread of the housing. This additionally implies that the dose dial sleeve is outside that housing or, in other words, that the housing is an "*internal housing*." Thus, this is also already included in the wording of claim 1 of the parent application.

It follows that the only feature of claim 1 of the divisional application that is possibly not already included in claim 1 of the parent application as filed is the feature that states that the "*internal housing should be within a main housing*".

The paragraph giving a definition of the word "*housing*" (page 3, line 28 onwards) includes the following sentences:

"The housing may be designed to enable the safe, correct, and comfortable handling of the drug delivery device or any of its mechanism. Usually, it is designed to house, fix, protect, guide, and/or engage with any

of the inner components of the drug delivery device (e.g., the drive mechanism, cartridge, plunger, piston rod) by limiting the exposure to contaminants, such as liquid, dust, dirt etc. In general, the housing may be unitary or a multipart component of tubular or non-tubular shape. Usually, the exterior housing serves to house a cartridge from which a number of doses of a medicinal product may by[sic] dispensed."

In all the embodiments described in the parent application as filed (in particular in the embodiment of Figure 17), there is an exterior housing in which the drive mechanism and the cartridge are placed. In the opinion of the Board, there is therefore a sufficient basis in the parent application as filed to define that there is a "main" housing in the general definition of the drive mechanism according to claim 1 of the patent as granted.

Therefore, the patent as granted fulfils the requirements of Article 76(1) EPC, so that the ground for opposition pursuant to Article 100(c) EPC does not prejudice the maintenance of the patent as granted.

4. Novelty

Concerning the lack of novelty objection based on D1 the Board agrees with the Appellant.

The drive mechanism shown in Figure 1 of D1 comes close to the mechanism of Figure 17 of the patent in suit, the most critical feature being the drive sleeve.

In its notice of opposition, the then opponent considered that the connection bars 12 should be considered to be the drive sleeve. In the opinion of

the Board, this is clearly not possible, because the claim requires a "sleeve". That the sleeve must be a true sleeve is confirmed by the definition of "drive sleeve" given in [0020]: *"The term "drive sleeve" according to instant invention shall mean any essentially tubular component of essentially circular cross-section and which is further releasibly connected to the dose dial sleeve."* The connection bars are clearly not a tubular component of circular cross-section.

Even if the connection bars 12 were considered to be the equivalent of the drive sleeve, there would still be no clutch means located between the drive sleeve and the dose dial sleeve.

Hence, the subject-matter of claim 1 is novel over D1.

Therefore, the requirements of Article 54 are fulfilled, so that the ground for opposition of lack of novelty pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent as granted.

5. Inventive step

While changing the shape of the connection bars 12 disclosed in the device of D1 into an essentially tubular shape might possibly be considered an obvious alternative (although it is not clear what should happen with the rack 10), the introduction of a clutch means located between the drive sleeve (in place of rods 12) and the dose dial sleeve 18 would necessitate a complete change of the mechanical construction. So the Board does not see how such re-design could be obvious for the person skilled in the art starting from D1.

The then opponent considered that the subject-matter of claim 1 lacked inventive step when starting from D2. However, the device according to D2 has a dose setting member 30 with an external thread (page 5, lines 22 to 27), so this member is quite obviously not cooperating with an internal housing having an external thread as well, as is required by claim 1. Moreover, introducing such a constructional change into the device of D2 would mean completely changing the construction of that device, so that, here as well, the Board does not see how this could be obvious for the person skilled in the art.

Therefore the requirements of Article 56 are fulfilled, so that the ground for opposition of lack of inventive step pursuant to Article 100(a) EPC does not prejudice the maintenance of the patent as granted.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is maintained as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated