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Datasheet for the decision of 6 November 2007

Case Number: T 1168/06 - 3.2.02

Application Number: 99931026.1

Publication Number: 1094858

IPC: A61M 5/24

Language of the proceedings: EN

Title of invention:
A medication delivery and a cartridge assembly for use in the same

Patentee:
NOVO NORDISK A/S

Opponent:
Sanofi-Aventis Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 54, 56, 84, 123(2)

Keyword:
"Novelty (main request, no)"
"Inventive step (auxiliary requests, no)"
"New subject-matter (auxiliary requests 5 and 7, yes)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1168/06 **-** 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 6 November 2007

Appellant: (Patent Proprietor)	NOVO NORDISK A/S Novo Allé DK-2880 Bagsvaerd (DK)
Representative:	HOFFMANN EITLE Patent- und Rechtsanwälte Arabellastrasse 4 D-81925 München (DE)
Respondent: (Opponent)	Sanofi-Aventis Deutschland GmbH Industriepark Höchst D-65926 Frankfurt am Main (DE)
Representative:	Isenbruck, Günter Patentanwälte Isenbruck - Bösl - Hörschler - Wichmann - Huhn Theodor-Heuss-Anlage 12 D-68165 Mannheim (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 26 May 2006 revoking European patent No. 1094858 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: T. Kriner
Members: S. Chowdhury
M. J. Vogel

Summary of Facts and Submissions

I. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division to revoke European patent No. 1 094 858. The decision was dispatched on 26 May 2006.

The appeal was received on 26 July 2006 and the fee for the appeal was paid on the same day. The statement setting out the grounds of appeal was received on 2 October 2006.

The opposition was filed against the whole patent and was initially based on Article 100(a) EPC (lack of novelty and inventive step) of the claimed subject-matter. Belatedly, a new ground of opposition under Article 100(b) EPC was introduced, which the opposition division disregarded, having regard to Article 114(2) EPC.

II. The following documents cited during the opposition procedure are particularly relevant in the appeal procedure:

D4: EP-A-0 688 571

D16: US-A-5 591 136.

III. During the opposition proceedings the patent proprietor filed sets of amended claims, upon which the opposition division ruled as follows:

Claims 1 and 10 of the main request met the requirements of Article 84 EPC and Article 123(2) EPC,

but their subject-matter was not novel, having regard to D16.

Claim 1 of the first auxiliary request did not involve an inventive step in view of D16 and D5.

Claim 1 of the second and third auxiliary requests did not meet the clarity requirement of Article 84 EPC.

The opposition division revoked the patent, accordingly.

IV. The appellant filed new sets of claims on 2 October 2006 as a main and first to eighth auxiliary requests. Oral proceedings were initially requested, but with its letter dated 27 September 2007 the appellant withdrew its request for oral proceedings and requested that a decision be taken on the basis of written proceedings.

The appellant makes the following requests:

That the decision under appeal be set aside and the subject-matter of the claims of the main request be found novel and the case be remitted to the first instance for an examination of inventive step.

That the decision under appeal be set aside and the patent be maintained on the basis of claims of the first auxiliary request.

That the decision under appeal be set aside and the claims of the second to eighth auxiliary requests be found admissible and the case be remitted to the first instance for an examination of the grounds of opposition vis-à-vis the respective sets of claims.

The respondent (opponent) requests that the appeal be dismissed.

V. Claims 1 and 10 of the main request read as follows:

"1. An insulin delivery device comprising a disposable cartridge assembly (1) having a distal end (22) and a proximal end (21) said distal end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, said cartridge assembly comprising a cartridge (5) having one end sealed with a pierceable sealing and having a stopper (4) adapted to receive plunger means, and said cartridge assembly (1) further comprising a housing for protecting all of the cartridge (5), a reusable dosing assembly (6) comprising plunger means (7), and an internal coupling (8) adapted for engagement with the cartridge assembly (1), and a needle assembly, wherein the cartridge assembly and the dosing assembly are releasably coupled together, and the device comprises a combination of couplings between the dosing assembly and the cartridge assembly and between the needle assembly and the cartridge assembly, said combination capable of securing that the plunger means abuts on the stopper during coupling and decoupling of the needle assembly.

10. A cartridge assembly for use in the insulin delivery device as claimed in any of claims 1-9, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means adapted to engage an internal coupling (8) of a dosing assembly, further comprising a

cartridge said cartridge comprising a slidable stopper, and said cartridge assembly (1) further comprising a housing for protecting all of the cartridge (5)."

Claims 2 to 9 and 11 to 14 are dependent claims.

Auxiliary requests

Claim 1 of the first auxiliary request is identical with claim 1 of the main request, except that it includes the additional feature that the delivery device further comprises a cap (14) for protecting the needle assembly and the cartridge assembly (1).

Claim 9 of this request is identical with claim 10 of the main request.

Claim 1 of the second auxiliary request reads as follows:

"Use, in a medication delivery device comprising: a cartridge assembly (1) having a distal end (22) and a proximal end (21) said distal end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, and said cartridge assembly comprising a cartridge (5) having one end sealed with a pierceb1e sealing and having a stopper (4) adapted to receive plunger means; a dosing assembly (6) comprising plunger means (7); and a needle assembly, of a combination of first and second reeaseab1e couplings which can be operated independently of one another, the first coupling connecting the dosing assembly (6) and the cartridge assembly (1) and the second coupling connecting the cartridge assemb1y (1) and the needle

assembly, to secure abutment of the plunger means on the stopper during coupling and decoupling of the needle assembly, to thereby avoid inaccurate medication dosing."

Claim 1 of the third auxiliary request is the same as claim 1 of the second auxiliary request, but includes the following features at the end thereof:

"said combination of releasable couplings being selected from the group consisting of:
(i) a threaded coupling combined with a snap coupling;
(ii) a bajonet lock or a luer lock combined with a snap lock; and
(iii) a snap lock combined with a snap lock."

Claim 1 of the fourth auxiliary request is the same as claim 1 of the third auxiliary request, except that the cartridge assembly (1) is defined as being of circular shape in transverse cross-section.

Claims 1 and 10 of the fifth auxiliary request correspond to claims 1 and 10, respectively, of the main request, except that claim 1 of the fifth auxiliary request additionally states that the plunger means abuts on the stopper during metering, as well as coupling and decoupling of the needle assembly.

Claims 1 and 10 of the sixth auxiliary request correspond to claims 1 and 10, respectively, of the fifth auxiliary request, except that claim 1 of the sixth auxiliary request additionally states that the delivery device further comprises a cap (14) for

protecting the needle assembly and the cartridge assembly (1).

Claim 1 of the seventh auxiliary request reads as follows:

"Use, in an insulin delivery device comprising: a disposable cartridge assembly (1) of circular shape in transverse cross-section having a distal end (22) and a proximal end (21) said distal end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, said cartridge assembly comprising a cartridge (5) of circular shape in transverse cross section having one end sealed with a pierceable sealing and having a stopper (4) adapted to receive plunger means, and said cartridge assembly (1) further comprising a housing for protecting all of the cartridge (5); a reusable dosing assembly (6) comprising plunger means (7) and an internal coupling (8) adapted for engagement with the cartridge assembly (1); a needle assembly; and a cap (14) for protecting the needle assembly and the cartridge assembly (1), of a combination of first and second releaseable couplings which can be operated independently of one another, the first coupling connecting the dosing assembly (6) and the cartridge assembly (1) and the second coupling connecting the cartridge assembly (1) and the needle assembly, to secure abutment of the plunger means on the stopper during metering as well as coupling and decoupling of the needle assembly, to thereby avoid inaccurate medication dosing."

Claim 1 of the eighth auxiliary request corresponds to claim 1 of the seventh auxiliary request and

additionally states that "said combination of releasable couplings being selected from the group consisting of:
(i) a threaded coupling combined with a snap coupling;
(ii) a bajonet lock or a luer lock combined with a snap lock; and
(iii) a snap lock combined with a snap lock."

Reasons for the decision

1. The appeal is admissible.

2. Although the appellant has requested a limited ruling on some requests, for example only a decision as to novelty as regards the main request, the Board considers it expedient, in accordance with Article 111(1) EPC, to exercise the power within the competence of the department of the first instance and perform a complete examination of all the requests on file.

3. *General considerations*

The expression "internal coupling" in claim 1 of the main request is not clear in the context. The only mention of such a coupling is in column 5, lines 17 to 19 of the patent in suit, and this passage does not explain the meaning of this expression. However, the Figures show that the coupling is a thread provided on the internal surface of the dosing assembly housing for engaging a corresponding thread on the external surface of the cartridge, so that this expression is taken to mean that the coupling part on the dosing assembly

housing is provided on or associated with the internal surface thereof.

Claim 1 of the main request specifies that the cartridge assembly further comprises a housing protecting all of the cartridge, but no great detail of such a housing is described in the patent, the only relevant parts being column 4, lines 8 to 10 and column 5, lines 36 to 38. Thus, "housing" may be broadly interpreted, for example it may consist of a plurality of parts.

4. *Novelty, main request*

Document D16 discloses an insulin delivery device comprising a disposable cartridge assembly (11) having a distal end and a proximal end said distal end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly (15, 18), said cartridge assembly comprising a cartridge (12) having one end sealed with a pierceable sealing (16) and having a stopper (14) adapted to receive plunger means (28, 29), and said cartridge assembly (11) further comprising a housing protecting all of the cartridge (12) (see point 4.1 below), a reusable dosing assembly (21) comprising plunger means (28, 29) and an internal coupling (see point 4.2 below) adapted for engagement with the cartridge assembly, and a needle assembly (15, 18), wherein the cartridge assembly and the dosing assembly are releasably coupled together (see point 4.3 below), and the device comprises a combination of couplings between the dosing assembly and the cartridge assembly and between the needle assembly and the cartridge assembly, said combination capable of

securing that the plunger means abuts on the stopper during coupling and decoupling of the needle assembly.

Therefore, the device of claim 1 of the main request lacks novelty.

4.1 The cartridge housing of D16 comprises the combination of the left housing part (11) and the extension of the housing part (see Figure 2) which is not numbered but extends over the end of the cartridge and forms the seat for the needle cap (18). Thus, the composite housing protects the whole cartridge.

4.2 As explained in point 3.1, by "internal coupling" is understood to mean any coupling part associated with the internal surface of the dosing assembly housing. In D16 the detent connections 20 of the cartridge housing are engaged in apertures formed on the internal surface of the housing and, moreover, the detent connections 20 engage the apertures from within the dosing assembly housing. The apertures, therefore, may be considered to form an "internal coupling".

4.3 That the cartridge assembly and the dosing assembly are releasably coupled together is indicated by the last paragraph of the description of D16, according to which a used cartridge may be replaced by a new one.

Bearing in mind that the Figures of D16 are drawn to scale, as admitted by the appellant (see also D16, column 8, lines 51 to 54) it would appear from Figure 2, for example, that the cartridge (12) cannot be removed from the distal end (the left end in Figure 2) of the housing since the latter is tapered at this end.

Therefore, the cartridge must be removable from the proximal end of the cartridge housing. It is for this reason the cartridge housing is releasably coupled to the dosing assembly housing by the detent connections (20).

4.4 D16 also discloses a cartridge assembly for use in the insulin delivery device as claimed in claim 1, having one end sealed with a pierceable sealing (16), said end of the cartridge assembly comprising coupling means for engaging a needle assembly (15, 18), and another end comprising coupling means (20) adapted to engage an internal coupling of a dosing assembly, further comprising a cartridge said cartridge comprising a slidable stopper (14), and the cartridge assembly further comprising a housing for protecting all of the cartridge.

Therefore, the device of claim 10 of the main request also lacks novelty.

5. *Auxiliary requests*

5.1 First auxiliary request

Claim 1 includes the additional feature that a cap protects the needle and cartridge assembly. This would appear to be a trivial feature since the use of caps to protect vulnerable parts of syringes, etc. are well known in the art, as exemplified by D4 see the cap (17) in D4.

The subject-matter of this claim does not involve an inventive step, accordingly.

Claim 9 is identical with claim 9 of the main request and its subject-matter lacks novelty.

5.2 Second auxiliary request

Claim 1 defines the combination of first and second releaseable couplings "which can be operated independently of one another", but it is not clear what this means. The only support for this feature is at column 3, lines 45 to 52 of the opposed patent, but this term is not explained here. It is, therefore, taken to mean that the coupling between the cartridge and the needle assembly works independently of the coupling between the cartridge and the dosing assembly.

However, this is how the couplings of D16 also work. The coupling of the needle assembly and the cartridge assembly is via a threaded cap (18), and that between the cartridge assembly and the dosing assembly is via the detents (20), which operate independently of the former coupling.

Therefore, Claim 1 merely defines the normal use of the prior art device shown in D16. The use defined in claim 1 lacks novelty, accordingly.

5.3 Third auxiliary request

Claim 1 is a use claim identical to claim 1 of the previous request, except for the definitions of the couplings which may be used. All these couplings are well known in the art. For example, the combination (i) of a threaded coupling combined with a snap coupling is

disclosed in D16. The use defined in claim 1 lacks novelty, accordingly.

5.4 Fourth auxiliary request

Claim 1 is identical with claim 1 of the previous request, except that the cartridge is said to have a circular cross-section. This is a trivial feature, and is a property of each of the devices shown in all the documents cited in the opposition procedure, and cannot clearly confer an inventive quality over the prior art.

5.5 Fifth auxiliary request

Claim 1 is based on claim 1 of the main request, with the additional feature that the combination is capable of securing that the plunger means abuts on the stopper during metering, as well as coupling and decoupling of the needle assembly. However, this feature is not disclosed in the application as originally filed, and is objectionable under Article 123(2) EPC.

5.6 Sixth auxiliary request

Claim 1 is based on claim 1 of the main request, with the additional feature that a cap is provided for the needle and cartridge assemblies, which feature is known in the prior art, as stated in point 5.1 above.

5.7 Seventh auxiliary request

Claim 1 includes the circular cross-section feature and the metering feature, the former of which is trivial,

as indicated above, and the latter is objectionable under Article 123(2) EPC.

5.8 Eight auxiliary request

Claim 1 is the same as claim 1 of the seventh auxiliary request, but amplified with the features of the couplings, as in the third auxiliary request. Apart from the comments on the previous auxiliary request, which also apply here, the coupling features would appear not to add anything of an inventive nature, see point 5.3.

5.9 It is also noted that auxiliary requests 1, 5, and 6 include a claim identical with claim 10 of the first auxiliary request, which claim was found to define subject-matter lacking in novelty. These requests are additionally not allowable for this reason.

6. From the foregoing it is evident that none of the requests is allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar | The Chairman

V. Commare | T. Kriner