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**Datasheet for the decision
of 24 March 2009**

Case Number: T 1922/06 - 3.2.02

Application Number: 99920567.7

Publication Number: 1079876

IPC: A61M 5/00

Language of the proceedings: EN

Title of invention:

A medical apparatus for use by a patient for medical self treatment of diabetes

Patentee:

NOVO NORDISK A/S

Opponents:

- I) Sanofi-Aventis Deutschland GmbH
II) TecPharma Licensing AG

Headword:

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Relevant legal provisions:

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Relevant legal provisions (EPC 1973):

EPC Art. 54, 99(1), 114(2)
EPC R. 55(c)

Keyword:

"Novelty (yes, after amendments)"

Decisions cited:

-

Catchword:

-



Case Number: T 1922/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 24 March 2009

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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 30 October 2006
revoking European patent No. 1079876 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: M. Noël
Members: D. Valle
A. Pignatelli

Summary of Facts and Submissions

- I. The appellant (patentee) lodged an appeal on 20 December 2006 against the decision of the opposition division to revoke the European patent No. 1079876 for lack of novelty. The notice of appeal was posted on 30 October 2006 and the appeal fee was paid simultaneously. The statement setting out the grounds for appeal was received on 26 February 2007.
- II. The patent was opposed on the basis of Article 100(a) EPC (lack of novelty and inventive step) and 100(b) EPC (insufficient disclosure).
- III. The following documents are relevant for the present decision:
- E2 = WO-A-95/09579
E11 = JP 05-049696 and a certified translation into English.
- IV. Oral proceedings were held on 24 March 2009.

At the end of the oral proceedings the appellant requested that the decision under appeal be set aside and that the patent be maintained as amended according to the main request or one of the auxiliary requests 1 and 3 filed during the oral proceedings, or according to one of the auxiliary requests 2 and 4 to 6 filed on 24 February 2009.

The respondents (opponents I and II) requested that the appeal be dismissed.

V. Claim 1 of the main request reads as follows:

"A medical apparatus for use by a patient for medical self-treatment of diabetes, the treatment including a first operation and at least a second operation, the apparatus comprising a first individual apparatus for performing the first operation and a second individual apparatus for performing the second operation, whereby the first individual apparatus and the second individual apparatus have mutually cooperating coupling means for detachably putting together the first and the second apparatus so as to form a single unit portable by the patient, characterized in that said individual apparatuses at least comprise a blood fluid analyser (34, 50) which is the first individual apparatus and a dosing apparatus (80, 82) for administering a predetermined dose of insulin to the patient which is the second individual apparatus."

Claim 1 of the first auxiliary request reads as follows:

"A medical apparatus for use by a patient for medical self-treatment of diabetes, the treatment including a first operation and at least a second operation, the apparatus comprising a first individual device for performing the first operation and a second individual device for performing the second operation, the first and second individual devices having mutually cooperating coupling means for detachably assembling the first and the second individual devices so as to form a single unit that is portable by the patient, the first individual device being a blood glucose monitor and the second individual device being a dosing device for

administering a predetermined dose of insulin to the patient, and the blood glucose monitor including means for inserting test strips containing a sample of blood for analysis by the blood glucose monitor."

VI. The appellant argued essentially as follows.

The opposition of the opponent II was not admissible since it was not substantiated but only based on general citations of a number of documents without any references to the specific and relevant passages. Their examination, therefore, constituted an excessive burden for the appellant.

The late filed document E11 should not be admitted into the proceedings since it was not relevant. Furthermore document E11 was submitted to support an alleged lack of inventive step objection and is irrelevant to the question of novelty at issue in the present decision.

Regarding the novelty of claim 1 of the main request, E11 did not disclose mutually cooperating coupling means. The schematic group of lines with the reference sign 3 could hardly be regarded as a cap. Even if it was a cap, it did not necessarily have coupling means. Furthermore, E11 did not disclose detachable and removable individual apparatuses for performing each autonomous operation in the sense of the invention, i.e. "stand alone" apparatuses.

E2 did not disclose mutually, i.e. directly, co-operating means in the sense of a detachable assembly as specified in claim 1 of the first auxiliary request. The band 25 in figure 10 did not belong to one

of the devices itself, contrary to the claimed coupling means, which are part of the individual devices. It was not disclosed in E2 either that the blood sugar meter 17 had means for inserting test strips containing a sample of blood.

VII. The respondent contested the statements of the appellant and argued essentially as follows.

The opposition of the opponent II was admissible.

E11 was highly relevant and, therefore, was to be introduced into the proceedings. Moreover, E11 had been extensively discussed during the opposition proceedings also by opponent I and was used in the decision under appeal.

Claim 1 of the main request was not novel against E11. Claim 1 of the first auxiliary request was not novel against E2, given that E2 disclosed mutually co-operating means in the form of complementary filling part 10 and recesses 17a, 18a shown in Figure 4 (see page 9, second paragraph, page 10 first paragraph) and of stick-on bands 25 shown in Figure 10 (see page 10).

Reasons for the Decision

1. The appeal is admissible.
2. *Admissibility of the opposition by the opponent II*

The requirement for admissibility under Article 99(1) and Rule 55(c) is restricted to the provision of a

sufficient indication of the relevant facts and evidence presented in support of the grounds for opposition. The process of ascertaining whether the opposition is well founded in substance has to be done only after it has been determined that the opposition is admissible. In the present case the statement setting out the grounds for opposition is deemed to be sufficient to allow the opposition division and the other parties to understand why the patent had to be revoked.

Accordingly the opposition by the opponent II is admissible.

3. *Admissibility of the late filed document E11*

E11 was correctly admitted into the proceedings by the opposition division, using its discretionary power conferred by Article 114(2) EPC 1973. The Board actually observes that the criteria considered by the opposition division in exercising its discretion, such as the stage of the procedure, the reasons for the late filing and the prima facie highly relevance of this document, were fully appropriate. The certified translation of E11 filed at the appeal stage by the respondent in reaction to the refusal by the opposition division of the machine translation, is also introduced into the appeal proceedings, as being useful for a better understanding of the technical content of the document.

4. *Main request - novelty of claim 1*

E11 discloses (see e.g. figure 1 and text referred to) a medical apparatus for use by a patient for medical self-treatment of diabetes, the treatment including a first operation (sensing the glucose level) and at least a second operation (injecting insulin), the apparatus comprising a first individual apparatus (sensing and measurement means 3-8) for performing the first operation and a second individual apparatus (injector 2) for performing the second operation, whereby the first individual apparatus and the second individual apparatus have mutually co-operating coupling means (cap 3) for detachably putting together the first and the second apparatus so as to form a single unit portable by the patient, whereby said individual apparatuses at least comprise a blood fluid analyser (glucose sensor 6 lodged in the upper cap 3) which is the first individual apparatus and a dosing apparatus (injector body 2) for administering a predetermined dose of insulin to the patient which is the second individual apparatus (see points 8, 9, 12 of the certified translation).

Contrary to the assertion of the appellant, the apparatus of E11 discloses mutually co-operating coupling means in the form of detachable parts of the cap and of the insulin injector, respectively, which makes it possible for the upper cap to "fit over" the proximal end of the insulin injector (see page 3, point 9). It is true that reference numeral 3 in Figure 1 refers schematically to a cap. However the complementary parts are necessarily mutually co-operating coupling means. Similarly, the contested

patent shows embodiments having a cap 10 fitted to the doser (see the top of column 4). Regarding the interpretation of the individual apparatuses being used as stand alone apparatuses, the Board sees no difference between the embodiments of the contested patent and those of E11. The difference, if any, is only of formal nature.

Accordingly, the subject-matter of claim 1 of the main request is not novel over the disclosure of E11.

5. *First auxiliary request*

5.1 Formal matters

With respect to the version according to the main request, the amendments made to claim 1 of the first auxiliary request (means for detachably assembling and means for inserting test strips) are supported in particular by the paragraph bridging pages 2 and 3, by page 7, first paragraph and by the original claim 1 of the application as filed. The requirements of Article 123(2) EPC are, therefore, met.

5.2 Novelty of claim 1

The novelty of claim 1 was objected against E2 only. E2 discloses a medical apparatus for use by a patient for medical self-treatment of diabetes, the treatment including a first operation and at least a second operation, the apparatus comprising a first individual device for performing the first operation and a second individual device for performing the second operation, the first individual device being a blood glucose

monitor 17 and the second individual device being a dosing device (insulin pens) 20 for administering a predetermined dose of insulin to the patient, and the blood glucose monitor including means (see Figure 4) for inserting test strips containing a sample of blood for analysis by the blood glucose monitor.

However, E2 does not disclose that the first and second individual devices have mutually co-operating coupling means for detachably assembling the first and the second individual devices so as to form a single unit that is portable by the patient.

Accordingly, the subject-matter of claim 1 of the first auxiliary request is novel over the disclosure of E2.

The argument put forward by the respondent that E2 discloses mutually co-operating coupling means in the form of either the filling part 10 forming recesses 17a, 18a in Figure 4 or stick-on bands 25 in Figure 10, is not convincing since coupling means in the meaning of the present patent are means able to "assemble" two individual devices and belong to the devices themselves, as recited in the claim by the wording: "the devices having mutually cooperating coupling means".

The argument put forward by the appellant that E2 does not disclose a blood glucose monitor including means for inserting test strips is also not convincing. E2 explicitly discloses that sticks are normally provided for known blood sugar meters (see page 2, line 18). It is believed that the distinction between the claimed strips and the disclosed sticks is irrelevant since

both terms are used in order to design a suitable support for inserting a blood sample in the measuring device without defining a specific form, consistence or material used for it. Moreover, it is assumed that the test sticks contained in the package 19 (see Figure 4 and page 9, line 15) are suitable for insertion into the blood sugar meter referred to in the same paragraph. Therefore, this feature is known from E2.

6. *Remittal*

Since the first instance decision was restricted to the matter of novelty of the claimed subject-matter, the Board finds it appropriate to remit the case to the first instance for further prosecution, using its discretion under Article 111(1) EPC.

Order

For these reasons it is decided that:

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

The Registrar:

The Chairman:

D. Sauter

M. Noël