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**Datasheet for the decision
of 27 April 2009**

Case Number: T 1895/07 - 3.2.02

Application Number: 99911071.1

Publication Number: 1066074

IPC: A61M 15/00

Language of the proceedings: EN

Title of invention:
Aerosolized active agent delivery

Applicant:
Nektar Therapeutics

Opponent:
-

Headword:
-

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC Art. 52(1), 54, 56, 96(2)
EPC R. 51(3)

Keyword:
"Novelty (yes)"
"Remittal for further prosecution"

Decisions cited:
-

Catchword:
-



Case Number: T 1895/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 27 April 2009

Appellant:

Nektar Therapeutics
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Representative:

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Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 30 April 2007
refusing European patent application
No. 99911071.1 pursuant to Article 97(1) EPC
1973.

Composition of the Board:

Chairman: M. Noël
Members: S. Chowdhury
A. Pignatelli

Summary of Facts and Submissions

- I. This appeal is against the decision of the examining division dated 30 April 2007 to refuse European patent application No. 99 911 071.1.

The application was refused on the grounds that the subject-matter of claim 1 then on file lacked novelty having regard to document D1 (US-A-5 672 581), claim 1 of the first auxiliary request lacked an inventive step having regard to D1 or D5 (US-A-5 320 094), and the subject-matter of claim 1 of the second auxiliary request lacked novelty in view of D1.

- II. On 4 July 2007 the appellant lodged an appeal against the decision and paid the prescribed fee on the same day. On 10 September 2007 a statement of grounds of appeal was filed.

The appellant requests that the decision be set aside and a patent be granted on the basis of claims 1 to 17 of the main request, or on the basis of the claims of three auxiliary requests, all filed on 10 September 2007 with the statement of grounds of appeal.

- III. Claim 1 of the present main request is identical with claim 1 of the main request before the examining division and reads as follows:

"A device for increasing the bioavailability of an active agent, said device comprising a flow restricter for limiting the flow of an aerosolized active agent formulation to less than 17 liters per minute".

Reasons for the Decision

1. The appeal is admissible.
2. Novelty - main request
 - 2.1 The present application relates to the problem of providing sufficient delivery of insulin to the lung for maintaining target blood glucose levels in diabetic patients (see the application, WO-A-99/47196, page 3, last two paragraphs). The solution, as defined in claim 1, is to use a flow restricter for limiting the flow of an aerosolized active agent formulation to less than 17 liters per minute.
 - 2.2 The apparatus of D1 works on a different principle. The patient breathes through the device, and the air flow through the device is measured. When the flow rate attains a given value (0.1 to 2 litres/s) a drug is released into the flow path by a valve under the control of a microprocessor (see the Abstract, column 3, lines 19 to 33, column 8, lines 24 to 45, and column 16, line 62 to column 17, line 21).
 - 2.3 The apparatus of D1 has no flow restricter as presently claimed. That is, there is no device which restricts the flow to less than 17 liters per minute. The impugned decision correctly argues that any impediment to air flow may be considered as a flow restricter, for example the air passages 8 and 10 shown in Figure 1 of D1. However, neither do these air passages nor any other feature of the device of D1 restrict the flow to less than 17 liters per minute because, as Figure 5

shows, the air flow is permitted to exceed this value most of the time.

The device of D1 allows air to flow such that flow rates of up to nearly 5 litres/second (300 litres per minute, see Figures 5 and 6) are possible and, when an optimum point in the respiration cycle is reached, insulin is released into the air flow. There is no device which restricts the flow to less than 17 liters per minute. Therefore, D1 does not anticipate the device of claim 1.

2.4 Since the subject-matter of claim 1 is novel over the disclosure of D1 the decision of the first instance must be set aside.

3. Further examination

3.1 The communications under Article 96(2) EPC 1973 from the examining division have given very meagre reasons why the claims are objectionable under Article 52(1) EPC 1973. The communications contain no claim analysis and refer only very briefly to passages of the cited documents. In the case of inventive step no technical problem has been identified and no discussion of the prior art with this in mind has occurred. The requirement of Rule 51(3) EPC 1973 are not met, accordingly.

For these reasons the Board considers it appropriate to remit the case to the department of the first instance for re-examination of the claims for novelty in view of the other cited documents and for inventive step.

Claim 17 is a new use claim which also requires examination as to patentability.

Order

For these reasons it is decided that:

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

The Registrar

The Chairman

D. Sauter

M. Noël