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D E C I S I O N
of 23 November 2004

Case Number: T 0374/01 - 3.3.2

Application Number: 90915978.2

Publication Number: 0500594

IPC: A61K 9/06

Language of the proceedings: EN

Title of invention:
Small particle drug compositions

Patentee:
West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited

Opponent:
Fidia Farmaceutici S.P.A.

Headword:
Small particle drug/WEST PHARMACEUTICAL

Relevant legal provisions:
EPC Art. 54

Keyword:
"Novelty (no) - claimed profile of size distribution of microspheres identical to the measured profile of a sample produced in accordance with the provisions of prior art

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0374/01 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 23 November 2004

(Opponent) Fidia Farmaceutici S.P.A.
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Respondent:
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Representative: Crowhurst, Charlotte Waveney
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 1 February 2001 rejecting the opposition filed against European patent No. 0500594 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
J. P. B. Seitz

Summary of Facts and Submissions

I. European patent No. 0 500 594 based on application No. 90 915 978.2 was granted with two sets of 12 claims for contracting states AT, BE, CH, DE, DK, FR, GB, IT, LI, LU, NL, SE and ES, GR respectively.

Claim 1 as granted for the contracting states other than ES and GR reads as follows:

"A drug delivery composition for intranasal delivery comprising a plurality of bioadhesive microspheres and active drug associated with or forming at least part of each microsphere, at least 90 wt % of the microspheres having a diameter of 0.1 μm or more but less than 10 μm characterised in that the drug is one for which systemic delivery is desired."

II. Opposition was filed against the granted patent by the appellant. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step.

The following documents were cited inter alia during the proceedings before the opposition division and the board of appeal:

(1) WO-A-8703197

(25) Declaration by Mr Davide Renier, Head of Chemistry Research of Fidia Advanced Biopolymers Srl, dated 25 July 2002 with Annex A and Annex B

(26) Declaration by Dr Paolo Pallado, dated 29 July 2002 with Annex 1 and Annex 2

III. The opposition division rejected the opposition under Article 102(2) EPC.

Concerning Article 54 EPC, it was of the opinion that the subject-matter of the patent as granted was new over the cited state of the art documents, since the compositions of the state of the art either did not meet the range of particle size defined in claim 1 of the patent in suit, or the microspheres were not bioadhesive.

As to Article 56 EPC, the opposition division found that the subject-matter of claim 1 was non-obvious over the state of the art, because the advantages of using the smaller microspheres had been shown by examples of the patent in suit and because no hint could be seen especially in the closest prior art (1) that the selection of the specific size of microspheres of a mean diameter between 1 and 10 µm resulted in the advantageous effects.

IV. The appellant (opponent) lodged an appeal against said decision.

V. The respondent (patentee) with a letter dated 10 December 2001 introduced two sets of claims for the two different groups of contracting states as auxiliary request.

The only substantial difference in claim 1 for the contracting states other than ES and GR with respect to claim 1 as granted was the insertion of the words "dry

and air dispersible" after "bioadhesive" which resulted in the following wording (amendments in italics):

"A drug delivery composition for intranasal delivery comprising a plurality of bioadhesive, *dry and air dispersible* microspheres and *an* active drug associated with or forming at least part of each microsphere, at least 90 wt % of the microspheres having a diameter of 0.1 µm or more but less than 10 µm characterised in that the drug is one for which systemic delivery is desired."

The respondent's submissions in writing can be summarised as follows:

Novelty of the subject-matter of the patent in suit was given over the state of the art because, from the teaching of the documents, either there was no use of microspheres in the correct size or no drug for systemic delivery was applied.

After the appellant had filed its declarations (25) and (26) referring to the working of example 2 of document (1) however, the respondent did not make any further substantial submissions.

VI. On 23 November 2004, oral proceedings took place before the board. The duly summoned proprietor (respondent) had informed the board in advance that it did not wish to attend the hearings.

VII. The appellant's arguments in written form and during the oral proceedings referred to the teaching of the

main request as well as to the auxiliary request under examination and may be summarised as follows:

With regard to Article 54 EPC, example 2 of document (1) had been worked. The resultant composition comprising microspheres matched the features of claim 1 of the current requests especially as far as they referred to diameters of particles. Since the drug administered by the microspheres of (1) also showed systemic activity, the subject-matter of the patent in suit was not new over the pharmaceutical composition set out in document (1).

VIII. The appellant (opponent) requested that the decision under appeal be set aside and that the European patent No. 0 500 594 be revoked.

IX. The respondent (patentee) requested in writing that the appeal be dismissed and that the patent be maintained. He auxiliarily requested that the decision under appeal be set aside and that the patent be maintained on the basis of his auxiliary request filed with letter dated 10 December 2001.

Reasons for the Decision

1. The appeal is admissible.

2. Compared with the claims as granted, the corresponding amendments forming the auxiliary request a priori must be considered to be occasioned by the arguments of the appellant. They are admitted into the proceedings.

3. The additional feature contained in the sets of claims of the auxiliary request may be found in the application as filed on page 17, last sentence, and in column 8, lines 9 and 10, of the patent in suit. There is no objection under Article 123(2) or (3) EPC.

4. Document (1) refers to a drug delivery composition for intranasal delivery (see claim 1 together with page 3, line 21, to page 4, line 2) comprising a plurality of bioadhesive (see page 5, lines 16 to 22), dry and air-dispersible (see page 3, line 24, to page 4, line 2) microspheres and an active drug associated with or forming at least part of each microsphere (see claim 1 together with page 3, lines 2 to 13), the active drug being sodium chromoglycate (see claim 1).

Sodium chromoglycate is the drug used in one of the examples of the patent in suit (see column 6, lines 25 to 26 and line 40, in combination with column 7, line 10) and consequently represents a drug meeting the provisions of claim 1 of the patent in suit, inter alia the feature of systemic delivery.

Whether or not the person producing the drug delivery composition or applying it "desires" this systemic delivery, makes no difference to the subject-matter of the claim since the features of a product claim are the properties of this product and not the intentions of the person using it.

Finally, the appellant has worked example 2 of (1) and measured the particle size distribution of the resulting powder. The respondent did not contest that the product obtained was a sample from the teaching of

document (1) and that the measurement was achieved in a correct manner. Beyond this, the board is satisfied to state that, as far as can be seen from the declarations (25) and (26), the product of which the particle size distribution was measured met the provisions of example 2 of (1) and the measurement was conducted correctly.

Therefore, it is clear that the working of example 2 of document (1) in accordance with the teaching of (1) results in a product comprising microspheres, at least 90 wt % of these microspheres having a diameter of 0.1 µm or more but less than 10 µm (see tables 1 and 2 in Annex 2 of (26)). Consequently, all features of claim 1 of the patent in suit with respect to the contracting states other than ES and GR, concerning the wording of the main request as well as the wording of the auxiliary request are anticipated by the teaching of document (1) and the subject-matter of the patent in suit is not new over this state of the art.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

A. Townend U. Oswald