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D E C I S I O N
of 24 June 2004

Case Number: T 1133/03 - 3.3.4

Application Number: 97953188.6

Publication Number: 0952843

IPC: A61K 38/00

Language of the proceedings: EN

Title of invention:
Pharmaceutical formulations for sustained drug delivery

Applicant:
Praecis Pharmaceuticals Incorporated

Opponent:
-

Headword:
Sustained drug delivery/PRAECIS PHARMACEUTICAL INC.

Relevant legal provisions:
EPC Art. 123(2), 82, 89, 54, 111(1)

Keyword:
-

Decisions cited:
-

Catchword:
-

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Case Number: T 1133/03 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 24 June 2004

Appellant: Praecis Pharmaceuticals Incorporated
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Representative: Price, Vincent Andrew
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 2 June 2003 refusing European application No. 97953188.6 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: U. Kinkeldey
Members: M. Wieser
R. Moufang

Summary of Facts and Submissions

I. The appeal was lodged by the Applicants (Appellants) against the decision of the Examining Division to refuse the patent application EP 97 953 188, international publication number WO-A-98/25 642, having the title: "Pharmaceutical formulations for sustained drug delivery".

II. Claim 1 of the main request before the Examining Division read:

"A pharmaceutical composition comprising a water insoluble solid complex whose formation is mediated at least in part by ionic interactions of a pharmaceutically active peptide and a carrier macromolecule, wherein the peptide in said complex is in excess relative to the carrier macromolecule on a weight basis."

The Examining Division decided that this claim lacked novelty (Article 54 EPC) in the light of the disclosure in document (3), WO-A-92/11 844.

Moreover, the Examining Division decided that the claims of a first and second auxiliary request before them lacked unity of invention contrary to the requirements of Article 82 EPC.

III. In the grounds of appeal the Appellants maintained their main request and first and second auxiliary requests and filed an additional, third auxiliary request.

In a communication dated 4 May 2004 the Board expressed their preliminary opinion about the allowability of a number of claims in the above mentioned requests in the light of the requirements of Articles 54, 82, 84 and 123(2) EPC.

Oral proceedings were held on 24 June 2004. In these proceedings the Appellants, in answer to these objections, replaced all former requests by a single new main request.

IV. The Appellants requested that the decision under appeal be set aside and that a patent be granted on the basis of the new main request consisting of claims 1 to 16 filed at the oral proceedings.

Claim 1 thereof reads:

"A pharmaceutical composition comprising a water insoluble solid complex whose formation is mediated at least in part by ionic interactions of an LHRH antagonist and a carrier macromolecule, wherein the LHRH antagonist in said complex is in excess relative to the carrier macromolecule on a weight basis."

Dependent claims 2 to 12 refer to preferred embodiments of the pharmaceutical composition. Claim 13 refers to a packaged formulation comprising the pharmaceutical composition, and claims 14 to 16 relate to its use in the manufacture of a medicament for the treatment of specific diseases.

V. The submissions of the Appellants, as far as they are relevant for the present decision, may be summarised as follows:

Claims 1 to 16 of the new main request were based on the application as originally filed (Article 123(2) EPC), they were clear and concise and supported by the description (Article 84 EPC).

By having restricted claim 1 to a pharmaceutical composition comprising a complex of an LHRH antagonist and a carrier, the claims referred to one invention only so that the requirements of Article 82 EPC were met. Moreover, as a composition comprising such complex was not disclosed in the cited prior art documents, the subject-matter of the claims was novel according to the requirements of Article 54 EPC.

VI. Besides document (3), mentioned in section (II) above, the following documents are referred to in this decision:

(1) WO-A-94/15 587

(2) EP-A-0 467 389

(4) EP-A-0 601 799

(6) WO-A-97/22 357

Reasons for the decision

1. The appeal meets the requirements of Articles 106 to 108 EPC and Rule 64 EPC and is thus admissible.

Amendments - Article 123(2) EPC

2. Claims 1 to 16 of the new main request filed at oral proceedings have a basis in the application as originally filed as follows:

claim no.	application as originally filed
(1)	claims 22,23,29; page 2, line 5; page 11, lines 12 to 13
(2)	claim 3
(3)	page 3, lines 20 to 22
(4)	page 11, lines 18 to 20
(5)	page 12, lines 2 to 4
(6)	claims 73 to 76
(7)	claim 10
(8)	page 7, lines 31 to 33; page 8, lines 22 to 23
(9)	claims 14 to 18
(10)	page 2, lines 4 to 7
(11)	claim 20
(12)	claims 30 and 31; page 10, lines 1 to 2; Examples 8 and 9
(13)	claim 43; page 10, lines 12 to 14
(14)	claims 72 to 77,88,89
(15)	page 10, lines 1 to 2; Examples 8 and 9

(16) claims 84 to 86

Thus, the claims meet the requirements of Article 123(2) EPC.

Clarity - Article 84 EPC

3. Claims 1 to 16 are clear, concise and supported by the description, in accordance with the requirements of Article 84 EPC.

Unity of invention - Article 82 EPC

4. Claims 1 to 16 refer to a pharmaceutical composition comprising a complex of an LHRH antagonist and a carrier, to a packaged formulation comprising the composition, and to the use of the composition in the manufacture of a medicament.

The requirements of Article 82 EPC that a European patent application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept, are met.

Novelty - Article 54 EPC

5. Document (3) was considered by the Examining Division to be novelty destroying for a claim referring to a water insoluble solid complex formed by a non-specified pharmaceutically active peptide and a carrier, wherein the peptide is in excess relative to the carrier (see section (II) above and point (2) of the reasons of the decision under appeal).

Document (3) does not mention a complex containing an LHRH antagonist.

6. Prior art documents disclosing sustained release formulations wherein a physiologically active peptide is encapsulated within a microparticle comprising a poly-lactide/poly-glycolide copolymer are acknowledged on page 1, lines 15 to 22 of the present application as originally filed.

Document (4) discloses such sustained release microparticles comprising an LHRH antagonist encapsulated within a biodegradable polymer (see claims 1 and 15). The peptide content of the produced microcapsules lies between 10 and 11 % (w/w) (see Examples 8 to 10).

Document (6), which belongs to the state of the art under Article 54(3) EPC, also discloses LHRH antagonist containing microcapsules (see claims 31 and 36). The document also refers to LHRH antagonists enclosed in an osmotic pump (claim 37). No figures are given concerning the LHRH antagonist content of these sustained release formulations.

7. Document (1) refers to ionic molecular conjugates made from polycarboxylic acid-tipped polyesters conjugated with mono- or poly-basic bioactive polypeptides, such as LHRH and the LHRH agonist D-Trp^{6}-LHRH (page 3, lines 15 to 24 and Table V on page 18). The claimed conjugates contain at most 50 percent of the bioactive polypeptides (claim 8). LHRH antagonists are not mentioned in document (1).

8. Document (2), not mentioning LHRH antagonists, discloses a drug delivery system comprising a hydrophobic biodegradable polymer and physiologically active polypeptide, wherein the polypeptide/polymer ratio ranges between 1:1 and 1:100 (see claim 1 and page 7, lines 8 to 11).

9. Accordingly, the board decides that the subject-matter of claims 1 to 16 is not anticipated under Article 54 EPC by the disclosure in the prior art documents on file.

Remittal - Article 111(1) EPC

10. The Examining Division, confronted with different sets of claims, which they found not to fulfil the requirements of Articles 54 and 82 EPC, did not examine whether the claimed invention involves an inventive step according to the requirements of Article 56 EPC.

Therefore, the Board at its discretion under Article 111(1) EPC remits the case to the Examining Division for further prosecution.

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 Chairwoman:

A. Wolinski U. Kinkeldey