BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen
(D) [ ] No distribution

Datasheet for the decision of 22 October 2009

Case Number: T 0816/06 - 3.3.02

Application Number: 98948113.0

Publication Number: 1015032

IPC: A61K 47/26

Language of the proceedings: EN

Title of invention:
High viscosity liquid controlled delivery system as a device

Applicant:
Durect Corporation

Headword:
High viscosity controlled delivery system/DURECT

Relevant legal provisions:
EPC Art. 56, 111

Relevant legal provisions (EPC 1973):
-

Keyword:
"Novelty (no): Main request: all features anticipated by state of the art"
"Novelty (yes): Auxiliary request: claimed subject-matter not individualised in closest state of the art"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0816/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 22 October 2009

Appellant: Durect Corporation
2 Results Way
Cupertino, CA 95014-4166 (US)

Representative: Woods, Geoffrey Corlett
J.A. KEMP & CO.
14 South Square
Gray's Inn
London WC1R 5JJ (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 28 November 2005 refusing European application No. 98948113.0 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
J. Van Moer

Summary of Facts and Submissions

I. European patent application No. 98 948 113.0, filed as WO 99/13913 on the basis of international patent application PCT/US98/18629, was refused by a decision of the examining division in accordance with Article 97(1) EPC 1973 for lack of novelty under Article 54 EPC.

The wording of claim 1 of the main request before the examining division was:

"Use of a carrier material for the manufacture of a wound dressing composition, wherein the carrier material comprises a non-polymeric, non-water soluble, high viscosity liquid carrier material having a viscosity of at least 5,000 cP at 37°C that does not crystallize neat under ambient or physiological conditions, and further wherein said composition includes at least one of an antibiotic, an anti-inflammatory compound, an analgesic, an anaesthetic, and a growth factor."

II. The following documents *inter alia* were cited during the proceedings before the examining division and the board of appeal:

(1) WO 96/39995 A1

(2) DE 1 569 231 A

(3) Declaration of F. Okumu, dated 7 April 2006 and submitted with the statement of grounds of appeal of 10 April 2006

III. The examining division held the subject-matter of the application to be not new with respect to document (1) since this document disclosed all the claimed features.

IV. There were no arguments or conclusions in the reasons for the decision with respect to Articles 84, 83 and 123 EPC.

V. The applicant (appellant) lodged an appeal against the decision of the examining division and filed grounds of appeal.

VI. Oral proceedings took place on 22 October 2009 in the presence of the appellant's representative.

During the oral proceedings, the requests submitted in writing were replaced by one set of claims as a main request and new first to fifth auxiliary requests replacing all previously filed requests.

The wording of claim 1 of the main request is:

"A composition comprising sucrose acetate isobutyrate (SAIB) and a growth factor for use in providing new tissue growth *in vivo* wherein said composition acts as scaffolding adaptive to said new tissue growth."

Claim 1 of the first auxiliary request reads:

"A composition comprising sucrose acetate isobutyrate (SAIB) and a growth factor for use in providing growth of bone or nerve cells *in vivo* wherein said composition

acts as scaffolding that provides a matrix for the attachment and growth of the bone or nerve cells."

VII. The appellant's arguments, as set out in writing and during the oral proceedings, may be summarised as follows:

As indicated in the statement by Mr Okumu in the last six lines of document (3), that he believed

"that the use of SAIB formulations in such applications to provide a scaffolding that is adaptive to new tissue growth, e.g., new bone tissue growth, is a novel and unique use of these materials since the SAIB carrier is an amorphous liquid and therefore not in a form that would provide a solid scaffolding structure with suitable mechanical strength as is common with state-of-the-art bone paste compositions."

the appellant has pointed out that the term "scaffolding" was to be understood in the sense of the paragraph on page 17, lines 13 to 18 of the application in suit, i.e. the "scaffolding" provided a matrix suitable for the attachment and growth of tissue cells. The SAIB carrier was able to perform this task because of its high viscosity under the given conditions and at the place of action in deficient tissue. With respect to the experiments described in the Okumu declaration (document (3)), for instance, the SAIB carrier was placed around and in the rupture of the broken bone, where it could be replaced by new growing tissue, the growth being supported by the growth factor.

The novelty of the subject-matter in claim 1 of the main request with respect to example 18 of document (1) had to be recognised, because example 18, describing the occlusion of the inguinal canal did not make any sense in itself. The inguinal canal carried the spermatic cord in the male body and the round ligament in the female body. Its occlusion would destroy the normal function of these organs passing through this canal and was thus not to be counted as a valid disclosure in the state of the art.

The subject-matter of the first auxiliary request was new since in document (1) there were different possibilities of applying the compositions as claimed, such as in soft tissue, hard tissue and cavities of the body and there were two lists of possible actives to be released by the carrier, the one carrying quite a lot of different substances and the other, which contained only six groups of substances, relating in particular to the agricultural use of the compositions of the application.

VIII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or any of the auxiliary requests 1 to 5 submitted during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. *Main and first to fifth auxiliary requests; admissibility*

The sets of claims which the appellant introduced during the oral proceedings were admitted into the proceedings, since their wording is a simple and clear-cut amendment, introduced in direct response to the objections of the board.

3. *Main request and first auxiliary request, Article 123(2) and Article 84 EPC*

The features of these claims may be derived from claims 1 and 2 of the original application together with page 4, lines 15 to 18, page 16, lines 11 to 18, and page 17, lines 13 to 18 of the description as originally filed.

In addition, in the light of the appellant's explanations (see point VII of this decision), the board sees no problems with respect to clarity and support.

4. *Main request, novelty*

4.1 The teaching of the main request refers to a composition comprising

- sucrose acetate isobutyrate (SAIB) and a
- growth factor for use in
- providing new tissue growth *in vivo*
- wherein said composition acts as scaffolding adaptive to said new tissue growth

whilst in the light of the appellant's explanations (see point VII of this decision), the board understands the term "scaffolding" in its broadest technically meaningful sense as providing a matrix suitable for the attachment and growth of tissue cells at the place of any deficiency.

4.2 Example 18 on page 43 of document (1) refers to

a composition comprising

- sucrose acetate isobutyrate (SAIB) (page 43, line 8) and a
- growth factor (page 43, line 9) for use in
- providing new tissue growth *in vivo* (page 43, lines 10 to 11)
- wherein said composition acts as scaffolding adaptive to said new tissue growth (page 43, lines 11 to 12).

In example 18 of document (1) which is repeated identically in the application in suit on page 35, it is stated that compositions as claimed were injected into the inguinal canal of a dog where they elicited a cellular response leading to occlusion of the canal.

The board is satisfied that this experiment - in full agreement with the obvious intention of the applicant - represents a successful application of the compositions as claimed. The inguinal canal is known to be a potential source of weakness. At least inducing a target-oriented growth of new and additional tissue connected to this canal and the living body around and not through the spermatic cord in the male and the

round ligament in the female, obviously has to be seen as a success in the sense of the claimed teaching.

4.3 On the other hand, no difference can be seen between such a target-oriented growth of new and additional tissue as is set out in example 18 and the SAIB carrier providing a matrix suitable for the attachment and growth of tissue cells.

4.4 Thus, all features of claim 1 of the main request are anticipated by the teaching of example 18 of document (1) and form part of the state of the art (Article 54(2) EPC).

5. The further arguments of the appellant with respect to claim 1 of the main request cannot hold:

The appellant doubted the validity of the teaching of example 18 of document (1) with respect to whether an "occlusion" of the inguinal canal makes sense or not.

Since, *in vivo* and under normal conditions, growth of tissue cells in the inguinal canal would never end in cutting or disrupting the spermatic cord in the male and the round ligament in the female in order to arrive at a full "occlusion" of the canal, the board can see in this wording only the description of an occlusion of the canal as far as the passing organs of the body allow such an occlusion without losing their function.

6. *First auxiliary request, novelty*

In line with the appellant's submissions (see point VII of this decision), the board considers that inducing

the growth of bone and nerve cells (in contrast to growth of cells in soft tissue or in cavities; see document (1), page 5, lines 14 to 18) by application of the SAIB carrier together with a growth factor (as one of the numerous substances from the paragraph bridging pages 14 and 15 of document (1) or one of the obviously agriculture-related substances on page 13, lines 19 to 21) was not individualised in document (1).

Therefore, the subject-matter of claim 1 of the first auxiliary request is new with respect to document (1).

Novelty with respect to document (2) is based on the absence of any growth factor or use in providing growth of bone or nerve cells (see claims 1 and 3 of (2) together with page 4, paragraph 2, and examples 11, 16 and 20).

7. Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered at two instances, it is recognised that any party may be given an opportunity for two readings of the important elements of a case.

In the present case, the teaching of the set of claims of the first auxiliary request is now found to be new, in contrast to the examining division's decision which was restricted to the subject of novelty with respect to the former claims. Thus, a new situation has been created with respect to the new claims, which should now be examined on their own merits.

The board has therefore decided to exercise its discretion under Article 111 EPC and remits the case to

the first instance for further prosecution on the basis of the first auxiliary request.

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 on the basis of the first auxiliary request.

The Registrar: The Chairman:

N. Maslin U. Oswald