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**Datasheet for the decision
of 13 November 2007**

Case Number: T 0631/03 - 3.3.02

Application Number: 96938326.4

Publication Number: 0862419

IPC: A61K 9/16

Language of the proceedings: EN

Title of invention:

Microencapsulated DNA for vaccination and gene therapy

Patentee:

MICROBIOLOGICAL RESEARCH AUTHORITY

Opponents:

Emerald Gene Systems, Ltd.
AVENTIS PASTEUR
Novartis Vaccines and Diagnostics, Inc.
Southern Research Institute

Headword:

Microencapsulated DNA/MICROBIOLOGICAL RESEARCH AUTHORITY

Relevant legal provisions:

EPC Art. 123(2), 123(3)

Keyword:

"Substantial amendments - remittal to first instance"

Decisions cited:

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Catchword:

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Case Number: T 0631/03 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 13 November 2007

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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 25 March 2003
rejecting the oppositions filed against
European patent No. 0862419 pursuant to
Article 102(2) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
J. Van Moer

Summary of Facts and Submissions

- I. European patent No. 0 862 419, which was filed as international application WO 97/17063, was granted on the basis of forty-five claims, including four independent product claims (claims 1, 17, 29 and 30), two independent method claims (claims 31 and 38) and four independent use claims (claims 42 to 45).

Independent claims 1 and 38 as granted read as follows (emphasis added):

"1. A composition comprising a microparticle and DNA, **wherein the DNA is in an aqueous solution**, is inside the microparticle and comprises a sequence coding for a polypeptide, wherein the DNA is active DNA, in that it retains its ability to induce expression of its coding sequence following administration to a recipient, and wherein the microparticle is 10µm or less in diameter.

38. A method of encapsulating DNA in a microparticle, wherein the DNA comprises a sequence coding for a polypeptide and is adapted to induce expression of the coding sequence, comprising the steps of preparing a mixture of the DNA and a water-in-oil-in-water emulsion suitable to form microparticles, forming microparticles **of 10µm or less in diameter** that contain DNA and separating DNA-containing microparticles from the mixture by centrifugation, characterised in that the DNA retains its ability to induce expression of its coding sequence."

- II. Oppositions were filed against the granted patent by opponents I to IV. The patent was opposed under Article 100(c) EPC (the subject-matter of the granted patent extends beyond the content of the application as filed), 100(b) EPC (insufficiency of disclosure) and 100(a) EPC (lack of novelty and lack of inventive step).
- III. The appeal lies from a decision of the opposition division rejecting the oppositions under Article 102(2) EPC.

The opposition division considered that none of the grounds for opposition prejudiced the patent as granted.

Regarding the objection under Article 100(c) EPC, the opposition division was of the opinion that a number of features introduced into the granted claims, such as "wherein the DNA is in aqueous solution", were disclosed in the application as originally filed.

- IV. The appellant (opponent IV) lodged an appeal against this decision and filed grounds of appeal.
- V. In response to the communication accompanying the summons to oral proceedings, in which the board gave its provisional opinion with respect to the opposition ground pursuant to Article 100(c) EPC, the respondent (patentee) submitted auxiliary requests I to IV with its letter of 13 September 2007.

Auxiliary request IV included a single independent claim which differed from claim 38 as granted in that the claimed method was defined as "a method of encapsulating DNA in a polymer microparticle" and in

that the following feature had been added at the end of the claim: "and that at least 25% DNA activity, as assessed by an assay of transformation of competent bacteria or transfection of cultured cells, is retained in the resultant microparticles".

VI. Opponents I to III as parties as of right announced by letters of 16 May 2007, 4 June 2007 and 13 September 2007, respectively, that they would not be attending oral proceedings.

VII. The appellant announced by fax received on 12 November 2007 that it would not attend the oral proceedings.

VIII. Oral proceedings were held before the board on 13 November 2007.

IX. During oral proceedings the respondent withdrew its main request and auxiliary requests I to III and only maintained auxiliary request IV as main and sole request (cf. point V).

Regarding the requirements of Article 123(2) EPC, the respondent indicated that the basis for said sole request was to be found in claim 41 as originally filed, which corresponded to claim 38 as granted, in combination with the disclosure on page 8, third paragraph to page 11, line 1.

X. The appellant did not submit any arguments in writing with respect to the sole request filed as auxiliary request IV with the letter of 13 September 2007.

XI. The appellant (opponent 04) requested in writing that the decision under appeal be set aside and that the European patent be revoked.

The respondent (patentee) requested that the appeal be dismissed and the patent be maintained on the basis of the fourth auxiliary request filed on 13 September 2007 now sole request or in the alternative to remit the case to the first instance for further prosecution.

Reasons for the Decision

1. The appeal is admissible.
2. *Article 123 EPC*

The sole request is based on claim 41 as originally filed. In addition, several features have been incorporated in accordance with the corresponding passage of the description as originally filed disclosing the method of encapsulating DNA as "a second aspect of the invention" (see page 8, third paragraph to page 11, line 1).

In particular, the features "polymer microparticle" and "of 10µm or less in diameter" introduced into claim 1 are disclosed on page 8, third paragraph, and page 9, third complete paragraph, respectively.

Furthermore, the requirement introduced into claim 1 that "that at least 25% DNA activity ... is retained in the resultant microparticles" has its basis on page 10, third complete paragraph, and the corresponding method

of measurement "as assessed by an assay of transformation of competent bacteria or transfection of cultured cells" on page 9, first complete paragraph. The board is convinced that this method of measurement is generally applicable, independently of the preparative steps of the particular embodiment in which it is mentioned.

Dependent claims 2 and 3 are directly and unambiguously derivable from page 8, last paragraph, and page 9, second complete paragraph, respectively.

Additionally, it is self-evident that the method now claimed in claim 1 has been restricted with respect to that of claim 38 of the granted version.

Consequently, the sole request meets the requirements of Article 123(2) and (3) EPC.

3. *Remittal to the department of first instance*

The now sole request filed as auxiliary request IV with the letter of 13 September 2007 contains only a single independent claim, namely claim 1, which is directed to a method, i.e. all product claims have been deleted.

Claim 1 now incorporates additional features from the description, which were not present in the corresponding independent method claim as granted. It has thus been substantially amended with respect to the corresponding claim 38 as granted, and the opposition division's findings therefore do not directly apply.

Additionally, the essential issues relating to novelty and inventive step with respect to the subject-matter now claimed have not been discussed during the written appeal procedure.

Moreover, the respondent has requested remittal to the department of first instance for further prosecution as auxiliary request.

Accordingly, the board has decided to make use of its discretionary power and remit the case to the department of first instance for further prosecution (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 on the basis of the sole request filed as fourth auxiliary request on 13 September 2007.

The Registrar:

The Chairman:

N. Maslin

U. Oswald