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D E C I S I O N
of 26 June 1996

Case Number: T 0845/93 - 3.3.4

Application Number: 82304513.3

Publication Number: 0073657

IPC: C12N 15/81

Language of the proceedings: EN

Title of invention:
Preparation of hepatitis B surface antigen in yeast

Patentee:
GENENTECH, INC.

Opponent:
Akzo Pharma B.V.
Pasteur Merieux Serums et Vaccins
Institut Pasteur

Headword:
Hepatitis B surface antigen in yeast/GENENTECH

Relevant legal provisions:
EPC Art. 84, 123, 111

Keyword:
"New main request filed at oral proceedings - admitted into proceedings because it met requirements of Article 123, 84 and 54 EPC - referred to first instance for examination of inventive step"

Decisions cited:
-

Catchword:
-

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Case Number: T 0845/93 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 26 June 1996

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 21 July 1993 revoking European patent No. 0 073 657 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: R. E. Gramaglia
S. C. Perryman

Summary of Facts and Submissions

I. European patent No. 073 657, based on European patent application No. 82 304 513.3 was filed on 26 August 1982 claiming priority from US 298236 filed on 31 August 1981 and was granted with eleven claims of which independent claim 8 read as follows:

"8. A method of producing hepatitis B surface antigen in particle form suitable for use in conferring immunogenicity to hepatitis B virus in susceptible human which comprises:

(a) providing a DNA transfer vector capable of replication and phenotypic selection in yeast host strains;

(b) providing a DNA fragment comprising a promoter compatible with a yeast host strain;

(c) providing a DNA fragment encoding hepatitis B surface antigen and lacking any sequence encoding HBsAg precursor sequence;

(d) assembling the fragments of steps (a), (b) and (c) to form a replicable expression vector wherein said sequence of step (c) is under control of said promoter, with appropriate translational start and stop signals, such that it is expressible to produce mature hepatitis B surface antigen;

(e) transforming a yeast strain with the vector of step (d);

(f) allowing the yeast transformant to grow until said hepatitis B surface antigen is produced therein; and

(g) recovering said hepatitis B surface antigen in discrete particle form."

II. Three oppositions were filed requesting revocation of the patent in its entirety on the grounds of lack of novelty, lack of inventive step (Articles 52, 54, 56 and 100(a) EPC) and insufficient disclosure (Articles 83 and 100(b) EPC), relying in particular on the following documents:

(1A) EP-A-0072318

(7) San Francisco Chronicle, 4 August 1981, pages 8 and 9

(16) Moriarty et al., PNAS USA Vol. 78, pages 2606-2610 (1978).

III. The Opposition Division revoked the patent. The decision was taken on the basis of the set of claims as filed on 17 July 1992, of which independent claim 8 was as claim 8 as granted except for changes to the introduction and feature (c) shown below by underlining and striking out respectively:

"8. A method for ~~of~~ producing hepatitis B surface antigen in particle form suitable for use in conferring immunogenicity to hepatitis B virus in a susceptible human which comprises:

.....

(c) providing a DNA fragment encoding hepatitis B surface antigen and lacking ~~any sequence encoding~~ all bases of the ~~HBsAg~~ 5' precursor sequence;

.....

IV. The Opposition Division considered that while the subject-matter of the claims was novel over the post-published European patent application (1A), which had an earlier priority date and so was prior art for the purpose of Article 54(3) EPC only, it lacked an inventive step over documents (16) and (7).

V. The Appellant appealed against this decision. In the statement of Grounds of Appeal submitted on 1 December 1993 and in subsequent written submissions the Appellant argued for the allowance of the appeal in relation to a main request and five subsidiary requests. Respondent I (Opponent 1) made no written submissions. The other two Respondents II and III made written submissions arguing that none of the requests were allowable and requesting that the appeal be dismissed.

VI. The Board sent a communication dated 24 April 1996, accompanying the summons to oral proceedings, raising various issues that required clarification.

VII. Oral proceedings were held on 26 June 1996, at which representatives of the Appellant and of the Respondents II and III (Opponents 2 and 3) were present. After discussion of the requests on file, and an indication by the Board of its views on these, the Appellant withdrew all previous requests and submitted a new main request and a new sole auxiliary request, which were then discussed.

VIII. Claim 1 of the main request filed at the oral proceedings read as follows (amendment in feature (g) underlined):

"A method of producing hepatitis B surface antigen in particle form suitable for use in conferring immunogenicity to hepatitis B virus in a susceptible human which comprises:

(a) providing a DNA transfer vector capable of replication and phenotypic selection in yeast host strains;

(b) providing a DNA fragment comprising a promoter compatible with a yeast host strain;

(c) providing a DNA fragment encoding hepatitis B surface antigen and lacking any sequence encoding the HBsAg precursor sequence;

(d) assembling the fragments of steps (a), (b) and (c) to form a replicable expression vector wherein said sequence of step (c) is under control of said promoter, with appropriate translational start and stop signals such that it is expressible to produce mature hepatitis B surface antigen;

(e) transforming a yeast strain with the vector of step (d);

(f) allowing the yeast transformant to grow until said hepatitis B surface antigen is produced therein; and

(g) <u>lysing the yeast cells with a glass bead suspension and</u> recovering therefrom said hepatitis B surface antigen in discrete particle form."

IX. The Appellant argued that the subject-matter of this claim, differing from granted claim 8 by the addition in step (g) of the wording "lysing the yeast cells with a glass bead suspension", met the requirements of the EPC because it was supported by the description as originally filed, it was novel and also not obvious when taking the document Liu et al, DNA, Vol. 1, pages 213-221 (1982) as an expert opinion.

X. The Appellant (Patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or the sole subsidiary claim request submitted at the oral proceedings on 26 June 1996. The Respondents II and III requested that the appeal be dismissed.

Reasons for the Decision

Main request

Articles 123 and 84 EPC

1. Claim 1 of the main request differs from claim 8 as granted by the requirement in step (g) that the hepatitis B surface antigen should be recovered by "lysing the yeast cells with a glass bead suspension". There is a basis on page 27 lines 11 and 12, and page 28, lines 1 and 2 of the application as filed (corresponding to the passage at column 15, lines 25 and 52 of the patent as granted) for this wording, so that the requirements of Article 123(2) EPC are met.

Furthermore, this additional requirement restricts the scope of the claim compared to the scope of claim 8 as granted. The amendment thus complies with the requirement of Article 123(3) EPC that claims may not be amended in such a way as extend the protection conferred.

2. Dependent claims 2 to 4 are identical with the corresponding granted claims 9 to 11. They were neither amended, nor were they objected to by the Respondents.

3. The amendment causes no lack of clarity that would be objectionable under Article 84 EPC.

4. Consequently, the requirements of Articles 123 and 84 EPC are met by the amendment.

Novelty (Article 54 EPC)

5. Novelty of claim 1 was not disputed

Inventive Step (Article 56 EPC)

6. The claims of the main request rely on a novel technical feature which in the Appellant's view also renders the claims inventive. That this feature is of some significance also appears from the submissions of Respondent III, (Opponent 3), in his letter of 19 July 1994 page 26, when pointing out that the patent in suit did not disclose secretion of HBsAg, but required lysis by beads. In these circumstances the Board is prepared to allow this main request into the proceedings. However, as inventive step in relation to a claim with this feature has not been considered by the first instance, the Board exercises its discretionary power under Article 111(1) EPC and remits the case to the Opposition for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The matter is referred to the first instance for further prosecution on the basis of the main request filed at oral proceedings on 26 June 1996.

The Registrar:

A. Townend

The Chairwoman:

U. M. Kinkeldey