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D E C I S I O N
of 22 March 2006

Case Number: T 0786/03 - 3.3.10

Application Number: 94116937.7

Publication Number: 0650736

IPC: A61L 2/04

Language of the proceedings: EN

Title of invention:

Method for sterilizing recombinant human serum albumin
pharmaceutical preparation

Applicant:

Mitsubishi Pharma Corporation

Opponent:

Delta Biotechnology Limited

Headword:

Sterilizing recombinant human serum albumin/MITSUBISHI PHARMA

Relevant legal provisions:

EPC R. 57a

Keyword:

"Amendments: all requests (not allowable) - not occasioned by
grounds for opposition - optional feature"

Decisions cited:

T 1066/00

Catchword:

-



Case Number: T 0786/03 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 22 March 2006

Appellant: Mitsubishi Pharma Corporation
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Respondent: Delta Biotechnology Limited
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Representative: Bassett, Richard Simon
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 12 May 2003
revoking European patent No. 0650736 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: R. Freimuth
Members: J. Mercey
D. Rogers

Summary of Facts and Submissions

- I. The Appellant (Proprietor of the Patent) lodged an appeal on 7 July 2003 against the decision of the Opposition Division dated 12 May 2003 revoking European patent No. 650 736 and on 22 September 2003 filed a written statement setting out the grounds of appeal.
- II. Notice of Opposition had been filed by the Respondent (Opponent), requesting revocation of the patent in its entirety on the grounds of lack of inventive step (Article 100(a) EPC) and insufficient disclosure (Article 100(b) EPC).
- III. The Opposition Division held that the subject-matter of the then pending main and auxiliary requests was not inventive.
- IV. Annexed to the Statement of the Grounds of Appeal, the Appellant submitted a main request and five auxiliary requests superseding any previous request. The main request comprised a set of two claims, independent claim 1 reading as follows:

"1. A method for sterilizing a liquid recombinant human serum albumin pharmaceutical preparation against microorganisms that may possibly be present as contaminants after aseptic packing of a pharmaceutical preparation of rHSA obtained by gene manipulation techniques, comprising subjecting a pharmaceutical preparation of recombinant human serum albumin, which is packed in a container in an administration unit, to heat treatment at 50 to 80°C for 30 minutes to 1 hour."

Claim 1 of each of the auxiliary requests 1 to 5 differed from claim 1 of the main request exclusively in that the feature "to heat treatment at 50 to 80°C for 30 minutes to 1 hour" was replaced by the feature(s):

"to heat treatment at 50 to 80°C for 30 minutes" in auxiliary request 1;

"to heat treatment at 50 to 60°C for 30 minutes" in auxiliary request 2;

"after ultrafiltration and sterile filtration of said preparation, to heat treatment at 50 to 80°C for 30 minutes" in auxiliary request 3;

"after ultrafiltration and sterile filtration of said preparation, to heat treatment at 50 to 60°C for 30 minutes" in auxiliary request 4; and by

"to heat treatment at 50 to 80°C for 30 minutes, wherein the microorganism is selected from *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Candida albicans*, *Pichia pastoris*, *Aspergillus niger*, and *Bacillus subtilis*" in auxiliary request 5.

V. The Appellant submitted that the amendments comprised in claim 1 of all of the requests *vis-à-vis* the granted claim 1 were as follows:

(a) the addition of the feature "liquid"; and

(b) the addition of the feature "against microorganisms that may possibly be present as

contaminants after aseptic packing of a pharmaceutical preparation of rHSA obtained by gene manipulation techniques".

The Appellant argued that each of these amendments fulfilled the requirements of Rule 57a EPC, since they were occasioned by grounds for opposition, namely those of Article 100(a) and/or 100(b) EPC. The Appellant further argued that these amendments found support in the application as filed, and thus complied with the requirements of Article 123(2) EPC. The Appellant submitted that the subject-matter of claim 1 of all requests was inventive.

VI. The Respondent argued in writing that the amendment identified under point V(b) above made to all the requests contravened the requirements of Rule 57a EPC, as it was not occasioned by a ground for opposition. The Respondent further argued that the amendment identified under point V(a) above offended against the requirements of Article 123(2) EPC, since the specification that the recombinant HSA was in liquid form was an unallowable generalisation of a feature disclosed in the context of specific embodiments only, in the application as filed. The Respondent submitted that the subject-matter of the main request and of auxiliary requests 1, 2 and 5 was not novel, and that the subject-matter of the claims of all requests was neither inventive nor sufficiently disclosed.

VII. In a communication pursuant to Article 11(1) of the Rules of Procedure of the Boards of Appeal, the Board indicated *inter alia* that discussion of whether or not

the amendments to the claims met the requirements of Rule 57a EPC was necessary.

VIII. The Appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request or, subsidiarily, on the basis of any of the auxiliary requests 1 to 5, all requests submitted on 22 September 2003.

The Respondent requested that the appeal be dismissed.

IX. Oral proceedings were held on 22 March 2006 in the absence of the Respondent, who, after having been duly summoned, informed the Board with a letter dated 17 March 2006 that he would not attend. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request, auxiliary requests 1 to 5

2. *Amendments (Rule 57a EPC)*

2.1 According to Rule 57a EPC, the claims of a granted patent may be amended, provided that the amendments are occasioned by a ground for opposition specified in Article 100 EPC, even if the respective ground has not been invoked by the opponent.

- 2.2 Claim 1 of the main request has been amended *vis-à-vis* the granted claim 1 *inter alia* by addition of the feature "against microorganisms that may possibly be present as contaminants after aseptic packing of a pharmaceutical preparation of rHSA obtained by gene manipulation techniques" (see point V(b) above). This feature is, by virtue of the wording "that may possibly be present", merely optional, i.e. it embraces methods whereby microorganisms are present or absent.
- 2.3 However, amendment of an independent claim by addition of an optional feature is not suitable for overcoming a ground for opposition pursuant to Article 100 EPC, since such a feature does not restrict the claimed subject-matter. Since the feature is not mandatory, but merely optional, it modifies the wording of the claim as granted but does not amend the subject-matter thereof. Thus a fresh optional feature does not delimit the subject-matter claimed from that as granted with the consequence that it cannot contribute towards rendering the subject-matter either novel or inventive, or to the invention being sufficiently disclosed, or to the subject-matter being based on the application as filed (see decision T 1066/00, points 22 to 26 of the reasons, not published in OJ EPO).
- 2.4 Thus in the present case, the insertion into claim 1 of the main request of the optional feature identified under point V(b) above, namely to sterilise against microorganisms that may possibly be present, does not restrict the subject-matter of claim 1 as granted, since the presence of the microorganisms is not mandatory with the consequence that this amendment can under no circumstances overcome and, hence, cannot be

occasioned by, any ground for opposition as required by Rule 57a EPC.

As a result, the Appellant's main request is not allowable.

2.5 The same amendment, namely the insertion of the aforesaid optional feature, has been made to claim 1 of each of the auxiliary requests 1 to 5, thereby offending against the provisions of Rule 57a EPC. Therefore, by the same token, these requests are also not allowable.

3. Thus, in the absence of any allowable request in the proceedings, the patent in suit must stay revoked, since there is no text qualifying as a basis on which the patent in suit may be maintained.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

C. Moser

R. Freimuth