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**Datasheet for the decision
of 28 January 2020**

Case Number: T 0057/17 - 3.3.10

Application Number: 07871218.9

Publication Number: 2077718

IPC: A61L27/36, A61L27/50, A01N1/02,
A61F2/24

Language of the proceedings: EN

Title of invention:
BIOLOGICAL TISSUE FOR SURGICAL IMPLANTATION

Patent Proprietor:
Edwards Lifesciences Corporation

Opponent:
Schulz Junghans
Patentanwälte PartGmbB

Headword:
BIOLOGICAL TISSUE/Edwards Lifesciences

Relevant legal provisions:
EPC Art. 100 (c)

Keyword:
Grounds for opposition - added subject-matter (no)

Decisions cited:

Catchword:



Beschwerdekammern
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Case Number: T 0057/17 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 28 January 2020

Appellant: Edwards Lifesciences Corporation
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Respondent: Schulz Junghans
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Representative: Schulz Junghans
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 20 December
2016 revoking European patent No. 2077718
pursuant to Article 101(3) (b) EPC.**

Composition of the Board:

Chairman P. Gryczka
Members: J.-C. Schmid
W. Van der Eijk

Summary of Facts and Submissions

- I. The Appellant (Proprietor of the patent) lodged an appeal against the decision of the opposition division revoking European patent No. 2 077 718.
- II. A notice of Opposition had been filed by the Respondent (Opponent) requesting the revocation of the patent in suit in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC), insufficiency disclosure of the invention (Article 100(b) EPC, and extension of the subject-matter of the patent in suit beyond the content of the application as filed (Article 100(c) EPC).
- III. The opposition division held that the subject-matter of the patent-in-suit as amended during the opposition proceedings did not meet the requirements of Articles 123(2) or (3) EPC. In particular, the opposition division arrived at the conclusion that there was no support in the application as filed for defining the tissue to be treated by the claimed method as a tissue that has been fixed by cross-linking the amine groups of the proteins of the tissue with aldehydes, the application as filed disclosing only that cross-linking occurs with an aldehyde. According to the opposition division, there was no basis in the application as filed for crosslinking the biological tissue with more than one aldehyde.
- IV. At the oral proceedings before the Board held on 28 January 2020 the Appellant defended the patent in suit on the basis of a main and an auxiliary request. The main request corresponds to the first auxiliary request which was held by the opposition division to contravene the requirement of article 123(2) EPC.

Independent claim 1 of the main request reads as follows:

"1. A method of treating a biological tissue that has been fixed by cross-linking the amine groups of the proteins of the tissue with aldehydes, the method comprising:

contacting the fixed biological tissue with a non-aqueous treatment solution comprising glycerol and a C₁-C₃ alcohol selected from the group consisting of methanol, ethanol, n-propanol, 2-propanol, and mixtures thereof, wherein the glycerol is 40 to 95% by volume; and

removing a portion of the treatment solution from the solution-treated biological tissue to provide a biological tissue ready for sterilized containment"

- V. According to the Appellant, the preparation of the biological tissue to be treated by the claimed method was supported by paragraph [0006] of the application as filed. There was no basis to interpret the characteristic present in the application as filed that the tissue is fixed by cross-linking the amine groups of the proteins in the tissue with an aldehyde as being necessarily restricted to the use of one single aldehyde compound. It was clear from the context of invention, and also from the wording of the feature itself, that any aldehyde compound can be used for cross-linking the amine groups, either as a single aldehyde or as a mixture of aldehydes.

Hence, the subject-matter of claim 1 of the main request did not contain any subject-matter extending beyond the content of the application as filed.

- VI. According to the Respondent, claim 1 of the main request by the wording "aldehydes" required the tissue to be fixed by more than one aldehyde compound. However, the application as filed provided a support for the tissue to be fixed by one single aldehyde compound only.

Hence, claim 1 of the main request violated the requirements of Article 123(2) EPC.

- VII. The Appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution.

The Respondent requested that the appeal be dismissed.

- VIII. 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

2. *Articles 100(c) and 123(2) EPC*

The patent in suit has been opposed *inter alia* on the ground that the subject-matter of the patent extended beyond the content of the application as filed (Article 100(c) EPC). With regard to this ground for opposition, the only issue still under dispute in these appeal

proceedings concerns the term "aldehydes" in the passage of claim 1 of the main request, which reads "a biological tissue that has been fixed by cross-linking the amine groups of the proteins of the tissue with aldehydes".

In order to determine whether or not the subject-matter of a claim in a patent extends beyond the content of the application as filed it has to be examined whether that claim comprises technical information which a skilled person would not have directly and unambiguously derived from the application as filed.

According to the Appellant, the contested feature is based on the sentence crossing page 5 and 6 of the application as filed, which reads "Typically, the tissue is fixed by cross-linking the amine groups of proteins of the tissue with an aldehyde".

According to the opposition division and the Respondent, this wording limited the possibility of fixing the tissue to a single aldehyde compound. Accordingly, the requirement of claim 1 of the main request that the tissue be fixed by more than one aldehyde compound, provided the skilled person with technical information not disclosed in the application as filed.

However, the argument that the wording "with an aldehyde" in the application as filed implies that only one single aldehyde compound must be used for fixing the tissue cannot be followed by the Board. The indefinite article "an" cannot be considered in the context of the application as meaning "one". The skilled person understands that fixing a biological tissue with an aldehyde unequivocally means fixing the

tissue with compounds having an aldehyde functionality, i.e. with aldehydes.

Accordingly, the contested feature in claim 1 of the main request "a biological tissue that has been fixed by cross-linking the amine groups of the proteins of the tissue with aldehydes" does not provide the skilled with technical information not directly and unambiguously derivable from the application as filed.

Consequently, the ground for opposition raised under Article 100(c) EPC does not preclude the maintenance of patent on the basis of the claims of the main request.

3. *Remittal*

The decision under appeal was based solely on the failure of the claims of the then pending requests to fulfil the requirements of Article 123(2) and (3) EPC. The opposition division has, however, not yet ruled on the other issues based on the other grounds for opposition pursuant to Article 100(a) and (b) EPC. Furthermore, there is no submission in the appeal proceedings dealing with these grounds for opposition.

Hence, the Board considers it appropriate to remit the case to the opposition division 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 opposition division for further prosecution.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated