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D E C I S I O N
of 7 June 2005

Case Number: T 0845/02 - 3.2.2

Application Number: 94925120.1

Publication Number: 0712301

IPC: A61F 2/14

Language of the proceedings: EN

Title of invention:
Segmented preformed intrastromal corneal insert

Applicant:
Addition Technology, Inc.

Opponent:

-

Headword:

-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (no)"
"Problem-solution approach"

Decisions cited:
T 0039/93, T 0013/84, T 0162/86, T 0386/89

Catchword:

-



Case Number: T 0845/02 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 7 June 2005

Appellant: Addition Technology, Inc.
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Representative: Goldin, Douglas Michael
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 11 March 2002
refusing European application No. 94925120.1
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. K. H. Kriner
Members: M. G. Noël
U. J. Tronser

Summary of Facts and Submissions

I. European patent application No. EP-A-94 925 120.1 (publication No. WO 95/03755) was refused by the examining division on 11 March 2002, on the ground that the claimed subject-matter lacked inventive step under Article 56 EPC vis-à-vis the prior art documents:

D1: WO-A-93 13 724 and

D2 : SU-A-1 771 730 (English translation of the Russian document).

II. The appellant (applicant) lodged an appeal against this decision by notice of appeal received on 10 May 2002 and paid the appeal fee in the prescribed time-limit. With its statement of grounds, received on 11 July 2002, it submitted, besides a main request corresponding to the version of the claims as refused, two additional auxiliary requests.

III. Oral proceedings were held on 7 June 2005.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the following sets of claims:

- claims 1 to 19 (main request), or
- claims 1 to 18 (first auxiliary request), or
- claims 1 to 16 (second auxiliary request),

respectively submitted with the letter dated 11 July 2002.

IV. The independent claims according to the different requests read as follows:

Main request:

"An intrastromal corneal insert (300, 400, 500, 600, 700, 800, 900) suitable for introduction into the corneal stroma comprising a pre-shaped, physiologically compatible, synthetic, polymeric segment adapted for introduction into an intrastromal intracorneal channel, characterised in that the segment has an arc angle less than 360° when inserted into the intrastromal channel and that the segment, either alone or in combination with one or more other said segments so inserted, is adapted to adjust corneal curvature thereby to correct vision abnormalities."

First auxiliary request:

the content of the main request, but with replacing the value " 360° " by " 270° ".

Second auxiliary request:

the content of the first auxiliary request, but with the introduction of the following feature in the preamble, before the word "characterized":

"the segment comprising a high modulus physiologically compatible polymer having a modulus of elasticity above about 24.2 MPa (3.5 Kpsi)".

V. At the oral proceedings the appellant submitted the following arguments:

With respect to the disclosure of document D1 which was considered as the closest prior art, the insert

according to the invention provided an arcuate segment of less than 360° when inserted, thus enabling more than one insert to be placed in the cornea.

Since the hard PMMA split ring according to D1 was inserted through a single incision, with its opposite ends first rubbing against each other and then fastened together, technical problems emerged such as corneal erosion and wound healing at the incision point. These problems were overcome by the insert of the invention, particularly because the corneal incisions were spaced from each other and both ends of the insert could be positioned away from the respective incisions.

The effects provided by the invention included the avoidance of the above recited problems. Although not specifically mentioned in the description, the avoidance of such problems was, therefore, implicitly derivable from the application as filed and thus to be considered for the assessment of the inventive step, in line with the guidelines for examination.

Document D2 used donor cornea as implant material, instead of the synthetic, polymeric material of D1. Therefore, D2 could not teach a solution to problems to which it was not confronted due to a different material choice. Since D1 and D2 related to different techniques, their combination was highly improbable and based on hindsight considerations. The claimed subject-matter, therefore, involved an inventive step.

The auxiliary requests were filed to specify more closely the claimed subject-matter. By further specifying the use of a high elasticity modulus for the

material the overall subject-matter was better distinguished from the teaching of D2, which instead exhibited a low modulus of elasticity.

Reasons for the Decision

1. The appeal is admissible.
2. *Inventive step (main request)*
 - 2.1 D1 is regarded as the closest prior art document. It belongs to the applicant and corresponds to the state of the art presented as background in the application as filed (cf. page 2, lines 11 to 27).

D1 discloses an intrastromal insert suitable for introduction into the corneal stroma comprising a pre-shaped, physiologically compatible, synthetic, polymeric segment adapted for introduction into an intrastromal intracorneal channel, in order to adjust the corneal curvature and to correct vision abnormalities (see figures 2 and 5A and text referred to page 7, lines 15 to 18 and 27 to 37 and page 8, lines 27 to 34).

As illustrated by figure 5A the segment has an arc angle less than 360° before insertion, but the ring is completely encircling the cornea when inserted, as explained at the top of page 9.

- 2.2 Claim 1 differs from this prior art only in that the segment has an arc angle less than 360° **when inserted** into the corneal channel. The remaining feature

according to which the insert can be made of more than one segment is optional ("or") and, consequently, can be left aside. It is, therefore, not excluded that the insert as claimed be principally made of only one single segment formed by a ring having an arc angle less than but close to 360°.

The skilled person who is aware of a split ring having the configuration of figure 5A in D1 will be incited if necessary, to increase the gap between the ends of the ring a bit further such that after insertion the ends of the segment will not contact each other so as to avoid irritation of the cornea. This minor modification is considered by the Board as a matter of normal design procedure, especially as the advantages thus achieved can be readily contemplated in advance.

Therefore the subject-matter of claims 1 according to the main request does not involve an inventive step vis-à-vis document D1 and the general technical knowledge of the skilled person.

- 2.3 Applying the problem-solution approach, when the original technical problem defined in the application as filed has to be modified to take account of the closest prior art, the objective, more restrictive, problem is determined by the underlying remaining features of the claim (T 0039/93, OJ EPO 1997, 134). However, reformulation of the problem is only allowable, if the new problem can be deduced from the application as filed (T 0013/84, OJ EPO 1986, 253), i.e. within the limit of the original description (T 0162/86, OJ EPO 1988, 452).

In the present case, the problems set forth by the appellant with respect to D1, such as avoiding corneal erosion and wound healing at the incision point, have no basis in the application as filed and neither are derivable therefrom. As a consequence, the appellant's arguments based on these alleged problems cannot be validly considered when assessing the inventive step.

The only criticisms made in the application as filed (page 2, lines 25 to 27) against the known polymeric rings are that they are completely encircling the cornea. Therefore, it seems that the invention resides rather in the provision of a corneal insert made in several parts so as to avoid the difficulties of insertion and positioning of a one-part intracorneal ring. As explained on page 20, lines 10 to 31, the use of several segments of different sizes at different places is advantageous in terms of adaptability (more easily inserted and removed) and adjustability (re-insertion after modifications of form or dimensions).

However, as explained before, the provision of an insert made in several segments is optional in claim 1. Therefore, the objective problem underlying the distinguishing feature of claim 1 (less than 360°), when formulated in a way which is not prejudging the solution as claimed, is only to provide an insert having a configuration after insertion which is different from that of a complete ring.

Since the essential feature regarding several segments is missing, the restricted solution (less than 360° when inserted) is unable to provide alone any improved

adaptability and adjustability of the insert, so that the solution as claimed cannot take advantage of the effects referred to in the application.

The other effects presented by the appellant as the avoidance of the problems of corneal erosion and wound healing have no basis nor justification in the application as filed. Therefore, contrary to the appellant's assertion, these alleged effects cannot be taken into account when determining the problem underlying the invention for the purpose of assessing inventive step (T 0386/89, 23 March 1992).

- 2.4 Even when considering the second claimed alternative with an insert made of more than one segment the subject-matter of claim 1 still would be lacking of inventive step vis-à-vis the combination of documents D1 and D2. In figure 2 of D2 it is clearly suggested to implant an insert made of two segments less than 360° each and placed in opposition, i.e. in a configuration which is identical to that of figure 14E of the application as filed.

The other differences of document D2 developed by the appellant are irrelevant since, finally, the skilled person is just looking for a configuration differing from the complete circle made by a ring in one part, in accordance with the above defined objective problem, the hard polymeric material being already known from the closest prior art document D1.

Therefore the subject-matter of claim 1 according to the main request does not imply an inventive step within the meaning of Article 56 EPC.

3. *Auxiliary requests*

3.1 One or several segments having an arc angle less than 270° is also known from document D2, such that the foregoing considerations apply in the same way to claim 1 according to the first auxiliary request. Therefore, the subject-matter of this claim does not involve an inventive step for the same reasons as for the main request.

3.2 The second auxiliary request differs from the first auxiliary request by the incorporation in the pre-characterising portion of claim 1 of a feature specifying the modulus of elasticity of the polymer used for the insert. As mentioned in the contested application (page 10, lines 10 to 17), among numerous suitable polymers, which are relatively stiff, one is the polymethylmethacrylate (PMMA), a commercially available material known under the trade name of Plexiglass. This material is also used for the insert of document D1 (cf. page 7, line 35) among many other biocompatible polymers.

Therefore, the incorporation in the preamble of claim 1 of a feature known from the closest prior art fails to add anything new and non obvious to the subject-matter of claim 1, even considered in combination with the remaining features.

As a result, the subject-matter of claim 1 according to the second auxiliary request does not meet the requirements of Article 56 EPC, either.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner