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Datasheet for the decision of 8 March 2007

Case Number: T 0937/05 - 3.2.02

Application Number: 96902080.9

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IPC: A61F 2/16

Language of the proceedings: EN

Title of invention:
IOL insertion apparatus

Patentee:
Advanced Medical Optics, Inc.

Opponents:
Alcon Laboratories Inc.
CORNEAL Laboratoires

Headword:
-

Relevant legal provisions:
EPC Art. 56, 84, 123(2)

Keyword:
"Inventive step (yes, after amendments) - Auxiliary request 4A"

Decisions cited:
-

Catchword:
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Case Number: T 0937/05 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 8 March 2007

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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 28 June 2005 rejecting the opposition filed against European patent No. 0804129 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: M. Noël
M. Vogel

Summary of Facts and Submissions

I. Following two oppositions filed by opponents 01 and 02 against European patent No. 0 804 129, the opposition division decided on 28 June 2005 to reject the oppositions.

The opposition division held that the grounds of opposition (lack of novelty and inventive step) did not prejudice the maintenance of the patent as granted.

II. The appellants (opponents 01 and 02) each lodged an appeal against this decision on 19 July 2005 and 3 August 2005, respectively, paying the appeal fees on the same days. Corresponding statements setting out the grounds of appeal were filed on 30 September 2005 and 27 October 2005, respectively.

III. Oral proceedings were held on 8 March 2007. For the discussion of novelty and inventive step the following prior art documents played a role:

D1: WO-A1-94/20027

D6: US-A-4 876 126

E3: WO-A1-94/07436

E7: US-A-5 094 876

E9: US-A-4 681 102.

IV. At the end of the oral proceedings the requests of the parties were as follows:

The appellants requested that the decision under appeal be set aside and that the European patent No. 0 804 129 be revoked.

The respondent (patentee) requested that the appeals be dismissed (main request) or auxiliarily that the patent be maintained on the basis of one of the auxiliary requests 1 to 6 and 4A, all filed during the oral proceedings.

V. Claim 1 according to the various requests reads as follows:

Main request:

"An apparatus (10) for inserting an intraocular lens (100) through a small incision into an eye comprising:

a hollow tube (14) including an interior wall (53) defining a hollow space (54) through which an intraocular lens (100) is passed and an outlet (26) through which said intraocular lens is passed from said hollow space into an eye; **characterized in that** a lubricity enhancing component (20) is covalently bonded to said hollow tube (14) at said interior wall (53) in an amount effective to facilitate the passage of said intraocular lens (100) through said hollow space (54)."

First auxiliary request:

The content of claim 1 of the main request, with the replacement of the expression "an interior wall (53)" by the expression "a tapering interior wall (53)".

Second auxiliary request:

The content of claim 1 of the first auxiliary request with the incorporation of the feature "a load chamber (12) and an injection tube integrally formed to define" before the words "a hollow tube (14)" in the pre-characterising portion.

Third auxiliary request:

The content of claim 1 of the first auxiliary request with the incorporation of the feature "in the form of a cartridge having a first member and a second member which are secured or joined together" after the words "a hollow tube (14)" in the pre-characterising portion.

Fourth auxiliary request:

The content of claim 1 of the first auxiliary request and the following additional feature at the end of the claim: "and that the hollow space (54) comprises a lumen having a proximal portion (58) with a taper which is more severe than the slight taper in distal portion (60) of the second lumen."

Auxiliary request 4A:

"An apparatus (10) for inserting an intraocular lens (100) through a small incision into an eye comprising:

a hollow injection tube (14) including a tapering interior wall (53) defining a hollow space (54) through which an intraocular lens (100) is passed and an outlet (26) through which said intraocular lens is passed from said hollow space into an eye; wherein a lubricity enhancing component (20) is covalently bonded to said hollow injection tube (14) at said interior wall (53) in an amount effective to facilitate the passage of said intraocular lens (100) through said hollow space (54), and wherein the hollow space (54) has a proximal portion (58) with a taper which is more severe than the slight taper in distal portion (60) of the hollow space."

VI. At the oral proceedings the appellants presented the following arguments:

E9 represented the closest prior art. This document disclosed among other things that the lumen defined by the load chamber was preferably treated with a lubricating material with the view to facilitate the passage of the intraocular lens (IOL). Therefore, the term "treated" could be interpreted as "bonded", and the subject-matter of claim 1 of the main request differed from the apparatus according to E9 only by the **covalent** bonding of the lubricity enhancing component. Document E7 suggested to modify the plastic surfaces of surgical instruments such as insertion tools, IOL implants or other articles in order to reduce the

adhesion between the surface and the living tissue by covalently bonding thereon a lubricity enhancing component. The method involved a.o. the use of gamma ray and/or electron beam irradiation to induce graft polymerisation for coating the surface. Since said instruments or articles were immersed (during the so-called pre-soaking) in a monomer containing solution prior to inducing graft polymerisation, all the surfaces thereof, including also the inner surfaces, were inevitably coated by covalently bonding. Furthermore document D6 suggested to enhance the surface lubricity and to reduce the frictional resistance of medical instruments such as catheters and guide wires, by forming a lubricating coating layer to the substrate through covalent bonding. Therefore, the subject-matter of claim 1 of the main request did not involve an inventive step vis-à-vis the combinations of E9 with E7 or D6.

The provision of a tapering interior wall for rolling or folding the IOL within the hollow tube of the inserter prior to insertion into the eye, addressed a problem different from that of enhancing the surface lubricity of the inserter. The feature added to the preamble of claim 1 of the first auxiliary request, therefore, had no relationship with the remaining characterising features and failed to add anything inventive to the claimed subject-matter. Moreover, a tapering interior wall was already disclosed by E9 (Figure 3A), E3 (Figure 20B) or D1 (Figure 21). Consequently, the subject-matter of claim 1 according to the first auxiliary request did not involve an inventive step.

An integrally formed load chamber and injection tube was disclosed by E9 in an alternative embodiment presented in Figure 9 and column 8. Moreover, E3 described a micro cartridge (see Figure 16) comprising a load chamber and an injection tube, wherein the cartridge was preferably made of injection moulded plastic. The subject-matter of claim 1 of the second auxiliary request, therefore, did not involve an inventive step, either.

As to the cartridge incorporated in claim 1 of the third auxiliary request, it was not clear whether or not the injection tube was included therein. In any case, a cartridge was already disclosed by E9. Claim 1 of the third auxiliary request, therefore, failed to add anything involving an inventive step.

The amendments made to claim 1 of the fourth auxiliary request were not clear and led to an extension of the claimed subject-matter beyond the content of the application as filed. In particular the second lumen was not previously defined in the claim and a confusion emerged between the hollow tube, the hollow space and the various lumens, so that the relative positions of the tapering portions within the tube through which the IOL was passed, were indeterminate. Moreover, the features added to claim 1 according to the fourth auxiliary request were disclosed by D1, in particular by Figures 7 and 9 in which two different tapering portions were provided in the lumen. Therefore this request was not acceptable, either.

VII. The respondent presented the following arguments:

In document E9 the term "treated" was used within the general meaning of "coated". Hence it could not be derived therefrom that the lumen was covalently bonded with a lubricating material. In E7 a coating was achieved by covalently bonding a lubricity enhancing component to the exterior surface of e.g. surgical instruments in order to reduce their adhesion with respect to body tissues. Nothing in E7, however, suggested to coat also the interior surface of these instruments, let alone the interior surface of IOL inserters. D6 was exclusively concerned with the improvement of the lubricity and the reduction of the frictional resistance of surgical instruments such as catheters and guide wires, during insertion. Although lubricating surface coating layers were formed through covalent bonding of polymer components, D6 could not suggest to apply this process also to the interior surface of IOL inserters. Since the combination of the cited documents would be the result of an ex-post reasoning, the subject-matter of claim 1 of the main request involved an inventive step.

The tapering portions illustrated in E9 and E3 were situated at the distal end of the injection tube and not, as shown in Figure 6 of the present patent, in the hollow space upstream of the distal opening. D1 additionally disclosed a gradually tapering section in the loading area at the input of the IOL inserter for the purpose of folding the IOL before its introduction in the subsequent staging area. Differently, in the present patent the folding of the IOL occurred primarily within the load chamber by bringing together

two hingeably movable members, and a further folding was achieved through a tapering portion downstream of the load chamber. Therefore, the subject-matter of claim 1 of the first auxiliary request was not suggested by the cited prior art. Moreover, in an attempt to arrive at the subject-matter of claim 1 at least three documents were needed.

An integrally formed load chamber and injection tube might be disclosed, as such, in documents E9 or E3. However the combination of this feature with the remaining features of claim 1 according to the second auxiliary request, still was not suggested by the cited documents. The subject-matter of claim 1 according to the second auxiliary request, therefore, involved an inventive step.

The subject-matter of claim 1 of the third auxiliary request incorporated a cartridge having two members joined together, including also the injection tube. These features were not disclosed in combination by the cited documents.

The features relating to different tapering portions added to claim 1 of the fourth auxiliary request were sufficiently clear and supported by the application as filed. D1 was not relevant because the different tapering portions were spaced to each other and formed on either side of the load chamber.

The wording of claim 1 according to auxiliary request 4A was further amended in order to remove the objections made against the subject-matter of claim 1 of the preceding fourth auxiliary request.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

E9, cited in the International Search Report, represents the closest prior art by reason of most structural and functional similarities with the claimed apparatus.

E9 discloses (see Figures 1 to 4) an IOL inserter having all the features recited in the preamble of claim 1, namely an apparatus for inserting an IOL through a small incision into an eye, comprising a hollow tube 38, 41 including an interior wall defining a hollow space through which the IOL is passed and an outlet 45 through which the IOL is passed from said hollow space into an eye. E9 further describes (see column 6, lines 16 to 23) the application of a lubricity enhancing component (Healon or Na-hyaluronic acid) to the lumen of a load chamber 15 and then to the hollow tube as the IOL is pushed towards the distal end of the apparatus, in a quantity sufficient to facilitate the passage of the IOL.

The subject-matter of claim 1 differs from the apparatus according to E9 in that the lubricity enhancing component is covalently bonded to the hollow tube. The advantage of fixing a lubricity agent to the interior surface of the inserter by covalent bonding is principally to avoid said agent to be wiped off into

the eye during insertion of the IOL, and the risk of causing trauma, irritation or damage of the eye, as set out in the present patent (see paragraphs [7] and [11]).

E7 refers principally to the reduction of tissue adhesion to tissue contacting devices or surgical instruments, such as positioning and inserting tools (see column 6, line 66 to column 7, line 8). However, E7 is not restricted to these applications. The technique of covalently bonding a lubricity enhancing component described therein is also applicable to reduce the interfacial abrasion and the friction between the components of joint protheses (see column 7, lines 32 to 35). In this later case, two surfaces are placed in a frictional relationship, without contacting a "tissue" within the meaning of E7 (see column 4, lines 36 to 38). Therefore, the skilled person finds in E7 a clear indication to coat also the interior surface of an article or instrument whenever this is necessary, depending on the envisaged application. Since insertion tools and the implantation of IOLs are both referred to in document E7, the provision of a lubricity enhancing component by covalently bonding the interior walls of IOL inserters, which clearly avoids this component to be wiped off into the eye during insertion of an IOL, appears to be an obvious measure when starting from E9.

It results therefrom that documents E9 and E7 are not incompatible and lead, in combination, in an obivious way to the subject-matter of claim 1 of the main request. Therefore, it lacks an inventive step vis-à-vis the teaching of these documents.

3. *First auxiliary request*

As illustrated in Figure 3A of E9 the distal end of the hollow tube 38 through which the IOL is passed has a bevelled configuration and forms a tapering interior wall 63. The feature added to the preamble of claim 1 of the first auxiliary request, therefore, does not confer any inventive step to its subject-matter. The consideration of a third document to arrive at the claimed subject-matter is not necessary, contrary to the respondent's assertion.

4. *Second auxiliary request*

As shown in Figure 9 of E9 and reported in column 8, lines 26 to 29 the apparatus comprises a load chamber 65 and an insertion cone, which are, preferably, integrally formed. The insertion cone is more specifically defined in connection with Figure 3 and comprises a.o. a cylindrical distal end portion 41 (see column 5, lines 25 to 29). Consequently, the feature added to the preamble of claim 1 of the second auxiliary request, according to which the load chamber and the injection tube are integrally formed, is also known from E9 and, therefore, fails to add anything inventive to the claimed subject-matter.

5. *Third auxiliary request*

According to the feature added to claim 1 of the third auxiliary request, the hollow tube is "in the form of a cartridge having a first member and a second member which are secured or joined together". As shown in

Figure 3 of the present patent and referred to in paragraph [45], the first member 16 and the second member 18 are here specifically addressed, which are hingeably movable relative to each other so as to form the load chamber 12, by bringing together the wings 38,40. Such a cartridge, which is clearly restricted to the load chamber which forms, when closed, a hollow tube for lodging the folded IOL, is also known from E9. As shown in Figures 2 and 3 of E9 the load chamber 15 of the known device comprises two members 19, 21 hingeably joined together so as to form a cartridge to be inserted into the bore 57 of a body 50 (see column 4, lines 44 to 54 and column 5, lines 44 to 51). It should be noted here that E9 is also cited and analysed in document D1 (see page 5) in which the load chamber is referred to as a "cartridge".

It results therefrom that the subject-matter of claim 1 of the third auxiliary request does not involve an inventive step, either.

6. *Fourth auxiliary request*

According to the feature added to claim 1 of the fourth auxiliary request the hollow space comprises a lumen having a proximal portion with a taper which is more severe than the slight taper in the distal portion of the second lumen. However, since the second lumen is not previously defined in the claim, the positions of the different taper portions within the hollow space are not clear. Moreover, since the hollow space is defined in the pre-characterising portion of claim 1 as a hollow tube which is not identified as such in the application as filed, it is also unclear which parts of

the hollow tube are concerned with the different tapering portions. As a consequence, a tapering interior wall can be situated indifferently at the inlet or the outlet of the inserting device.

Therefore, claim 1 of the fourth auxiliary request lacks clarity and comprises subject-matter which extends beyond the content of the application as filed, contrary to the requirements of Articles 84 and 123(2) EPC, respectively.

7. *Auxiliary request 4A*

7.1 Formal aspects

The amendments made to claim 1 of the auxiliary request 4A remove the objections raised against the fourth auxiliary request. In details:

According to the original claim 1, the apparatus comprises "a hollow tube including an interior wall defining a hollow space". According to the application as filed (see page 14, lines 22 to 24), the "Injection tube 14 includes a tapering interior wall defining a hollow space". It results from the simultaneous consideration of these two informations that in claim 1 under consideration the "hollow tube" is the "injection tube 14" and that the "hollow space" is the "second lumen 54". Therefore, the amended feature according to which "a hollow injection tube (14) including a tapering interior wall (53) defining a hollow space (54)" is at present clear and supported by the application as filed.

Further, according to the application as filed (see page 14, lines 31 to 33) "the taper of proximal portion 58 of the second lumen 54 is more severe than the slight taper which exists in the distal portion 60 of the second lumen". It results therefrom that the feature added at the end of claim 1 "and wherein the hollow space has a proximal portion (58) with a taper which is more severe than the slight taper in distal portion (60) of the hollow space", is also clear and supported by the application as filed.

The amendments made to claim 1 of the auxiliary request 4A, therefore, meet the requirements of Articles 84 and 123(2) EPC.

7.2 Inventive step

Paragraph [52] of the present patent specifies:

"The taper of proximal portion 58 of second lumen 54 is more severe than the slight taper which exists in the distal portion 60 of the second lumen. The more severe taper in the proximal portion 58 is effective to further fold the IOL as the IOL is passed into the second lumen 54. This further folding is advantageous because the further folded IOL can be inserted into the eye through a smaller incision. The enhanced lubricity resulting from the coating 20 facilitates this further folding so that a reduced amount of force is required to further fold the IOL and/or the degree of further holding of the IOL can be increased so that ultimately, the IOL can be inserted through an even smaller incision."

Hence the object to be achieved by the subject-matter of claim 1 of the auxiliary request 4A is the provision of an IOL inserter which allows an insertion of the IOL through a very small incision.

This object is achieved in particular by the combination of the coating and the specific tapering of the hollow space defined in claim 1.

Among the cited documents, only D1 (see Figure 5 and page 5, lines 22 to 27) addresses the problem of improving the operations of folding an IOL and positioning it before insertion into the eye. The folding of the IOL is achieved in D1 by pushing it through a circular passageway which gradually tapers towards a staging area. From there, the IOL is pushed out of the distal tip of the staging area into the eye (see Figures 1, 7 and 21; page 6, lines 21 to 27; page 13, lines 5 to 10 and page 16, lines 6 to 10).

However, in D1, the tapering portion is provided in a passageway (loading chamber) having a constantly decreasing diameter and positioned upstream of the staging area whereas according to the solution as claimed, the tapering portion is made variable and is provided in the hollow space formed by the injection tube, downstream of the load chamber (staging area in D1). These features still facilitate the passage of the IOL and in particular allow for the further folding of the IOL in a controlled manner, without excessive force, as mentioned in paragraph [8] of the present patent.

In the light of the foregoing and since the available state of the art does not suggest the provision of two different tapers in an IOL inserter, the subject-matter of claim 1 of the auxiliary request 4A involves an inventive step within the meaning of Article 56 EPC.

Consequently there is no need to proceed further with the fifth and sixth auxiliary requests.

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 with the order to maintain the patent on the basis of the following documents:

claims 1 to 12 according to the auxiliary request 4A, filed during the oral proceedings;

description pages 1 to 8, as granted; and

drawings, Figures 1 to 7, as granted.

The Registrar: The Chairman:

V. Commare T. Kriner