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Datasheet for the decision of 27 January 2010

Case Number: T 0204/07 - 3.2.02

Application Number: 98930177.5

Publication Number: 0925044

IPC: A61F 2/16

Language of the proceedings: EN

Title of invention:
Intraocular lens

Patentee:
BAUSCH & LOMB INCORPORATED

Opponent:
ALCON LABORATORIES, INC.

Headword:
-

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
-

Keyword:
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0204/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 27 January 2010

Appellant: (Patent Proprietor)
BAUSCH & LOMB INCORPORATED
One Bausch & Lomb Place
Rochester
New York 14604-2701 (US)

Representative:
Carpmael, Robert Maurice Charles
Marks & Clerk LLP
90 Long Acre
London WC2E 9RA (GB)

Respondent: (Opponent)
ALCON LABORATORIES, INC.
6201 South Freeway
Fort Worth TX 76134-2099 (US)

Representative:
Lederer, Franz
Lederer & Keller
Patentanwälte
Prinzregentenstraße 16
D-80538 München (DE)

Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 1 December 2006 concerning maintenance of European patent No. 0925044 in amended form.

Composition of the Board:

Chairman: M. Noël
Members: P. L. P. Weber
M. J. Vogel

Summary of Facts and Submissions

I. The appeal is against the decision of the Opposition Division dated 1 December 2006 that taking account of the amended claims according to the 2nd auxiliary request, the patent and the invention to which it relates fulfil the requirements of the EPC.

The notice of appeal of the patent proprietor was filed on 6 February 2007 and the appeal fee paid on the same day.
The statement setting out the grounds of appeal was filed on 12 April 2007.

II. The documents mentioned by the respondent (opponent) in its reply of 5 November 2007 are :

D1 : US-A-5071432
D2 : US-A-4174543
D3 : WO-A-97/20523

III. Oral proceedings took place on 27 January 2010.

The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request or of one of the auxiliary requests 1 to 7, all filed on 23 December 2009.

The respondent requested that the appeal be dismissed.

IV. Claim 1 according to the main request reads as follows:

"A soft or foldable intraocular lens (20) to be implanted in the anterior chamber (6) in a patient's

eye and positioned generally perpendicular to the optical axis (OA-OA) of the eye (10) when implanted in a patient's eye (10), comprising:

(a) an optic portion (22) having an outer peripheral edge (24);

(b) at least two haptic elements (26) each having an inner portion (28) and an outer end (30) for supporting the optic portion (22) in a patient's eye (40), the respective inner portions (28) of the haptic elements (26) being connected to the outer peripheral edge (24) of the optic portion (22);

(c) each haptic element (26) including at least one footplate (32) on the outer end (30), and further including a central portion (38) extending between the footplate (32) and the inner portion (22); and

(d) the central portion (38) of each haptic element (26) having a greater resistance to bending in a plane (40-40) generally parallel to an optical axis (OA-OA) of the patient's eye (10) than in a plane (36-36) generally perpendicular to the optical axis (CA-CA), wherein the optical portion (22) and haptic elements (26) are formed of a foldable or compressible material."

V. The arguments of the appellant can be summarised as follows:

The words "soft" and "foldable" used in the present claim 1 were synonyms for the person skilled in the art. The concept of "soft lenses" and "hard lenses" was well

known to the person skilled in the art working in the field of the intraocular lenses. In addition the type of material which was considered soft or foldable in the context of the present invention was defined at the beginning of the description so that for the man skilled in the art there could be no doubt as to the meaning of these words.
The same applied to the terms "to be implanted in the anterior chamber": for an average human, the diameter of the anterior chamber was about 12 mn whereas the diameter of the capsular bag was about 9-10 mn. The retention force applicable in the anterior chamber was lower than in the capsular bag as the capsular bag was better adapted to absorb greater forces and translational movements of the lens were less critical when the lens was implanted in the capsular bag, the natural lens having been removed. On the contrary, in the anterior chamber the available space was reduced and translational movements of the lens could damage the iris or the endothelial layer.

Novelty over D3

The lens described in D3 was not for implantation in the anterior chamber, it was for implantation in the capsular bag. As the average diameter of the capsular bag was 9-10 mn, the lens described in D3 had to have the haptic elements compressed so that when implanted the diameter of the lens was approximately 25 to 30% less than when uncompressed. This lens was therefore not suitable for implantation in the anterior chamber where the diameter of 12 mn would, undesirably, leave the lens loose since the compression of the haptic

elements was necessary for centralisation and fixation of the lens.
Additionally there was no direct and unambiguous disclosure that there was a central portion of each haptic element having the properties defined in feature d).
On the contrary, the thinnest part was the gusset which was said to be preferably 0,3 mn thick. The haptic elements would thus flex in the direction other than the one aimed for by the invention. This was confirmed by page 4, lines 8,9 of D3 where the desire was expressed to have any vaulting of the optic occurring posteriorly. By vaulting could only be meant a vaulting when the lens was in place, because the lens being a soft lens, would be rolled for implantation.

While the dimensions of the lens might be identical in the unimplanted state, this was not true in the implanted state because as already mentioned the lens according to D3 was meant to be implanted in a 30% compressed state.

Hence the lens according to D3 was not suitable for implantation in the anterior chamber and did not exhibit feature d). The subject-matter according to claim 1 was therefore new.

Inventive step

Strictly speaking, an inventive step reasoning should have as a starting point a soft intraocular lens to be implanted in the anterior chamber but none of the cited documents showed such a lens.

D3 which showed a soft intraocular lens to be implanted in the capsular bag could not suggest a lens for implantation in the anterior chamber as this would necessitate a considerable redesign to adapt the maintaining forces, to avoid any risk of damaging the iris, to increase the resistance to bending, etc… Such a redesign could not be an obvious development.

VI. The arguments of the respondent can be summarised as follows:

The wording "soft or foldable" introduced into claim 1 according to the main request to define the lens was not clear as it was not clear which part of the lens should be soft or foldable. It could be that only a part of the lens exhibited the said property. In addition the term "soft" in itself was relative and therefore vague and unclear. Any material would qualify as soft or rigid depending on the circumstances.

Similarly the wording "to be implanted in the anterior chamber" did not define anything other than the features already in claim 1. No specific dimensions were given in the description, which would particularly adapt the lens for the anterior chamber.

The amendments could thus not be said to be occasioned by a ground of opposition.

Novelty over D3

The wording "to be implanted in the anterior chamber" could not be limiting as it only expressed an intended use but no additional features were mentioned in the

claim which would specifically adapt the lens for this use.
Nevertheless it should be noted that the dimensions of the lens given in the patent in suit in paragraph [0020] were identical to the dimensions of the lens disclosed in D3 so that the lens of D3 was also adapted for implantation in the anterior chamber. Both lenses could be said to stretch up to their maximum size of 12,5 mn, so that the fixation forces developed must be the same. Starting from the dimensions given in D3 for the radii R2 and R8 and for the thicknesses T1 and T2 it could be calculated that the width and thickness of the elbow 18 were respectively 0,365 mn and 0,43 mn so that the property defined in feature d) was also disclosed in D3.

By posteriorly vaulting, mentioned on page 4, lines 9,10, was only meant that during the implantation of the lens it was preferred to have a posterior vaulting rather than an anterior one.

The lens disclosed in D3 could not be said to be unsuitable for implantation in the anterior chamber of the eye, so that it must be considered novelty destroying for the subject-matter of claim 1.

Given the general meaning of "soft" the lenses made of PMMA disclosed in D1 and D2 also anticipated the subject-matter of claim 1.

Inventive step

Document D3 led the person skilled in the art to the preferred embodiment mentioned therein. As discussed in relation with novelty when the preferred dimensions

were used the elbow had a width which was smaller than the thickness so that the properties defined in feature d) were automatically present. Thus D3 directed the person skilled in the art directly to the invention claimed in Claim 1.

Reasons for the Decision

1. The appeal is admissible.

2. *Formal matters*

Claim 1 according to the main request is based on granted claim 1 amended by the addition of the following features:

a) a soft or foldable intraocular lens
b) to be implanted in the anterior chamber of the patient's eye
c) wherein the optical portion and haptic elements are formed of a foldable or compressible material

2.1 The respondent considers the word "soft" not to be clear.

The Board cannot share this point of view as for the person skilled in the art working in the field of the intraocular lenses the difference between soft lenses and rigid lenses is clear. The main difference being that soft lenses can be rolled so as to be introduced into the eye through a small incision whereas rigid lenses necessitate a larger incision for introduction into the eye.

In addition in the patent in suit at the beginning of the description (see beginning of paragraph [0004] or paragraph [0005]) the materials considered rigid or soft in the context of the claimed invention are defined as follows:

"*IOLs have been made from a variety of biocompatible materials, ranging from the so-called rigid materials such as polymethylmethacrylate (PMMA) to the so-called soft materials that can be folded or compressed such as silicones, certain acrylics, and hydrogels.*" (emphasis added).

"*Soft IOLs have gained popularity because they can be compressed, folded, rolled or otherwise deformed and inserted through an incision in the cornea that is much smaller than necessary for the rigid lenses which must be inserted through an incision slightly larger than the diameter of the optic portion. When implanted in the eye, these soft lenses then open to their original shape because of the memory characteristics of the soft materials*."(emphasis added).

There can thus be no doubt about the meaning of "soft" in the context of the patent in suit, nor can there be any doubts about the support for this feature in the originally filed application documents.

2.2 Feature b), while defining the intended use, amounts to an indication of the size of the IOL as the space available in the anterior chamber is bigger compared to that available in the capsular bag. The person skilled in the art also knows that the capsular bag has

particular properties which the anterior chamber does not have, as for instance some resiliency because of the thickness of the tissues, so that it is clear that an intraocular lens adapted for the capsular bag is not necessarily adapted for the anterior chamber and vice versa. In most of the cases such an indication of the intended use further amounts to an indication of the shape and dimensions of the IOL, most implantations in the anterior chamber being in an eye still having its natural lens, a phakic eye, and any contact with the iris or the natural lens is prohibited.

The feature was also originally disclosed as it is mentioned several times in the description that the IOL of the invention is preferably for implantation in the anterior chamber (see for example page 4, lines 21 to 23, page 6, lines 7 to 9 of the application as filed).

2.3 Feature c) is the feature of granted claim 2 so that it may not be objected to as regards clarity. Since the wording of claim 2 as that granted is the same as that of claim 2 as originally filed there is no doubt about support there for in the originally filed documents either.

2.4 As explained above, the amendments restrict the scope of claim 1 as granted so that they must be said to be occasioned by a ground of opposition.

2.5 Thus the amendments to claim 1 fulfil the requirements of Article 84, Rule 57a and Article 123(2) and (3) EPC.

3. *Novelty - Main request*

3.1 D1 discloses an IOL made of PMMA (see col. 3, lines 44 to 46), so that this is not a soft lens in the sense of the patent in suit.
The IOL disclosed in D2 is also not foldable or compressible. As for the IOL according to D1, the material used is PMMA (see col. 3, lines 13,14) which according to the patent in suit is a rigid material.
The lenses disclosed in the documents D1 and D2 being made of rigid material the subject-matter of claim 1 is already new over these documents for this reason alone.

3.2 Novelty over D3

The appellant and the respondent disagreed in respect of the question whether the IOL disclosed in D3 could be considered "to be for implantation in the anterior chamber of the patient's eye" and about the presence of a central portion having the property defined in feature d) of claim 1.

3.2.1 Document D3 discloses a foldable intraocular lens for the replacement of the natural lens in case of cataract (see page 1, lines 9 to 15 "*an accepted treatment for this condition is surgical removal of the lens and replacement of the lens function by an IOL*"). Most commonly in these cases the IOL is implanted in the capsular bag. This is the case of the IOL according to D3 as can be seen for instance on page 4, lines 15 to 17 where it is mentioned that "*The relatively long length and radius of distal portion 20 provides greater contact with the capsular bag for better fixation when IOL 10 is implanted in the eye.*" (emphasis added). This can also be gathered from the overall shape of the IOL disclosed in D3 which is relatively flat as can be seen

in Figure 2, which would at least be unlikely if the IOL were meant for implantation in the anterior chamber when the natural lens is still present, as can be the case of the lens according to the patent in suit (see page 1, lines 9,10).

The Board is therefore convinced that the lens according to D3 was conceived for replacement of the natural lens and for placement in the posterior capsular bag and that it was not the intention of the inventor of the lens according to D3 to place this lens in the anterior chamber of the patient's eye.

It however remains to be examined whether the lens disclosed in D3 would be appropriate for implantation in the anterior chamber. In D3 it is explained that in order to increase centration and fixation of the lens in the eye a specific open loop haptic design had to be chosen. Considering that the average dimension of the capsular bag of a human being is of 9-10 mn, the lens of D3, which in its preferred overall dimension has a diameter of 12,5 mn, must be compressed by approximately 20-25% when implanted in the capsular bag. The implantation of such a lens in the anterior chamber is therefore highly questionable because the haptic elements would be less compressed and thus could not guarantee the same fixation force or centration of the lens as achieved when the IOL is implanted in the capsular bag. Additionally given that the lens according to D3 is flat and is said to vault posteriorly (see page 4, lines 8,9) there exists a serious risk of damaging the iris and/or the natural lens of patient, if present, when the lens is implanted in the anterior chamber of a patient's eye.

For these reasons the Board considers that the lens disclosed in D3 is not implantable in the anterior chamber, not even implicitly.

For this reason alone the subject-matter of claim 1 must be considered novel over D3.

3.2.2 Moreover according to claim 1 of the patent in suit each haptic element should have a central portion and this central portion should have a greater resistance to bending in a plane generally parallel to the optical axis of the patient's eye than in a plane generally perpendicular to the optical axis. According to paragraph [0009] of the description this way of designing the haptic elements should guarantee that no translation of the optic portion along the optical axis takes place when the haptic elements are compressed radially.

If one considers the enlarged rounded outermost portion of the haptic elements of the lens shown in D3 to be the footplate, then a central portion corresponding to that claimed in feature d) of claim 1 must extend somewhere between the footplate and the optic portion. The question is therefore whether D3 discloses a lens having part of the haptic portion between the footplate and the optic portion which exhibits the properties claimed in feature d). In the description of D3 numerous dimension indications can be found. However each indication is associated with a range of possible values for the corresponding dimension.
More precisely there are 15 dimensions to be chosen (T1, T2, L1, L2, R1-R10, and the diameter of optic portion)

and for each one of these parameters a range of possible values is disclosed in D3.
But there is no mention in D3 for preferably using a combination of dimensions exhibiting the properties claimed in feature d) of claim 1. Neither is there any incitation to consider such a combination of dimensions given the above mentioned indication that posterior vaulting was desired.
In the opinion of the Board there is thus no direct and unambiguous disclosure in D3 of a lens having a central part of its haptic elements exhibiting the property according to feature d) of claim 1.

3.2.3 The respondent considered that when the preferred dimensions indicated in D3 were used for R2, R8, T1 and T2 at the elbow 18 the width of the haptic element would be less than its thickness and the lens would thus exhibit the said properties, so that feature d) must be considered to be disclosed.

The Board cannot share this point of view. As explained above for each dimension of the lens disclosed in D3 a range of values is given. The respondent has chosen one value for R2, R8 and T1 which according to him would lead to the properties defined in feature d). Not only is there no evidence that by choosing these dimensions the said property would be present but as explained above the person skilled in the art would not contemplate this combination of dimensions.

Thus in the opinion of the Board the subject-matter of claim 1 is clearly novel over D3.

4. *Inventive step - Main request*

4.1 A strict application of the problem-solution approach requires that the closest prior art be a soft IOL for implantation in the anterior chamber. However none of the cited documents discloses such an IOL. From the three documents cited by the respondent only D3 discloses a soft IOL so that this document represents the prior art IOL which is closest to the claimed one.

4.2 Starting from the lens according to D3 the objective problem is to adapt the lens for use in the anterior chamber and to further redesign the lens so that a radial compression of the haptic elements would not lead to a translational movement of the optic portion along the optical axis.

4.3 In the opinion of the Board even if the person skilled in the art were to wish to adapt this lens for the anterior chamber of the eye, this would mean a complete redesign of the lens as any posterior movement of the lens would have to be avoided so as to prevent any risk of damaging the iris or the possibly still present natural lens, and the haptic elements would have to be redesigned to be adapted for the anterior chamber of the eye, i.e. to provide the necessary fixation and centration of the lens in the anterior chamber. There is further no teaching in D3 that such a redesign should include a central portion with the specific flexing feature claimed in feature d) for avoiding translational movement of the optic portion along the optical axis.

The Board considers that so many steps of amendments of the design of the IOL of D3 are not obvious for the person skilled in the art. Thus the subject-matter of

Claim 1 involves an inventive step in the sense of Article 56 EPC.

4.4 The respondent argued that D3 would lead the person skilled in the art to the design of the IOL claimed in claim 1 as the dimension ranges given in D3 include values which would automatically give the lens the features of claim 1.

The Board does not share this opinion. As already mentioned, the IOL disclosed in D3 is adapted for use in the capsular bag and it necessitates a radial compression of the haptic elements by 20-25% to achieve a good centration and fixation in the capsular bag. The relatively long length and radius of arms 20 are said to be so in order to provide greater contact with the capsular bag for better fixation when the IOL is implanted. The arms 20 also have a widened portion to increase the stiffness and strength of the arms at a critical stress point (see page 4, lines 15 to 20). In the opinion of the Board, this means that the arms 20 are meant to have a longer contact area with the relatively soft tissue forming the capsular bag so that, as already mentioned, such arms are not suitable for an implantation in the anterior chamber which has a bigger diameter and whose borderline tissues are stiffer. This means that not only the overall dimensions of the IOL but also the shape of the haptic elements must be amended to be better adapted for use and fixation of the IOL in the anterior chamber. On top of that the link between arms and optic portion must be designed so as not to induce any posterior vaulting when the arms are compressed, which is just the contrary of what is

desired for the lens according to D3 (see page 4, lines 8,9).

In the opinion of the Board there is thus no suggestion whatsoever in D3 to build a lens having the features of the lens according to claim 1.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of the first instance with the order to maintain the patent on the basis of the following documents:
   - claims 1 to 18, filed as main request on 23 December 2009;
   - description columns 1 to 4 as filed during oral proceedings,
     columns 5 to 7 as granted;
   - drawings Figures 1 to 14 as granted.

The Registrar: The Chairman:

D. Sauter M. Noël