PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of WORST

Patent No. 5,192,319 Issued: March 09, 1993

Application No. 07/703,271 Filed: May 20, 1991

For: INTRAOCULAR REFRACTIVE LENS

TRANSMITTAL LETTER

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Alexandria, VA 22313-1450 on 11-8-04.

Reg. No. 40,764
Mark D. Passler

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please find enclosed for filing:

1. Application For Patent Term Extension Under 35 U.S.C. §156, together with 2 additional copies thereof;
2. Copy of patent specification, including claims and drawings;
3. Copy of patent maintenance fee statements;
4. Drawings showing approved products; and
5. Copy of letter confirming agency relationship between marketing applicant and patent owner; and
6. Check in the amount of $1,120 in payment of the prescribed fee for receiving and acting upon the application for extension according to 37 CFR §1.20(j).

Please charge any fee deficiencies or credit any overpayments to Deposit Account No. 50-0951.

Respectfully submitted on behalf of the patent owner,

Date: 11-8-04

Mark D. Passler
Registration No. 40,764
AKERMAN SENTERFITT
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West Palm Beach, FL 33402-3188
Telephone: (561) 653-5000

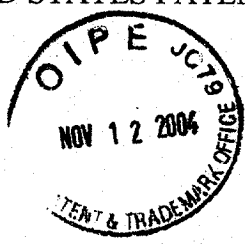
Docket No. 6975-4
{WP200868;1}

2006E-0282

APP 1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Patent of WORST

Patent No. 5,192,319 Issued: March 09, 1993

Application No. 07/703,271 Filed: May 20, 1991

For: INTRAOCULAR REFRACTIVE LENS

APPLICATION FOR PATENT TERM EXTENSION UNDER 35 U.S.C. §156

CERTIFICATE OF TRANSMISSION/MAILING

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Reg. No. 40,764
Mark D. Passler

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INTRODUCTORY COMMENTS

Patent owner hereby applies for the extension of term of the above-identified patent under 35 U.S.C. §156. The paragraph numbering used herein accords with the paragraph numbering of 37 CFR §1.740.

IDENTIFICATION OF THE APPROVED PRODUCT

1. The approved products are Phakic Intraocular Lenses (IOL's) manufactured from polymethylmethacrylate (PMMA) with a refractive index of 1.49. Phakic lenses are lenses designed for implantation into the anterior chamber of the phakic human eye (an eye having the natural lens still in place) for the treatment of myopia, hyperopia and astigmatism. In the implanted condition, the lenses are affixed to the anterior mid-periphery of the iris stoma by two iridoplastic bridges with enclavation mechanisms. The optic portion is available in 5.0 mm or 6.0 mm diameters, with a convex-concave configuration. The optic carrier is generally elliptical in shape and has an overall length of 8.5 mm with a slight anterior vault. One fixation arm mechanism is located on each side of the two peripheral supports.

IDENTIFICATION OF FEDERAL STATUTE

2. The Federal statute under which the regulatory review occurred is Section 515 of the Federal Food, Drug and Cosmetic Act.

DATE OF PERMISSION FOR COMMERCIAL MARKETING

3. The product received premarket approval on September 10, 2004.

4. (Not Applicable)

5. It is hereby stated that this application is being submitted within the sixty day period permitted for submission pursuant to 37 CFR §1.720(f). The date of the last day on which this application could be submitted is November 9, 2004.

IDENTIFICATION OF PATENT FOR WHICH AN EXTENSION IS SOUGHT

6. The Patent for which extension is sought is -

Patent Number: 5,192,319

Name of Inventor: Jan G. F. Worst

Date of Issue: March 9, 1993

Date of Expiration: May 20, 2011

7. A copy of the patent is attached hereto, including the entire specification (including claims) and drawings.

8. No terminal disclaimers, certificates of correction or reexamination certificates have been applied for or issued. Copies of the Maintenance Fee Statements are attached hereto.

STATEMENT THAT THE PATENT CLAIMS THE APPROVED PRODUCT

9. Claims 1, 2, 6, 7, 8, 9 and 10 claim the approved product. The attached figures showing the 5.0 mm and 6.0 mm lenses (Models 204 and 206) have been given the same reference numerals as the patent figures. As a showing of the manner in which at least one such patent claim reads on the approved product is required, the following table demonstrates how claim 1 reads on the approved product.

Claim features	**Model 204 and 206 lenses**
1. An iris tissue support fixation intraocular lens comprising:	The lenses are for intraocular implantation supported by and fixed against iris tissue.
a) an optical portion having a periphery and adapted to be positioned in the anterior chamber of a phakic eye;	The lenses each have an optical portion 31 having a periphery and are suitable for implantation in the anterior chamber of an eye including its natural lens (phakic eye).
b) a support portion extending radially from the optical portion, and comprising flexible, normally abutting pincer arm means for pinching a portion of the anterior surface only of iris tissue without penetrating to the posterior surface;	A support portion formed by pairs of arms 32, 33 and 32a, 33a extend radially from the optical portion 31. The arms 32, 33 and 32a, 33a are flexible and normally abutting pincer arms suitable for pinching a portion of the anterior surface only of iris tissue without penetrating to the posterior surface.
c) said pincer arm means comprising a plurality of pincer arms that define generally a plane, and including at least first and second pairs of pincer arms that are spaced circumferentially about the optical portion;	The arms 32, 33 and 32a, 33a define a plane 45 and include two pairs of pincer arms 32, 33 and 32a, 33a. The pincer arms 32, 33 and 32a, 33a are spaced circumferentially about the optical portion.
d) a gap positioned between the two pincer arms that form each of the pairs, said gaps communicating with the periphery of the optical portion;	Between each pair of the pincer arms 32, 33 and 32a, 33a a gap 39, 39a is located. The gaps 39, 39a communicate with the periphery of the optical portion 31.

Claim features	Model 204 and 206 lenses
e) said optical portion being a lens having a flat or convex curve on its front and a concave curve on its back, said concave curve forming, when the pincer arms pinch the anterior surface of the iris tissue, a space between said optical portion and the pupil of the eye, said space being defined generally by said optical portion and said plane; and	The optical portion 31 is a lens. The lens has a flat or convex curve on its front 46 and a concave curve on its back 47. When the pincer arms 32, 33 and 32a, 33a pinch the anterior surface of the iris tissue, the concave curve forms a space 48 between the optical portion 31 and the pupil of the eye. This space 48 is defined by the optical portion 31 and the plane 45 defined by the pincer arms 32, 33 and 32a, 33a.
f) a plurality of lateral side gates formed in the optical portion and positioned between the optical portion and the gap between respective pairs of pincer arms, and each gate communicating with the space.	Four lateral side gates 36 are formed in the optical portion 31 and two of these side gates are positioned between the optical portion 31 and the gap 39, 39a between respective pairs of the pincer arms 32, 33, and 32a, 33a. Each of the gates 36 communicates with the space 48.

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RELEVANT DATES AND INFORMATION PURSUANT TO 35 U.S.C. §156(g)

10. In order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory period, the relevant dates and information pursuant to 35 U.S.C. §156 are as follows:

a) Date of the (conditional) investigational device exemption (IDE): September 24, 1997. The IDE number is G970147/A1, A2, A3.

b) Date of submission of the application for product approval under Section 515 of the Federal Food, Drug and Cosmetic Act: July 1, 2003. Number of the application: P030028

c) Date of approval of the application: September 10, 2004

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BRIEF DESCRIPTION OF THE ACTIVITIES OF THE MARKETING APPLICANT BEFORE THE REGULATORY AGENCY

11. As agent for the patent owner, Jan G.F. Worst, Ophtec USA, Inc., a wholly-owned subsidiary of patent licensee Ophtec B.V., undertook activities including corresponding with the Food and Drug Administration regarding IDE application and application for premarket approval, and organizing and arranging clinical trials.

Identification of significant communications of substance with the regulatory agency and the dates related to such communications follows (all communications are from/to Ophtec USA, Inc. and to/from FDA):

February 2, 1997: Pre IDE (Investigational Device Exemption) submitted;

March 12, 1997: Additional information provided for Pre IDE;

August 1, 1997: Letter from FDA regarding deficiencies in the IDE application;

August 12, 1997: Meeting with FDA staff at FDA headquarters;

August 20, 1997, August 25, 1997, September 6, 1997, September 22, 1997: Various communications regarding additional information required/provided;

September 24, 1997: Conditional approval of IDE application by FDA;

November 7, 1997, November 10, 1997, December 10, 1997, December 15, 1997, January 16, 1998, January 21, 1998, February 19, 1998, February 24, 1998, March 2, 1998, March 27, 1998, April 2, 1998: Various communications regarding additional information required/provided;

April 8, 1998: Request to expand study to Phase 2;

April 16, 1998, April 28, 1998, April 29, 1998, April 30, 1998, May 1, 1998, May 8, 1998, May 11, 1998, May 13, 1998: Various communications regarding additional information required/provided;

June 12, 1998: Conditional approval of Phase 2 by FDA, and request for additional information;

July 7, 1998, August 7, 1998, August 27, 1998: Various communications regarding additional information required/provided;

September 11, 1998: Request to expand power range and add new lens model;

September 30, 1998: Annual progress report to FDA;

October 6, 1998: Additional information provided to FDA;

October 14, 1998: FDA approval to expand power range and add new lens model;

October 28, 1998, December 1, 1998, December 10, 1998: Various communications regarding additional information required/provided;

March 5, 1999: Request to expand study to Phase 3;

April 7, 1999: FDA approves expansion of study to Phase 3;

April 29, 1999: Additional information provided to FDA;

September 30, 1999, October 6, 2000: Annual progress reports to FDA;

November 3, 2000: Request to open a substudy to enroll patients who do not fit study protocol;

November 22, 2000: FDA approval to conduct a substudy;

November 16, 2001: Annual progress report to FDA;

June 21, 2002: Additional information provided to FDA;

November 10, 2002: Annual progress report to FDA;

December 5, 2002: Request to expand study to enroll subjects in an open ended enrollment study;

January 8, 2003: FDA approval to enroll subjects in an open ended study;

July 1, 2003: Submission of Premarket Approval (PMA) Application to FDA;

August 13, 2003: Letter from FDA regarding completion of initial review of PMA, PMA accepted for filing;

August 21, 2003, August 22, 2003, September 22, 2003, September 25, 2003, October 2, 2003, October 21, 2003, October 29, 2003: Various communications including amendments to PMA application;

November 6, 2003: Annual progress report to FDA;

November 10, 2003, December 11, 2003, May 12, 2004, June 10, 2004, July 1, 2004, July 6, 2004, July 21, 2004, July 30, 2004, August 30, 2004, September 2, 2004, September 7, 2004, September 8, 2004: Various communications including amendments to PMA application; and

September 10, 2004: Letter from FDA regarding approval of PMA

EXTENSION PERIOD

12. In the opinion of the applicant, the patent is eligible for extension under 35 U.S.C. §156 and the length of the extension claimed is 1484 days. The length of the extension was determined by following the calculation set forth in 37 CFR §1.777 (paraphrased below using different paragraph numbers).

a) The length of regulatory review period is the sum of:

(i) the number of days in the period beginning on the date a clinical investigation on humans was initiated (10/7/97) and ending on the date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (7/1/03); and

Number of days = 2093

(ii) the number of days in the period beginning on the date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (7/1/03), and ending on the date such application was approved under such Act (9/10/04) or the period beginning on the date a notice of completion of a product development protocol was initially submitted under 515(f)(5) of the Act and ending on the date the protocol was declared completed.

Number of days = 437

Total number of days in regulatory review period = 2530

b) Further factors affecting the patent term extension period are:

(i) The number of days in the periods of paragraphs a)(i) and a)(ii) which were on and before the date on which the patent issued;

Number of days = 0

(ii) the number of days in the periods of paragraphs a)(i) and a)(ii) during which it is determined under 35 U.S.C. §156(d)(2)(B) by the Secretary of Health and Human Services that applicant did not act with due diligence; and

Number of days = 0

(iii) one-half the number of days remaining in the period defined by paragraph a)(i) after that period is reduced in accordance with paragraphs b)(i) and b)(ii).

Number of days = 1046

Total number of days in section b) = 1046

c) The total number of days in section b) is subtracted from the regulatory review period determined in section a).

Total number of days = 1484

d) The number of days in section c) is added to the original term of the patent, as shortened by any terminal disclaimer.

Adjusted expiry date of patent = June 12, 2015

e) 14 years is added to the date of approval of the application under section 515 of the Federal Food, Drug, and Cosmetic Act or the date a product development protocol was declared completed under section 515(f)(6) of the Act.

Date of approval + 14 years = September 10, 2018

f) The earlier date of dates d) and e) is taken.

Earlier date = June 12, 2015

g) For a patent issued after September 24, 1984, 5 years is added to the original expiration date of the patent.

Expiry date of patent + 5 years = May 20, 2016

h) The earlier date of dates f) and g) is taken.

Earlier date = June 12, 2015

This final date is the date that Applicant believes should be the extended expiry date for the patent. The total extension period in days is thus 1484 days. Applicant requests that any errors in Applicant's calculation of the extension period be corrected by the Secretary and/or Director.

DUTY OF DISCLOSURE

13. Applicant acknowledges a duty in accordance with 37 CFR §1.765 to disclose to the Director of the United States Patent and Trademark Office and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

14. A check in the amount of $1,120 in payment of the prescribed fee for receiving and acting upon the application for extension according to 37 CFR §1.20(j) is attached hereto.

15. The name, address, and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed is:

Mark D. Passler, Registration No. 40,764
AKERMAN SENTERFITT (customer number 30448)
P.O. Box 3188
West Palm Beach, FL 33402-3188
Tel: (561) 653-5000

This application is accompanied by two additional copies hereof.

Respectfully submitted on behalf of the patent owner,

Date: 11-8-04

Mark D. Passler
Registration No. 40,764
AKERMAN SENTERFITT
Post Office Box 3188
West Palm Beach, FL 33402-3188
Telephone: (561) 653-5000

US005192319A

United States Patent [19]

Worst

[11] Patent Number: 5,192,319

[45] Date of Patent: Mar. 9, 1993

[54] INTRAOCULAR REFRACTIVE LENS

[76] Inventor: Jan G. F. Worst, Julianalaan 11, Haren, Netherlands

[21] Appl. No.: 703,271

[22] Filed: May 20, 1991

[51] Int. Cl.[5] A61F 2/16

[52] U.S. Cl. 623/6

[58] Field of Search 623/6

[56] References Cited

U.S. PATENT DOCUMENTS

2,834,023	5/1958	Lieb	623/6
4,215,440	8/1980	Worst	623/6
4,277,851	7/1981	Choyce	623/6

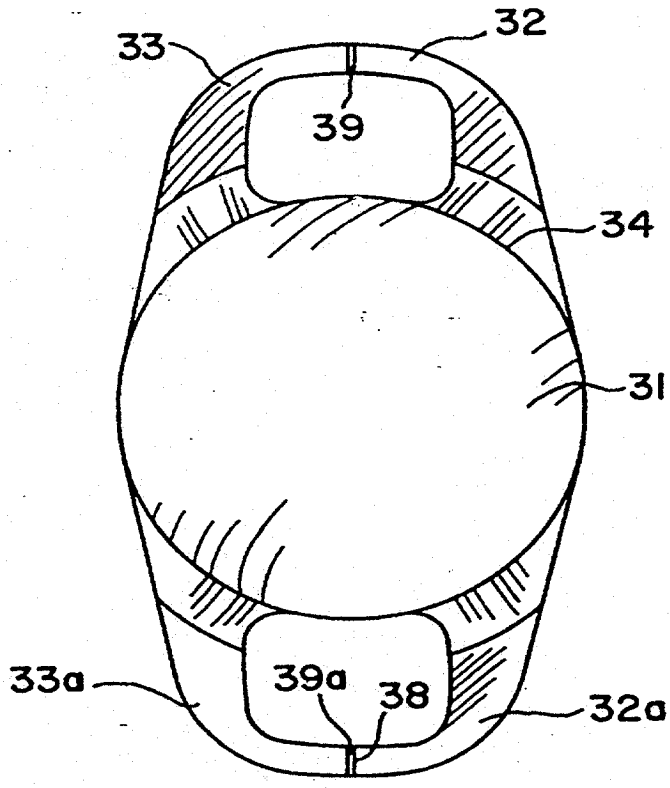
Primary Examiner—Randy C. Shay

Attorney, Agent, or Firm—Joseph Zallen

[57] ABSTRACT

An intraocular lens surgically positioned in the anterior chamber and to be used in addition to the natural lens to correct the refraction. The lens is fixated by iris stromal support, comprising an optical portion of inner concave and outer convex shape and a side support portion which has one or more pairs of pincerlike extensions for holding a portion of iris tissue. The design provides safe clearance away from the vital structures both anteriorly and posteriorly. This technique of stromal iris support permits full pupil motility. Lack of any postoperative decentration allows the system to be used for myopia, hyperopia, presbyopia or astigmatism. A non-transparent, light-impermeable ring may be incorporated to prevent glare or edge effects. The lens provides high predictability of the precalculated optical power.

10 Claims, 4 Drawing Sheets



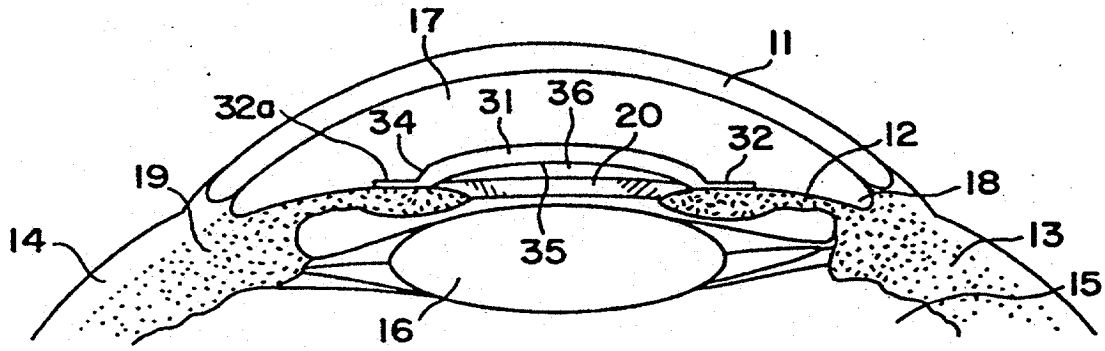


FIG. 1

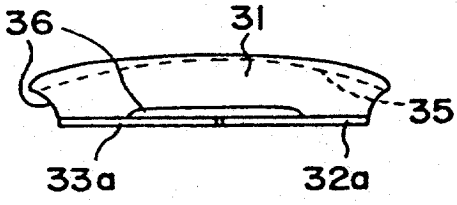


FIG. 3

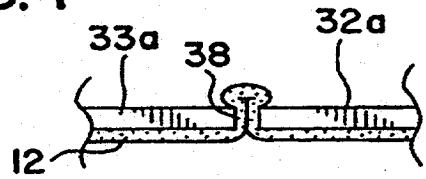


FIG. 2A

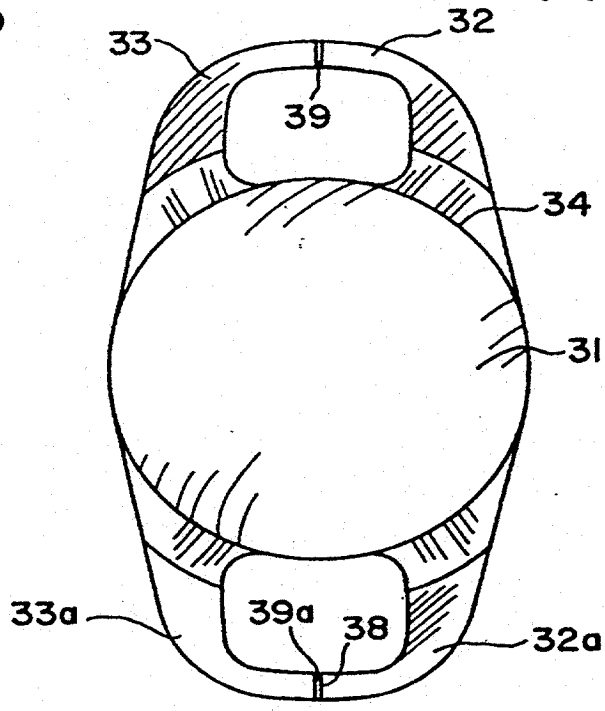


FIG. 2

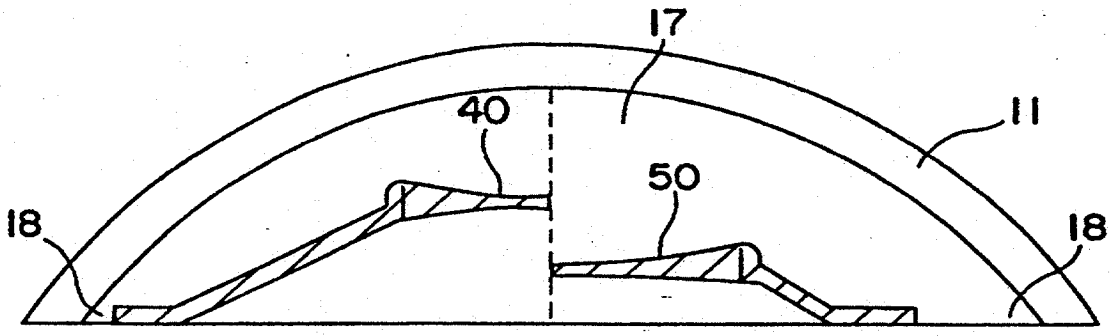
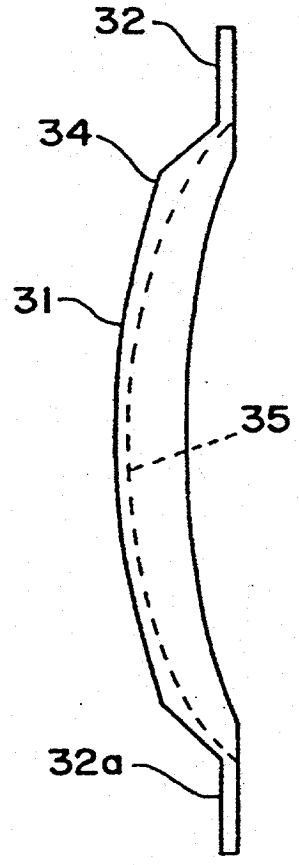


FIG. 6



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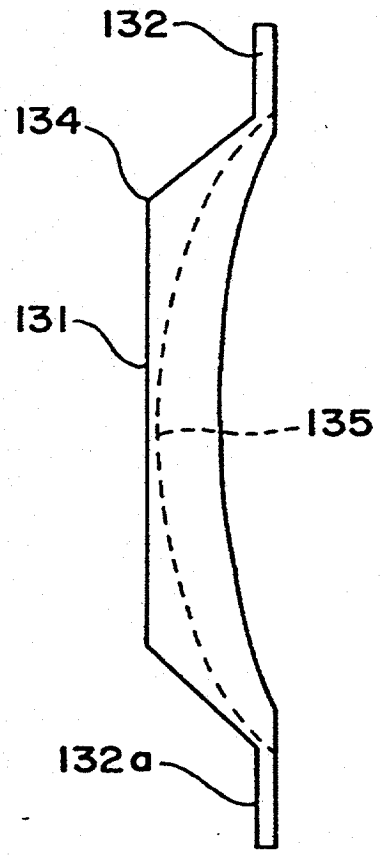

FIG. 5

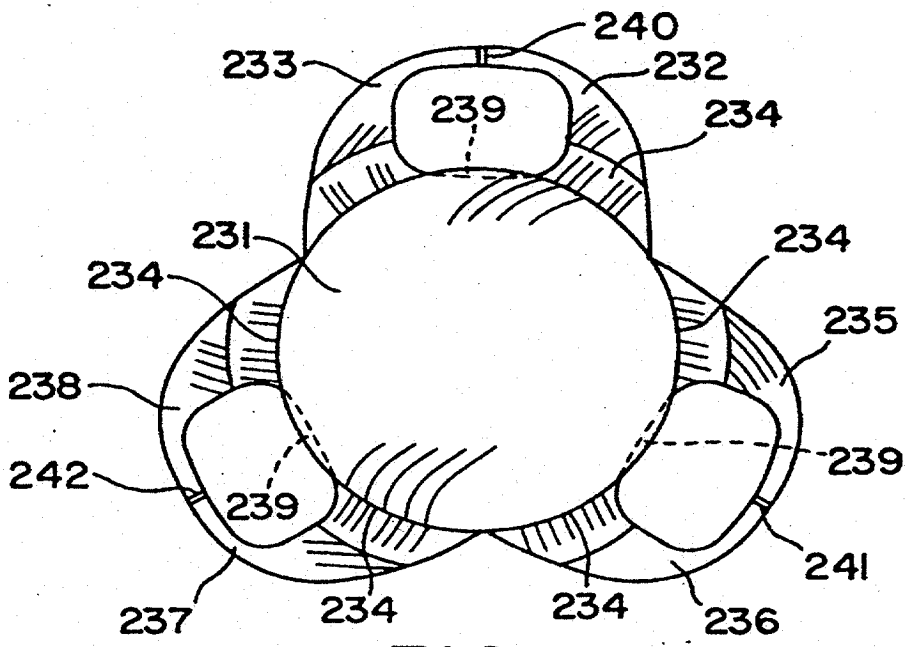
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FIG. 7

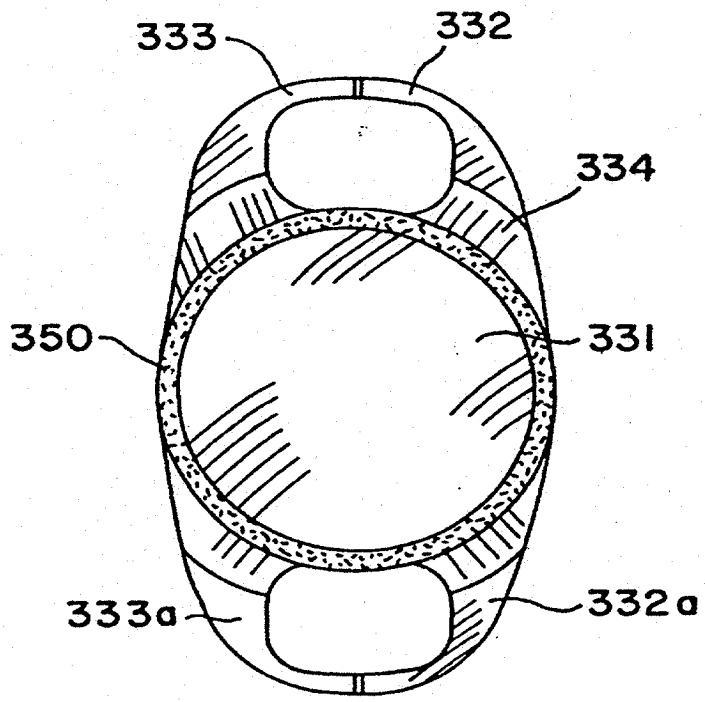
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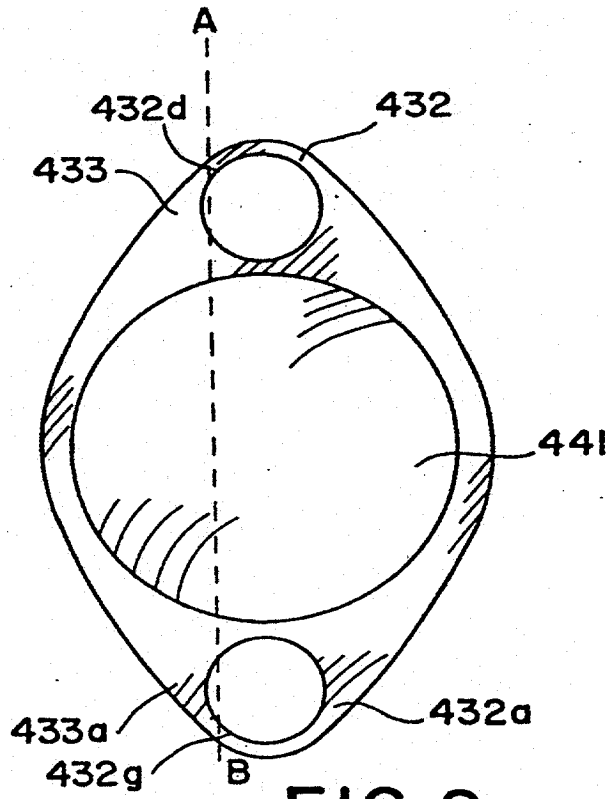
FIG. 8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433a
432a
432g
B

FIG. 9

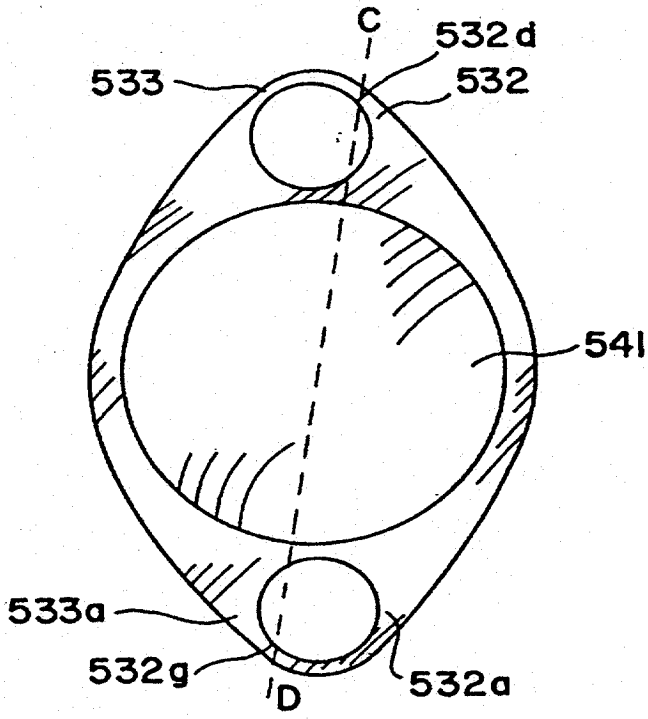
C
532d
533
532
541
533a
532g
532a
D

FIG. 10

INTRAOCULAR REFRACTIVE LENS

BACKGROUND OF INVENTION

The present invention relates to surgical refractive correction wherein the result is a correction of the normal refraction of the eye to permit improved vision Surgical correction of corneal curvature has been proposed in various forms, such as correction with radial keratotomy, excimer laser, corneal inlays, epikeratophakia, or keratomileusis. In addition, surgical corrections have been disclosed, wherein the correction is achieved by an anterior chamber biconcave implant, in addition to the natural lens (phakic eye). In one example, a biconcave lens, manufactured by Domilens, France, is supported by the chamber angle, which can lead to serious complications such as corneal edema, chronic iridocyclitis or hyphema, generally known as being related to chamber angle supported anterior chamber implant The height of this lens and the biconcave optics add an additional risk of corneal edema and corneal decompensation. In another example, as described in "European Journal Ref. Surgery", Vol. 1, page 41–43, March 1989, a biconcave lens is supported by iris claws (U.S. Pat. No. 4,215,440 describes iris claws.). Although such biconcave lenses can provide a high predictability of precalculated refraction, the height of the lens and the biconcavity may be a risk of corneal edema or corneal decompensation in shallow anterior chambers Other examples of prior art implant lenses intended for refractive correction include U.S. Pat. No. 4,585,456 in which the optical body is positioned against the natural lens; U.S. Pat. No. 4,769,035 in which the optical body is also positioned against the natural lens, and U.S. Pat. No. 4,950,288 in which the lens is flat inside and supported by the chamber angle.

OBJECTS OF THE INVENTION

The principal object of the present invention is to provide a novel intraocular lens, the entire structure of which is located in the anterior chamber as an addition to the natural lens (phakic eye) and which is fixated by iris stromal support providing a system with a high predictability of the precalculated refraction for correction of myopia or hyperopia or presbyopia and astigmatism.

Other objects and advantages of this invention will be apparent from the description and claims which follow taken together with the appended drawings

SUMMARY OF THE INVENTION

The invention comprises broadly an intraocular lens having an optical portion whose inner curvature is concave and outer curvature convex with a specific geometrical shape. The shape is adapted to the anatomy and physiology of the cornea, the iris, the aqueous outflow through the pupillary area and the clearance between the natural lens and the optical portion of the intraocular lens in the case of implantation in a phakic eye.

The support portion of the intraocular lens, which comprises one or more pairs of flexible pincer arms, provides full pupil motility, a safe distance from chamber angle and trabecular meshwork and a safe distance from the corneal endothelium as a result of the impossibility of post operative decentration. The arms can be placed symmetrically or asymmetrically. The optical

design guarantees safe clearance away from all vital structures anteriorly and posteriorly.

This invention relates particularly to an intraocular lens which is surgically implanted into the eye with the purpose of adding or subtracting the refractive power of the natural lens with the purpose of correcting myopia, hyperopia, presbyopia or astigmatism. It may also be used to provide lost power in the case of aphakia.

It is preferred that all embodiments of this invention be made of a clinical quality clear plastic material such as polymethylmethacrylate or polycarbonate, or any other materials with a combination of high flexibility ratios, resulting in proper pincer movement and a high refractive index, resulting in a lens with considerably thinner optics and a larger distance to the corneal endothelium.

SIGNIFICANT ADVANTAGES AND FEATURES OF THE INVENTION

The present invention pertains to an intraocular lens with pincerlike extensions for fixation to the iris, thus preventing postoperative decentration and moreover an intraocular lens with an inner concave and outer convex curvature providing safe clearance from critical posterior and anterior eye tissues. The lens may also have a non-transparent light-impermeable ring to prevent glare or edge effects. The intraocular lens is surgically implanted into the eye with the purpose of adding or subtracting the refractive power of the natural lens in the phakic eye in the case of correcting myopia, hyperopia, presbyopia or astigmatism thus providing an optical system with high predictability of the precalculated dioptric power. The intraocular lens can also be used to provide lost power in the aphakic eye.

The choice of which correction to use is a medical decision. However, they are all very different in what they accomplish. Spectacles provide a limited field and disturbed peripheral vision. A contact lens provides a better peripheral vision, but cannot always be well tolerated by the eye. Correction by radial keratotomy provides only limited dioptric power correction (4–6 dpt). Moreover the predictability of the optical correction is poor. Correction by excimer laser provides limited dioptric power correction (4–6 dpt). It requires a complicated and expensive apparatus. Long-term results are not known. Correction by corneal inlays provide dioptric power fluctuation in correction (Reduction of refractive correction with time) The predictability of the optical correction is poor. Correction by keratomileusis provides a result with poor predictability. The surgical technique is difficult and requires complicated and expensive instrumentation.

In the present invention, the intraocular lens for refractive surgery (myopia, hypermetropia, presbyopia and astigmatism correction) in the phakic eye, with convex-concave optics, guarantees safe clearance from vital structures like natural lens and corneal endothelium. Stromal iris support ensures full pupil motility and prevents decentration. The back curve combined with side gates provides natural outflow of aqueous through the pupillary area Incorporating a non-transparent, light-impermeable ring eliminates glare and edge effects.

None of the prior art techniques can be used for the principal purpose covered by the invention namely, safe, accurate predictable correction of myopia, hyperopia, presbyopia or astigmatism.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is a sectional view of one embodiment of this invention implanted in the eye.

FIG. 2 is a plan view of this embodiment.

FIG. 2A is an enlarged partial sectional view of FIG. 1.

FIG. 3 is an end view of this embodiment.

FIG. 4 is a side view of this embodiment.

FIG. 5 is a side view of another embodiment of this invention with a plano outer surface.

FIG. 6 is a cross-sectional diagrammatic view comparing an angle supported biconcave lens (mfg. by Domilens) on the left with an example of an iris stromal supported biconcave lens on the right. (Both prior art).

FIG. 7 is a plan view of another form of this invention: a lens supported by three pincer pairs.

FIG. 8 is a plan view of another form of this invention: showing a peripheral, non-transparent ring embedded in the body of the optical portion.

FIG. 9 is a plan view of another form of this invention: unequal length pincer arms and asymmetrically placed slits along fixation line a–b.

FIG. 10 is a plan view of another form of this invention: Unequal length pincer arms and mirror symmetrically placed slits along fixation line c–d

SPECIFIC EXAMPLE OF INVENTION

Referring now to FIGS. 1, 2, 2A, and 3, the portions of the eye illustrated therein are the cornea 11, iris 12, sclerotic tissue 14, vitreous 15, anterior chamber 17, chamber angle 18, and trabecular meshwork 19. The regular human lens is shown at 16. In the course of this invention the convex-concave optical portion 31 with its pairs of pincer arms 32, 33, 32*a* and 33*a* is fixed in the anterior chamber wherein the pairs of pincers grasp iris tissue 12 to form bulge 38, thus positioning the optical portion of the present invention directly in front of the natural lens 16. The arms 32, 33, are spaced apart with gap 39 therebetween. Gap 39*a* is between arms 32*a* and 33*a*. The inner surface of the optical portion 31 is concave, providing a safe distance to the natural lens. The outer surface is convex. The flexible pincerlike arms 32 permit full pupil motility and are a safe distance from the chamber angle 18, the trabecular meshwork 19, and the corneal endothelium 11. The tips of the pincerlike arms are covered by ,the iris tissue 12, which reduces the possibility of corneal dystrophy. The lens has four lateral side gates 36 to permit the aqueous to flow undisturbed from the pupillary area 20. Two of the side gates communicate with gaps 39 and 39*a*.

FIGS. 4 and 5 show a comparison of a −10 diopter in FIG. 4 and a −25 diopter lens in FIG. 5. The outer portion of each oclar has a peripheral highest point 34,, 134, a curved surface 31 or a flat surface 131 with iris clasping pairs of pincers 32, 32*a*, and 132, 132*a*. Because the tips of the pincerlike arms 32 are covered by the iris 12, even if there is an occasional touch to the cornea, the touch would be by iris tissue and not by the lens materials, greatly reducing the possibility of corneal dystrophy. The post operative decentration and dislocation rate of the intraocular lens with pincerlike fixation is almost zero.

As illustrated in FIG. 6 a biconcave lens 40 of the prior art is shown fixated to the chamber angle 18 in the anterior chamber 17. On the right side is shown an example of a biconcave lens 50 of the prior art fixated to iris tissue by pincerlike arms.

As shown in FIG. 7, the support portion for optical portion 231 comprises three equally spaced pairs of pincer arms 232, 233; 237, 238; and 235, 236, with side gates 239 and peripheral highest points 234 and slits 240, 241, and 242.

In FIG. 8 the optical portion 331 has a peripheral non-transparent portion 350 to prevent glare, but otherwise has similar pairs of iris pincer arms 332, 333, 333*a*, and 332*a* and peripheral highest point 334.

FIG. 9 illustrates an embodiment wherein the optical portion 441 has off- center pairs of pincer arms of unequal length 432, 433, and 432*a*, 433*a*, with asymmetrically placed abutting slits 432*d* and 432*g* along line A–B.

FIG. 10 illustrates an embodiment wherein the optical portion 541 has off-center pairs of pincer arms of unequal length 532, 533, and 532*a*, 533*a* with mirror symmetrically placed abutting slits 532*d* and 532*g* along line C–D.

Varieties of the invention can be made of other materials where a combination of high flexibility of lens material and a high refractive index, result respectively in a proper pincer movement and fixation performance and a lens with the largest critical distance to the corneal endothelium.

All designs are a compromise between the anatomical limitations caused by the position of the intraocular lens in the anterior chamber and the optical requirements.

Construction of equal length arms gives equal tensile strength and flexibility to each arm. Placing the slit asymmetrically provides a lens with unequal arms. One arm will obtain a greater mobility, facilitating in some situations the technical surgical procedure.

An anatomically correct convex-concave optical design is obtained with this invention where a negative power is obtained by combining a back curve of a fixed high dioptric power with a front curve of a lower power, resulting in a negative power lens to correct high myopia. Where the design has a back curve of a fixed dioptric power with a front curve of a higher power one can obtain a positive power lens to correct hyperopia or presbyopia. If the design has a back curve of a fixed dioptric power with a front curve of a cylinder curve it can correct astigmatism.

I claim:

1. An iris tissue support fixation intraocular lens comprising:

a) an optical portion having a periphery and adapted to be positioned in the anterior chamber of a phakic eye;

b) a support portion extending radially from the optical portion, and comprising flexible, normally abutting pincer arm means for pinching a portion of the anterior surface only of iris tissue without penetrating to the posterior surface;

c) said pincer arm means comprising a plurality of pincer arms that define generally a plane, and including at least first and second pairs of pincer arms that are spaced circumferentially about the optical portion;

d) a gap positioned between the two pincer arms that form each of the pairs, said gaps communicating with the periphery of the optical portion;

e) said optical portion being a lens having a flat or convex curve on its front and a concave curve on its back, said concave curve forming, when the pincer arms pinch the anterior surface of the iris tissue, a space between said optical portion and the

pupil of the eye, said space being defined generally by said optical portion and said plane; and

f) a plurality of lateral side gates formed in the optical portion and positioned between the optical portion and the gap between respective pairs of pincer arms, and each gate communicating with the space.

2. The intraocular lens of claim 1 wherein said support portion comprises two opposite pairs of said pincer arms.

3. The intraocular lens of claim 1 wherein said support portion comprises three pairs of said pincer arms.

4. The intraocular lens of claim 1 wherein said optical portion has a light-impervious portion on its periphery.

5. The intraocular lens of claim 1 wherein said pincer arms are of unequal length and asymmetrically positioned.

6. The lens of claim 1 wherein there are 2 additional lateral side gates, each positioned along the optical portion and spaced away from the gaps.

7. The lens of claim 1 wherein each of the pincer arms provides inner and outer end portions, each outer end portion abuts a corresponding outer end portion of an adjacent pincer arm, the outer end portions defining a grasping portion for grasping iris tissue.

8. The lens of claim 7 wherein the inner end portions attach to the lens at positions spaced circumferentially about the lens.

9. The lens of claim 1 wherein each of the pincer arms are arc shaped.

10. The lens of claim 1 wherein the optical portion is generally circular in shape.

* * * * *

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PATENT NUMBER	FEE CODE	FEE AMT	SUR CHARGE	APPLICATION NUMBER	PATENT DATE	FILE DATE	PAY YR	SML ENT	STAT	ATTY DKT NUM
5,192,319	283	$495.00	$0.00	07/703,271	03/09/93	05/20/91	04	NO	PAID	W-0001

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If the statement of small entity status is defective the reason is indicated below in column 10 for the related patent number. THE STATEMENT OF SMALL ENTITY STATUS WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION.

PATENT NUMBER	FEE CODE	FEE AMT	SUR CHARGE	APPLICATION NUMBER	PATENT DATE	FILE DATE	PAY YR	SML ENT	STAT	ATTY DKT NUM
5,192,319	184	$1,900.00	$0.00	07/703,271	03/09/93	05/20/91	08	NO	PAID	W-0001

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If a maintenance fee payment is defective, the reason is indicated by code in column 10, "STAT" below. TIMELY CORRECTION IS REQUIRED IN ORDER TO AVOID EXPIRATION OF THE PATENT. NOTE 37 CFR 1.377. THE PAYMENT(S) WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION. IF PAYMENT OR CORRECTION IS SUBMITTED DURING THE GRACE PERIOD, A SURCHARGE IS ALSO REQUIRED. NOTE 37 CFR 1.20(k) and (l).

If the statement of small entity status is defective the reason is indicated below in column 10 for the related patent number. THE STATEMENT OF SMALL ENTITY STATUS WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION.

PATENT NUMBER	FEE CODE	FEE AMT	SUR CHARGE	APPLICATION NUMBER	PATENT DATE	FILE DATE	PAY YR	SML ENT	STAT	ATTY DKT NUM
5,192,319	1553	$3,320.00	$130.00	07/703,271	03/09/93	05/20/91	12	NO	PAID	W-0001

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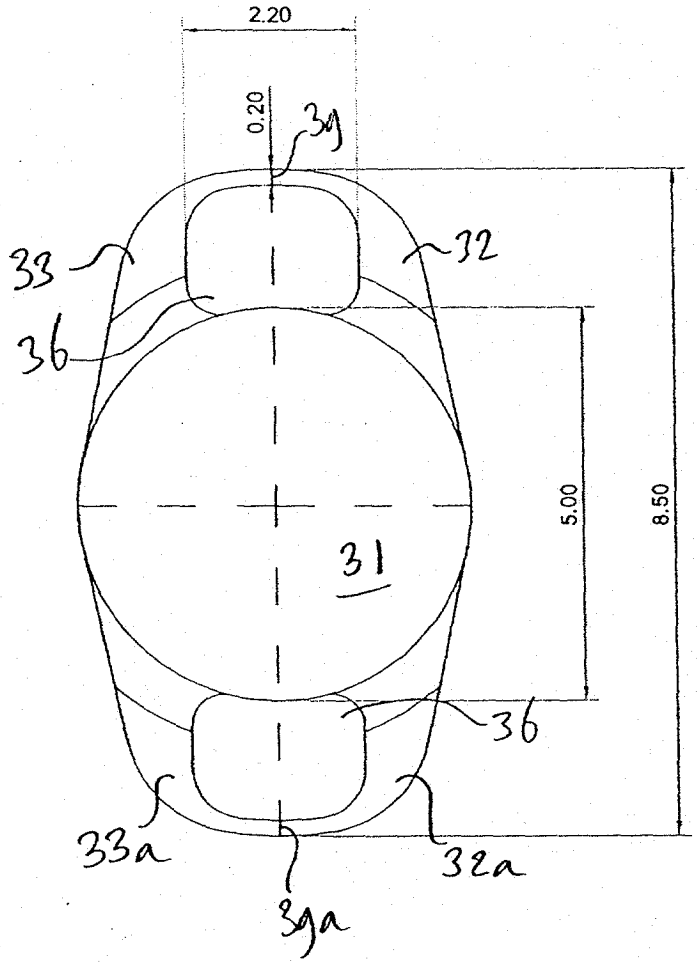
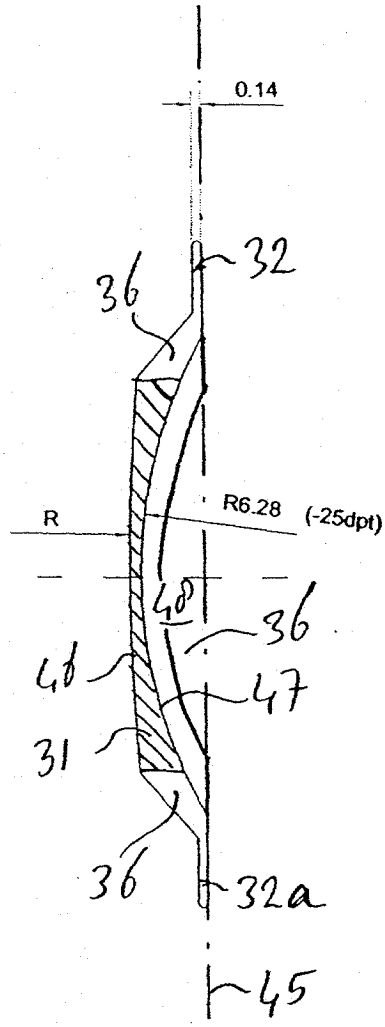




1	1	LENS	PERSPEX CQ UV		R AFH. VAN DIOPTRIE
STUK NR.	AANTAL	BENAMING	MATERIAAL	TEKENING NR.	OPMERKING

PROJECTIE

TEK.NR.: S206001W.A01 | GETEKEND :
MAATEENHEID : mm | GECONTROLEERD :
SCHAAL : 10:1 | REVISIE :
TOLERANTIES : | AKKOORD ONTW :

DATUM | PARAAF

ARTIKELCODE: 206001W

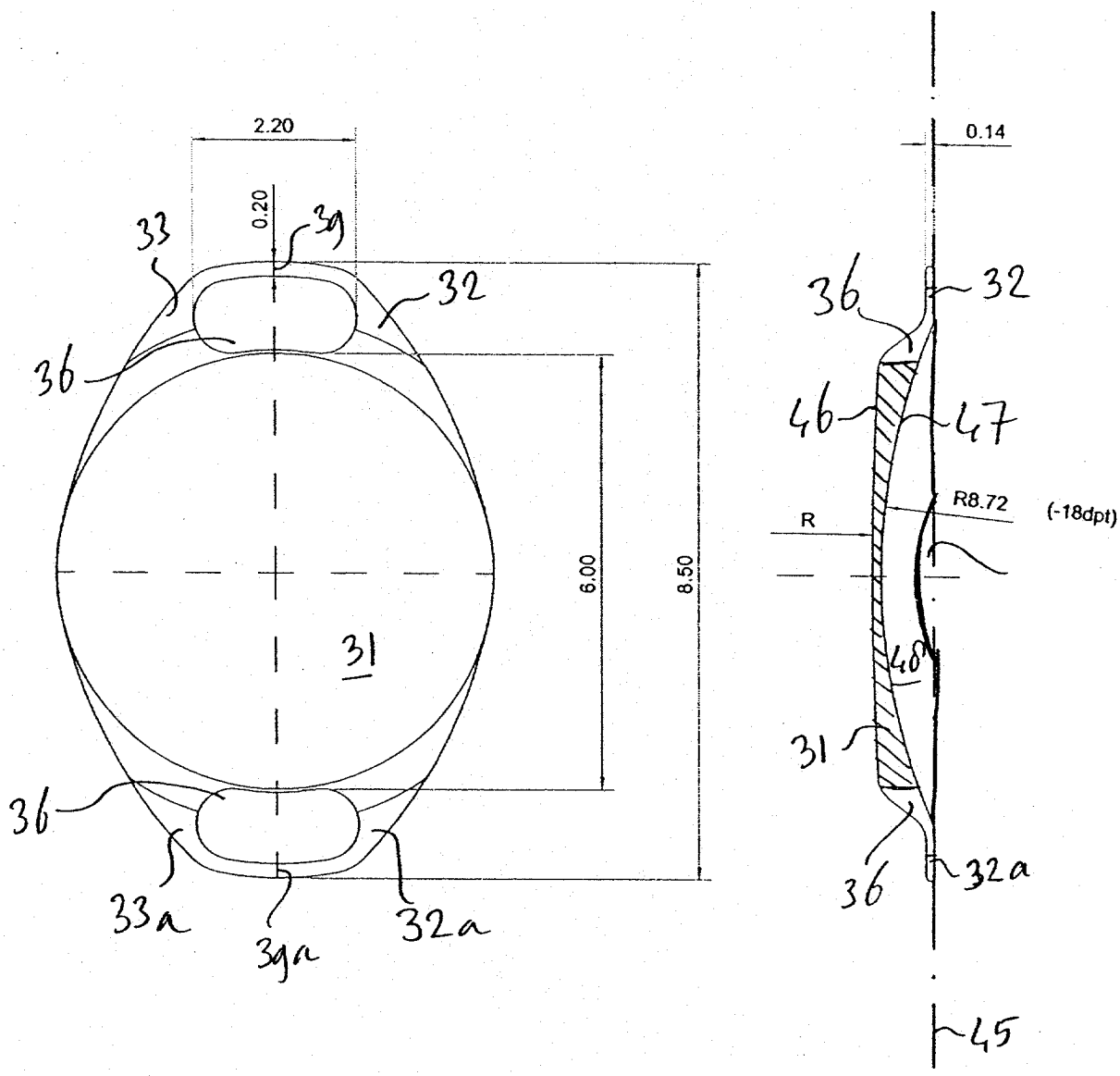
OMSCHRIJVING : ARTISAN™ Myopia 5/8,5

AKKOORD ARTS :

OPHTEC

BLAD : 1

A4



1	1	LENS	PERSPEX CQ UV		R AFH. VAN DIOPTRIE
STUK NR.	AANTAL	BENAMING	MATERIAAL	TEKENING NR.	OPMERKING

PROJECTIE

TEK.NR.: S204001W.A02		GETEKEND :	DATUM / PARAAF
MAATEENHEID : mm		GECONTROLEERD :	
SCHAAL : 10:1		REVISIE :	
TOLERANTIES :		AKKOORD ONTW :	

ARTIKELCODE
204001W

OMSCHRIJVING :
ARTISAN™ Myopia 6/8,5

AKKOORD ARTS :

OPHTEC
International · Ophthalmological · Laboratories

BLAD : 1
AANTAL BLADEN : 1

A4

OPHTEC

International • Ophthalmological • Laboratories

November 8, 2004

Re: Patent 5,192,319 Intraocular Refractive Lens, Jan G.F.Worst, ARTISAN® (Model 204 and 206) Phakic Intraocular Lens / Verisyse (Model VRSM5US and VRSM6US) Phakic Intraocular Lens

To Whom It May Concern:

I, Ronald E. "Rick" McCarley, as President and CEO of OPHTEC USA, Inc., the applicant for marketing approval for the ARTISAN® / Verisyse Phakic Intraocular Lens before the US Food and Drug Administration, confirm:

1. The application for marketing approval was submitted in my capacity as agent for the owner, Prof. Jan G.F. Worst, MD, which capacity existed during the entire regulatory review period; and
2. I hereby authorize the patent owner to rely on the activities of OPHTEC USA, Inc. before the US Food and Drug Administration in this application for patent term extension for US Patent No. 5,192,319

Sincerely,

R. McCarley

Rick McCarley
President & CEO

6421 Congress Avenue • Suite 112 • Boca Raton, FL 33487 • Tel. (561) 989-8767 • Fax (561) 989-9744 • ophtecusa@aol.com

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From: Sarah E. Smith Date: June 6, 2006

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Please call (561) 653-5000, Ext. 30005 if you do not receive all the pages.

Comments/Special Instructions

Please see attached Response to Requirement for Information filed January 18, 2005.

Thank you,
Sarah E. Smith

Client/Matter No: 24440.148435 Equitrac ID: 3052

Patent
~~Serial~~ No.: 5,192,319 Docket No.: 6975-4
Client: Vereen de / Optec

Commissioner for Patents

Sir:

Please acknowledge receipt of the paper(s) noted hereon by stamping the date received and returning this card to the undersigned.

Respectfully,

MDP

AKERMAN SENTERFITT

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- ☐ Declaration/POA
- ☐ Fee ($ _____)
- ☒ ~~Amendment~~/Response to Req. for Info.
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- ☐ PTOL-85 Fee Transmittal
- ☐ IDS, PTO/SB008A&B, Refs.
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of WORST

Patent No. 5,192,319 Issued: March 09, 1993

Application No. 07/703,271 Filed: May 20, 1991

For: INTRAOCULAR REFRACTIVE LENS

TRANSMITTAL LETTER

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Mark D. Passler

Mail Stop Patent Ext.
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P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please find enclosed for filing:

- Response to Requirement for Information

Please charge any fee deficiencies or credit any overpayments to Deposit Account No. 50-0951.

Respectfully submitted on behalf of the patent owner,

Date: 1-18-05

Mark D. Passler
Registration No. 40,764
AKERMAN SENTERFITT
Post Office Box 3188
West Palm Beach, FL 33402-3188
Telephone: (561) 653-5000

Docket No. 6975-4

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of WORST

Patent No. 5,192,319 Issued: March 09, 1993

Application No. 07/703,271 Filed: May 20, 1991

For: INTRAOCULAR REFRACTIVE LENS

RESPONSE TO REQUIREMENT FOR INFORMATION

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Mark D. Passler

Commissioner for Patents
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Alexandria, VA 22313-1450

Sir:

Patent owner has received a Requirement for Information dated November 18, 2004 in response to the application for patent term extension filed November 12, 2004. The Requirement for Information set a two month period for response, making a response due by January 18, 2005. This response is timely filed.

The Requirement for Information stated:

> For the claims to claim the Phakic Intraocular Lens approved by the Food and Drug Administration, the iris tissue support fixation must have a gap positioned between two pincer arms. From the drawings of Models 204 and 206, the Office is unable to determine whether the approved device includes such a gap. Items 39 and 39[a] appear to reference the thickness of the support, or a midline. Furthermore, further details of the lateral side gates 36 are required. The gates are not clearly illustrated in the figures provided.

Gap 39, 39a

With respect to the gap 39, 39a, Applicant notes that feature b) of claim 1 requires that the pincer arms comprise "flexible, normally abutting pincer arm means for pinching a portion of the anterior surface only of iris tissue without penetrating to the posterior surface" (emphasis added), whereas feature d) recites "a gap positioned between the two pincer arms that form each

of the pairs, said gaps communicating with the periphery of the optical portion". The approved product has free ends of the pincer arms that normally abut, in accordance with feature b) and which are spread apart during and after implantation when a pleat of iris material is clamped between opposite free ends of the pincer arms, in accordance with feature d). In the figures showing Models 204 and 206, the gap 39, 39a is difficult to see in the front views. In the cross-sectional views to the side of the figures, it can be seen, however, that the ends of arms 32, 32a are not hatched, and are thus not cross-sectioned. Thus, it is clear that the arms 32, 32a end at gaps 39, 39a, which is a break or discontinuity in the material.

In the patent figures, the embodiments in figures 1-8 are shown in the implanted condition, with the gaps 39, 39a open. The pairs of pincers grasp iris tissue 12 to form bulge 38, thus positioning the optical portion of the present invention directly in front of the natural lens 16. The arms 32, 33 are spaced apart with gap 39 therebetween. Gap 39a is between arms 32a and 33a. See column 3, lines 36-41.

In figures 9 and 10, the gaps (referred to as slits) are shown in the closed condition. Additionally, it is clear from claim 7 of the patent that claim 1 is intended to include the situation where "each of the pincer arms provides inner and outer end portions, each outer end portion abuts a corresponding outer end portion of an adjacent pincer arm, the outer end portions defining a grasping portion for grasping iris tissue".

For the foregoing reasons, it is believed that the figures submitted with the application for patent term extension, and particularly the cross-sectional views, show the gap 39, 39a in accordance with the patent claims.

Lateral Side Gates 36

The side gates 36 are designed to permit the aqueous to flow undisturbed from the pupillary area 20. Two of the side gates communicate with gaps 39 and 39a. See column 3, lines 48-51. The side gates 36 are areas or openings where the side of the lens is raised to allow for flow of the aqueous humor. Figures 1 and 3 show the side gate 36 that is visible above the pincer arms 32, 33. Figures 4 and 5 each show a side gate 36, although the figures are not labeled as such. The side gate 36 is the open area underneath the side of the lens. In the figures of the approved product, in the "Artisan Myopia 5/8,5" figure, three side gates 36 are shown in the cross-sectional view. In the "Artisan Myopia 6/8,5" figure, the cross-sectional view again shows three side gates 36, but only the end gates are numbered. An unnumbered reference line points to the other side gate, which is shown smaller than it should be. A replacement figure is attached, showing the side gate edges in bold lines, and with the reference number included.

A photograph of an approved lens is attached, in which the gates can be more easily seen (in addition to the abutting ends of arms 32, 33). The side gate edges are marked in red.

Patent Owner respectfully submits that this paper contains sufficient additional details of the approved device to assist the Office in determining whether the patent claims the approved product. If any additional information is required, patent owner requests that the Office

Patent No. 5,192,319
Application for Patent Term Extension
Response to Requirement for Information

Docket No. 6975-4

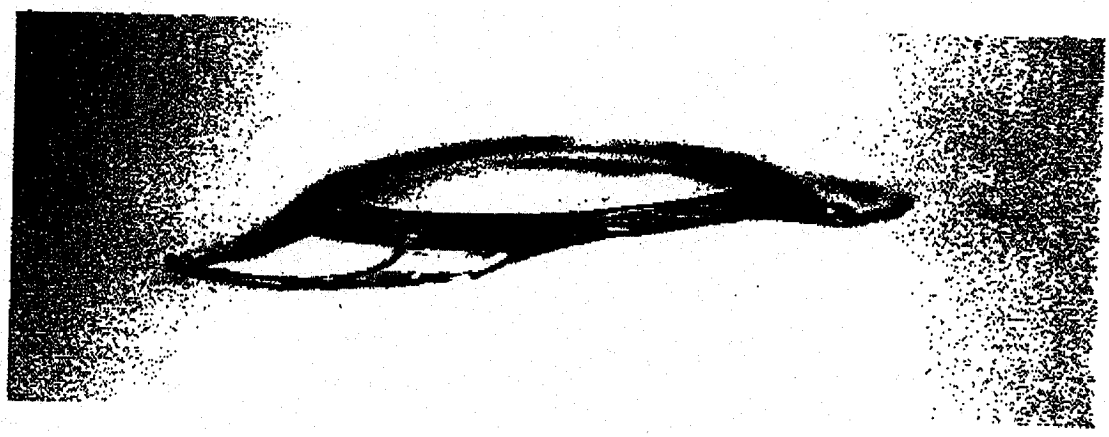
telephone or contact the undersigned. No fees are believed necessary for this response, but any deficiency in fees should be charged to Deposit Account No. 50-0951.

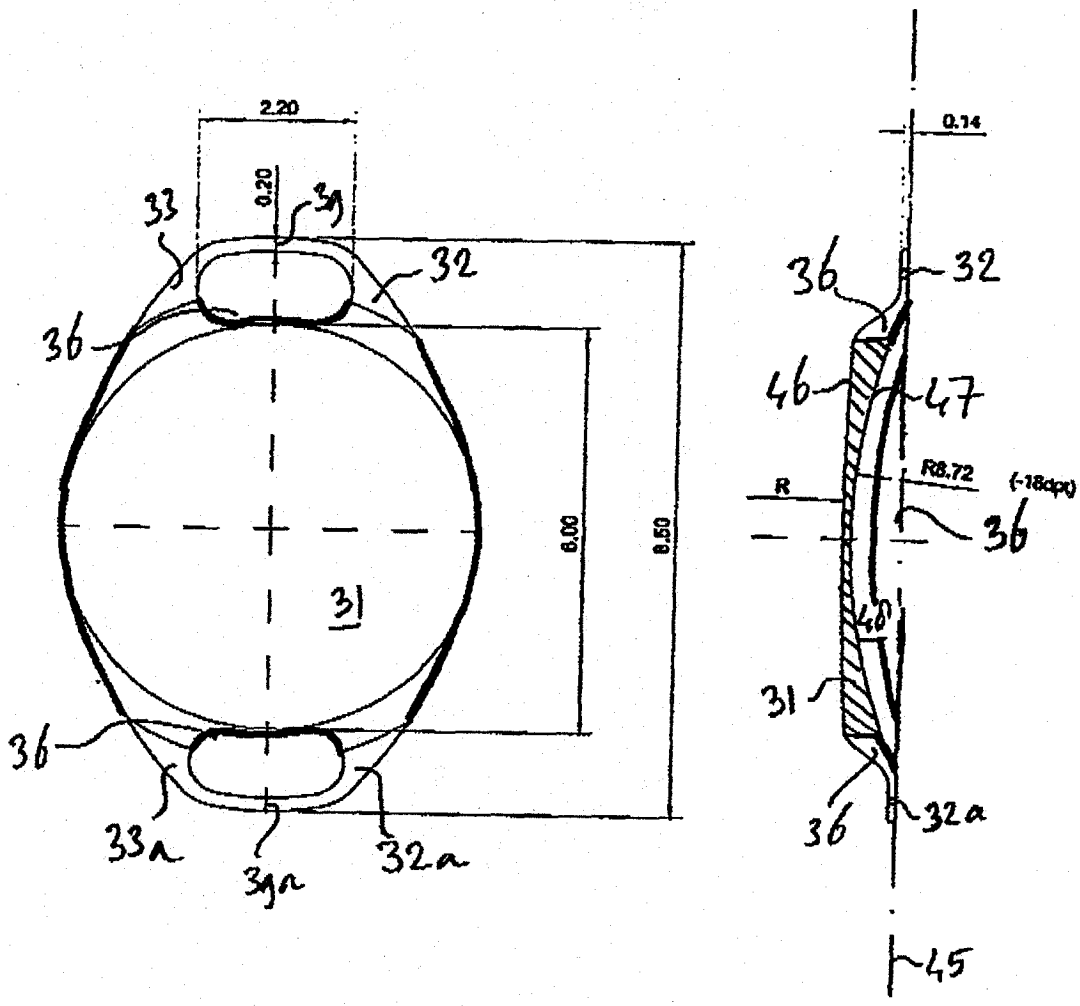
Respectfully submitted on behalf of the patent owner,

Date: 1-18-05

Mark D. Passler
Registration No. 40,764
AKERMAN SENTERFITT
Post Office Box 3188
West Palm Beach, FL 33402-3188
Telephone: (561) 653-5000

Docket No. 6975-4





1	1	LENS	PERSPEX CQ UV		R AFH. VAN DIOPTRIE
STUK NR.	AANTAL	BENAMING	MATERIAAL	TEKENING NR.	OPMERKING

PROJECTIE	TEK.NR.: S204001W.A02	GETEKEND :	DATUM / PARAAF
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	SCHAAL : 10:1	REVISIE :	
	TOLERANTIES :	AKKOORD ONTW :	

ARTIKELCODE: 204001W	OMSCHRIJVING: ARTISAN™ Myopia 6/8,5	AKKOORD ARTS :
OPHTEC International - Ophthalmological - Laboratories	BLAD : 1 / AANTAL BLADEN : 1	A4

0170 JUL 12 P1:32

Memorandum

Date: JUL 11 2006

From: Beverly Friedman, Project Management
Office of Regulatory Policy (HFD-7)

Subject: Patent Term Restoration Application for Phakic Intraocular Lenses

To: Dockets Management (HFA-305)

Attached please find a copy of the Application for Extension of Patent Term Under 35 U.S.C. § 156 for the above-referenced medical device, together with the cover letter from the Patent and Trademark Office. The applicant is Ophtec USA, Inc., subsidiary of Ophtec B.V., and the product's trade name is Phakic Intraocular Lenses. Please assign a docket number to this application for patent extension and advise me of same.

If you have any questions, please contact me at 301-594-2041. Thank you for your assistance.

Attachment

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form. Beverly