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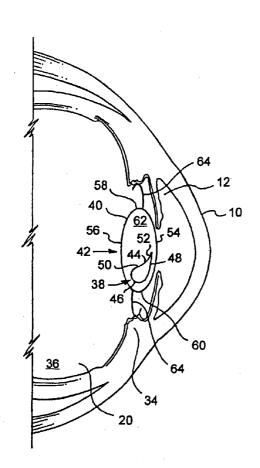
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INTRAOCULAR MULTIFOCAL LENS



(57) Abstract: In accordance with the present invention, a multifocal intraocular lens provides greater or lesser refraction in relation to the position of the head and eyes of a user. A multifocal intraocular lens body (38) for insertion into a fluid-filled enucleated natural lens capsule (26) of an eye is provided wherein the lens body (38) encompasses the optical axis of the eye and provides different greater or lesser refraction depending upon the position of the eye. In a second embodiment, the lens body can be used with an artificial lens capsule (40) implanted within an eye.

TITLE:

INTRAOCULAR MULTIFOCAL LENS

INVENTOR:

Marguerite B. McDonald, M.D.

TECHNICAL FIELD OF THE INVENTION

[0001] This invention relates to a intraocular lenses (IOLs), specifically, to IOLs that may

have a plurality of refractive indices.

BACKGROUND OF THE INVENTION

[0002] The human eye includes an anterior chamber between the cornea and iris, a

posterior chamber, defined by a capsular bag, containing a crystalline lens enclosed by a clear

capsule, a vitreous chamber behind the lens containing the vitreous humor, and a retina at the rear

of this chamber. The human eye has a natural accommodation ability. The constriction or

contraction and relaxation of the ciliary muscle provides the eye with near and distant vision,

respectively. This ciliary muscle action shapes the natural crystalline lens to the appropriate

optical configuration for focusing light rays entering the eye on the retina. The removal of the

natural lens leaves the eye with no means to focus at different distances and necessitates the use of

bifocal lenses for near and far work.

[0003] Many different IOL designs have been developed over the years and proven

successful in phakic and aphakic eyes. IOL implants have been used for years in aphakic eyes as

replacements for diseased natural crystalline lenses that have been surgically removed from the

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eyes. IOLs for aphakic eyes are now implanted after cataract surgery in over 98 % of the cases. Visual acuity deficiencies remaining after cataract surgery such as myopia (nearsightedness), hyperopia (farsightedness), and presbyopia (age-related farsightedness) are typically corrected with eyeglasses or contact lenses, though the accuracy of IOL power calculation has decreased the need for full-time postoperative spectacle use. The use of surgically implanted phakic IOLs as a permanent form of refractive correction has been gaining in popularity as well, though they are still considered investigational.

[0004] IOLs are generally of a fixed focal length. Fused bifocal and aspheric lenses have two or more optical focal planes that are engaged by changing the relationship of the light path or the observer to the lens. All such lenses require movement of either the lens (not possible with a standard IOL), light path, or observer to engage a different focal plane and can therefore be difficult to use. They also have an adverse effect on contrast sensitivity and can cause glare, halos, double vision (polyopia), and other optical aberration all of which compromises visual quality.

[0005] Accordingly, there is a need for a multifocal intraocular lens having a variable power of refraction that does not require deliberate engagement of different focal planes for near and far vision.

SUMMARY OF THE INVENTION

[0006] In accordance with the present invention, a multifocal intraocular lens provides greater or lesser refraction in relation to the position of the head and eyes of a user. A multifocal intraocular lens body for insertion into a fluid- or gel-filled enucleated natural lens capsule of an eye is provided wherein the lens body encompasses the optical axis of the eye and provides different greater or lesser refraction depending upon the position of the eye. In a second embodiment, the lens body can be used with an artificial lens capsule implanted within an eye.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0007] For a more complete understanding of the present invention and for further advantages thereof, reference is now made to the following Description of the Preferred Embodiments taken in conjunction with the accompanying Drawings in which:
 - FIG. 1 is a sectional view of a human eye illustrating the basic components of the eye;
- FIG. 2 is a sectional view of a human eye illustrating the present intraocular lens body inserted within the artificial capsule situated within an eye;
- FIG. 3 is a side-elevated view of the present intraocular lens body and artificial capsule shown in FIG. 2.
 - FIG. 4 is a plan view of the present intraocular lens body shown in FIG. 2; and
- FIG. 5 is a sectional view of a human eye illustrating the present intraocular lens body inserted within the natural lens capsule of an eye.
 - FIG. 6 is a sectional view of the present intraocular lens body through the line 6-6 of FIG.
- FIG. 7 is a sectional view of the present intraocular lens body through the line 7-7 of FIG. 3.

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DETAILED DESCRIPTION OF THE INVENTION

[0008] Turning now to these drawings and first to FIG. 1 for reference in the following description, the human eye comprises from front to rear an outer transparent cornea 10, an anterior chamber 12, an iris 14 containing a pupil 16, a posterior chamber 18, and a vitreous cavity 20. A natural lens 22 comprises a crystalline lens structure 24 contained within an optically clear bag called a lens capsule 26 having a posterior capsule 28 and an anterior capsule 30. The lens is peripherally joined by zonules 32 to the surrounding ciliary muscles 34. The vitreous cavity 20 contains vitreous 36.

The present invention is particularly useful in correcting the eye disorder known as a cataract which is characterized by progressive opacification of the natural lens 22 and resultant progressive attenuation of the light rays reaching the retina. Simply stated, this condition is corrected by removing the cataract, that is the cataractous (i.e. opaque) nucleus and cortex of the natural lens, and implanting an artificial intraocular lens in the eye. Cataract removal may be accomplished by intracapsular extraction (removal of the entire lens 22) or by extracapsular extraction (removal of the cataractous nucleus and cortex through the anterior side of the lens capsule 26) utilizing either nucleus expression through a relatively large opening in the eye or phacoemulsification through a relatively small opening in the eye.

[0010] The anterior capsule opening required for extracapsular extraction may be provided by (a) removing most of the anterior capsule 30 except small peripheral remnants of the anterior capsule, (b) tearing the anterior capsule to allow the human lens nucleus to be expressed, or (c) continuous tear circular capsulotomy, i.e. capsulorhexis. The essentially empty lens capsule

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26 remaining after removal of the cataract is referred to as a capsular bag. Removal of the nucleus and cortex of the natural lens from the bag creates a space immediately behind the iris 14, between the latter and the posterior capsule 28 of the bag, which is approximately 10 mm in diameter and 5 mm front to back.

[0011] It is possible to implant an intraocular lens in any one or more of the eye chambers, i.e. anterior chamber 12, posterior chamber 18, capsular bag 26, or vitreous cavity 20. Intraocular implants according to the present invention may be placed in any one of these eye chambers or cavities. However, the invention is particularly concerned with an intraocular lens body for placement in a natural capsular bag having an anterior capsulotomy or in the anterior or posterior chambers, or in an artificial capsular bag and will be described primarily in these contexts.

Referring now to FIGS. 2-4, in accordance with the present invention, there is illustrated multifocal intraocular lens body, generally identified by the numeral 38, positioned within an artificial capsular bag 40 to form a multifocal intraocular lens system, generally identified by the numeral 42, situated within a human eye from which the natural lens 22 has been removed (i.e. an aphakic eye). Multifocal intraocular lens body 38 has an upper portion 44, a lower portion 46, anterior surface 48, and a posterior surface 50. The following description of the lens body is as viewed from the medial-lateral axis. Anterior surface 48 and posterior surface 50 of lower portion 46 taper upwardly to form upper portion 44 to provide a tapering periphery 52. Anterior surface 48 and posterior surface 50 of upper portion 44 of lens body 38 each have at least one radius of curvature having its respective center positioned posteriorly the posterior surface 50 of lens body 38. An aspheric multifocal intraocular lens body is contemplated in one embodiment

of the present lens body. At least one radius of curvature of posterior surface 50 of upper portion 44 of the lens body is preferably shorter than the radius of curvature of that along anterior surface 48 so as to form a comma-shaped lens body or any multifocal shape, preferably aspheric. Multiple radii of curvature are also contemplated as well as possibly a lens made of a material that increases in its index of refraction along the lens axes. As seen FIGS. 4, 6 and 7, the lens body is approximately elliptical when viewed anteriorly or posteriorly. The multifocal intraocular lens body may comprise any material suitable as a lens body and having a high index of refraction. Such material is preferably translucent and colorless, such as silicone, gel, or acrylic, and specifically may include polymethylmethacrylate (PMMA). However, such material may have a color for aesthetic or physiological purposes, e.g. to filter unwanted wavelengths such as those in the ultraviolet spectrum.

Multifocal intraocular lens body 38 is positioned within lens capsule 40. Lens capsule 40 has anterior surface 54, posterior surface 56, upper edge 58, and lower edge 60. Lens capsule 40 is approximately circular in shape and adapted to fit in the anterior or posterior chambers of an eye. Anterior surface 54 and posterior surface 56 completely encompass the optical axis formed by pupil 16. The distance between anterior surface 48 and posterior surface 56 of lens capsule 40 defines a thickness that corresponds to a first axis that extends generally perpendicularly between the surfaces. A second axis that is generally perpendicular to said first axis is also formed. The thickness of the lens capsule along the first axis is smaller than its width along its second axis. Lens capsule 40 can be made from a translucent and colorless pliable or substantially pliable material such as silicone or similar material, or other materials as would be known to one of skill in the art.

[0014] The multifocal intraocular lens body 38 is positioned within the lens capsule 40 so that lower portion 46 of lens body 38 lies adjacent to lower edge 60 of the lens capsule and anterior surface 48 of the lens body lies adjacent to anterior surface 54 of lens capsule 40. Tapering periphery 52 is the feature of lens body 38 that lies nearest to the approximate center of the lens capsule when the short axis of the lens capsule is parallel to the ground or as when the user is looking straight ahead. The approximate center of the lens capsule encompasses the optical axis of the eye. Multifocal intraocular lens body 38 provides only minimal additional refraction or no refraction consummate with the minimal or no additional refraction or required when looking at infinity, i.e. at the horizon. When anterior surface 54 of lens capsule 40 is tilted downwardly, lens body 38 moves towards upper edge 58 of the lens capsule and begins to "float" or slide more and more over the visual axis (i.e. the line of sight). After implantation, and when the user requires more focusing power, i.e. refraction, such as when reading, lens body 38 similarly slides upwards into the optical axis as the user tilts their head downwardly causing anterior surface 54 of lens capsule 40 to also move downwardly. By doing so, the lower portion of the lens body which has a higher add component, moves into the optical axis and provides greater correction at near. Movement of the multifocal intraocular lens body 38 within artificial capsule bag 40 is slowed by the presence of translucent fluid 62 contained within bag 40. Translucent fluid 62 may be a liquid, gel, or sol, is preferably visco-elastic, and can be silicone or a related material or a combination of materials. However, any translucent substance capable of slowing movement of the multifocal intraocular lens body 38 within the artificial capsule bag 40 consistent with the practice of this invention is suitable.

In another embodiment of the present invention, attached to the outside edge of artificial capsule bag 40 is securer 64. Securer 64 secures artificial capsule bag 40 containing multifocal intraocular lens body 38 within the eye. Securer 64 are preferably positioned so as to extend from upper edge 58 and lower edge 60 of artificial capsule bag 40 and hold the artificial capsule bag 40 in place within either the posterior chamber, the capsular bag or remnants thereof, or anterior chamber, or a combination thereof. Haptics 64, as shown in FIGS. 2-4, are commonly used in the art. Any haptic shape, configuration, or number may be utilized in accordance with the teachings of the present invention. While haptics are satisfactory for the present invention, any other suitable securer is acceptable if a securer is desired.

Referring now to FIG. 5, there is illustrated multifocal intraocular lens body 38 according to another embodiment of the present invention. Multifocal intraocular lens body 38 is placed within capsular bag 26 of the human phakic eye from which the nucleus of the natural lens has been removed, i.e. the lens is enucleated. The capsular bag 26 has an anterior capsulotomy (not shown) through which the lens body 38 is inserted into the bag 26. In this embodiment the natural lens capsule 26 contains the lens body 38 rather than the artificial capsule bag 40 as described above. The anterior capsulotomy, probably small in size, may be plugged with a natural or synthetic material after the lens body is inserted and the capsular bag filled with a translucent substance. Similarly to the embodiment of the present invention that utilizes an artificial capsule bag 40, a translucent substance such as a liquid, gel, oil or sol, or any similar substance, is placed within capsular bag 26 to slow movement of the lens body 38. The structure and composition of the lens body 38 is also as described above with respect to FIGS. 2-4.

[0017] Whereas it is intended that the description of the present invention is but one embodiment for implementing the invention. Variations in the description likely to be conceived by those skilled in the art still fall within the breadth and scope of the disclosure of the present invention. It is also understood that additional applications of the present invention will be apparent to those skilled in the art upon a reading of the description and a consideration of the appended claims and drawings.

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CLAIMS

Claim 1. A multifocal intraocular lens for insertion into an enucleated natural lens capsule of an eye, said lens comprising:

a lens body having a substantially elliptical anterior surface, a substantially elliptical posterior surface, an upper portion, and a lower portion,

said lower portion having a semicircular shape in cross-section and tapering upwardly toward said upper portion to create a tapering periphery,

said anterior surface and said posterior surface of said upper portion each having at least one radius of curvature,

wherein said lens body encompasses the optical axis of the eye depending upon the position of the eye.

- Claim 2. The multifocal intraocular lens of Claim 1, wherein said at least one radius of curvature of said posterior surface of said upper portion is shorter than said anterior surface of said upper portion.
- Claim 3. The multifocal intraocular lens of Claim 1, wherein said anterior and posterior surfaces of said upper portion of said lens body each have multiple radii of curvature.
- Claim 4. The multifocal intraocular lens of Claim 3, wherein said at least one multiple radii of curvature of said posterior surface of said lens body is shorter than said multiple radii of curvature of said anterior surface.

Claim 5. The multifocal intraocular lens of Claim 1, wherein the cross-sectional profile of said lens body is comma-shaped.

- Claim 6. The multifocal intraocular lens of Claim 1, wherein said lens body has at least one index of refraction.
- Claim 7. The multifocal intraocular lens of Claim 6, wherein said lens body has multiple indices of refraction.
- Claim 8. The multifocal intraocular lens of Claim 7, wherein said lower portion of said lens body has a greater index of refraction than said upper portion.
- Claim 9. The multifocal intraocular lens of Claim 1, wherein said lens body is substantially aspheric.
- Claim 10. The multifocal intraocular lens of Claim 1, wherein said lens body comprises a material that is not colorless.
- Claim 11. The multifocal intraocular lens of Claims 1 or 10, wherein said lens body comprises a material selected from the group consisting of silicone, acrylic, and polymethylmethacrylate.

Claim 12. A multifocal intraocular lens system for insertion of a multifocal intraocular lens into an artificial lens capsule for placement within an eye having a posterior chamber and an anterior chamber, said lens system comprising:

a lens body having a substantially elliptical anterior surface;

said lens body having a substantially elliptical posterior surface;

said lens body having an upper portion and a lower portion;

said lower portion having a semicircular shape and tapering upwardly toward said upper portion to create a tapering periphery;

said anterior surface and said posterior surface of said upper portion, each surface having at least one radius of curvature;

an artificial lens capsule having an anterior surface and a posterior surface and adapted to be positioned within the eye, said lens body being disposed within said artificial lens capsule;

a substance dispersed within said artificial lens capsule for allowing said lens body to move within said artificial lens capsule; and

wherein said lens body encompasses the optical axis of the eye depending upon the position of the eye.

- Claim 13. The multifocal intraocular lens system of Claim 12, wherein said artificial lens capsule is so dimensioned as to replace the natural lens capsule of the eye.
- Claim 14. The multifocal intraocular lens system of Claim 12, wherein said artificial lens capsule is adapted to be positioned in the posterior chamber of an eye.

Claim 15. The multifocal intraocular lens system of Claim 12, wherein said artificial lens capsule is adapted to be positioned in the anterior chamber of an eye.

- Claim 16. The multifocal intraocular lens system of Claim 12, wherein the distance between said anterior and posterior surface of said artificial lens capsule defines a thickness, said artificial lens capsule having a first axis extending generally perpendicular to said anterior and posterior surfaces and a second axis generally perpendicular to said first axis that defines a width.
- Claim 17. The multifocal intraocular lens system of Claim 16, wherein the thickness of said artificial lens capsule along the first axis is smaller than its width along its second axis.
- Claim 18. The multifocal intraocular lens system of Claim 16, wherein said artificial lens capsule is adapted to be positioned in the eye so that the first axis is approximately parallel with the optical axis of the eye.
- Claim 19. The multifocal intraocular lens system of Claim 12, wherein said artificial lens capsule is not colorless.
- Claim 20. The multifocal intraocular lens system of Claim 12, wherein said artificial lens capsule comprises a material selected from the group consisting of silicone, acrylic, and polymethylmethacrylate.

Claim 21. The multifocal intraocular lens system of Claim 12, wherein said artificial lens capsule is substantially pliable.

- Claim 22. The multifocal intraocular lens system of Claim 12, wherein said artificial lens capsule has at least one index of refraction.
- Claim 23. The multifocal intraocular lens system of Claim 12, wherein said at least one radius of curvature of the posterior surface of said upper portion of said lens body is shorter than said upper portion of said anterior surface of said lens body.
- Claim 24. The multifocal intraocular lens system of Claim 12, wherein said anterior and posterior surfaces of said upper portion of said lens body each have multiple radii of curvature.
- Claim 25. The multifocal intraocular lens system of Claim 24, wherein said at least one radii of curvature of said posterior surface of said lens body in the aggregate are shorter than said multiple radii of curvature of said anterior surface.
- Claim 26. The multifocal intraocular lens system of Claim 12, wherein the cross-sectional shape of said lens body is comma-shaped.
- Claim 27. The multifocal intraocular lens system of Claim 12, wherein said lower portion of said lens body has a greater index of refraction than said upper portion.

Claim 28. The multifocal intraocular lens system of Claim 12, wherein said lens body is substantially aspheric.

- Claim 29. The multifocal intraocular lens system of Claim 12, wherein said lens body comprises a material that is not colorless.
- Claim 30. The multifocal intraocular lens system of Claims 12 or 29, wherein said lens body comprises a material selected from the group consisting of silicone, acrylic, and polymethylmethacrylate.
- Claim 31. The multifocal intraocular lens system of Claim 12, wherein said substance is not colorless.
- Claim 32. The multifocal intraocular lens system of Claims 12 or 31, wherein said substance is a member of the group consisting of silicone, gel, sol, liquid, oil, and acrylic.
- Claim 33. The multifocal intraocular lens system of Claims 12, wherein said substance slows movement of said lens body within said artificial lens capsule compared to movement of said lens body in the absence of said substance.
- Claim 34. The multifocal intraocular lens system of Claim 12, wherein said lens system further comprises a securer.

Claim 35. The multifocal intraocular lens system of Claim 34, wherein said securer comprises at least two structures that extend from opposite sides of said lens capsule.

- Claim 36. The multifocal intraocular lens system of Claim 34, wherein said structures are spring-like.
- Claim 37. The multifocal intraocular lens system of Claim 35 or 36, wherein said structures comprise haptics or half-ticks.
- Claim 38. The multifocal intraocular lens system of Claim 34, wherein said securer holds said artificial lens capsule in place within the eye.
- Claim 39. The multifocal intraocular lens of Claim 1, further wherein said lens body is immersed in a substance dispersed within said enucleated natural lens capsule for allowing said lens body to move within said enucleated natural lens capsule.
- Claim 40. The multifocal intraocular lens of Claim 39, further wherein said substance is a member of the group consisting of silicone, gel, sol, liquid, oil, and acrylic.
- Claim 41. The multifocal intraocular lens of Claim 39, further wherein said substance slows movement of said lens body within said enucleated natural lens capsule compared to movement of said lens body in the absence of said substance.

Claim 42. The multifocal intraocular lens of Claim 39, further wherein said substance is not colorless.

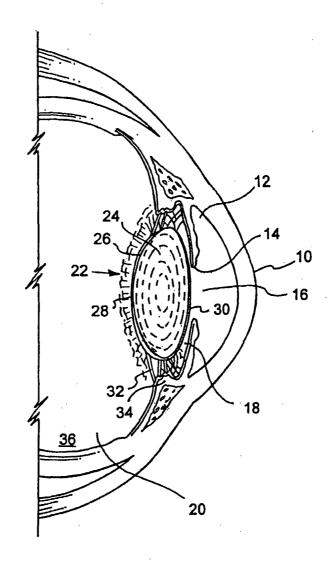


FIG. 1 OF 7
PRIOR ART

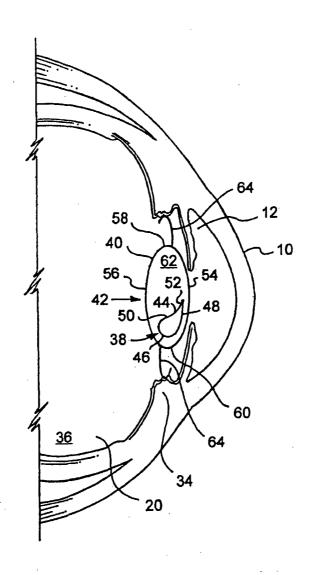


FIG. 2 OF 7

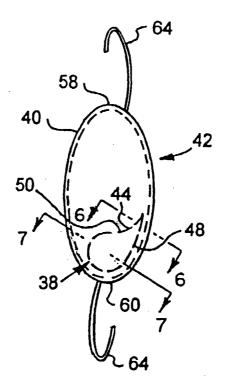


FIG. 3 OF 7

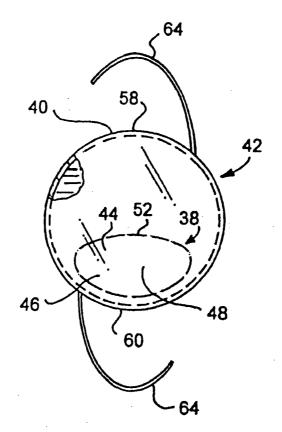


FIG. 4 OF 7

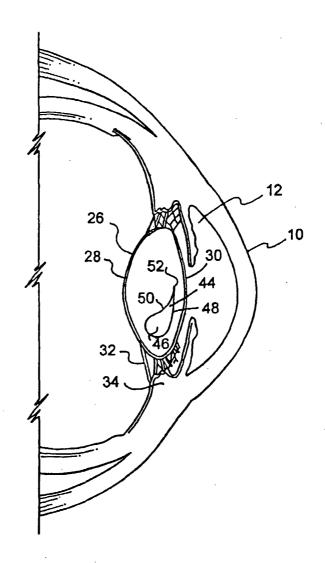


FIG. 5 OF 7

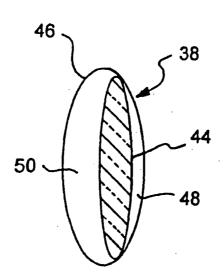


FIG. 6 OF 7

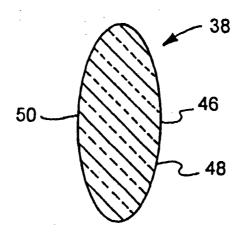


FIG. 7 OF 7

INTERNATIONAL SEARCH REPORT

tional Application No /US2005/016537

A. CLASSIFICATION OF SUBJECT MATTER A61F2/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

 $\begin{tabular}{ll} \begin{tabular}{ll} Minimum documentation searched (classification system followed by classification symbols) \\ A61F \end{tabular}$

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 522 891 A (KLAAS ET AL) 4 June 1996 (1996-06-04)	1,6, 11-18, 30, 32-34, 39,40
A	column 2, line 52 - column 5, line 5; figures	5,26
A	US 2003/083744 A1 (KHOURY ELIE) 1 May 2003 (2003-05-01) paragraph '0068! - paragraph '0069! paragraph '0093! - paragraph '0095!; figures	1,12
A ·	US 2002/101564 A1 (HERRICK ROBERT S) 1 August 2002 (2002-08-01) paragraph '0154! - paragraph '0157!; figures 20,21	1,12

X Further documents are listed in the continuation of box C.	Patent family members are listed in annex.			
Special categories of cited documents: A' document defining the general state of the art which is not considered to be of particular relevance E' earlier document but published on or after the international filing date 'L' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	 "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is taken alone 			
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Date of the actual completion of the international search	Date of mailing of the international search report			
9 November 2005	02/12/2005			
Name and mailing address of the ISA	Authorized officer			
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Ruff, C			

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tional Application No /US2005/016537

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT						
category ° Citation of	document, with indication, where appropriate, of the relevant passages	Relevant to claim No.				
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