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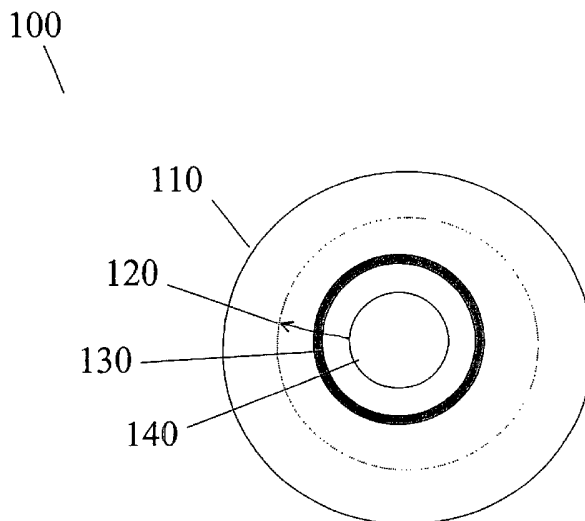
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[Continued on next page]

(54) Title: MYOPIA CORRECTION ENHANCING BIODYNAMIC ABLATION



(57) Abstract: This invention is directed to a method for providing a LASIK or a LASEK myopia vision correction, and to a medium that has stored therein an instruction for directing a laser vision correcting laser platform to deliver a controlled biodynamic ablation according to the invention. A known biodynamic response of the eye is induced by performing a controlled laser ablation in a cornea of the eye outside of an optical zone for the nominal ablation in a laser vision correction surgery. An ablation ring, or portion thereof, outside of the optical zone produces a biodynamic flattening of the central region of the cornea which in turn provides for a decreased depth of volumetric ablation to correct a myopic refractive defect of the eye. Such controlled biodynamic flattening may provide the opportunity for laser vision correction in patients whose corneas would otherwise be too thin post-operatively to warrant laser vision correction.

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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.*

MYOPIA CORRECTION ENHANCING BIODYNAMIC ABLATION

## BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention is generally directed to the field of laser vision correction and, more particularly, to a method and device for inducing and utilizing a corneal biodynamic effect for improving laser vision correction.

2. Description of Related Art

The field of laser vision correction currently offers several types of procedures for correcting or improving refractive defects by laser photoablation of the corneal surface. These procedures include PRK, LASIK, and LASEK, which are typically used to correct myopic and hyperopic defects with or without astigmatism, and in some cases provide customized treatments to address the higher order aberrations of the eye.

The evolution of laser technology and its use in the vision correction field has contributed significantly to the state of the art of laser vision correction. Ten years ago, broad-beam lasers utilizing variable diaphragms and/or masks were used to treat myopia by flattening the central region of the cornea and, to a lesser extent, for the treatment of hyperopia. Shortly thereafter, scanning beam technology contributed to the development of small-beam, scanning-type laser systems, and flying-spot beam delivery systems producing laser beams from 0.5mm to 2.0mm on the corneal surface. These smaller beam sizes in combination with optimized scanning patterns, and now with much higher laser pulse repetition rates, define the landscape for photoablative contouring of the cornea.

A well known technique for delivering a conventional myopic LASIK treatment is the Planoscan<sup>®</sup> ablation algorithm delivered by the Technolas 217A<sup>®</sup> laser system (Bausch & Lomb Incorporated, Rochester, New York). In this system, selected scanning patterns of a 2mm diameter laser beam are used to ablate the corneal surface. The interested reader is referred to U.S. Patent Nos. 6,090,100 and 5,683,379 which are herein incorporated by reference in its entirety to the full extent allowed by applicable laws and rules. Recently, Bausch & Lomb Incorporated introduced the Zypotix<sup>®</sup> vision correction system incorporating the Zywave<sup>®</sup> Hartmann-Shack wavefront sensor and the 217Z<sup>®</sup> excimer laser system which delivers 1mm to 2mm diameter, truncated Gaussian beams onto the cornea for customized laser vision correction.

A long-standing concern held by laser manufacturers and surgeons alike, is the amount of corneal tissue ablated by any laser vision correction. In general terms, a surgeon intending to perform a myopia correction to a patient's eye will determine the amount of refractive correction necessary to correct the person's vision (typically measured in diopters), and also determine the optical zone (OZ) over which the ablation should occur. The OZ typically ranges from about 3mm to 7mm depending upon a variety of factors well appreciated by those skilled in the art. Once the desired refractive correction and the optical zone size are determined, the maximum central ablation depth required for the correction will be known. Corneal ablation will be contraindicated when the corneal thickness remaining after the removal of corneal tissue by the ablation procedure will be less than what is considered to be a minimum residual thickness under a reasonable standard of care. Typically, no less than 200 microns and, preferably, about 250 microns is the minimum tolerable residual corneal thickness. One solution is to

decrease the OZ size; however, one cause of post-LASIK spherical aberration resulting in glare and halo effects in low-light conditions is believed to be due to an ablated OZ that is smaller than the patient's pupil in low light conditions.

It is also recognized that the response of the eye to trauma due, for example, to a LASIK keratectomy or the ablation of corneal tissue, adds a degree of uncertainty to the effect induced by the traumatic cause. Thus, changes in the structural integrity of the eye produce what will be referred to herein as biodynamic responses that manifest themselves in the form of corneal flattening, corneal thickening, regression, wound healing responses, and in other physical ways that are not yet fully understood.

In view of the foregoing, the inventors have recognized a need for overcoming the limitations and concerns discussed above in providing improved vision through laser vision correction.

### SUMMARY OF THE INVENTION

An embodiment of the invention is directed to a method for a LASIK or a LASEK myopia (with or without astigmatism) laser vision correction, including the control and improvement thereof. The method generally relies on a corneal biodynamic effect to reduce the amount of tissue ablation, i.e., ablation depth, as a function of increased optical zone size. According to the invention, a corneal biodynamic effect is induced which results in a flattening of the central corneal region. By flattening the cornea in a controlled manner, a shallower myopia correcting ablation can be performed over an optical zone area than would occur over the same optical zone area if the cornea were not flattened from its original shape. In a preferred aspect, the trauma inflicted to the eye is a

biodynamic ablation in the form of at least one or more portions of, or a complete, ring or annulus. The biodynamic ring may be circular or non-circular (i.e., elliptical or other shape). In this aspect, the ring or annulus of ablated corneal tissue is outside of and surrounding the optical zone. The parameters of the biodynamic ring, particularly the distance from the optical zone edge, and the width and depth of the ring, all of which are variable as a function of biodynamic ablation location, will produce a controlled biodynamic effect that will be advantageous for reducing the ablation depth of corneal tissue in the optical zone to effect a myopia correction.

Another embodiment of the invention is directed to an improved device readable medium having stored therein an executable instruction or instruction code for directing an ophthalmic vision correcting laser platform to deliver a myopia correcting nominal ablation in an optical zone of a corneal surface, where the improvement comprises an executable instruction or instruction code stored in the medium for directing the ophthalmic vision correcting laser platform to deliver a myopia correction enhancing biodynamic ablation in the corneal surface outside of the optical zone.

The objects and advantages of the invention will be further appreciated in view of the detailed description and drawings that follow, and by the appended claims which define the invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification illustrate embodiments of the present invention and, together with the

description, serve to explain the objects, advantages and principals of the invention. In the drawings,

Fig. 1 is a schematic front view of an eye showing a biodynamic ablation region according to an embodiment of the invention;

Fig. 2 is an enlargement of a central portion of Fig. 1 showing a more detailed representation of the biodynamic ablation region;

Fig. 3 is a schematic cross-sectional view of the biodynamic ablation according to a preferred embodiment of the invention;

Fig. 4 is a schematic cross-sectional view of a corneal profile showing the effect on the profile due to the biodynamic ablation according to an embodiment of the invention;

Fig. 5 is an illustration of a laser beam profile associated with a preferred embodiment of the invention;

Fig. 6 is an enlarged photocopy of a laser beam profile shaping aperture associated with a preferred embodiment of the invention; and

Fig. 7 is a schematic illustration of a device embodiment of the invention.

#### DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

The invention is directed to a method for a LASIK or a LASEK myopia (with or without astigmatism) laser vision correction, and to a computer or device readable medium having stored therein an executable instruction or instruction code for directing an ophthalmic vision correcting laser platform to perform a myopia correction enhancing biodynamic ablation according to an embodiment of the invention.

Fig. 1 schematically shows a front view of an eye 100 including an optical zone (OZ) 140 of the eye, and the outer boundary 110 of the iris of the eye. When LASIK or LASEK corrective surgery is performed on an eye, the actual vision correcting ablation which is referred to herein as the nominal ablation, is typically performed over a region of the pupil (dilated or undilated) referred to as the optical zone 140. A transition zone 120 typically lies outside of and immediately adjacent to the optical zone and defines a boundary between the ablated and non-ablated areas of the cornea. According to an embodiment of the invention, a controlled biodynamic response will be induced in the eye by inflicting a controlled trauma represented as 130 in the exposed corneal surface outside of the optical zone 140 of the eye and preferably within the transition zone 120.

The most commonly occurring refractive defect in the general population is called myopia. Myopia, or nearsightedness, is due to a corneal shape that is too prolate or bullet shaped in profile, such that images are formed in front of the retina instead of at the retinal plane. Fig. 4 schematically shows a pre-operative corneal profile 410 for a typically myopic eye. It will be appreciated that the drawings referred to herein are not to scale but are intended to illustrate embodiments of the invention as defined herein and in the appended claims.

It is well appreciated by those skilled in the art that to correct for myopia, the pre-operative corneal profile 410 having a pre-operative radius  $R$  must be flattened over the optical zone 140. A desired post-operative surface 410' having a larger radius  $R'$  necessary to correct the myopic defect determines the ablation depth,  $d_{abl}$ , for the nominal volumetric ablation of corneal tissue, as shown in Fig. 4. It often occurs, however, that the necessary ablation depth  $d_{abl}$  results in a residual, post-operative corneal thickness that

is not thick enough (typically 200-250 microns) to maintain the structural integrity of the cornea, and/or meet a reasonable standard of care in the medical community. If the depth of ablation  $d_{abl}$  decreases and  $R'$  is maintained, the optical zone would shrink correspondingly. This becomes problematic since one cause of poor low-light vision, manifested by glare and halo effects, is believed to be due to a nominal ablation in an optical zone that is smaller than the (dilated) pupil size in the low-light environment. As such, laser corrective surgery may not be an option under these circumstances.

Advantageously, it has been found that by inflicting a controlled trauma to a selected region of the cornea, a controlled biodynamic response of the eye can be induced that is manifested by a flattening of the corneal profile at least over a central region of the cornea. The biodynamic flattening, represented by dotted line 420 in Fig. 4 is preferably induced by ablating a ring of tissue illustrated at 130 in Figs. 1, 2, and 4. As further shown in Fig. 4, the biodynamic flattening of the cornea illustrated at 420 increases the optical zone size to the dimensions schematically shown at 140' (OZ'). Now the calculated post-operative radius of curvature  $R'$  can be created by surface profile 410'' over the new optical zone 140' by ablating a corneal tissue volume depth  $d''_{abl}$  that is less than the original nominal ablation depth  $d_{abl}$ .

Although the biodynamic ablation according to a preferred aspect of the invention as set forth below is described in the form of a circular annulus or ring, it is to be understood that the ring may be elliptical or otherwise shaped, and may constitute only a portion, or discontinuous portions, of any such ring ablation. Biodynamic ring shape and location, including ring width and depth, may depend upon corneal thickness and/or refractive properties (e.g., astigmatism), or other factors. Thus, the illustrative description

set forth below is not intended to limit the scope of the invention in any manner, but only to simplify the understanding of the invention described and claimed herein.

As illustrated in Figs. 1 and 2, the biodynamic ring 130 has an inner boundary edge 132 and an outer boundary edge 134 defining a ring width,  $w$ . The inner boundary of the biodynamic ring 132 is adjacent an outer boundary of the nominal ablation optical zone 140 and separated therefrom by a minimum distance,  $d$ , as shown in Fig. 2. The distance  $d$  is preferably between about 200 microns to 600 microns. As illustrated in the schematic cross-section in Fig. 3, the biodynamic ring 130 has an ablation depth,  $t$ . In a preferred aspect, the width,  $w$ , of the biodynamic ring is nominally 1mm, and the depth of ablation,  $t$ , is between about 10 microns to 70 microns.

It is preferred that the ablation channel formed by the biodynamic ring have sidewalls 310 that are nominally perpendicular to the floor surface 312 of the channel. This is illustrated by the angle,  $\alpha$ , shown in Fig. 3. Such a controlled ablation ring profile can be produced by a laser beam at the target surface having an energy profile 500 shown schematically in Fig. 5. Fig. 5 shows what is referred to herein as a "soft-spot" profile, which is described in detail in co-owned published application WO 01/28478, the description of which is incorporated by reference herein in its entirety to the extent allowed by applicable laws and rules. As illustrated, the soft-spot profile 500 is defined as having a center portion 501 that is flat or substantially flat, and an edge 502 of the profile is continuous with the center portion and is rounded. The center portion 501 is preferably symmetric about the radius of the profile and extends across about 60 to 80 percent and, more preferably, across about 65 to 70 percent of the total profile 500. At a certain point, such as an intensity threshold point 504 at which the eye tissue ablation intensity threshold

is no longer reached, the profile 500 preferably quickly drops off or diminishes as a substantially square, vertical, or truncated edge 506. The ablation threshold or any variations in it are known in the art. The amount of energy falling below the threshold for ablation is preferably about 5 percent or less of the total energy encompassed by the profile 500. The profile 500 is non-Gaussian, between square and Gaussian shaped, referred to herein as a truncated Gaussian. Referring to Fig. 6, the soft-spot energy profile 500 can be produced by what is referred to herein as a soft-spot aperture 600. The aperture 600 comprises a larger, central, directly transmitting aperture portion 605 surrounded by a plurality of smaller subapertures 603 that diffractively transmit the laser beam. These apertures can be obtained from Fraunhofer Institut Siliziumtechnologie, Faunhoferstrabe 1, D-25524 Itzehoe, Germany, and from others, and are further described in detail in the published application referred to immediately above.

Other beam energy profiles will produce corresponding different ablation channel profiles. The determination of the specific parameters associated with the size, shape, and placement of the biodynamic ring, will benefit from continued modeling refinements, and further empirical analysis of statistically significant population groups will lead to more accurate relationships between biodynamic ablation parameters and desired biodynamic responses.

Another embodiment according to the invention, shown with reference to Fig. 7, is directed to an improved device readable medium 710 having stored therein an executable instruction for directing an ophthalmic laser platform 730 to deliver a myopia correcting nominal ablation in an optical zone of the corneal surface, where the improvement is directed an executable instruction 720 stored in the medium 710 for directing the laser

platform to deliver a myopia correction enhancing biodynamic ablation 130 in the corneal surface outside of the optical zone 140 as described hereinabove. The particular architecture of the executable instruction can take various forms. In a preferred exemplary aspect, an enablement type card used with the laser platform may have a data storage capability comprising software that is downloadable by the laser platform instructing it to deliver the biodynamic ablation. In an alternative aspect, the medium may contain a code that can match a pre-programmed instructional routine resident in, or external to, the laser platform, whereupon matching the instruction code with the resident instruction will enable the laser platform to execute the biodynamic ablation. These foregoing aspects are in no way intended to limit the invention as described but merely to set forth exemplary implementations of the invention. A further description of a device readable medium and associated instructional code relating to the control of laser vision correction is presented in co-pending application S.N. 10/184,441 entitled Laser Vision Correction Apparatus and Control Method, filed concurrently and commonly owned with the instant application.

Notwithstanding the preferred embodiments specifically illustrated and described herein, it will be appreciated that various modifications and variations of the instant invention are possible in light of the description set forth above and the appended claims, without departing from the spirit and scope of the invention.

What is claimed is:

1. A method for laser vision correction, comprising providing a controlled biodynamic response in corneal tissue of an eye by inflicting a controlled trauma to an exposed corneal surface outside an identified optical zone for a myopia correcting nominal laser ablation of the cornea.
2. The method of claim 1, wherein providing the controlled biodynamic response includes a flattening of the corneal surface over at least a central portion of the optical zone.
3. The method of claim 1, wherein inflicting the controlled trauma comprises laser ablating a portion of the exposed corneal surface.
4. The method of claim 3, wherein laser ablating a portion of the exposed corneal surface comprises ablating at least a portion of a ring of corneal tissue having a circular or an acircular shape.
5. The method of claim 4, wherein the at least a portion of the ablation ring has an inner boundary adjacent an outer boundary of the optical zone.
6. The method of claim 5, wherein the inner boundary of the at least a portion of the ablation ring begins at a distance,  $d$ , from the outer boundary of the optical zone, where  $200\mu\text{m} \leq d \leq 600\mu\text{m}$ .
7. The method of claim 4, comprising ablating the at least a portion of the ring to a depth,  $t$ , where  $10\mu\text{m} \leq t \leq 70\mu\text{m}$ , and having a width,  $w$ .
8. The method of claim 7, wherein  $t$  and  $w$  are variable as a function of biodynamic ablation location on the cornea.

9. The method of claim 7, wherein  $w$  is a function of the laser beam diameter on the cornea.
10. The method of claim 7, wherein  $w$  has a nominal value of about 1mm.
11. The method of claim 4, comprising ablating the at least a portion of the ring within a transition zone of the nominal ablation of the cornea.
12. The method of claim 1, wherein providing the controlled biodynamic response comprises creating a tissue ablation volume for a desired refractive correction that is less than a corresponding tissue ablation volume for the desired refractive correction in the absence of the controlled biodynamic response.
13. The method of claim 12, wherein the lessened tissue ablation volume has a smaller ablation depth over the optical zone than a corresponding ablation depth over the optical zone in the absence of the controlled biodynamic response.
14. The method of claim 1, wherein providing the controlled biodynamic response comprises empirically determining the controlled biodynamic response from a statistically significant population.
15. The method of claim 1, wherein providing the controlled biodynamic response comprises delivering a plurality of photoablative light pulses onto the corneal surface, all of which have only a 1mm diameter.
16. The method of claim 15, wherein the plurality of photoablative light pulses have a direct aperture transmission portion and a diffractive aperture transmission portion so as to produce a soft-spot beam intensity profile.
17. A method for a LASIK or a LASEK myopia correction, comprising:

ablating a volume of corneal tissue outside an optical zone of a nominal ablation region of the cornea.

18. The method of claim 17, wherein the volume of ablated corneal tissue is in the form of at least a portion of a ring of ablated corneal tissue having a circular or an acircular shape.

19. The method of claim 18, wherein the at least a portion of the ring has an inner boundary adjacent an outer boundary of the optical zone.

20. The method of claim 19, wherein the inner boundary of the at least a portion of the ablation ring begins at a distance,  $d$ , from the outer boundary of the optical zone, where  $200\mu\text{m} \leq d \leq 600\mu\text{m}$ .

21. The method of claim 20, comprising ablating the at least a portion of the ring to a depth,  $t$ , where  $10\mu\text{m} \leq t \leq 70\mu\text{m}$ , and a width,  $w$ .

22. The method of claim 21, wherein  $t$  and  $w$  are variable as a function of biodynamic ablation location on the cornea.

23. The method of claim 21, wherein  $w$  is a function of the laser beam diameter on the cornea.

24. The method of claim 21, wherein  $w$  has a nominal value of about 1mm.

25. The method of claim 24, comprising ablating the at least a portion of the ring within a transition zone of the nominal ablation of the cornea.

26. The method of claim 17, wherein ablating the volume of corneal tissue comprises creating a tissue nominal ablation volume in the optical zone for a desired refractive correction that is less than a corresponding tissue nominal

ablation volume in the optical zone for the desired refractive correction in the absence of the controlled biodynamic response.

27. The method of claim 26, wherein the lessened tissue nominal ablation volume has a smaller ablation depth over the optical zone than a corresponding ablation depth over the optical zone in the absence of ablating the volume of corneal tissue.

28. In an improved device readable medium having stored therein an executable instruction for directing an ophthalmic vision correcting laser platform to deliver a myopia correcting nominal ablation in an optical zone of a corneal surface,  
the improvement comprising an executable instruction stored in the medium for directing the ophthalmic vision correcting laser platform to deliver a myopia correction enhancing biodynamic ablation in the corneal surface outside of the optical zone.

29. The device readable medium of claim 28, wherein the biodynamic ablation has the form of at least a portion of a ring having an inner boundary adjacent an outer boundary of the optical zone, wherein the ring has a circular or an acircular shape.

30. The device readable medium of claim 29, wherein the inner boundary of the biodynamic ablation is separated from the outer boundary of the optical zone by a distance,  $d$ , where  $200\mu\text{m} \leq d \leq 600\mu\text{m}$ .

31. The device readable medium of claim 29, wherein the at least a portion of the ring has a depth,  $t$ , where  $10\mu\text{m} \leq t \leq 70\mu\text{m}$ , and a width,  $w$ .

32. The device readable medium of claim 31, wherein  $t$  and  $w$  are variable as a function of biodynamic ablation location on the cornea.
33. The device readable medium of claim 31, wherein  $w$  is a function of the laser beam diameter on the cornea
34. The method of claim 29, wherein  $w$  has a nominal value of about 1mm.
35. The device readable medium of claim 29, wherein the at least a portion of the ring is located within a transition zone of the nominal ablation of the cornea.
36. The device readable medium of claim 29, wherein the controlled delivered biodynamic ablation comprises a plurality of photoablative light pulses delivered to the corneal surface, all of which have only a 1mm diameter.

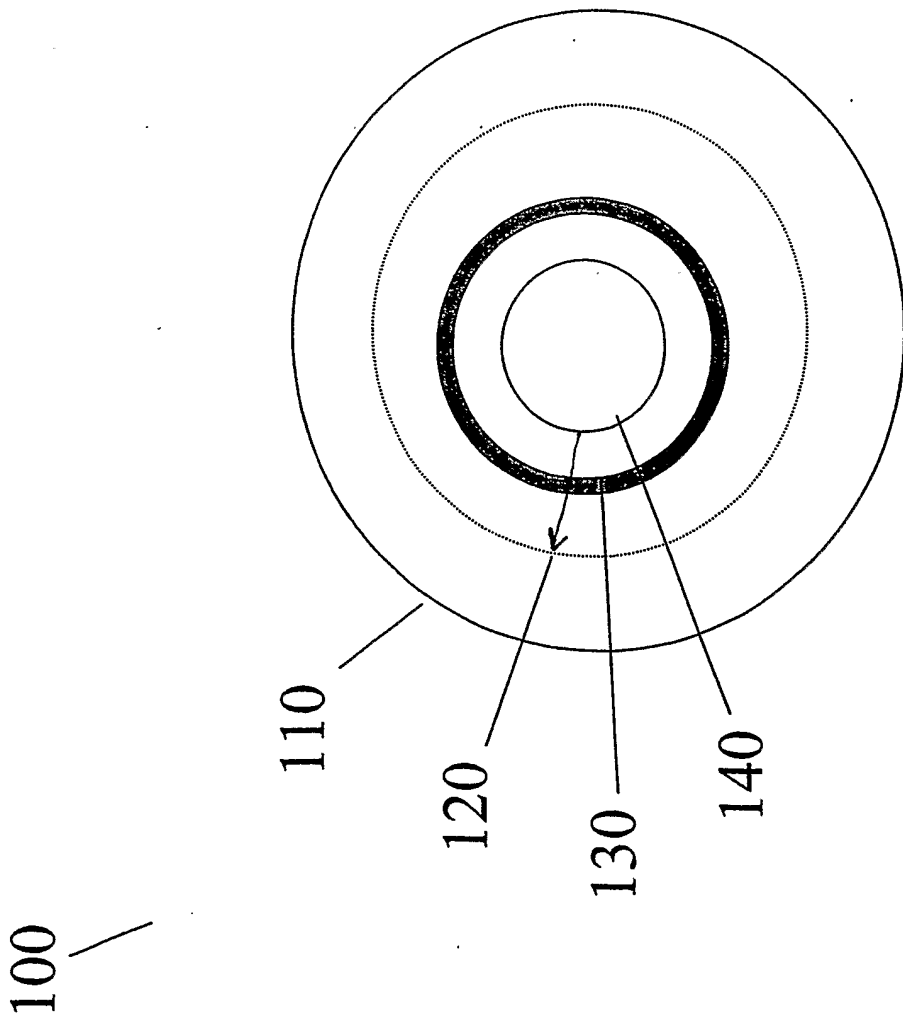


FIG. 1

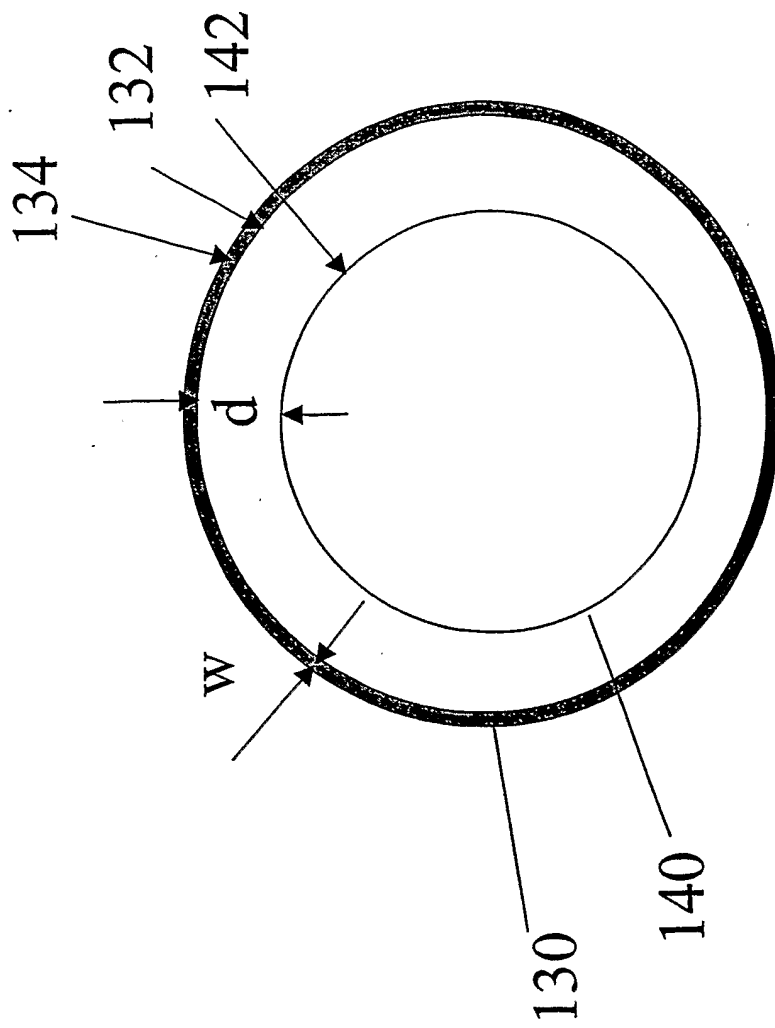


FIG. 2

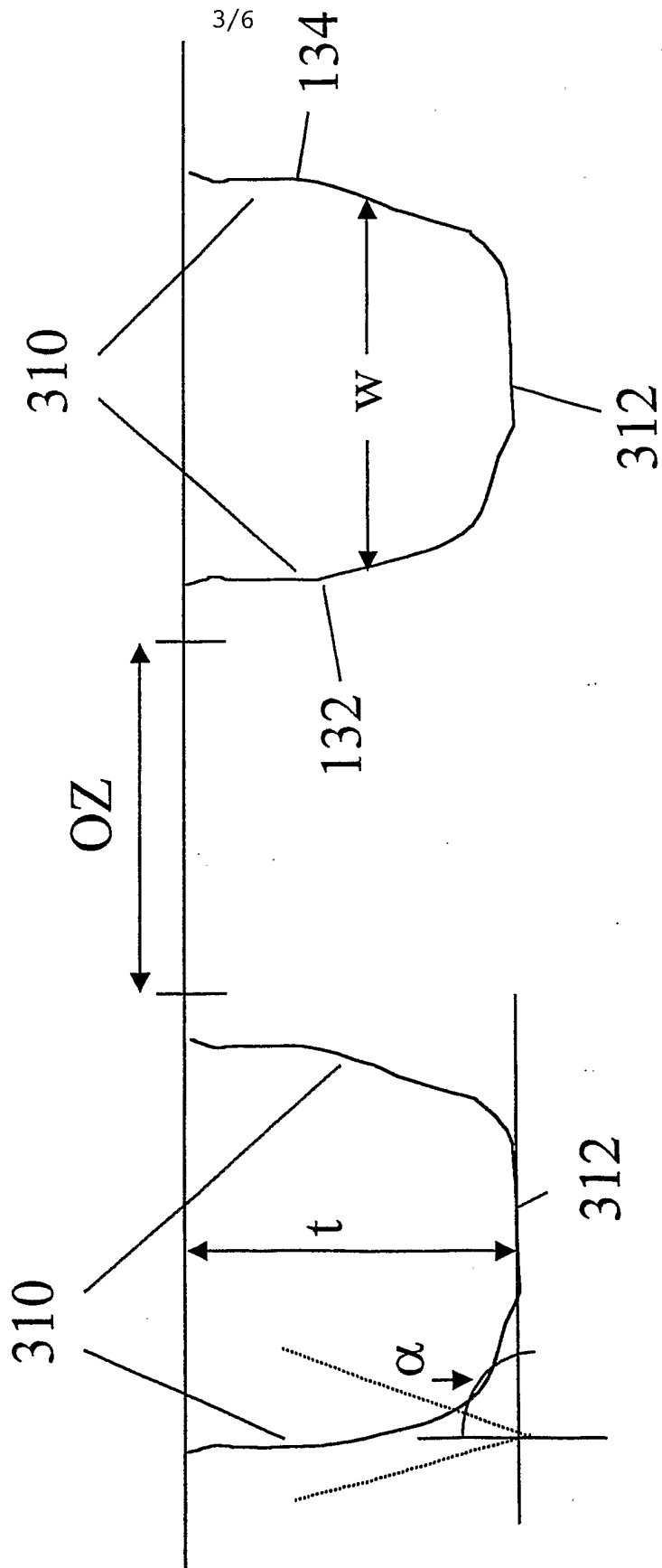


FIG. 3

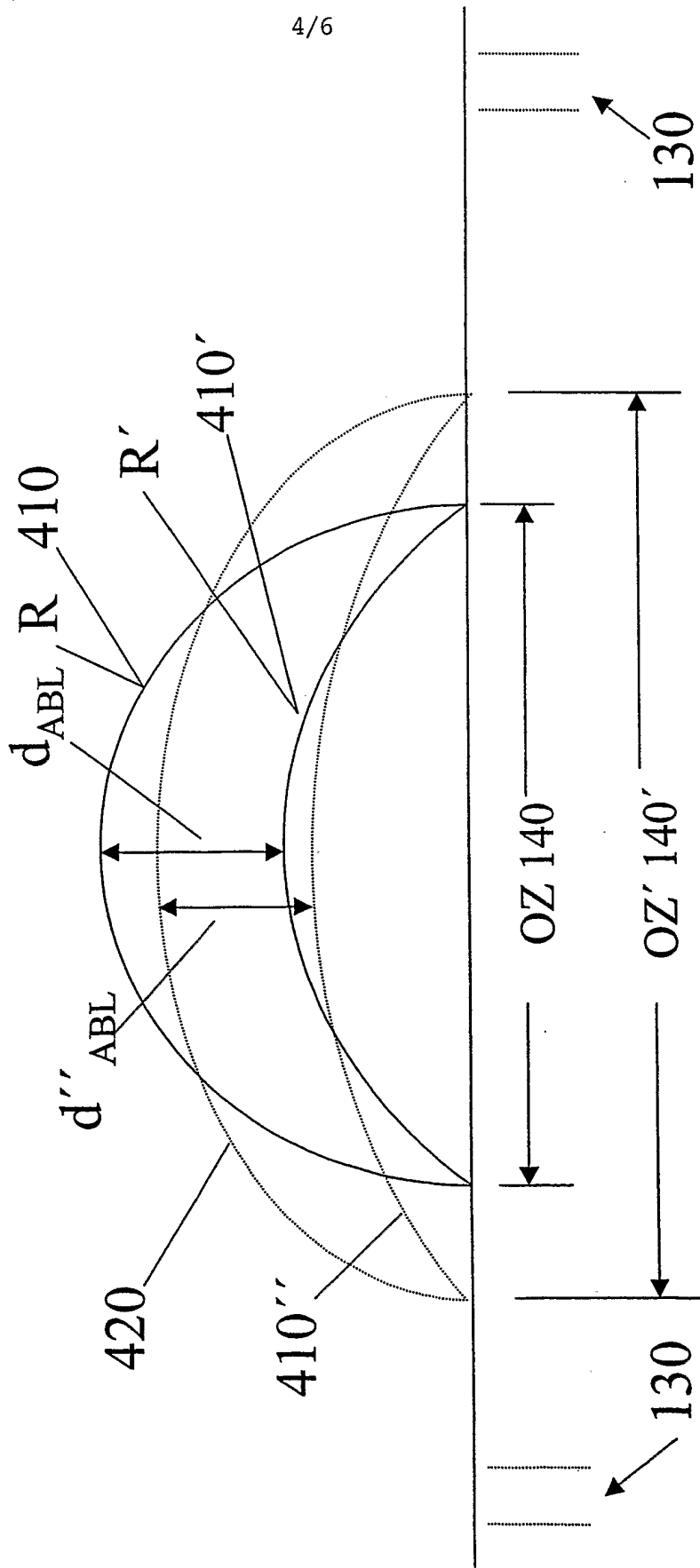


FIG. 4

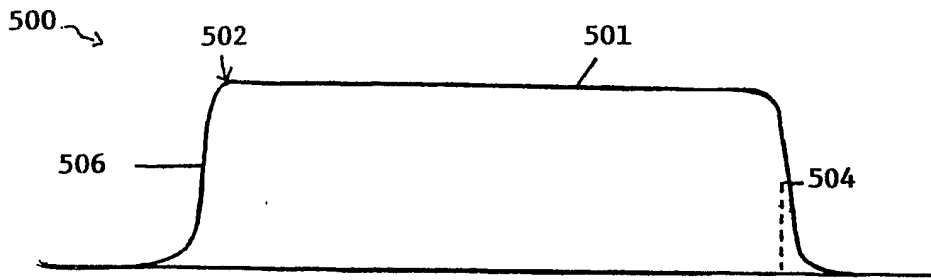


FIG. 5

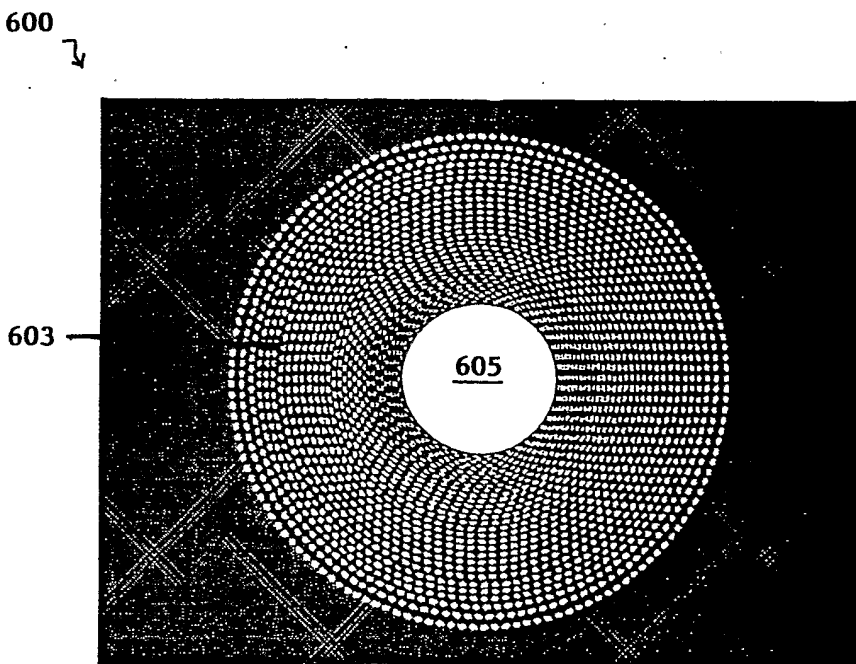


FIG. 6

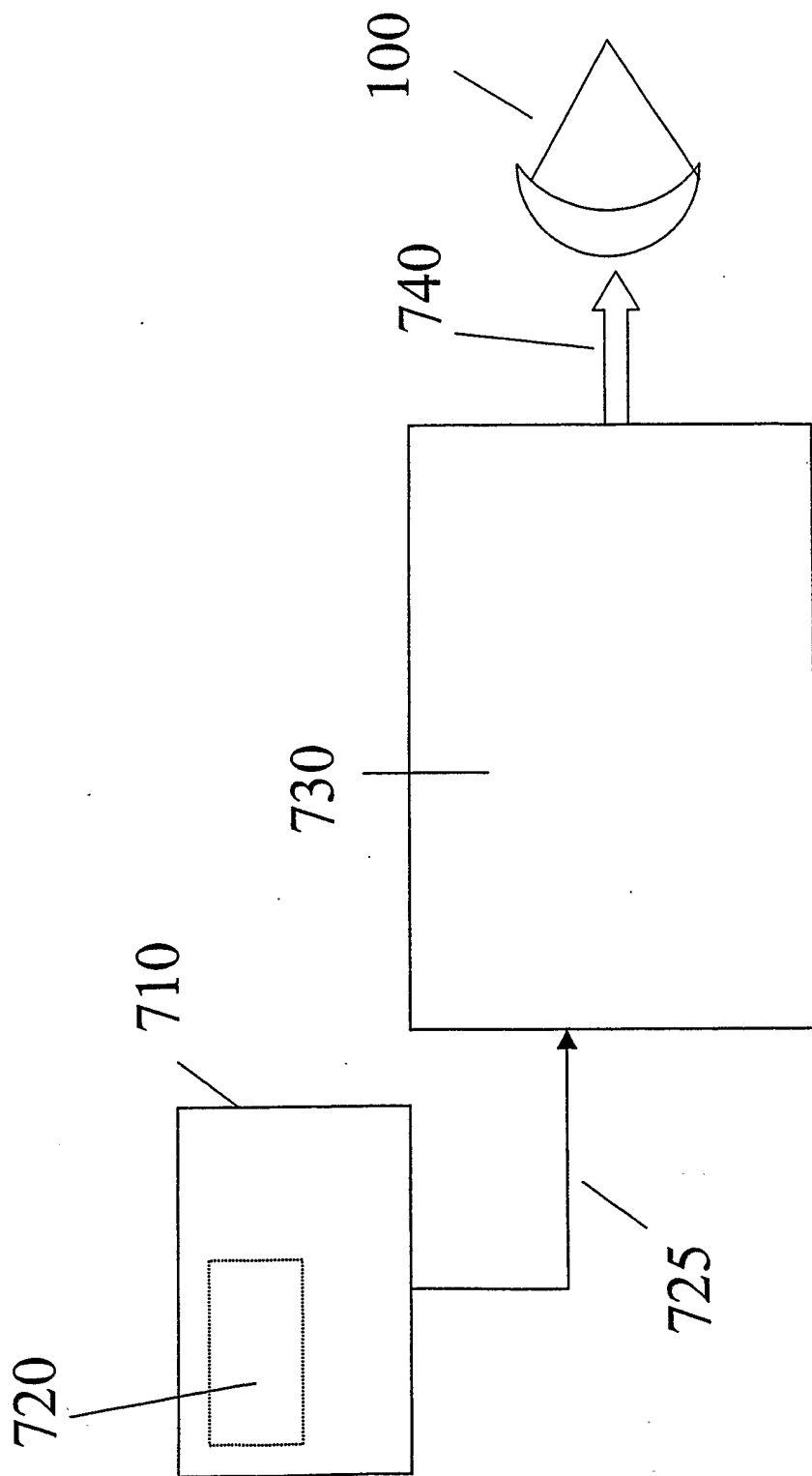


FIG. 7

INTERNATIONAL SEARCH REPORT

Internationa Application No  
PCT/EP 03/06778

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61F9/01

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

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61F

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, BIOSIS, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 302 877 B1 (RUIZ LUIS ANTONIO) 16 October 2001 (2001-10-16) column 6, line 32 -column 7, line 36 column 9, line 5 - line 13 column 11, line 8 - line 28 column 12, line 53 -column 13, line 39 column 17, line 45 - line 60; claims 1-4,11,13,14,16-18,22,24,26,27,29; figures 3,4,5A	
A	US 6 193 710 B1 (LEMBERG VLADIMIR) 27 February 2001 (2001-02-27) column 2, line 56 -column 3, line 11 column 5, line 53 - line 67 column 8, line 1 - line 14 column 10, line 1 - line 33; claims 1,2,5; figures 1,7	
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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	*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
*E* earlier document but published on or after the international filing date	*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
*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)	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
*O* document referring to an oral disclosure, use, exhibition or other means	*&* document member of the same patent family
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search <b>14 October 2003</b>	Date of mailing of the international search report <b>22/10/2003</b>
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Name and mailing address of the ISA 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	Authorized officer <b>Rick, K</b>
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## INTERNATIONAL SEARCH REPORT

Internat. Application No.

PCT/EP 03/06778

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 01 28478 A (HOHLA KRISTIAN ;TECHNOLAS GMBH OPHTHALMOLOGISC (DE); TOENNIES ROLA) 26 April 2001 (2001-04-26) cited in the application page 2, line 9 - line 20 page 7, line 26 -page 8, line 2; figures 9-14  -----	

# INTERNATIONAL SEARCH REPORT

In international application No.  
PCT/EP 03/06778

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 1-36  
because they relate to subject matter not required to be searched by this Authority, namely:  
see FURTHER INFORMATION sheet PCT/ISA/210
  
2.  Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
  
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
  
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 1-36

Rule 39.1(iv) PCT - Claims 1-27 relate to a method for treatment of the human or animal body by surgery and claims 28-36 to a device readable medium with corresponding instructions, thus also excluded from patentability. However claims 1-36 have been searched for the structural features of a corresponding system.

## INTERNATIONAL SEARCH REPORT

on on patent family members

Internat Application No.

PCT/EP 03/06778

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