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BIFOCAL INTRAOCULAR LENS WITH SPHERICAL ABERRATION CORRECTION

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(56) Prior Art Documents
US 4813955
US 463629
WO 89/02251

(57) Claim

1. An intraocular lens having an optic portion with a zone surface and a non-zone surface, the zone surface comprising a central zone, for the provision of distance vision, having a diameter of about 1.5 to 2.0 mm, a second zone, for the provision of near vision, surrounding the central zone, with an inside diameter of about 1.5 to 2.0 mm and an outside diameter of about 2.8 to 3.5 mm, and a third zone, for the provision of distance vision, which extends from the outer diameter of the second zone to the edge of the optic, the radius of curvature of the third zone differing from that of the central zone to correct for spherical aberration such that images formed by the central and third zones are coincident in aqueous.

.../2

14. A method for providing bifocal vision which comprises, selecting an intraocular lens having an optic portion with a zone surface and a non-zone surface, the zone surface comprising a central zone, for the provision of distance vision, having a diameter of about 1.5 to 2.0 mm, a second zone, for the provision of near vision, surrounding the central zone, with an inside diameter of about 1.5 to 2.0 mm and an outside diameter of about 2.8 to 3.5 mm, and a third zone, for the provision of distance vision, which extends from the outer diameter of the second zone to the edge of the optic, the radii of curvature of the third zone differing from that of the central zone to correct for spherical aberration such that images formed by the central and third zones are coincident in aqueous, and implanting said lens into the eye of a patient.

28. A soft acrylate intraocular lens having an optic portion with a zone surface and a non-zone surface, the zone surface comprising, a central zone, for the provision of distance vision, having a diameter of about 1.5 to 2.0 mm, a second zone, for the provision of near vision, surrounding the central zone, with an inside diameter of about 1.5 to 2.0 mm and an outside diameter of about 2.8 to 3.5 mm, and a third zone, for the provision of distance vision, which extends from the outer diameter of the second zone to the edge of the optic, the radius of curvature of the third zone differing from that of the central zone to correct for spherical aberration such that images formed by the central and third zones are coincident in aqueous.

CORRECTED VERSION *

16830/92

PCT

under INID Number (30) "Priority Data", replace "845,306" by "845,300"

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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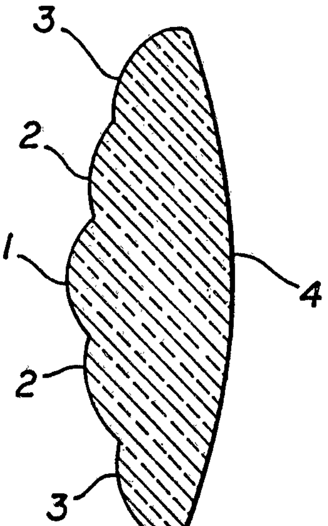
(54) Title: BIFOCAL INTRAOCULAR LENS WITH SPHERICAL ABERRATION CORRECTION



(57) Abstract

Intraocular lenses with three zones for the provision of bifocal vision are described. Methods for the lenses' use are also described. The three zones comprise a central zone (1) for the provision of distance vision, a second zone (2) surrounding the central zone for provision of near vision, and a third zone (3) surrounding the second zone for provision of distance vision. The radius of curvature of the third zone differs from that of the central zone such that images formed by the central and third zones are coincidental in aqueous. Such an arrangement corrects for spherical aberration.

* (Referred to in PCT Gazette No. 26/1993, Section II)

BIFOCAL INTRAOCULAR LENS WITH SPHERICAL ABERRATION CORRECTION

This application is a continuation-in-part of U.S. Patent No. 5147393 ~~Application Serial No. 07/681,814~~, filed April 5, 1991.

Field of the Invention

The present invention is directed to artificial intraocular lenses with a bifocal optic.

Background of the Invention

The majority of patients undergoing cataract removal receive an intraocular lens which does not provide for both near and distance vision. These patients then usually require some form of refractive correction, such as spectacles or contact lenses to achieve both near (reading) and distance (driving) vision. There is thus a need for intraocular lenses that will enable cataract surgery patients to perform activities requiring near and distance vision, especially in extreme lighting conditions, without spectacles.

Concentric bifocal intraocular lenses are known. U.S. Patent No. 4,636,211, issued to Nielsen et al., discloses an intraocular lens with concentrically oriented near vision and far vision zones, with the near vision portion centrally positioned and the far vision portion coaxial with and surrounding the near vision portion. U.S. Patent No. 4,813,955, issued to Achatz et al., discloses a multifocal intraocular lens whose optic portion is divided into near and far range zones such that the rays received by the pupil of the eye pass through near and far range zones of approximately equal areas.

Although prior, concentric, bifocal lenses have optics with portions which will provide for near and distance vision, there can be problems upon implantation due to, among other things, fluctuations in pupil size and spherical aberration phenomenon resulting in non-coincident images from different zones in a lens intended for the same distance correction.

The intraocular lenses of the present invention overcome the aforementioned problems through the use of a three zoned refractive optic for the provision of near and distance vision over the entire human pupil range, especially in extreme lighting conditions, with the peripheral distance zone corrected for spherical aberration such that rays of light passing through the central and peripheral zones form a coincident image in aqueous.

Disclosure of the Invention

The lenses of the present invention have an optic portion with a zone surface and a non-zone surface, the zone surface having three zones. A central zone is for distance vision and is approximately 1.5 to 2.0 millimeters (mm) in diameter. A second annular zone is for near vision, and has an inside diameter of about 1.5 to 2.0 mm and an outside diameter of amount 2.8 to 3.5 mm. The second zone also has an increased power over the power for distance vision by 2.0 - 5.0 diopters in aqueous. A third, or peripheral zone, for distance vision, extends from the outer edge of the second zone to the edge of the optic. Additionally, the radius of curvature of the surface of the peripheral zone has been selected with reference to the central zone to correct for spherical aberration as discussed below.

the lenses of the present invention are used to replace the natural lens of the eye when it is necessary to remove the natural lens, usually due to the development of cataracts.

Brief Description of Drawings

Figure 1 illustrates the anterior surface of a biconvex, bifocal lens of the present invention.

Figure 2 illustrates a side view of a biconvex, bifocal optic of the present lens invention.

Detailed Description of the Preferred Embodiments

Intraocular lenses are most frequently implanted in the elderly. Therefore, the lenses of the present invention are designed to best meet the needs of an elderly patient, that is, provide distance vision (greater than 6 meters) throughout the overall pupil range of 1.8 - 6.5 mm and high resolution near vision (.35 meters) in a pupil range of 2.5 - 4.5 mm. To achieve these goals, an intraocular lens with three zones for near and distance vision was created. The intraocular lenses (IOLs) of the present invention can be made of any optically transparent material suitable for an IOL, including, but not limited to, PMMA, soft acrylates (acrylate/methacrylate copolymers), hydrogels, polycarbonates, and silicones. The refractive index of the optical material can range from 1.40 to 1.60. The cross sectional shape of the optic portion of the intraocular lens is not limited, that is, it can be biconvex, plano convex, convex plano, or of a meniscus design. In addition, the optic portion can be of any desired closed shape geometry, including variations of circular geometry, such as oval, such that the lens can be inserted by a surgeon through a relatively small incision in the eye. The dimensions of the optic can be of any size which is suitable for implantation into the eye. The lenses of the present invention can include any suitable shape and number of haptics. Any suitable material for use as haptics can be used. Such materials include, but are not limited to, PMMA, polypropylene, and polyimide. In addition, the lenses can be of a single or multi-piece design. The three zones for near and distance vision are placed on either the anterior or posterior face of the optic, the fact containing the three zones will be referred to herein as the "zone surface," the anterior face being that surface of a lens nearest the anterior, or forward, part of the eye and the posterior face, that surface closest to the back or posterior part of the eye. For example, in a biconvex lens, the zones can be placed on either the anterior or posterior surface of the lens. The other surface, not encompassing the zones, referred to herein as the "non-zone surface" can then be manufactured with a single radius of curvature to provide for the additional power so that the total distance and near power of the lens is achieved. The total power of the lens can range from 1 to 35 diopters.

The three zones of the intraocular lenses of the present invention have defined sizes to provide for near and distance vision over the entire pupil range. The size of these zones is not dependent on the cross sectional shape of the optic or the materials used in the lens. The central zone, for distance vision, is approximately 1.5 to 2.0 mm in diameter. The second zone is an annulus surrounding the central zone, and has an inside diameter of about 1.5 to 2.0 mm and an outside diameter of about 2.8 to 3.5 mm. The second zone is for the provision of near vision. The third zone, for the provision of distance vision, surrounds the second zone and extends from the outer diameter of the second zone to the edge of the optic.

All surfaces of the intraocular lens of the present invention are spherical. As previously discussed, the zone surface can be on the anterior or posterior face of the IOL and the non-zone surface will be on the corresponding side. The total power for distance and near vision is determined by these two surfaces of the IOL. Power, in terms of diopters, expresses the ability of the optical lens to bend light rays to a point of focus at a distance from the optic expressed as focal length. Power is inversely proportional to the effective focal length. The distance vision power for the IOL ranges from about 1 to 30 diopters. The central zone radius together with the radius of the non-zone surface determines the power of the distance vision as per the lens maker formula for monofocal IOLs (see American National Standard for Ophthalmics - Intraocular Lenses - Optical and physical Requirements Z80.7 - 1984). The power for distance vision of the central zone of the three zone surface can be selected from 1 to 30 diopters. The second annular zone radius, together with the radius of the non-zone surface determines the power of the near vision as per the routinely used lens maker formula for monofocal IOLs. The power of the near vision zone provides additional power over the distance power of the central zone. This add power can be in the range of 2 to 5 diopters depending on the patient's eye dimensions and their need. The current state of clinical knowledge indicates that the preferred add power is in the range of 3.5 - 4.5 diopters. The third zone or peripheral zone radius together with the radius of the non-zone surface determines the focal length for image formation for distance vision from this zone If the radius of this zone was made identical to that of the central zone for distance vision, then, because of what is referred to in the field of optics as spherical aberration from this peripheral zone, its image would be formed at a shorter focal length and thus, not coincident with the image formed by the central distance zone. If spherical aberration is not corrected, the distance image formed on the retina will be less sharp over a broad range of pupil sizes. In order to correct for this effect and make the two images coincident, it is necessary to increase the radius of the peripheral zone. The determination of the necessary radius of the peripheral zone is done by tracing a ray representing the peripheral zone to form the image on the optical axis at the same location for a ray representing the central zone. The height of the ray used to represent any zone is selected to best approximate the best focus image formed by that zone. The computation of the height of the representative ray is done such that it equally divides the area of the zone. The wave length selected for ray tracing can be in the range of 400 - 700 nm, but is preferably 550 nm, which represents photopic human vision. Ray tracing can be carried out by various methods known to those skilled in the art of optics, including application of the fundamentals of Snell's law and traditional geometry, or with readily available optical software packages such as GENII®, CODE V™, OSLO®, ACCOS V™, etc.

The radii of curvature of the three zones will vary depending on the type of material used in the optic of the lens. The material used will typically have a refractive index in the range of about 1.4-1.6. For example, when the optic is made of polymethyl methacrylate (PMMA), which has a refractive index of about 1.49, the zones can have radii of curvature as follows> The central zone's radius of curvature can be about 28.5 mm. The second zone's radius of curvature can be between about 14.9 - 20.9 mm (this provides for about a 2.0 - 5.0 diopter increase over the distance vision power). The third zone's radius of curvature can be about 30.0 mm. The radius of curvature of the third zone differs from that of the central zone, both of which provide for distance vision, in order to correct for the spherical aberration such that rays passing through the central and third zones form a coincident image in aqueous.

If a soft acrylate copolymer, such as one disclosed in ~~copending~~ U.S. Patent, No. 5290892 ~~Application Serial No. 07/609,863~~ and the Continuation-in-Part Application entitled "Polymers and Their Use for Ophthalmic Lenses" filed on February 17, 1992, which comprises 65 wt% 2-phenylethyl acrylate (PEA), 30 wt.% 2-phenylethyl methacrylate (PEMA), 3.2 wt.% 1,4-butamediol acrylate (BDDA), and 1.8 wt.% 2-(3'methallyl-2'-hydroxy-5'-methyl phenyl)benzotriazole is used to make an IOL of the present invention, then the central zone's radius of curvature can be about 32.0, and the second zone's radius of curvature can be about 24.7 mm - 18.4 mm (2.0 - 5.0 diopter add). The third zone's radius of curvature can be about 33.3, again the radius of curvature of the third zone differs from that of the central zone to correct for spherical aberration.

Figures 1 and 2 illustrate a preferred embodiment of the present invention. Figure 1 shows the anterior face of a single piece, PMMA intraocular lens comprising an optic and two haptics. The anterior face of the optic is comprised of three zones to provide for bifocal vision. The first zone (1) is a central zone for the provision of distance vision. It is about 1.8 millimeters in diameter. The second zone (2) is an annulus with an inside diameter of 1.8 mm and an outside diameter of 3.0 mm for the provision of near vision. The third zone (3) surrounds the second zone and extends from the outer diameter of the second zone to the edge of the optic for the provision of distance vision.

Figure 2 represents a cross sectional view of the optic of Figure 1 and shows the radii of curvature of the zones. The central zone (1) has a radius of curvature of about 28.5 mm for the provision of distance vision. The second zone has a radius of curvature of 17.4 mm for the provision of near vision (for about a 3.5 diopter increase over the distance vision power). The third zone (3) has a radius of curvature of about 30.0 mm for provision of distance vision. The radius of curvature for the third zone has been adjusted to correct for spherical aberration making light rays passing through the central and third zones form a coincident image in aqueous. The posterior surface of the optic (4) has a radius of curvature to provide for additional power so that the total distance vision power of the lens is from about 1 to about 30 diopters and the total near vision power is 3.0 - 35.0 diopters. Within these ranges, the near vision power is greater than the distance vision power by 2.0 - 5.0 diopters.

The lenses of the present invention can be used to replace the natural lens of the eye by a skilled clinician. The natural lens is most usually removed from the elderly upon their development of cataracts.

The present invention, having been fully described, is only limited as set forth in the following claims.

Claims

1. An intraocular lens having an optic portion with a zone surface and a non-zone surface, the zone surface comprising a central zone, for the provision of distance vision, having a diameter of about 1.5 to 2.0 mm, a second zone, for the provision of near vision, surrounding the central zone, with an inside diameter of about 1.5 to 2.0 mm and an outside diameter of about 2.8 to 3.5 mm, and a third zone, for the provision of distance vision, which extends from the outer diameter of the second zone to the edge of the optic, the radius of curvature of the third zone differing from that of the central zone to correct for spherical aberration such that images formed by the central and third zones are coincident in aqueous.

2. The lens of claim 1, wherein the central zone has a diameter of 1.8 mm and the second zone has an inside diameter of 1.8 mm and an outside diameter of 3.0 mm.

3. The lens of claim 1, wherein the second zone provides for a 2.0 - 5.0 diopter power increase over the central and third zones.

4. The lens of claim 3, wherein the diopter power increase is 3.5 - 4.5.

5. The lens of claim 1, wherein the optic portion is PMMA and the central zone has a diameter of 1.8 mm and the second zone has an inside diameter of 1.8 mm and an outside diameter of 3.0 mm.

6. The lens of claim 2, wherein the second zone provides for a 2.0 - 5.0 diopter power increase over the central and third zones.

7. The lens of claim 2, wherein the optic portion is PMMA and the radius of curvature of the central zone is about 28.5 mm, the radius of curvature of the second zone is about 14.9 mm - 20.9 mm, and the radius of curvature of the third zone is about 30.0 mm.

8. The lens of claim 7, wherein the radius of curvature of the second zone is about 17.4 mm.

9. The lens of claim 7, wherein the radius of curvature of the second zone is about 15.7 mm.

10. The lens of claim 1, wherein the optic is biconvex.

11. The lens of claim 1, wherein the optic is comprised of a material with a refractive index of 1.40 to 1.60.

12. The lens of claim 11, wherein the optic comprises PMMA.

13. The lens of claim 11, wherein the optic comprises soft acrylates.

14. A method for providing bifocal vision which comprises, selecting an intraocular lens having an optic portion with a zone surface and a non-zone surface, the zone surface comprising a central zone, for the provision of distance vision, having a diameter of about 1.5 to 2.0 mm, a second zone, for the provision of near vision, surrounding the central zone, with an inside diameter of about 1.5 to 2.0 mm and an outside diameter of about 2.8 to 3.5 mm, and a third zone, for the provision of distance vision, which extends from the outer diameter of the second zone to the edge of the optic, the radii of curvature of the third zone differing from that of the central zone to correct for spherical aberration such that images formed by the central and third zones are coincident in aqueous, and implanting said lens into the eye of a patient.

15. The method of claim 14, wherein the central zone has a diameter of 1.8 mm, and a second zone has an inside diameter of 1.8 mm and an outside diameter of 3.0 mm.

16. The method of claim 14, wherein the second zone has a 2.0 - 5.0 diopter power increase over the central and third zones.

17. The method of claim 16, wherein the diopter power increase is 3.5 - 4.5.

18. The method of claim 14, wherein the optic portion is PMMA and the radius of curvature of the central zone is about 28.5 mm, the radius of curvature of the second zone is about 14.9 mm - 20.9 mm, and the radius of curvature of the third zone is about 30.0 mm.

19. The method of claim 18, wherein the radius of curvature of the second zone is about 17.4 mm.

20. The method of claim 14, wherein the lens is biconvex.

21. The method of claim 14, wherein the optic is comprised of a material with a refractive index of 1.40 - 1.60.

22. The method of claim 15, wherein the radius of curvature of the central zone is about 28.5 mm, the radius of curvature of the second zone is about 14.9 mm - 20.9 mm, and the radius of curvature of the third zone is about 30.0 mm.

23. The method of claim 22, wherein the radius of curvature of the second zone is about 17.4 mm.

24. The method of claim 14, wherein the lens is comprised of a soft acrylate.

25. An intraocular lens having an optic portion with a zone surface and a non-zone surface, the zone surface comprising a central zone with a radius of curvature of about 28.5 mm, a second zone having a

radius of curvature of about 14.9 mm - 29.9 mm and a third zone having a radius of curvature of about 30.0 mm, the second zone concentric with and surrounding the central zone and the third zone concentric with and surrounding the second zone.

26. The lens of claim 25 having a biconvex optic portion.

27. The lens of claim 25, wherein the optic portion is PMMA.

28. A soft acrylate intraocular lens having an optic portion with a zone surface and a non-zone surface, the zone surface comprising, a central zone, for the provision of distance vision, having a diameter of about 1.5 to 2.0 mm, a second zone, for the provision of near vision, surrounding the central zone, with an inside diameter of about 1.5 to 2.0 mm and an outside diameter of about 2.8 to 3.5 mm, and a third zone, for the provision of distance vision, which extends from the outer diameter of the second zone to the edge of the optic, the radius of curvature of the third zone differing from that of the central zone to correct for spherical aberration such that images formed by the central and third zones are coincident in aqueous.

29. The lens of claim 28, wherein the central zone has a diameter of 1.8 mm and the second zone has an inside diameter of 1.8 mm and an outside diameter of 3.0 mm.

30. The lens of claim 28, wherein the optic portion comprises about 65 wt.% PEA, 30 wt.% PEMA, 3.2 wt.% BDDA, and 1.8 wt.% 2-(3'methallyl-2'(hydroxy-5'-methyl phenyl)benzotriazole.

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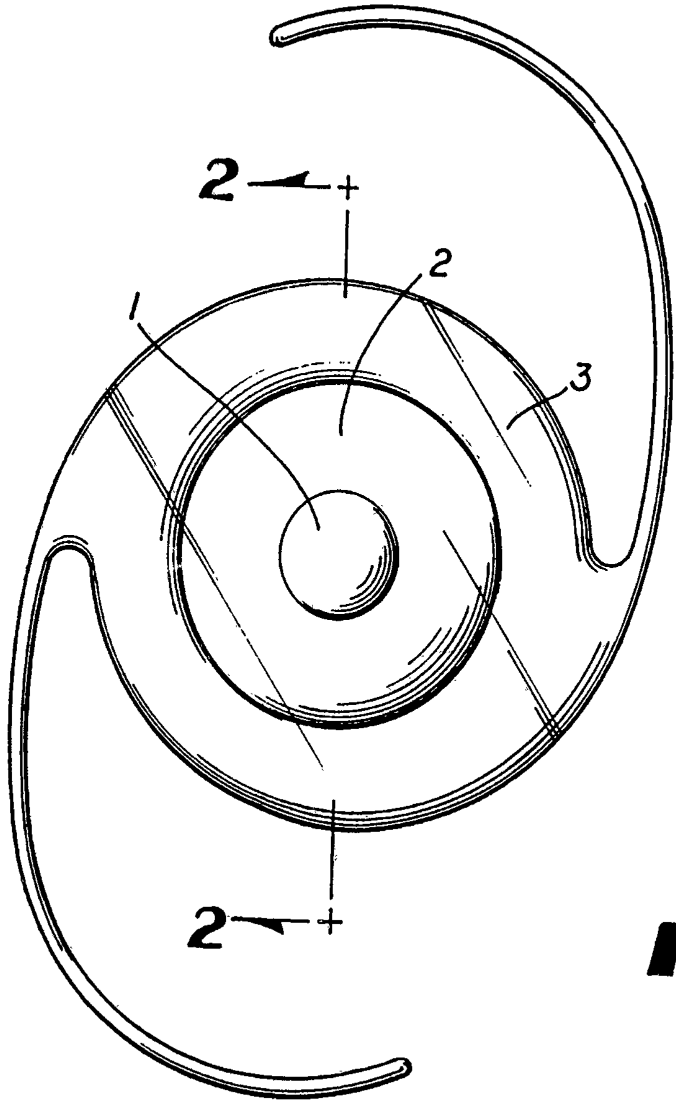

FIG 1

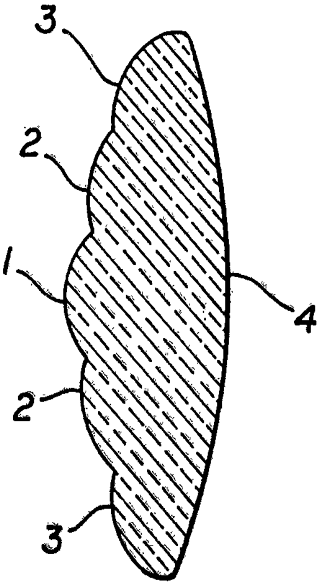

FIG 2

INTERNATIONAL SEARCH REPORT

International Application No PCT/US92/02161

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61F 2/16 US Cl. 623/6

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
US	623/6 351/161

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	US, A, 4,795,462 (GRENDAHL) 03 January 1989, See abstract.	1-30
A	US, A, 4,636,211 (NIELSEN ET AL) 13 January 1987, See abstract.	1-30
A	US, A, 4,813,955 (ACHATZ ET AL) 21 March 1989, See abstract.	1-30
A	US, A, 4,890,913 (DeCARLE) 02 January 1990, See abstract.	1-30
A	WO, A 89/02,251 (NIELSEN) 23 March 1989, See summary of the Invention.	1-30

* Special categories of cited documents: [10]

"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)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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

"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.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
18 June 1992	03 AUG 1992
International Searching Authority	**Signature of Authorized Officer**
ISA/US	Randy Shay

Form PCT/ISA/210 (second sheet) (Rev.11-87)

International Application No. PCT US92 02161

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers , because they relate to subject matter [13] not required to be searched by this Authority, namely:

2. ☐ Claim numbers ...., 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 [13], specifically:

3. ☐ Claim numbers__________, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

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 of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. ☐ 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 claim numbers:
4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.