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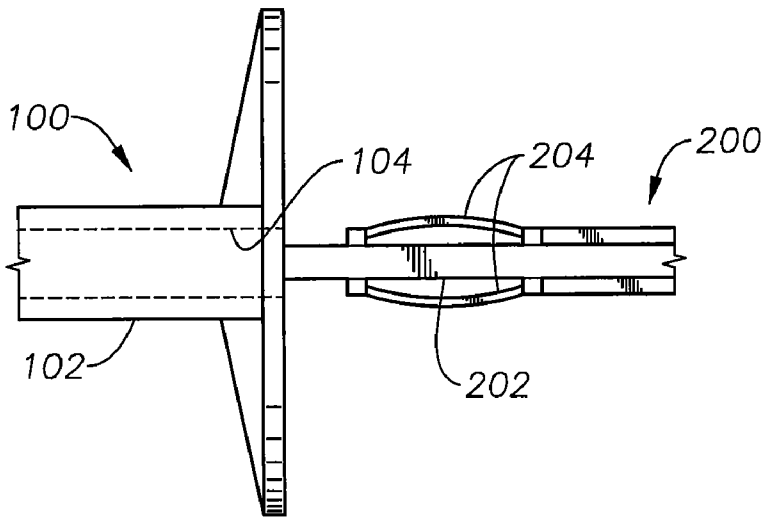
[Continued on next page]

(54) Title: LENS DELIVERY SYSTEM

Fig. 1



(57) Abstract: An intraocular lens delivery system includes an injector body having a bore surrounded by an inner wall. The system further includes a plunger configured to fit within the bore. The system also includes a plurality of deflectable members connected to the plunger and configured to contact the inner wall and to be deflected when the plunger is inserted within the bore. The deflectable members center the shaft and, when inserted within the injector body, contribute to producing a predetermined force resisting advancement of the plunger when deflected in the bore.

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— *with international search report (Art. 21(3))*

LENS DELIVERY SYSTEM

Related Applications

This application claims priority to U.S. provisional application Serial No. 61/185428, filed on June 9, 2009, the contents which are incorporated herein by reference.

Field of the Invention

This invention relates to intraocular lenses (IOLs) and more particularly to devices use to inject IOLs into an eye.

Background of the Invention

The human eye in its simplest terms functions to provide vision by transmitting and refracting light through a clear outer portion called the cornea, and further focusing the image by way of the lens onto the retina at the back of the eye. The quality of the focused image depends on many factors including the size, shape and length of the eye, and the shape and transparency of the cornea and lens. When trauma, age or disease cause the lens to become less transparent, vision deteriorates because of the diminished light which can be transmitted to the retina. This deficiency in the lens of the eye is medically known as a cataract. The treatment for this condition is surgical removal of the lens and implantation of an artificial lens or IOL.

While early IOLs were made from hard plastic, such as polymethylmethacrylate (PMMA), soft, foldable IOLs made from silicone, soft acrylics and hydrogels have become increasingly popular because of the ability to fold or roll these soft lenses and insert them through a smaller incision. Several methods of rolling or folding the lenses are used. One popular method is an injector cartridge that folds the lenses and provides a relatively small diameter lumen through which the lens may be pushed into the eye, usually by a soft tip plunger, such as the one described in U.S. Patent No. 4,681,102 (Bartell), which includes a split, longitudinally hinged cartridge. Similar designs are illustrated in U.S. Patent Nos. 5,494,484 and 5,499,987 (Feingold) and 5,616,148 and 5,620,450 (Eagles, et al.). Other cartridge designs include, for example, U.S. Patent No. 5,275,604 (Rheinish, et al.) and 5,653,715 (Reich, et al.).

It is desirable for any combination of cartridge and handpiece used in an intraocular lens delivery system to be comfortable and intuitive for the surgeon to use. An intraocular lens delivery system with a good "feel" for the surgeon can improve the ease and success rate of surgical procedures in which the intraocular lens delivery system is employed.

Brief Summary of the Invention

In a particular embodiment of the present invention, an intraocular lens delivery system includes an injector body having a bore surrounded by an inner wall. The system further includes a plunger configured to fit within the bore. The system also includes a plurality of deflectable members connected to the plunger and configured to contact the inner wall and to be deflected when the plunger is inserted within the bore. The deflectable members center the shaft and, when inserted within the injector body, contribute to producing a predetermined force resisting advancement of the plunger when deflected in the bore.

In another embodiment of the present invention, a method of manufacturing an intraocular lens delivery system includes determining a resistance force to advancement of a plunger within an injector body having a bore surrounded by an inner wall. The method also includes determining a shape for a plurality of deflecting members connected to the plunger that will deflect when the plunger is received within the bore of the injector body to contribute to producing the predetermined resistance force. The method further includes manufacturing an intraocular lens delivery system including the injector body, the plunger, and the plurality of deflecting members.

Other objects, features and advantages of the present invention will become apparent with reference to the drawings, and the following description of the drawings and claims.

Brief Description of the Drawings

FIGURE 1 illustrates an intraocular lens delivery system according to a particular embodiment of the present invention;

FIGUREs 2A and 2B show different views of a plunger according to a particular embodiment of the present invention; and

FIGURE 3 is a flowchart showing an example method of manufacturing an intraocular lens delivery system according to another embodiment of the present invention.

Detailed Description of the Invention

FIGURE 1 illustrates an intraocular lens delivery system 100 according to a particular embodiment of the present invention. The delivery system 100 includes an injector body 102 having a bore 104 along with a plunger 200 to advance an intraocular lens within the injector body 102. As used within this specification, the term "injector body," an example of which is injector body 102, refers to any portion, components, or collection of components enclosing a bore 104 through which the plunger 200 advances when pushing the intraocular lens. The term "plunger" describes any component advanced through the bore 104 to push an intraocular lens through the injector body, which can be (but need not be) connected to other components of the intraocular lens delivery system 100. In particular, plungers 200 of various embodiments of the present invention may be made compatible with the lens delivery systems described in detail in U.S. Patent No. 7,156,854 to Brown *et al.*, which is incorporated herein by reference.

In particular embodiments, the entire injector body 102 may be formed as a single piece from a suitable material, which may include, for example, polypropylene or polyethylene. In other embodiments, the injector body 102 may be formed by coupling part of a reusable handpiece that forms a continuous bore 104 to a disposable cartridge holding the intraocular lens having a nozzle portion for injecting the intraocular lens through a surgical incision. Various embodiments may also include a lubricious coating within the bore 104 of the injector body 102 to facilitate advancement of the intraocular lens. However, one difficulty with previous intraocular lens delivery systems is that the plungers may also slide too easily within the bore 104, thus removing any real tactile feedback during advancement of the intraocular lens. Particular embodiments of the present invention provide a solution to this difficulty by producing a resistance to advancement of the plunger 200, as described in greater detail below.

The plunger 200 pushes the intraocular lens by advancing a shaft 202 of the plunger 200 through the bore 104. Coupled to the plunger 200 are two deflectable members 204 on opposite sides of the plunger 200. FIGUREs 2A and 2B show additional views of the deflectable members 204 of FIGURE 1. In the depicted embodiment, the deflectable members 204 are arc-shaped, resilient extensions from the shaft 202 of the plunger 200. The peaks of the deflectable member 204 are configured to contact and to be deflected by an inner wall of the injector body 102 when the plunger 200 is placed within the bore 104. The resulting force from the deflection of the deflectable members 204 helps to position the plunger 200 within the bore 104 so that the shaft 202 of the plunger 200 is reliably oriented relative to the intraocular lens. The deflectable members 204 also fit sufficiently tightly within the

bore 104 that, when the deflectable members 204 are compressed by the inner wall of the injector body 102, the friction against the inner wall resists advancement of the plunger 200. This produces a tactile resistance to the plunger 200 sliding through the bore 104, which in turn both assists the surgeon in realizing when the plunger 200 is correctly engaged in the intraocular lens delivery system 100 and provides a steady resistance that facilitates controlled application of force during the lens delivery process.

Because the resistance varies with the force produced by deflection of the deflectable members 204, it is possible to adjust a design for the deflectable members 204 in order to vary the resistance of the intraocular lens delivery system 100. Advantageously, the force can be adjusted to correspond to a desired "feel" for surgeons. For example, the resistance may be calibrated based on a survey of physicians to evaluate what resistance feels most suitable. In another example, typical resistance forces for handpieces of intraocular lens delivery systems preferred by various surgeons can be measures, and the deflectable members 204 can be adjusted to produce a suitable resistance. In yet another example, multiple different resistance values can be selected for multiple intraocular lens delivery systems 100, allowing physicians to choose plungers 200 that are relatively "stiff" (i.e., having high resistance to advancement) or plungers 200 that are relatively "yielding" (i.e., having lower resistance to advancement).

The deflectable members 204 can be formed separately from the plunger 200 or formed simultaneously as a single piece with the plunger 200 from a selected material suitable for use in ophthalmic applications, e.g., polypropylene. Forming the plunger 200 with the deflectable members 204 as a single piece has an advantage in reducing the number of manufacturing steps using techniques such as injection molding. The resistance force created by the deflectable members 204 can then be adjusted by varying the shape of the deflectable members 204 with respect to a selected material, so that plungers 200 with characteristic resistances can be produced. Alternatively, the same shape for the deflectable members 204 could be used with a variety of selected materials of different resiliency. In general, any adjustment known to be suitable to change the resistance of the plunger 200 to advancement may be employed.

Multiple deflectable members 204 placed along the plunger 200 could also be used to help the stability of the plunger 200. Thus, for example, one pair of deflectable members 204 could be placed closer to a distal end of the plunger 200 ("distal" in this context referring to an end of the plunger 200 configured to be placed nearest the incision during lens injection), while another pair is placed nearer to a proximal end ("proximal" referring to the end farthest from the incision during lens

injection). Such configurations of deflectable members 204 can help to keep the plunger 200 aligned within the bore 104 as it is advanced.

FIGURE 3 is a flowchart 300 illustrating an example method of manufacturing an intraocular lens delivery system 100 according to a particular embodiment of the present invention. At step 302, a desired resistance to advancement of a plunger 200 for the intraocular lens delivery system 100 is determined. The desired resistance may be determined based on a survey of physicians using various designs, force measurements of lens delivery systems used by the physicians, theoretical calculations based on the overall sources of resistance in the system 100, or a combinations of these techniques and/or any other suitable techniques for determining the value. At step 304, a shape for at least two deflectable members 204 is determined so that the deflectable members 204 hold the plunger 200 within the bore 104 and provide the predetermined resistance to advancement of the plunger 200. The deflectable members 204 may be designed according to any of the various considerations described above, including consideration of the material for the deflectable members 204 in determining the shape of the deflectable members 204. Steps 302 and 304 may also be repeatedly iteratively, such as particular designs being made and evaluated by physicians providing feedback used in the next design iteration. Finally, at step 306, the intraocular lens delivery system 100 is manufactured. Suitable manufacturing techniques may include injection molding, press formation, lathing, or any other technique known for forming the material in the art.

In a variation of the method presented above, multiple plungers 200 for intraocular lens delivery systems 200 with different resistances can be manufactured by selecting different forces at step 302. In particular embodiments of this variant method, step 302 may include selection of multiple resistance values based on considerations similar to the ones described above to provide for different surgical needs. Likewise, multiple designs for the deflectable members 204 may be determined that correspond to the different resistances, and step 306 would then include the manufacture of multiple plungers 200 along with injector bodies 102 that may be either common to the various plungers 200 or customized to work with plungers 200 having particular deflectable members 204. Although this particular variation has been described in detail, it should also be understood that other variations to the manufacturing method consistent with the description of the various embodiments of the intraocular lens delivery system 100 described herein could also be employed.

While certain embodiments of the present invention have been described above, these descriptions are given for purposes of illustration and explanation. Variations, changes, modifications and departures from the devices and methods

disclosed above may be adopted without departure from the scope of the present invention as claimed.

What is claimed is:

1. An intraocular lens delivery system, comprising:

an injector body having a bore surrounded by an inner wall;

a plunger configured to fit within the bore; and

a plurality of deflectable members connected to the plunger and configured to contact the inner wall and to be deflected when the plunger is inserted within the bore, wherein the deflectable members center the shaft and wherein the plurality of deflectable members, when inserted within the injector body, contribute to producing a predetermined force resisting advancement of the plunger when deflected in the bore.

2. The system of Claim 1, wherein the deflectable members are arc-shaped and configured such that a peak of each arc-shaped deflectable members contacts the inner wall.

3. The system of Claim 1, wherein the predetermined force resisting advancement of the plunger is based on a survey of a plurality of physicians.

4. The system of Claim 1, wherein the plurality of deflectable members comprises a first pair of deflectable members and a second pair of deflectable members, wherein the first pair is closer to a distal end of the plunger than the second pair.

5. The system of Claim 1, wherein the plunger and the plurality of deflectable members are formed as a single piece from a material.

6. The system of Claim 5, wherein the material is selected from polypropylene or polyethylene.

7. A method of manufacturing an intraocular lens delivery system, comprising:

determining a resistance force to advancement of a plunger within an injector body having a bore surrounded by an inner wall;

determining a shape for a plurality of deflecting members connected to the plunger that will deflect when the plunger is received within the bore of the injector body to contribute to producing the predetermined resistance force; and

manufacturing an intraocular lens delivery system including the injector body, the plunger, and the plurality of deflecting members.

8. The method of Claim 7, wherein the deflectable members are arc-shaped and configured such that a peak of each arc-shaped deflectable members contacts the inner wall.

9. The method of Claim 7, wherein the predetermined force resisting advancement of the plunger is determined based on a survey of a plurality of physicians.

10. The method of Claim 7, wherein the step of manufacturing the intraocular lens delivery system comprises forming the plunger and the plurality of deflectable members as a single piece from a material.

11. The method of Claim 10, wherein the material is selected from polypropylene or polyethylene.

12. The method of Claim 7, wherein:

the predetermined force is a first predetermined force;

the intraocular lens delivery system is a first intraocular lens delivery system with a first plurality of deflectable members; and

the method further comprises:

determining a second predetermined force different from the first predetermined force;

determining a shape for a second plurality of deflectable members connected to the plunger that will deflect when the plunger is received within the bore of the injector body to contribute to producing the second predetermined resistance force; and

manufacturing a second intraocular lens delivery system including the cartridge, the plunger, and the second plurality of deflectable members.

13. The method of Claim 12, wherein:

the plunger for the first intraocular lens delivery system is formed with the first plurality of deflectable members as a single piece from a material; and

the plunger for the second intraocular lens delivery system is formed with the second plurality of deflectable members as a single piece from the material.

14. The method of Claim 13, wherein the material is selected from polypropylene and polyethylene.

Fig. 1

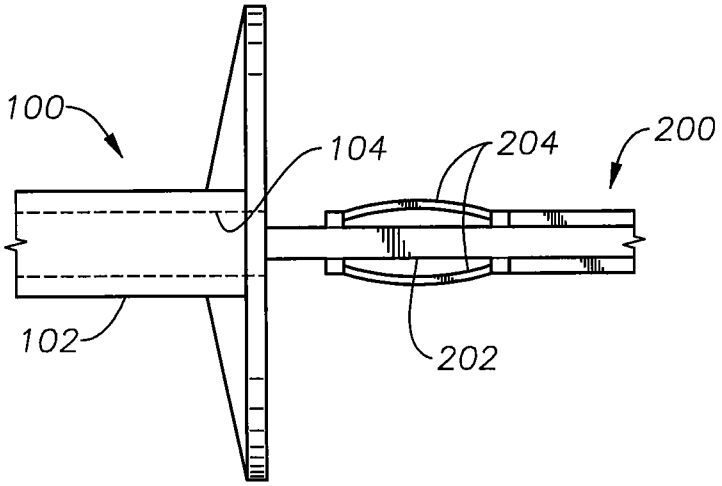


Fig. 2A

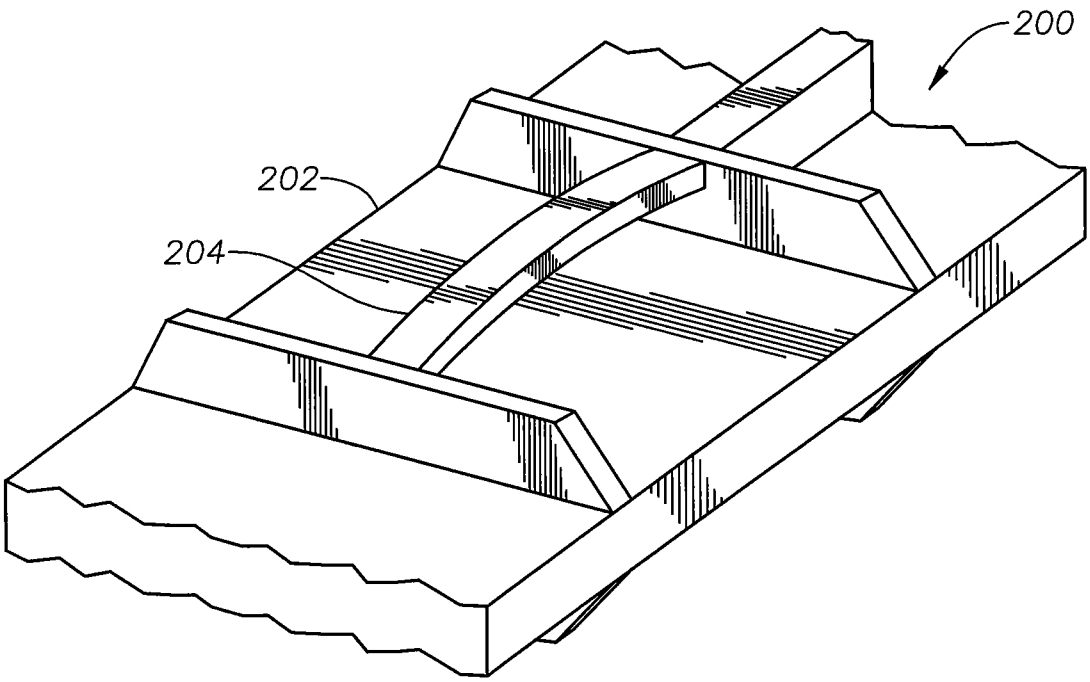


Fig. 2B

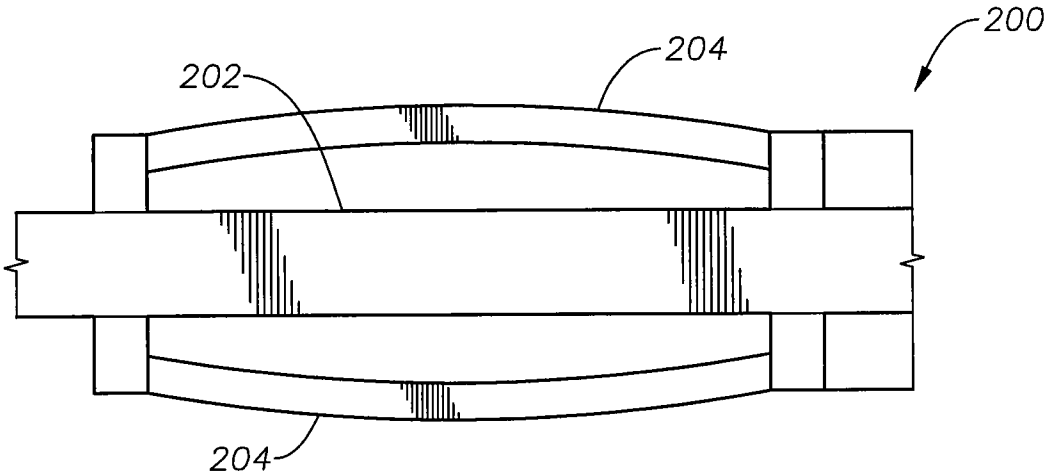
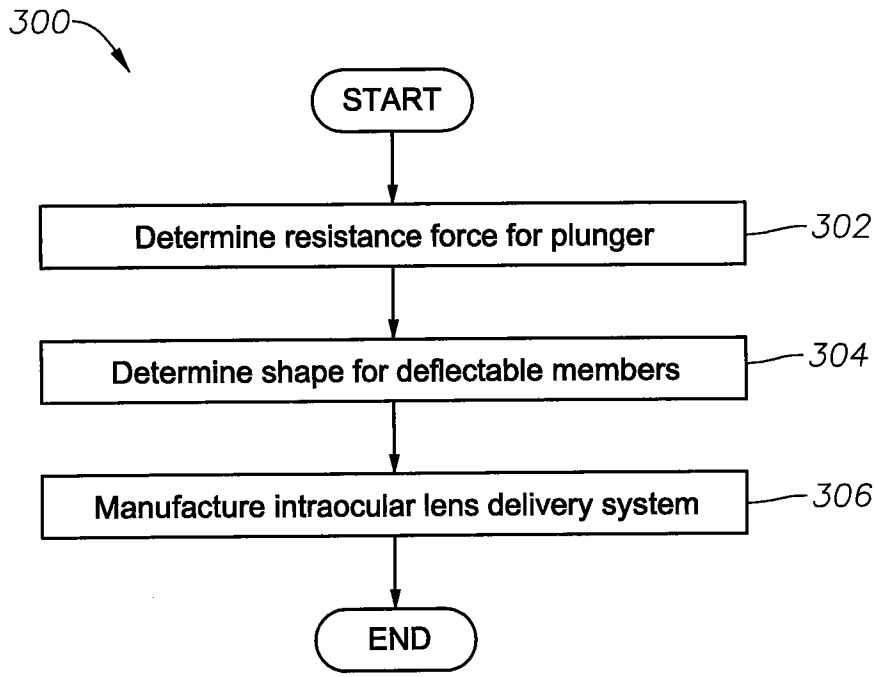

200
204
202
204

Fig. 3


300
START
Determine resistance force for plunger
302
Determine shape for deflectable members
304
Manufacture intraocular lens delivery system
306
END

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/037374

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/16
ADD.

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)
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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/149057 A1 (RATHERT BRIAN D [US]) 7 July 2005 (2005-07-07) paragraph [0016] - paragraph [0021]; figures 2-5	1,2,4-8, 10,11
X	WO 2007/080868 A1 (HOYA CORP [JP]; ICHINOHE TAKASHI [JP]; KUDOH KAZUNORI [JP]) 19 July 2007 (2007-07-19) * abstract paragraphs [0004] - [0007], [0048]; figure 12	1,2,4-8, 10-14
X	EP 1 958 594 A1 (ALCON RES LTD [US]) 20 August 2008 (2008-08-20) paragraphs [0013] - [0015]; figure 3	1,4,7

☐ Further documents are listed in the continuation of Box C.

☒ See patent family 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)

"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 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 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

Date of the actual completion of the international search	Date of mailing of the international search report
27 August 2010	03/09/2010

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, Fax: (+31-70) 340-3016	Chevalot, Nicolas

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/037374

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 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. [X] Claims Nos.: 3, 9
because they relate to subject matter not required to be searched by this Authority, namely:

The subject-matter of claims 3 and 9 will not be search: said subject-matter is related to performing a purely mental act, Rule 39(1)(iii) PCT.

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 No. III Observations where unity of invention is lacking (Continuation of item 3 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 fees, this Authority did not invite payment of additional fees.

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 and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2010/037374

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005149057 A1	07-07-2005	WO 2005065589 A1	21-07-2005
WO 2007080868 A1	19-07-2007	NONE	
EP 1958594 A1	20-08-2008	AR 065375 A1	03-06-2009
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		JP 2008194478 A	28-08-2008
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		RU 2375992 C2	20-12-2009
		US 2008200921 A1	21-08-2008