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(54) Title: MINIATURE GLAUCOMA SHUNT

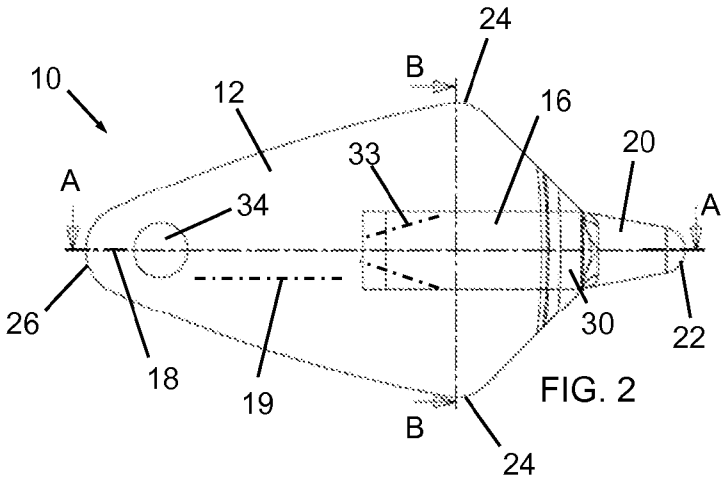

FIG. 2

(57) Abstract: A glaucoma shunt (10) for reducing intraocular pressure (IOP) is provided. The glaucoma shunt (10, 50) includes a first planar element (12) from which extends a divider element (16). The first planar element (12) and the divider element (16) form two passageways (32) for aqueous evacuation.

WO 2014/152072 A1

MINIATURE GLAUCOMA SHUNT

FIELD OF THE INVENTION

The present invention relates generally to an ophthalmic implant for treating glaucoma, and particularly to a miniature glaucoma shunt.

BACKGROUND OF THE INVENTION

There are well known surgical techniques to treat glaucoma. The most widely used is the trabeculectomy, which involves removing a portion of scleral tissue that includes part of the trabecular meshwork and Schlemm's canal.

Another way to treat glaucoma is to surgically implant a drainage device in the eye. The drainage device functions to allow aqueous humor to drain from the anterior chamber and thereby reduce the intraocular pressure. The drainage device is usually implanted using an invasive surgical procedure. Pursuant to one such procedure, a flap is surgically cut in the sclera. The flap is folded back to form a small pocket and the drainage device is inserted into the eye through the flap. This procedure can be quite problematic as the implants are large and can result in various adverse events such as infections, erosions, and scarring, leading to the need to re-operate.

Another surgical technique, although currently less commonly performed, is the so-called Non-Penetrating Glaucoma Surgery (NPGS) in which the trabecular meshwork is left in place to act as a natural filtering membrane. NPGS includes variations such as Deep Sclerectomy, Viscocanalostomy and Canaloplasty. It is much safer than trabeculectomy, but requires extreme dexterity and a very long learning curve in order to be at least as efficient as trabeculectomy.

US Patent 7118547, to the co-inventor of the present invention, discloses a glaucoma surgery implant for non-penetrating glaucoma surgery (NPGS) made of a non-absorbable hydrophilic material. The implant is configured to be entirely covered by a scleral flap and totally contained in the intrascleral space.

US Patent 7862531, to the co-inventor of the present invention and a co-worker, provides a flow regulating implant with one or more grooves for allowing fluid flow.

SUMMARY OF THE INVENTION

The present invention seeks to provide an improved miniature glaucoma shunt (MGS), as is described more in detail below.

The MGS of the present invention is made of biocompatible materials that have been widely used intraocularly for decades, such as but not limited to, poly(methyl methacrylate) (PMMA) and poly(2-hydroxyethyl methacrylate) (polyHEMA) or

hydrophilic acrylic. The MGS of the present invention is minimally invasive, usually requiring an incision of less than 1 mm in length for its insertion. The MGS is placed under a scleral flap (similar to classic trabeculectomy) and does not require a high conjunctival bleb for its function. The aqueous from the anterior chamber is drained via the MGS into an intrascleral pocket (intrascleral bleb) and also suprachoroidally, and achieves a mainly blebless drainage of the aqueous humor.

The MGS of the present invention is advantageous over all the currently known drainage devices of the prior art used to treat glaucoma.

For example, tube shunts, such as the seton tube shunts (e.g., the Ahmed Valve, the Baerveldt and Molteno implants) are bulky and the surgery is heavily invasive. Consequently, setons are used primarily in end stage refractory glaucoma. In contrast, the MGS of the present invention is only a few millimeters in size and can be used in regular cases of glaucoma (open angle glaucoma), as well as in complicated cases (for example, narrow angle glaucoma, with the option of removing the natural lens of the eye beforehand, such as by phacoemulsification, in order to widen the angle of the eye). Setons are made from silicone tubes that are less biocompatible than the materials that can be used for the MGS of the present invention, such as PMMA, polyHEMA, or other hydrophilic acrylic or hydrophobic acrylic materials. Setons have a considerable extrusion rate whereas it is unlikely that the MGS of the present invention placed under a scleral flap will extrude.

The EX-PRESS glaucoma filtration drainage device (from Alcon) is made of metal. Although the MGS of the present invention can be made of metal, it is preferably made of non-metallic biocompatible materials, as mentioned before, with which ophthalmologists are more familiar for surgical use in the eye. More importantly, the EX-PRESS needs an accurate direction for the pre-incision so the device tip does not touch the iris. The MGS of the present invention protrudes less into the anterior chamber than the EX-PRESS (1.5 mm versus 2.5 mm) and its tip is round and smooth and not sharp like the metallic EX-PRESS. The MGS of the present invention has at least two passageways for aqueous evacuation whereas the EX-PRESS has only one lumen, which can be blocked by blood or fibrin.

The iSTENT from Glaukos is a micro-invasive glaucoma surgery (MIGS) device that creates a permanent opening in the trabecular meshwork. The MGS of the present invention is much easier to insert than the iSTENT. The iSTENT is inserted into the Schlemm's canal using a surgical gonioscopy lens. This procedure is quite difficult

because the patient' head has to be tilted to allow good visualization of the trabecular meshwork and requires a high skill technique from the surgeon. In contrast, the MGS of the present invention is easily inserted into the anterior chamber by direct visualization. The iSTENT is made of metal. Although the MGS of the present invention can be made of metal, it is preferably made of non-metallic biocompatible materials, as mentioned before. The same advantages hold for the MGS of the present invention versus the GOLD SHUNT from iMED PHARMA.

There is thus provided in accordance with an embodiment of the present invention a glaucoma shunt including a first planar element from which extends at least one divider element. The first planar element and the divider element form at least two passageways for aqueous evacuation. The divider preferably, but not necessarily, has a minimal height of 20 microns.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawing in which:

Fig. 1 is a simplified sectional illustration of a portion of the human eye; and

Figs. 2-4 are simplified planar-view, sectional end-view and sectional side-view illustrations, respectively, of a glaucoma shunt, constructed and operative in accordance with an embodiment of the present invention, wherein Fig. 3 is taken along lines B-B in Fig. 2 and Fig. 4 is taken along lines A-A in Fig. 2; and

Figs. 5-8 are simplified planar-view, end-view, side-view and perspective view illustrations, respectively, of a glaucoma shunt, constructed and operative in accordance with another embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Reference is made to Fig. 1, which illustrates the anatomy of the human eye, and is presented here for better understanding of the implantation of the glaucoma shunt of the present invention.

The eye is covered on the outside by the sclera S and the cornea C. The conjunctiva CNJ lines the inside of the eyelids and covers the sclera S. The lens L is located near the front of the eye. The lens L provides adjustment of focus and is suspended within a capsular bag from the ciliary body CB, which contains the muscles that change the focal length of the lens. A volume in front of the lens L is divided into two by the iris I, which controls the aperture of the lens and the amount of light striking the retina. The pupil is a hole in the center of the iris I through which light passes. The

volume between the iris I and the lens L is the posterior chamber PC. The volume between the iris I and the cornea C is the anterior chamber AC. Both chambers are filled with aqueous humor, a clear liquid. The posterior section of the eye is filled and supported by the vitreous body, a clear, jelly-like substance. The supraciliary space SCi is the region between the ciliary body CB and the sclera S, and the suprachoroidal space SCh is the region between the sclera S and the choroid Ch.

The ciliary body CB continuously forms aqueous humor in the posterior chamber PC by secretion from the blood vessels. The aqueous humor flows around the lens L and iris I into the anterior chamber AC and exits the eye through the trabecular meshwork, a sieve-like structure situated at the corner of the iris I and the wall of the eye (the iridocorneal angle). Some of the aqueous humor filters through the trabecular meshwork into Schlemm's canal, a small channel that drains into the ocular veins (aqueous veins). A smaller portion rejoins the venous circulation after passing through the ciliary body CB and eventually through the sclera S. This outflow path is known as the uveoscleral outflow path. In glaucoma one or more of the drainage flow paths becomes blocked.

Reference is now made to Figs. 2-4, which illustrate a glaucoma shunt 10, constructed and operative in accordance with a non-limiting embodiment of the present invention.

Glaucoma shunt 10 includes a first planar element 12 and a second planar element 14 that extend from opposite faces of a divider element 16, which may be positioned symmetrically on a central longitudinal axis 18 of elements 12 and 14. Alternatively, divider element 16 may be asymmetric with respect to the central longitudinal axis 18 of elements 12 and 14, as indicated by the broken line 19 in Fig. 2. A distal member 20 with a rounded tip 22 extends distally from a distal end of divider element 16 (or also from the distal ends of first and second planar elements 12 and 14). Distal member 20 has a streamlined or hydrodynamic shape (e.g., a rounded cone shape) for easy insertion of shunt 10 through the incision.

The first planar element 12 has a length and width extending along a planar surface 13 and a thickness perpendicular to the planar surface 13. The divider element 16 extends perpendicularly from planar surface 13. The divider element 16 is shorter than or equal to the length of first planar element 12 and the width of divider element 16 is less than the width of first planar element 12.

First and second planar elements 12 and 14 may gradually widen from their distal ends to a maximum width portion indicated by reference numeral 24 (Fig. 2) and then

taper to a rounded proximal extremity 26. Shapes of first and second planar elements 12 and 14 may include, without limitation, egg and leaf shapes, e.g., ovate, obovate, cuneate, truncate and others. In one embodiment, first and second planar elements 12 and 14 are substantially parallel to each other. First and second planar elements 12 and 14 can be flexible to bend inwards or outwards with respect to each other.

The portions of first and second planar elements 12 and 14 proximal to divider element 16 are separated by a gap 28. First and second planar elements 12 and 14, divider element 16 and gap 28 form two flow passageways 32 (Fig. 3) for aqueous evacuation. The proximal end of divider element 16 may have a streamlined or hydrodynamic shape for reducing drag of the liquid flow through passageways 32, as indicated by broken lines 33 in Fig. 2.

A stopper element 30, which may be shaped like a dorsal fin, extends from a distal portion of one of first and second planar elements 12 and 14, such as first planar element 12. Stopper element 30 may be useful in preventing egress (extrusion) of the shunt 10 from the eye after implantation. Stopper element 30 can easily be inserted through the small insertion incision at an angle.

The MGS 10 is only a few millimeters in size (from distal to proximal ends the length can be 3-6 mm, with a maximum width portion 24 of about 2 mm and plate thickness of 0.1-0.3 mm); the invention is not limited to these dimensions. The MGS 10 can be placed under a scleral flap and is small in size so it does not have the disadvantages of trying to insert large devices in a scleral flap. The MGS 10 protrudes only about 1.5 mm into the anterior chamber; the invention is not limited to these dimensions. The MGS 10 is easily inserted into the anterior chamber by direct visualization.

In one embodiment, both first and second planar elements 12 and 14 are inserted into the intrascleral space, that is, both are situated in the sclera S. In another embodiment, one of the first and second planar elements 12 and 14 is inserted into the suprachoroidal space SCh while the other one is inserted into the intrascleral space.

One of first and second planar elements 12 and 14 may be formed with an opening 34, which may assist in fixation of MGS 10. For example, a suture (not shown) may be passed through opening 34 for tying to tissue. In other embodiment, when the element with opening 34 is inserted into the suprachoroidal space SCh, choroidal tissue may jut through opening 34 and adhere to the sclera S, without any need for a suture.

Accordingly, shunt 10 drains aqueous humor from the anterior chamber of the eye into the subscleral, suprachoroidal and subconjunctival spaces, thereby reducing intraocular pressure (IOP). Shunt 10 achieves a mainly blebless drainage of the aqueous humor.

Reference is now made to Figs. 5-8, which illustrate a glaucoma shunt 50, constructed and operative in accordance with a non-limiting embodiment of the present invention.

Glaucoma shunt 50 is constructed basically the same as shunt 10, except that shunt 50 has only the first planar element 12 and does not have a second planar element. As with shunt 10, in shunt 50 the divider element 16 creates two flow passageways 32 for aqueous evacuation, except that the passageways are not bound by a second planar element. In all embodiments of the invention, more dividers may be added to the central divider in order to optimize the flow of the aqueous humor through the implant. The additional dividers may be parallel or not parallel to the first divider (as shown in broken lines in Fig. 5), and as mentioned previously, the first divider does not have to be central.

CLAIMS

What is claimed is:

1. A device comprising:

a glaucoma shunt (10, 50) comprising a first planar element (12) that has a length and width extending along a planar surface;

characterised by at least one divider element (16) extending perpendicularly from the planar surface, said divider element (16) having a length shorter than or equal to the length of said first planar element (12) and a width less than the width of said first planar element (12), wherein said divider element (16) and said first planar element (12) form at least two flow passageways (32) on opposite sides of said divider element (16) for aqueous evacuation.

2. The device according to claim 1, further comprising a second planar element (14), wherein said first planar element (12) and said second planar element (14) extend from opposite faces of said divider element (16), and wherein portions of said first and second planar elements (12, 14) proximal to said divider element (16) are separated by a gap (28).

3. The device according to claim 1 or claim 2, wherein a distal member (20) with a rounded tip extends distally from a distal end of said divider element (16).

4. The device according to claim 1 or claim 2, wherein said divider element (16) is positioned symmetrically on a central longitudinal axis (18) of said first planar element (12).

5. The device according to claim 1 or claim 2, wherein said divider element (16) is positioned asymmetrically with respect to a central longitudinal axis (18) of said first planar element (12).

6. The device according to claim 2, wherein each of said first and second planar elements (12, 14) gradually widen from a distal end thereof to a maximum width portion and then taper to a rounded proximal extremity.

7. The device according to claim 2, wherein said first and second planar elements (12, 14) are substantially parallel to each other.

8. The device according to claim 2, wherein said first and second planar elements (12, 14) are sufficiently flexible to bend inwards or outwards with respect to each other.

9. The device according to any one of claims 1-8, wherein a proximal end of said divider element (16) has a streamlined or hydrodynamic shape for reducing drag of liquid flow through said passageways (32).

10. The device according to any one of claims 1-9, wherein a stopper element (30) extends from a distal portion of said first planar element (12), said stopper element (30) being configured to prevent egress of said shunt (10) from an eye after implantation.

11. The device according to any one of claims 1-10, wherein said first planar element (12) is formed with an opening (34).

12. The device according to claim 2, wherein one of said first and second planar elements (12, 14) is formed with an opening (34).

13. The device according to any one of claims 1-12, wherein said divider element (16) comprises more than one divider element.

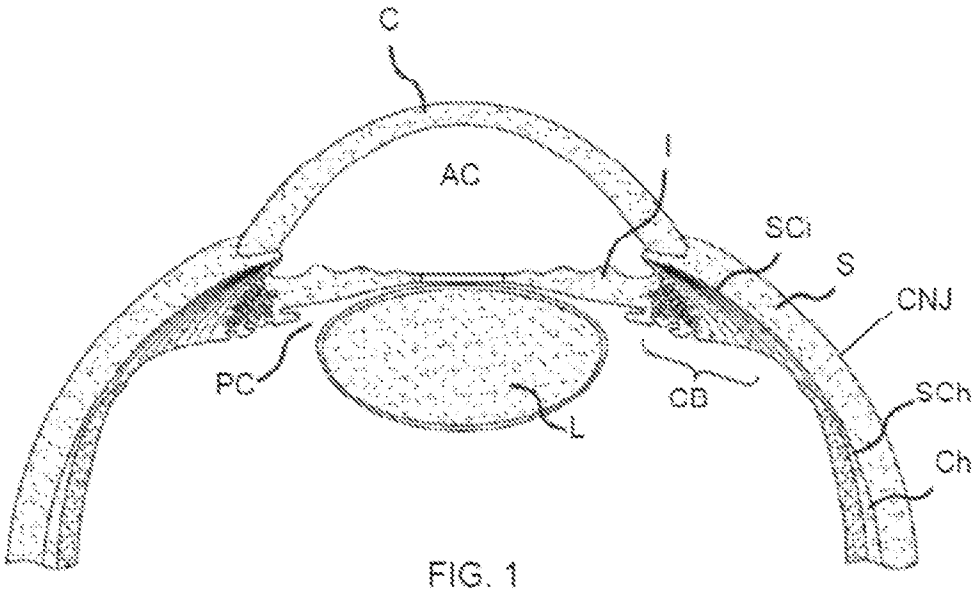

FIG. 1
PRIOR ART

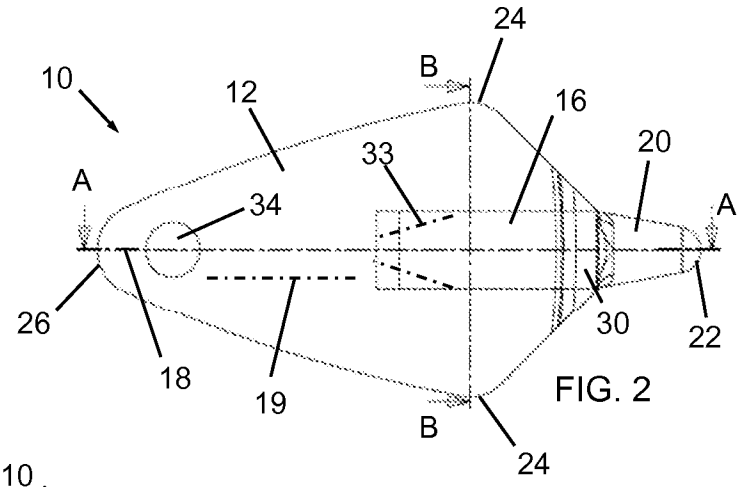

FIG. 2

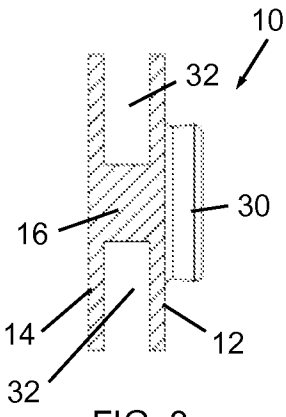

FIG. 3

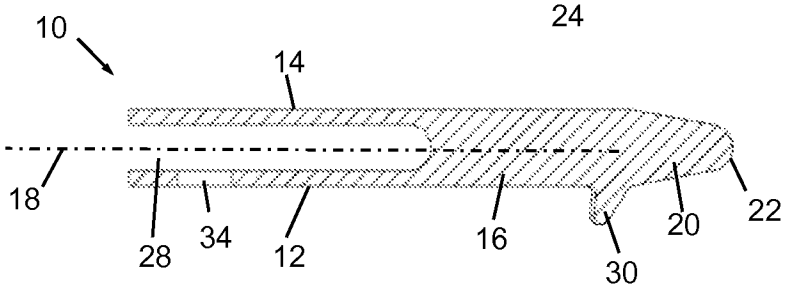

FIG. 4

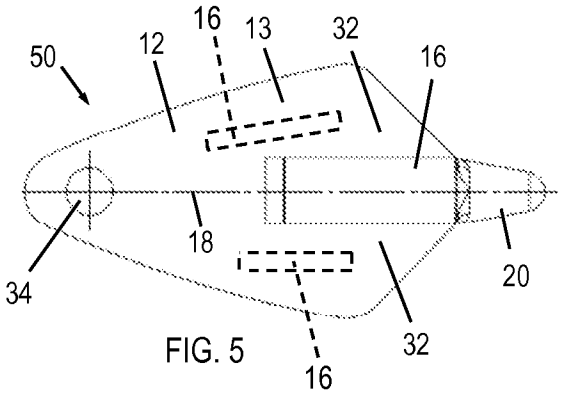

FIG. 5

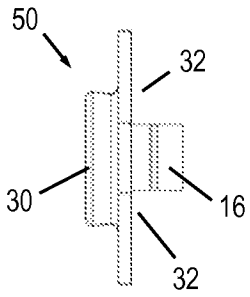

FIG. 6

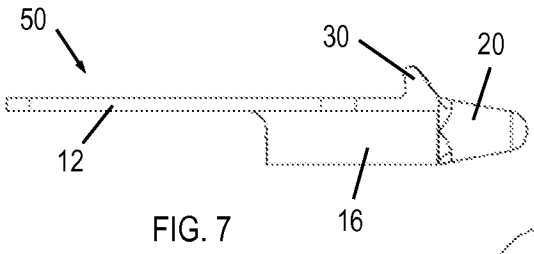

FIG. 7

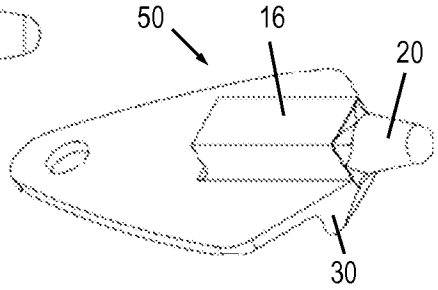

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/026917

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F9/007
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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/254521 A1 (SIMON GABRIEL [ES]) 16 December 2004 (2004-12-16) paragraph [0069]; figure 4	1-13
X	US 2005/288617 A1 (YARON IRA [IL] ET AL) 29 December 2005 (2005-12-29) cited in the application paragraphs [0026] - [0035]; figures 1-3	1-13
X	US 2011/105990 A1 (SILVESTRINI THOMAS A [US]) 5 May 2011 (2011-05-05) paragraphs [0034], [0035]; figure 6C	1,4

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

☒ See patent family annex.

* Special categories of cited documents :

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"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
8 July 2014	17/07/2014

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

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2014/026917

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004254521 A1	16-12-2004	AU 2004247272 A1	23-12-2004
		CA 2529495 A1	23-12-2004
		EP 1638508 A2	29-03-2006
		JP 2007526013 A	13-09-2007
		US 2004254521 A1	16-12-2004
		WO 2004110391 A2	23-12-2004
US 2005288617 A1	29-12-2005	AU 2005267539 A1	02-02-2006
		CA 2571871 A1	02-02-2006
		CN 101076305 A	21-11-2007
		CN 101732125 A	16-06-2010
		EP 1765234 A2	28-03-2007
		JP 4723577 B2	13-07-2011
		JP 2008504063 A	14-02-2008
		SG 153828 A1	29-07-2009
		US 2005288617 A1	29-12-2005
		US 2008077071 A1	27-03-2008
		WO 2006012009 A2	02-02-2006
US 2011105990 A1	05-05-2011	NONE	