(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
23 December 2010 (23.12.2010)

PCT

(10) International Publication Number
WO 2010/147658 A1

(51) International Patent Classification:
A61F 2/90 (2006.01)

(21) International Application Number:
PCT/US2010/001748

(22) International Filing Date:
17 June 2010 (17.06.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/187,689 17 June 2009 (17.06.2009) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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

(54) **Title**: MEDICAL DEVICE FIXATION ANCHOR SUITED FOR BALLOON EXPANDABLE STENTS

(57) **Abstract**: A balloon expandable anchor (204) for a medical device (200). The anchor barb is contained within the device compacted delivery profile and is balloon expanded to rest outside of the expanded device profile.

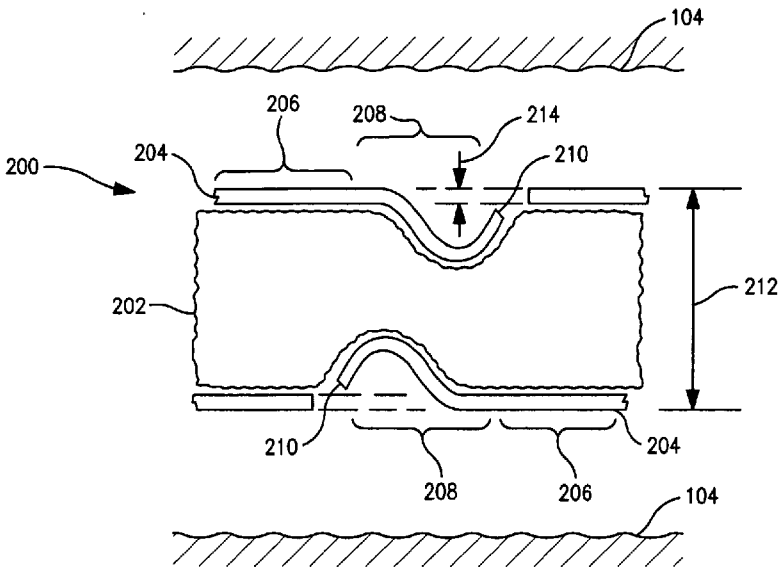


FIG. 2A

WO 2010/147658 A1

TITLE OF THE INVENTION

MEDICAL DEVICE FIXATION ANCHOR
SUITED FOR BALLOON EXPANDABLE STENTS

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims priority to provisional application US Serial No. 61/187,689, filed June 17, 2009.

BACKGROUND OF THE INVENTION

Field of the Invention

The invention relates to a medical device fixation anchor and in particular with an anchor that is suitable for use with a balloon expandable stent.

Discussion of the Related Art

Various medical devices require some form of fixation or anchoring to a targeted site. Common anchoring means include barbs, hooks, sutures, or other features used to attach a device to the surrounding anatomy. Some examples of devices requiring a means to anchor include vena-cava filters, stents, stent grafts, bile/urinary duct stents, intestinal/gastro stents and liners, occluders, electrophysiological leads, various monitors or diagnostic devices, central venous catheters, and other devices as commonly know in the art. Many of these devices incorporate a balloon expandable component that is expanded to bear against the surrounding anatomy, thus providing an anchoring means. The degree of positional anchoring of the medical device is normally dependent upon the degree of "over-expansion" of the balloon expandable component. When over-expanded, the expandable portion is aggressively forced against the surrounding anatomy, affecting a frictional or "interference-fit" means of anchoring. If the degree of over-expansion is excessive, the surrounding anatomy can be damaged. Conversely, if the degree of over-expansion is minimal, the device may dislodge due to poor anchoring.

An improved means of anchoring a balloon expandable component incorporates expandable anchors or barbs. These expandable anchors eliminate the need for aggressive over-expansion and provide a degree of anchoring if the over-expansion is minimal. An improved, balloon expandable anchor can also improve the retention of the expandable component to the balloon. The improved balloon expandable anchors can be contained within the profile of the expandable device, so they do not interfere with the delivery of the device.

SUMMARY OF THE INVENTION

An embodiment of the present invention includes a medical fixation device, comprising:

a medical fixation device having

a balloon expandable anchor with a device attachment portion, an expansion bearing portion and a barb portion;

the anchor expansion bearing portion being positioned between the anchor device attachment portion and the anchor barb portion;

the device attachment portion being coupled to an expandable medical device having a first compacted profile and a second expanded profile;

the anchor barb portion positioned within the first compacted profile; and the anchor being deformed to extend the anchor barb portion outside the second expanded profile.

Additional features and advantages of the invention will be set forth in the description or may be learned by practice of the invention. These features and other advantages of the invention will be realized and attained by the structure particularly pointed out in the written description and claims hereof as well as the appended drawings.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory and are intended to provide further explanation of the invention as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings are included to provide a further understanding of the invention and are incorporated in and constitute a part of this specification, to illustrate embodiments of the invention, and together with the description serve to explain the principles of the invention.

Figure 1A is a partial side view of a medical device prior to implantation. The medical device shown is a balloon expandable stent surrounding a balloon and a delivery catheter.

Figure 1B is a partial side view of a medical device that has been balloon expanded.

Figures 2A and 2B are partial side views of an improved balloon expandable anchor showing the anchor barb contained within a first compacted device profile and shown outside of an expanded device profile.

Figure 3 is a partial side view of a balloon expanded medical device having two anchor barbs extending outside of a device expanded profile.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

The invention is directed to a medical device anchoring or fixation means that enhances the ease of initial compaction and subsequent device deployment.

Figures 1A and 1B show a general example of a medical device delivery sequence. Shown in partial side view, Figure 1A is a compacted medical device 100. The specific medical device shown is a balloon expandable stent 102. The medical device is shown positioned within a lumen 104. The balloon expandable stent 102 is shown compacted onto a balloon (not shown) and delivery catheter 106.

Shown in partial side view, Figure 1B is the medical device 100 in an expanded state. Shown are a balloon expandable stent 102 (shown in an expanded shape), an expanded balloon 108 and the delivery catheter 106. In a typical procedure, the internal balloon pressure expands a malleable stent (or other device), forcing the malleable stent into contact with the surrounding anatomy or lumen wall 104. The

magnitude of balloon pressure normally dictates the outer profile of the stent and the degree of over-expansion or embedding into a vessel wall.

Figures 2A and 2B are partial side views of an improved balloon expandable anchor. The expandable medical device 200 is shown within a lumen 104 and surrounding an inflatable balloon 202. The medical device has an expandable anchor 204 having a device attachment portion 206 (used to couple the anchor to a medical device), an expansion bearing portion 208 and a barb portion 210. As shown in Figure 2A, the medical device 200 is shown having a first compacted profile 212. As shown, the anchor barb portion 210 is contained within 214 the first compacted profile 212. An expansion bearing portion 208 can be configured in a variety of ways and may include curved, protruding, flat, or any other profile that will result in the barb portion 210 being contained within the first compacted profile 212.

As shown in Figure 2B, the internal balloon pressure 216 forces the medical device 200 to expand to a second expanded profile 218. Upon expansion, the balloon 202 contacts the expansion bearing portion 208 forcing the expandable anchor 204 to expand so that the barb portion 210 extends outside 220 of the second expanded profile 218.

Shown in Figure 3 is a partial side view of a balloon expandable medical device 300, surrounding an expanded balloon 108 and a delivery catheter 106. The expanded medical device 300 is shown having a second expanded profile 302 and two anchor barb portions 210. The two anchor barb portions 210 are shown extending outside 304 of the second expanded profile 302.

Although shown with expanding balloons, the expandable anchors of the present invention may also be used with other means to expand, such as mechanical bow-arms, expandable "Chinese lanterns", expandable baskets, or other expanding devices or materials.

Balloon expandable anchors can comprise commonly known materials (or combinations of materials) used in the manufacture of balloon expandable stents. Typical materials include 316L stainless steel, cobalt-chromium-nickel-molybdenum-iron alloy ("cobalt-chromium"), other cobalt alloys such as L605, tantalum, malleable Nitinol, or other bio-compatible malleable metals. Other suitable materials include specialized malleable polymers, malleable bio-absorbable materials, and the like.

Typical methods used in the assembly of anchors to medical devices include commonly known techniques used to attach two or more components. Examples of permanent attachments include the use of glues, adhesives, welds, insert molding, heavy press-fits, one-way snap or lock features, pressed pins, heat staking, and rivets. Examples of semi-permanent attachments or those that require a tool to separate the components include screws, threaded fasteners, snap-rings, and snap-fits. Examples of releasable attachments or those that can be separated by hand without the use of an additional tool include snap-fits, twist lock features, push to release features, squeeze to release features, slide levers, latches, and light press-fits.

Anchors can have various cross-sectional profiles such as circular, oval, rectangular, or other polygon shapes. Anchors can also incorporate external lubricious layers, lubricious coatings, or lubricious wrappings to minimize friction. Anchors can also incorporate therapeutic agents tailored for specific biological results. Anchors can also include radiopaque markers or radiopaque intensifiers.

While particular embodiments of the present invention have been illustrated and described herein, the present invention should not be limited to such illustrations and descriptions. It should be apparent that changes and modifications may be incorporated and embodied as part of the present invention within the scope of the following claims.

WHAT IS CLAIMED IS:

1. An anchor comprising a device attachment portion, a barb portion, and an expansion bearing portion.

2. A medical fixation device, comprising:
a balloon expandable anchor having a device attachment portion, an expansion bearing portion and a barb portion;
the anchor expansion bearing portion being positioned between the anchor device attachment portion and the anchor barb portion;
the device attachment portion being coupled to an expandable medical device having a first compacted profile and a second expanded profile;
the anchor barb portion positioned within the first compacted profile; and
the anchor being deformed to extend the anchor barb portion outside the second expanded profile.

3. The device of claim 1 wherein the expansion bearing portion is positioned between the device attachment portion and the barb portion.

4. An anchorable medical device, comprising:
a. a medical device
b. a barb and
c. an expansion bearing portion positioned between the device and the barb.

5. The medical fixation device of claim 1 wherein the barb portion is metal.

6. The medical fixation device of claim 1 wherein the expansion bearing portion is linear.

7. The medical fixation device of claim 1 wherein the expansion bearing portion is non-linear.

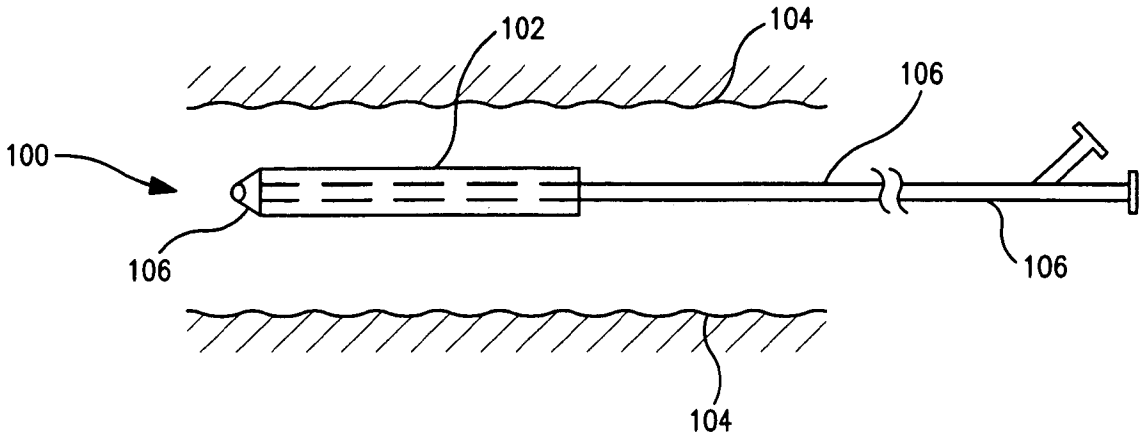


FIG. 1A
PRIOR ART

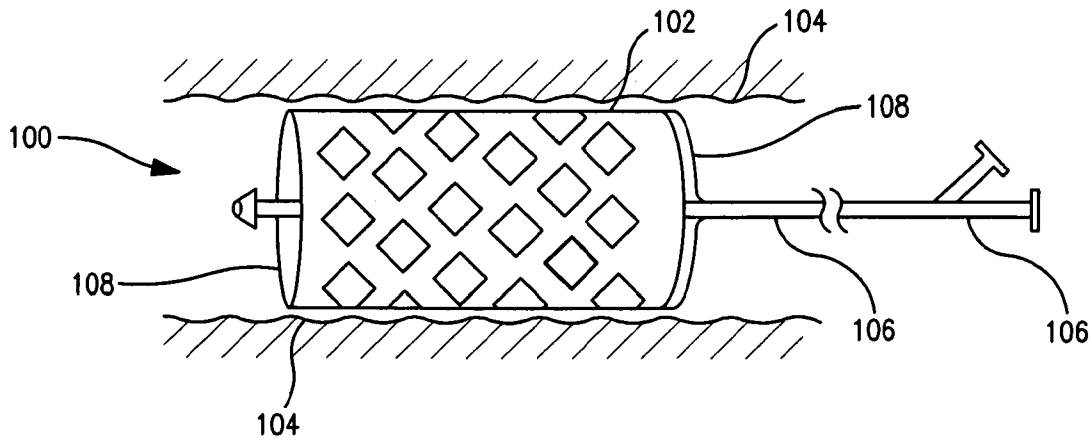
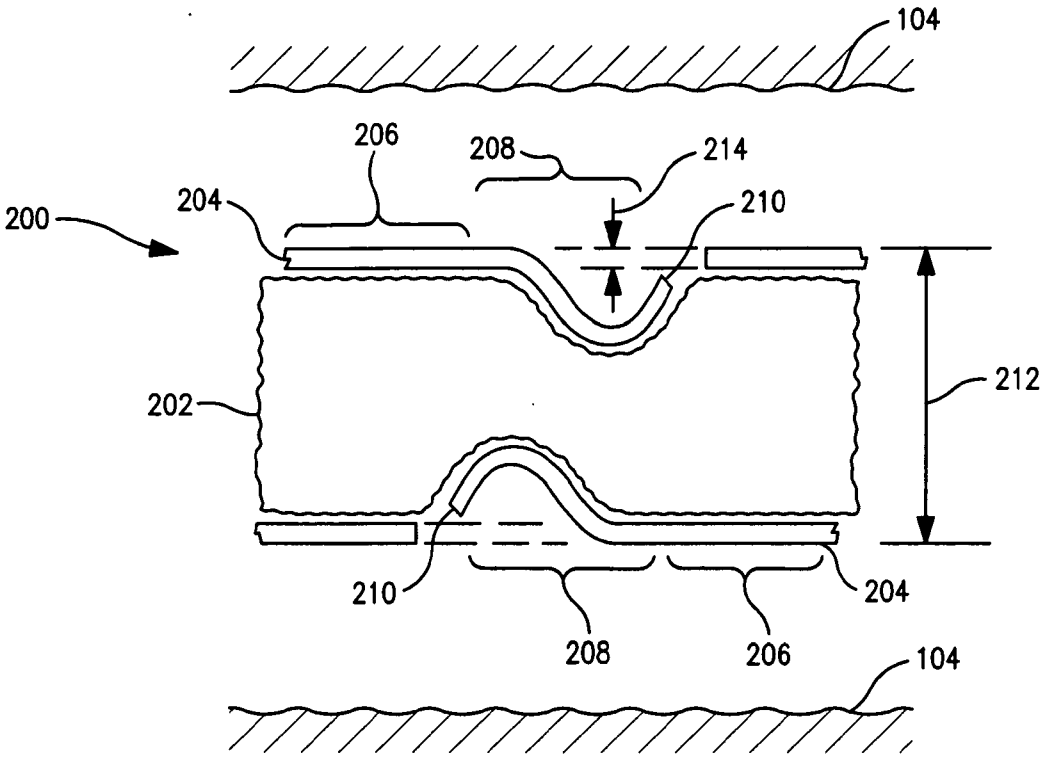


FIG. 1B
PRIOR ART


104
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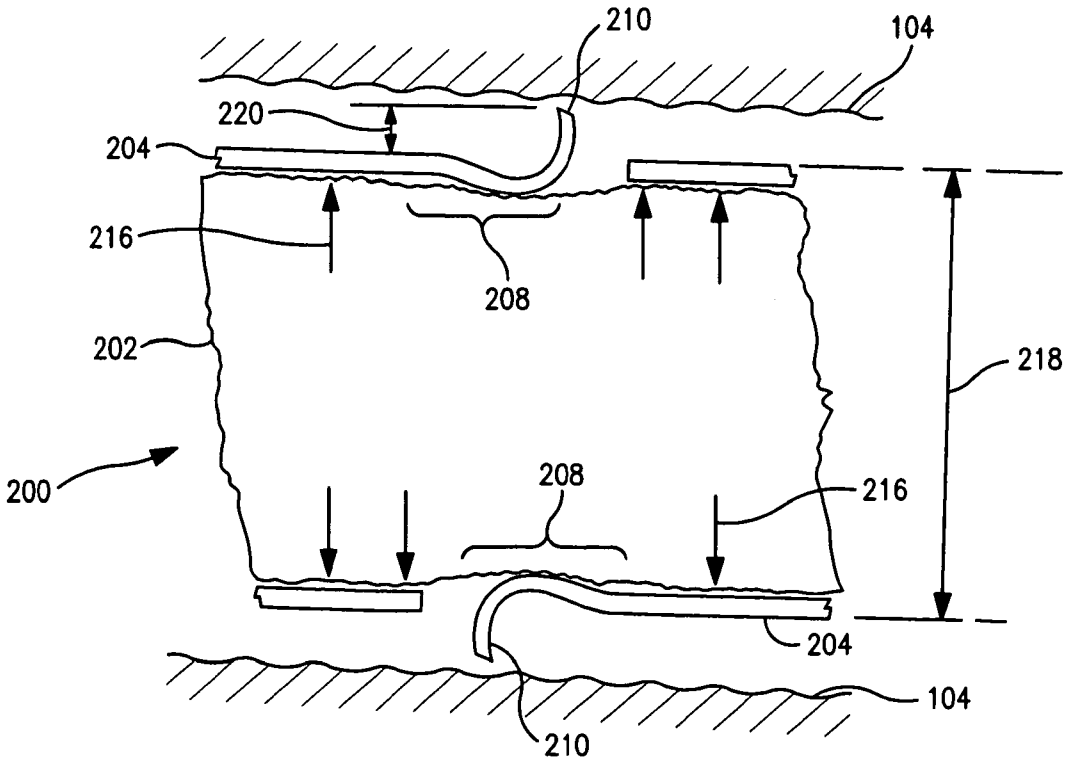
104

FIG. 2A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216
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FIG. 2B

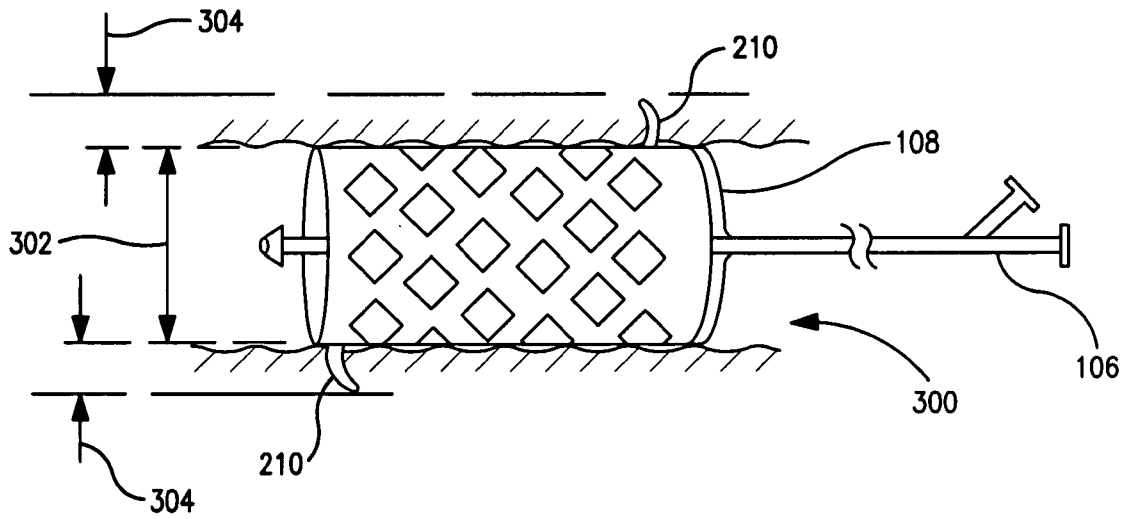

FIG. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/001748

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/90
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	WO 01/76509 A1 (ENDOVASCULAR TECH INC [US]) 18 October 2001 (2001-10-18) page 6, line 2 - line 12; figures 1,2	1-7
X	EP 0 732 088 A2 (ADVANCED CARDIOVASCULAR SYSTEM [US]) 18 September 1996 (1996-09-18) column 7, line 29 - column 10, line 8; figures 1,2	1-7

☐ 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
28 July 2010	04/08/2010

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2010/001748

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