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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
11 November 2010 (11.11.2010)

PCT

(10) International Publication Number
WO 2010/129685 A1

(51) International Patent Classification:
A61F 2/06 (2006.01)

(21) International Application Number:
PCT/US2010/033745

(22) International Filing Date:
5 May 2010 (05.05.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0907809.8 6 May 2009 (06.05.2009) GB

(71) Applicants *(for all designated States except US)*: **WILLIAM COOK EUROPE APS** [DK/DK]; Sandet 6, DK-4632 Bjaeverskov (DK). **COOK INCORPORATED** [US/US]; 750 N. Daniels Way, Bloomington, IN 47404 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **MOERK, Tina** [DK/DK]; Ringstedvewj 632C, DK-4100 Ringsted (DK). **PETERSEN, Jesper, Schade** [DK/DK]; Dystedvej 12, DK-4684 Holmegaard (DK). **SOERENSEN, Marianne** [DK/DK]; Kaerehave Skovvej 19, DK-4100 Ringsted (DK).

(74) Agent: **GODLEWSKI, Richard, J.**; Cook Group Patent Office, P.O. Box 2269, Bloomington, IN 47402-2269 (US).

(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: STENT GRAFT

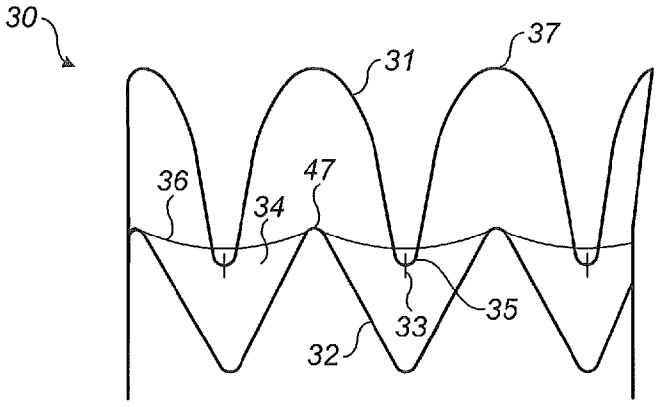


FIG. 2

(57) Abstract: A stent graft (30) has a bare end stent (31) which partially overlaps the next stent (32) with the end (36) of the graft material (34) being shaped to follow the distal peaks (35) of the end stent and the proximal peaks (47) of the next stent. The proximal peaks (37) of the end stent have a greater radius of curvature than the distal peaks (35) of the end stent.

WO 2010/129685 A1

STENT GRAFT

Description

Technical Field

The present invention relates to a stent graft and in particular to a stent graft for deployment in a curved body vessel such as the aortic arch.

Background Art

A problem with the deployment of stent grafts in the aortic arch is that a satisfactory engagement against the interior of the body vessel wall has to be maintained at the same time as matching the curved shape of the aortic arch. Satisfying both constraints involves a compromise in design and conventional stent grafts do not bend satisfactorily around the aortic arch.

Another design constraint is that the proximal end stent should be at least partly bare, i.e. have no graft material thereon, in order that blood flow may be maintained with side vessels.

US 2005/0049674 A1 discloses a stent graft having a proximal end stent which is substantially bare. The distal end of the proximal stent partially overlaps with the proximal end of the second stent. Viewed from the side, the end of the graft material is a straight line connecting the proximal bends of the second stent.

US 2006/0195172 A1 also discloses a stent graft with a substantially bare end stent which partially overlaps the second stent.

Stent grafts are also disclosed in US 5,824,037 and US 7,294,147 for example.

US 2006/0195177 discloses a stent graft in which stent graft material between two end rings is shaped with a V-recess to allow access to side vessels of the aortic arch.

A recent proposal for stent grafts for curved vessels is the so-called tri-fold device. This offers some improvement over conventional devices, but in certain cases the two most proximal stents can touch each other during deployment, which may cause the curvature of the stent graft to differ from the curvature of the body vessel.

Disclosure of The Invention

Aspects of the present invention seek to provide a stent graft, at least the proximal end of which can curve to match the curvature of a body vessel.

Other aspects of the invention seek to provide a stent graft, at least the proximal end of which can be compressed for passage through a relatively narrow pathway through the body before it is expanded at its deployment site.

According to a first aspect of the present invention, there is provided a stent graft member comprising a plurality of stents secured to graft material in which the distal end of a proximal, at least partially bare, stent overlaps longitudinally with the proximal end of the next stent, with distal peaks of the proximal stent lying between proximal peaks of the next stent, wherein the proximal end of the graft material has a shape with proximal peaks and distal peaks.

An advantage of this configuration is that is satisfies several design constraints. For example, it provides a flexible interconnection between the end stent and the next stent to enable the stent graft to more closely follow the inner curve of the aortic arch, and thus a more precisely aligned location of the stent graft in the body vessel. Furthermore, the configuration permits the stent graft, and in particular its proximal end, to be folded into a compact arrangement when compressed. This can be attributed, at least in part, to the absence of graft material where it is not required.

Preferably, the stents are formed of wire and the distal peaks of the bare stent overlap the proximal peaks of the next stent, at least in a compressed configuration of the stent graft member, by a distance equal to at least twice the thickness of the wire. This further assists in enabling a compact compressed configuration. Viewed circumferentially, there is effectively double thickness of wire at each stent peak; by avoiding alignment of the distal peaks of the proximal stent and the proximal peaks of the next stent, resistance to compression is avoided.

In an alternative arrangement, when folded in a compressed configuration, the distal end of the proximal stent does not overlap longitudinally with the proximal end of the next stent.

In preferred arrangements the distal peaks of the curve in the graft material are located at or adjacent distal peaks of the proximal stent, and proximal peaks of the curve are located at or adjacent proximal peaks of the next stent. This provides a substantially symmetrical configuration which can be neatly folded into a compressed configuration.

Preferably, the proximal peaks of the proximal stent have a greater radius of curvature than the distal peaks of the proximal stent. The relatively large radius of the proximal peaks avoids their undesired entry into side vessels of the aorta. The relatively small radius of curvature of the distal peaks contributes to a smaller volume of wire which assists in packing when the end of the stent is compressed.

According to a second aspect of the present invention, there is provided a method of folding a stent graft member according to the first aspect comprising exerting radially inward forces on the proximal end of the stent graft member whereby the distal peaks of the end stent are moved radially inwardly beyond the proximal peaks of the next stent into a compressed configuration in which the distal peaks of the end stent are not aligned longitudinal with the proximal peaks of the next stent.

In one preferred method, in the compressed configuration, there is a longitudinal overlap between the distal peaks of the end stent and the proximal peaks of the next stent. Where the stents are made of wire, the longitudinal overlap of the peaks is equal to at least twice the thickness of the wire. Thus although there is still an overlap of the stents, the distal peaks of the end stent are sufficiently out of longitudinal alignment with the proximal peaks of the next stent that a concentration of wire material in one place is avoided.

In an alternative method, in the compressed configuration, there is no longitudinal overlap between the distal peaks of the end stent and the proximal peaks of the next stent.

Brief Description of the Drawings

Preferred embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, of which:

Figure 1 shows a side view of the proximal end of a stent graft member in accordance with the prior art;

Figure 2 shows the corresponding view of a stent graft member in accordance with the present invention in its expanded configuration;

Figure 3 shows a side view of the stent graft member of Figure 2 in a partially-folded configuration;

Figure 4 shows an end view of the stent graft member in the partially-folded configuration of Figure 3 but with the stents other than the end stent omitted for the purposes of clarity.

Figure 5 shows the stent graft member of Figures 2 to 4 in conjunction with an introducer apparatus; and

Figure 6 shows a side view of the proximal end of the stent graft member of Figures 2 to 5 in its deployed configuration.

Description of the Preferred Embodiments

Referring to the drawings, Figure 1 shows a stent graft 10 in accordance with the prior art. A proximal end stent 11 is substantially bare, that is only a relatively small part of the stent is covered with graft material 12. For most of its length, the wire forming stent 11 has no graft material on either side; at intervals, relatively short lengths of the wire have graft material on all sides. The next stent 14 is completely covered by the graft material. Viewed in the sideways or radial direction of the Figure, the end 16 of the graft material is a straight line. The graft material 12 and the stent members 11, 14 attached thereto are substantially circular in cross-section.

As seen in Figure 1, the distal peaks 21 of stent 11 overlap the proximal peaks 22 of the next stent 12 in the longitudinal direction. The peaks 21 and 22 alternate in regular manner around the periphery of the stent graft.

Problems can arise when compressing the stent graft 10 for passage through a relatively narrow body vessel to a deployment site. In particular, the graft material can interfere with the desired inward movement of the stents, for example it can directly constrain relative movement of the stents, or the material may fold to block the desired movement.

Figures 2 to 6 show the proximal end of an embodiment of a stent graft 30 in accordance with the present invention. The stent graft 30 is typically deployed in the aortic arch with a second stent graft (not shown) attached to its distal end. The length of the stent graft 30 lies between 145 and 220mm and the length of the distal stent graft lies between 145 and 195mm with a three stent overlap of the two stent grafts. The diameter of stent graft 30 lies within the range 22mm to 46mm and preferably in the range 30mm to 40mm. The stent graft 30 has a substantially free or bare stent 31 which differs from the stent 11 of Figure 1 in a number of ways. Firstly, the stent 31 is attached by suture

stitches 33 at or directly adjacent to respective distal peaks 35 of the stent. Thus there is, at most, only a very small area of graft material 34 covering stent 31. Secondly, the proximal peaks 37 of stent 31 have a relatively large radius of curvature compared to the distal peaks 35.

Stent 32 is conveniently configured to have five proximal peaks 37.

As before, the next stent 32 is completely covered by graft material 34 and is arranged with its proximal peaks 47 arranged regularly between the distal peaks 35 of stent 31. Stent 32 is conveniently configured as a laser cut canula stent which is formed from a tube in the manner of a silver stent with internal barbs.

Instead of being straight, the edge 36 of the graft material has a sinusoidal shape with its proximal peaks coinciding with the proximal peaks 47 of stent 32 and with its distal peaks aligned with and almost coincident with the distal peaks 35 of stent 31. The peak-to-peak dimension or wave "w" of the edge 36 is within the range 1-3mm, preferably 2mm.

Table 1 below gives the preferred internal diameter in French of a deployment sheath for use in introducing stent grafts of various diameter into a body vessel. The Table also gives the preferred number of points on the stents of the grafts.

Table 1

Graft Diameter in mm	Sheath I.D. (Fr)	Number of Points on Stent
22	16	5
24	16	5
26	16	5
28	16	5
30	16	5
32	18	6
34	18	6
36	18	6
38	18	6
40	18	7

42	18	7
44	20	8
46	20	8

Figure 2 shows the stent graft 30 in expanded configuration before folding or compression into a compact form before passage through a body vessel. Figures 3 and 4 show the stent graft 30 as folding commences. The distal peaks 35 of the end stent 31 move radially inwardly beyond the proximal peaks 47 of the next stent 32 to enable full compression. The peaks 35 are arranged at a sufficient axial spacing from the peaks 47 such that when folded the peaks 35 do not overlap the peaks 47.

Figure 5 shows the stent graft member 30 in its configuration after it has been deployed in a body vessel and expanded, but before it is released from an introducer apparatus 50. The proximal peaks 37 of the end stent 31 are held at the centre by the graft member by release wires 51 extending through apertures in a sleeve 52 of the introducer apparatus. For the purposes of clarity, the next stent 32 is indicated in broken lines in Figure 5.

Figure 6 shows the stent graft member 30 in its configuration after full deployment in a curved body vessel. The end stent 31 has been fully released for full expansion so that it can firmly engage the walls of the body vessel to hold the stent graft member in position.

The above-described stent graft has the advantage of being highly compressible. Volume is saved by the end stent being substantially completely bare. Moreover; the shaping of the end 36 of the graft material means that there is more space available for the stents; in addition by connecting the stents 31, 32, the graft material produces the desired relative movement of the stents so that, during compression, the distal peaks 35 move radially inwardly beyond the proximal peaks 47.

The packing efficiency of the arrangement is further improved by the relatively small radius of curvature of the distal peaks 35, which leads to a small volume. The relatively large radius of curvature of the proximal peaks 37 prevents these peaks from accidental entry into side blood vessels, while maintaining the desired engagement with the wall of the aortic arch.

During deployment of the stent graft 30, the flexible interconnection between the end stent 31 and the next stent 32 enables the end of the graft to more closely follow the inner curve of the aortic arch, which in turn leads to a more precisely aligned location of the graft in the body vessel. How this is achieved will now be briefly described. As a sheath covering the positioned stent graft is withdrawn, an introducer tip of the deployment assembly is arranged to automatically bend more tightly around the inner curve of the aortic arch. This bending causes the stent graft 30 to bend and the distal peaks 35 to fold inwardly and, by means of the graft material 34, pull in the proximal peaks 47 of the next stent 32 to allow precise and controlled bending of the graft 30.

Various modifications may be made to the above-described arrangement. The edge 36 of the graft material may be of any suitable curved or sinuous shape. The edge may have a regular saw-tooth shape with adjacent proximal and distal peaks being connected by straight lines.

The stent-graft may be deployed in any curved body vessel instead of the aortic arch.

Claims

1. A stent graft member (30) comprising a plurality of stents (31, 32) secured to graft material (34) in which the distal end of a proximal, at least partially bare, stent (31) overlaps longitudinally with the proximal end of the next stent (32), with distal peaks (35) of the proximal stent lying between proximal peaks (47) of the next stent, wherein the proximal end (36) of the graft material has a shape with proximal peaks and distal peaks.

2. A stent graft member according to claim 1, wherein the stents (31, 32) are formed of wire and the distal peaks (35) of the bare stent (31) overlap the proximal peaks (47) of the next stent (32), at least in a compressed configuration of the stent graft member, by a distance equal to at least twice the thickness of the wire.

3. A stent graft member according to claim 1 or 2, wherein the distal peaks of the curve in the graft material are located at or adjacent distal peaks (35) of the proximal stent (31), and proximal peaks of the curve are located at or adjacent proximal peaks of the next stent.

4. A stent graft member according to any preceding claim, wherein the proximal peaks (37) of the proximal stent (31) have a greater radius of curvature than the distal peaks (35) of the proximal stent.

5. A stent graft member according to any preceding claim, wherein the proximal end (36) of the graft material has a sinuous shape.

6. A stent graft member according to claim 5, wherein the peak-to-peak dimension of the sinuous shape lies within the range 1mm to 3mm.

7. A stent graft member according to claim 5 or 6, wherein the proximal end (36) of the graft material has a sinusoidal shape.

8. A stent graft member according to claim 1, wherein the proximal stent (31) is formed of wire and, except for relatively short lengths at the distal peaks thereof, the wire is free of graft material on all sides.

9. A stent graft member according to any preceding claim, wherein the dimensions of the stents (31, 32) and the graft material (34) are selected such that the member is able to be folded to a configuration in which the distal end (35) of the proximal stent (31) does not overlap longitudinally with the proximal end (47) of the next stent (32).

10. A method of folding a stent graft member (30) according to claim 1 comprising exerting radially inward forces on the proximal end of the stent graft member whereby the

distal peaks (35) of the end stent (31) are moved radially inwardly beyond the proximal peaks (47) of the next stent (32) into a compressed configuration in which the distal peaks of the end stent are not aligned longitudinally with the proximal peaks of the next stent.

11. A method according to claim 10 wherein, in the compressed configuration, there is a longitudinal overlap between the distal peaks (35) of the end stent (31) and the proximal peaks (47) of the next stent (32).

12. A method according to claim 11 wherein the stents (31, 32) are formed of wire and the longitudinal overlap is equal to at least twice the thickness of the wire.

13. A method according to claim 10 wherein, in the compressed configuration, there is no longitudinal overlap between the distal peaks (35) of the end stent (31) and the proximal peaks (47) of the next stent (32).

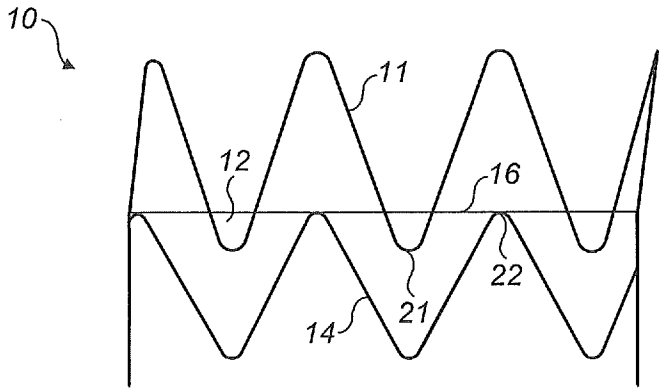


FIG. 1

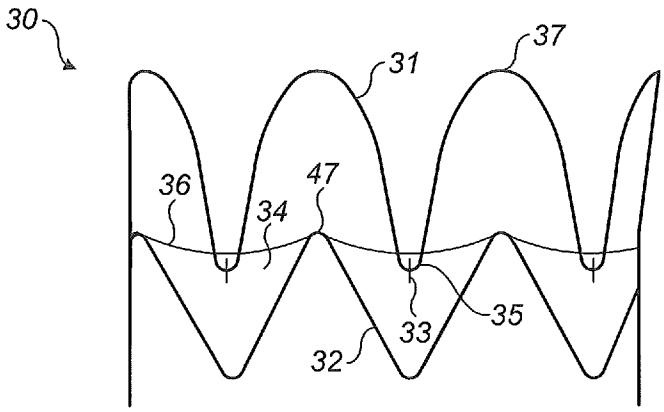


FIG. 2

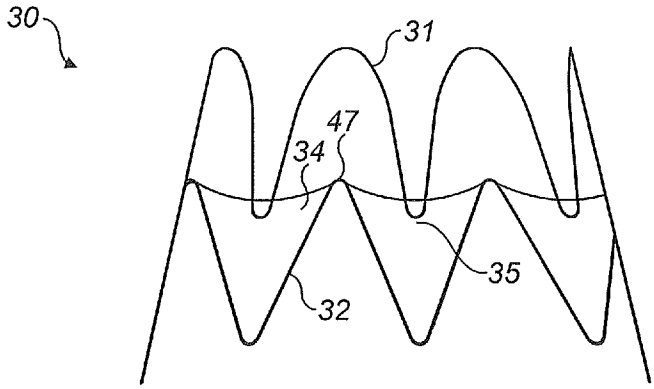


FIG. 3

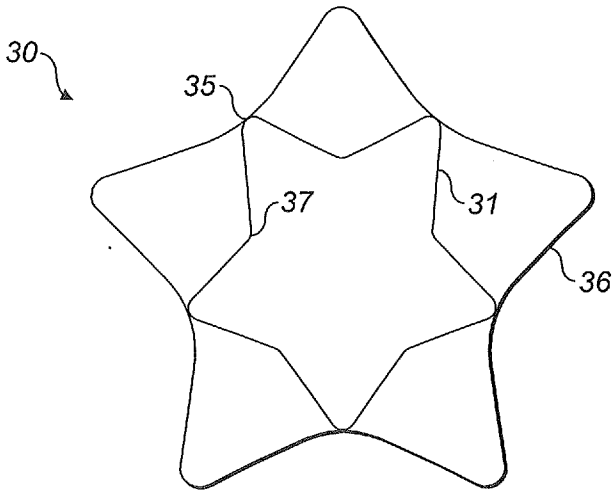


FIG. 4

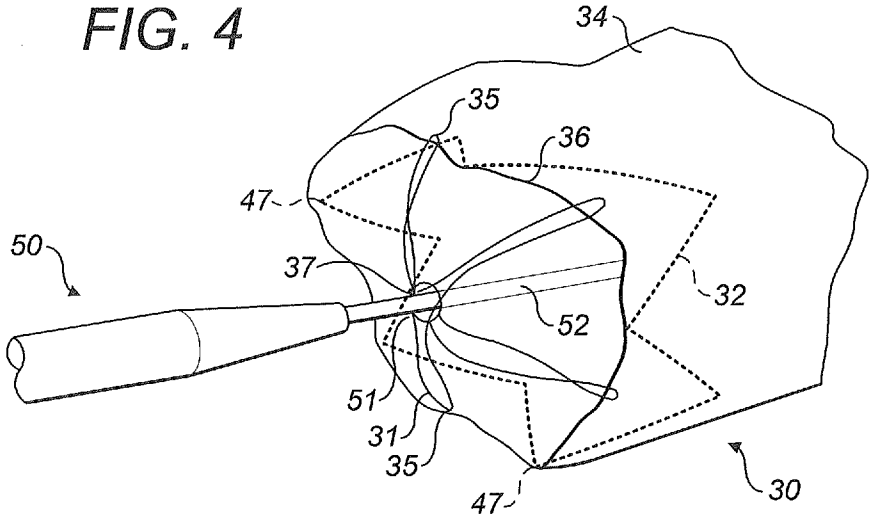


FIG. 5

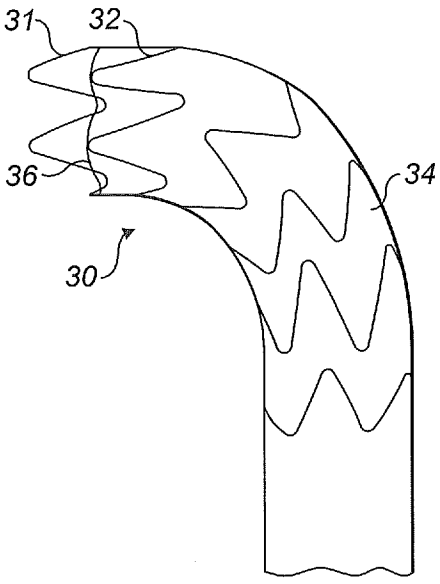


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/033745

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/06
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.
A	EP 1 772 120 A2 (BOLTON MEDICAL INC [US]; ARBEFEUILLE SAMUEL [US]) 11 April 2007 (2007-04-11) cited in the application paragraph [0058] - paragraph [0062]; figure 1	1
A	US 2006/195172 A1 (LUO QIYI [CN] ET AL) 31 August 2006 (2006-08-31) paragraph [0015]; figure 1	1
A	US 2008/114441 A1 (RUST MATTHEW [US] ET AL) 15 May 2008 (2008-05-15) paragraph [0041]; figure 6	1

☐ 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
9 July 2010	20/07/2010

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	Espuch, Antonio

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2010/033745

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1772120 A2	11-04-2007	EP 1776938 A2	25-04-2007
US 2006195172 A1	31-08-2006	NONE	
US 2008114441 A1	15-05-2008	NONE	