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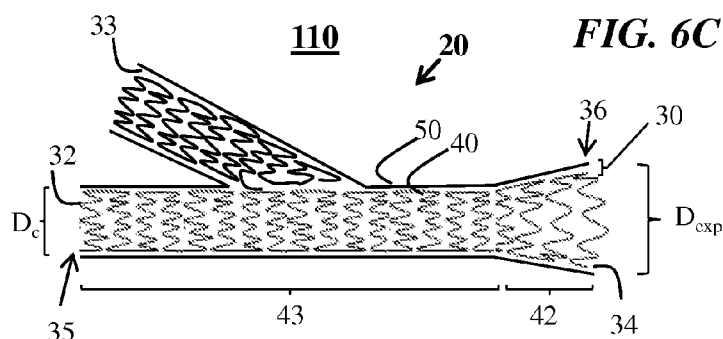
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- before the expiration of the time limit for amending the
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amendments (Rule 48.2(h))

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26 March 2015

(54) Title: GRAFT WITH EXPANDABLE REGION AND METHODS OF MAKING AND USING THE SAME

(57) Abstract: A vascular graft suitable for implantation, and more particularly to a vascular graft having an expandable outflow re-
gion for restoring patency of the graft after implantation into a body lumen.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2014/047711

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/07 (2014.01)

CPC - A61F 2/07 (2014.12)

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)

IPC(8) - A61F 2/00, 2/02, 2/04, 2/06, 2/07, 2/24, 2/82, 2/84, 2/88, 2/90, 2/92 (2014.01)

CPC - A61F 2/00, 2/02, 2/04, 2/06, 2002/065, 2/07, 2002/072, 2002/075, 2/82, 2/84, 2/88, 2/90, 2/92, 2002/30316

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 623/1.1, 1.12, 1.13, 1.15, 1.2, 1.21, 1.24, 1.35, 2.1, 2.18, 900 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Orbit, Google Patents, Google Scholar.

Search terms used: graft, vascular graft, vessel, expandable region, stress, load, compressive, outflow region, conduit, wall, support.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,693,088 A (LAZARUS) 02 December 1997 (02.12.1997) entire document	1-20,40-52,92-168,224
A	US 2010/0145434 A1 (THORNTON et al) 10 June 2010 (10.06.2010) entire document	1-20,40-52,92-168,224
A	US 2012/0323303 A1 (IVANCEV) 20 December 2012 (20.12.2012) entire document	1-20,40-52,92-168,224
A	US 5,676,697 A (MCDONALD) 14 October 1997 (14.10.1997) entire document	1-20,40-52,92-168,224
A	US 2012/0203264 A1 (KARWA et al) 09 August 2012 (09.08.2012) entire document	1-20,40-52,92-168,224

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

* 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 application or patent 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

06 January 2015

Date of mailing of the international search report

12 JAN 2015

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2014/047711

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. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 214-216
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:
Claims 214-216 are held to be unsearchable, since the claims are omnibus claims as they refer to the design and configuration as shown in the figures.

3. ☒ Claims Nos.: 21-40, 172-202, 207-211, 220
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:
see extra sheet

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 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.:
1-20, 41-52, 92-168, 224

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.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees need to be paid.

Group I, claims 1-20, 41-52, 92-168, 224 are drawn to a graft comprising a first vessel insertion region and a second vessel insertion region.

Group II, claims 53-91, 169-171, 203-206, 212, 213, 224, 225 are drawn to a graft comprising a conduit having a wall comprising a first inflow region having a first inflow end and a second inflow region having a second inflow end, the first and second inflow regions merging together at an inflow junction.

Group III, claims 217-219, 221-223 are drawn to a body comprising a plurality of rings.

The inventions listed in Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2 they lack the same or corresponding special technical features for the following reasons:

The special technical features of Group I, a first vessel insertion region, a second vessel insertion region, and a coupling region providing fluid communication therebetween are not present in Groups II and III; the special technical features of Group II at least one inflow aperture at an inflow end of a body region; and an outflow aperture at an outflow end of an outflow region opposite from the at least one inflow aperture are not present in Groups I and III; the special technical features of Group III, a support structure comprising: a body comprising a plurality of rings R1 through Rn, wherein n is an integer, each ring R1 through Rn having a pattern are not present in Groups I and II.

Unity exists between claims 1-20, 41-52, 92-168, 224 (Group I) or between claims 53-91, 169-171, 203-206, 212, 213, 224, 225 (Group II). However, unity does not exist between claims 1-20, 41-52, 92-168 and 53-91, 169-171, 203-206, 212, 213, 225 since there exists no common special technical feature between independent claims 1 and 92 and independent claims 53, 169, 203, 204, 212, 213 and 225 (see PCT Examination Guidelines Chapter 10 at 10.37 Example 17).

Groups I and II share the technical feature of an expandable outflow region; a biocompatible layer constraining the expandable outflow region under a continuous radial inward compressive stress that enables the outflow region to expand upon application of a radial outward counter force to the outflow region, a first fluid flow region and a second fluid flow region merging together at a junction, a first aperture disposed at an end of a first fluid flow region, and a second aperture at an end of a second fluid flow region. However, these shared technical features do not represent a contribution over the prior art.

Specifically, US 6,673,107 B1 to Brandt et al in view of US 2005/0096732 A1 to Marotta et al.

Brandt et al discloses an expandable outflow region (Col. 8, Lns. 13-27), a first fluid flow region (Fig. 7D, 22) and a second fluid flow region (Fig. 7D, 20) merging together at a junction (Fig. 7D at 33), a first aperture disposed at an end of a first fluid flow region (Fig. 7D 29 at end of 22), a second aperture at an end of a second fluid flow region (Fig. 7D 29 at end of 20; see Col. 7, Ln. 49-Col. 8, Ln. 5). Brandt et al fails to disclose a biocompatible layer constraining the expandable outflow region under a continuous radial inward compressive stress that enables the outflow region to expand upon application of a radial outward counter force to the outflow region. Marotta et al discloses a biocompatible layer constraining the expandable outflow region under a continuous radial inward compressive stress that enables the outflow region to expand upon application of a radial outward counter force to the outflow region (para. 0086 regarding partially expanded leaf portion 120 is coated with a covering material such as a silicone-based dispersion described above. This involves immersing partially expanded leaf portion 120 in the dispersion followed by carrying of the dispersion to result in adhesion of the covering material to leaf portion 120. Once a suitable coating has been disposed over leaf portion 120, partially pre-expanded prosthesis 100 is compressed; para. 0077 regarding once endovascular prosthesis 100 is in the correct position, balloon 55 is expanded thereby exerting radially outward forces on first expandable portion 130 and third expandable portion 135. Initially, this results in expansion of body 105 such that a portion of it is urged against the walls of both of basilar artery 10 and secondary artery 20. This results in expansion of leaf portion 120). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the expandable outflow region, a first fluid flow region and a second fluid flow region merging together at a junction, a first aperture disposed at an end of a first fluid flow region, a second aperture at an end of a second fluid flow region of Brandt et al to include a biocompatible layer constraining the expandable outflow region under a continuous radial inward compressive stress that enables the outflow region to expand upon application of a radial outward counter force to the outflow region as taught by Marotta et al for the purpose of providing an implant of controllable diameter for implantation in specific body lumens.

Since none of the special technical features of the Group I, II and III inventions are found in more than one of the inventions, unity of invention is lacking.