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Published:

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

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

[Continued on next page]

(54) Title: EXPANDABLE BODY DEVICE AND METHOD OF USE

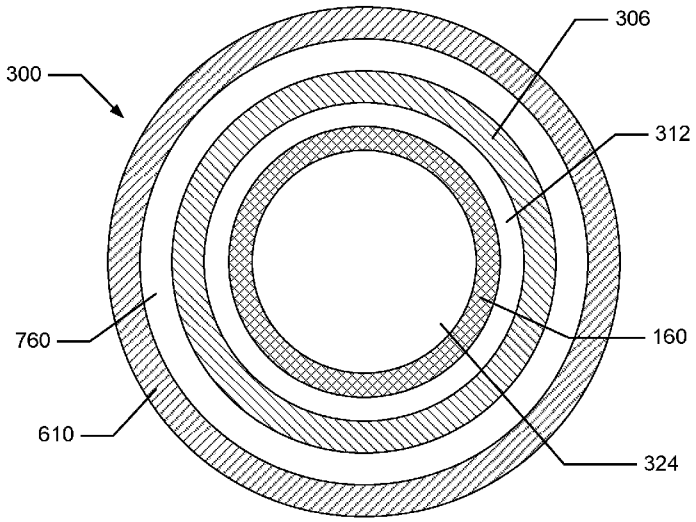

FIG. 20D

(57) Abstract: Disclosed herein are devices, designs, methods of manufacturing and using medical devices comprising expandable bodies for treating saccular vascular aneurysms and occluding segments of blood vessels and other biological conduits. Exemplary expandable bodies include hollow gold structures that can be folded, wrapped, and compressed, joined to a delivery device, advanced to location in the body of patient in need of treatment, expanded by injection of a fluid into the central void, and separated from the delivery device, remaining in place in an open, expanded form without the addition of support structures to the central void. Other expandable bodies include coiled wires that can be loaded into delivery catheters and expelled from the delivery catheters using pusher devices. Also disclosed herein, are methods of using multiple medical devices and expandable bodies where the expandable bodies are placed adjacent to each other to occlude a saccular aneurysm.

WO 2016/044647 A3

(88) Date of publication of the international search report:
2 June 2016

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 78498-500023	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 15/50783	International filing date *(day/month/year)* 17 September 2015 (17.09.2015)	(Earliest) Priority Date *(day/month/year)* 17 September 2014 (17.09.2014)
Applicant METACTIVE MEDICAL, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (see Box No. II).

3. ☒ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

   a. the figure of the **drawings** to be published with the abstract is Figure No. 20D

   ☐ as suggested by the applicant.

   ☒ as selected by this Authority, because the applicant failed to suggest a figure.

   ☐ as selected by this Authority, because this figure better characterizes the invention.

   b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/50783

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.: 18, 47, 51-52, 58, 63, 68-240 and 253-264
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:
The above claims, as non-elected claims, do not comply with the prescribed requirements because they are so unclear that no meaningful international search or opinion could be formed. Particularly, these claims lead to a lack of clarity in the claims as a whole due to a lack of conciseness. Please refer to ISA/Form 224 mailed on 13 November 2015 (13.11.2015).

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:
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 must be paid.

Group I: Claims 1-17, 19-46, 48-50, 53-57, 59-62, and 64-67, directed to a medical device having a metallic expandable body with a distal, proximal and intermediate regions and a wall extending therethrough, wherein the wall assumes a pleated configuration.

Group II: Claim 241-252 directed to a method for treating a peripheral blood vessel comprising obstructing the flow of blood within the interior volume of the expanded expandable body with the one or more elastomeric valves.

-*-Continued in Supplemental Box-*-

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.:

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

International application No.
PCT/US 15/50783

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/135 (2016.01)
CPC - A61B 2017/12054
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)
CPC - A61B 2017/12054; IPC(8) - A61B 17/135 (2016.01); USPC - 606/195

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61B 17/12022, A61B 17/12136, A61B17/1214, A61B 17/12109, A61B 17/12113, A61B 2017/1205 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase; Google (Web, Patents, Scholar) Search Terms Used: Medical metal expand balloon Delivery catheter third three triple lumen detach remove release decouple separate Hollow tube cylinder lumen aneurysm implant Pleat fold crimp ruffle Guidewire shaft rod Fluid contrast Friction fit Elastomer rubber flexible valve Nosecone Support structure

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y -- A	WO 2013/109309 A1 (NOVITA THERAPEUTICS, LLC), 25 July 2013 (25.07.2013), entire document, especially Fig. 5A, 6, 9A and 16B; para [0006], [0016], [0114]-[0124], [0154], [0194]-[0195], [0206], [0227], [0237], [0262], and [0279]; Claim 1	241-246 and 248-252 ---------- 1-17, 19-46, 48-50, 53-57, 59-62, 64-67, 247
Y -- A	US 6,312,405 B1 (Meyer et al.), 06 November 2001 (06.11.2001), entire document, especially Fig. 1 and 3; col 5, ln 1-10; col 4, ln 58-67	241-246 and 248-252 ---------- 1-17, 19-46, 48-50, 53-57, 59-62, 64-67, 247
A	US 2010/0222803 A1 (Seifert et al.), 02 September 2010 (02.09.2010), entire document, especially Fig. 44A-D; para [0012] and [0215]	1-17, 19-46, 48-50, 53-57, 59-62, 64-67
A	US 2002/0143383 A1 (Parodi), 03 October 2002 (03.10.2002), entire document, especially Fig. 1-2; para [0005] and [0007]	1-17, 19-46, 48-50, 53-57, 59-62, 64-67
A	US 6,156,005 A (Theron), 05 December 2000 (05.12.2000), entire document	1-17,19-46,48-50,53-57, 59-62,64-67
A	US 5,327,885 A (Griffith), 12 July 1994 (12.07.1994), entire document	1-17,19-46,48-50,53-57, 59-62,64-67
A	US 5,833,671 A (Macoviak et al.), 10 November 1998 (10.11.1998), entire document	1-17,19-46,48-50,53-57, 59-62,64-67
A	US 7,955,246 B2 (Lubock et al.), 07 June 2011 (07.06.2011), entire document	1-17,19-46,48-50,53-57, 59-62,64-67

☐ 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	Date of mailing of the international search report
16 March 2016	11 APR 2016
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/50783

-*- Box III - Observations where Unity of Invention is Lacking -*-

The inventions listed as Groups I-II 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:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical features of the metallic expandable body comprising: a distal region, a proximal region, an intermediate region, a center axis, a wall extending generally continuously through the intermediate region, a central void of the expandable body, a proximal neck, a distal neck, a proximal nosecone, and a distal nosecone; a triple lumen delivery catheter assembly; wherein, the one or more elastomeric valves are configured to close a proximal neck or a distal neck when separated from the delivery catheter such that the pressure inside the central void of the expanded expandable body, after separation from the delivery catheter, is less than or equal to the pressure outside the expanded expandable body; and wherein, when the expandable body is in the deliverable configuration, the wall assumes a pleated configuration comprising a plurality of pleats folded over in a clockwise direction relative to the center axis or a counter-clockwise direction relative to the center axis to form a folded-over region of the expandable body, not required by the claims of Group II.

The invention of Group II includes the special technical features of a the metallic expanding body being single lobed; wherein the delivery catheter is engaged to a proximal region of the expandable body by the friction fit; the expandable body is decoupled by disengaging the friction fit; and obstructing the flow of blood within the interior volume of the expanded expandable body with the one or more elastomeric valves, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of a metallic expandable body with one or more elastomeric valves, wherein the expandable body is engaged by a friction fit with a delivery catheter disposed within a multi-lumen delivery catheter assembly, wherein the expandable body is configured to expand from a deliverable configuration to an expanded configuration; delivering the expandable body into the biological space of the patient; wherein the delivery catheter, disposed within the delivery catheter assembly, defines a first lumen of the detachment catheter assembly; delivering a fluid medium into the interior volume of the expandable body via a second lumen of the delivery catheter assembly; and decoupling the expandable body from the delivery catheter assembly. However, these shared technical features do not represent a contribution over prior art as being obvious over US 2014/0012307 A1 to NOVITA THERAPEUTICS, LLC (hereinafter 'NOVITA') in view of US 6,312,405 B1 to Meyer, et al. (hereinafter 'Meyer').
NOVITA discloses a metallic expandable body (metal balloon 100 which can be inflated and expanded, para [0040]; Fig. 1A-1E) which is affixed to a delivery catheter by friction fit (first inner cylindrical member 304 of catheter operates with a guidance member to deliver catheter, para [0046] and [0086]; Fig. 9B; affixed to catheter 300 by friction, para [0072]). The delivery catheter is part of a multi-lumen catheter assembly (first inner cylindrical member 304 is within second outer cylindrical member 306, para [0086]; Fig. 3A-3C and particularly 9B) and the first inner cylindrical member defines a first lumen (guidance lumen 324, Fig. 9B; para [0062]; cylindrical members are hollow, para [0086]). The expandable body is delivered into the biological space of the patient (may be placed into blood vessels, para [0040]) in a first state (the balloon can be delivered to the desired location before expansion, para [0041]) and expands after being delivered into an expanded state (balloon is inflated and expanded after delivery, para [0041]). In order to expand the balloon , fluid is delivered into the expandable body (fluid delivered into void 108 of the balloon 100, para [0041]) by the lumen of the second cylindrical member (para [0046]) and the expandable body is thereafter decoupled from the delivery catheter assembly (detached from the catheter, para [0042]).
Franano does not disclose the expandable body having elastomeric valves. It does, however, disclose that the balloon may be sealed after detachment in order to retain the balloon in its expanded configuration (para [0071]).
Meyer teaches a detachable balloon (balloon 10, Fig. 1) having a valve (valve 12 including valve body 22, Fig. 3) formed from an elastomeric material (valve body 22 is made of an elastomer such as silicone, col 5, ln 1-7). The valve allows the balloon, after detachment, to seal the opening of the balloon (col 5, ln 7-10) in order to maintain pressure and prevent leakage from within the balloon (col 4, ln 58-67). Accordingly, it would be obvious to one of ordinary skill in the art to modify the medical device of NOVITA to include an elastomeric valve at the balloon opening in order to maintain expansion and prevent leakage.

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

NOTES:
*Claim 241 recites "decoupling the expandable from the delivery catheter assembly." This is a clear typographical error and based on the balance of the specification, the claim is intended to recite "decoupling the expandable body from the delivery catheter assembly." As such, for the purposes of this search report and written opinion claim 241 is treated as such.**

**Claims 242-244 and 248-250 depend from claim 240. However, these claims are method claims while claim 240 is an apparatus claim. This dependency creates mixing of claim types, rendering them unsearchable. However, it is apparent from the claim grouping and numbering that this is a typographical error, and that the claims are intended to depend from the method claim 241. As such, for the purposes of this search report and written opinion, claims 242-244 and 248-250 are treated as depending from claim 241.

***Claims 245-247 depend from claim 243 and recite "the fluid contrast agent." However, there is no antecedent basis for this element in the claim nor the claims from which they depend. However, claim 244 recites "a fluid contrast agent." It is apparent from the claim grouping and number that this is a typographical error, and resultant from the above improper dependency of claims 242-244. The claims appear intended to depend from claim 244. As such, for the purposes of this search report and written opinion, claims 245-247 are treated as depending from claim 244.

Claims 18, 47, 51-52, 58, 63, 68-240, and 253-264, as non-elected claims, do not comply with the prescribed requirements because they are so unclear that no meaningful international search or opinion could be formed. Particularly, these claims lead to a lack of clarity in the claims as a whole due to a lack of conciseness. Please refer to ISA/Form 224 mailed on 13 November 2015 (13.11.2015). Accordingly, these claims are held as unsearchable and are not included in any group.