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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RESTAINO, ANDREW PETER	

ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
02/18/2026	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

BSC.USPTO@stwiplaw.com

Office Action Summary	Application No. 18/930,183	Applicant(s) Onushko et al.	
	Examiner Andrew Restaino	Art Unit 3771	AIA (First Inventor to File) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 10/24/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 10/29/2024 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: reference number "628" in Fig. 10 (Examiner's note: based on Specification paragraph [0069] it appears that reference number "628" should be reference number "638"). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claims 1, 13, 19, and 20 are objected to because of the following informalities:

a. Claims 1, 13, and 20 recite "an occlusive implant" in lines 9, 9, and 12, respectively, although the lines are understood by the Examiner to mean "the occlusive implant, as the "occlusive implant" was defined in the preamble of the claim, the Examiner suggests the lines be amended to read "the occlusive implant" for the purpose of maintaining consistent language throughout the claims;

b. Claim 13 recites "having spacer assembly" in line 7, however this is not grammatically correct as there is no article (a/an/the) before the noun, therefore the Examiner suggests the line be amended to read "having a spacer assembly";

c. Claim 19 recites "wherein spacer member" in line 2, however this is not grammatically correct as there is no article (a/an/the) before the noun, and although the line does not rise to the level of being indefinite as the line is understood by the Examiner to mean "spacer assembly", based on Applicant's disclosure, the Examiner suggests the line be amended to read "wherein the spacer assembly" for the purpose of maintaining consistent language throughout the claims;

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis (i.e., changing from AIA to pre-AIA) for the rejection will

not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

6. **Claims 1 – 5, 7 – 9, 12 – 13, and 16 – 19 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Perszyk et al (US 2018/0235658 A1).**

7. **Regarding claim 1**, Perszyk discloses a delivery device (introducer assembly 100 and delivery cable 200) for an occlusive implant (medical device 201) (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], and Figs. 1 – 5, 12), the delivery device comprising:

d. a delivery sheath (delivery sheath 203) having a proximal region, a distal tip region, and a lumen formed therein (paragraphs [0006 – 0007], [0024], [0030 – 0031], [0039 – 0040], and Fig. 2);

e. a core wire (delivery cable 200) slidably disposed in the lumen (paragraphs [0006 – 0007], [0032 – 0036], and Fig. 5,12);

f. wherein the core wire (delivery cable 200) includes a central shaft (inner member 202), a first region (proximal section 206) having a first coil assembly (proximal outer member 210) disposed along the central shaft (inner member 202), a second region (distal section 204) having a second coil assembly (distal outer member 208) disposed along the central shaft, and a distal implant

securing region (end screw 212) (paragraphs [0036 – 0040], [0055], and Fig. 12); and

g. an occlusive implant (implant 201) coupled to the distal implant securing region (paragraphs [0026], [0030], [0032], and Fig. 2).

8. **Regarding claim 2**, Perszyk discloses wherein the central shaft (inner member 202) includes stainless steel (paragraph [0034]).

9. **Regarding claim 3**, Perszyk discloses wherein the central shaft (inner member 202) includes a nickel-titanium alloy (paragraph [0034]).

10. **Regarding claim 5**, Perszyk discloses wherein the first region (proximal section 206) includes an outer jacket (heat shrink material 302) disposed over the first coil assembly (paragraph [0044] and Fig. 5).

11. **Regarding claim 7**, Perszyk discloses wherein the first coil assembly (proximal outer member 210) includes a single coil (proximal outer member 210) (Fig. 5).

12. **Regarding claim 9**, Perszyk discloses wherein the second coil assembly (distal outer member 208) includes two or more coils (Examiner's note: as stated in paragraph [0059] the distal outer member 208 is a double layer coil, thus comprising two coils).

13. **Regarding claim 12**, Perszyk discloses wherein the first region (proximal section 206) has a first outer diameter and wherein the second region (distal section 204) has a second outer diameter different from the first outer diameter (Fig. 5).

14. **Regarding claim 13**, Perszyk discloses a delivery device (introducer assembly 100 and delivery cable 200) for an occlusive implant (medical device 201) (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], and Figs. 1 – 5), the delivery device comprising:

h. a delivery sheath (delivery sheath 203) having a proximal region, a distal tip region, and a lumen formed therein (paragraphs [0006 – 0007], [0024], [0030 – 0031], [0039 – 0040], and Fig. 2);

i. a core wire (delivery cable 200) slidably disposed in the lumen paragraphs [0006 – 0007], [0032 – 0036], and Fig. 5);

j. wherein the core wire (delivery cable 200) includes a central shaft (inner member 202), a first region (proximal section 206) having a first coil assembly (proximal outer member 210) disposed along the central shaft (inner member 202), a second region (distal section 204) with having spacer assembly (distal outer member 208) disposed along the central shaft, and a distal implant securing region (end screw 212) (paragraphs [0036 – 0040] and Fig. 5); and

k. an occlusive implant (implant 201) coupled to the distal implant securing region (paragraphs [0026], [0030], [0032], and Fig. 2).

15. **Regarding claim 16**, Perszyk discloses wherein the spacer assembly (distal outer member 208) includes a spiral tube (distal outer member 208 is a coil, which is a spiral tube) disposed about the central shaft (inner member 202) (paragraphs [0036 – 0040] and Fig. 5).

16. **Regarding claim 17**, Perszyk discloses wherein the central shaft (inner member 202) includes stainless steel (paragraph [0034])

17. **Regarding claim 1**, *(alternate interpretation – changes italicized below)* Perszyk discloses a delivery device (introducer assembly 100 and delivery cable 200) for an occlusive implant (medical device 201) (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], and Figs. 1 – *6*), the delivery device comprising:

l. a delivery sheath (delivery sheath 203) having a proximal region, a distal tip region, and a lumen formed therein (paragraphs [0006 – 0007], [0024], [0030 – 0031], [0039 – 0040], and Fig. 2);

m. a core wire (delivery cable 200) slidably disposed in the lumen paragraphs [0006 – 0007], [0032 – 0036], and Fig. 5);

n. wherein the core wire (delivery cable 200) includes a central shaft (inner member 202 with *core wire 406, first layer 404, and second layer 406*), a first region (*distal section 204*) having a first coil assembly (*distal outer member 208*) disposed along the central shaft (inner member 202), a second region (*proximal section 206*) with having a second coil assembly (*proximal outer member 210*) disposed along the central shaft (inner member 202), and a distal implant

securing region (end screw 212) (paragraphs [0036 – 0040], *[0046 – 0047], and Fig. 6*); and

o. an occlusive implant (implant 201) coupled to the distal implant securing region (paragraphs [0026], [0030], [0032], and Fig. 2).

18. **Regarding claim 2**, *(alternate interpretation)* Perszyk discloses wherein the central shaft (inner member 202) includes stainless steel (paragraph [0034]).

19. **Regarding claim 3**, *(alternate interpretation)* Perszyk discloses wherein the central shaft (inner member 202) includes a nickel-titanium alloy (paragraph [0034]).

20. **Regarding claim 4**, *(alternate interpretation)* Perszyk discloses wherein the central shaft (inner member 202) includes a stainless steel member (second layer 406) and a nickel-titanium alloy member (first layer 404) secured to the stainless steel member (paragraph [0047]).

21. **Regarding claim 8**, *(alternate interpretation)* Perszyk discloses wherein the first coil assembly (*distal outer member 208*) includes two or more coils (Examiner's note: as stated in paragraph [0059] the distal outer member 208 is a double layer coil, thus comprising two coils).

22. **Regarding claim 13**, *(alternate interpretation – changes italicized below)* Perszyk discloses a delivery device (introducer assembly 100 and delivery cable 200)

for an occlusive implant (medical device 201) (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], and Figs. 1 – *6*), the delivery device comprising:

p. a delivery sheath (delivery sheath 203) having a proximal region, a distal tip region, and a lumen formed therein (paragraphs [0006 – 0007], [0024], [0030 – 0031], [0039 – 0040], and Fig. 2);

q. a core wire (delivery cable 200) slidably disposed in the lumen paragraphs [0006 – 0007], [0032 – 0036], and Fig. 5);

r. wherein the core wire (delivery cable 200) includes a central shaft (inner member 202 with *core wire 406, first layer 404, and second layer 406*), a first region (proximal section 206) having a first coil assembly (proximal outer member 210) disposed along the central shaft (inner member 202), a second region (distal section 204) with having spacer assembly (distal outer member 208) disposed along the central shaft, and a distal implant securing region (end screw 212) (paragraphs [0036 – 0040] and Fig. 5); and

s. an occlusive implant (implant 201) coupled to the distal implant securing region (paragraphs [0026], [0030], [0032], and Fig. 2).

23. **Regarding claim 18**, *(alternate interpretation)* Perszyk discloses wherein the central shaft (inner member 202) includes a stainless steel member (second layer 406) and a nickel-titanium alloy member (first layer 404) secured to the stainless steel member (paragraph [0047]).

24. **Regarding claim 19**, *(alternate interpretation)* Perszyk discloses wherein the delivery sheath (delivery sheath 203) has an inner diameter and wherein spacer member (distal outer member 208) has an outer diameter that closely approximates the inner diameter (paragraph [0028]).

25. **Claims 13 – 15 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Barajas et al (US 2023/0389930 A1).**

26. **Regarding claim 13**, Barajas discloses a delivery device (delivery system 1900) for an occlusive implant (flow diverter 300) (abstract, paragraphs [0214], [0107], and Figs. 23,24) the delivery device comprising:

t. a delivery sheath (catheter 104) having a proximal region, a distal tip region, and a lumen formed therein (paragraph [0089 – 0093] and Fig. 23);

u. a core wire (core wire 112 and coupling wire 1020) slidably disposed in the lumen (paragraph [0216] and Fig. 23);

v. wherein the core wire includes a central shaft (core wire 112 and coupling wire 1020), a first region (portion from proximal end to the distal end of support coil 510) having a first coil assembly (support coil 510) disposed along the central shaft (paragraph [0237] and Figs. 23/24), a second region (portion from proximal end of friction bump 508a to distal end of self-expanding element 1902) having a spacer assembly (self-expanding element 1902 and proximal friction bump 508a) disposed along the central shaft (Examiner's note: the self-expanding element 1902 is disposed along the coupling wire 1020 (i.e., a portion of the central shaft)), and a distal implant securing region (distal most friction bump 508b); and

w. an occlusive implant (flow diverter 300) coupled to the distal implant securing region (distal most friction bump 508b) (Fig. 23).

27. **Regarding claim 14**, Barajas discloses wherein the spacer assembly (self-expanding element 1902 and proximal friction bump 508a) includes one or more bead members (proximal friction bump 508a) (Examiner's note: "bead" is defined as a small rounded piece of material; and the friction bump is a small rounded piece of material).

28. **Regarding claim 15**, Barajas discloses wherein the spacer assembly (self-expanding element 1902 and proximal friction bump 508a) includes a stent-like structure (self-expanding element 1902) (paragraph [0227] and Fig. 23/24).

Claim Rejections - 35 USC § 103

29. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis (i.e., changing from AIA to pre-AIA) for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

30. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

31. The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

32. This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

33. **Claims 6 and 15 are rejected under 35 U.S.C. 103 as being unpatentable over Perszyk et al (US 2018/0235658 A1) as applied to claims 1 and 13, respectively, above, and further in view of Okajima (US 5,554,139)**.

34. **Regarding claim 6**, as discussed above, Perszyk discloses the delivery device of claim 1.

35. However, Perszyk is silent regarding **(i)** wherein the first region includes a braid coupled to the first coil assembly.

36. **As to the above**, Okajima teaches a medical device comprising a sheath (guiding catheter 9) and a core wire (catheter 1; which equates to the delivery cable 200 of Perszyk) extending through the sheath (abstract, col. 12 lines 50 – 63, col. 21 lines 10 – 25 and Figs. 1,3,8) comprising the core wire comprising a central shaft (inner layer 6; which equates to the inner member 202 of Perszyk), a first region (main body portion 2; which equates to the proximal region 206 of Perszyk) with a first coil assembly (coil 8; which equates to the proximal outer coil 210) and wherein the first region includes a braid (metal braid layer 30) for the purpose of restricting possible deformation of the coil (col. 7 lines 52 – 54 and col. 16 lines 53 – 65).

37. It would have been obvious to one of ordinary skill in the art, prior to the effective filing date of the claimed invention, based on the teachings of Okajima, to modify the first region of Perszyk to incorporate a braid attached to the first coil assembly for the purpose of restricting possible deformation of the coil (col. 7 lines 52 – 54 – Okajima).

38. **Regarding claim 15,** as discussed above, *(alternate interpretation)* Perszyk discloses the delivery device of claim 13.

39. However, Perszyk is silent regarding **(i)** wherein the spacer assembly includes a stent-like structure.

40. **As to the above**, Okajima teaches a medical device comprising a sheath (guiding catheter 9) and a core wire (catheter 1; which equates to the delivery cable 200 of Perszyk) extending through the sheath (abstract, col. 12 lines 50 – 63, col. 21 lines 10 – 25 and Figs. 1,2,3,8) comprising the core wire comprising a central shaft (inner layer 6; which equates to the inner member 202 of Perszyk), a second region (tip

portion 4; which equates to the distal region 204 of Perszyk) with a spacer assembly (portion of coil 8 in the tip portion 4; which equates to the distal outer coil 208) and wherein the spacer assembly includes a stent like structure (metal braid layer 30) for the purpose of restricting possible deformation of the coil (col. 7 lines 52 – 54 and col. 16 lines 53 – 65).

41. It would have been obvious to one of ordinary skill in the art, prior to the effective filing date of the claimed invention, to modify the spacer assembly (i.e., the distal outer coil 208) of Perszyk to incorporate a braid (i.e., a stent-like structure), based on the teachings of Okajima, for the purpose of restricting possible deformation of the coil (col. 7 lines 52 – 54 – Okajima).

42. **Claims 10, 11, and 14 are rejected under 35 U.S.C. 103 as being unpatentable over Perszyk et al (US 2018/0235658 A1) as applied to claim 1 above, and further in view of Chin et al (US 2012/0191012 A1) and Douk et al (US 6,183,420 B1)**.

43. **Regarding claims 10 and 11**, as discussed above, Perszyk discloses the delivery device of claim 1. Perszyk further discloses in paragraph [0055] and Fig. 12 wherein the delivery device comprises an intermediate outer member 240.

44. However, Perszyk is silent regarding **(i) [claims 10 and 11]** one or more bead members disposed adjacent to the first region and/or disposed between the first region and the second region

45. **As to the above,** Chin teaches guidewire (which equates to the delivery wire 200 of Perszyk) for an implant delivery catheter a core wire with a central shaft (core wire

101; which equates to the inner member 202 of Perszyk) comprising one or more bead members (beads 109) disposed along the length for the purpose of imparting a desired rigidity / controllable stiffness to the core wire (core wire 101) (abstract, paragraph [0004], [0009], [0019 – 0022], [0031], and Fig. 1A/B).

46. **Additionally,** Douk teaches an angioplasty guidewire with a core wire (core wire 162; which equates to the inner member 202 of Perszyk) comprising a central shaft (core wire 162) with a distal coil assembly (stiffening spring 168) or a plurality of beads (beads 175) (abstract, col. 8 lines 24 – 55, and Fig. 15). Therefore, Douk teaches coil assemblies and bead assemblies are functionally similar and are interchangeable.

47. It should be understood that Perszyk and Chin with Douk are known references in the art that teach a delivery system comprising a core wire with stiffening elements (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], and Figs. 1 – Perszyk ; abstract, paragraph [0004], [0009], [0019 – 0022], [0031], and Fig. 1A/B – Chin ; abstract, col. 8 lines 24 – 55, and Fig. 15 – Douk); and the Examiner contends that it would have been obvious to one of ordinary skill in the art before the effective filling date of the claimed invention to have substituted one known stiffening element for another (i.e., substituting *one of the* stiffening coils for a series of beads), and the results of the substitution would have been predictable and resulted in the modified delivery cable 200 of Perszyk being able to function as intended to properly push/pull the occluder/implant to the desired treatment site. The examiner notes the rejection above is based on KSR int'l Co. V. Teleflex inc., 550 U.S. 398, 415-421, 82 USPQ2d 1385, 1395-97 (2007), rational B, outlined in MPEP 2143. **Furthermore,** it has been held that choosing any solution from a finite number of solutions to obtain a predictable

result is well within the purview of ordinary skill in the art. KSR International Co. v. Teleflex Inc. (KSR), 550 U.S., 82 USPQ2d 1385 (2007). It can be seen that there are only a finite number of coils that can be substituted for a series of beads, it can be either: all of the outer member coils (proximal, intermediate, distal), only the proximal outer member coil, only the intermediate outer member coil, only the distal outer member coil, or some variation of the three outer coils. Therefore, it would have been obvious to one of ordinary skill in the art to modify the intermediate outer member 240 to be a series of beads since there are a limited number of possible coils to be substituted and having the intermediate outer member 240 be a series beads would have yielded, with a reasonable expectation of success, a delivery cable with enough column strength to push / pull the occluder through the catheter and after/prior to deployment of the occluder. Therefore, the modification encompasses one or more beads in the intermediate region of the delivery cable adjacent to the first (proximal) region and in between the first (proximal) region and the second (distal) region.

48. **Regarding claim 14,** as discussed above, *(alternate interpretation)* Perszyk discloses the delivery device of claim 13.

49. However, Perszyk is silent regarding **(i)** wherein the spacer assembly includes one or more bead members.

50. **As to the above,** Chin teaches guidewire (which equates to the delivery wire 200 of Perszyk) for an implant delivery catheter a core wire with a central shaft (core wire 101; which equates to the inner member 202 of Perszyk) comprising one or more bead members (beads 109) disposed along the length for the purpose of imparting a desired

rigidity / controllable stiffness to the core wire (core wire 1091) (abstract, paragraph [0004], [0009], [0019 – 0022], [0031], and Fig. 1A/B).

51. **Additionally,** Douk teaches an angioplasty guidewire with a core wire (core wire 162; which equates to the inner member 202 of Perszyk) comprising a central shaft (core wire 162) with a distal coil assembly (stiffening spring 168) or a plurality of beads (beads 175) (abstract, col. 8 lines 24 – 55, and Fig. 15). Therefore, Douk teaches coil assemblies and bead assemblies are functionally similar and are interchangeable.

52. It should be understood that Perszyk and Chin with Douk are known references in the art that teach a delivery system comprising a core wire with stiffening elements (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], and Figs. 1 – Perszyk ; abstract, paragraph [0004], [0009], [0019 – 0022], [0031], and Fig. 1A/B – Chin ; abstract, col. 8 lines 24 – 55, and Fig. 15 – Douk); and the Examiner contends that it would have been obvious to one of ordinary skill in the art before the effective filling date of the claimed invention to have substituted one known stiffening element for another (i.e., substituting *the distal outer member coil* of Perszyk for a series of beads), and the results of the substitution would have been predictable and resulted in the modified delivery cable 200 of Perszyk being able to function as intended to properly push/pull the occluder/implant to the desired treatment site. The examiner notes the rejection above is based on KSR int'l Co. V. Teleflex inc., 550 U.S. 398, 415-421, 82 USPQ2d 1385, 1395-97 (2007), rational B, outlined in MPEP 2143.

53. **Claim 20 is rejected under 35 U.S.C. 103 as being unpatentable over as Perszyk et al (US 2018/0235658 A1) and in view of Larsen et al (US 2014/0142617 A1)**.

54. **Regarding claim 20**, Perszyk discloses a method for implanting an occlusive implant (occluder / medical device 201) (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], [0050], and Figs. 1 – 5, 8, 12) *to a treatment site*, the method comprising:

x. advancing a delivery device (introducer assembly 100 and delivery cable 200) to a position adjacent to *a treatment site* (paragraphs [0024] and [0050]), the delivery device comprising:

i. a delivery sheath (delivery sheath 203) having a proximal region, a distal tip region, and a lumen formed therein (paragraphs [0006 – 0007], [0024], [0030 – 0031], [0039 – 0040], and Fig. 2);

ii. a core wire (delivery cable 200) slidably disposed in the lumen paragraphs [0006 – 0007], [0032 – 0036], and Fig. 5,12);

iii. wherein the core wire (delivery cable 200) includes a central shaft (inner member 202), a first region (proximal section 206) having a first coil assembly (proximal outer member 210) disposed along the central shaft (inner member 202), a second region (distal section 204) with having a second coil assembly (distal outer member 208) disposed along the central shaft, and a distal implant securing region (end screw 212) (paragraphs [0036 – 0040], [0055], and Fig. 12); and

iv. an occlusive implant (implant 201) coupled to the distal implant securing region (paragraphs [0026], [0030], [0032], and Fig. 2); and

y. advancing the core wire (delivery cable 200) such that the occlusive implant (implant 201) advances out from the distal tip region of the delivery sheath (paragraph [0050] and Fig. 8).

55. However, Perszyk is silent regarding **(i)** wherein the implant is a left atrial appendage occlusive implant and wherein the method is for implanting the occlusive implant into the left atrial appendage.

56. **As to the above**, Larsen teaches, in the same field of endeavor, a method of implanting an occlusive implant (occlusive device 100) into a left atrial appendage comprising advancing a delivery device (delivery sheath 168 and delivery catheter 170) to a position adjacent to the left atrial appendage, the delivery device comprising a sheath (sheath 168) and a core wire (delivery catheter 170; which equates to the delivery cable 200 of Perszyk), and advancing the core wire (delivery catheter 170) such that the occlusive implant (occlusive device 100) advances out from the delivery sheath (sheath 168) for the purpose of treating thrombus formation in the LAA of arrhythmic patients (abstract, paragraphs [0004], [0064], [0066 – 0067], and Figs. 1,6).

57. It would have been obvious to one of ordinary skill in the art, prior to the effective filing date of the claimed invention, to modify the system and method of Perszyk to incorporate the step of placing a LAA occlusive implant to/into the LAA, as taught by Larsen, for purpose of treating thrombus formation in the LAA of arrhythmic patients (paragraph [0004] – Larsen).

Conclusion

58. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

z. Lentz (US 2012/0004606 A1), Yutori et al (US 5,306,252), Viera (US 5,497,785), Mirzaee et al (US 5,605,162), and Jacobsen et al (US 6,428,489 B1) teach core wires (extendable through a sheath) with reinforced regions.

Contact Information

59. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Restaino whose telephone number is (571)272-4748. The examiner can normally be reached Mon - Fri 8:00 - 4:00 ET.

60. Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

61. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Elizabeth Houston can be reached at 571-272-7134. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

62. Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-

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Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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