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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/930,183	10/29/2024	David John Onushko	2001.3357101	3963

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EXAMINER	
RESTAINO, ANDREW PETER	
ART UNIT	**PAPER NUMBER**
3771	
NOTIFICATION DATE	**DELIVERY MODE**
10/20/2026	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 10/01/2026.

☐ 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) 1-13,17-18 and 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) 1-13,17-18 and 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 05/05/2026 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.

Response to Amendment

2. This Office action is in response to the applicant's communication filed 10/01/2026.

Status of the claims:

Claims 1 – 13, 17, 18, and 20 are pending in the application.

Claims 1, 13, and 20 are amended.

Claim Rejections - 35 USC § 103

3. 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.

4. 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.

5. 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.

6. 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.

7. **Claims 1 – 5, 7 – 14, and 17 – 18 are rejected under 35 U.S.C. 103 as being unpatentable over Perszyk et al (US 2018/0235658 A1) *(previously cited)* and in view of Hansen et al (US 2016/0089515 A1) and Douk et al (US 6,183,420 B1) *(previously cited)*.**

8. **Regarding claims 1, 10, and 11**, 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], [0054 – 0058], and Figs. 1 – 5, 12), the delivery device comprising:

a. 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);

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

c. 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

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

e. a third coil assembly (intermediate outer member 240) disposed over the central shaft (inner member 202) for providing flexibility to the core wire while maintaining sufficient column strength to the core wire (paragraph [0054]) and defining an outer diameter approximately equal to an inner diameter of the lumen (paragraphs [0028], [0040], and [0058]) (Examiner's note: the term "approximately" is defined as very close to but not equal to. As stated in paragraph [0040] the outer diameter of the distal outer member 208 is greater

than 98% of the inner diameter of the delivery sheath, and because the outer diameter of the distal outer member 208 being within less than two percent of the inner diameter of the lumen of the delivery sheath the outer diameter of the distal outer member 208 is considered to be approximately equal to the inner diameter of the lumen. Furthermore, paragraph [0058] recites wherein the intermediate outer member 240 has the same outer diameter as the distal outer member 208. Therefore, Perszyk discloses the intermediate outer member 240 defines an outer diameter approximately equal to the inner diameter of the sheath (i.e., the lumen)).

9. However, Perszyk is silent regarding **(i) [claims 1, 10, and 11]** *wherein the third coil assembly is* a plurality of beads members disposed over the central shaft adjacent to the first region and/or disposed over the central shaft between the first region and the second region and **(ii) [claim 1]** wherein the plurality of bead members are spaced apart from one another along the central shaft such that a portion of the central shaft is exposed between adjacent bead members of the plurality of bead members and each of the plurality of bead members defines an outer diameter approximately equal to an inner diameter of the lumen.

10. **As to the above,** Hansen teaches a core wire (guidewire 134; which equates to the delivery wire 200 of Perszyk) for a catheter comprising a central shaft (core wire 128; which equates to the inner member 202 of Perszyk) comprising one or more bead members (members 112) disposed along the length of the central shaft (core wire 128) and spaced apart from each other such that the central shaft is exposed between the bead members (shown in Fig. 5) (abstract, paragraphs [0022], [0036], and Figs. 1 and

5). Hansen teaches the bead members (members 112) are used for the purpose of increasing the flexibility of the distal portion *while maintaining the desired torsional rigidity* (paragraphs [0006 – 0007]); Hansen further teaches wherein the members can be varied to optimize the flexibility vs navigability characteristics for particular procedures (paragraph [0030]).

11. **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) for stiffening the core wire (core wire 162) (abstract, col. 8 lines 1 – 20, col. 8 lines 24 – 50, and Figs. 15,16). Therefore, Douk teaches coil assemblies and bead assemblies are functionally equivalent and are interchangeable without changing the principle operation of the system.

12. 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 intermediate coil assembly of Perszyk to incorporate / be replaced by a plurality of beads, based on the teachings of Hansen in view of Douk, for the purpose of being able to impart a desired rigidity / flexibility to the core wire while maintaining the desired torsional rigidity (paragraphs [0006 – 0007], [0030] – Hansen). Additionally, it should be understood that Perszyk and Hansen with the teachings of Douk are known references in the art that teach a delivery system comprising a core wire with elements / members for stiffening and/or providing the desired strength and flexibility to an inner core (abstract, paragraphs [0005 – 0007], [0024 – 0026], [0054], [0058], and Figs. 1 – Perszyk ; abstract, paragraphs [0006 – 0007], [0030] – Hansen; abstract, col. 8 lines 1 – 20, col. 8 lines 24 – 55, and Figs.

15,16 – 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 intermediate outer coil 240* for a series of spaced apart beads), and the results of the substitution would have been predictable and resulted in the modified intermediate member being able to function as intended to provide the desired rigidity / flexibility to the core member as desired and resulted in the delivery cable 200 of Perszyk being able to function as intended to properly push/pull the occluder/implant to the desired treatment site while also being able to mitigate "snaking" of the core member through the catheter. 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.

13. **As to (ii)**, the intermediate outer coil 240 has an outer diameter that approximates the inner diameter of the lumen; and as modified above, the combination would encompass or, at least, make obvious to one of ordinary skill in the art for the plurality of beads to have the same diameter as the intermediate outer coil 240 such that the plurality of beads have an outer diameter that approximates the inner diameter of the lumen as claimed.

14. **Regarding claim 2**, as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Hansen in view of Douk. Additionally, Perszyk discloses wherein the central shaft (inner member 202) includes stainless steel (paragraph [0034]).

15. **Regarding claim 3**, as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Hansen in view of Douk. Additionally, Perszyk discloses wherein the central shaft (inner member 202) includes a nickel-titanium alloy (paragraph [0034]).

16. **Regarding claim 5**, as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Hansen in view of Douk. Additionally, 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).

17. **Regarding claim 7**, as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Hansen in view of Douk. Additionally, Perszyk discloses wherein the first coil assembly (proximal outer member 210) includes a single coil (proximal outer member 210) (Fig. 5).

18. **Regarding claim 9**, as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Hansen in view of Douk. Additionally, 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).

19. **Regarding claim 12**, as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Hansen in view of Douk. Additionally, 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).

20. **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], [0054 – 0058], and Figs. 1 – *6*, 12), the delivery device comprising:

f. 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);

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

h. 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],* [0054 – 0058], *and Figs. 6*, 12); and

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

j. a third coil assembly (intermediate outer member 240) disposed over the central shaft (inner member 202) for providing sufficient column strength to the core wire (paragraph [0054]) and defining an outer diameter approximately equal to an inner diameter of the lumen (paragraphs [0028], [0040], and [0058]) (Examiner's note: the term "approximately" is defined as very close to but not equal to. As stated in paragraph [0040] the outer diameter of the distal outer member 208 is greater than 98% of the inner diameter of the delivery sheath (i.e., the diameter of the lumen), and because the outer diameter of the distal outer member 208 being within less than two percent of the inner diameter of the lumen of the delivery sheath the outer diameter of the distal outer member 208 is considered to be approximately equal to the inner diameter of the lumen. Furthermore, paragraph [0058] recites wherein the intermediate outer member 240 has the same outer diameter as the distal outer member 208. Therefore, Perszyk discloses the intermediate outer member 240 defines an outer diameter approximately equal to the inner diameter of the sheath (i.e., the lumen)).

21. However, Perszyk is silent regarding **[claims 1, 10, and 11] (i)** *wherein the third coil assembly is* a plurality of beads members disposed over the central shaft adjacent to the first region and/or disposed over the central shaft between the first region and the second region and **(ii)** wherein the plurality of bead members are spaced apart from one

another along the central shaft such that a portion of the central shaft is exposed between adjacent bead members of the plurality of bead members and each of the plurality of bead members defines an outer diameter approximately equal to an inner diameter of the lumen.

22. **As to the above,** Hansen teaches a core wire (guidewire 134; which equates to the delivery wire 200 of Perszyk) for a catheter comprising a central shaft (core wire 128; which equates to the inner member 202 of Perszyk) comprising one or more bead members (members 112) disposed along the length of the central shaft (core wire 128) and spaced apart from each other such that the central shaft is exposed between the bead members (shown in Fig. 5) (abstract, paragraphs [0022], [0036], and Figs. 1 and 5). Hansen teaches the bead members (members 112) are used for the purpose of increasing the flexibility of the distal portion *while maintaining the desired torsional rigidity* (paragraphs [0006 – 0007]); Hansen further teaches wherein the members can be varied to optimize the flexibility vs navigability characteristics for particular procedures (paragraph [0030]).

23. **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) for stiffening the core wire (core wire 162) (abstract, col. 8 lines 1 – 20, col. 8 lines 24 – 50, and Figs. 15,16). Therefore, Douk teaches coil assemblies and bead assemblies are functionally equivalent and are interchangeable without changing the principle operation of the system.

24. 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 intermediate coil assembly of Perszyk to incorporate / be replaced by a plurality of beads, based on the teachings of Hansen in view of Douk, for the purpose of being able to impart a desired rigidity / flexibility to the core wire while maintaining the desired torsional rigidity (paragraphs [0006 – 0007], [0030] – Hansen). Additionally, it should be understood that Perszyk and Hansen with the teachings of Douk are known references in the art that teach a delivery system comprising a core wire with elements / members for stiffening and/or providing the desired strength and flexibility to an inner core (abstract, paragraphs [0005 – 0007], [0024 – 0026], [0054], [0058], and Figs. 1 – Perszyk ; abstract, paragraphs [0006 – 0007], [0030] – Hansen; abstract, col. 8 lines 1 – 20, col. 8 lines 24 – 55, and Figs. 15,16 – 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 intermediate outer coil 240* for a series of spaced apart beads), and the results of the substitution would have been predictable and resulted in the modified intermediate member being able to function as intended to provide the desired rigidity / flexibility to the core member as desired and resulted in the delivery cable 200 of Perszyk being able to function as intended to properly push/pull the occluder/implant to the desired treatment site while also being able to mitigate “snaking” of the core member through the catheter. 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.

25. **As to (ii)**, the intermediate outer coil 240 has an outer diameter that approximates the inner diameter of the lumen; and as modified above, the combination would encompass or, at least, make obvious to one of ordinary skill in the art for the plurality of beads to have the same diameter as the intermediate outer coil 240 such that the plurality of beads have an outer diameter that approximates the inner diameter of the lumen as claimed.

26. **Regarding claim 2**, *(alternate interpretation)* as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Hansen in view of Douk. Additionally, Perszyk discloses wherein the central shaft (inner member 202) includes stainless steel (paragraph [0034]).

27. **Regarding claim 3**, *(alternate interpretation)* as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Hansen in view of Douk. Additionally, Perszyk discloses wherein the central shaft (inner member 202) includes a nickel-titanium alloy (paragraph [0034]).

28. **Regarding claim 4**, *(alternate interpretation)* as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Hansen in view of Douk. Additionally, 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]).

29. **Regarding claim 8**, *(alternate interpretation)* as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Hansen in view of Douk. Additionally, 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).

30. **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], [0054 – 0058], and Figs. 1 – 5, 12), the delivery device comprising:

k. 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);

l. a core wire (delivery cable 200) slidably disposed in the lumen (paragraphs [0006 – 0007], [0032 – 0036], and Fig. 5) (Examiner's note: paragraph [0007] recites "The method further includes advancing the delivery cable through the deployed delivery sheath");

m. 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

(intermediate outer member 240 and distal outer member 208) disposed along the central shaft, and a distal implant securing region (end screw 212) (paragraphs [0036 – 0040], [0054 – 0058], and Figs. 5, 12); and

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

o. the spacer assembly comprises a *third coil assembly* (intermediate outer member 240) disposed over the central shaft (inner member 202) for providing sufficient column strength to the core wire (paragraph [0054]) and defining an outer diameter approximately equal to an inner diameter of the lumen (paragraphs [0028], [0040], and [0058]) (Examiner's note: the term "approximately" is defined as very close to but not equal to. As stated in paragraph [0040] the outer diameter of the distal outer member 208 is greater than 98% of the inner diameter of the delivery sheath (i.e., the diameter of the lumen), and because the outer diameter of the distal outer member 208 being within less than two percent of the inner diameter of the lumen of the delivery sheath the outer diameter of the distal outer member 208 is considered to be approximately equal to the inner diameter of the lumen. Furthermore, paragraph [0058] recites wherein the intermediate outer member 240 has the same outer diameter as the distal outer member 208. Therefore, Perszyk discloses the intermediate outer member 240 defines an outer diameter approximately equal to the inner diameter of the sheath (i.e., the lumen)).

31. However, Perszyk is silent regarding **(i)** *wherein the third coil assembly is* a plurality of beads members and **(ii)** wherein the plurality of bead members are spaced

apart from one another along the central shaft such that a portion of the central shaft is exposed between adjacent bead members of the plurality of bead members and each of the plurality of bead members defines an outer diameter approximately equal to an inner diameter of the lumen.

32. **As to the above,** Hansen teaches a core wire (guidewire 134; which equates to the delivery wire 200 of Perszyk) for a catheter comprising a central shaft (core wire 128; which equates to the inner member 202 of Perszyk) comprising one or more bead members (members 112) disposed along the length of the central shaft (core wire 128) and spaced apart from each other such that the central shaft is exposed between the bead members (shown in Fig. 5) (abstract, paragraphs [0022], [0036], and Figs. 1 and 5). Hansen teaches the bead members (members 112) are used for the purpose of increasing the flexibility of the distal portion *while maintaining the desired torsional rigidity* (paragraphs [0006 – 0007]); Hansen further teaches wherein the members can be varied to optimize the flexibility vs navigability characteristics for particular procedures (paragraph [0030]).

33. **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) for stiffening the core wire (core wire 162) (abstract, col. 8 lines 1 – 20, col. 8 lines 24 – 50, and Figs. 15,16). Therefore, Douk teaches coil assemblies and bead assemblies are functionally equivalent and are interchangeable without changing the principle operation of the system.

34. 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 intermediate coil assembly of Perszyk to incorporate / be replaced by a plurality of beads, based on the teachings of Hansen in view of Douk, for the purpose of being able to impart a desired rigidity / flexibility to the core wire while maintaining the desired torsional rigidity (paragraphs [0006 – 0007], [0030] – Hansen). Additionally, it should be understood that Perszyk and Hansen with the teachings of Douk are known references in the art that teach a delivery system comprising a core wire with elements / members for stiffening and/or providing the desired strength and flexibility to an inner core (abstract, paragraphs [0005 – 0007], [0024 – 0026], [0054], [0058], and Figs. 1 – Perszyk ; abstract, paragraphs [0006 – 0007], [0030] – Hansen; abstract, col. 8 lines 1 – 20, col. 8 lines 24 – 55, and Figs. 15,16 – 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 intermediate outer coil 240* for a series of spaced apart beads), and the results of the substitution would have been predictable and resulted in the modified intermediate member being able to function as intended to provide the desired rigidity / flexibility to the core member as desired and resulted in the delivery cable 200 of Perszyk being able to function as intended to properly push/pull the occluder/implant to the desired treatment site while also being able to mitigate “snaking” of the core member through the catheter. 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.

35. **As to (ii)**, the intermediate outer coil 240 has an outer diameter that approximates the inner diameter of the lumen; and as modified above, the combination would encompass or, at least, make obvious to one of ordinary skill in the art for the plurality of beads to have the same diameter as the intermediate outer coil 240 such that the plurality of beads have an outer diameter that approximates the inner diameter of the lumen as claimed.

36. **Regarding claim 17**, as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Hansen in view of Douk. Additionally, Perszyk discloses wherein the central shaft (inner member 202) includes stainless steel (paragraph [0034])

37. **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], [0054 – 0058], 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) (Examiner's note:

paragraph [0007] recites "The method further includes advancing the delivery cable through the deployed delivery sheath");

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 (intermediate outer member 240 distal outer member 208) disposed along the central shaft, and a distal implant securing region (end screw 212) (paragraphs [0036 – 0040], [0054 – 0058], and Fig. 6, 12); and

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

t. the spacer assembly comprises a *third coil assembly* (intermediate outer member 240) disposed over the central shaft (inner member 202) for providing sufficient column strength to the core wire (paragraph [0054]) and defining an outer diameter approximately equal to an inner diameter of the lumen (paragraphs [0028], [0040], and [0058]) (Examiner's note: the term "approximately" is defined as very close to but not equal to. As stated in paragraph [0040] the outer diameter of the distal outer member 208 is greater than 98% of the inner diameter of the delivery sheath (i.e., the diameter of the lumen), and because the outer diameter of the distal outer member 208 being within less than two percent of the inner diameter of the lumen of the delivery sheath the outer diameter of the distal outer member 208 is considered to be

approximately equal to the inner diameter of the lumen. Furthermore, paragraph [0058] recites wherein the intermediate outer member 240 has the same outer diameter as the distal outer member 208. Therefore, Perszyk discloses the intermediate outer member 240 defines an outer diameter approximately equal to the inner diameter of the sheath (i.e., the lumen)).

38. However, Perszyk is silent regarding **(i)** *wherein the third coil assembly is* a plurality of beads members and **(ii))** wherein the plurality of bead members are spaced apart from one another along the central shaft such that a portion of the central shaft is exposed between adjacent bead members of the plurality of bead members and each of the plurality of bead members defines an outer diameter approximately equal to an inner diameter of the lumen.

39. **As to the above,** Hansen teaches a core wire (guidewire 134; which equates to the delivery wire 200 of Perszyk) for a catheter comprising a central shaft (core wire 128; which equates to the inner member 202 of Perszyk) comprising one or more bead members (members 112) disposed along the length of the central shaft (core wire 128) and spaced apart from each other such that the central shaft is exposed between the bead members (shown in Fig. 5) (abstract, paragraphs [0022], [0036], and Figs. 1 and 5). Hansen teaches the bead members (members 112) are used for the purpose of increasing the flexibility of the distal portion *while maintaining the desired torsional rigidity* (paragraphs [0006 – 0007]); Hansen further teaches wherein the members can be varied to optimize the flexibility vs navigability characteristics for particular procedures (paragraph [0030]).

40. **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) for stiffening the core wire (core wire 162) (abstract, col. 8 lines 1 – 20, col. 8 lines 24 – 50, and Figs. 15,16). Therefore, Douk teaches coil assemblies and bead assemblies are functionally equivalent and are interchangeable without changing the principle operation of the system.

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 intermediate coil assembly of Perszyk to incorporate / be replaced by a plurality of beads, based on the teachings of Hansen in view of Douk, for the purpose of being able to impart a desired rigidity / flexibility to the core wire while maintaining the desired torsional rigidity (paragraphs [0006 – 0007], [0030] – Hansen). Additionally, it should be understood that Perszyk and Hansen with the teachings of Douk are known references in the art that teach a delivery system comprising a core wire with elements / members for stiffening and/or providing the desired strength and flexibility to an inner core (abstract, paragraphs [0005 – 0007], [0024 – 0026], [0054], [0058], and Figs. 1 – Perszyk ; abstract, paragraphs [0006 – 0007], [0030] – Hansen; abstract, col. 8 lines 1 – 20, col. 8 lines 24 – 55, and Figs. 15,16 – 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 intermediate outer coil 240* for a series of spaced apart beads), and the results of the substitution would have been predictable and resulted in the modified intermediate member being

able to function as intended to provide the desired rigidity / flexibility to the core member as desired and resulted in the delivery cable 200 of Perszyk being able to function as intended to properly push/pull the occluder/implant to the desired treatment site while also being able to mitigate "snaking" of the core member through the catheter. 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.

42. **As to (ii)**, the intermediate outer coil 240 has an outer diameter that approximates the inner diameter of the lumen; and as modified above, the combination would encompass or, at least, make obvious to one of ordinary skill in the art for the plurality of beads to have the same diameter as the intermediate outer coil 240 such that the plurality of beads have an outer diameter that approximates the inner diameter of the lumen as claimed.

43. **Regarding claim 18**, *(alternate interpretation)* as discussed above, it would be obvious to modify the device of Perszyk to incorporate a plurality of beads as taught by Hansen in view of Douk. Additionally, 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]).

44. **Claim 6 is rejected under 35 U.S.C. 103 as being unpatentable over Perszyk et al (US 2018/0235658 A1) *(previously cited)* in view of Hansen et al (US**

2016/0089515 A1) and Douk et al (US 6,183,420 B1) *(previously cited)*, as applied to claim 1 above, and further in view of Kajima (US 5,554,139) *(previously cited)*.

45. **Regarding claim 6**, as discussed above, the combination of Perszyk, Hansen, and Douk teaches the delivery device of claim 1.

46. However, the combination of Perszyk, Hansens, and Douk is silent regarding **(i)** wherein the first region includes a braid coupled to the first coil assembly.

47. **As to the above**, Kajima 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).

48. 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 Kajima, to modify the first region of Perszyk in view of Hansen and Douk 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 – Kajima).

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

(US 2014/0142617 A1) *(previously cited)*, Hansen et al (US 2016/0089515 A1), and Douk et al (US 6,183,420 B1) *(previously cited)*.

50. **Regarding claim 20**, Perszyk discloses a method for implanting an occlusive implant (occluder / medical device 201) (abstract, paragraphs [0003], [0006], [0024 – 0026], [0029 – 0030], [0054 – 0058], and Figs. 1 – 5, 8, 12) *to a treatment site*, the method comprising:

u. 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) having a *second coil assembly* (intermediate outer member 240) 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

v. 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);

w. the *second coil assembly* (intermediate outer member 240) disposed over the central shaft (inner member 202) for providing sufficient column strength to the core wire (paragraph [0054]) and defining an outer diameter approximately equal to an inner diameter of the lumen (paragraphs [0028], [0040], and [0058]) (Examiner's note: the term "approximately" is defined as very close to but not equal to. As stated in paragraph [0040] the outer diameter of the distal outer member 208 is greater than 98% of the inner diameter of the delivery sheath (i.e., the diameter of the lumen), and because the outer diameter of the distal outer member 208 being within less than two percent of the inner diameter of the lumen of the delivery sheath the outer diameter of the distal outer member 208 is considered to be approximately equal to the inner diameter of the lumen. Furthermore, paragraph [0058] recites wherein the intermediate outer member 240 has the same outer diameter as the distal outer member 208. Therefore, Perszyk discloses the intermediate outer member 240 defines an outer diameter approximately equal to the inner diameter of the sheath (i.e., the lumen)).

51. However, Perszyk is silent regarding **(i)** wherein the implant is a left atrial appendage occlusive implant, wherein the method is for implanting the occlusive implant into the left atrial appendage, **(ii)** wherein *the second region is* a plurality of beads members, and **(iii)** wherein the plurality of bead members are spaced apart from one another along the central shaft such that a portion of the central shaft is exposed

between adjacent bead members of the plurality of bead members and each of the plurality of bead members defines an outer diameter approximately equal to an inner diameter of the lumen.

52. **As to (i)**, 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).

53. 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 to include a LAA occlusive implant and modify the method of Perszyk to incorporate the step of placing the 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).

54. **As to (ii) and (iii),** Hansen teaches a core wire (guidewire 134; which equates to the delivery wire 200 of Perszyk) for a catheter comprising a central shaft (core wire 128; which equates to the inner member 202 of Perszyk) comprising one or more bead members (members 112) disposed along the length of the central shaft (core wire 128) and spaced apart from each other such that the central shaft is exposed between the bead members (shown in Fig. 5) (abstract, paragraphs [0022], [0036], and Figs. 1 and

5). Hansen teaches the bead members (members 112) are used for the purpose of increasing the flexibility of the distal portion *while maintaining the desired torsional rigidity* (paragraphs [0006 – 0007]); Hansen further teaches wherein the members can be varied to optimize the flexibility vs navigability characteristics for particular procedures (paragraph [0030]).

55. **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) for stiffening the core wire (core wire 162) (abstract, col. 8 lines 1 – 20, col. 8 lines 24 – 50, and Figs. 15,16). Therefore, Douk teaches coil assemblies and bead assemblies are functionally equivalent and are interchangeable without changing the principle operation of the system.

56. 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 intermediate coil assembly of Perszyk to incorporate / be replaced by a plurality of beads, based on the teachings of Hansen in view of Douk, for the purpose of being able to impart a desired rigidity / flexibility to the core wire while maintaining the desired torsional rigidity (paragraphs [0006 – 0007], [0030] – Hansen). Additionally, it should be understood that Perszyk and Hansen with the teachings of Douk are known references in the art that teach a delivery system comprising a core wire with elements / members for stiffening and/or providing the desired strength and flexibility to an inner core (abstract, paragraphs [0005 – 0007], [0024 – 0026], [0054], [0058], and Figs. 1 – Perszyk ; abstract, paragraphs [0006 – 0007], [0030] – Hansen; abstract, col. 8 lines 1 – 20, col. 8 lines 24 – 55, and Figs.

15,16 – 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 intermediate outer coil 240* for a series of spaced apart beads), and the results of the substitution would have been predictable and resulted in the modified intermediate member being able to function as intended to provide the desired rigidity / flexibility to the core member as desired and resulted in the delivery cable 200 of Perszyk being able to function as intended to properly push/pull the occluder/implant to the desired treatment site while also being able to mitigate "snaking" of the core member through the catheter. 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.

57. **As to (iii)**, the intermediate outer coil 240 has an outer diameter that approximates the inner diameter of the lumen; and as modified above, the combination would encompass or, at least, make obvious to one of ordinary skill in the art for the plurality of beads to have the same diameter as the intermediate outer coil 240 such that the plurality of beads have an outer diameter that approximates the inner diameter of the lumen as claimed.

Response to Arguments

58. Applicant's arguments, filed 10/01/2026, with respect to the rejection of claims 1, 13, and 20 under Perszyk, Chin, and Douk or Perszyk, Chin, Douk, and Larsen have been considered but are moot as the arguments are directed to Applicant's amendments, and the previous rejection of the claims has been withdrawn in light of

said amendments. Specifically, the rejections were withdrawn because the combinations above do not teach wherein the bead members are spaced from each other such that a portion of the core wire is exposed. It is noted that a new rejection has been made over Perszyk, Hansen, Douk and, separately, Perszyk, Hansen, Douk, and Larsen. The teachings of Hansen are relied upon for teaching the newly added limitations as discussed above.

Conclusion

59. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

60. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any nonprovisional extension fee (37 CFR 1.17(a)) pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

61. 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.

62. 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.

63. 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.

64. 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-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew Restaino/
Primary Examiner, Art Unit 3771