UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Cook Group Incorporated and Cook Medical LLC,

Petitioners

v.

Boston Scientific Scimed, Incorporated,

Patent Owner

Patent No. 8,974,371
Issue Date: March 10, 2015

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,974,371

Case No. IPR 2017-00135

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Cook Group Incorporated and Cook Medical LLC (collectively "Petitioners"), respectfully request *inter partes* review ("IPR") of claims 1, 3-15, and 17 of U.S. Patent No. 8,974,371 ("'371 patent") (Ex. 1027).

I. MANDATORY NOTICES (37 C.F.R. §42.8)

A. Real Parties-in-Interest (§42.8(b)(1))

Petitioners Cook Group Incorporated and Cook Medical LLC, along with Cook Incorporated and Cook Medical Technologies LLC are the real parties-in-interest.

B. Related Matters (§42.8(b)(2))

The '371 patent is the subject of litigation in the U.S. District Court for the District of Delaware in a case entitled, *Boston Scientific Corp. et. al. v. Cook Group Inc. et al.*, No. 15-980-LPS-CJB ("the Litigation"). Petitioners are also aware of pending U.S. Patent Application No. 15/159,512 filed on May 19, 2016, which claims priority to the '371 patent.

C. Lead and Back-Up Counsel (§42.8(b)(3))

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D. Service Information (§42.8(b)(4))

Service of any documents via hand delivery, express mail, or regular mail may be made to the lead and backup counsel at the postal mailing address above. Petitioners also consent to service by email at the above-designated email addresses.

E. Fee for *Inter Partes* Review

The Office is authorized to charge the filing fees specified by 37 C.F.R. §42.15(a), as well as any other necessary fee, to Deposit Account No. 231925.

II. CERTIFICATION OF STANDING (37 C.F.R. §42.104(a))

Petitioners certify that the '371 patent is available for IPR and that Petitioners are not barred or estopped from requesting an IPR challenging the patent claims on the grounds identified in this petition.

III. PRECISE RELIEF REQUESTED (37 C.F.R. §42.104(b))

Petitioners seek review and cancellation of claims 1, 3-15, and 17 of the '371 patent in view of the following references and specific grounds:

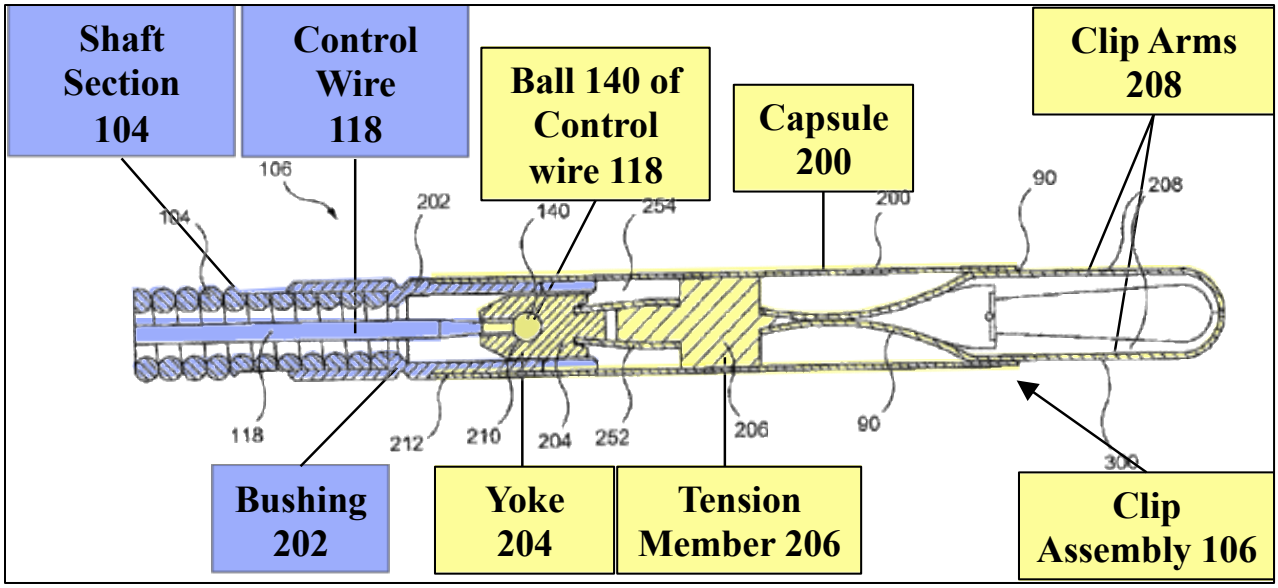
No.	Grounds
1	Claims 1, 3, 8, 9, 11, and 15 are anticipated under §102(b) by Adams
2	Claims 4, 5, 7, 13, and 14 are obvious under §103 in view of Adams
3	Claims 1, 3-5, and 7-9 are obvious under §103 in view of Adams
4	Claims 10 and 17 are rendered obvious under §103 by Adams combined with Sackier
5	Claims 1, 3, and 10 are rendered obvious under §103 by Sackier
6	Claims 11, 15, and 17 are anticipated under §102(b) by Sackier
7	Claims 4, 5, 7, 13, and 14 are rendered obvious under §103 by Sackier combined with Adams
8	Claims 1, 3-5, 7, 10, and 15 are rendered obvious under §103 by Sackier combined with Adams
9	Claims 11-13 are anticipated under §102(b) by Kimura
10	Claims 1, 3-6, and 15 are rendered obvious under §103 by Kimura
11	Claims 10 and 17 are rendered obvious under §103 by Kimura combined with Sackier

IV. SUMMARY OF THE RELEVANT TECHNOLOGY AND THE '371 PATENT

A. Overview of Compression Clip Technology and the '371 Patent

The '371 patent recognizes that, before its filing date, "[h]emostatic clipping tools have been inserted through endoscopes to deploy hemostatic clips." (*See* Ex. 1027 at 1:21-22; *see also* pp. 1-2 (citing numerous prior art references, especially U.S. Pat. Pub. Nos. 2002/0045909, 2002/0151916, 2002/0177861, 2003/0069592; Ex. 1029, ¶ 18). These prior art clips are used to treat bleeding, such as in the stomach or intestines, "by clamping together the edge of a wound" to achieve "hemostasis." (Ex. 1027 at 1:17-28; Ex. 1029, ¶ 18). The prior art clips typically are attached to the distal end of a delivery device and passed through a channel in an endoscope to a target site. (Ex. 1027 at 1:23-26; Ex. 1029, ¶ 18). This allows the physician to remotely position the clip, clamp the clip over the target site, and then detach the clip from the delivery system. (Ex. 1027 at 1:26-28; Ex. 1029, ¶ 18).

The '371 patent discloses a hemostatic clip apparatus having two main components: "[1] a hemostatic clip assembly for mounting on [2] a delivery device." (Ex. 1027 at 1:44-62; Ex. 1029, ¶ 19). The clip assembly 106 includes a capsule 200, clip arms 208, tension member 206, and yoke 204:



'371 Patent Fig. 10

(*See e.g.*, Ex. 1027 at 1:44-62, 6:55-7:3; Ex. 1029, ¶ 19). The delivery device includes a shaft section 104 and control wire 118 that can be moved with respect to shaft section 104 to open and close the clip arms 208. (Ex. 1027 at 4:27-30, 4:42-46; Ex. 1029, ¶ 19). Shaft section 104 of the delivery system is releasably coupled to capsule 200 of clip assembly 106 via a bushing 202. (Ex. 1027 at 7:4-10, 8:60-62; Ex. 1029, ¶ 19).

Moving the control wire 118 back and forth with respect to the shaft section 104 opens and closes the clip arms 208. (Ex. 1027 at 4:42-43; Ex. 1029, ¶ 20). Once the clip arms 208 have been closed around a target tissue, the delivery device may be removed from the patient's body while the clip assembly 106 remains in place. (Ex. 1027 at 10:16-18; Ex. 1029, ¶ 20). This removal occurs in a two-stage process. First, as the control wire 118 is moved proximally (to the left in Fig. 10

above), the first separation occurs between the yoke 204 and the tension member 206. (Ex. 1027 at 9:43-10:15; Ex. 1029, ¶ 20). Second, as the control wire 118 is further moved proximally, the control wire 118 fractures and the bushing 202 separates from capsule 200. (*Id*.).

The '371 patent notes that earlier endoscopic hemostatic clipping devices were inferior because the physician has trouble discerning when the clip assembly has been released from the delivery system. (Ex. 1027 at 1:33-40; Ex. 1029, ¶ 21). To fix this prior art defect, the '371 patent touts that when the control wire 118 fractures, a "large tactile feedback" is provided that indicates to the physician that the clip assembly 106 has been fully deployed. (Ex. 1027 at 9:59-64; Ex. 1029, ¶ 21). Notably, neither this purportedly novel feature nor the use of the device through an endoscope is claimed.

B. The Prosecution History

The '371 patent was filed on December 16, 2011 as U.S. App. Serial No. 13/328,171. (Ex. 1027 at p. 1). The '371 patent claims priority to U.S. App. Serial No. 10/674,512 filed on September 30, 2003, issued as U.S. Patent No. 7,494,461. The '371 patent also claims priority to several continuation applications and to U.S. Prov. App. Serial No. 60/568,418 filed on May 5, 2004. (*Id*.).

C. Level of Ordinary Skill in the Art

The person having ordinary skill in the art ("PHOSITA") in the 2003 timeframe (purported 2003 priority date) would have possessed the knowledge and skill known by an engineer or similar professional with at least an undergraduate degree in engineering, or a physician having experience designing medical devices. (Ex. 1029, ¶ 11). This person would also have an understanding of engineering or medical device design principles. (Ex. 1029, ¶ 20).

D. Claim Construction (§42.104(b)(3))

Claims in an IPR are given the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. §42.100(b) (2015); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2136 (2016). In light of the broadest reasonable construction standard and for the purposes of this IPR only,[1] Petitioners adopt the following constructions proposed by BSSI in the Litigation or during prosecution of the '371 patent or its related applications:

[1] By proposing these constructions, Petitioners do not agree or admit that any limitation is entitled to coverage under the doctrine of equivalents, that the claims are entitled to such a scope in other proceedings, or satisfy the requirements of 35 U.S.C. §112.

1. "sheath"

In the Litigation, BSSI argued that the term "sheath" means "one or more components that encloses the control wire." (Ex. 1008 at 7).

2. "an opening"

In the Litigation, BSSI argued that the term "opening" in the limitations "an opening formed in a proximal end thereof" and "an opening at a proximal end of the capsule" carries its plain and ordinary. (Ex. 1008 at 18). BSSI explained that this limitation includes more than just openings in the capsule's sidewall, and includes the inherent opening "at the exact proximal end of the capsule" (i.e, the existing opening defining the end of a hollow tube). (*Id.*).

3. bushing "coupled to the sheath"

In the Litigation, BSSI argued that the term bushing "coupled to the sheath" carries its plain and ordinary meaning, which includes bushings that are "slideable inside the sheath" and where "the sheath confines the bushing and, therefore, is coupled to it." (Ex. 1008 at 19).

4. "a control element including a connector element"

In the Litigation, BSSI argued that the term "a control element including a connector element" carries its plain and ordinary meaning, and explained that this limitation may be "made up of multiple, distinct structures." (Ex. 1013 at 16). As an example, BSSI argued that the claimed "connector element" in the '371 patent

is the distinct yoke 204 described above in Section IV.A. (*Id*. at 17; Ex. 1031 at p. 21).

5. "frangible link"

In the Litigation, BSSI argued that the term "frangible link" means "a link between at least two components that become unlinked when a tensile load is applied." (Ex. 1008 at 22). BSSI explained that this includes a "ball-and-socket link, [where] the ball could be pulled from the socket under a tensile force, thus breaking the link, but neither the ball nor the socket would itself be broken." (*Id*.).

6. "yoke"

During prosecution of a continuation of the '371 patent, BSSI defined "yoke" to mean a structure "configured with sides or overhangs that extend around another element so that the element is held within the yoke." (Ex. 1030 at Response to Office Action dated November 10, 2015, p. 7).

7. "tension member"

In the Litigation, BSSI argued that the term "tension member" carries its plain and ordinary meaning: "it fits inside the capsule, is positioned between the clip arms, and engages the clip arms to urge them radially outward." (Ex. 1008 at 26).

V. PROPOSED GROUNDS OF REJECTION

A. The Prior Art References

1. Adams (Ex. 1023)

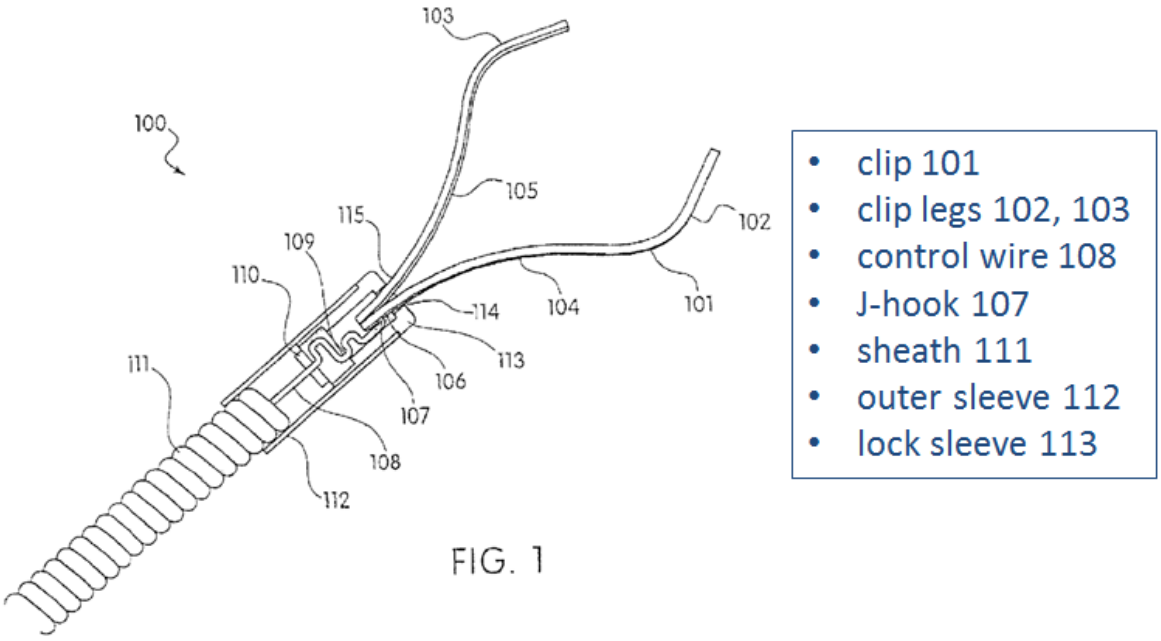
Adams qualifies as prior art under 35 U.S.C. §102(e), issuing on April 1, 2014 from a U.S. patent application filed April 16, 2013 that claims priority to U.S. Patent Application No. 09/971,488 filed on October 5, 2001.

A related publication of Adams was cited during the '371 patent prosecution (Ex. 1020). However, Petitioners' invalidity grounds and recent BSSI statements in the Litigation regarding the construction of certain claim terms raise new issues not previously considered by the Patent and Trademark Office ("PTO").

Adams discloses several embodiments of devices for endoscopic hemostatic clipping; two are relied upon in this Petition:

a. The "J-Hook" Embodiment

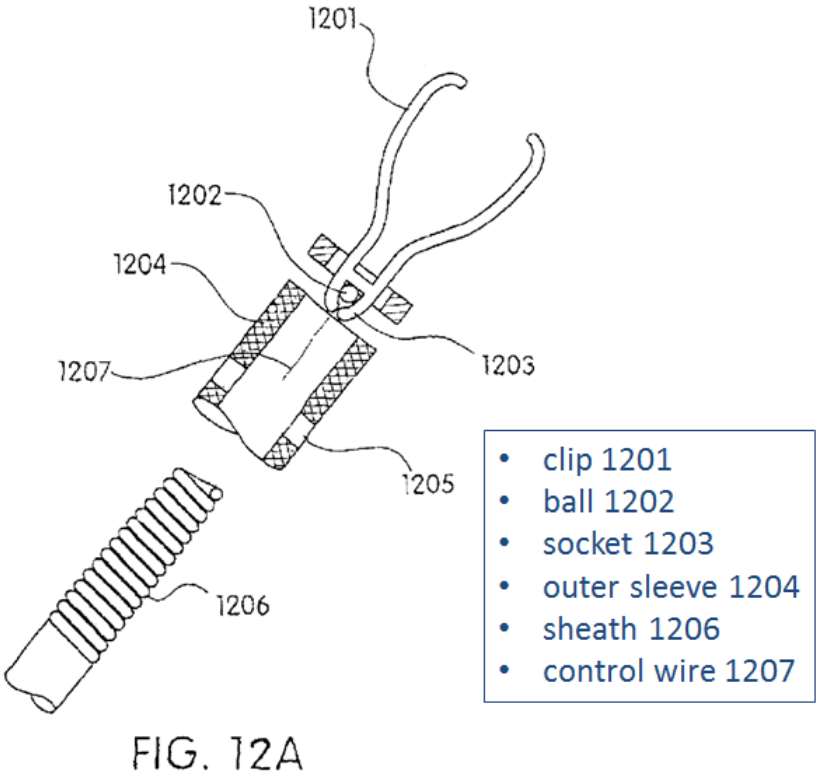
The "J-Hook" embodiment is shown in Figs. 1-7 and described at col. 5:21 to col. 8:12 ("The clip 101 is a deformable, multi-legged, grasping device attached to the distal portion of a flexible shaft (the sheath 111) via a frangible link (the j-hook 107)."). (Ex. 1029, ¶ 26).



Adams Fig. 1

b. The "Ball-and-Socket" Embodiment

The "Ball-and-Socket" embodiment is shown in Figs. 12A-12B and described at col. 9:46-64 ("Another alternative to the j-hook type frangible link is shown in FIGS. 12A and 12B. This embodiment uses a ball 1202 fitting into a socket, where the socket is defined by socket tabs 1203, to attach the control wire 1207 to the clip 1201."). (Ex. 1029, ¶ 27).

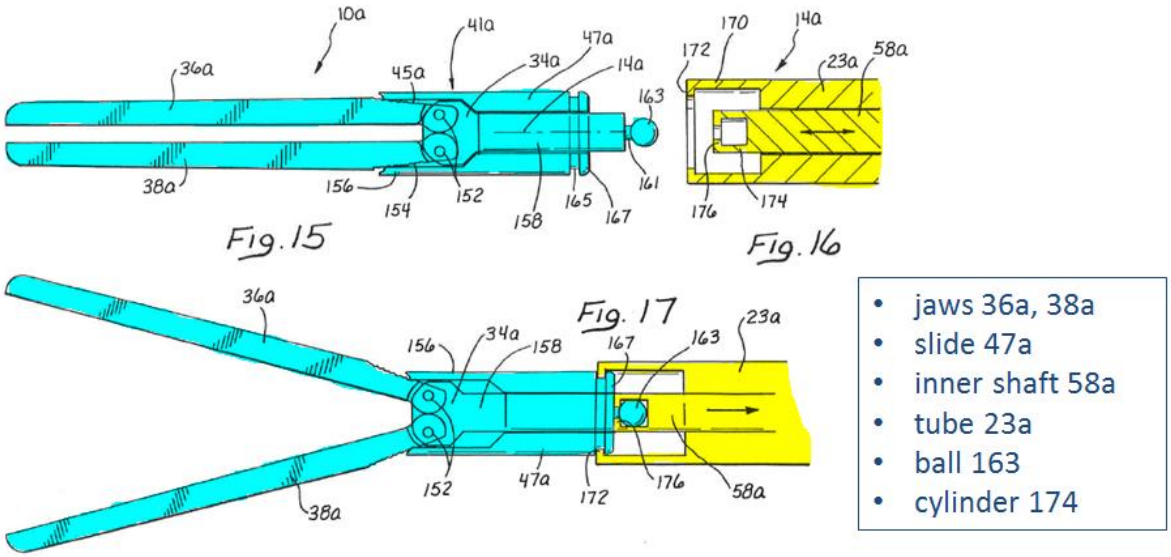


Adams Fig. 12A

2. Sackier (Ex. 1008)

Sackier is prior art under 35 U.S.C. §102(b), issuing on May 12, 1998 and Sackier was not cited during prosecution of the '371 patent.

Sackier discloses a clamp applier with a detachable surgical clamp, or clip, used to occlude a body conduit. The surgical clamp includes a pair of jaws with a spring to bias the jaws to the open position: "the shaft 58a can be moved relative to the tube 23a to engage the slide 47a and move it relative to . . . the jaws 36a, 38a. As noted, this axial movement of the slide 47a relative to the jaws 36a and 38a is accompanied by relative movement of the jaws 36a, 38a between the open and closed positions." (Ex. 1008 at 10:28-34; Ex. 1029, ¶ 29).



Sackier Figs. 15-17[2]

[2] Figures 15-26 of Sackier published without reference numbers, even though Figures 15-26 with reference numbers were submitted during prosecution (Ex.

3. Kimura (Ex. 1007)

Kimura published on April 18, 2002 from a U.S. patent application filed October 11, 2001, and is prior art under 35 U.S.C. §102(b).

Kimura was considered during prosecution of the '371 patent. However, Petitioners' grounds here and BSSI's recent statements regarding the construction of certain claim terms raise new issues not previously considered by the PTO.

Kimura discloses a clipping apparatus with "a clip capable of being arbitrarily opened/closed." (Ex. 1007 at ¶ [0033]; Ex. 1029, ¶ 31). The clip may be secured onto tissue via a clip applicator and then detached from the clip applicator. (Ex. 1007 at ¶ [0031]; Ex. 1029, ¶ 31).

1012 at Transmittal of Formal Drawings dated September 18, 1997). Those figures became a "printed publication" under 35 U.S.C. §102 upon Sackier's issuance. *See Bruckelmyer v. Ground Heaters, Inc*., 445 F.3d 1374, 1377-78 (Fed. Cir. 2006) (figures omitted from issued patent but submitted during prosecution were "printed publications" as of patent's issue date). The figures with reference numerals are used in this petition for ease of explanation. *See In re Baxter Travenol Labs*., 952 F.2d 388, 390 (Fed. Cir. 1991) (extrinsic evidence may be used to explain the meaning of a reference when conducting an analysis under 35 U.S.C. 102).

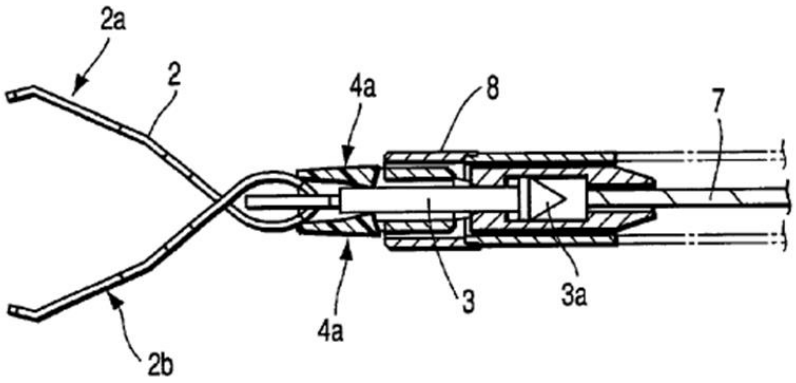


FIG. 3B

- clip 2
- stop tube 4
- manipulating wire 7

Kimura Fig. 3B

B. Ground 1: Claims 1, 3, 8, 9, 11, and 15 are Anticipated by Adams

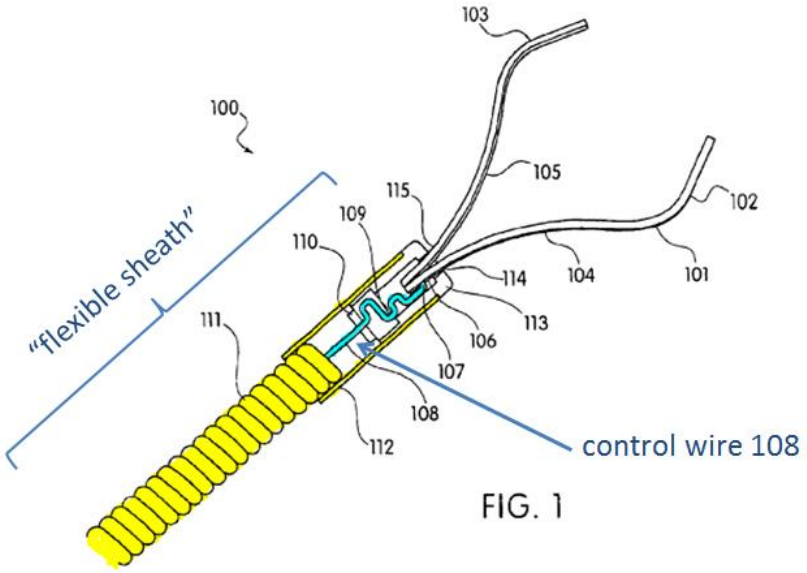
1. Independent Claim 1[3]

a. "*An apparatus for applying clips to tissue, comprising*:"

Adams discloses "a compression clip used to cause hemostasis of blood vessels and a mechanism for deploying the clip." (Ex. 1023 at 2:58-60; *see also, e.g.*, *id*. at Abstract, 1:21-22; Ex. 1029, ¶ 33).

b. "*a flexible sheath extending from a proximal end which, in an operative configuration, extends into a living body to a target portion of tissue to be clipped*;"

This limitation is met by sheath 111 and tubular outer sleeve 112 fixedly attached to the distal end of sheath 111:



Adams Fig. 1

[3]Claims 1-10 were never rejected in view of Adams. (Ex. 1028 at Office Action dated May 27, 2014).

(Ex. 1023 at 5:31-33, 6:44-46 ("The outer sleeve 112 . . . is rigidly attached to the sheath 111 . . . ."); Ex. 1029, ¶ 34). These sheath components enclose control wire 108. (*Id*. at 5:31-33, 5:64-66). Sheath 111 and sleeve 112 extend from a proximal end into a living body to a target portion of tissue to be clipped. (Ex. 1023 at 5:42-63; Ex. 1029, ¶ 34).

c. "*a capsule extending from a proximal to a distal end and having an opening formed in a proximal end thereof*;"

This limitation is met by lock sleeve 113 ("capsule") extending from a proximal to a distal end and having a retainer hole 116 ("opening") formed in a proximal end thereof. (Ex. 1023 at 7:12-16; *see also, e.g., id*. at 5:39-41, 5:56-63, Fig. 1; Ex. 1029, ¶ 35).[4]

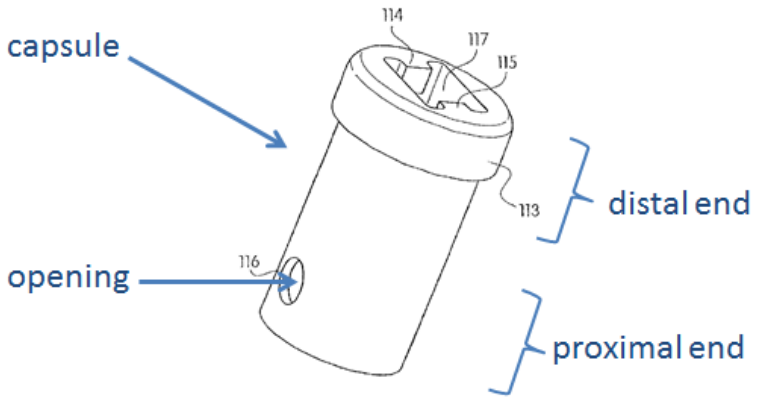


FIG. 4

Adams Fig. 4

[4] Although Adams discloses two retainer holes 116, only one is necessary to satisfy the "opening" limitation. (Ex. 1029, ¶ 35 n3).

d. "*a clip assembly provided in the capsule and configured to be operably movable between a closed configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration in which the first and second arms are separated from one another to receive target tissue therebetween*;"

This limitation is met by clip 101 ("clip assembly") having a first clip leg 102 and a second clip leg 103 ("first and second arms of the clip assembly") provided in the lock sleeve 113 ("capsule"). (Ex. 1023 at 5:22-23; Ex. 1029, ¶ 36). The clip legs 102, 103 are configured to be operably movable between a "closed configuration" in which the clip legs 102, 103 are drawn towards one another (Fig. 2) and an "expanded configuration" in which the clip legs 102, 103 are separated from one another to receive target tissue therebetween (Fig. 3). (*See* Ex. 1023 at 5:22-23, 5:49-52; Ex. 1029, ¶ 36).

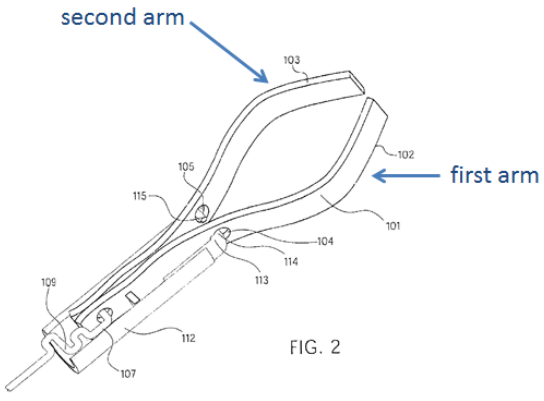


FIG. 2

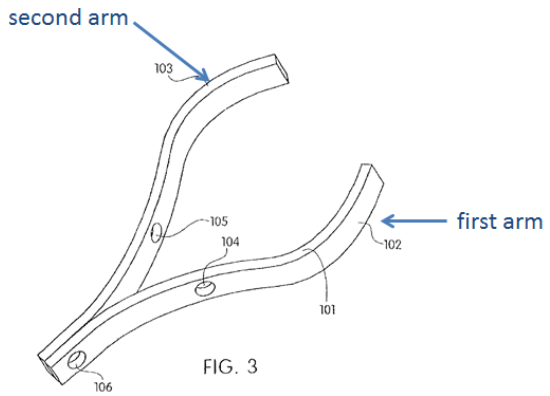
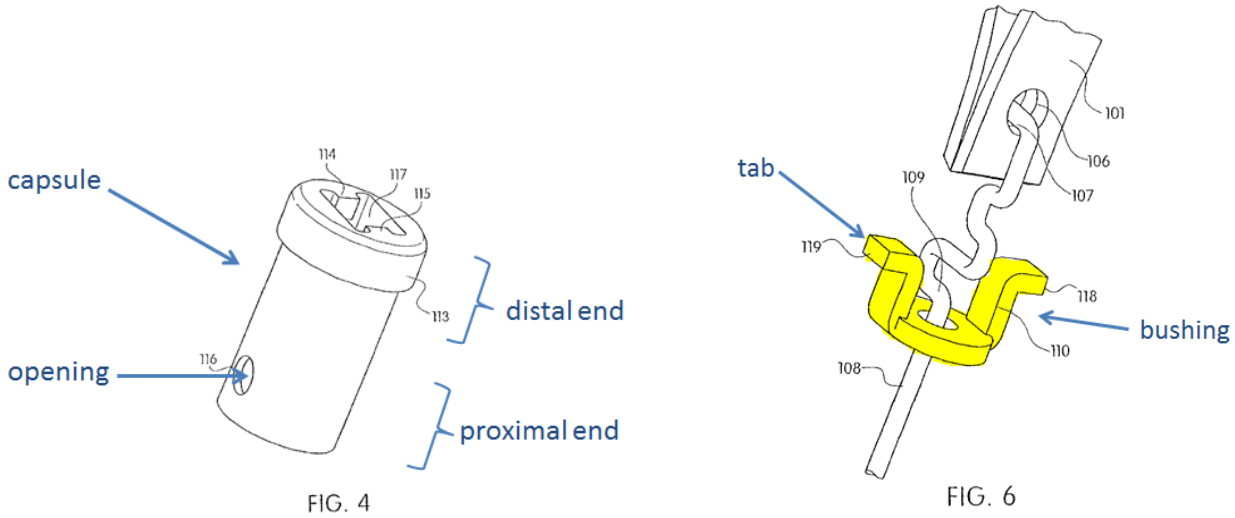


FIG. 3

Adams Figs. 2 and 3

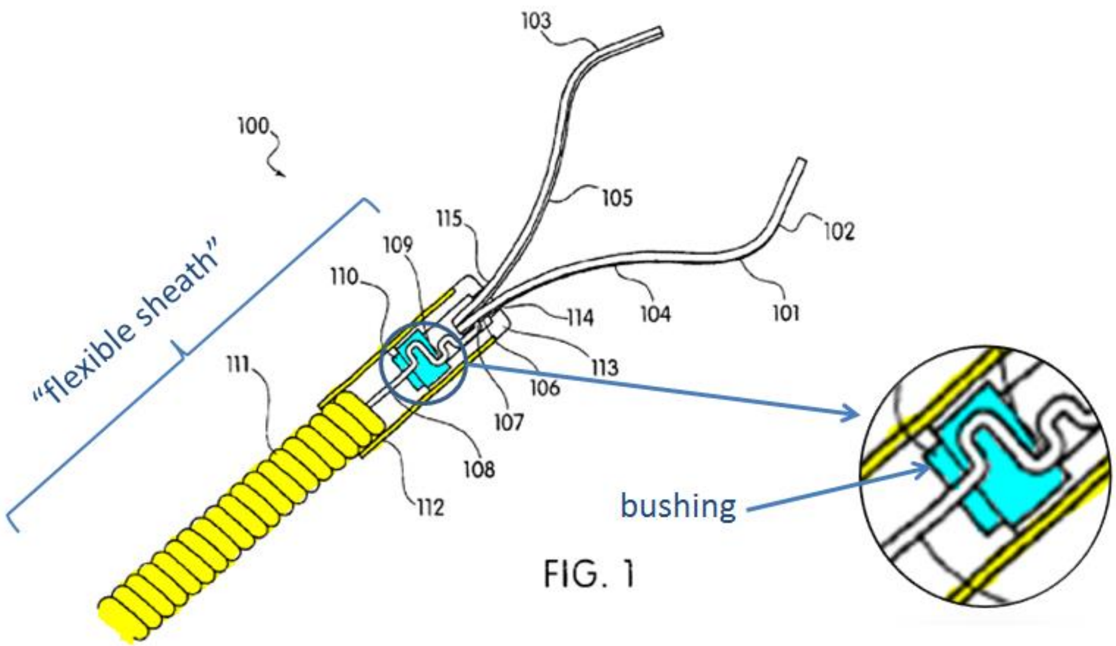
e. "*a bushing extending between a proximal end coupled to the sheath and a distal end releasably coupled to the capsule via a tab on the distal end of the bushing engaging the opening of the capsule; and*"

This limitation is met by retainer 110 ("bushing") releasably coupled to lock sleeve 113 ("capsule") via one of its distal end retainer tabs 118 or 119 releasably engaging the retainer hole 116 ("opening") of the lock sleeve 113 as shown in Figs. 6 and 1. (Ex. 1023 at 7:12-16, 7:34-40; Ex. 1029, ¶ 37).



Adams Figs. 4 and 6

As Dr. Nicosia explains, retainer 110 is slidable inside the sheath when a sufficient tensile force is applied to the control wire to cause disengagement. (Ex. 1023 at 5:27-31; Ex. 1029, ¶ 38). During that entire process, both before and after disengagement, the retainer is confined (i.e., to hold within a location, to keep within limits) by the sheath at its proximal end, center portion and distal end. (Ex. 1029, ¶ 38). Thus, under BSSI's interpretation of "coupled to the sheath" in the Litigation, the retainer is coupled to the sheath at its proximal end. (*Id.*).


103
100
105
115
102
109
110
"flexible sheath"
114
104
101
111
113
106
107
108
112
bushing
FIG. 1

Adams Fig. 1

f. "*a control member a distal end of which is releasably coupled to the clip assembly to transmit to the clip assembly forces applied thereto to move the clip assembly between the insertion*[5] *and expanded configurations*."

This limitation is met by control wire 108 ("control member") having j-hook 107 on its distal end that is releasably coupled to clip 101 ("clip assembly") which transmits forces to clip 101 to move it between insertion and expanded configurations. (Ex. 1023 at 7:39-61 ("The control wire 108 [is] used to actuate the clip 101 . . . ."), 7:26-27; Ex. 1029, ¶ 39).

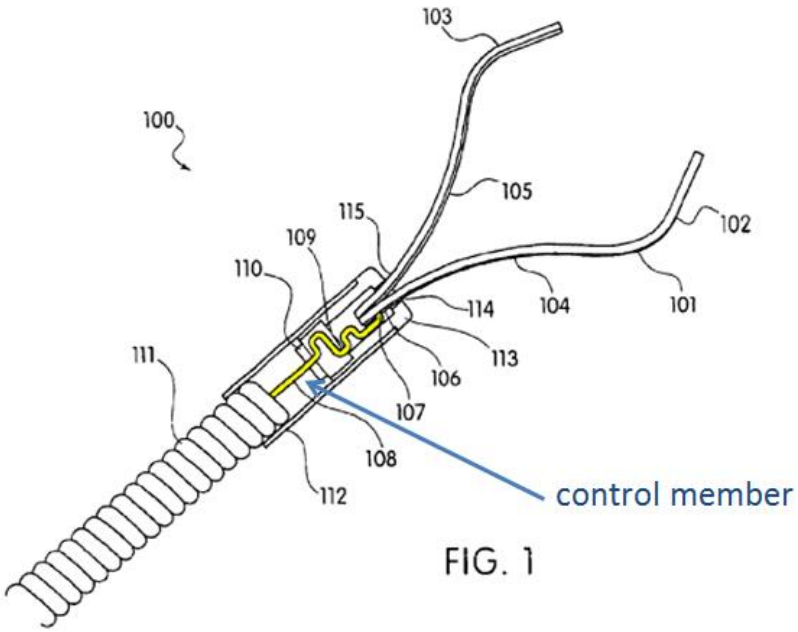


FIG. 1

Adams Fig. 1

[5] For purposes of this Petition only, Petitioners treat "the insertion configuration" as the "closed configuration," even though it lacks antecedent basis.

2. Claim 3

Claim 3 adds the limitation "*wherein a proximal end of the control member is coupled to a control handle which, when the apparatus is in an operative position, remains outside the body accessible to a user*."

This limitation is met by a handle coupled to the proximal end of control wire 108 ("control member") that "acts as a means of actuating the clip 101 between the open and closed position." (Ex. 1023 at 5:42-52; *see also*, *e.g.*, *id*. at 2:58-60, 7:64-8:12; Ex. 1029, ¶ 41). The Adams handle remains outside the body accessible to a user at all times. (Ex. 1023 at 5:42-63; Ex. 1029, ¶ 41).

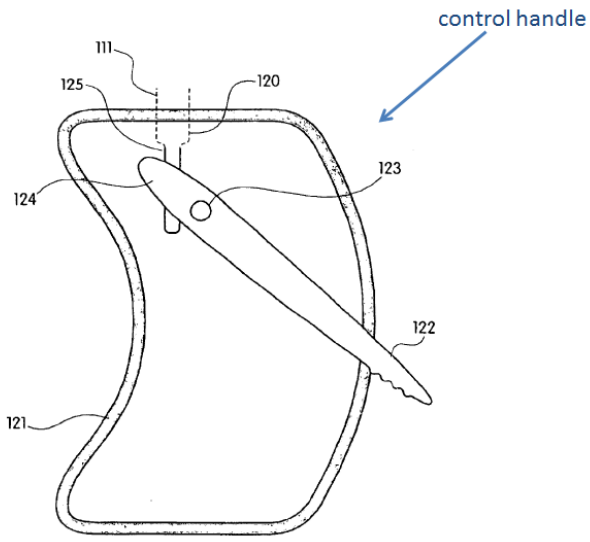


FIG. 7

Adams Fig. 7

3. Claim 8

Claim 8 adds the limitation "*wherein the proximal end of the capsule comprises a keyed portion aligning the capsule in a desired rotational orientation with respect to the bushing*."

This limitation is met by one of retainer holes 116 ("keyed portion") on either side of the proximal end of lock sleeve 113 ("capsule"). Each hole is designed to mate with corresponding retainer tab 118, 119 on retainer 110 ("bushing"):

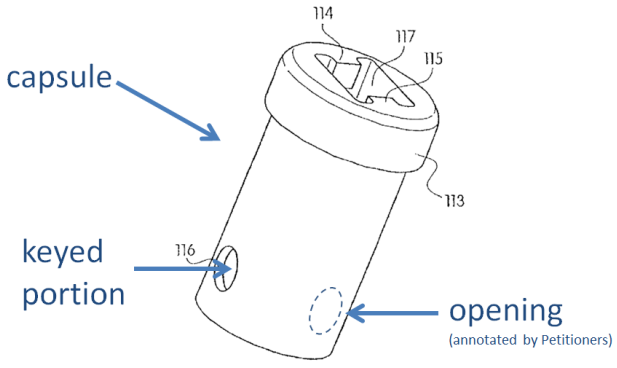


FIG. 4

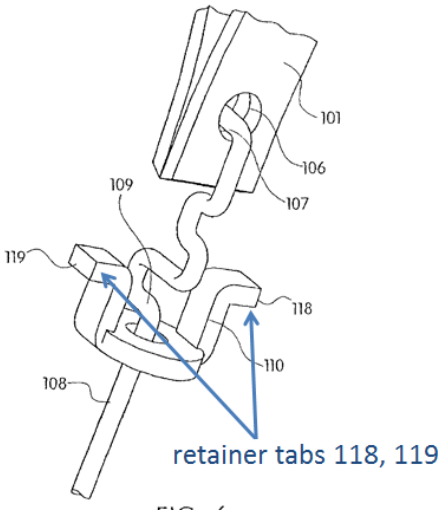


FIG. 6

Adams Figures 4 and 6

(Ex. 1023 at 6:44-53, 7:12-16; Ex. 1029, ¶ 43). Retainer tabs 118, 119 ("keyed portion") and retainer holes 116 align lock sleeve 113 ("capsule") in a desired rotational orientation with respect to retainer 110 ("bushing"). (Ex. 1023 at 6:44-53, 7:12-16; Ex. 1029, ¶ 43).

As discussed in Section V.B.1.c, one of retainer holes 116 meets the "opening" limitation of claim 1. The other retainer hole 116 meets the "keyed portion" limitation. (Ex. 1029, ¶ 44).

4. Claim 9

Claim 9 adds the limitation "*wherein the distal end of the bushing comprises a feature configured to mate with the keyed portion of the capsule*."

This limitation is met because the distal end of retainer 110 ("bushing") comprises retainer tabs 118, 119 ("feature") configured to mate with retainer holes 116 ("keyed portion") of lock sleeve 113 ("capsule"):

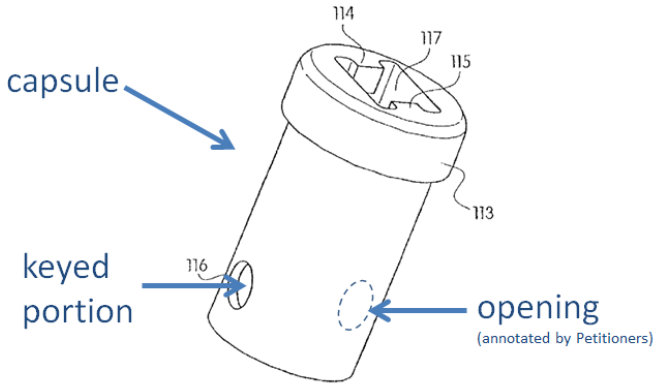


FIG. 4

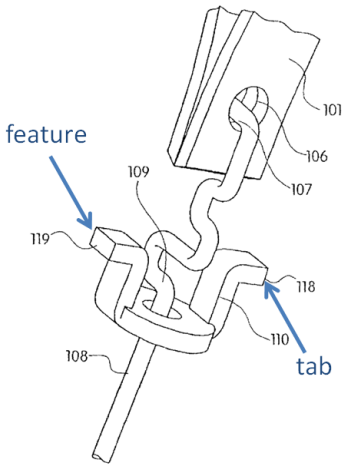


FIG. 6

Adams Figs. 4 and 6

(Ex. 1023 at 6:44-53, 7:12-16; Ex. 1029, ¶ 46). As discussed at Section V.B.1.e, one of retainer tabs 118, 119 meets the "tab" limitation of claim 1. The other retainer tab 118, 119 is the claimed "feature configured to mate with the keyed portion of the capsule." (Ex. 1029, ¶ 46).

5. Independent Claim 11[6]

a. "*An apparatus for applying clips to tissue within a living body, comprising*:"

This limitation is disclosed by Adams for the reasons discussed in Section V.B.1.a. (*See also* Ex. 1029, ¶ 47).

b. "*a capsule*;"

This limitation is disclosed by Adams for the reasons discussed in Section V.B.1.c. (*See also* Ex. 1029, ¶ 48).

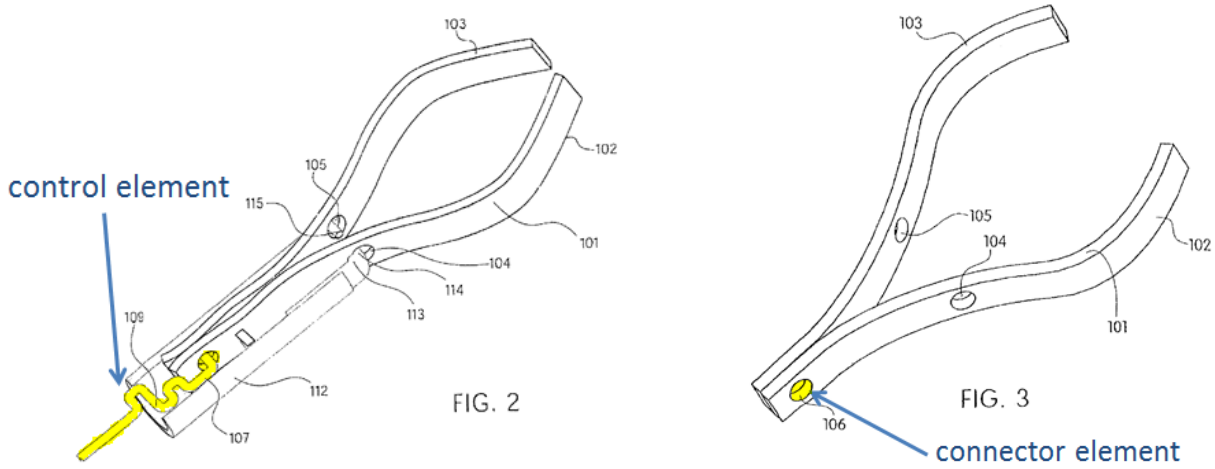
c. "*a clip assembly housed within the capsule for movement between an insertion configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration in which the first and second arms are separated from one another to receive tissue therebetween*;"

For purposes of this Petition only, Petitioners treat "insertion configuration" to be equivalent to "closed configuration" in claim 1. Thus, Adams discloses this limitation for the reasons discussed in Section V.B.1.d. (*See also* Ex. 1029, ¶ 49).

[6] The Examiner rejected an earlier version of this claim based on a different Adams embodiment. (Ex. 1028 at Office Action dated May 27, 2014, page 5).

d. "*a control element including a connector element, extending between a proximal end which, during use, remains outside the body accessible to a user and a distal end removably connected to the clip assembly via the connector element*,"

This limitation is met by control wire 108 having j-hook 107 on the distal end that is removably connected to the clip 101 ("clip assembly") via a cut-out 106:



Adams Figs. 2 and 3

(Ex. 1023 at 7:45-61; *see also*, *e.g.*, *id*. at 5:26-31, 5:42-44, 5:52-63; Ex. 1029, ¶ 50). Control wire 108, j-hook 107, and cut-out 106 are multiple, distinct structures that collectively makeup the claimed "control element including a connector element," with cut-out 106 as the claimed "connector element." (Ex. 1029, ¶ 50). During use, the proximal end of control wire 108 (part of the "control element") remains outside the body accessible to a user. (Ex. 1023 at 7:45-61; Ex. 1029, ¶ 50).

BSSI alleges that the "connector element" may be part of the "clip assembly." (*See* Section IV.D.4). Specifically, BSSI argues that yoke 204 is the claimed "connector element" despite the '371 patent describing yoke 204 as part of clip assembly 106. (Ex. 1031 at p. 21; Ex. 1027 at 6:64-7:3 ("Some of the components of the clip assembly include . . . a yoke 204.")). Thus, even though cut-out 106 of Adams is part of clip 101 ("clip assembly"), it meets the "connector element" limitation under BSSI's interpretation. (Ex. 1029, ¶ 51).

e. "*wherein the control element detaches from the connector element via a frangible link; and*"

Adams discloses that j-hook 107 and control wire 108 (structures forming the "control element") form a link with cut-out 106 ("connector element"), which unlinks when a tensile load is applied (i.e., a "frangible link.") (Ex. 1023 at 5:56-59, 7:26-27 ("Forming the end of the control wire 108 into a j-hook 107 makes a frangible link . . . ."); Ex. 1029, ¶ 52). In the Litigation, BSSI conceded that this connection between j-hook 107 and cut-out 107 is a frangible link. (*See* Ex. 1004 at 22-23).

f. "*a sheath extending from a proximal to a distal end and covering a portion of the control element, wherein the distal end of the sheath is releasably coupled to the capsule*."

This limitation is met by sheath 111 and tubular outer sleeve 112 fixedly attached to the distal end of sheath 111. (Ex. 1023 at 5:31-33, 6:44-46 ("The outer sleeve 112 . . . is rigidly attached to the sheath 111 . . . .); *see also*, *e.g.*, *id.* at 5:64-66; Ex. 1029, ¶ 53). These sheath components (*i.e.*, sheath 111 and outer sleeve 112) extend from a proximal to a distal end and cover a portion of control wire 118, j-hook 107, and cut-out 106 ("control element"). Further, the distal end of outer sleeve 112 (component of the "sheath") is releasably coupled to lock sleeve 113 ("capsule"). (Ex. 1023 at 5:64-66, 6:58-62; Ex. 1029, ¶ 53).

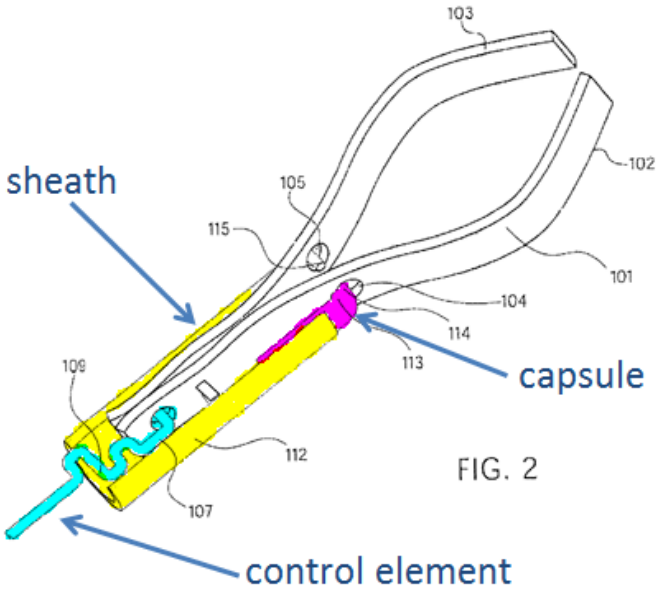


FIG. 2

Adams Fig. 1

6. Claim 15

Claim 15 adds the limitation "*wherein the sheath is coupled to the capsule via a bushing including a tab on a distal end thereof received in an opening at a proximal end of the capsule*."

This limitation is met by retainer 110 ("bushing"), which couples outer sleeve 112 (component of the "sheath") to lock sleeve 113 ("capsule"):

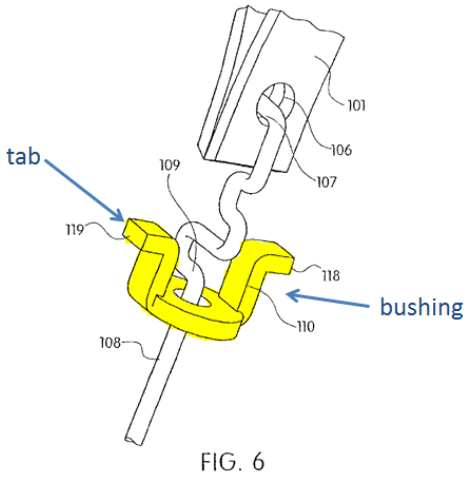


FIG. 6

Adams Fig. 6

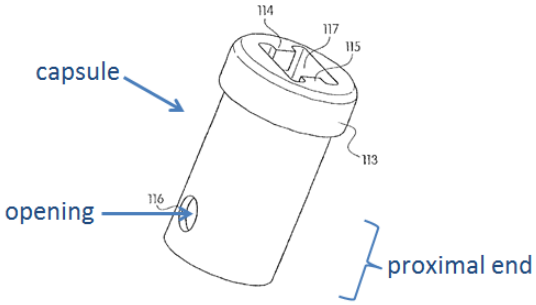
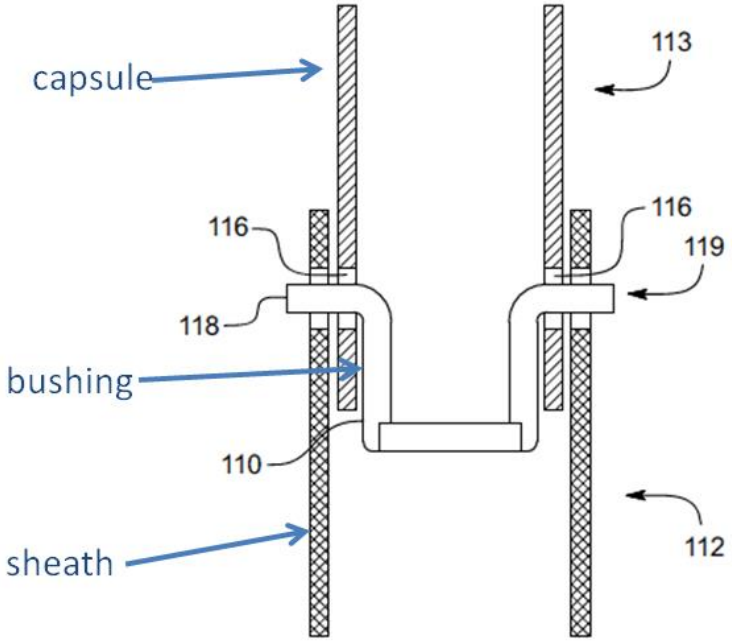


FIG. 4

Adams Fig. 4

(Ex. 1023 at 7:12-16, 5:39-41, 5:56-63, Fig. 1; Ex. 1029, ¶ 55). Fig. 4 above shows lock sleeve 113 ("capsule") with retainer holes 116 ("opening") at its proximal end. (*Id*. at 7:12-16). Retainer 110 ("bushing") includes retainer tabs 118, 119 ("tab") on the distal end thereof which are received in retainer holes 116 ("opening") of lock sleeve 113 ("capsule"). (Ex. 1023 at 7:14-16 ("Retainer hole 116 and opposite retainer hole (not shown) in the lock sleeve 113 receive the retainer tabs 118, 119 . . . ."), 7:34-40); Ex. 1029, ¶ 43). As shown in the figure

below,[7] retainer tabs 118, 119 also engage two retainer cut-outs of outer sleeve 112 (component of the "sheath"):



(Ex. 1023 at 6:44-50; Ex. 1029, ¶¶ 55-56). Since retainer tabs 118, 119 ("tab") engage openings in both outer sleeve 112 (component of the "sheath") and lock sleeve 113 ("capsule"), retainer 110 ("bushing") couples together the two components. (Ex. 1029, ¶¶ 55-56).

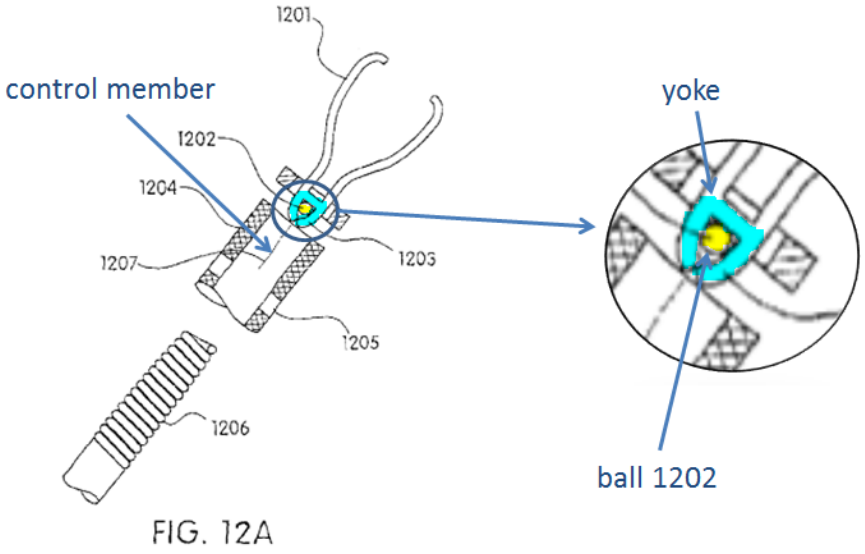
[7] This figure was prepared based on Dr. Nicosia's understanding of Adams. (Ex. 1029, ¶ 56)

C. Ground 2: Claims 4, 5, 7, 13, and 14 are Rendered Obvious by Adams

1. Claim 4

Claim 4 depends from claim 3, which is anticipated by Adams. (*See* Section V.B.2). Claim 4 adds the limitation "*wherein the clip assembly further comprises a yoke slidably received in the capsule and releasably coupled to the control member*."

This limitation is obvious in view of Adams' Ball-and-Socket embodiment. Fig. 12A shows "ball 1202 fitting into a socket . . . to attach the control wire 1207 to the clip 1201":



Adams Fig. 12A

(Ex. 1023 at 9:47-50; Ex. 1029, ¶ 58). The socket is the claimed "yoke" under BSSI's description of "yoke" to the PTO. (Ex. 1029, ¶ 58). The socket is configured with sides or overhangs, socket tabs 1203, which extend around another element, ball 1202, so that the ball 1202 is held within the socket. (Ex. 1023 at

9:47-50; Ex. 1029, ¶ 58). Socket tabs 1203 are slidably received in outer sleeve 1204 ("capsule") and releasably coupled to control wire 1207 ("control member"). (Ex. 1023 at 9:56-64; Ex. 1029, ¶ 58).

Just like j-hook 107 and cut-out 106 in Adams' "J-Hook" embodiment, ball 1202 and socket 1203 link together two components: the "control member" and "clip assembly" that become unlinked when a tensile load is applied. (*Id*. at 9:59-64; Ex. 1029, ¶ 59).

In the 2003 timeframe, it would have been obvious to a PHOSITA to substitute Adams' j-hook 107 and cut-out 106 with Adams' alternative ball 1202 and socket 1203 as an alternative way of releasably connecting a "clip assembly" to a "control member."

First, the proposed substitution is a "[s]imple substitution of one known element for another to obtain predictable results." MPEP §2143 (I)(B). The substitution of the j-hook 107 and cut-out 106 disclosed in Adams for the ball 1202 and socket 1203 also disclosed in Adams is the simple substitution of one known element for another to obtain the predictable result of linking two components, a "control member" and a "clip assembly," that become unlinked when a tensile load is applied. (Ex. 1029, ¶ 61).

Second, the proposed substitution merely involves "choosing from a finite number of identified, predictable solutions, with a reasonable expectation of

success." MPEP §2143 (I)(E). There are a finite number of mechanical couplings that link two components together and become unlinked when a tensile load is applied. (Ex. 1029, ¶ 62). The ball 1202 and socket 1203 connection and j-hook 107 and cut-out 106 connection disclosed in Adams are two such examples that would have been obvious to a PHOSITA to try. (*Id*.).

Third, there was a "teaching, suggestion, or motivation in the prior art that would have led a [PHOSITA] to modify" Adams "to arrive at the claimed invention." MPEP §2143 (I)(G). Specifically, Adams teaches that releasable connections (or "frangible links") are interchangeable. (Ex. 1023 at 15:22-27 ("It will be obvious to those skilled in the art, with regard to this disclosure, that other variations on this invention beyond those specifically exemplified here may be made. These variations include . . . closing mechanisms, locking mechanisms, [and] frangible links . . . ."). A PHOSITA would understand this statement to teach, suggest, or motivate substituting j-hook 107 and cut-out 106 connection disclosed in Adams with ball 1202 and socket 1203 connection also disclosed in Adams. (Ex. 1029, ¶ 63).

Thus, it would have been obvious to a PHOSITA to simply substitute the j-hook 107 connection described in Adams with the alternative ball 1202 and socket 1203 connection also described in Adams. (*Id*. at ¶ 64).

2. Claim 5

Claim 5 depends from claim 3, which is anticipated by Adams. (*See* Section V.B.2). Claim 5 adds the limitation: "*wherein the control member is coupled to the yoke*[8] *via a frangible link*."

This limitation is disclosed in Adams. As discussed with respect to claim 4, Adams' Ball-and-Socket embodiment discloses "ball 1202 fitting into a socket . . . to attach the control wire 1207 to the clip 1201" where the socket, or socket tabs 1203, is the claimed "yoke," and it would have been obvious to a PHOSITA to simply substitute the j-hook and cut-out 106 connection between the "clip assembly" and "control member" described in Adams with the alternative ball-and-socket connection also described in Adams. (*See* Section V.C.1; Ex. 1029, ¶ 66).

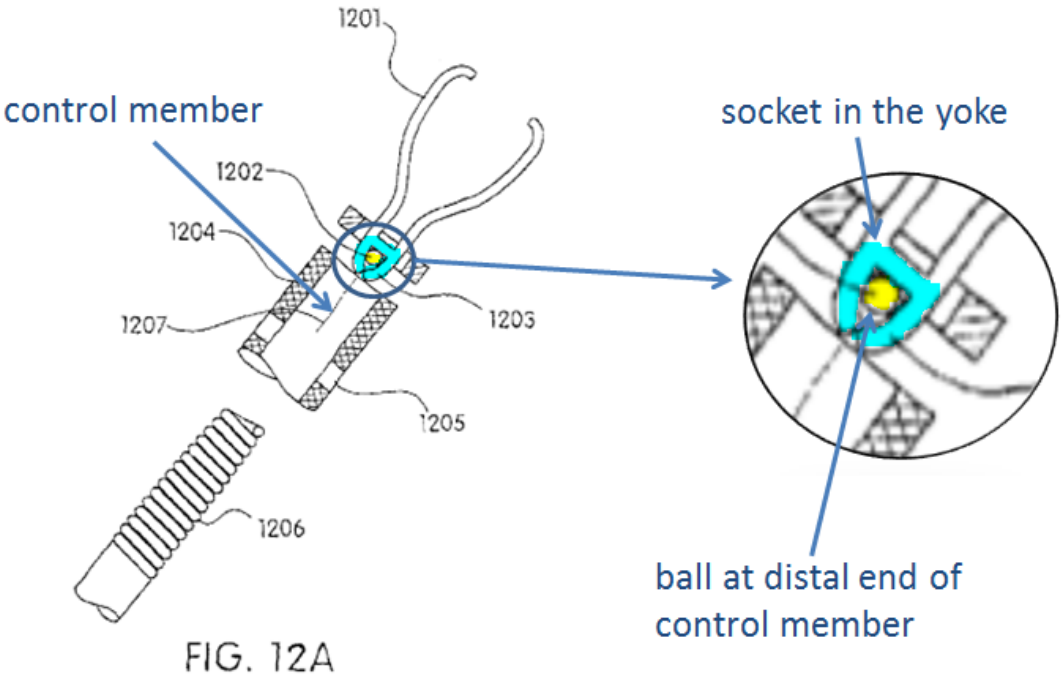
In Adams' Ball-and-Socket embodiment, the ball 1202 and socket tabs 1203 ("socket") connection form a frangible link between two components, clip 1201 ("clip assembly") and control wire 1207 ("control member"), that become unlinked when a tensile load is applied. (Ex. 1023 at 9:56-64; Ex. 1029, ¶ 67). In the Litigation, BSSI conceded that the ball-and-socket connection of Adams is a "frangible link." (*See* Ex. 1004 at 23).

[8] "[T]he yoke" lacks antecedent basis. For purposes of this Petition only, Petitioners treat this limitation as "a yoke."

3. Claim 7

Claim 7 depends from claim 5 and adds the limitation "*wherein the distal end of the control member comprises a ball received in a socket in the yoke*."

Adams' Ball-and-Socket embodiment discloses ball 1202 ("ball") at the distal end of control wire 1207 ("control member") received in a socket, or socket tabs 1203 ("socket in the yoke"). (*See* Section V.C.1; *see also* Ex. 1023 at 9:47-51; Ex. 1029, ¶ 69).



Adams Fig. 12A

4. Claim 13

Claim 13 depends from claim 11, which is anticipated by Adams. (*See* Section V.B.5.) Claim 13 adds the limitation "*wherein the clip assembly includes a yoke slidably received in the capsule and removably coupled to the control element*."

This limitation is disclosed in Adams for the reasons discussed in Section V.C.1. (*See also* Ex. 1029, ¶ 71).

5. Claim 14

Claim 14 depends from claim 13 and adds the limitation "*wherein the yoke is connected to the control element via a ball and socket joint*."

This limitation is disclosed in Adams for the reasons discussed in Section V.C.3. (*See also* Ex. 1029, ¶ 73).

D. Ground 3: Claims 1, 3-5, and 7-9 are Rendered Obvious by Adams

1. Independent Claim 1

a. "*An apparatus for applying clips to tissue, comprising*:"

Adams meets this limitation for the reasons discussed in Section V.B.1.a.

(*See also* Ex. 1029, ¶ 74).

b. "*a flexible sheath extending from a proximal end which, in an operative configuration, extends into a living body to a target portion of tissue to be clipped*;"

Adams meets this limitation for the reasons discussed in Section V.B.1.b.

(*See also* Ex. 1029, ¶ 75).

c. "*a capsule extending from a proximal to a distal end and having an opening formed in a proximal end thereof*;"

Adams meets this limitation for the reasons discussed in Section V.B.1.c.

(*See also* Ex. 1029, ¶ 76).

d. "*a clip assembly provided in the capsule and configured to be operably movable between a closed configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration in which the first and second arms are separated from one another to receive target tissue therebetween*;"

Adams meets this limitation for the reasons discussed in Section V.B.1.d.

(*See also* Ex. 1029, ¶ 77).

e. "*a bushing extending between a proximal end coupled to the sheath and a distal end releasably coupled to the capsule via a tab on the distal end of the bushing engaging the opening of the capsule; and*"

As discussed in Section V.B.1.e, this limitation is disclosed by Adams. To the extent that BSSI argues that the proximal end of retainer 110 ("bushing") is not "coupled to the sheath" (i.e., "confined") because it is not touching the sheath, it would have been obvious to a PHOSITA to have modified retainer 110 ("bushing") such that the proximal end physically contacts, and thus is coupled to (i.e., "confined"), outer sleeve 112 (component of the "sheath"). (Ex. 1029, ¶ 78).

Various bushings have been long known in the prior art. (*Id*. at ¶ 79). A PHOSITA would understand that retainer 110, or any other "bushing" can take a variety of shapes and forms. (*Id*.). Adams is not limited to any specific type of retainer 110. In fact, the specification makes clear that the invention is not limited by the disclosure and includes "variations" and "different combinations" of various mechanical mechanisms. (Ex. 1023 at 15:22-27; Ex. 1029, ¶ 79). A PHOSITA knows that a stable and smooth release mechanism to decouple retainer 110 from lock sleeve 113 ("capsule") is desirable; and that simply increasing the diameter of the proximal end of retainer 110 such that it physically contacts the walls of outer sleeve 112 would help stabilize retainer 110 and allow for a smooth sliding action within outer sleeve 112 when retainer 110 is released from lock sleeve 113. (Ex. 1029, ¶ 79). Thus, a PHOSITA would immediately understand that retainer 110, a

simple bushing, may be modified various ways as desired, including simply expanding the proximal end of retainer 110 such that it contacts the walls of the outer sleeve 112. (*Id*.).

f. "*a control member a distal end of which is releasably coupled to the clip assembly to transmit to the clip assembly forces applied thereto to move the clip assembly between the insertion and expanded configurations*."

Adams meets this limitation for the reasons discussed in Section V.B.1.f. (*See also* Ex. 1029, ¶ 80).

2. Claims 3-5 and 7-9

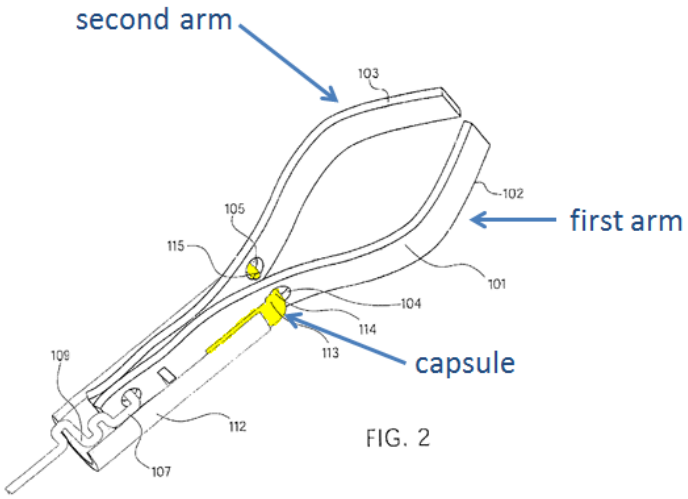
Claims 3-5 and 7-9 all depend from independent claim 1. The additional limitations recited by these dependent claims are all disclosed in Adams as set forth in Sections V.B.2, V.C.1, V.C.2, V.C.3, V.B.3, V.B.4, respectively. (*See also* Ex. 1029, ¶¶ 81-92).

E. Ground 4: Claims 10 and 17 are Rendered Obvious by Adams Combined with Sackier

1. Claim 10

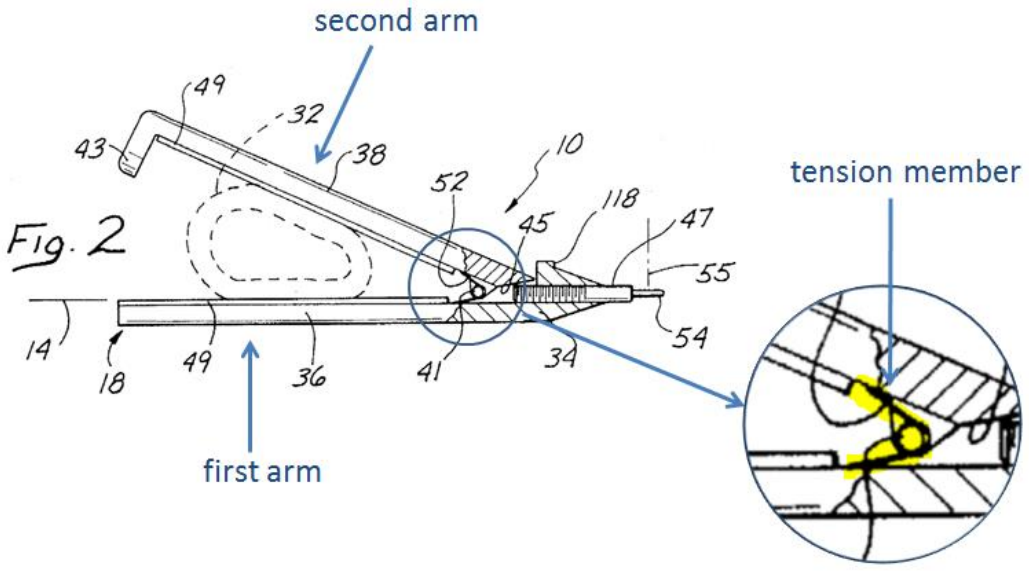
Claim 10 depends from claim 1, which is anticipated by Adams and alternatively is obvious in view of Adams. (*See* Sections V.B.1 and V.D.1). Claim 10 adds the limitation "*further comprising a tension member slidably received in the capsule and configured to bias the first and second arms to the expanded configuration*."

This limitation is met by Adams in combination with Sackier. Fig. 2 of Adams shows first and second clip legs 102, 103 ("first and second arms") that are slidably received in lock sleeve 113 ("capsule"):



Adams Fig. 2

(Ex. 1023 at 6:55-62; Ex. 1029, ¶ 94). Fig. 2 of Sackier shows a clip device including spring 52 ("tension member") configured to bias jaws 36 and 38 ("first and second arms") to the expanded configuration:



Sackier Fig. 2

(*See, e.g.*, Ex. 1008 at 5:4-5 ("A spring 52 can be provided in the hinge 41 in order to bias the jaws 36 and 38 to the open position."); Ex. 1029, ¶ 94).

It would have been obvious to a PHOSITA in the 2003 timeframe to include in the apparatus described in Adams spring 52 ("tension member") as disclosed in Sackier to bias the first and second clip legs 102, 103 ("the first and second arms") to the expanded configuration. (Ex. 1029, ¶ 95). In the resulting medical device, spring 52 ("tension member") would be disposed between first and second clip legs 102, 103 ("the first and second arms") of Adams. Thus, together with clip legs 102,103, spring 52 would be slidably received within lock sleeve 113 ("capsule"). (*Id.*).

There are numerous PTO and Supreme Court endorsed rationales supporting this obvious combination.

First, the proposed combination is the "[c]ombin[ation] of prior art elements according to known methods to yield predictable results." MPEP §2143 (I)(A). The combination of Adams' tissue clipping apparatus with Sackier's spring 52 is the simple combination of mechanical elements to yield the predictable result of biasing clip legs 102, 103 to the expanded configuration. (Ex. 1029, ¶ 96).

Second, the proposed combination is the "[s]imple substitution of one known element for another to obtain predictable results." MPEP §2143 (I)(B). Specifically, the substitution of Adams' naturally biased-open clip legs with Sackier's separate spring 52 to bias open the clip legs is the simple substitution of one known element for another to obtain the predicted result of biasing clip legs 102, 103 to the expanded configuration. (Ex. 1029, ¶ 97).

Third, the proposed substitution is the "[u]se of a known technique to improve similar devices . . . in the same way." MPEP §2143 (I)(C). Specifically, the use of spring 52 as disclosed in Sackier to bias clip legs 102, 103 to the expanded configuration ensures that the clip legs open as wide as possible to ensure sufficient capture of tissue between the clip legs. (Ex. 1029, ¶ 98).

Fourth, the proposed combination is the application of "a known technique to a known device . . . ready for improvement to yield predictable results." MPEP §2143 (I)(D). Specifically, using Sackier's spring 52 to bias clip legs 102, 103 to the expanded configuration is nothing more than the use of a known technique for

improving Adams' clip applying apparatus, which a PHOSITA would have appreciated was ready for such an improvement to yield predictable results. (Ex. 1029, ¶ 99).

Fifth, it would have been obvious to try Sackier's spring in Adams' clip applying apparatus to bias clip legs 102, 103 to the expanded configuration. *See* MPEP §2143 (I)(E). The proposed combination merely involves choosing from a finite number of ways to open clip legs to ensure capture of tissue therebetween. (Ex. 1029, ¶ 100).

Thus, it would have been obvious to a PHOSITA to include in the clip applying apparatus disclosed in Adams a "tension member" as disclosed in Sackier to bias clip legs 102, 103 to the expanded configuration. (*Id*. at ¶ 101).

2. Claim 17

Claim 17 depends from claim 11 which is anticipated by Adams. (*See* Section V.B.5). Claim 17 adds the limitation: "*further comprising a tension member slidably received in the capsule and configured to bias the first and second arms to the expanded configuration*."

This limitation is disclosed by Adams in combination with Sackier for the reasons discussed in Section V.E.1. (*See also* Ex. 1029, ¶ 103).

F. Ground 5: Claims 1, 3, and 10 are Rendered Obvious by Sackier

1. Independent Claim 1

a. "*An apparatus for applying clips to tissue, comprising*:"

Sackier discloses a "surgical clamp apparatus and . . . clamps and clamp appliers for use in occluding body conduits." (Ex. 1008 at 1:6-8). These clamps and clamp appliers constitute apparatuses for applying clips ("clamps") to tissue. (Ex. 1029, ¶ 104).

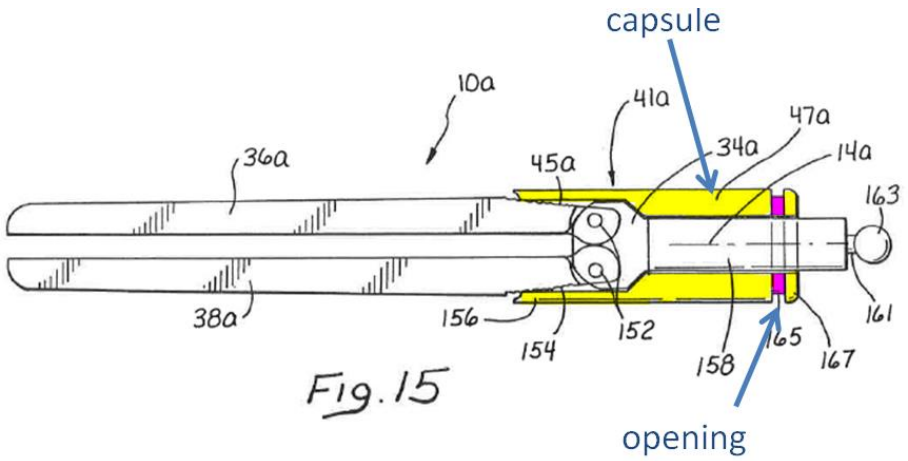
b. "*a flexible sheath extending from a proximal end which, in an operative configuration, extends into a living body to a target portion of tissue to be clipped*;"

Sackier discloses tube 23a extending from a proximal end which, in an operative configuration, extends into a living body to a target portion of tissue to be clipped. (Ex. 1008 at 10:10-13, 10:27-34; Ex. 1029, ¶ 105). A PHOSITA would understand that tube 23a could be either flexible or rigid. (Ex. 1029, ¶ 105). Sackier is not limited to any particular type of surgical clamp. In fact, the specification makes clear that "given the wide variation in the possibilities for embodying [the] concept," the scope of the invention should not be determined by "the drawings and description but rather by the claims." (Ex. 1008 at 11:65-12:2). Sackier's claims are not limited to any particular type of tube. Indeed, several of the independent claims do not require any tube at all. (Ex. 1008 at claims 1, 20, 31; Ex. 1029, ¶ 105). A PHOSITA knows that a flexible tube would be used for an endoscopic procedure whereas a rigid tube might be used for a different procedure.

(Ex. 1029, ¶ 105). Thus, a PHOSITA would immediately understand that a flexible tube or rigid tube could be used with Sackier depending on the application. (*Id*.).

c. "*a capsule extending from a proximal to a distal end and having an opening formed in a proximal end thereof*;"

This limitation is met by slide 47a ("capsule") extending from a proximal to a distal end and having annular recess 165 ("opening") formed in a proximal end thereof. (Ex. 1008 at 9:41-48, 10:4-6; Ex. 1029, ¶ 106).

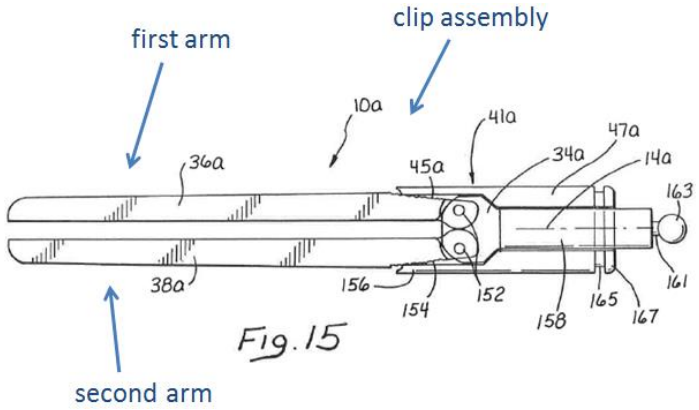


Sackier Fig. 15

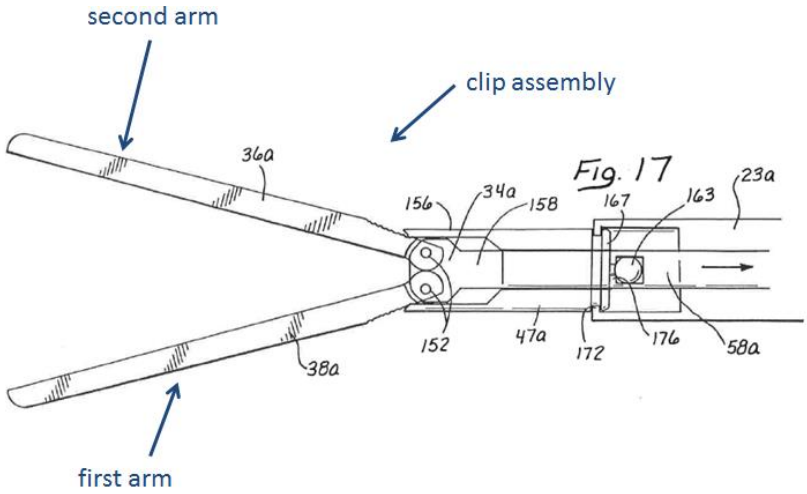
d. "*a clip assembly provided in the capsule and configured to be operably movable between a closed configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration in which the first and second arms are separated from one another to receive target tissue therebetween*;"

This limitation is met by clamp 150 ("clip assembly") having jaws 36a and 38a ("first and second arms of the clip assembly") provided in slide 47a ("capsule"). (Ex. 1008 at 9:16-23, 10:27-34; Ex. 1029, ¶ 107). Jaws 36a, 38a are

configured to be operably movable between a "closed configuration" in which jaws 36a, 38a are drawn towards one other (Fig. 15) and an "expanded configuration" in which jaws 36a, 38a are separated from one another to receive target tissue therebetween (Fig. 17). (Ex. 1008 at 9:16-23, 10:27-34; Ex. 1029, ¶ 107).



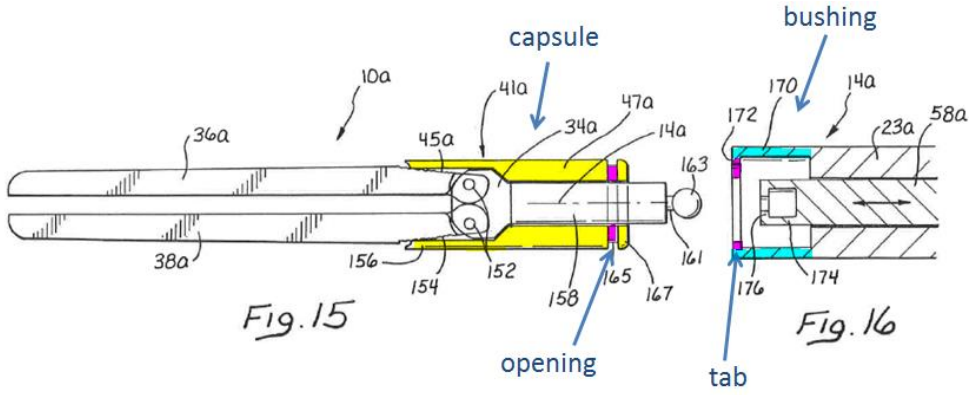
Sackier Fig. 17 (Closed Configuration)



Sackier Fig. 17 (Expanded Configuration)

e. "*a bushing extending between a proximal end coupled to the sheath and a distal end releasably coupled to the capsule via a tab on the distal end of the bushing engaging the opening of the capsule; and*"

Fig. 15 of Sackier shows the "capsule" (slide 47a) and its "opening" (annular recess 165):

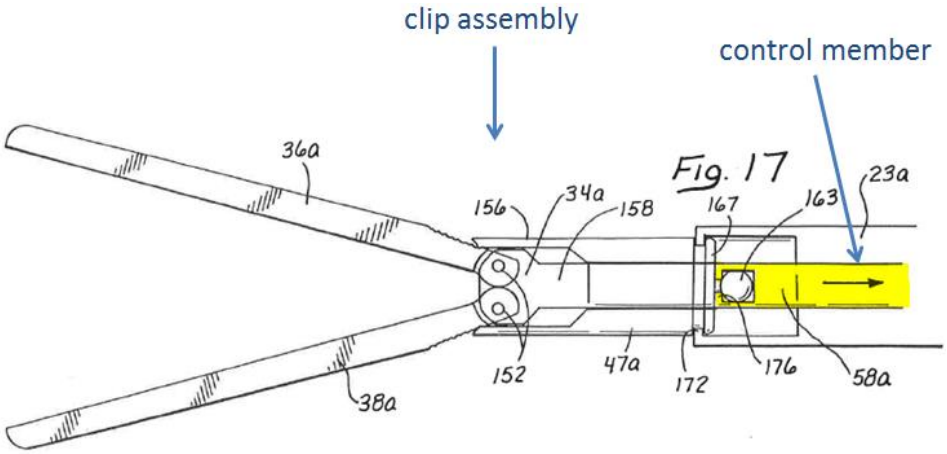


Sackier Figs. 15, 16

(Ex. 1008 at 9:41-48, 10:4-6; Ex. 1029, ¶ 108). Fig. 16, above, shows cylinder 170 ("bushing") having a proximal end coupled to tube 23a ("flexible sheath"). (Ex. 1008 at 10:13-15; Ex. 1029, ¶ 108). The distal end of cylinder 170 ("bushing") is releasably coupled to slide 47a ("capsule") via an inwardly facing flange 172 ("tab") on the distal end of cylinder 170 ("bushing"), which engages annular recess 165 ("opening") of slide 47a ("capsule"). (Ex. 1008 at 9:64-10:6, 10:13-15, 10:25-27 ("[T]he cylinder[] 170 can be configured to open laterally in order to permit the [] flange[] 172 to engage the recess[] 165."); Ex. 1029, ¶ 108).

f. "*a control member a distal end of which is releasably coupled to the clip assembly to transmit to the clip assembly forces applied thereto to move the clip assembly between the insertion and expanded configurations*."

This limitation is met by inner shaft 58a ("control member") having cylinder 174 and annular flange 176 on its distal end that is releasably coupled to clamp 150 ("clip assembly") via ball 163 on the proximal end of cylindrical shaft 158. (Ex. 1008 at 9:60-64, 10:10-13, 10:25-34; Ex. 1029, ¶ 109). Inner shaft 58a transmits forces to clamp 150 to move clamp 150 between the insertion and expanded configurations. (Ex. 1008 at 10:27-34; Ex. 1029, ¶ 109).

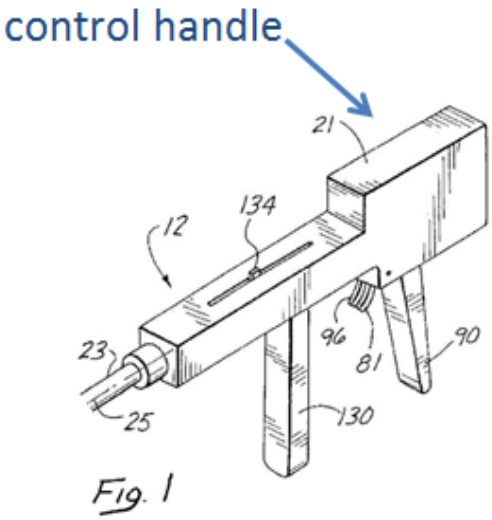


Sackier Fig. 17

2. Claim 3

Claim 3 adds the following limitation "*wherein a proximal end of the control member is coupled to a control handle which, when the apparatus is in an operative position, remains outside the body accessible to a user*."

As shown in Fig. 1, this limitation is met by handle 21 ("control handle") coupled to the proximal end of the inner shaft 58a ("control member"). (Ex. 1008 at 10:10-13, 5:33-40; Ex. 1029, ¶ 111). When the apparatus of Sackier is in an operative position, handle 21 remains outside the body accessible to a user. (Ex. 1008 at 10:10-13, 5:33-40; Ex. 1029, ¶ 111).

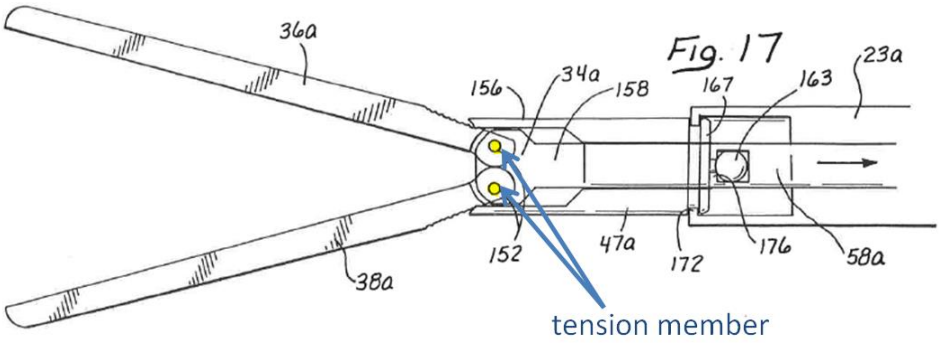


Sackier Fig. 1

3. Claim 10

Claim 10 depends from claim 1 and adds the following limitation "*further comprising a tension member slidably received in the capsule and configured to bias the first and second arms to the expanded configuration*."

This limitation is met by spring 152 ("tension member") slidably received in slide 47a ("capsule") that is configured to bias jaws 36a, 38a ("first and second arms") to the expanded configuration. (Ex. 1008 at 9:30-32 ("[O]ne or both of the jaws 36a and 38a are preferably biased to the open position, for example by a spring 152."); Ex. 1029, ¶ 113).



Sackier Fig. 17

G. Ground 6: Claims 11, 15, and 17 Are Anticipated by Sackier

1. Independent Claim 11

a. "*An apparatus for applying clips to tissue within a living body, comprising*:"

Sackier discloses the preamble for the reasons discussed in Section V.F.1.a. (*See also* Ex. 1029, ¶ 114).

b. "*a capsule*;"

Sackier discloses this limitation for the reasons discussed in Section V.F.1.c. (*See also* Ex. 1029, ¶ 115).

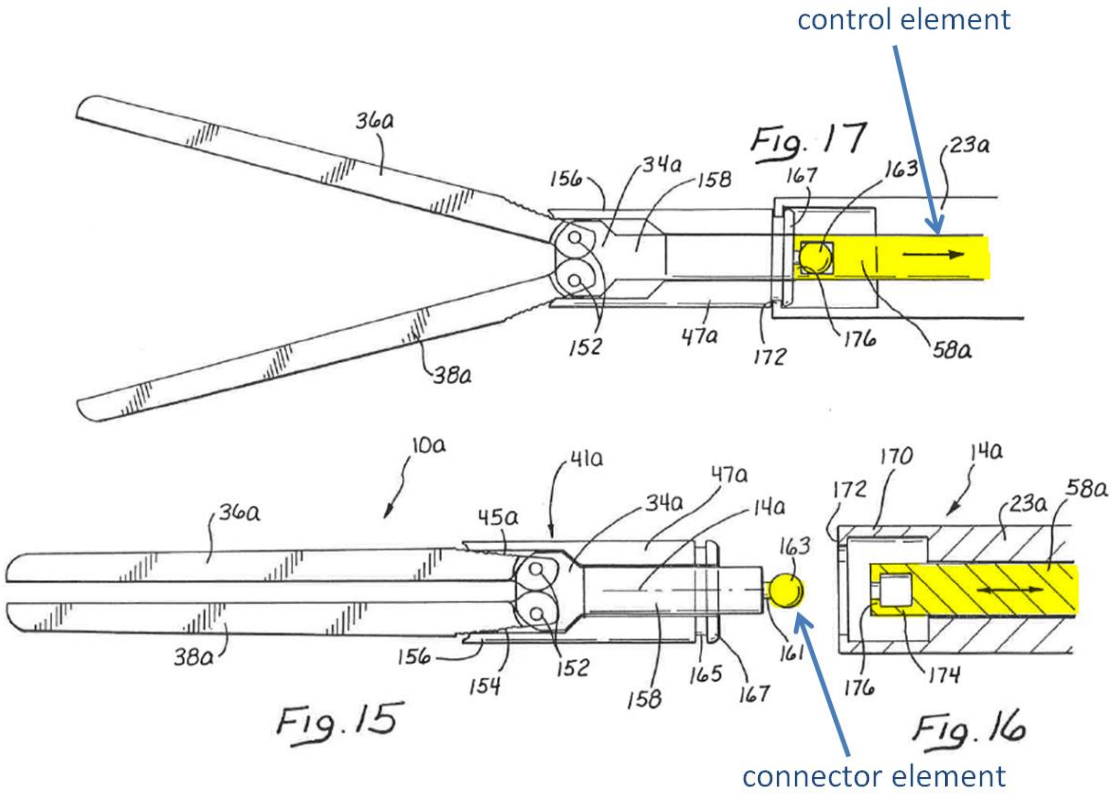
c. "*a clip assembly housed within the capsule for movement between an insertion configuration*[9] *in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration in which the first and second arms are separated from one another to receive tissue therebetween*;"

Sackier discloses this limitation for the reasons discussed in Section V.F.1.d. (*See also* Ex. 1029, ¶ 116).

[9] For purposes of this Petition only, Petitioners treat "insertion configuration" to be the "closed configuration" of claim 1.

d. "*a control element including a connector element, extending between a proximal end which, during use, remains outside the body accessible to a user and a distal end removably connected to the clip assembly via the connector element*,"

This limitation is met by inner shaft 58a including at its distal end a cylinder 174 that engages a ball 163:



Sackier Figs. 15-17

(Ex. 1008 at 10:10-34; Ex. 1029, ¶ 117). Together these multiple, distinct structures (58a, 174, 163) form the "control element." (Ex. 1029, ¶ 117). This "control element" (58a, 174, 163), which includes ball 163 ("connector element"), extends between a proximal end which, during use, remains outside the body accessible to a user. (Ex. 1008 at 10:10-34; Ex. 1029, ¶ 117). The distal end of the

"control element" (58a, 174, 163) is removably connected to clamp 150 ("clip assembly") via ball 163 ("connector element"). (Ex. 1008 at 10:10-34; Ex. 1029, ¶ 117).

e. "*wherein the control element detaches from the connector element via a frangible link; and*"

Sackier meets this limitation. Cylinder 174 and inner shaft 58a (both parts of the "control element") form a link with ball 163 ("connector element") that is unlinked when a tensile load is applied (i.e., a "frangible link"). (Ex. 1008 at 10:10-34; Ex. 1029, ¶ 118). In the Litigation, BSSI conceded that a ball-and-socket connection, such as the one between cylinder 174 and ball 163 in Sackier, is a "frangible link." (*See* Ex. 1004 at 24).

f. "*a sheath extending from a proximal to a distal end and covering a portion of the control element, wherein the distal end of the sheath is releasably coupled to the capsule*."

This limitation is met by tube 23a ("sheath") extending from a proximal to a distal end and covering a portion of the inner shaft 58a (part of the "control element"). (Ex. 1008 at 10:10-13, 10:27-34, Figs. 16, 17; Ex. 1029, ¶ 119). Further, the distal end of tube 23a is releasably coupled to slide 47a ("capsule"). (Ex. 1008 at 10:13-16, 10:25-27; Ex. 1029, ¶ 119).

2. Claim 15

Claim 15 adds the limitation: "*wherein the sheath is coupled to the capsule via a bushing including a tab on a distal end thereof received in an opening at a proximal end of the capsule*."

Sackier discloses this limitation for the reasons discussed in Section V.F.1.e. (*See also*, Ex. 1029, ¶ 121).

3. Claim 17

Claim 17 adds the limitation: "*further comprising a tension member slidably received in the capsule and configured to bias the first and second arms to the expanded configuration*."

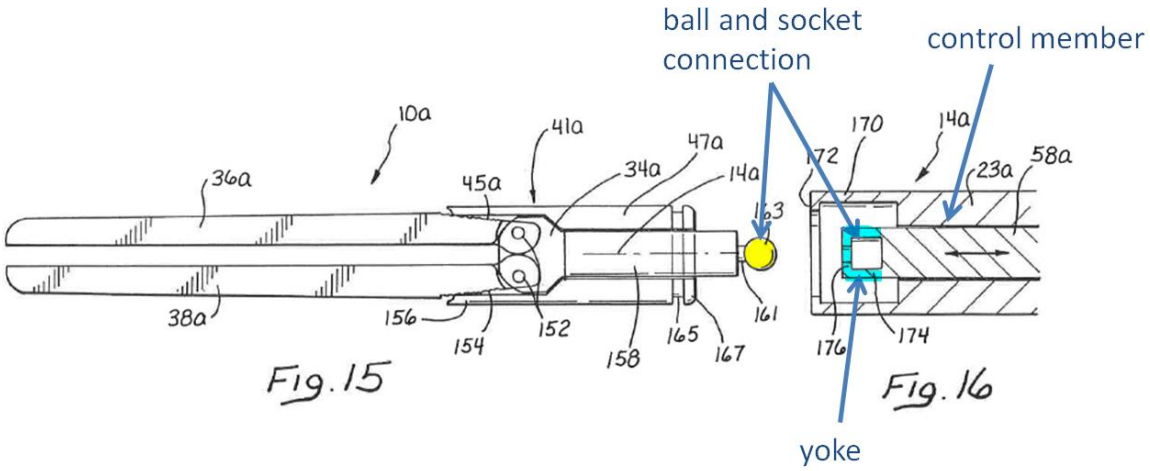
Sackier discloses this limitation for the reasons discussed in Section V.F.3. (*See also* Ex. 1029, ¶ 123).

H. Ground 7: Claims 4, 5, 7, 13, and 14 are Obvious in View of Sackier Combined with Adams

1. Claim 4

Claim 4 depends from claim 3, which is rendered obvious by Sackier. (*See* Section V.F.2.) Claim 4 adds the limitation "*wherein the clip assembly further comprises a yoke slidably received in the capsule and releasably coupled to the control member*."

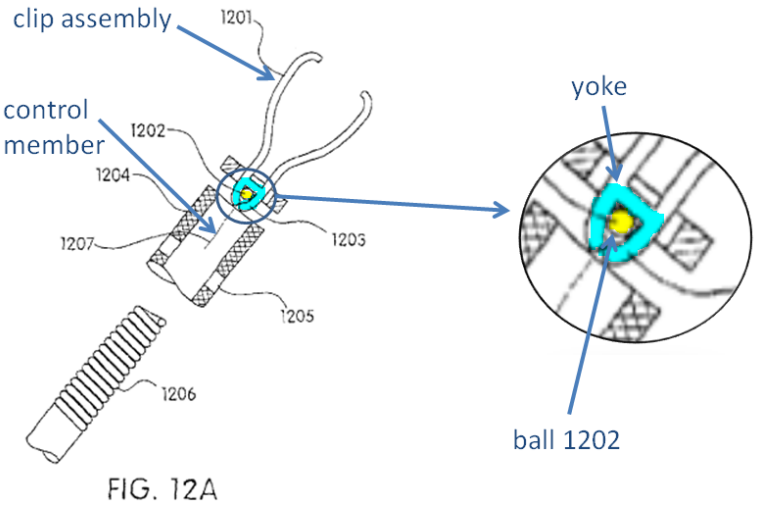
This limitation is disclosed by Sackier in combination with Adams. Figs. 15 and 16 of Sackier show a ball-and-socket connection as ball 163 mating with the "yoke" consisting of cylinder 174 and inwardly facing flange 172 to connect clamp 150 ("clip assembly") to inner shaft 58a ("control member"):



Sackier Figs. 15-16

(Ex. 1008 at 9:60-64, 10:25-27; Ex. 1029, ¶ 125). This ball-and-socket arrangement in Sackier is identical to the arrangement recited in claim 4, except that in Sackier the ball-and-socket merely is reversed. In claim 4, the socket

("yoke") is on the distal side of the separation ("clip assembly further comprises a yoke") after it separates from the yoke. (Ex. 1029, ¶ 125). In Sackier, the ball is on the distal side of the separation (and thus part of the "clip assembly"). (*Id.*). Fig. 12A of Adams also shows a ball-and-socket connection (ball 1202 mating with socket tabs 1203, which are the socket) between clip 1201 ("clip assembly") and control wire 1207 ("control member"):



Adams Fig. 12A

(Ex. 1023 at 9:47-50; Ex. 1029, ¶ 125). As explained in Section V.C.1, socket tabs 1203 are the claimed "yoke." (Ex. 1029, ¶ 125). Socket tabs 1203 are slidably received in outer sleeve 1204 ("capsule") and releasably coupled to control wire 1207 ("control member"). (Ex. 1023 at 9:56-62; Ex. 1029, ¶ 125).

In Adams, unlike in Sackier, the socket ("yoke") is part of the "clip assembly" as required by claim 4. Adams teaches a PHOSITA that a ball-and-socket connection can be reversed such that the socket, or "yoke," is part of the

"clip assembly" as an alternative way of connecting the "clip assembly" to the "control member." *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("[W]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.") (citation omitted).

For this reason, as well as the reasons described above in Section V.C.1, it would have been obvious to a PHOSITA in the 2003 timeframe to include in the apparatus described in Sackier the "yoke," as disclosed in Adams. (Ex. 1029, ¶ 127). The resulting device would include each and every limitation of claim 4.

2. Claim 5

Claim 5 depends from claim 3 which is rendered obvious by Sackier. (*See* Section V.F.2). Claim 5 adds the limitation: "*wherein the control member is coupled to the yoke via a frangible link*."

This limitation is disclosed by Sackier in combination with Adams. As discussed with respect to claim 4, Sackier in combination with Adams discloses a "yoke," and it would have been obvious to a PHOSITA to include the "yoke" from Adams in the Sackier apparatus. (*See* Section V.H.1).

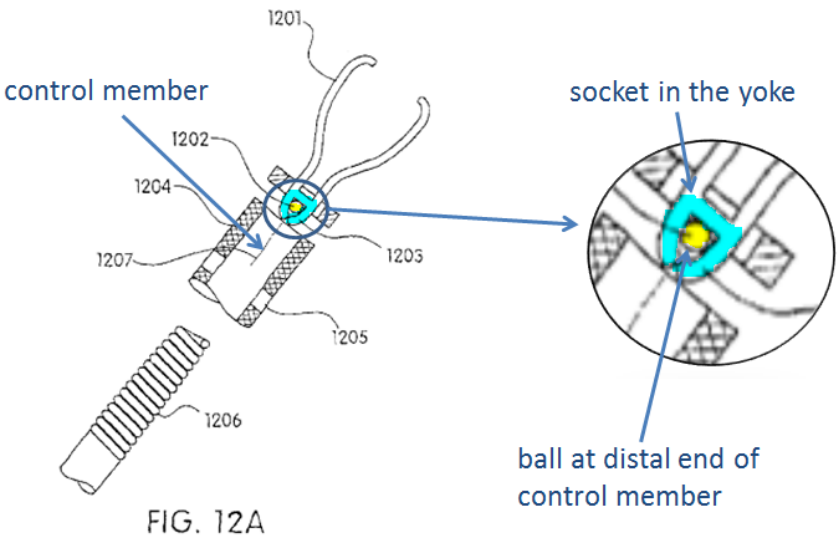
In Figs. 12A-12B of Adams, ball 1202 is linked to socket tabs 1203 (collectively, "frangible link") that become unlinked when a tensile load is applied so as to release the "control member" from the "clip assembly". (Ex. 1023 at 9:56-

62; Ex. 1029, ¶ 130). Further, in the Litigation, BSSI conceded that a ball-and-socket connection is a "frangible link." (Ex. 1004 at 23).

3. Claim 7

Claim 7 depends from claim 5 and adds the limitation: "*wherein the distal end of the control member comprises a ball received in a socket in the yoke*."

This limitation is disclosed by Sackier in combination with Adams. As discussed with respect to claims 4 and 5, Adams discloses ball 1202 ("ball") at the distal end of control wire 1207 ("control member") that is received into a socket, or socket tabs 1203 ("socket in the yoke"). (*See* Section V.H.1, V.H.2; Ex. 1023 at 9:47-50; Ex. 1029, ¶ 132).



Adams Fig. 12A

4. Claim 13

Claim 13 depends from claim 11 which is anticipated by Sackier. (*See* Section V.G.1). Claim 13 adds the limitation: "*wherein the clip assembly includes a yoke slidably received in the capsule and removably coupled to the control element*."

This limitation is disclosed by Sackier in combination with Adams for the reasons discussed in Section V.H.1. (*See also* Ex. 1029, ¶ 134).

5. Claim 14

Claim 14 depends from claim 13 and adds the limitation: "*wherein the yoke is connected to the control element via a ball and socket joint*."

This limitation is disclosed by Sackier in combination with Adams for the reasons discussed in Section V.H.3. (*See also* Ex. 1029, ¶ 136).

I. Ground 8: Claims 1, 3-5, 7, 10, and 15 are Rendered Obvious by Sackier Combined with Adams

1. Independent Claim 1

a. "*An apparatus for applying clips to tissue, comprising*:"

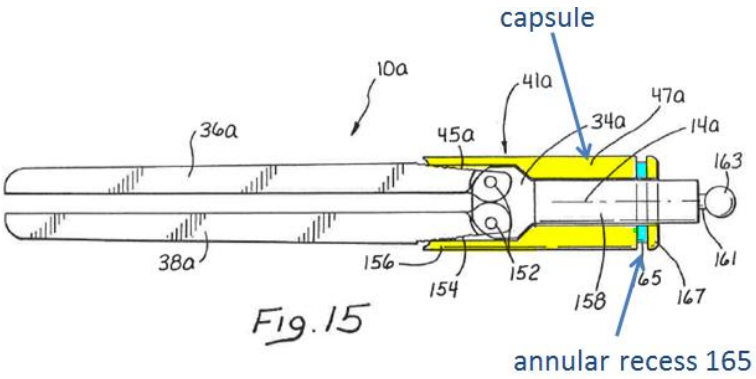
Sackier discloses this preamble for the reasons discussed in Section V.F.1.a. (*See also* Ex. 1029, ¶ 137).

b. "*a flexible sheath extending from a proximal end which, in an operative configuration, extends into a living body to a target portion of tissue to be clipped*;"

Sackier discloses this limitation for the reasons discussed in Section V.F.1.b. (*See also* Ex. 1029, ¶ 138).

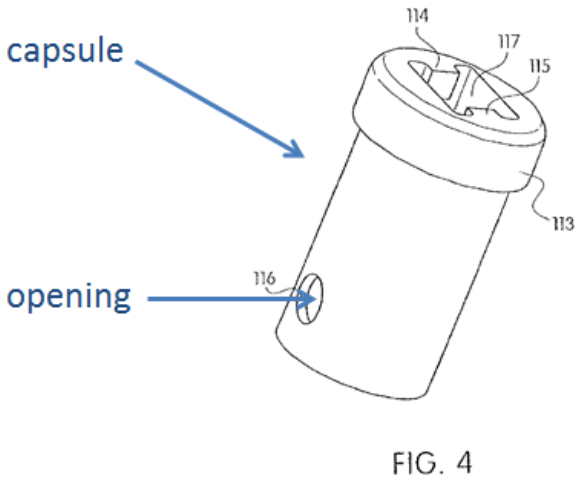
c. "*a capsule extending from a proximal to a distal end and having an opening formed in a proximal end thereof*;"

Fig. 15 of Sackier discloses slide 47a ("capsule") extending from a proximal to a distal end and having annular recess 165 formed in a proximal end thereof. (Ex. 1008 at 9:41-48, 10:4-6; Ex. 1029, ¶ 139).



Sackier Fig. 15

To the extent that BSSI argues that annular recess 165 in Sackier is not an "opening," this limitation is disclosed by Sackier in combination with Adams. Fig. 4 of Adams discloses lock sleeve 113 ("capsule") extending from a proximal to a distal end and having retainer hole 116 ("opening") formed in a proximal end thereof. (Ex. 1023 at 7:12-16; *see also, e.g., id.* at 5:39-41, 5:56-63, Fig. 1; Ex. 1029, ¶ 140).



Adams Fig. 4

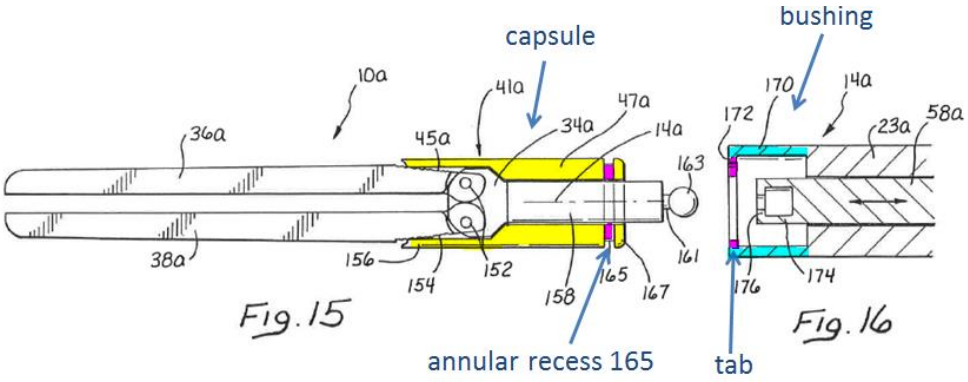
For the reasons described below in Section V.I.1.e it would have been obvious to a PHOSITA to simply substitute the annular recess 165 in Sackier with one or more "openings," such as retainer hole 116 as disclosed in Adams. The resulting medical device would include this limitation.

d. "*a clip assembly provided in the capsule and configured to be operably movable between a closed configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration in which the first and second arms are separated from one another to receive target tissue therebetween*;"

Sackier discloses this limitation for the reasons discussed in Section V.G.c. (*See also* Ex. 1029, ¶ 141).

e. "*a bushing extending between a proximal end coupled to the sheath and a distal end releasably coupled to the capsule via a tab on the distal end of the bushing engaging the opening of the capsule; and*"

This limitation is disclosed by Sackier in combination with Adams. Fig. 15 of Sackier shows the previously discussed slide 47a ("capsule") and annular recess 165:

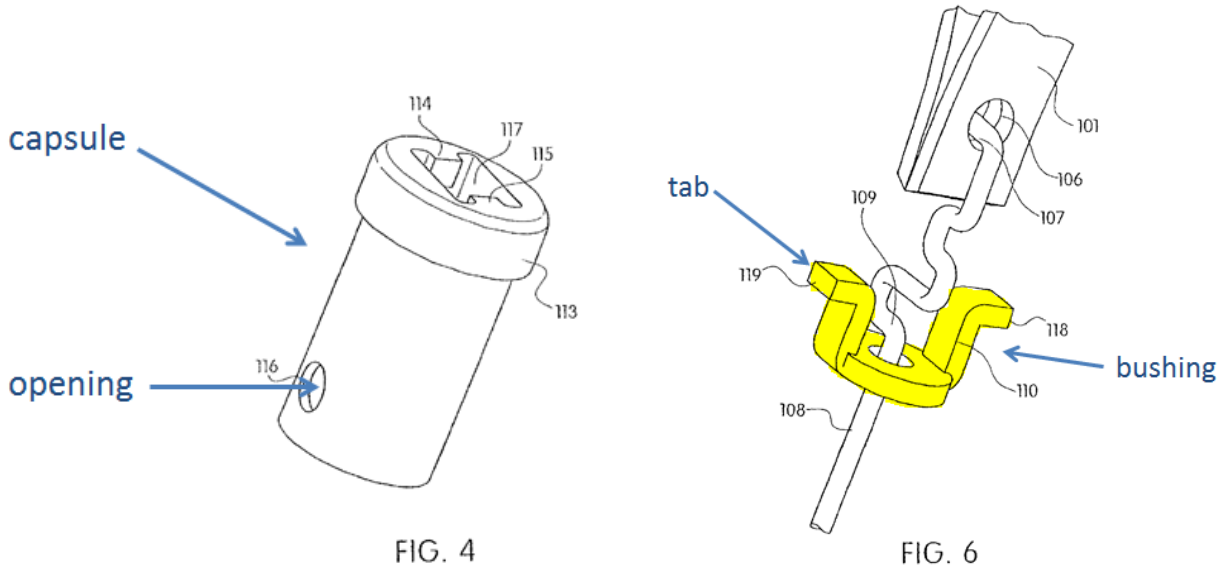


Sackier Figs. 15, 16

(Ex. 1008 at 9:41-48, 10:4-6; Ex. 1029, ¶ 1142). Fig. 16, above, shows cylinder 170 ("bushing") having a proximal end coupled to tube 23a ("flexible sheath"). (Ex. 1008 at 10:13-16; Ex. 1029, ¶ 142). The distal end of cylinder 170

("bushing") is releasably coupled to slide 47a ("capsule") via inwardly facing flange 172 on the distal end of cylinder 170 ("bushing") which engages annular recess 165 of slide 47a ("capsule"). (Ex. 1008 at 9:64-10:6, 10:13-16, 10:25-27; Ex. 1029, ¶ 142).

Figs. 4 and 6 of Adams show retainer 110 ("bushing") and the previously described lock sleeve 113 ("capsule"):



Adams Figures 4 and 6

(Ex. 1023 at 7:12-16; Ex. 1029, ¶ 143). Retainer 110 ("bushing") is releasably coupled to lock sleeve 113 ("capsule") via retainer tabs 118, 119 ("tab") that engage retainer holes 116 ("opening") of lock sleeve 113 ("capsule"). (Ex. 1023 at 7:12-16; Ex. 1029, ¶ 143). Retainer holes 116 ("opening") penetrate through the sidewall of lock sleeve 113 ("capsule"). (Ex. 1023 at 7:12-16; Ex. 1029, ¶ 143).

Adams and Sackier teach alternative ways of releasably coupling together two components. Sackier teaches that two components can be releasably coupled using inwardly facing flange 172 that engages corresponding annular recess 165. (Ex. 1029, ¶ 144). Similarly, Adams teaches that two components can be releasably coupled using retainer tabs 118, 119 ("tab") that engage corresponding retainer holes 116 ("opening"). (*Id*.).

In the 2003 timeframe, it would have been obvious to a PHOSITA to simply substitute flange 172 and recess 165 connection described in Sackier with retainer tabs 118, 119 and retainer holes 116 connection as disclosed in Adams as an alternative way of releasably coupling the "bushing" to the "capsule." (Ex. 1029, ¶ 145).

First, the proposed combination is the "[s]imple substitution of one known element for another to obtain predictable results." MPEP §2143 (I)(B). Specifically, replacement of Sackier's flange/recess connection with Adams' retainer tabs/retainer holes connection is the simple substitution of one known element for another to obtain the predicted result of releasably coupling the "bushing" to the "capsule." (Ex. 1029, ¶ 146).

Second, the proposed combination is the application of "a known technique to a known device ready for improvement to yield predictable results." MPEP §2143 (I)(D). Specifically, using Adams' retainer tabs/retainer holes connection

instead of Sackier's flange/recess connection is nothing more than the use of a known technique for improving Sackier's clip apparatus, which a PHOSITA would have appreciated was ready for such an improvement to yield predictable results. (Ex. 1029, ¶ 147).

Third, it would have been obvious to try Adams' retainer tabs/retainer holes connection instead of Sackier's flange/recess connection as an alternative way of releasably coupling the "bushing" to the "capsule." *See* MPEP §2143 (I)(E). The proposed substitution merely involves choosing from a finite number of ways to releasably couple two components together. (Ex. 1029, ¶ 148).

Thus, in the 2003 timeframe, it would have been obvious to a PHOSITA to simply substitute the flange/recess connection in Sackier with the retainer tabs/retainer holes connection in Adams. (*Id*. at ¶ 149). The resulting medical device would include this limitation.

f. "*a control member a distal end of which is releasably coupled to the clip assembly to transmit to the clip assembly forces applied thereto to move the clip assembly between the insertion and expanded configurations*."

Sackier discloses this limitation for the reasons discussed in Section V.F.1.f. (*See* Ex. 1029, ¶ 150).

2. Claim 3

Claim 3 adds the limitation: "*wherein a proximal end of the control member is coupled to a control handle which, when the apparatus is in an operative position, remains outside the body accessible to a user*."

This limitation is disclosed by Sackier in combination with Adams for the reasons discussed in Section V.F.2. (*See also* Ex. 1029, ¶ 152).

3. Claim 4

Claim 4 depends from claim 3 and adds the limitation: "*wherein the clip assembly further comprises a yoke slidably received in the capsule and releasably coupled to the control member*."

This limitation is disclosed by Sackier in combination with Adams for the reasons discussed in Section V.H.1. (*See also* Ex. 1029, ¶ 154).

4. Claim 5

Claim 5 depends from claim 3 and adds the limitation: "*wherein the control member is coupled to the yoke via a frangible link*."

This limitation is disclosed by Sackier in combination with Adams for the reasons discussed in Section V.H.2. (*See also* Ex. 1029, ¶ 156).

5. Claim 7

Claim 7 depends from claim 5 and adds the limitation: "*wherein the distal end of the control member comprises a ball received in a socket in the yoke*."

This limitation is disclosed by Sackier in combination with Adams for the reasons discussed in Section V.H.3. (*See also* Ex. 1029, ¶ 158).

6. Claim 10

Claim 10 depends from claim 1 and adds the limitation: "*further comprising a tension member slidably received in the capsule and configured to bias the first and second arms to the expanded configuration*."

Sackier discloses this limitation for the reasons discussed in Section V.F.3. (*See also* Ex. 1029, ¶ 160).

7. Claim 15

Claim 15 depends from claim 11, which is anticipated by Sackier. (*See* Section V.G.1). Claim 15 adds the limitation: "*wherein the sheath is coupled to the capsule via a bushing including a tab on a distal end thereof received in an opening at a proximal end of the capsule*."

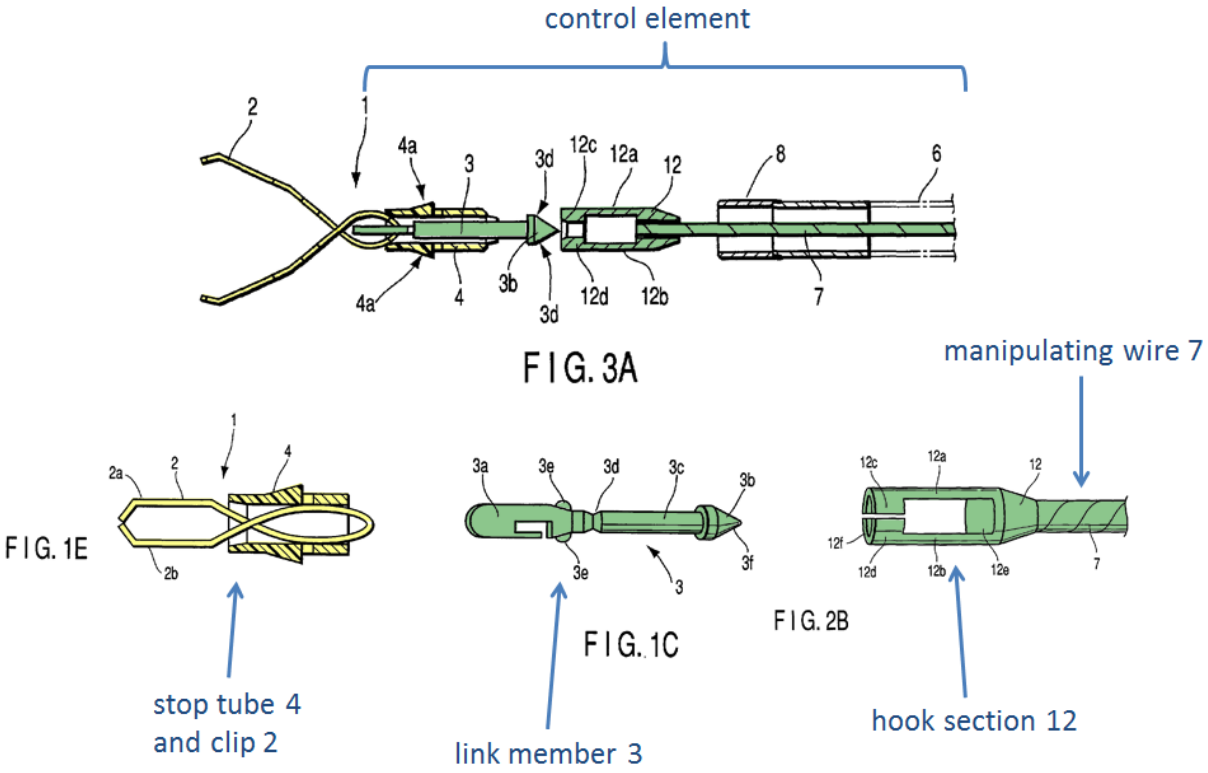
This limitation is disclosed by Sackier in combination with Adams for the reasons discussed in Section V.I.1.e. (*See also* Ex. 1029, ¶ 162).

J. Ground 9: Claims 11-13 are Anticipated by Kimura

1. BSSI Incorrectly Described Key Components of Kimura During Prosecution of the '371 Patent

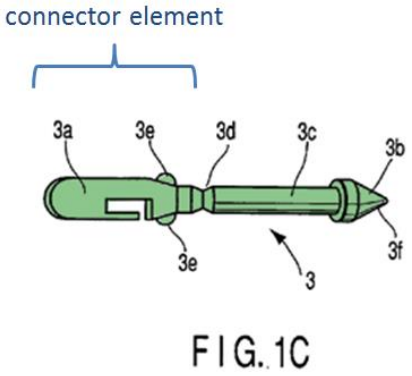
As issued, claim 11 requires "a control element including a connector element . . . wherein the control element detaches from the connector element via a frangible link." (Ex. 1027 at 18:10-15).

During prosecution, the Examiner twice rejected claim 11 as anticipated by Kimura. (Ex. 1028 at Office Action dated May 27, 2014, pp. 5-6, Office Action dated September 16, 2014, pp. 2, 4). In the second rejection, the Examiner explained that Kimura disclosed a "control element including a connector element" as manipulation wire 7, the hook section 12, and link member 3 (highlighted in green in the figures below). (*Id.* at Office Action dated September 16, 2014, pp. 2, 4) ("Kimura et al. disclose[s] . . . a control element 3/12/7 *including* a connector element 3a . . . wherein the control element detaches from the connector element via a frangible link 3d . . . ."; "The 'control element' is interpreted as being wire 7, hook section 12 and link member 3 as a whole . . . ."). Those parts are shown below.



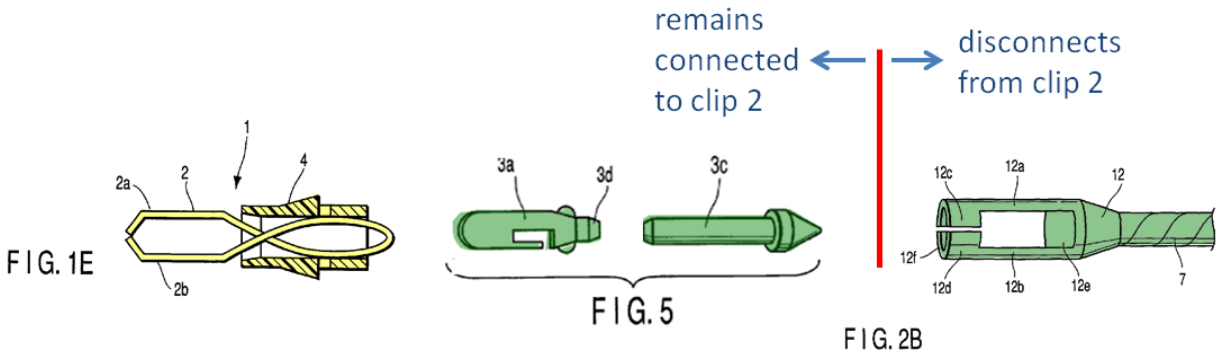
Kimura Figs. 1C, 1E, 2B, and 3A

As shown in Fig. 1C below, the Examiner used fracture section 3d as the point of reference and identified portions 3a and 3e of link member 3 as the claimed "connector element" that separates from the rest of the "control element" (*i.e.*, remaining portions 3b, 3c and 3f of link member 3 + hook section 12 + manipulating wire 7) via a frangible link (fracture section 3d):



Kimura Fig. 1C

In response, BSSI argued that the "control element" in Kimura includes only a single component: manipulation wire 7. (*See id*. at Response Under Rule 116 dated October 29, 2014, pages 2-3). BSSI further argued that even if the Examiner's interpretation of Kimura's "control element including a connector element" (*i.e.*, parts 3/12/7) was proper, the Examiner's reasoning still failed because the "fracture section 3d disconnects the hook section 12 from the *entire* link member 3 which is still connected to the clip arms after fracture."[10] (*Id*. at p. 3 (emphasis added)). BSSI's incorrect interpretation of Kimura is shown in the figures below:

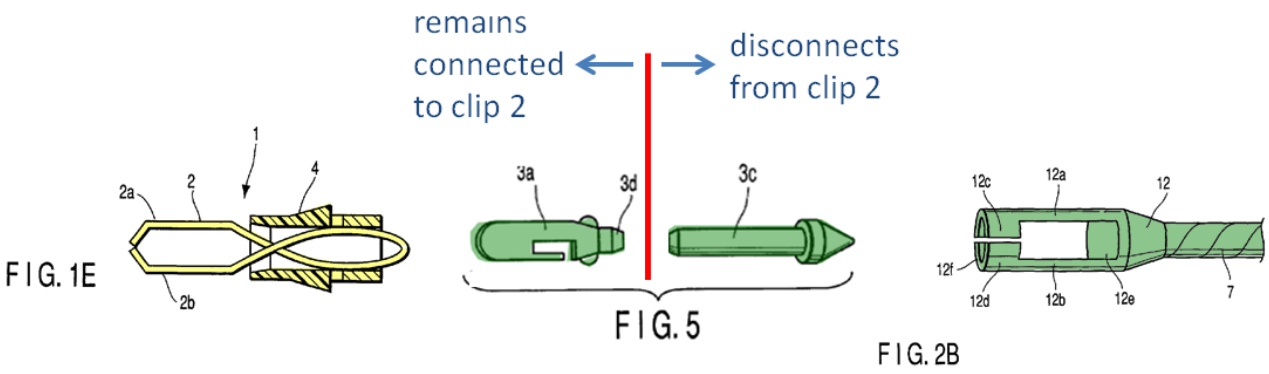


Kimura Figs. 1E, 2B, and 5 (BSSI's Incorrect Description)

[10] In prosecuting a later-filed related application, BSSI directly contradicted its statement by arguing: "a fracture section 3d of the link member 3 breaks so that *the clip 2 is disengaged from the link member 3* and the clip unit 1 is released." (Ex. 1030 at Response to Office Action dated November 10, 2015, p. 7). However, as discussed below, even this description is wrong.

Based on this incorrect interpretation, BSSI argued that a portion of the "control element" (element 3c of the link member 3) identified by the Examiner does not detach from the "connecting element" (element 3a of link member 3) as required by the claim limitation. (*Id*.). This incorrect statement formed the basis for BSSI to argue that Kimura did not meet the "control element including a connector element" limitation. This, in turn, resulted in the Examiner's allowance of claim 11. (*Id*. at Notice of Allowance dated October 31, 2014).

BSSI's characterization of Kimura was incorrect. The fracture section 3d of Kimura *does not* disconnect the hook section 12 from the <u>*entire*</u> link member 3. (Ex. 1029, ¶ 168). Rather, as shown in the figures below, upon fracture of fracture section 3d, link member 3 breaks into two pieces. (*Id*.) The portion of link member 3 that is distal to fracture section 3d (elements 3a and 3d of link member 3) remains with the clip 2:



Kimura Figures 1E, 2B, and 5 (Petitioners' Interpretation)

(*See* Ex. 1007 at ¶ [0152], ¶¶ [0155]-[0156]; Ex. 1029, ¶ 168). Further, the portion

of link member 3 proximal to fracture section 3d (element 3c) is removed with the delivery system. (Ex. 1029, ¶ 168). The actual operation directly conflicts with BSSI's assertion that "the *entire* link member 3 [] is still connected to the clip arms after fracture." (Ex. 1028 at Response Under Rule 116 dated October 29, 2014, page 3 (emphasis added); Ex. 1029, ¶ 168).

Properly interpreted, Kimura renders unpatentable claim 11 as discussed in more detail below.

2. Independent Claim 11

a. "*An apparatus for applying clips to tissue within a living body, comprising*:"

Kimura discloses "a physiological tissue clip apparatus . . . for . . . clipping a physiological tissue." (Ex. 1007 at ¶ [0002]). This physiological tissue clip apparatus constitutes an apparatus for applying clips to tissue. (Ex. 1029, ¶ 170).

b. "*a capsule*;"

In Fig. 1E, Kimura shows stop tube 4 ("capsule"). (Ex. 1007 at ¶¶ [0138]-[0139]; Ex. 1029, ¶ 171).

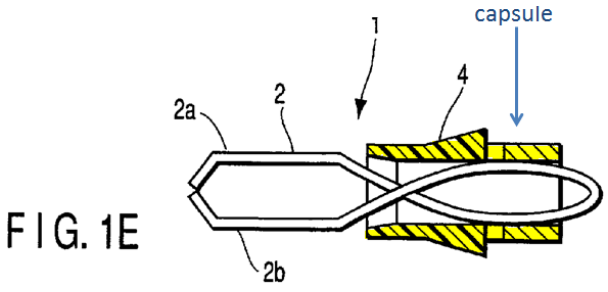
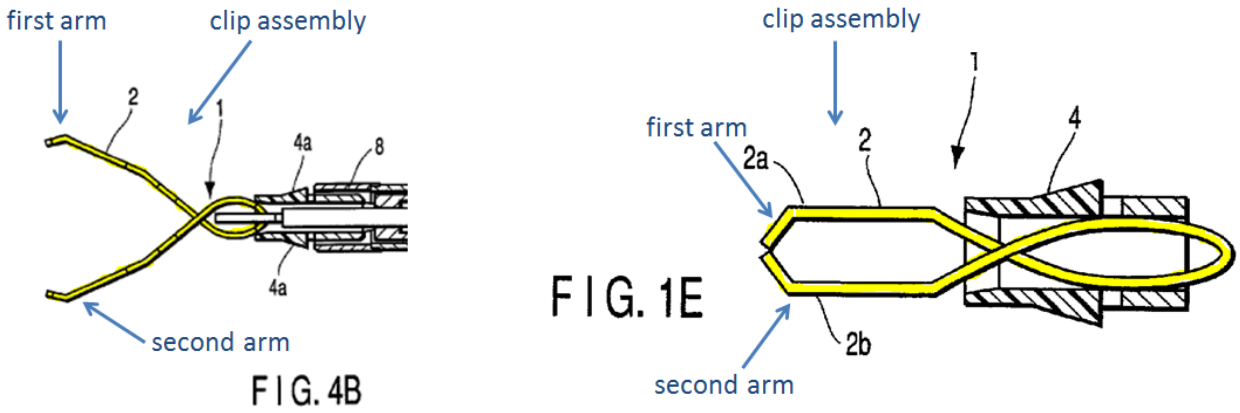


FIG. 1E

Kimura Fig. 1E

c. "*a clip assembly housed within the capsule for movement between an insertion configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration in which the first and second arms are separated from one another to receive tissue therebetween*;"

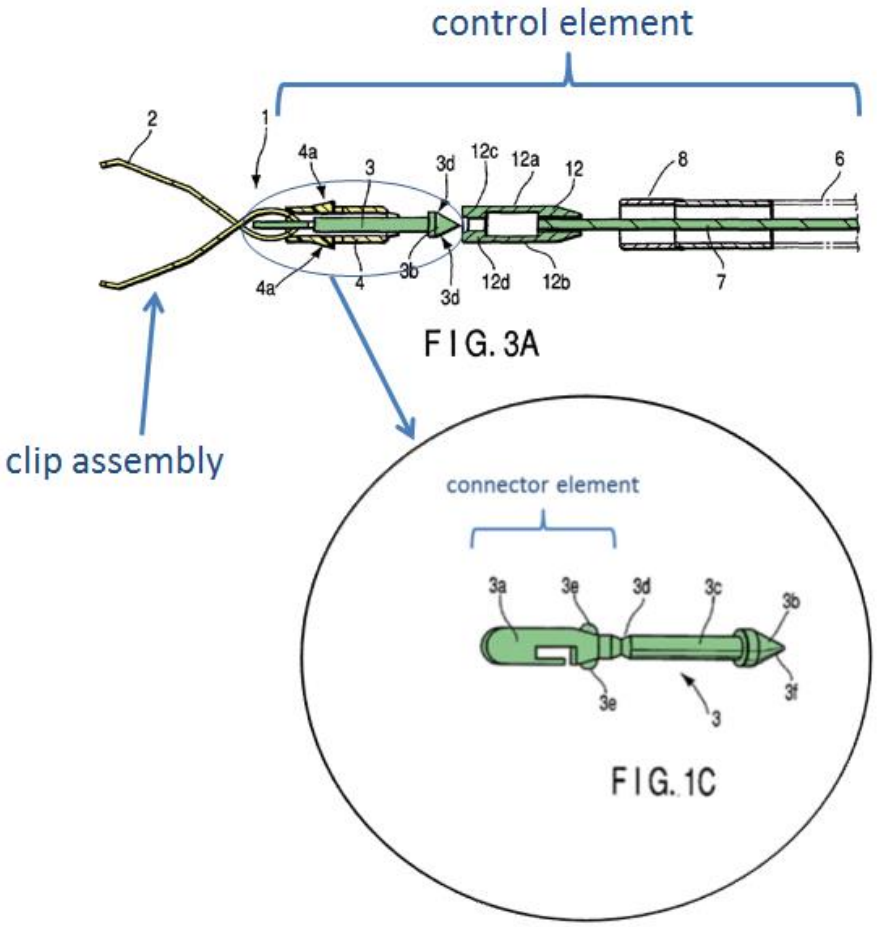
Kimura meets this limitation. Specifically, Kimura discloses clip 2 ("clip assembly") having arm sections 2a and 2b ("first and second arms of the clip assembly") housed within stop tube 4 ("capsule"). (Ex. 1007 at ¶ [0133], ¶¶ [0151]-[0152]; Ex. 1029, ¶ 172). Arm sections 2a and 2b move between an "insertion configuration" where arm sections 2a and 2b are drawn towards one another (Fig. 1E below) and an "expanded configuration" where the arm sections 2a and 2b are separated from one another to receive tissue therebetween (Fig. 4B below). (Ex. 1007 at ¶ [0133], ¶¶ [0151]-[0152]; Ex. 1029, ¶ 172).



Kimura Figures 4B and 1E

d. "*a control element including a connector element, extending between a proximal end which, during use, remains outside the body accessible to a user and a distal end removably connected to the clip assembly via the connector element*,"

Kimura meets this limitation. Kimura discloses manipulating wire 7, hook section 12, and link member 3 (collectively, "control element") including claw hook 3a ("connector element"):



Kimura Figures 1C and 3A

(Ex. 1007 at ¶¶ [0151]-[0152]; *see also*, *e.g.*, *id*. at ¶¶ [0134]-[0137], ¶ [0143]; Ex. 1029, ¶ 173). This "control element" extends between a proximal end which, during use, remains outside the body accessible to a user and a distal end that is removably coupled to clip 2 ("clip assembly") via claw hook 3a ("connector element"). (Ex. 1007 at ¶¶ [0151]-[0152]; Ex. 1029, ¶ 173).

e. "*wherein the control element detaches from the connector element via a frangible link; and*"

Kimura meets this limitation. As shown in Fig. 1C, claw hook 3a ("connector element") located at the distal end of link member 3 separates from the rest of the "control element" (manipulating wire 7, hook section 12, and parts 3b, 3c, and 3f of the link member 3) via fracture section 3d ("frangible link"), which is a link designed to unlink when a tensile load is applied. (Ex. 1007 at ¶¶ [0151]-[0152]; *see also*, *e.g.*, *id*. at ¶¶ [0134]-[0137], ¶ [0143]; Ex. 1029, ¶ 174).

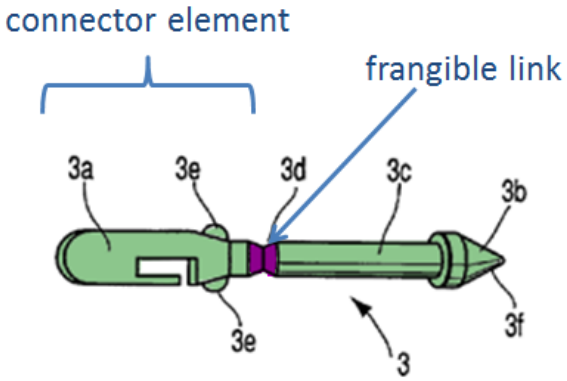


FIG. 1C

Kimura Fig. 1C

f. "*a sheath extending from a proximal to a distal end and covering a portion of the control element, wherein the distal end of the sheath is releasably coupled to the capsule*."

Kimura meets this limitation. As shown in Figs. 2A and 4B, Kimura discloses coil sheath 9 ("sheath") extending from a proximal to a distal end and covers a portion of manipulating wire 7 (part of the "control element"). (Ex. 1007 at ¶ [0141]-[0142]; Ex. 1029, ¶ 175). Further, coil sheath 9 is releasably coupled to stop tube 4 ("capsule"). (Ex. 1007 at ¶ [0141]-[0142]; Ex. 1029, ¶ 175).

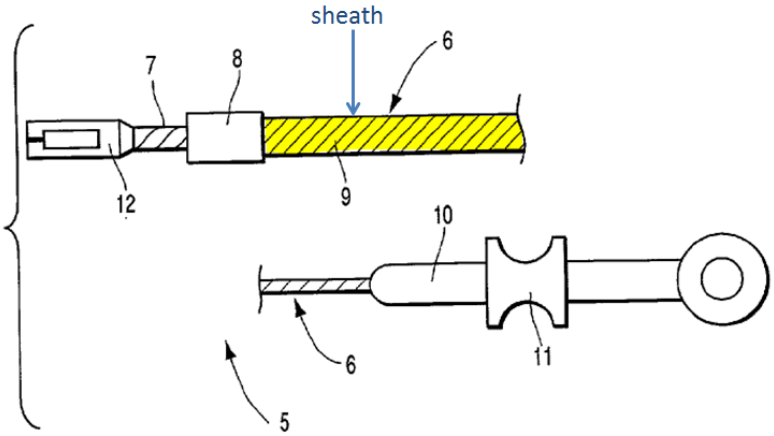


FIG. 2A

Kimura Fig. 2A

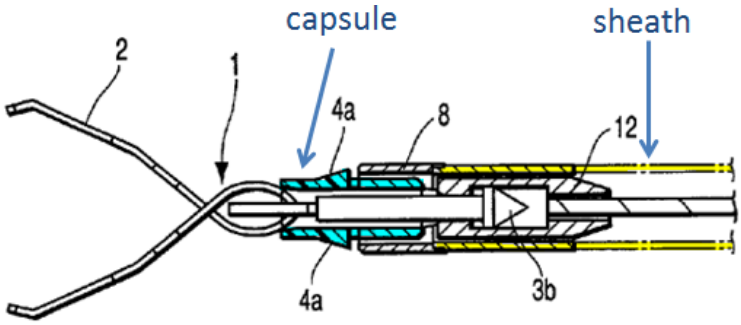


FIG. 4B

Kimura Fig. 4B

3. Claim 12

Claim 12 adds the limitation: "*wherein the frangible link is formed as a reduced diameter portion of the control element*."

Kimura meets this limitation. Specifically, fracture section 3d ("frangible link") on link member 3 (part of the "control element") is described as having a reduced diameter of "0.4 mm to 0.6 mm" as compared to the diameter of the cylinder section 3c of the link member 3, which is "0.7 mm to 1.0 mm in diameter." (Ex. 1007 at ¶¶ [0136]-[0137]; Ex. 1029, ¶ 177).

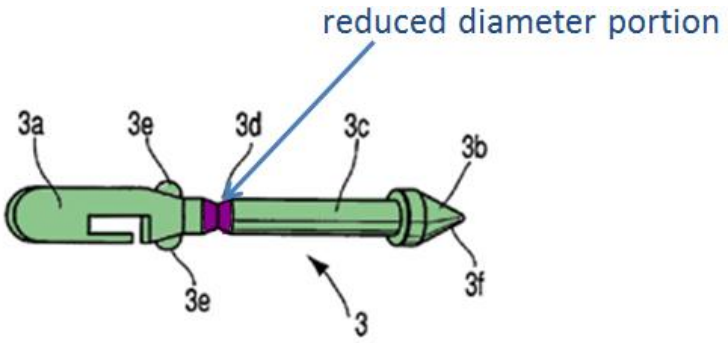


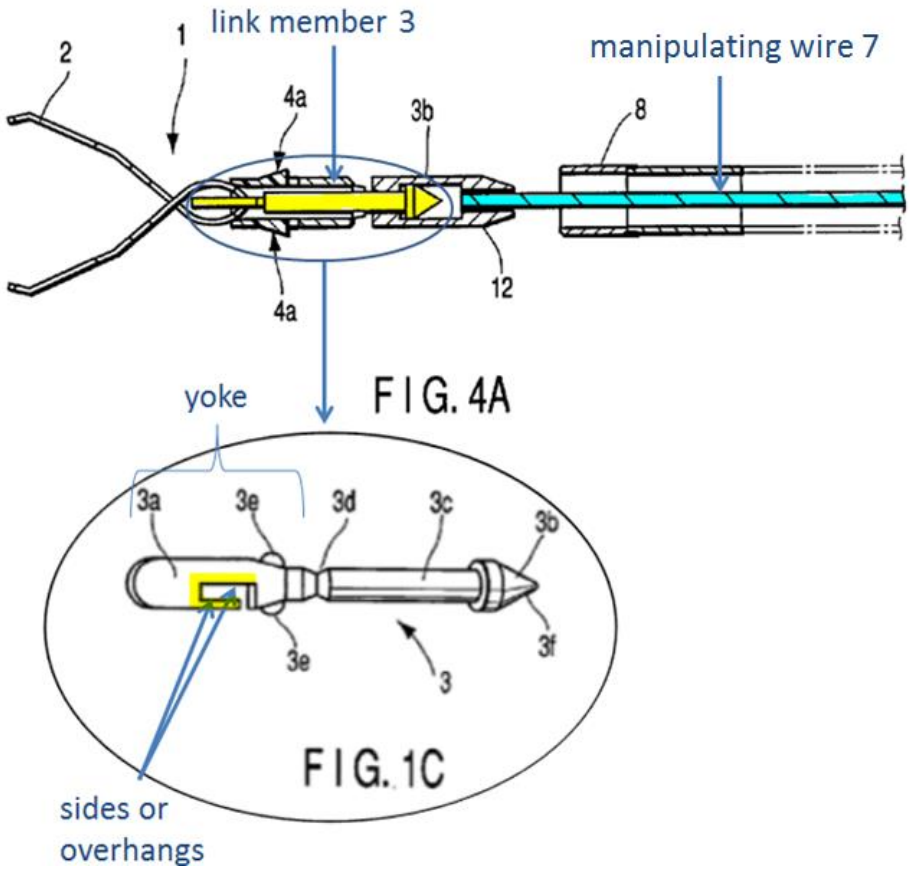
FIG. 1C

Kimura Fig. 1C

4. Claim 13

Claim 13 adds the limitation: "*wherein the clip assembly includes a yoke slidably received in the capsule and removably coupled to the control element*."

Kimura meets this limitation. Figs. 1C and 4A show link member 3 having claw hook 3a ("yoke")[11] designed to engage the proximal end of clip 2:



Kimura Figs. 1C and 4A

[11] Claw hook 3a satisfies both the "connector element" and "yoke" limitations of claim 13. *See Retractable Techs., Inc. v. Becton*, 653 F.3d 1296, 1303-1304 (Fed. Cir. 2011).

(Ex. 1007 at ¶ [0134]; Ex. 1029, ¶ 179). Claw hook 3a is configured with sides or overhangs on each side of claw hook 3a, which extend around another element, the proximal end of clip 2. (Ex. 1007 at ¶ [0134]; Ex. 1029, ¶ 179). Thus, claw hook 3a is the claimed "yoke." (Ex. 1029, ¶ 179). Further, claw hook 3a is slidably received in stop tube 4 ("capsule") and removably coupled to the rest of link member 3 (part of the "control member"). (Ex. 1007 at ¶¶ [0134], [0137]; Ex. 1029, ¶ 179).

K. Ground 10: Claims 1, 3-6, and 15 are Rendered Obvious by Kimura

1. Independent Claim 1

a. "*An apparatus for applying clips to tissue, comprising*:"

Kimura discloses the preamble for the reasons discussed in Section V.J.2.a. (*See also* Ex. 1029, ¶ 180).

b. "*a flexible sheath extending from a proximal end which, in an operative configuration, extends into a living body to a target portion of tissue to be clipped*;"

This limitation is met by coil sheath 9 ("flexible sheath") extending from a proximal end which, in an operative configuration, extends into a living body to a target portion of tissue to be clipped. (Ex. 1007 at ¶¶ [0141]-[0142]; Ex. 1029, ¶ 181).

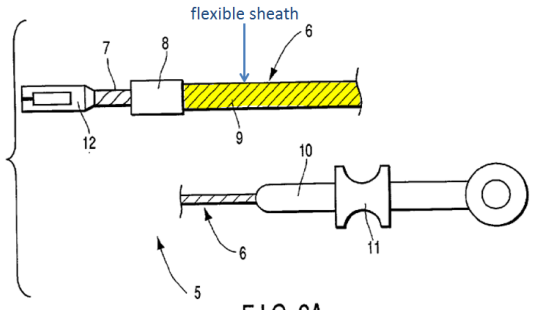


FIG. 2A

Kimura Fig. 2A

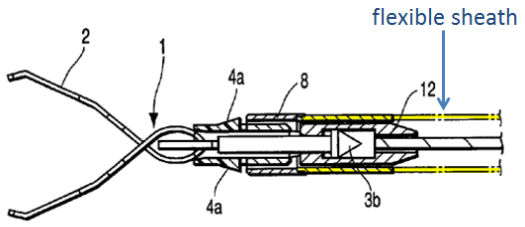
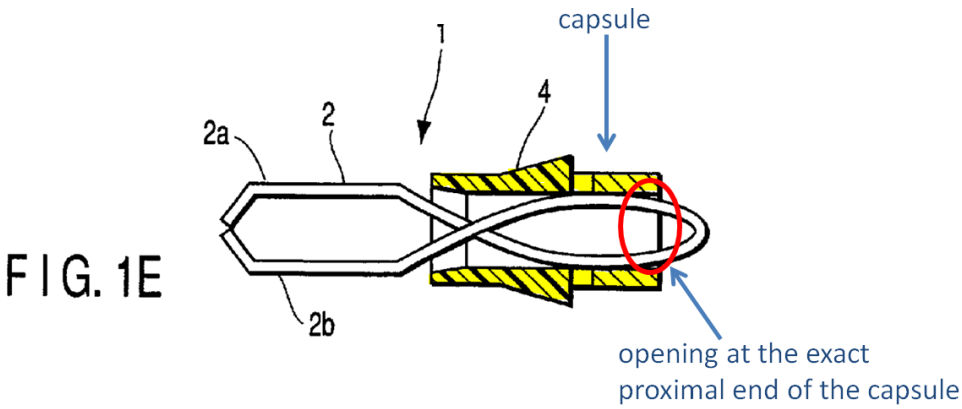


FIG. 4B

Kimura Fig. 4B

c. "*a capsule extending from a proximal to a distal end and having an opening formed in a proximal end thereof*;"

This limitation is met by stop tube 4 ("capsule") extending from a proximal to a distal end that is hollow with an opening at its proximal end. (Ex. 1007 at ¶¶ [0138]-[0139], [0151]; Ex. 1029, ¶ 182).



Kimura Fig. 1E

d. "*a clip assembly provided in the capsule and configured to be operably movable between a closed configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration in which the first and second arms are separated from one another to receive target tissue therebetween*;"

Kimura discloses this limitation for the reasons discussed in Section V.J.2.c. (*See also* Ex. 1029, ¶ 183).

e. "*a bushing extending between a proximal end coupled to the sheath and a distal end releasably coupled to the capsule via a tab on the distal end of the bushing engaging the opening of the capsule; and*"

This limitation is obvious in view of Kimura. Kimura discloses coil pipe 8 ("bushing") having a proximal end coupled to coil sheath 9 ("flexible sheath"):

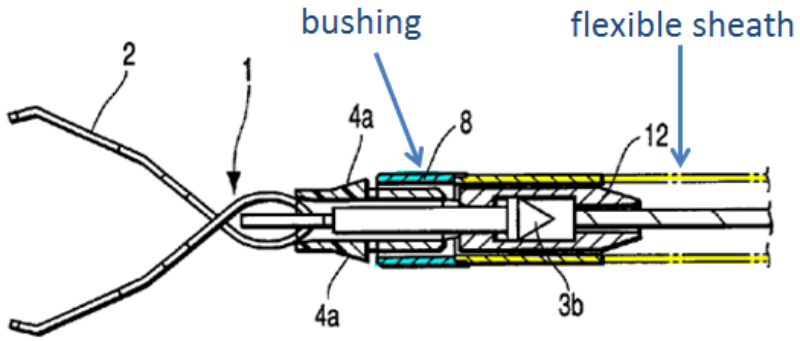


FIG. 4B

Kimura Fig. 4B

(Ex. 1007 at ¶ [0142]; Ex. 1029, ¶ 184). Further, the coil pipe 8 ("bushing") has a distal end releasably coupled to the stop tube 4 ("capsule"):

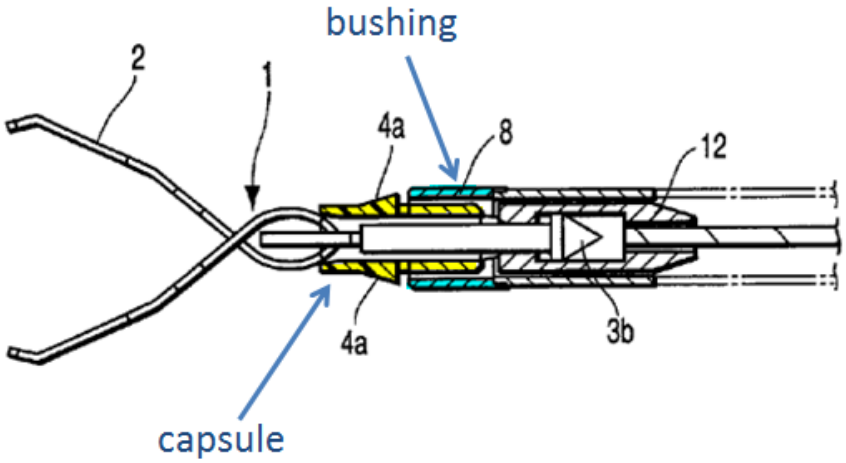


FIG. 4B

Kimura Fig. 4B

(Ex. 1007 at ¶ [0151] ("[T]he proximal end face of the protrusion 4a of the stop tube 4 is engaged with an end face of the coil pipe 8."); *see also, e.g., id*. at ¶¶ [0139]-[0140], [0142]; Ex. 1029, ¶ 184). However, Kimura does not explicitly disclose that coil pipe 8 ("bushing") is releasably coupled to stop tube 4 ("capsule") "via a tab on the distal end of the bushing engaging the opening of the capsule." Instead, the connection in Kimura is reversed: the claimed "tab" is on stop tube 4 ("capsule") and the "opening" is on coil pipe 8 ("bushing"). Specifically, the proximal end ("tab") of stop tube 4 ("capsule") slides into the hollow portion ("opening") of coil pipe 8 ("bushing"):[12]

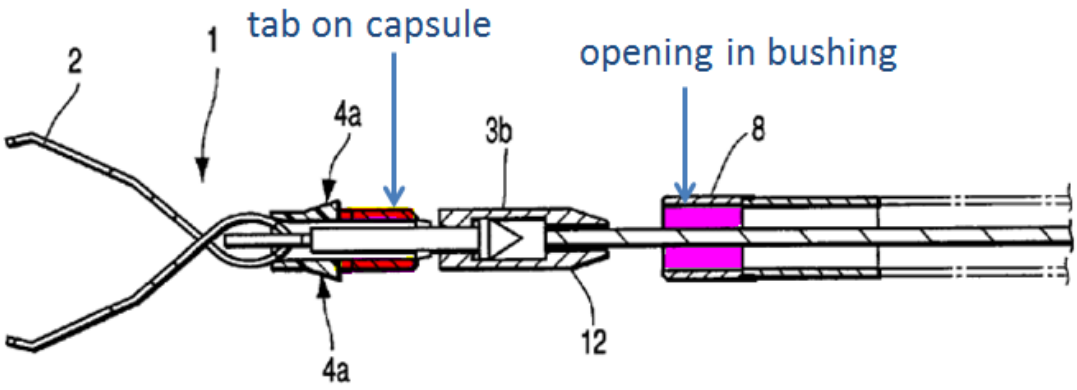


FIG. 4A

Kimura Fig. 4A

[12] BSSI contends this limitation broadly covers this connection type. (Ex. 1004 at 18-19).

(Ex. 1007 at ¶ [0151]; Ex. 1029, ¶ 184). To a PHOSITA, stop tube 4 ("capsule") and coil pipe 8 ("bushing") described in Kimura can engage each other in one of two ways: (1) stop tube 4 ("capsule") sliding into the lumen of coil pipe 8 ("bushing") as disclosed in Kimura; or (2) coil pipe 8 ("bushing") sliding into the lumen of stop tube 4 ("capsule") as required by claim 1. (Ex. 1029, ¶ 184). By reversing the connection between stop tube 4 ("capsule") and coil pipe 8 ("bushing") as disclosed in Kimura, claim 1 of the '371 patent is simply rearranging old elements that were well known in the prior art to perform the same function without any unexpected results. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("[W]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.").

In the 2003 timeframe, it would have been obvious to a PHOSITA to reverse the connection between stop tube 4 and coil pipe 8 as described in Kimura. (Ex. 1029, ¶ 185).

First, it would have been obvious to try reversing the connection between Kimura's stop tube 4 and coil pipe 8. MPEP §2143 (I)(E). The proposed combination merely involves choosing from one of two ways to slidably fit a tube over another tube: (1) the first tube sliding over the second tube; and (2) the second tube sliding over the first tube. (Ex. 1029, ¶ 186).

Second, there was a "teaching, suggestion, or motivation in the prior art that would have led a [PHOSITA] to modify the prior art reference to arrive at the claimed invention." MPEP §2143 (I)(G). Specifically, Kimura recognizes that "[a]dditional advantages and modifications will readily occur to those skilled in the art. Therefore, the invention in its broader aspects is not limited to the specific details and representative embodiments shown and described herein." (Ex. 1007 at ¶ [0316].) A PHOSITA would understand this portion of Kimura to teach, suggest, or motivate to modify the connection between Kimura's stop tube 4 and coil pipe 8. (Ex. 1029, ¶ 187).

Thus, it would have been obvious to a PHOSITA to reverse the connection between stop tube 4 and coil pipe 8 as described in Kimura. (*Id*. at ¶ 188). The resulting medical device would include this limitation.

f. "*a control member a distal end of which is releasably coupled to the clip assembly to transmit to the clip assembly forces applied thereto to move the clip assembly between the insertion and expanded configurations*."

This limitation is met by manipulating wire 7 ("control member") with a distal end releasably coupled to clip 2 ("clip assembly"). (Ex. 1007 at ¶¶ [0151]-[0152]; *see also*, *e.g.*, *id*. at ¶¶ [0134]-[0137], [0143]; Ex. 1029, ¶ 189). Manipulating wire 7 causes clip 2 to move "between the insertion and expanded configurations." (Ex. 1007 at ¶¶ [0151]-[0152]; Ex. 1029, ¶ 189).

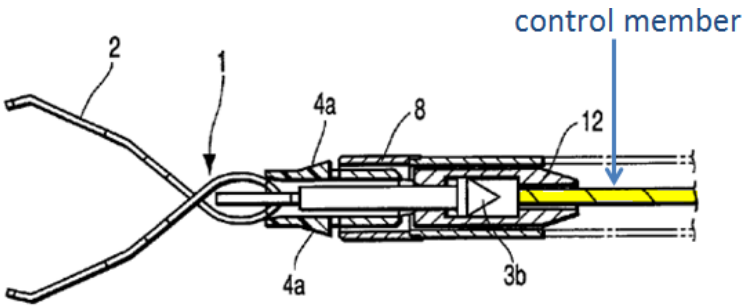


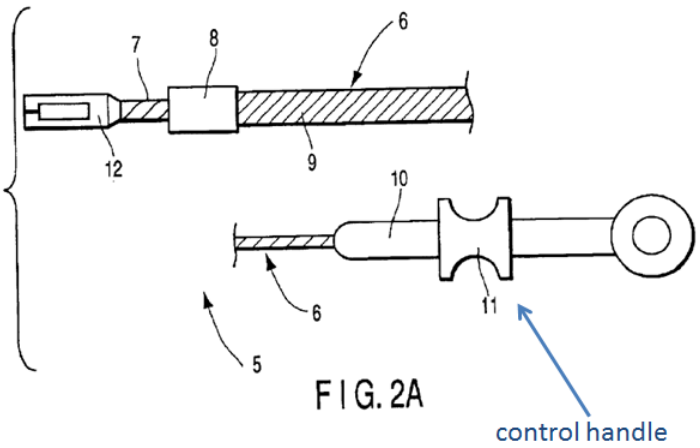
FIG. 4B

Kimura Fig. 4B

2. Claim 3

Claim 3 adds the limitation: "*wherein a proximal end of the control member is coupled to a control handle which, when the apparatus is in an operative position, remains outside the body accessible to a user*."

This limitation is met by slider 11 ("control handle") coupled to the proximal end of manipulating wire 7 (part of the "control member"). (Ex. 1007 at ¶ [0142]; Ex. 1029, ¶ 191). When the apparatus is in an operative position, slider 11 remains outside of the body and accessible to a user. (Ex. 1007 at ¶¶ [0150]-[0152]; Ex. 1029, ¶ 191).

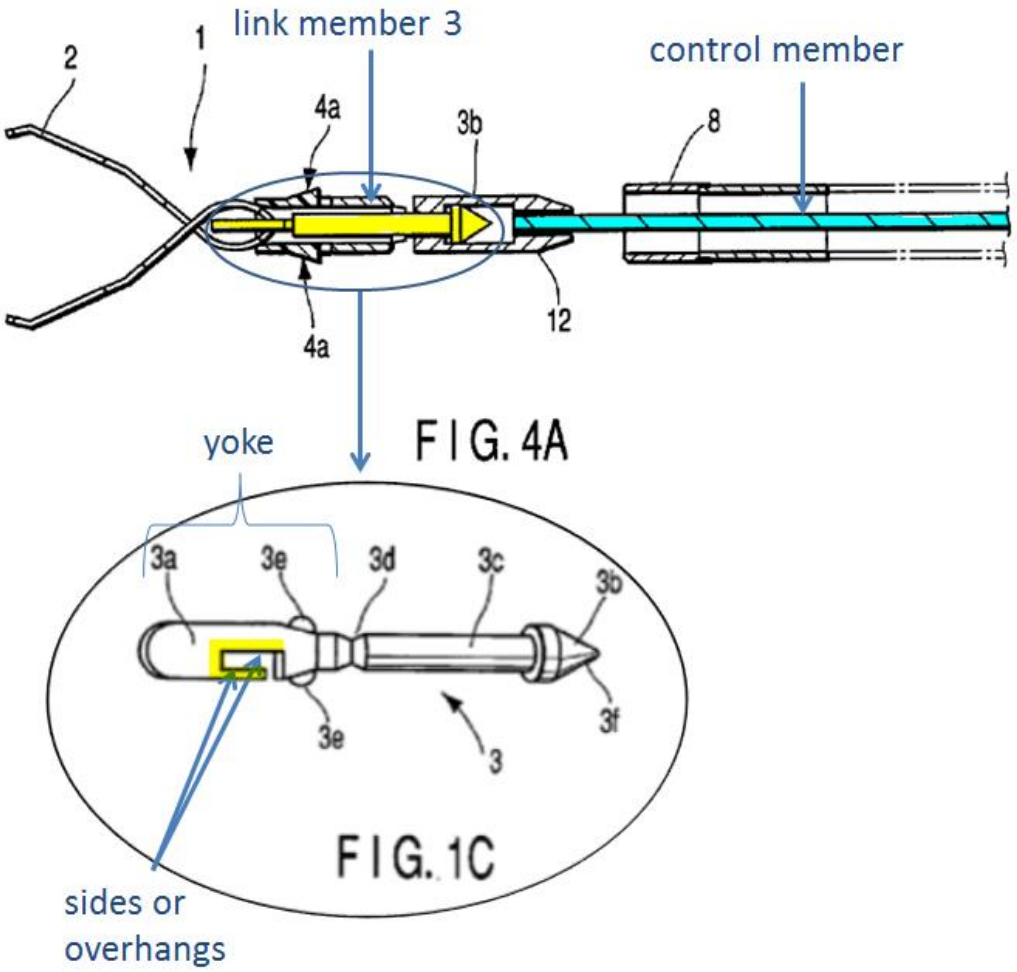


Kimura Fig. 2A

3. Claim 4

Claim 4 depends from claim 3 and adds the limitation: "*wherein the clip assembly further comprises a yoke slidably received in the capsule and releasably coupled to the control member*."

Kimura discloses this limitation. Figs. 1C and 4A of Kimura show link member 3, which is coupled to manipulating wire 7 ("control member") via hook section 12:



Kimura Figs. 1C and 4A

(Ex. 1007 at ¶¶ [0134]-[0137], [0142]; Ex. 1029, ¶ 193). Claw hook 3a at the distal end of link member 3 corresponds with the claimed "yoke." (Ex. 1007 at ¶¶ [0134]-[0137]; Ex. 1029, ¶ 193). Claw hook 3a is designed to engage the proximal end of clip 2 and is configured with sides or overhangs (the sides of claw hook 3a) which extend around another element, the proximal end of clip 2. (Ex. 1007 at ¶ [0134]; Ex. 1029, ¶ 193). Further, claw hook 3a is slidably received in stop tube 4 ("capsule") and releasably coupled to manipulating wire 7 ("control member") via fracture section 3d on link member 3, which is designed to fracture when a tensile load is applied. (Ex. 1007 at ¶ [0137]; Ex. 1029, ¶ 193). Following the separation, claw hook 3a remains with the clip and forms a part of the clip assembly. (Ex. 1007 at ¶¶ [0134], [0151]-[0152], [0155]; Ex. 1029, ¶ 193).

4. Claim 5

Claim 5 depends from claim 3 and adds the limitation: "*wherein the control member is coupled to the yoke via a frangible link*."

Kimura meets this limitation. As discussed with respect to claim 4, Kimura discloses a "yoke." (*See* Section V.K.3). Further, as shown in Fig. 1C, link member 3 includes fracture section 3d ("frangible link") that separates claw hook 3a ("yoke") from manipulating wire 7 ("control member") and is designed to unlink when a tensile load is applied. (Ex. 1007 at ¶¶ [0137], [0152]; Ex. 1029, ¶ 195).

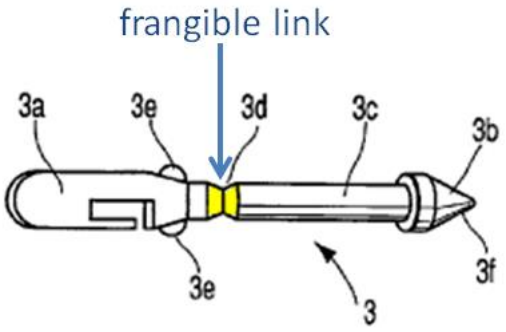


FIG. 1C

Kimura Fig. 1C

5. Claim 6

Claim 6 depends from claim 5 and adds the limitation: "*wherein the frangible link is formed as a reduced strength portion of the control member*."

Kimura meets this limitation. Specifically, fracture section 3d ("frangible link") on link member 3 (part of the "control member") is described as a reduced strength portion designed to fracture "[w]hen an amount of tensile force of about 3 kgf to 5 kgf is applied to the link member 3." (Ex. 1007 at ¶¶ [0136]-[0137]; Ex. 1029, ¶ 197).

6. Claim 15

Claim 15 depends from claim 11 and adds the limitation: "*wherein the sheath is coupled to the capsule via a bushing including a tab on a distal end thereof received in an opening at a proximal end of the capsule*."

This limitation is disclosed by Kimura for the reasons discussed in Section V.K.1.e. (*See also* Ex. 1029, ¶ 199).

L. Ground 11: Claims 10 and 17 are Rendered Obvious by Kimura Combined with Sackier

1. Claim 10

Claim 10 depends from claim 1, which is obvious in view of Kimura. (*See* Section V.K.1). Claim 10 adds the limitation: "*further comprising a tension member slidably received in the capsule and configured to bias the first and second arms to the expanded configuration*."

This limitation is disclosed by Kimura in combination with Sackier. Fig. 1E of Kimura shows arm sections 2a, 2b ("first and second arms") that are slidably received in stop tube 4 ("capsule"):

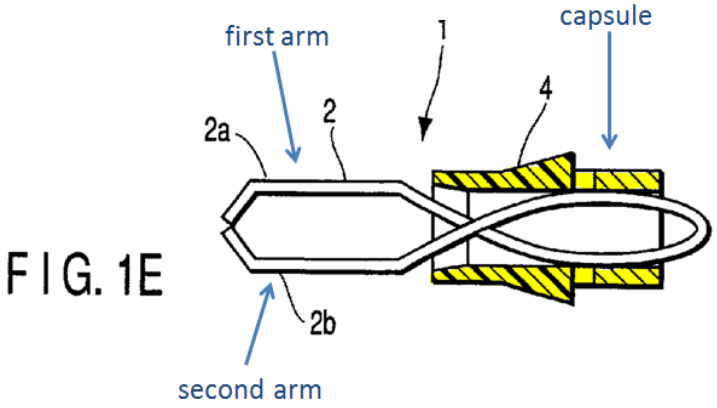
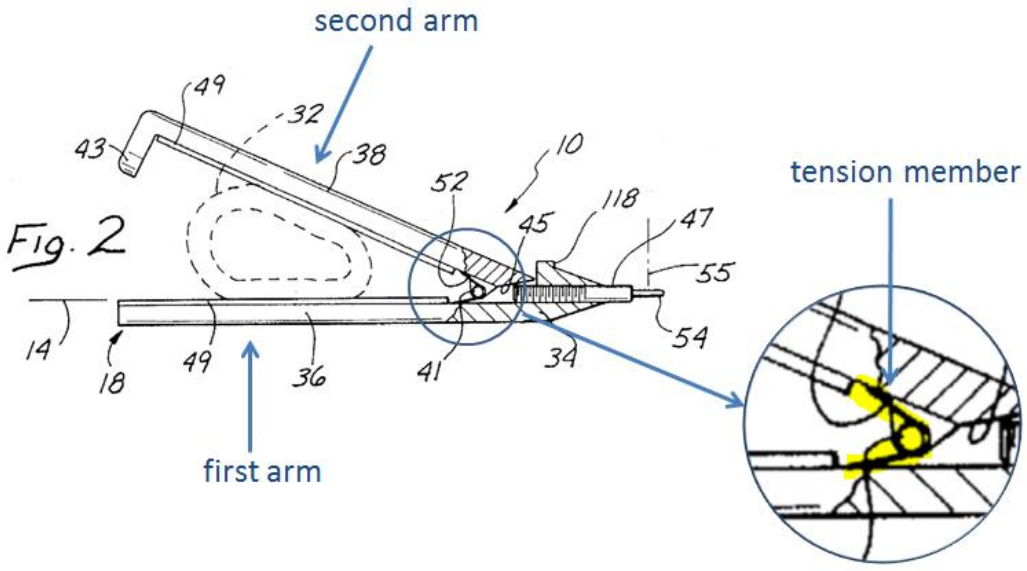


FIG. 1E

Kimura Fig. 1E

(Ex. 1007 at ¶ [0133]; Ex. 1029, ¶ 201). Fig. 2 of Sackier, below, shows a clip device including spring 52 ("tension member") configured to bias jaws 36 and 38 ("first and second arms") to the expanded configuration:



Sackier Fig. 2

(Ex. 1008 at 5:4-5 ("A spring 52 can be provided in the hinge 41 in order to bias the jaws 36 and 38 to the open position."); Ex. 1029, ¶ 201).

For the reasons described in Section V.E.1, it would have been obvious to a PHOSITA to include in Kimura's clip applying apparatus a spring ("tension member") as disclosed in Sackier that is slidably received in Kimura's stop tube 4 ("capsule") and biases Kimura's arm sections 2a, 2b ("first and second arms of the clip assembly") to the expanded configuration. (Ex. 1029, ¶ 202).

2. Claim 17

Claim 17 depends from claim 11, which is anticipated by Kimura. (*See* Section V.J.2). Claim 17 adds the limitation: "*further comprising a tension member slidably received in the capsule and configured to bias the first and second arms to the expanded configuration*."

This limitation is disclosed by Kimura in combination with Sackier for the reasons discussed in Section V.L.1. (*See also* Ex. 1029, ¶ 204).

VI. CONCLUSION

Petitioners respectfully request the PTAB to grant this petition for *inter partes* review and cancellation of claims 1, 3-15, and 17 of the '371 patent.

Dated: October 27, 2016

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned certifies that this brief complies with the type-volume limitations of 37 CFR § 42.24(a)(1)(i). This brief (including figure labels and annotations) contains 13,987 words as calculated by the "Word Count" feature of Microsoft Word 2010, the word processing program used to create it, and manual counting of the annotations in the figures.

The undersigned further certifies that this brief complies with the typeface requirements of 37 CFR § 42.6(a)(2)(ii) and typestyle requirements of 37 CFR § 42.6(a)(2)(iii). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14 point font.

Dated: October 27, 2016

Respectfully submitted,

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Dominic P. Zanfardino (Reg. No. 36,068)
Lead Attorney for Petitioners

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 8,974,371, as well as the accompanying Power of Attorney, and Exhibits 1004, 1007, 1008, 1012, 1013, 1020, 1023, 1027, 1028, 1029, 1030, and 1031 have been served in their entirety on October 27, 2016, by Federal Express (Overnight Delivery) on:

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Counsel of Record for Boston Scientific Scimed, Inc. at the U.S. Patent & Trademark Office with respect to U.S. Patent No. 8,974,371	*Counsel of Record for Boston Scientific Scimed, Inc. in Civil Action No. 15-980-LPS-CJB (D. Del.) with respect to the assertion of U.S. Patent No. 8,974,371*.

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