**UNITED STATES PATENT AND TRADEMARK OFFICE**

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Cook Group Incorporated and Cook Medical LLC,

Petitioners

v.

Boston Scientific Scimed, Incorporated,

Patent Owner

Patent No. 8,685,048
Issue Date: April 1, 2014

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**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,685,048**

Case No. IPR2017-00132

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Cook Group Incorporated and Cook Medical LLC (collectively "Petitioners") respectfully request *inter partes* review of claims 1-3, 5-18, and 20-30 of U.S. Patent No. 8,685,048 ("the '048 patent") (Ex. 1023). USPTO assignment records show that the Patent Owner is Boston Scientific Scimed, Inc. ("BSSI").

## 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))

#### 1. Pending District Court Litigation

The '048 patent is the subject of litigation in the U.S. District Court for the District of Delaware in *Boston Scientific Corp. et. al. v. Cook Group Inc. et al.*, No. 15-980-LPS-CJB. Petitioners were served with the Complaint on October 29, 2015.

This Petition is being filed and served concurrently with a petition for *inter partes* review in IPR No. 2017-00131, which challenges the patentability of claims 1-30 of the '048 patent, and with petitions for *inter partes* review in IPR Nos. 2017-00133 and 2017-00134, which challenge the patentability of the claims of a related patent, U.S. Patent No. 8,709,027.

### 2. Related Pending Applications

The following patent applications are related to the ’048 patent, and are currently pending before the U.S. Patent Office: U.S. Patent Application Nos. 14/988,447; 15/009,358; and 15/091,147.

## 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.

## II. FEE FOR INTER PARTES REVIEW (37 C.F.R. § 42.103)

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.

## III. SUMMARY OF THE RELEVANT TECHNOLOGY AND THE '048 PATENT

The '048 patent relates generally to compression clips that can be used "to cause hemostasis of blood vessels located along the gastrointestinal tract." (*See* Ex. 1023, 1:20-23). The clips stop internal bleeding by clamping together the edge of a wound to achieve "hemostasis." (*Id*. at 2:37-38). The patent acknowledges that such clipping devices were known in the art before the '048 patent was filed. (*See id.*, pp. 1-2 (citing numerous prior art references); 1:49-51 (describing "Olympus Endoclips"); 2:30-37 (describing prior art "clamps, clips, staples, sutures" that are "able to apply sufficient constrictive forces to blood vessels so as

to limit or interrupt blood flow"); *see also* Ex. 1026, ¶ 18).

For example, a person of ordinary skill in the art would have been familiar with prior art clip devices in the form of forceps. Annotated Figures 1 and 2, below, depict an example of a prior art forceps (clip) disclosed in U.S. Patent No. 5,645,075 ("Palmer"). (Ex. 1017).[1]

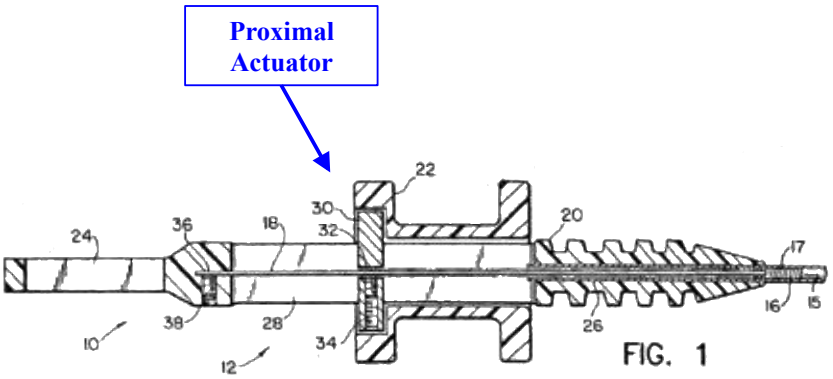



FIG. 1

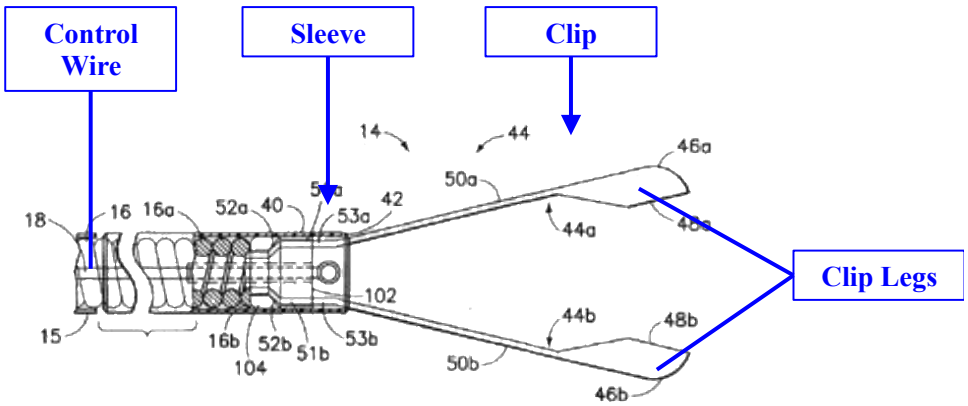


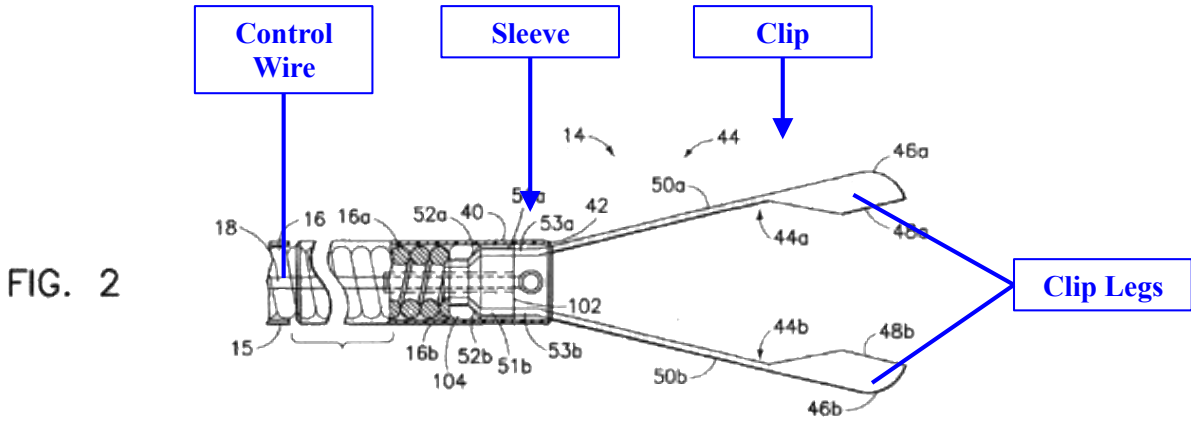

FIG. 2

The forceps (also referred to as a "bioptome") includes a proximal actuator (handle

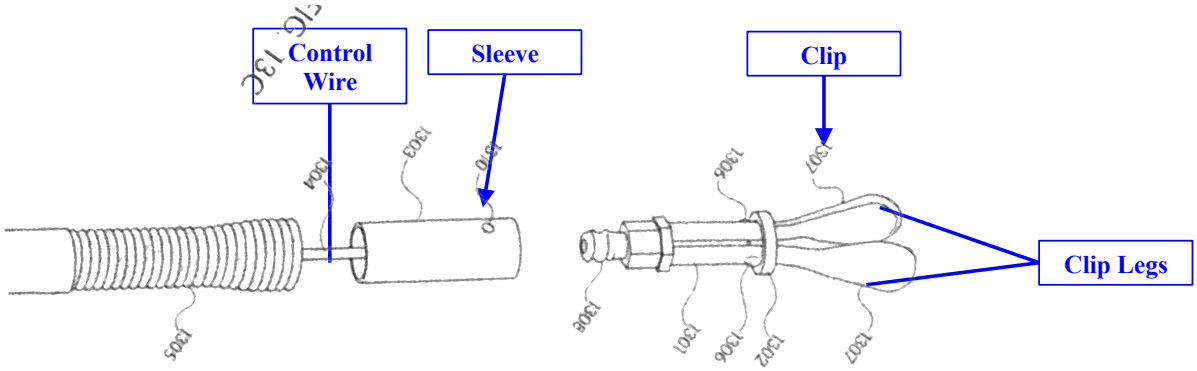
[1] Palmer issued on July 8, 1997, and names as an inventor Vincent A. Turturro – one of the named inventors of the '048 patent. Palmer was not cited during prosecution of the '048 patent.

portion 12, Figure 1), and a "distal end effector portion 14" (Figure 2) including a clip (jaw assembly 44) with two clip legs (end effectors 44a, 44b, with jaw cups 46a, 46b). (Ex. 1017, 5:50-53, 6:64-7:6). In addition, the forceps includes a control wire (control wire 18) and a sleeve (cylindrical sleeve 40), which moves relative to the clip to open and close the clip legs. (*Id.*; *see also id.*, 8:5-46, 11:5-13; Ex. 1026, ¶ 19).

The named inventors of the '048 patent were aware of prior art forceps, and acknowledged in their specification that structures described in the '048 patent are "analogous to biopsy forceps." (*See* Ex. 1023, 5:44-46). Indeed, as shown below in annotated Figures 2 (Palmer) and 13C ('048 patent), the structures depicted in Figure 13C of the '048 patent are analogous to the structures depicted in Figure 2 of Palmer:




**Palmer, Figure 2**



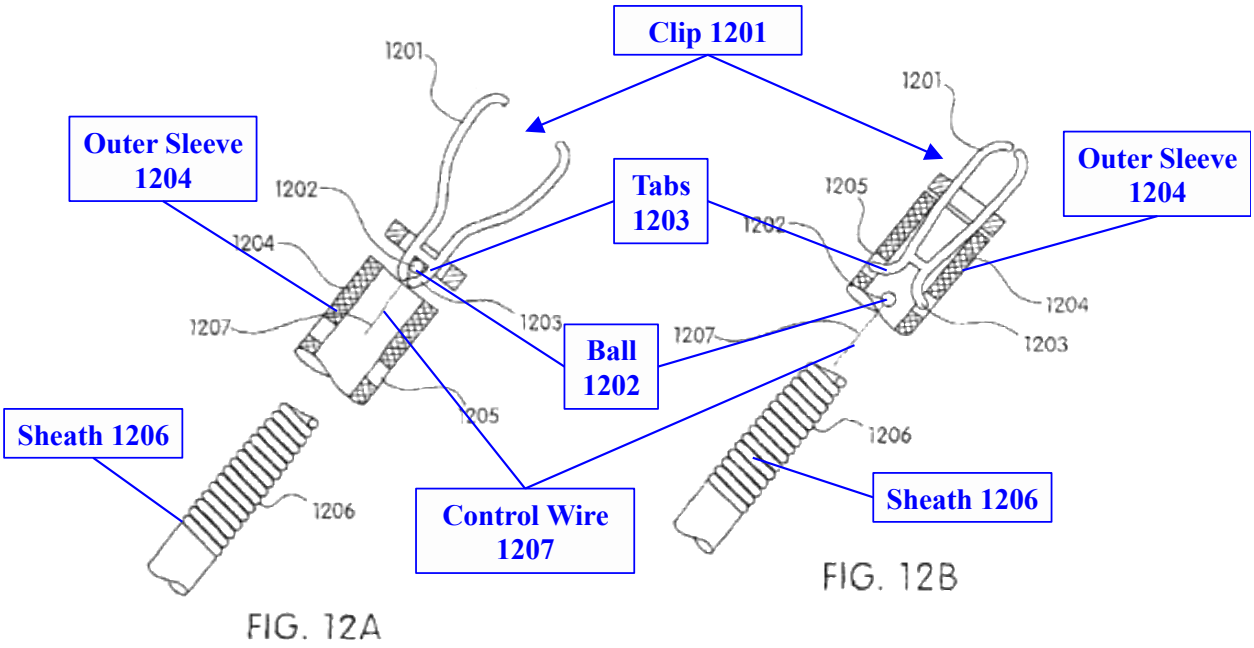

**'048 Patent, Figure 13C**

(Ex. 1026, ¶ 20).

Consistent with the prior art, independent claims 1, 15, and 29 of the '048 patent describe medical devices (claims 1 and 15) and a method (claim 29) including "*a clip*," a "*control wire*" to open and close the clip legs, an "*actuator*" to move the control wire, and a "*sheath*" enclosing a portion of the control wire. Each of these claims also describes how the control wire releases from the clip. In claim 1, a "*link*" coupling the control wire to the clip has "*arms* of [a] link" that move radially outward "at an area of the sheath." In claim 15, the clip has "*legs* of

[a] clip" that "spread laterally away from the control wire." In claim 29, applying a tensile force to the control wire "separate[s] a separable link coupling the control wire to the clip."

The specification of the '048 patent does not describe releasing a control wire from a clip using "arms of [a] link" that move outward "at an area of the sheath," or by spreading the "legs of [a] clip." Rather, as shown below in annotated Figures 12A and 12B, the '048 patent describes a "clip 1201" with "socket tabs 1203," that releases from a "ball 1202" of a "control wire 1207."




(Ex. 1023, 9:46-64). As shown above, the "socket tabs 1203" move radially outward within the area of the "outer sleeve 1204." (*See also* Ex. 1026, ¶ 22).

## IV. REQUIREMENTS FOR INTER PARTES REVIEW (37 C.F.R. § 42.104)

### A. Certification Of Standing (§ 42.104(a))

Petitioners certify that the ’048 patent is available for *inter partes* review and that Petitioners are not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition.

### B. Identification Of Challenge And Precise Relief Requested (§ 42.104(b) and (b)(1))

The precise relief requested is that claims 1-3, 5-18, and 20-30 of the ’048 patent (Ex. 1023) be found unpatentable, and canceled.

### C. The Specific Art And Statutory Grounds On Which The Challenge Is Based (§ 42.104(b)(2))

*Inter partes* review of the challenged claims is requested in view of the following references and specific grounds for rejection under 35 U.S.C. §§ 102 and 103:[2]

| No. | Grounds |
|---|---|
| 1 | Claims 1-3, 5-18, and 20-28 are anticipated under § 102 by U.S. Patent No. 3,958,576 ("Komiya") |
| 2 | Claims 2 and 17 are obvious under § 103 in view of Komiya |
| 3 | Claims 1, 3, 5-14, 21, 24, 25, 27, and 28 are obvious under § 103 in view of Komiya in combination with U.S. Patent No. 5,174,276 ("Crockard") |
| 4 | Claims 29 and 30 are obvious under § 103 in view of Japanese Unexamined Patent Application Publication No. 60-103946 ("Shinozuka") in combination with U.S. Patent No. 5,766,189 ("Matsuno") |

Petitioners submit that although the limitations of the challenged claims are disclosed in multiple references, the above challenges are not redundant. This is

[2] The '048 patent claims priority to U.S. Patent Application No. 09/971,488, filed October 5, 2001. Accordingly, the pre-AIA sections of 35 U.S.C. §§ 102 and 103 apply here.

because the structures and features in one reference that disclose a particular claim limitation differ from the structures and features in another reference that disclose the same claim limitations.

### D. Level Of Ordinary Skill In The Art

The person having ordinary skill in the art as of the time of the filing of the application that became the '048 patent 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 with designing medical devices. This person would also have an understanding of engineering or medical device design principles. (Ex. 1026, ¶ 11).[3]

Petitioners submit with this Petition the Declaration of Mark A. Nicosia, Ph.D. (Ex. 1026). Dr. Nicosia is a Professor and Chairman of the Department of Mechanical Engineering at Widener University in Chester, Pennsylvania. He received his Ph.D. in Mechanical Engineering in 1997 from Penn State University. As reflected in his *curriculum vitae* (included in Ex. 1026), Dr. Nicosia has extensive experience in the medical field in general, and with hemostatic clips in particular. Dr. Nicosia, for example, is named as a co-inventor of U.S. Patent No. 8,852,211, which relates to hemostatic clips. Dr. Nicosia's Declaration (Ex. 1026) addresses the prior art at issue from the view of a person of ordinary skill in the art

[3] The same definition of a person or ordinary skill in the art, as well as the analysis of the prior art references discussed in this petition, would apply in the 2000 timeframe. (Ex. 1026, ¶ 11).

in the relevant timeframe. (Ex. 1026, ¶ 12).

### E. 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 *inter partes* review only,[4] Petitioners adopt the following construction proposed by BSSI in the district court litigation.

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

**1. "sheath"**

Independent claims 1, 15, and 29 require "*a sheath* enclosing [a portion of] the control wire." BSSI argued in district court litigation that "sheath" means "one or more components that enclose the control wire." (Ex. 1004, p. 7). BSSI explained that, under this construction, "sheath" can include a component of the clip assembly that detaches from the sheath during delivery and remains in the body, such as the "outer sleeve 1204" in Figure 12B (reproduced below).

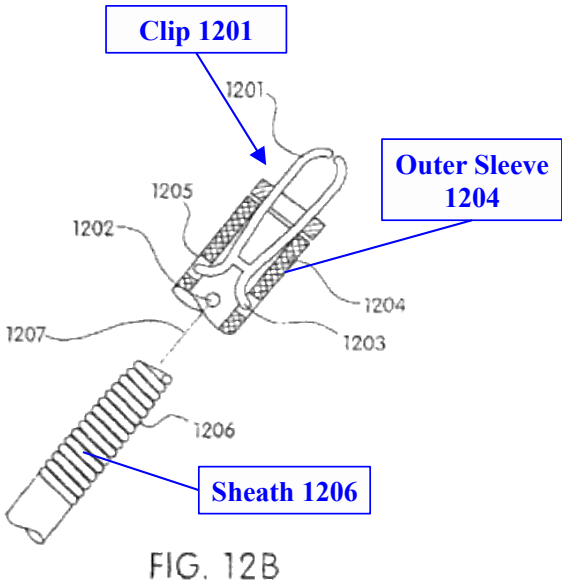



FIG. 12B

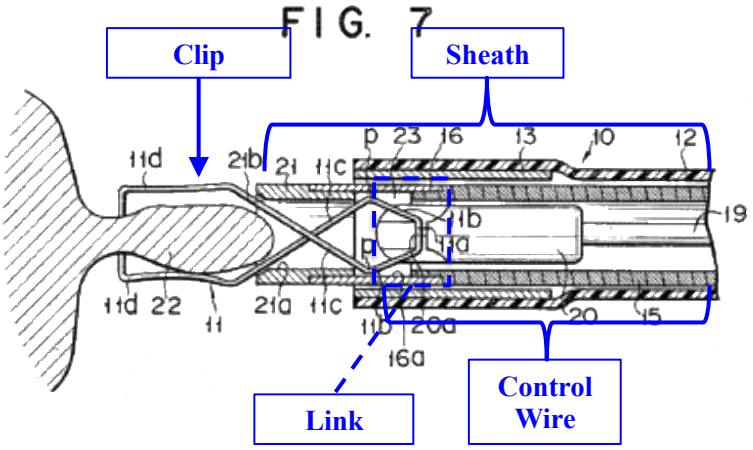
(*Id.*, p. 8 ("a portion of the sheath can stay unseparated from the clip"); Ex. 1013, p. 6 ("As the control wire 1207 [in Figure 12] is advanced distally, it pushes clip 1201 distally out of *the sheath* . . . .")).

For purposes of this IPR proceeding, Petitioners accept BSSI's construction of "sheath" as "one or more components that enclose the control wire," which may include components of the clip assembly that are left behind in the body.

## V. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO THE CHALLENGED CLAIMS

Claims 1-3, 5-18, and 20-30 of the '048 patent are unpatentable in view of one or more of the grounds identified above in Section IV.C. Only two of the references cited in these grounds were before the Patent Office. Individually and/or combined, the references cited in these grounds disclose medical devices including "*a clip*," coupled to a "*control wire*" via a separable "*link.*"

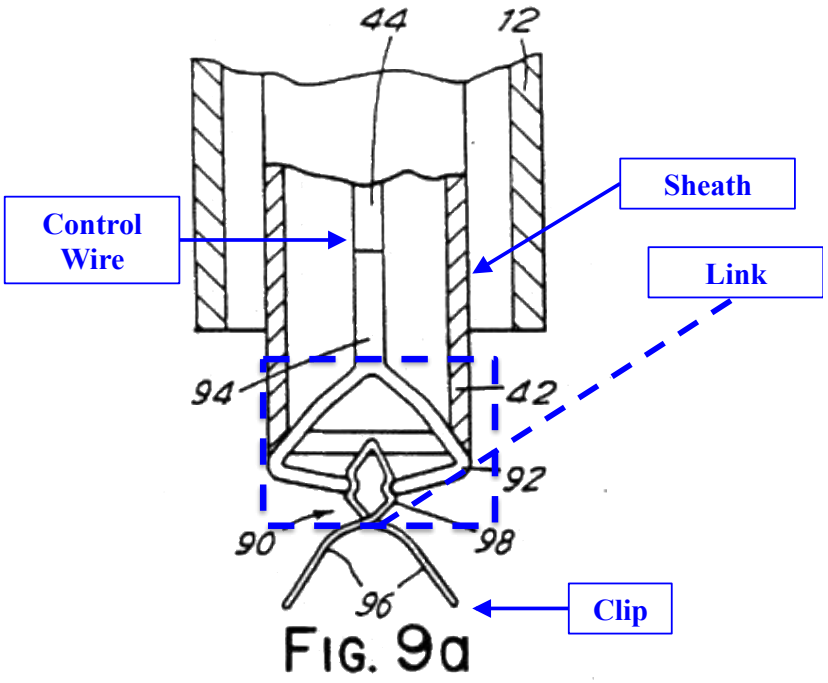
Komiya discloses a clip that separates from a control wire via a link, so that the clip can stay behind in the patient's body:




**Komiya, Figure 7**

(Ex. 1026, ¶ 26).

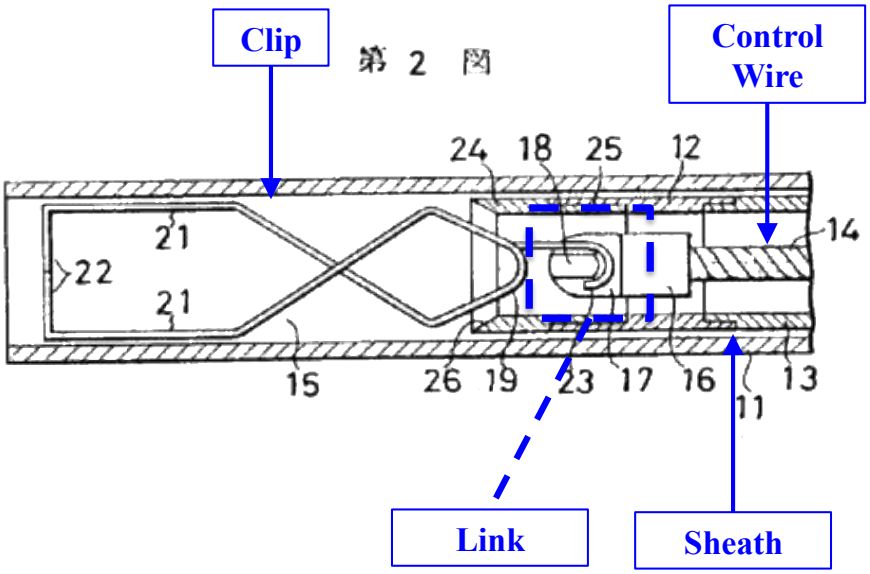
Crockard also discloses a clip that separates from a control wire via a link, so that the clip can stay behind in the patient's body:

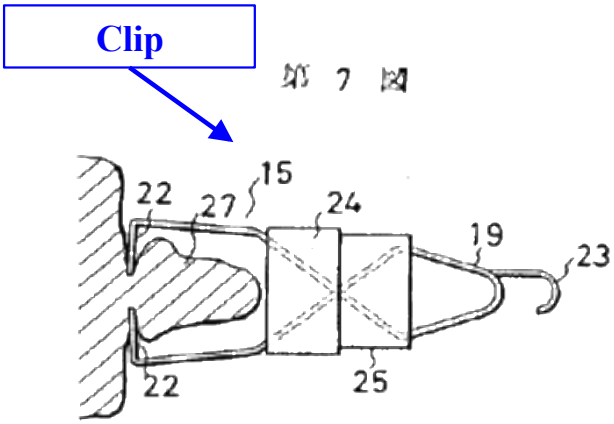



**Crockard Figure 9A**

(Ex. 1026, ¶ 28).

In addition, Shinozuka discloses a clip that separates from a control member via a link, so that the clip can stay behind in the patient's body:




**Shinozuka, Figures 2 and 7**

(Ex. 1026, ¶ 30).

Likewise, Matsuno discloses a clip that separates from a control wire via a link, so that the clip can stay behind in the patient's body:

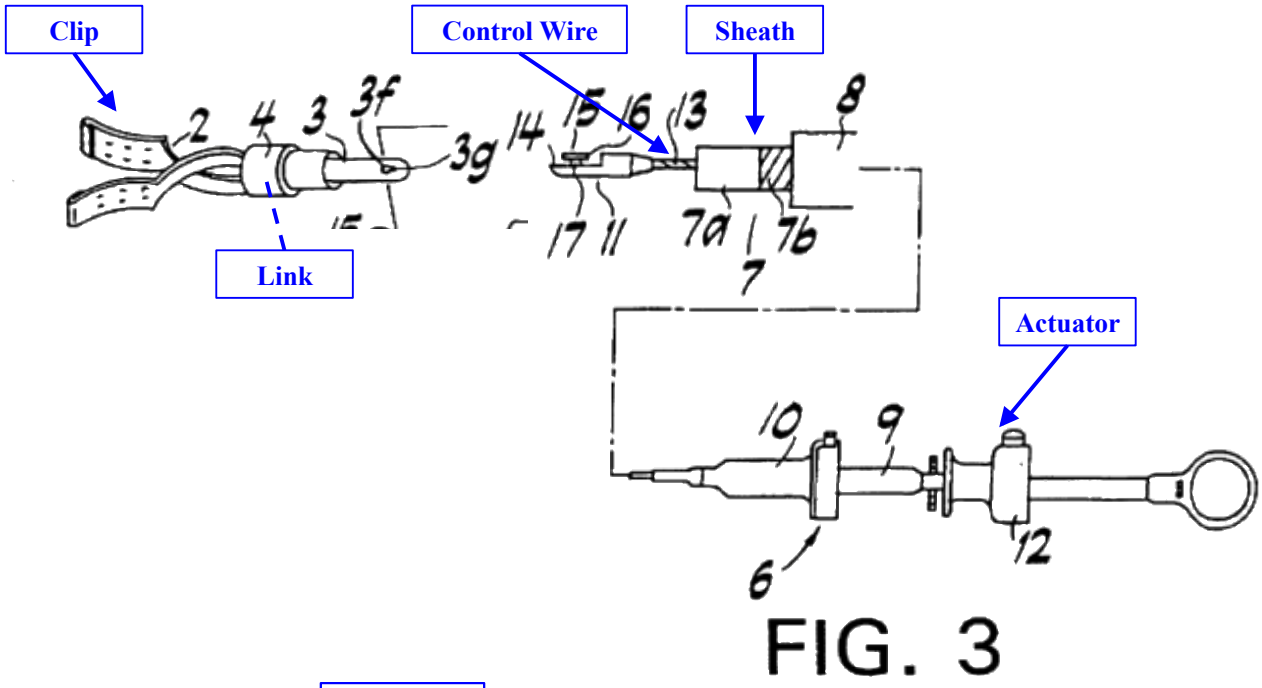



FIG. 3

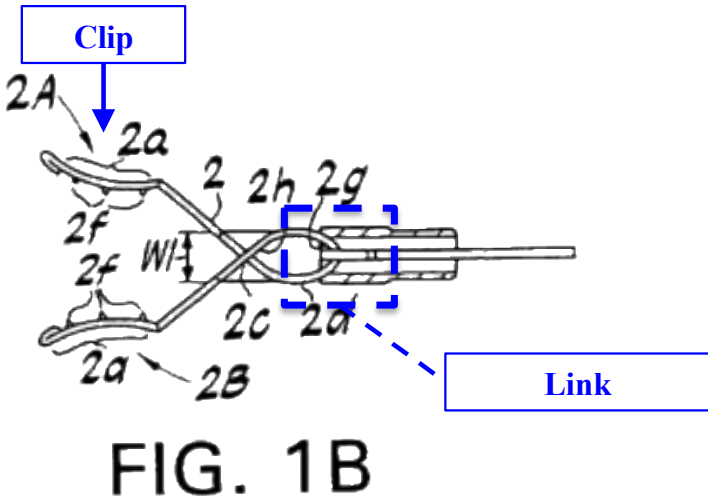



FIG. 1B

**Matsuno, Figures 1B, 3 and 4 (excerpt)**

(Ex. 1026, ¶ 32).

### A. Ground 1: There Is A Reasonable Likelihood That Claims 1-3, 5-18, And 20-28 Are Anticipated By Komiya (Ex. 1014)

Komiya issued on May 25, 1976 and qualifies as prior art at least under 35 U.S.C. §§ 102(a), (b), and (e). Komiya was cited by the Patent Office during prosecution of U.S. Patent No. 7,879,052 ("'052 patent"), which issued from an application that is a parent application for the '048 patent. The claims at issue in this Petition were not presented during prosecution of the '052 patent. Further, Komiya was never raised or discussed by BSSI or the Patent Office during prosecution of the application that matured into the '048 patent.

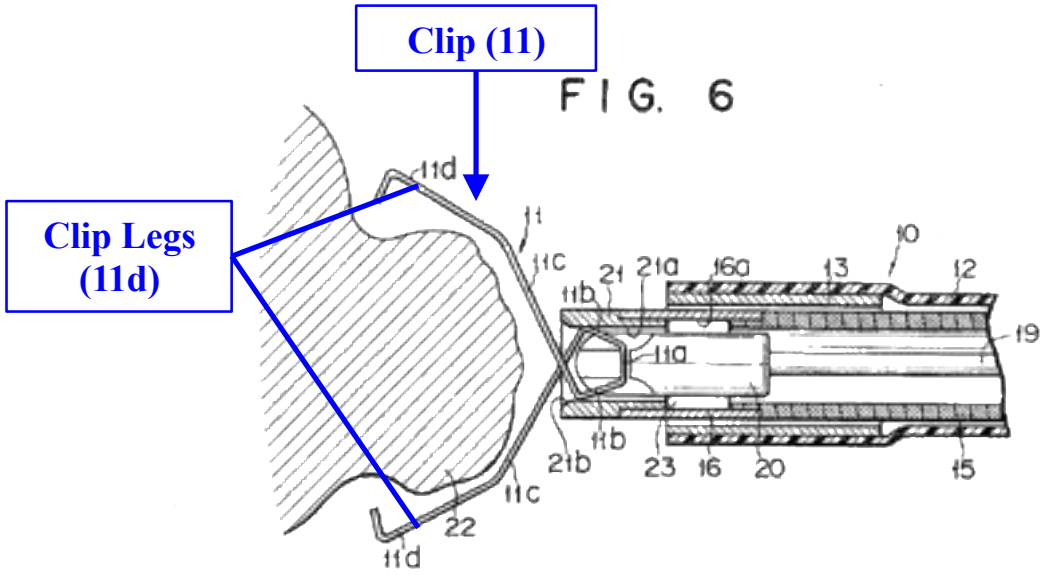
#### 1. Independent Claim 1

##### *a. "A medical device, comprising"*

Komiya discloses a medical device. (Ex. 1014, 1:6-8 ("[A] surgical instrument for clipping any affected portion of a body cavity of a human being."); *see also* 1:63-65, 2:34-45; Ex. 1026, ¶ 34).

***b. "a clip having first and second clip legs"***

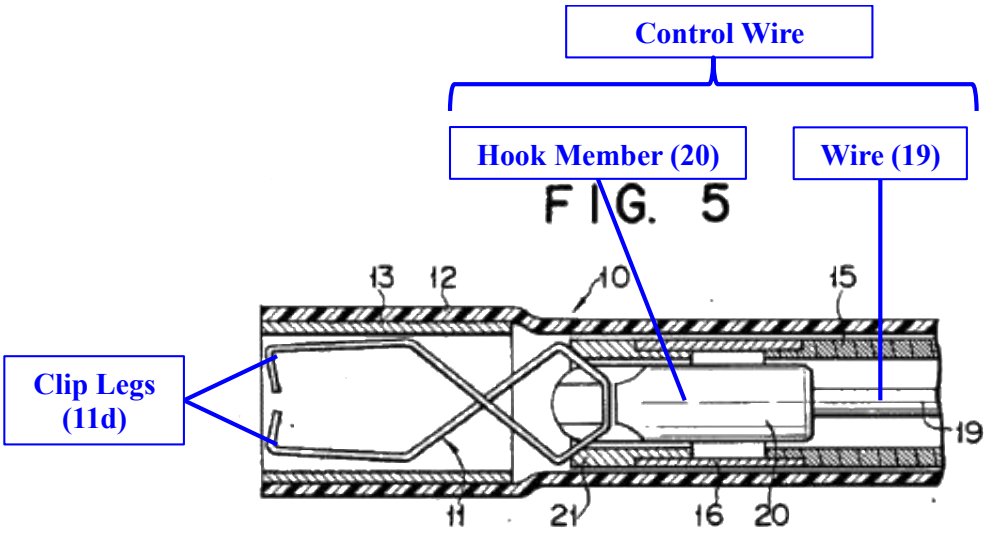
As shown below in annotated Figure 6, Komiya discloses a clip (11) having first and second clip legs (11d):

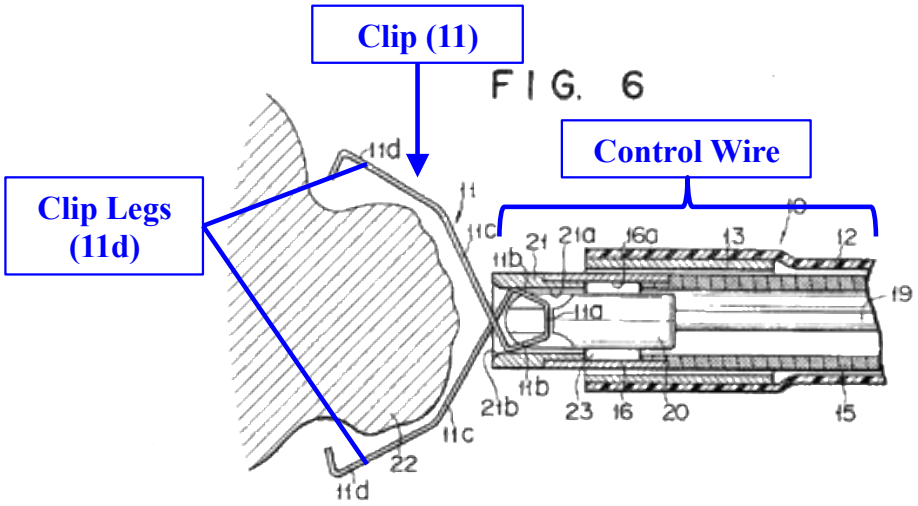


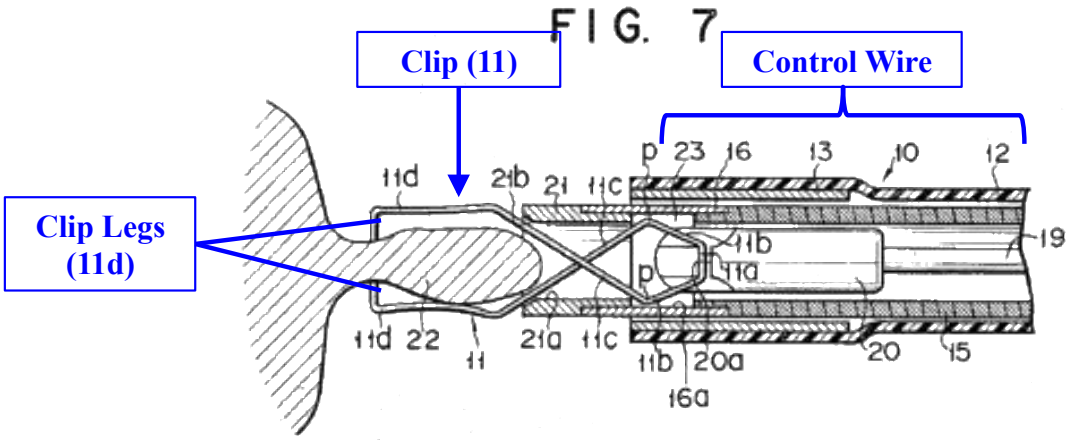

(Ex. 1014, 2:50-59 ("The clip member is formed by bending an elongated metal sheet into a shape of a figure 'eight'. . . and comprises a rear end portion 11a, a pair of offset portions 11b having one end connected to the rear end portion 11a and the other end outwardly extending away from an axis X-X thereof, a pair of portions 11c connected to the other end of the offset portions 11b and intersecting each other, and a pair of clamping portions 11d connected to the other end of the intersecting portions 11c."); *see also id.*, Abstract, 2:1-3, Figures 1, 3, 5-7; Ex. 1026, ¶ 35).

***c. "a control wire being operable both to open the clip legs and to close the clip legs"***

As shown below in annotated Figures 5-7, Komiya discloses a control wire (wire 19 with hook member 20) being operable both to open the clip legs (11d) (from Figure 5 to Figure 6) and to close the clip legs (11d) (from Figure 6 to Figure 7):



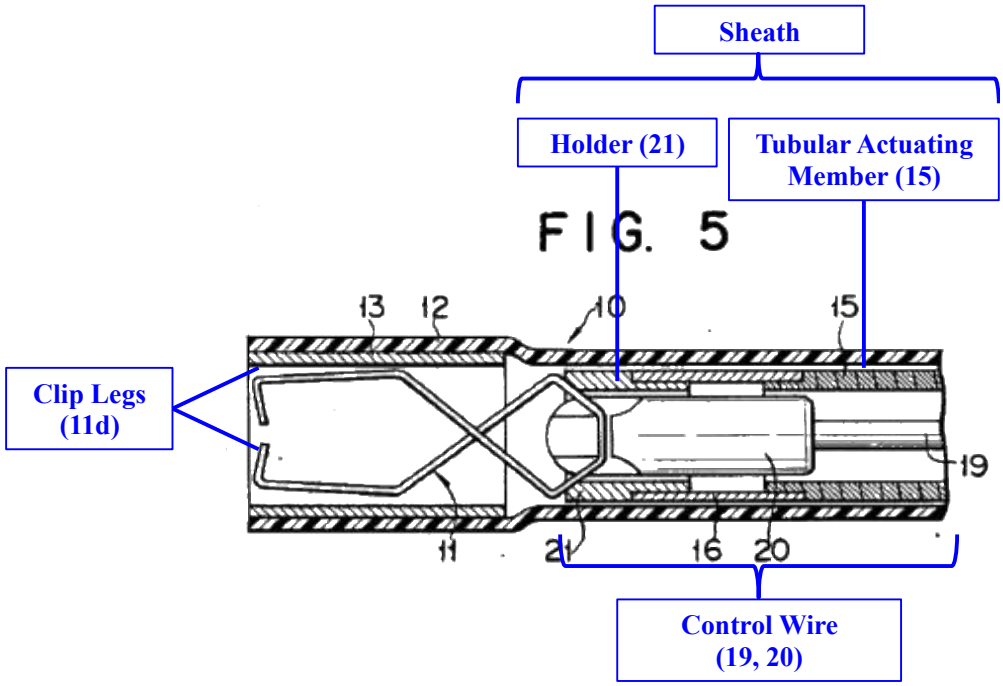






(Ex. 1014, 3:36-37 ("[W]ire 19 is moved within the actuating member 15 and, in consequence, the hook member 20 is axially moved . . . ."), 4:35-48 ("[T]he wire 19 [is] slightly withdrawn . . . to permit only the hook member 20 to be retracted relative to the holder 21. . . . to permit the pair of clamping portions 11d of the clip member 11 to be greatly opened."), 4:55-64 ("[W]ire 19 [is] further withdrawn . . . to cause the hook member 20 to be retracted as shown in FIG. 7. . . . to cause the clamping portions 11d of the clip member 11 to be closed to permit the neck of the portion 22 of the body cavity to be clipped."); *see also id.*, Abstract, 2:3-7, 5:48-51, 5:67 – 6:3, 6:32-35; Ex. 1026, ¶ 36).

***d. "a sheath enclosing the control wire"***

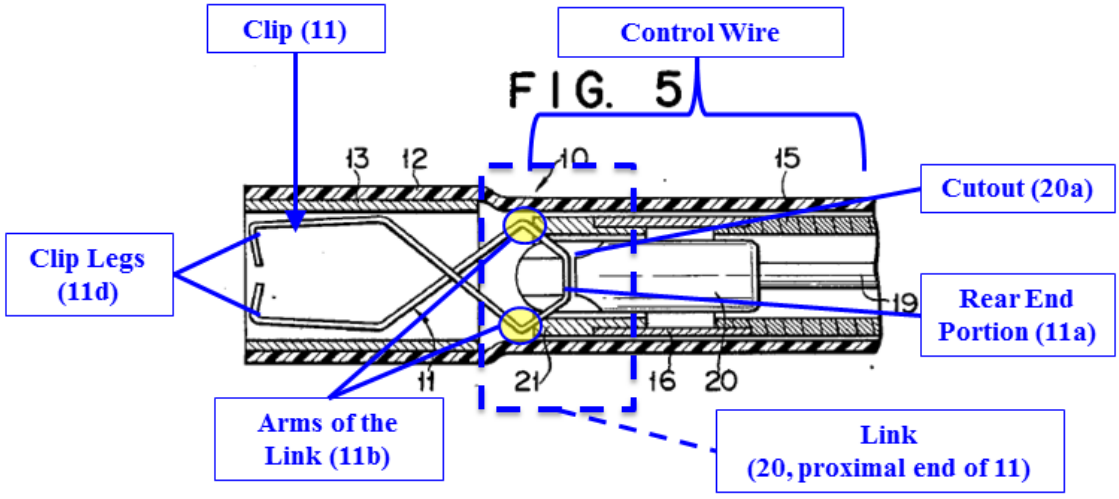
As shown below in annotated Figure 5, Komiya discloses a sheath (tubular actuating member 15 + holder 21) enclosing the control wire (19, 20):




(Ex. 1014, 3:28-29 ("A lengthy metal wire 19 is inserted within and over the length of the actuating member 15."); *see also id.*, 3:7-14, 4:34-48; Ex. 1026, ¶ 37).

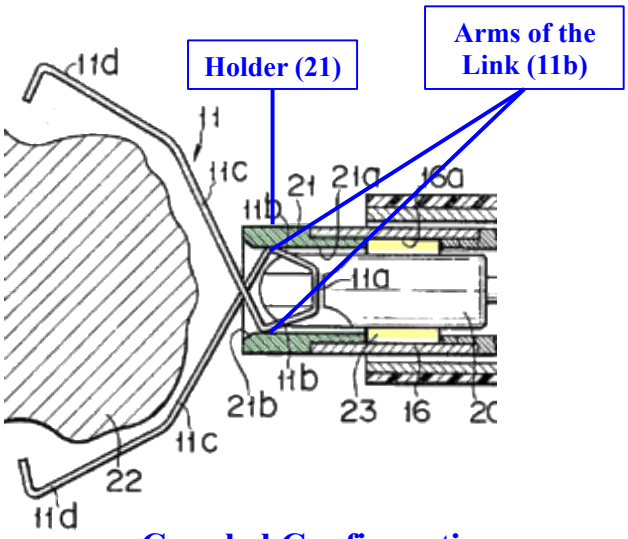
***e. "a link coupling the control wire to the clip, the link being movable from a coupled configuration in which the clip is coupled to a distal end of the control wire to a released configuration in which first and second arms of the link are configured to move radially outward at an area of the sheath to release the control wire from the clip"***

As shown below in annotated Figure 5, Komiya discloses a link (hook member 20 and proximal end of clip (11)) coupling the control wire (19, 20) to the clip (11):




(Ex. 1014, 3:41-43 ("Within the cutout 20a of the hook member 20 the rear end portion 11a of the clip member 11 is detachably anchored."). The link (hook member 20 and proximal end of clip (11)) has first and second arms (offset portions 11(b), highlighted above in yellow). (Ex. 1026, ¶ 38).

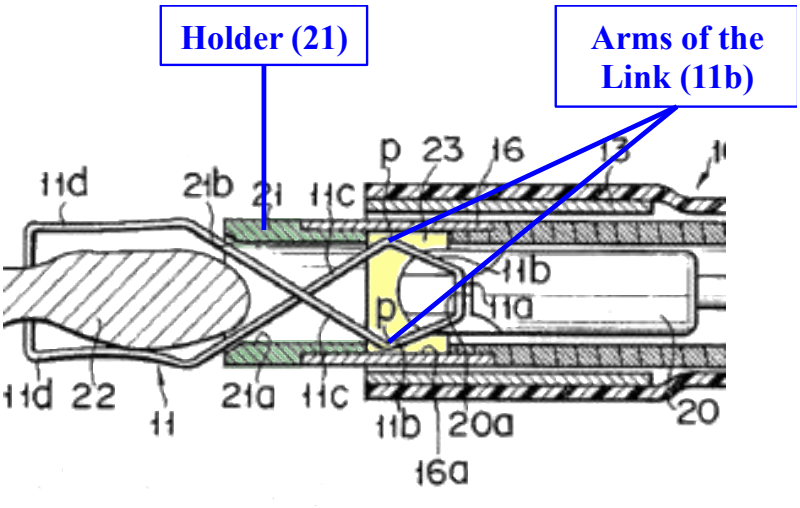
Annotated Figure 6 below shows clip (11) in an open position, and the arms of the link (offset portions 11(b)) in a *coupled configuration* in which the arms of the link (11(b)) contact the inner wall of holder (21):




**Coupled Configuration**

As the control wire (19, 20) pulls the clip (11) proximally, the arms of the link (offset portions 11(b)) are configured to move radially outward at a relief area of the sheath (highlighted above in yellow (hole 16)). (Ex. 1026, ¶ 39). In fact, BSSI confirmed during prosecution of the related '052 patent that "the proximal end of the [Komiya] clip 11 [expands] *under its own bias* as it enters the holes 16 of the guide member 16." (Ex. 1032, August 24, 2007 Response to Office Action, p. 13 (emphasis added)).

Annotated Figure 7, below, reflects the arms of the link (offset portions 11(b)) moved radially outward at the relief area of the sheath (highlighted below in yellow):



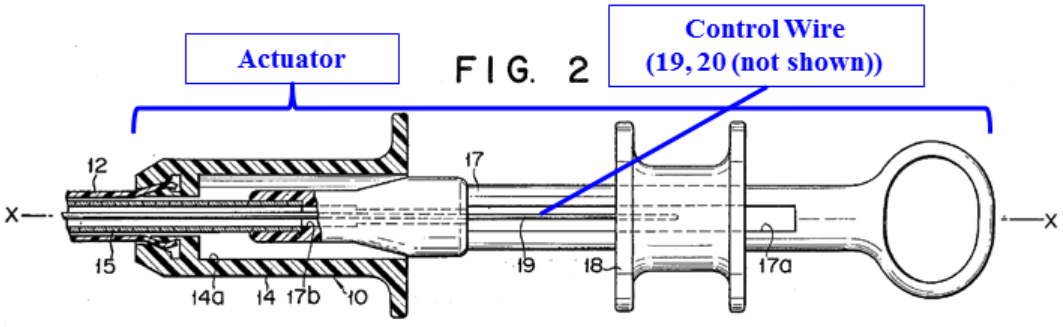

**Released Configuration**

(Ex. 1014, 4:67 – 5:10 ("[T]he offset portions 11b of the clip member 11 [are] positioned within the hole 16a . . . between the forward end of the actuating member 15 and the rear end of the holder 21. Since, however, the hole 16a of the guide member 16 is large enough to allow a clearance to be formed with respect to the junctions p between the offset portions 11b and intersecting portions of the clip member 11c, the offset portions 11b of the clip member 11 are not urgingly compressed by the guide member 16."); Ex. 1026, ¶ 40).

In the released configuration reflected in Figure 7, the hook member 20 is able to detach from the proximal end of the clip (11), and thereby release the control wire (19, 20) from the clip (11). The radially outward movement of link arms (11b) in the released configuration also allows holder 21 to detach from guide member 16 and stay with clip (11). (Ex. 1014, 5:14-29; Ex. 1026, ¶ 41).

***f. "an actuator coupled to the control wire, the control wire engageable by the actuator to move the control wire to open and close the clip legs and to move the link from the coupled configuration to the released configuration."***

As shown below in annotated Figure 2, Komiya discloses an actuator (instrument body) coupled to control wire (19, 20).

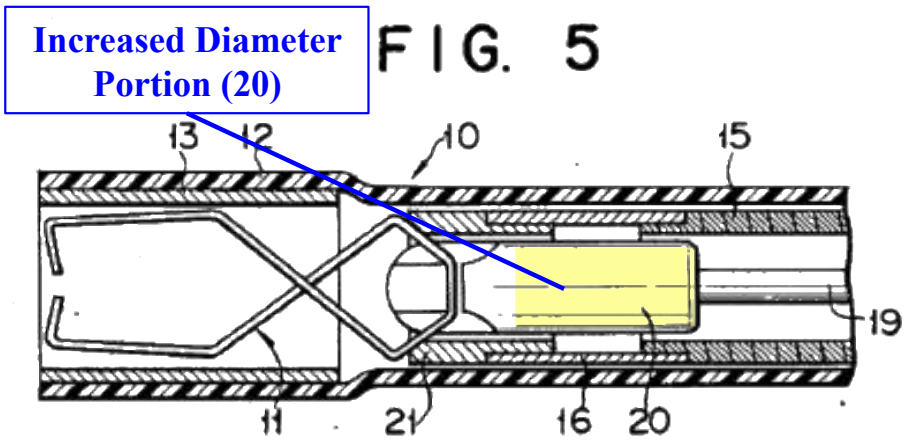



The control wire (19, 20) is engageable by the actuator to move the control wire (19, 20) to open and close the clip legs (11) and to move the link (hook member 20 and proximal end of clip (11)) from the coupled configuration (shown in annotated Figure 6, above) to the released configuration (shown in annotated Figure 7, above). (*See also* Section V.A.1.e, *supra* at pp. 23-25; Ex. 1014, 3:30-37, 4:34-48, 4:66-5:10, 5:14-29; Ex. 1026, ¶ 42).

**2. Claim 2**

Claim 2 depends from claim 1 and further requires "the distal end of the control wire comprises an increased diameter portion having a substantially spherical cross section." The cross section of a sphere is circular in shape. To the extent the term "substantially spherical cross section" refers to a cross section that is circular in shape, Kimura discloses this limitation. (Ex. 1026, ¶ 43).

As shown below in annotated Figures 4 and 5, the distal end of the control wire (19, 20) comprises an increased diameter portion (20):



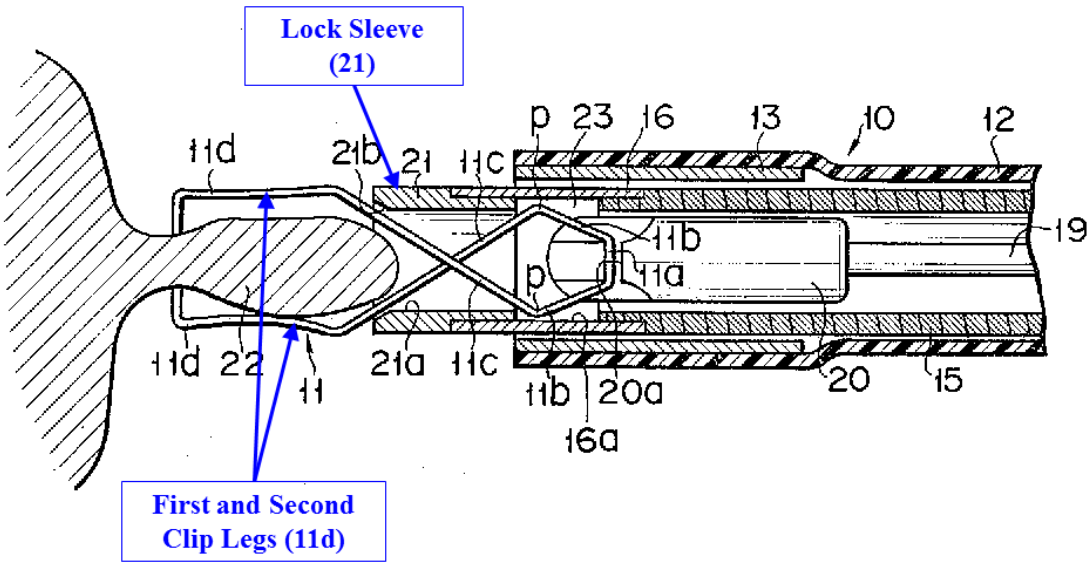

(Ex. 1014, 3:30-31). The distal end of the increased diameter portion (20) is formed into the shape of a hook, which forms a link with the clip (11). A person of ordinary skill in the art would understand based on Figure 5 that the proximal end of the increased diameter portion (20) (highlighted above in yellow) has a cylindrical shape. (Ex. 1026, ¶ 44). The cross section of a cylinder taken perpendicular to its long axis is, like the cross section of a sphere, circular in shape.

Accordingly, the distal end of the control wire comprises an increased diameter portion having a substantially spherical cross section. (Ex. 1026, ¶ 44).

### 3. Claim 3

Claim 3 depends from claim 1 and further requires "a lock sleeve surrounding a part of the clip so that, as the clip is drawn proximally thereinto, the clip legs are drawn toward one another, wherein the lock sleeve radially surrounds part of the first and second clip legs." As shown below in annotated Figure 7, Komiya discloses a lock sleeve (holder 21) surrounding part of the clip (11) so that, as the clip is drawn proximally thereinto, the clip legs (11d) are drawn toward one another, wherein the lock sleeve (21) radially surrounds part of the first and second clip legs (11d):

FIG. 7

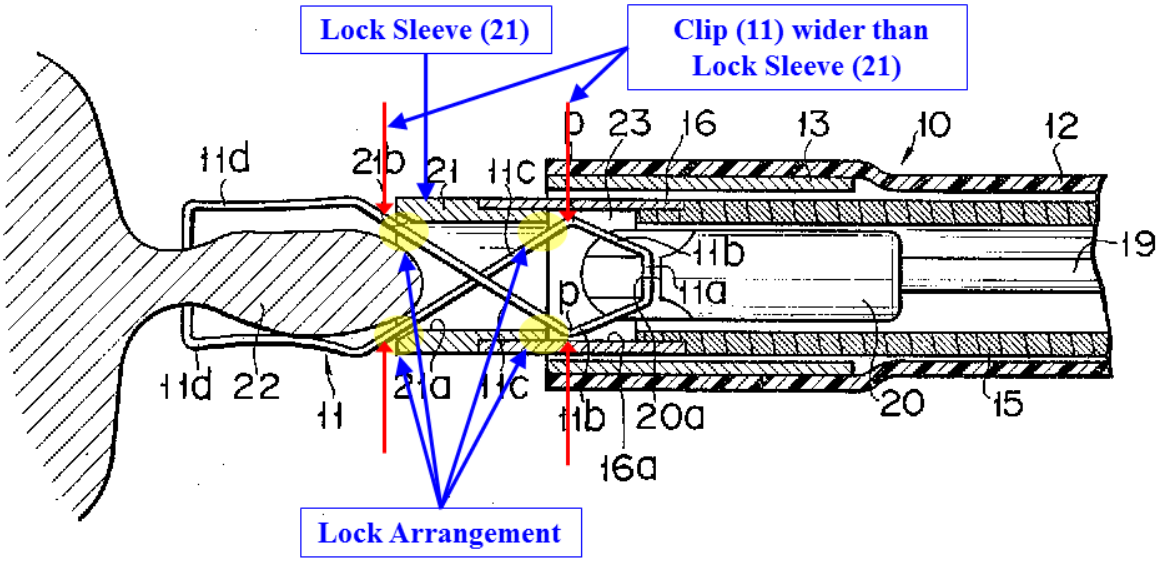



(Ex. 1026, ¶ 45; *see also* Section V.A.1, *supra* at pp. 18-26.

**4. Claim 5**

Claim 5 depends from claim 3 and further requires "a lock arrangement for locking the clip within the lock sleeve with the first and second clip legs closed." Annotated Figure 7 of Komiya (reproduced below) illustrates the clip (11) in a lock arrangement within lock sleeve (21), with the clip legs (11d) closed.

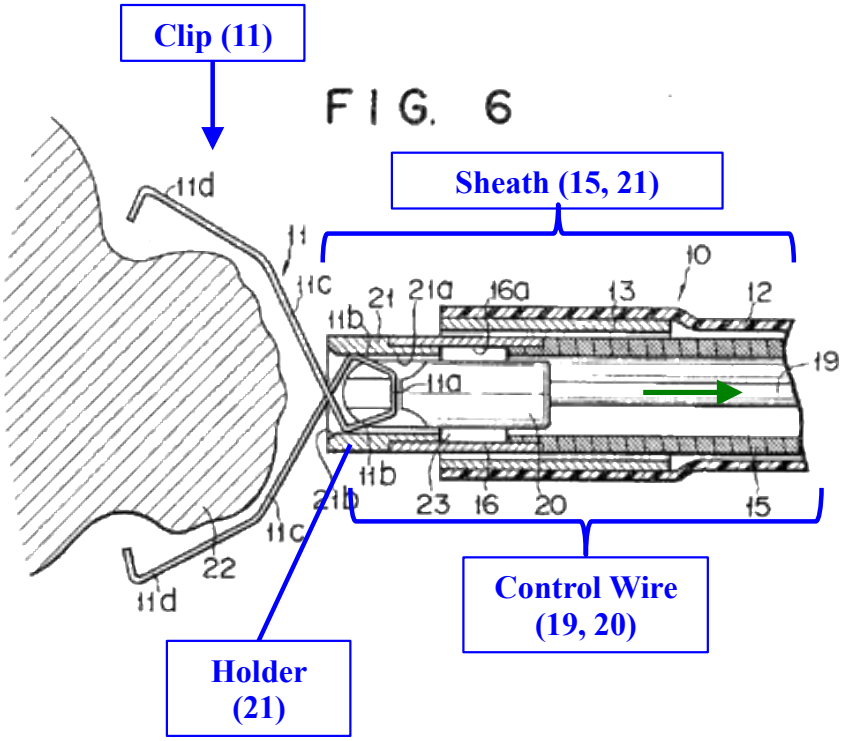
FIG. 7




Clip (11) locks due to a mechanical interlocking between clip (11) and the lock sleeve (21) at the proximal and distal ends of the sleeve (21). (Ex. 1026, ¶ 46; *see also*; Ex. 1014, 4:5-13, 4:66-5:22, Figure 5; Section V.A.3, *supra* at p. 28).

**5. Claim 6**

Claim 6 depends from claim 1 and further requires "a proximal tensile force applied to the clip via the control wire is opposed by a distal compressive force on the sheath, wherein the sheath is constructed to communicate the distal compressive force via the control wire when the control wire is coupled to the link." Komiya discloses that a proximal tensile force (indicated by green arrow) applied to the clip (11) via the control member (19, 20) is opposed by a distal compressive force on the sheath (15 + 21). (Ex. 1026, ¶ 47).




In particular, pulling the control wire (19 + 20) in the proximal direction while holding the proximal end of the sheath (15 + 21) steady pulls the clip (11) in the proximal direction, causing the clip (11) to contact the cylindrical holder (21)

of the sheath (15 + 21). The clip (11) exerts a force on the holder (21) of the sheath (15 + 21) as the control wire (19 + 20) is pulled in the proximal direction. This force is further communicated to the sheath (15 + 21) as a result of the connection between the holder (21) and the tubular actuating member (15) via guide member (16). These forces in the proximal direction also result in reaction forces in the distal direction. Therefore, a proximal tensile force applied to the clip (11) via the control wire (19 + 20) is opposed by a distal compressive force on the sheath (15 + 21). (Ex. 1026, ¶ 48).

The sheath (15 + 21) is constructed to communicate the distal compressive force via the control wire (19 + 20) when the control wire is coupled to the link, because the operator would sense the distal compressive force via the control wire as the operator pulls the control wire proximally relative to the sheath and causes the forces described above. As the clip (11) is pulled proximally into the holder (21), for example, the distal compressive force on the sheath is felt by the operator via the control wire as a resistance to further pulling the control wire in the proximal direction. (Ex. 1026, ¶ 49; *see also* Ex. 1014, 3:7-14, 28-29, 3:53-57, 4:34-48)).

### 6. Claim 7

Claim 7 depends from claim 1 and further requires "the clip legs are separated from one another by a spring member positioned therebetween and biased to urge the first and second clip legs away from one another." As shown below in annotated Figures 1 and 3, the clip legs (11d) in Komiya are separated from one another by a spring member (11a, 11b, 11c) positioned between the clip legs (11d):

FIG. 1

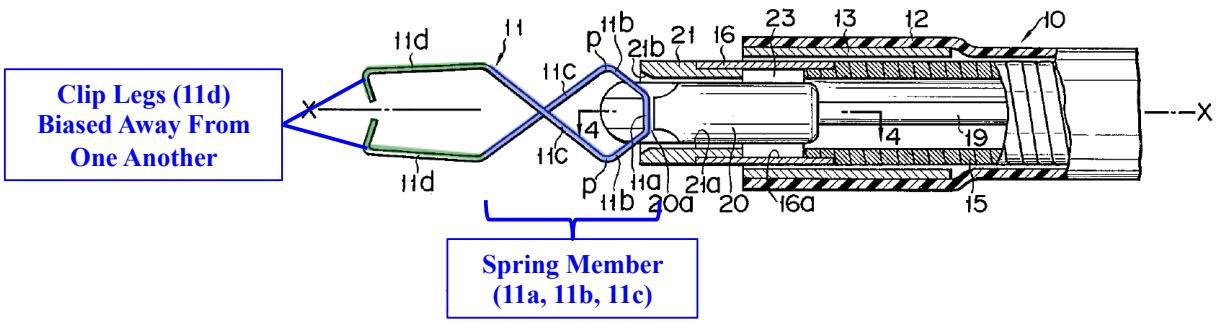
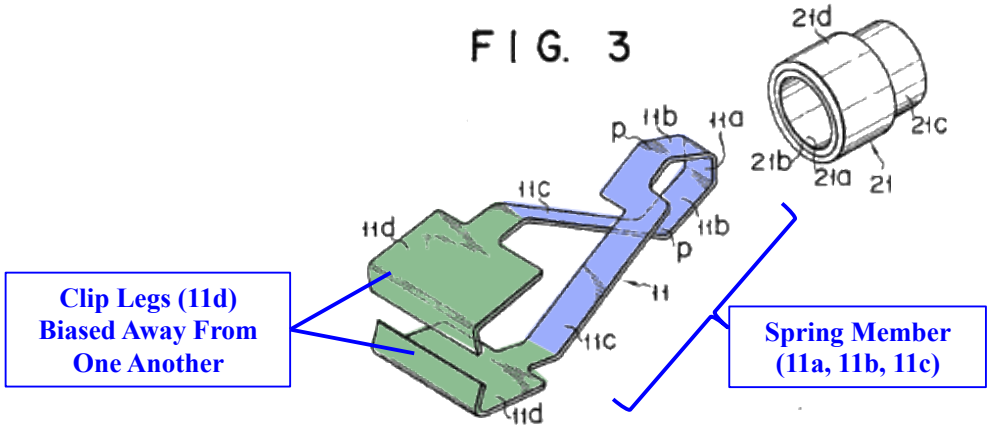



FIG. 3




(Ex. 1026, ¶ 50). Spring member (11a, 11b, 11c) is located in series, as well as in the space, between clip legs (11d). The clip (11) is formed from a single elongated

metal sheet and the portion of the sheet that becomes spring member (11a, 11b, 11c) is located between the portions at the ends of the sheet that become the clip legs (11d), such that if clip (11) was unfolded the spring member (11a, 11b, 11c) portions would be between the two clip leg (11d) portions. (Ex. 1026, ¶ 50; Ex. 1014, 2:50-59). Spring member (11a, 11b, 11c) is biased by its figure "eight" shape to urge clip legs (11d) away from one another, as shown above in Figures 1 and 3. (Ex. 1026, ¶ 50; *see also* Section V.A.1.b, *supra* at p. 19; Ex. 1014, 2:50-59, Figure 5).

**7. Claim 8**

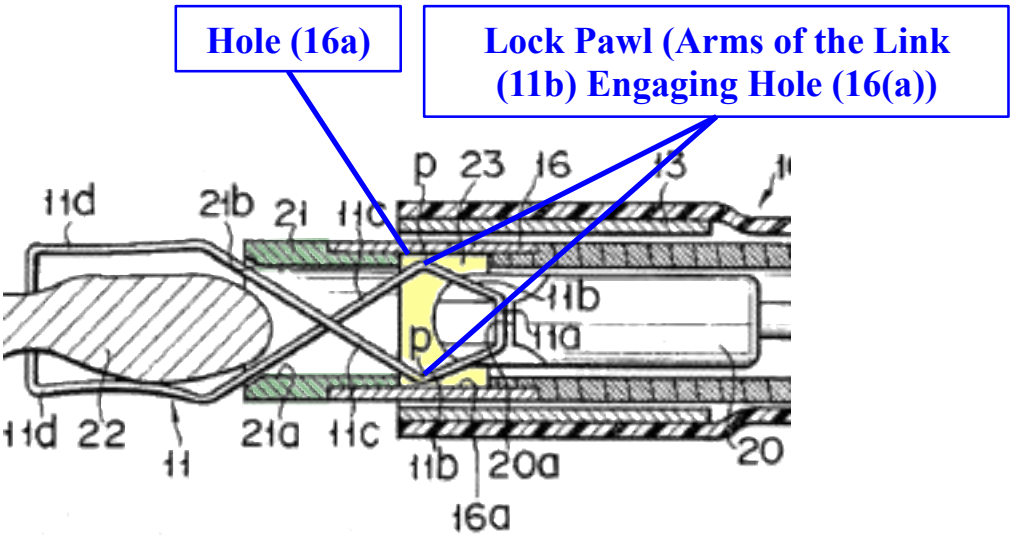
Claim 8 depends from claim 1 and further requires that "the link comprises the distal end of the control wire and the proximal end of the clip." Komiya discloses this limitation, for the reasons in Section V.A.1.e, *supra* at pp. 23-25. (Ex. 1026, ¶ 51).

**8. Claim 9**

Claim 9 depends from claim 1 and further requires that "the control wire is reversibly operable." Komiya discloses that the control wire is reversibly operable. For example, pulling control wire (19, 20) proximally first opens, and then closes, the legs of clip (11), and pushing control wire (19, 20) distally releases the clip (11). (Ex. 1026, ¶ 52; *see also* Ex. 1014, 4:34-54, 5:14-29; Section VIII.A.1.e, *supra* at pp. 23-25).

**9. Claim 10**

Claim 10 depends from claim 1 and further requires "a lock pawl associated with the link that inhibits proximal movement of the link at a predetermined location." Komiya discloses a lock arrangement for locking the clip within the lock sleeve with the first and second clip legs closed, for the reasons in Section V.A.4, *supra* at p. 29. In addition, as shown below in annotated Figure 7 Komiya discloses a lock pawl in the form of arms of the link (11b) that move radially outward within hole 16a:



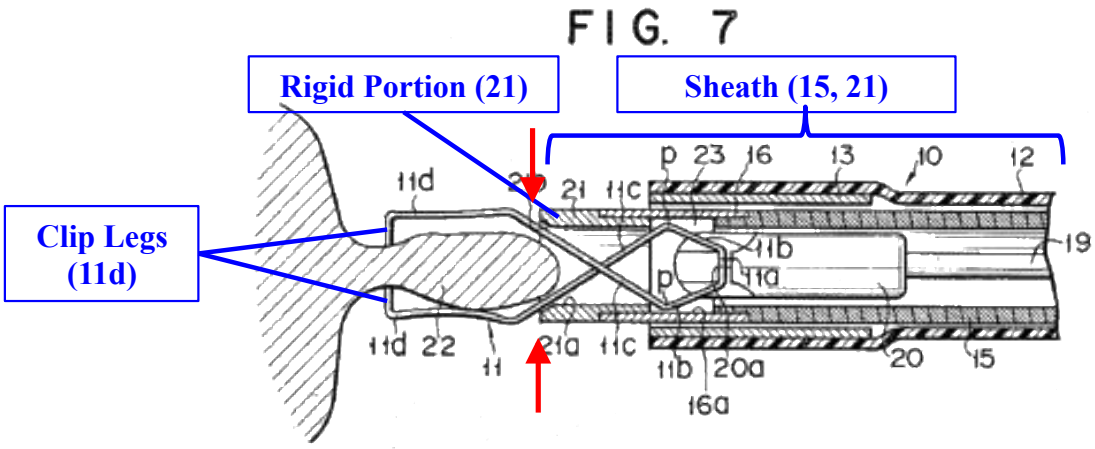

The lock pawl inhibits proximal movement of the link (hook member 20 and proximal end of clip (11)) when the arms of the link (11b) move radially outward and lock within hole (16). (Ex. 1026, ¶ 54).

**10. Claim 11**

Claim 11 depends from claim 1 and further requires that "the first and second arms of the link are configured to automatically move radially outward at a relief area of the sheath when a tensile load is applied to the arms via the control wire due to resilience." Komiya discloses first and second arms (11b) of the link (11a, 11b, 20) are configured to automatically move radially outward at a relief area of the sheath when a tensile load is applied due to resilience, for the reasons in Section V.A.1.e, *supra* at pp. 23-25. (Ex. 1026, ¶ 55; *see also* Ex. 1014, 2:50-59, 4:66 – 5:22). Furthermore, BSSI confirmed during prosecution of the related '052 patent that "the proximal end of the [Komiya] clip 11 [expands] *under its own bias* as it enters the holes 16 of the guide member 16." (Ex. 1032, August 24, 2007 Response to Office Action, p. 13 (emphasis added)).

### 11. Claim 12

Claim 12 depends from claim 1 and further requires "a distal portion of the sheath is comprised of a rigid portion, wherein the first and second legs are configured to move radially inward when the clip is drawn proximally relative to the sheath due to a compressive force between one of (a) the rigid portion and the first and second legs and (b) the sheath and the first and second legs." As shown below in annotated Figure 7, a distal portion of the sheath (15 + 21) is comprised of a rigid portion (holder 21):




(Ex. 1026, ¶ 56). Rigid portion (holder 21) holds the clip legs closed. (*See* Ex. 1014, 5:32-35 (explaining that holder 21 ensures that "the clamping portions 11d of the clip member 11 is maintained in a closed position"). The legs (11d) are configured to move radially inward when the clip is drawn proximally relative to the sheath due to a compressive force (indicated in annotated Figure 7 above by red arrows) between the rigid portion (21) (which is part of the sheath (15 + 21))

and the first and second legs. (Ex. 1026, ¶ 56; Ex. 1014, 2:63-64, 4:55-64; *see also* Section V.A.5, *supra* at pp. 30-31.

### 12. Claim 13

Claim 13 depends from claim 1 and further requires "the link is formed integrally with one of the clip and the control wire." To the extent the phrase "formed integrally with one of the clip and the control wire" means that a component of the "link" is formed integrally with the clip, and a component of the "link" is formed integrally with the control wire, then this limitation is disclosed by Komiya. (Ex. 1026, ¶ 57).

As shown below in annotated Figures 3 and 4, the proximal end of the Komiya clip (11a and 11b) is part of, and formed integrally with, the clip (11), and the hook member (20) is part of, and formed integrally with, the control wire (19 + 20):

FIG. 3

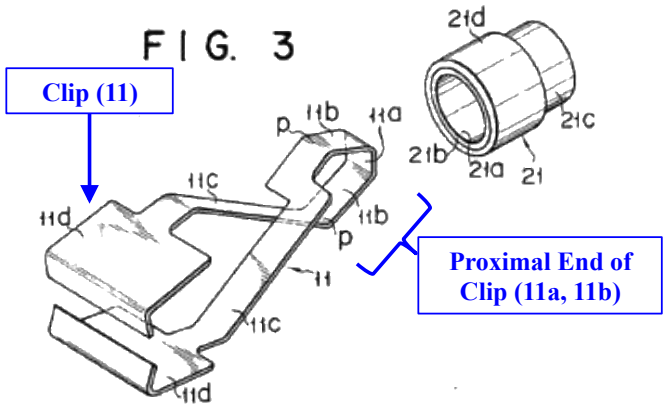
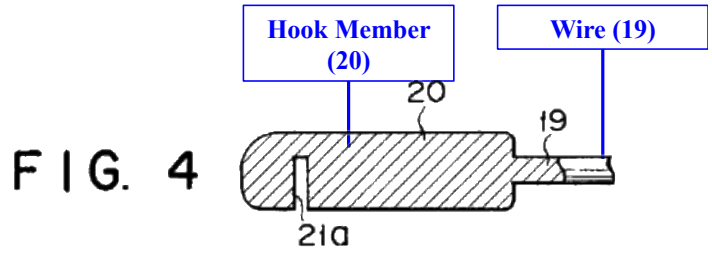


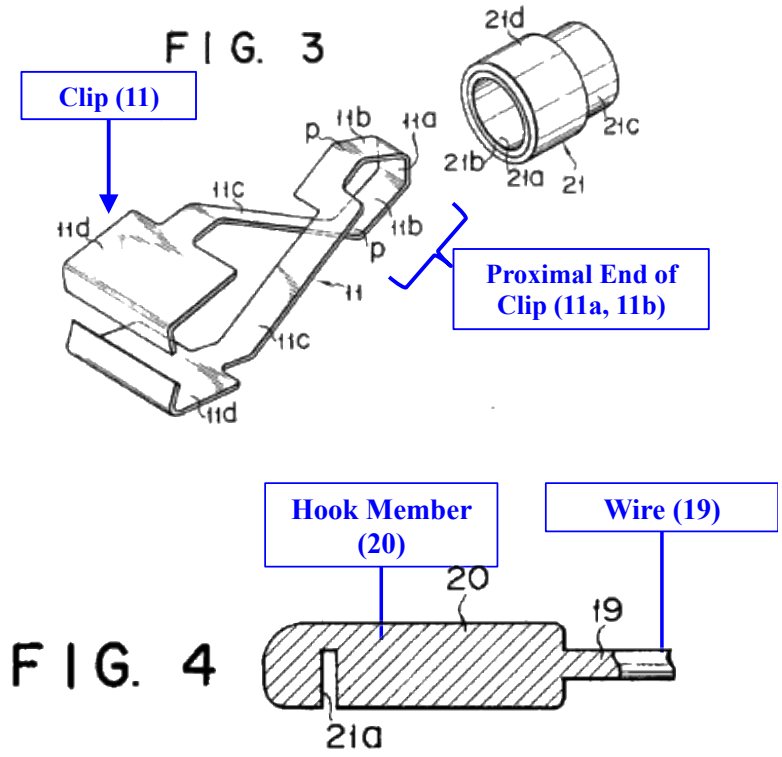

FIG. 4



(Ex. 1026, ¶ 58; Ex. 1014, 2:50-59).

### 13. Claim 14

Claim 14 depends from claim 1, and further requires "the link is not formed integrally with the control wire or the clip." As shown below in annotated Figures 3 and 4, the proximal end of clip (11a, 11b) is not formed integrally with the control wire (19), and the hook 20 is not formed integrally with the clip (11):




Therefore, the link is not formed integrally with the control wire or the clip. (Ex. 1026, ¶ 59).

### 14. Independent Claim 15

Claim 15 describes a medical device comprising, among other things, a "clip having first and second *clip legs*" and a "control wire . . . [with] a distal end of the control wire received between *legs of the clip*." According to the claim, "the control wire is configured to release from the clip *as the legs spread laterally away from the control wire*." Thus, claim 15 appears to contemplate a clip with *at least four "legs*": (1) first and second "clip legs"; and (2) "legs of the clip." The "legs of the clip" spread laterally away from the control wire when the control wire releases from the clip. Although not entirely clear, these structures appear to be analogous to the structures described in claim 1, where the "first and second clip legs" in claim 1 are instead called "clip legs" in claim 15, and the "arms of the link" in claim 1 are instead called "legs of the clip" in claim 15. (Ex. 1026, ¶ 60).

#### *a. "A medical device, comprising"*

Komiya discloses a medical device, for the reasons in Section V.A.1.a, *supra* at p. 18. (Ex. 1026, ¶ 61).

#### *b. "a clip having first and second clip legs"*

Komiya discloses a clip (11) having first and second clip legs (11d), for the reasons in Section V.A.1.b, *supra* at p. 19. (Ex. 1026, ¶ 62).

***c. "a control wire coupled to the clip, the control wire being movable relative to a sheath to open and close the clip legs, a distal end of the control wire received between legs of the clip"***

Komiya discloses a control wire (19, 20) coupled to the clip (11), the control wire (19, 20) being movable relative to a sheath (15, 21) to open and close the clip legs (11d), the distal end of the control wire (hook member 20) received between legs of the clip (11b), for the reasons in Section V.A.1.c, *supra* at pp. 20-21. (Ex. 1026, ¶ 63).

***d. "the sheath enclosing a distal portion of the control wire, wherein the control wire is configured to release from the clip as the legs spread laterally away from the control wire"***

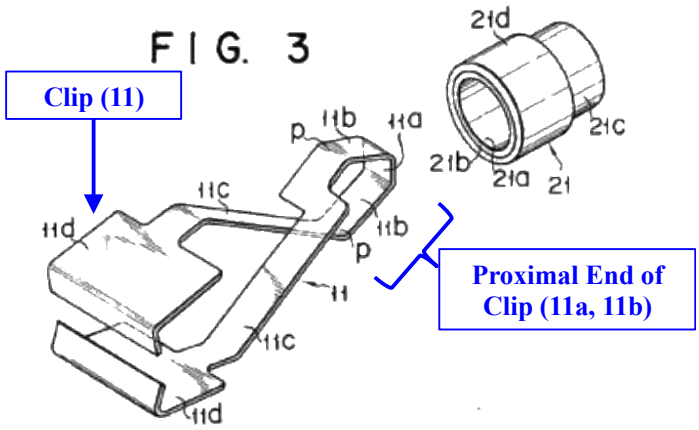
Komiya discloses the sheath (15, 21) encloses a distal portion (20) of the control wire (19, 20), where the control wire (19, 20) is configured to release from the clip as the legs (11b) spread laterally away from the control wire, for the reasons in Section V.A.1.d and e, *supra* at pp. 22-25. (Ex. 1026, ¶ 64).

***e. "an actuator coupled to the control wire to move the control wire relative to the sheath and to release the control wire from the clip."***

Komiya discloses an actuator (instrument body) coupled to the control wire (19, 20) to move the control wire relative to the sheath (15, 21) and to release the control wire (19, 20) from the clip (11), for the reasons in Section V.A.1.f, *supra* at p. 26. (Ex. 1026, ¶ 65).

### 15. Claim 16

Claim 16 depends from claim 15 and further requires "the legs are formed integrally with the clip." Komiya discloses that the legs (11b) are formed integrally with the clip 11, as shown below in annotated Figure 3:




(Ex. 1026, ¶ 66; *see also* Section V.A.12, *supra* at pp. 38-29).

### 16. Claim 17

Claim 17 depends from claim 15, and further requires "the distal end of the control wire comprises an increased diameter portion having a substantially spherical cross section." Komiya discloses the distal end (20) of the control wire (19, 20) comprises an increased diameter portion (20) having a substantially spherical cross section, for the reasons in Section V.A.2, *supra* at pp. 27-28. (Ex. 1026, ¶ 67).

**17. Claim 18**

Claim 18 depends from claim 15, and further requires "a lock sleeve surrounding a part of the clip so that, as the clip is drawn proximally thereinto, the clip legs are drawn toward one another, wherein the lock sleeve radially surrounds part of the first and second clip legs." Komiya discloses this limitation, for the reasons in Section V.A.3, *supra* at p. 28. (Ex. 1026, ¶ 68).

**18. Claim 20**

Claim 20 depends from claim 18, and further requires "a lock arrangement for locking the clip within the lock sleeve with the first and second clip legs closed." Komiya discloses this limitation, for the reasons in Section V.A.4, *supra* at p. 29. (Ex. 1026, ¶ 69).

**19. Claim 21**

Claim 21 depends from claim 15, and requires "a proximal tensile force applied to the clip via the control wire is opposed by a distal compressive force on the sheath, wherein the sheath is constructed to communicate the distal compressive force via the control wire when the control wire is coupled to the link, the link coupling the control wire to the clip and comprising the distal end of the control wire and the proximal end of the clip." Komiya discloses this limitation, for the reasons in Section V.A.5, supra at pp. 30-31. (Ex. 1026, ¶ 70).

**20. Claim 22**

Claim 22 depends from claim 15, and further requires "the clip legs are separated from one another by a spring member positioned therebetween and biased to urge the first and second clip legs away from one another." Komiya discloses this limitation, for the reasons in Section V.A.6, *supra* at pp. 32-33. (Ex. 1026, ¶ 71).

**21. Claim 23**

Claim 23 depends from claim 15, and further requires "the control wire is reversibly operable." Komiya discloses this limitation, for the reasons in Sectoin V.A.8, *supra* at p. 33. (Ex. 1026, ¶ 72).

**22. Claim 24**

Claim 24 depends from claim 15, and further requires "a lock pawl associated with a link coupling the control wire to the clip that inhibits proximal movement of the link at a predetermined location." Komiya discloses this limitation, for the reasons in Section V.A.9, *supra* at p. 34. (Ex. 1026, ¶ 73).

**23. Claim 25**

Claim 25 depends from claim 24, and further requires "first and second arms of the link are configured to automatically move radially outward at a relief area of the sheath when a tensile load is applied to the first and second arms via the control wire due to resilience." Komiya discloses this limitation, for the reasons in Section V.A.10, *supra* at p. 35. (Ex. 1026, ¶ 74).

**24. Claim 26**

Claim 26 depends from claim 15, and further requires "a distal portion of the sheath is comprised of a rigid portion and wherein the first and second legs are configured to move radially inward when the clip is drawn proximally relative to the sheath due to a compressive force between one of (a) the rigid portion and the first and second legs and (b) the sheath and the first and second legs." Komiya discloses this limitation, for the reasons in Section V.A.11, *supra* at pp. 36-37. (Ex. 1026, ¶ 75).

**25. Claim 27**

Claim 27 depends from claim 25, and further requires "the link is formed integrally with one of the clip and the control wire." Komiya discloses this limitation, for the reasons in Section V.A.12, *supra* at pp. 38-39. (Ex. 1026, ¶ 76).

**26. Claim 28**

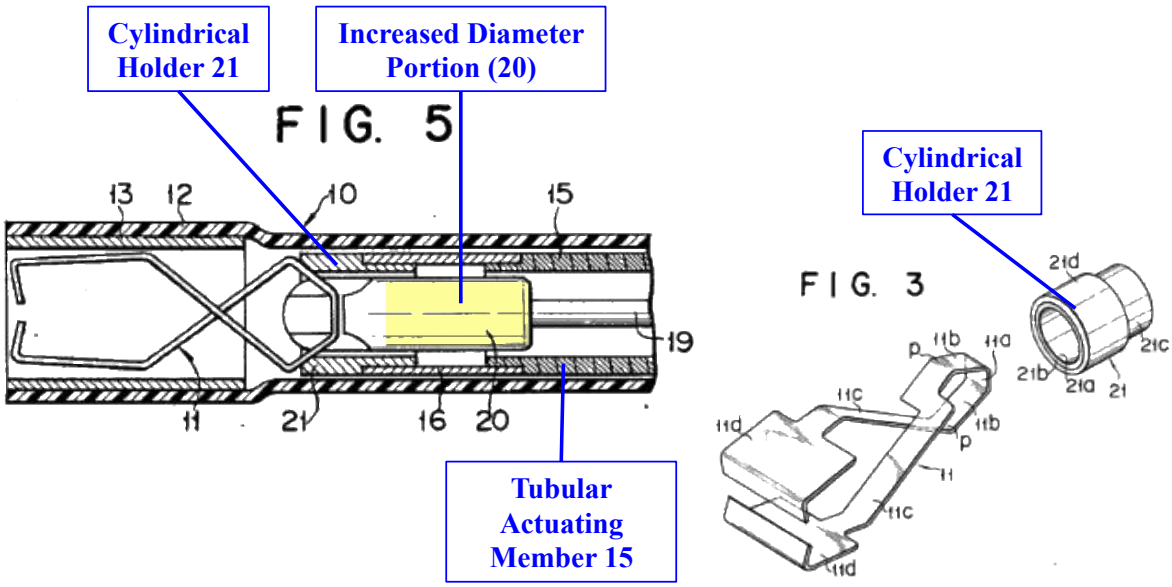
Claim 28 depends from claim 15, and further requires "the link is not formed integrally with the control wire or the clip." Komiya discloses this limitation, for the reasons in Section V.A.13, *supra* at p. 39. (Ex. 1026, ¶ 77).

### B. Ground 2: There Is A Reasonable Likelihood That Claims 2 and 17 Would Have Been Obvious In View Of Komiya

#### 1. Claim 2

Claim 2 depends from claim 1 and further requires "the distal end of the control wire comprises an increased diameter portion having a substantially spherical cross section." Kimura discloses this limitation, for the reasons in Section V.A.2, *supra* at pp. 27-28. (Ex. 1026, ¶ 78).

To the extent the Board finds that Kimura does not explicitly disclose that the proximal end of the increased diameter portion (20) in Kimura has a substantially spherical cross section, it would have been obvious to a person of ordinary skill to form the proximal end of the increased diameter portion (20) with a cylindrical shape. (Ex. 1026, ¶ 79). As shown below in annotated Figures 3 and 5, the increased diameter portion is configured to fit and slide within "*cylindrical* holder 21" and "*tubular* actuating member 15":



(Ex. 1014, 3:28-38, 3:58-62, 4:5-13). It would have been obvious to a person of ordinary skill to form the hook member 20 with a generally cylindrical shape, to match the generally cylindrical inner lumen of the holder 21 and actuating member 15. The skilled artisan would have expected that forming the hook member 20 with a generally cylindrical shape would allow the hook member to move more easily within the cylindrical inner lumen of the holder 21, and of the actuating member 15, than if the hook member was formed with a non-cylindrical shape. (Ex. 1026, ¶ 79).

**2. Claim 17**

Claim 17 depends from claim 15, and further requires "the distal end of the control wire comprises an increased diameter portion having a substantially spherical cross section." This limitation would have been obvious, for the reasons in Sectoin V.B.1, *supra* at pp. 46-47.

### C. Ground 3: There Is A Reasonable Likelihood That Claims 1, 3, 5-14, 21, 24, 25, 27, And 28 Would Have Been Obvious In View Of Komiya (Ex. 1014) In Combination With Crockard (Ex. 1019)

Crockard issued on December 29, 1992 and qualifies as prior art at least under 35 U.S.C. §§ 102(a), (b), and (e). Crockard was not cited during prosecution of the '048 patent.

#### 1. Independent Claim 1

##### *a. "A medical device, comprising"*

For the reasons in Section V.A.1.a, *supra* at p. 18, Komiya discloses this limitation. (Ex. 1026, ¶ 81).

##### *b. "a clip having first and second clip legs"*

For the reasons in Section V.A.1.b, *supra* at p. 19, Komiya discloses this limitation. (Ex. 1026, ¶ 82).

##### *c. "a control wire being operable both to open the clip legs and to close the clip legs"*

For the reasons in Section V.A.1.c, *supra* at pp. 20-21, Komiya discloses this limitation. (Ex. 1026, ¶ 83).

##### *d. "a sheath enclosing the control wire"*

For the reasons in Section V.A.1.d, *supra* at p. 22, Komiya discloses this limitation. (Ex. 1026, ¶ 84).

***e. "a link coupling the control wire to the clip, the link being movable from a coupled configuration in which the clip is coupled to a distal end of the control wire to a released configuration in which first and second arms of the link are configured to move radially outward at an area of the sheath to release the control wire from the clip"***

For the reasons in Section V.A.1.e, *supra* at pp. 23-25, Komiya discloses this limitation. (Ex. 1026, ¶ 85). To the extent BSSI argues that Komiya does not disclose radial outward movement of the link arms "to release the control wire from the clip," claim 1 would nevertheless have been obvious in view of Komiya combined with Crockard. (Ex. 1026, ¶ 86). As shown below in annotated Figure 9a, Crockard discloses a link (92, 98) between a clip (90) and a control wire (shaft 44), the link including first and second link arms (92):

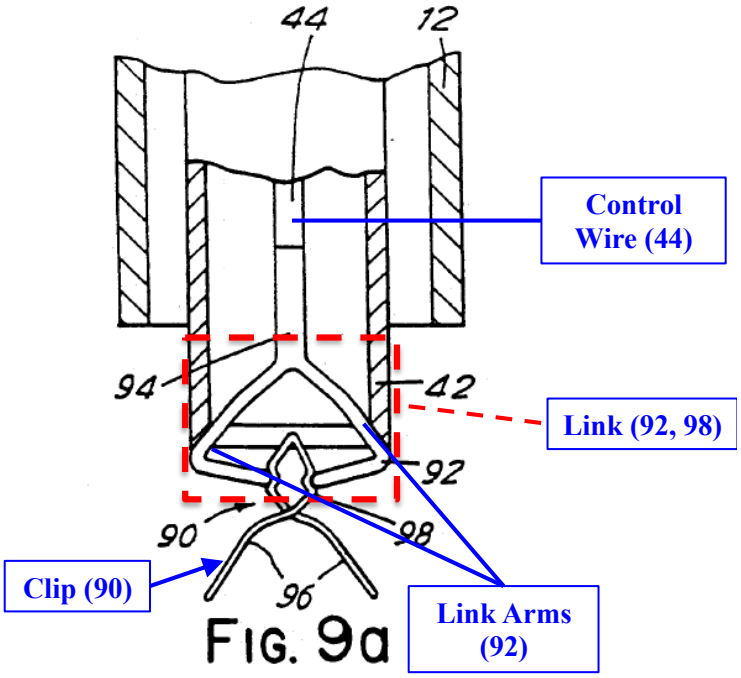
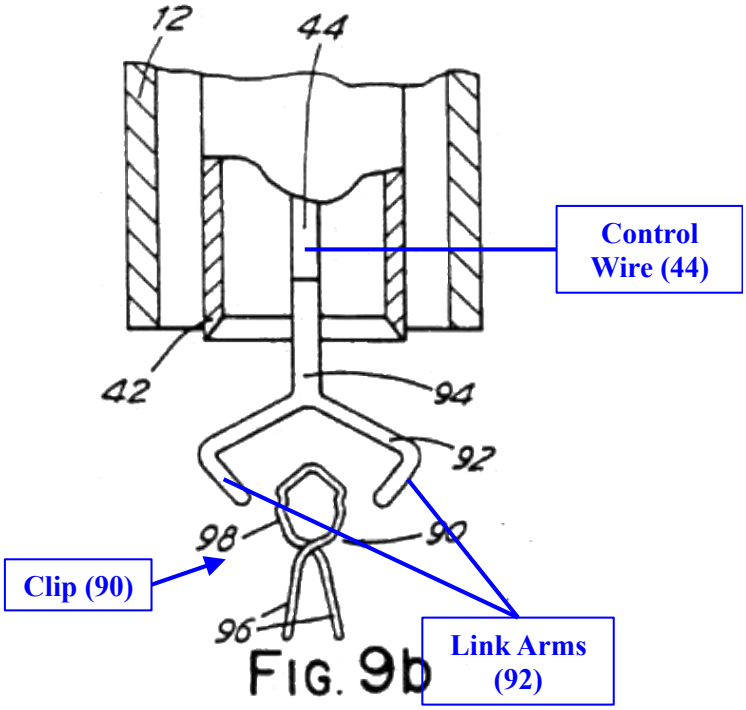


Figure 9a illustrates the link arms (92) in a *coupled configuration*. Figure 9b (reproduced and annotated below), illustrates the link arms (92) in a *released configuration*, where the arms (92) are configured to move radially outward to release the control wire (44) from the clip (90):




(Ex. 1019, 7:46-49 ("The aneurysm clip applicator comprises jaws 92 pivotally mounted on a stem 94, itself attached to the distal end of the shaft 44 . . . ."); *see also* 7:55-59). The link arms (92) are biased radially outward to an open configuration, as reflected in Figure 9b. In Figure 9a, the link arms are compressed radially inward by sheath (conduit 42). (Ex. 1019, 3:5-15; *see also* 7:46-59). (Ex. 1026, ¶ 86).

It would have been obvious to one of ordinary skill in the art to substitute the hook member 20 in Komiya with the link arms (92), as described in Crockard. (Ex. 1026, ¶ 87). The skilled artisan would have been motivated to make this substitution, for example, in order to simplify the operation of using Komiya's clip (11) by limiting the deployment steps, such as eliminating the step of pushing the control wire (19, 20) proximally to release control wire (19, 20) from clip (11). (*See* Ex. 1014, 5:14-29). The modified Komiya device would include Crockard link arms (92) coupled to the distal end of the Komiya control wire 19. The link arms (92) would be compressed by holder 21 in the coupled configuration, just as the link arms (11b) described in Komiya are compressed by holder 21 in the coupled configuration (*see* Figure 6 of Komiya). Likewise, as with the Komiya link arms (11b), the Crockard link arms (92) would expand radially outward at an area of the Komiya sheath (hole (16a)) as the control wire (19, 92) is drawn proximally, to release the link arms (92), and the control wire (19, 92), from the clip (11). (Ex. 1026, ¶ 87).

The person of ordinary skill would have expected that the proposed modification would simplify the operation of the Komiya clip because the clip would be released immediately upon radial outward movement of the link arms (92), as opposed to the embodiment in Komiya, which requires that the hook member 20 move distally and sideways to completely separate the clip (11) from

the control wire (19, 20). (Ex. 1026, ¶ 87; Ex. 1014, 4:67-5:27, Figure 7). One of ordinary skill in the art would recognize the importance of simplifying the operation of the Komiya hemostatic clip, because such clips are used in medical procedures potentially involving significant risks. The skilled artisan would understand that simplifying the operation would potentially reduce the risk of error, and potentially decrease the time required to perform the medical procedure, both leading to potentially improved clinical outcomes. In addition, this link arrangement would also limit the possibility of problems associated with attempting to uncouple the hook member 20 from the clip 11 (such as the hook member getting caught or snagged on the clip 11 when trying to separate the two items). (Ex. 1026, ¶ 88).

Substituting the hook member 20 in Komiya with the link arms (92) in Crockard would have been a matter of routine skill in the art and a modification that is mechanical in nature, and would have been accomplished according to known methods to yield predictable results. (Ex. 1026, ¶ 89). *See Tokai*, 632 F.3d at 1371 ("[T]he nature of the mechanical arts is such that 'identified, predictable solutions' to known problems may be within the technical grasp of a skilled artisan.") (citations omitted). One of ordinary skill in the art would have known how to combine the link feature of releasing the control wire from the clip from Crockard with the clip in Komiya because the links and the clips in Komiya and

Crockard function in a similar manner. In both Komiya and Crockard, for example, the links remain constrained because the link arms (offset portions 11b in Komiya and jaws 92 in Crockard) are restrained within walls (holder 21 in Komiya and conduit 42 in Crockard; *see* Ex. 1014, 4:34-48, Figure 6; Ex. 1019, 7:46-59, Figure 9A) and both link arms move radially outward when the restraining walls are removed (*see* Ex. 1014, 4:66-5:10, Figure 7; Ex. 1019, 3:5-15, 7:46-59, Figure 9B). In both Komiya and Crockard, furthermore, the clips open as the proximal end of the clips are compressed (Komiya Figure 6 and Crockard Figure 9A) and both clips close as the compression on the proximal end of the clips is released (Komiya Figure 7 and Crockard Figure 9B). (Ex. 1026, ¶ 89).

***f. "an actuator coupled to the control wire, the control wire engageable by the actuator to move the control wire to open and close the clip legs and to move the link from the coupled configuration to the released configuration"***

For the reasons in Section V.A.1.f, *supra* at p. 26, Komiya discloses this limitation. (Ex. 1026, ¶ 90).

**2. Claim 3**

Claim 3 depends from claim 1 and further requires "a lock sleeve surrounding a part of the clip so that, as the clip is drawn proximally thereinto, the clip legs are drawn toward one another, wherein the lock sleeve radially surrounds part of the first and second clip legs." Komiya discloses this limitation, for the reasons in Section V.A.3, *supra* at p. 28. (Ex. 1001, ¶ 91).

**3. Claim 5**

Claim 5 depends from claim 3 and further requires "a lock arrangement for locking the clip within the lock sleeve with the first and second clip legs closed." Komiya discloses this limitation, for the reasons in Section V.A.4, *supra* at p. 29. (Ex. 1026, ¶ 92).

**4. Claim 6**

Claim 6 depends from claim 1 and further requires "a proximal tensile force applied to the clip via the control wire is opposed by a distal compressive force on the sheath, wherein the sheath is constructed to communicate the distal compressive force via the control wire when the control wire is coupled to the link." Komiya discloses this limitation, for the reasons in Sections V.A.5, *supra* at pp. 30-31. (Ex. 1026, ¶ 93).

**5. Claim 7**

Claim 7 depends from claim 1 and further requires "the clip legs are separated from one another by a spring member positioned therebetween and biased to urge the first and second clip legs away from one another." Komiya discloses this limitation, for the reasons in Section V.A.6, *supra* at pp. 32-33. (Ex. 1026, ¶ 94).

**6. Claim 8**

Claim 8 depends from claim 1 and further requires that "the link comprises the distal end of the control wire and the proximal end of the clip." Komiya in combination with Crockard discloses this limitation, for the reasons in Sections V.A.7 and V.C.1.e, *supra* at pp. 33 and 49-53. (Ex. 1026, ¶ 95).

**7. Claim 9**

Claim 9 depends from claim 1 and further requires that "the control wire is reversibly operable." Komiya discloses this limitation, for the reasons in Section V.A.8, *supra* at p. 33. (Ex. 1026, ¶ 96).

**8. Claim 10**

Claim 10 depends from claim 1 and further requires "a lock pawl associated with the link that inhibits proximal movement of the link at a predetermined location." Komiya discloses this limitation, for the reasons in Section V.A.9, *supra* at p. 34. (Ex. 1026, ¶ 97).

**9. Claim 11**

Claim 11 depends from claim 1 and further requires that "the first and second arms of the link are configured to automatically move radially outward at a relief area of the sheath when a tensile load is applied to the arms via the control wire due to resilience." Komiya in combination with Crockard discloses this limitation, for the reasons in Sections V.A.10 and V.C.1.e, *supra* at pp. 35 and 49-53. (Ex. 1026, ¶ 98).

**10. Claim 12**

Claim 12 depends from claim 1 and further requires "a distal portion of the sheath is comprised of a rigid portion, wherein the first and second legs are configured to move radially inward when the clip is drawn proximally relative to the sheath due to a compressive force between one of (a) the rigid portion and the first and second legs and (b) the sheath and the first and second legs." Komiya discloses this limitation, for the reasons in Section V.A.11, *supra* at pp. 36-37. (Ex. 1026, ¶ 99).

**11. Claim 13**

Claim 13 depends from claim 1 and further requires "the link is formed integrally with one of the clip and the control wire." To the extent the phrase "formed integrally with one of the clip and the control wire" means that a component of the "link" is formed integrally with the clip, and a component of the "link" is formed integrally with the control wire, Komiya in combination with

Crockard discloses this limitation, for the reasons in V.A.12 and V.C.1.e, *supra* at pp. 38-39 and 49-53. (Ex. 1026, ¶ 100).

**12. Claim 14**

Claim 14 depends from claim 1, and further requires "the link is not formed integrally with the control wire or the clip." Komiya in combination with Crockard discloses this limitation, for the reasons in Sections V.A.13 and V.C.1.e, *supra* at pp. 39 and 49-53. (Ex. 1026, ¶ 101).

In addition, it would have been obvious when combining Komiya and Crockard not to form integrally the link arms (92) with the Komiya control wire (20). A person of ordinary skill in the art would have understood generally that, in the context of the limitation at issue here, there are only a finite number of options (2) for forming a link between two components: (1) form the link integrally with one (or both) of the components; or (2) form the link non-integrally with either of the components. (Ex. 1026, ¶ 102).

The skilled artisan would have found it obvious to apply this general principal to a link between a clip and a control wire. (Ex. 1026, ¶ 103). The person of ordinary skill in the art would have been motivated not to form the link (92) integrally with the control wire or clip, for example, to permit the clip, control wire, and link to be formed using different materials. For example, it would have been obvious to form the clip and control wire using high strength materials, such

as stainless steel, to minimize deformation of these structures during use, whereas it would have been obvious to form the link using more resilient, and deformable materials, such as a deformable plastic material, to allow the link to be released without fracturing the link materials. Accordingly, one of ordinary skill in the art would recognize advantages of making the link not integral with either the control wire or the clip. (Ex. 1026, ¶ 103).

In addition, a person of ordinary skill in the art would have understood that the Crockard control wire (44) is flexible and has a square cross section, (Ex. 1019, Abstract, 6:4-5), whereas the link arms (92) should "resiliently bias[] [the link (92)] to the open position" and also squeeze clip (90) to counteract the resiliently closed bias of clip (90). (Ex. 1019, 7:49-63). Therefore, the control wire and link arms may require different material properties because they perform different functions. (Ex. 1026, ¶ 104).

Combining Komiya and Crockard so that the link arms (92) are not formed integrally with control wire (19) or clip (11) would have been a matter of routine skill in the art and a modification that is mechanical in nature, and would have been accomplished according to known methods to yield predictable results. (Ex. 1026, ¶ 105). *See Tokai*, 632 F.3d at 1371 ("[T]he nature of the mechanical arts is such that 'identified, predictable solutions' to known problems may be within the technical grasp of a skilled artisan.") (citations omitted).

**13. Claim 21**

Claim 21 depends from independent claim 15, and further requires "wherein a proximal tensile force applied to the clip via the control wire is opposed by a distal compressive force on the sheath, wherein the sheath is constructed to communicate the distal compressive force via the control wire when the control wire is coupled to a link, the link coupling the control wire to the clip and comprising the distal end of the control wire and the proximal end of the clip." Komiya discloses this limitation, for the reasons in Section V.A.5, V.C.1.e, and V.C.4, *supra* at pp. 30-31, 49-54. (Ex. 1026, ¶ 106).

**14. Claim 24**

Claim 24 depends on independent claim 15 and further requires "further comprising a lock pawl associated with a link coupling the control wire to the clip that inhibits proximal movement of the link at a predetermined location." Komiya discloses this limitation, for the reasons in Section V.A.9, *supra* at p. 34. (Ex. 1026, ¶ 107).

**15. Claim 25**

Claim 25 depends on claim 24 and further requires "wherein first and second arms of the link are configured to automatically move radially outward at a relief area of the sheath when a tensile load is applied to the first and second arms via the control wire due to resilience." Komiya in combination with Crockard discloses this limitation, for the reasons in Sections V.A.10 and V.C.1.e, *supra* at pp. 35 and 49-53. (Ex. 1026, ¶ 108).

**16. Claim 27**

Claim 27 depends on claim 25 and further requires "wherein the link is formed integrally with one of the clip and the control wire." Komiya in combination with Crockard discloses this limitation, for the reasons in Sections V.A.12 and V.C.1.e, *supra* at pp. 38-39 and 49-53. (Ex. 1026, ¶ 109).

**17. Claim 28**

Claim 28 depends on claim 15 and further requires "wherein the link is not formed integrally with the control wire or the clip." Komiya in combination with Crockard discloses this limitation, for the reasons in Sections V.A.13, V.C.1.e, and V.C.12, *supra* at 39, 49-53, 57-58. (Ex. 1026, ¶ 110).

### D. Ground 4: There Is A Reasonable Likelihood That Claims 29 And 30 Would Have Been Obvious In View Of Shinozuka (Ex. 1009) In Combination With Matsuno (Ex. 1016)

Shinozuka was published on June 8, 1985 and qualifies as prior art at least under 35 U.S.C. §§ 102(a) and (b).[5] Shinozuka was not cited during prosecution of the '048 patent.

Matsuno issued on May 12, 1997. Accordingly, Matsuno qualifies as prior art at least under 35 U.S.C. §§ 102(a), (b), and (c). Matsuno was not cited during prosecution of the '048 patent.

#### 1. Independent Claim 29

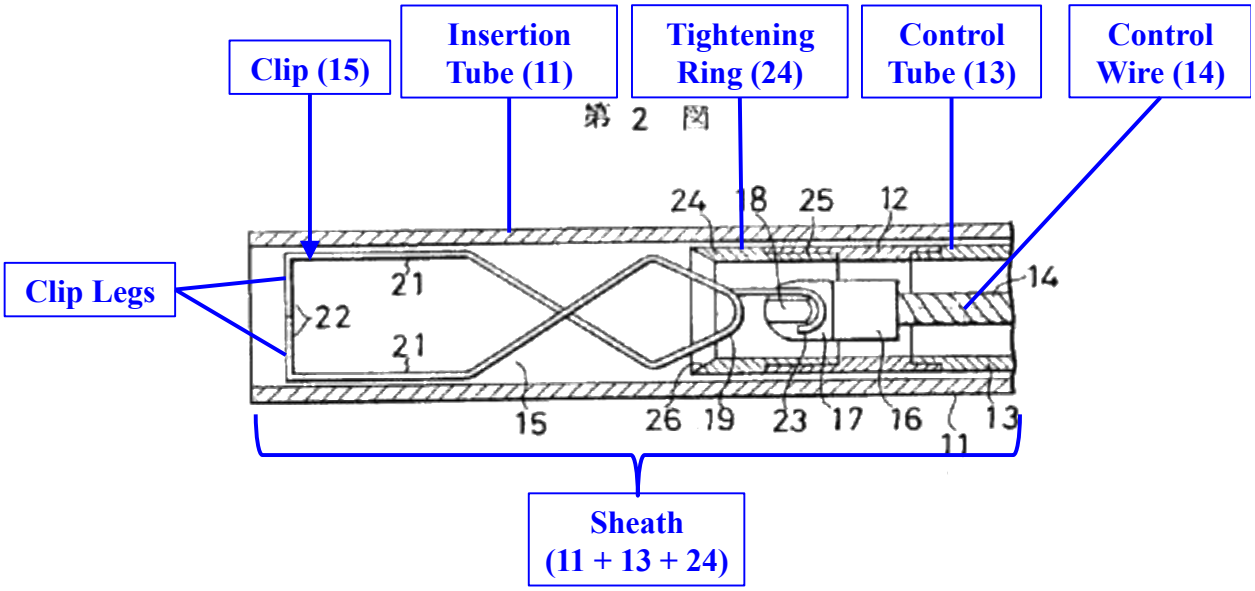
##### *a. "A method, comprising"*

Shinozuka discloses a "method." (Ex. 1009, English translation, p. 261 ("medical treatment method of introducing a treatment tool into a body through an endoscope"), pp. 262-263, Figures 2-7). (Ex. 1026, ¶ 111).

[5] Shinozuka is written in the Japanese language. Exhibit 1009 includes the original Shinozuka reference, as well as a translation of this reference from Japanese to English. Exhibit 1010 is the Declaration of James Thornton certifying the translation.

***b. "inserting a medical device comprising a clip having first and second clip legs, a control wire, a sheath enclosing the control wire and a proximal portion of the clip"***

Shinozuka discloses inserting a medical device. (Ex. 1009, English translation, p. 261 ("medical treatment method of introducing a treatment tool into a body through an endoscope"), pp. 262-263). As shown below in annotated Figure 2, the medical device comprises a clip (clip 15) having first and second clip legs (arm parts 21), a control wire (control wire 14), and a sheath (insertion tube 11 + control tube 13 + tightening ring 24) enclosing the control wire (14) and a proximal portion of the clip (15):



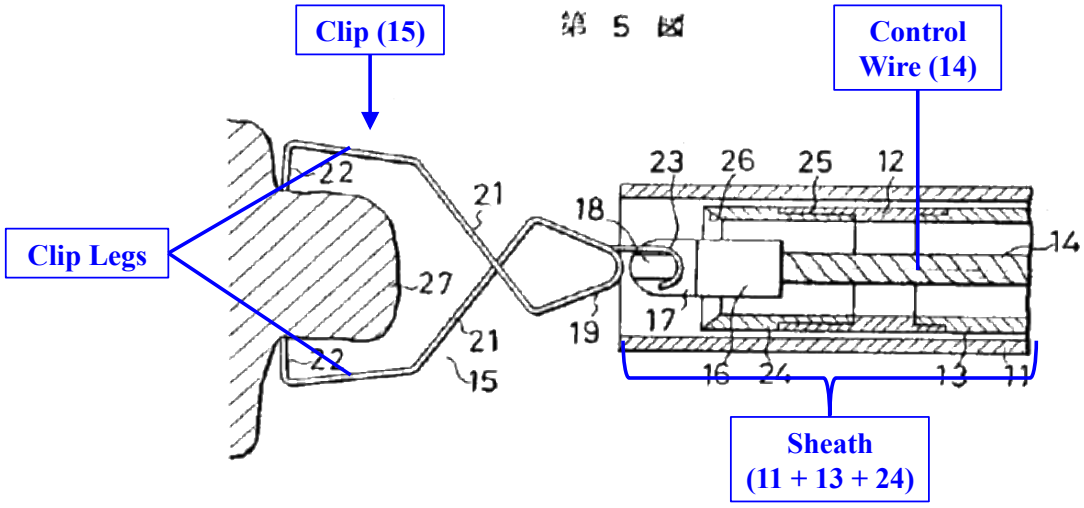

(Ex. 1009, English translation pp. 262-63; Ex. 1026, ¶ 112).

***c. "positioning the medical device at a desired deployment location"***

Shinozuka discloses positioning the medical device at a desired deployment location. (Ex. 1009, English translation, p. 263 ("Then, after this entire insertion tube 11 is introduced through an endoscope channel into a body cavity, the control wire 14 is pushed forward and by way of the hook 16 the clip 15 is projected out to the outside as shown in Fig. 5. As a result of this the clip 15 opens and becomes able to pinch some biotissue 27, and accordingly it is pushed onto a portion of biotissue 27 needing to be pinched.")). (Ex. 1026, ¶ 113).

***d. "moving the control wire distally relative to the sheath to deploy the first and second clip legs distally from the sheath"***

As shown below in annotated Figure 5, Shinozuka discloses moving the control wire 14 distally relative to the sheath (11 + 13 + 24) to deploy the clip legs (21) distally from the sheath.



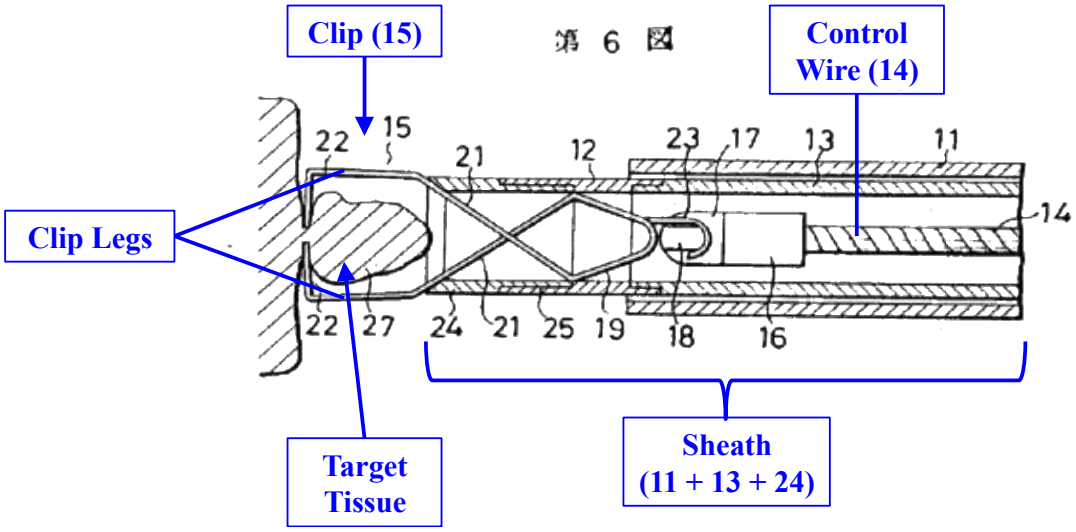

(Ex. 1009, English translation, p. 263 ("[T]he control wire 14 is pushed forward and by way of the hook 16 the clip 15 is projected out to the outside as shown in Figure 5. As a result of this the clip 15 opens and becomes able to pinch some biotissue 27, and accordingly it is pushed onto a portion of biotissue 27 needing to be pinched. . . . It may be noted that the clip 15 can be pinched onto the biotissue in the same way not only by pushing out the control tube 13 but alternatively by pulling the control wire 14."). (Ex. 1026, ¶ 114).

***e. "adjusting a position of the clip so that target tissue is received between the first and second clip legs"***

Shinozuka discloses adjusting a position of the clip (15) so that target tissue is received between the first and second clip legs, as reflected in Figure 5 reproduced above. (Ex. 1009, English translation p. 263). (Ex. 1026, ¶ 115).

***f. "drawing the control wire proximally relative to the sheath to draw the clip into the sheath to receive the target tissue between the first and second clip legs"***

As shown below in annotated Figure 6, Shinozuka discloses drawing the control wire (14) proximally relative to the sheath (13, 24) to draw the clip (15) into the sheath to receive the target tissue between the first and second clip legs:

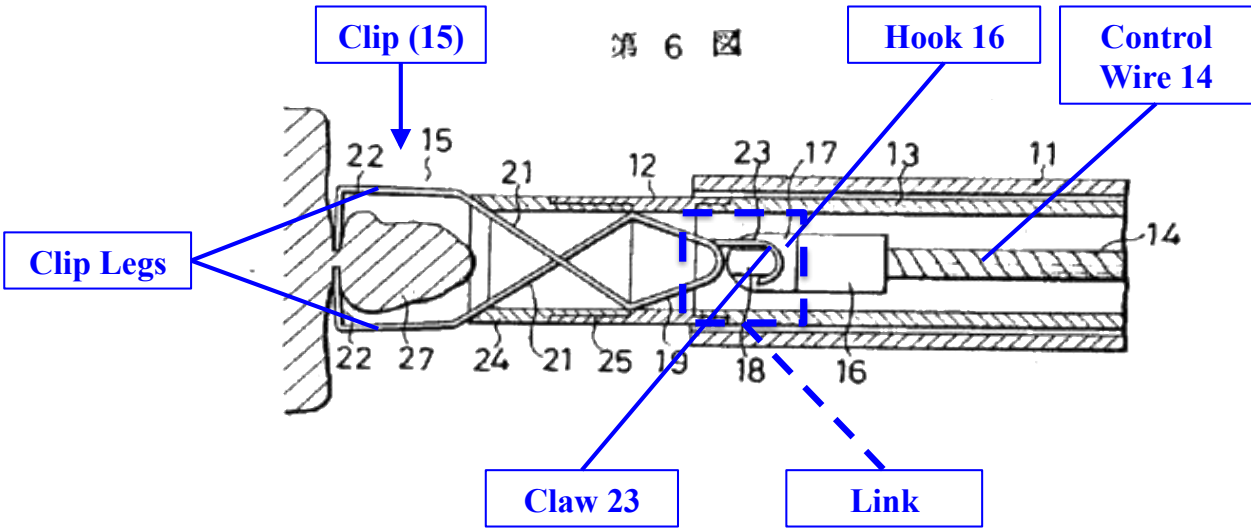



(Ex. 1009, English translation, p. 263 ("[A]s shown in Figure 6 the control tube 13 is pushed so as to fit the clip-tightening ring 24 onto the clip 15 and close the clip 15. As a result of this the pinching parts 22, 22 pinch the biotissue 27. It may be noted that the clip 15 can be pinched onto the biotissue in the same way not only

by pushing out the control tube 13 but alternatively by pulling the control wire 14.")). (Ex. 1026, ¶ 116).

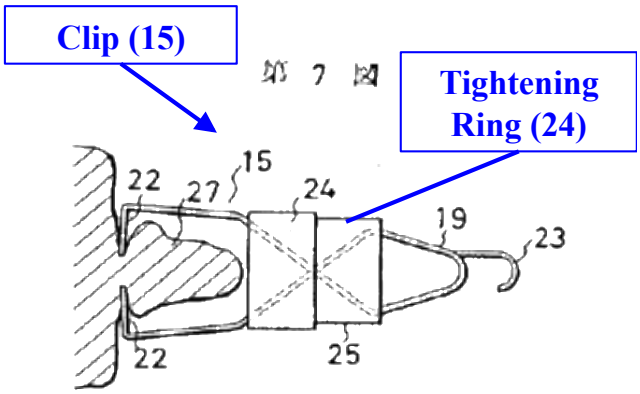
***g. "applying a tensile force of at least a threshold level to the control wire to separate a separable link coupling the control wire to the clip"***

As shown below in annotated Figure 5, Shinozuka discloses a link (hook 16 + claw 23) that "detachably coupl[es]" the clip (15) with the control wire (14), so that the clip can be left behind in the body:




(Ex. 1009, English translation pp. 262-263). (Ex. 1026, ¶ 117). The clip (15) and control wire (14) become unlinked by "jiggl[ing]" the control wire (14) so that the hook (16) at the proximal end of the clip (15) disengages from the claw (23) at the distal end of the control wire (14), and then pulling the control wire (14) proximally, away from the clip (15). (*Id.* at p. 263 ("With this invention, because the direction in which the hook can be detached from the clip is not a single direction but rather has become at least two directions, just by moving the hook

randomly the hook can be easily detached from the clip.")). Annotated Figure 7 below depicts the clip (15) and tightening ring (24) in the body after the separable link has been separated:




(Ex. 1026, ¶ 117).

To the extent BSSI argues that separating the separable link in Shinozuka does not involve applying a tensile force of at least a threshold level to the control wire, claim 29 nevertheless would have been obvious. (Ex. 1026, ¶ 118). The idea of applying a tensile force of at least a threshold level to a control wire to separate a separable link coupling the control wire to a clip was known in the prior art. For example, as shown below in annotated Figures 1A, 1B, and 5, Matsuno discloses a separable link between a clip (2) and a control wire (13) including a "hook portion 3a," which hooks on a "recess 2e of the clip 2 to removably engage with the clip 2" (hook portion 3a highlighted below in yellow):

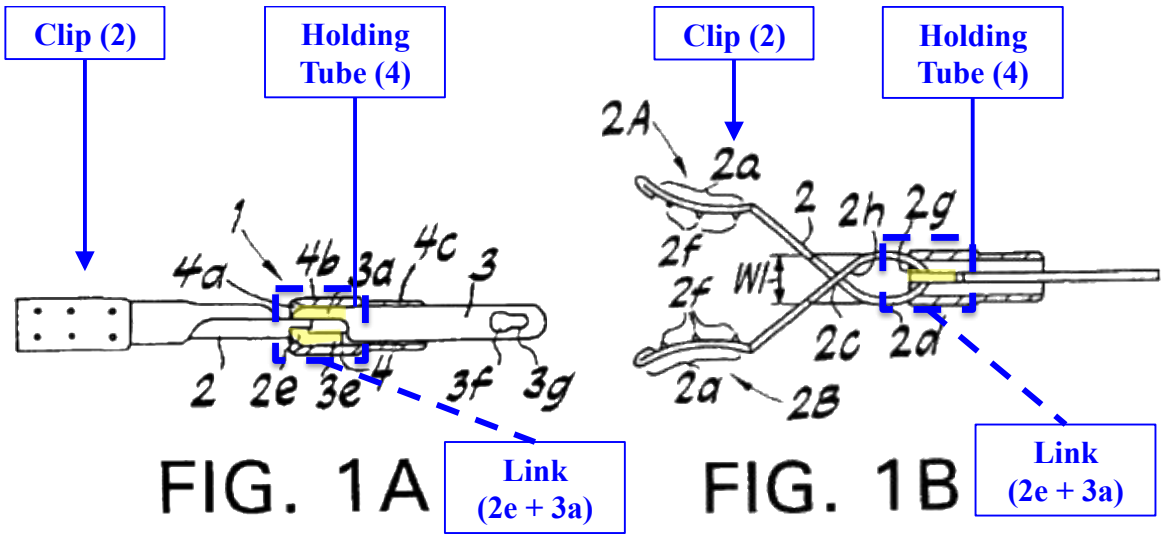



FIG. 1A FIG. 1B

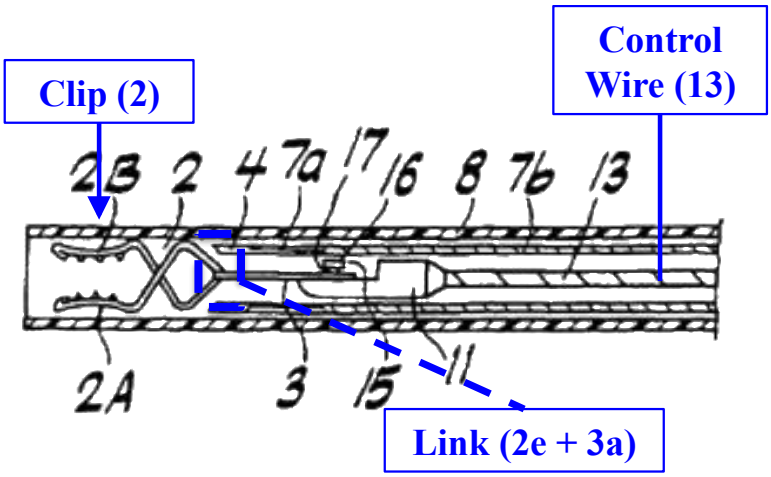



FIG. 5

(Ex. 1016, 3:31-32; *see also* 4:2-7; Ex. 1026, ¶ 118).

As shown below in Figures 2A and 2B, applying a tensile force of at least a threshold level to the control wire causes the hook portion 3A of the link (2e, 3a) to straighten (from Figure 2A to Figure 2B):

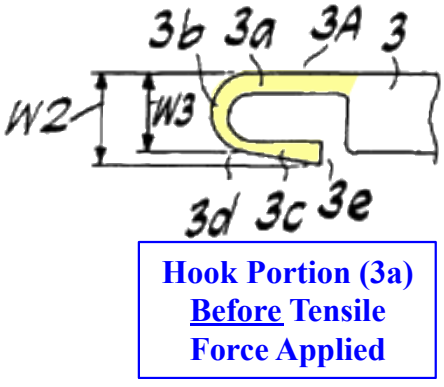



FIG. 2A

Hook Portion (3a) Before Tensile Force Applied

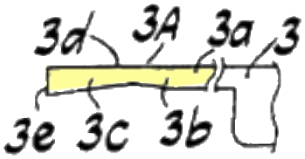



FIG. 2B

Hook Portion (3a) After Tensile Force Applied

The link (3A and 2e) between the control wire and clip becomes unlinked when a tensile force is applied, thereby straightening hook portion 3A so that it can pull

away and disengage from the clip (2). (Ex. 1016, 5:58-65 ("When the arm portions 2A and 2B of the clip 2 reliably grasp the living tissue and the slider 12 is further pulled toward the proximal end side to retract the operating wire 13, the hook portion 3A of the coupling plate 3 of the clip 2 is deformed and stretched as shown in FIGS. 7 and 8. The clip 2 disengages from the coupling plate 3, becomes detached from the clip operating device 6 and is left inside the body cavity, holding the tissue."); *see also id.*, Figures 7 and 8; Ex. 1026, ¶ 119).

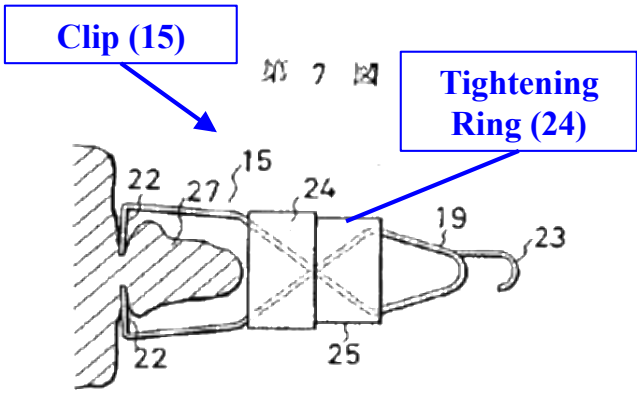
It would have been obvious to a person of ordinary skill in the art to substitute the hook portion 3a in Matsuno for the hook 16 in Shinozuka. (Ex. 1026, ¶ 120). The skilled artisan would have been motivated to make this substitution in order to simplify and improve the procedure for separating the separable link. In contrast with the hook 16 in Shinozuka, which separates from the clip by "jiggling," the hook portion 3a in Matsuno is separated simply by pulling back on the control wire to straighten the hook portion 3a. The person of ordinary skill in the art would have recognized potential problems with "jiggling" the control wire in a patient's body, including the inability to know precisely when the control wire is separated from the clip, as well as the potential for causing damage to the patient. The skilled artisan would have expected that substituting the straightening hook portion 3A would reduce the risk of damage to the patient,

and provide a simpler, and more precise method of unlinking the clip. (Ex. 1026, ¶ 120).

Substituting the Matsuno hook portion 3a for the Shinozuka hook 16 would have been a matter of routine skill in the art, using simple mechanical elements disclosed in Shinozuka and Matsuno to yield predictable results. (Ex. 1026, ¶ 121). *See Tokai*, 632 F.3d at 1371 ("[T]he nature of the mechanical arts is such that 'identified, predictable solutions' to known problems may be within the technical grasp of a skilled artisan.") (citations omitted).

**2. Claim 30**

Claim 30 depends from claim 29 and further requires "the separation uncoupling the clip from the control wire and separating a capsule from the sheath to lock the clip over the coupled target tissue." As shown below in annotated Figure 7, Shinozuka discloses the separation uncoupling the clip (15) from the control wire (14) and separating a capsule (tightening ring 24) from the sheath (11 + 13 + 24)[6] to lock the clip over the coupled target tissue:




(Ex. 1009, English translation, p. 263 ("Now, because the clip-tightening ring 24 is compressing the rear half of the clip 15, as shown in Figure 7 it does not detach

[6] As discussed above in Section IV.E.1, *supra* at p. 13, BSSI has argued in district court litigation that "a portion of the sheath can stay unseparated from the clip." Consistent with this meaning of "sheath," Petitioners have identified capsule (24) both as a component of the "sheath," and well as a "capsule" that separates from the sheath.

from the clip 15, and it is left inside the body along with the clip 15."); Ex. 1026, ¶ 122).

## VI. CONCLUSION

There is a reasonable likelihood that Petitioners will prevail in their challenge of patentability for claims 1-3, 5-18, and 20-30 of the '048 patent. Therefore, Petitioners respectfully request the PTAB to grant this petition for *inter partes* review.

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 10,937 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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*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. 8,685,048, as well as the accompanying Power of Attorney, and Exhibits 1004, 1009-10, 1013-14, 1016-17, 1019, 1023-24, 1026, and 1032 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. 8,685,048* | *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. 8,685,048.* |

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