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. 8,685,048
Issue Date: April 1, 2014

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

Case No. IPR2017-00131

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TABLE OF EXHIBITS

Cook Group Incorporated and Cook Medical LLC (collectively "Petitioners") respectfully request *inter partes* review of claims 1-30 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. 2017-00132, which challenges the patentability of claims 1-3, 5-18, and 20-30 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); 1:46-51 (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. 1025, ¶ 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]

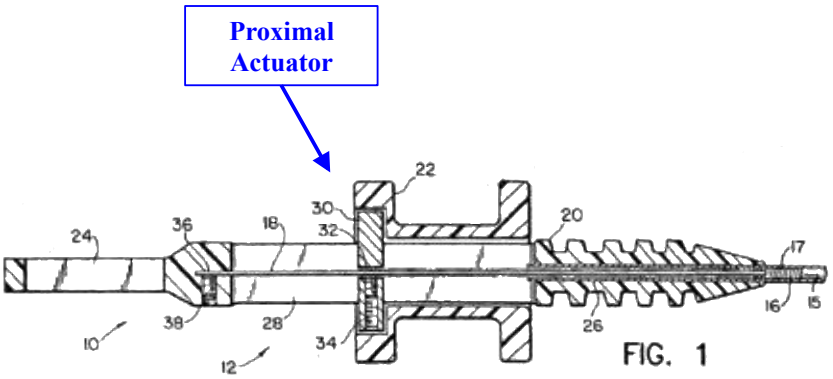


FIG. 1

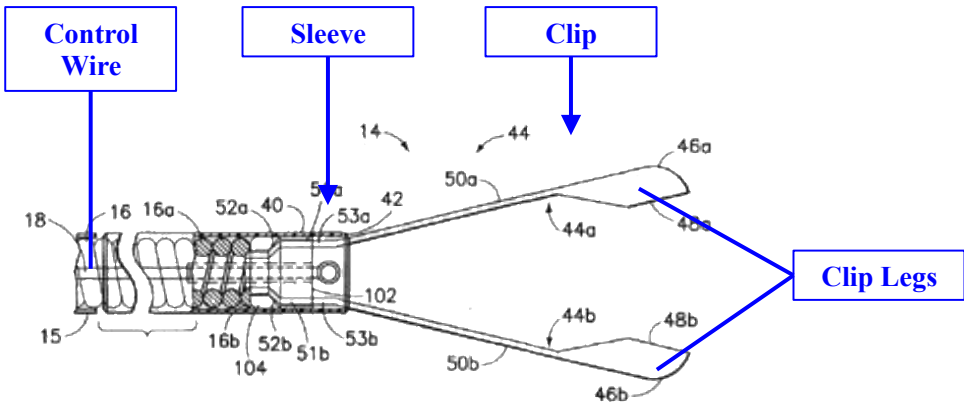


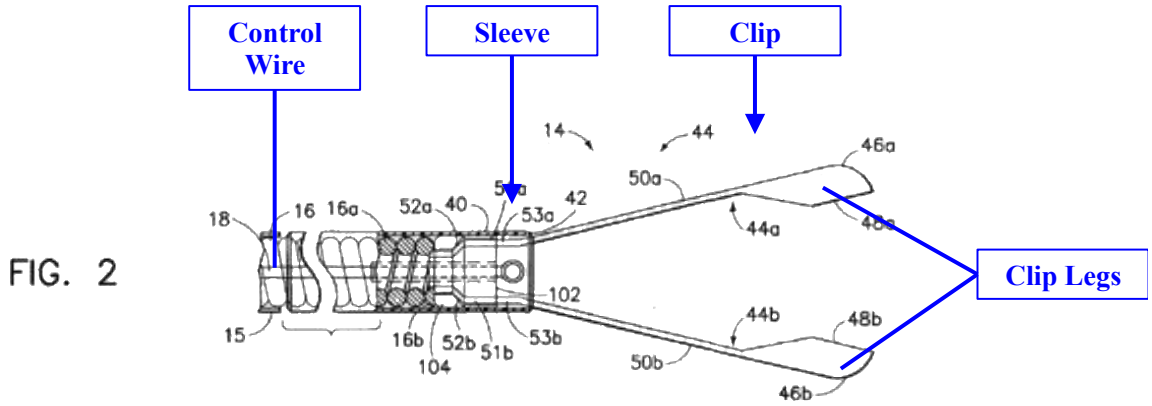
FIG. 2

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

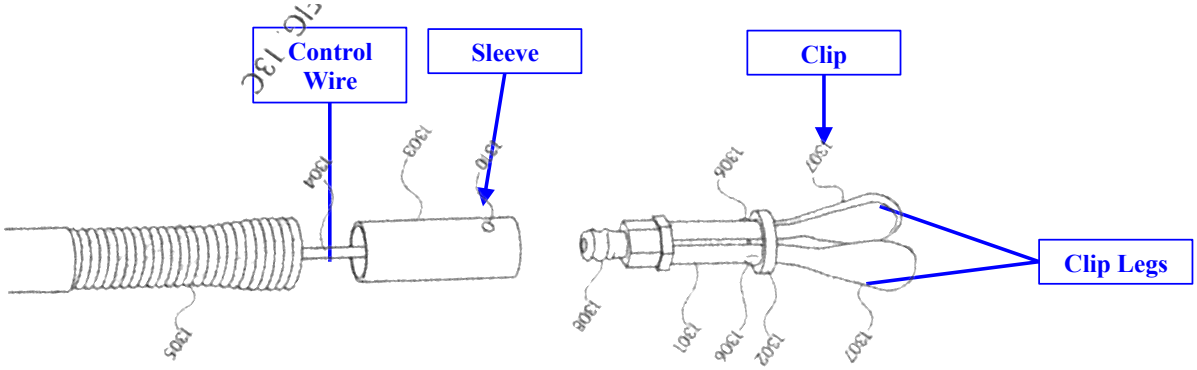
[1] Palmer issued on July 8, 1997, and names as an inventor Vincent A. Turturro – one of the named inventors of the '048 patent. Palmer was not cited during prosecution of the '048 patent.

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. 1025, ¶ 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



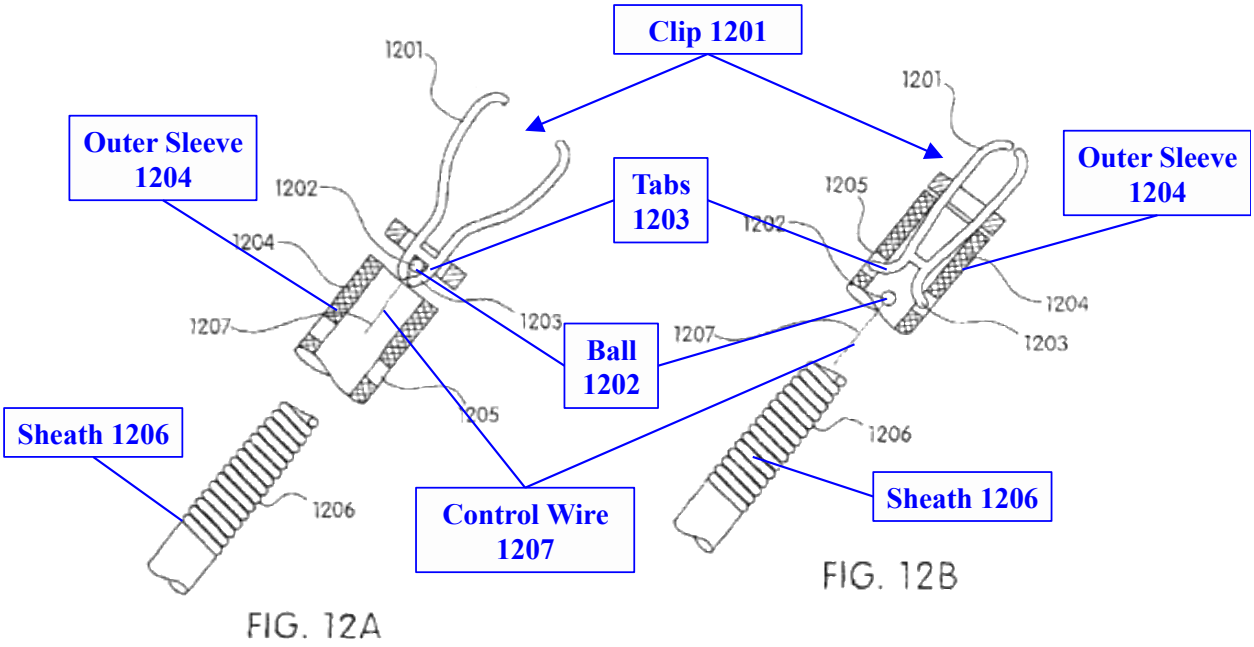
'048 Patent, Figure 13C

(Ex. 1025, ¶ 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. 1025, ¶ 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 1-30 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 1-28 are obvious under § 103 in view of U.S. Patent No. 5,749,881 ("Sackier") in combination with U.S. Patent No. 5,569,274 ("Rapacki")
2	Claims 29 and 30 are anticipated under § 102 by Sackier
3	Claims 14 and 28 are obvious under § 103 in view of Sackier in combination with Rapacki and U.S. Patent No. 5,304,183 ("Gourlay")

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

[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.

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. 1025, ¶ 11).[3]

Petitioners submit with this Petition the Declaration of Mark A. Nicosia, Ph.D. (Ex. 1025). 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. 1025), 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. 1025) 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. 1025, ¶ 11).

in the relevant timeframe. (Ex. 1025, ¶ 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).

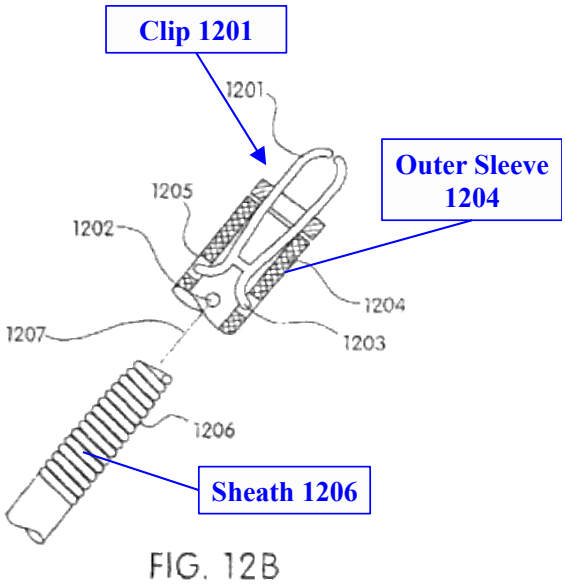


FIG. 12B

(*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* . . . .")).

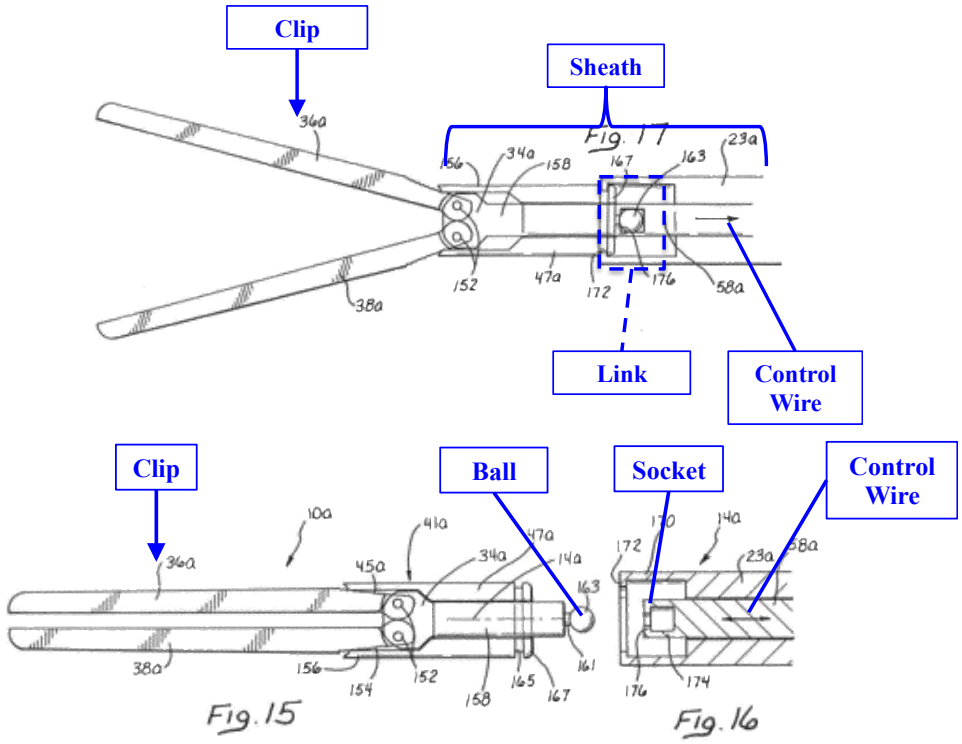
For purposes of this IPR proceeding, Petitioners accept BSSI's construction of "sheath" as "one or more components that enclose the control wire," which may include components of the clip assembly that are left behind in the body.

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

Claims 1-30 of the '048 patent are unpatentable in view of one or more of the grounds identified above in Section IV.C. None 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.*"

Sackier discloses a clip that separates from a control wire via a link (*i.e.*, a ball and socket link), so that the clip can stay behind in the patient's body:[5]

[5] Figures 15-26 of Sackier published without reference numbers. (*See* Ex. 1008). However, Sackier submitted Figures 15-26 with reference numbers during prosecution. (*See* Ex. 1012 at 224-227, 268-276). Figures 15-26 with reference numbers constitute a "printed publication" under 35 U.S.C. § 102 as of Sackier's issue date. *See Bruckelmyer v. Ground Heaters, Inc*., 445 F.3d 1374, 1377-78 (Fed. Cir. 2006) (holding that figures submitted during prosecution were "printed publications" as of the issue date of the corresponding patent, even though the figures were not included in the issued patent). While the figures without reference numerals fully disclose the claim limitations, for ease of reference and explanation Petitioners use the figures with the reference numbers in this petition. *See In re Baxter Travenol Labs*., 952 F.2d 388, 390 (Fed. Cir. 1991) (extrinsic



Sackier, Figures 15-17

(Ex. 1025, ¶ 26).

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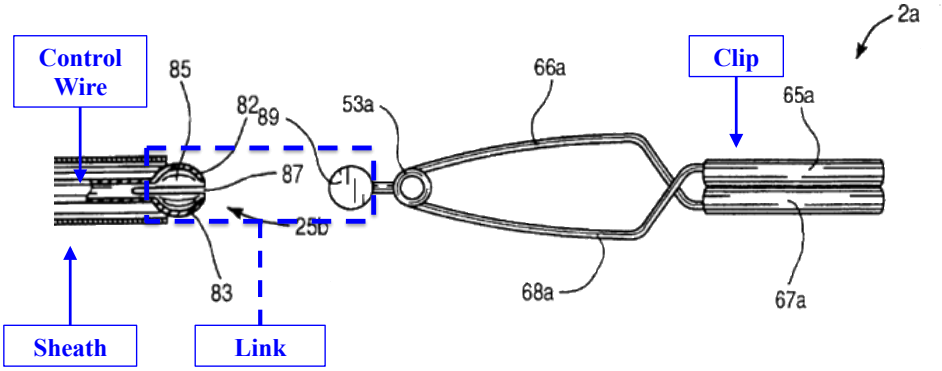
evidence may be used to explain the meaning of a reference when conducting an analysis under 35 U.S.C. 102).

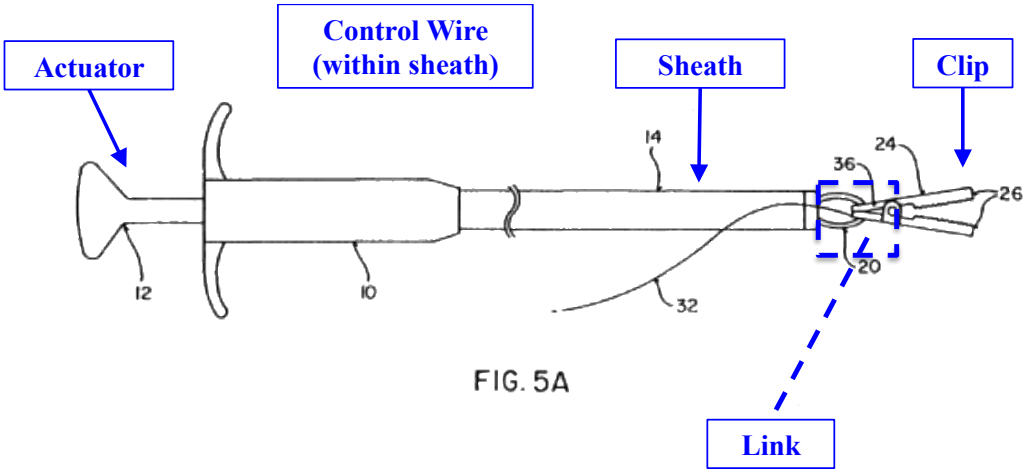
Rapacki also discloses a clip that separates from a control wire via a link (*i.e.*, a ball and socket link), so that the clip can stay behind in the patient's body:



Rapacki Figures 5B and 6A

(Ex. 1025, ¶ 28).

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



Gourlay Figure 5A

(Ex. 1025, ¶ 30).

A. Ground 1: There Is A Reasonable Likelihood That Claims 1-28 Would Have Been Obvious In View Of Sackier (Ex. 1008) In Combination With Rapacki (Ex. 1021)

Sackier issued on May 12, 1998 and qualifies as prior art at least under 35 U.S.C. §§ 102(a), (b), and (e). Sackier was not cited during prosecution of the '048 patent.

Rapacki issued on October 29, 1996 and qualifies as prior art at least under 35 U.S.C. §§ 102(a), (b), and (e). Rapacki is listed as a cited reference on the cover of the '048 patent, but was never substantively addressed during prosecution.

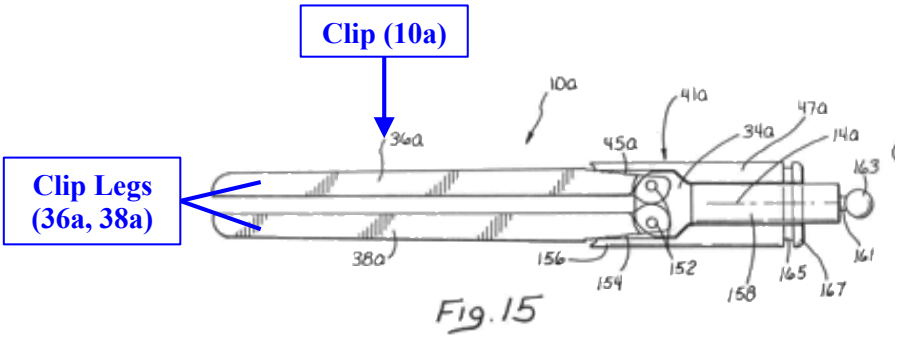
1. Independent Claim 1

a. "A medical device, comprising"

Sackier discloses this preamble: a medical device in the form of a "surgical clamp apparatus and more specifically . . . clamps and clamp appliers for use in occluding body conduits." (Ex. 1008, 1:6-8; *see also* Abstract; Ex. 1025, ¶ 32).

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

As shown below in annotated Figure 15, Sackier discloses a clip (10a) having first and second clip legs (36a, 38a).



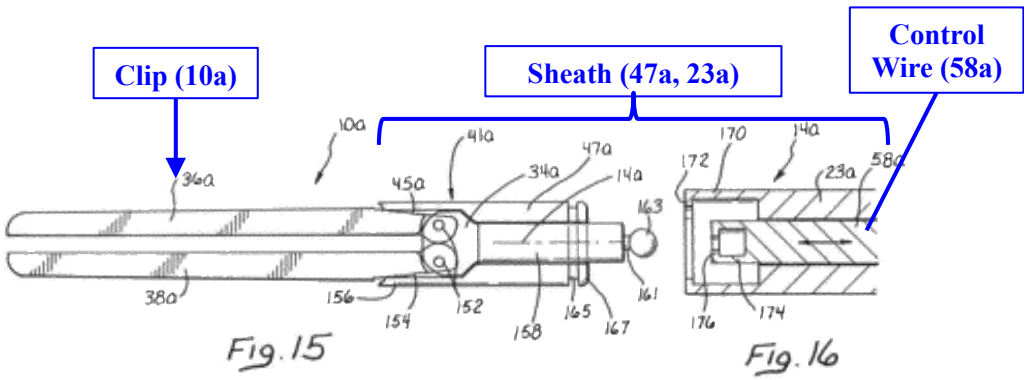
(Ex. 1008, 9:16-19; Figures 15-17; Ex. 1025, ¶ 33).

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

Sackier discloses a control wire (58a) operable both to open (Figure 17) and close (Figure 15) the clip legs (36a, 38a). (Ex. 1008, 10:27-34 ("[S]haft 58a can be moved relative to the tube 23a to engage the slide 47a and move it relative to the supporting structure 34a and the jaws 36a, 38a."); *see also* 2:56-67, 9:41-48, 10:10-13, 10:50-58).

d. "a sheath enclosing the control wire"

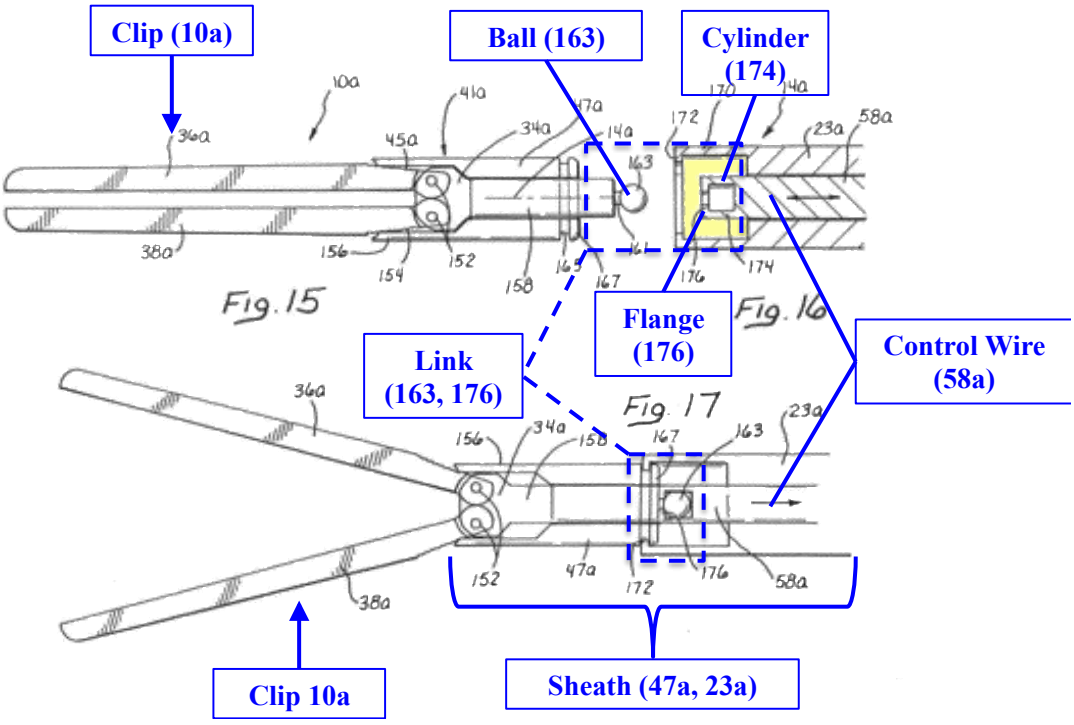
As shown below in annotated Figures 15 and 16, Sackier discloses a sheath (23a + 47a) enclosing the control wire (58a).



(Ex. 1008, 10:10-13; *see also, id.* 10:27-34; Ex. 1025, ¶ 35).

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 Figures 15-17, Sackier discloses a link in the form of ball 163 at the proximal end of the clip (10a), which couples to the components of cylinder 174 (including flange 176) at the distal end of the control wire (58a).



The link is movable from a coupled configuration in which the clip (10a) is coupled to a distal end of the control wire (58a) (Figure 17), to a released configuration (Figure 15) in which the cylinder 174 (including flange 176) is

configured to move radially outward at an area of the sheath (area of the sheath highlighted above in yellow) to release the control wire (58a) from the clip (10a). (Ex. 1008, 10:24-27 ("[C]ylinder[] . . . 174 can be configured to open laterally in order to permit the associate flanges 172 and 176 to engage the recesses 165 and 161," where recess 161 is located at the neck of ball 163); *see also* 2:56-67, 9:60-64; Ex. 1025, ¶ 36).

Sackier does not explicitly disclose that the cylinder 174 with flange 176 is made up of two, distinct "arms," but Rapacki discloses this limitation. As shown below in annotated Figures 5B and 6A, Rapacki discloses a clip (clamp 2a) with a ball (89) at its proximal end (Figure 6A) that links with a control wire (21b) via a pair of link arms (jaws 82, 83), which form a "socket 85" (Figure 5B):

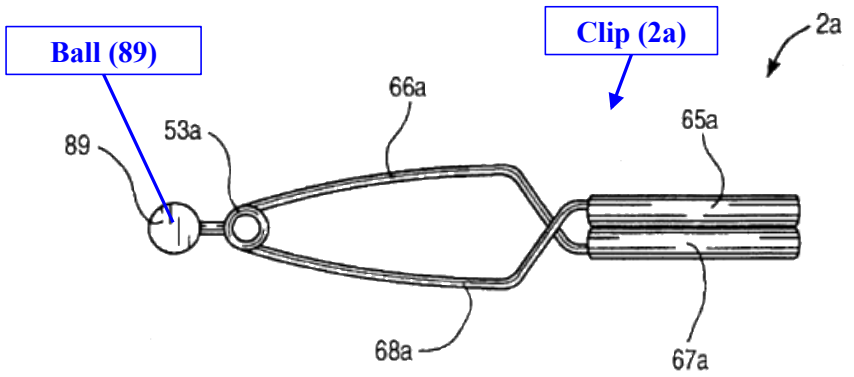


FIG. 6A

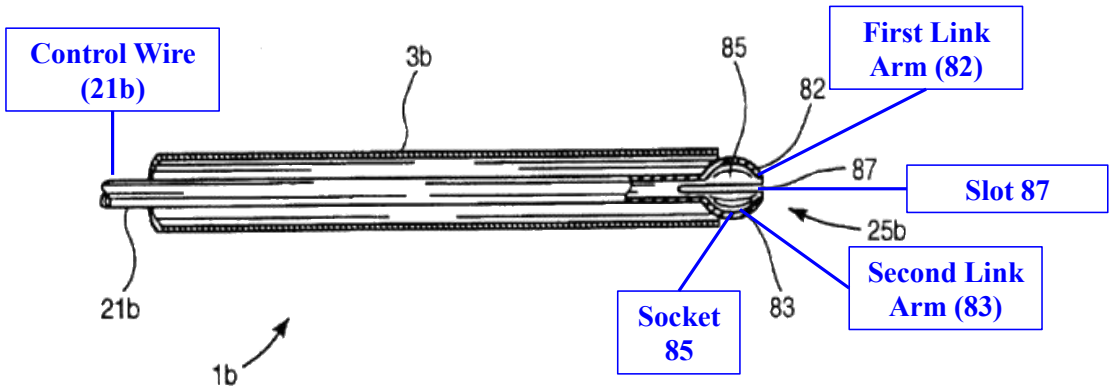


FIG. 5B

The first and second arms of the link (82, 83) are configured to move radially outward to release the clip (2a) from the control wire (21b). (Ex. 1021, 9:52-10:8; *see also* Ex. 1025, ¶ 37).

The link arms (82, 83) each have a generally hemispherical shape and are separated by a slot 87, which allows the link arms (82, 83) to move radially outward to release the ball 89 of the clip (2a). (Ex. 1021, 9:57-60 ("Jaws 82, 83 are separated by a slot 87 in the distal end of rod 21b and are biased radially outward so that axial movement of shaft 3b with respect to jaws 82, 83 opens and closes the jaws."), 9:67 – 10:2; *see also* Ex. 1025, ¶ 38).

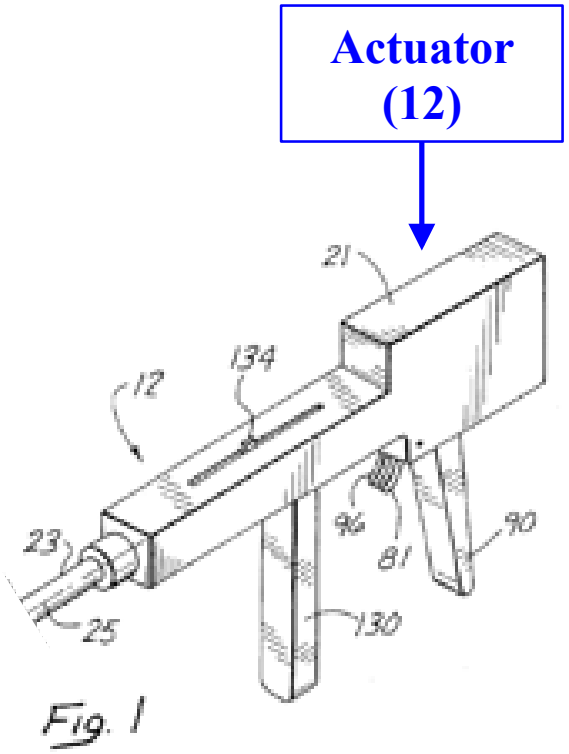
It would have been obvious to one of ordinary skill in the art to modify the Sackier cylinder 174 (with flange 176) to include a longitudinal slot, as disclosed in Rapacki, to provide distinct hemi-cylindrical (or similar to hemi-cylindrical) first and second link arms. Modifying the cylinder 174 to include a longitudinal slot would allow the cylinder 174 to "open laterally," as taught by Sackier. (Ex. 1008, 10:24-27). The skilled artisan would have expected that adding a slot to the cylinder 174 would decrease the force required to separate the link between the clip (10a) and control wire (58a), making the cylinder 174 easier to open. A person of ordinary skill would have recognized the importance of making the cylinder 174 easier to open, as the clip (10a) is used to secure delicate internal organs within a body. Using excessive force to release ball 163 could potentially

damage the organs. This would have motivated a person of ordinary skill in the art to include a slot, as disclosed in Rapacki, or at least to try it. (Ex. 1025, ¶ 39).

Modifying the cylinder 174 in Sackier to include a slot 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. 1025, ¶ 40). *See Tokai Corp. v. Easton Enters.*, 632 F.3d 1358, 1371 (Fed. Cir. 2011) ("[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). For example, it would have been obvious to form a slot in the cylinder 174 by cutting two longitudinal notches in the distal end of the cylinder 174 (including flange 176), each disposed across from the other. (Ex. 1025, ¶ 40).

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."

Sackier discloses an actuator (12a) coupled to the control wire (58a), as shown for example in annotated Figure 1.



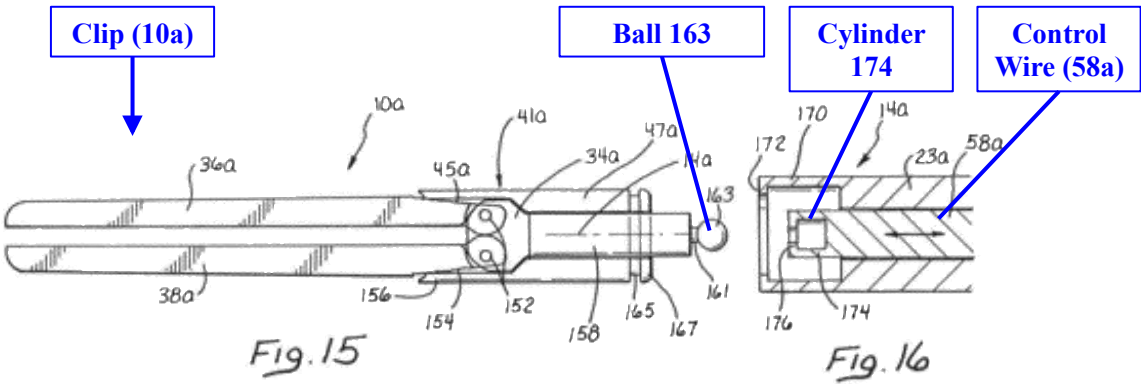
(Ex. 1008, 2:47-51 (explaining that the invention includes "a tube [(23a)] and engaging means [(58a)] disposed within the tube for engaging the moving means at the proximal end of the clamp"); *see also* Abstract, 10:10-13, 10:27-34; Ex. 1025, ¶ 41).

The control wire (58a) is engageable by the actuator to move the control wire (58a) to open and close the clip legs (36a, 38a) and to move the link (163,

174, 176) from the coupled configuration (Figure 17) to the released configuration (Figure 15). In particular, distal movement of the control wire (58a) opens the clip legs (36a, 38a), as shown in Figure 17. Conversely, proximal movement of the control wire (58a) closes the clip legs and moves the link (163, 174, 176) from the coupled configuration (Figure 17) to the released configuration (Figures 15 and 16). (Ex. 1008, 10:27-34; *see also* Ex. 1025, ¶ 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." As shown below in annotated Figures 15 and 16, Sackier discloses the distal end of the control wire (58a) comprises a cylinder 174, and the proximal end of the clip (10a) comprises a ball 163 (*i.e.*, "an increased diameter portion having a substantially spherical cross section"):



As explained above in Section V.A.1.e, *supra* at pp. 19-23, the ball 163 and cylinder 174 form a link coupling the control wire (58a) to the clip (10a). (*See also* Ex. 1025, ¶ 43).

It would have been obvious to reverse the positions of the cylinder 174 and the ball 163 so that the ball 163 was on the distal end of the control wire (58a), and the cylinder 174 was on the proximal end of the clip (10a). The link between the ball 163 and cylinder 174 is a ball and socket link. A person of ordinary skill in the art would have recognized that there are a finite number of permutations for

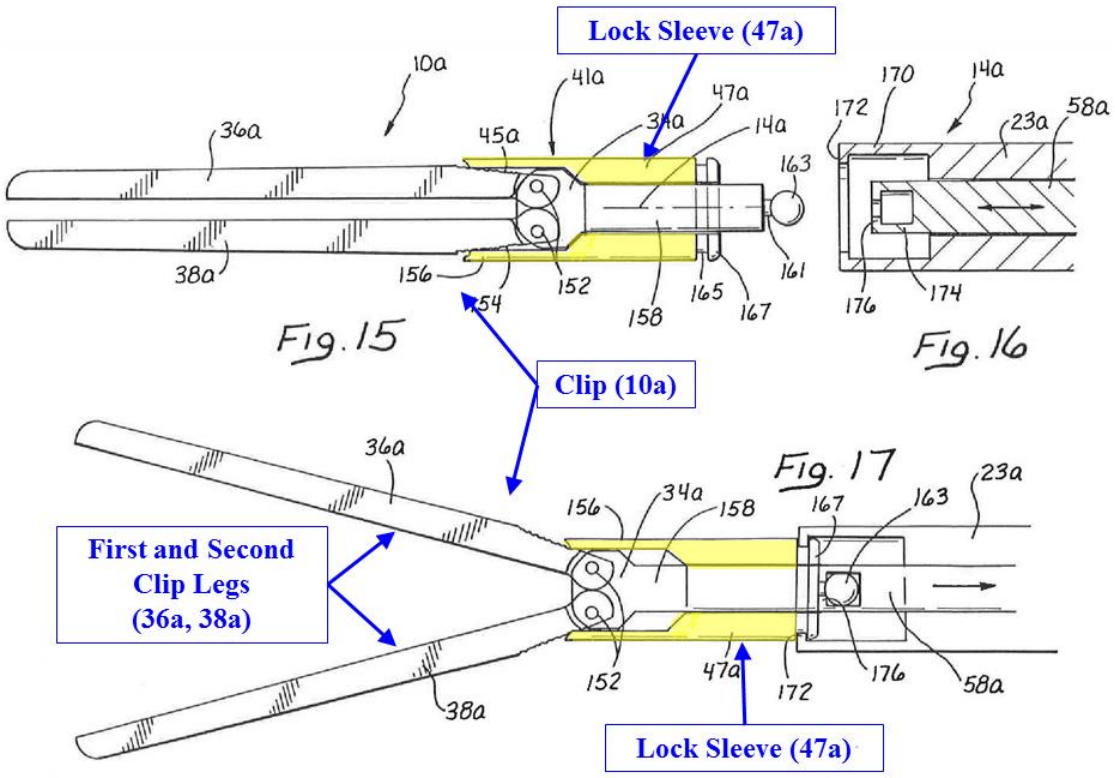
attaching the ball 163 and a socket (cylinder 174) to a clip (10a) and control wire (58a): (1) the ball 163 attached to the clip (10a) and the socket (174) attached to the control wire (58a) (depicted in Sackier); or (2) the socket (174) attached to the clip (10a) and the ball 163 attached to the control wire (58a). (Ex. 1025, ¶ 44). *See In re Japikse*, 181 F.2d 1019, 1023 (CCPA 1950) (holding claims unpatentable because shifting the position of an element would not have modified the operation of the device); *see also 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); MPEP § 2144.04 (VI.C)).

Modifying the Sackier device by reversing the positions of the ball 163 and cylinder 174 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. 1025, ¶ 45). *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). The modified Sackier device (with the ball 163 on the distal end of the control wire (58a)) would have an increased diameter portion

at the distal end of the control wire with a substantially spherical cross-section. (Ex. 1025, ¶ 45).

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 Figures 15-17, Sackier discloses a lock sleeve (slide 47a) (highlighted in yellow) radially surrounding part of the first and second clip legs (36a, 36b) of the clip (10a):

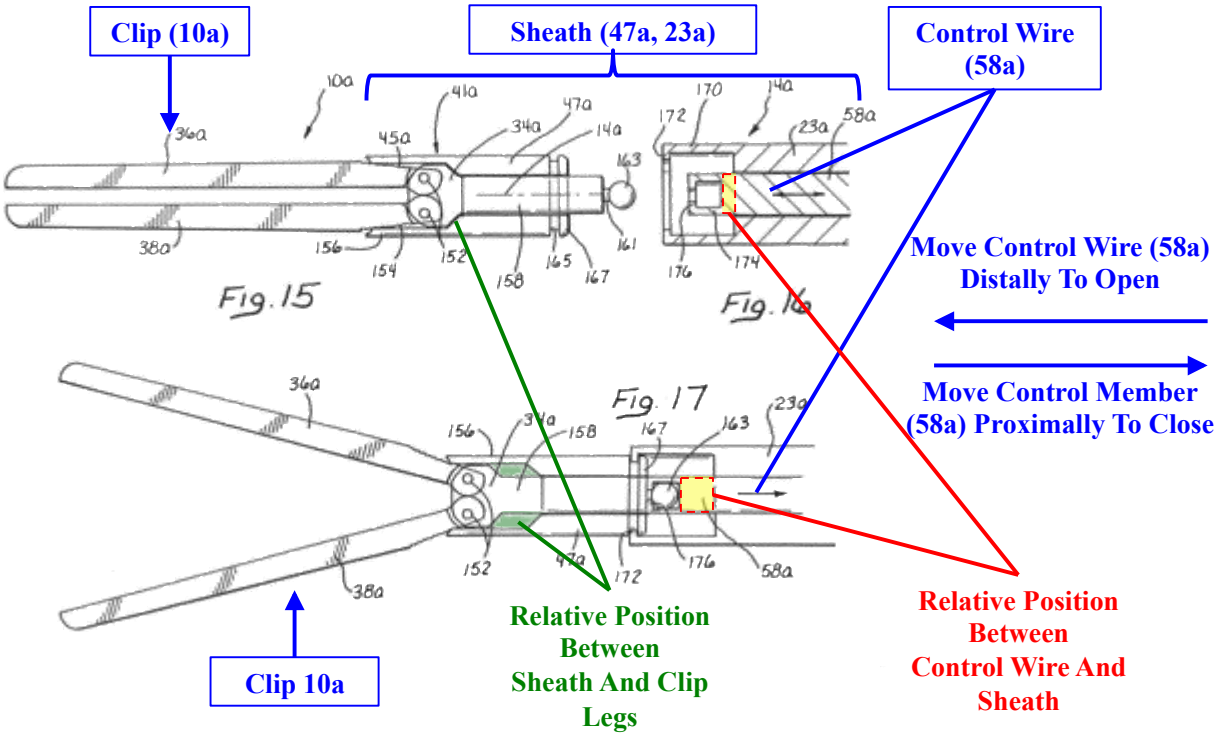


(Ex. 1008, 9:64-67 (the slide 47a "functions as a sleeve which is slidable on the shaft 158 between the proximal and distal positions illustrated in FIGS. 17 and 15, respectively."); *see also* 9:41-48). As shown above, as the clip (10a) is drawn proximally into the lock sleeve (47a) (from position in Figure 17 to position in Figure 15), the clip legs (36a, 38a) are drawn toward one another. (Ex. 1025, ¶ 46).

4. Claim 4

Claim 4 depends from claim 3 and further requires "before the clip is separated from the control wire, moving the sheath proximally relative to the control wire moves the clip out of the lock sleeve, opening the clip legs." Sackier discloses that before the clip (10a) is separated from the control wire (58a), moving the sheath (23a + 47a) proximally relative to the control wire (58a) (*i.e.*, moving the control wire (58a) distally relative to the sheath (23a, 47a)) moves the clip (10a) out of the lock sleeve (47a), opening the clip legs (36a, 38a). (Ex. 1008, 10:27-34 ("[A]xial 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."); *see also, id.* 9:41-48, 11:57-64; Ex. 1025, ¶ 47)).

A comparison of Figures 15-16 and 17 below demonstrates that the relative position between the control wire (58a) and the sheath (23a + 47a)) changes when the clip (10a) moves from a closed position (Figure 15) to an open position (Figure 17).



(Ex. 1008, 9:41-48, 10:27-34). Similarly, as shown above, the relative position between the sheath (47a) and the clip legs (36a, 38a) changes when the clip (10a) moves from a closed position (Figure 15) to an open position (Figure 17). (Ex. 1025, ¶ 48).

5. 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." As shown below in annotated Figure 15, Sackier discloses a lock sleeve (slide 47a) for locking the clip (10a) with the first and second clip legs (36a, 38a) closed:

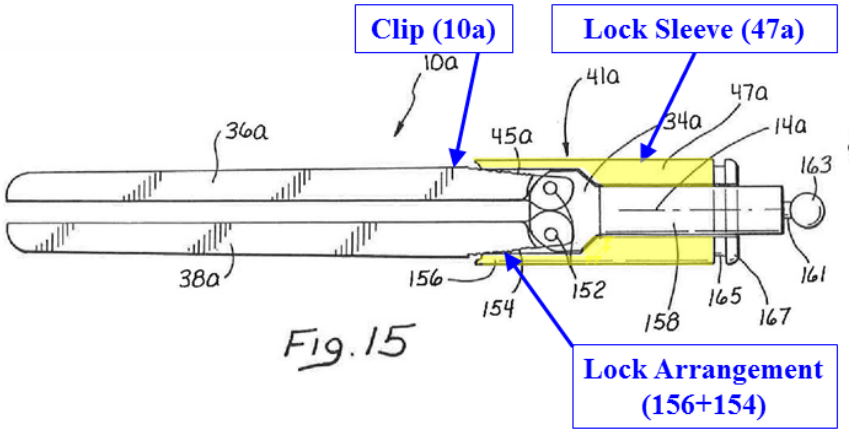


Fig. 15

The lock sleeve (47a) includes a lock arrangement (projection 156 on the lock sleeve (47a) engaging recesses 154 on the clip legs (36a, 38a)) for locking the clip (10a) within the lock sleeve (47a) with the clip legs (36a, 38a) closed:

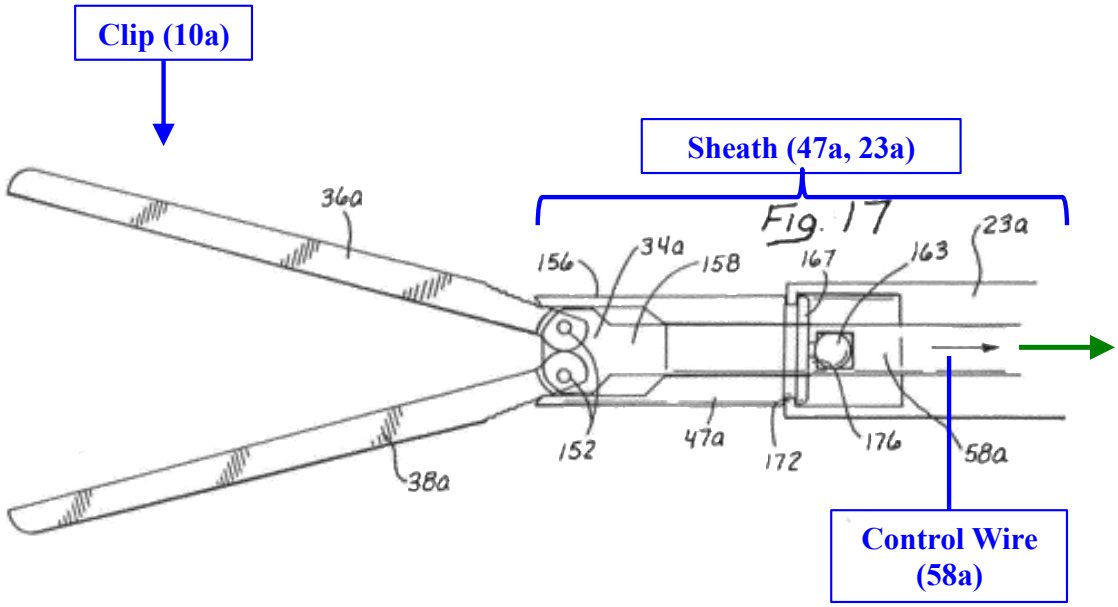
> [T]he surface 45a [of the clip (10a)] is provided with a plurality of recesses 154 which form discrete locations along the surface 45a. Each of these locations is associated with a different relative position of the jaws 36a and 38a between the open position illustrated in FIG. 17 and the closed position illustrated in FIG. 15. . . . In proximity to the particular surface 45a, the slide 47a is provided with a projection 156 which forms a plurality of detents with

> each of the recesses 154 on the surface 45a. Thus the projection 156 engages a recess at one end of the surface 45a when the shaft 47a is in the proximate position, and engages a recess 154 at the opposite end of the surface 45a when the slide 47a is in the distal position. As the projection 156 sequentially engages the recesses 154 along the surface 45a, the jaws 36a and 38a move between the open and closed positions.

(Ex. 1008, 9:35-58). The clip legs (36a, 38a) are locked when clip (10a) is located in lock sleeve (47a). (Ex. 1025, ¶ 49).

6. 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." Sackier discloses a proximal tensile force (indicated by green arrow below) applied to the clip (10a) via the control wire (58a) is opposed by a distal compressive force on the sheath (23a + 47a).



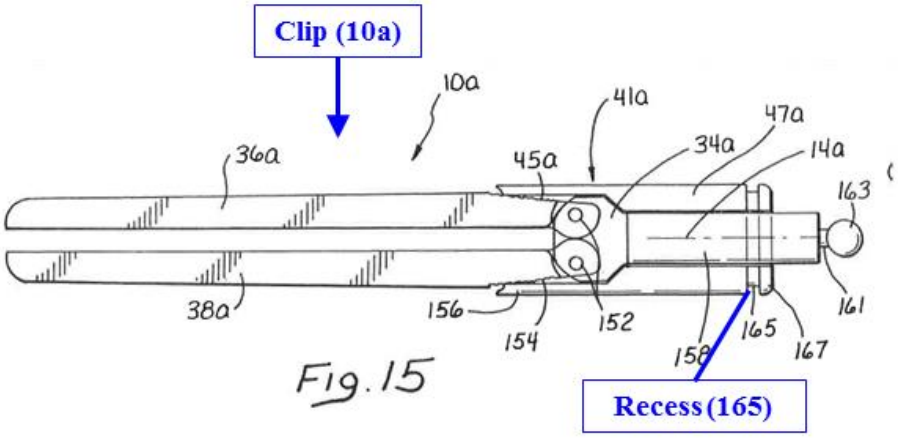


Fig. 15

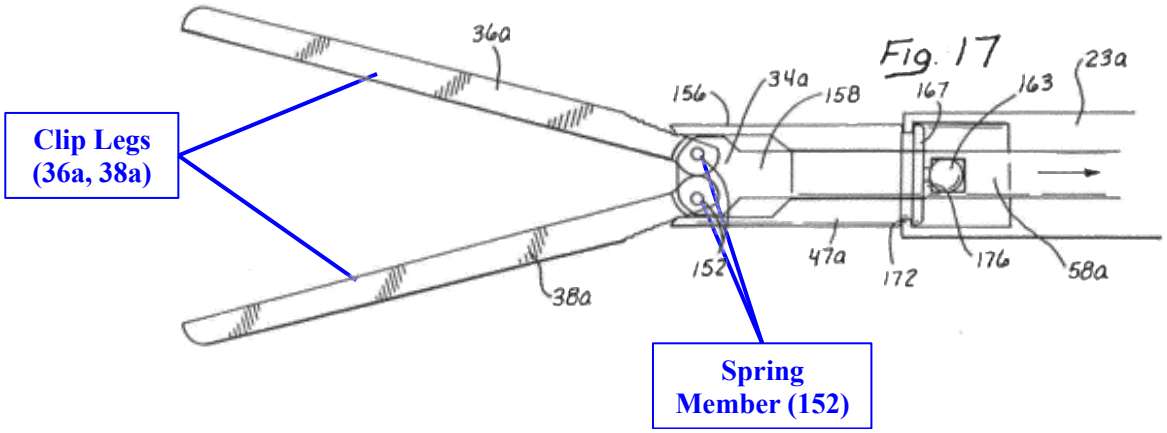
(Ex. 1025, ¶ 50).

In particular, pulling the control wire (58a) in the proximal direction while holding the proximal end of the sheath (23a + 47a) steady pulls the supporting structure (34a) of the clip and clip legs (36a and 38a) into the sleeve (47a). The supporting structure (34a) of the clip and clip legs (36a and 38a) exerts a force on the sleeve (47a) as the control wire (58a) is pulled in the proximal direction. This force is further communicated to the sheath (23a + 47a) as a result of the connection between the clip (10a) and the outer tube (23a) (such as the connection between the recess (165) on the clip (10a) and the flange (172) on the outer tube (23a)). These forces in the proximal direction also result in reaction forces in the distal direction. Therefore, a proximal tensile force applied to the clip (10a) via the control wire (58a) is opposed by a distal compressive force on the sheath (23a + 47a). (Ex. 1025, ¶ 51).

The sheath (23a + 47a) is constructed to communicate the distal compressive force via the control wire (58a) 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 supporting structure (34a) of the clip and clip legs (36a and 38a) are pulled proximally into the sleeve (47a), 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. 1025, ¶ 52; *see also* Ex. 1008, 9:16 – 10:34).

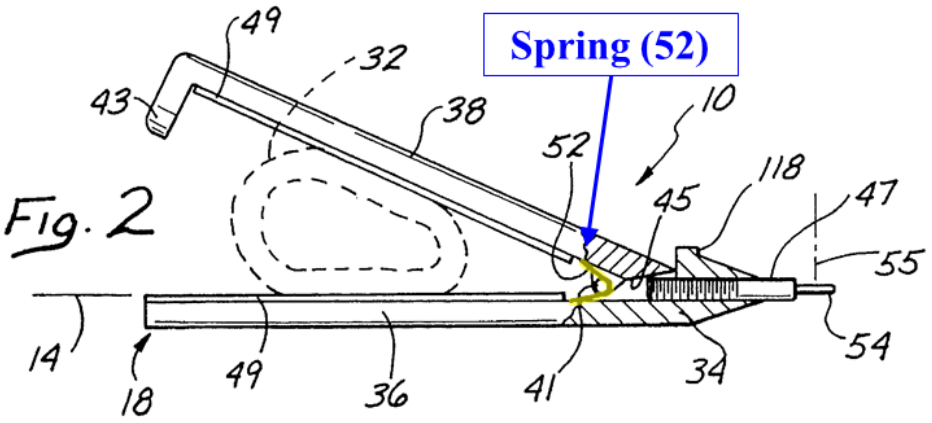
7. Claim 7

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 Figure 17, Sackier discloses the clip legs (36a, 38a) are separated from one another by a spring member (spring 152) positioned between the clip legs.



The spring member (152) is biased to urge the clip legs (36a, 38a) away from one another. (Ex. 1008, 9:30-32 ("[T]he jaws 36a and 38a are preferably biased to the open position, for example by a spring 152.")). The spring member (152) is located between the clip legs (36a, 38a), both in terms of being located within the area between the clip legs as well as being located in series between the clip legs. (Ex. 1025, ¶ 53).

Sackier also discloses that instead of having two pivotal clip legs (jaws 36a, 38a) as shown in Figures 15-17, the embodiment depicted in Figures 15-17 "can . . . be formed with the jaw 38a in a fixed relationship to the supporting structure 34a and the jaw 36a pivotal relative to the supporting structure 34a on a hinge 41a in the manner previously discussed." (Ex. 1008, 9:25-30). One of the "manner[s] previously discussed" is depicted in Figure 2 (reproduced and annotated below), which includes a spring member (spring 52) located between clip legs:



The spring member (52) separates the clip legs from one another and is biased to urge the clip legs away from one another. (Ex. 1008, 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."); *see also id.*, 9:5-12). As shown in Figure 2, the spring member (52) is located between the clip legs, both in terms of being located within the area between the clip legs as well as being located in series between the clip legs. (Ex. 1025, ¶ 54).

8. Claim 8

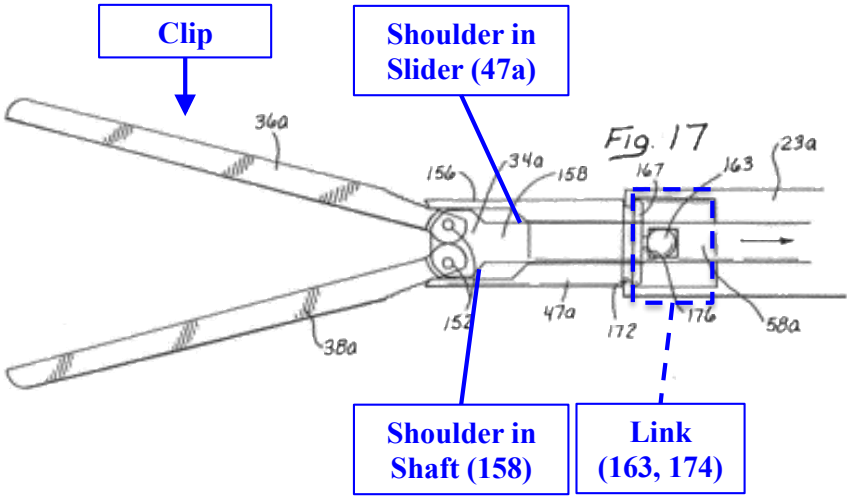
Claim 8 depends from claim 1 and further requires "the link comprises the distal end of the control wire and the proximal end of the clip." Sackier discloses this limitation, for the reasons in Section V.A.1.e, *supra* at pp. 19-23. (Ex. 1025, ¶ 55).

9. Claim 9

Claim 9 depends from claim 1 and further requires that "the control wire is reversibly operable." Sackier discloses this limitation, for the reasons in Section V.A.1.e and f and V.A.3-4, *supra* at pp. 19-25, 28-31. (Ex. 1025, ¶ 56).

10. 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." As shown below in annotated Figure 17, Sackier discloses a lock pawl including the shoulder in sleeve (47a), which inhibits proximal movement of the link (163, 174) at a predetermined location (*i.e.*, where the shoulder in the shaft 158 contacts the shoulder in the sleeve (47a)).

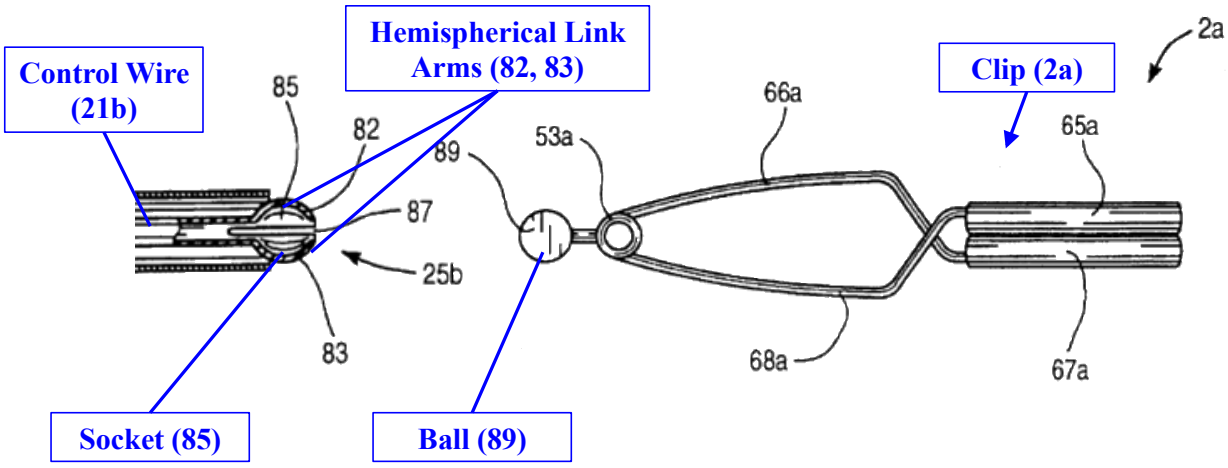


(Ex. 1025, ¶ 57; *see also* Section V.A.3, *supra* at pp. 28-29). In addition, Sackier discloses a lock arrangement for locking the clip within the lock sleeve (including projection 156 on the sleeve (47a) which engages recesses 154 on the clip legs (36a, 38a)), for the reasons in Sectoin V.A.5, *supra* at pp. 32-33. The lock arrangement and shoulder in sleeve (47a) act as a pawl, locking the clip (10a) in place and inhibiting proximal movement of the link (163, 174). The lock pawl is associated with the link (163, 174) such that it prevents the clip (10a) from moving

proximally as the control wire (58a) is moved proximally, thereby allowing the link between the clip (10a) and the control wire (58a) to separate. (Ex. 1025, ¶ 57; *see also* Ex. 1008, 9:16 – 10:34).

11. Claim 11

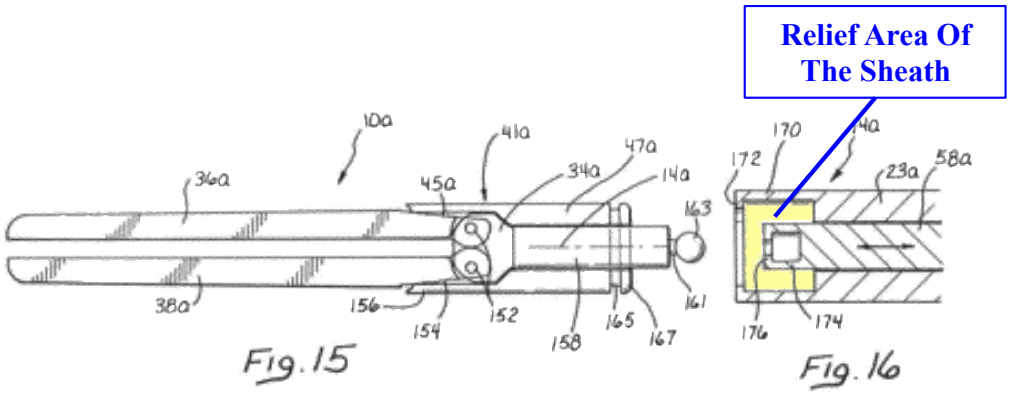
Claim 11 depends from claim 1 and further requires "the first and second arms of the link are configured to automatically move radially outward at a relief area of the sheath when a tensile load is applied to the arms via the control wire due to resilience." As explained above in Section V.A.1.e, *supra* at pp. 19-23, and as shown below in annotated Figures 5B (left) and 6A (right), Rapacki discloses linking a control wire (21b) and clip (2a) via a ball (89), and a socket (85) defined by link arms (82, 83) that move radially outward. (Ex. 1025, ¶ 58).



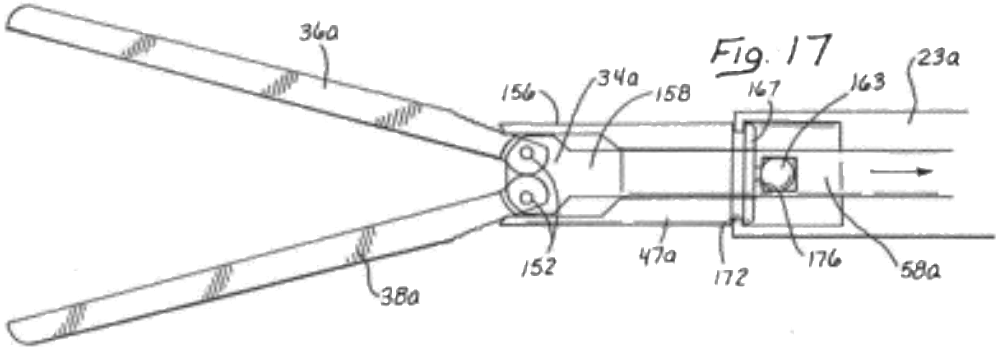
The arms (82, 83) of the link are specifically "configured to grasp [the] ball-shaped handle" of the clip (10a) and automatically move radially outward due to resilience. (Ex. 1021, 9:54-56; *see also id.*, 9:57-60 (arms (82, 83) are "biased radially outward").

It would have been obvious to substitute the hemispherical shaped arms (82, 83) in Rapacki for the cylinder 174 in Sackier, for the reasons in Section V.A.1.e, *supra* at pp. 19-23. The skilled artisan would have expected that because the Rapacki arms (82, 83) were specifically configured to grasp a ball shape, the same arms would offer an improvement in grasping and releasing the Sackier ball (163), in comparison with the cylinder 174 described in Sackier. In addition, the person of ordinary skill would have expected that this modification would advantageously decrease the force required to separate the link between the clip (10a) and the control wire (58a), making these components easier to separate. (Ex. 1025, ¶ 59).

Substituting the hemispherical shaped arms (82, 83) from Rapacki for the Sackier cylinder 174 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. *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). To accomplish this substitution, the person of ordinary skill would have found it obvious to move proximally the relief area of the sheath (highlighted in yellow below in annotated Figure 16),



so that the arms (82, 83 in Rapacki) would be constrained within the outer tube (23a) when the clip is in the open configuration (the open configuration is shown below in Figure 17),



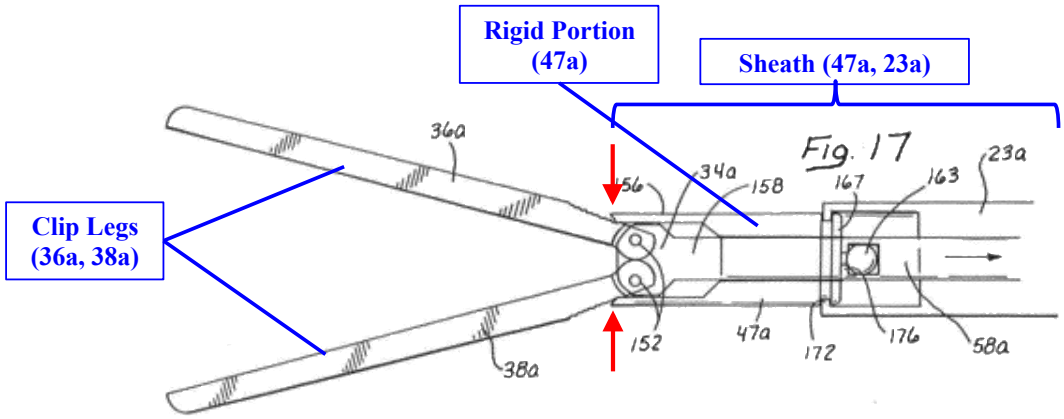
and the arms (82, 83 in Rapacki) would move radially outward at the relief area only after the clip (10a) has been closed and a tensile force has been applied to the arms (82, 83 in Rapacki) via the control wire. (Ex. 1025, ¶ 60).

The combination of Sackier and Rapacki, therefore, would include first and second arms of the link (82, 83 from Rapacki), which are configured to automatically move radially outward at a relief area of the sheath (the relief area is within the lumen of outer tube (23a), shown in Sackier Figure 17) when a tensile

force is applied to the arms via the control wire (58a) due to resilience. (Ex. 1025, ¶ 61).

12. 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 17, a distal portion of the sheath (23a + 47a) is comprised of a rigid portion (slide 47a):



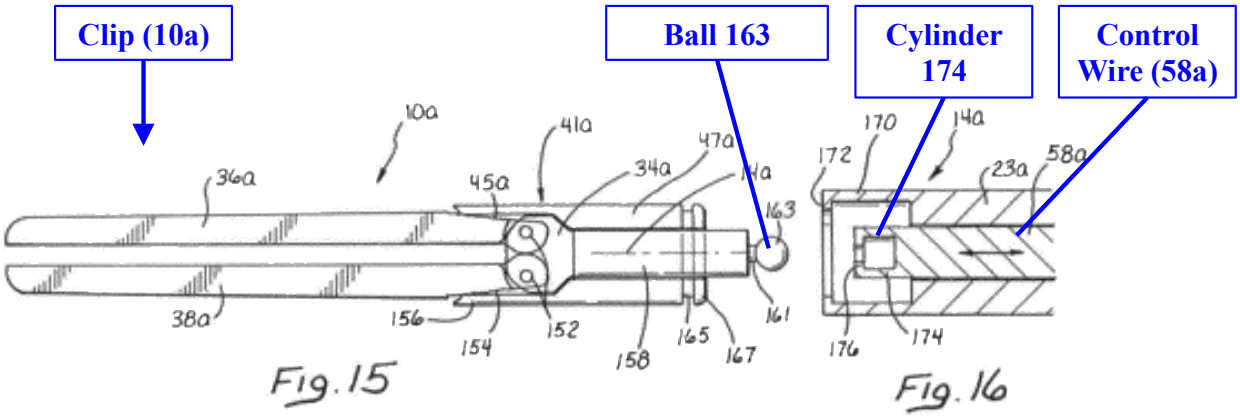
(Ex. 1025, ¶ 62). The first and second legs (36a, 38a) are configured to move radially inward when the clip is drawn proximally relative to the sheath due to a compressive force (indicated in annotated Figure 17 above by red arrows) between the rigid portion (47a) (which is part of the sheath (23a + 47a)) and the first and

second legs. (Ex. 1008, 9:16 – 10:34; Ex. 1025, ¶ 62; *see also* Section V.A.6, *supra* at pp. 34-36.

13. Claim 13

Claim 13 depends from claim 1 and 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 Sackier. (Ex. 1025, ¶ 63).

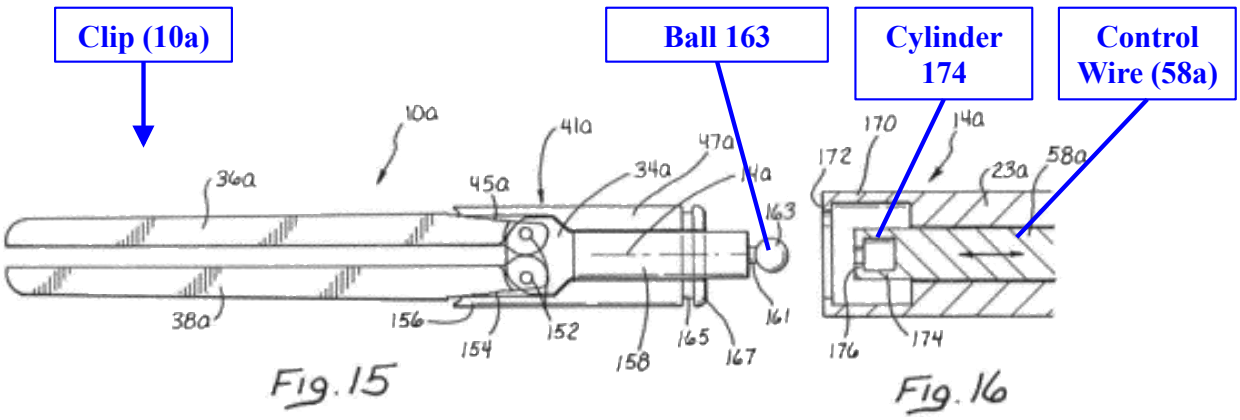
As shown below in annotated Figures 15 and 16, the ball 163 of the link is part of, and formed integrally with, the clip (10a), and the cylinder 174 of the link is part of, and formed integrally with, the control wire (58a):



(Ex. 1008, 9:60-64, 10:18-19; Ex. 1025, ¶ 63).

14. 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 15 and 16, the ball 163 of the link is not formed integrally with the control wire (58a), and the cylinder 174 of the link is not formed integrally with the clip (10a):



(Ex. 1008, 9:60-64, 10:18-19). Therefore, the link is not formed integrally with the control wire or the clip. (Ex. 1025, ¶ 65).

15. 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. 1025, ¶ 66).

As explained below, claims 15-29 would have been obvious to a person of ordinary skill in the art for the reasons explained above in Sections V.A.1-14, *supra* at pp. 16-47.

a. "A medical device, comprising"

Sackier discloses a medical device for the reasons in Section V.A.1.a, *supra* at p. 16. (Ex. 1025, ¶ 67).

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

Sackier discloses a clip (10a) having first and second clip legs (36a, 38a), for the reasons in Section V.A.1.b, *supra* at p. 17. (Ex. 1025, ¶ 68).

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"

Sackier in combination with Rapacki discloses a control wire (58a) coupled to the clip (10a), the control wire (58a) being movable relative to a sheath (23a + 47a) to open and close the clip legs (36a, 38a), a proximal end of the clip (10a) having a ball 163 received in cylinder 174 at the distal end of the control wire (58a), for the reasons in Sections V.A.1.c-f, *supra* at pp. 17-25. For the reasons in Sections V.A.1, 2, and 11, *supra* at pp. 16-28, and 42-45, it would have been obvious: (1) to reverse the positions of the cylinder 174 and the ball 163, so that the ball 163 was on the distal end of the control wire (58a) and the cylinder 174 was on the proximal end of the clip (10a); and (2) to substitute the hemispherical shaped arms (82, 83) in Rapacki for the cylinder 174 in Sacker. (Ex. 1025, ¶ 69).

The resulting medical device would include a control wire (58a) coupled to the clip (10a), the control wire (58a) being movable relative to a sheath (47a, 23a)

to open and close the clip legs (36a, 38a), a distal end of the control wire (58a) having a ball 163 received between legs (Rapacki arms (82, 83)) of the clip (10a). (Ex. 1025, ¶ 70).

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"

The combination of Sackier and Rapacki discussed above with respect to claim 2 discloses the sheath (47a, 23a) encloses a distal portion of the control wire (58a), where the control wire (58a) is configured to release from the clip (10a) as the legs of the clip (Rapacki arms (82, 83)) spread laterally away from the control wire (58a), for the reasons in Sections V.A.1 and 11, *supra* at pp. 16-25 and 42-45. (Ex. 1025, ¶ 71).

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."

Sackier discloses an actuator (12a) coupled to the control wire (58a) to move the control wire (58a) relative to the sheath (47a, 23a) and to release the control wire (58a) from the clip (10a), for the reasons in Section V.A.1.f, *supra* at pp. 24-25. (Ex. 1025, ¶ 72).

16. Claim 16

Claim 16 depends from claim 15 and further requires "the legs are formed integrally with the clip." Sackier modified in view of Rapacki discloses that the legs (Rapacki arms (82, 83)) are formed integrally with the clip (10a), for the reasons in Section V.A.13, *supra* at p. 46. (Ex. 1025, ¶ 73).

17. 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." Sackier modified in view of Rapacki discloses the distal end of the control wire (58a) comprises an increased diameter portion having a substantially spherical cross section (ball 163), for the reasons in Sections V.A.1, 2, and 11, *supra* at pp. 16-28, and 42-45. (Ex. 1025, ¶ 74).

18. 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." Sackier discloses this limitation, for the reasons in Section V.A.3, *supra* at pp. 28-29. (Ex. 1025, ¶ 75).

19. Claim 19

Claim 19 depends from claim 18, and further requires "before the clip is separated from the control wire, moving the sheath proximally relative to the control wire moves the clip out of the lock sleeve, opening the clip legs." Sackier discloses this limitation, for the reasons in Section V.A.4, *supra* at pp. 30-31. (Ex. 1025, ¶ 76).

20. 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." Sackier discloses this limitation, for the reasons in Section V.A.5, *supra* at pp. 32-33. (Ex. 1025, ¶ 77).

21. 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." Sackier discloses this limitation, for the reasons in Section V.A.6, *supra* at pp. 34-36. (Ex. 1025, ¶ 78).

22. 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." Sackier discloses this limitation, for the reasons in Section V.A.7, *supra* at pp. 37-38. (Ex. 1025, ¶ 79).

23. Claim 23

Claim 23 depends from claim 15, and further requires "the control wire is reversibly operable." Sackier discloses this limitation, for the reasons in Section V.A.9, *supra* at p. 39. (Ex. 1025, ¶ 80).

24. 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." Sackier discloses this limitation, for the reasons in Section V.A.10, *supra* at pp. 40-41. (Ex. 1025, ¶ 81).

25. 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." Sackier in combination with Rapacki discloses this limitation, for the reasons in Section V.A.11, *supra* at pp. 42-45. (Ex. 1025, ¶ 82).

26. 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." Sackier discloses this limitation, for the reasons inSectoin V.A.12, *supra* at pp. 45-46. (Ex. 1025, ¶ 83).

27. 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." Sackier modified in of Rapacki discloses this limitation, for the reasons in Section V.A.13, *supra* at p. 46. (Ex. 1025, ¶ 84).

28. Claim 28

Claim 28 depends from claim 15, and further requires "the link is not formed integrally with the control wire or the clip." Sackier modified in view of Rapacki discloses this limitation, for the reasons in Section V.A.14, *supra* at p. 47. (Ex. 1025, ¶ 85).

B. Ground 2: There Is A Reasonable Likelihood That Claims 29 And 30 Are Anticipated By Sackier (Ex. 1008)

1. Independent Claim 29

a. "A method, comprising"

Sackier discloses "[a] method for operating [a] clamp." (Ex. 1008, 3:1-2; *see also id.*, 9:5-7, Figures 11-19; Ex. 1025, ¶ 86).

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"

Sackier discloses inserting into a body a medical device comprising a clip (*i.e.*, a "clamp"). (Ex. 1008, 1:6-8 ("clamps and clamp appliers for use in occluding body conduits"); *see also id.*, 3:1-15, 9:5-12, 11:57-64, 14:5-24; Ex. 1025, ¶ 87).

The medical device comprises a clip (10a) having first and second clip legs (36a, 38a), a control wire (58a), a sheath (23a + 47a) enclosing the control wire (58a) and a proximal portion of the clip (10a), for the reasons in Section V.A.1, *supra* at pp. 16-25. (Ex. 1025, ¶ 88).

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

Sackier discloses positioning the medical device at a desired deployment location: "Initially a clamp 10a is engaged by the clamp applier 12 and inserted through the trocar 25 to operatively occlude the bowel between the section 32a and 32b." (Ex. 1008, 8:29-31; *see also, e.g.*, 11:57-64; Ex. 1025, ¶ 89).

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

Sackier discloses moving the control wire (58a) distally relative to the sheath (47a, 23a) to deploy the first and second clip legs (36a, 38a) distally from the sheath, for the reasons in Sections V.A.1 and 4, *supra* at pp. 16-25 and 30-31. (Ex. 1025, ¶ 90).

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

Sackier discloses adjusting a position of the clip (10a) so that target tissue is received between the clip legs (36a, 38a): "the clamp applier can be operated to open and close the clamp 10 about a body conduit, such as a bowel 32." (Ex. 1008, 4:35-37; *see also id.*, 3:14-15; Ex. 1025, ¶ 91).

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"

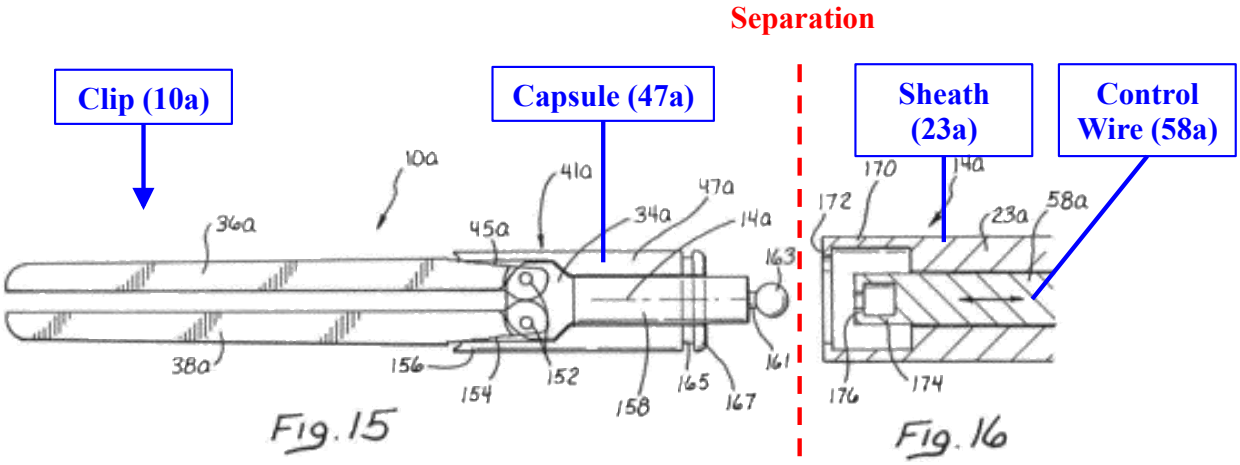
Sackier discloses drawing the control wire (58a) proximally relative to the sheath (47a, 23a), to draw the clip into the sheath to receive the target tissue between the first and second clip legs (36a, 38a), for the reasons in Sections V.A.1 and 3, *supra* at pp. 16-25, and 29-29. (*See also* Ex. 1008, 3:14-15 ("[B]y operating the shaft to close the jaws of the clamp, the body conduit can be occluded."); Ex. 1025, ¶ 92).

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."

Sackier discloses applying a tensile force of at least a threshold level to the control wire (58a) to separate a separable link (ball 163 separates from flange 176 (located at the opening of cylinder 174)), coupling the control wire (58a) to the clip (10a), for the reasons in Section V.A.1, 6, and 11, *supra* at pp. 16-25, 34-36, and 42-45. (*See also* Ex. 1008, Figures 15 and 16, Abstract, 2:56-59, 8:29-34, 8:51-53, 9:60 – 10:34; Ex. 1001, ¶ 93).

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 Figures 15 and 16, Sackier discloses the separation uncoupling the clip (10a) from the control wire (58a) and separating a capsule (47a) of the sheath (47a + 23a) from the rest of the sheath:[6]



(Ex. 1008, 10:4-27; *see also* Section V.A.1, *supra* at pp. 16-25; Ex. 1001, ¶ 94).

[6] As discussed above in Section IV.E.1, *supra* at p. 12, 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 slide 47a both as a component of the "sheath" and as a "capsule" that separates from the sheath.

The capsule 47a, furthermore, locks the clip over the coupled target tissue,

for the reasons in Sections V.A.4 and 5, *supra* at pp. 30-33. (Ex. 1025, ¶ 95).

C. Ground 3: There Is A Reasonable Likelihood That Claims 14 And 28 Would Have Been Obvious In View Of Sackier (Ex. 1008) In Combination With Rapacki (Ex. 1021) And Gourlay (Ex. 1018)

Gourlay issued on April 19, 1994 and qualifies as prior art at least under 35 U.S.C. §§ 102(a), (b), and (e). Gourlay was not cited during prosecution of the '048 patent.

1. Claim 14

Claim 14 depends from claim 1 and further requires that "the link is not formed integrally with the control wire or the clip." Sackier discloses this limitation for the reasons in Section V.A.14, *supra* at p. 47. In particular, in Sackier the ball 163 of the link is not formed integrally with the control wire (58a), and the cylinder 174 of the link is not formed integrally with the clip (10a). (Ex. 1025, ¶ 96).

To the extent the Board determines that this limitation requires that a component of the link not be formed integrally either with the clip *or* the control member, claim 14 nevertheless would have been obvious. 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 (here, two) 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. 1025, ¶ 97).

The skilled artisan would have found it obvious to apply this general principal to a link between a clip and a control wire. As shown below in annotated Figures 3 and 5A (Figure 3 is a cross-sectional view of clamp applier shown in Figure 5A), Gourlay discloses a clip (clamp 24 (Figure 5A)) coupled to a control wire (linkage 18 (Figure 3, highlighted in blue)) via a component of a link (arms 20 (highlighted in yellow in Figure 3)) that is not formed integrally with either the control wire (18) or the clip (2a):

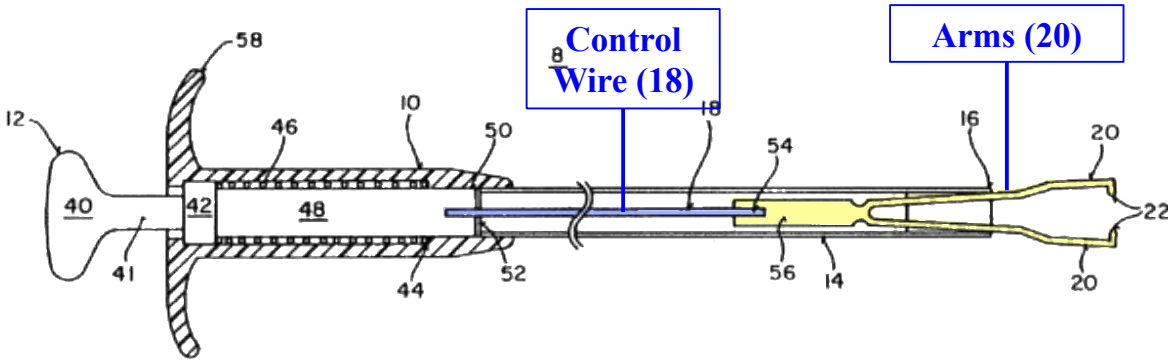


FIG. 3

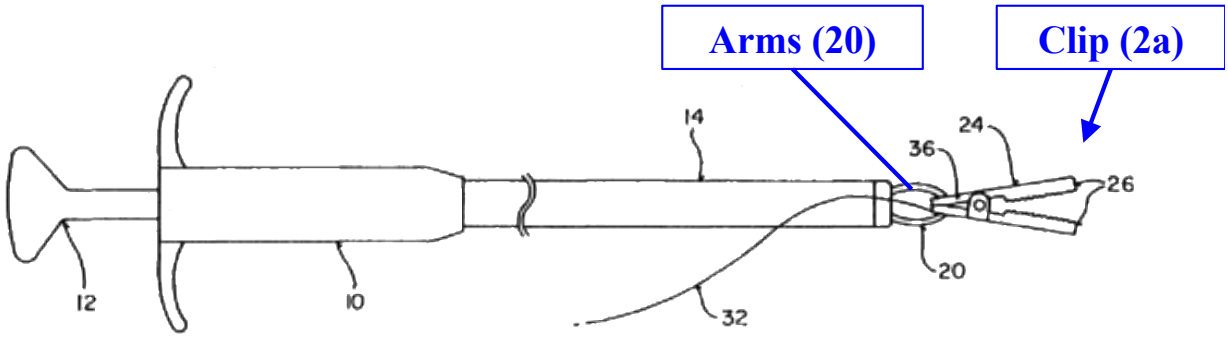


FIG. 5A

(Ex. 1018, 5:22-28 ("Linkage 18 [(control wire)], [is] usually a steel rod . . . Distal end 54 of linkage 18 is attached to proximal portion 56 of arms 20. Arms 20, [are] preferably of stainless steel . . . ."). (Ex. 1025, ¶ 98).

It would have been obvious to one of ordinary skill in the art in view of Gourlay to modify the link in Sackier Figures 15-17 so that it is not formed integrally either with control wire (58a) or the clip (10a). (Ex. 1025, ¶ 99). The skilled artisan would have recognized that such a modification would be advantageous, 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 a component of the link not integral with either the control wire or the clip. (Ex. 1025, ¶ 99).

Modifying a component of the link in Sackier so that it is not integral with the control wire or the clip 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. 1025, ¶ 100). *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 modify the components of the link in Sackier to not be formed integrally with the control wire or the clip, as shown in Gourlay's link (56). For example, it would have been obvious to form the cylinder (174) of the link in Sackier separately from the control wire (58a), or to form the ball (163) of the link separately from the clip (10a). (Ex. 1025, ¶ 100).

2. Claim 28

Claim 28 depends from claim 15, and further requires "the link is not formed integrally with the control wire or the clip." This claim would have been obvious, for the reasons in Section V.A.14, *supra* at p. 47. (Ex. 1025, ¶ 101).

VI. CONCLUSION

There is a reasonable likelihood that Petitioners will prevail in their challenge of patentability for claims 1-30 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 9,378 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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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, 1008, 1012-13, 1017, 1018, 1021, and 1023-25 have been served in their entirety on October 27, 2016, by Federal Express (Overnight Delivery) on:

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