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. 8,709,027
Issue Date: April 29, 2014

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,709,027

Case No. IPR 2017-00134

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TABLE OF EXHIBITS

Cook Group Incorporated and Cook Medical LLC (collectively "Petitioners"), respectfully request *inter partes* review of claims 1-20 of U.S. Patent No. 8,709,027 ("the '027 patent") (Ex. 1001). The 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 '027 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. 2017-00133, which also challenges the patentability of claims 1-20 of the '027 patent, and with petitions for *inter partes* review filed in IPR Nos. 2017-00131 and 2017-00132, which challenge the patentability of the claims of a related patent, U.S. Patent No. 8,685,048.

2. Related Pending Applications

The following patent applications are related to the ’027 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 '027 PATENT

A. Description Of The Alleged Invention Of The '027 Patent

The '027 patent relates generally to compression clips that can be used "to cause hemostasis of blood vessels located along the gastrointestinal tract. . ." (*See* Ex. 1001, 1:21-24). The clips stop internal bleeding by clamping together the edge of a wound to achieve "hemostasis." (*Id*. at 2:38-40). The patent acknowledges that such clipping devices were known in the art before the '027 patent was filed. (*See id.*, pp. 1-2 (citing numerous prior art references); 1:50-52 (describing

"Olympus Endoclips"); 2:31-38 (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")).

For example, a person of ordinary skill in the art would have been familiar with prior art clip devices in the form of forceps. (Ex. 1015, ¶¶ 18-20). 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]

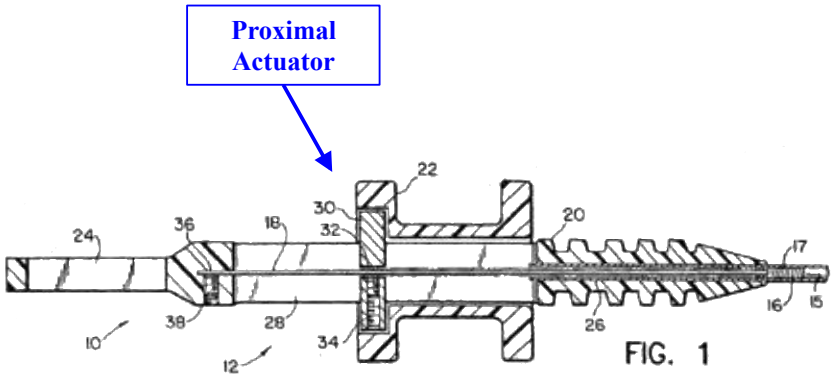
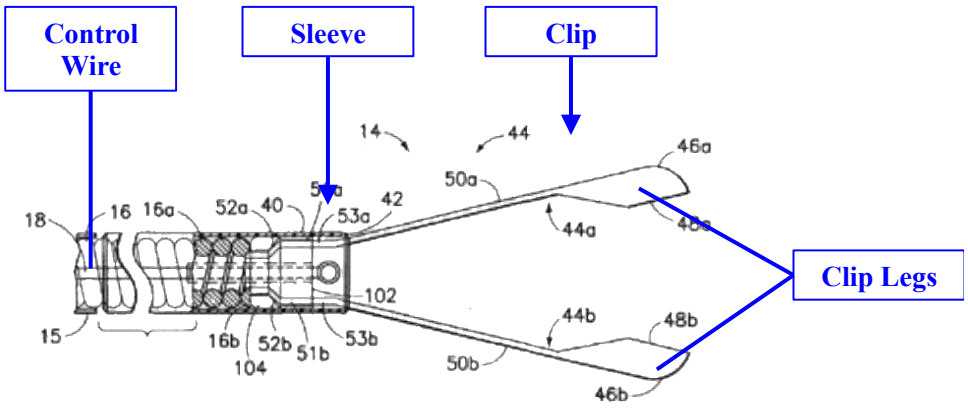


FIG. 1

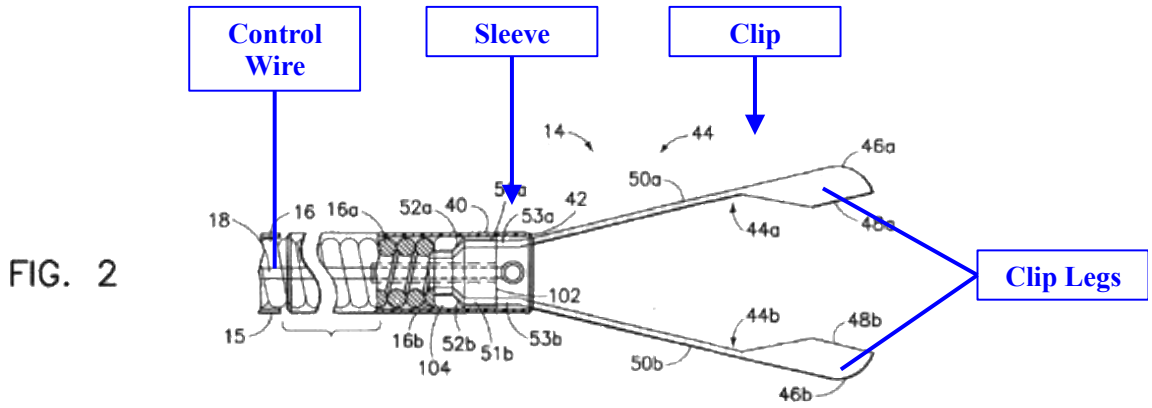
[1] Palmer issued on July 8, 1997, and names as an inventor Vincent A. Turturro – one of the named inventors of the '027 patent. Palmer was not cited during prosecution of the '027 patent.

FIG. 2

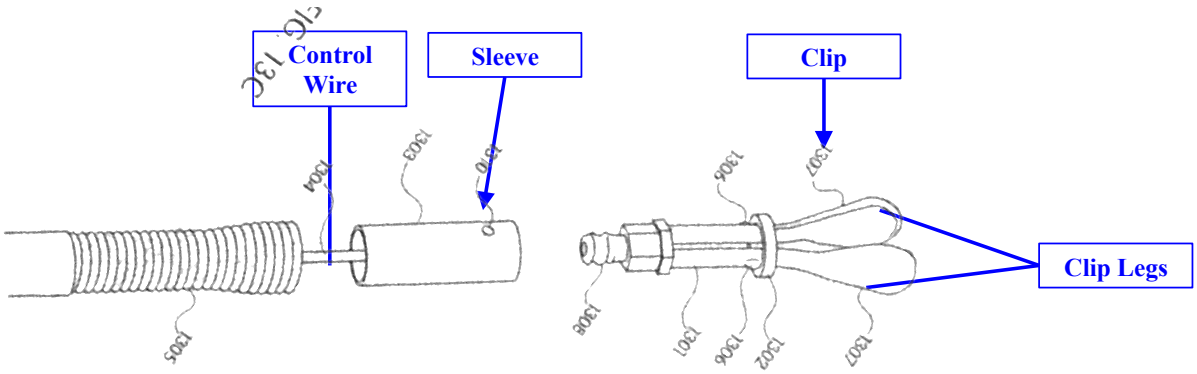


The forceps (also referred to as a "bioptome") includes a proximal actuator (handle portion 12, Figure 1), and a "distal end effector portion 14" (Figure 2) including a clip (jaw assembly 44) with two clip legs (end effectors 44a, 44b, with jaw cups 46a, 46b). (Ex. 1017, 5:50-53, 6:64 – 7:6). In addition, 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).

The named inventors of the '027 patent were aware of prior art forceps, and acknowledged in their specification that structures described in the '027 patent are "analogous to biopsy forceps." (*See* Ex. 1001, 5:45-46). Indeed, as shown below in annotated Figures 2 (Palmer) and 13C ('027 patent), the structures depicted in Figure 13C of the '027 patent are virtually identical to the structures depicted in Figure 2 of Palmer such that there is no distinction between jaws in one and clips in the other:



Palmer, Figure 2

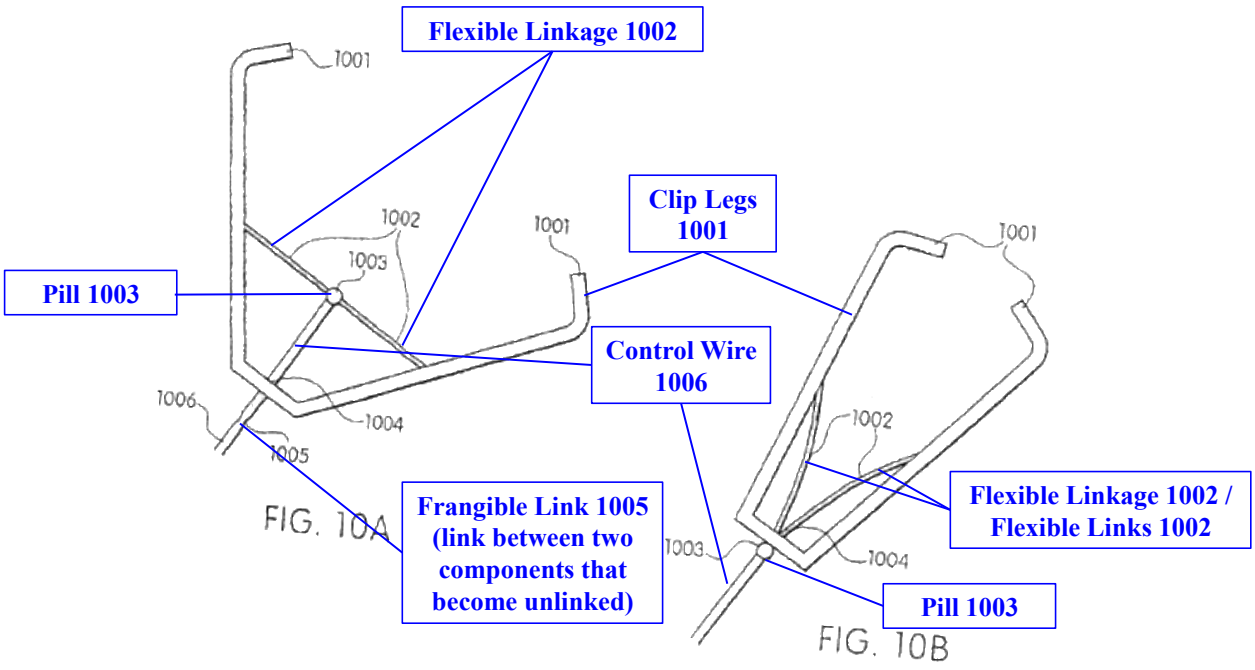


'027 Patent, Figure 13C

Consistent with the prior art, independent claims 1, 13, and 20 describe medical devices and methods including "*a clip*" and a "*control member* extending from a proximal actuator to the clip." Independent claims 13 and 20 further describe a "*sleeve*" housing a portion of the clip, and movable relative to the clip. In addition, each of these claims describes a "*linkage*" that "spread[s]" the clip legs apart from one another (claims 1 and 13), that "drive[s]" the clip legs radially outward as the control member is moved distally (claims 1, 13, and 20), and that "move[s]" the clip distally relative to a sleeve (claims 13 and 20). (*See id.* at

15:32-17:6.)

Figures 10A and 10B (reproduced and annotated below) depict the only "linkage" ("flexible linkage 1002") identified and described as such in the '027 patent:



(*See also id.*, 8:60-9:25). The device includes a clip (including clip legs 1001), a control member (control wire 1006), a "frangible link 1005" (taper in the control wire 1006), and a "flexible linkage 1002." According to the specification, the "flexible linkage 1002" is used to close and lock the clip legs 1001 as the control wire 1006 is moved proximally:

> *[T]he clip legs 1001 are closed by drawing the two flexible links 1002 proximally*, in the direction of the control wire 1006, while a compressive

> force is applied to the base of the clip legs 1001 by a rigid sheath (not shown). This in turn pulls the legs of the clip toward each other. FIG. 10A shows the clip legs 1001 in an open position. FIG. 10B shows the clip legs in a closed position. The *clip legs 1001 are locked in a closed position* when the pill 1003, located at the center of the flexible linkage 1002, is drawn through a one way hole 1004 in the center of the clip legs 1001.

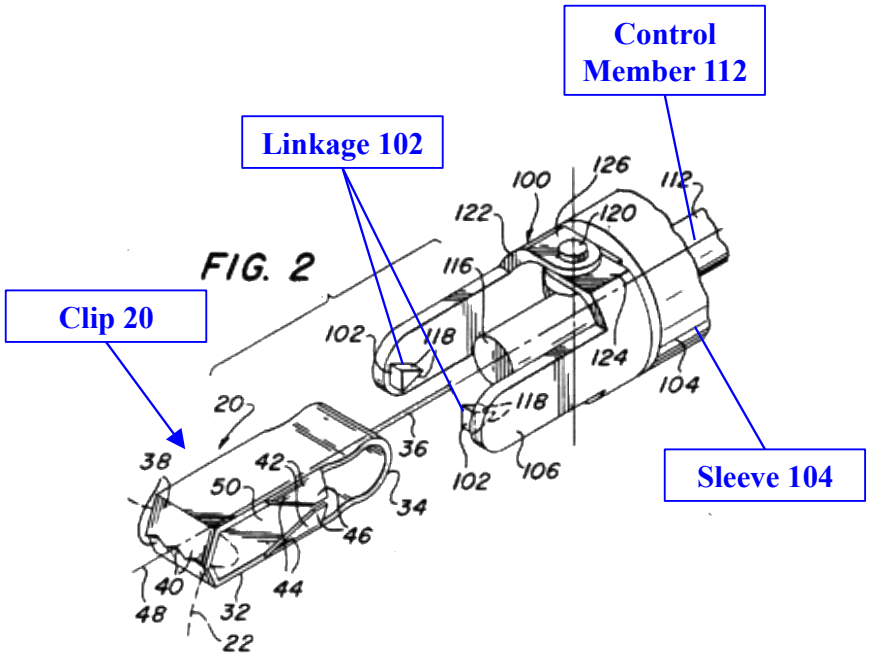
(*Id.*, 8:67-9:9). The specification does not describe using the "flexible linkage 1002" to spread open, or drive outward the clip legs 1002. (Ex. 1015, ¶¶ 18-20). Nor does the specification describe a "sleeve" housing a portion of the clip, and movable relative to the clip. (Ex. 1015, ¶¶ 18-20). However, the specification states that these variations would have been obvious:

> *It will be obvious to those skilled in the art*, having regard to this disclosure, that other variations on this invention beyond those specifically exemplified here may be made. These variations include, but are not limited to, *different combinations of clips, closing mechanisms, locking mechanisms, frangible links, and clip leg formations*.

(*Id*., 15:22-27).

B. Summary Of The Prosecution History

During prosecution, the Examiner rejected independent claims 1 and 13 (application claims 46 and 58) as anticipated by U.S. Patent No. 5,242,456 ("Nash '456"). (*See* Ex. 1002, Office Action dated August 29, 2013). Figure 2 of Nash '456 is reproduced below, and depicts the claimed "clip," "control member," "linkage," and "sleeve," as identified by the Examiner:



(Exhibit 1006, Nash '456). BSSI did not dispute that Nash '456 discloses a "clip" (clip 20), "control member" (pusher member 112), "linkage" (trunnion 102), or "sleeve" (body portion 104). Instead, BSSI distinguished Nash '456 on the basis that the control member ("pusher member 112") does not move distally *relative to the clip* ("clip 20"). (Ex. 1002, Response dated November 26, 2013, pp. 4-5). According to BSSI, "the pusher member 112 [of Nash '456] maintains a spatial

relationship with the clip 20 throughout the procedure." (*Id.* at 4). In contrast, the "novel concept" of the "present invention" according to BSSI is having "a control wire *movable relative to the clip* which also controls radial expansion of the clip." (*Id.* (emphasis added)). The Examiner subsequently issued a Notice of Allowance based on BSSI's argument. (*Id*., Notice of Allowance dated December 27, 2013).

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

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

Petitioners certify that the '027 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 1-20 of the '027 patent (Ex. 1001) 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, 3-6, 13-15, 17, and 20 are anticipated under § 102 by U.S. Patent No. 5,749,881 ("Sackier")
2	Claims 1-20 are obvious under § 103 in view of Sackier in combination with U.S. Patent No. 5,843,000 ("Nishioka")
3	Claims 1-12 and 20 are anticipated under § 102 by U.S. Patent No. 5,626,607 ("Malecki")
4	Claims 1-12 are obvious under § 103 in view of Malecki

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 discloses the same claim limitations.

[2] The '027 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 '027 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. (Ex. 1015, ¶ 11). This person would also have an understanding of engineering or medical device design principles.[3] (Ex. 1015, ¶ 11).

In support of this Petition, Petitioners have submited the Declaration of Mark A. Nicosia, Ph.D. (Ex. 1015). 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. 1015), 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. 1015) addresses the prior art at issue from the view of a person of

[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. 1015, ¶ 11).

ordinary skill in the art in the relevant timeframe.

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 are for the purposes of *inter partes* review only,[4] Petitioners adopt the following constructions proposed by BSSI in the Litigation:

1. "a linkage"

All of the challenged claims require a "linkage" to perform the following functions:

- to *"spread*" the clip legs apart from one another (claims 1 and 13),
- to *"drive*" the clip legs radially outward (claims 1, 13, and 20), and
- to *"move*" the clip distally relative to the sleeve (claims 13 and 20).

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

In the litigation, BSSI argued that the "plain and ordinary" meaning of the word "linkage" is a structure "that transmits force between interconnected components," or that "link[s] multiple parts of the clip." (Ex. 1004 at 11, 13). In addition, BSSI has identified the following figures in the '027 patent (Figures 10A and 10B) as disclosing the claimed "linkage":

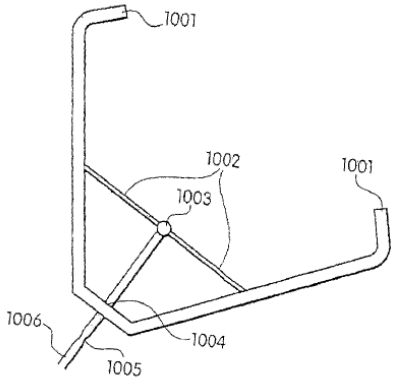


FIG. 10A

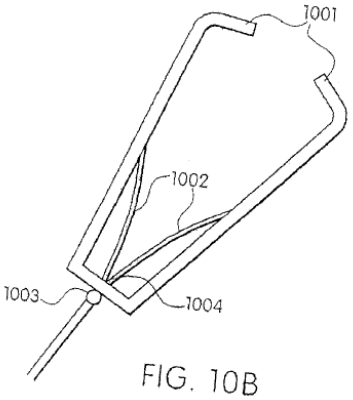


FIG. 10B

(*Id.*, pp. 12-13, n.13).

2. "operably associated with the control member"

Independent claims 1 and 13 require a linkage "operably associated with the control member." In the litigation, BSSI argued that the "plain and ordinary" meaning of "operably associated with the control member" does not require any physical connection between the linkage and the control member, but instead "only an association of operability." (Ex. 1004 at 13-14).

3. "frangible link"

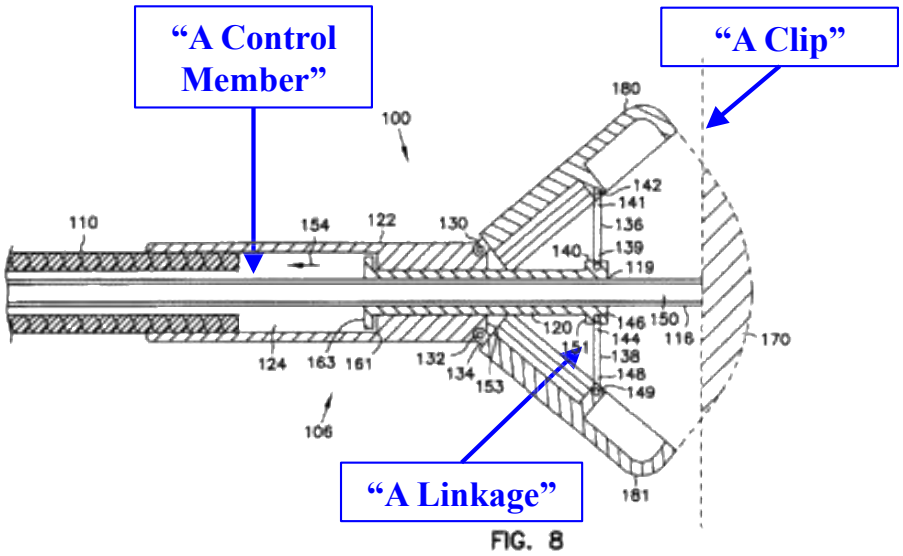
Claim 4 of the '027 patent requires a "frangible link" that couples the clip to

the control member. In the litigation, BSSI argued that the term "frangible link" means a "link between at least two components that become unlinked when a tensile load is applied." (Ex. 1004 at 22). BSSI explained that this includes a "ball-and-socket link, [where] the ball could be pulled from the socket under a tensile force, thus breaking the link, but neither the ball nor the socket would itself be broken." (*Id*.)

V. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO THE CHALLENGED CLAIMS (§§ 42.104(b)(4) AND (b)(5))

Claims 1-20 of the '027 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 Examiner. Individually and/or combined, these references disclose each and every limitation of the challenged claims, including "*a clip*," "*a control member*," and a "*linkage*" operably associated with, or coupled to, the control member:

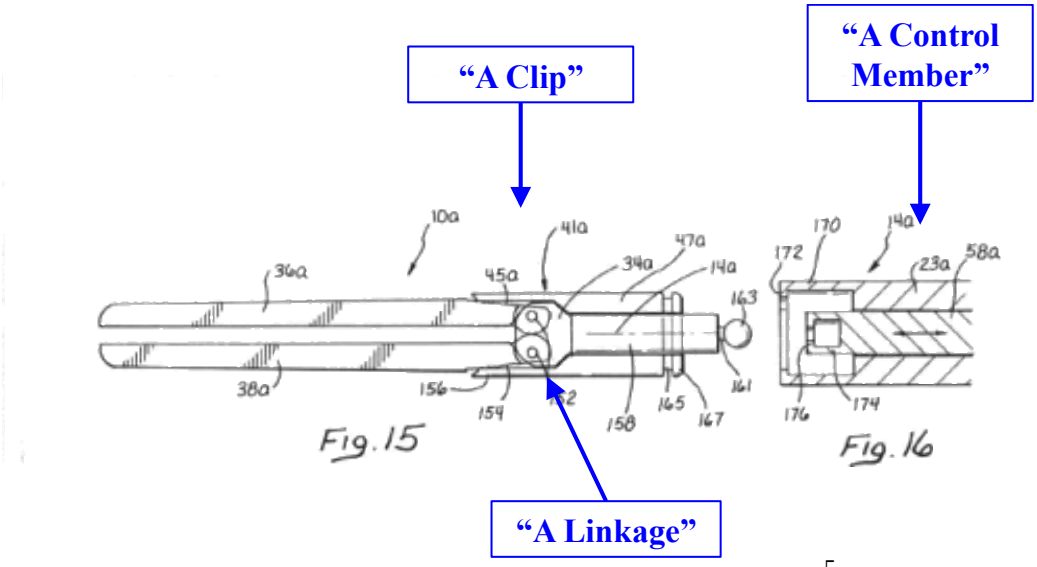
Nishioka discloses biopsy forceps with jaws that pivot via a linkage to open and close in response to movement from control wires:



Nishioka, Figure 8 (Annotated)

(Ex. 1015, ¶ 28).

Sackier discloses a clip and sleeve that detach from a control member, where the clip legs are opened through a linkage:



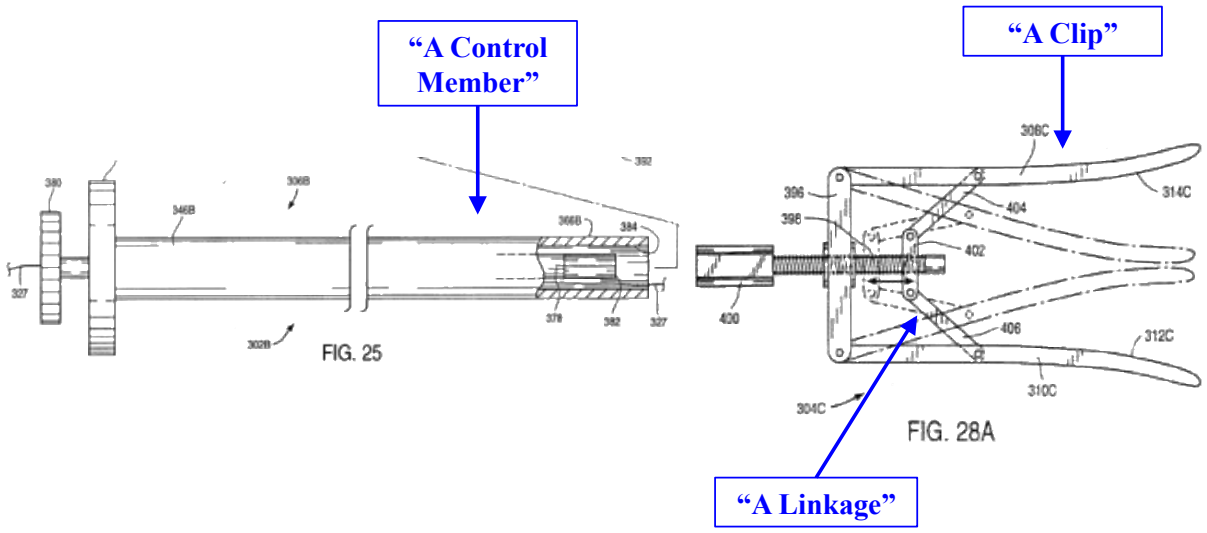
Sackier, Figures 15 and 16 (Annotated)[5]

[5] The Patent Office published Figures 15-26 of Sackier without reference numbers. (*See* Ex. 1005). However, Sackier submitted Figures 15-26 *with* reference numbers during prosecution. (Ex. 1012, Transmittal of Formal Drawings dated September 18, 1997). The version of Figures 15-26 with reference numbers constitutes 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, 1379 (Fed. Cir. 2006) (holding that figures submitted during prosecution of patent application were "printed publications" as of the issue date of the corresponding patent, even though the figures were not included in the issued patent). For ease of reference, when

(Ex. 1015, ¶ 24).

Malecki discloses a detachable clip with legs that are opened via a linkage and a control member coupled to a clamp applier:

Petitioners have reproduced any of Figures 15-26 in this petition, Petitioners have reproduced the version of these figures with reference numbers submitted during prosecution. In any event, Petitioner's discussion of Sackier, including Petitioner's discussion of these figures, applies equally to the version of Figures 15-26 without reference numbers, as published. The version of Figures 15-26 with reference numbers submitted during prosecution simply reflects what is already described and illustrated by Sackier with respect to the version of Figures 15-26 without reference numbers, as published. The version of Figures 15-26 with reference numbers can be used to help explain Sackier's disclosure. *See In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991) ("extrinsic evidence may be considered when it is used to explain, but not expand, the meaning of a reference" for purposes of an anticipation analysis under 35 U.S.C. 102).



Malecki, Figures 25 and 28A (Annotated)

(Ex. 1015, ¶ 26). In addition, as explained below, the prior art disclosed that the control member is "movable relative to the clip which also controls radial expansion of the clip" – a limitation that BSSI claimed was the "novel concept" of the claimed invention. (Ex. 1002, Response dated November 26, 2013, pp. 4-5).

The challenged claims merely describe obvious combinations of "familiar elements according to known methods," which "do[] no more than yield predictable results." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007); MPEP § 2143(I). The motivation to combine embodiments and references would have come from the references themselves, as well as from the knowledge generally available to a person of ordinary skill in the art. (*See e.g.* Ex. 1015 ¶ 64).

A. Ground 1: There is a Reasonable Likelihood That Claims 1, 3-6, 13-15, 17, and 20 Are Anticipated By Sackier (Ex. 1008)

Sackier issued on May 12, 1998 and qualifies as prior art at least under 35 U.S.C. §§ 102(a) and (b). Sackier was not cited during prosecution of the '027 patent.

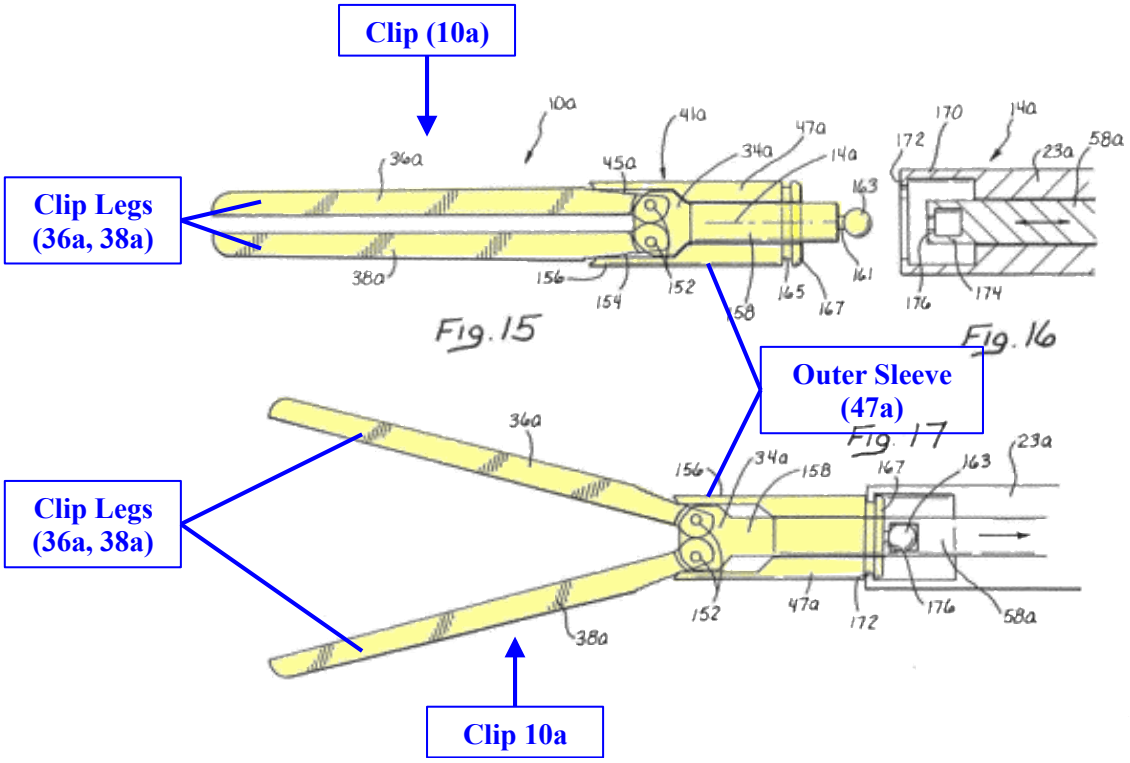
1. Independent Claim 1

a. "A medical device, comprising"

Sackier discloses a medical device: a "surgical clamp apparatus and more specifically . . . clamps and clamp appliers for use in occluding body conduits." (Ex. 1015, ¶ 30; Ex. 1008, 1:6-8; *see also* Abstract).

b. "a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface"

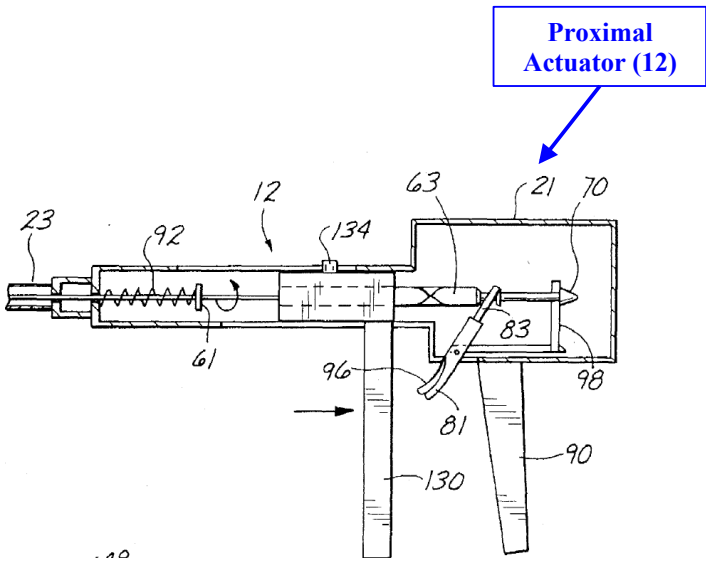
As shown below in annotated Figures 15-17, Sackier discloses a clip (clamp 10a and slide 47) having first and second clip legs (jaws 36a and 38a), each leg having an inner surface:



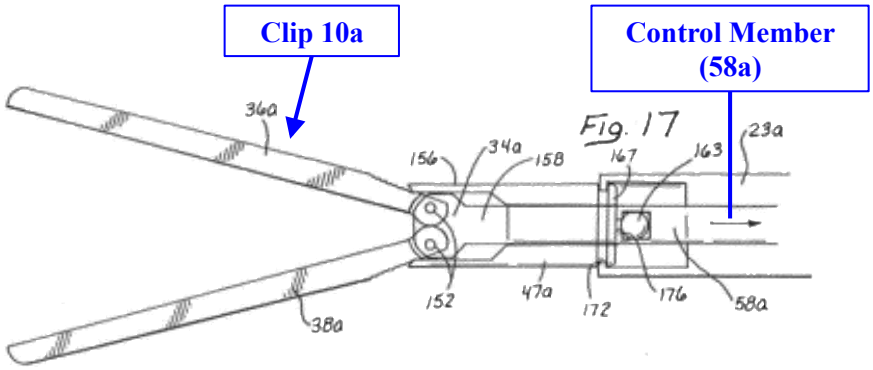
(Ex. 1015, ¶ 31; Ex. 1008, 9:16-19, 9:60-67, Figs. 15-23).

c. "a control member extending from a proximal actuator to the clip"

As shown below in annotated Figures 9 and 17, Sackier discloses a control member (inner shaft 58a (Figure 17)) extending from a proximal actuator (clamp applier 12a (*see* Figure 9)) to the clip (10a) (Figure 17):



Sackier, Figure 9 (Excerpt)

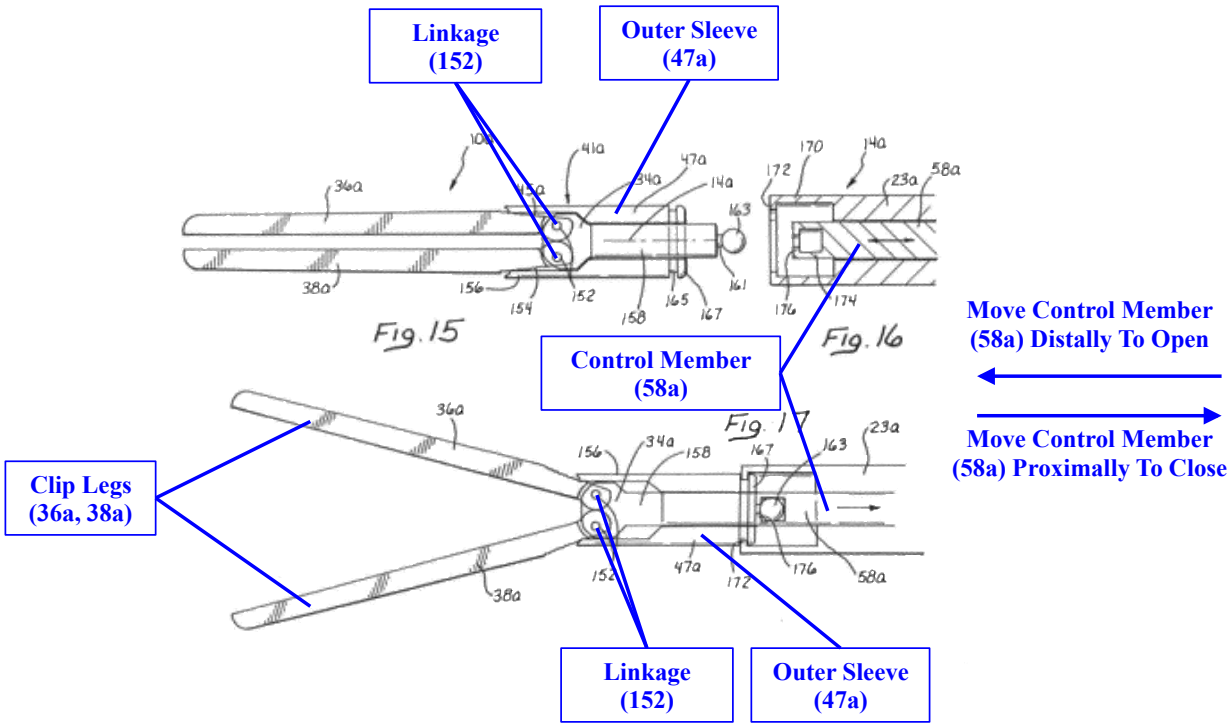


Sackier, Figure 17

(Ex. 1015, ¶ 32; Ex. 1008, 2:56-59, 9:41-48, 10:10-12, 10:27-31).

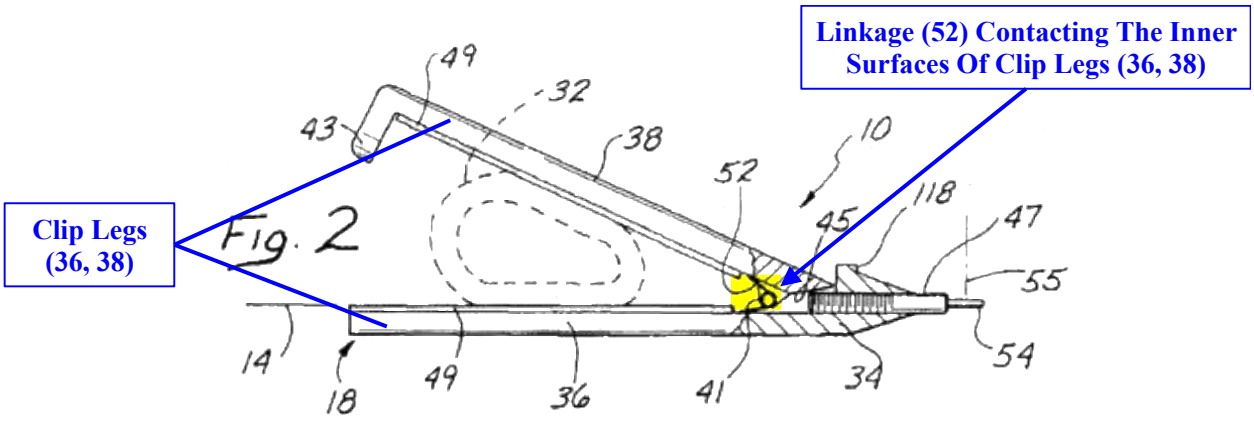
d. "a linkage operably associated with the control member to spread the first and second clip legs apart from one another into a tissue-receiving configuration as the control member is moved distally relative to the clip, the linkage contacting the inner surfaces of the first and second clip legs to drive the first and second clip legs radially outward as the control member is moved distally relative to the clip."

As shown below in annotated Figures 15-17, Sackier discloses a linkage (spring 152) operably associated with the control member (58a) "to spread" the first and second clip legs (36a, 38a) apart from one another into a tissue-receiving configuration as the control member is moved distally relative to the clip, and "to drive" the clip legs (36a, 38a) radially outward as the control member is moved distally relative to the outer sleeve 47a of the clip:



(Ex. 1015, ¶ 33; Ex. 1008, 9:19-23 (the clip legs (36a, 38a) have two relative positions: "[t]he first relative position is illustrated in FIG. 17 . . . in a generally open configuration," and a "second relative position is illustrated in FIG. 15 . . . in a generally closed configuration."), 9:30-32 ("[T]he jaws 36a and 38a are preferably biased to the open position, for example by a spring 152."), 9:41-48, 10:27-31). As shown above in Section V.A.1.b, *supra* at pp. 20-21, the clip includes outer sleeve 47a, which remains in the body when the clip is separated from the control member. (Ex. 1015, ¶ 33). Annotated Figures 15-17 above show that control member (58a) moves distally relative to clip (47a) as the linkage (152) spreads the clip legs (36a, 38a) apart. (Ex. 1015, ¶ 33).

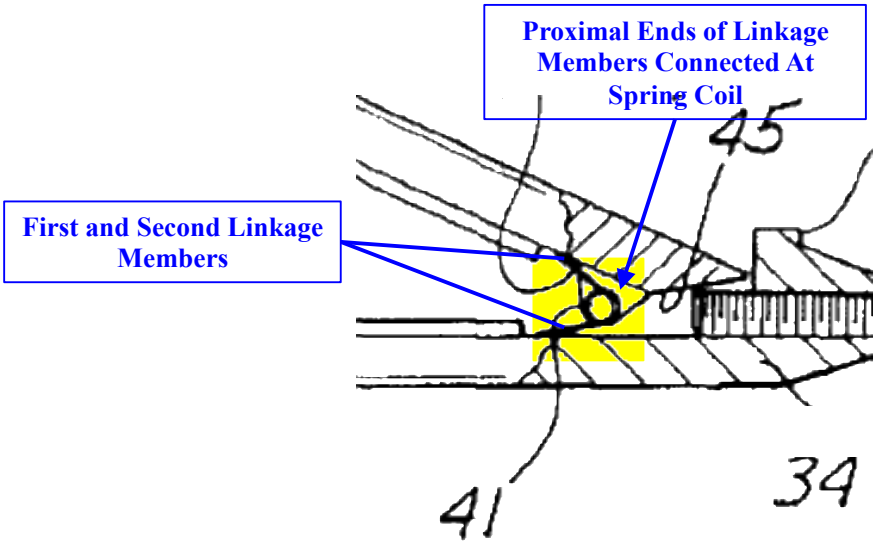
Sackier discloses biasing open the jaws 36a, 38a using a linkage (spring 152). (Ex. 1015, ¶ 34). Sackier also discloses that instead of having two pivotal clip legs (jaws 36a, 38a) as shown in Figures 15-17, the embodiment depicted in Figures 15-17 "can . . . be formed with the jaw 38a in a fixed relationship 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 linkage (spring 52) contacting the inner surfaces of the first and second clip legs to bias open the clip legs:



(Ex. 1015, ¶ 34; Ex. 1008, 5:4-12; *see also id.*, 9:5-12). The linkage (52) contacts the inner surfaces of first and second clip legs to spread open and drive outward the clip legs. (Ex. 1015, ¶ 34). Furthermore, Sackier describes spring 152 as just an "example" of what could be used to bias the jaws 36a and 38a to the open position, again confirming that spring 52 may also be used with the embodiment shown in Figures 15-17. (Ex. 1015, ¶ 34).

2. Claim 3

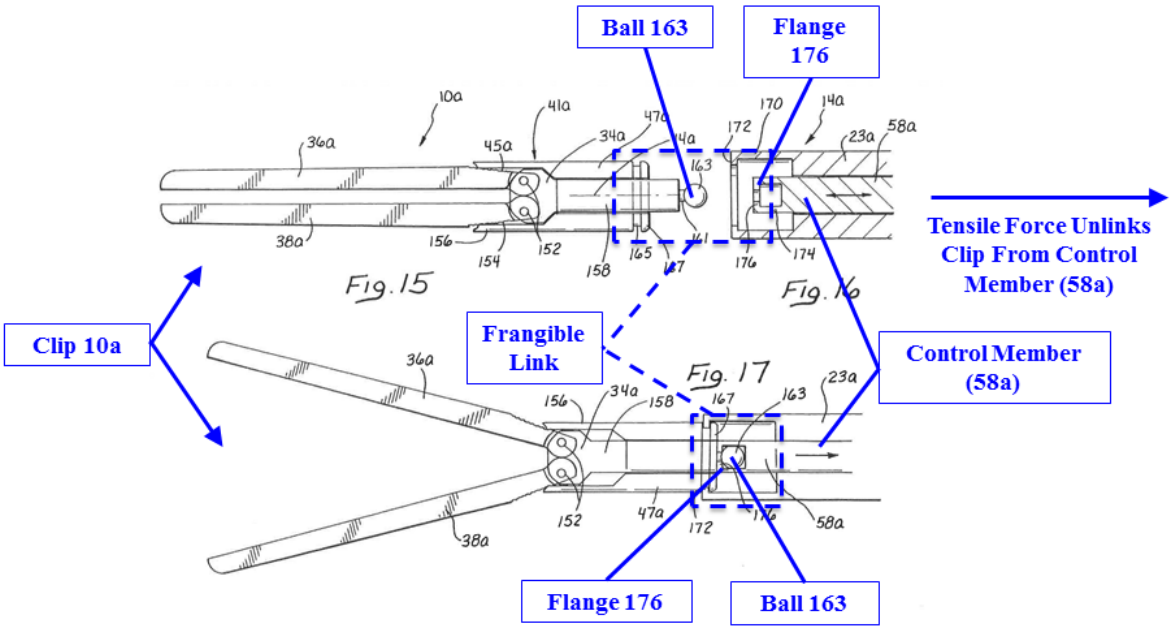
Claim 3 depends from claim 1 and further states that "the linkage comprises first and second linkage members, proximal ends of the first and second linkage members being connected to one another." As shown below in annotated Figure 2, the linkage (coil spring 52) has first and second linkage members (*i.e.*, the linear arms of the spring):



(Ex. 1015, ¶ 35). The distal ends of the linkage members contact a respective inner surface of a clip leg. (Ex. 1015, ¶ 35). The proximal ends of the linkage members are connected to one another via the coil. (Ex. 1015, ¶ 35).

3. Claim 4

Claim 4 depends from claim 1 and further requires "a frangible link coupling the clip to the control member." As shown below in annotated Figures 15-17, a ball 163 and cylinder 174 (with flange 176) form a link coupling the clip to the control member, the link being frangible in that it becomes unlinked when a tensile load is applied:



(Ex. 1015, ¶ 36; Ex. 1008, 10:18-30). The clip (10a) becomes unlinked from the control member (58a) (*i.e.*, the ball 163 separates from cylinder 174 (with flange 176)) when a tensile load is applied to the control member (58a). (Ex. 1015, ¶ 36; *see* Ex. 1008, Figures 15 and 16, 2:56-59 ("A clamp applier is adapted to releasibly

engage the clamp [(clip)] . . . ."); *see also*, *e.g.*, *id.*, Abstract, 8:29-34, 8:51-53, 9:60 – 10:34).

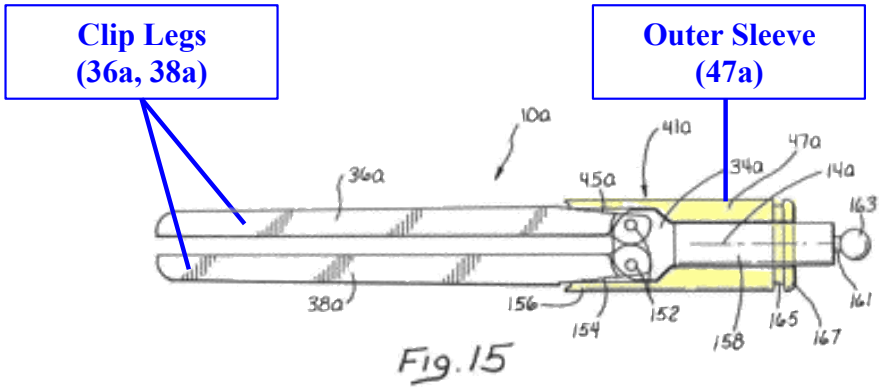
4. Claim 5

Claim 5 depends from claim 4 and further requires "the control member is reversibly operable to move the clip between the tissue-receiving configuration and a closed configuration." Sackier discloses that the control member (58a) is reversibly operable to open and close the clip legs (jaws 36a, 38a). (Ex. 1015, ¶ 37; Ex. 1008, Figures 15-17, 4:35-37 ("[T]he clamp applier can be operated to open and close the clamp 10 about a body conduit . . . ."), 10:27-33 ("[T]he shaft 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. As noted, this axial movement of the slide 47a relative to the jaws 36a and 38a is accompanied by relative movement of the jaws 36a, 38a between the open and closed positions."); *see also id.*, 3:14-15. 9:41-48, 14:5-24)).

5. Claim 6

Claim 6 depends from claim 5 and further requires "an outer sleeve housing a proximal portion of the clip therewithin, wherein an engagement of outer walls of the first and second clip legs with inner walls of the sleeve prevents movement of the clip to the tissue-receiving configuration."

The embodiment in Figures 15-17 includes an outer sleeve (slide 47a) housing a proximal portion of the clip legs (jaws 36a, 38a) therewithin. (Ex. 1015, ¶ 39).



(Ex. 1008, 9:64-65 ("The slide 47a is also formed with a cylindrical configuration and functions as a sleeve . . . ."); *see also id.*, 9:41-48, 9:60 – 10:6). An engagement of the outer walls of the first and second clip legs (36a, 38a) with inner walls of the outer sleeve (slide 47a) prevents movement of the clip to the open tissue-receiving configuration. (Ex. 1015, ¶ 39; Ex. 1008, 9:49-55 ("[T]he slide 47a is provided with a projection 156 which forms a plurality of detents with each of the recesses 154 on the surface 45a [of the clip legs]. 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.")).

6. Independent Claim 13

a. "A medical device, comprising"

Sackier discloses "a medical device," for the reasons in Section V.A.1.a, *supra* at p. 20.

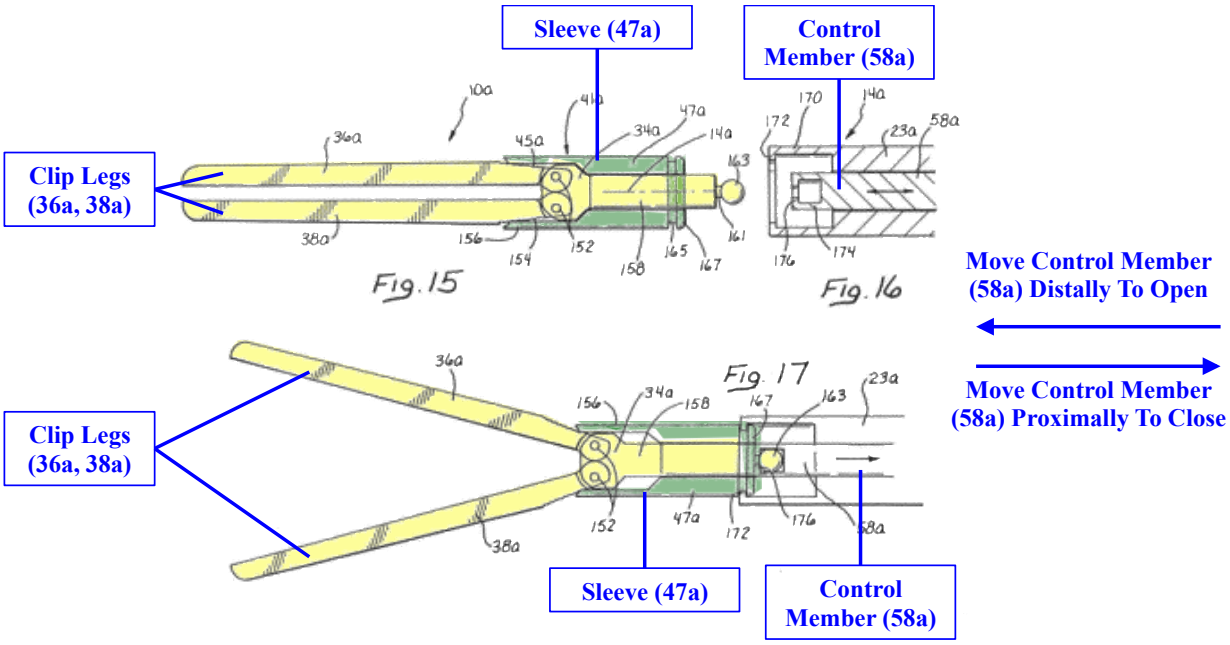
b. "a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface"

Sackier discloses "a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface," for the reasons in Section V.A.1.b, *supra* at pp. 20-21.

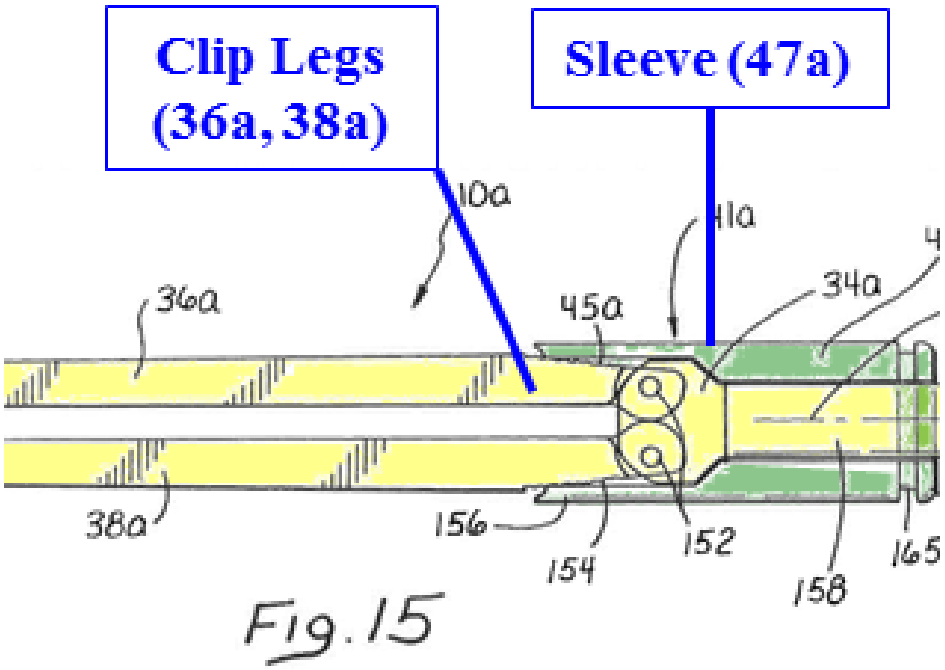
c. "a sleeve housing a portion of the clip therein, the clip being axially movable relative to the sleeve by a control member extending from a proximal actuator to the clip"

Sackier discloses a "control member extending from a proximal actuator to the clip," for the reasons in Section V.A.1.c, *supra* at pp. 21-22.

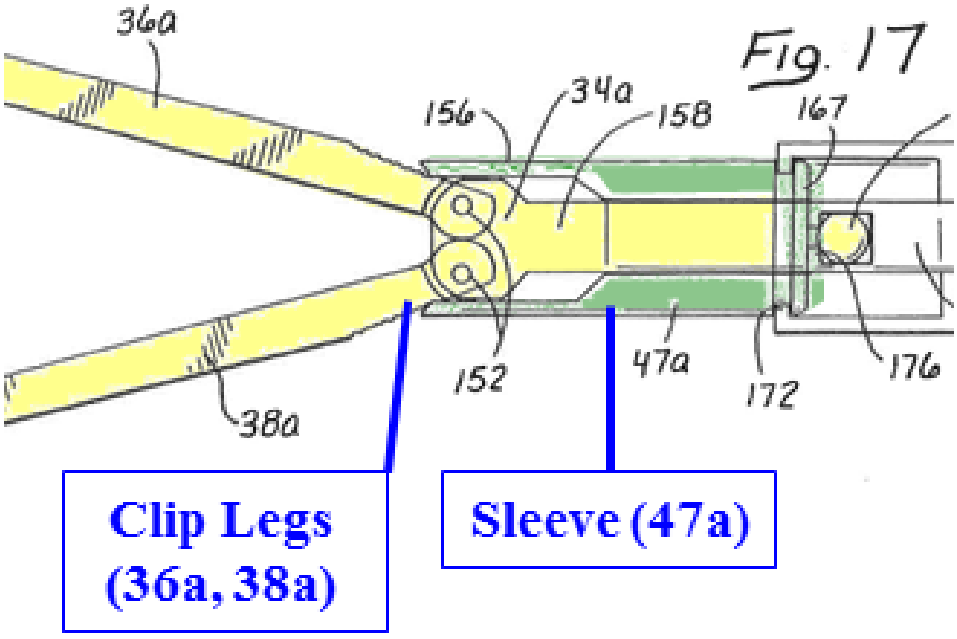
As shown below in annotated Figures 15-17, Sackier discloses a sleeve (47a) housing a portion of the clip (clip legs 36a, 38a) therein:



(Ex. 1015, ¶ 43; Ex. 1008, 9:64-65 ("The slide 47a is also formed with a cylindrical configuration and functions as a sleeve . . . ."); *see also id.*, 9:41-48, 9:60 – 10:6). The clip is axially movable relative to the sleeve (47a) by the control member (58a), as evidenced by the fact that the sleeve (47a) houses a greater portion of the clip legs (36a, 38b) in Figure 15 than in Figure 17. (Ex. 1015, ¶ 43). (*See* relevant excerpts of annotated Figures 15 and 17 below).



Sackier Figure 15 (excerpt)

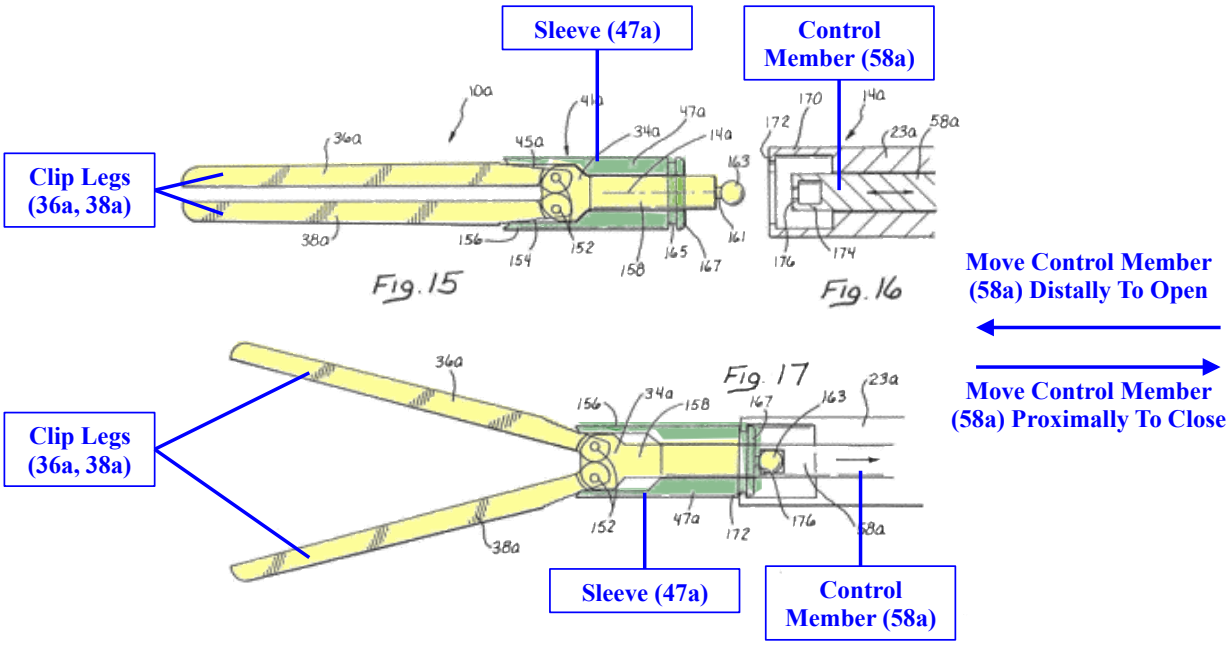


Sackier Figure 17 (excerpt)

d. "a linkage operably associated with the control member to move the clip distally out of the sleeve and cause the first and second clip legs to spread apart from one another into a tissue-receiving configuration as the clip is moved distally relative to the sleeve, the linkage contacting the inner surfaces of the first and second clip legs to drive the first and second clip legs radially outward as the control member is moved distally relative to the clip."

Sackier discloses "a linkage operably associated with the control member" to" "cause the first and second clip legs to spread apart from one another into a tissue-receiving configuration as the clip is moved distally," and "contacting the inner surfaces of the first and second clip legs to drive the first and second clip legs radially outward as the control member is moved distally relative to the clip," for the reasons in Section V.A.1.d, *supra* at pp. 23-25. (Ex. 1015, ¶ 44).

As shown below in annotated Figures 15-17 of Sackier, moving the clip legs (36a, 38a) distally relative to sleeve (47a) moves the clip legs (36a, 38a) out of the sleeve (47a) and causes the clip legs (36a, 38a) to spread apart:



(Ex. 1015, ¶ 45; Ex. 1008, 10:31-34 ("As noted, this axial movement of the slide 47a relative to the jaws 36a and 38a is accompanied by relative movement of the jaws 36a, 38a between the open and closed positions."); *see also* 9:41-48). As shown above in Section V.A.1.b, *supra* at pp. 20-21, the clip includes sleeve 47a, which remains in the body when the clip is separated from the control member. (Ex. 1015, ¶ 45). Annotated Figures 15-17 above show that control member (58a) moves distally relative to clip (47a) as the linkage (152) drives the clip legs (36a, 38a) apart. (Ex. 1015, ¶ 45).

7. Claim 14

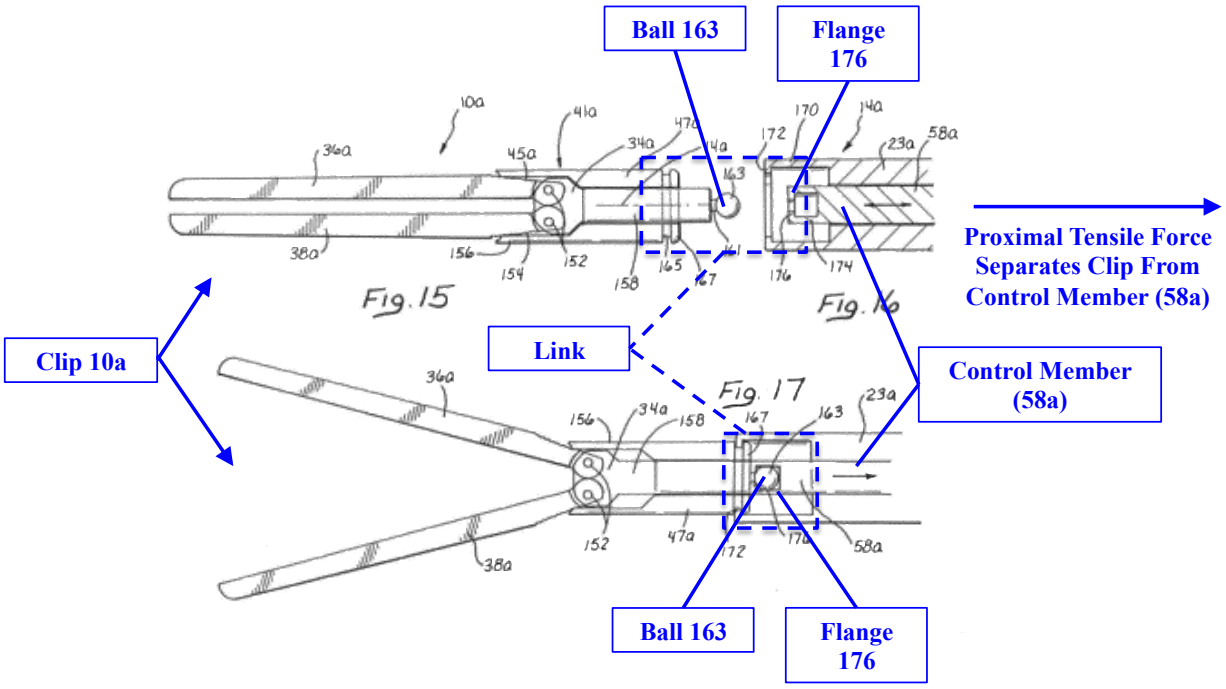
Claim 14 depends from claim 13 and further requires "movement of the control member proximally causes a corresponding proximal movement of the clip into the sleeve, moving the clip from the tissue-receiving configuration to a closed configuration in which the first and second clip legs are moved radially inward toward one another."

Sackier discloses that movement of the control member (58a) proximally causes a corresponding proximal movement of the clip legs (36a, 38a) into the sleeve, moving the clip from the tissue-receiving configuration (*see* Figure 17) to a closed configuration in which the clip legs (36a, 38a) are moved radially inward toward one another (*see* Figure 15). (Ex. 1015, ¶ 47; Ex. 1008, Figures 15-17, 4:35-37 ("[T]he clamp applier can be operated to open and close the clamp 10 about a body conduit . . . ."), 10:27-33 ("[T]he shaft 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. As noted, this axial movement of the slide 47a relative to the jaws 36a and 38a is accompanied by relative movement of the jaws 36a, 38a between the open and closed positions."); *see also id.*, 3:14-15. 9:41-48, 14:5-24).

8. Claim 15

Claim 15 depends from claim 13 and further requires "a link positioned proximally of the clip, wherein application of a proximal tensile force to the link

via the control member causes the clip to separate from the control member." As shown below in annotated Figures 15-17, the clip (10a) connects with the control member (58a) via a ball 163 and flange 176 connection:



(Ex. 1015, ¶ 48; Ex. 1008, 10:18-30). The clip (10a) separates from the control member (58a) (*i.e.*, the ball 163 separates from flange 176) upon application of a proximal tensile force to the link. (Ex. 1015, ¶ 48; *see* Ex. 1008, Figures 15 and 16, 2:56-59 ("A clamp applier is adapted to releasibly engage the clamp [(clip)] . . . ."); *see also, e.g., id.*, Abstract, 8:29-34, 8:51-53, 9:60 – 10:34).

9. Claim 17

Claim 17 depends from claim 13 and further requires "the linkage comprises first and second linkage members, proximal ends of the first and second linkage members being connected to one another." Sackier discloses this limitation, for the reasons in Section V.A.2, *supra* at p. 26. (Ex. 1015, ¶ 49).

10. Independent Claim 20

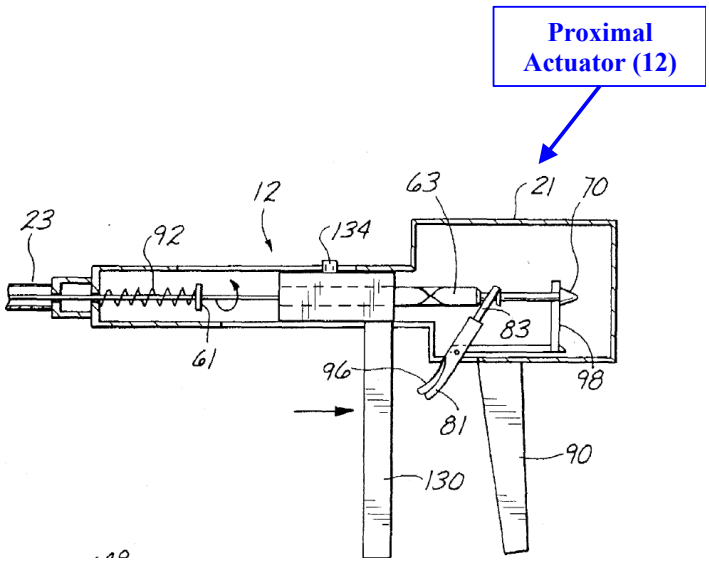
a. "a method, comprising"

Sackier discloses "[a] method for operating [a] clamp." (Ex. 1015, ¶ 50; Ex. 1008, 3:1-2; *see also id.*, 9:5-7, Figures 11-19).

b. "inserting into a body a medical device comprising a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface, a control member extending from a proximal actuator to the clip and a linkage coupled to the control member"

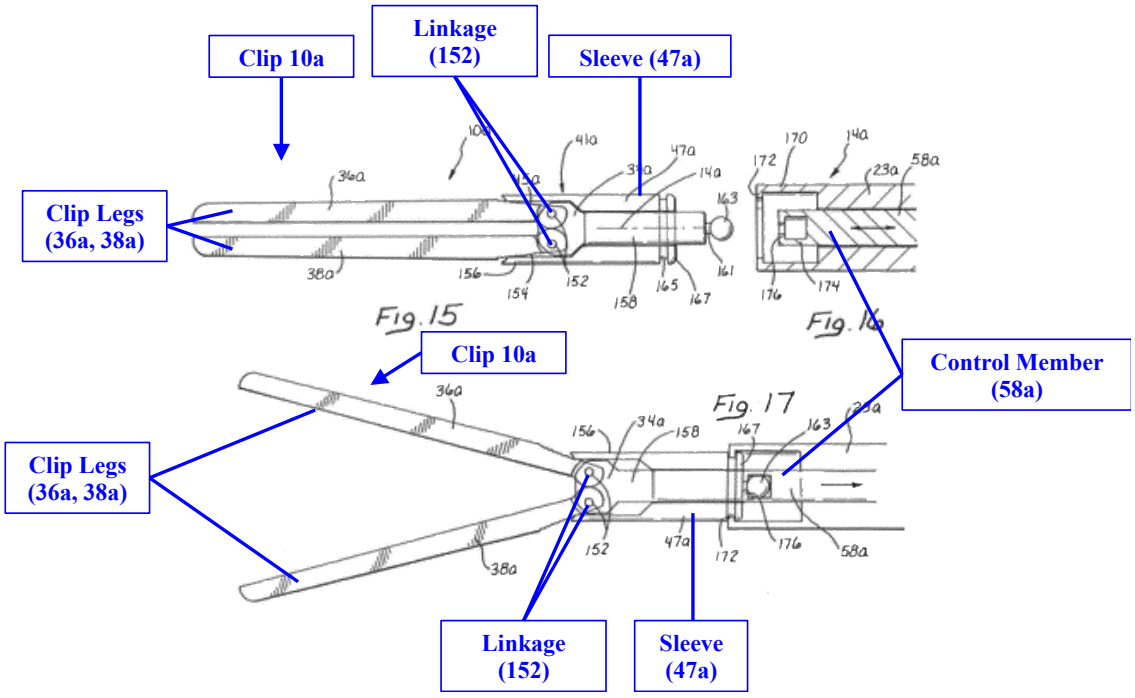
Sackier discloses inserting into a body a medical device including a clip (i.e, a "clamp"). (Ex. 1015, ¶ 51; Ex. 1008, 1:6-8 ("clamps and clamp appliers for use in occluding body conduits"); *see also id.*, 3:1-15, 9:5-12, 11:57-64, 14:5-24).

The medical device includes a proximal actuator, such as the one depicted below in annotated Figure 9 of Sackier:



Sackier, Figure 9 (Excerpt)

(Ex. 1015, ¶ 52). As shown below in annotated Figures 15-17, the medical device includes a clip (10a) having first and second clip legs (36a, 38a), each with an inner surface, a control member (58a) extending from the proximal actuator (*see* Figure 9, above) to the clip (10a), and a linkage (spring 152) coupled to the control member (58a):



(Ex. 1015, ¶ 52).

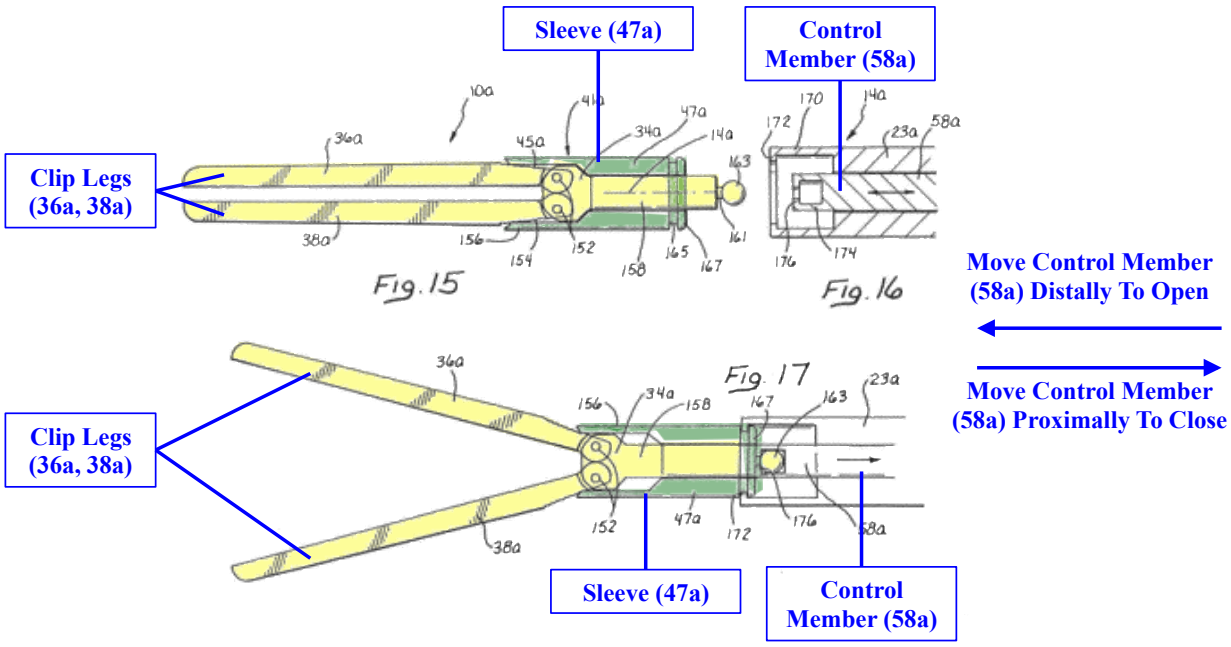
c. "positioning the medical device at a desired deployment location"

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. 1015, ¶ 53; Ex. 1008, 8:29-31; *see also, e.g.*, 11:57-64).

d. "moving the control member distally to cause the clip to move distally relative to a sleeve housing at least a portion of the clip therein, the movement causing the linkage to contact the first and second inner surfaces to drive the first and second clip legs radially outward to a tissue-receiving configuration"

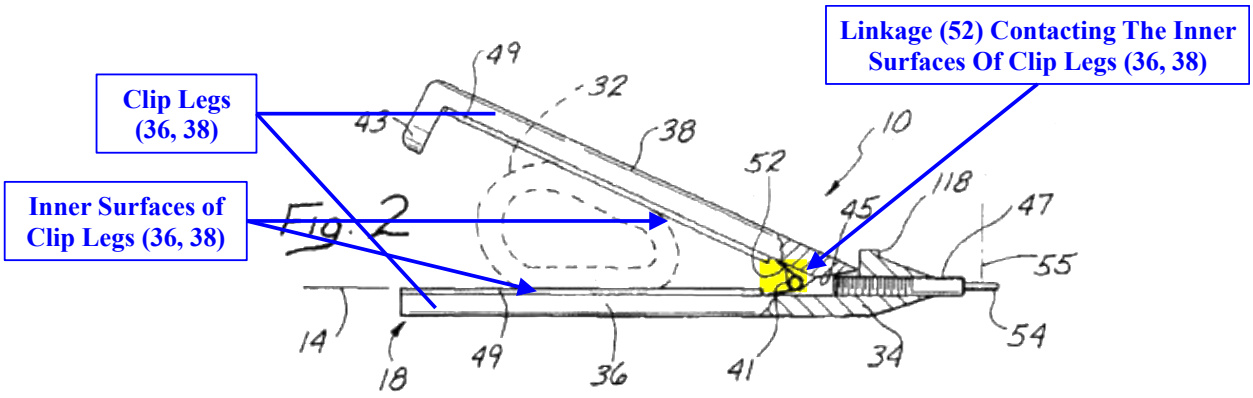
As shown below in annotated Figures 15-17, Sackier discloses moving the control member (58a) distally relative to a sleeve (47a) housing the clip legs 36a,

38a), to cause the clip (10a) to move distally relative to the sleeve (47a) (*i.e.*, clip (10a) moves from position in Figure 15 to position in Figure 17):



(Ex. 1015, ¶ 54). The clip moves distally relative to the sleeve (47a), as evidenced by the fact that the sleeve (47a) houses a greater portion of the clip legs (36a, 38b) in Figure 15 than in Figure 17. (Ex. 1015, ¶ 54).

For the reasons in Section V.A.1.d, *supra* at pp. 23-25, Sackier discloses a linkage (spring 52) to "contact the first and second inner surfaces to drive the first and second clip legs radially outward to a tissue-receiving configuration." (Ex. 1015, ¶ 55). As shown below in annotated Figure 2, Sackier discloses that the linkage (spring 52) contacts the inner surfaces of first and second clip legs (36, 38) to spread open and drive outward the clip legs (36, 38):



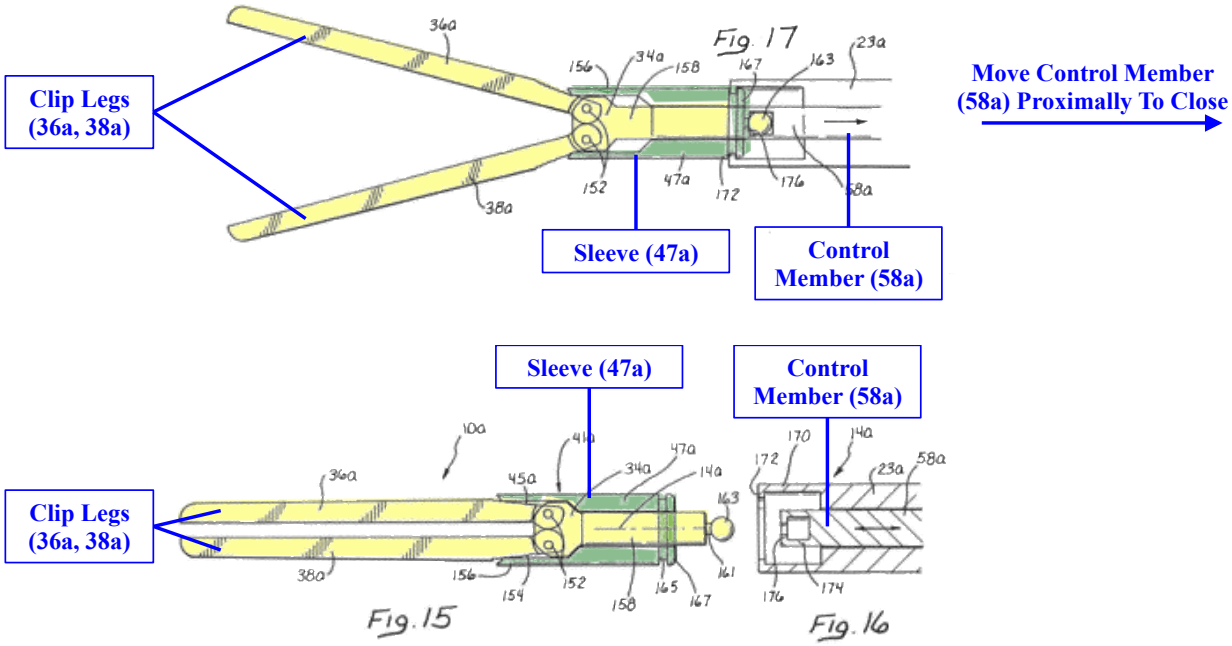
(Ex. 1015, ¶ 55; Ex. 1008, 9:25-30; *see also* 5:4-12, 9:5-12).

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. 1015, ¶ 56; Ex. 1008, 4:35-37; *see also id.*, 3:14-15).

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

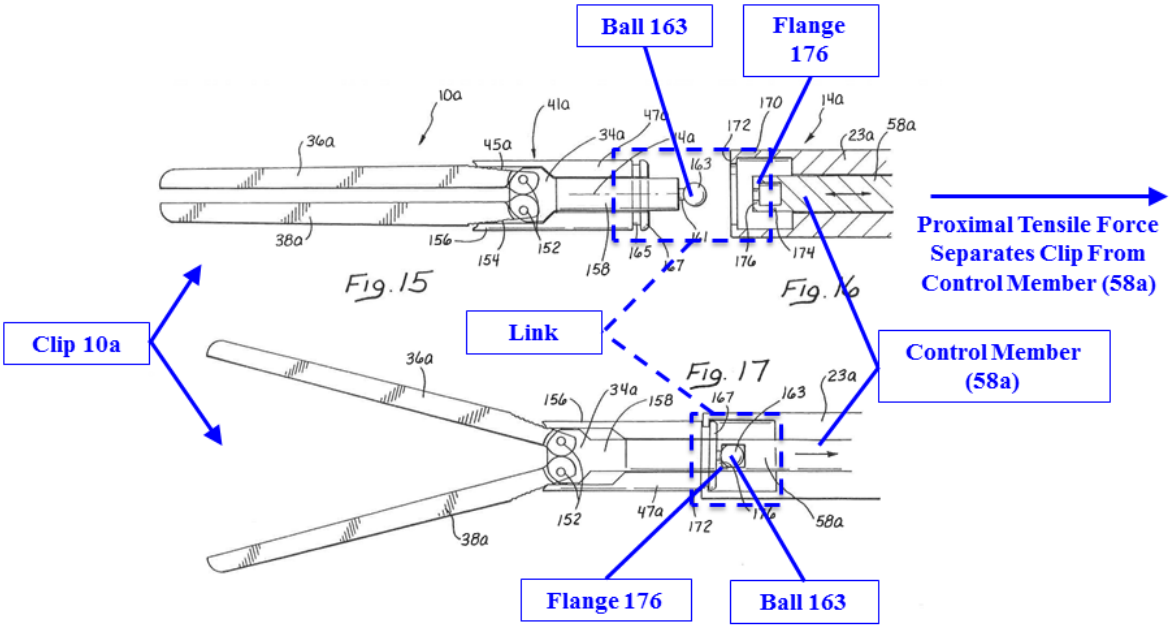
As shown below in annotated Figures 15-17, Sackier discloses drawing (moving) the control member (58a) proximally relative to the sleeve (47a) (*i.e.*, the control member (58a) moves proximally away from the sleeve (47a)) to draw the clip (10a) into the sleeve (47a) to receive the target tissue between the first and second clip legs (36a, 38a) (*i.e.*, clip (10a) moves from position in Figure 17 to position in Figure 15):



(Ex. 1015, ¶ 57; Ex. 1008, 3:14-15 ("[B]y operating the shaft to close the jaws of the clamp, the body conduit can be occluded.").

g. "applying a proximal tensile force of at least a threshold level to the control member to separate a link coupling the control member to the clip."

As shown below in annotated Figures 15-17, Sackier discloses a link (connection between ball 163 and flange 176) coupling the control member (58a) to the clip (10a):



(Ex. 1015, ¶ 58). The link (163, 176) separates upon application of a proximal tensile force of at least a threshold level to the control member (58a). (Ex. 1015, ¶ 58; *see* Ex. 1008, Figures 15 and 16, 2:56-59 ("A clamp applier is adapted to releasibly engage the clamp [(clip)] . . . ."); *see also*, *e.g.*, *id.*, Abstract, 8:29-34, 8:51-53, 9:60 – 10:34).

B. Ground 2: There Is A Reasonable Likelihood That Claims 1-20 Are Obvious In View Of Sackier (Ex. 1008), in Combination With Nishioka (Ex. 1005)

Nishioka issued on December 1, 1998. Accordingly, Nishioka qualifies as prior art at least under 35 U.S.C. §§ 102(a), (b), and (e). Nishioka was not cited during prosecution of the '027 patent.

1. Independent Claim 1

a. "A medical device, comprising"

Sackier discloses this limitation, for the reasons in Section V.A.1.a, *supra* at p. 20.

b. "a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface"

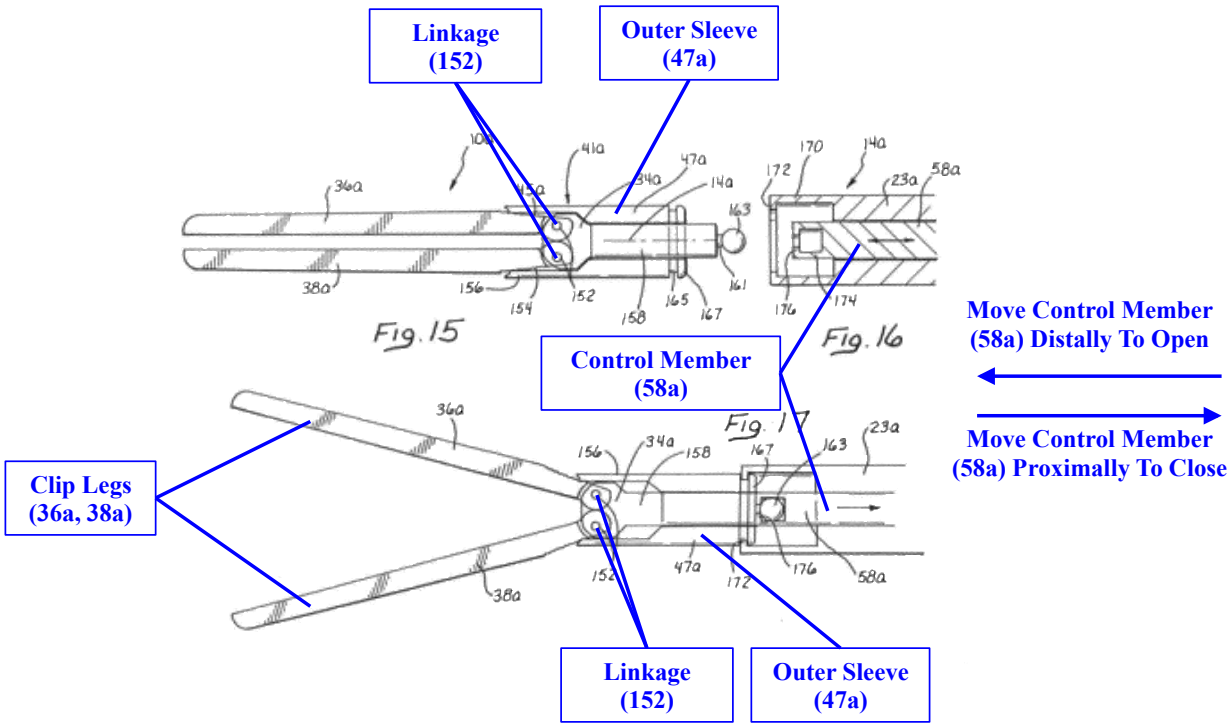
Sackier discloses this limitation, for the reasons in Section V.A.1.b, *supra* at pp. 20-21.

c. "a control member extending from a proximal actuator to the clip"

Sackier discloses this limitation, for the reasons in Section V.A.1.c, *supra* at pp. 21-22.

d. "a linkage operably associated with the control member to spread the first and second clip legs apart from one another into a tissue-receiving configuration as the control member is moved distally relative to the clip, the linkage contacting the inner surfaces of the first and second clip legs to drive the first and second clip legs radially outward as the control member is moved distally relative to the clip."

As shown below in annotated Figures 15-17, Sackier discloses "a linkage" (spring 152) operably associated with the control member (58a) "to spread" the first and second clip legs (36a, 38a) apart from one another into a tissue-receiving configuration as the control member is moved distally relative to the clip, and "to drive" the clip legs (36a, 38a) radially outward as the control member is moved distally relative to outer sleeve 47a of the clip:



(Ex. 1015, ¶ 62; Ex. 1008, 9:19-23 (the clip legs (36a, 38a) have two relative positions: "[t]he first relative position is illustrated in FIG. 17 . . . in a generally open configuration," and a "second relative position is illustrated in FIG. 15 . . . in a generally closed configuration."), 9:30-32 ("[T]he jaws 36a and 38a are preferably biased to the open position, for example by a spring 152."), 9:41-48, 10:27-31). As shown above in Section V.A.1.b, *supra* at pp. 20-21, the clip includes outer sleeve 47a, which remains in the body when the clip is separated from the control member. (Ex. 1015, ¶ 62). Annotated Figures 15-17 above show that control member (58a) moves distally relative to clip (47a) as the linkage (152) spreads the clip legs (36a, 38a) apart. (Ex. 1015, ¶ 62). Additionally, for the reasons in Section V.A.1.d, *supra* at pp. 23-25, Sackier discloses a linkage (spring 52) "contacting the inner surfaces of the first and second clip legs." (Ex. 1015, ¶ 62).

To the extent BSSI argues that Sackier does not explicitly state that the linkage (spring 152 or spring 52) contacts the inner surfaces of the clip legs (36a, 38a) to drive the first and second clip legs radially outward, claim 1 nevertheless would have been obvious. (Ex. 1015, ¶ 63). Such linkages were known in the prior art. (Ex. 1015, ¶ 63). For example, as shown below in annotated Figure 8,

Nishioka[6] discloses a linkage (slide member 120 and control links 136, 138 (highlighted in yellow)) coupled to a control member (fiber 150), and contacting the inner surfaces of clip legs (jaws 180, 181):

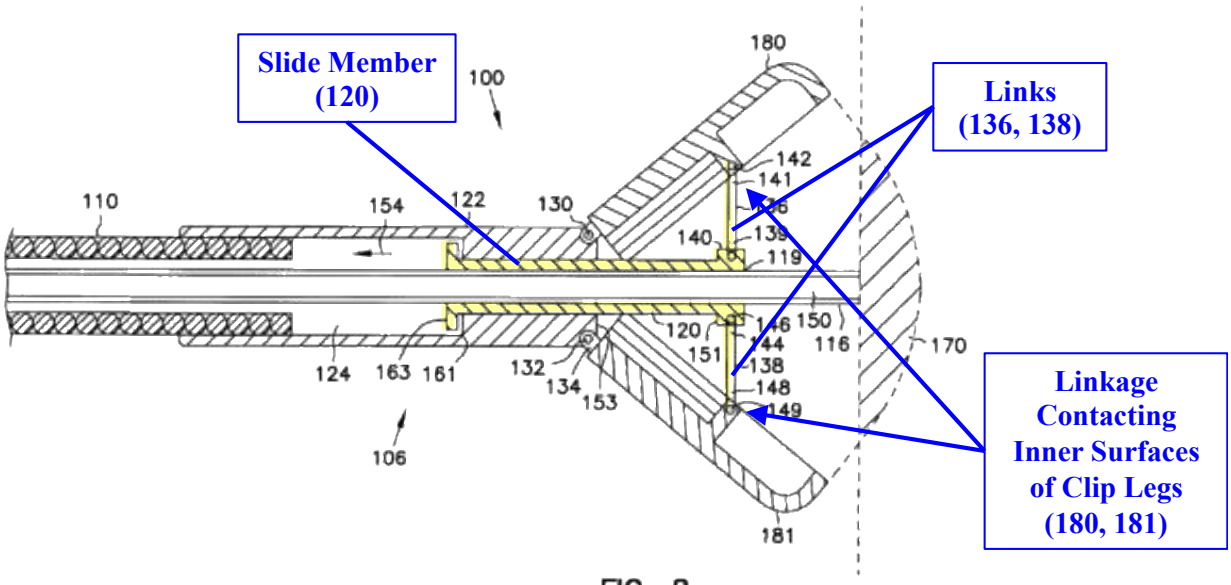
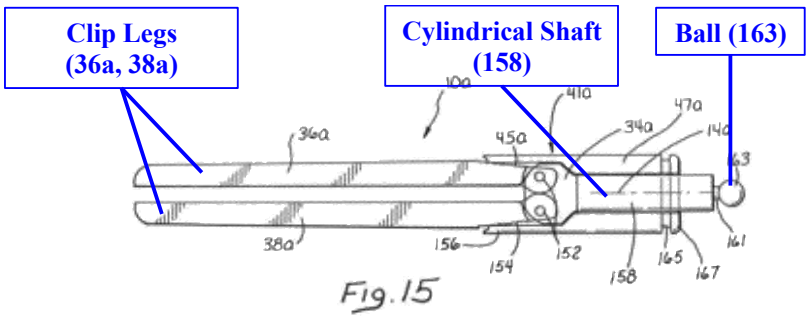


FIG. 8

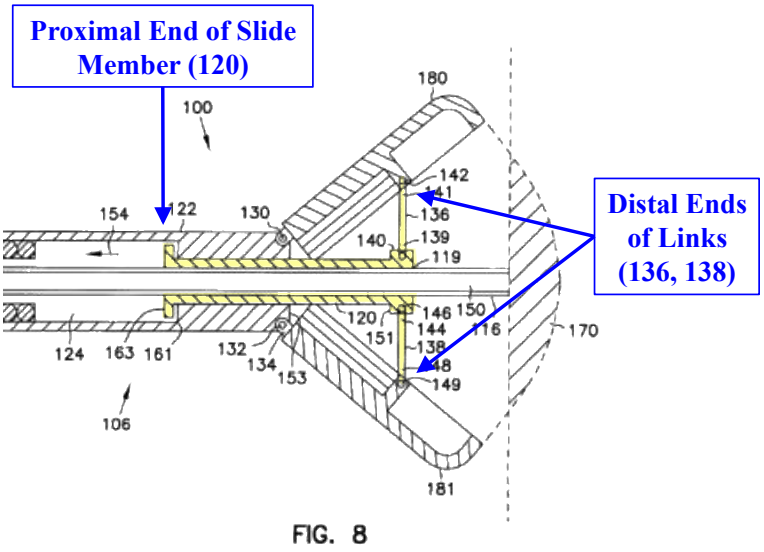
(Ex. 1015, ¶ 63; Ex. 1005, 7:3-7, 7:27-32, 8:8-10, 8:12-21). The linkage (120, 136, 138) drives the clip legs (180, 181) radially outward as the control member (150) moves distally relative to the clip legs (180, 181). (Ex. 1015, ¶ 63; Ex. 1005, 8:21-26, 8:32-35, 8:44-52, 8:59 – 9:2).

[6] The '027 patent acknowledges that forceps structures are "analogous" to the clip structures disclosed in the '027 patent. (Ex. 1001, 5:45-46 ("[T]he handle [is] analogous to biopsy forceps.")).

It would have been obvious to a person of ordinary skill in the art to combine the linkage disclosed in Nishioka with the clip of Sackier to assist in driving open the clip legs (21). (Ex. 1015, ¶ 64). Modifying the Sackier clip to include the Nishioka linkage would have been a matter of routine skill in the art, using simple mechanical elements such as those disclosed in Nishioka and Sackier to achieve predictable results. (Ex. 1015, ¶ 64). For example, it would have been obvious to modify the Sackier clip by connecting the distal ends of the Nishioka links (136, 138) to the inner surface of the Sackier clip legs (36a, 38a), placing the Nishioka slide member (120) slidingly within the Sackier cylindrical shaft (158), and attaching the Sackier ball (163) to the proximal end of the Nishioka slide member (120) instead of the proximal end of the cylindrical shaft (*see* annotated Figure 15 (Sackier) and Figure 8 (Nishioka), reproduced below). (Ex. 1015, ¶ 64).



Sackier, Figure 15 (Annotated)



Nishioka, Figure 8 (Annotated)

The skilled artisan would have expected that modifying the clip in Sackier to include the Nishioka linkage would improve the performance of the clip. (Ex. 1015, ¶ 65). In particular, the linkage described in Nishioka would provide more leverage to drive open the clip legs because the relatively longer linkage member provides a longer moment arm than the spring arms in Sackier. (Ex. 1015, ¶ 65). Additionally, the linkage described in Nishioka would stabilize the clip legs through contact of the linkage more distally along the clip leg. (Ex. 1015, ¶ 65).

2. Claim 2

Claim 2 depends from claim 1 and further states that "the linkage is received through an opening formed in a proximal end of the clip." The combination of Sackier and Nishioka satisfies this limitation (obvious to place the Nishioka slide member (120) slidably disposed within the Sackier cylindrical shaft (158)). (Ex.

1015, ¶ 66). As shown below in annotated Figures 2 and 8, Nishioka discloses that the linkage (40, 41 (Figure 2), 120 (Figure 8)) is received through an opening formed in a proximal end of the clip (opening indicated in red):

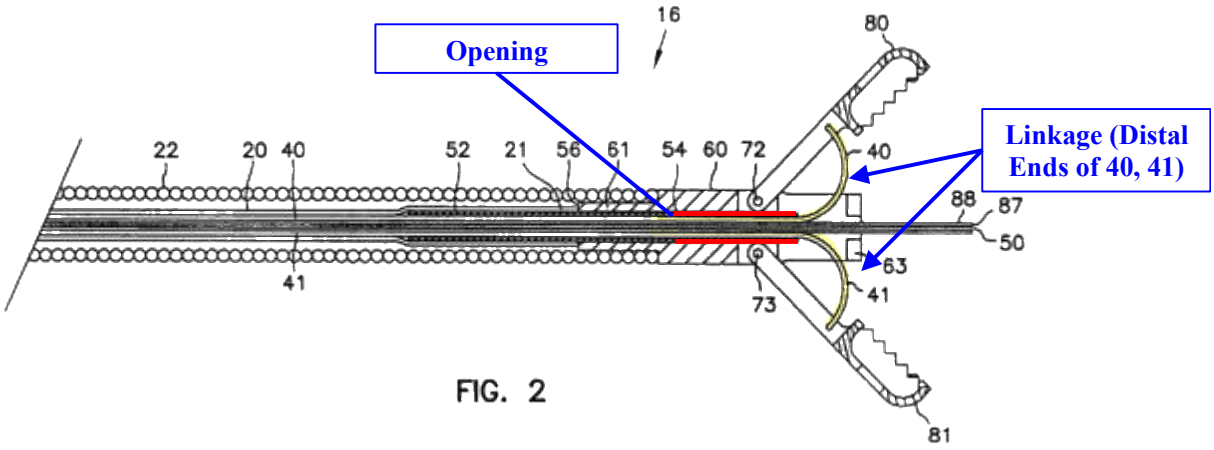


FIG. 2

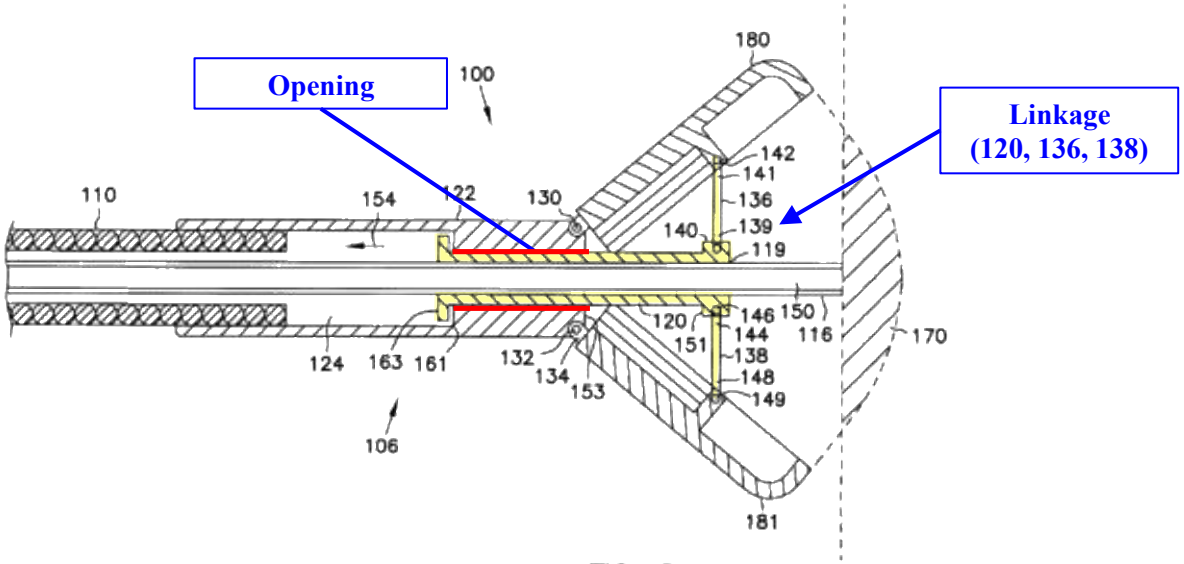


FIG. 8

(Ex. 1015, ¶ 66).

For the reasons in Section V.B.1.d, *supra* at pp. 47-49, it would have been obvious to combine the linkage disclosed in Nishioka with the clip of Sackier. (Ex. 1015, ¶ 67).

3. Claim 3

Claim 3 depends from claim 1 and further states that "the linkage comprises first and second linkage members, proximal ends of the first and second linkage members being connected to one another." Nishioka discloses this limitation. (Ex. 1015, ¶ 68). As shown below in annotated Figures 2 and 8, the linkage (highlighted in yellow) comprises first and second linkage members (distal ends of 40, 41 (Figure 2), links 136, 138 (Figure 8)):

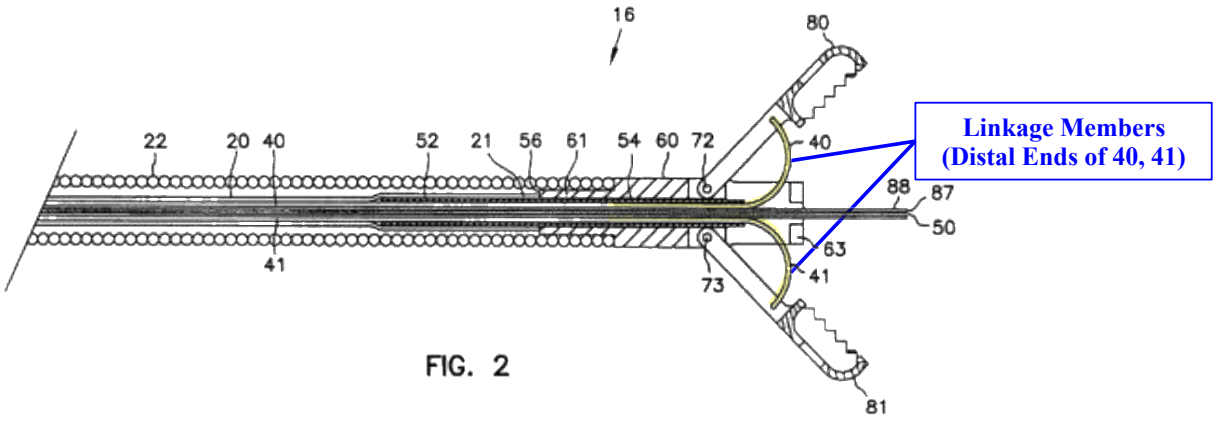


FIG. 2

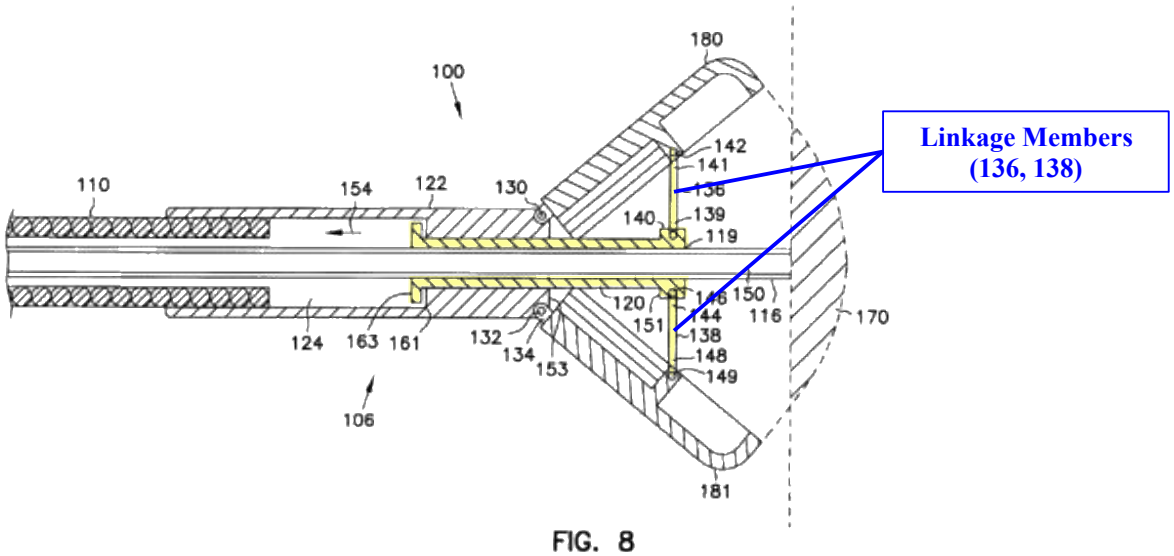


FIG. 8

(Ex. 1015, ¶ 68). In both embodiments, the proximal ends of the linkage members are connected to one another. (Ex. 1015, ¶ 68). In the embodiment of Figure 2, the proximal ends of the linkage members (40, 41) are "secured to slider 30" (shown in Figure 1 (reproduced and annotated below), which "form[s] an actuator mechanism for the forceps 10." (Ex. 1005, 4:11-13, Figure 1). (Ex. 1015, ¶ 68).

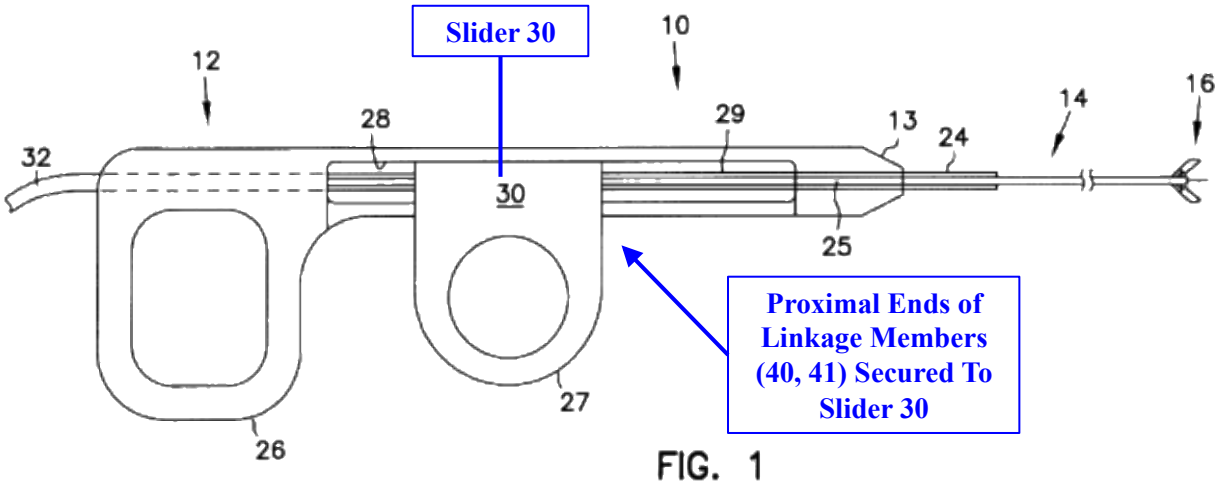


FIG. 1

In Figure 8, the proximal ends of the linkage members (136, 138) are connected to one another via slide member 120. (Ex. 1015, ¶ 69; Ex. 1005, 8:10-26 ("Control link 136 has one end 139 connected to tubular slide member 120 by a pin 140 . . . [and its other end] connected to jaw 180 by a pin 142. Similarly, control link 138 has one end 144 connected to tubular slide member 120 by a pin 146 and its other end 148 connected to jaw 181 by a pin 149.").

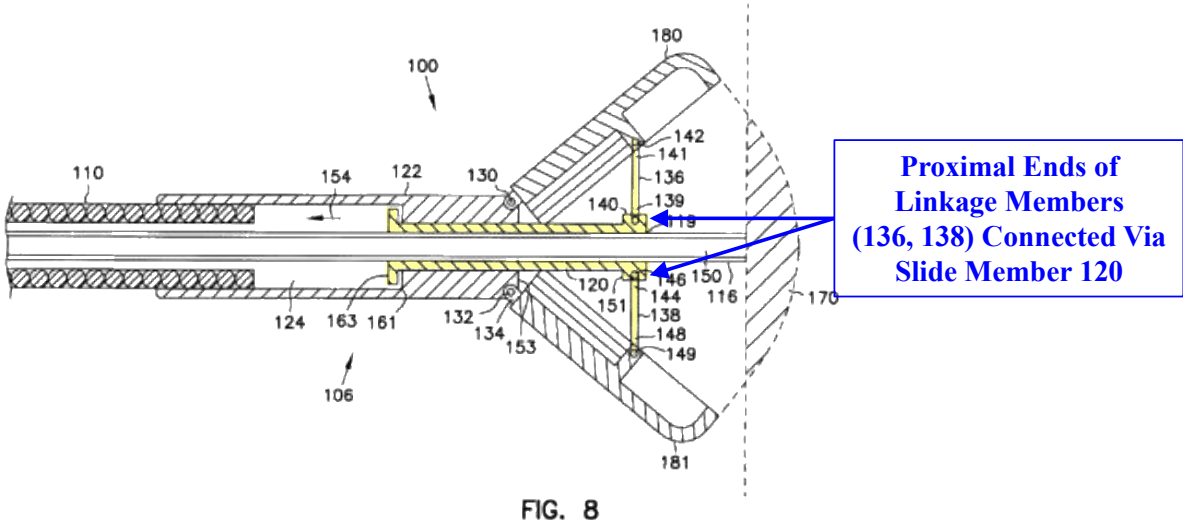
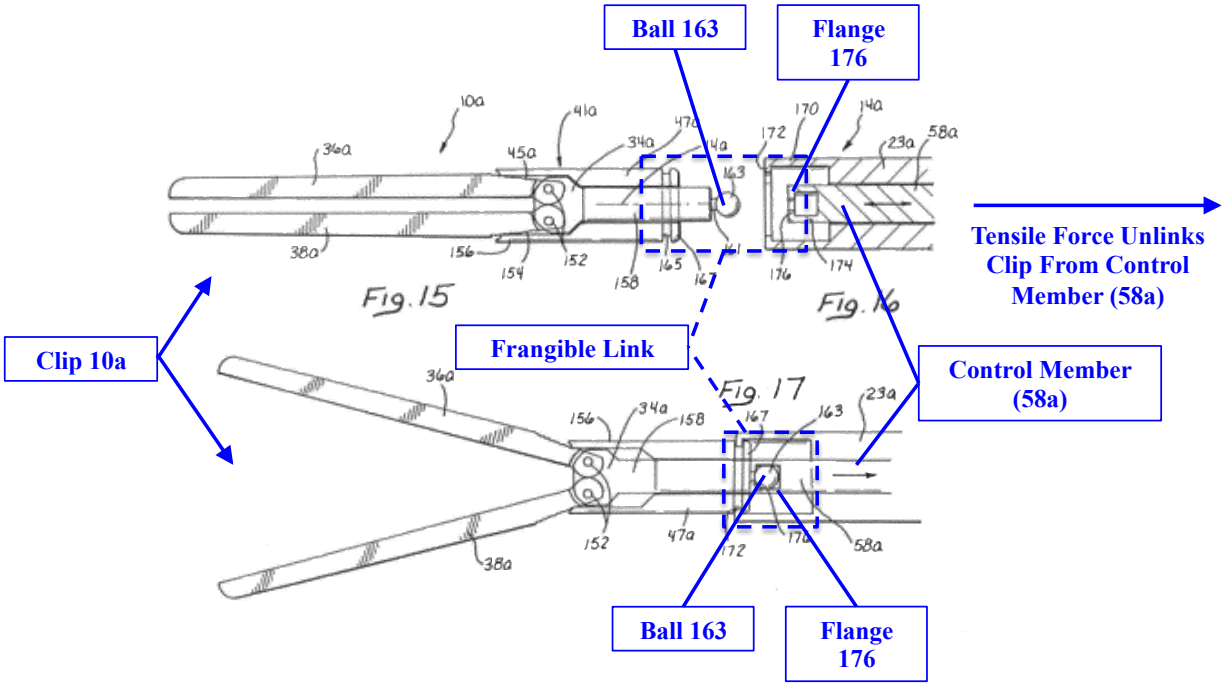


FIG. 8

4. Claim 4

Claim 4 depends from claim 1 and further requires "a frangible link coupling the clip to the control member." As shown below in annotated Figures 15-17, a ball 163 and flange 176 form a link coupling the clip to the control member, the link being frangible in that it becomes unlinked when a tensile load is applied:



(Ex. 1015, ¶ 70; Ex. 1008, 10:18-30, 2:56-59 ("A clamp applier is adapted to releasibly engage the clamp [(clip)] . . . ."); *see also, e.g., id.*, Abstract, 8:29-34, 8:51-53, 9:60 – 10:34, Figures 15 and 16). Thus, the link coupling the clip to the control member (58) is a "*frangible link*" (i.e., "a link between at least two components that become unlinked when a tensile load is applied."). (Ex. 1015, ¶ 70).

5. Claim 5

Claim 5 depends from claim 4 and further requires "the control member is reversibly operable to move the clip between the tissue-receiving configuration and a closed configuration." Sackier discloses this limitation, for the reasons in Section V.A.1.d, *supra* at pp. 21-25. (Ex. 1015, ¶ 71).

6. Claim 6

Claim 6 depends from claim 5 and further requires "an outer sleeve housing a proximal portion of the clip therewithin, wherein an engagement of outer walls of the first and second clip legs with inner walls of the sleeve prevents movement of the clip to the tissue-receiving configuration." Sackier discloses this limitation, for the reasons in Section V.A.5, *supra* at pp. 29-30. (Ex. 1015, ¶ 73).

7. Claims 7-8

Claim 7 depends from claim 1 and further requires "distal ends of the first and second clip legs include curved projections which are angled with respect to a longitudinal axis of the clip." Claim 8 depends from claim 7 and further requires "the curved projections are angled radially inward."

Sackier does not explicitly disclose clip legs with the claimed "curved projections." (Ex. 1015, ¶ 75). However, a person of ordinary skill in the art would have understood that the clip leg shapes and configurations described in Sackier were merely exemplary. (Ex. 1015, ¶ 75; Ex. 1008, 11:47- ("[A] preferred

embodiment of the clamp 10 . . . ha[s] been described. Many modifications of these embodiments will now be apparent. For example, many clamp configurations can be adapted . . . .”). The skilled artisan would have recognized that the clip legs in Sackier could easily be modified to include any one of the common shapes and configurations known in the art, such as serrated edges to improve gripping of tissue or with inwardly curving tips to aid in containing tissue between the jaws. (Ex. 1015, ¶ 75).

For example, a person of ordinary skill in the art would have been aware of the clip configurations disclosed in Nishioka, which, as shown below in annotated Figure 6A, include the curved projections angled radially inward with respect to a longitudinal axis:

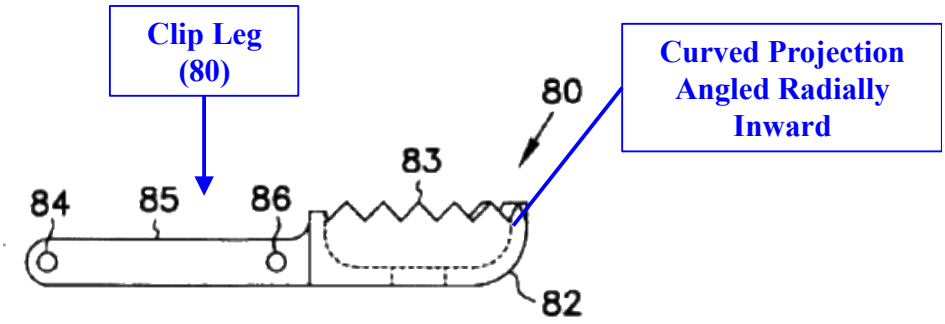


FIG. 6A

(Ex. 1015, ¶ 76; Ex. 1005, 5:1-7). Nishioka describes advantages of the clip configuration, including meshing serrations, and a distal cup for securely capturing tissue. (Ex. 1015, ¶ 76; Ex. 1005, 5:1-7).

It would have been obvious to a person of ordinary skill in the art to modify the distal ends of the Sackier clip legs (36a, 38a) to include curved projections angled radially inward, as described in Nishioka. (Ex. 1015, ¶ 77). Likewise, it would have been obvious simply to substitute the Nishioka clip legs (80) for the Sackier clip legs (36a, 38a). (Ex. 1015, ¶ 77). Modifying or substituting the Sackier clip legs would have been a matter of routine skill in the art, using simple mechanical elements disclosed in Sackier and Nishioka to achieve predictable results. (Ex. 1015, ¶ 77). The skilled artisan would have been motivated to make the substitution or modification, for example, to provide improved clip leg meshing and tissue-capturing ability, as described in Nishioka. (Ex. 1015, ¶ 77). *See Tokai Corp. v. Easton Enters.*, 632 F.3d 1358, 1371 (Fed. Cir. 2011); *KSR*, 550 U.S. at 417.

8. Claims 9-12

Claim 9 depends from claim 1 and further requires "a distal end of the first clip leg includes an angled protrusion which interlocks with a corresponding angled recess formed in a distal end of the second clip leg."

Claims 10, 11, and 12 each depend from claim 9 and further require:

- "the protrusion is a pointed tooth and the recess is a pointed recess" (claim 10);

- "the protrusion is a plurality of pointed teeth and the recess is a plurality of correspondingly shaped pointed recesses" (claim 11); and
- "the protrusion is one of a multi-toothed wave and an offset L-tooth" (claim 12).

It would have been obvious to modify the Sackier clip legs (36a, 38a) to include the shape and configuration of the clip legs (80) described in Nishioka, or to substitute the Nishioka clip legs (80) for the Sackier clip legs (36a, 38a), for the reasons in Section V.B.7, *supra* at pp. 55-57. (Ex. 1015, ¶ 80).

As shown below in annotated Figures 3 and 6A, Nishioka discloses the "angled protrusion" in the Figure 2 and Figure 8 embodiments includes one or more "pointed teeth" which "interlock" with one or more "corresponding angled recesses" as described in claims 9-12:

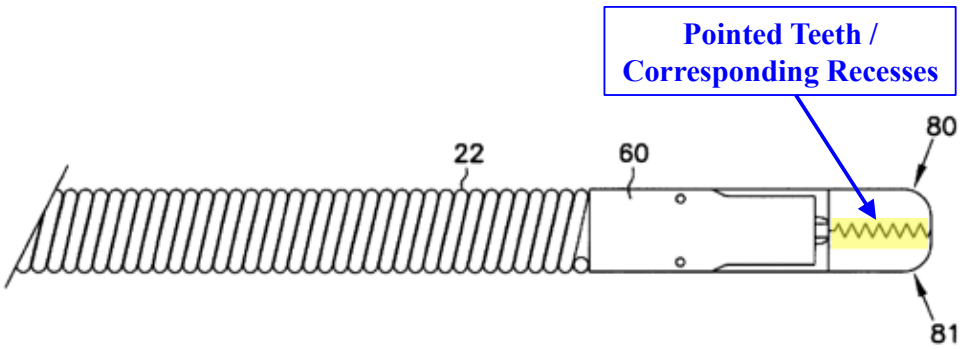
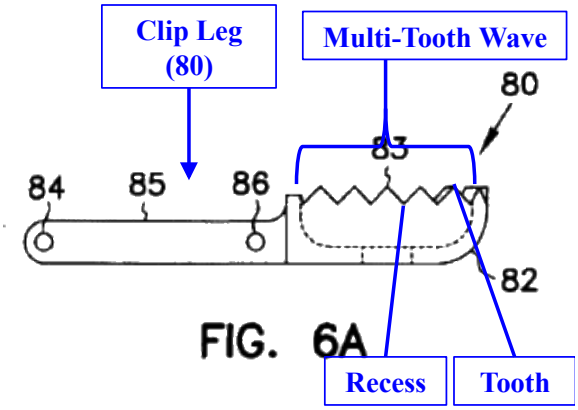


FIG. 3



(Ex. 1015, ¶ 81; Ex. 1005, 5:1-3 ("Because jaws 80 and 81 are similar only one is described in detail here. The two jaws are mirror-image identical, but with their serrations staggered so that they will mesh."), 5:3-7, 6:60-64 (explaining that the jaws in the Figure 8 embodiment (181, 181) can be similar to the jaws in the Figure 2 embodiment (80, 81)).

9. Independent Claim 13

a. "A medical device, comprising"

Sackier discloses this limitation, for the reasons in Section V.A.1.a, *supra* at p. 20. (Ex. 1015, ¶ 82).

b. "a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface"

Sackier discloses this limitation, for the reasons in Section V.A.1.b, *supra* at pp. 20-21. (Ex. 1015, ¶ 83).

c. "a sleeve housing a portion of the clip therein, the clip being axially movable relative to the sleeve by a control member extending from a proximal actuator to the clip"

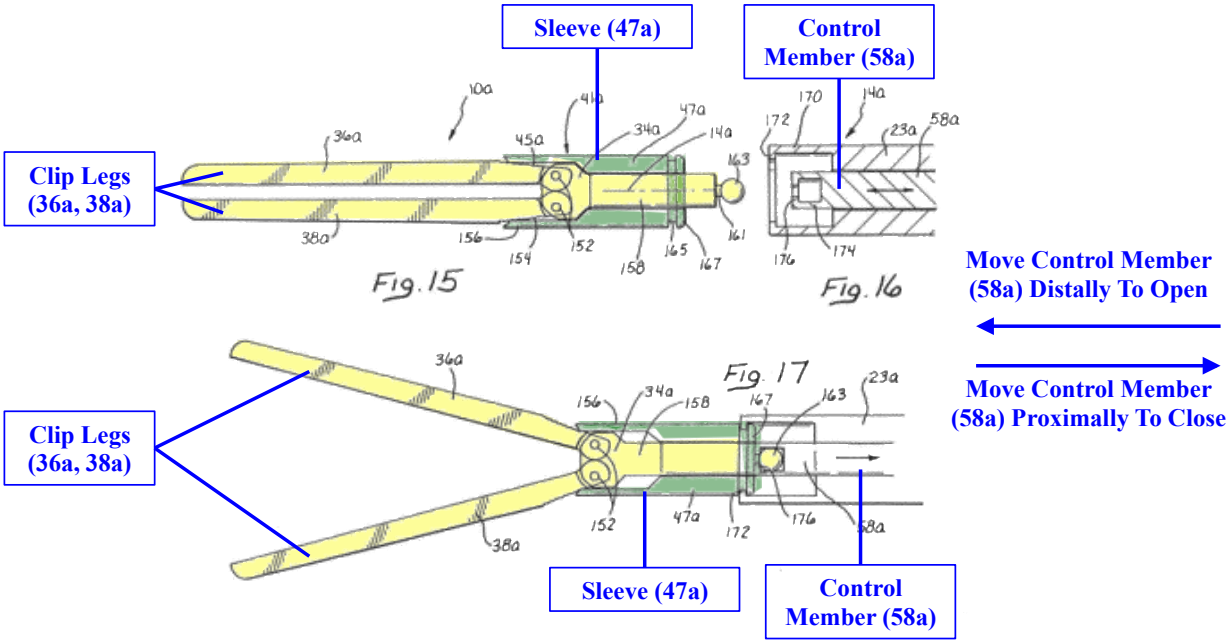
Sackier discloses this limitation, for the reasons in Sections V.A.1.c and V.A.5, *supra* at pp. 21-22, 29-30. (Ex. 1015, ¶ 84).

d. "a linkage operably associated with the control member to move the clip distally out of the sleeve and cause the first and second clip legs to spread apart from one another into a tissue-receiving configuration as the clip is moved distally relative to the sleeve, the linkage contacting the inner surfaces of the first and second clip legs to drive the first and second clip legs radially outward as the control member is moved distally relative to the clip."

The combination of Sackier and Nishioka discloses "a linkage operably associated with the control member to spread the first and second clip legs apart from one another into a tissue-receiving configuration as the control member is moved distally relative to the clip, the linkage contacting the inner surfaces of the first and second clip legs to drive the first and second clip legs radially outward as the control member is moved distally relative to the clip," for the reasons in Section V.B.1.d, *supra* at pp. 48-49. (Ex. 1015, ¶ 85).

As shown below in annotated Figures 15-17, Sackier discloses that the operable association of the linkage with the control member moves the clip legs (36a, 38a) distally out of the sleeve (47a) and causes the clip legs (36a, 38a) to

spread apart into a tissue-receiving configuration as the clip legs (36a, 38a) are moved distally relative to the sleeve (47a):



(Ex. 1015, ¶ 86; Ex. 1008, 10:31-34 ("As noted, this axial movement of the slide 47a relative to the jaws 36a and 38a is accompanied by relative movement of the jaws 36a, 38a between the open and closed positions."); *see also* 9:41-48). As shown above in Section V.A.1.b, *supra* at pp. 20-21, the clip includes sleeve 47a, which remains in the body when the clip is separated from the control member. (Ex. 1015, ¶ 86). Annotated Figures 15-17 above show that control member (58a) moves distally relative to clip (47a) as the linkage (152) drives the clip legs (36a, 38a) apart. (Ex. 1015, ¶ 86).

10. Claim 14

Claim 14 depends from claim 13 and further requires "movement of the control member proximally causes a corresponding proximal movement of the clip into the sleeve, moving the clip from the tissue-receiving configuration to a closed configuration in which the first and second clip legs are moved radially inward toward one another." Sackier discloses this limitation, for the reasons in Section V.A.7, *supra* at p. 35. (Ex. 1015, ¶ 87).

11. Claim 15

Claim 15 depends from claim 13 and further requires "a link positioned proximally of the clip, wherein application of a proximal tensile force to the link via the control member causes the clip to separate from the control member." Sackier discloses this limitation, for the reasons in Section V.A.8, *supra* at pp. 35-36. (Ex. 1015, ¶ 88).

12. Claim 16

Claim 16 depends from claim 13 and further requires "the linkage is received through an opening formed in a proximal end of the clip." The combination of Sackier and Nishioka discloses this limitation, for the reasons in Section V.B.2, *supra* at pp. 49-51. (Ex. 1015, ¶ 89).

13. Claim 17

Claim 17 depends from claim 13 and further requires "the linkage comprises first and second linkage members, proximal ends of the first and second linkage members being connected to one another." The combination of Sackier and Nishioka discloses this limitation, for the reasons in Section V.B.3, *supra* at pp. 51-53. (Ex. 1015, ¶ 90).

14. Claim 18

Claim 18 depends from claim 13 and further requires "distal ends of the first and second clip legs include curved projections which are angled radially inward with respect to a longitudinal axis of the clip." The combination of Sackier and Nishioka discloses this limitation, for the reasons in Section V.B.7, *supra* at pp. 55-57. (Ex. 1015, ¶ 91).

15. Claim 19

Claim 19 depends from claim 13 and further requires "a distal end of the first clip leg includes a plurality of pointed protrusions interlocking with a plurality of corresponding recesses formed in a distal end of the second clip leg." The combination of Sackier and Nishioka discloses this limitation, for the reasons in Section V.B.8, *supra* at pp. 57-59. (Ex. 1015, ¶ 92).

16. Independent Claim 20

a. "A method, comprising"

Sackier discloses "[a] method for operating [a] clamp." (Ex. 1015, ¶ 93; Ex. 1008, 3:1-2 ; *see also id.*, 9:5-7, Figures 11-19).

b. "inserting into a body a medical device comprising a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface, a control member extending from a proximal actuator to the clip and a linkage coupled to the control member"

Sackier discloses inserting into a body a medical device. (Ex. 1015, ¶ 94; Ex. 1008, 1:6-8 ("clamps and clamp appliers for use in occluding body conduits"), 3:1-15, 9:5-12, 11:57-64, 14:5-24). The medical device described in Sackier comprises a clip having first and second clip legs, each having an inner surface, a control member extending from a proximal actuator to the clip, and a linkage coupled to the control member, for the reasons in Section V.B.1, *supra* at pp. 20-25. (Ex. 1015, ¶ 95).

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

Sackier discloses positioning the medical device at a desired deployment location. (Ex. 1015, ¶ 96; Ex. 1008, 8:29-31 ("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."), 11:57-64).

d. "moving the control member distally to cause the clip to move distally relative to a sleeve housing at least a portion of the clip therein, the movement causing the linkage to contact the first and second inner surfaces to drive the first and second clip legs radially outward to a tissue-receiving configuration"

Sackier discloses moving the control member distally to cause the clip to move distally relative to a sleeve housing at least a portion of the clip therein, for the reasons in Section V.B.9.d, *supra* at pp. 60-61. (Ex. 1015, ¶ 97).

Nishioka discloses moving the control member distally to cause the linkage to contact the first and second inner surfaces to drive the first and second clip legs radially outward to a tissue-receiving configuration. (Ex. 1015, ¶ 98). As shown below in annotated Figure 2, Nishioka discloses in one embodiment a linkage (distal end portion of control wires 40, 41 (highlighted in yellow)) coupled to the control member (40, 41), where moving the control member (40, 41) distally causes the linkage to contact the inner surfaces of the clip legs (80, 81) to drive the clip legs radially outward to a tissue-receiving configuration:

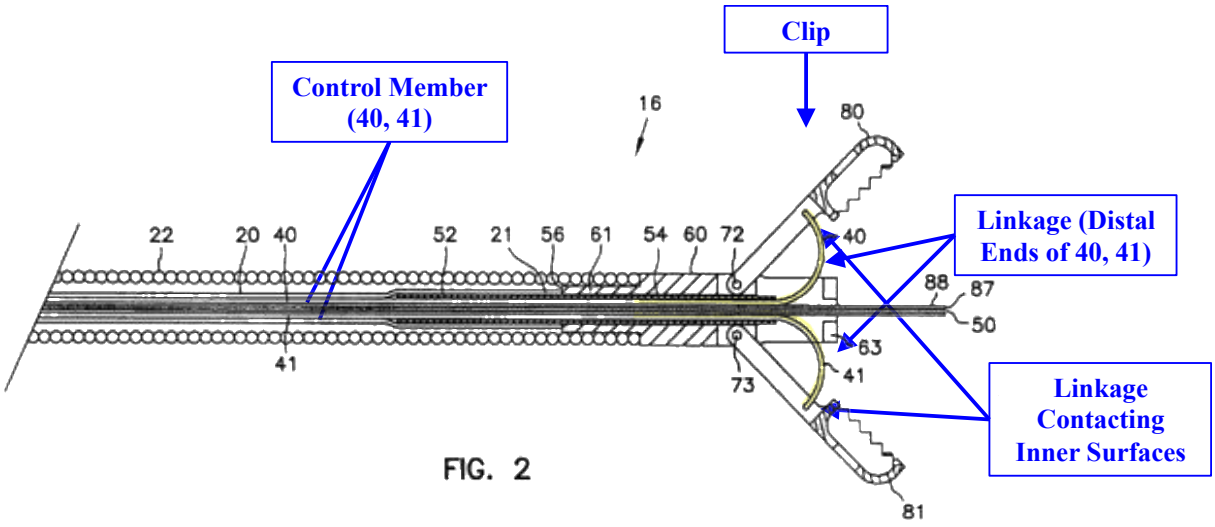


FIG. 2

(Ex. 1015, ¶ 98; Ex. 1005, 4:10-15 ("[C]ontrol wires 40, 41 are secured to slider 30 which . . . form[s] an actuator mechanism for the forceps 10. Movement of slider 30 causes axial movement of reinforcing tube 29, tube 20 and control wires 40, 41 relative to coil 22, which is used to actuate the cutting jaws."), 5:12-15 ("The control wires are formed of wire which is stiff enough to push against the jaws to open them, but flexible enough to flex as the wires are retracted to pull the jaws together."), 5:49-54 ("[T]he forceps jaws can be opened by pushing slider 30 of the control handle forward. This causes movement (to the right in FIG. 2) of . . . the control wires 40, 41, and the optical fiber 50. The control wires push against the jaws, causing them to open.")).

Likewise, as shown below in annotated Figure 8, Nishioka discloses in another embodiment a linkage (tubular slide member 120, control links 136, 138 (highlighted in yellow)) coupled to the control member (fiber 150), where moving

the control member (150) distally causes the linkage to contact the inner surfaces of the clip legs (180, 181) to drive the clip legs radially outward to a tissue-receiving configuration:

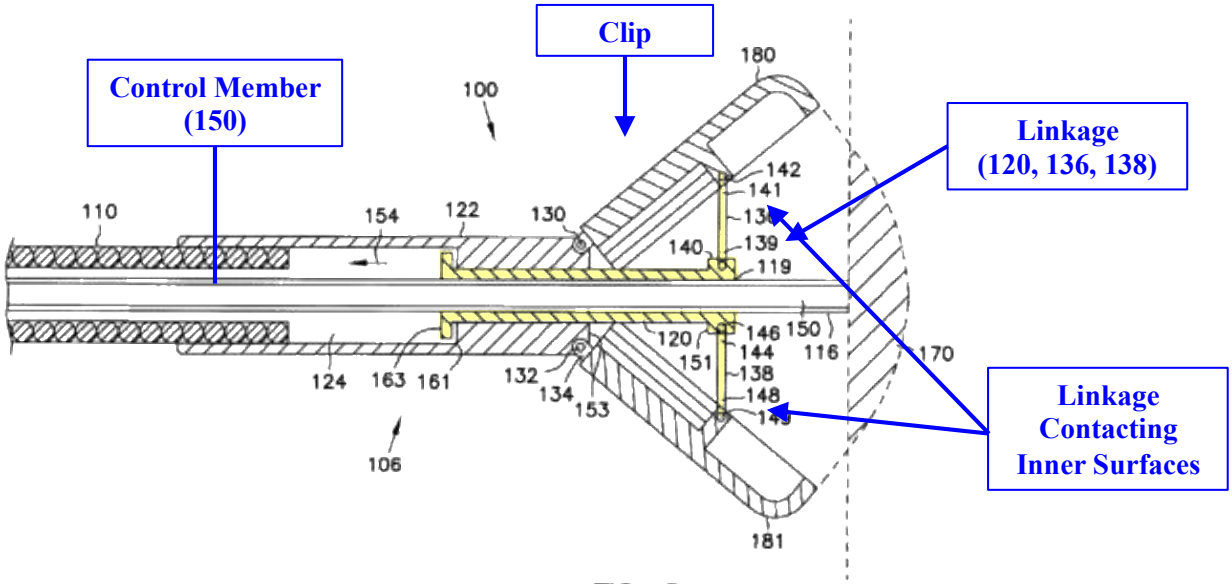


FIG. 8

(Ex. 1015, ¶ 99).

> "The fiber 150 is secured to the tubular slide member 120 in a suitable manner such as with cement. The jaws 180, 181 are connected to the tubular slide member 120 by a pair of control links 136, 138, which are rigid members that function as a linkage mechanism connecting the cutting jaws to the tubular slide member. Control link 136 has one end 139 connected to tubular slide member 120 by a pin 140. The other end 141 of the control link 136 is connected to of jaw 180 by a pin 142. Similarly, control link 138 has one end 144 connected to

> tubular slide member 120 by a pin 146 and its other end 148 connected to jaw 181 by a pin 149. Thus, axial movement of the optical fiber in the direction of arrow 154, as the optical fiber is retracted, causes axial movement of tubular slide member 120, pivoting the control links 136, 138, about their ends 139 and 144, respectively, drawing the jaws together to actuate the cutting jaws 180, 181.

(Ex. 1005, 8:10-26).

> [T]he forceps jaws can be opened by advancing the slider 30, thereby advancing the optical fiber 150 forwardly through the handle. This causes the tubular slide member 120 to move forwardly (to the right in FIG. 8), which in turn causes pivoting of the control links 136 and 138. As the control links pivot, the control links push against the jaws, causing the jaws to open."

(Id. at 8:63-9:2).

It would have been obvious to modify the device reflected in Figures 15-17 of Sackier to include the linkage described in Nishioka, such that moving the control member of the modified device distally would cause the linkage to contact the first and second inner surfaces to drive the first and second clip legs radially

outward to a tissue-receiving configuration, for the reasons in Section V.B.1.d, *supra* at pp. 48-49. (Ex. 1015, ¶ 100).

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 so that target tissue is received between the clip legs, for the reasons in Section V.A.10.e, *supra* at p. 41.

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

Sackier discloses drawing the control member proximally relative to the sleeve to draw the clip into the sleeve to receive the target tissue between the first and second clip legs, for the reasons in Section V.A.10.f, *supra* at p. 41.

g. "applying a proximal tensile force of at least a threshold level to the control member to separate a link coupling the control member to the clip."

Sackier discloses applying a proximal tensile force of at least a threshold level to the control member to separate a link coupling the control member to the clip, for the reasons in Section V.A.10.g, *supra* at pp. 42-43.

C. Ground 3: There is a Reasonable Likelihood That Claims 1-12 and 20 Are Anticipated By Malecki (Ex. 1003)

Malecki issued on May 6, 1997 and qualifies as prior art at least under 35 U.S.C. §§ 102(a) and (b). Malecki was not cited during prosecution of the '027 patent.[7] As demonstrated below, Malecki discloses medical devices and methods with each and every limitation described in claims 1-12 and 20. Accordingly, these claims are anticipated by Malecki.

1. Independent Claim 1

a. "A medical device, comprising"

Malecki discloses a medical device in the form of "[a] clamp for clamping a body structure in a patient." (Ex. 1015, ¶ 104; Ex. 1003, Abstract; *see also*, *e.g.*, 3:32-36, Figs. 17-32).

b. "a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface"

As shown below in annotated Figure 28A, Malecki discloses a clip (clamp 304C) having first and second clip legs (jaws 308C, 310C), each having an inner surface:

[7] Malecki is related to U.S. Patent No. 5,618,307 ("Donlon"), which is listed as a cited reference on the cover of the '027 patent, but Donlon was not substantively addressed on the record during prosecution.

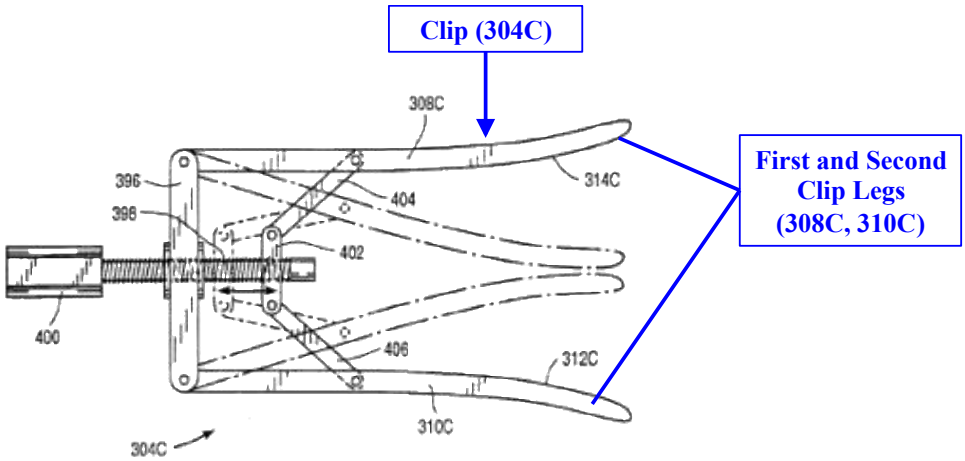


FIG. 28A

(Ex. 1015, ¶ 105; Ex. 1003, 17:43-48; *see also, e.g.*, 17:42-43, Figure 28A).

c. "a control member extending from a proximal actuator to the clip"

As shown below in annotated Figures 25 and 28A, Malecki discloses a control member (hollow drive body 346B) extending from a proximal actuator (clamp positioner 306B) to the clip (304C):

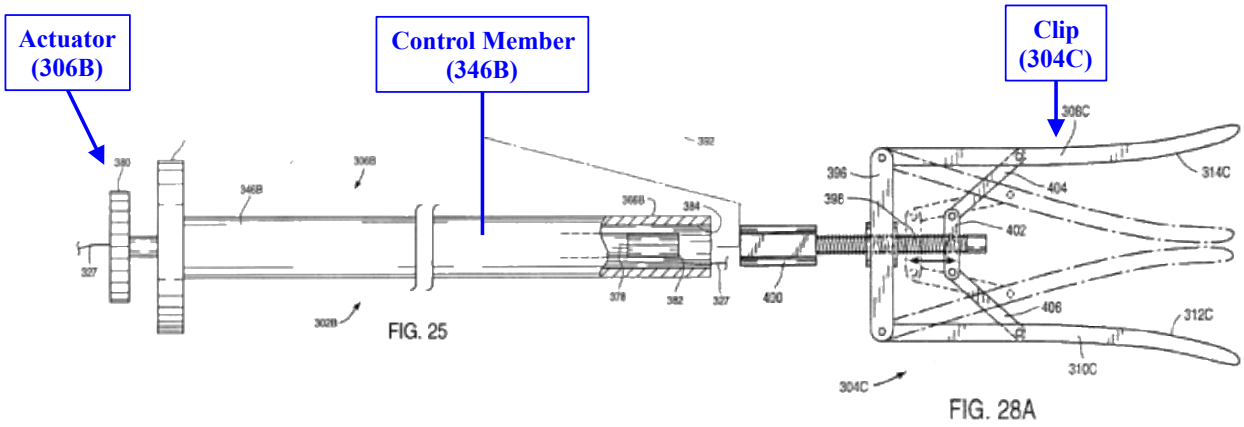


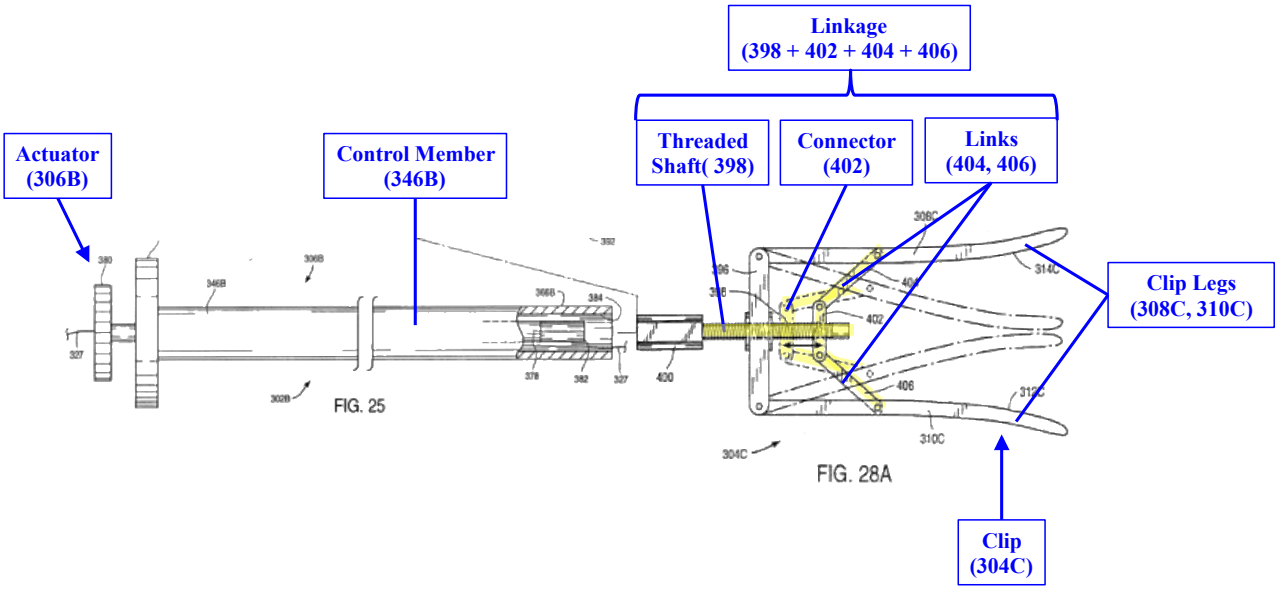
FIG. 25

FIG. 28A

(Ex. 1015, ¶ 106; Ex. 1003, 17:50-62; *see also, e.g.*, Figs. 25).

d. "a linkage operably associated with the control member to spread the first and second clip legs apart from one another into a tissue-receiving configuration as the control member is moved distally relative to the clip, the linkage contacting the inner surfaces of the first and second clip legs to drive the first and second clip legs radially outward as the control member is moved distally relative to the clip."

As shown below in annotated Figures 25 and 28A, Malecki discloses a linkage (threaded shaft 398 and connector 402 and links 404, 406 (highlighted in yellow)) operably associated with the control member:

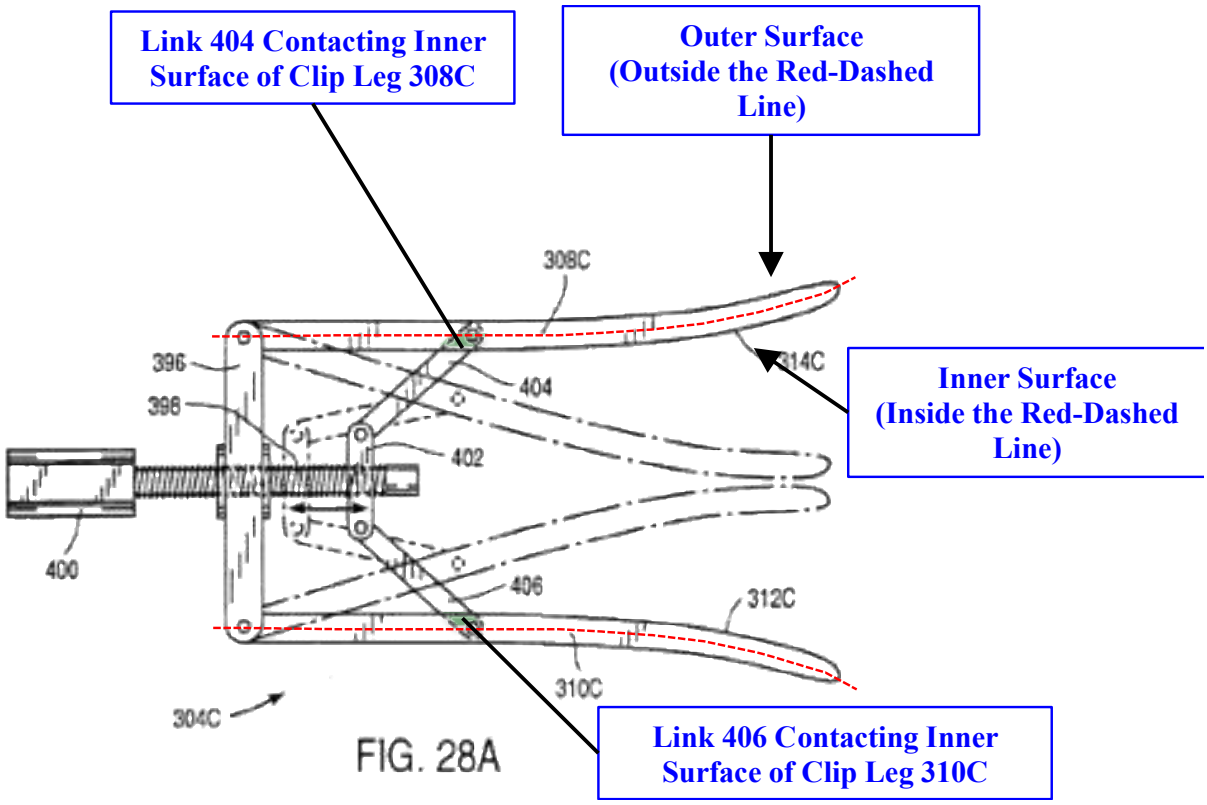


(Ex. 1015, ¶ 107).

The linkage (398, 402, 404, 406) is operably associated with the control member (346B) to spread the first and second clip legs (308C, 310C) apart from one another into a tissue-receiving configuration as the control member (346B) is

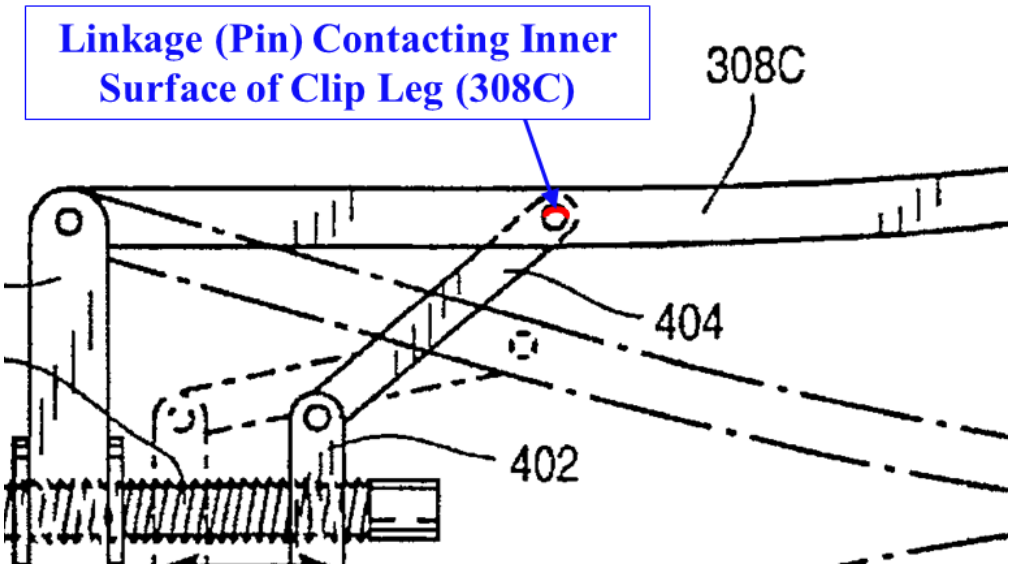
moved distally relative to the clip (304C), and to drive the first and second clip legs (308C, 310C) radially outward as the control member (346B) is moved distally relative to the clip (304C). (Ex. 1015, ¶ 108). In particular, when the clip 304C is in a closed configuration (illustrated in Figure 28A as a "dashed line position"), distal movement of the hollow drive body 346B relative to the clip 304C causes the connector 402 and links 404, 406 of the linkage to spread the first and second clip legs (308C, 310C) apart from one another, and to drive the first and second clip legs radially outward into a tissue-receiving configuration (illustrated in Figure 28A as a "solid line position"). (Ex. 1015, ¶ 108; Ex. 1003, 17:50-62 (explaining that "the connector 402 is coupled to first and second jaws 308C, 310C by links 404, 406 so axial displacement of shaft 398 moves jaws 308C, 310C between the open, solid line position to the closed, dashed line position.")

As shown below in annotated Figure 28A, the links 404, 406 contact the inner surfaces of the first and second clip legs (308C, 310C) to spread and drive the clip legs radially outward (inner surface contact highlighted in green):



(Ex. 1015, ¶ 109).

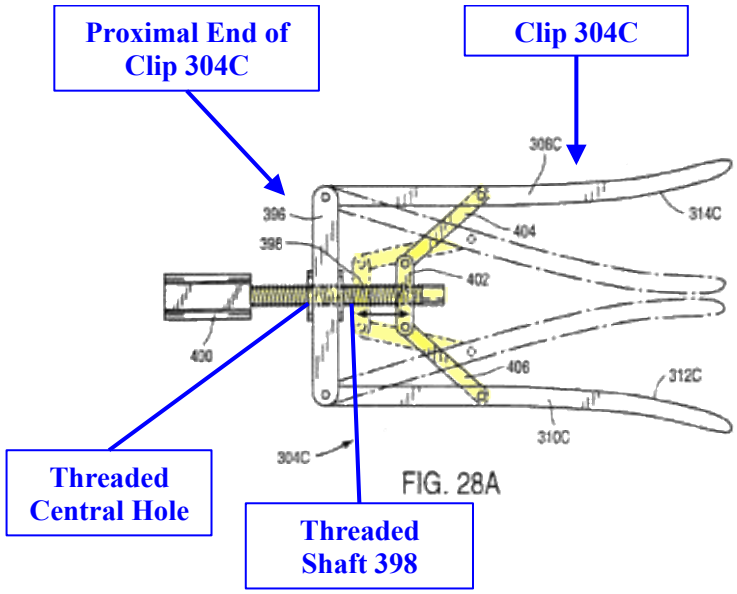
Additionally, Malecki discloses alternate "inner surfaces of the first and second clip legs." (Ex. 1015, ¶ 110). As shown below in an annotated excerpt of Figure 28A, the linkage (pins connecting links 404, 406 to clip legs (308C, 310C)) contact the inner bearing surface of the pin holes (*i.e.*, inner surfaces of the clip legs) located in clip legs (308C, 310C). (Ex. 1015, ¶ 110). The linkage (pins) contact the inner bearing surfaces (highlighted in red) to spread and drive the clip legs radially outward. (Ex. 1015, ¶ 110).



Excerpt of Figure 28A

2. Claim 2

Claim 2 depends from claim 1 and further states that "the linkage is received through an opening formed in a proximal end of the clip." As shown below in annotated Figure 28A, Malecki discloses that the threaded shaft 398 of the linkage is received through an opening (threaded central hole) formed in a proximal end of the clip (base 396 of the clip (304C)):



(Ex. 1015, ¶ 111; Ex. 1003, 117:50-51, Figure 28A).

3. Claim 3

Claim 3 depends from claim 1 and further states that "the linkage comprises first and second linkage members, proximal ends of the first and second linkage members being connected to one another." As shown below in annotated Figure 28A, the linkage (highlighted in yellow) comprises first and second linkage members (links 404, 406), which are connected at their proximal ends via connector 402:

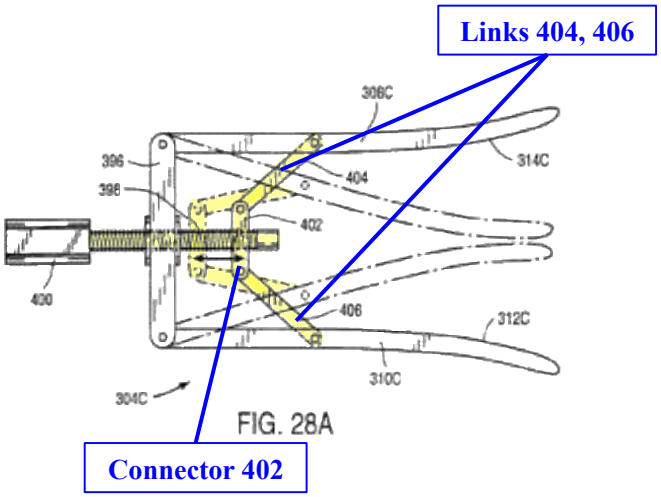


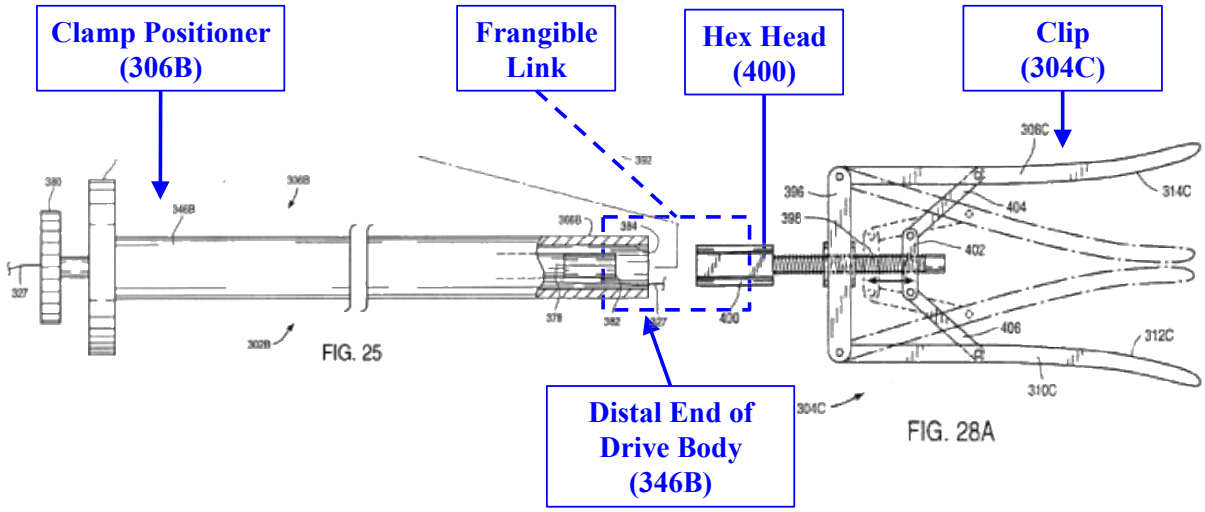
FIG. 28A

(Ex. 1015, ¶ 112; Ex. 1003, 17:58-59).

4. Claim 4

Claim 4 depends from claim 1 and further requires "a frangible link coupling the clip to the control member." As explained above with respect to claim 1, the clip 304C in Figure 28A is actuated using "[a] clamp positioner similar to that shown in FIG. 25." (Ex. 1015, ¶ 113; Ex 1003, 17:55-57). Figures 25 and 28A

(reproduced and annotated below) depict the clip (304C) and clamp positioner (306B), respectively:



During operation, the distal end of the clamp positioner 306B links to the clip 304C via hex head 400. (Ex. 1015, ¶ 113). Once the clip (304C) has been clamped onto a structure in the body, the clamp positioner 306B is "removed from the patient through trocar sleeve [(not shown)]," while the clip (304C) remains behind in the body. (Ex. 1015, ¶ 113; Ex. 1003, 17:35-39, 18:34-37 (the clip is "completely separable from the clamp positioner . . . after being clamped onto a hollow body structure")). The clamp positioner 306B is removed by pulling proximally on the positioner, thereby applying a tensile load to the link (346B, 400) and causing the clip (304C) and clamp positioner 306B to become unlinked. (Ex. 1015, ¶ 113). Thus, the link between the two components (clip (304C) and

control member (346B)) become unlinked when a tensile load is applied ("frangible link"). (Ex. 1015, ¶ 113).

5. Claim 5

Claim 5 depends from claim 4 and further requires "the control member is reversibly operable to move the clip between the tissue-receiving configuration and a closed configuration." Malecki discloses that the control member (including hollow drive body 346B) is reversibly operable to move the clip (304C) between an open, tissue-receiving configuration and a closed configuration:

> [T]he proximal end 394 of hollow drive body 346B is *rotated thereby . . . permitting jaws 308B, 310B to open*. Once the aorta is properly positioned between jaws 308B, 310B, proximal end 394 of hollow drive body 346B is *rotated in the opposite direction to close the jaws 308B, 310B.*

(Ex. 1015, ¶ 114; Ex. 1003, 17:34-37; *see also id.*, 17:58-62).

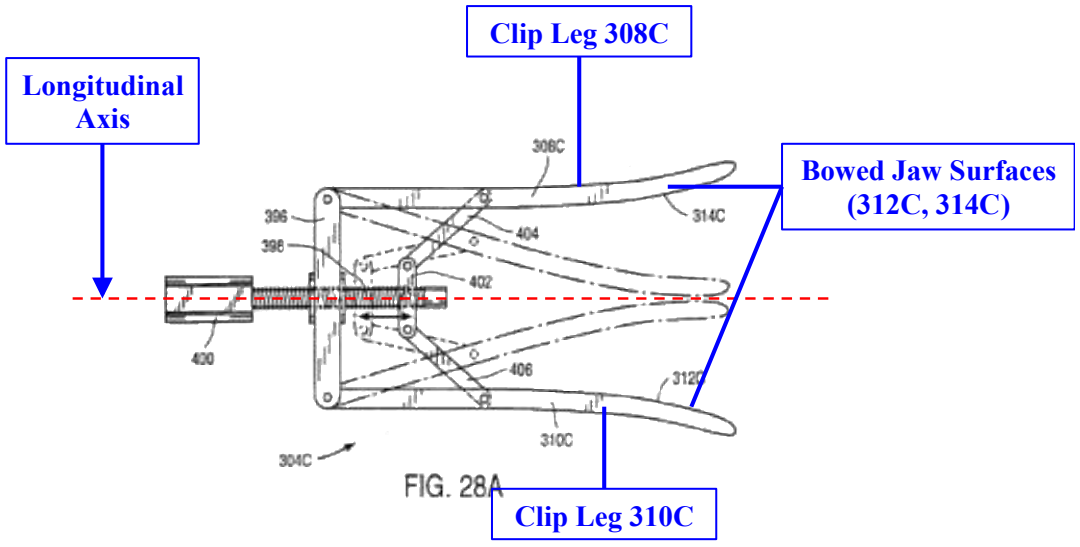
6. Claim 6

Claim 6 depends from claim 5 and further requires "an outer sleeve housing a proximal portion of the clip therewithin, wherein an engagement of outer walls of the first and second clip legs with inner walls of the sleeve prevents movement of the clip to the tissue-receiving configuration." Malecki discloses that the clip is introduced into the body "through a trocar sleeve" while the clip is in a closed configuration. (Ex. 1015, ¶ 115; Ex. 1001, 17:28-30, Figure 23 (trocar sleeve

348)). The trocar sleeve is an outer sleeve housing the clip within, and engagement of outer walls of the clip legs with inner walls of the trocar sleeve prevents movement of the clip to the open tissue-receiving configuration. (Ex. 1015, ¶ 115).

7. Claim 7

Claim 7 depends from claim 1 and further requires "distal ends of the first and second clip legs include curved projections which are angled with respect to a longitudinal axis of the clip." As shown below in annotated Figure 28A, the distal ends of the first and second clip legs (308C, 310C) include curved projections ("bowed jaw surfaces 312C, 314C"), which are angled with respect to a longitudinal axis of the clip:



(Ex. 1015, ¶ 116; Ex. 1003, 17:43-46; *see also id.*, 17:46-48 ("Jaws 308C, 310C are also preferably curved when viewed from the side as shown in FIG. 28C.")).

8. Claim 8

Claim 8 depends from claim 7 and further requires "the curved projections are angled radially inward." As shown below in annotated Figure 28A, the curved projections ("bowed jaw surfaces 312C, 314C") are angled radially outward with respect to the longitudinal axis:

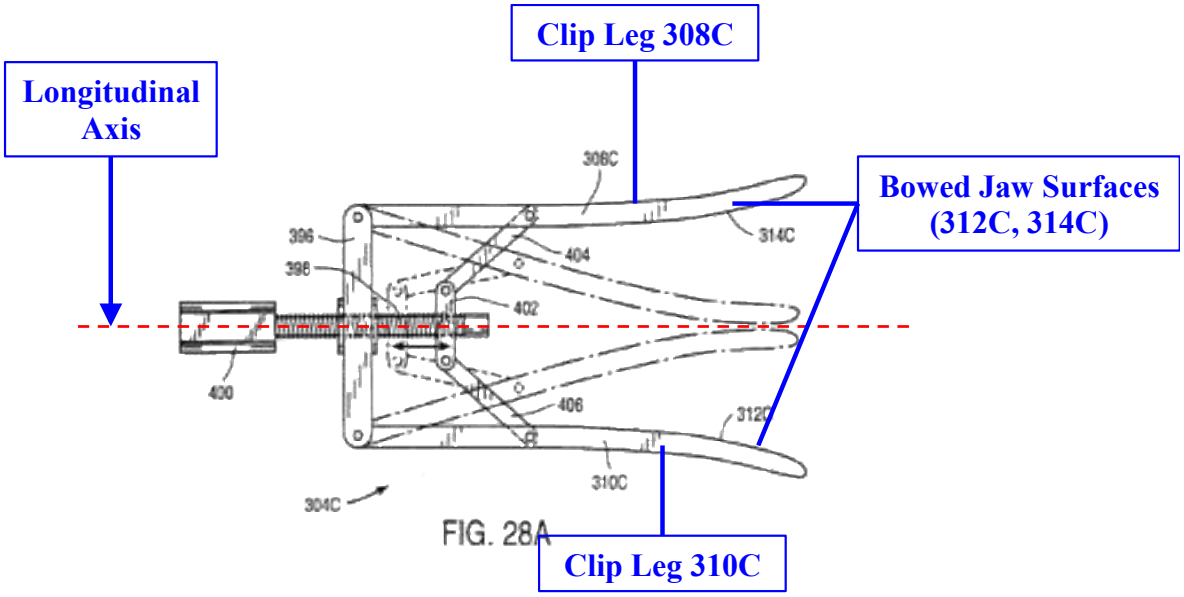
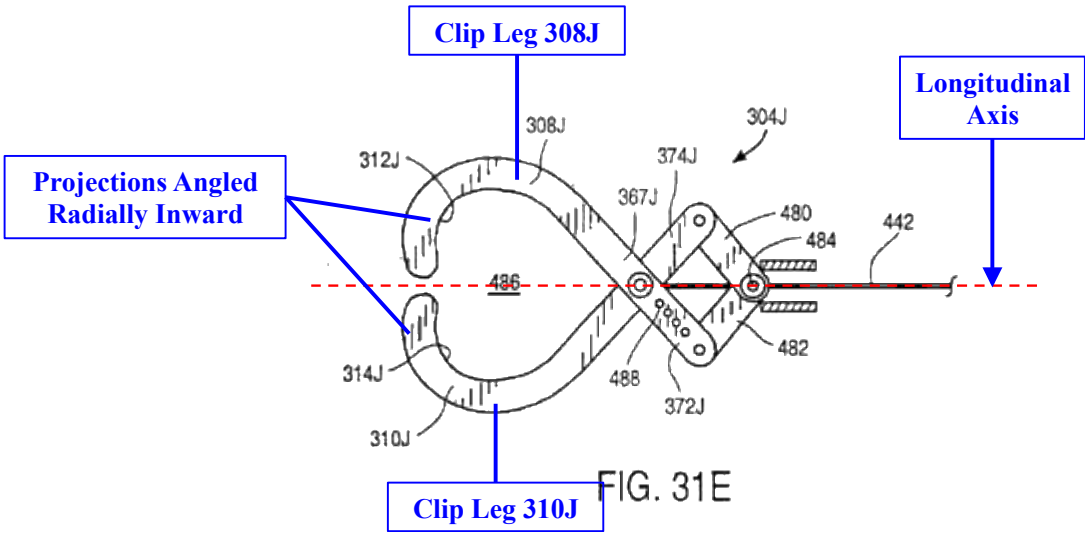


FIG. 28A

(Ex. 1015, ¶ 117). However, Malecki discloses that "any jaw shape may be used with the clamps and actuating mechanisms described herein." (Ex. 1015, ¶ 117; Ex. 1003, 24:52-56). As shown below in annotated Figure 31E, Malecki discloses that the clip may include "concave jaws (308J, 310J)," which include curved projections that are angled radially inward with respect to the longitudinal axis:



(Ex. 1015, ¶ 117; Ex. 1003, 20:1-2; *see also id.*, 15:35-40, 19:43-45, 21:65-67).

9. Claims 9-12

Claim 9 depends from claim 1 and further requires "a distal end of the first clip leg includes an angled protrusion which interlocks with a corresponding angled recess formed in a distal end of the second clip leg."

Claims 10, 11, and 12 each depend from claim 9 and further require:

- "the protrusion is a pointed tooth and the recess is a pointed recess" (claim 10);
- "the protrusion is a plurality of pointed teeth and the recess is a plurality of correspondingly shaped pointed recesses" (claim 11); and
- "the protrusion is one of a multi-toothed wave and an offset L-tooth" (claim 12).

Malecki discloses that "any jaw shape may be used with the clamps and actuating mechanisms described herein." (Ex. 1003, 24:52-56). As shown below in annotated Figure 31B, Malecki discloses that the distal ends of the clip legs may include a plurality of angled protrusions (and a multi-tooth wave) which interlock with corresponding angled recesses:

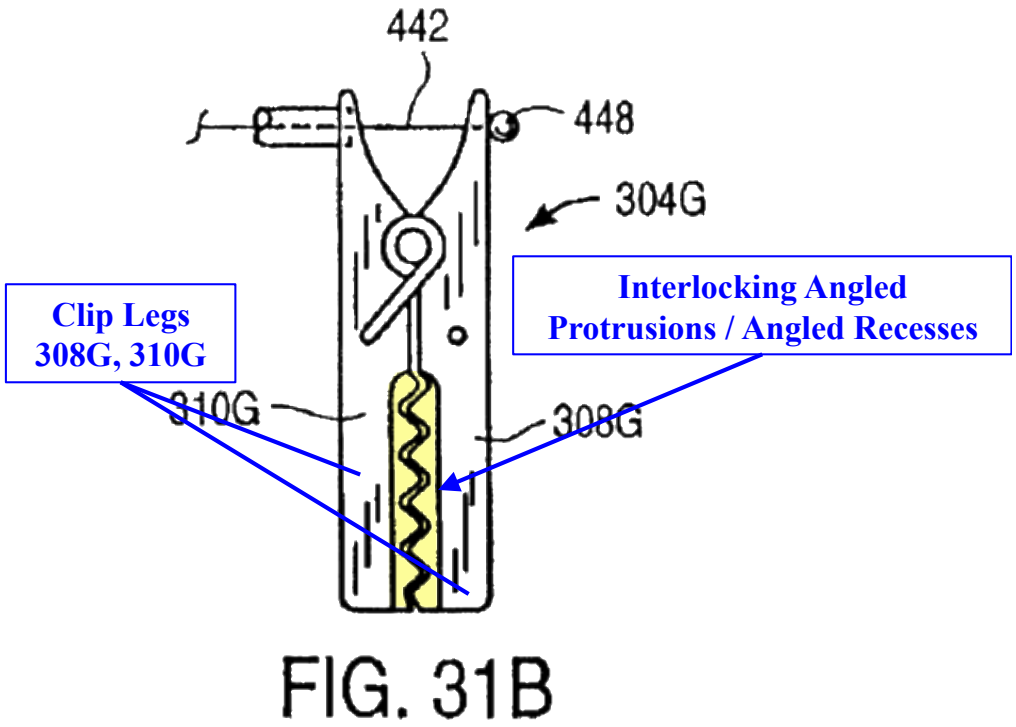


FIG. 31B

(Ex. 1015, ¶ 120; *see also* Ex. 1003, 7:48-50, 18:15-18, Figures 35, 37-39, 49).

10. Independent Claim 20

a. "A method, comprising"

Malecki discloses a "[c]lamp assembly and method of use." (Ex. 1015, ¶ 121; Ex. 1003, Title; *see also id.*, 16:51-52).

b. "inserting into a body a medical device comprising a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface, a control member extending from a proximal actuator to the clip and a linkage coupled to the control member"

Malecki discloses inserting into a body a medical device including a clip (clamp 304B). (Ex. 1015, ¶ 122; Ex. 1003, 17:28-34 ("The clamp 304B is introduced into the thoracic cavity TC through a trocar sleeve 348 while in the closed position of FIG. 25."); *see also* 16:53-59, 16:60 –17:2, 17:7-15, 28-39, Figures 27A and 27B; Section V.C.1). As shown below in annotated Figure 25, the medical device includes a clip (304B) having first and second clip legs (308B, 310B), each with an inner surface, and a control member (stabilizing rod 378 and square shaft 382) extending from a proximal actuator (306B) to the clip (304B):

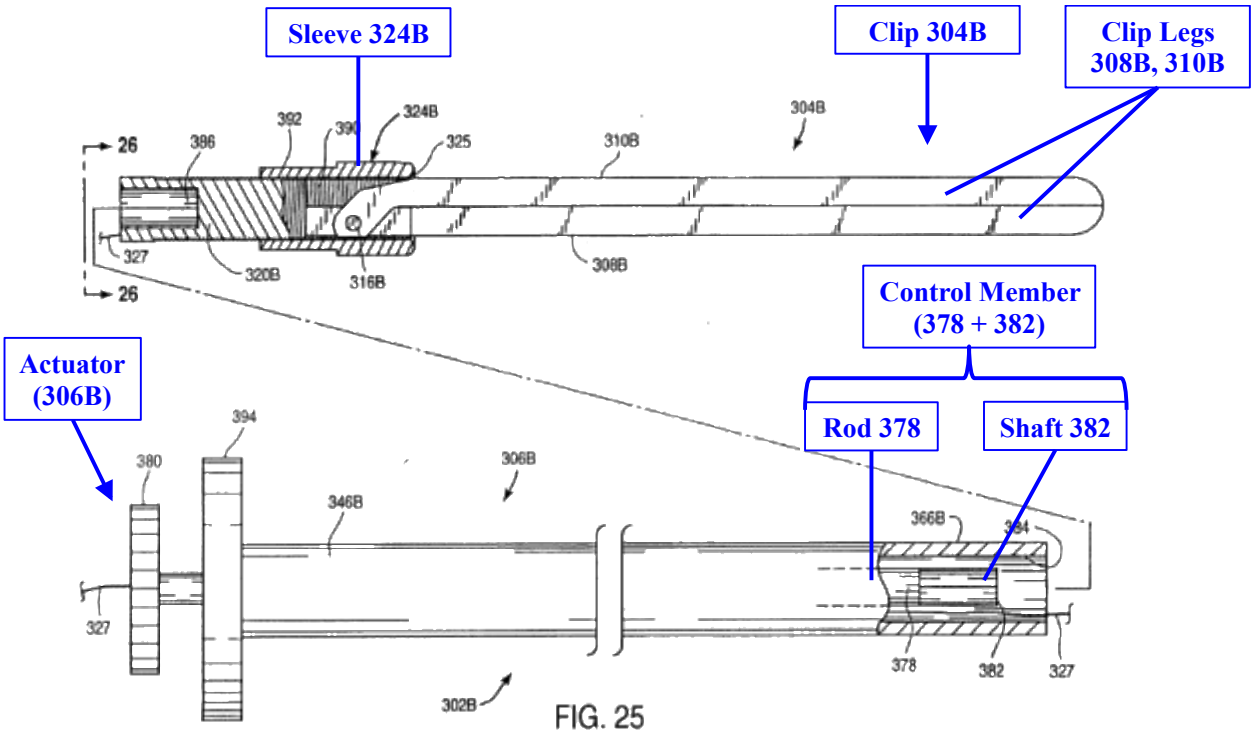
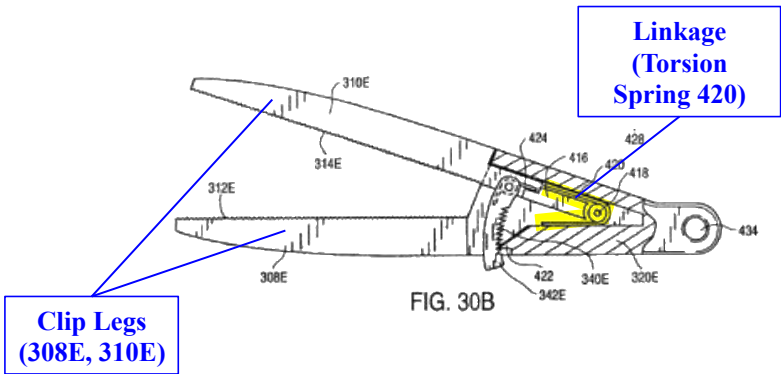


FIG. 25

(Ex. 1015, ¶ 122). The device also includes a linkage ("torsion spring"), which is coupled to the control member (378, 382) when the actuator (306B) is linked with the clip (304B), and which biases the clip legs (jaws 308B, 310B) towards the open position. (Ex. 1015, ¶ 122; Ex. 1003, 16:57-59 ("Jaws 308B, 310B are normally biased towards the open position of FIG. 27B by a torsion spring (not shown)."). The "torsion spring" is shown in Figure 30B, with respect to another embodiment. (Ex. 1015, ¶ 122; Ex. 1003, 18:14-15 ("A torsion spring 420 is mounted about pivot 418 which biases jaws 308, 310 to the open position of FIG. 30B.")). Figure 30B is reproduced and annotated below, and illustrates the interaction between the linkage ("torsion spring") and clip legs (308E, 310E):



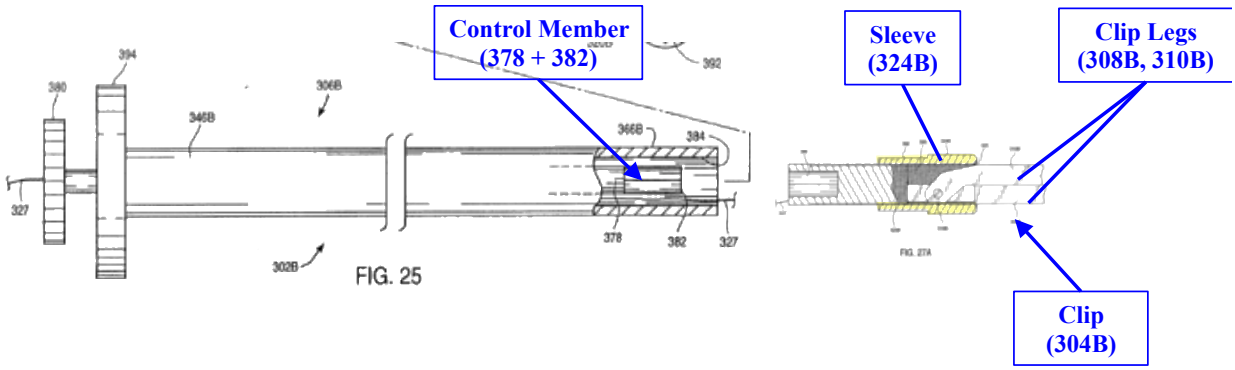
(Ex. 1015, ¶ 122).

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

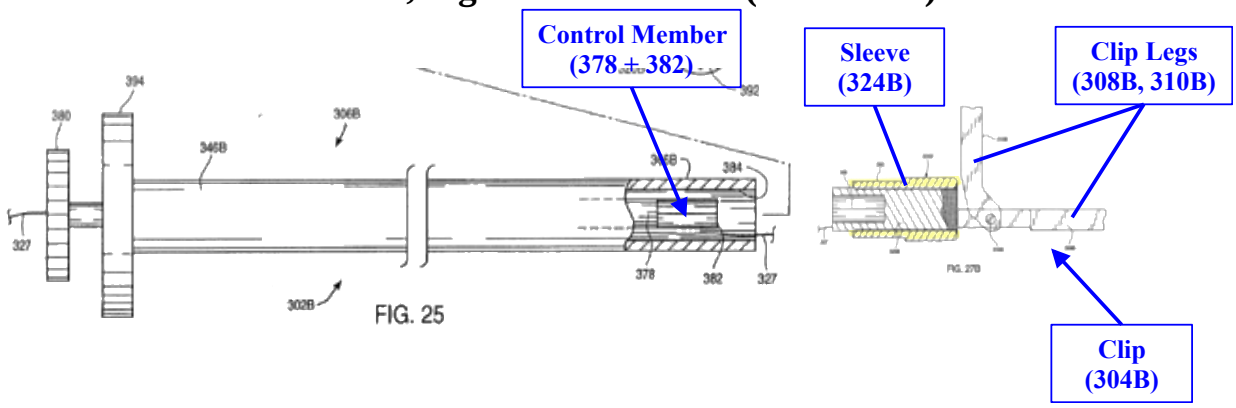
Malecki discloses positioning the medical device at a desired deployment location: "The clamp 304B is introduced into the thoracic cavity TC through a trocar sleeve 348 . . . . [until] clamp 304B is properly positioned . . . ." (Ex. 1003, 17:28-39).

d. "moving the control member distally to cause the clip to move distally relative to a sleeve housing at least a portion of the clip therein, the movement causing the linkage to contact the first and second inner surfaces to drive the first and second clip legs radially outward to a tissue-receiving configuration"

As shown below in annotated Figures 25, 27A, and 27B, Malecki discloses moving the control member (378, 382) distally relative to a sleeve (324B) housing at least a portion of the clip therein (304B), the movement causing the clip (304B) to move distally relative to the sleeve (324B) and the clip legs (308, 310B) to move radially outward:

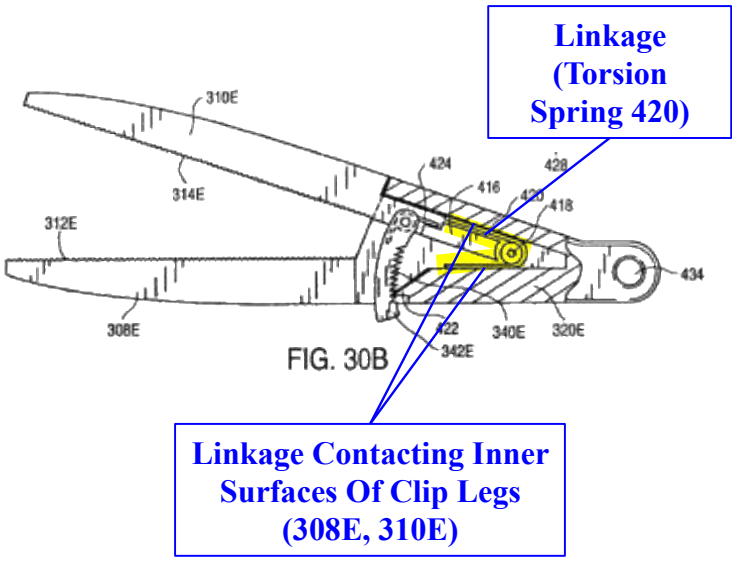


Malecki, Figures 25 and 27A (Annotated)



Malecki, Figures 25 and 27B (Annotated)

(Ex. 1015, ¶ 124). As the control member (320B) moves distally (from Figure 27A to Figure 27B), the movement causes the linkage ("torsion spring," shown below in annotated Figure 30B) to contact the first and second inner surfaces of the clip legs (308B, 310B) to drive the clip legs radially outward to a tissue-receiving configuration. (Ex. 1015, ¶ 124).

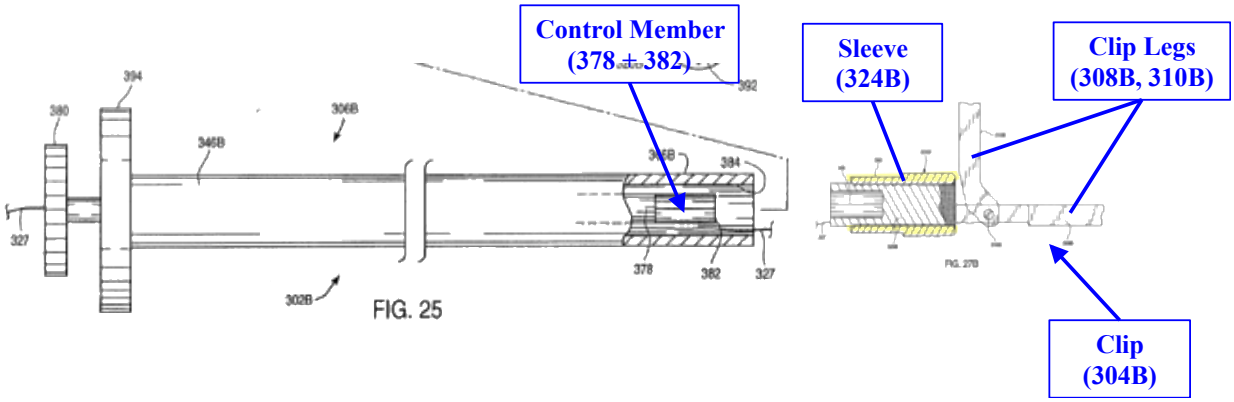


e. "adjusting a position of the clip so that target tissue is received between the first and second clip legs"

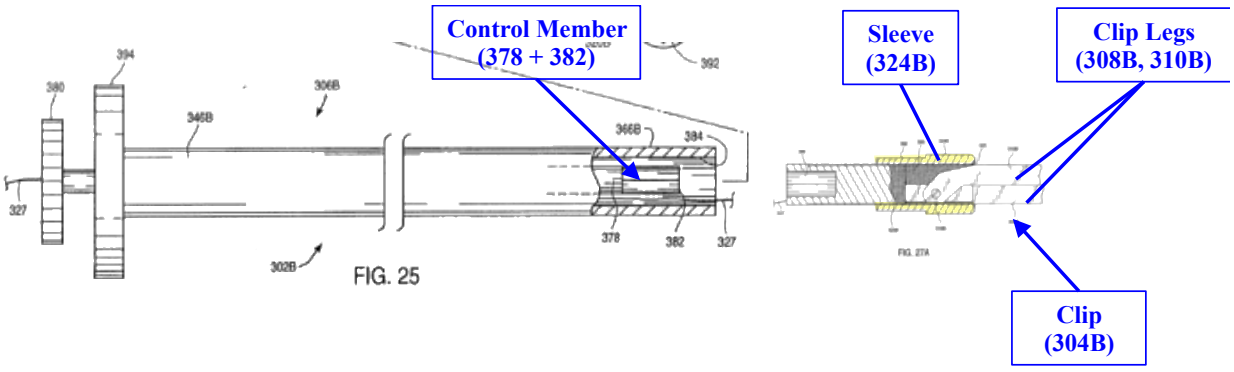
Malecki discloses adjusting a position of the clip so that target tissue is received between the first and second clip legs: "properly position[] [the aorta] between jaws 308, 310B." (Ex. 1015, ¶ 125; Ex. 1003, 17:34-37).

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

As shown below in annotated Figures 25, 27A, and 27B, Malecki discloses drawing the control member (378, 382) proximally relative to the sleeve (324B) to draw the clip (304B) into the sleeve to receive target tissue between the clip legs (308B, 310B):



Malecki, Figures 25 and 27B (Annotated)



Malecki, Figures 25 and 27A (Annotated)

(Ex. 1015, ¶ 126; Ex. 1003, 17:28-39).

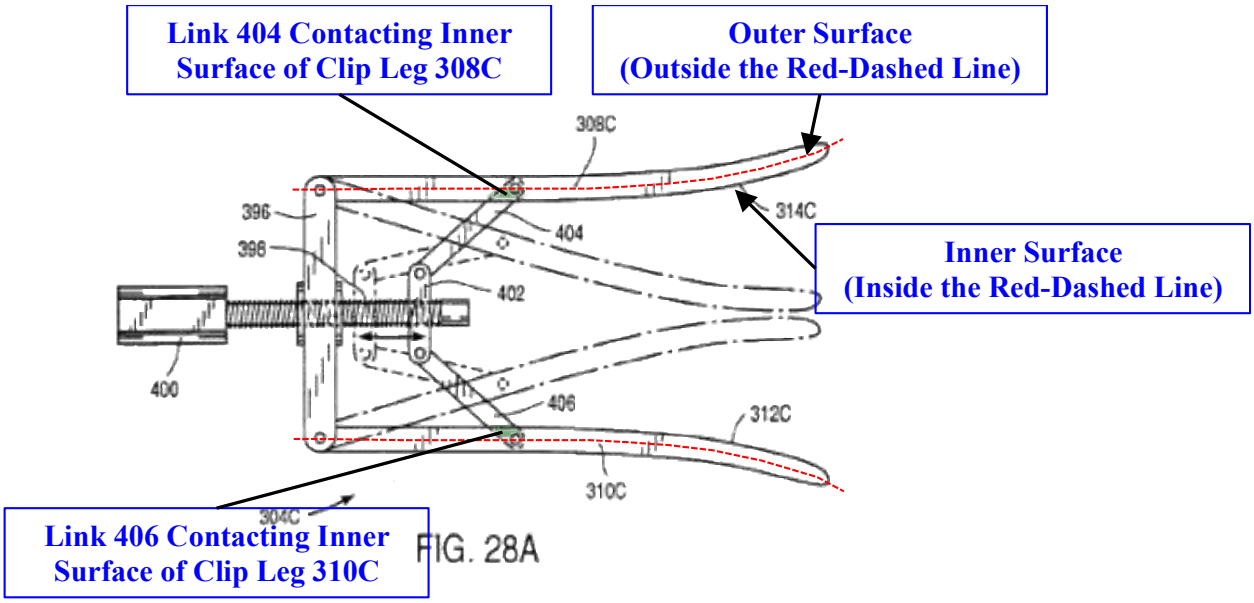
g. "applying a proximal tensile force of at least a threshold level to the control member to separate a link coupling the control member to the clip."

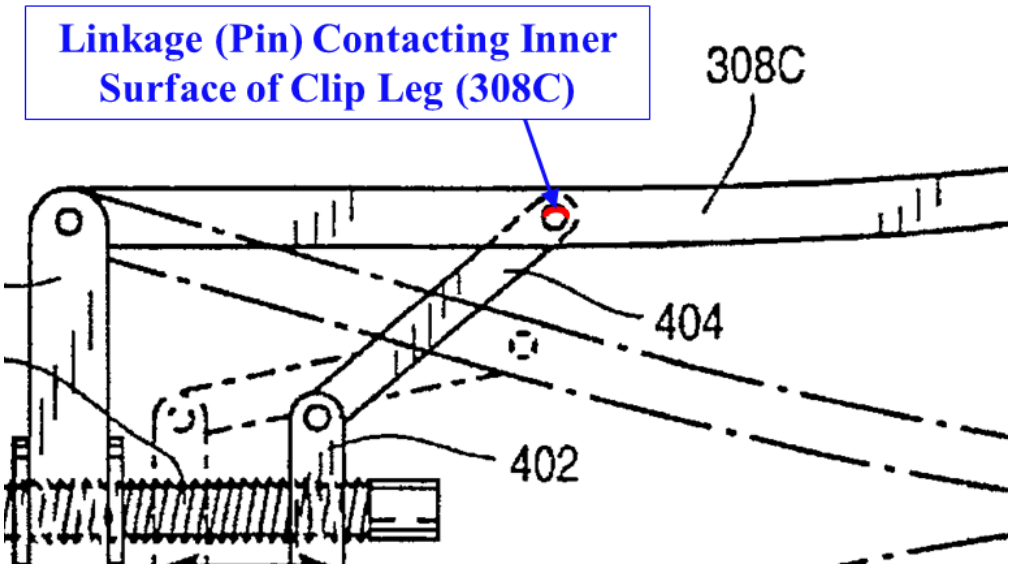
Malecki discloses applying a proximal tensile force of at least a threshold level to the control member to separate a link coupling the control member to the clip: "the clamp positioner 306B is preferably removed from the patient through trocar sleeve 348," while the clip (304B) remains behind in the body. (Ex. 1015, ¶ 127; Ex. 1003, 17:35-39, 18:34-37 (the clip is "completely separable from the clamp positioner . . . after being clamped onto a hollow body structure")). *See also* reasons in Section V.C.4, *supra* at pp. 77-79. (Ex. 1015, ¶ 127).

D. Ground 4: There is a Reasonable Likelihood That Claims 1-12 Are Obvious In View Of Malecki (Ex. 1003)

1. Independent Claim 1

Malecki discloses each and every limitation of claim 1, for the reasons in Section V.C.1, *supra* at pp. 70-75, including that the linkage in Figure 28A "contact[s] the inner surfaces of the first and second clip legs" in the alternative ways shown below (*see* Section V.C.1.d):





Excerpt of Figure 28A

(Ex. 1015, ¶ 128).

To the extent the Board disagrees, the "inner surface" limitation is not, in any event, a patentable distinction over Malecki. (Ex. 1015, ¶ 129). Indeed, the specification of the '027 patent, itself, does not explain how the "flexible linkage 1002" in Figures 10A and 10B is connected to or contacts the clip legs. (Ex. 1015, ¶ 129; *see* Ex. 1001, 8:60-9:25). Nor is there any disclosure in the specification of the '027 patent that contacting "inner surfaces" is in any way important, or provides any meaningful distinction over a linkage that connects to the clip legs without contacting "inner surfaces." (Ex. 1015, ¶ 129).

At most, the clip legs in Figure 28A of Malecki have three surfaces: (1) radially outward-facing surfaces; (2) radially inward-facing surfaces; and (3) side, or lateral surfaces:

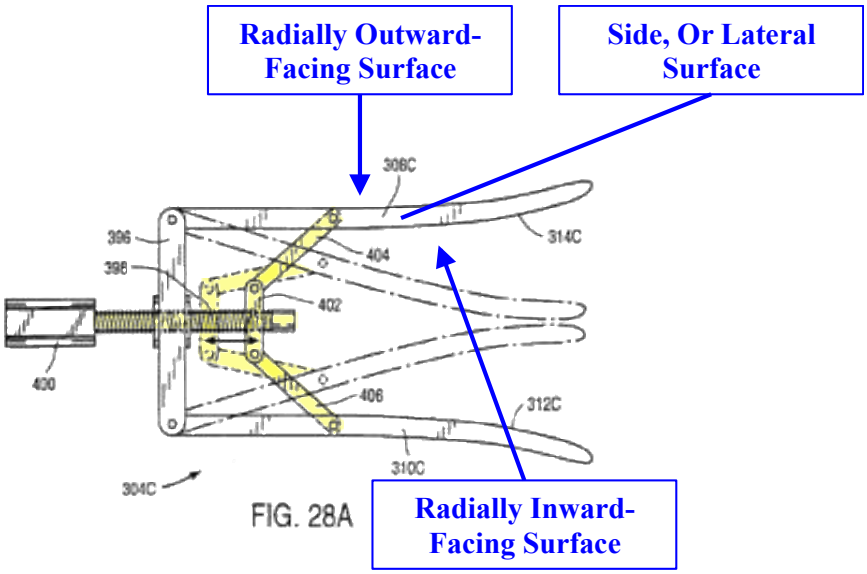


FIG. 28A

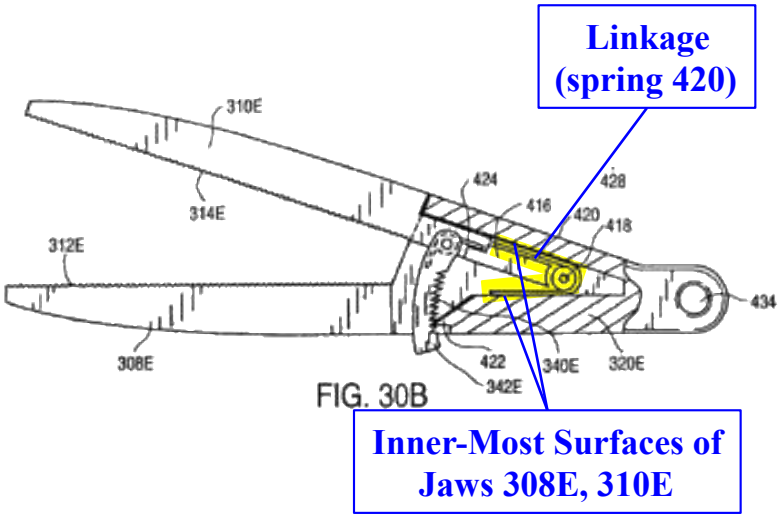
(Ex. 1015, ¶ 130).

It would have been obvious to a person of ordinary skill in the art to construct the device shown in Malecki's Figure 28A such that the links 404, 406 contact any one of these three surfaces, including especially the radially inner-facing surfaces of the first and second clip legs (308C, 310C). (Ex. 1015, ¶ 131). *KSR*, 550 U.S. at 421 ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.") Here, the three identified surfaces are a finite number of identified, predictable solutions to where to make the contact. (Ex. 1015, ¶ 131).

The person of ordinary skill in the art would have recognized that connecting the linkage in Figure 28A of Malecki with the radially-inward facing surfaces would provide advantages, such as the ability to expand the clip legs further and provide a narrower profile. (Ex. 1015, ¶ 132). Contacting the radially-inward facing surfaces would expand the clip legs further at least by the width of both clip legs because the linkage would be pushing on the radially-inward facing surfaces, as opposed to somewhere in the middle of the clip legs, as is shown in Figure 28A. (Ex. 1015, ¶ 132). Accordingly, with the same amount of linkage movement, the clip legs would be spread open farther. (Ex. 1015, ¶ 132). One of ordinary skill would recognize the importance of opening the clip legs apart as far as possible in order to more easily grasp objects or to grasp larger objects. (Ex. 1015, ¶ 132). Also, contacting the radially-inward facing surfaces would provide a narrower profile (where the profile is measured into the page shown in Figure 28A above) because the linkage would not sit on the top or bottom of the clip leg, as is currently shown in Figure 28A. (Ex. 1015, ¶ 132). One of ordinary skill in the art would recognize the importance of a narrow profile because the clips are often used in endoscopic procedures and enter the body through narrow tubes or trocars. (Ex. 1015, ¶ 132).

The skilled artisan also would have recognized that Malecki discloses other embodiments with linkages that contact the radially inner-most surfaces of the jaws

to spread the clip legs open and drive the clip legs radially outward. (Ex. 1015, ¶ 133; Ex. 1003, 16:58-59, 18:14-15, 19:45-46, Figs. 29B, 30B, and 31C). For example, Figure 30B (reproduced below) discloses a linkage (torsion spring 420) that contacts the radially inner-most surfaces of jaws 308E and 310E. (Ex. 1003, Figs. 30B, 31C). (Ex. 1015, ¶ 133).



The person of ordinary skill in the art would have recognized that the linkage in Figure 28A likewise could be configured to contact the radially inner-most surfaces of the clip legs 308C, 310C. (Ex. 1015, ¶ 133).

Modifying the device depicted in Figure 28A of Malecki so that the links 404, 406 contact the radially inner-facing surfaces would have been a matter of routine skill in the art, using simple mechanical elements such as those disclosed in Malecki to achieve predictable results. (Ex. 1015, ¶ 134). All that would have been required is to move the pivot connections between the links (404, 406) and

the clip legs (308C, 310C) from the lateral surfaces of the clip legs, to the inner-most surfaces of the clip legs. (Ex. 1015, ¶ 134). For example, a bracket that contained a pivot connection could be attached to the inner-most surface of the clip legs to attach the links (404, 406) to the clip legs (308C, 310C). (Ex. 1015, ¶ 134). Alternatively, for example, the links (404, 406) could be modified to include a hook on their distal ends that pivotally connects to a rod located at the inner-most surface of the clip legs. (Ex. 1015, ¶ 134). The modification would have been a common sense choice from a finite number of known possibilities, and would have been expected to improve the operation of the medical device by permitting the clip legs to spread apart as far as possible and reducing the profile of the clip. (Ex. 1015, ¶ 134). *See KSR*, 550 U.S. at 421.

2. Claim 2

Claim 2 depends from claim 1 and further states that "the linkage is received through an opening formed in a proximal end of the clip." Malecki discloses this limitation, for the reasons in Section V.C.2, *supra* at p. 76.

3. Claim 3

Claim 3 depends from claim 1 and further states that "the linkage comprises first and second linkage members, proximal ends of the first and second linkage members being connected to one another." Malecki discloses this limitation, for the reasons in Section V.C.3, *supra* at p. 77.

4. Claim 4

Claim 4 depends from claim 1 and further requires "a frangible link coupling the clip to the control member." Malecki discloses this limitation, for the reasons in Section V.C.4, *supra* at pp. 77-79.

5. Claim 5

Claim 5 depends from claim 4 and further requires "the control member is reversibly operable to move the clip between the tissue-receiving configuration and a closed configuration." Malecki discloses this limitation, for the reasons in Section V.C.5, *supra* at p. 79.

6. Claim 6

Claim 6 depends from claim 5 and further requires "an outer sleeve housing a proximal portion of the clip therewithin, wherein an engagement of outer walls of the first and second clip legs with inner walls of the sleeve prevents movement of the clip to the tissue-receiving configuration." Malecki discloses this limitation, for the reasons in Section V.C.6, *supra* at pp. 79-80.

7. Claim 7

Claim 7 depends from claim 1 and further requires "distal ends of the first and second clip legs include curved projections which are angled with respect to a longitudinal axis of the clip." Malecki discloses this limitation, for the reasons in Section V.C.7, *supra* at p. 80.

8. Claim 8

Claim 8 depends from claim 7 and further requires "the curved projections are angled radially inward." Malecki discloses this limitation, for the reasons in Section V.C.8, *supra* at pp. 81-82.

9. Claims 9-12

Claim 9 depends from claim 1 and further requires "a distal end of the first clip leg includes an angled protrusion which interlocks with a corresponding angled recess formed in a distal end of the second clip leg."

Claims 10, 11, and 12 each depend from claim 9 and further require:

- "the protrusion is a pointed tooth and the recess is a pointed recess" (claim 10);
- "the protrusion is a plurality of pointed teeth and the recess is a plurality of correspondingly shaped pointed recesses" (claim 11); and
- "the protrusion is one of a multi-toothed wave and an offset L-tooth" (claim 12).

Malecki discloses these limitations, for the reasons in Section V.C.9, *supra* at pp. 82-83.

VI. CONCLUSION

The grounds identified above establish a reasonable likelihood that Petitioners will prevail in their challenge of claims 1-20 of the '027 patent. Therefore, Petitioners respectfully request institution of an *inter partes* review to cancel those claims.

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, excluding a table of contents, a table of authorities, and a certificate of service or word count, contains 13,253 words as calculated by the "Word Count" feature of Microsoft Word 2010, the word processing program used to create it.

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

Dated: October 27, 2016

Respectfully submitted,

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

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 8,709,027, as well as the accompanying Power of Attorney, and Exhibits 1001, 1002, 1003, 1004, 1005, 1006, 1008, 1012, 1015, and 1017 have been served in their entirety on October 27, 2016, by Federal Express (Overnight Delivery) on:

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/ Dominic P. Zanfardino/
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