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. 9,271,731
Issue Date: March 1, 2016

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,271,731

Case No. IPR 2017-00440

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Cook Group Incorporated and Cook Medical LLC (collectively "Petitioners") respectfully request *inter partes* review of claims 1-20 of U.S. Patent No. 9,271,731 ("the '731 patent") (Ex. 1033). 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 '731 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 (the "Litigation"). Petitioners were served with an amended Complaint asserting the '731 patent on March 9, 2016.

2. Related *Inter Partes* Review Petitions

This Petition is being filed and served concurrently with a petition for *inter partes* review in IPR No. 2017-00435, which also challenges the patentability of claims 1-20 of the ’731 patent. Petitioners have also filed and served petitions for *inter partes* review in IPR Nos. 2017-00131, 2017-00132, 2017-00133, and 2017-00134, which challenge the patentability of the claims of related patents, U.S. Patent Nos. 8,685,048 and 8,709,027.

3. Related Pending Applications

The following patent applications are related to the ’731 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 '731 PATENT

The '731 patent relates generally to compression clips that can be used "to cause hemostasis of blood vessels located along the gastrointestinal tract." (Ex. 1033, 1:25-26; Ex. 1041, ¶18). The clips stop internal bleeding by clamping together the edge of a wound to achieve "hemostasis." (*Id*. at 2:62-66). The patent acknowledges that such clipping devices were known in the art before the '731 patent was filed. (*See id.*, pp. 1-2 (citing numerous prior art references); 1:53-55 (describing "Olympus Endoclips"); 2:32-38 (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")). (Ex. 1041, ¶18).

Besides this knowledge of the prior art clipping devices, a person of ordinary skill in the art also would have been familiar with prior art *clip devices in the form*

of forceps. (Ex. 1041, ¶19). Annotated Figures 1 and 2, below, depict an example of a prior art forceps disclosed in U.S. Patent No. 5,645,075 ("Palmer"). (Ex. 1017; Ex. 1041, ¶19).[1]

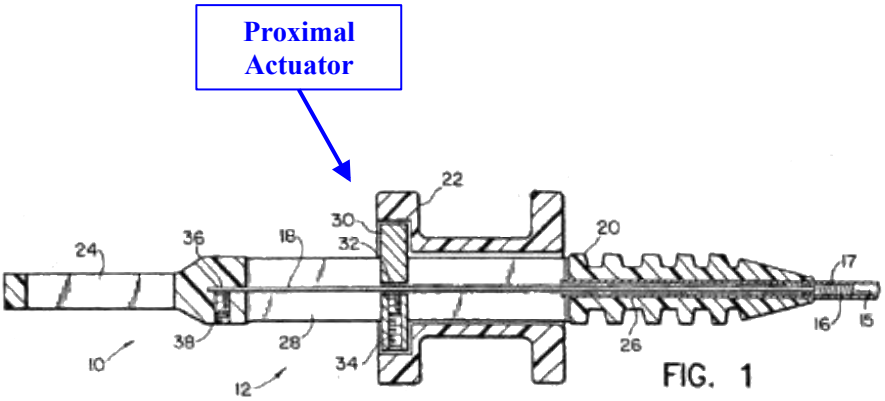


FIG. 1

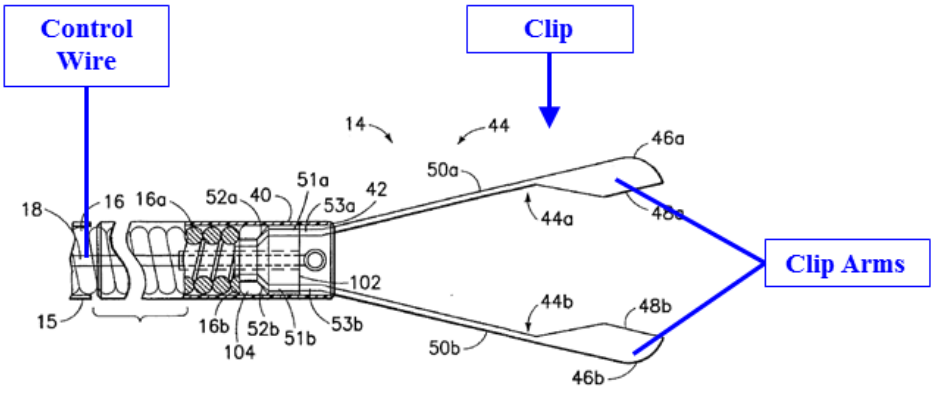


FIG. 2

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

[1] Palmer issued on July 8, 1997, and names as an inventor Vincent A. Turturro – one of the named inventors of the '731 patent. Palmer was not cited during prosecution of the '731 patent.

clip (jaw assembly 44) with two clip arms (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 18" for moving the clip between open and closed configurations. (*Id.*; *see also id.*, 8:5-46, 11:5-13; Ex. 1041, ¶20).

In fact, the named inventors of the '731 patent were aware of prior art forceps. The inventors acknowledged in the '731 patent specification that structures described in the '731 patent are "analogous to biopsy forceps." (*See* Ex. 1033, 5:46-48; Ex. 1041, ¶21). Moreover, the comparison below between annotated Figures 2 of Palmer and annotated Figure 13A of the '731 patent shows that the structures depicted in these figures are virtually identical such that there is no distinction between jaws in one and clips in the other:

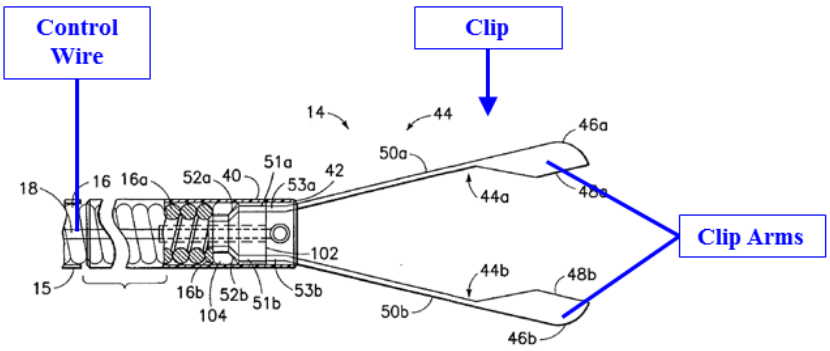


FIG. 2

Palmer, Figure 2

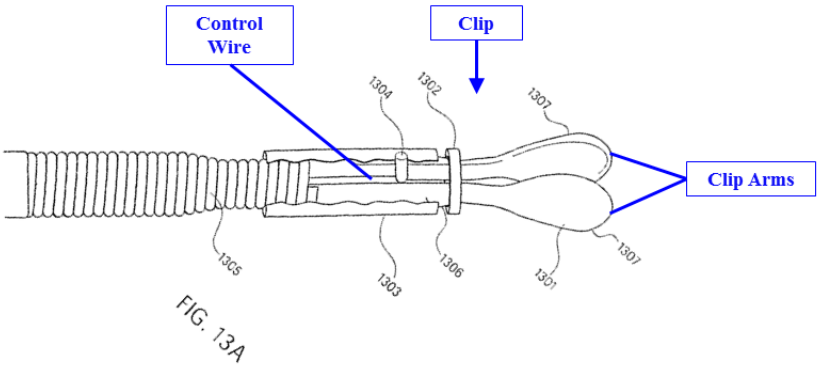


FIG. 13A

'731 Patent, Figure 13A

(Ex. 1041, ¶21).

Consistent with the prior art, the claims of the '731 patent describe medical devices and methods including "a clip" with "clip arms," and a "control wire" for moving the clip between open and closed configurations. In addition, the claims describe an "opening element" for urging the clip arms into the open configuration. (*See* Ex. 1033 at 15:37-17:15). The term "opening element" does not appear anywhere in the '731 patent specification. As explained below in Section IV.E.1, *infra* at pp. 12-14, BSSI identified in the Litigation several figures in the '731 patent that BSSI contends describe an "opening element."

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

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

Petitioners certify that the '731 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 '731 patent (Ex. 1033) 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]

[2] The '731 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.

No.	Grounds
1	Claims 1-2, 4, 6-9, 12-13, and 20 are anticipated under § 102 by U.S. Patent No. 5,749,881 ("Sackier").
2	Claims 3, 5, 10-11, and 14-19 are obvious under § 103 in view of Sackier.
3	Claims 1-3, 10-16, and 18 are anticipated under § 102 by U.S. Patent No. 5,843,000 ("Nishioka").
4	Claims 1-3, 10-16, and 18 are obvious under § 103 in view of Nishioka alone, or in combination with Sackier.
5	Claims 1-20 are obvious under § 103 in view of Japanese Unexamined Patent Application Publication No. 60-103946 ("Shinozuka") in combination with Sackier or Nishioka.

Although the limitations of the challenged claims are disclosed in multiple references, the above challenges are not redundant. The structures and features in one reference that discloses a particular claim limitation differ from the structures and features in another reference that discloses the same claim limitations.

D. Level Of Ordinary Skill In The Art

The person having ordinary skill in the art as of the time of the filing of the application that became the '731 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. 1041, ¶11). This person would also have an understanding of engineering or medical device design principles.[3] (Ex. 1041, ¶11).

Petitioners submit the Declaration of Mark A. Nicosia, Ph.D. (Ex. 1041). 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. 1041), 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. 1041) addresses the prior art at issue from the view of a person of ordinary skill in the art in the

[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. 1041, ¶11).

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 for the purposes of this *inter partes* review only,[4] Petitioners adopt the following constructions consistent with BSSI's positions in the Litigation.

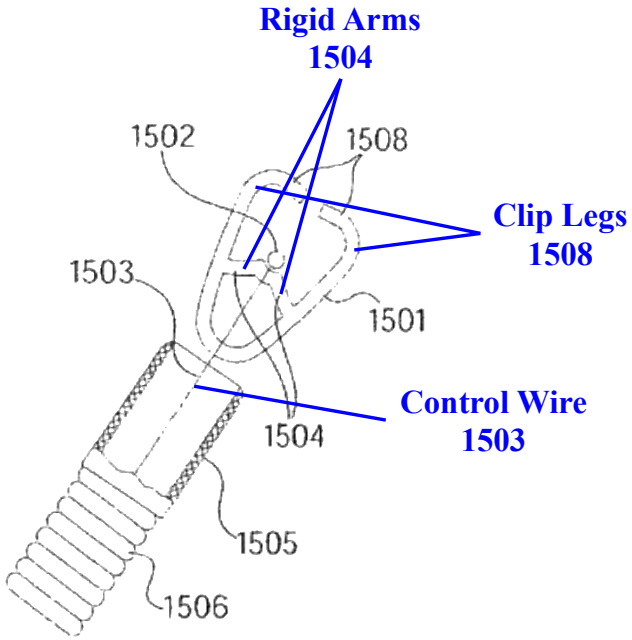
[4] By proposing these constructions, Petitioners do not agree or admit that any claim element of the challenged claims is entitled to coverage under the doctrine of equivalents, that the claims are entitled to such a scope in other proceedings, or that the claims satisfy the requirements of 35 U.S.C.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

1. "opening element"

All of the challenged claims require an "opening element" for performing the following functions:

- opening by "engaging inner walls of the first and second clip arms" and "urging the first and second clip arms away from one another into the open tissue-receiving configuration" (claims 1 and 12), and
- opening by "engaging inner walls of the first and second clip arms" and "urging the clip to an open tissue receiving configuration" (claim 20).

The term "opening element" does not appear in the specification of the '731 patent. In the Litigation, BSSI argued that the "plain and ordinary" meaning of "opening element" is a structure that "engages the inner walls of the clip arms and urges them away from one another." (Ex. 1039 at 16). According to BSSI, the specification describes the opening element as "[t]wo rigid arms 1504, located between the clip legs 1508, [that] translate the tensile force on the control wire 1503 to an outward radial force on the clip legs 1508." (Ex. 1039 at 16-17). "Rigid arms 1504," "clip legs 1508," and control wire 1503" are depicted in Figure 15A of the '731 patent, reproduced below.



'731 Patent, Figure 15A (Annotated)

BSSI also argued that Figures 8A, 8B, 10A, and 10B of the '731 patent (reproduced below with annotations by BSSI) depict examples of "opening elements."

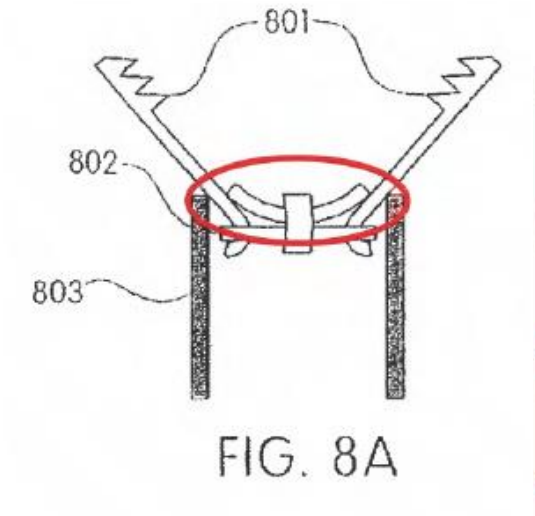


FIG. 8A

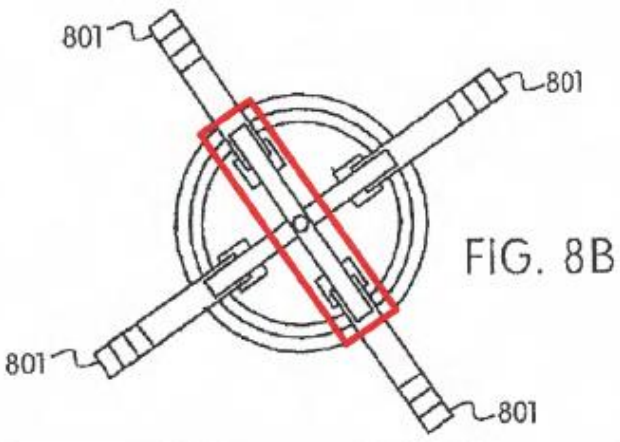


FIG. 8B

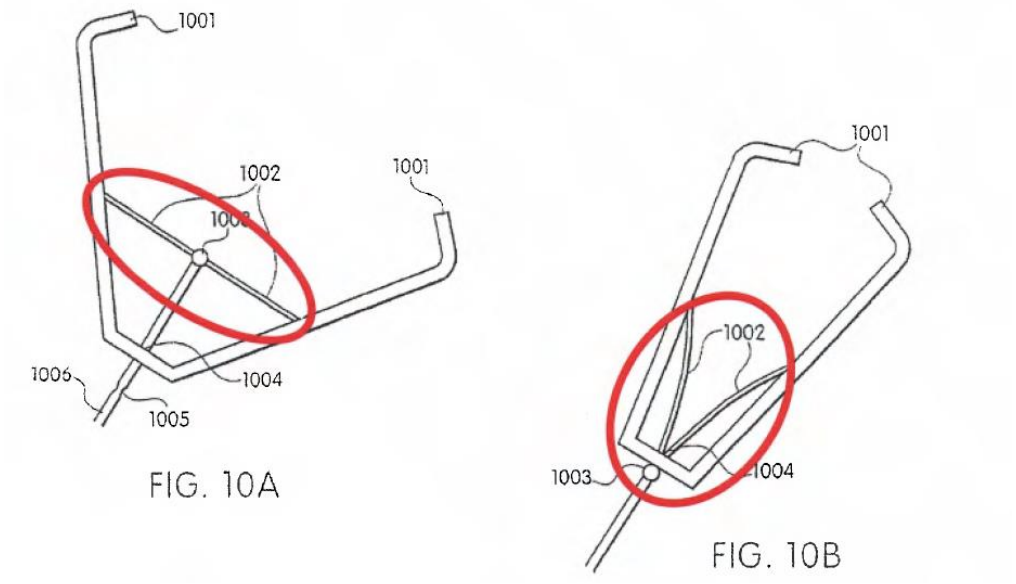


FIG. 10A

FIG. 10B

(Ex. 1035, pp. 60, 66, 76). According to BSSI, Figure 8A is the "prototypical example" of an opening element. (Ex. 1036, 152:23-153:2).

For purposes of this IPR proceeding, Petitioners accept BSSI's construction of "opening element" as encompassing any structure that "engages the inner walls of the clip arms and urges them away from one another," including the structures in Figures 8A, 8B, 10A, 10B, and 15A-C identified above.

2. "engaging inner walls of the first and second clip arms"

In the Litigation, BSSI argued that the "plain and ordinary" meaning of "engaging inner walls" simply requires that the opening element "contact[]" the inner walls, without requiring a "physical connection." (Ex. 1039 at 17). In addition, BSSI argued that "engaging inner walls of the first and second clip arms" requires that the "opening element' is "positioned between the clip arms and of sufficient size to be able to engage the clip arms." (Ex. 1035, p. 62).

For purposes of this IPR proceeding, Petitioners accept BSSI's construction of "engaging inner walls of the first and second clip arms" as "contacting" the inner walls, without requiring a physical connection, and "positioned between the clip arms and of sufficient size to be able to engage the clip arms."

3. "movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip"

The claims require an opening element "movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip." In the Litigation, BSSI argued the "structural feature" associated with this phrase is the fact that the "opening element" "expands and retracts." (Ex. 1035, p. 62). For purposes of this IPR proceeding, Petitioners accept BSSI's construction.

4. "link arms are axially aligned with one another"

Claims 3 and 14 require first and second link arms "axially aligned with one another." As explained in the Nicosia Declaration, the term "axially aligned" ordinarily refers to two structures aligned along a single common axis, as shown below.

Blue And Green Structures Aligned Along Single Common Axis

(Ex. 1041, ¶25).

However in the Litigation, BSSI alleges that the "Internal Nitinol strips" identified in the figure below are "link arms . . . axially aligned with one another," even though the purported link arms do not meet the ordinary meaning of "axially aligned."

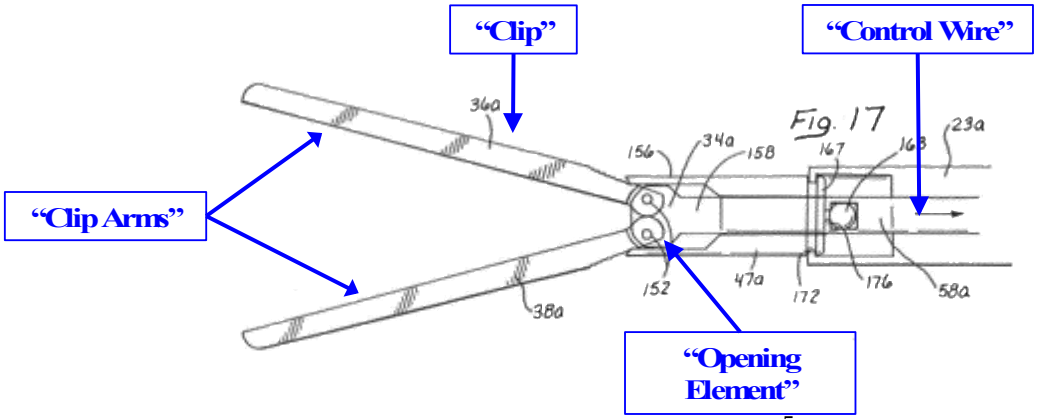
(Ex. 1038, pp. 18-19; Ex. 1041, ¶¶25-26).

Petitioners disagree with BSSI's application of the term "axially aligned." However for purposes of this IPR proceeding only, Petitioners accept BSSI's application of "link arms are axially aligned with one another" as encompassing the "Internal Nitinol strips" in the configuration shown above.

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

There is a reasonable likelihood that Claims 1-20 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 was before the Examiner. Individually and/or combined, these references disclose each and every limitation of the challenged claims, including "a clip," an "opening element," and "a control wire."

As shown below, Sackier, Nishioka, and Shinozuka each disclose a clip with clip arms, and a control wire for opening and closing the clip. In Sackier and Nishioka, an opening element urges the clip arms away from one another into an open tissue-receiving configuration as the control wire is moved distally.



Sackier, Figure 17 (Annotated)[5]

[5] Figures 15-26 of Sackier published without reference numbers. (*See* Ex. 1008). However, Sackier submitted Figures 15-26 with reference numbers during

(Ex. 1041, ¶28; Ex. 1008, 9:16-10:34).

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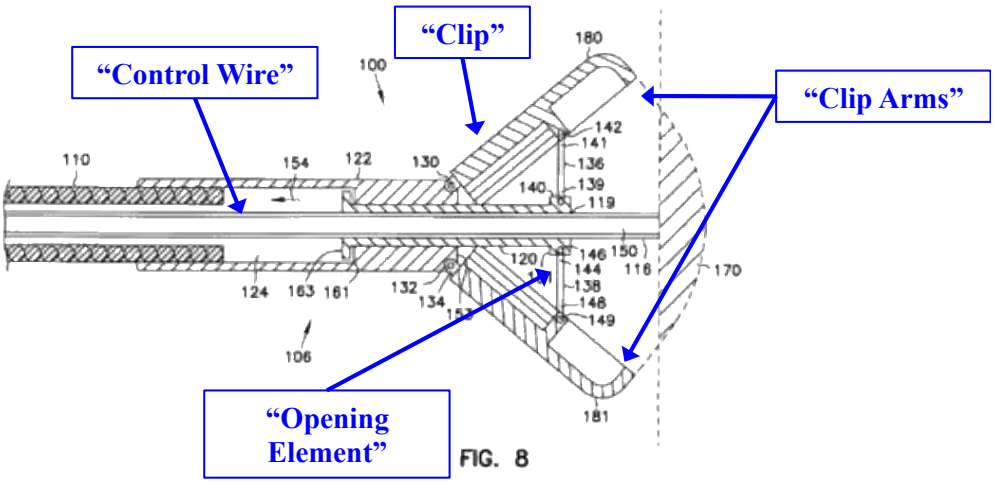
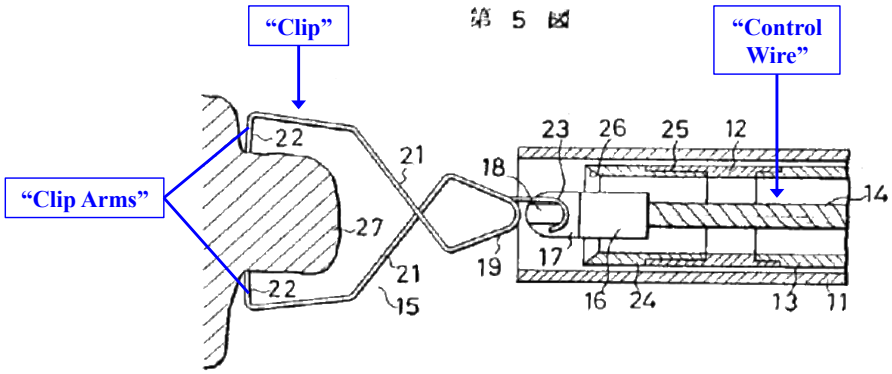
prosecution. (Ex. 1012 at 224-227, 268-276). Figures 15-26 with reference numbers constitutes a "printed publication" under 35 U.S.C. 102 as of Sackier's issue date. *See Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1379 (Fed. Cir. 2006) (holding that figures submitted during prosecution were "printed publications" as of the issue date of the corresponding patent, even though the figures were not included in the issued patent). While the figures without reference numerals fully disclose the claim limitations, for ease of reference and explanation Petitioners use the figures with the reference numbers in this petition. *See In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991) ("extrinsic 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).



Nishioka, Figure 8 (Annotated)

(Ex. 1041, ¶28; Ex. 1005, 6:58-8:42).

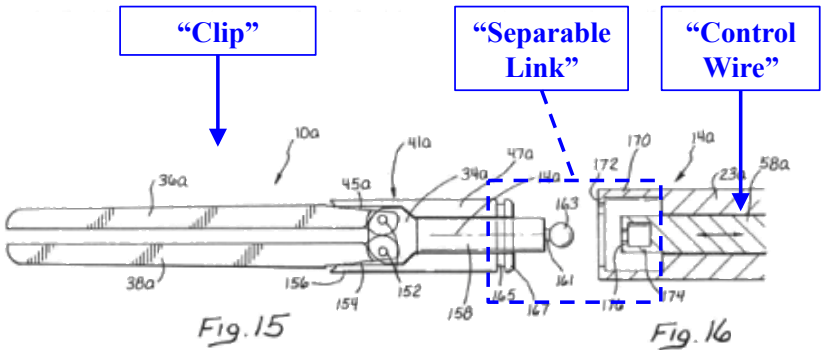


Shinozuka, Figure 5 (Annotated)

(Ex. 1041, ¶28; Ex. 1009,[6] pp. 261-63).

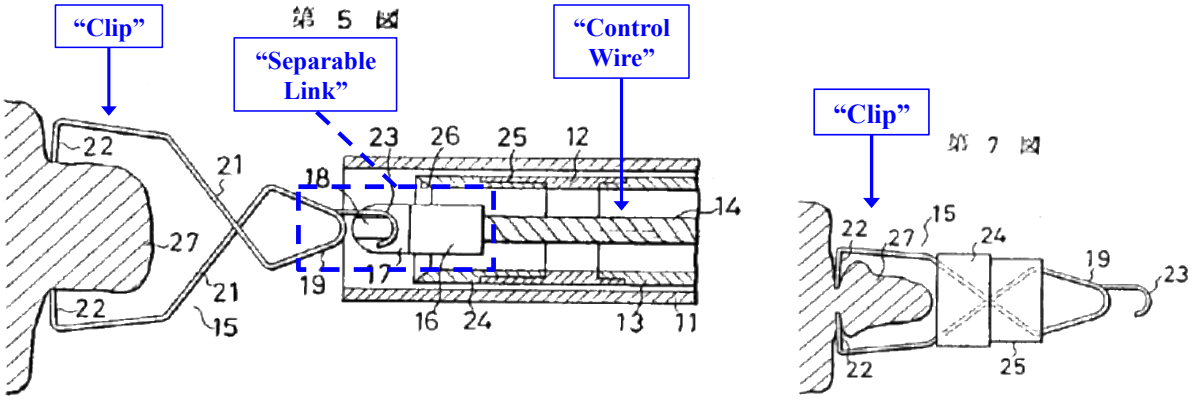
[6] Shinozuka is written in the Japanese language. Exhibit 1009 includes the original Shinozuka reference, as well as a translation of this reference from Japanese to English. Exhibit 1010 is the Declaration of James Thornton certifying the translation.

Sackier and Shinozuka also disclose a separable link between the control wire and clip, to allow the clip to remain in a patient's body, as shown below.



Sackier, Figures 15 and 16 (Annotated)

(Ex. 1041, ¶29; Ex. 1008, 9:16-10:34).



Shinozuka, Figures 5 and 7 (Annotated)

(Ex. 1041, ¶29; Ex. 1009, pp. 261-63).

As demonstrated below, the challenged claims are anticipated by the prior art. Moreover, these claims are obvious because they 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.

A. Ground 1: Claims 1-2, 4, 6-9, 12-13, 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), (b) and (e). Sackier was not cited during prosecution of the '731 patent.

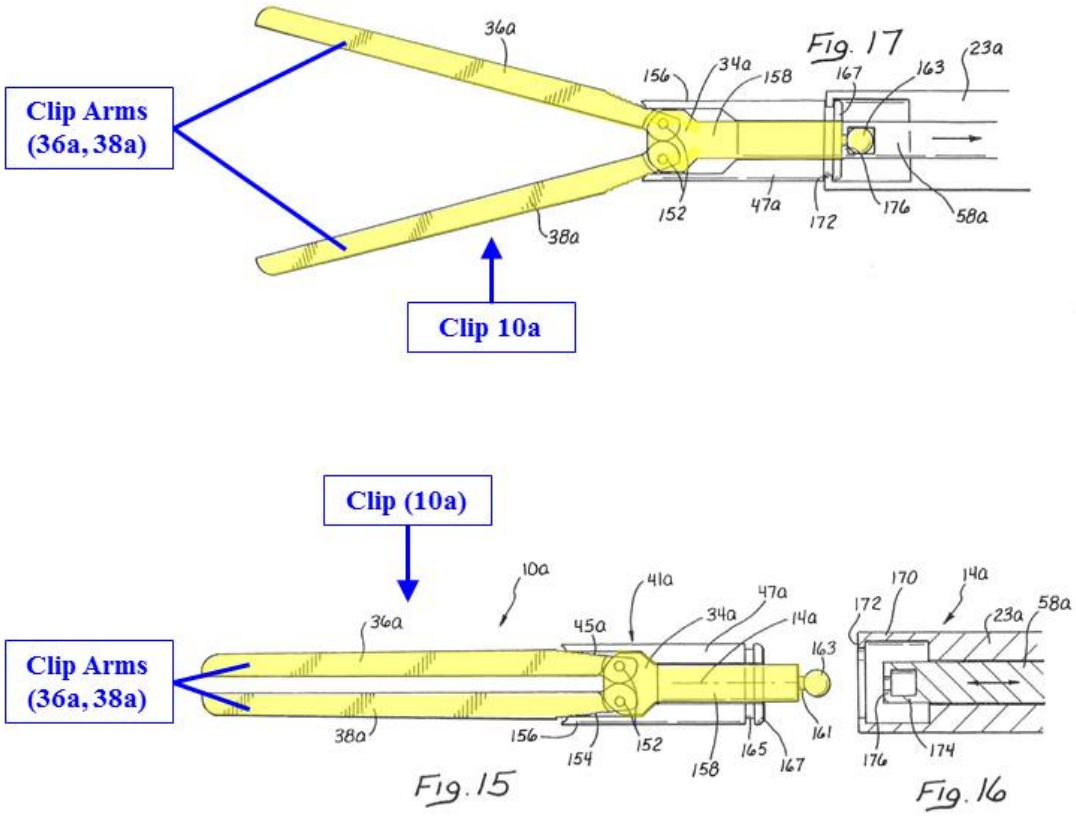
1. Independent Claim 1

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. 1041, ¶31; Ex. 1008, 1:6-8, Abstract).

b. "a clip including first and second clip arms, the clip being movable between an open tissue receiving configuration in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween"

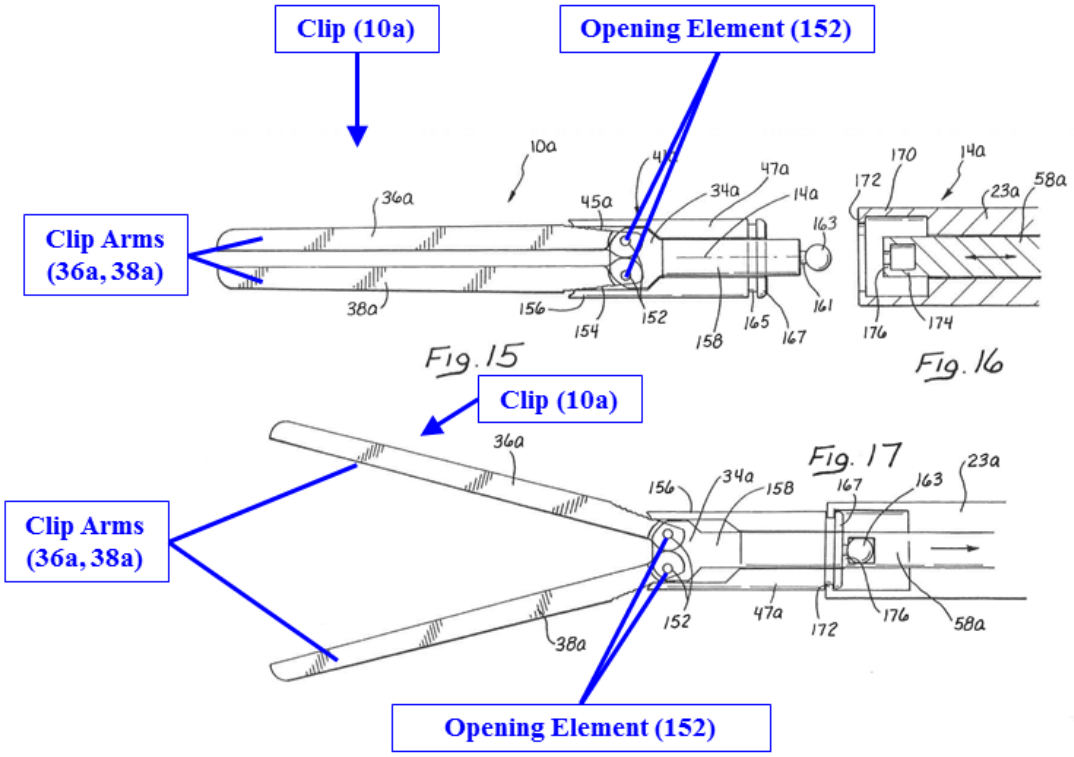
As shown below in annotated Figures 15-17, Sackier discloses a clip (clamp 10a (highlighted in yellow)) having first and second clip arms (jaws 36a and 38a), and moveable between an open tissue receiving configuration (Figure 17) in which the first and second arms are separated from one another by a distance selected to receive tissue and a closed configuration (Figure 15) in which the first and second arms are moved inward to capture the tissue received therebetween.



(Ex. 1041, ¶32; Ex. 1008, 9:16-25, 9:60-67, 10:30-33, Figs. 15-17).

c. "an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration, wherein the opening element is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration."

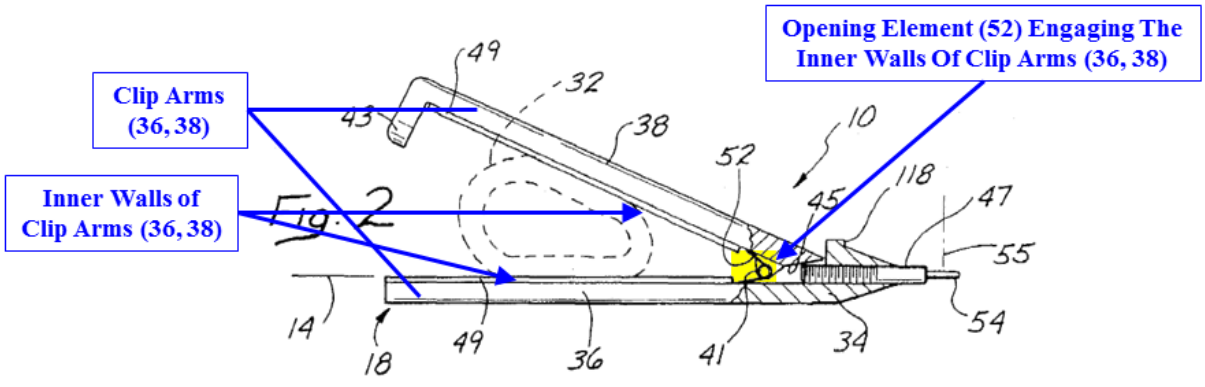
As shown below in annotated Figures 15-17, Sackier discloses an opening element (spring 152) urging the first and second clip arms away from one another into the open tissue-receiving configuration (Figure 17).



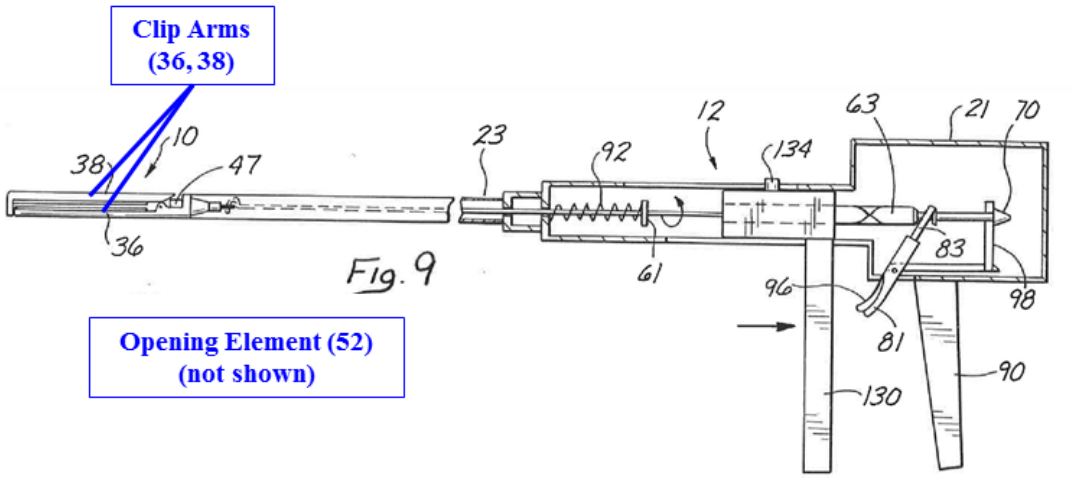
(Ex. 1041, ¶33; Ex. 1008, 9:19-23 (the clip arms (36a, 38a) have two relative positions: "[t]he first relative position is illustrated in FIG. 17 . . . in a generally

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).

Sackier discloses biasing open the jaws 36a, 38a using an opening element (spring 152). (Ex. 1041, ¶34). Sackier also discloses that instead of having two pivotal clip arms (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 an opening element (spring 52) engaging the inner walls of the first and second clip arms and urging the clip arms away from one another into an open tissue-receiving configuration.



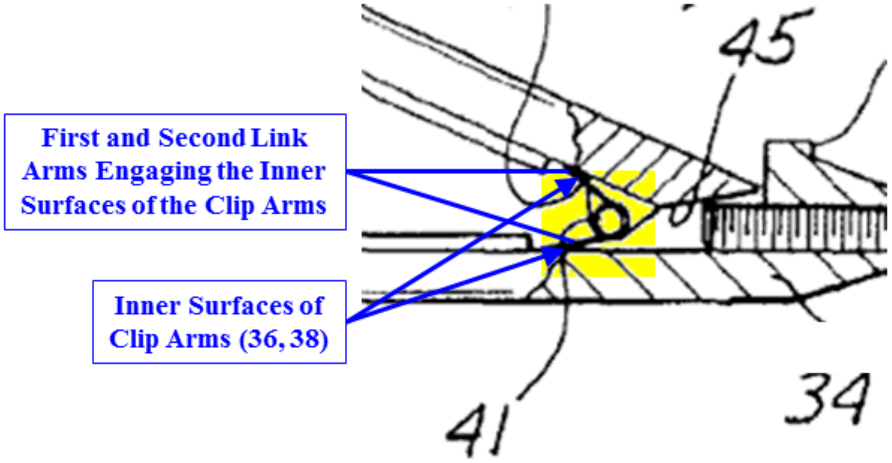
(Ex. 1041, ¶34; Ex. 1008, 5:4-12; *see also id.*, 9:5-12). The opening element (spring 52) engages inner walls of the first and second clip arms (36, 38) and is movable between an expanded configuration when the clip arms are in the open tissue receiving configuration (shown above in Figure 2) and a retracted configuration when the clip arms (36a, 38a) are in the closed configuration (shown below in Figure 9).



(Ex. 1041, ¶34; Ex. 1008, 3:38-40). Sackier describes spring 152 as one "example" of what could be used to bias the jaws 36a and 38a to the open position, confirming that the embodiment shown in Figures 15-17 includes spring 52 as an alternative to spring 152. (Ex. 1041, ¶34; Ex. 1008, 9:30-32).

2. Claim 2

Claim 2 depends from claim 1 and further requires "the opening element comprises first and second link arms engaging the inner surfaces of the first and second clip arms, respectively." As shown below in annotated Figure 2, the opening element (spring 52) comprises first and second link arms (*i.e.*, the linear arms of the spring) engaging the inner surfaces of the first and second clip arms, respectively.

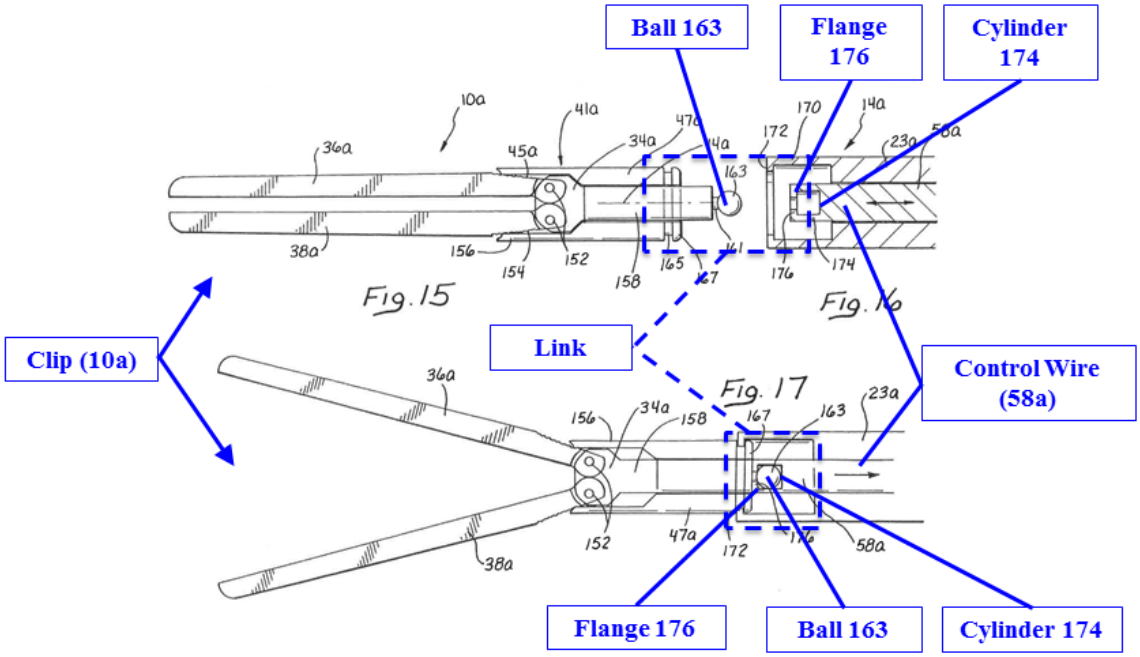


Excerpt of Figure 2

(Ex. 1041, ¶35; *see also* Ex. 1008, 5:4-12, 9:25-32).

3. Claim 4

Claim 4 depends from claim 1 and further requires "a proximal end of the clip is coupled to a control wire via a separable link." As shown below in annotated Figures 15-17, ball 163 located at the proximal end of clip (10a) is coupled to cylinder 174 (with flange 176) at the distal end of the control wire (inner shaft 58a) via a separable link.



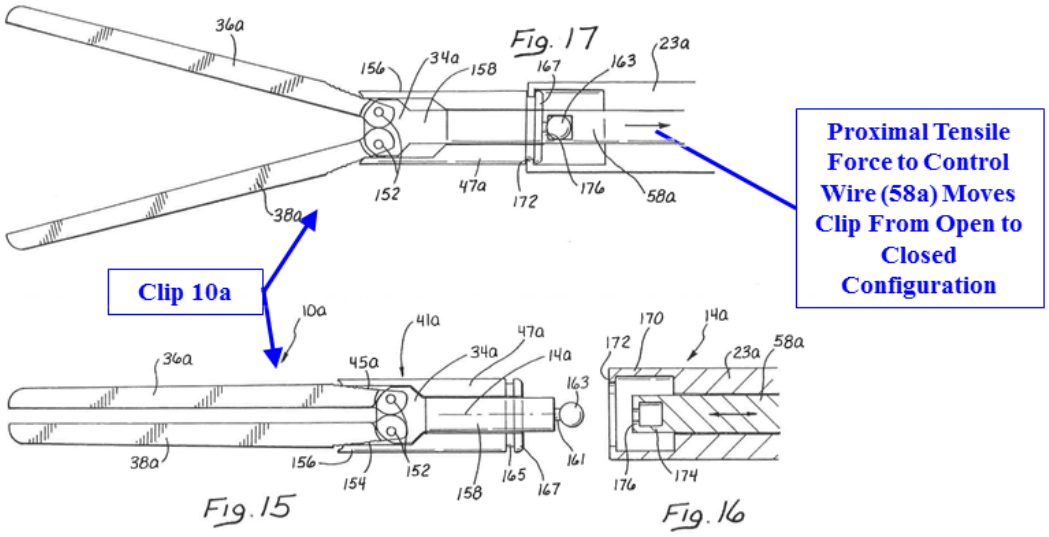
(Ex. 1041, ¶36; Ex. 1008, 10:18-30). Clip (10a) and control wire (58a) separate by pulling the control wire (58a) proximally (*i.e.*, applying a proximal tensile force) to cause ball 163 to separate from cylinder 174 (with flange 176)), as shown in Figures 15 and 16. (Ex. 1041, ¶36; Ex. 1008, Abstract, 2:56-59 ("A clamp applier

is adapted to releasibly engage the clamp [(clip)] . . . .”); *see also id.*, 8:29-34, 8:51-53, 9:60-10:34).

4. Claim 6

Claim 6 depends from claim 4 and further requires “application of a proximal tensile force to the control wire causes movement of the clip from the open tissue receiving configuration to the closed configuration.”

As shown below in annotated Figures 15-17, applying a proximal tensile force to control wire (58a) causes movement of clip (10a) from the open tissue receiving configuration (*see* Figure 17) to the closed configuration (*see* Figure 15).



(Ex. 1041, ¶38; 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."), 3:14-15, 9:41-48, 14:5-24).

5. Claim 7

Claim 7 depends from claim 6 and further requires "application of a proximal tensile force greater than a predetermined threshold value causes the clip to lock in the closed configuration."

As shown below in annotated Figures 15-17, Sackier discloses slide 47a (highlighted in yellow) that locks clip arms (jaws 36a, 38a) in the closed configuration when clip (10a) is pulled proximally.

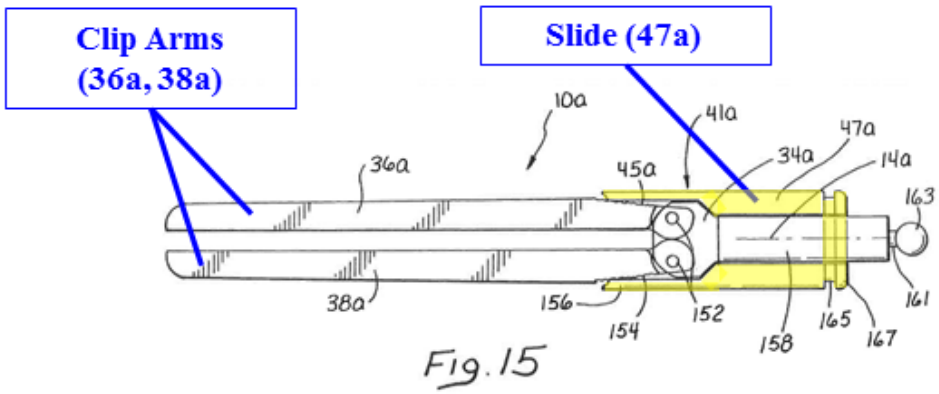


Fig. 15

(Ex. 1041, ¶40; 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). Engagement of the outer walls of first and second clip arms (36a, 38a) with inner walls of slide 47a prevents movement of clip (10a) to the open tissue-receiving

configuration. (Ex. 1041, ¶40). Slide 47a includes a lock arrangement (projection 156 on the slide 47a engaging recesses 154 on the clip arms (36a, 38a)) for locking the clip (10a) within the slide 47a with the clip arms (36a, 38a) closed:

> [T]he surface 45a [of the clip (10a)] is provided with a plurality of recesses 154 which form discrete locations along the surface 45a. Each of these locations is associated with a different relative position of the jaws 36a and 38a between the open position illustrated in FIG. 17 and the closed position illustrated in FIG. 15. . . . In proximity to the particular surface 45a, the slide 47a is provided with a projection 156 which forms a plurality of detents with each of the recesses 154 on the surface 45a. Thus the projection 156 engages a recess at one end of the surface 45a when the shaft 47a is in the proximate position, and engages a recess 154 at the opposite end of the surface 45a when the slide 47a is in the distal position. As the projection 156 sequentially engages the recesses 154 along the surface 45a, the jaws 36a and 38a move between the open and closed positions.

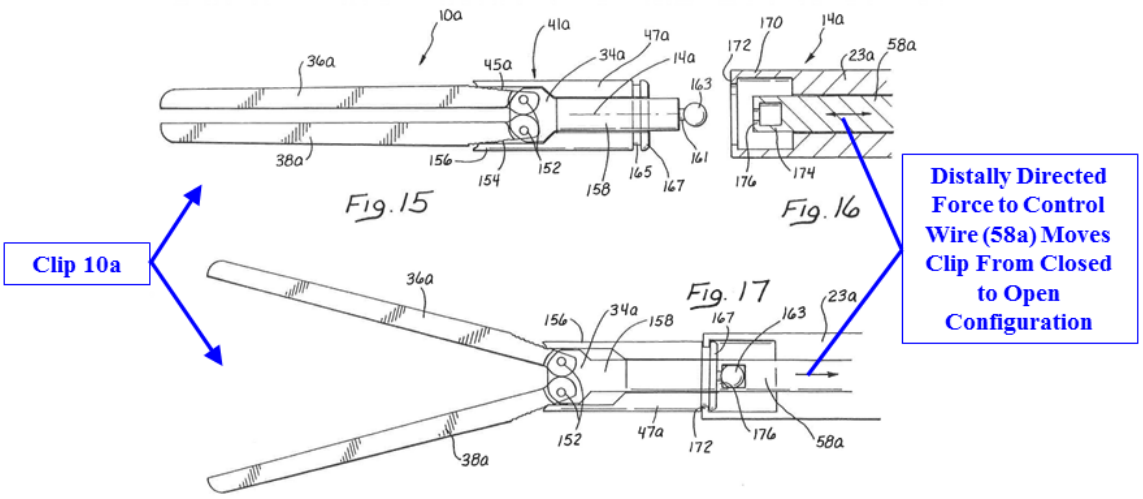
(Ex. 1008, 9:35-58). The clip legs (36a, 38a) are locked when clip (10a) is located in slide 47a. (Ex. 1041, ¶40). Locking the clip (10a) in the closed configuration requires the application of a proximal tensile force greater than a predetermined threshold value (*i.e.*, the pulling force required to cause the clip (10a) to lock in the closed configuration). (Ex. 1041, ¶40).

6. Claim 8

Claim 8 depends from claim 7 and further requires "application of a proximal tensile force greater than the predetermined threshold value causes the control wire to disengage from the clip." Sackier discloses control wire (58a) disengages from clip (10a) by pulling control wire (58a) proximally (*i.e.*, applying a proximal tensile force) to cause ball 163 to separate from cylinder 174 (with flange 176)), for the reasons in Section V.A.3, *supra* at pp. 29-30. (Ex. 1041, ¶41). Separating control wire (58a) from clip (10a) requires the application of a proximal tensile force greater than the predetermined threshold value (*i.e.*, the pulling force required to cause cylinder (174 (with 176)) of control wire (58a) to disengage from ball 163 of clip (10a)). (Ex. 1041, ¶41; *see also* Section V.A.5, *supra* at pp. 31-32).

7. Claim 9

Claim 9 depends from claim 6 and further requires "application of a distally directed force to the control wire causes movement of the clip from the closed configuration to the open tissue receiving configuration." As shown below in annotated Figures 15-17, Sackier discloses application of a distally directed force to control wire (58a) causes movement of clip (10a) from the closed configuration (*see* Figure 15) to the open tissue-receiving configuration (*see* Figure 17).



(Ex. 1041, ¶42; Ex. 1008, Figures 15-17, 4:35-37 ("Within the abdominal cavity, the clamp applier can be operated top open and close the clamp 10 about a body conduit, such as a bowel 32."); *see also id.*, 3:14-15, 9:41-48, 10:27-33, 14:5-24).

8. Independent Claim 12

a. "A medical device, comprising"

Sackier discloses "a medical device," for the reasons in Section V.A.1.a, *supra* at p. 23. (Ex. 1041, ¶43).

b. "a clip including first and second clip arms, the clip being movable between an open tissue receiving configuration in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween"

Sackier discloses this limitation, for the reasons in Section V.A.1.b, *supra* at pp. 23-24. (Ex. 1041, ¶44).

c. "an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration, wherein the opening element is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration"

Sackier discloses this limitation, for the reasons in Section V.A.1.c, *supra* at pp. 25-27. (Ex. 1041, ¶45).

d. "a control wire coupled to a proximal end of the clip and operable to move the clip between the open and closed configurations."

Sackier discloses this limitation, for the reasons in Sections V.A.3, *supra* at pp. 29-30, V.A.4, *supra* at pp. 30-31, and V.A.7, *supra* at pp. 33-34. (Ex. 1041, ¶46).

9. Claim 13

Claim 13 depends from claim 12 and further requires "the opening element comprises first and second link arms engaging the inner surfaces of the first and second clip arms, respectively." Sackier discloses this limitation, for the reasons in Section V.A.2, *supra* at p. 28. (Ex. 1041, ¶47).

10. Independent Claim 20

a. "a method, comprising"

Sackier discloses a method: "[a] method for operating [a] clamp." (Ex. 1041, ¶48; Ex. 1008, 3:1-2; *see also id.*, 9:5-7, Figures 11-19).

b. "inserting a medical device comprising a clip having first and second clip arms to a target tissue site, the clip including an opening element engaging inner walls of the first and second clip arms and urging the clip to an open tissue receiving configuration"

Sackier discloses inserting a medical device including a clip (*i.e.*, a "clamp") to a target tissue site. (Ex. 1041, ¶49; 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). Sackier discloses the medical device includes a clip (10a) including an opening element (spring 52) engaging inner walls of the first and second clip arms (36a, 38a) and urging the clip to an open tissue receiving configuration, for the reasons in Section V.A.1, *supra* at pp. 23-27.

c. "moving a control wire coupled to a proximal end of the clip distally to move the first and second clip arms away from one another to the open tissue receiving configuration"

Sackier discloses "moving a control wire coupled to a proximal end of the clip distally to move the first and second clip arms away from one another to the open tissue receiving configuration," for the reasons in Section V.A.7, *supra* at pp. 33-34. (Ex. 1041, ¶50).

d. "moving the control wire proximally to move the first and second clip arms toward one another to a closed tissue capturing configuration"

Sackier discloses "moving the control wire proximally to move the first and second clip arms toward one another to a closed tissue capturing configuration," for the reasons in Section V.A.4, *supra* at pp. 30-31. (Ex. 1041, ¶51).

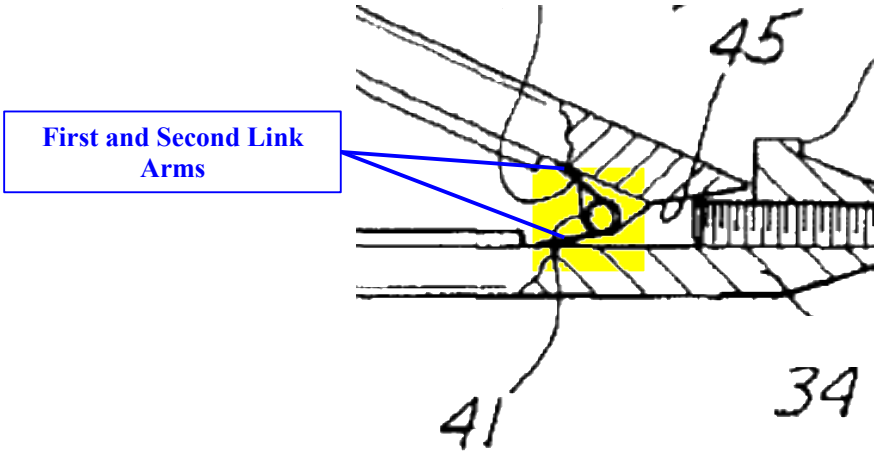
e. "applying a proximal tensile force exceeding a threshold level to the control wire to separate the control wire from the clip."

Sackier discloses "applying a proximal tensile force exceeding a threshold level to the control wire to separate the control wire from the clip," for the reasons in Section V.A.6, *supra* at p. 33. (Ex. 1041, ¶52).

B. Ground 2: Claims 3, 5, 10-11, and 14-19 Are Obvious In View Of Sackier (Ex. 1008)

1. Claim 3

Claim 3 depends from claim 2. Sackier discloses the limitations of claim 2, for the reasons in Section V.A.2, *supra* at p. 28. Claim 3 further requires "when the clip is in the open tissue receiving configuration, the first and second link arms are axially aligned with one another." As shown below in annotated Figure 2, Sackier discloses first and second link arms (the linear arms of the spring 52).



Excerpt of Figure 2

(Ex. 1041, ¶53; *see also* Ex. 1008, 5:4-12, 9:25-32).

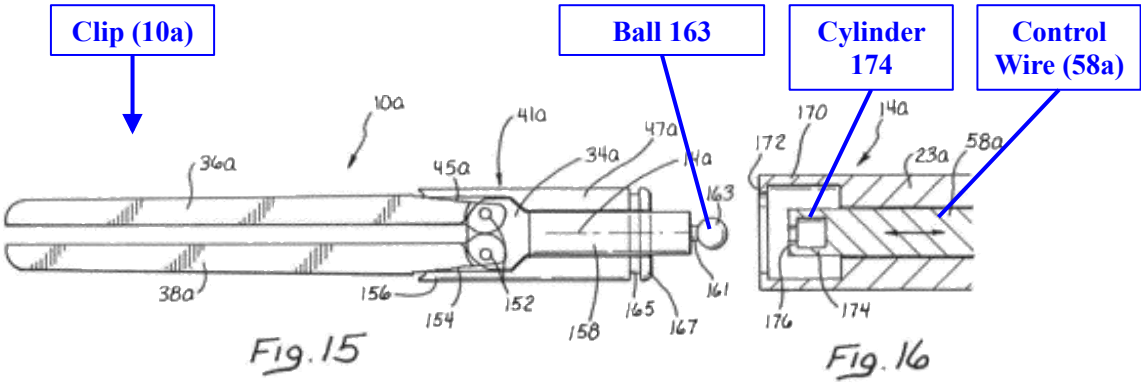
To the extent these link arms are not "axially aligned" with one another when the clip is in the open tissue receiving configuration, this is not a patentable distinction. (Ex. 1041, ¶54). A person of ordinary skill would have been motivated to modify spring 52, as necessary, to permit the spring to open the Sackier clip arms over a range of open tissue receiving configurations, including a

position where the link arms are "axially aligned" (*i.e.*, either aligned along a single common axis, as explained in the Nicosia Declaration (Ex. 1041, ¶54), or in a configuration consistent with BSSI's application of this term in the Litigation (*see* Section IV.E.4, *supra* at pp. 16-17)). (Ex. 1041, ¶54). The skilled artisan would have expected that this modification would improve the performance of the clip, allowing the clip arms to spread further apart and over a wider range of tissue receiving configurations than shown in Figure 2. (Ex. 1041, ¶ 54). This modification would have been a matter of routine skill in the art, using simple mechanical elements disclosed in Sackier to achieve predictable results. (Ex. 1041, ¶54). *See Tokai Corp. v. Easton Enters.*, 632 F.3d 1358, 1371 (Fed. Cir. 2011) ("[T]he nature of the mechanical arts is such that 'identified, predictable solutions' to known problems may be within the technical grasp of a skilled artisan.") (citations omitted); *KSR*, 550 U.S. at 416.

2. Claim 5

Claim 5 depends from claim 4. Sackier discloses the limitations of claim 4, for the reasons in Section V.A.3, *supra* at pp. 29-30. Claim 5 further requires "a distal end of the control wire includes an increased width portion formed to removably engage the clip." As shown below in annotated Figures 15 and 16, Sackier discloses that the proximal end of the clip (10a) comprises an increased

width portion (ball 163) formed to removably engage cylinder 174 (with flange 176) at the distal end of the control wire (58a).



(Ex. 1008, 10:18-30; Ex. 1041, ¶55; s*ee also* Section V.A.4, *supra* at pp. 30-31).

It would have been obvious to reverse the positions of cylinder 174 (with flange 176) and ball 163 so that ball 163 was on the distal end of control wire (58a), and cylinder 174 (with flange 176) was on the proximal end of clip (10a). The link between the ball 163 and cylinder 174 (with flange 176) is a ball and socket link. A person of ordinary skill in the art would have recognized that there are a finite number of obvious permutations for attaching ball 163 and socket (cylinder 174 (with flange 176)) to clip (10a) and control wire (58a): (1) the ball 163 attached to the clip (10a) and the socket (174) attached to the control wire (58a) (depicted in Sackier); or (2) the socket (174) attached to the clip (10a) and the ball 163 attached to the control wire (58a) (obvious modification of Sackier). (Ex. 1041, ¶56). A person of ordinary skill in the art would have considered both

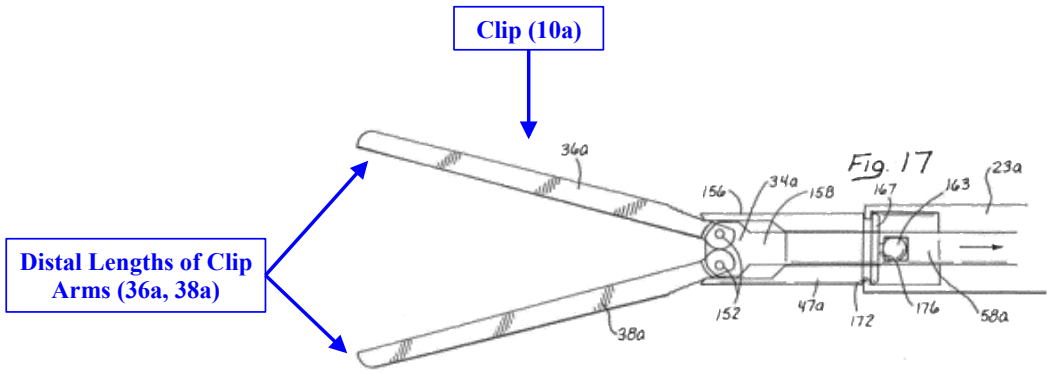
of these permutations, and each of them would have been obvious to try. (Ex. 1041, ¶56). *See In re Japikse*, 181 F.2d 1019, 1023 (CCPA 1950) (holding claims unpatentable because shifting the position of an element would not have modified the operation of the device); *see also KSR*, 550 U.S. at 417 ("[W]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious.") (citation omitted); MPEP § 2144.04 (VI.C)).

Modifying the Sackier device by reversing the positions of the ball 163 and cylinder 174 (with flange 176) would have been a matter of routine skill in the art and a modification that is mechanical in nature, and would have been accomplished according to known methods to yield predictable results. (Ex. 1041, ¶57). *See Tokai*, 632 F.3d at 1371; *KSR*, 550 U.S. at 416. The modified Sackier device would have a distal end of the control wire (58a) including an increased width portion (ball 163) formed to removably engage the cylinder 174 (with flange 176) of the clip (10a). (Ex. 1041, ¶57).

3. Claims 10 and 11

Duplicate claims 10 and 11 depend from claim 1. Sackier discloses all of the limitations of claim 1, for the reasons in Section V.A.1, *supra* at pp. 23-27. Claims 10 and 11 further require "a distal length of the first clip arm includes a first offset tip extending along an axis offset relative to a longitudinal axis of the first clip arm and wherein a distal length of the second clip arm includes a second offset tip extending along an axis offset relative to a longitudinal axis of the second clip arm."

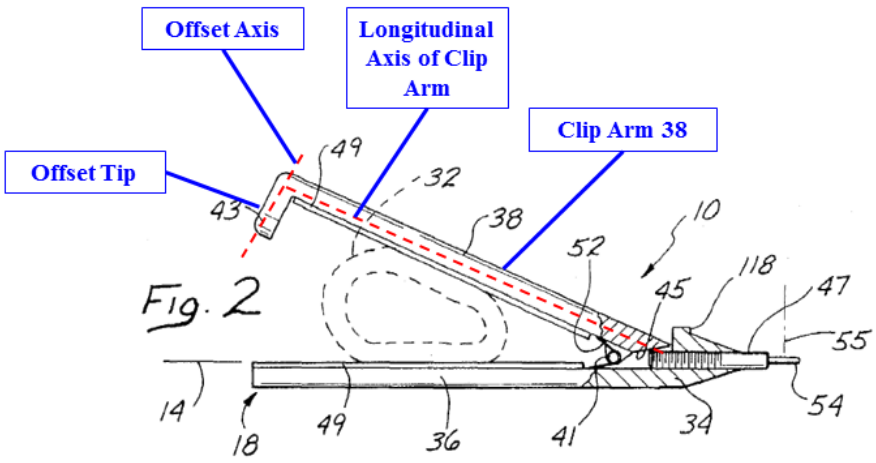
Annotated Figure 17 of Sackier is reproduced below and depicts the distal lengths of the first and second clip arms (36a, 38a).



To the extent the distal lengths of clip arms (36a, 38a) do not include offset tips extending along an axis offset relative to a longitudinal axis of the first clip arms, claims 10 and 11 still would have been obvious. A person of ordinary skill in the art would have understood that the shape of the clip arms described in Figures 15-

17 of Sackier was merely exemplary. (Ex. 1041, ¶59; Ex. 1008, 11:47-54 ("[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 arms in Figures 15-17 of Sackier could easily be modified to include other clip arm shapes described in Sackier and elsewhere in the prior art, including offset tips. (Ex. 1041, ¶59; *see also*, *e.g.*, Section V.E.10, *infra* at p. 85 (describing clip arms with offset tips described in Shinozuka)).

For example, as shown below in annotated Figure 2, Sackier discloses a clip arm (38) including an offset tip extending along an axis offset relative to a longitudinal axis of clip arm (38).



(Ex. 1041, ¶60; Ex. 1008, 4:46-50). Sackier discloses that the offset tip (overhang 42) helps to "insure[] that [the clipped material] is captured between the jaws 36, 38 as the final occluding pressure is applied." (Ex. 1008, 4:8-52).

A person of ordinary skill in the art would have recognized that the clip arms (36a, 38a) depicted in Figures 15-17 likewise could be modified to include offset tips. (Ex. 1041, ¶61). *See* MPEP §§ 2143(I)(C) and (D) (obviousness rationales including using "a known technique to improve similar devices in the same way," and applying "a known technique to a known device . . . ready for improvement to yield predictable results."). This modification would have been a matter of routine skill in the art, using simple mechanical elements disclosed in Sackier to achieve predictable results. (Ex. 1041, ¶61). *See Tokai*, 632 F.3d at 1371; *KSR*, 550 U.S. at 416. The skilled artisan would have been motivated to modify the clip arms (36a, 38a) to improve the ability of the clip to capture tissue, as further disclosed in Sackier. (Ex. 1041, ¶61). A person of ordinary skill would have considered the modification to be merely a simple substitution of one known element for another, to obtain predictable results. (Ex. 1041, ¶61). MPEP §2143(I)(B).

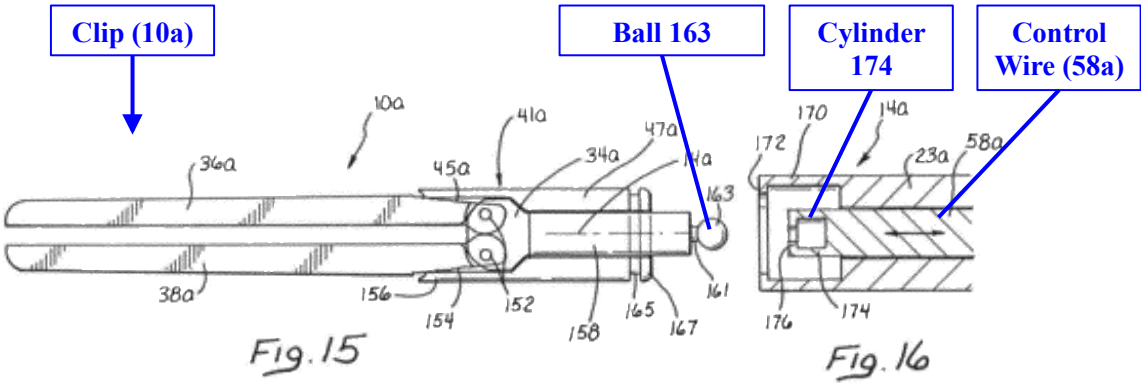
4. Claim 14

Claim 14 depends from claim 13. Sackier discloses the limitations of claim 13, for the reasons in Section V.A.9, *supra* at p. 36. Claim 14 further requires "when the clip is in the open tissue receiving configuration, the first and second link arms are axially aligned with one another." Sackier discloses this limitation, for the reasons in Section V.B.1, *supra* at pp. 39-40. (Ex. 1041, ¶62).

5. Claim 15

Claim 15 depends from claim 12. Sackier discloses the limitations of claim 12 for the reasons in Section V.A.8, *supra* at pp. 35-36. Claim 15 further requires "a proximal end of the clip includes an opening formed to receive a control wire."

As explained above in Section V.B.2, *supra* at pp. 40-42, it would have been obvious to modify Sackier by reversing the positions of cylinder 174 (with flange 176) and ball 163 (shown below in annotated Figures 15 and 16) so that ball 163 was on the distal end of control wire (58a), and cylinder 174 (with flange 176) was on the proximal end of clip (10a).



As modified, the proximal end of the clip would include an opening (within cylinder 174) formed to receive ball 163 of the control wire (58a). (Ex. 1041, ¶64).

6. Claim 16

Claim 16 depends from claim 15 and further requires "application of a proximal tensile force to the control wire causes movement of the clip from the open tissue receiving configuration to the closed configuration." Sackier discloses this limitation, for the reasons in Section V.A.4, *supra* at pp. 30-31. (Ex. 1041, ¶65).

7. Claim 17

Claim 17 depends from claim 16 and further requires "application of a proximal tensile force greater than a predetermined threshold value causes one or both of a locking of the clip in the closed configuration and a disengagement of the control wire from the clip."[7] Sackier discloses this limitation, for the reasons in Section V.A.5, *supra* at pp. 31-32 (locking of the clip in the closed configuration) and Section V.A.6, *supra* at p. 33 (disengagement of the control wire from the clip). (Ex. 1041, ¶66).

[7] The use of the phrase "one *or* both" indicates the claim is satisfied by meeting either the claimed "locking," the "disengagement," or both. *Brown v. 3M*, 265 F.3d 1349, 1353 (Fed. Cir. 2001).

8. Claim 18

Claim 18 depends from claim 16 and further requires "application of a distally directed force to the control wire causes movement of the clip from the closed configuration to the open tissue receiving configuration." Sackier discloses this limitation, for the reasons in Section V.A.7, *supra* at pp. 33-34. (Ex. 1041, ¶67).

9. Claim 19

Claim 19 depends from claim 12 and further requires "a distal end of the control wire includes an increased width portion formed to removably engage the clip." Claim 19 would have been obvious, for the reasons in Section V.B.2, *supra* at pp. 40-42. (Ex. 1041, ¶68).

C. Ground 3: Claims 1-3, 10-16, and 18 Are Anticipated by Nishioka (Ex. 1005)

Nishioka issued on December 1, 1998 and qualifies as prior art at least under 35 U.S.C. §§ 102(a), (b), and (e). Nishioka was not cited during prosecution of the '731 patent.

1. Independent Claim 1

a. "A medical device, comprising"

Nishioka discloses a medical device in the form of a "forceps device." (Ex. 1005, 1:6-9, 1:64-66, 2:58-65; Ex. 1041, ¶69).

b. "a clip including first and second clip arms, the clip being movable between an open tissue receiving configuration in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween"

As shown below in two embodiments (Figures 2 and 8), Nishioka discloses clips (forceps)[8] having first and second clip arms (jaws 80, 81 (Figure 2), jaws 180,

[8] A person of ordinary skill in the art would have considered a forceps cutting device to be a type of clip (*i.e.*, a device that clips tissue). For example, a common dictionary definition of "clip" is "a 2-bladed instrument for cutting especially the nails." (Ex. 1040). In addition, as explained above in Section III, *supra* at pp. 4-7,

181 (Figure 8)), and moveable between an open tissue receiving configuration (shown in Figures 2 and 8) in which the first and second clip arms are separated from one another by a distance selected to receive tissue, and a closed configuration in which the first and second clip arms are moved inward to capture the tissue received therebetween.

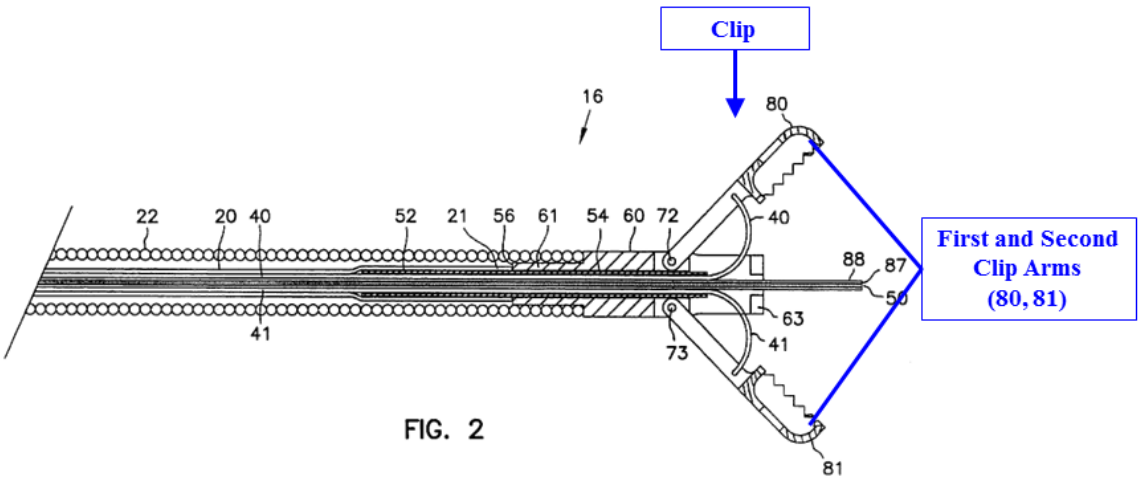


FIG. 2

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the specification of the ’731 patent acknowledges that the disclosed structures are “analogous to biopsy forceps.”

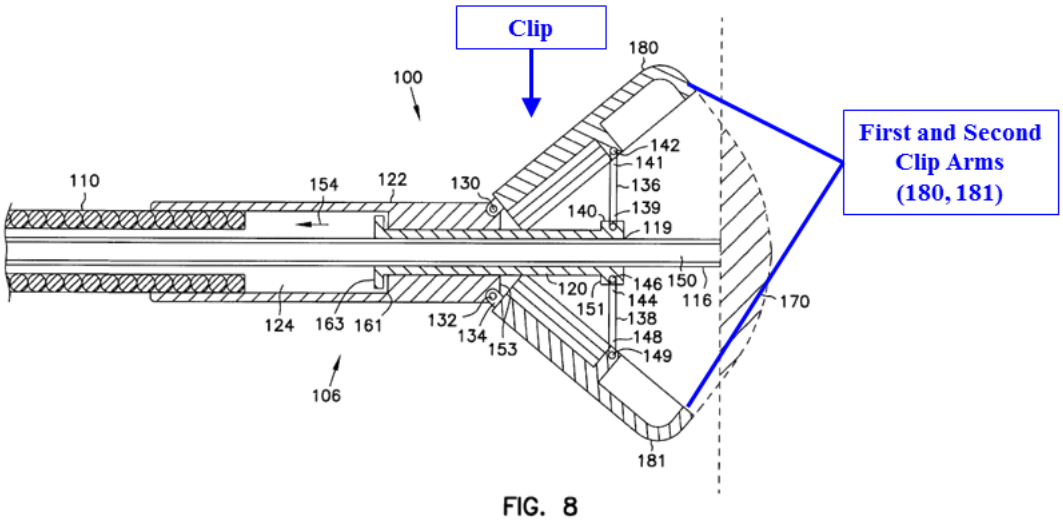


FIG. 8

(Ex. 1005, 2:11-14, 3:13-15, 3:44-49, 4:10-15, 5:12-15, 5:49-54, 6:27-31, 6:48-50, 6:60-64, 8:10-26, 8:63-9:2, Figures 1-4, 7-8; Ex. 1041, ¶70).

c. "an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration, wherein the opening element is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration."

As shown below in annotated Figure 2, Nishioka discloses in one embodiment an opening element (distal end portion of control wires 40, 41, (highlighted in yellow)) engaging inner walls of the first and second clip arms (80, 81) and urging the first and second clip arms away from one another into the open-tissue receiving configuration.

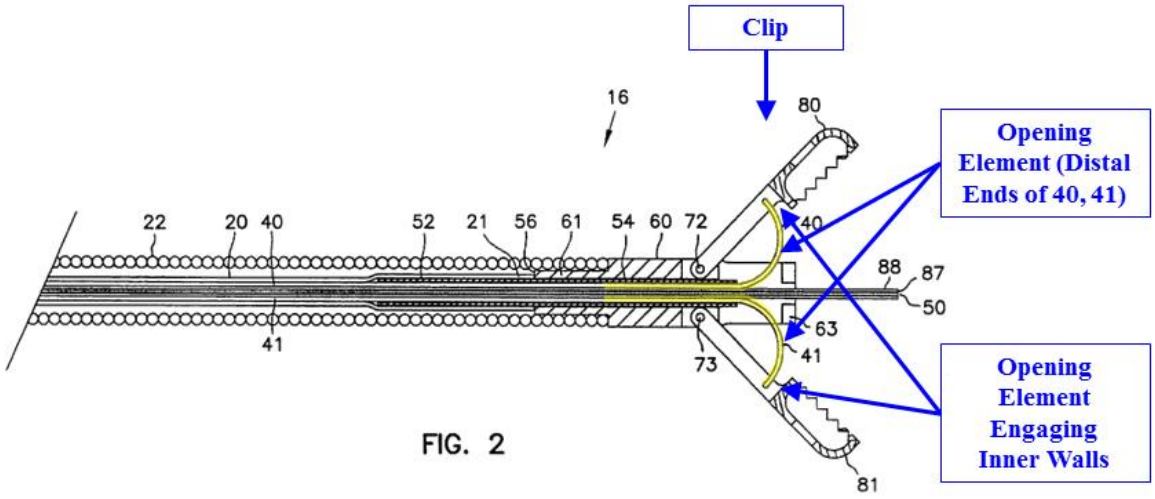


FIG. 2

(Ex. 1005, 2:14-17, 4:10-15, 5:37-38; 5:49-54; Ex. 1041, ¶71). The opening element (40, 41) is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration (Figure 2) and the closed configuration. (Ex. 1005, 2:14-17 ("an actuator mechanism operatively connected to the jaws for selectively controlling the opening and closing of the cutting jaws"); 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."); Ex. 1041, ¶71).

Likewise, as shown below in annotated Figure 8, Nishioka discloses in another embodiment an opening element (control links 136, 138 (highlighted in yellow)) engaging inner walls of the first and second clip arms (180, 181) and urging the first and second clip arms away from one another into the open-tissue receiving configuration.

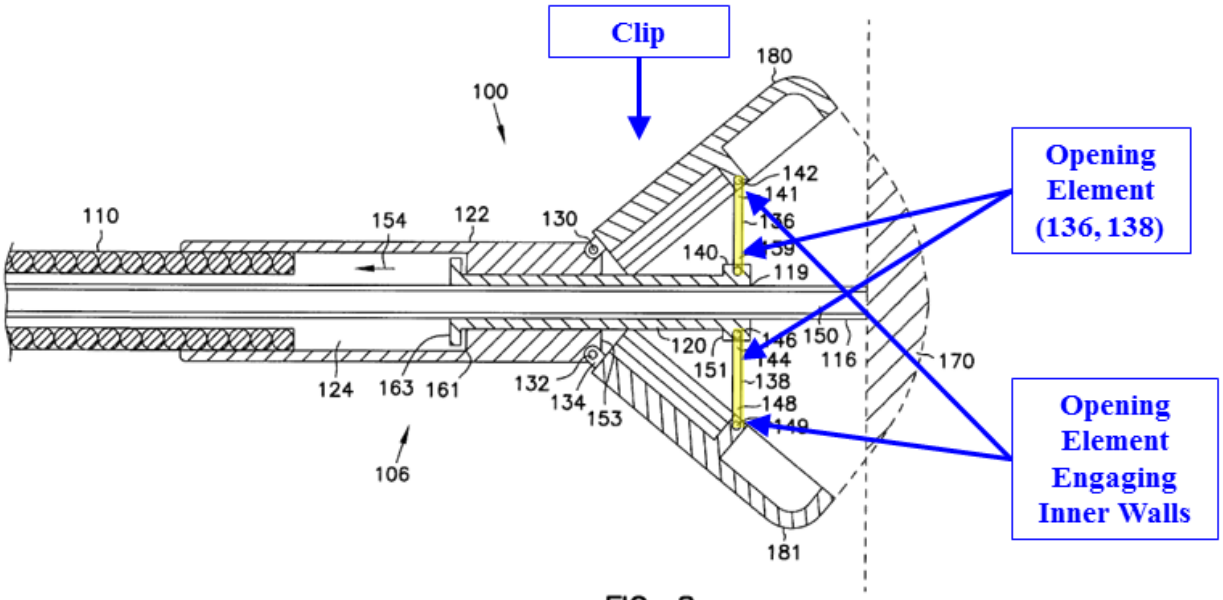


FIG. 8

(Ex. 1005, 8:10-26, 8:63-9:2; Ex. 1041, ¶72). The opening element (136, 138) is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration (Figure 8) and the closed configuration.

> 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 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 the 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.*, 8:63-9:2; Ex. 1041, ¶72).

2. Claim 2

Claim 2 depends from claim 1 and further requires "the opening element comprises first and second link arms engaging the inner surfaces of the first and second clip arms, respectively." Nishioka discloses the opening element comprises first and second link arms (40, 41 (Figure 2), 136, 138 (Figure 8)) engaging the inner surfaces of the first and second clip arms (80, 81 (Figure 2), 180, 181 (Figure 8)), for the reasons in Section V.C.1, *supra* at pp. 49-55 (*see, e.g.*, distal end portion of control wires 40, 41 in Figure 2, and links 136, 138 in Figure 8). (Ex. 1041, ¶73).

3. Claim 3

Claim 3 depends from claim 2 and further requires "when the clip is in the open tissue receiving configuration, the first and second link arms are axially aligned with one another." As shown below in annotated Figure 8, Nishioka discloses the first and second link arms (136, 138 (highlighted in yellow)) are aligned along a single common axis (*i.e.*, axially aligned with one another) when the clip is in the open tissue receiving configuration.

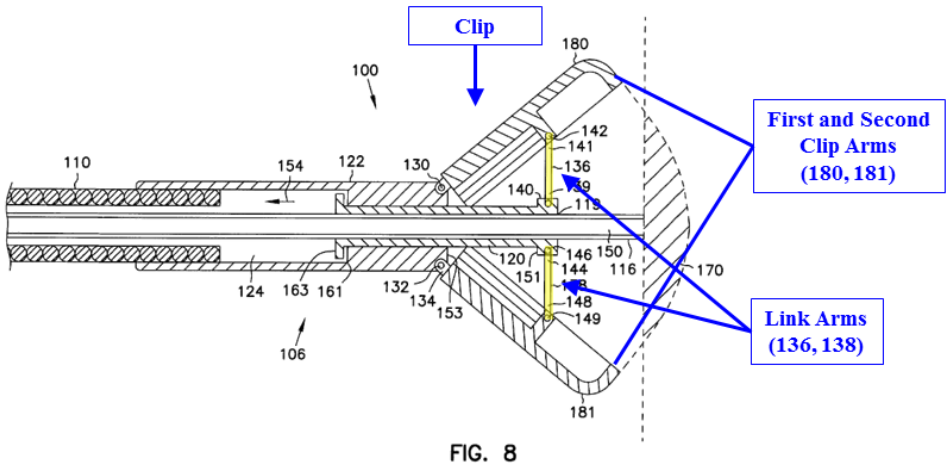


FIG. 8

(Ex. 1041, ¶74; Ex. 1005, 8:10-26).

4. Claims 10 and 11

Duplicate claims 10 and 11 depend from claim 1 and further require "a distal length of the first clip arm includes a first offset tip extending along an axis offset relative to a longitudinal axis of the first clip arm and wherein a distal length of the second clip arm includes a second offset tip extending along an axis offset relative to a longitudinal axis of the second clip arm." As shown below in annotated Figure 6A, the distal ends of the clip arms in the Figure 2 and Figure 8 embodiments include an offset tip extending along an axis offset relative to a longitudinal axis of the clip arm.

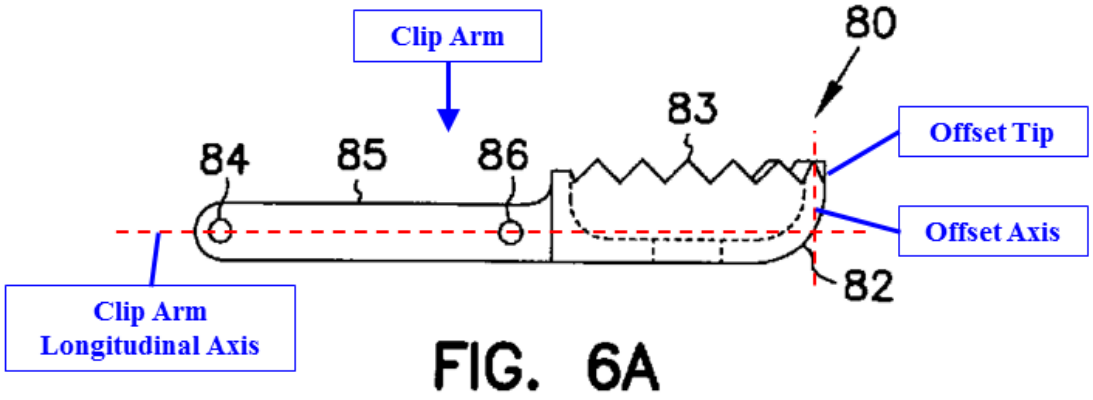


FIG. 6A

(Ex. 1041, ¶75; Ex. 1005, 5:1-7, 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)).

5. Independent Claim 12

a. "A medical device, comprising"

Nishioka discloses "a medical device," for the reasons in Section V.C.1.a, *supra* at p. 49. (Ex. 1041, ¶76).

b. "a clip including first and second clip arms, the clip being movable between an open tissue receiving configuration in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween"

Nishioka discloses this limitation, for the reasons in Section V.C.1.b, *supra* at pp. 49-51. (Ex. 1041, ¶77).

c. "an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration, wherein the opening element is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration"

Nishioka discloses this limitation, for the reasons in Section V.C.1.c, *supra* at pp. 51-55. (Ex. 1041, ¶78).

d. "a control wire coupled to a proximal end of the clip and operable to move the clip between the open and closed configurations."

As shown below in annotated Figure 2 and 8, Nishioka discloses in two embodiments a control wire (control wire 40, 41 (Figure 2), fiber 150 (Figure 8)) coupled to a proximal end of the clip and operable to move the clip between the open and closed configurations.

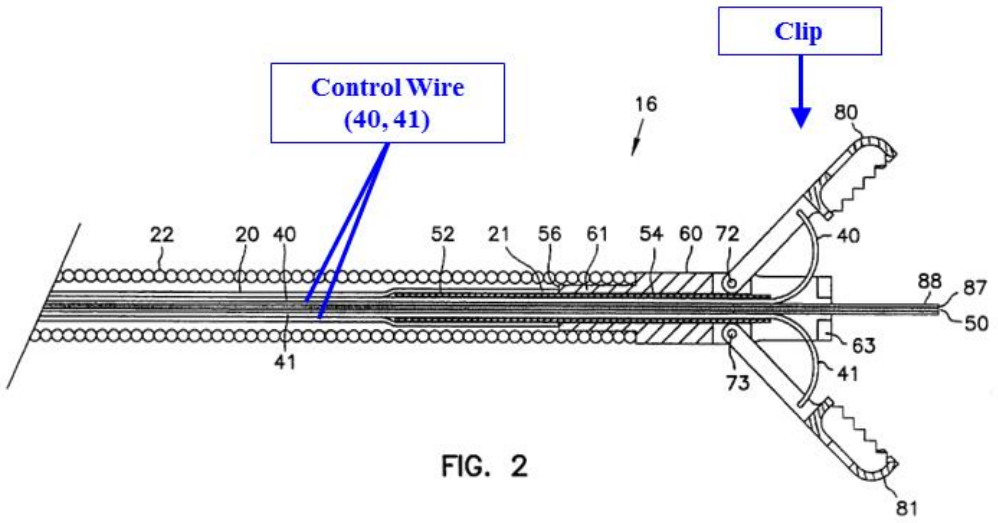


FIG. 2

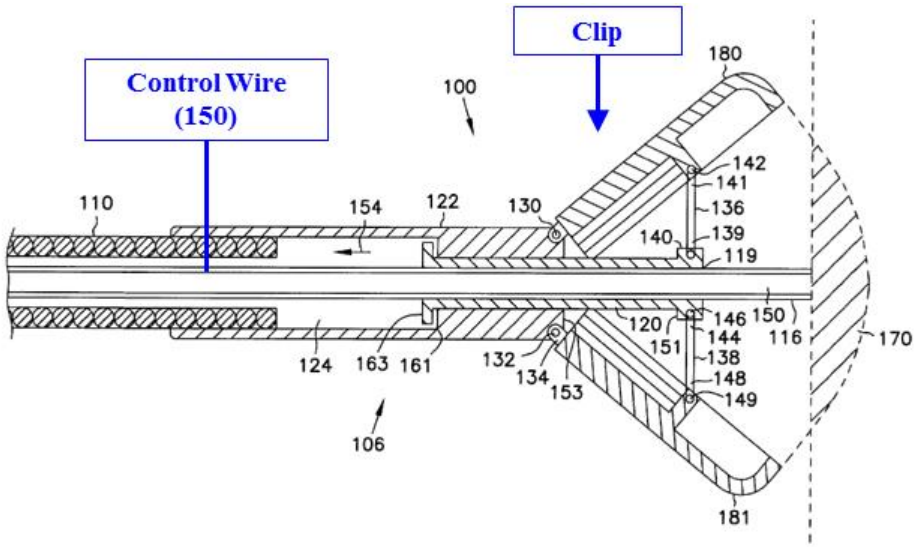


FIG. 8

(Ex. 1041, ¶79; Ex. 1005, 5:49-54 ("Once in place in the general area of interest, the forceps jaws can be opened by pushing slider 30 of the control handle forward. This causes movement (to the right in FIG. 2) of plastic tube 20, the fiber tube assembly 52, the control wires 40, 41, and the optical fiber 50. The control wires push against the jaws, causing them to open."); *see also id.*, 4:10-17, 6:60-64, 7:3-32, 8:10-26, 8:63-9:2; *see also* Section V.C.1.b and c, *supra* at pp. 49-55).

6. Claim 13

Claim 13 depends from claim 12 and further requires "the opening element comprises first and second link arms engaging the inner surfaces of the first and second clip arms, respectively." Nishioka discloses this limitation, for the reasons in Section V.C.2, *supra* at p. 55. (Ex. 1041, ¶80).

7. Claim 14

Claim 14 depends from claim 13 and further requires "when the clip is in the open tissue receiving configuration, the first and second link arms are axially aligned with one another." Nishioka discloses this limitation, for the reasons in Section V.C.3, *supra* at p. 56. (Ex. 1041, ¶81).

8. Claim 15

Claim 15 depends from claim 12 and further requires "a proximal end of the clip includes an opening formed to receive a control wire." As shown below in annotated Figures 2 and 8, Nishioka discloses in two embodiments the control wire (40, 41 (Figure 2), 150 (Figure 8)) is received through an opening formed in a proximal end of the clip (opening indicated in red).

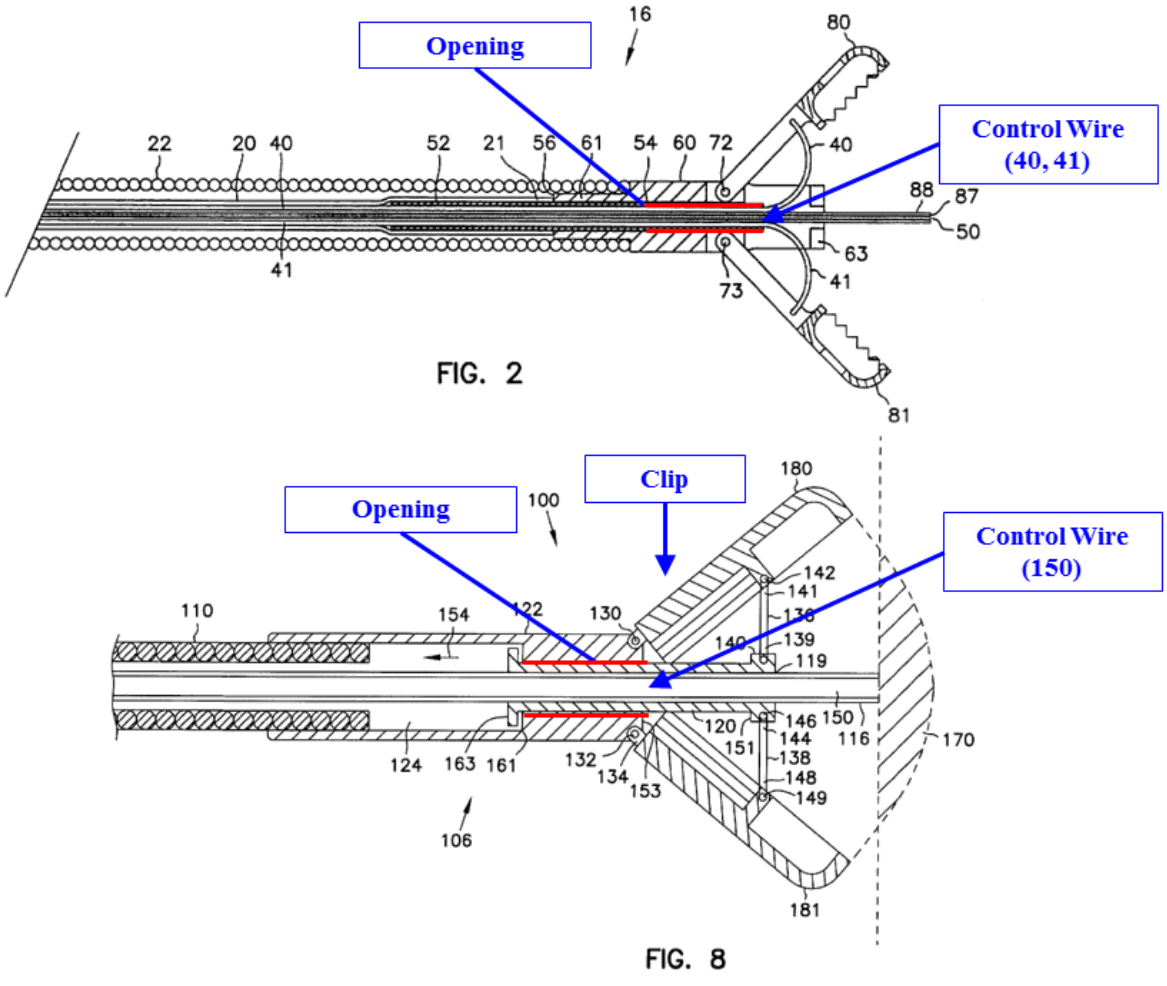


FIG. 2

FIG. 8

(Ex. 1005, 4:10-15; Ex. 1041, ¶82).

9. Claim 16

Claim 16 depends from claim 15 and further requires "application of a proximal tensile force to the control wire causes movement of the clip from the open tissue receiving configuration to the closed configuration." Nishioka discloses application of a proximal tensile force to the control wire (40, 41 (Figure 2), 150 (Figure 8)) – *i.e.*, pulling the control wire proximally – causes movement of the clip from the tissue receiving configuration to the closed configuration. (Ex. 1041, ¶83; Ex. 1005, 2:14-17 ("an actuator mechanism operatively connected to the jaws for selectively controlling the opening and closing of the cutting jaws"); 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 ("[T]he wires are retracted to pull the jaws together."), 8:21-26 ("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."); *see also* Sections V.C.1.b and c, *supra* at pp. 49-55).

10. Claim 18

Claim 18 depends from claim 16 and further requires "application of a distally directed force to the control wire causes movement of the clip from the closed configuration to the open tissue receiving configuration." Nishioka discloses application of a distally directed force to the control wire (40, 41 (Figure 2), 150 (Figure 8)) – *i.e.*, pushing the control wire distally – causes movement of the clip from the closed configuration to the open tissue receiving configuration. (Ex. 1041, ¶84; Ex. 1005, 2:14-17, 4:10-15, 4:52-55, 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."), 6:55-57 ("When the operating lever is moved in the opposite direction, the control wires are advanced within tube 20, causing the jaws to open."), 8:32-35 ("[W]hen the optical fiber 150 is advanced into the sheath 112, the tubular slide member 120 is moved axially in the opposite direction, causing the control links 136, 138 to move the jaws apart."), 8:63-9:2 ("[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."); *see also* Sections V.C.1.b and c, *supra* at pp. 49-55).

D. Ground 4: Claims 1-3, 10-16, and 18 Are Obvious In View Of Nishioka (Ex. 1005) Alone, or in Combination With Sackier (Ex. 1008)

1. Independent Claim 1

Nishioka discloses each and every limitation of claim 1, including a clip with first and second clip arms, for the reasons in Section V.C.1, *supra* at pp. 49-55. (Ex. 1041, ¶85).

Nishioka discloses a clip in the form of a biopsy forceps device. As shown below in annotated Figures 2 and 8, Nishioka discloses in two embodiments a forceps including first and second cutting jaws (80, 81 (Figure 2), 180, 181 (Figure 8)), which are used to grasp, cut, and remove tissue from the body.

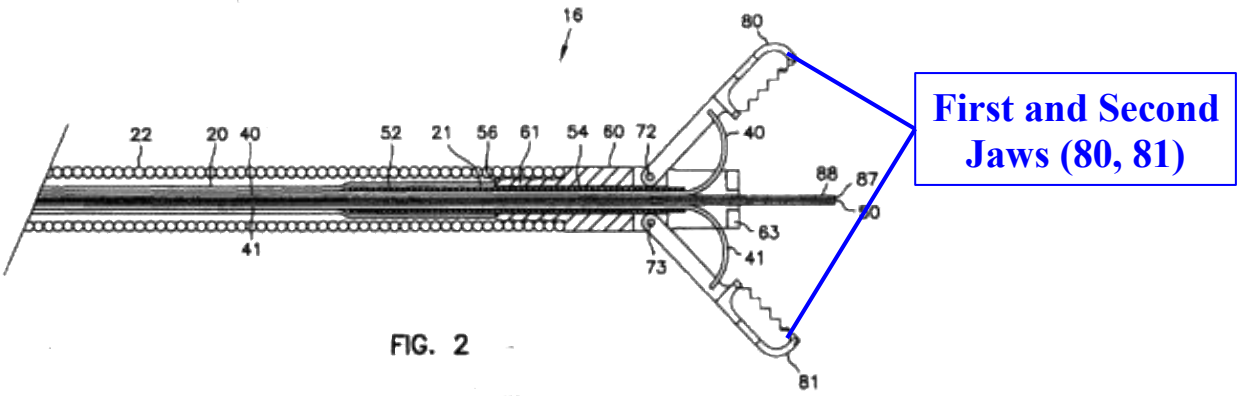


FIG. 2

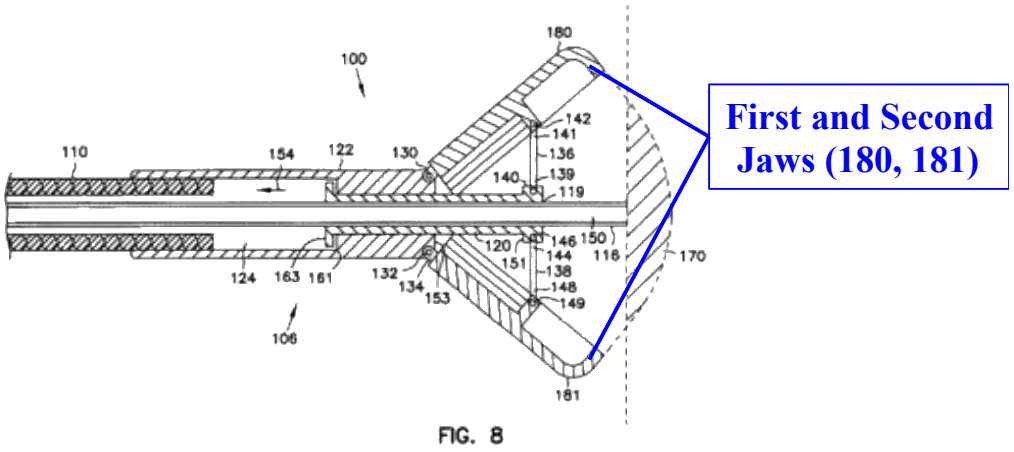


FIG. 8

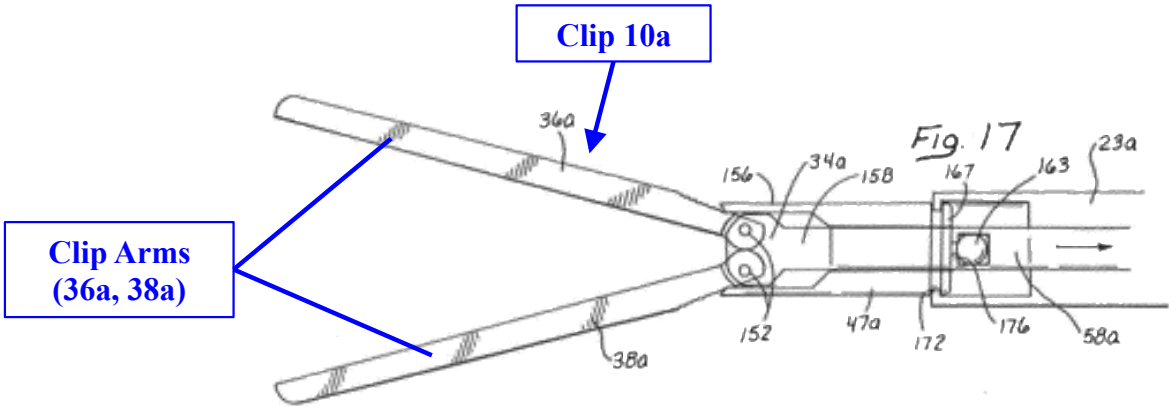
(Ex. 1041, ¶86; Ex. 1005, 1:5-26, 66-67).

Forceps devices were well known to a person of ordinary skill in the art in the 2000 timeframe. (*See* Section III, *supra* at pp. 4-7; Ex. 1041, ¶86). In addition, hemostatic clipping devices were well known to the skilled artisan in the 2000 timeframe. (Ex. 1041, ¶87; Section V.A., *supra* at pp. 23-38 (describing Sackier clips); Ex. 1033, 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")). In contrast with biopsy forceps, which are designed to grasp and cut tissue, hemostatic clips are designed to grasp and clamp tissue, to cause hemostasis. (Ex. 1041, ¶87). While these two devices perform different functions in the body, a person of ordinary skill in the art would have recognized that the basic structures of biopsy forceps and hemostatic clips are the same. (Ex. 1041, ¶87; Section III, *supra* at pp. 4-7). For example, a person of ordinary skill in the art would have

recognized that both devices include multiple arms, or jaws, that are actuated remotely via a control wire mechanism. (Ex. 1041, ¶87; *See* Section V, *supra* at pp. 18-22). A person of ordinary skill in the art would have considered forceps devices and hemostatic clips to be analogous, and their basic structures and mechanisms interchangeable. (Ex. 1041, ¶87).

To the extent the forceps and jaws disclosed in Nishioka are not considered a "clip" and "clip arms" because they are designed to cut, rather than clamp tissue, claim 1 still would have been obvious to a person of ordinary skill in the art. While the forceps described in Nishioka have jaws designed to cut tissue, it would have been obvious to modify the Nishioka devices so that they instead are designed to grasp, and clamp tissue. (Ex. 1041, ¶88). The skilled artisan would have recognized that the Nishioka devices could easily be modified for grasping and clamping tissue, simply by dulling the Nishioka jaws. (Ex. 1041, ¶88). Alternatively, it would have been obvious to substitute the Nishioka jaws with any one of the various clip arms known in the art. (Ex. 1041, ¶88; *see* Section V.A.1, *supra* at pp. 23-27).

For example, it would have been obvious to substitute the Nishioka cutting jaws with the Sackier clip arms (36a, 38a) shown in the annotated figure below.



(Ex. 1041, ¶89; Ex. 1008, 9:16-19). A person of ordinary skill in the art would have been motivated to make this modification, for example, so that the Nishioka devices were able to clamp, rather than cut, tissue. (Ex. 1041, ¶89). The resulting combination would include each and every limitation of claim 1, including a "clip including first and second clip arms." (Ex. 1041, ¶89). *KSR*, 550 U.S. at 417 ("[W]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious.") (citation omitted); MPEP § 2144.04 (VI.C)).

Modifying Nishioka to include arms that clamp, rather than cut, would have been a matter of routine skill in the art involving simple mechanical structures, and yielding predictable results. (Ex. 1041, ¶89). *See Tokai*, 632 F.3d at 1371; *KSR*, 550 U.S. at 417.

2. Claims 2-3 and 10-11

Claim 2-3 and 10-11 depend from claim 1. Nishioka discloses each of the limitations of the claims, for the reasons in Sections V.C.2, V.C.3, and V.C.4, *supra* at pp. 55-57. (Ex. 1041, ¶90).

3. Independent Claim 12

Nishioka discloses each and every limitation of claim 12, for the reasons in Section V.C.5, *supra* at pp. 58-60. (Ex. 1041, ¶91). Claim 12 would have been obvious, for the reasons in Section V.D.1, *supra* at pp. 65-68. (Ex. 1041, ¶91).

4. Claims 13-16 and 18

Claim 13-16 and 18 depend from claim 12. Nishioka discloses each of the limitations of the claims, for the reasons in Sections V.C.6, V.C.7, and V.C.8, V.C.9, and V.C.10, *supra* at pp. 60-64. (Ex. 1041, ¶92).

E. Ground 5: Claims 1-20 Are Obvious In View Of Shinozuka (Ex. 1009) in Combination With Sackier (Ex. 1008) Or Nishioka (Ex. 1005)

Shinozuka published on June 8, 1985 and qualifies as prior art at least under 35 U.S.C. §§ 102(a) and (b). Shinozuka was not cited during prosecution of the '731 patent.

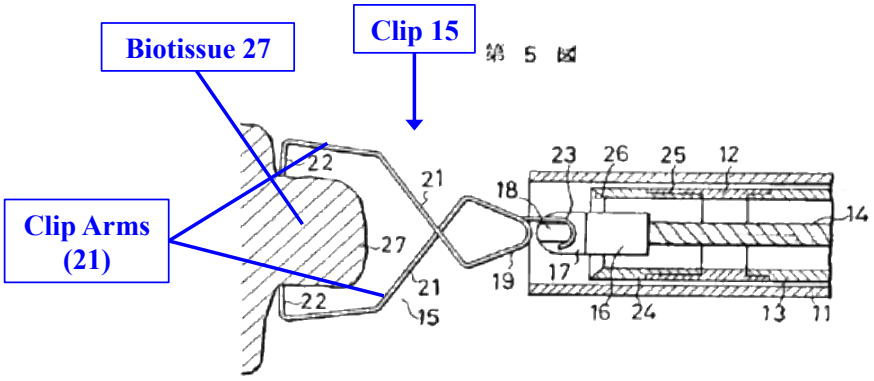
1. Independent Claim 1

a. "A medical device, comprising"

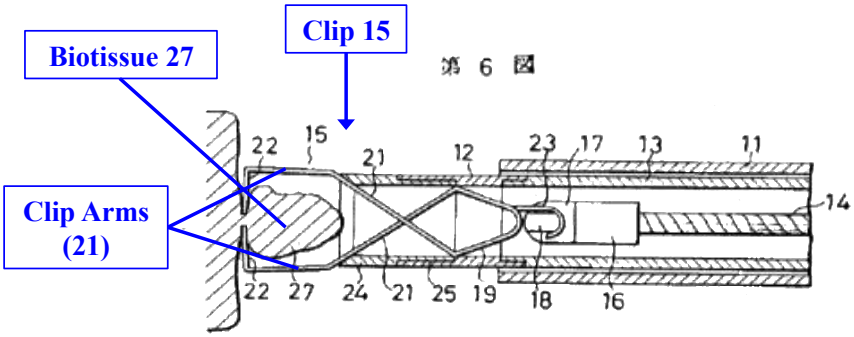
Shinozuka discloses a medical device: a "biotissue clip device." (Ex. 1041, ¶93; Ex. 1009, Title, pp. 261-263).

b. "a clip including first and second clip arms, the clip being movable between an open tissue receiving configuration in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween"

As shown below in annotated Figures 5 and 6, Shinozuka discloses clip 15 having first and second clip arms (arm parts 21), moveable between an open tissue receiving configuration (Figure 5) in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration (Figure 6) in which the first and second arms are moved inward to capture the tissue received therebetween.



Shinozuka, Figure 5 (Annotated)



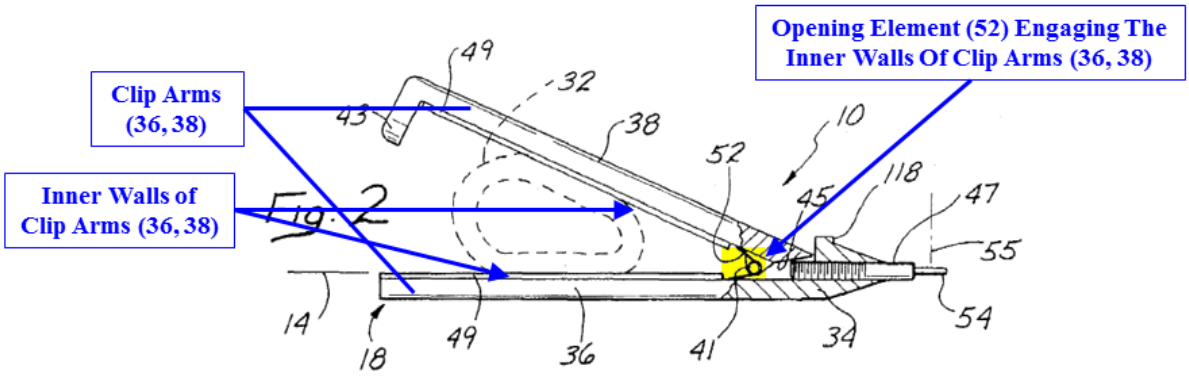
Shinozuka, Figure 6 (Annotated)

(Ex. 1041, ¶94; Ex. 1009, p. 262 ("[T]he clip 15 opens and becomes able to pinch some biotissue 27, and accordingly it is pushed onto a portion of biotissue 27 needing to be pinched. Then, as shown in FIG. 6 the control tube 13 is pushed so as to fit the clip-tightening ring 24 onto the clip 15 and close the clip 15. As a result of this the pinching parts 22, 22 pinch the biotissue 27.").

c. "an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration, wherein the opening element is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration."

Shinozuka discloses that clip 15 has an "opening bias so that [it] tend[s] to open." (Ex. 1041, ¶95; Ex. 1009, p. 263). Apart from this opening bias, Shinozuka does not explicitly disclose a separate structure in the form of an opening element for urging the clip arms away from one another. However this is not a patentable distinction. (Ex. 1041, ¶95). Clips with opening elements were well known in the art in the 2000 timeframe, as explained above in Sections V.A.1.c and V.C.1.c, *supra* at pp. 25-27 and 51-55, respectively. (Ex. 1041, ¶95).

For example, as shown below in annotated Figure 2, Sackier discloses a clip (10) with first and second clip arms (36, 38), and an opening element (spring 52) engaging inner walls of first and second clip arms, urging the clip arms away from one another into the open tissue-receiving configuration (shown in Figure 2), and movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration.



(Ex. 1041, ¶96; Ex. 1008, 5:4-12; *See also* Section V.A.1.c, *supra* at pp. 25-27).

Likewise, as shown below in annotated Figure 8, Nishioka discloses a clip (biopsy forceps) including first and second clip arms (jaws 180, 181) and an opening element (control links 136, 137 (highlighted in yellow)) engaging inner walls of first and second clip arms, urging the clip arms away from one another into the open tissue-receiving configuration, and movable between an expanded configuration (Figure 8) and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration.

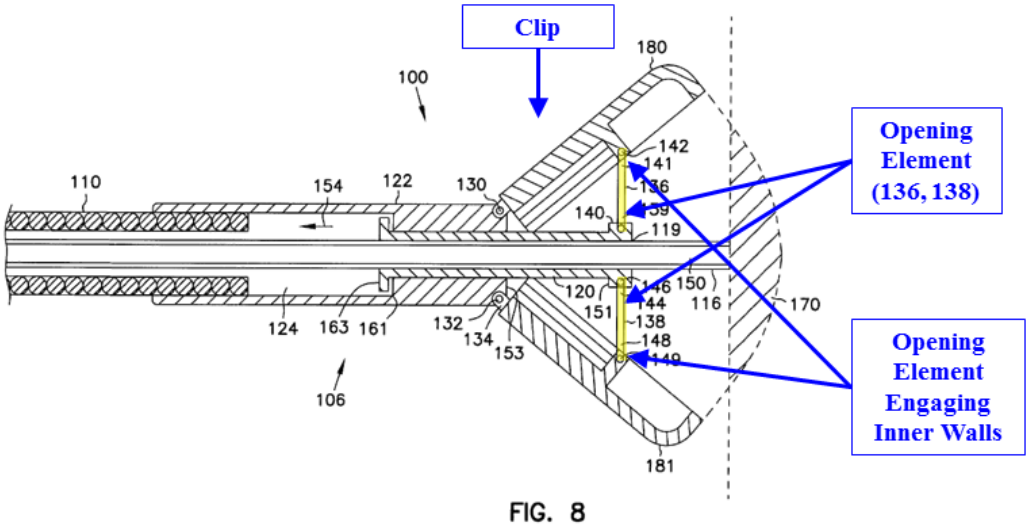


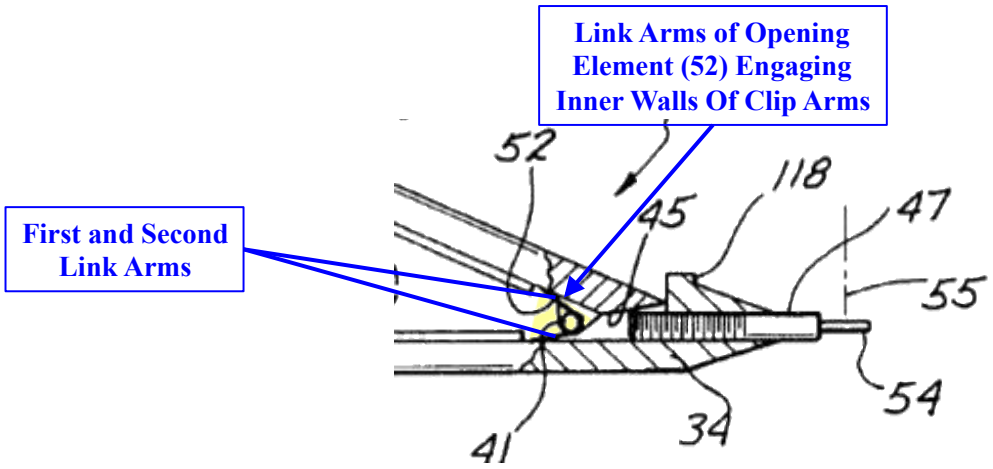
FIG. 8

(Ex. 1041, ¶97; Ex. 1008, 8:10-26, 8:63-9:2; *see also* Section V.C.1.c, *supra* at pp. 51-55).[9]

It would have been obvious to modify clip 15 of Shinozuka to include an opening element, as described in either Sackier or Nishioka, to assist in urging open the Shinozuka clip arms (21). (Ex. 1041, ¶98). *See* MPEP §§ 2143(I)(C) and (D) (obviousness rationales including using "a known technique to improve similar devices in the same way," and applying "a known technique to a known device . . . ready for improvement to yield predictable results."). A person of ordinary skill in

[9] Nishioka discloses a clip in the form of a biopsy forceps device. A person of ordinary skill in the art would have considered biopsy forceps devices to be analogous to hemostatic clipping devices, and their basic structures and mechanisms interchangeable, for the reasons in Section V.D.1, *supra* at pp. 65-68.

the art would have considered this modification to be a matter of routine skill in the art, using simple mechanical elements disclosed in Shinozuka, Sackier, and Nishioka to achieve predictable results. (Ex. 1041, ¶98). *See Tokai*, 632 F.3d at 1371; *KSR*, 550 U.S. at 416. For example, it would have been obvious to modify Shinozuka to include a spring (*e.g.*, spring 52), and to engage the link arms of the spring (*i.e.*, the linear arms of the spring) with the inner surfaces of the Shinozuka clip arms (21), as disclosed in Sackier (*see* annotated Figure 2, below).



Excerpt of Sackier Figure 2

(Ex. 1041, ¶98; *see also* Section V.A.1.c, *supra* at pp. 25-27).

Likewise, it would have been obvious to modify Shinozuka to include control links (*e.g.*, control links 136, 138) and a slide member (120), and to engage the control links with the inner surfaces of the Shinozuka clip arms (21), as disclosed in Nishioka (*see* annotated Figure 8, below).

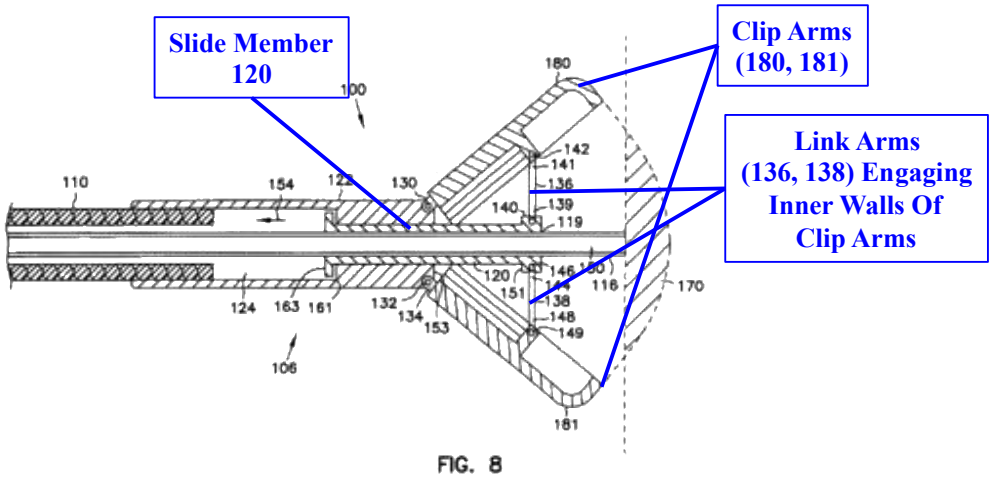


FIG. 8

(Ex. 1041, ¶99; Ex. 1008, 8:11-20 ("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 the tubular slide member 120 by a pin 140. The other end 140 of the control link 136 is 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.")).

The skilled artisan would have been motivated to modify Shinozuka to include an opening element, as disclosed in Sackier or Nishioka, to improve the performance of the Shinozuka clip. (Ex. 1041, ¶100). For example, the opening elements described in Sackier and Nishioka would have been expected to provide more force to urge open the clip arms (21), permitting the clip arms to open wider than without an opening element. (Ex. 1041, ¶100). Additionally, the opening

element described in Nishioka would have been expected to provide more control to the physician, allowing the physician to reversibly open and close the clip during a procedure, for example if the clip requires repositioning during deployment. (Ex. 1041, ¶100). The skilled artisan would have been motivated to include these features in the Shinozuka clip, in order to provide a wider range of open tissue receiving configurations, as well as more accurate and precise deployment. (Ex. 1041, ¶100).

2. Claim 2

Claim 2 depends from claim 1 and further requires "the opening element comprises first and second link arms engaging the inner surfaces of the first and second clip arms, respectively." This claim would have been obvious, for the reasons in Section V.E.1.c, *supra* at pp. 72-77. (Ex. 1041, ¶101).

3. Claim 3

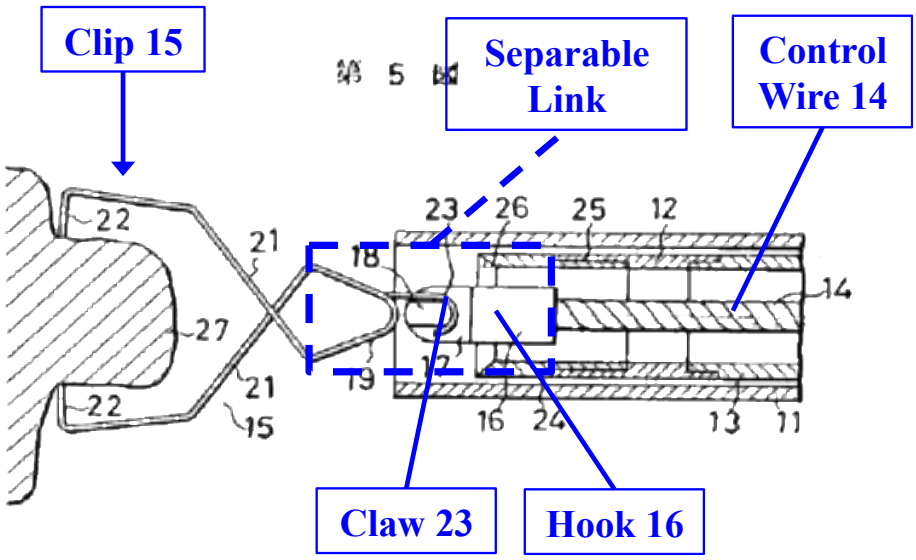
Claim 3 depends from claim 2 and further requires "when the clip is in the open tissue receiving configuration, the first and second link arms are axially aligned with one another." The opening element disclosed in Nishioka satisfies this limitation, and this claim would have been obvious in view of Nishioka for the reasons in Section V.C.3, *supra* at p. 56 and V.E.1.c, *supra* at pp. 72-77. (Ex. 1041, ¶102). In addition, this claim would have been obvious in view of Sackier,

for the reasons in Section V.B.1, *supra* at pp. 39-40 and V.E.1.c, *supra* at pp. 72-77. (Ex. 1041, ¶102).

4. Claim 4

Claim 4 depends from claim 1 and further requires "a proximal end of the clip is coupled to a control wire via a separable link."

As shown below in annotated Figure 5, Shinozuka discloses claw 23 at the proximal end of clip 15 is coupled via a separable link to hook 16 at the distal end of control wire 14.

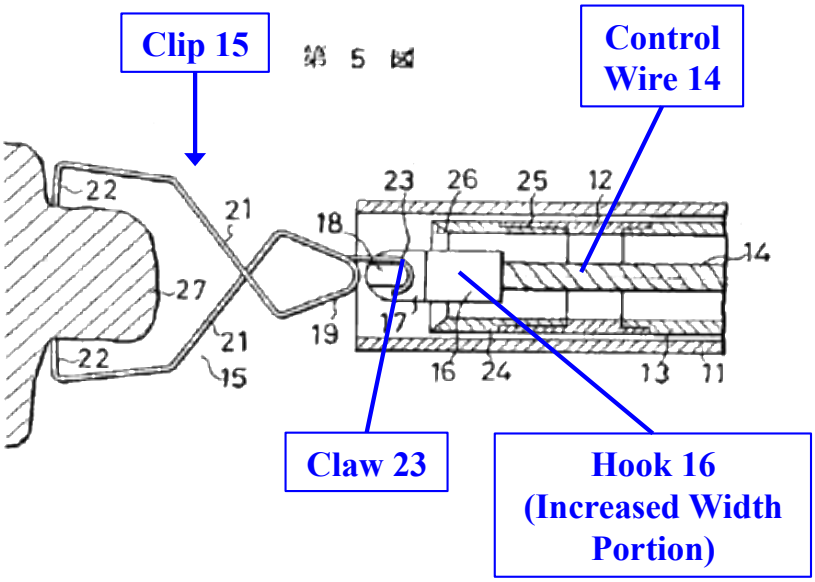


(Ex. 1041, ¶104; Ex. 1009, p. 261 ("a claw provided projecting from the base end part of this clip, for detachably engaging with the hook"), p. 262 ("This invention, in detachably coupling a clip with a control cord, provides a claw on the clip side and engages a hook on the control wire side with this, and by this means makes it easy to detach the hook from the clip."), p. 263 ("[W]hen the control wire 14 is

pushed well out and then the control wire 14 is jiggled, the hook 16 on it comes off the claw 23 of the clip 15.")).

5. Claim 5

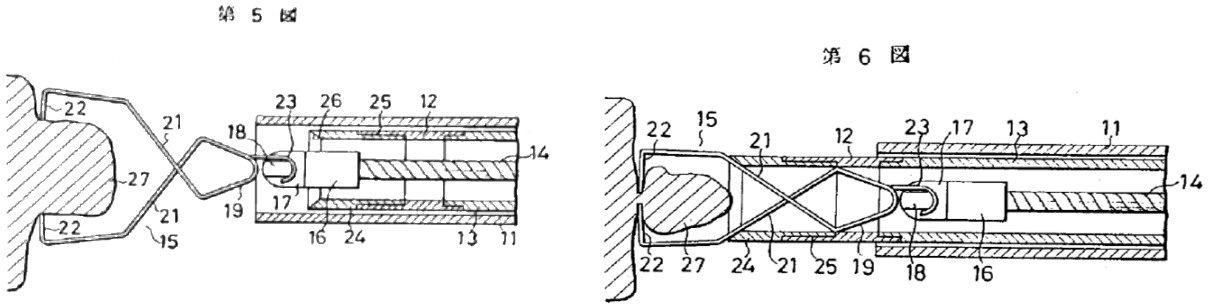
Claim 5 depends from claim 4 and further requires "a distal end of the control wire includes an increased width portion formed to removably engage the clip." As shown below in annotated Figure 5, Shinozuka discloses a distal end of control wire 14 includes an increased width portion (hook 16) formed to removably engage clip 15 via claw 23.



(Ex. 1041, ¶105; Ex. 1009, pp. 261-263).

6. Claim 6

Claim 6 depends from claim 4 and further requires "application of a proximal tensile force to the control wire causes movement of the clip from the open tissue receiving configuration to the closed configuration." Shinozuka discloses "pulling the control wire 14" (*i.e.*, applying a proximal tensile force to the control wire) causes movement of the clip from the open tissue receiving configuration (Figure 5, reproduced below on the left) to the closed configuration (Figure 6, reproduced below on the right).

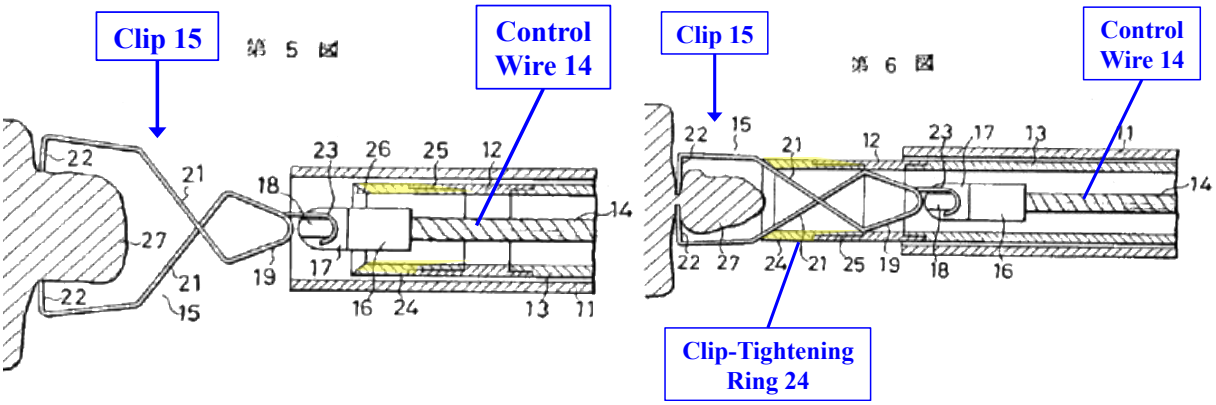


Shinozuka, Figures 5 and 6

(Ex. 1041, ¶106; Ex. 1009, p. 263).

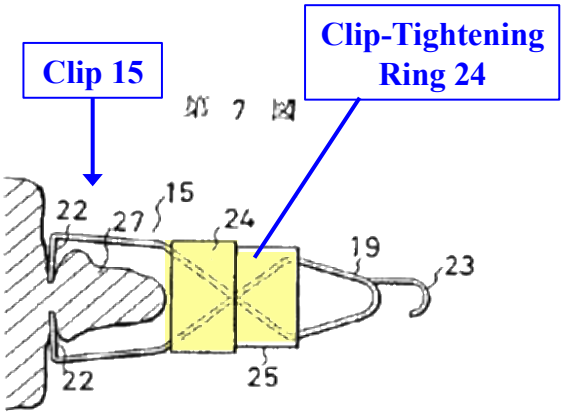
7. Claim 7

Claim 7 depends from claim 6 and further requires "application of a proximal tensile force greater than a predetermined threshold value causes the clip to lock in the closed configuration." As shown below in annotated Figures 5 and 6, Shinozuka discloses application of a proximal tensile force greater than a predetermined threshold value ("pulling on the control wire 14") compresses the clip 15 within clip-tightening ring 24 (highlighted in yellow), which locks the clip 15 in a closed configuration.



Shinozuka, Figures 5 and 6 (Annotated)

(Ex. 1041, ¶107; Ex. 1009, pp. 261-263). Figure 7 (reproduced and annotated below) shows clip 15 locked within clip-tightening ring 24 (highlighted in yellow) after release of the clip within the body.



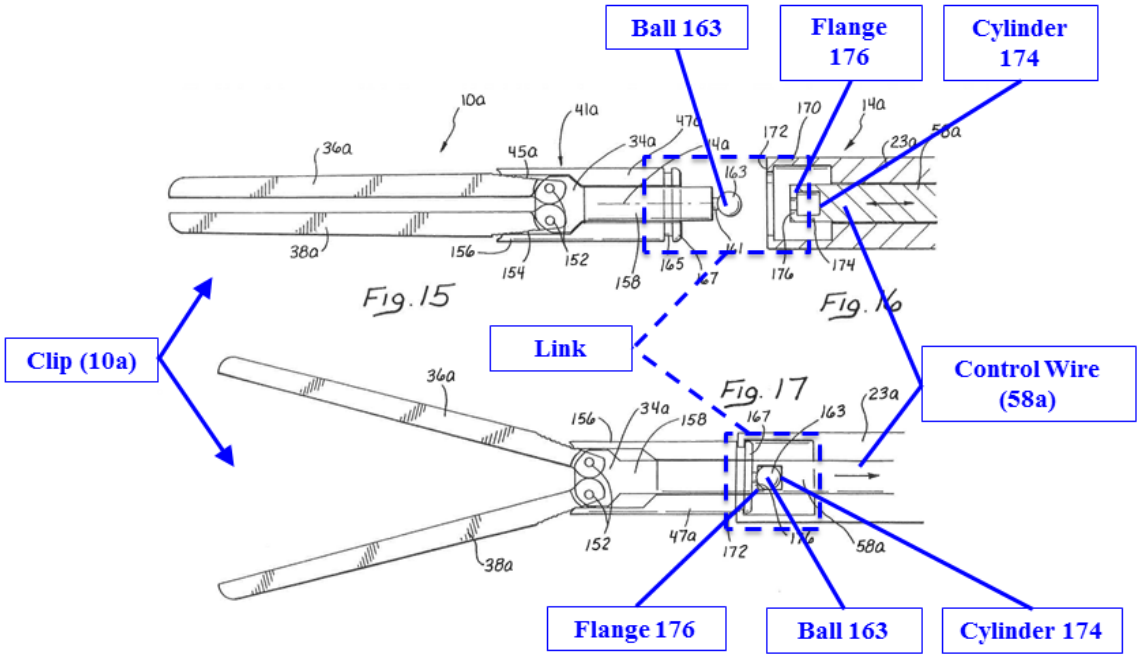
(Ex. 1041, ¶107; Ex. 1009, p. 263-264).

8. Claim 8

Claim 8 depends from claim 7 and further requires "application of a proximal tensile force greater than the predetermined threshold value causes the control wire to disengage from the clip." Shinozuka discloses the control wire 14 disengages from the clip 15 by "jiggl[ing]" the wire so that hook 16 comes off claw 23. ((Ex. 1041, ¶108; Ex. 1009, p. 263).

To the extent the "jiggl[ing] required to separate control wire 14 and clip 15 is not considered an application of a proximal tensile force greater than the predetermined threshold value, this is not a patentable distinction. (Ex. 1041, ¶109). As shown below in annotated Figures 15-17, Sackier discloses engaging a control wire (58a) and clip (10a) via a ball (ball 163) and socket (cylinder 174 (with flange 176)) connection, such that application of a proximal tensile force

greater than the predetermined threshold value (*i.e.*, pulling on the control wire) causes control wire to disengage from the clip.

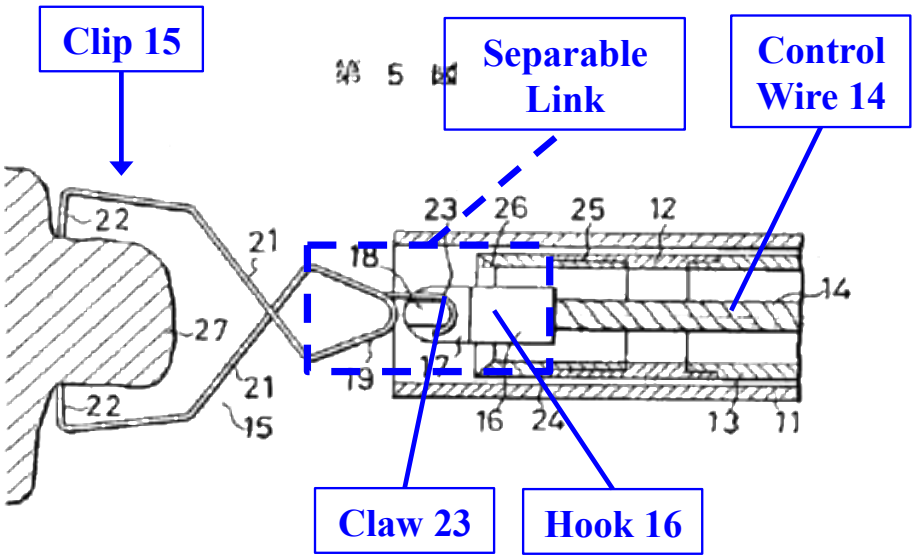


(Ex. 1041, ¶109; Ex. 1008, Abstract, 2:56-59, 8:29-34, 8:51-53, 9:60-10:34; *see also* reasons in Section V.A.3, *supra* at pp. 29-30).

It would have been obvious to substitute the Sackier ball and socket link for the Shinozuka link. A person of ordinary skill would have been motivated to make this substitution, for example to simplify and improve the operation of the Shinozuka device. (Ex. 1041, ¶110). *See Tokai*, 632 F.3d at 1371; MPEP §§ 2143(I)(C) and (D). A person of ordinary skill in the art would have recognized that "jiggl[ing]" a control wire within the body is an imprecise way to separate the clip. (Ex. 1041, ¶110). This person would have recognized the undesirable

"jiggl[ing]" could be avoided, simply by substituting the Shinozuka claw and hook link with the Sackier ball and socket link. (Ex. 1041, ¶110).

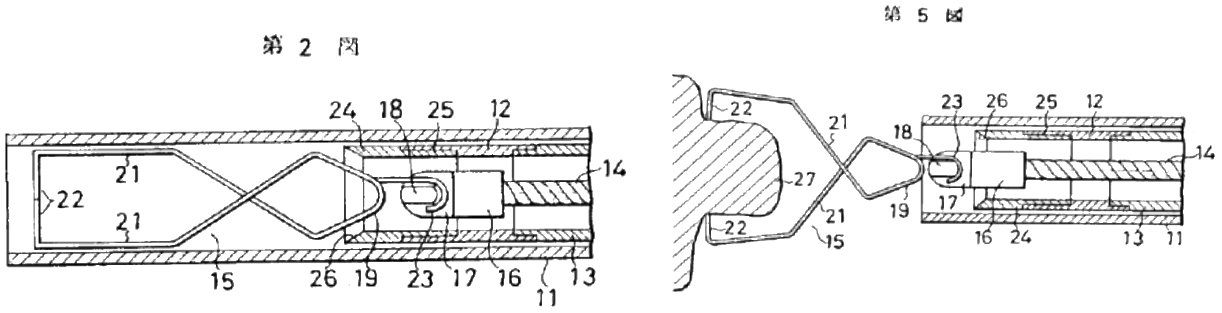
This modification would have been a matter of routine skill in the art, using simple mechanical elements disclosed in Sackier to achieve predictable results. (Ex. 1041, ¶111). *See Tokai*, 632 F.3d at 1371; *KSR*, 550 U.S. at 416. For example, it would have been obvious to substitute claw 23 at the proximal end of the Shinozuka clip 15 with a socket (174 (with 176)), and to substitute hook 16 at the distal end of the Shinozuka control wire 14 with a ball 163, as shown below. (Ex. 1041, ¶111).



In the resulting device, application of a proximal tensile force greater than the predetermined threshold value (*i.e.*, the pulling force required to separate ball 163 from cylinder (174 (with 176))) would cause the control wire 14 to disengage from the clip 15. (Ex. 1041, ¶111).

9. Claim 9

Claim 9 depends from claim 6 and further requires "application of a distally directed force to the control wire causes movement of the clip from the closed configuration to the open tissue receiving configuration." Shinozuka discloses "the control wire 14 is pushed forward" (*i.e.*, applying a distally directed force to the control wire) to move of the clip 15 from the closed configuration (Figure 2, reproduced below on the left) to the open tissue receiving configuration (Figure 5, reproduced below on the right).

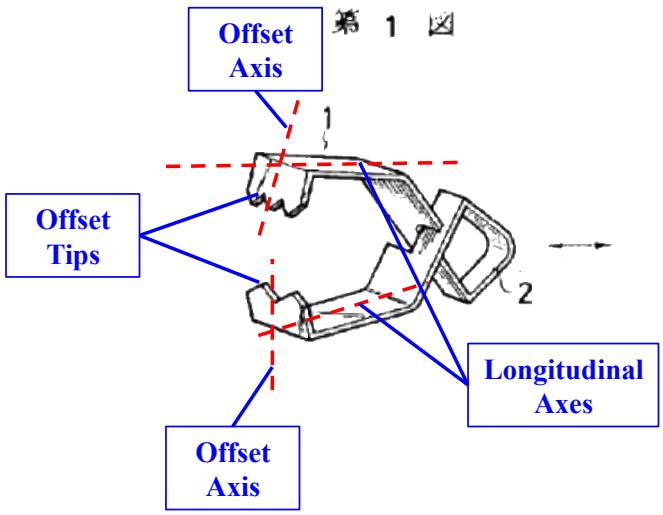


Shinozuka, Figures 2 and 5

(Ex. 1041, ¶112; Ex. 1009, p. 263).

10. Claims 10 and 11

Duplicate claims 10 and 11 depend from claim 1 and further require "a distal length of the first clip arm includes a first offset tip extending along an axis offset relative to a longitudinal axis of the first clip arm and wherein a distal length of the second clip arm includes a second offset tip extending along an axis offset relative to a longitudinal axis of the second clip arm." Shinozuka discloses this limitation, as shown below in annotated Figure 1.



(Ex. 1041, ¶113; Ex. 1009, p. 263).

11. Independent Claim 12

a. "A medical device, comprising"

Shinozuka discloses "a medical device," for the reasons in Section V.E.1.a, *supra* at p. 70. (Ex. 1041, ¶114).

b. "a clip including first and second clip arms, the clip being movable between an open tissue receiving configuration in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween"

Shinozuka discloses this limitation, for the reasons in Section V.E.1.b, *supra* at pp. 70-71. (Ex. 1041, ¶115).

c. "an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration, wherein the opening element is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration"

It would have been obvious to modify Shinozuka to include this limitation, for the reasons in Section V.E.1.c, *supra* at pp. 72-77. (Ex. 1041, ¶116).

d. "a control wire coupled to a proximal end of the clip and operable to move the clip between the open and closed configurations."

Shinozuka discloses this limitation, for the reasons in Section V.E.4, *supra* at pp. 78-79. (Ex. 1041, ¶117).

12. Claim 13

Claim 13 depends from claim 12 and further requires "the opening element comprises first and second link arms engaging the inner surfaces of the first and second clip arms, respectively." This claim would have been obvious, for the reasons in Section V.E.2, *supra* at p. 77. (Ex. 1041, ¶118).

13. Claim 14

Claim 14 depends from claim 13 and further requires "when the clip is in the open tissue receiving configuration, the first and second link arms are axially aligned with one another." This claim would have been obvious, for the reasons in Section V.E.3, *supra* at p. 77-78. (Ex. 1041, ¶119).

14. Claim 15

Claim 15 depends from claim 12 and further requires "a proximal end of the clip includes an opening formed to receive a control wire." As explained above in Section V.E.8, *supra* at pp. 82-84, it would have been obvious to modify Shinozuka to substitute claw 23 at the proximal end of the Shinozuka clip 15 with a socket (*e.g.*, Sackier cylinder 174 (with flange 176)), and to substitute hook 16 at the distal end of the Shinozuka control wire 14 with a ball (*e.g.*, Sackier ball 163). (Ex. 1041, ¶120). In the resulting device, a proximal end of the clip would include cylinder 174 (with flange 176) (including an opening) formed to receive ball 163 of the control wire 14. (Ex. 1041, ¶120).

15. Claim 16

Claim 16 depends from claim 15 and further requires "application of a proximal tensile force to the control wire causes movement of the clip from the open tissue receiving configuration to the closed configuration." Shinozuka discloses this limitation, for the reasons in Section V.E.6, *supra* at p. 80. (Ex. 1041, ¶121).

16. Claim 17

Claim 17 depends from claim 16 and further requires "application of a proximal tensile force greater than a predetermined threshold value causes one or both of a locking of the clip in the closed configuration and a disengagement of the control wire from the clip." Shinozuka discloses this limitation, for the reasons in Section V.E.7, *supra* at pp. 81-82 (locking of the clip in the closed configuration). (Ex. 1041, ¶122). In addition, this claim would have been obvious, for the reasons in Section V.E.8, *supra* at pp. 82-84 (disengagement of the control wire from the clip). (Ex. 1041, ¶122).

17. Claim 18

Claim 18 depends from claim 16 and further requires "application of a distally directed force to the control wire causes movement of the clip from the closed configuration to the open tissue receiving configuration. Shinozuka discloses this limitation, for the reasons in Section V.E.9, *supra* at p. 85. (Ex. 1041, ¶123).

18. Claim 19

Claim 19 depends from claim 12 and further requires "a distal end of the control wire includes an increased width portion formed to removably engage the clip." Shinozuka discloses this limitation, for the reasons in Section V.E.5, *supra* at p. 79. (Ex. 1041, ¶124).

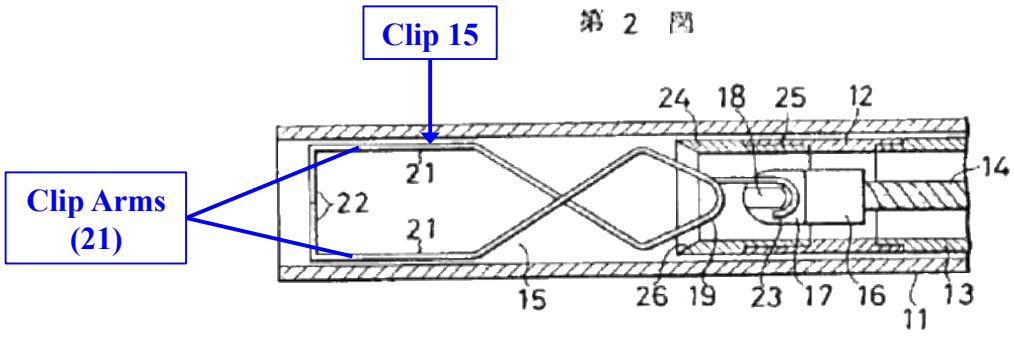
19. Independent Claim 20

a. "a method, comprising"

Shinozuka discloses a method. (Ex. 1009, pp. 261-63, Figures 2, 5-6; Ex. 1041, ¶125).

b. "inserting a medical device comprising a clip having first and second clip arms to a target tissue site, the clip including an opening element engaging inner walls of the first and second clip arms and urging the clip to an open tissue receiving configuration"

Shinozuka discloses inserting a medical device. (Ex. 1041, ¶126; Ex. 1009, p. 263 ("[T]his entire insertion tube 11 is introduced through an endoscope channel into a body cavity.")). As shown below in annotated Figure 2, Shinozuka discloses the medical device comprises a clip having first and second clip arms.

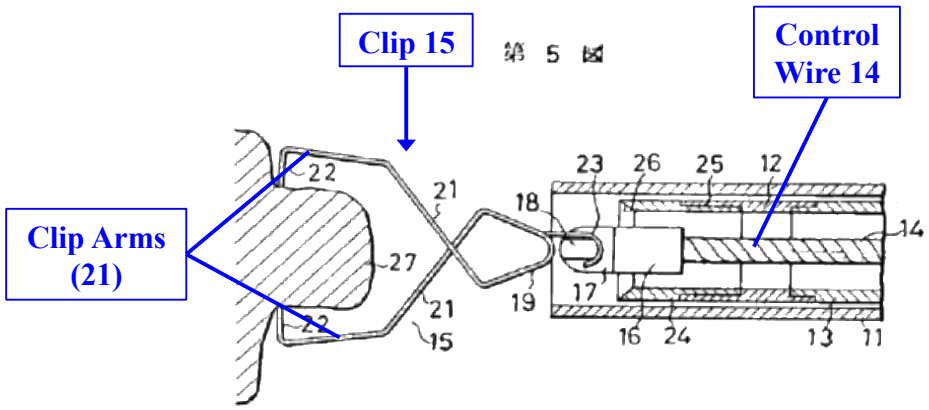


(Ex. 1041, ¶126*; see also* Section V.E.1.b, *supra* at pp. 70-71).

It would have been obvious to modify Shinozuka to include an opening element engaging inner walls of the first and second clip arms and urging the clip to an open tissue receiving configuration, for the reasons in Section V.E.1.c, *supra* at pp. 72-77. (Ex. 1041, ¶127).

c. "moving a control wire coupled to a proximal end of the clip distally to move the first and second clip arms away from one another to the open tissue receiving configuration"

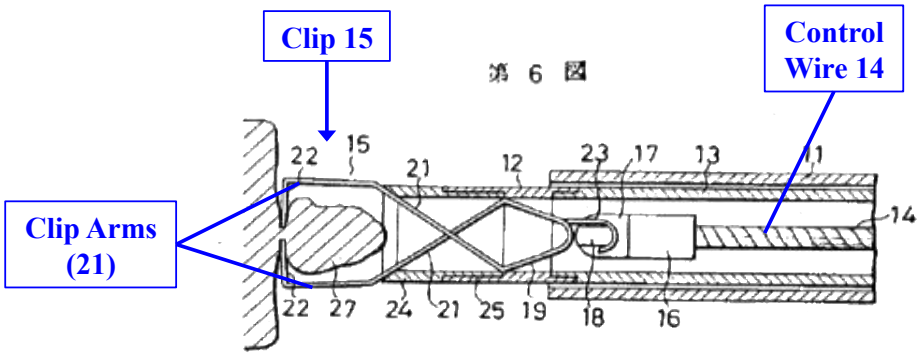
Shinozuka discloses moving a control wire 14 coupled to a proximal end of the clip 15 distally ("push[ing] forward") moves the first and second clip arms (21) away from one another to the open tissue receiving configuration (Figure 5, reproduced and annotated below).



(Ex. 1009, p. 263 ("[T]he control wire 14 is pushed forward and by way of the hook 16 the clip 15 is projected out to the outside as shown in Fig. 5. As a result of this the clip 15 opens and becomes able to pinch some biotissue 27, and accordingly it is pushed onto a portion of biotissue 27 needing to be pinched."); Ex. 1041, ¶128).

d. "moving the control wire proximally to move the first and second clip arms toward one another to a closed tissue capturing configuration"

Shinozuka discloses moving the control wire 14 proximally ("pulling the control wire 14") to move the first and second clip arms (21) toward one another to a closed tissue capturing configuration (Figure 6, reproduced and annotated below).



(Ex. 1009, p. 263 ("Then, as shown in Fig. 6 the control tube 13 is pushed so as to fit the clip-tightening ring 24 onto the clip 15 and close the clip 15. As a result of this the pinching parts 22, 22 pinch the biotissue 27. It may be noted that the clip 15 can be pinched onto the biotissue in the same way not only by pushing out the control tube 13 but alternatively by pulling the control wire 14."); Ex. 1041, ¶129).

e. "applying a proximal tensile force exceeding a threshold level to the control wire to separate the control wire from the clip."

Shinozuka discloses this limitation, for the reasons in Section V.E.4, *supra* at pp. 78-79. This claim would have been obvious, for the reasons in Section V.E.8, *supra* at pp. 82-84. (Ex. 1041, ¶130).

VI. CONCLUSION

The grounds identified above establish a reasonable likelihood that Petitioners will prevail in their challenge of claims 1-20 of the '731 patent. Therefore, Petitioners respectfully request institution of an *inter partes* review to cancel those claims.

Dated: December 13, 2016

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CERTIFICATE OF COMPLIANCE

The undersigned certifies that this brief complies with the type-volume limitations of 37 CFR § 42.24(a)(1)(i). This brief (including figure labels and annotations) contains 13,970 words as calculated by the "Word Count" feature of Microsoft Word 2010, the word processing program used to create it, and manual counting of the annotations in the figures.

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

Dated: December 13, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 9,271,731, as well as the accompanying Power of Attorney, and Exhibits 1005, 1008-1010, 1012, 1017, 1033-1036, and 1038-1041 have been served in their entirety on December 13, 2016, by Federal Express (Overnight Delivery) on:

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