UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Cook Group Incorporated and Cook Medical LLC,

Petitioners

v.

Boston Scientific Scimed, Incorporated,

Patent Owner

Patent No. 8,709,027
Issue Date: April 29, 2014

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

Case No. IPR 2017-00133

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TABLE OF EXHIBITS

1016	U.S. Patent No. 5,766,189 (“Matsuno”)
1017	U.S. Patent No. 5,645,075 (“Palmer”)

Cook Group Incorporated and Cook Medical LLC (collectively "Petitioners"), respectfully request *inter partes* review of claims 1-20 of U.S. Patent No. 8,709,027 ("the '027 patent") (Ex. 1001). The USPTO assignment records show that the Patent Owner is Boston Scientific Scimed, Inc. ("BSSI").

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

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

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

B. Related Matters (§ 42.8(b)(2))

1. Pending District Court Litigation

The '027 patent is the subject of litigation in the U.S. District Court for the District of Delaware in *Boston Scientific Corp. et al. v. Cook Group Inc. et al.*, No. 15-980-LPS-CJB. Petitioners were served with the Complaint on October 29, 2015.

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

2. Related Pending Applications

The following patent applications are related to the ’027 patent, and are currently pending before the U.S. Patent Office: U.S. Patent Application Nos. 14/988,447; 15/009,358; and 15/091,147.

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

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D. Service Information (§ 42.8(b)(4))

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

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

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

III. SUMMARY OF THE RELEVANT TECHNOLOGY AND THE '027 PATENT

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

The '027 patent relates generally to compression clips that can be used "to cause hemostasis of blood vessels located along the gastrointestinal tract. . ." (*See* Ex. 1001, 1:21-24). The clips stop internal bleeding by clamping together the edge of a wound to achieve "hemostasis." (*Id*. at 2:38-39). The patent acknowledges that such clipping devices were known in the art before the '027 patent was filed. (*See id.*, pp. 1-2 (citing numerous prior art references); 1:50-52 (describing

"Olympus Endoclips"); 2:31-38 (describing prior art "clamps, clips, staples, sutures" that are "able to apply sufficient constrictive forces to blood vessels so as to limit or interrupt blood flow")).

For example, a person of ordinary skill in the art would have been familiar with prior art clip devices in the form of forceps. (Ex. 1011, ¶¶ 18-20.) Annotated Figures 1 and 2, below, depict an example of a prior art forceps (clip) disclosed in U.S. Patent No. 5,645,075 ("Palmer"). (Ex. 1017).[1]

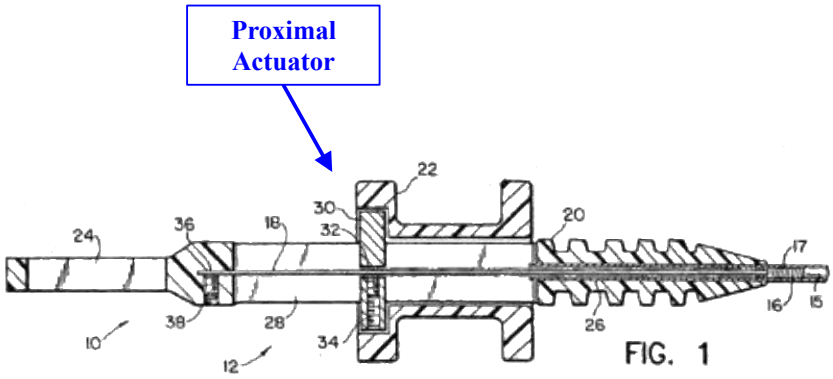
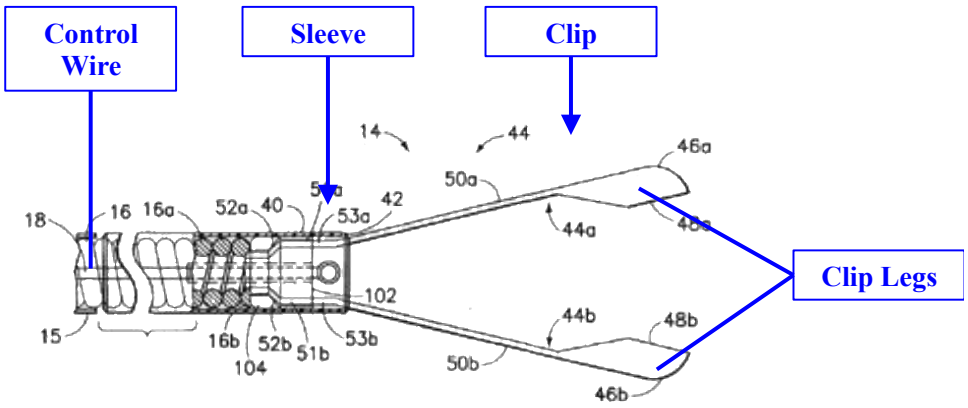


FIG. 1

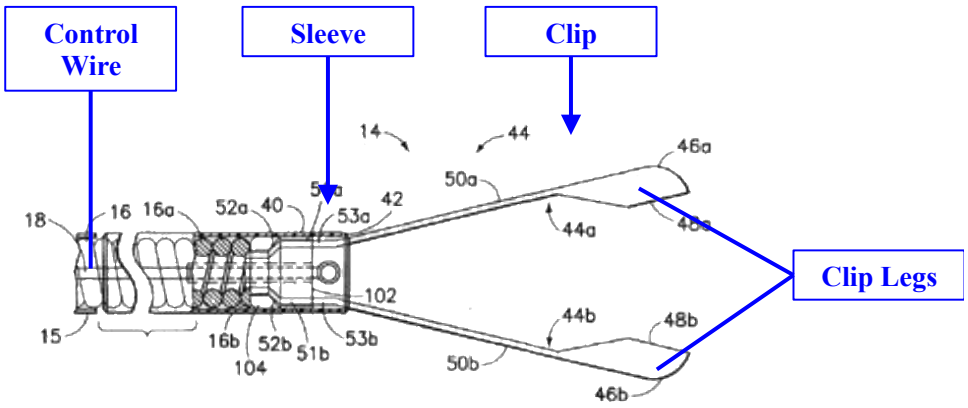
[1] Palmer issued on July 8, 1997, and names as an inventor Vincent A. Turturro – one of the named inventors of the '027 patent. Palmer was not cited during prosecution of the '027 patent.

FIG. 2

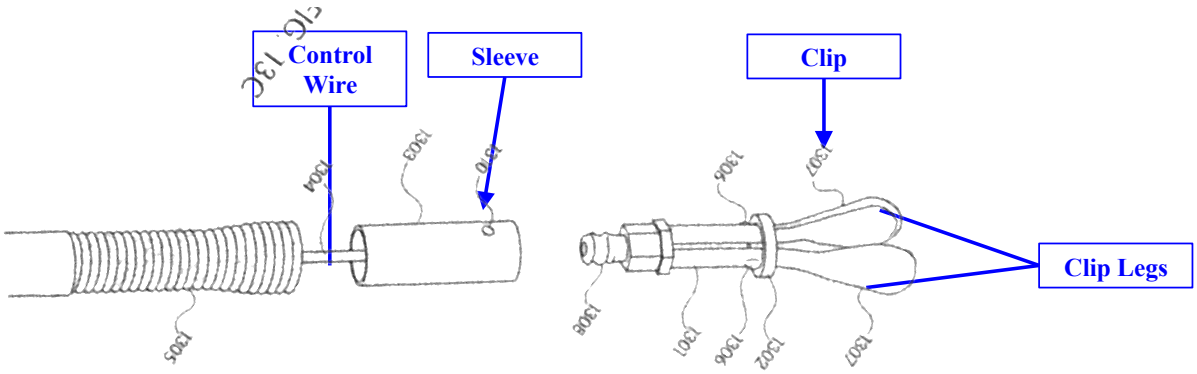


The forceps (also referred to as a "bioptome") includes a proximal actuator (handle portion 12, Figure 1), and a "distal end effector portion 14" (Figure 2) including a clip (jaw assembly 44) with two clip legs (end effectors 44a, 44b, with jaw cups 46a, 46b). (Ex. 1017, 5:50-53, 6:64 – 7:6). In addition,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

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



Palmer, Figure 2

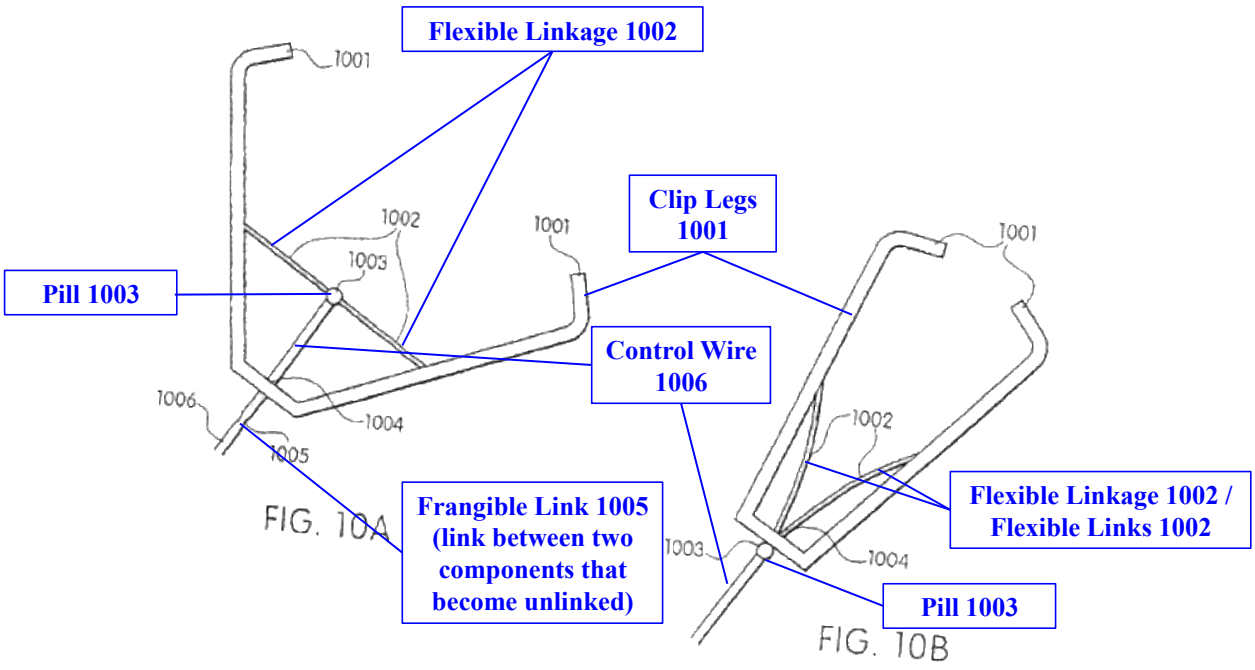


'027 Patent, Figure 13C

Consistent with the prior art, independent claims 1, 13, and 20 describe medical devices and methods including "*a clip*" and a "*control member* extending from a proximal actuator to the clip." (Ex. 1011, ¶ 19). Independent claims 13 and 20 further describe a "*sleeve*" housing a portion of the clip, and movable relative to the clip. In addition, each of these claims describes a "*linkage*" that "spread[s]" the clip legs apart from one another (claims 1 and 13), that "drive[s]" the clip legs radially outward as the control member is moved distally (claims 1, 13, and 20), and that "move[s]" the clip distally relative to a sleeve (claims 13 and 20). (*See id.*

at 15:32-17:6.)

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



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

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

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

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

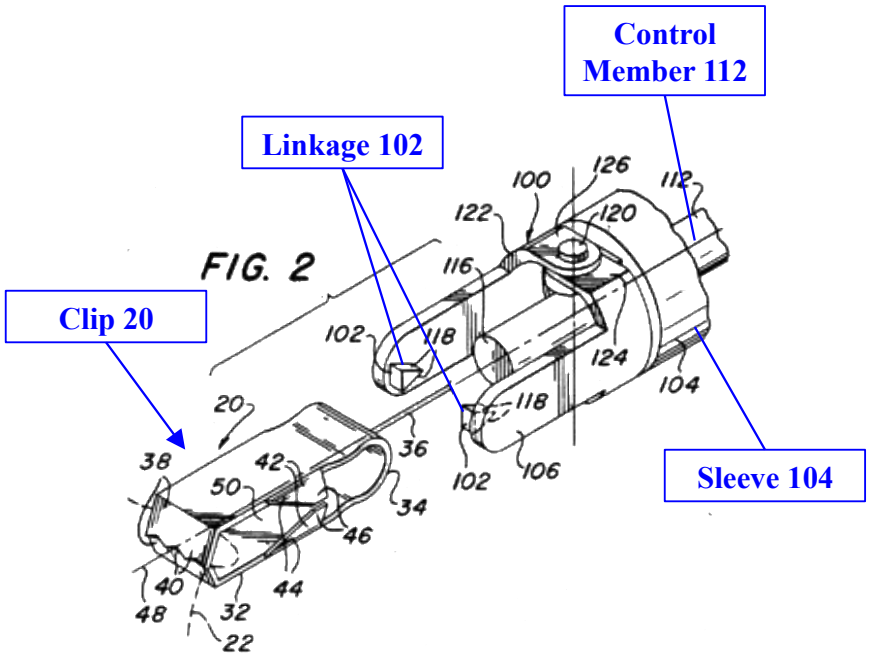
> *It will be obvious to those skilled in the art*, having regard to this disclosure, that other variations on this invention beyond those specifically exemplified here may be made. These variations include, but are not limited to, *different combinations of clips, closing mechanisms, locking mechanisms,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

(Ex. 1001, 15:22-27).

B. Summary Of The Prosecution History

During prosecution, the Examiner rejected independent claims 1 and 13 (application claims 46 and 58) as anticipated by U.S. Patent No. 5,242,456 ("Nash

'456"). (*See* Ex. 1002, Office Action dated August 29, 2013). Figure 2 of Nash '456 is reproduced below, and depicts the claimed "clip," "control member," "linkage," and "sleeve," as identified by the Examiner:



(Exhibit 1006, Nash '456). BSSI did not dispute that Nash '456 discloses a "clip" (clip 20), "control member" (pusher member 112), "linkage" (trunnion 102), or "sleeve" (body portion 104). Instead, BSSI distinguished Nash '456 on the basis that the control member ("pusher member 112") does not move distally *relative to the clip* ("clip 20"). (Ex. 1002, Response dated November 26, 2013, pp. 4-5). According to BSSI, "the pusher member 112 [of Nash '456] maintains a spatial relationship with the clip 20 throughout the procedure." (*Id.* at 4). In contrast, the "novel concept" of the "present invention" according to BSSI is having "a control wire *movable relative to the clip* which also controls radial expansion of the clip."

(*Id.* (emphasis added)). The Examiner subsequently issued a Notice of Allowance based on BSSI's argument. (*Id*., Notice of Allowance dated December 27, 2013).

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

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

Petitioners certify that the '027 patent is available for *inter partes* review and that Petitioners are not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this petition.

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

The precise relief requested is that claims 1-20 of the '027 patent (Ex. 1001) be found unpatentable, and canceled.

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

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

[2] The '027 patent claims priority to U.S. Patent Application No. 09/971,488, filed October 5, 2001. Accordingly, the pre-AIA sections of 35 U.S.C. §§ 102 and 103 apply here.

No.	Grounds
1	Claims 1-3 and 7-12 are anticipated under § 102 by U.S. Patent No. 5,843,000 ("Nishioka")
2	Claims 13-14 and 16-19 are obvious under § 103 in view of Nishioka in combination with Japanese Unexamined Patent Application Publication No. 60-103946 ("Shinozuka")
3	Claims 4-6 and 13-20 are obvious under § 103 in view of Nishioka in combination with U.S. Patent No. 5,766,189 ("Matsuno")

Petitioners submit that although the limitations of the challenged claims are disclosed in multiple references, the above challenges are not redundant. This is because the structures and features in one reference that disclose a particular claim limitation differ from the structures and features in another reference that discloses the same claim limitations.

D. Level Of Ordinary Skill In The Art

The person having ordinary skill in the art as of the time of the filing of the application that became the '027 patent would have possessed the knowledge and skill known by an engineer or similar professional with at least an undergraduate degree in engineering, or a physician having experience with designing medical devices. (Ex. 1011, ¶ 11). This person would also have an understanding of

engineering or medical device design principles.[3] (Ex. 1011, ¶ 11).

In support of this Petition, Petitioners have submited the Declaration of Mark A. Nicosia, Ph.D. (Ex. 1011). 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. 1011), 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. 1011) addresses the prior art at issue from the view of a person of ordinary skill in the art in the relevant timeframe.

E. Claim Construction (§ 42.104(b)(3))

Claims in an IPR are given the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b) (2015); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2136 (2016). In light of the broadest reasonable construction standard and are for the purposes of *inter*

[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. 1011, ¶ 11).

partes review only,[4] Petitioners adopt the following constructions proposed by BSSI in the Litigation:

1. "a linkage"

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

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

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

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

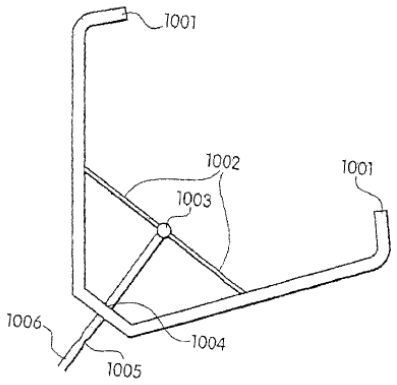


FIG. 10A

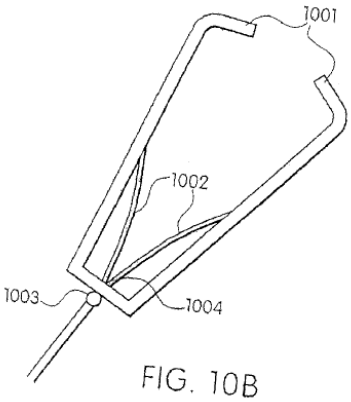


FIG. 10B

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

2. "operably associated with the control member"

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

3. "frangible link"

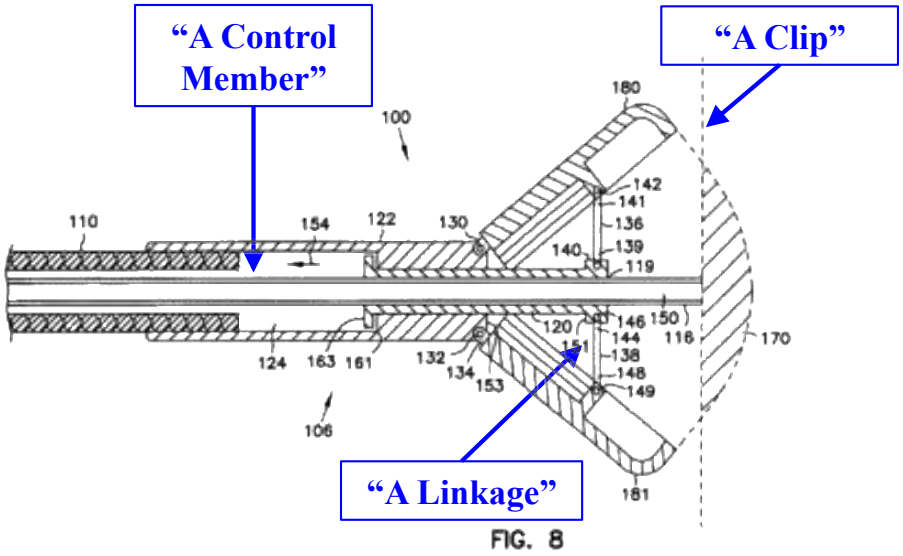
Claim 4 of the '027 patent requires a "frangible link" that couples the clip to the control member. In the litigation, BSSI argued that the term "frangible link" means a "link between at least two components that become unlinked when a tensile load is applied." (Ex. 1004 at 22). BSSI explained that this includes a "ball-and-socket link, [where] the ball could be pulled from the socket under a tensile force, thus breaking the link, but neither the ball nor the socket would itself

be broken." (*Id*.)

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

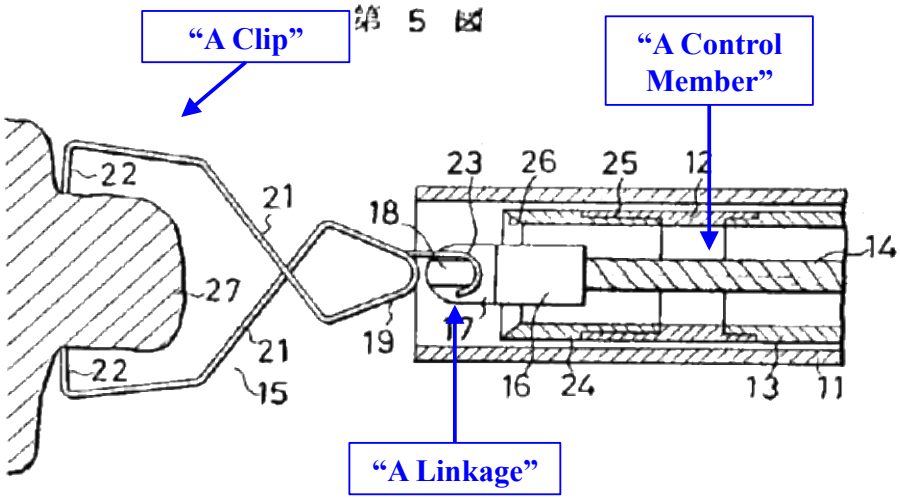
Claims 1-20 of the '027 patent are unpatentable in view of one or more of the grounds identified above in Section IV.C. (Ex. 1011, ¶ 29). Only one of the references cited in these grounds was before the Examiner. Individually and/or combined, these references disclose each and every limitation of the challenged claims, including "*a clip*," "*a control member*," and a "*linkage*" operably associated with, or coupled to, the control member:

Nishioka discloses biopsy forceps with jaws that mechanically pivot open and closed in response to movement from control wires extending from a handle. (Ex. 1011, ¶ 24).



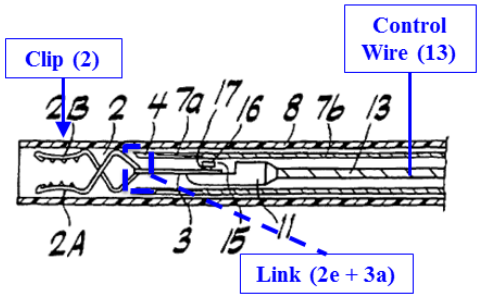
Nishioka, Figure 8 (Annotated)

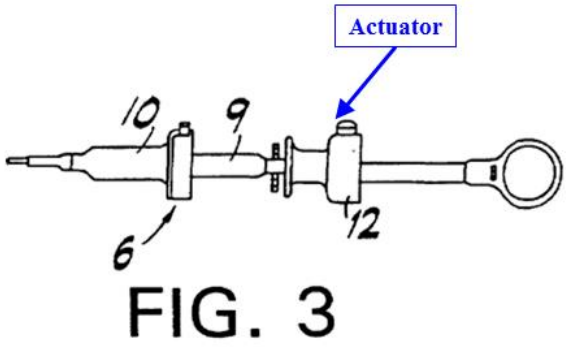
Shinozuka discloses a detachable biotissue clip with jaws for clipping a body structure in a patient. (Ex. 1011, ¶ 26).



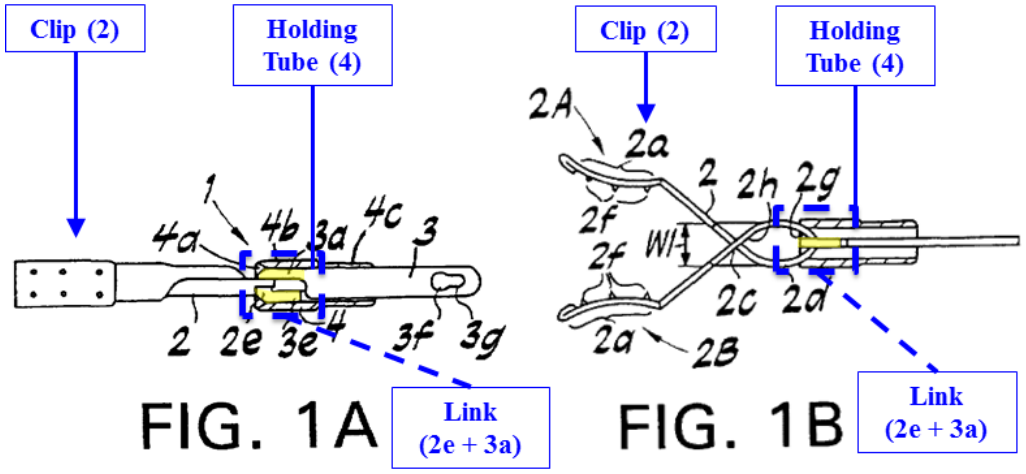
Shinozuka, Figure 5 (Annotated)

Matsuno discloses a clip device that can be detached from an operating wire after forcefully straightening an attachment link. (Ex. 1011, ¶ 28).





Matsuno, Figures 5 and 3 (Annotated)



Matsuno, Figures 1A and 1B (Annotated)

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

To the extent not anticipated, the challenged claims merely describe obvious combinations of "familiar elements according to known methods," which "do[] no more than yield predictable results." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007); MPEP § 2143(I). The motivation to combine embodiments and references would have come from the references themselves, as well as from the knowledge generally available to a person of ordinary skill in the art. (*See e.g.* Ex. 1011, ¶¶ 47-49).

A. Ground 1: There is a Reasonable Likelihood That Claims 1-3 and 7-12 are Anticipated In View Of 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 '027 patent.

1. Independent Claim 1

a. "A medical device, comprising"

Nishioka discloses the preamble: a medical device in the form of a "forceps device." (Ex. 1005, 1:6-9, 1:64-66, 2:58-65; Ex. 1011, ¶ 30).

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

As shown below in annotated Figures 2 and 8, Nishioka discloses forceps (clips)[5] having first and second clip legs (jaws 80, 81 (Figure 2), jaws 180, 181 (Figure 8)), each having an inner surface:

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

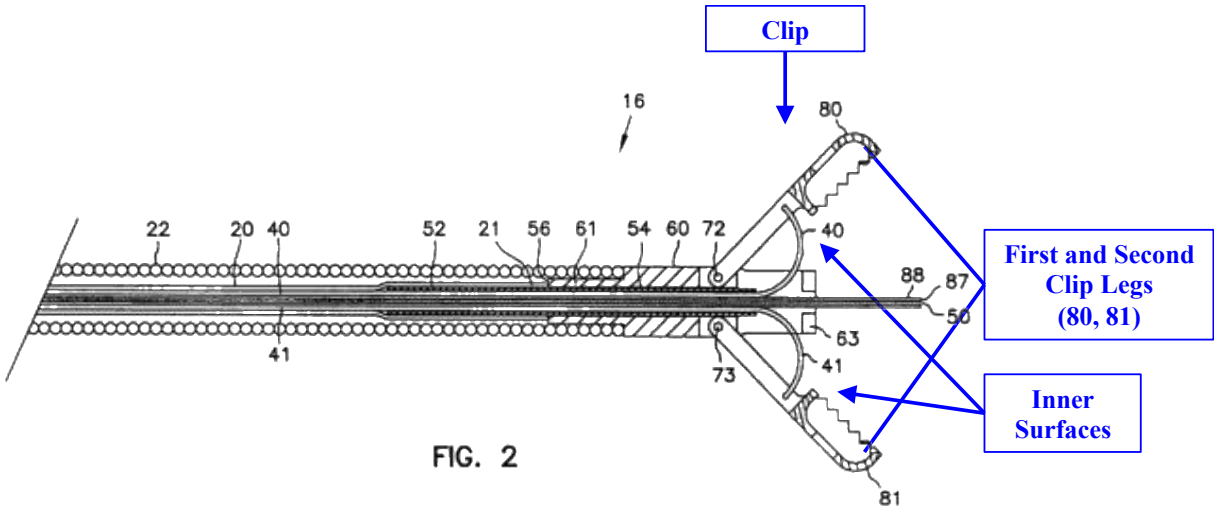


FIG. 2

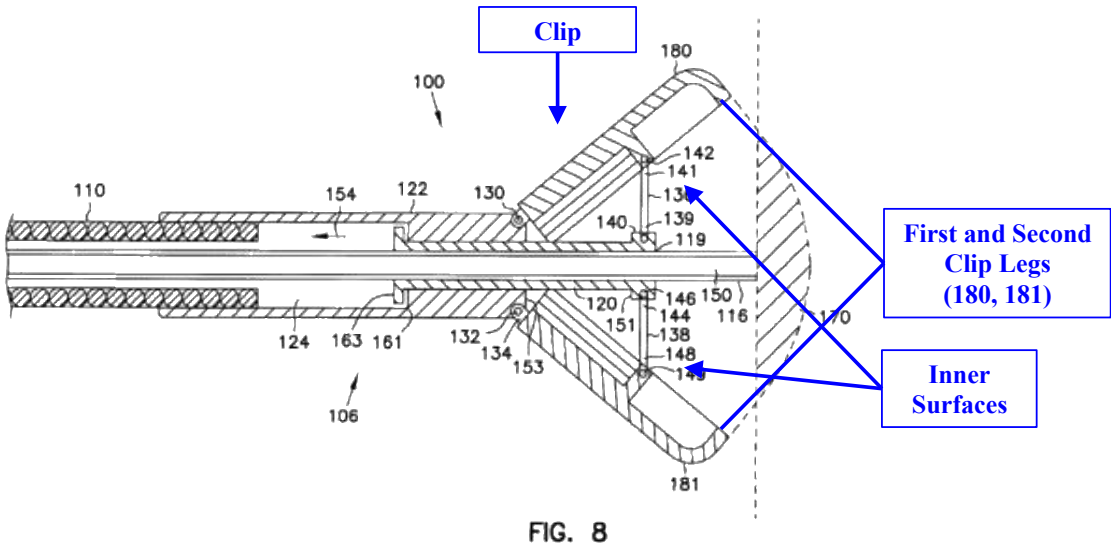


FIG. 8

(Ex. 1005, 1:66 – 7:1, 2:11-14, 3:13-15, 3:44-49, 6:27-31, 6:48-50, 6:60-64, Figures 1-4, 7-8; Ex. 1011, ¶ 31).

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

As shown below in annotated Figures 1, 2, and 8, Nishioka discloses a "control member" (control wires 40, 41 (Figure 2), fiber 150 (Figure 8)) extending from a proximal actuator (control handle portion 12 (Figure 1)) to the clip:

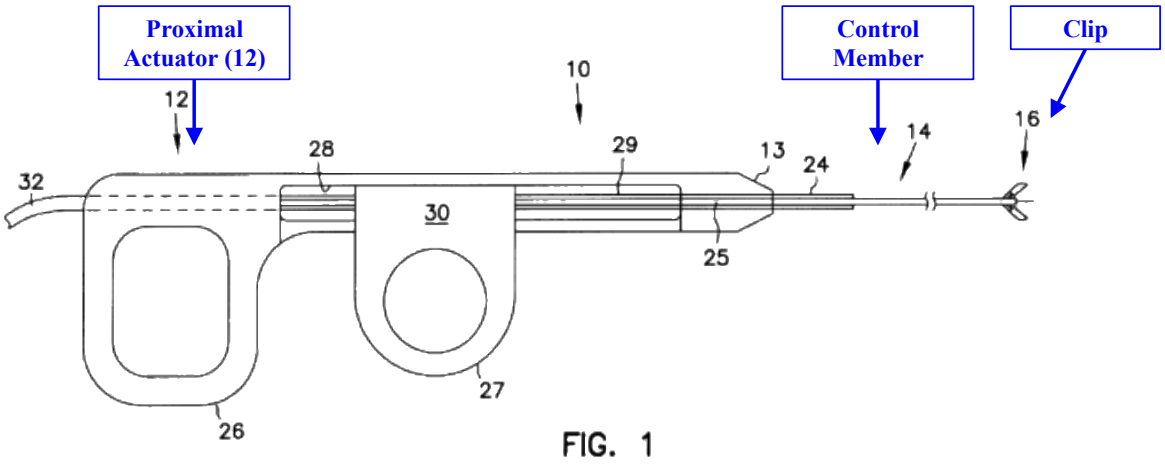


FIG. 1

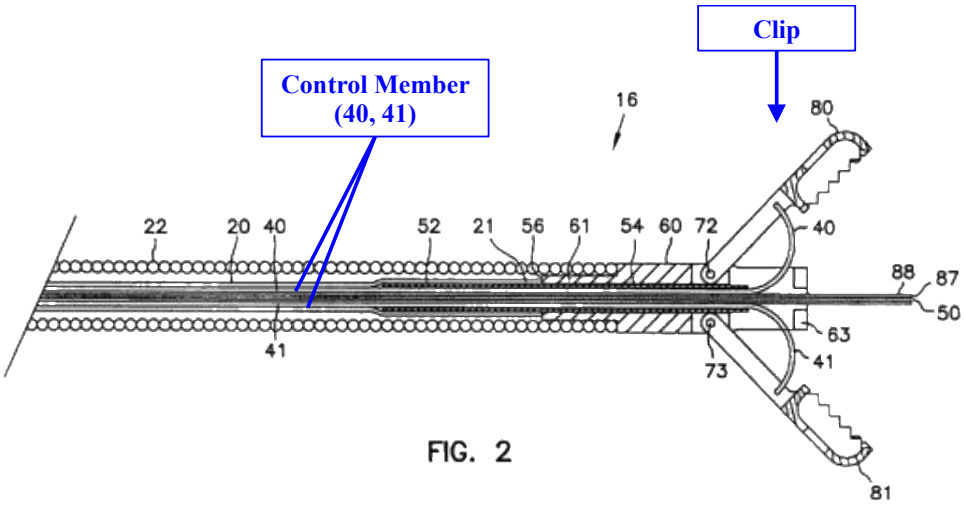


FIG. 2

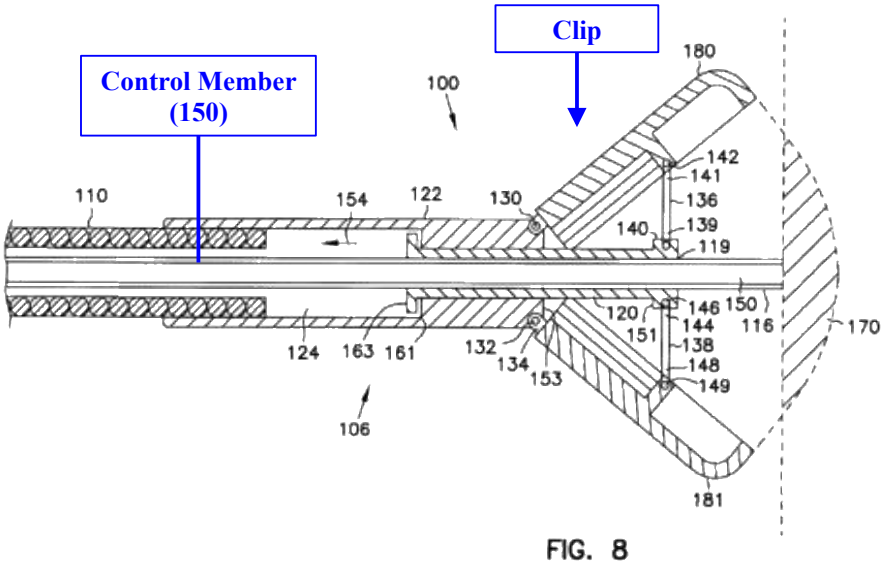


FIG. 8

(Ex. 1005, 3:44-49, 3:64-65, 4:10-17, 6:60-64, 7:3-32, Figures 1-4, 7-8; Ex. 1011, ¶ 32).

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

As shown below in annotated Figure 2, Nishioka discloses in one embodiment a linkage (distal end portion of control wires 40, 41 (highlighted in yellow)) operably associated with the control member (40, 41) to spread the first and second clip legs (80, 81) apart from one another into a tissue-receiving configuration as the control member (40, 41) is moved distally relative to the clip, the linkage contacting the inner surfaces of the clip legs (80, 81) to drive the clip

legs radially outward as the control member (40, 41) is moved distally relative to the clip:

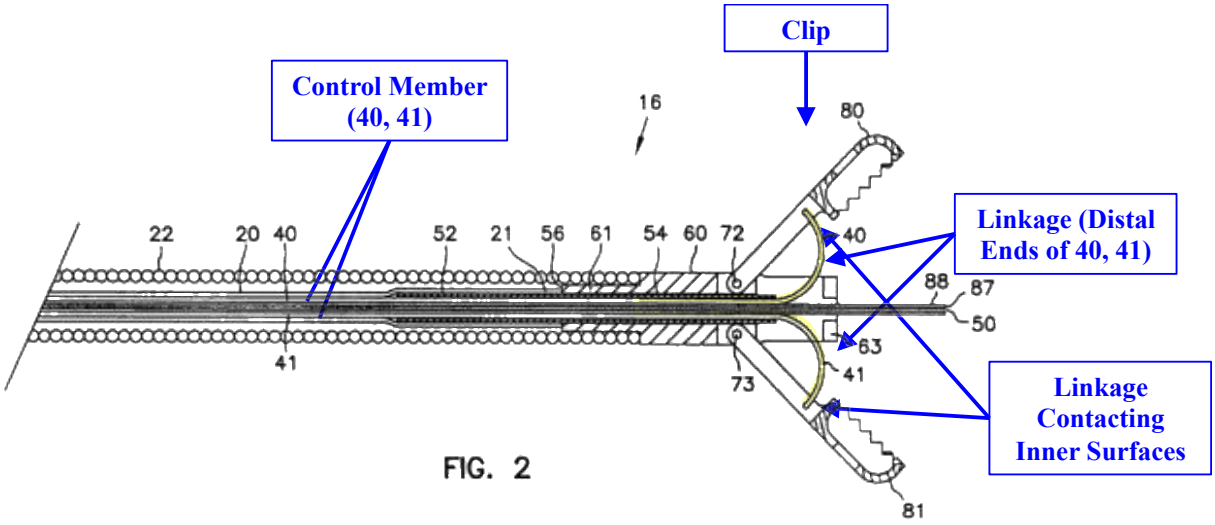


FIG. 2

(Ex. 1005, 4:10-15 ("[C]ontrol wires 40, 41 are secured to slider 30 which . . . form[s] an actuator mechanism for the forceps 10. Movement of slider 30 causes axial movement of reinforcing tube 29, tube 20 and control wires 40, 41 relative to coil 22, which is used to actuate the cutting jaws."), 5:12-15 ("The control wires are formed of wire which is stiff enough to push against the jaws to open them, but flexible enough to flex as the wires are retracted to pull the jaws together."), 5:49-54 ("[T]he forceps jaws can be opened by pushing slider 30 of the control handle forward. This causes movement (to the right in FIG. 2) of . . . the control wires 40, 41, and the optical fiber 50. The control wires push against the jaws, causing them to open."); Ex. 1011, ¶ 33).

Likewise, as shown below in annotated Figure 8, Nishioka discloses in another embodiment a linkage (tubular slide member 120, control links 136, 138 (highlighted in yellow)) operably associated with the control member (fiber 150) to spread the first and second clip legs (180, 181) apart from one another into a tissue-receiving configuration as the control member (150) is moved distally relative to the clip, the linkage contacting the inner surfaces of the clip legs (180, 181) to drive the clip legs radially outward as the control member (150) is moved distally relative to the clip:

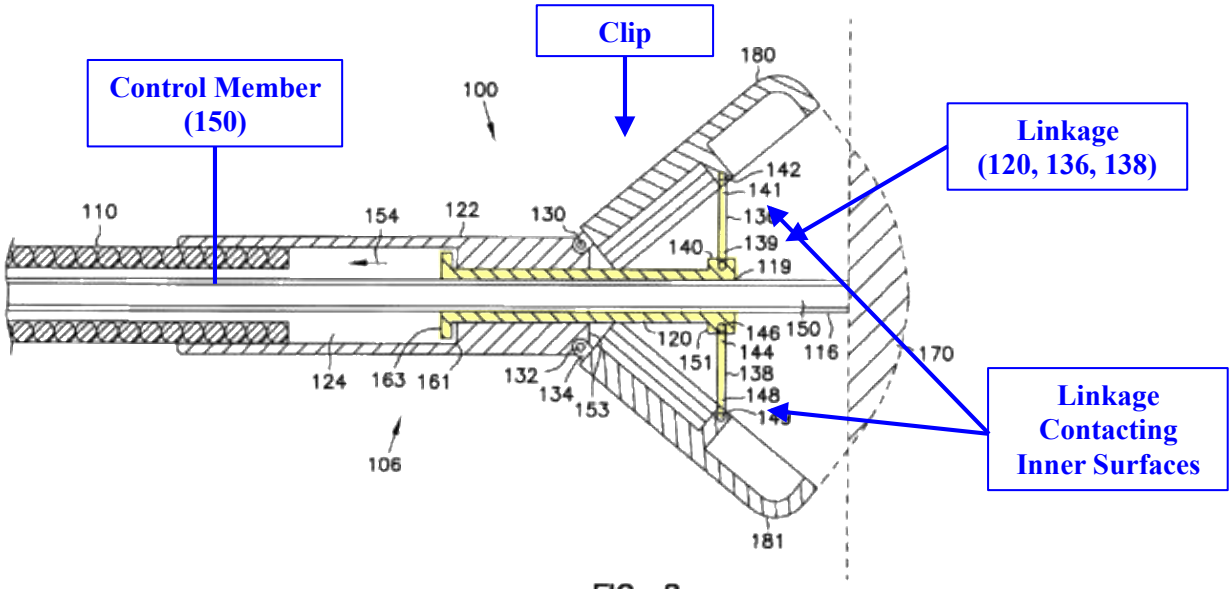


FIG. 8

"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. at 8:63-9:2) (Ex. 1011, ¶ 34).

2. Claim 2

Claim 2 depends from claim 1 and further states that "the linkage is received through an opening formed in a proximal end of the clip." As shown below in annotated Figures 2 and 8, Nishioka discloses that the linkage (40, 41 (Figure 2), 120 (Figure 8)) is received through an opening formed in a proximal end of the clip (opening indicated in red):

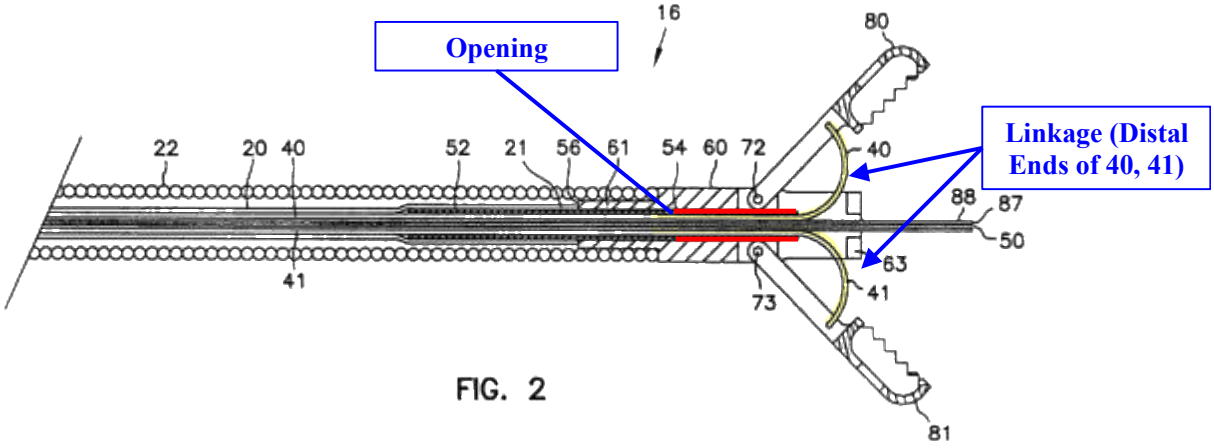


FIG. 2

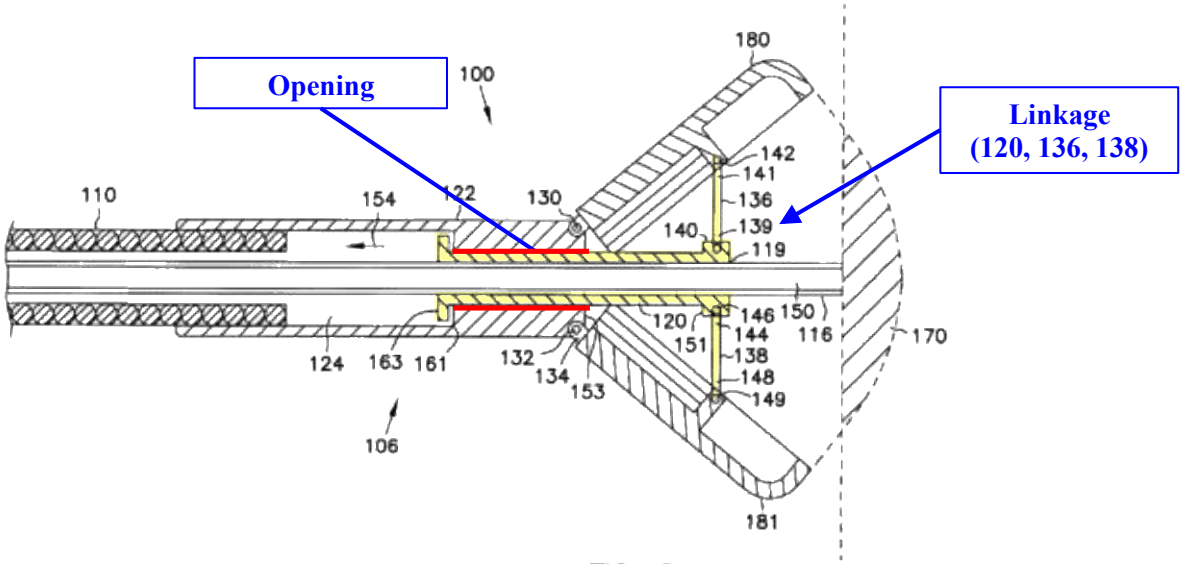


FIG. 8

(Ex. 1011, ¶ 35).

3. Claim 3

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

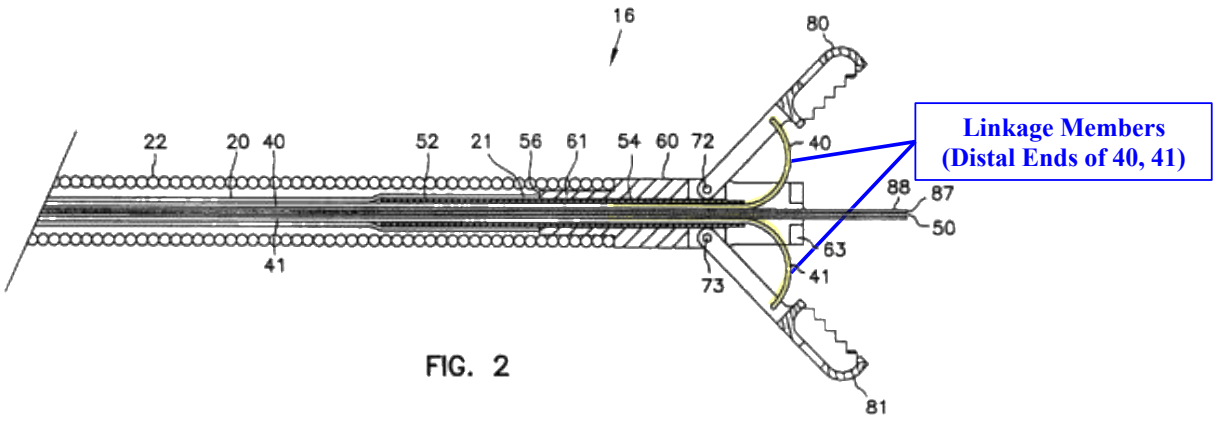


FIG. 2

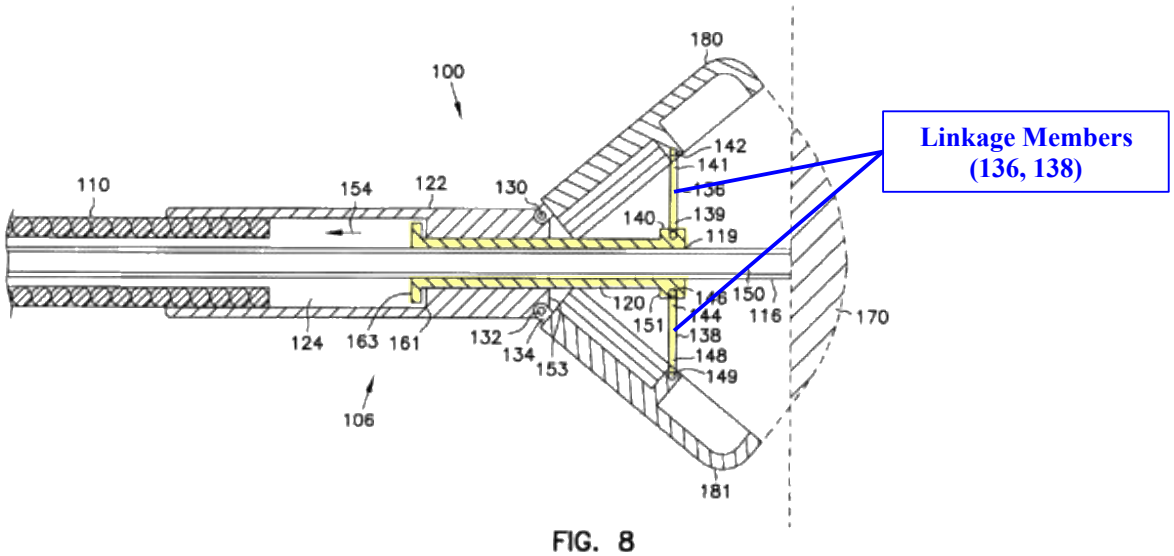


FIG. 8

In both embodiments, the proximal ends of the linkage members are connected to one another. (Ex. 1011, ¶ 36). In the embodiment of Figure 2, the proximal ends of the linkage members (40, 41) are "secured to slider 30" (shown in Figure 1 (reproduced and annotated below), which "form[s] an actuator mechanism for the forceps 10." (Ex. 1005, 4:11-13, Figure 1; Ex. 1011, ¶ 36).

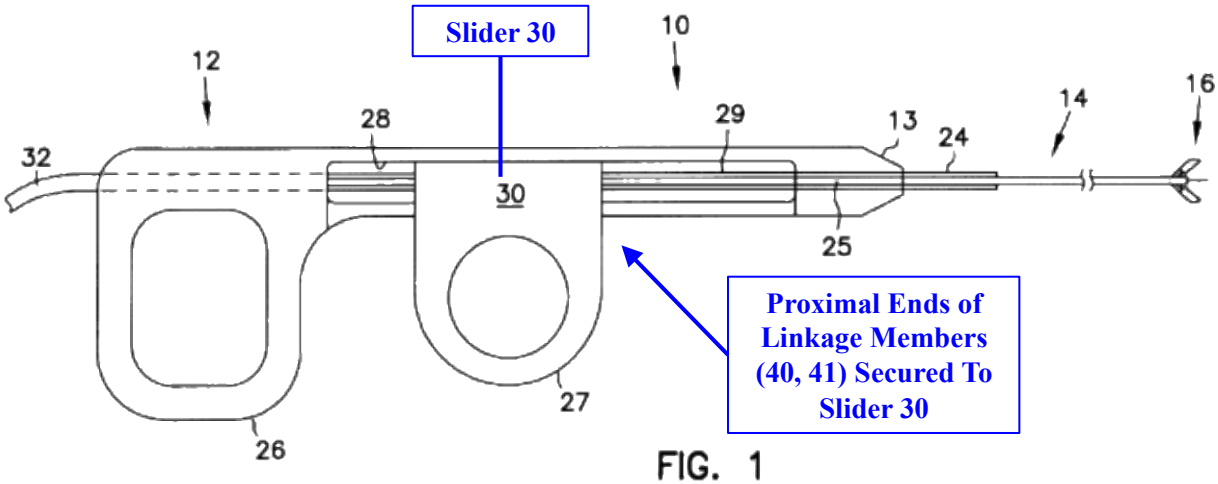


FIG. 1

In Figure 8, the proximal ends of the linkage members (136, 138) are connected to one another via slide member 120. (Ex. 1011, ¶ 37; Ex. 1005, 8:16-21 ("Control link 136 has one end 139 connected to tubular slide member 120 by a pin 140. . . . [and its other end] connected to jaw 180 by a pin 142. Similarly, control link 138 has one end 144 connected to tubular slide member 120 by a pin 146 and its other end 148 connected to jaw 181 by a pin 149.")).

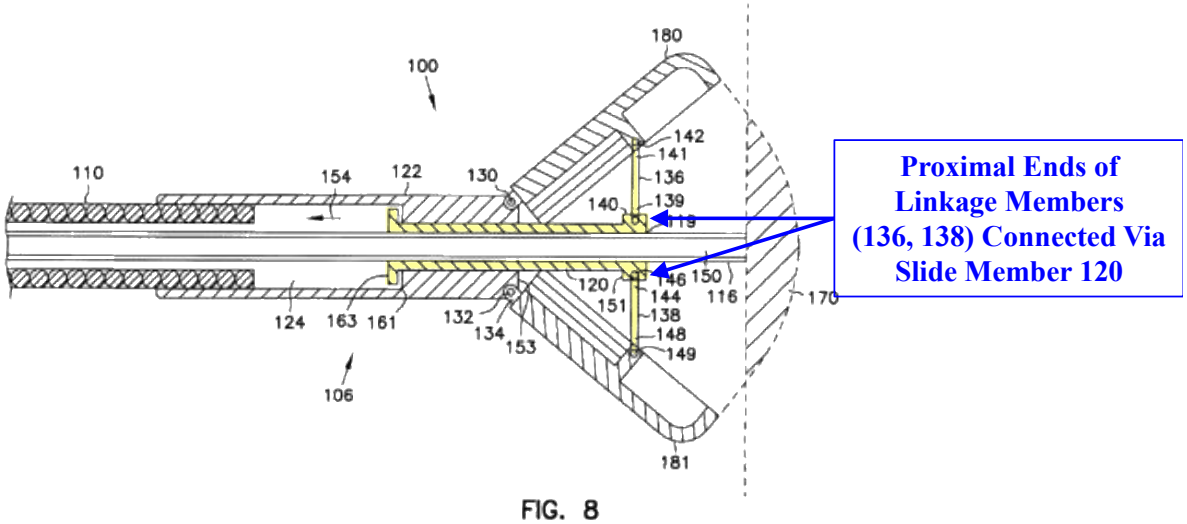


FIG. 8

4. Claims 7 and 8

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

As shown below in annotated Figure 6A, the distal ends of the clip legs in the Figure 2 and Figure 8 embodiments include the curved projections angled radially inward with respect to a longitudinal axis:

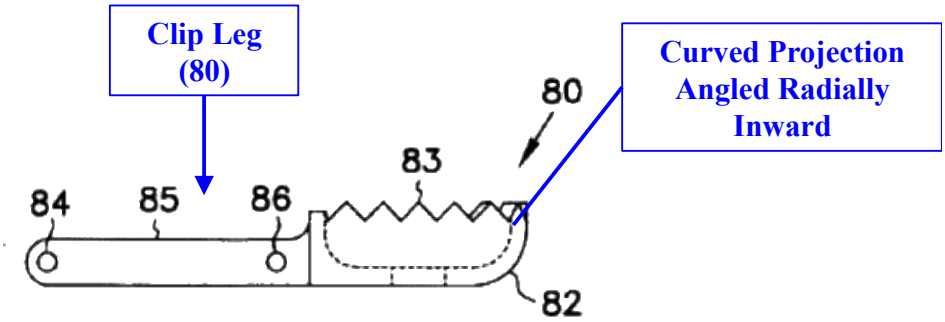


FIG. 6A

(Ex. 1011, ¶ 39; 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. Claims 9-12

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

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

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

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

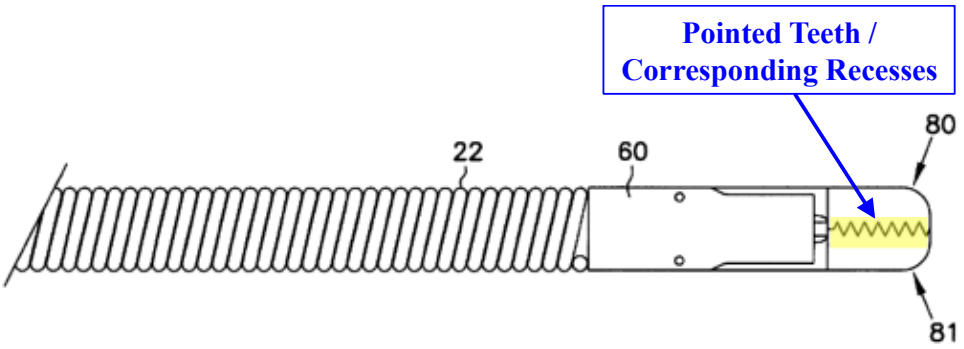
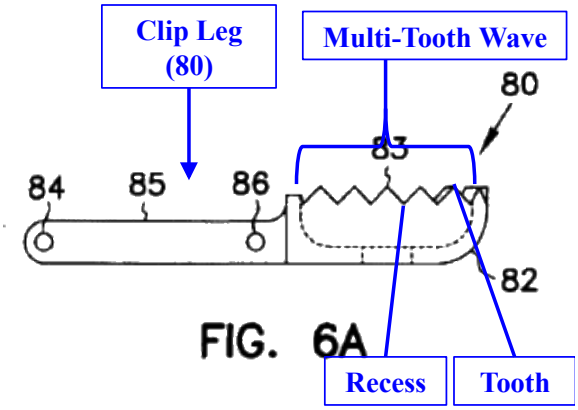


FIG. 3



(Ex. 1011, ¶ 42; Ex. 1005, 5:1-3 ("Because jaws 80 and 81 are similar only one is described in detail here. The two jaws are mirror-image identical, but with their serrations staggered so that they will mesh."), 5:3-7, 6:60-64 (explaining that the jaws in the Figure 8 embodiment (181, 181) can be similar to the jaws in the Figure 2 embodiment (80, 81)).

B. Ground 2: There Is A Reasonable Likelihood That Claims 13-14 and 16-19 Are Obvious In View Of Nishioka (Ex. 1005), in combination with Shinozuka (Ex. 1009)

Shinozuka[6] was 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 '027 patent.

1. Independent Claim 13

a. "A medical device, comprising"

Nishioka discloses "a medical device," for the reasons in Section V.A.1.a, *supra* at p. 18.

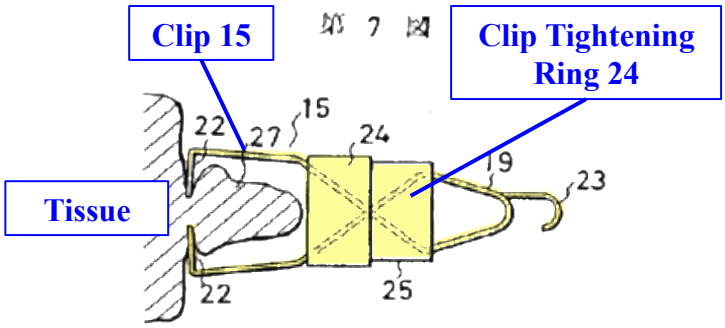
b. "a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface"

Nishioka discloses "a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface," for the reasons in Section V.A.1.b, *supra* at pp. 18-19.

[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.

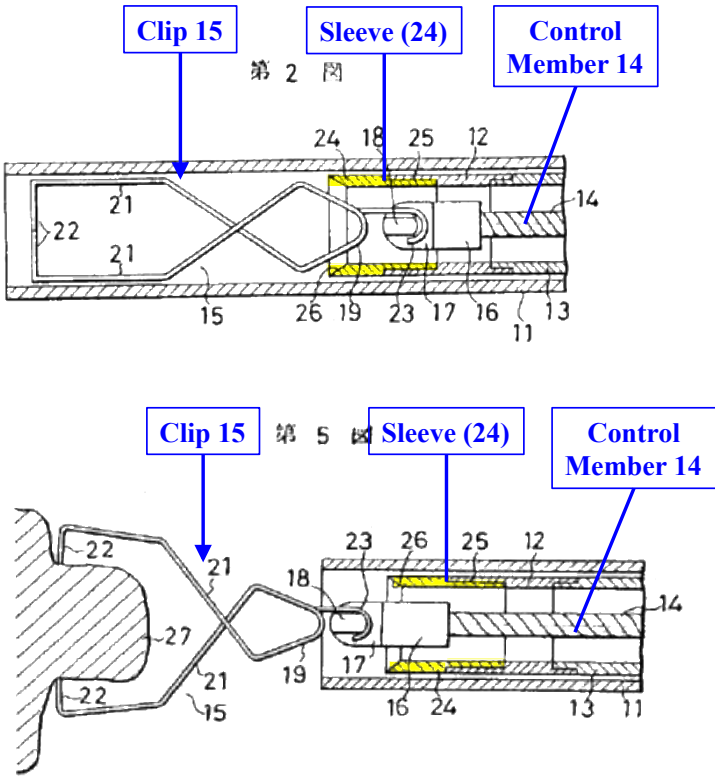
c. "a sleeve housing a portion of the clip therein, the clip being axially movable relative to the sleeve by a control member extending from a proximal actuator to the clip"

Nishioka discloses a "control member extending from a proximal actuator to the clip," for the reasons in Section V.A.1.c, *supra* at pp. 20-21. Nishioka does not disclose the claimed sleeve. (Ex. 1011, ¶ 45). However, as shown below in Figure 7, Shinozuka discloses a clip tightening ring 24 ("sleeve") housing a portion of the clip (15) therein:



(Ex. 1011, ¶ 45).

As shown below in annotated Figures 2 and 5, Shinozuka discloses that the clip (15) is axially movable relative to the sleeve (tightening ring 24) by a control member (control wire 14) extending from a proximal actuator (not shown) to the clip (15):



(Ex. 1011, ¶ 46).

It would have been obvious to combine the sleeve from Shinozuka with the clip devices in Nishioka, to, for example, solve perceived problems with clip devices that "cut[] off . . . diseased tissue inside the body cavity," including the potential for "large amounts of blood being produced at the treated site" and the cut "being difficult to treat." (Ex. 1011, ¶ 47; Ex. 1009, English translation p. 261). Shinozuka explains that to solve this problem a clip and a sleeve housing the clip can remain in the body, where the sleeve prevents the clip from reopening in the body. (Ex. 1011, ¶ 47; Ex. 1009 at pp. 261-262). In particular, Shinozuka discloses "detachably coupling" a clip and a sleeve to the control member, so that

the clip and a sleeve can be left behind in the body. (Ex. 1011, ¶ 47; Ex. 1009, English translation p. 262). Figure 7 of Shinozuka (reproduced and annotated above) depicts the clip (15) and sleeve (24) left behind in the body after the clip and control member (14) have become unlinked, where the sleeve is used to prevent the clip from reopening in the body. (Ex. 1011, ¶ 47; Ex. 1009, English translation pp. 261-263).

It would have been obvious to a person of ordinary skill in the art to modify the devices described in Nishioka to include a sleeve (clip tightening ring 24) housing the clip to allow the physician to leave the Nishioka clip behind in the body. (Ex. 1011, ¶ 48). The skilled artisan would have been motivated to make this modification based on the perceived problems identified in Shinozuka, including unwanted blood loss and difficult treatment options associated with using clips to cut tissue inside the body. (Ex. 1011, ¶ 48). Shinozuka discloses solving these perceived problems by detaching the clip from the control member within a clip tightening ring, so that the clip can stay closed when it is left behind in the body. (Ex. 1011, ¶ 48). The person of ordinary skill in the art would have been motivated to modify Nishioka in order to obtain the same benefits for the Nishioka clip that are described by Shinozuka. (Ex. 1011, ¶ 48).

Nishioka and Shinozuka describe simple mechanical structures, such that modifying Nishioka to include a sleeve (24) would have been a matter of routine

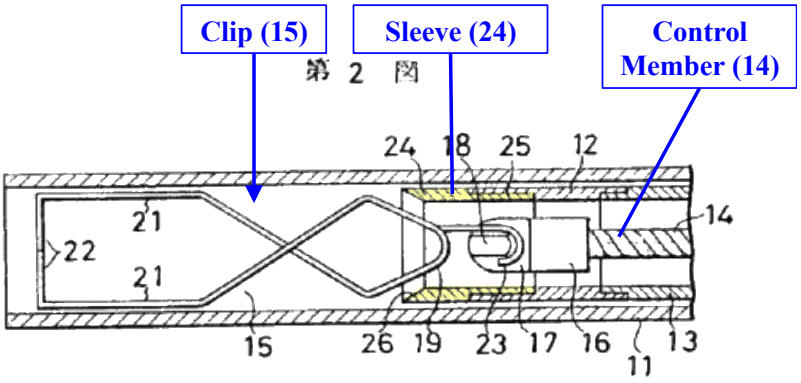
skill in the art. (Ex. 1011, ¶ 49). The modification uses known elements such as those disclosed in Nishioka and Shinozuka to achieve predictable results. (Ex. 1011, ¶ 49). *See Tokai Corp. v. Easton Enters.*, 632 F.3d 1358, 1371 (Fed. Cir. 2011); *KSR*, 550 U.S. at 417.

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

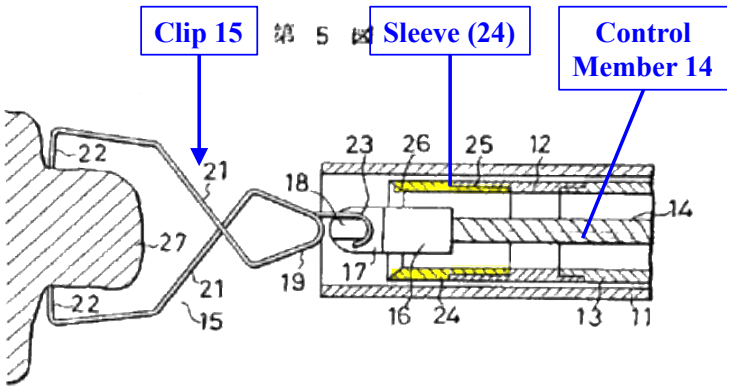
Nishioka discloses "a linkage operably associated with the control member" to "cause the first and second clip legs to spread apart from one another into a tissue-receiving configuration as the clip is moved distally," and "contacting the inner surfaces of the first and second clip legs to drive the first and second clip legs radially outward as the control member is moved distally relative to the clip," for the reasons explained above in Section V.A.1.d, *supra* at pp. 21-24.

Nishioka does not disclose that the linkage is operably associated with the control member "to move the clip distally out of the sleeve" and spreads apart the clip legs "as the clip is moved distally relative to the sleeve." (Ex. 1011, ¶ 51). As shown below in annotated Figure 2, Shinozuka discloses that in the "closed state,"

the proximal end of the clip (15) is disposed within the distal end of the sleeve (24):



(Ex. 1011, ¶ 51; Ex. 1009, English translation p. 263). The control member (14) is then "pushed forward [(*i.e.*, moved distally)] and . . . the clip 15 is projected out to the outside" and opened, as shown below in annotated Figure 5:



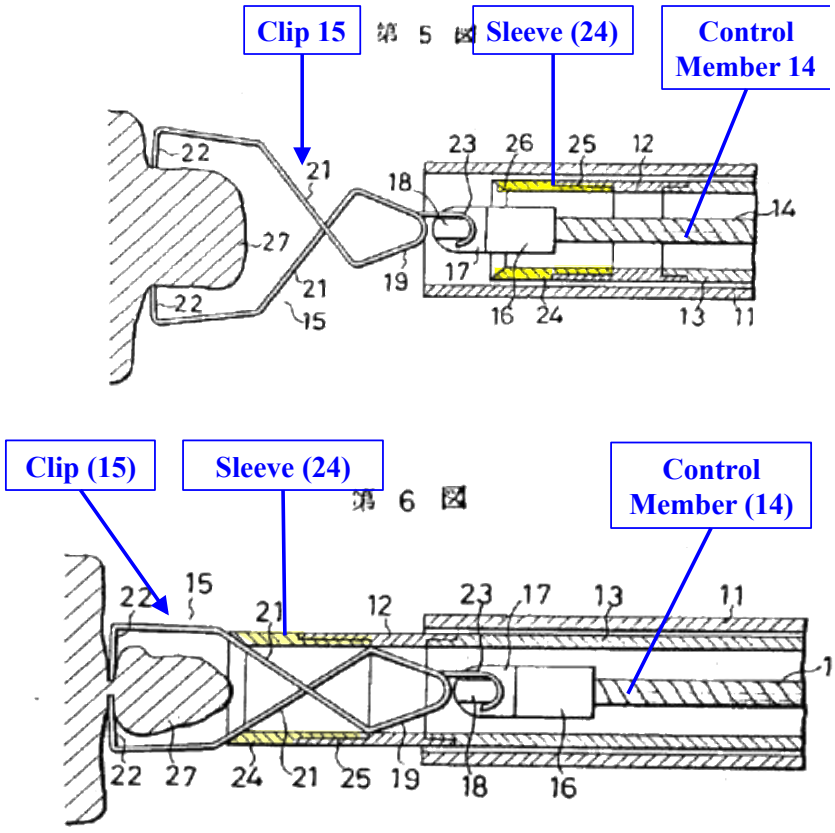
(Ex. 1011, ¶ 51; Ex. 1009, English translation p. 263). As the control member (14) is moved distally, clip (15) moves distally from a position within sleeve (24), as shown in Figure 2, to position outside sleeve (24) with the clip legs spread apart, as shown in Figure 5. (Ex. 1011, ¶ 51).

The combination of Nishioka and Shinozuka discloses all of the limitations of claim 13. (Ex. 1011, ¶ 52). The combination would have been obvious to a person of ordinary skill in the art, for the reasons in Sections V.B.1.c, *supra* at pp. 34-36.

2. Claim 14

Claim 14 depends from claim 13 and further requires "movement of the control member proximally causes a corresponding proximal movement of the clip into the sleeve, moving the clip from the tissue-receiving configuration to a closed configuration in which the first and second clip legs are moved radially inward toward one another." The combination of Nishioka and Shinozuka described above with respect to claim 13 satisfies this limitation. (Ex. 1011, ¶ 53).

In particular, as shown below in annotated Figures 5 and 6, Shinozuka discloses that movement of the control member (14) proximally (from position in Figure 5 to position in Figure 6) causes a corresponding proximal movement of the clip (15) into the sleeve (24), moving from the tissue-receiving configuration (Figure 5) to a closed configuration in which the clip legs are moved radially inward (Figure 6):



(Ex. 1011, ¶ 54; Ex. 1009, English translation p. 263 ("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.")).

3. Claim 16

Claim 16 depends from claim 13 and further states that "the linkage is received through an opening formed in a proximal end of the clip." Nishioka discloses this limitation for the reasons in Section V.A.2, *supra* at pp. 25-26. (Ex. 1011, ¶ 55).

4. Claim 17

Claim 17 depends from claim 13 and further requires "the linkage comprises first and second linkage members, proximal ends of the first and second linkage members being connected to one another." Nishioka discloses this limitation for the reasons in Section V.A.3, *supra* at pp. 26-28. (Ex. 1011, ¶ 56).

5. Claim 18

Claim 18 depends from claim 13 and further requires "distal ends of the first and second clip legs include curved projections which are angled radially inward with respect to a longitudinal axis of the clip." Nishioka discloses this limitation for the reasons in Section V.A.4, *supra* at p. 29. (Ex. 1011, ¶ 57).

6. Claim 19

Claim 19 depends from claim 13 and further requires "a distal end of the first clip leg includes a plurality of pointed protrusions interlocking with a plurality of corresponding recesses formed in a distal end of the second clip leg." Nishioka discloses this limitation for the reasons in Section V.A.5, *supra* at pp. 29-31. (Ex. 1011, ¶ 58).

C. Ground 3: There Is A Reasonable Likelihood That Claims 4-6 and 13-20 Are Obvious In View Of Nishioka (Ex. 1005), in combination with Matsuno (Ex. 1016)

Matsuno issued on June 16, 1998 and qualifies as prior art at least under 35 U.S.C. §§ 102(a), (b), and (c). Matsuno is listed as a cited reference on the cover of the '027 patent, but was never substantively addressed during prosecution.

1. Claim 4

Claim 4 depends from claim 1 and further requires "a frangible link coupling the clip to the control member." Nishioka discloses all of the limitations of claim 1, for the reasons in Section V.A.1, *supra* at pp. 18-24.

Nishioka does not expressly describe a link between the clip and control member that becomes unlinked when a tensile load is applied. (Ex. 1011, ¶ 60). However, the concept of providing a frangible link coupling the clip to the control member was known in the art decades before the '027 patent was filed. (Ex. 1011, ¶ 60). For example, Matsuno discloses a link between the clip and control member that becomes unlinked when a tensile load is applied. (Ex. 1011, ¶ 60).

In particular, Matsuno discloses "[t]he clip 2 disengages from the coupling plate 3, becomes detached from the clip operating device 6 and is left inside the body cavity, holding the tissue." (Ex. 1016, 5:62-65). Figures 1A and 5 of Matsuno (reproduced and annotated below) disclose a clip (clip 2) detachably

coupled to a control member (operating wire 13) by a frangible link (hook portion 3A and recess 2e (highlighted in yellow)):

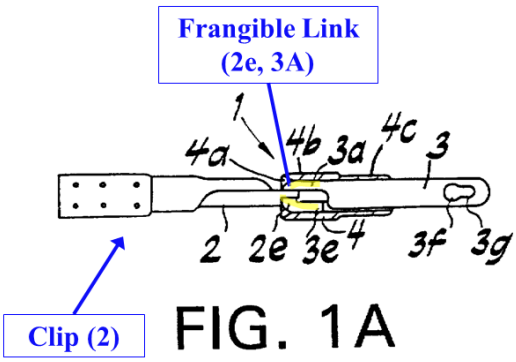


FIG. 1A

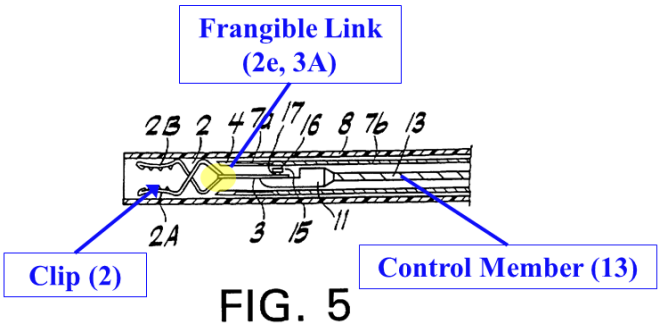
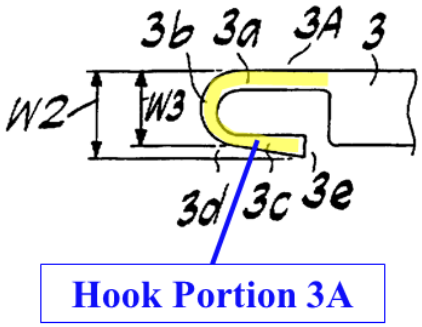


FIG. 5

(Ex. 1011, ¶ 61; Ex. 1022, 3:31-32 ("The hook portion 3A is hooked on the recess 2e of the clip 2 to removably engage with the clip 2."); *see also* 4:2-7).

The link (3A and 2e) becomes unlinked when a tensile load is applied that deforms and straightens hook portion 3A such that it disengages clip (2). An undeformed hook portion 3A and straightened hook portion 3A are shown in annotated Figures 2A and 2B, respectively. (Ex. 1011, ¶ 62).

FIG. 2A



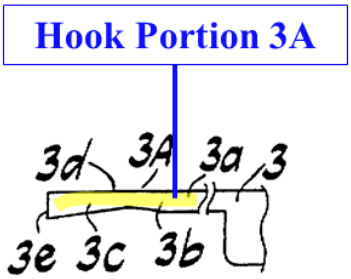


FIG. 2B

(Ex. 1022, 5: 58-65 ("When the arm portions 2A and 2B of the clip 2 reliably grasp the living tissue and the slider 12 is further pulled toward the proximal end side to retract the operating wire 13, the hook portion 3A of the coupling plate 3 of the clip 2 is deformed and stretched as shown in FIGS. 7 and 8. The clip 2 disengages from the coupling plate 3, becomes detached from the clip operating device 6 and is left inside the body cavity, holding the tissue.").

Figure 1D of Matsuno (reproduced and annotated below) depicts the clip left behind in the body after the clip 2 and control member 13 have become unlinked:

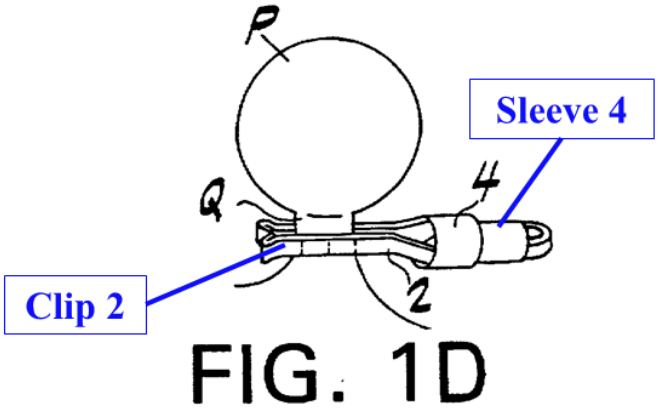


FIG. 1D

(Ex. 1011, ¶ 63). As shown above, the clip 2 is left behind in the body housed within a sleeve (holding tube 4), which is used to close the clip and prevent it from reopening in the body. (Ex. 1011, ¶ 63; Ex. 1016, 5:47-57 (explaining that "arm portions 2A and 2B of the clip 2 are pulled into the holding tube 4 . . . and are closed" around polyp P.). Thus, Matsuno provides a link between the clip and

control member that becomes unlinked when a tensile load is applied. (Ex. 1011, ¶ 63).

It would have been obvious to a person of ordinary skill in the art to modify the devices described in Nishioka to include a link between the clip and control member that becomes unlinked when a tensile load is applied, and a housing tube 4 housing the clip, to allow the physician to leave the Nishioka clip behind in the body. (Ex. 1011, ¶ 64). The skilled artisan would have been motivated to make this modification based on the known problems with devices that cut off tissue in the body, including unwanted blood loss and difficult treatment options associated with using clips to cut tissue inside the body. (Ex. 1011, ¶ 64). Additionally, the skilled artisan would have been motivated to make this modification to allow an operator of the clip to know precisely when the clip becomes unlinked from the control member. (Ex. 1011, ¶ 64). Using a tensile load to unlink the clip from the control member, such as by straightening a portion of the link, would allow the operator to know precisely what action needs to be taken and what force needs to be applied in order to release the clip from the control member. (Ex. 1011, ¶ 64; Ex. 1016, 4:31-34 ("The amount of the resilient force caused by the deformation of the hook portion 3A can be selected properly in accordance with the purpose, by selecting the material of the coupling plate 3 and the size and shape of the boundary portion 3d."). Matsuno discloses solving these problems by detaching

the clip from the control member within a holding tube, so that the clip can stay behind in the body. (Ex. 1011, ¶ 64). The person of ordinary skill in the art would have been motivated to modify Nishioka in order to obtain the same benefits for the Nishioka clip that are disclosed in Matsuno. (Ex. 1011, ¶ 64).

Nishioka and Matsuno describe simple mechanical structures, such that modifying Nishioka to include a link between the clip and control member that becomes unlinked when a tensile load is applied and holding tube 4 would have been a matter of routine skill in the art. (Ex. 1011, ¶ 65). The modification uses known elements such as those disclosed in Nishioka and Matsuno to achieve predictable results. (Ex. 1011, ¶ 65). *See Tokai*, 632 F.3d at 1371; *KSR*, 550 U.S. at 417.

2. Claim 5

Claim 5 depends from claim 4 and further requires "the control member is reversibly operable to move the clip between the tissue-receiving configuration and a closed configuration."

Nishioka discloses that the control member (control wires 40, 41, fiber 150) is reversibly operable to move the clip between the tissue-receiving configuration and a closed configuration. (Ex. 1011, ¶ 67; Ex. 1005, 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."), 7:26-

31 ("The slider 30 of the handle is adapted to push the reinforced optical fiber 150, which in turn pushes the tubular slide member 120, to open the jaws of the optical biopsy forceps and to pull the reinforced optical fiber, pulling the tubular slide member 120, to close the jaws.").

3. Claim 6

Claim 6 depends from claim 5 and further requires "an outer sleeve housing a proximal portion of the clip therewithin, wherein an engagement of outer walls of the first and second clip legs with inner walls of the sleeve prevents movement of the clip to the tissue-receiving configuration." It would have been obvious to modify the devices described in Nishioka to include a "holding tube 4" as disclosed in Matsuno, for the reasons in Section V.C.1, *supra* at pp. 41-45. (Ex. 1011, ¶ 68).

As shown below in annotated Figure 1C, the holding tube 4 in Matsuno is an outer sleeve housing a proximal portion of the clip (2) therewithin, wherein an engagement of outer walls of the clip legs with inner walls of the sleeve (4) prevents movement of the clip (2) to the tissue-receiving configuration:

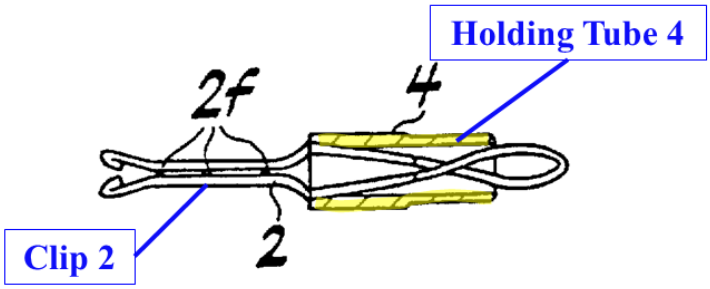


FIG. 1C

((Ex. 1011, ¶ 69; Ex. 1016, 3:9-11 ("The width WI of the oval portion of the proximal end portion 2d is larger than the inside diameter of the holding tube 4."), 5:39-45 ("When the slider 12 is pulled toward the proximal end side to retreat the operating wire 13 toward the proximal end side, the oval-shaped portion of the proximal end portion 2d of the clip 2 is squeezed, because the width W1 of the oval-shaped portion of the proximal end portion 2d of the clip 2 is larger than the inside diameter of the holding tube 4."), 5:47-52 ("By further pulling the slider 12 toward the proximal end side, the operating wire 13 is retracted, and the arm portions 2A and 2B of the clip 2 are pulled in the holding tube 4. With this operation, the arm portions 2A and 2B are closed as shown in FIG. 1(C).")).

4. Independent Claim 13

a. "A medical device, comprising"

Nishioka discloses "a medical device," for the reasons in Section V.A.1.a, *supra* at p. 18.

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

Nishioka discloses "a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface," for the reasons in Section V.A.1.b, *supra* at pp. 18-19.

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

Nishioka discloses a "control member extending from a proximal actuator to the clip," for the reasons in Section V.A.1.c, *supra* at pp. 20-21. Nishioka does not disclose the claimed sleeve. (Ex. 1011, ¶ 72). However, Matsuno discloses a sleeve housing a portion of the clip therein, and it would have been obvious to combine the sleeve with the clip devices in Nishioka, for the reasons in Sections V.C.1, *supra* at pp. 41-45. (Ex. 1011, ¶ 72).

As shown below in annotated Figures 1C and 5, Matsuno discloses the clip (2) is axially movable relative to the sleeve (holding tube 4) by a control member

(operating wire 13) extending from a proximal actuator (not shown) to the clip (2). (Ex. 1011, ¶ 73).

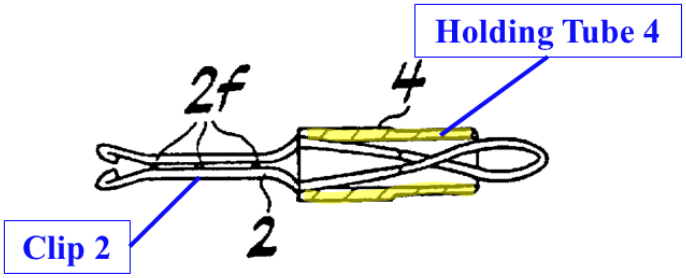


FIG. 1C

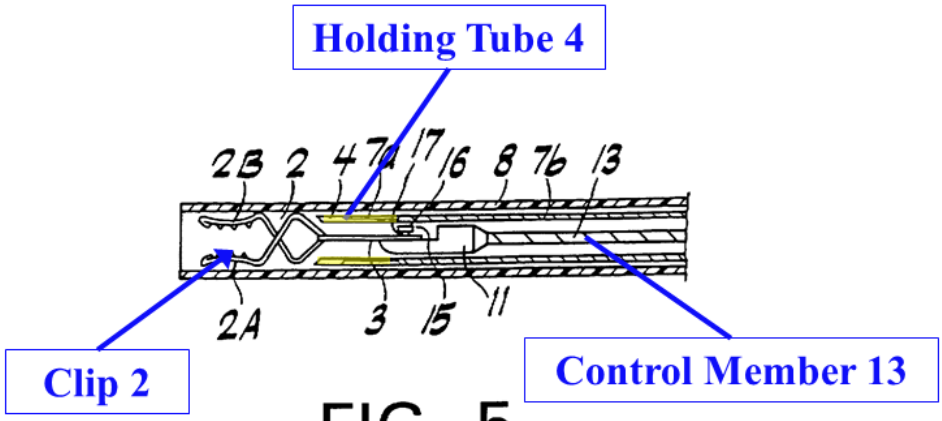


FIG. 5

(Ex. 1016, 5:47-51 ("By further pulling the slider 12 toward the proximal end side, the operating wire 13 is retracted, and the arm portions 2A and 2B of the clip 2 are pulled in the holding tube 4.").

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

Nishioka discloses "a linkage operably associated with the control member" to "cause the first and second clip legs to spread apart from one another into a tissue-receiving configuration as the clip is moved distally," and "contacting the inner surfaces of the first and second clip legs to drive the first and second clip legs radially outward as the control member is moved distally relative to the clip," for the reasons explained above in Section V.A.1.d, *supra* at pp. 21-24. (Ex. 1011, ¶ 74).

Because Nishioka does not disclose the claimed sleeve, Nishioka does not disclose that the linkage is operably associated with the control member "to move the clip distally out of the sleeve" and spreads apart the clip legs "as the clip is moved distally relative to the sleeve." (Ex. 1011, ¶ 75). However, as shown below in annotated Figure 1C, Matsuno discloses a sleeve, and further discloses that the clip legs are closed as the clip is pulled proximally into the sleeve. (Ex. 1011, ¶ 75).

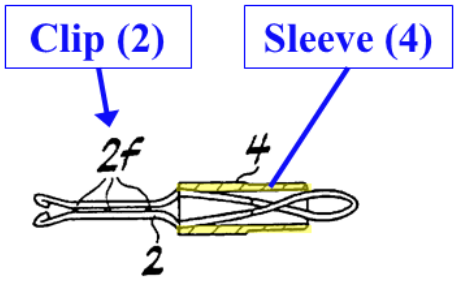


FIG. 1C

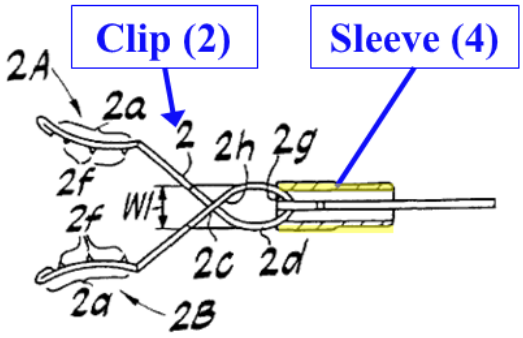


FIG. 1B

(Ex. 1016, 5:39-52). One of ordinary skill in the art would know that control member (13) can be used to push clip (2) distally out of sleeve (4), which would cause the clip legs to spread apart as clip (2) moves distally relative to sleeve (4), as shown in annotated Figure 1B above. (Ex. 1011, ¶ 75; *see* Ex. 1016, 5:46-52).

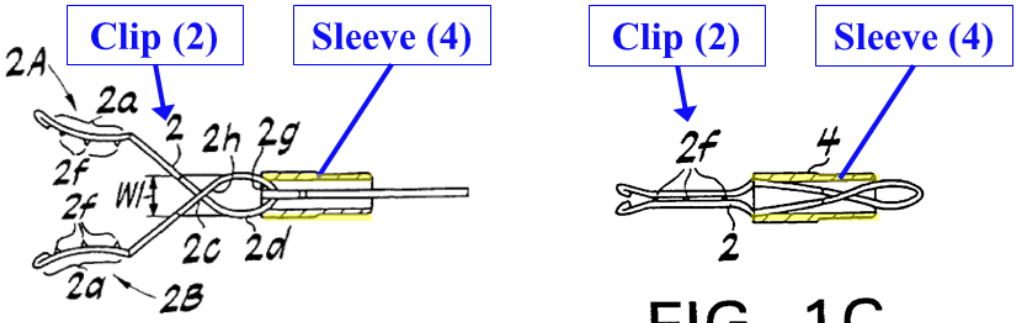
The combination of Nishioka and Matsuno discloses all of the limitations of claim 13. (Ex. 1011, ¶ 76). The combination would have been obvious to a person of ordinary skill in the art, for the reasons in Sections V.C.1, *supra* at pp. 41-45. (Ex. 1011, ¶ 76).

5. Claim 14

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

toward one another." The combination of Nishioka and Matsuno described above with respect to claim 13 satisfies this limitation. (Ex. 1011, ¶ 77).

In particular, as shown below in annotated Figures 1B and 1C, Matsuno discloses that movement of the control member (13) (not shown) proximally causes a corresponding proximal movement of the clip (2) into the sleeve (4), moving from the tissue-receiving configuration (Figure 1B) to a closed configuration in which the clip legs are moved radially inward (Figure 1C):



(Ex. 1011, ¶ 78; Ex. 1016, 5:47-52 ("By further pulling the slider 12 toward the proximal end side, the operating wire 13 is retracted, and the arm portions 2A and 2B of the clip 2 are pulled in the holding tube 4. With this operation, the arm portions 2A and 2B are closed as shown in FIG. 1(C)."); *see also* 5:39-45).

6. Claim 15

Claim 15 depends from claim 13 and further requires "a link positioned proximally of the clip, wherein application of a proximal tensile force to the link via the control member causes the clip to separate from the control member." This claim would have been obvious in view of Nishioka in combination with Matsuno, for the reasons in Section V.C.1, *supra* at pp. 41-45. (Ex. 1011, ¶ 79).

7. Claim 16

Claim 16 depends from claim 13 and further states that "the linkage is received through an opening formed in a proximal end of the clip." Nishioka discloses this limitation for the reasons in Section V.A.2, *supra* at pp. 25-26. (Ex. 1011, ¶ 80).

8. Claim 17

Claim 17 depends from claim 13 and further requires "the linkage comprises first and second linkage members, proximal ends of the first and second linkage members being connected to one another." Nishioka discloses this limitation for the reasons in Section V.A.3, *supra* at pp. 26-28. (Ex. 1011, ¶ 81).

9. Claim 18

Claim 18 depends from claim 13 and further requires "distal ends of the first and second clip legs include curved projections which are angled radially inward with respect to a longitudinal axis of the clip." Nishioka discloses this limitation for the reasons in Section V.A.4, *supra* at p. 29. (Ex. 1011, ¶ 82).

10. Claim 19

Claim 19 depends from claim 13 and further requires "a distal end of the first clip leg includes a plurality of pointed protrusions interlocking with a plurality of corresponding recesses formed in a distal end of the second clip leg." Nishioka discloses this limitation for the reasons in Section V.A.5, *supra* at pp. 29-31. (Ex. 1011, ¶ 83).

11. Independent Claim 20

a. "A method, comprising"

Nishioka discloses a method. (Ex. 1005, Title ("Optical Biopsy Forceps and Method of Diagnosing Tissue")). (Ex. 1011, ¶ 84).

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

Nishioka discloses inserting into a body a medical device. (Ex. 1011, ¶ 85; Ex. 1005, 2:6-11 ("The method comprises introducing into the body an integrated optical biopsy forceps . . . ."). The medical device described in Nishioka comprises a clip having first and second clip legs, each having an inner surface, a control member extending from a proximal actuator to the clip, and a linkage coupled to the control member, for the reasons in Section V.A.1, *supra* at pp. 18-24. (Ex. 1011, ¶ 85).

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

Nishioka discloses positioning the medical device at a desired deployment location. (Ex. 1011, ¶ 86; Ex. 1005, 8:59-62 ("The endoscopist advances the optical biopsy forceps through the biopsy channel of the endoscope to the general area of interest, i.e., such as a tissue site or tissue analysis zone with a body . . . .").

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

Nishioka discloses moving the control member distally to cause the linkage to contact the first and second inner surfaces of the first and second clip legs, respectively, to drive the first and second clip legs radially outward to a tissue-receiving configuration, for the reasons in Section V.A.1, *supra* at pp. 20-24. (Ex. 1011, ¶ 87).

Matsuno discloses moving the control member (13) distally to cause the clip (2) to move distally relative to a sleeve (4) housing at least a portion of the clip (2) therein to move the first and second clip legs radially outward to a tissue-receiving configuration, for the reasons in Section V.C.4.d, *supra* at pp. 50-51. (Ex. 1011, ¶ 88).

It would have been obvious to modify the devices described in Nishioka to include a sleeve as described in Matsuno, such that moving the control member of the modified device distally would cause the clip to move distally relative to the sleeve, for the reasons in Sections V.C.1, *supra* at pp. 41-45. (Ex. 1011, ¶ 89).

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

Nishioka discloses adjusting a position of the clip so that target tissue is received between the clip legs. (Ex. 1011, ¶ 90; Ex. 1005, 8:59-9:2).

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

Nishioka discloses drawing the control member proximally to receive target tissue between the first and second clip legs, for the reasons in Sections V.A.1.d and V.C.2, *supra* at pp. 21-24, 45-46. (Ex. 1011, ¶ 91).

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

Matsuno discloses applying a proximal tensile force of at least a threshold level to the control member to separate a link coupling the control member to the clip, for the reasons in Section V.C.1, *supra* at pp. 41-45, where the threshold level is the amount of force required to straighten Matsuno's hook portion 3A. (Ex. 1011, ¶ 92).

VI. CONCLUSION

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

Dated: October 27, 2016

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned certifies that this brief complies with the type-volume limitations of 37 CFR § 42.24(a)(1)(i). This brief, excluding a table of contents, a table of authorities, and a certificate of service or word count, contains 8,290 words as calculated by the "Word Count" feature of Microsoft Word 2010, the word processing program used to create it.

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

Dated: October 27, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 8,709,027, as well as the accompanying Power of Attorney, and Exhibits 1001, 1002, 1004, 1005, 1006, 1009, 1010, 1011, 1016, and 1017 have been served in their entirety on October 27, 2016, by Federal Express (Overnight Delivery) on:

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Counsel of Record for Boston Scientific Scimed, Inc. at the U.S. Patent & Trademark Office with respect to U.S. Patent No. 8,685,048	*Counsel of Record for Boston Scientific Scimed, Inc. in Civil Action No. 15-980-LPS-CJB (D. Del.) with respect to the assertion of U.S. Patent No. 8,685,048.*

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