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Paper 7
Entered: May 3, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COOK GROUP INCORPORATED
and
COOK MEDICAL LLC,
Petitioner,

v.

BOSTON SCIENTIFIC SCIMED, INC.,
Patent Owner.

Case IPR2017-00133
Patent 8,709,027 B2

Before JAMES T. MOORE, JAMES A. TARTAL,
and ROBERT L. KINDER, *Administrative Patent Judges.*

MOORE, *Administrative Patent Judge*.

DECISION
Instituting *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Cook Group Incorporated and Cook Medical LLC ("Petitioner") filed a Petition (Paper 1, "Pet.") to institute an *inter partes* review of claims 1–20, of U.S. Patent No. 8,709,027 B2 (Ex. 1001, "the '027 patent"). Boston Scientific Scimed, Incorporated ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314. Based on the specific facts presented, we institute review under 35 U.S.C. § 325(d).

A. Related Matter

The '027 patent is the subject of *Boston Scientific Corp. v. Cook Group Inc.*, Civil Action No. 1:15-cv-00980-LPS-CJB (D. Del). Pet. 1; Paper 4, 2. Petitioner also has identified multiple additional petitions for *inter partes* review related to this proceeding, identified more fully below, including one petition also challenging claims 1–20 of the '027 patent (IPR2017-00134).

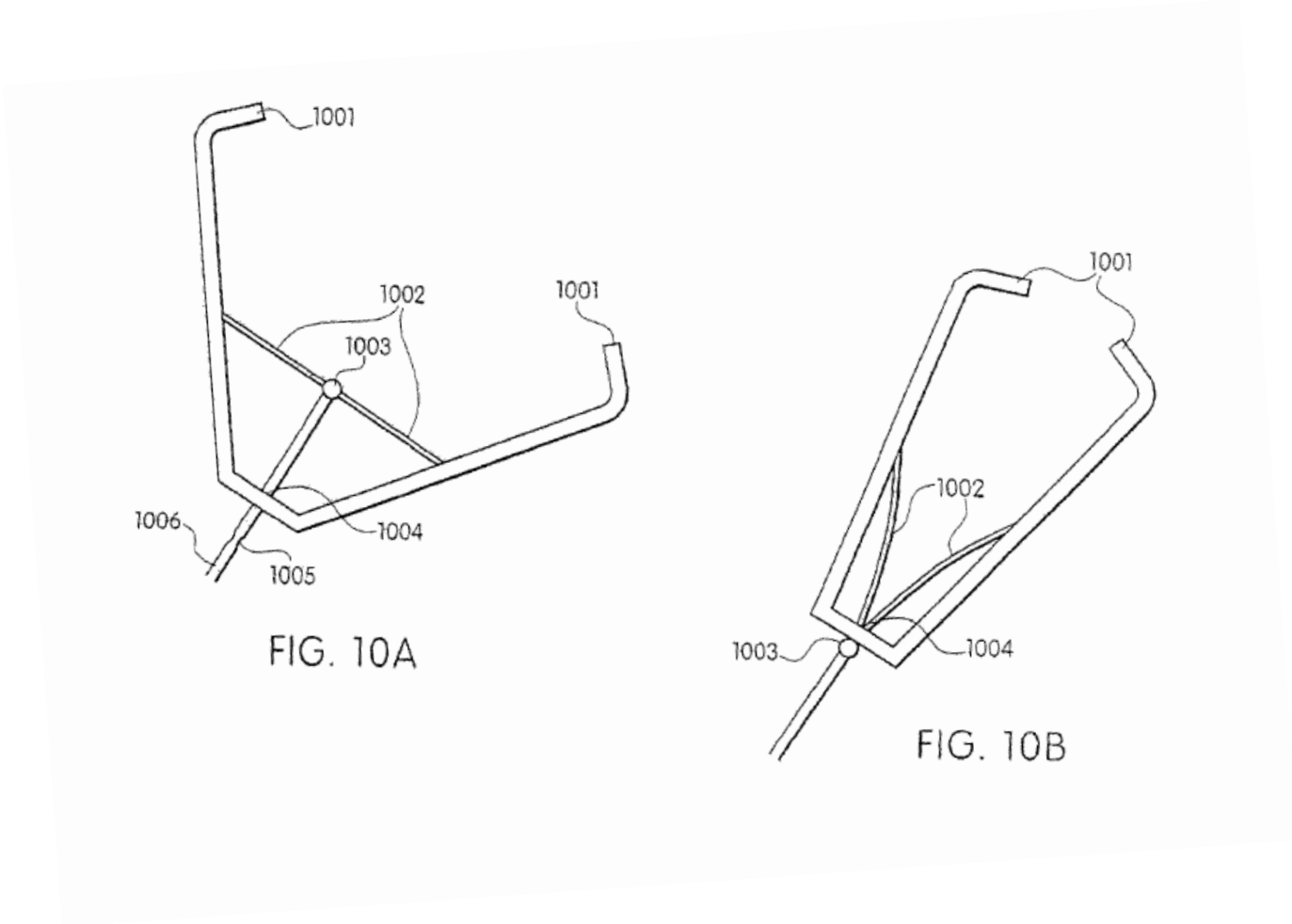
B. The '027 Patent

The '027 patent is titled "Device and Method for Through the Scope Endoscopic Hemostatic Clipping," and is directed towards devices and methods of causing hemostasis of a blood vessel through an endoscope. Ex. 1001, Abstract. A focus of the invention is to provide medical devices that cause hemostasis of blood vessels along the gastrointestinal tract. *Id*. at 2:51–53. The basic device and method include a compression clip used to cause hemostasis of blood vessels and a mechanism for deploying the clip. *Id*. at 2:59–62.

Various embodiments of the invention include a lock arrangement for locking the clip closed; a control wire connected to the clip and able to be

disconnected from the clip; an axially rigid sheath enclosing the control wire and communicating a compressive force opposing a tensile force of the control wire; a handle connected to the axially rigid sheath; and/or a trigger enclosed within the handle and engaging the control wire to close and lock the clip and to uncouple the control wire from the clip. *Id*. at 2:63–3:5.

Figures 10A and 10B from the ’027 patent are reproduced below.



Figures 10A and 10B depict cross–sectional views of a compressive clip in an opened and a closed position. *Id*. at 9:4–6.

C. Illustrative Claims

Petitioner challenges claims 1–20 of the '027 patent. Claims 1, 13, and 20 are independent, and the remaining claims depend therefrom. Claims 1 and 20 are illustrative of the claimed subject matter and recite the following (paragraphing and line structure maintained from printed patent):

> 1. 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 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.

Ex. 1001, 15:33–45.

> 20. A method, comprising:
> 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;
> positioning the medical device at a desired deployment location;
> 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;

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

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; and

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.

Ex. 1001, 16:52–17:6.

D. References Relied Upon

Petitioner relies upon the following prior art references:

U.S. Patent No. 5,766,189, filed on Feb. 26, 1997, and issued June 16, 1998. ("Matsuno") (Ex. 1016);

U.S. Patent No. 5,843,000, filed on May 7, 1996, and issued on Dec. 1, 1998. ("Nishioka") (Ex. 1005); and,

Japanese Unexamined Patent Application Publication No. 60-103946 ("Shinozuka") (Ex. 1009; certified translation at Ex. 1010). Pet. 11.

Petitioner also supports its Petition with the testimony of Mark A. Nicosia, Ph.D. (Ex. 1011, "Nicosia Decl."). Pet. 12.

E. The Asserted Grounds

Petitioner contends that the challenged claims are unpatentable based on the following specific grounds (Pet. 11):

Reference(s)	Basis	Claim(s) Challenged
Nishioka	§ 102	1–3 and 7–12
Nishioka and Shinozuka	§ 103	13–14 and 16–19
Nishioka and Matsuno	§ 103	4–6 and 13–20

II. ANALYSIS

A. Procedural Background

We are aware currently of two petitions filed against the ’027 patent and five additional petitions against related patents. This is the first of those to be decided with respect to institution. For sake of completeness of the record, we observe that those petitions have been designated as IPR2017-00131 (U.S. Patent 8,685,048); IPR2017-00132 (U.S. Patent 8,685,048); IPR2017-00134 (the ’027 patent); IPR2017-00135 (U.S. Patent 8,974,371); IPR2017-00435 (U.S. Patent 9,271,731); and IPR2017-00440 (U.S. Patent 9,271,731).

B. The Standards

Institution

The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a) (Post AIA) as follows:

> THRESHOLD -- The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Anticipation

The novelty standard is set forth in 35 U.S.C. § 102 (Pre-AIA) as follows:

> A person shall be entitled to a patent unless-
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more

> than one year prior to the date of the application for patent in the United States…

Obviousness

A patent claim is unpatentable if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. § 103(a) (Pre-AIA). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). In that regard, an obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

III. Person of Ordinary Skill in the Art

Petitioner proposes that a person of 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 of an engineer or similar professional with at least an undergraduate degree in engineering, or a physician having experience with designing medical devices. Pet. 11–12, citing Ex. 1011, ¶ 11. Patent Owner does not dispute Petitioner's proposal.

We also consider the level of skill implied by the disclosures of the prior art references. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed.

Cir. 2001) (the prior art itself can reflect the appropriate level of skill in the art). Additionally, this person is of ordinary creativity, not an automaton. *KSR*, 550 U.S. at 421. In view of the references, we find the Petitioner's level of skill in the art to be appropriate as it corresponds to the technical skill level of the art disclosures.

IV. Claim Construction

Petitioner identifies several terms for construction. Pet. 12–15. Patent Owner does not challenge those specific constructions but proposes a specific construction for a different term. Prelim. Resp. 8–11.

Claims in an *inter partes* review 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).

Linkage

Petitioner asserts that "linkage" is a structure that transmits force between interconnected components or links multiple parts of the clip. Pet. 13. Petitioner's proposed construction is based, in part, on Patent Owner's proposed assertion of the plain and ordinary meaning of the term in the related district court proceeding. Pet. 13. Patent Owner does not dispute this interpretation.

We find the term "linkage" to encompass the second portion of the definition urged by the Petitioner: A linkage links the clip's component parts. Ex. 1004, 00008:2–3.

Operably Associated With the Control Member

Petitioner asserts that the term "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" as this is what Patent Owner asserted is the plain and ordinary meaning in the related district court proceeding. Pet. 14 (citing Ex. 1004, 13–14). Patent Owner does not dispute this interpretation. We agree, and find this term means the components have a functional relationship. Ex. 1004-00009.

Frangible Link

Petitioner asserts that the term "frangible link" means a "link between at least two components that become unlinked when a tensile load is applied." Pet. 14. Again, this interpretation is proposed in part because Patent Owner asserted it in the related district court proceeding. Ex. 1004-00013. Patent Owner does not dispute this interpretation. We agree this is an appropriate interpretation, as frangible means breakable, as defined by the Patent Owner in its own claim construction brief. Ex. 1004-00013–14.

Clip

Patent Owner asserts that the term "clip" should be interpreted as a "device component having hemostatic compression legs." Prelim. Resp. 10–11. Patent Owner provides multiple medical dictionaries describing that clips can be used to arrest bleeding. Prelim. Resp. 9 (citing Exs. 2001, 2003, 2004, 2005, and 2006). We partially agree. Hemostatic is a statement of intended use and certainly clips can be used for that purpose.

However, no such express limitation is in the claim; for example, claim 1 recites "a clip," and the word "hemostatic" does not appear in the claim. Further, the '027 patent specification makes it clear that the clips of

the claimed invention have more uses than hemostasis, including pinching, marking, and tagging. Ex. 1001, 15:5–9. The clips can be used on any tissue "the operator wishes to apply a pinching pressure for whatever reason." *Id.* at 15:8–9.

"Clip," as the term is generally understood, and as used in the Specification, is therefore somewhat broader than as presently urged by Patent Owner. We consequently interpret "clip" herein as a device having compression legs and capable of applying a pinching pressure.

V. Claims 1–3 and 7–12 as anticipated by Nishioka

Petitioner contends claims 1–3 and 7–12 are unpatentable, under 35 U.S.C. § 102, as anticipated by Nishioka. Pet. 18–31.

1. Overview of Nishioka (Ex. 1005)

Nishioka is directed to a biopsy forceps. Ex. 1005, Abstract. Figure 8 of Nishioka is reproduced below.

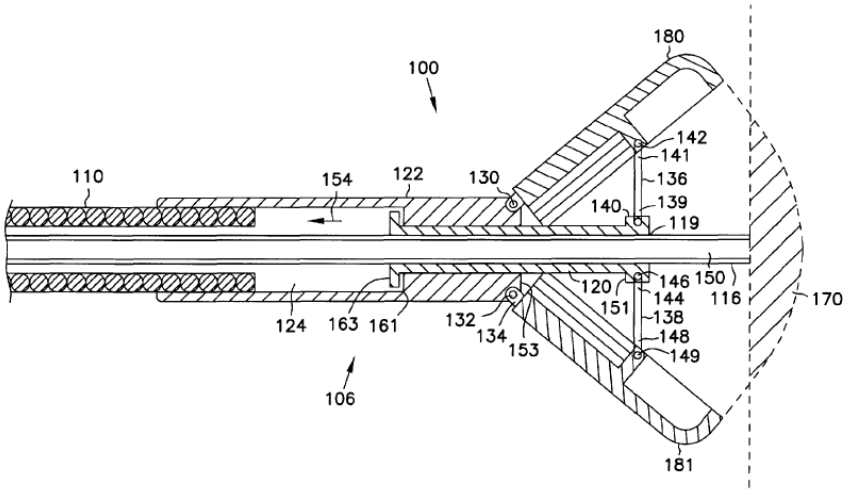


FIG. 8

Figure 8 is a cross-sectional view of a biopsy forceps. Ex. 1005, 3:34–36.

As shown in Figure 8 above, forceps 100 include cutting jaws 180, 181. Ex. 1005, 7:58. The cutting jaws are hingedly connected to support block 122. *Id.* at 7:65–66. Control links 136 and 138 operate to open and close the jaws when an optical fiber is displaced. *Id.* at 8:8–43.

2. Discussion of Claim 1

We begin our analysis with independent claim 1. Petitioner asserts that Nishioka, alone, teaches all elements of claim 1. Pet. 18–24.

Claim 1 is directed to a medical device, which comprises a clip, a control member, and a linkage. Ex. 1001, 15:33–45. Petitioner points to Figures 2 and 8 of Nishioka and related teachings, as well as the supporting declaration of Dr. Nicosia. Pet. 19 (citing *e.g.*, 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, and 7–8; Ex. 1011, ¶ 31).

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;

Consistent with Petitioner's contentions (*id.*), based on the record before us at this juncture, Nishioka appears to describe a medical device. Pet. 18 citing Ex. 1005, 1:6–9, 1:64–66. The medical device is a forceps device capable of applying a pinching pressure. *Id.* The device includes jaws 80, 81 (in Figure 2) and 180, 181 (in Figure 8) each having an inner surface (in this case designed for retrieving biopsy samples). Figure 6B more closely illustrates the jaw inner surface having serrations 83, and is reproduced below.

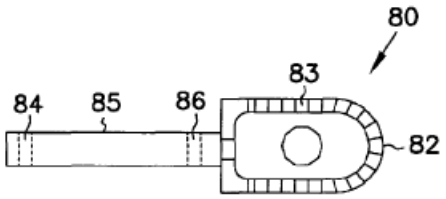


FIG. 6B

Figure 6B is a plan view of one jaw of a biopsy device. Ex. 1005, 3:28–30.

a control member extending from a proximal actuator to the clip; and

Petitioner asserts that Nishioka also describes a control member for opening and closing the jaws. We observe that based on the record before us at this juncture, Nishioka appears to teach the "proximal" actuator 30 which is a slider connected to control wires 40, 41 and manipulated by handles 26 and 27. Pet. 20. *See also* Ex. 1005, 4:7–18, and Figs. 1 and 2.

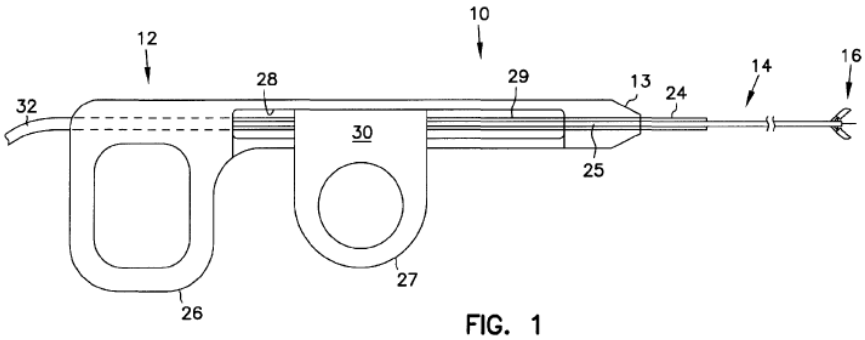


FIG. 1

Figure 1 is a side view of a biopsy forceps. Ex. 1005, 3:28–30.

Nishioka Figure 2 more closely illustrates the control wires 40, 41 below:

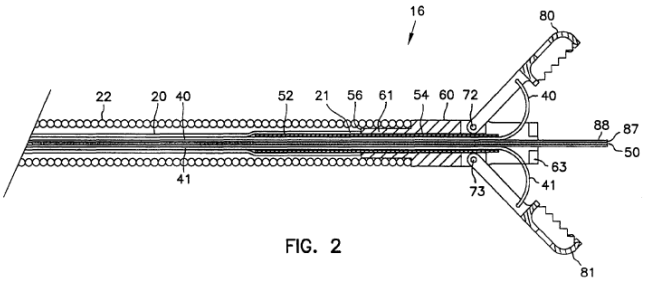


FIG. 2

Figure 2 is a cross sectional view of the distal end of a forceps. Ex. 1005, 3:13–15.

Given that we have interpreted "clip" as an element capable of applying pinching pressure, *supra*, ('027 patent 15:7–9), it appears that the biopsy forceps jaws are capable of applying sufficient pressure to remove a tissue sample. Moreover, the control wires extend to the clip.

> *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.*

Turning to the final claim element, Petitioner asserts that Nishioka discloses in one embodiment a linkage (distal end portion of control wires 40, 41) 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. Petitioner further asserts that the linkage is 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. Pet. 21–22.

Nishioka appears to teach the final structure recited in claim 1 (*see, e.g.*, Ex. 1005, Fig. 8). For instance, the control member 150 in this embodiment is the fiber optic cable connected to tubular slide member 120, which then connect to control links 136, 138 which open and close the jaws depending upon the motion of the control member. Pet. 24 citing Ex. 1005, 8:63–9:2, Ex. 1011, ¶ 34.

Turning now to the Patent Owner's contentions, Patent Owner correctly asserts that Nishioka describes a biopsy cutting forceps. Prelim. Resp. 12–13. Where we disagree with Patent Owner is Patent Owner's position that the term "clip," as claimed, cannot encompass the cutting jaws of Nishioka. The intrinsic evidence of record indicates that an apparatus capable of application of pinching pressure alone is sufficient to fall within the definition of a "clip," with or without release of any component designated a clip from an endoscopic hemostatic clipping device. For example, the Specification explains:

> A method of using the endoscopic hemostatic clipping device is provided. The method involves placing an endoscope in a body cavity as is known in the art. The device provided herein is then inserted through the endoscope. At the distal end, the endoscope is positioned near the target area. As noted above, the target area may be a lesion, a bleeding ulcer, a tumor, other abnormality, or any number of other tissues to be pinched, marked, tagged, **or to which the operator wishes to apply a pinching pressure for whatever reason.** The device provided is then positioned so that the clip legs embrace the target area, then the actuator is activated to close the clip legs. The success or

> failure of the application of pressure can be reviewed through the optical components provided separately in the endoscope. If the pinching is unsuccessful or only marginally successful, the clip legs of the device may be opened by reversing the actuation of the activator. Alternatively, if the pinching is successful, and the operator wishes to deploy the device, the actuator is fully activated, or the alternative deployment activator is activated. Finally, the remaining portion of the medical device and the endoscope are removed from the body.

Ex. 1001, 15:1–21. (Emphasis added).

Patent Owner makes multiple arguments concerning Nishioka's cutting jaws causing bleeding, not hemostasis. Prelim. Resp. 13–18. Although on this record we agree that Nishioka does not appear to cause hemostasis, we do not find that hemostasis is required by the language of claim 1, specifically the term "clip," as discussed above. Patent Owner states that the '027 patent "consistently refers to the clip as compressive against vessels to achieve hemostasis." *Id.* 17. This statement, however, does not address the discussion contained in the specification concerning simply using the clip for pinching tissue.

Having reviewed the Petition and Preliminary Response, and the evidence cited therein, based on the record before us at this juncture, we determine that Petitioner has demonstrated a reasonable likelihood of showing claim 1 to be unpatentable based on Nishioka.

3. Claims 2–3, and 7–12

Petitioner asserts that Nishioka alone teaches all elements of these claims. Patent Owner has not discussed any of these claims with particularity separately. Prelim. Resp. *passim.*

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." Ex.

1001, 15:46–48. Petitioner asserts that Nishioka Figures 2 and 8 describe that the linkage (40, 41 (Figure 2), 120 (Figure 8)) is received through an opening formed in a proximal end of the clip. Pet. 25.

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." Ex. 1001, 15:49–52. Petitioner asserts that Nishioka describes that the linkage comprises first and second linkage members – the distal ends of 40, 41 in Figure 2, and links 136, 138 – in Figure 8. The proximal ends are said to be connected by the slider 120. Pet. 26–28.

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." Ex. 1001, 15:63–67.

Petitioner asserts that Nishioka Figure 6A describes the distal ends of the clip legs in Figure 2 and Figure 8 include curved projections angled radially inward with respect to a longitudinal axis. Pet. 29.

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." Ex. 1001, 16:1–4.

Claim 10 depends from claim 9, and recites that "the protrusion is a pointed tooth and the recess is a pointed recess." *Id.* 16:5–6.

Claim 11 also depends from claim 9 and recites that "the protrusion is a plurality of pointed teeth and the recess is a plurality of correspondingly

shaped pointed recesses." *Id.* 16:7–9.

Claim 12 likewise depends from claim 9 and recites that "the protrusion is one of a multi-toothed wave and an offset L-tooth." *Id.* 16:10–11.

Petitioner asserts that Nishioka Figures 3 and 6A describe 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 claimed in claims 9–12. Pet. 29–31.

Nishioka Figure 3 is reproduced below:

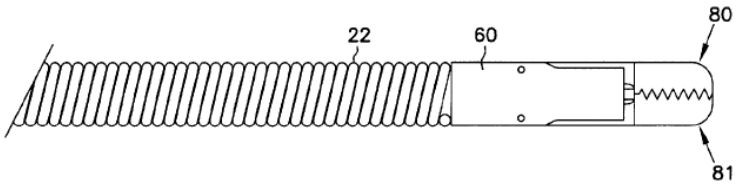


FIG. 3

Figure 3 is a side view of a forceps device. Ex. 1005, 3:16–17.

Petitioner has made a sufficient showing with respect to claims 2–3 and 7–12 similar to its showing with respect to claim 1. *See, e.g.*, Pet. 25–31.

Having reviewed the Petition and Preliminary Response, and the evidence cited therein, based on the record before us at this juncture, we determine that Petitioner has demonstrated a reasonable likelihood of showing claims 1–3 and 7–12 are unpatentable in view of Nishioka.

VI. Obviousness of Claims 13–14 and 16–19 over Nishioka and Shinozuka

Petitioner contends claims 13–14 and 16–19 are unpatentable under 35 U.S.C. § 103(a) as obvious over Nishioka and Shinozuka. Pet. 32–40.

Claim 13 reads as follows (paragraphing and line structure maintained from the printed patent):

> 13. 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 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; and
> 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.

Ex. 1001 16:12:26.

1. Overview of Shinozuka

Shunozuka is directed to a "Biotissue Clip Device." Ex. 1010-00010[1] The clip is said to be detachably coupled to a control. Pet. 34–35 citing Ex. 1011 ¶ 47, Ex. 1010-00011. Nishioka is relied upon for the description discussed above. Petitioner urges that Shinozuka describes the claimed clip-

1 We cite to the translation provided as an exhibit to the Declaration of the translator. Ex. 1010. The original reference is Ex. 1009, containing the Figures.

tightening ring, or "sleeve" of claim 13. Pet. 33. Figure 5 of Shinozuka is reproduced below:

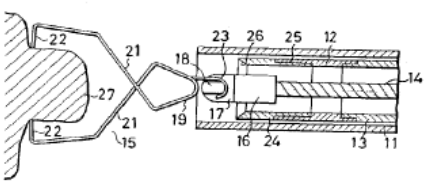


Figure 5 is a cross sectional view of a biotissue clip. Ex. 1010-00012.

2. Analysis

Petitioner asserts that it would have been obvious to combine the clip tightening ring of Shinozuka with the clip of 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.'" Pet. 34 (citing Ex. 1011 ¶ 47; Ex. 1009, English translation p. 261).

Dr. Nicosia testifies that:

> 48. It would have been obvious to a PHOSITA 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. The PHOSITA 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. 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. The PHOSITA 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 is designed to be inserted into the body and to be removed with a sample of tissue. Ex. 1005, Abstract. It uses a fiber optic device that enables the tissue between the jaws to be positively identified. *Id.* As Nishioka states: "[t]he catheter is adapted for in vivo tissue identification of tissue types through optical techniques using the optical fiber, and biopsy sampling of identified tissue areas for withdrawal from the body for conventional examination and analysis." Ex. 1005, 1:10–13.

Contrastingly, Shinozuka is a clip which is designed to be left in the body. Ex. 1010, Fig. 7. In discussing the prior art of removing diseased tissue, the drawback of cutting endoscopically and the resulting bleeding is discussed. Ex. 1010-00010. Immediately below that discussion is a discussion of the use of clips to pinch tissue. The tissue then dies and drops off, along with the clip. These are discussed as known treatment alternatives. *Id.* at 00010–11. Shinozuka then goes on to discuss the benefits of its device which is easily detachable. *Id.* at 00011.

Dr. Nicosia asserts that modifying Nishioka to include a sleeve would have been a matter of routine skill in the art. Ex. 1011 ¶ 48–49. Patent Owner disagrees and contends this analysis "is flawed because a person of ordinary skill would actually need to replace the entire design in Nishioka for any combination with Shinozuka." Prelim. Resp. 26.

We are unpersuaded by Petitioner's contentions. Modifying Nishioka with the clip of Shinozuka (or sleeve) is counter to the intended purpose of Nishioka's identification and retrieval of a tissue sample. *See, e.g.*, *In re Sponnoble*, 405 F.2d 578, 587 (CCPA 1969) (references taken in

combination teach away since they would produce a "seemingly inoperative device").

We do not see how the detachable clip would operatively serve in the device of Nishioka. We are left with numerous unanswered engineering and operational questions. How would the Nishioka tissue sample be obtained? Where would the fiber optic cable go if the end is taken from its central location between the jaws in Nishioka? Would the sample first be taken and then the endoscope be reintroduced to the patient with a removable clip? Why would one want to leave a biopsy instrument inside a patient? *See, e.g.*, *In re Caldwell*, 319 F.2d 254, 256 (CCPA 1963) (reference teaches away if it leaves the impression that the product would not have the property sought by the applicant).

Modifying Nishioka by using a clip and sleeve of Shinozuka would apparently destroy both of Nishioka's stated goals – close identification of, and excision of, tissue. We therefore find the combination as presented in the Petition with the rationale given by Dr. Nicosia to be unpersuasive, and insufficient to institute on this ground.

On this record, we are therefore not persuaded that Petitioner has established a reasonable likelihood that it would prevail in showing that claims 13–14 and 16–19 are unpatentable as obvious over Nishioka and Shinozuka.

VII. Obviousness of Claims 4–6 and 13–20 over Nishioka and Matsuno

1. Overview of Matsuno (Ex. 1016)

Petitioner asserts that Nishioka describes all of claim 1, but does not describe a frangible link coupling the clip to the control member as claimed in claims 4–6 (Pet. 41), or the sleeve of claims 13–20 (Pet. 48). Matsuno is

relied upon as describing a link between the clip and control member that becomes unlinked when a tensile load is applied. Pet. 41, citing Ex. 1011 ¶ 60. Matsuno is also relied upon for the sleeve of claims 13–20. Pet. 48, citing Ex. 1011 ¶ 72.

Matsuno's clip is reproduced below:

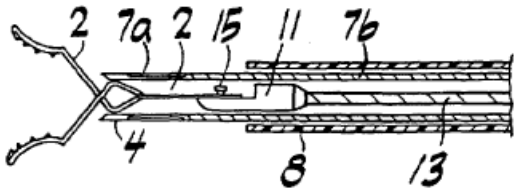


FIG. 6

Figure 6 is a cross-sectional view of a clip and control rod. Ex. 1016, 5:35–45.

By pulling hard on the control rod, a user can disengage the clip of Matsuno and leave it behind in the body. Ex. 1016, 1:55–2:20.

2. Discussion

The rationale for making the combination comes from Dr. Nicosia's testimony that:

> 64. It would have been obvious to a PHOSITA 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. The PHOSITA 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. Additionally, the PHOSITA 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. 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. 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. The PHOSITA would have been motivated to modify Nishioka in order to obtain the same benefits for the Nishioka clip that are disclosed in Matsuno.
>
> 65. 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. The modification uses known elements such as those disclosed in Nishioka and Matsuno to achieve predictable results.

Ex. 1011 ¶ 64–65.

As with the combination of Nishioka and Shinozuka, we are left with unanswered questions and the apparent loss of the key functions of the Nishioka device to identify and excise tissue samples. A simple conclusory statement that the person of ordinary skill in the art could modify Nishioka to obtain the same benefits for the Nishioka clip that are disclosed in Matsuno fails to address the loss of both functions in Nishioka such that it would not satisfy its intended purpose. Moreover, how the combination would function remains unclear to us.

On this record, we are therefore not persuaded that Petitioner has established a reasonable likelihood that it would prevail in showing that claims 4–6 and 13–20 are unpatentable as obvious over Nishioka and Matsuna.

VIII. CONCLUSION

For the foregoing reasons, we determine that the information presented establishes a reasonable likelihood that Petitioner would prevail in showing that claims 1–3 and 7–12 of the '027 patent are unpatentable. We, however, determine that Petitioner has not made a sufficient showing with respect to claims 4–6 and 13–20. At this preliminary stage, we have not made a final determination with respect to the patentability of the challenged claims or any underlying factual and legal issues.

IX. ORDER

Accordingly, it is:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1–3, and 7–12 of the '027 patent on the following ground of unpatentability:

Reference	Basis	Challenged Claim(s)
Nishioka	§ 102	1–3 and 7–12

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, which commences on the entry date of this decision; and

FURTHER ORDERED that the trial is limited to the grounds identified immediately above, and no other ground is authorized.

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