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Paper 70
Entered: November 1, 2018

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*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a)

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.").

On May 3, 2017, we instituted an *inter partes* review of claims 1–3 and 7–12 on a limited set of grounds. Paper 7 ("Dec. on Inst."). Patent Owner subsequently filed a Patent Owner Response (Paper 14, "PO Resp.") and Petitioner filed a Reply (Paper 23, "Reply"). Patent Owner also filed a Motion to Exclude (Paper 33, "Mot.") certain evidence submitted by Patent Owner, to which Petitioner filed an Opposition (Paper 41) and Patent Owner filed a Reply (Paper 43).

A combined oral hearing with Case IPR2017-00132, IPR2017-00134, and IPR2017-00135 was held on February 8, 2018, and a transcript of the hearing is included in the record (Paper 50, "Tr. 1.").

Subsequent to the oral hearing, on April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on less than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018). Consequently, we instituted review on all claims and grounds, set new times, and permitted additional briefing. Paper 55. The parties filed a joint motion to limit the proceeding (Paper 56), which motion was granted. Paper 57.

The parties then re-briefed the issues with a Patent Owner's Supplemental Response ("Supp. Resp.") (Paper 58); a Petitioner's Supplemental Reply ("Supp. Reply") (Paper 60); a Patent Owner's Sur

Reply (Paper 65) and a Petitioner's Sur Rebuttal (Paper 66). A second oral hearing was held September 17, 2018, and a transcript of the supplemental hearing is included in the record ("Tr. 2.") (Paper 69).

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–3 and 7–12 are anticipated by Nishioka.

A. 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 is said to include a compression clip used in certain applications to cause hemostasis of blood vessels and a mechanism for deploying the clip. *Id*. at 2:59–62. The clip can also provide a pinching pressure as desired. *Id.* at 15:8–9.

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.

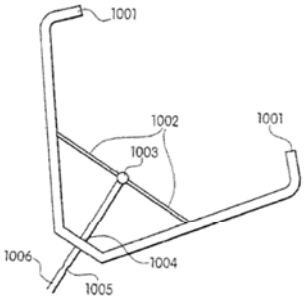


FIG. 10A

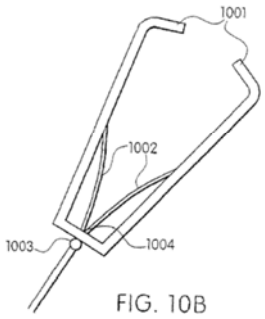


FIG. 10B

Figures 10A and 10B depict cross–sectional views of a clip in an opened and a closed position, including linkages 1002 and clip legs 1001. *Id*. at 9:4–6.

B. Illustrative Claims

Claims 1 and 20 are illustrative of the claimed subject matter and recites 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.

Claim 1, an apparatus claim, is not directed to the use of the clip, and thus does not require the clip be closed or left in the body. By way of contrast, Claim 20, a method claim, requires separation of a link coupling the clip to the control member.

C. Prior Art

The pending grounds of unpatentability in the instant *inter partes* review are based on the following prior art:

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

Japanese Unexamined Patent Application Publication No. 60-103946, June 8, 1985 (Translation added). ("Shinozuka")(Ex. 1009);

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

D. The Pending Grounds

In the instant *inter partes* review, Petitioner challenges claims 1–3 and 7–12 as being unpatentable as anticipated by Nishioka under 35 U.S.C. § 102(b).[1]

Petitioner also challenges claims 13–14 and 17–19 as being unpatentable as obvious over Nishioka and Shinozuka under 35 U.S.C. § 103(a).

Finally, Petitioner challenges claims 4–6, 13–15, and 17–20 as being unpatentable as obvious over Nishioka and Shinozuka under 35 U.S.C. § 103(a).

E. Witness Testimony

The Petitioner and the Patent Owner rely on the testimony of several witnesses. They are the following:

i. James Thornton (Exs. 1010 and 1042). Mr. Thornton testifies that he provided an accurate translation of the Japanese portions of Exhibit 1009, which is the Shinozuka reference. We find him to be qualified to perform such a translation. *Id.* ¶¶ 3–4.

ii. Mark. A. Nicosia, Ph. D. (Exs. 1011, 1068, and 1106). Dr. Nicosia

[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '027 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. §§ 102 and 103.

testifies to the substantive issues in this proceeding on behalf of Petitioner. We find him qualified to testify as to the subject matter of this proceeding. Ex. 1011 ¶¶ 4–7 and Exhibit B. Dr. Nicosia was deposed by the Patent Owner. Ex. 2039.

iii. Jeffrey J. Vaitekunas, Ph. D. (Ex. 2030). Dr. Vaitekunas testifies to the substantive issues in this proceeding on behalf of Patent Owner. We find him qualified to testify as to the subject matter of this proceeding. Ex. 2030 ¶¶ 4–9 and Appendix A. Dr. Vaitekunas was deposed by Petitioner. Ex. 1065.

We have carefully considered the testimony of the witnesses, as well as the prior art.

II. ANALYSIS

A. Claim Interpretation

The Board, for purposes of this decision, presently interprets claims in an unexpired patent using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b)(2016). Under this standard, we interpret claim terms using "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997); *see In re Smith Int'l, Inc.*, 871 F.3d 1375, 1382–83 (Fed. Cir. 2017) ("[The] broadest reasonable interpretation . . . is an interpretation that corresponds with what and how the inventor describes his invention in the specification."). "Under a broadest reasonable interpretation, words of the claim must be given their

plain meaning, unless such meaning is inconsistent with the specification and prosecution history." *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016).

Our interpretation "'cannot be divorced from the specification and the record evidence,' and 'must be consistent with the one that those skilled in the art would reach.' A construction that is 'unreasonably broad' and which does not 'reasonably reflect the plain language and disclosure' will not pass muster." *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (citations omitted), *overruled on other grounds by Aqua Prods., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017).

Linkage

Petitioner asserts in the Petition 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.[2] Pet. 13.

Patent Owner takes the position that the linkage links components of the clip, based upon the claim language and the description of Figures 10A and 10B. PO Resp. 11–12.

In the Reply, Petitioner states only that the parties agree upon the definition. Reply 2.

We find the broadest reasonable interpretation of the term "linkage" to encompass structure that links multiple parts of the clip, as set forth in the

[2] *Boston Scientific Corp. et al. v. Cook Group Inc. et al.*, No. 15-980-LPS-CJB (D. Del.).

second portion of the definition urged by Petitioner, which comports with the definition asserted by the Patent Owner. We do not find that a linkage must necessarily always transmit force between components.

The linkage links the clip's component parts. This linking enables the clip to operate as claimed in the final paragraph of claim 1, reproduced below – linking the control member to the linkage to drive the legs apart.

> [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.

Id. at 15:38–45.

We find that this definition is also consistent with that urged by the Patent Owner in the related district court proceeding. *See, e.g.*, Ex. 1004, 8:2–3.

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. Resp. generally.

We find this term needs no express construction for purposes of this decision.

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. Paper 14, *passim.* We agree this is an appropriate interpretation, as "frangible" means "breakable," and is as defined by Patent Owner in its own claim construction brief. Ex. 1004, 13–14.

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 provided 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 agreed in our Institution Decision, and found that the clip requires compression legs. Dec. 9–10. However, we also found that "hemostatic" is a statement of intended use and the specification does not expressly limit the clips to only hemostatic uses. *Id.*

However, we again observe that no such express limitation is in the claims for which review is sought; for example, claim 1 is an apparatus claim that recites "a clip," and the word "hemostatic" does not appear in the claim. Claim 20 is a method claim, and the same applies. 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 [to] for whatever reason." *Id.* at 15:8–9.

"Clip," as the term is generally understood, and as used in the Specification, is therefore broader than as urged by Patent Owner. We consequently interpret "clip" as used in the '027 patent as a device having compression legs and capable of applying a pinching pressure. Patent Owner and Petitioner do not contest this finding. PO Resp. 10, Reply 2.

Inner Surfaces of the Clip Legs

Determination of this claim element is dispositive of this proceeding. Each of the claims, by virtue of dependency from claims 1 and 20, requires the linkage to contact the inner surfaces of the clip legs. *See* Ex. 1001, 15:41–42 and 16:62–54. Petitioner did not construe this element in the Petition.

Patent Owner asserts that the "inner surfaces of the two clip legs are said to face each other and engage tissue to compress or pinch it." PO Resp. 13. Such a reading would exclude any surfaces that do not engage tissue, such as a side or a pocket in the side which might have what could be considered an inwardly facing surface. We are not persuaded by this contention for numerous reasons, but principally because it requires more to define a surface than the claim itself states, i.e. that the surface must engage tissue.

The term "outer surface" is used in the '027 patent to characterize the male threads 2002 on the outer surface of the clip found in Figure 20B. Figure 20B is reproduced below:

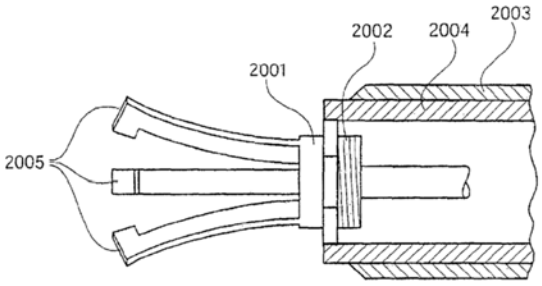


FIG. 20B

Figure 20 B is an enlarged partial cross-sectional diagram of a clip

It is apparent to us that the "outside surface" means what it says, the surface that faces outwardly. Ex. 1001 13:24–25. The specification goes on to describe that the "inner sleeve 2004 has female threads (not shown) on its inside diameter." *Id.* 13:30–31. Although the term "inner surface" does not appear in the specification, by logical extension an inner surface would be consistent with the inner diameter that faces inwardly to engage the threads.

Petitioner, on the other hand, criticizes the Patent Owner's position but provides no meaningful interpretation of the claim term. Reply 2–6. Dr. Nicosia does not meaningfully discuss the definition of inner surface in his declaration either. Exs. 1011 and 1068 *passim.*

Dr. Vaitekunas testified at some length as to what makes up an inner surface. He testified that he understands that:

> Patent Owner argues that the broadest reasonable construction of 'inner surfaces of the . . . clip legs' is 'the exterior surface of the clip that is radially inward-facing or inward-facing relative to the longitudinal axis of the clip.' Patent Owner's proposed construction of "inner surfaces of the . . . clip legs" is consistent with what I, as a person of at least ordinary skill in the art, would understand the term to mean in the '027 Patent. This construction is also consistent with the intrinsic evidence.

> Figures 10A and 10B of the '027 Patent show flexible linkage 1002 contacting the radially inward facing surfaces of clip legs 1001. Furthermore, Patent Owner's original claim 42 recites that 'the handle is able to be rotated to thread a base of the clip into a female thread situated on a radially inner side of an outer sleeve, . . . and the at least two clip legs able to close when the base is threaded into the outer sleeve.' Ex. 1002 – 00037. The 'radially inner side of an outer sleeve' in Patent Owner's original claim 42 must refer to an exterior surface that is radially inward-facing, as the female thread must be located on an exterior surface so that it can be threaded with the base of the clip to close the clip.

Ex. 2030 ¶ 29.

We find this testimony to be credible and consistent with the intrinsic evidence of record. We do not, however, agree that the claim requires the inner surface to specifically face "radially" inwardly, merely inwardly such that it can be engaged in some manner by the linkage. We find that the claim language is specific enough as it stands - an inner surface would appear to be a surface that faces inwardly, from the perspective of the clip.

B. Principles of Law

To prevail in challenging claims 1–6 of the '027 patent, Petitioner must demonstrate by a preponderance of the evidence that the claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

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…

Anticipation requires evidence "that a single prior art reference discloses each and every element of a claimed invention." *Silicon Graphics, Inc. v. ATI Techs., Inc.*, 607 F.3d 784, 796 (Fed. Cir. 2010).

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).

C. Level 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.

D. Anticipation Ground Based on Nishioka (Claims 1–3 and 7–12)

Overview of Nishioka (Ex. 1005)

Nishioka is directed to a biopsy forceps. Ex. 1005, Abstract. The forceps are used for tissue identification and biopsy sampling. *Id.* Figure 8 of Nishioka is reproduced below.

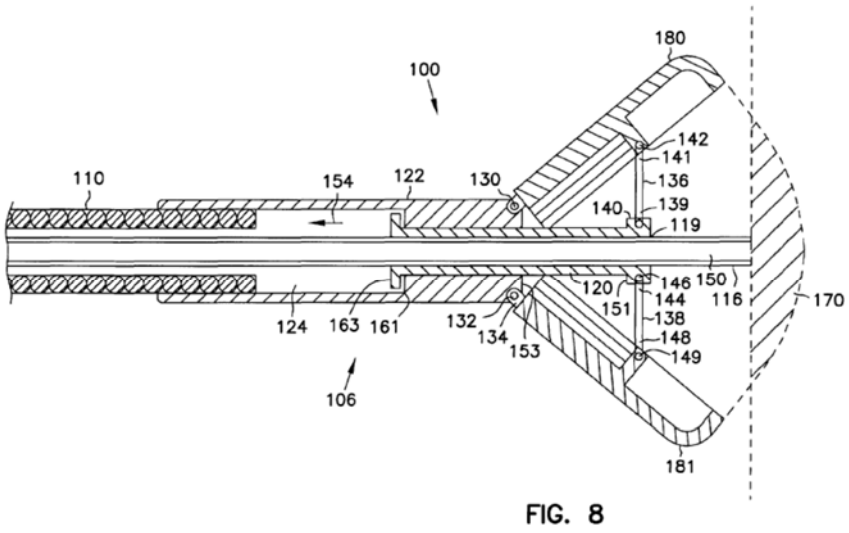


FIG. 8

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. The principal objective of the forceps in use is tissue identification, either visually or by biopsy sampling. *Id.* at 1:62–64.

1. Discussion of Claim 1

We begin our analysis with independent claim 1. Petitioner asserts that Nishioka, alone, describes 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, Figs. 1–4, and 7–8; Ex. 1011 ¶ 31).

Importantly, Figures 2 and 8 represent separate embodiments within Nishioka, hereinbelow referenced as embodiment 1 and embodiment 2 as we analyze the prior art against the language of claim 1 below.

Analysis of Claim 1 Anticipation by Nishioka Embodiment 1

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.

Because the bolded portion of claim 1 is dispositive of our analysis as regards Nishioka's embodiment 1, we direct our focus there initially. 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 at first blush in Figure 2 to teach the final structure recited in claim 1 (*see, e.g.*, Ex. 1005, Fig. 2).

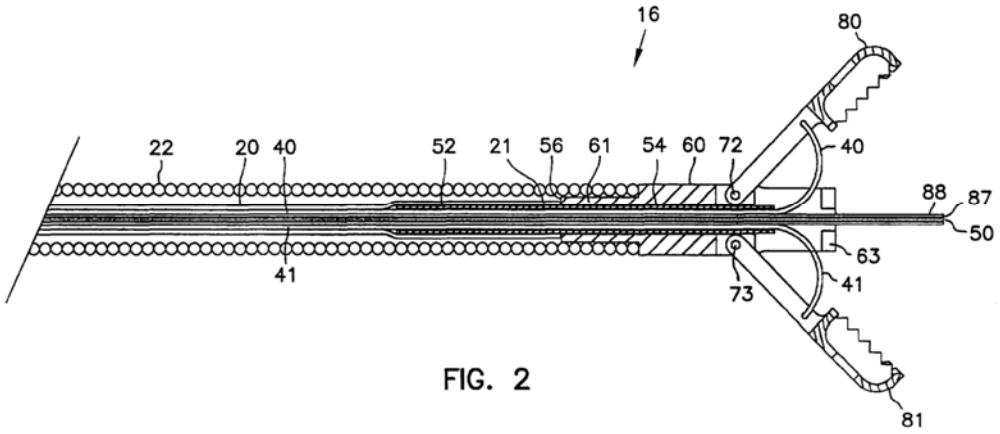


FIG. 2

Figure 2 is a cross-sectional view of a biopsy forceps

Control wires 40, 41 from this side view appear to enter the inner surface of the clip legs in Figure 2.

However, as pointed out by Patent Owner, the control wires in Nishioka embodiment 1 do not actually penetrate the inner surface of the clip leg, but are mounted to the side. Resp. 19, 27. Patent Owner observes that the control wires contact only the side surfaces of the clip. *Id.*

Petitioner urges in reply that the method of attachment of the control wires results in contact with an inner surface. Reply 17. More specifically:

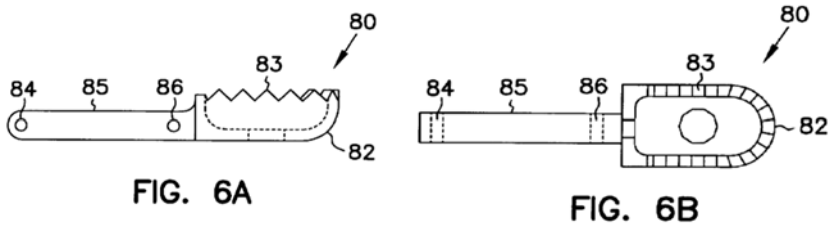


FIG. 6A FIG. 6B

> As shown above, hole 86 has a circular cross-section (*see* Figure 6A) and extends through the width of the jaw 80 (*see* Figure 6B). As Dr. Nicosia explained, '[w]ires 40 and 41 are inserted into hole 86," which "penetrates through the [jaw] - - from one side to the other." (Ex.2011, 188:17-189:1, 188:25-26; *see also id.,* 189:10-19, 191:23-192:2). Further, Dr. Nicosia explained that "[t]he hole in the jaw has a surface" that is "inward-facing." (*Id.*, 195:19-22, 197:8-11). The contact between the distal ends of wires 40, 41 ("linkage") and the inward-facing bearing surface of holes 86 ("inner surface") satisfies the claim limitation "a linkage contacting the inner surfaces of . . . the clip legs." (*Id.*).

Reply 17.

We are unpersuaded by this argument. The method of attachment of the wire is by passing it through a hole in the neck of the clip leg. Although the attachment mechanism — the hole itself — may have an inwardly facing hole surface, we do not find that this inwardly facing hole surface is the required inner surface relative to the clip. We are especially persuaded by the annotated perspective view of Figure 4, as highlighted on page 29 of the Response. We reproduce that figure below:

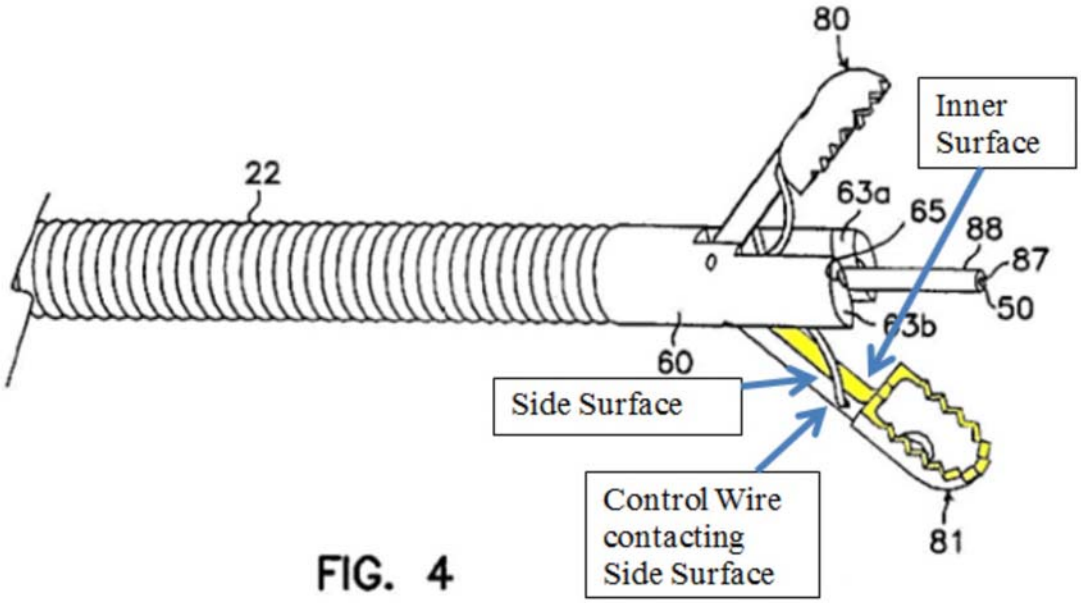


FIG. 4

Figure 4 is a perspective view of a biopsy forceps

Accordingly, we conclude that Nishika embodiment 1 fails to anticipate claim 1.

We now turn to embodiment 2 of Nishioka.

Analysis of Claim 1 Anticipation by Nishioka Embodiment 2

1. A medical device, comprising:

Petitioner asserts that Nishioka describes 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.* We find that the evidence supports that Nishioka's device is a medical device.

a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface;

Petitioner asserts that the device includes jaws 180 and 181 in Figure 8 each having an inner surface (in this case designed for retrieving biopsy samples). Pet. 18. We find that the evidence supports that Nishioka's jaws include legs with inner surfaces.

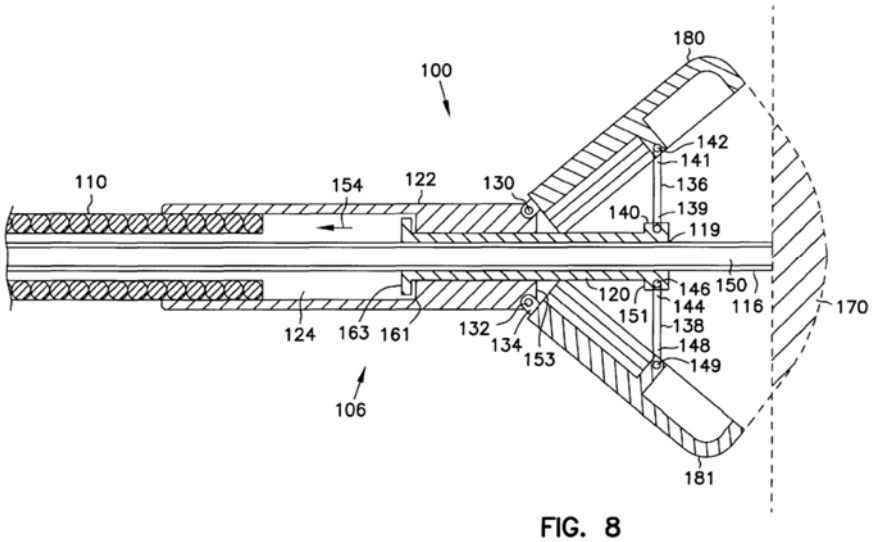


FIG. 8

Figure 8 is a cross sectional view of a biopsy forceps

Patent Owner asserts that embodiment 2 does not describe a clip. Resp. 39, citing Resp. 20–23. More specifically, Patent Owner asserts that Nishioka's cutting jaws apply a shear force, not a compressive force, and therefore they do not constitute a "clip" under the Board's construction of that term. *Id.* 20.

Patent Owner's witness Dr. Vaitekunas, testifies that Nishioka describes cutting a tissue sample using a shear force, not pinching tissue using a compressive force. Ex. 2030 ¶¶ 40–41, 43. The staggered serrations of Nishioka's cutting jaws are said to slide past one another in operation, much as the blades of a pair of scissors or shears. *Id.* ¶ 43. As a result, Patent Owner contends that Nishioka's jaws cut tissue by exerting forces that push the tissue in opposing directions to effect the cut. Resp. 21.

On the other hand, Petitioner's witness Dr. Nicosia testifies that a person of ordinary skill in the art would understand that all biopsy forceps, including the Nishioka forceps, apply a combination of forces when applied

to tissue, including both pinching (compression) *and* shear forces. Reply 9, citing Ex.1068 ¶¶ 15–16. In short, it depends upon the use to which the forceps are put.

Dr. Nicosia analogizes this to using pruning shears to pick up and move tree clippings without cutting the clippings, or to using cutting pliers to hold, bend, and loop wire, without cutting the wire. *Id.* According to Dr. Nicosia, pruning shears and cutting pliers are designed to shear and cut, but they also are capable of being used to pinch and compress without cutting. *Id.*

Petitioner observes that Dr. Nicosia's opinion is confirmed by medical literature, including an example where biopsy forceps are used to grasp. DeBeer et al. (Ex. 1070).[3]

On balance, we find Dr. Nicosia's testimony more persuasive, and consistent with the description in the specification of the '027 patent that a pinching pressure can be applied for whatever purpose the operator desires. More specifically, as the claimed clips can be used on any tissue "the operator wishes to apply a pinching pressure for whatever reason" we find Patent Owner's shear versus pinch argument unpersuasive. *See* Ex. 1001 15:8–9.

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 find that Nishioka describes "proximal" actuator 30 which is a slider connected to control wires 40, 41 and

[3] Patent Owner filed a motion to exclude DeBeer, which we address below. *See* Paper 33.

manipulated by handles 26 and 27. Pet. 20. *See also* Ex. 1005 4:7–18, and Figs. 1 and 2. The handle of embodiment 2 is said to be similar to that of the optical biopsy forceps of Figure 1. *Id.* 7:8–10.

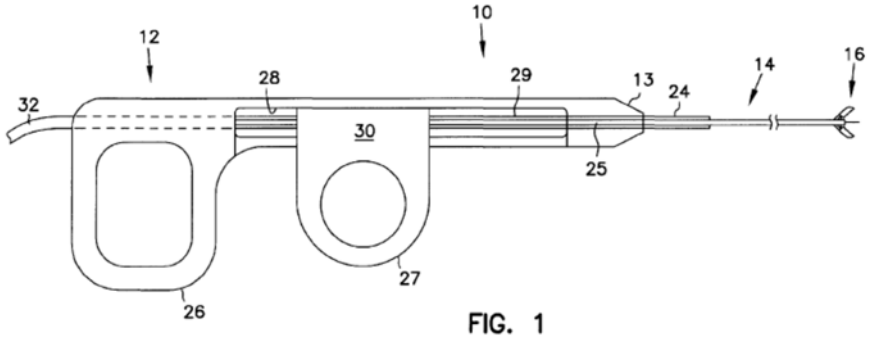


FIG. 1

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

Nishioka Figure 8 illustrates the control member 150 slider in embodiment 2:

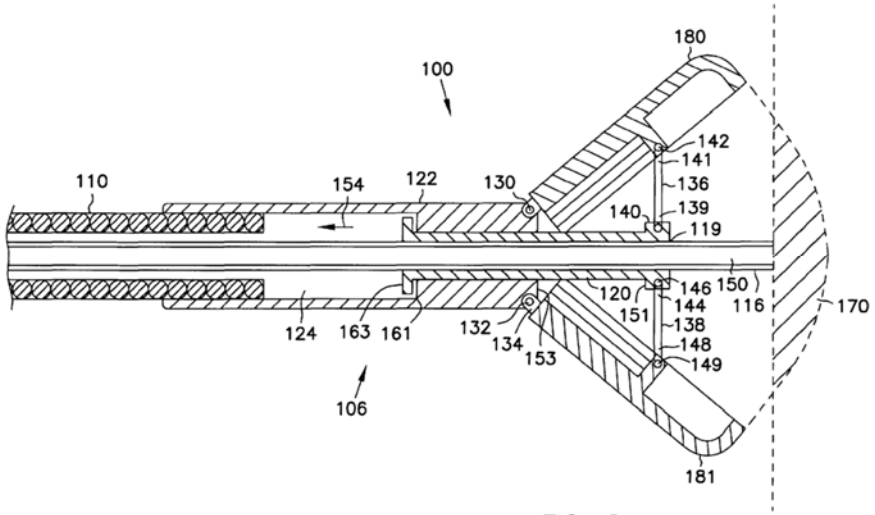


FIG. 8

Figure 8 is a cross sectional view of a biopsy forceps

Pet. 21, citing Ex. 1005 3:44–49, 3:64–65, 4:10–17, 6:60–64, 7:3–32, Figs. 1–4, 7–8; and Ex. 1011.

Given that we have interpreted "clip" as an element capable of applying pinching pressure, *supra*, ('027 patent 15:7–9), we find that the biopsy forceps jaws in each embodiment are capable of applying sufficient pressure to remove a tissue sample. Moreover, as the control wires or sliding member extend to the clip, we find that the evidence in the Petition supports a conclusion that Nishioka describes the actuator and clip as claimed in this element.

> *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*.

Petitioner asserts that Nishioka embodiment 2 describes the final structure recited in claim 1. Pet 21–23, citing Ex. 1005, Fig. 8.

We find that the control member 150 in embodiment 2 connects 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. As illustrated in Figure 8 (annotated) on page 23 of the Petition and reproduced below, it is the position of the Petitioner that the three cooperating components 120, 136, and 138 are the linkage.

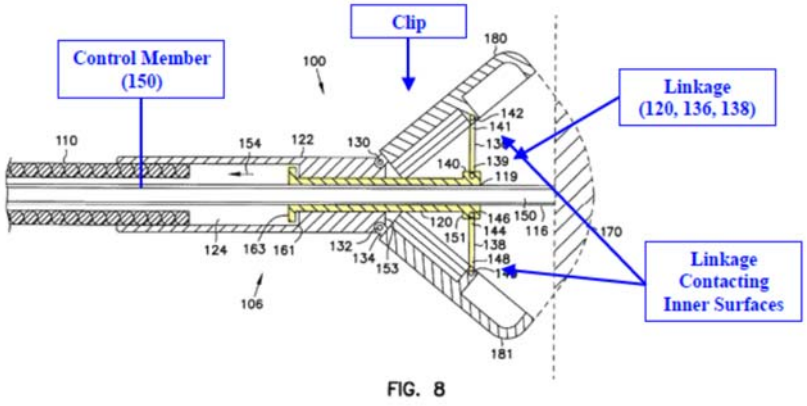


Figure 8 is an annotated cross sectional view of a biopsy forceps

Patent Owner is of the view that Nishioka Embodiment 2 fails to disclose the claimed linkage contacting the inner surfaces of the first and second clip legs. Resp. 40. Patent Owner relies on annotated Figure 8, reproduced below.

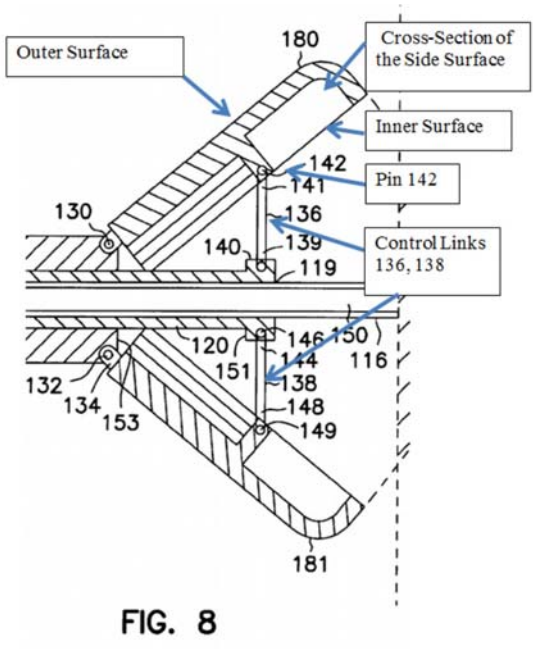


Figure 8 is a partial annotated cross sectional view of a biopsy forceps

According to Patent Owner, Figure 8 provides a cross-sectional view of the distal end of Nishioka Embodiment 2. *Id.* Also according to Patent Owner, because Figure 8 is a two-dimensional representation of the biopsy forceps, the figure shows only a cut-away portion of the *side* surface of the cutting jaws. *Id.* at 41. Patent Owner then interprets the figure as illustrating the linkage as being on the *side* of the jaws, and not the inner surface. *Id.* Patent Owner asserts the links would interfere with the closing of the jaws otherwise and the links fit into a recessed portion on the side of the jaws, as shown below. Resp. 42–43.

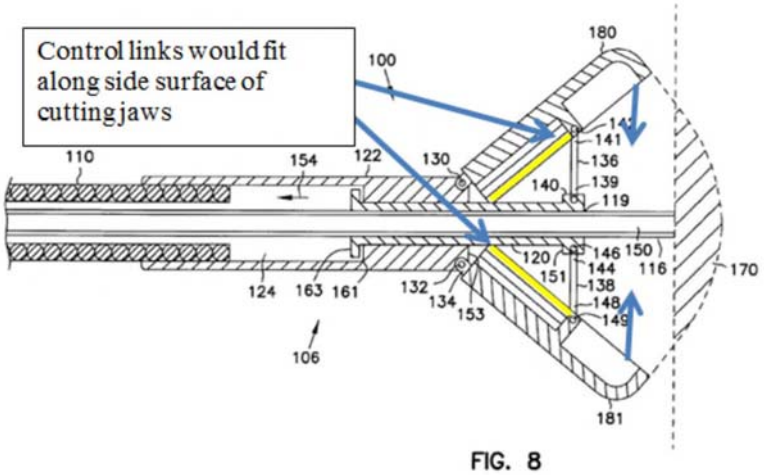


FIG. 8

Figure 8 is a partial annotated cross sectional view of a biopsy forceps

Petitioner characterizes this position as incorrect. Reply 19. Specifically, Petitioner is of the viewpoint that the control links contact the jaws on the inner surface, not the side of the jaws. Reply 21–22. We reproduce Petitioner's annotated Figures 6B and 8 as provided in the Reply on page 21 to show this point that the axial view of Figure 8 is central, not off to one side.

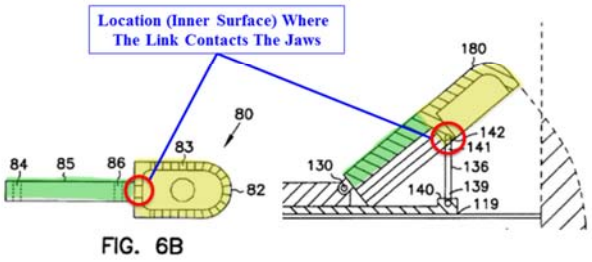


FIG. 6B

Annotated Figures 6B and 8 (Reply 21) are partial cross sectional views depicting Nishioka Embodiment 2.

Petitioner asserts that mounting this link on the side does not make sense because the misalignment would cause undesirable torque, uneven jaw pressure, and potential interference with the ability of the jaws to close and grasp tissue. Reply 23, citing the testimony of Dr. Nicosia, Ex. 1068 ¶¶ 25–28.

We do find this comparison of Figure 6B with the portion of Figure 8 helpful and it, along with Dr. Nicosia's testimony, to carry significant weight. It does appear to provide evidence that the cross sectional view of Figure 8 is a *central* cross section. We think the characterization of the view by Patent Owner as including a cross-section of the side wall is incorrect

because the side wall is not centrally located.[4] Thus, we are not persuaded by Patent Owner's argument that the linkage is on the side of the clip.

Accordingly, we conclude that Petitioner has established by a preponderance of the evidence that Nishioka Embodiment 2 anticipates claim 1.

2. Claims 2–3, and 7–12

Petitioner asserts that Nishioka alone describes all elements of claims 2, 3, and 7–12.

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 Figure 8 describes that linkage 120 is received through an opening formed in a proximal end of the clip. Pet. 25.

Patent Owner asserts that the cutting jaws of Nishioka do not have an integral proximal end through which the claimed opening could be formed because they are connected by the support block. Resp. 47–48. While this may be true, this argument does not address the claim language. While we agree with Patent Owner that slider 120 passes through an opening formed in jaw support block 122 (Resp., 48.), that is a part of the clip. Nowhere in claim 2 is a requirement that the clip must have to be a unitary structure.

Accordingly, we find that Petitioner has shown by a preponderance of evidence that Nishioka anticipates claim 2.

Claim 3 depends from claim 1 and further states that "the linkage

[4] Additionally, a cross sectional view would normally have cross hatching if the piece were solid. *See* 37 C.F.R. § 1.84(g)(3). The Patent Owner's asserted side wall does not.

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 – links 136, 138 – in Figure 8. The proximal ends are said to be connected by the slider 120. Pet. 26–28.

Patent Owner asserts that the first linkage and second linkage are not connected to each other in Nishioka, but instead the linkages are connected to separate portions of the distal end of the tubular slide member 120. Resp. 50.

Patent Owner points to Figure 10A, annotated, reproduced below in support of its assertion.

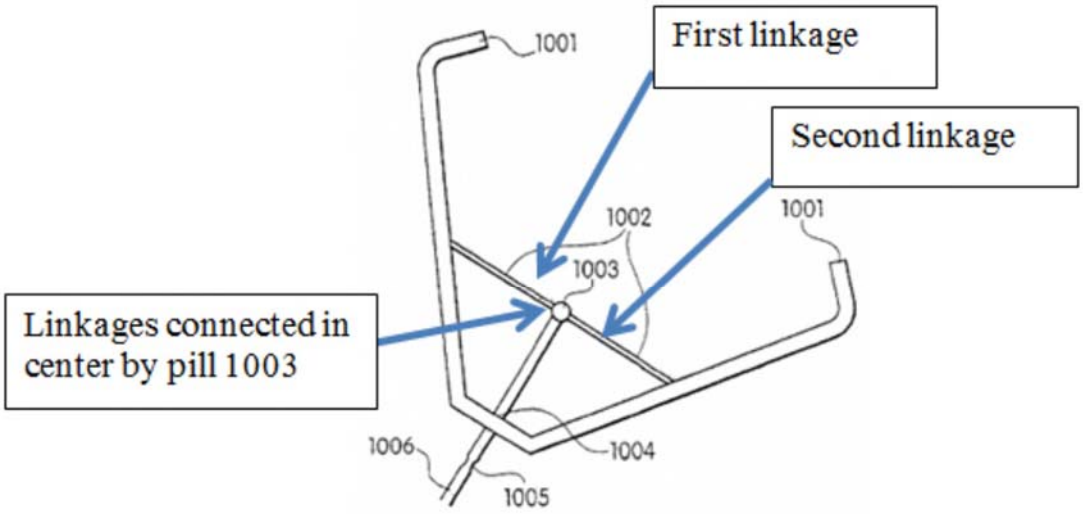


FIG. 10A

Figure 10 A is a cross sectional view of a clip

Patent Owner relies on the exemplary embodiment of Figure 10A of the '027 patent and argues that the two linkage members 1002 are connected to each other by the pill 1003. In constrast, in Nishioka it is urged that they are connected to different portions of the slider. Resp. 50–51.

Patent Owner notes that Petitioner's witness admitted that "there's not a direct physical contact between the two linkages" in Nishioka. Resp. 51, citing Ex. 2011 203:8–204:6. Thus, according to Patent Owner, "Nishioka Embodiment 2 does not disclose 'proximal ends of the first and second linkage members [that are] connected to one another' and does not anticipate Claim 3." *Id.*

We find this argument unpersuasive. Claim 3 requires only that the linkages are connected to each other, not directly connected with physical contact, or otherwise integral as a single unit. By claiming that the linkages are "connected to one another," Patent Owner claimed a structure that allows for intermediate linkages. *See American Piledriving Equip., Inc. v. Geoquip, Inc.*, 637 F.3d 1324, 1340 (Fed. Cir. 2011) ("claim 16 merely requires that the components be 'connected to' one another, which encompasses the use of bolts"). For example, the plain and ordinary meaning of "connected to" generally requires only that two structures are "joined together, united or linked." *See, e.g.*, *Am. Piledriving Equip., Inc. v. Equip. Corp. of Am.*, 2009 WL 3401726, at *11 (W.D. Pa. Oct. 20, 2009) ("'connected to' be construed to mean: 'joined together, united or linked'").

The specification of the '027 patent allows for embodiments where legs have intermediate structures connecting them to form the clip. See, e.g. Fig. 8E, reproduced below.

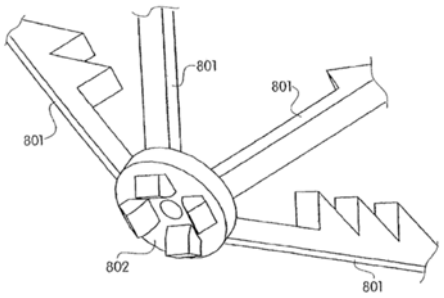


FIG. 8E

Figure 8E is a perspective view of a clip embodiment.

We find that the comparable slider 120 serves the purpose of joining, or linking the linkages as seen in Figure 8 of Nishioka, and, thus, the linkages are connected to one another.

Accordingly, we conclude that Petitioner has met its burden of establishing by a preponderance of the evidence that claim 3 is anticipated by Nishioka.

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 shows 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.

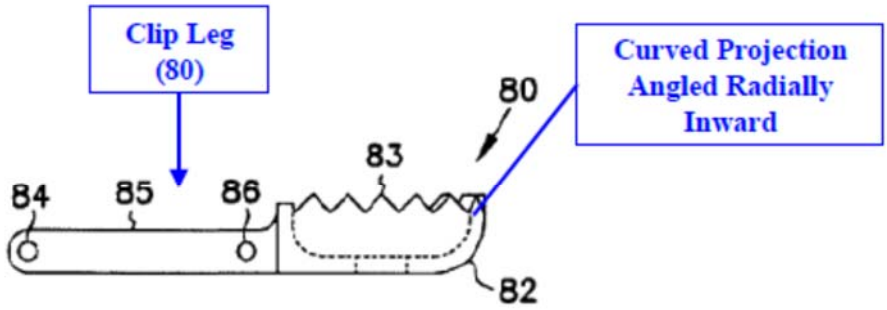


FIG. 6A

Figure 6A is an annotated cross sectional view of a biopsy forceps jaw

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. Patent Owner does not challenge the arguments raised against these claims individually.

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 and Figure 6A, annotated by the Petitioner at pages 30–31, are reproduced below:

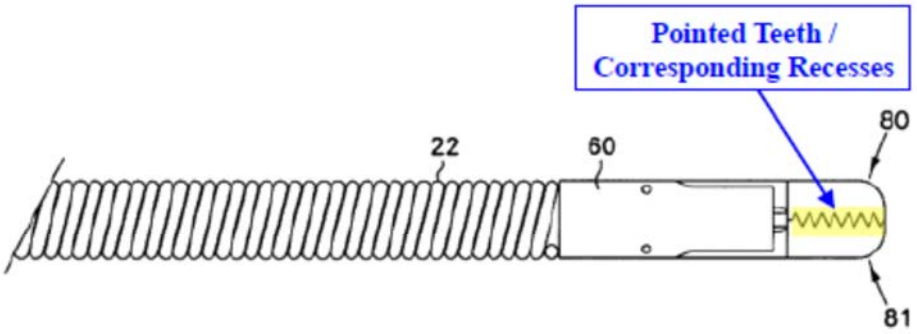


FIG. 3

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

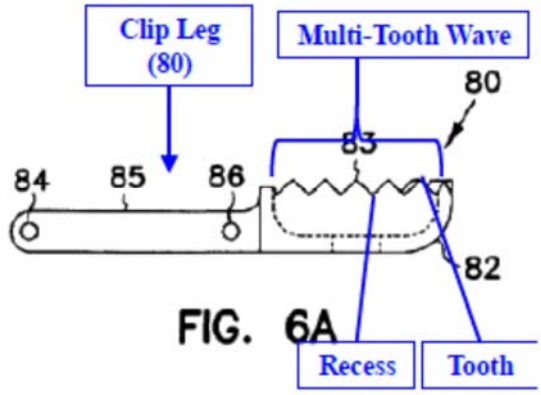
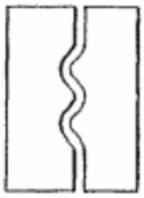


FIG. 6A

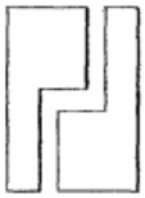
Figure 6A is an annotated cross sectional view of a biopsy forceps jaw

We observe that the Petitioner has pointed to angled protrusions, angled protrusions that interlock, a plurality of teeth and recesses, and a multi-toothed wave. The evidence of record supports a finding that Nishioka describes such.

Patent Owner asserts, for claim 12 only, that the broadest reasonable interpretation of "multi-toothed wave" is "a repeating wave-shaped tooth pattern" and provides an illustration from Ex. 1001, Figure 8G. Resp. 52.



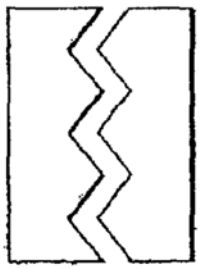
Multi-Toothed Waved



Offset-L Tooth

Patent Owner asserts that the triangular protrusions found in Nishioka are not a wave pattern. *Id.* 53. Specifically, Patent Owner contends that the staggered serrations of Nishioka are triangularly shaped teeth, and thus not a "multi-toothed wave" or "an opposed 'L'-shaped tooth pattern," as required by claim 12. *Id.* at 52–53

Petitioner rejoins that Dr. Nicosia testified that one of ordinary skill in the art would recognize that a multi toothed wave includes the triangular wave pattern of Nishioka. Reply 30–31, citing Ex. 1011 ¶ 42. Moreover, Petitioner observes that the claim should not be limited to a preferred embodiment when others are described in the specification, including the multi-tooth pointed of Fig. 8G.



Multi-Tooth Pointed

On balance, we find the Petitioner's evidence and argument more compelling. The illustration of a multi toothed waved sinusoidal jaw profile in Ex. 1001 is exemplary, absent more specific and persuasive evidence of a specific definition made by the specification restricting the wave to the illustrated sinusoidal shape.

Accordingly, we conclude that Petitioner has established by a preponderance of evidence that Claim 12 is anticipated by Nishioka.

Therefore, we conclude the Petition has established by a preponderance of the evidence that claims 1-3 and 7-12 are unpatentable as anticipated by Nishioka.

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

Petitioner next 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 mem-ber 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

Shinozuka is directed to a "Biotissue Clip Device." Ex. 1010, 10[5] The clip is said to be detachably coupled to a control. Pet. 34–35 citing Ex. 1011 ¶ 47, Ex. 1010, 11. Nishioka is relied upon for the description discussed above. Petitioner urges that Shinozuka describes the claimed clip-tightening ring, or "sleeve" of claim 13. Pet. 33. Figure 5 of Shinozuka is reproduced below:

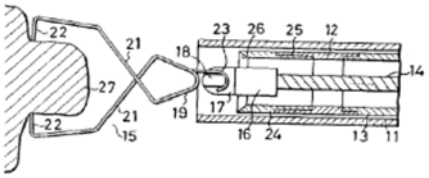


Figure 5 is a cross sectional view of a biotissue clip. Ex. 1010, 12.

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

5 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.

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:

> 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.

Patent Owner urges that in ground 2, neither Nishioka nor Shinozuka discloses a linkage contacting the inner surfaces of the first and second clip legs. Patent Owner Sur-Reply 1. This argument has merit as regards embodiment 1 of Nishioka, as stated above, but is not persuasive as regards embodiment 2, which describes the linkage as claimed.

Patent Owner next urges that there is no motivation to combine Nishioka and Shinozuka. Patent Owner Sur-Reply, 7–8. More specifically, Patent Owner states that Nishioka states throughout its description that the biopsy forceps are used only for cutting biopsy specimens. *Id.* at 8.

For example, we are directed to the Abstract which introduces a "biopsy forceps device" for "biopsy sampling at a site within the body." Ex. 1005, Abstract. The Abstract further describes that "[t]he fiber tip is

positioned coaxially with the jaws at the zone of contact and cutting of the jaws . . . ." *Id.* Continuing on, the Summary of the Invention discloses that the biopsy forceps "includ[e] cutting jaws mounted at the distal end of the catheter body for selective opening and closing in a biopsy cutting movement in the tissue analysis zone." *Id.* at 2:11–14.

Patent Owner observes that Nishioka's biopsy forceps functioned effectively to cut a biopsy sample at a site within the body, and that Petitioners did not supply any evidence that a POSITA would be motivated to modify Nishioka so that it would not cut tissue to obtain a biopsy sample. Patent Owner Sur-Reply 13.

Petitioner asserts that the combination of Nishioka and Shinozuki is designed to provide a clip that can be left behind in the body. Petitioner's Supplemental Reply 12. This will result in the situation where the tissue dies and drops off. *Id*. This is said to be consistent with Nishioka's purpose of performing diagnosis of conditions. *Id.* at 13–14. Petitioner asserts that the proposed combination does not require Nishioka's visualization and cutting uses in order to obtain the benefits described in Shinozuka. *Id*. at 15.

We observe that Nishioka is designed to be inserted into the body and to be removed with a sample of tissue. It uses a fiber optic device that enables the tissue between the jaws to be positively identified. 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. The intent of Nishioka is to identify or retrieve tissue.

In stark contrast, 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, Shinozuka discusses the drawback of bleeding resulting from cutting endoscopically. Ex. 1010, 10. 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 10–11. Shinozuka then goes on to discuss the benefits of its device which is easily detachable. *Id.* at 11.

Leaving the tissue in place, to die and drop off, would frustrate the purpose of Nishioka's clip entirely – which is designed to retrieve the tissue, issues of optical identification aside.

We therefore are not persuaded by Petitioner's contention, which appears to be impermissible hindsight. Patent Owner correctly observes that the purpose of the jaws and linkage is to close about tissue and retrieve it, even if the tool has other purposes. Patent Owner Sur Reply 9. We remain unconvinced that a biopsy tool's jaws would be modified such that the tool could no longer retrieve a sample and the sample would be left in place to die and drop off to prevent bleeding.

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 hindsight based.

On this record, we are therefore not persuaded that Petitioner has established by a preponderance of evidence that claims 13–14 and 16–19 are unpatentable as obvious over Nishioka and Shinozuka.

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

1. Overview of Matsuno (Ex. 1016)

Petitioner asserts that Nishioka describes all the elements 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:

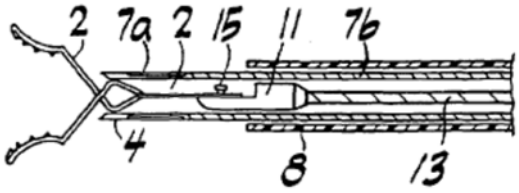


FIG. 6

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:

> 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.
>
> 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 the loss of the key functions of the Nishioka device – to identify and excise tissue samples. A 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 motivation to make the combination in the first place. Moreover, the loss of both functions in Nishioka again is such that it would not satisfy its intended purpose. We find this combination most likely motivated solely by impermissible hindsight.

On this record, we are therefore not persuaded that Petitioner has established by a preponderance of the evidence that claims 4–6 and 13–20 are unpatentable as obvious over Nishioka and Matsuna.

H. The Motion to Exclude.

The Motion to Exclude (Paper 33) seeks exclusion of exhibits 1009, 1010, 1011 (partially), 1016, 1017, 1047, 1070, 1071, 1072, 1073, 1074, 1075, 1079, and 1084. Paper 33, 1.

As regards exhibits 1009, 1010, 1011, 1016, the grounds asserted for exclusion are that the exhibits relate to grounds that were not instituted. Paper 33, 1–3. As those grounds were later instituted in Paper 55, we deny this portion of the motion.

As regards exhibits 1017, 1047, 1071, 1072, 1073, 1074, 1075, 1079, and 1084, we dismiss this motion as the decision does not rely upon any of those exhibits.

As regards exhibit 1070, Patent Owner asserts that it should be excluded as irrelevant under FRE 402, and even if relevant, subject to

exclusion under FRE 403. Objections were timely made on December 15, 2017 in Paper 24 at II(A), (C), and (D). Paper 33, 4.

Patent Owner observes that Exhibit 1070 is an article by DeBeer, entitled "Colonic lipomas, An endoscopic Analysis," Gastrointestinal Endoscopy, Volume 22, No. 2 (1975). Patent Owner asserts that Petitioners cite Exhibit 1070 on pages 9–10 of the Reply Brief and on pages 10–11 of Nicosia's Reply Declaration, seeking to rely on DeBeer's description of biopsy forceps allegedly being used to "grasp and 'pull[] up' mucosa in the body, causing the mucosa to 'tent[] away' from underlying tissue mass." Paper 33, 5, citing Reply Brief at 9.

Patent Owner urges that Exhibit 1070 is "irrelevant because the articles describe biopsy forceps other than the Nishioka biopsy forceps. Petitioners attempt to reframe the issue as whether biopsy forceps in general can apply a compressive or pinching pressure. This *Inter Partes* Review, however, is focused only on whether the Nishioka biopsy forceps anticipate the claims of the '027 Patent, not whether biopsy forceps in general are anticipatory. Thus, Exhibit[]1070 [is] irrelevant to this *Inter Partes* Review." Paper 33, 5–6.

Petitioner observes that Patent Owner made the argument through Dr. Vaitekunas "that 'cutting and pinching tissue are mutually exclusive,' (*id*. at 22), and that the mere fact that Nishioka's biopsy forceps are sharp, serrated, and meshing "makes [Nishioka's] jaws unsuited for pinching tissue using a compression force." Paper 41, 6, citing Paper 14, 22–23. This exhibit, along with others, was presented to establish that "contrary to BSSI's and Dr. Vaitekunas' assertions, biopsy forceps with sharp, meshing, and serrated

jaws are capable of pinching and compressing tissue (including causing hemostasis). Paper 41, 7, citing Ex.1068 ¶¶14–22.

Patent Owner rejoins that Exhibit 1070 relates to a different forceps, and is irrelevant. Paper 43, 3.

We do not think Exhibit 1070 is irrelevant. It was introduced to support the Petitioner's argument raised to counter the general statement made by Patent Owner that cutting and pinching are mutually exclusive. As Patent Owner placed the end use of the forceps into play in the first instance, in our view it is only fair that Petitioner could raise evidence to counter that proposition. Accordingly, this motion is denied as to Exhibit 1070.

VIII. CONCLUSION

For the foregoing reasons, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–3 and 7–12 are unpatentable as anticipated by Nishioka.

We also determine that Petitioner has not shown by a preponderance of evidence that claims 4–6 and 13–20 are unpatentable as obvious over Nishioka and either of Shinozuka and Matsuna.

IX. ORDER

Accordingly, it is:

ORDERED that claims 1–3 and 7–12 of the '027 patent are held to be unpatentable; and

ORDERED that Patent Owner's motion to exclude is DENIED in part and DISMISSED in part, and

FURTHER ORDERED that, because this is a Final Written Decision, parties to this proceeding seeking judicial review of our decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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