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Paper No. 71
Entered: November 14, 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 IPR2017-00132
Patent 8,685,048 B2

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

TARTAL, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
Inter Partes Review
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Cook Group Incorporated and Cook Medical LLC ("Petitioner") filed a Petition (Paper 1, "Pet.") challenging the patentability of claims 1–3, 5–18, and 20–30 of U.S. Patent No. 8,685,048 B2 (Ex. 1023, "the '048 patent"), owned by Boston Scientific Scimed, Inc. ("Patent Owner"). We have jurisdiction under 35 U.S.C. § 6(c) to hear this *inter partes* review instituted pursuant to 35 U.S.C. § 314. In this Final Written Decision, issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73, we deny Patent Owner's Motion to Exclude (Paper 36) and find on the record before us that Petitioner has shown by a preponderance of the evidence only that claims 29 and 30 of the '048 patent are unpatentable. *See* 35 U.S.C. § 316(e).

A. PROCEDURAL HISTORY

Petitioner filed a Petition requesting institution of *inter partes* review of claims 1–3, 5–18, and 20–30 of the '048 patent. Pet. 9. Patent Owner filed a Preliminary Response (Paper 6, "Prelim. Resp."). We initially instituted review only of challenged claims 1, 3, 5–14, 29, and 30, because we determined the Petition showed a reasonable likelihood that Petitioner would prevail as to those challenged claims on the following two grounds:

References	Basis	Claims challenged
Komiya[1] and Crockard[2]	§ 103	1, 3, 5–14
Shinozuka[3] and Matsuno[4]	§ 103	29 and 30

Paper 7 ("Inst. Dec."); *see also* 35 U.S.C. § 314.

[1] U.S. Patent No. 3,958,576, iss. May 25, 1976 (Ex. 1014, "Komiya").
[2] U.S. Patent No. 5,174,276, iss. Dec. 29, 1992 (Ex. 1019, "Crockard").
[3] Japanese Unexamined Patent Application Publication No. 60-103946, pub. Jun. 8, 1985 (Ex. 1009, "Shinozuka").
[4] U.S. Patent No. 5,766,189, iss. Jun. 16, 1998 (Ex. 1016, "Matsuno").

After institution of *inter partes* review, Patent Owner filed a Response to the two grounds instituted. Paper 16; Paper 15 (publicly available redacted version of the Patent Owner Response) ("PO Resp."). Petitioner filed a Reply to the Patent Owner Response. Paper 26 ("Pet. Reply").

Patent Owner also filed a Motion to Exclude exhibits and expert testimony (Paper 36, "Mot."), to which Petitioner filed a Response in opposition (Paper 44, "Mot. Resp."), further to which Patent Owner filed a Reply in support (Paper 47, "Mot. Reply"). Oral argument was held before the Board on February 8, 2018. Paper 53 ("Feb. Tr.").

After the February oral argument in this case, the Supreme Court held in *SAS Inst., Inc. v. Iancu* that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. 138 S. Ct. 1348, 1359–60 (2018). As explained above, prior to *SAS Inst.*, we had not instituted review on all of the claims challenged in the Petition. *See* Inst. Dec. 20. In accordance with *SAS Inst.*, we modified the Institution Decision to include review of all challenged claims on all grounds asserted in the Petition. Paper 55, 4. In particular, we further instituted review on the following claims and bases asserted in the Petition:

References	Basis	Claims challenged
Komiya	§ 102	1–3, 5–18, and 20–28
Komiya	§ 103	2 and 17
Komiya and Crockard	§ 103	21, 24, 25, 27, and 28

Id. at 2–4; *see also* Paper 54 (providing that good cause existed to extend the one-year period for issuing a final written decision by up to an additional six months).

In addition to authorizing certain additional briefing and modifying the schedule, we also authorized the Parties to file a joint motion to limit the proceeding. Paper 56, 7–8. Subsequently, the Parties filed a Joint Motion to Limit the Proceeding (Paper 58), which we granted in the interest of resolving this proceeding in a just, speedy, and inexpensive manner. Paper 59, 2–3 (citing 37 C.F.R. § 42.1(b)). Accordingly, this proceeding is limited as requested by the Parties to the following grounds:

References	Basis	Claims challenged
Komiya	§ 102	1–3 and 5–14
Komiya	§ 103	2
Komiya and Crockard	§ 103	1, 3, and 5–14
Shinozuka and Matsuno	§ 103	29 and 30

Id. at 3.

Patent Owner filed a Supplemental Patent Owner Response to address claims and grounds not addressed in the Patent Owner Response. Paper 60 ("PO Supp. Resp."). In particular, with our prior authorization, Patent Owner adopted the arguments it presented in its Preliminary Response (pages 19–25 and 30–31) as its opposition to the grounds based on anticipation by, or obviousness over, Komiya. PO Supp. Resp. 2. Petitioner filed a Supplemental Reply. Paper 61 (Pet. Supp. Reply). Patent Owner filed a Surreply. Paper 66 ("PO Surreply"). Supplemental oral argument was held before the Board on September 17, 2018. Paper 69 ("Sep. Tr.").

B. RELATED MATTERS

According to the Parties, the '048 patent is a subject of a case captioned *Boston Scientific Corp. v. Cook Group Inc.*, Case No. 1:15-cv-00980-LPS-CJB (D. Del.). Pet. 1; Paper 4, 2. The Parties also state that the

following pending patent applications are related to the ’048 patent: U.S. Patent Application Nos. 14/988,447; 15/009,358; and 15/091,147. Pet. 2; Paper 4, 2.

A second petition concurrently filed by Petitioner challenging claims 1–30 of the ’048 patent in Case IPR2017-00131 was denied institution. *Cook Group Inc. and Cook Medical LLC v. Boston Scientific Scimed, Inc.*, Case IPR2017-00131, slip op. at 15 (PTAB May 15, 2017) (Paper 13). Petitioner also filed petitions challenging claims of related patents in the following cases: U.S. Patent No. 8,709,027 in Case IPR2017-00133 and Case IPR2017-00134; U.S. Patent No. 8,974,371 in Case IPR2017-00135; and U.S. Patent No. 9,271,731 in Case IPR2017-00435 and Case IPR2017-00440. *See* Paper 4, 3; *see also Cook Group Inc. and Cook Medical LLC v. Boston Scientific Scimed, Inc.*, Case IPR2017-00440, Paper 3, 2–3.

C. REAL PARTIES IN INTEREST

Petitioner identifies Cook Group Inc., Cook Medical LLC, Cook Inc., and Cook Medical Technologies LLC as real parties in interest. Pet. 1. Patent Owner identifies Boston Scientific Scimed, Inc. and Boston Scientific Corp. as real parties in interest. Paper 4, 2.

II. BACKGROUND

The ’048 patent, titled “Device and Method for Through the Scope Endoscopic Hemostatic Clipping,” issued April 1, 2014, from U.S. Application No. 13/863,494 (the ’494 application), filed April 16, 2013. Ex. 1023. As background information, below we provide a summary of the ’048 patent, along with two illustrative claims from the ’048 patent, and we identify the proffered witness testimony.

A. SUMMARY OF THE '048 PATENT

The '048 patent generally relates to devices and methods of causing hemostasis of blood vessels using a clip delivered through an endoscope. Ex. 1023, Abstract. A focus of the invention is to provide medical devices that cause hemostasis of blood vessels along the gastrointestinal tract. *Id*. at 2:50–52. 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 2:58–62. 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 2:62–3:4.

The '048 patent discloses several distinct embodiments that may be used to detach a clip from a delivery device. One embodiment uses a ball and socket to detach the clip from the delivery device, as illustrated in Figures 12A and 12B of the '048 patent (the "Figure 12 Embodiment").

Figures 12A and 12B of the ’048 patent are reproduced below.

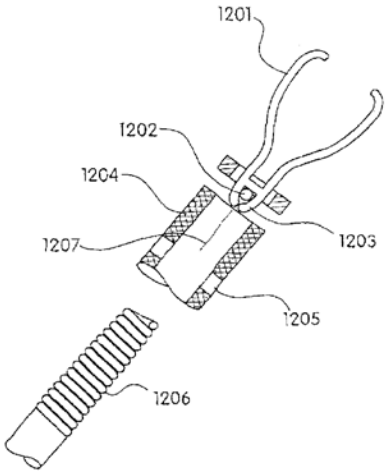


FIG. 12A

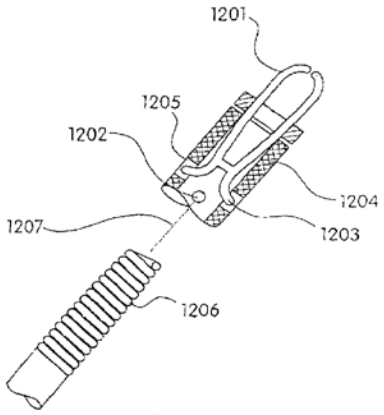


FIG. 12B

A partial view of the claimed device is illustrated showing clip 1201 in an open position in Figure 12A and in a closed position in Figure 12B. Ex. 1023, 4:12–16. The elements shown include clip 1201 with socket tabs 1203, outer sleeve 1204 attached by way of a breakaway connection (not shown) to sheath 1206, and ball 1202 formed on the end of control wire 1207. *Id.* at 9:46–62. Ball 1202 on control wire 1207 fits into a socket defined by socket tabs 1203 of clip 1201 to attach control wire 1207 to clip 1201. *Id.* at 9:47–50.

Clip 1201 is released when socket tabs 1203 are aligned with cut-outs 1205 in outer sleeve 1204. *Id.* at 9:56–59. In particular, “cut-outs 1205 act as a relief area into which the socket tabs 1203 can be deformed when a predetermined tensile load is applied to them via the ball 1202.” *Id.* at 9:59–62. Outer sleeve 1204 is released with clip 1201 so that clip 1201 remains locked after deployment. *Id.* at 9:62–64.

B. ILLUSTRATIVE CLAIMS

Of the claims at issue, claims 1 and 29 are independent. Claims 2, 3, and 5–14 depend from claim 1. Claim 30 depends from claim 29. Claims 1 and 29, reproduced below, are illustrative of the claimed subject matter:

> 1. A medical device, comprising:
> a clip having first and second clip legs;
> a control wire being operable both to open the clip legs and to close the clip legs;
> a sheath enclosing the control wire;
> a link coupling the control wire to the clip, the link being movable from a coupled configuration in which the clip is coupled to a distal end of the control wire to a released configuration in which first and second arms of the link are configured to move radially outward at an area of the sheath to release the control wire from the clip; and
> an actuator coupled to the control wire, the control wire engageable by the actuator to move the control wire to open and close the clip legs and to move the link from the coupled configuration to the released configuration.

Ex. 1023, 15:32–46.

> 29. A method, comprising:
> inserting a medical device comprising a clip having first and second clip legs, a control wire, a sheath enclosing the control wire and a proximal portion of the clip;
> positioning the medical device at a desired deployment location;
> moving the control wire distally relative to the sheath to deploy the first and second clip legs distally from the sheath;
> adjusting a position of the clip so that target tissue is received between the first and second clip legs;
> drawing the control wire proximally relative to the sheath to draw the clip into the sheath to receive the target tissue between the first and second clip legs;
> applying a tensile force of at least a threshold level to the control wire to separate a separable link coupling the control wire to the clip.

Id. at 18:3–19.

C. PROFFERED WITNESS DECLARATIONS

Petitioner supports its challenge with the Declaration of Mark A. Nicosia, PhD., dated October 27, 2016 (Ex. 1026), the reply declaration of Dr. Nicosia, dated December 8, 2017 (Ex. 1045), and the supplemental reply declaration of Dr. Nicosia, dated August 3, 2018 (Ex. 1105). Dr. Nicosia is a Professor and Chairman of the Department of Mechanical Engineering at Widener University. Ex. 1026 ¶ 4. Dr. Nicosia states that he has "conducted and published peer-reviewed research in the fields of hemostatic clips, oropharyngeal swallowing, esophageal peristalsis, and biomechanical modeling of the human body," and that he is a co-inventor on a patent directed towards hemostatic clips for closing surgical wounds. *Id.* ¶¶ 5–6.[5]

In support of its opposition, Patent Owner relies on the Declaration of Dr. Jeffrey Vaitekunas, Ph.D., dated September 1, 2017. Ex. 2010 (filed under the same exhibit number in both a redacted version and under seal in an unredacted version). Dr. Vaitekunas is an Assistant Professor at Penn State University in the Mechanical Engineering Technology department. *Id.* ¶ 4. Dr. Vaitekunas states that he has worked or been involved in the field of medical device design for over 25 years, including "seven years as a development engineer, responsible for designing and developing laparoscopic medical devices including clip appliers, biopsy forceps and other instruments designed for cutting and coagulation of tissues," and that

[5] Petitioner also provides a declaration and a corrected declaration from James Thornton certifying and attaching a translation from Japanese to English of Shinozuka. Exs. 1010 and 1042.

he is the inventor on a patent directed to a laparoscopic clip applier system. *Id.* ¶ 5.

Patent Owner also relies on the Declaration of Demetrios Petrou, dated August 31, 2017. Ex. 2028 (filed under the same exhibit number in both a redacted version and under seal in an unredacted version). Mr. Petrou is employed by Boston Scientific Corporation as the Global Group Product Manager for GI Therapies and supported the sales force in 2015 and 2016 with hemostatic devices including the Resolution ™ and Resolution 360™ clips. Ex. 2028 ¶ 2.

III. ANALYSIS

In our analysis of Petitioner's unpatentability contentions with respect to claims 1–3, 5–14, 29, and 30 of the '048 patent, we next address the applicable principals of law; the level of ordinary skill in the art, the construction of the claim terms "sheath," "at an area of," and "first and second arms of the link are configured . . . to release the control wire from the clip"; the scope and content of the asserted prior art of Komiya, Crockard, Shinozuka, and Matsuno; the differences between the claimed subject matter and the asserted prior art; the objective evidence of nonobviousness; and, finally, the reasons supporting obviousness.

A. PRINCIPLES OF LAW

To prevail in its challenge to the patentability of claims 1–3, 5–14, 29, and 30 of the '048 patent, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). "In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016)

(citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326–27 (Fed. Cir. 2008)) (discussing the burden of proof in *inter partes* review).

In an *inter partes* review, "[a] claim in an unexpired patent . . . shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (upholding the use of the broadest reasonable interpretation standard). In determining the broadest reasonable construction, we presume that claim terms carry their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). A patentee may define a claim term in a manner that differs from its ordinary meaning; however, any special definitions must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

A claim is anticipated if a single prior art reference either expressly or inherently discloses every limitation of the claim. *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 975 (Fed. Cir. 2010). "A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference." *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014) (citing *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

A patent claim is unpatentable as obvious 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). An invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 418 (2007). Rather, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.*

An obviousness determination "cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)); *see In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). 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. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

B. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, 35 U.S.C. § 103 requires us to resolve the level of ordinary skill in the pertinent art at the time of the invention. *Graham*, 383 U.S. at 17. "The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry."

Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 718 (Fed. Cir. 1991). The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Factors that may be considered in determining the level of ordinary skill in the art include, but are not limited to, the types of problems encountered in the art, the sophistication of the technology, and educational level of active workers in the field. *Id.* In a given case, one or more factors may predominate. *Id.* Generally, it is easier to establish obviousness under a higher level of ordinary skill in the art. *Innovention Toys, LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1323 (Fed. Cir. 2011) ("A less sophisticated level of skill generally favors a determination of nonobviousness . . . while a higher level of skill favors the reverse.").

Petitioner contends that a person of ordinary skill in the art at the time of the claimed invention "would have possessed the knowledge and skill known by an engineer or similar professional with at least an undergraduate degree in engineering, or a physician having experience with designing medical devices," and "would also have an understanding of engineering or medical device design principles." Pet. 11 (citing Ex. 1026 ¶ 11). Patent Owner does not contest Petitioner's asserted level of ordinary skill in the art.

Based on the evidence provided, including the prior art of record, we agree with Petitioner's proposed level of ordinary skill and also find that the prior art of record further reflects the level of ordinary skill in the art. *See also Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (noting that the prior art of record may reflect the level of ordinary skill in the art).

C. CLAIM CONSTRUCTION

1. "sheath"

Claim 1 of the '048 patent recites "a sheath enclosing the control wire." Ex. 1023, 15:36. Claim 29 similarly recites "a sheath enclosing the control wire and a proximal portion of the clip." *Id.* at 18:5–6. Purportedly based on Patent Owner's contentions in related district court proceedings, Petitioner contends that the term "sheath" means "one or more components that enclose the control wire" and that it "may include components of the clip assembly that are left behind in the body." Pet. 13 (further providing an annotated Fig. 12B of the '048 patent illustrating outersleeve 1204 corresponding to a "sheath" that is a component of the clip assembly that detaches from sheath 1206 during delivery and remains in the body). Patent Owner does not dispute Petitioner's proposed construction. PO Resp. 8.

Even in the absence of any opposition from Patent Owner, to the extent Petitioner's proposed construction is merely duplicative of the claim language, we find it unhelpful in expressly construing the claim language. In particular, there is no benefit in defining "sheath" to mean components "that enclose the control wire" when, for example, claim recites 1 recites "a sheath enclosing the control wire." Petitioner, however, has sufficiently shown that a "sheath" may include one or more components and that it may include components of the clip assembly left behind in the body. An express construction of "sheath" is not necessary. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy").

2. "at an area of"

Claim 1 recites "the link being movable from a coupled configuration . . . to a released configuration in which first and second arms of the link are configured to move radially outward *at an area of* the sheath to release the control wire from the clip." Ex. 1023 15:37–42 (emphasis added). Petitioner did not construe "at an area of" in the Petition. Patent Owner contends that "at an area of" means "within," such that "at an area of the sheath" means "within the one or more components that enclose the control wire." PO Resp. 8. Patent Owner contends its proposed construction is consistent with the Figure 12 Embodiment of the '048 patent, which illustrates socket tabs 1203 move radially into cut-outs 1205 within outersleeve 1204 (corresponding to the recited "sheath"). *Id*. at 9.

Patent Owner further argues that the ordinary meaning of "area," as supported by dictionary definitions, is "the 'extent' or 'range' of some thing." *Id.* at 10 (citing Exs. 2012, 2013, 2014). Patent Owner further reasons that "[s]ince the sheath is a three dimensional structure (or structures) that encloses the control wire, it follows that the range or extent of the three-dimensional sheath denotes 'within' or 'inside the range of' the sheath." *Id.* at 10 (citing Exs. 2015, 2016, 2017) (emphasis omitted). Further, according to Patent Owner, Dr. Nicosia testified that he understood "at an area of the sheath" to mean "inside the sheath, within the lumen." *Id.* at 11 (quoting Ex. 2011, 44:12–15). Patent Owner also asserts that the Parties agreed in the district court proceeding "to construe 'at an area of the sheath' to mean '*within* the lumen or wall of the sheath.'" *Id.* at 11 (quoting and emphasizing Ex. 2003, 1 n.1).

In its Reply, Petitioner does not dispute Patent Owner's proposed construction and instead states that we need not address this claim term because the proposed combination of Komiya and Crockard meets this limitation even if it is construed as proposed by Patent Owner. Pet. Reply 2. Accordingly, Patent Owner has persuasively shown that "at an area of" means "within."

3. "first and second arms of the link are configured to move radially outward . . . to release the control wire from the clip"

Claim 1 recites "the link being movable from a coupled configuration . . . to a released configuration in which first and second arms of the link *are configured to move* radially outward at an area of the sheath *to release the control wire* from the clip." Ex. 1023 15:37–42 (emphasis added). Petitioner contends in its Supplemental Reply that the recited "released configuration" only requires that the radially outward movement of the link arms "allows or leads to the control wire releasing from the clip," and does not require "simultaneous movement and release." Pet. Supp. Reply 2–3. Petitioner further asserts that the absence of "any simultaneous requirement" in claim 1 is apparent because other claims of the '048 patent include a temporal requirement by using language such as "when" or "as." *Id.* at 3. Dr. Nicosia supports Petitioner's construction and reasons that the claim language only requires that "the control wire *cannot* be released from the clip until the link arms move radially outward," even if "some steps are necessary after the radially outward movement" to release the clip. Ex. 1105 ¶¶ 8–10.

Patent Owner asserts that claim 1 "requires that the radially outward movement of the link arms release the control wire from the clip to cause the link to have the requisite released configuration." PO Surreply 2. Patent

Owner shows that its proposed construction is consistent with the Figure 12 Embodiment of the ’048 patent, discussed above, in which clip 1201 is released by the radially outward movement of link arms (socket tabs 1203). *Id.* at 3–4 (citing Ex. 1023, 9:46–64, Figs. 12A, 12 B). Patent Owner also contends that neither the use of “when” in claim 11 “to recite what happens when a tensile load is applied” nor the use of “as” in claim 15 “to recite what happens when the clip ‘legs spread laterally away from the control wire,’” “derogates from claim 1’s unequivocal recitation that a ‘released configuration’ is one in which the link arms move radially outward to release the control wire from the clip.” PO Surreply 5. We agree with Patent Owner that the recitation in the ’048 patent of “as” in claim 11 or “when” in claim 15 does not alter or distinguish the plain meaning of claim 1.

On its face, Petitioner’s construction appears inconsistent with the claim language, which recites a “released configuration,” not a configuration that “allows or leads” to release. Moreover, the claim language “configured to” requires structure designed to perform the function, not merely structure capable of performing the function. *See Aspex Eyeware, Inc. v. Marchon Eyeware, Inc.*, 672 F.3d 1335, 1349 (Fed. Cir. 2012). Petitioner’s attempt to focus the construction on whether the recited “released configuration” contains a “simultaneous” component is misplaced. The plain language of claim 1 is not directed to the timing of the release, but to what is configured to cause the release of the control wire from the clip. The arms of the link must be “configured to move radially outward . . . to release the control wire from the clip” to constitute the claimed “released configuration.” Thus, it is

the radially outward movement of the arms of the link that must cause the control wire to release from the clip in accordance with claim 1.

Petitioner's proposed construction of the "released configuration" turns this requirement into a nullity by eliminating any causation and requiring merely that the radially outward movement of the arms of the link "allows or leads to the control wire releasing from the clip." Virtually any step in the operation of the device may be said to "allow" or "lead" to some subsequent step, no matter how far removed. The claim language, however, is narrower than that and recites "configured . . . to release the control wire," not "configured . . . to *allow* release *of* the control wire" or "configured . . . to *lead to* release *of* the control wire." Dr. Nicosia's suggestion that the claim language only requires that "the control wire *cannot* be released from the clip until the link arms move radially outward" likewise would encompass any radially outward movement of the link arms for any purpose unrelated to the release of the clip, so long as it necessarily precedes the release of the clip. We find no persuasive support for such a broad construction.

Thus, we are not persuaded that the claimed "released configuration" encompasses all radial movement of link arms that leads to or allows the possibility that the clip might be released from the control wire simply because the radial movement precedes the release of the clip. The link arms must not only be "configured to move radially outward," but that configuration is expressly required "to release the control wire from the clip." Accordingly, the plain language of claim 1 requires that the radially outward movement of the link arms causes the release of the control wire from the clip, regardless of whether that release occurs simultaneous with

the movement or subsequent to the movement of the link arms. No further express construction is necessary. Whether the asserted prior art discloses this limitation is a separate issue addressed below.[6]

D. Scope and Content of the Prior Art

To demonstrate the unpatentability of the challenged claims of the '048 patent, Petitioner relies on Komiya, Crockard, Shinozuka, and Matsuno, each of which is briefly summarized below.

1. Summary of Komiya

Komiya, titled "Surgical Instrument for Clipping Any Affected Portion of a Body," describes a clip member detachably attached to an instrument body. Ex. 1014, Abstract; s*ee also* Pet. 14; PO Resp. 16–19 (describing Komiya).

[6] Petitioner asserts that the Institution Decision originally denied institution of grounds based on Komiya because the Board "incorrectly assumed" that claim 1 required "that the [link] arms move 'radially outward' *simultaneously* with the 'release [of] the control wire from the clip." Pet. Supp. Reply 1; *see also* Sep. Tr. 6:13–18 (same). Petitioner's assertion is incorrect. The Institution Decision did not construe the claim term at issue and did not apply an "assumed" meaning. *See* Inst. Dec. 7–8. Instead, institution of the ground based on Komiya was initially denied because Petitioner "fail[ed] to explain how radial movement of the link arms of Komiya corresponds to the release of the control wire from the clip." *Id.* at 11. Having modified our decision on institution to include all grounds and claims asserted in the Petition, below we revisit Petitioner's contentions based on Komiya anew in light of the record as fully developed during the trial.

Figures 1 and 2 of Komiya are reproduced below.

FIG. 1

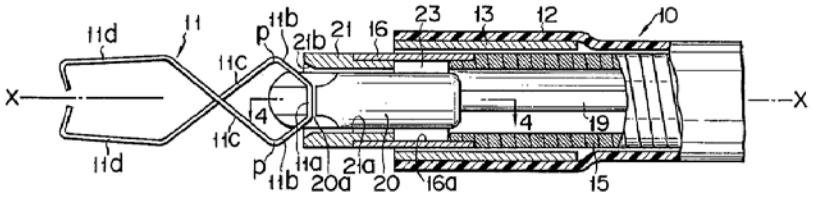
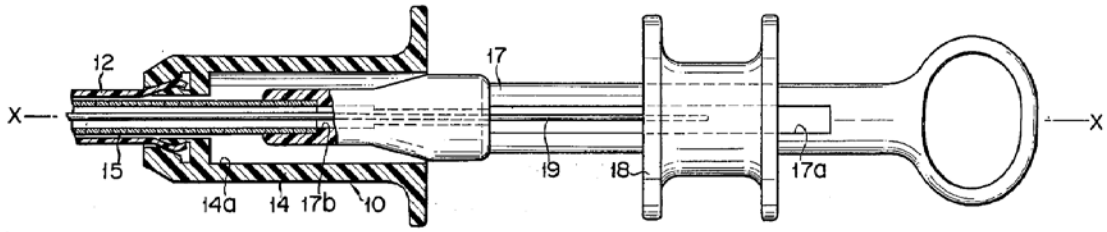


FIG. 2



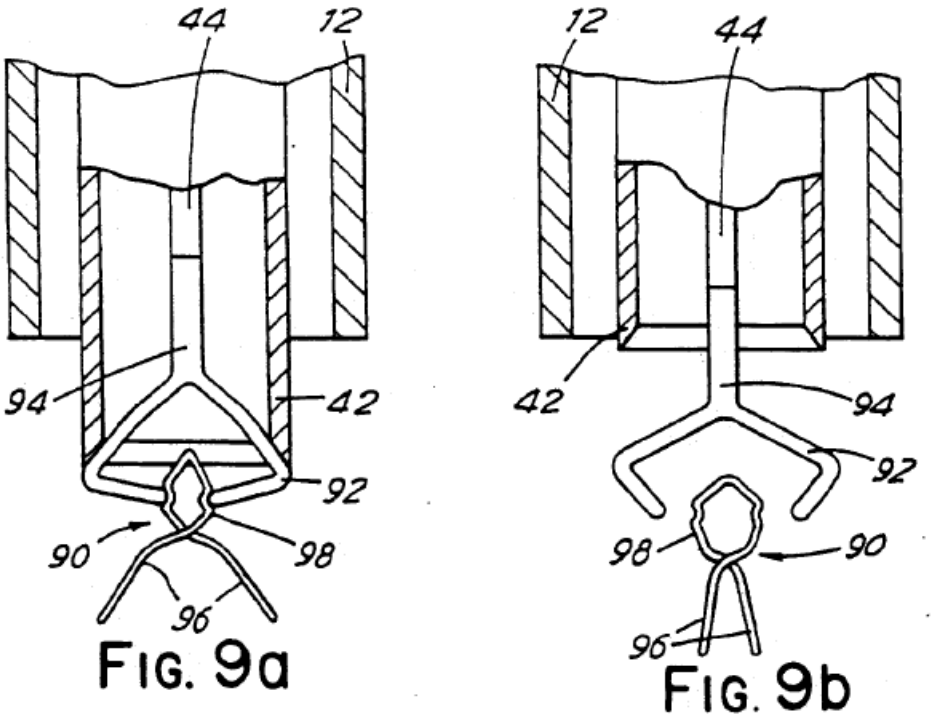
Figures 1 and 2 illustrate a partial side view, partly broken away, of a surgical instrument for clipping an affected portion of a body cavity, with Figure 1 directed to the forward end of a surgical body and Figure 2 directed to the base portion of a surgical body. Ex. 1014, 1:6–8, 2:22–26. Clip member 11 is attached at the forward end of body 10 while outer flexible tube 12 extends from the forward end shown in Figure 1 toward the base of the instrument shown in Figure 2. *Id.* at 2:43–45, 2:65–3:1. A lengthy metal wire 19 is inserted within and over the length of actuating member 15. *Id.* at 3:28–29. Metal wire 19 is connected at its free end to hook member 20 and at its base end to sliding member 18. *Id.* at 3:29–33. "When the sliding member 18 is slidably moved relative to the operating member 17 the wire 19 is moved within the actuating member 15 and, in consequence, the hook

member 20 is axially moved within the forward end portion of the actuating member 15." *Id.* at 3:33–37. Cylindrical holder 21 constitutes an engaging means. *Id.* at 3:44–45. The operation of Komiya is discussed in further detail below.

2. Summary of Crockard

Crockard, titled "Endoscope Device for Applying an Aneurysm Clip," describes a device that includes an applicator for a clip comprising a remote actuator in the form of a flexible shaft inside a flexible conduit. Ex. 1019, Abstract; *see also* Pet. 15; PO Resp. 19–20 (describing Crockard).

Figures 9A and 9B of Crockard are reproduced below.



Figures 9a and 9b illustrate a section through an aneurysm clip applicator as described by Crockard, including steerable endoscope tube 12, flexible conduit 42, and shaft 44. Ex. 1019, 3:50–57. The applicator includes jaws 92, resiliently biased in the open position, pivotally mounted on stem 94 which is attached to the distal end of shaft 44. *Id.* at 7:46–51. Aneurysm

clip 90, comprised of two legs 96 and handle 98, is held in jaws 92. *Id.* at 7:55–64. When handle loop 98 of aneurysm clip 90 is squeezed closed by jaws 92, clip legs 96 move apart. *Id.* at 7:62–69, FIG. 9a. "When the applicator is withdrawn inside the conduit 42 of the surgical device [] the jaws are closed, since they are restrained against opening by the internal wall of the conduit 42." *Id.* at 7:52–55. When handle 98 is released, the resilience of the clip causes legs 96 to move together. *Id.* at 7:64–68.

3. Summary of Shinozuka

Shinozuka is directed to a "Biotissue Clip Device." Ex. 1009, 261; *see also* Pet. 16; PO Resp. 21–22 (describing Shinozuka). The device includes a clip detachably coupled to a control cord. *Id.* at 262.

Figures 2, 5, and 6 of Shinozuka are reproduced below:

Fig. 2

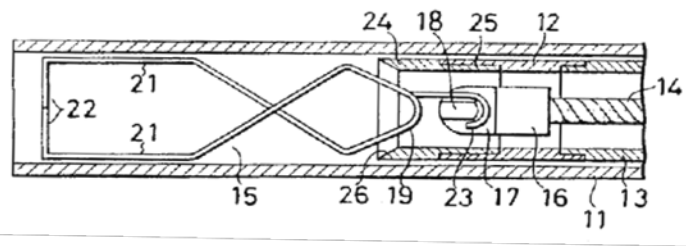


Fig. 5

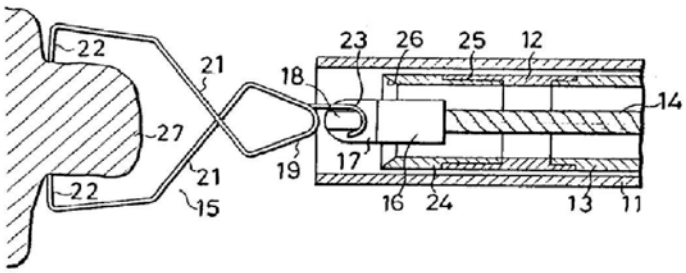
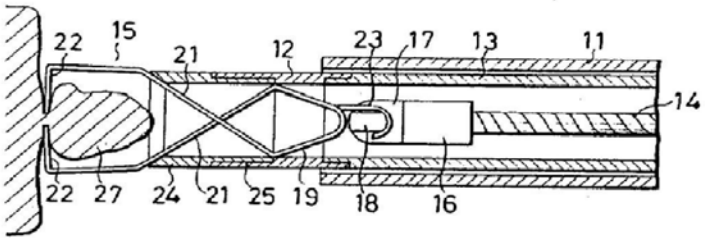


Fig. 6



Figures 2, 5, and 6 illustrate sectional side views of the distal end of an embodiment of the clip device of Shinozuka, with Figures 5 and 6 illustrating the device in use, including insertion tube 11, control tube 13, control wire 14, and hook 16 for detachably engaging with clip 15. *Id.* at 262–63. Clip 15 includes two arm parts 21, two pinching parts 22, and J shape claw 23 attached at base end part 19. *Id.* at 262. In a closed state, shown in Figure 2, hook 16 of control wire 14 is hooked onto claw 23 of clip 15, and clip 15 is drawn into insertion tube 11. *Id.* at 263. As shown in Figure 5, after insertion tube 11 is introduced through an endoscope into a body cavity, control wire 14 is pushed forward to project out and open clip 15. *Id.* As shown in Figure 6, control tube 13 may then be pushed, or control wire 14 may be pulled, to fit clip tightening ring 24 onto clip 15, thereby closing clip 15. When control wire 14 is "jiggled" hook 16 comes off claw 23 of clip 15. *Id.* Clip tightening ring 24 does not detach from clip 15 because it is compressing the rear half of clip 15, and is left inside the body along with clip 15. *Id.*

4. Summary of Matsuno

Matsuno, titled "Clip Device," is directed to a device used for hemostasis, marking, and ligation of a living tissue in a body cavity. Ex. 1016, 1:6–7; *see also* Pet. 17; PO Resp. 22–23 (describing Matsuno).

Figures 5 and 6 of Matsuno are reproduced below.

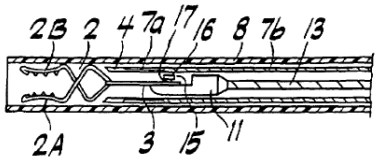


FIG. 5

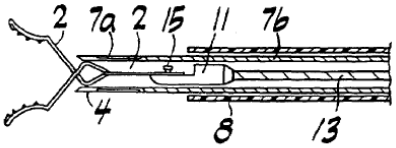


FIG. 6

Figure 5 illustrates a clip within a tube sheath and Figure 6 illustrates the clip open after being exposed from the tube sheath. Ex. 1016, 2:41–44. Petitioner contends that in Matsuno, clip 2 may be disengaged from control wire 13 by applying a sufficient tensile force to cause a hook portion of coupling plate 3 to straighten. Pet. 68–70 (*citing, inter alia*, Ex. 1016, 5:58–65). The operation of Matsuno is discussed in further detail below.

E. ASSERTED ANTICIPATION BY KOMIYA

Petitioner contends that claims 1–3 and 5–14 of the '048 patent are anticipated by Komiya. Pet. 18–39; Pet. Supp. Reply 4–20. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 19–26;[7] PO Surreply 6–14.

1. Claim 1

With regard to claim 1, Petitioner identifies how the device disclosed by Komiya operates, as well as which features of Komiya purportedly correspond to the recited features of claim 1. *See* Pet. 18–26. For example, with reference to Figures 5, 6, and 7 of Komiya, Petitioner contends that Komiya discloses clip 11 with clamping portions 11d corresponding to the claimed "clip having first and second clip legs," metal wire 19 and hook

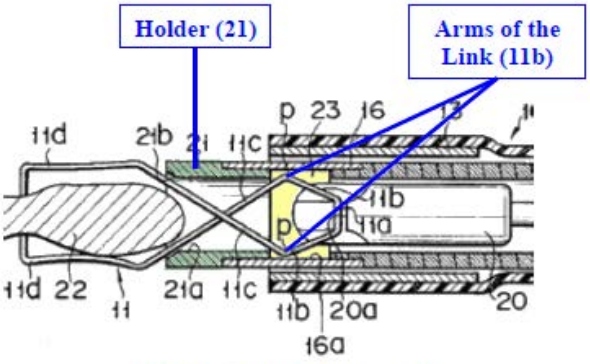
[7] As explained above, Patent Owner was authorized to rely on its Preliminary Response as to the asserted anticipation of claims by Komiya in lieu of filing a Supplemental Patent Owner Response because this ground of unpatentability was added to the review when the Institution Decision was modified after the Patent Owner Response was filed. *See* Paper 56, 7.

member 20 corresponding to the claimed "control wire," and tubular actuating member 15 and holder 21 corresponding to the claimed "sheath." Pet. 19–22. Petitioner further contends that the claimed "actuator" is disclosed by Komiya as an instrument body (shown in Komiya Figure 2) coupled to a control wire (metal wire 19 and hook member 20, not shown in Figure 2). *Id.* at 26.

Whether Petitioner has shown by a preponderance of the evidence that Komiya anticipates claim 1, however, turns on whether Komiya discloses the following limitation:

> the link being movable from a coupled configuration . . . to a released configuration in which first and second arms of the link are configured to move radially outward at an area of the sheath to release the control wire from the clip.

Ex. 1023, 15:37–42. Petitioner identifies hook member 20 and proximal end of clip 11 as corresponding to "a link coupling the control wire to the clip," as recited by claim 1. Pet. 23. Petitioner also provides the following annotated version of a portion of Figure 7 of Komiya to purportedly show that Komiya discloses the claimed "released configuration" of the movable link:



Id. at 25. The annotated portion of Figure 7 appears in the Petition and is labeled by Petitioner as "Released Configuration." *Id.* Contrary to

Petitioner's assertion, Komiya identifies Figure 7 as "an explanatory view showing the manner in which any diseased portion of the body cavity of a human being is clipped by the clip member," not as a "released configuration." Ex. 1014, 2:37–39.

The operation of Komiya is not in dispute. To clip the affected portion 22 of the body cavity, hook member 20 is retracted, "the offset portions 11*b* of the clip member 11 is positioned within the hole 16*a* of the guide member 16 and between the forward end of the actuating member 15 and the rear end of the holder 21," such that "the offset portions 11*b* of the clip member 11 are not urgingly compressed by the guide member 16." *Id.* at 4:67–5:10. Petitioner equates the claimed "configured to move radially outward at an area of the sheath" to the movement of the offset portions 11*b* of clip member 11 into hole 16*a*. Pet. 25.

Claim 1, however, requires more than radially outward movement of the link arms. Claim 1 requires that arms of the link are configured to move radially outward "to release the control wire from the clip." Petitioner's explanation of this feature is cursory and conclusory, as Petitioner argues as follows:

> In the released configuration reflected in Figure 7, the hook member 20 is able to detach from the proximal end of the clip (11), and thereby release the control wire (19, 20) from the clip (11). The radially outward movement of link arms (11b) in the released configuration also allows holder 21 to detach from guide member 16 and stay with clip (11). (Ex. 1014, 5:14–29; Ex. 1026, ¶ 41).

Pet. 25; *see also* Ex. 1026 ¶ 41 (the portion of Dr. Nicosia's declaration cited by Petitioner which is identical to what appears in the Petition). Contrary to Petitioner's argument, the portion of Komiya cited by Petitioner does not

address the radially outward movement of link arms but instead details a series of unrelated actions that occur to separate clip member 11 and holder 21 from instrument body 10. *See* Ex. 1014, 5:14–29. Notably, Komiya states that it is "by manipulating the endoscope, the rear end portion 11a of the clip member 11 is disengaged from the cutout 21a of the hook member 20." Ex. 1014, 5:24–27; *see also* Prelim. Resp. 19–20 (arguing that in Komiya it is the sideways movement of the forward end portion of the surgical instrument that causes the clip member to become disengaged).

Petitioner offers no persuasive explanation in the Petition to show that the movement of the offset portions 11*b* of clip member 11 into hole 16*a* in Komiya corresponds to arms of the link that are configured to move radially outward "to release the control wire from the clip." Petitioner's reasoning only became apparent in its Supplemental Reply in which it asserted for the first time that link arms configured to move radially outward "to release the control wire from the clip" simply means "outward movement of the link arms *allows* or *leads* to the control wire releasing from the clip." Pet. Supp. Reply 3 (emphasis added). For the reasons provided above in our claim construction discussion, Petitioner's proposed construction is unreasonably broad.

We further find that even under Petitioner's proposed construction, Petitioner has not persuasively shown that the radial movement of offset portions 11*b* of clip member 11 into hole 16*a* "allows or leads to the control wire releasing from the clip." Komiya explains that because offset portions 11*b* of clip member 11 are displaced into hole 16*a*, holder 21 is trapped at intersecting portions 11*c* of the clip member such that when sliding member 18 and wire 19 are pushed forward, holder 21 is moved out of engagement

and is pushed forward along with clip member 11. Ex. 1014 5:14–22. Thus, although the purported radial movement of offset portions 11*b* of clip member 11 "allows or leads to" holder 21 being *advanced* along with clip member 11, Petitioner has not shown persuasively that such radial movement of offset portions 11*b* of clip member 11 has any bearing on the control wire (metal wire 19 and hook member 20) releasing from clip member 11.

To the contrary, Komiya is clear: "[i]f after the complete exposure of the clip member 11 the forward end portion of the surgical instrument is moved sidewise, by manipulating the endoscope, the rear end portion 11*a* of the clip member 11 is disengaged from the cutout 21*a* of the hook member 20." *Id.* at 5:22–27. That is the action that is required to release the control wire from the clip and although it follows, among many other things, the displacement of offset portions 11*b* of clip member 11 into hole 16*a*, Petitioner fails to persuasively show that such displacement "allows or leads to" the control wire releasing from the clip. It is the manipulation of the endoscope that disengages clip member 11 from hook member 20. There is no persuasive evidence that the manipulation of the endoscope to cause such release is dependent on the radial movement of offset portions 11*b* of clip member 11.

For all these reasons, we find that Petitioner has not shown by a preponderance of the evidence that Komiya discloses "the link being movable from a coupled configuration . . . to a released configuration in which first and second arms of the link are configured to move radially outward at an area of the sheath to release the control wire from the clip," as

required by claim 1. Accordingly, Petitioner has not shown by a preponderance of the evidence that Komiya anticipates claim 1.

2. Claims 2, 3, and 5–14

We find that Petitioner has not shown by a preponderance of the evidence that Komiya anticipates claims 2, 3, and 5–14, which each depend from claim 1, for the same reasons we found above that Petitioner has not shown by a preponderance of the evidence that Komiya anticipates claim 1.

F. ASSERTED OBVIOUSNESS OVER KOMIYA

Petitioner contends claim 2 of the '048 patent would have been obvious over Komiya. Pet. 46–47.[8] Claim 2 depends from claim 1. For the reasons provided above, Petitioner has not shown by a preponderance of the evidence that claim 1 is anticipated by Komiya. Petitioner does not resolve this deficiency by arguing that additional features of claim 2 would have been obvious over Komiya. Accordingly, Petitioner has not shown by a preponderance of the evidence that the subject matter of claim 2 would have been obvious over Komiya.

G. ASSERTED OBVIOUSNESS OVER KOMIYA AND CROCKARD

Petitioner contends claims 1, 3, and 5–14 of the '048 patent would have been obvious over the combination of Komiya and Crockard. Pet. 48–58; Pet. Reply 2–18. Patent Owner disputes Petitioner's contentions. PO Resp. 23–48. For the reasons provided below, we find that Petitioner has shown by a preponderance of the evidence that the combination of Komiya and Crockard teaches each limitation of claim 1, but we further find that Petitioner has not shown by a preponderance of the evidence a legally

[8] We understand references in the Petition to "Kimura" are typographical errors and that Petitioner intended to refer to "Komiya."

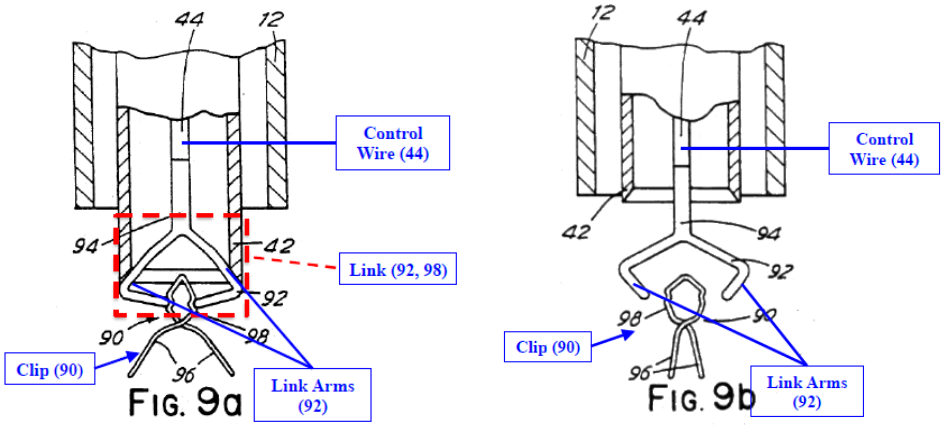
sufficient rationale for why Komiya and Crockard would have been combined in the manner proposed by Petitioner.

1. Claim 1

a) Differences Between the Subject Matter of Claim 1 and the Teachings of Komiya and Crockard

With regard to claim 1, Petitioner contends that Komiya discloses the elements of a clip with clip legs, a control wire, a sheath, and an actuator, as set forth in Petitioner's ground based on anticipation by Komiya discussed above. Pet. 48, 53 (citing Pet. 18–22, 26 (in turn, citing Ex. 1014, Abstract, 1:6–8, 1:63–65, 2:1–7, 2:34–45, 2:50–59, 3:7–14, 3:28–37, 4:34–48, 4:55–64, 4:66–5:10, 5:14–29, 5:48–51, 5:67–6:3, 6:32-35, Figs. 1, 3, 5–7); and Ex.1026 ¶¶ 81–84, 90). Petitioner further argues that "[t]o the extent" Patent Owner argues Komiya fails to disclose "radial outward movement of the link arms 'to release the control wire from the clip,'" Crockard discloses this feature. *Id.* at 49.

Petitioner provides the following annotated versions of Figures 9a and 9b from Crockard to illustrate how Crockard discloses the clamed released configuration:



Pet. 49. As shown in Petitioner's annotated versions of the aneurysm clip applicator of Figures 9a and 9b of Crockard, Crockard's handle 98 and

jaws 92 correspond to a link (with first and second link arms) between clip 90 and shaft 44, with shaft 44 corresponding to a control wire. Petitioner further asserts that Figure 9a illustrates jaws 92 corresponding to link arms in a coupled configuration and that Figure 9b illustrates jaws 92 corresponding to link arms in a released configuration in which jaws 92 are "configured to move radially outward to release the control wire (44) from clip (90)." *Id*. at 49–50 (citing Ex. 1019, 3:5–15, 7:46–59; Ex. 1026 ¶ 86).

Patent Owner argues that neither Komiya nor Crockard teaches link arms "configured to move radially outward *at an area of the sheath* to release the control wire from the clip," as recited by claim 1. PO Resp. 24–26; *see also* Ex. 2010 ¶¶ 56–59. We agree with Patent Owner and Dr. Vaitekunas that neither Komiya nor Crockard teach this feature, individually. However, Petitioner's contentions are based on the combination of Komiya and Crockard, and Patent Owner's attempt to refute those contention by attacking the references individually is not persuasive. Petitioner explains that "[t]he modified Komiya device would include Crockard link arms (92) coupled to the distal end of the Komiya control wire 19," and that "[t]he link arms (92) would be compressed by holder 21 in the coupled configuration, just as the link arms (11b) described in Komiya are compressed by holder 21 in the coupled configuration." Pet. 51; *see also* Pet. Reply 2–3 (reiterating that the proposed combination substitutes Crockard's jaws 92 for Komiya's hook 20 at a location "within one or more components that enclose the control wire," corresponding to Patent Owner's construction of "at an area of the sheath").

Thus, Petitioner's asserted combination places Crockard's link arms within the sheath taught by Komiya, demonstrating that the combination of

the teachings of the two references corresponds to the claimed "configured to move radially outward at an area of the sheath to release the control wire from the clip." Patent Owner does not argue that the combination of Komiya and Crockard fails to teach any other limitation of claim 1. We find that Petitioner has shown by a preponderance of the evidence that the combination of Komiya and Crockard teaches each limitation of claim 1 as set forth in the Petition with the support of Dr. Nicosia's declaration. *See* Pet. 18–22, 27, 48–53, Ex. 1026 ¶¶ 81–90.

b) Reasons for the Combination of Komiya and Crockard

Petitioner argues that it would have been obvious to replace hook member 20 of Komiya with jaws 92 of Crockard "to simplify the operation of using Komiya's clip (11) by limiting the deployment steps, such as eliminating the step of pushing the control wire (19, 20) proximally to release control wire (19, 20) from clip (11)." Pet. 51 (citing Ex. 1014, 5:14–29). Under such a configuration, Petitioner asserts that "the clip would be released immediately upon radial outward movement of the link arms (92), as opposed to the embodiment of Komiya, which requires that the hook member 20 move distally and sideways to completely separate the clip (11) from the control wire (19, 20). *Id.* at 51–52 (citing Ex. 1026 ¶ 87; Ex. 1014, 4:67–5:27, Fig. 7).

In further support of the asserted combination, Petitioner contends that a person of ordinary skill would have "recognized the importance of simplifying the operation of the Komiya hemostatic clip," because "simplifying the operation would potentially reduce the risk of error, and potentially decrease the time required to perform the medical procedure," would "limit the possibility of problems associated with attempting to

uncouple the hook member 20 from the clip 11," and would have been a routine substitution "according to known methods to yield predictable results." *Id.* at 52. Petitioner also asserts that a person of ordinary skill would have known how to combine the link feature of Crockard with the clip in Komiya because they function in a similar manner. *Id.* at 52–53.

Petitioner has not shown by a preponderance of the evidence that replacing hook member 20 of Komiya with jaws 92 of Crockard either would have simplified the operation of Komiya or would have been a "routine substitution," which Petitioner contends to be the rationale for the proposed modifications. *See id.*; *see also KSR*, 550 U.S. at 418 ("Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.").

Petitioner suggests that applying Crockard's jaws 92 to Komiya would eliminate the step of pushing the control wire (19, 20) proximally to release control wire (19, 20) from clip (11). Pet. 51. The step Petitioner proposes to eliminate from Komiya, however, is described by Komiya as essential to the function of Komiya. As explained above, Komiya describes the operation of releasing the clip as follows:

> After the clip member 11 so clips the affected portion 22 of the body cavity, the sliding member 18 and thus the wire 19 are pushed forward relative to the operating member 17 to cause the hook member 20 to be advanced together with the clip member 11. At this time, the *holder 21 trapped at the intersecting portions 11c of the clip member 21 is moved out of engagement with the guide member 16 and pushed forward together with the clip member 11*.

Ex. 1014, 5:14–22 (emphasis added). Petitioner proposes eliminating the need to push forward wire 19 and hook member 20 proximally, but does not address in the Petition the impact such a modification would have on holder 21. *See also* Ex. 2010 ¶¶ 99 (stating, for example, that "Crockard's jaws 92 could not be used to disengage holder 21 from guide member 16 without interfering with clip member 11"). According to Komiya, wire 19 and hook member 20 must be pushed forward for holder 21 to be pushed forward and moved out of engagement. Ex. 1014, 5:14–22. Komiya details why the forward movement of holder 21 is essential, explaining as follows:

> The holder 21 serves to maintain the clipping engagement of the clip member 11 with the affected portion 22 of the body cavity and the clamping portions 11*d* of the clip member 11 is maintained in a closed position. Therefore, there is no fear that the clip member 11 will inadvertently drop away from the affected portion 22 of the body cavity.

Id. at 5:32–38.

In its Reply, Petitioner attempts to salvage its contentions by making arguments not developed in the Petition. In particular, Petitioner argues that Dr. Nicosia explained how the combination of Komiya and Crockard would operate *in his deposition*. Reply (citing Ex. 2011 116:6–24). Petitioner further asserts that "the final step of moving the control wire sideways to separate the control wire from the clip is unnecessary in the Komiya/Crockard device." *Id.* at 6–7, 16. It is unnecessary only because Petitioner contends in the Petition that "the clip would be released immediately upon radial outward movement of the link arms (92)," not because Petitioner has shown that the asserted combination still deploys holder 21, as required by Komiya.

Patent Owner, as supported by Dr. Vaitekunas, similarly raised doubt about how Petitioner's proposed modifications would enable the device of Komiya to operate as intended, particularly in light of the insufficient explanation provided by Petitioner in the Petition. PO Resp. 40–48; Ex. 2010 ¶¶ 85–102. After Patent Owner raised doubt over the asserted combination in its Response, Dr. Nicosia was asked to explain how he thought the asserted combination would function, and answered as follows:

> Q: Once Crockard's jaws open in hole 16, wire 19 cannot move clip 11 distally, correct?
>
> MR. ZANFARDINO: Objection, form, foundation.
>
> THE WITNESS: The open arms of Crockard can engage the recess and push 21 right out which will move the clip out.
>
> Q: Engage recess 16?
>
> A: Correct.
>
> Q: But it's still the case that Crockard's jaws 92, once they are released from clip 11, mean that wire 19 is not going to work on the end portion of clip 11 to push it out, right?
>
> MR. ZANFARDINO: Objection, form, foundation.
>
> THE WITNESS: Crockard arms will work on the distal end -- sorry, the proximal end of holder 21 to push it out just like the legs of Komiya did in the previous -- in the original Komiya.
>
> Q: So you're saying that Crockard's jaws would push on holder 21, right?
>
> A: Correct.
>
> Q: But would not – wouldn't there be a possibility then that in pushing on 21 that they interfere with clip 11?
>
> A: I don't think so, no. The idea is they would be 90 degrees, so it would be pushing opposite where the clip is or 90 degrees from where the clip is.
>
> Q: But you can have some rotation in that wire, right?
>
> A: I don't think it's likely.

> Q: You didn't do any analysis to determine the likelihood, did you?
>
> MR. ZANFARDINO: Objection, form, foundation.
>
> THE WITNESS: No.

Ex. 2011, 116:6–117:17.

Dr. Nicosia may have had ideas about how to combine the teachings of Komiya and Crockard, but Petitioner has not explained the details of the proposed modification adequately to provide rational underpinning for the combination, as the Petition is practically devoid of any analysis of what changes would have been necessary or why a person of ordinary skill in the art would have made those changes, instead portraying it as a "routine substitution." *See* 42 C.F.R. §§ 42.22(a)(2), 42.104(b)(4). As explained above, we find insufficient support from Petitioner to establish that "limiting the deployment steps" either would be beneficial as a simplification or even allow the device of Komiya to continue operating as intended. Thus, even if Dr. Nicosia believes that design modifications are theoretically possible to enable Komiya to continue to function with jaws 92 of Crockard, Petitioner has not shown that a person of ordinary skill in the art would have had reason to combine Komiya and Crockard as proposed by Petitioner, or would have had a reasonable expectation of success in doing so. *See, e.g.*, Ex. 2011, 139:2–140:20 (Dr. Nicosia discussing changes required to Crockard's jaws in combination with Komiya as a "small optimization").

Importantly, even assuming a person of ordinary skill could have "optimized" Komiya to still operate using jaws 92 of Crockard, Petitioner fails to show persuasively that Komiya would have operated as intended such that replacing hook member 20 of Komiya with jaws 92 of Crockard would have been a "routine substitution," much less a simpler design. See

Pet. Reply 6–7, 11–17. Thus, because the Petition fails to explain adequately *why* a person of ordinary skill in the art would have made the modifications to Komiya based on Crockard proposed by Petitioner, while still preserving the operability of Komiya, Petitioner has not provided a persuasive rationale for the asserted combination. Rather than a routine substitution or simplification, Petitioner's rationale primarily reflects a hindsight reconstruction of the limitations of claim 1 of the '048 patent.

We also find persuasive Patent Owner's contention that Petitioner fails to explain adequately how Crockard's jaws 92 would engage Komiya's clip member 11, particularly in light of the uniquely configured handle loop 98 taught by Crockard to enable jaws 92 to squeeze and hold clip 90. *See* PO Resp. 40–44. Petitioner argues that the law does not require such details. Pet. Reply 11 (quoting *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) ("[I]t is not necessary that [references] be physically combinable" to render a claim obvious).)

We agree that Petitioner need not show the references are physically combinable to demonstrate obviousness, but the burden remains on Petitioner to show that the proposed modification of Komiya based on Crockard would not, *inter alia*¸ render Komiya unsuitable for its intended purpose and Petitioner has failed to carry that burden. *See Pers. Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 ("[A] clear, evidence-supported account of the contemplated workings of the combination is a prerequisite to explaining adequately and supporting a conclusion that a relevant skilled artisan would have been motivated to make the combination and reasonably expect success in doing so."). Petitioner also asserts that Dr. Nicosia

explained how the combination could be optimized based on the ordinary creativity of person of ordinary skill. *Id.* at 12 (citing Ex. 1045 ¶¶ 7–8).

We find Petitioner's arguments inconsistent with the rationale asserted by Petitioner for the combination, i.e., that it would simplify the operation of Komiya and would have been a routine substitution. *See* Pet. 52. We also credit the testimony of Dr. Vaitekunas over Dr. Nicosia in finding that Petitioner has not shown sufficiently that the proposed combination of Komiya and Crockard could simply be optimized to overcome any issue with the operability of the combination. *See* Ex. 2010 ¶¶ 86–91. For all of these reasons, we find that Petitioner has not shown by a preponderance of the evidence a legally sufficient rationale that convinces us Komiya and Crockard would have been combined in the manner proposed by Petitioner.

2. Claims 3 and 5–14

Petitioner contends claims 3 and 5–14, which depend from claim 1, would have been obvious over Komiya and Crockard. Pet. 54–58. Petitioner has not shown by a preponderance of the evidence a legally sufficient rationale for why Komiya and Crockard would have been combined in the manner proposed by Petitioner as to claims 3 and 5–14 for the same reasons provided above with regard to claim 1.

H. ASSERTED OBVIOUSNESS OVER SHINOZUKA AND MATSUNO

Petitioner contends claims 29 and 30 would have been obvious over the combination of Shinozuka and Matsuno. Pet. 61–73; Pet. Reply 18–28. Patent Owner disputes Petitioner's contentions. PO Resp. 48–58. For the reasons provided below, we find that Petitioner has shown by a preponderance of the evidence that the combination of Shinozuka and Matsuno teaches each limitation of claims 29 and 30, as well as a legally

sufficient rationale for why Shinozuka and Matsuno would have been combined in the manner proposed by Petitioner. We also consider Patent Owner's objective evidence of nonobviousness and ultimately determine, upon consideration of all of the *Graham* factors, that Petitioner has shown by a preponderance of the evidence that the subject matter of claims 29 and 30 of the '048 patent would have been obvious over Shinozuka and Matsuno.

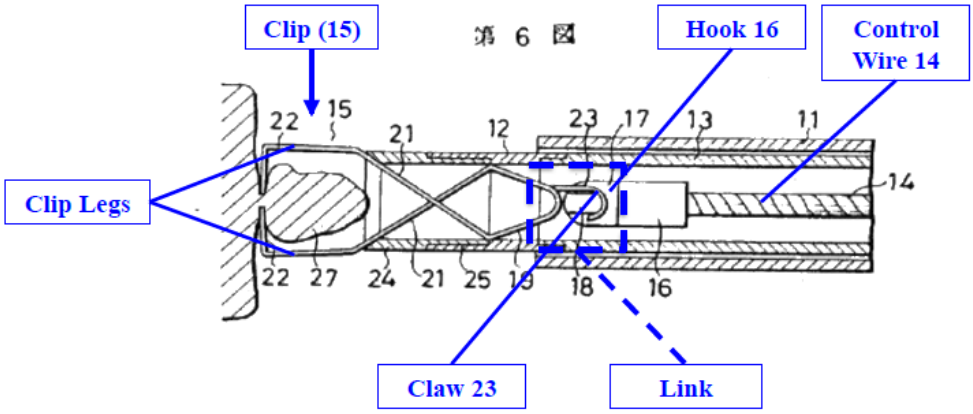
*1. Differences Between the Subject Matter of Claim*s 29 and 30 *and the Teachings of Shinozuka and Matsuno*

Petitioner identifies how Shinozuka teaches each of the limitations of claims 29 and 30 other than "applying a tensile force of at least a threshold level to the control wire to separate a separable link coupling the control wire to the clip," as recited by claim 29. Pet. 61–73 (citing Ex. 1109, 261–263, Figs. 2–7; Ex. 1026 ¶¶ 111–116, 122). For the "applying a tensile force" limitation, Petitioner fails to show it was taught by Shinozuka, alone, but persuasively shows that it was taught by the combination of Matsuno with Shinozuka, as further explained below.

First, Petitioner states that Shinozuka teaches jiggling control wire 14 to unlink hook 16 on clip 15 from claw 23 on control wire 14. Pet. 66 (citing Ex. 1109, 263). Because neither Petitioner nor Dr. Nicosia provides a persuasive explanation or evidence to demonstrate that "jiggling" corresponds to "applying a tensile force," Petitioner has not shown by a preponderance of the evidence that Shinozuka teaches "applying a tensile force." *See* Pet. 66–67; *see also* Ex. 1026 ¶¶ 117–118.

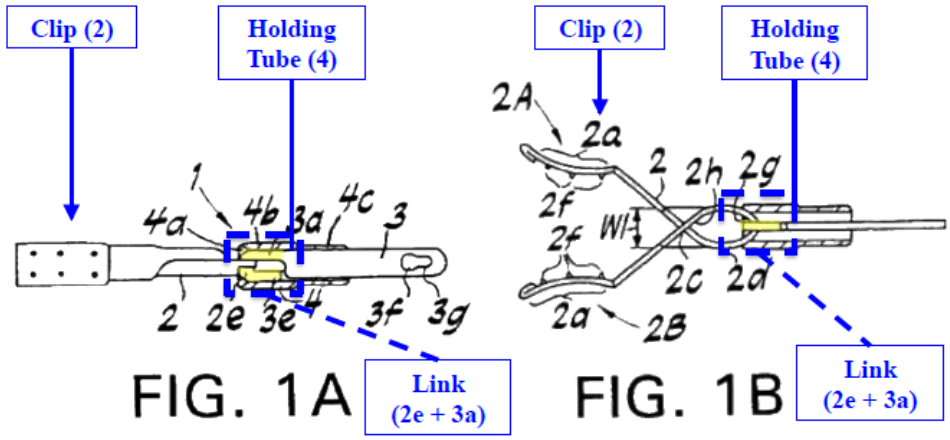
Second, Petitioner argues that "to the extent [Patent Owner] argues that separating the separable link in Shinozuka does not involve applying a tensile force of at least a threshold level to the control wire, claim 29

nevertheless would have been obvious," as taught by Matsuno. *Id.* at 68. Petitioner and Dr. Nicosia provide the following annotated version of Figure 6 of Shinozuka:



Pet. 66; Ex. 1026 ¶ 117. Annotated Figure 6 of Shinozuka illustrates clip 15 with clip legs, claw 23, hook 16, and control wire 14, with the connection between claw 23 and control wire 14 constituting a "separable link" as required by claim 29.

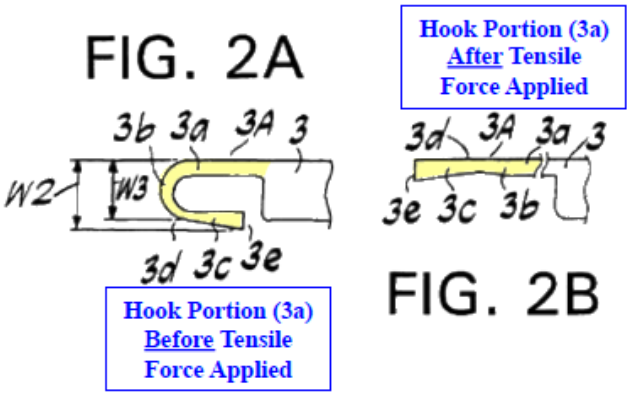
Petitioner and Dr. Nicosia also provide the following annotated versions of Figures 1A and 1B of Matsuno:



Annotated Figures 1A and 1B of Matsuno illustrate clip 2 with a curved portion 2*g* provided with recess 2*e* and with arm portions 2A and 2B, coupling plate 3 with hook portion 3A, and holding tube 4 for use as a clip

squeezing ring. Pet. 68; Ex. 1026 ¶ 118; Ex. 1016, 2:63–65, 3:13–6, 3:29–31. "The hook portion 3A is hooked on the recess 2e of the clip 2 to removably engage with the clip 2." Ex. 1023, 3:31–33.

Annotated versions of Figures 2A and 2B of Matsuno provided by Petitioner and Dr. Nicosia illustrate how coupling plate 3 operates and are reproduced below:



Pet. 69. Annotated Figures 2A and 2B illustrate coupling plate 3 of Matsuno prior to and after elastic deformation, as explained by Dr. Nicosia: "[t]he link (3A and 2e) between the control wire and clip becomes unlinked when a tensile force is applied, thereby straightening hook portion 3A so that it can pull away and disengage from the clip (2)." Ex. 1026 ¶ 119 (citing Ex. 1016, 5:58–65). Petitioner has persuasively shown that Matsuno teaches applying a tensile force of at least a threshold level to a control wire to separate a separable link coupling the control wire to a clip for the reasons provided in the Petition, as supported by Dr. Nicosia. Pet. 67–68 (citing Ex. 1016, 3:31–32, 4:2–7, 5:58–65, Figs. 1A, 1B, 2A, 2B, 5, 7, 8; Ex. 1026 ¶¶ 118–119).

Patent Owner does not dispute that the combination of Shinozuka and Matsuno teaches every limitation of claims 29 and 30 of the '048 patent.

See PO Resp. 48–49. We are persuaded that Petitioner has shown by a preponderance of the evidence that the combination of Shinozuka and Matsuno teaches every limitation of claims 29 and 30 for the reasons identified in the Petition (pages 61–66, 68–70, 72–73), which we adopt as our own findings.[9]

2. Reasons for the Combination of Shinozuka and Matsuno

Petitioner argues that it would have been obvious to a person of ordinary skill to replace Shinozuka's hook 16 with hook portion 3a of Matsuno's coupling plate 3 to "simplify and improve the procedure for separating the separable link," to avoid potential problems with "jiggling" the control wire in a patient's body, and to reduce the potential for causing damage to the patient. Pet. 70 (citing Ex. 1026 ¶ 120). Petitioner also argues such a substitution would have been a matter of routine skill using simple mechanical elements taught in Shinozuka and Matsuno to yield predictable results. *Id.* at 71 (citing Ex. 1026 ¶ 121).

Petitioner does not suggest any additional modification of Shinozuka is necessary for the combination with Matsuno to accomplish the same result, thereby separating the clip from the applicator by using a hook that is deformed by a tensile load as taught by Matsuno in place of the non-deformable hook that is disengaged by jiggling taught by Shinozuka. Petitioner has persuasively shown that its proposed substitution of Shinozuka's hook 16 with hook portion 3a of Matsuno is a simple substitution of one known element for another to yield a predictable result.

[9] To be clear, we do not adopt as our own findings Petitioner's contention that Shinozuka, alone, teaches "applying a tensile force," for the reasons provided above. *See* Pet. 66–67.

Patent Owner argues unpersuasively that Petitioner's proposed combination of Shinozuka and Matsuno is "counterintuitive and would not function so as to achieve the intended purposes of the claimed inventions." PO Resp. 49. First, Patent Owner argues that the problem "solved" by the '048 patent was unknown such that its solution could not have been obvious. *Id.* at 49–50. Patent Owner's argument is unpersuasive because Patent Owner has not shown that the subject matter claimed in the '048 patent solves the "unknown problem" identified by Patent Owner as "the inability of the prior art clips to be reversibly deployed." PO Resp. 38. Patent Owner does not expressly assert or explain how claim 29 or claim 30 of the '048 patent teaches a clip that is "reversibly deployed," thereby solving the purportedly unknown problem.

Dr. Vaitekunas suggests in a conclusory fashion that the steps of claim 29 "enables reversible closure," but does not state that claim 29 requires "clips to be reversibly deployed" and does not explain how claim 29 enables such operation. *See* Ex. 2010 ¶ 24. The Specification of the '048 patent states that "[t]he medical devices of the present invention include: a compression clip used to cause hemostasis of blood vessels and a mechanism for deploying the clip that includes an arrangement for closing the clip and for reversing the closing process to reopen the clip after closure has begun." Ex. 1023 2:58–62. Indeed, claim 9 of the '048 patent (which is not at issue in this review under the obviousness ground based on Shinozuka and Matsuno) recites "the control wire is reversibly operable." *Id.* at 16:8–9. Patent Owner, however, does not persuasively explain why a "reversibly operable" limitation should be read into claim 29 or claim 30. *See also* Ex. 2010 ¶ 104 (offering only conclusory support for the proposition that claim

29 or claim 30 solved the inability of prior art clips to be reversibly deployed). We further credit the testimony of Dr. Nicosia who persuasively explains that neither claim 29 nor claim 30 require a clip that is reversibly deployed. Ex. 1045 ¶¶ 22, 23, 25, 26.

Second, Patent Owner argues that Petitioner "identifies no problem with Shinozuka or Matsuno" that would motivate the proposed modification, noting that Dr. Nicosia was not aware of any patent or publication "identifying problems with Shinozuka and Matsuno devices" and that Shinozuka and Matsuno were owned by the same company, but that company did not combine the references as Petitioner proposed. PO Resp. 50. The premise of Patent Owner's argument is contrary to the record in this case. The Petition expressly identifies a problem solved by the asserted combination, as supported by Dr. Nicosia: "[t]he person of ordinary skill in the art would have recognized potential problems with 'jiggling' the control wire in a patient's body, including the inability to know precisely when the control wire is separated from the clip, as well as the potential for causing damage to the patient." Pet. 70; Ex. 1026 ¶ 120. Moreover, even if it were relevant to the issue of obviousness, Patent Owner directs us to no evidence to support its speculative assertion that a company owning Shinozuka and Matsuno did not combine them as proposed by Petitioner. *See* PO Resp. 50. Further, Petitioner notes that Shinozuka was developed in the 1980's, while Matsuno was developed in the 1990s, supporting Petitioner's contention that a person of ordinary skill would have been motivated to improve Shinozuka by applying the simplified deployment mechanism later taught by Matsuno. Pet. Reply 18–19.

Third, Patent Owner argues that the proposed combination "would not achieve Shinozuka's express goals." PO Resp. 50–52. In particular, Patent Owner argues that an intended purpose of Shinozuka was to provide a device where the clip "could be disengaged in 'two direction' and 'any direction between the two directions." PO Resp. 51 (quoting Ex. 1009, 262–63). Patent Owner reasons that replacing the hook of Shinozuka with the hook of Matsuno would permit the clip of Shinozuka to be disengaged in one direction, contrary to the purpose of Shinozuka. *Id.* According to Patent Owner, "Shinozuka thus teaches away from such a combination that would limit the direction in which the clip could be released." *Id.* at 51–52. Petitioner asserts that Patent Owner's argument misses the greater objective of Shinozuka, which was to provide "a biotissue clip device with which it is easy, after pinching the biotissue with the clip, to remove the hook from the clip." Pet. Reply 19 (quoting Ex. 1009, 262).

Patent Owner's argument is not persuasive because Petitioner has identified a rational basis for the proposed modification, i.e., to simplify operation and reduce the potential for harm by eliminating the need to jiggle the control wire to release the clip. While that modification may come at the expense of other benefits taught by Shinozuka attributable to jiggling, we are not persuaded jiggling constitutes a teaching away. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000) ("The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another.").

Patent Owner also asserts that relying on a tensile force for separation of the clip as taught by Matsuno in place of the jiggling taught by Shinozuka

"could damage the tissue to which the clip is applied." *Id.* at 50–53 (citing Ex. 2011, 135:7–12; Ex. 2010 ¶ 112–113). To the contrary, Petitioner argues that eliminating the need to jiggle the control wire from the clip would in fact reduce the risk of injury to tissue and that Matsuno teaches grasping the tissue before applying the tensile force, thereby avoiding tissue damage. Pet. Reply 20 (citing Ex. 1026 ¶120).

First, Patent Owner does not demonstrate that "jiggling" precludes any application of a tensile force and therefore does not convincingly show that the application of Matsuno to Shinozuka would have caused more damage or would have been contrary to Shinozuka's express goals. Second, we agree with Petitioner that even if the asserted combination would have been inferior in some respects to the device of Shinozuka, the asserted combination may still have been obvious. *See* Pet. Reply 20 (citing *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) (citation omitted) (finding that an obvious product "does not become patentable simply because it has been described as somewhat inferior to some other product").

Fourth, Patent Owner argues that the asserted combination "would result in a device that is less stable at deployment and more prone to coming off the clip applier," because Dr. Nicosia "admits that the substitution would result in additional lateral movement," and that such a result would not lead to a more "simple" or "precise" device as Petitioner contends. PO Resp. 53–54 (citing Ex. 2011, 135:7–12). Patent Owner's argument is not persuasive because it misrepresents Dr. Nicosia's testimony. Dr. Nicosia agreed that "there could be some lateral movement" in the asserted combination, but did not state that it would have been "additional" movement. Ex. 2011, 135:7–12. To the contrary, Dr. Nicosia stated that any lateral movement permitted

by the asserted combination is "[n]ot necessarily any more than in the original device." *Id.* at 133:8–17.

Fifth, Patent Owner argues that the asserted combination would not work for its intended purpose and that a person of ordinary skill would not have had a reasonable expectation of success. PO Resp. 54–57. We have carefully considered each of Patent Owner's additional arguments, several of which overlap with Patent Owner's contentions addressed above, and find them unpersuasive. In this regard, Patent Owner begins by arguing that it is insufficient for Petitioner to only argue that it "would have been a matter of routine skill in the art, using simple mechanical elements disclosed in Shinozuka and Matsuno to yield predictable results." *Id.* at 54–55 (citing Pet. 71).

Patent Owner concedes all claimed elements are taught by Shinozuka and Matsuno and we agree with Petitioner that it has sufficiently shown a one of ordinary skill in the art would have a reasonable expectation of success as the asserted combination is a simple mechanical combination based on prior art that is clear and easily understood, requiring no complicated explanation to demonstrate a reasonable expectation of success.

Patent Owner further argues that there is no evidence that the asserted combination would "create a clip with reversible jaw (clip) closure," as purportedly claimed in the '048 patent. *Id.* at 55. Patent Owner has not shown, as explained above, that either claim 29 or claim 30 requires "a clip with reversible jaw (clip) closure."

Next Patent Owner argues that a person of ordinary skill would reasonably expect that during operation of the asserted combination "it would be difficult for hook portion 3A to stay engaged with claw 23,"

because Matsuno teaches clip 3A grasping an oval portion of a clip whereas Shinozuka teaches grasping claw 23 which is "not a complete circle." *Id.* at 55–56. According to Patent Owner, as a result, the asserted combination would have been "at greater risk of inadvertently detach[ing]," thereby creating a danger and thus no reasonable expectation hook portion 3A could be used to control clip 15 of Shinozuka via claw 23. *Id.* (citing Ex. 2010 ¶¶ 117–118).

We are not persuaded that the asserted combination would be at greater risk of inadvertently detaching, as Petitioner shows the asserted combination would decrease the risk of inadvertent detachment. On this point we find persuasive and credit the testimony of Dr. Nicosia. Ex. 1045 ¶¶ 16–21. Even if the asserted combination were inferior, we are not persuaded that fact, alone, demonstrates that it would not have been obvious. *See Fulton*, 391 F.3d at 1200.

Next Patent Owner argues that the asserted combination does not include holding tube 4 of Matsuno or an equivalent structure, that there would not be space for such a tube, and that without holding tube 4 clip 15 of Shinozuka "would not be sufficiently held in place on hook 3A." PO Resp. at 57 (citing Exs. 119–120). Petitioner has sufficiently shown that the asserted combination is sufficient even though it does not include Matsuno's holding tube 4 because Shinozuka teaches an analogous structure in tightening ring 24 that would operate with Matsuno's hook 3A. Pet. Reply 26 (citing Ex. 1045 ¶ 21).

Patent Owner separately argues that Petitioner's asserted combination would not have had a reasonable expectation of satisfying the additional limitation of claim 30, which depends from claim 29. PO Resp. 58. Claim

29 recites "applying a tensile force of at least a threshold level to the control wire to separate a separable link coupling the control wire to the clip" and claim 30 further requires "the separation uncoupling the clip from the control wire and separating a capsule from the sheath to lock the clip over the coupled target tissue." Ex. 1023, 18:17–23.

Patent Owner argues a person of ordinary skill would not have been motivated to combine Shinozuka with Matsuno with a reasonable expectation of success based on the following:

> As argued by Petitioners with respect to claim 29, the control wire and clip would separate when a tensile force is applied to the control wire 14 causing the Matsuno hook portion 3A to deform. Petition at 69–70. In this scenario, as the control wire 14 is pulled, the clip 15 is pulled against the clip-tightening ring 24, which is connected to coupling ring 12. *See, e.g.*, Ex. 1009 at Figure 6. Even assuming that Matsuno's hook portion 3A would deform, it would not, however, be possible to disengage clip 15 from control tube 13. Ex. 2010 at ¶¶ 122-123. The reason is that clip-tightening ring 24 would still be connected to coupling ring 12 when control wire 14 and clip 15 separate. Once hook 3A disengaged, control wire 14 could not be used to separate clip 15 and clip tightening ring 24 from coupling ring 12 that couples the clip-tightening ring 24 to control tube 13. *Id.*

PO Resp. 58.

From Patent Owner's argument we are not persuaded that Shinozuka would operate any differently in regard to "separating a capsule from the sheath to lock the clip over the coupled target tissue," as required by claim 30, whether uncoupling the clip is accomplished through jiggling as taught by Shinozuka or through the use of a tensile force applied to straighten a hook portion, as proposed by Petitioner.

Petitioner provides a detailed explanation for how the combination of Shinozuka and Matsuno teaches separating a capsule from a sheath (Pet.

Reply 27–28) which we adopt as our own findings in this regard. *See* Ex. 1009, 263; Ex. 1026 ¶¶ 122.

3. Objective Evidence of Nonobviousness

Patent Owner makes and sells hemostatic clips called the Resolution™ Clip and Resolution 360™ Clip (together, the "Resolution Clips"). PO Resp. 59. Patent Owner contends that use of the Resolution Clips practices the method of claim 29 of the '048 patent. *Id.* at 61–62. Patent Owner further argues that the Resolution Clips have enjoyed considerable commercial success and industry praise, which serve as objective indicia of non-obviousness. *Id.* at 62–64.

According to Patent Owner, the "primary driver" of the commercial success of the Resolution Clips is the "superior repositionability of the Resolution Clips which is provided by the reversible open/close feature and the tactile feel feature," which Patent Owner contends are features "now demanded by most physicians." *Id.* at 63. Patent Owner's argument is fundamentally flawed, as Petitioner explains, because Patent Owner has not established persuasively that claim 29 requires either a "reversible open/close feature" or a "tactile feel feature," the two features the commercial success is purportedly attributable to. *See* Pet. Reply 28–29 (citing Ex. 1045 ¶¶ 22–29).

Patent Owner's entire analysis of how claim 29 requires either a "reversible open/close feature" or a "tactile feel feature" consists of the following single conclusory sentence and citation to the '048 patent: "These are the features of claim 29. *See* Ex. 1023 at claim 29 (claiming the ability to position, move and adjust the clip)." We have also considered the declarations of Dr. Vaitekunas and Mr. Petrou in support of Patent Owner.

While Dr. Vaitekunas explains how the Resolution Clips practice claim 29 of the '048 patent, he merely states as an assumption that the Resolution Clips have been a commercial success and received industry praise "due to the reversible opening & closing and tactile feedback features." Ex. 2010 ¶ 126. Mr. Petrou supports Patent Owner's contentions of commercial success and industry praise, but, like Dr. Vaitekunas, fails to explain how claim 29 of the '048 patent requires a "reversible open/close feature" or a "tactile feel feature." *See* Ex. 2028.

For the foregoing reasons we not only find that Patent Owner has failed to make a sufficient showing that claim 29 requires the features attributed to the commercial success and industry praise of the Resolution Clips, but we also further find persuasive Dr. Nicosia's testimony that claim 29 does not require a "reversible open/close feature" or a "tactile feel feature." *See* Ex. 1045 ¶¶ 22–29. The alleged drivers of commercial success and industry praise are not commensurate in scope with the claims of the patented invention.

As the Federal Circuit has explained, "if the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006). Further, even if the challenged claims are broad enough to cover apparatuses both with and without these features, Patent Owner's arguments still fail because Patent Owner's evidence is not commensurate in scope with the claims. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1336 (Fed. Cir. 2010) ("Because the claims are broad enough to cover devices that either do or do not solve the 'short fill' problem, [Patent Owner's] objective evidence of non-obviousness fails because it is not

'commensurate in scope with the claims which the evidence is offered to support.'"). For the reasons set forth above, we determine that Patent Owner has not persuasively shown that its objective evidence of nonobviousness weighs in favor of the nonobviousness of either claim 29 or claim 30 of the '048 patent.

4. Collective Consideration of the Graham Factors

Having considered each of the *Graham* factors individually, we now consider them collectively. Petitioner has shown that all of the limitations of claims 29 and 30 are taught by Shinozuka and Matsuno such that the scope and content of the prior art, as well as the differences between the prior art and the challenged claims, heavily favor Petitioner's contention that the subject matter would have been obvious over Shinozuka and Matsuno.

The level of ordinary skill in the art also favors obviousness because the level of ordinary skill in the art at issue is relatively high while the modification of Shinozuka only involves incorporating a well-known element taught by Matsuno to achieve the same goal.

Patent Owner has not persuasively shown that its objective evidence of nonobviousness weighs in favor of the nonobviousness of either claim 29 or claim 30. Finally, Petitioner has persuasively shown that an ordinarily skilled artisan would have had reason to combine the teachings of Shinozuka and Matsuno in the manner asserted by Petitioner.

On the whole, we find that the information provided by Petitioner and Patent Owner in consideration of the *Graham* factors collectively demonstrates by a preponderance of the evidence that the subject matter of claims 29 and 30 of the '048 patent is unpatentable as obvious over Shinozuka and Matsuno.

I. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner moves to exclude Exhibits 1017, 1020, 1026 (in part), 1045 (in part), 1048, 1049, 1052, 1054–1056, and 1081. Mot. 2–11. In consideration of the Motion, as well as Petitioner's opposition and Patent Owner's Reply, we deny the motion for the provided below. *See id.*; *see also* Mot. Resp. 1–15; Mot. Reply. 1–5.

1. Palmer (U.S. Patent No. 5,645,075 (Ex. 1017)).

Patent Owner seeks to exclude Exhibit 1017 as irrelevant under FRE 402 because it relates to jaw assemblies used in biopsy procedures rather than a clip device that compresses the tissue. Mot. 2–3; *see also* Mot. Reply 1–2. Petitioner contends Exhibit 1017 is relevant background information. Mot. Resp. 1–2. We are not persuaded that the distinction Patent Owner draws is a sufficient basis for establishing a lack of relevance as the devices at issue both relate to clamping. Moreover, this decision does not rely on Exhibit 1017.

2. Adams (U.S. Patent App. No. 2003/0069592 A1 (Ex. 1020)).

Patent Owner seeks to exclude Exhibit 1020 as irrelevant under FRE 402 because it was filed with, but not cited by, Petitioner's Reply Brief, and is discussed and cited in the Declaration of Dr. Mark Nicosia in Support of Petition (Ex. 1026), but the citation is inaccurate. Mot. 3–4; *see also* Mot. Reply 2. Petitioner contends that Exhibit 1020 is not irrelevant because it was relied on by Dr. Nicosia and cited in Exhibit 1026. Mot. Resp. 2–4. There is no dispute that Exhibit 1020 is cited in Dr. Nicosia's declaration. We find Patent Owner has not shown that Exhibit 1020 is irrelevant to what information Dr. Nicosia considered in forming his opinions. Moreover, this decision does not rely on Ex. 1020.

3. Declaration of Dr. Nicosia in Support of Petition (Exhibit 1026).

Patent Owner seeks to exclude portions of Exhibit 1026 as irrelevant under FRE 402 because they relate to grounds not initially instituted. Mot. 4. Because we subsequently modified our institution decision to include all grounds asserted in the Petition, there is no longer a reason supporting Patent Owner's request to exclude portions of Exhibit 1026. *See* Paper 55.

4. Declaration of Dr. Nicosia in Support of Reply (Exhibit 1045).

Patent Owner seeks to exclude paragraph 30 of Exhibit 1045 under FRE 702 purportedly because: (1) Dr. Nicosia is not qualified as an expert concerning the commercial success of a product, particularly the nexus between commercial success and the patented invention; and (2) Dr. Nicosia's opinion is not helpful to the Board, is not based on sufficient facts or data, is not the product of reliable principles and methods, and is not the result of reliably applying principles and methods to the facts of the case. Mot. 4–8; Mot. Reply 2–4. Petitioner contends that Dr. Nicosia is not "acting as a marketing or accounting expert," but is providing a technical opinion on whether the products Patent Owner relies on to demonstrate commercial success practice the limitations of claim 29 of the '048 or include other features not claimed. Mot. Resp. 8. We have considered Patent Owner's arguments and find they go to the weight to be afforded to the testimony of Dr. Nicosia, but do not establish such testimony should be excluded. Moreover, this decision does not rely on paragraph 30 of Exhibit 1045.

5. *Durgin U.S. Patent No. 7,452,327 B2 (Exhibit 1048) and U.S. Patent App. No. 10/955,624 (Exhibit 1049).*

Patent Owner seeks to exclude Exhibit 1048 and Exhibit 1049 as irrelevant under FRE 402. Mot. 8–9; Mot. Reply. 4. According to Patent Owner, Dr. Nicosia cites both exhibits in his reply declaration. Mot. 8. Patent Owner then appears to dispute the opinions Dr. Nicosia reached, which is not a basis for excluding the information upon which Dr. Nicosia relied. *See* Mot. Resp. 10–12. Moreover, this decision does not rely on Exhibit 1048 or Exhibit 1049.

6. *Materials Concerning Patent Owner's Resolution™ or Resolution 360™ Clips (Exhibits 1052 and 1054–1056).*

Patent Owner seeks to exclude Exhibits 1052 and 1054–1056, which Patent Owner describes as "brochures and website printouts related to Boston Scientific's Resolution™ or Resolution 360™ Clips," because "Dr. Nicosia quotes them as alleged evidence that 'Boston Scientific's marketing literature promotes other, unclaimed features,'" but Petitioner fails to provide "any expert testimony connecting the disclosed features to the success of the Resolution™ and Resolution 360™ Clips." Mot. 9–10; *see also* Mot. Reply. 4–5. We find Patent Owner has not shown that Exhibits 1052 and 1054–1056 are irrelevant as to what information Dr. Nicosia considered in forming his opinions. *See* Mot. Resp. 12–14. Moreover, this decision does not rely on Exhibits 1052 and 1054–1056.

7. *Patent Owner's Motion to Amend in IPR2017-00435 (Exhibit 1081).*

Patent Owner seeks to exclude Exhibit 1081 as irrelevant under FRE 402 and FRE 403 because it is from a different *inter partes* review proceeding concerning amending claims in a different patent and its

probative value is substantially outweighed by the danger of confusion. This decision does not rely on Exhibit 1081.

For the foregoing reasons we deny and dismiss as moot Patent Owner's Motion to Exclude Exhibits 1017, 1020, 1026 (in part), 1045 (in part), 1048, 1049, 1052, 1054–1056, and 1081.

IV. CONCLUSION

Based on the evidence and arguments, Petitioner has demonstrated by a preponderance of the evidence that the subject matter of claims 29 and 30 of the '048 patent would have been obvious over Shinozuka and Matsuno. Petitioner has not shown by a preponderance of the evidence that any of claims 1–3 or 5–14 is anticipated by Komiya, that the subject matter of claim 2 would have been obvious over Komiya, or that the subject matter of any of claims 1, 3, or 5–14 would have been obvious over Komiya and Crockard.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Patent Owner's Motion to Exclude is *denied*;

ORDERED that claims 29 and 30 of the U.S. Patent No. 8,685,048 B2 have been shown to be unpatentable; and

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

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