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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MICRO-TECH (NANJING) CO., LTD. AND MICRO-TECH ENDOSCOPY USA, INC.,
Petitioner,

v.

BOSTON SCIENTIFIC SCIMED, INC.,
Patent Owner.

IPR2020-00185
Patent 7,094,245 B2

Before JAMES A. TARTAL, MICHAEL L. WOODS, and AMANDA F. WIEKER, *Administrative Patent Judges*.

WIEKER, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background

Micro-Tech (Nanjing) Co., Ltd and Micro-Tech Endoscopy USA, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–15 ("challenged claims") of U.S. Patent No. 7,094,245 B2 (Ex. 1001, "the '245 patent"). Paper 1 ("Pet."). Boston Scientific Scimed, Inc. ("Patent Owner") filed a Preliminary Response. Paper 10 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review, under 35 U.S.C. § 314 and 37 C.F.R. § 42.4. An *inter partes* review may not be instituted unless it is determined that "the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314; *see also* 37 C.F.R § 42.4(a) ("The Board institutes the trial on behalf of the Director.").

For the reasons provided below and based on the record before us, we determine that Petitioner has not demonstrated a reasonable likelihood that Petitioner would prevail in showing the unpatentability of at least one of the challenged claims. Accordingly, we do not institute an *inter partes* review.

B. Related Proceedings

The parties state that the '245 patent is at issue in a district court proceeding in the U.S. District Court for the District of Delaware, Case No. 1:18-cv01869-CFC. Pet. 1; Paper 5, 2.

Patent Owner also states:

> A number of patents and pending applications claim priority to the '245 Patent. Several related patents were involved in proceedings before the Board (see, e.g., IPR2017-00131, 132,

> 133, 134, 135, 435, 440), and are involved in current appeals to the Federal Circuit (Case Nos. 19-1594, -604, -1605). Related patents are also involved in litigation filed in the District of Delaware as civil action No. 15-980-LPS-CJB, and later transferred to the Southern District of Indiana as civil action No. 17-cv-03448.

Paper 5, 2. Petitioner identifies a subset of these proceedings. Pet. 1.

C. The '245 Patent

The '245 patent is titled "Device and Method for Through the Scope Endoscopic Hemostatic Clipping," and issued on August 22, 2006, from U.S. Patent Application No. 09/971,488, filed October 5, 2001. Ex. 1001, codes (21), (22), (45), (54).

The '245 patent discloses "compression clips used to cause hemostasis of blood vessels located along the gastrointestinal tract delivered to a target site through an endoscope." Ex. 1001, 1:8–10. In describing deficiencies in the prior art, the '245 patent explains that once the jaws of a prior art clip began to close, they could not be reopened. *Id.* at 2:24–30. "In other words, jaw closure [was] not reversible," even if the clip was applied improperly. *Id.* at 2:30–35. The '245 patent purports to disclose a device with the "ability to repeatedly open and close the clip until the desired tissue pinching is accomplished," which "lead[s] to a quicker procedure, requiring less clips to be deployed, with a higher success rate." *Id.* at 2:62–66.

Figure 1 of the ’245 patent is reproduced below.

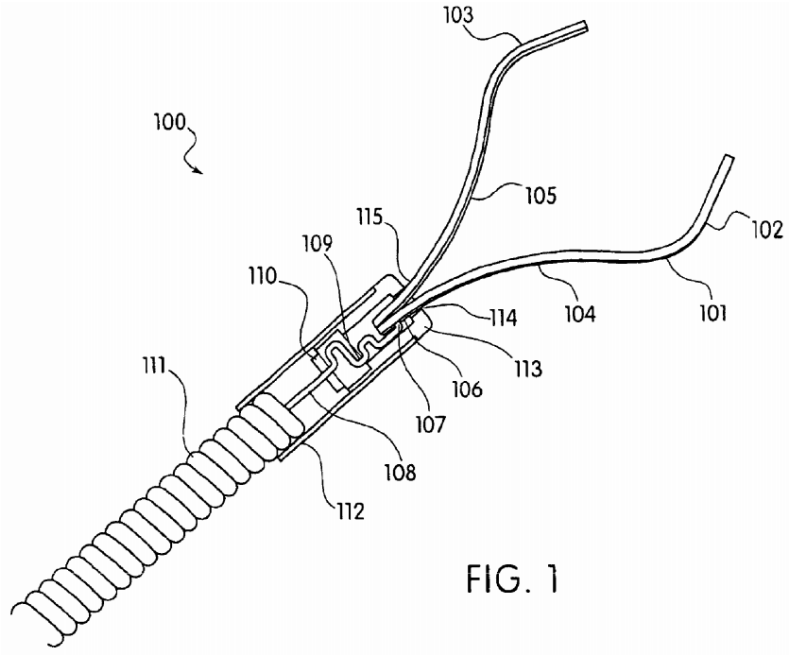

Figure 1 depicts an enlarged partial view of a clip. *Id.* at 3:24–25, 5:15–17. Clip 101 includes sheath 111, with outer sleeve 112 connected to the distal end of sheath 111, and lock sleeve 113 connected to the distal end of outer sleeve 112. *Id.* at 5:25–35. Sheath 111 encloses semi-rigid control wire 108, including retainer release 109 formed by several bends in the wire. *Id.* at 5:20–30; *see also id.* at 5:41 (“semi-rigid”). Frangible j-hook 107 is formed on the distal end of control wire 108. *Id.* at 5:20–30, 5:39 (“frangible”). Clip 101 includes two clip legs 102, 103, each of which includes lock hole 104, 105. *Id.* at 5:15–20. Lock holes 104, 105 are formed to engage lock pawls 114, 115 in lock sleeve 113. *Id.* at 5:33–36.

The ’245 patent explains that semi-rigid control wire 108 “is routed from [a] handle to the clip 101” and “acts as a means of actuating the clip 101 between the open and closed position. The clip 101 can be actuated between the open and closed position multiple times as long as the lock holes 104 and 105 do not become engaged with the lock pawls 114 and

115." *Id.* at 5:39–47. More specifically, the '245 patent explains that when the handle is actuated to close the clip, sheath 111 supplies a resistive force opposite the pulling force applied to control wire 108. *Id.* at 5:60–65. By contrast, "[t]he forces reverse when the lever [of the handle] is moved in the opposite direction, and the control wire 108 is compressed to push clip 101 forward [to open the clip]. In this function, the combination of control wire 108 and sheath 111 acts as a simple push-pull, cable actuation mechanism." *Id.* at 5:65–6:3; *see also id.* at 14:40–57 (disclosing a stainless steel wire with "sufficient strength in both tension and compression").

In this manner, the '245 patent discloses that the clip may be opened and closed repeatedly until the desired portion of tissue is compressed. *Id.* at 2:62–66, 5:44–47, 7:20–23. "If the pinching is unsuccessful or only marginally successful, the clip legs of the device may be opened by reversing the actuation of the activator. Alternatively, if the pinching is successful, and the operator wishes to deploy the device, the actuator is fully activated." *Id.* at 15:26–31.

> Once the operator decides the clip 101 should be permanently deployed, the handle can be fully actuated, which causes the retainer release 109 to pull the retainer 110 free from the outer sleeve 112 and lock sleeve 113. After the retainer 110 is released, increasing force will begin straightening the j-hook 107. The j-hook 107 is then pulled from the cut-out 106 on the proximal side of clip 101. At this point, the retainer 110 and control wire 108 are no longer attached to the distal portion of the device (the clip 101 and lock sleeve 113) and the delivery device (e.g.[,] an endoscope, not shown) can be removed while leaving the clip 101 (with lock sleeve 113) in place.

Id. at 5:47–59.

D. Illustrative Claim

Of the challenged claims, claims 1, 14, and 15 are independent. Claim 1 is illustrative and is reproduced below.

> 1. A medical device for causing the hemostasis of a blood vessel for use through an endoscope, said medical device comprising:
>
> a clip, the clip having at least two clip legs;
>
> a breakable link adapted to couple a control wire to the clip and adapted to be broken by a first predetermined tensile force applied by the control wire;
>
> *the control wire reversibly operable both to open the at least two clip legs and to close the at least two clip legs* when the control wire is coupled to the clip;
>
> an axially rigid sheath enclosing the control wire, the sheath able to communicate a first force opposing a second force of the control wire;
>
> a handle coupled to the axially rigid sheath; and
>
> an actuator coupled to the control wire, the control wire engageable by the actuator to open the at least two clip legs, to close the at least two clip legs, and to uncouple the control wire from the clip;
>
> wherein when the breakable link is broken, the control wire uncouples from the clip.

Ex. 1001, 15:46–67 (emphasis added). Independent claim 14 generally recites similar limitations except also recites "an outer sleeve reversibly movable with respect to the clip both to open the at least two clip legs and to close the at least two clip legs; [and] a control wire coupled to the outer sleeve for moving the outer sleeve relative to the clip," and independent claim 15 recites a method of providing and using a device similar to that recited in claim 1. *Id.* at 17:3–18:26.

E. Applied References

Petitioner relies upon the following references:

> Kortenbach et al., U.S. Patent No. 6,808,491 B2, filed May 20, 2002, issued October 26, 2004 (Ex. 1004, "Kortenbach I");
>
> Kortenbach et al., U.S. Patent No. 6,569,085 B2, filed August 16, 2001, issued Mat 27, 2003 (Ex. 1006, "Kortenbach II");
>
> Matsuno et al. U.S. Patent No. 5,766,184, filed Nov. 2, 1995, issued June 16, 1998 (Ex. 1007, "Matsuno");
>
> Rapacki et al., U.S. Patent No. 5,569,274, filed June 24, 1994, issued October 29, 1996 (Ex. 1008, "Rapacki");
>
> Kirsch et al., U.S. Patent No. 4,733,664, filed October 15, 1985, issued March 29, 1988 (Ex. 1009, "Kirsch").

Pet. 3. Petitioner also submits the Declaration of Dr. Morton O. Jensen (Ex. 1002). Patent Owner does not offer declarant testimony at this stage of the proceeding.

F. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–15 of the '245 patent based on the following asserted grounds of unpatentability. Pet. 4–5.

Claim(s) Challenged	35 U.S.C. §[1]	Reference(s)/Basis
1, 4, 5, 7, 8, 10, 12, 13, 15	102(e)	Kortenbach I
1, 3–5, 7, 9, 10, 12, 13, 15	103	Kortenbach I
1, 7, 9, 12, 13, 15	102(e)	Kortenbach II
1, 7, 9, 12, 13, 15	103	Kortenbach II

[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102, 103. Because the application from which the '245 patent issued was filed before March 16, 2013, the effective date of the relevant amendment, the pre-AIA versions of §§ 102, 103 apply.

Claim(s) Challenged	35 U.S.C. §[1]	Reference(s)/Basis
1, 3–7, 9–15	102(b)	Matsuno
1, 3–7, 9–15	103	Matsuno, Kirsch[2]
1, 3–13, 15	103	Matsuno, Rapacki[3]
2	103	Kortenbach I, Kirsch

II. DISCUSSION

A. Claim Construction

For petitions filed on or after November 13, 2018, a claim shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. 37 C.F.R. § 42.100(b) (2019). The Petition was filed November 26, 2019. Thus, we apply the claim construction standard as set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

Accordingly, claim terms are generally given their ordinary and customary meaning as would have been understood by one with ordinary skill in the art in the context of the specification, the prosecution history, other claims, and even extrinsic evidence including expert and inventor testimony, dictionaries, and learned treatises, although extrinsic evidence is less significant than the intrinsic record. *Phillips*, 415 F.3d at 1312–1317.

[2] Petitioner identifies this ground as based on "Matsuno in view of the knowledge of a POSITA and/or Kirsch." Pet. 4.

[3] Petitioner identifies this ground as based on "Matsuno in view of the knowledge of a POSITA and/or Rapacki." *Id.*

Usually, the specification is dispositive, and it is the single best guide to the meaning of a disputed term.

Only those claim terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017). We determine that no claim term requires express construction for purposes of this Decision.

B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 102 if a prior art reference discloses every limitation of the claimed invention, either explicitly or inherently. *Glaxo Inc. v. Novopharm Ltd.,* 52 F.3d 1043, 1047 (Fed. Cir. 1995). To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present" in the single anticipating reference. *Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

A claim is unpatentable under 35 U.S.C. § 103 if "the differences between the subject matter sought to be patented 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." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). 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 non-

obviousness.[4] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, we must also "determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of prior art elements would have produced a predictable result weighs in the ultimate determination of obviousness. *Id.* at 416–417.

In an *inter partes* review, the petitioner must show with particularity why each challenged claim is unpatentable. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016); 37 C.F.R. § 42.104(b). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

C. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art "would have possessed the knowledge and skill known by an engineer or similar professional with at least a bachelor's 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. 5. Petitioner relies upon Dr. Jensen's declaration to support this position. *Id.* (citing Ex. 1002 ¶¶ 34–37). Patent Owner does not dispute Petitioner's definition. PO Resp. 8.

[4] At this stage of the proceeding, Patent Owner has not presented objective evidence of non-obviousness.

For purposes of this Decision, we adopt Petitioner's identification of the appropriate level of skill in the art, which is consistent with the level of ordinary skill in the art reflected in the prior art of record and the cited testimony of Dr. Jensen.

D. Kortenbach I

Petitioner contends that claims 1, 4, 5, 7, 9, 10, 12, 13, and 15 of the '245 patent are unpatentable as anticipated by Kortenbach I; that claims 1, 3–5, 7, 9, 10, 12, 13, and 15 are unpatentable as obvious over Kortenbach I; and that claim 2 is unpatentable as obvious over the combined teachings of Kortenbach I and Kirsch. Pet. 4–5.

1. Overview of Kortenbach I (Ex. 1004)

Kortenbach I is a U.S. patent titled "Methods and Apparatus for On-Endoscope Instruments Having End Effectors and Combinations of On-Endoscope and Through-Endoscope Instruments." Ex. 1004, code (54). Kortenbach I discloses an apparatus for treating gastric ulcers that includes a treatment device, e.g., a clip, mounted on the outer surface of an endoscope. *Id.* at code (57), 1:60–62. Kortenbach I explains that prior art devices were inadequate for treating large gastric ulcers because the clip was delivered through the working lumen of an endoscope, which limited the size of the clip to one that could fit through the endoscope. *Id.* at 1:43–57. Thus, Kortenbach I discloses an "on-scope" device capable of treating large ulcers. *Id.* at code (57), 2:66–2:2.

Figures 15, 16, and 20 of Kortenbach I are reproduced below.

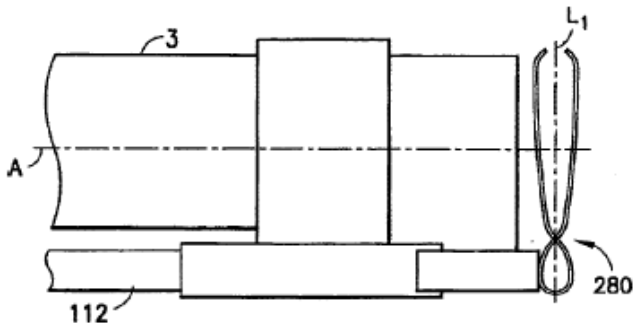

FIG.15

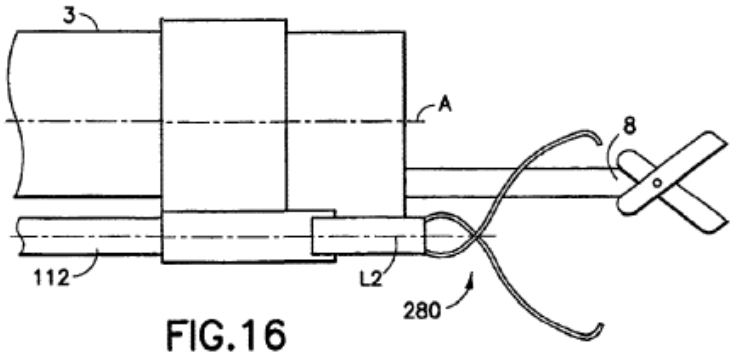

FIG.16

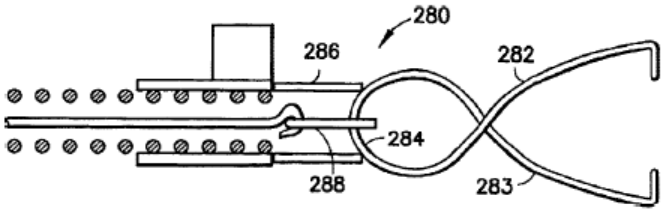

FIG.20

Figures 15, 16, and 20 depict broken side elevation views of an embodiment of Kortenbach I in which the on-scope device is a hemoclip, depicted in first, second, and third positions, respectively. *Id.* at 7:56–57.

Figure 15 depicts hemoclip 280 mounted on endoscope 3, and oriented in a first position in which clip jaws 282, 283 are closed and perpendicular to axis A of the endoscope, permitting visualization through the lumen of the endoscope and through the jaws of the clip. *Id.* at 7:56–67, 8:3–5; *see also id.* at 5:5–6. In operation, the endoscope is moved toward

the target tissue in this position and the hemoclip is then moved into a second position, shown in Figure 16, using a combination of a pull wire and coil. *Id.* at 8:5–15; *see also id.* at 2:7–17, 2:57–61, 4:18–21, 5:6–9.

Figure 16 depicts the second position in which jaws 282, 283 are open and substantially parallel to the axis of the endoscope. *Id.* at 7:57–8:3. In this position, "grasper 8 is then passed through the working channel of the endoscope 3 to grasp tissue and pull it between the jaws 282, 283 of the hemoclip." *Id.* at 8:13–16; *see also id.* at 5:10–18.

Figure 20 depicts a third position in which jaws 282, 283 are substantially closed about the tissue that was pulled by the grasper. *Id.* at 8:10–19. In operation, the hemoclip is "closed about the tissue by pulling the pull wire 118 relative to the coil 112 such that the proximal portions of the jaws 282, 283 are pulled into the tubes 285, 286 and effect closure of the jaws about the tissue." *Id.* at 8:16–19 *see also id.* at 5:18–20. Continuing to pull the pull wire breaks frangible link 288 "such that the hemoclip separates from the endoscope and remains on the tissue." *Id.* at 8:19–23.

2. Anticipation by Kortenbach I

Claim 1 recites "[a] control wire reversibly operable both to open the at least two clip legs and to close the at least two clip legs when the control wire is coupled to the clip." Ex. 1001, 15:54–56. Claim 15 includes a similar limitation. *Id.* at 18:3–5. Dependent claims 4, 5, 7, 9, 10, 12, and 13 incorporate this limitation of claim 1.

Petitioner contends that claims 1, 4, 5, 7, 9, 10, 12, 13, and 15 of the '245 patent are unpatentable as anticipated by Kortenbach I. Pet. 16–34. Petitioner identifies Kortenbach I's clip 280, which includes two legs 282, 283, as the claimed clip. Pet. 21; *see, e.g.*, Ex. 1004, 7:55–60, Figs. 15–20.

Petitioner identifies pull wire 118 as the claimed control wire. Pet. 22–23, Ex. 1004, 7:55–8:23. Petitioner alleges, "Kortenbach I discloses that the control wire reversibly opens the two clip legs and closes the two legs." Pet. 23 (citing Ex. 1002 ¶¶ 76–78). According to Petitioner,

> [A]s shown in Fig. 15, when the control wire is extended distally, the clip legs are closed. Then, as shown in Fig. 16, when the control wire is pulled proximally, the clip legs are caused to open. As the control wire is pulled more proximally, the clip and clip legs contact the sides of the tube, and the clip legs begin to close towards each other. Should the control wire (or rod) be released or pushed distally, the clip legs will return to the open state, or all the way to the initial closed state depicted in Fig. 15. This operation may continue until the clip is pulled all the way into the tube, which locks it into place so that the breakable link can be broken to separate the clip from the control wire.

Id. at 23–24 (citations omitted). Finally, although Petitioner argues that the claims do not require the capability to repeatedly open and close the clip legs, and do not specify the degree of opening and closing, "a POSITA would understand that the clip can be opened and closed as many times as desired and can move from fully open to fully closed positions as well." *Id.* at 25 (citing Ex. 1002 ¶ 79).[5]

Patent Owner disagrees and argues, *inter alia*, that Kortenbach I does not disclose a control wire "reversibly operable" to both open and close the clip. Prelim. Resp. 15–18, 20–26. Patent Owner contends that Kortenbach I discloses "a 'pull-wire,' and only ever describes pulling the wire proximally to cause opening and closing of the jaws of the clip." *Id.* at 20. Patent

[5] We need not resolve whether the claims require repeated opening and closing, or a certain degree of opening or closing, because Petitioner has not shown the art to disclose or suggest a "control wire reversibly operable."

Owner argues that Kortenbach I does not disclose pushing the wire in the opposite (distal) direction. *Id.* Instead, according to Patent Owner, "the clip starts out closed when the wire is in its most proximal location" and then, "as the pull-wire is pulled, it pulls the proximal portions of the clip (i.e., proximal bridging portion 284) into closing tubes 285/286, forcing the distal portions of the clip jaws to open." *Id.* at 21. Patent Owner explains that "as the pull-wire is pulled further, the proximal ends of the clip enter the tubes and the clip is closed and detached." *Id.* at 21 (citing Ex. 1004, 8:17–24).

According to Patent Owner, Kortenbach I discloses "unidirectional operation of the pull-wire—being pulled proximally—and does not address whether the pull-wire is reversibly operable (i.e., can also be pushed distally) to open and close the clip." *Id.* (quoting, e.g., Ex. 1004, 2:60–61 ("single linear movement"). Patent Owner alleges that reversible operation is not needed in Kortenbach I because the grasper is used to place tissue between the jaws before closing the clip, such that repositioning is unnecessary. *Id.* Further, Patent Owner argues that neither Petitioner nor Kortenbach I "say[] anything about the rigidity of the wire or why it can allegedly transmit a compressive force to the clip. [Petitioner] also fails to explain how the jaws of the clip could be pushed back out of closing tubes 285 and 286, once part of the clip has entered the tubes." *Id.* at 22. According to Patent Owner, Dr. Jensen provides testimony that is nearly verbatim to the Petition and also lacks any persuasive supporting evidence. *Id.* at 23.

On the record before us, we determine that Petitioner has not shown a reasonable likelihood of prevailing with respect to this limitation. Petitioner does not cite any disclosure in Kortenbach I in which the pull wire is pushed

distally away from the operator to open or close the clip legs.[6] Pet. 23–25 (citing Ex. 1004, 2:57–61, 7:55–8:23). Rather, the cited portion of column two describes that the jaws are "moved from the first closed position [e.g., Figure 15] to an open position [e.g., Figure 16], to the second closed position [e.g., Figure 20], and back to the first closed position [e.g., Figure 15] with a single actuation device having a *single linear movement.*" Ex. 1004, 2:57–61 (emphasis added). Petitioner does not explain how a control wire that uses a "single linear movement" to both open and close the clip legs is, somehow, "reversibly operable" to both open and close the clip legs.

Likewise, the cited portion of columns seven and eight describes similar movement, i.e., "hemoclip 280 is moved relative to the end of the endoscope . . . using a combination of a pull wire 118 and a coil 112" and, after the grasper pulls tissue toward the jaws, the "hemoclip is then closed about the tissue by pulling the pull wire 118 relative to the coil 112 . . . [to] effect closure of the jaws about the tissue." *Id.* at 7:55–8:23. Thus, none of the cited portions of Kortenbach I describe distal, pushing movement of the "pull wire" to open or close the jaws.[7]

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[6] Petitioner relies upon the embodiment shown in Figures 15–20, due to its teaching of a breakable link. Pet. 18. Petitioner acknowledges that this embodiment "use[s] the same conventional components shown above [in Figure 1] from the sheath back to the proximal end of the device at the handle." *Id.* Accordingly, we consider both of Kortenbach I's embodiments, disclosing pull wire 18 and 118.

[7] Although not cited by Petitioner, we recognize that Kortenbach I discloses that the pull wire and coil move relative to each other. Ex. 1004, 2:11–17, 4:12–16. However, neither Petitioner nor Dr. Jensen discuss these

Petitioner relies upon Dr. Jensen's testimony to support its argument that "[s]hould the control wire (or rod) be released or pushed distally, the clip legs will return to the open state, or all the way to the initial closed state depicted in Fig. 15." Pet. 24 (citing Ex. 1002 ¶¶ 76–78; Ex. 1004, 7:55–8:23). However, although Dr. Jensen makes a nearly verbatim statement, he provides no evidence to support it. Ex. 1002 ¶ 77 (citing nothing); 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."). In other paragraphs of his declaration, Dr. Jensen cites the same portions of Kortenbach I discussed above which, again, do not disclose distally pushing the pull wire. Ex. 1002 ¶¶ 78, 79. Moreover, Dr. Jensen does not offer any persuasive reasoning to support his opinion, for example, based upon the structure or materials disclosed by Kortenbach I. *Cf.* Prelim. Resp. 22. For example, Dr. Jensen does not discuss the material from which the pull wire is manufactured, or explain whether it is sufficiently strong to permit distal pushing. Accordingly, we give little to no weight to Dr. Jensen's testimony. 37 C.F.R. § 42.65(a).

For the foregoing reasons, Petitioner has not supported adequately its contention that Kortenbach I discloses this limitation of claims 1 and 15. Accordingly, we are not persuaded that Petitioner has shown a reasonable likelihood of prevailing with respect to independent claims 1 or 15, or claims 4, 5, 7, 9, 10, 12, or 13, which each depends from claim 1.

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disclosures or explain whether relative movement between two components constitutes a control wire being reversibly operable, as claimed.

3. Obviousness over Kortenbach I

Petitioner contends that claims 1, 3–5, 7, 9, 10, 12, 13, and 15 of the '245 patent are unpatentable as obvious over Kortenbach I. Pet. 34–37. Petitioner contends that, to the extent Kortenbach I does not disclose a reversibly operable control wire, a person of ordinary skill in the art "would find this limitation obvious over Kortenbach I." *Id.* at 34–35 (citing Ex. 1002 ¶¶ 101–104).[8] According to Petitioner, "Kortenbach I repeatedly discusses moving the clip between closed to open to closed positions." *Id.* at 34. Petitioner quotes Kortenbach I's disclosure that "relative movement of the coil and pull wire causes opening and closing of the jaws," and alleges that the clip legs may continue to be manipulated until the frangible link is broken. *Id.* at 35 (quoting Ex. 1004, 2:15–18, citing Ex. 1004, 8:11–23). Accordingly, Petitioner asserts that Kortenbach I "at a minimum strongly suggests[] the ability to reversibly operate the clip arms via the control wire," and a person of ordinary skill in the art would have understood "that the clip may be opened and closed based on the movement of the control wire by the operator." *Id.* at 34–35.

Patent Owner argues, *inter alia*, that Petitioner fails to explain why a person of ordinary skill in the art would have understood Kortenbach I to disclose reversible operation, contending that Petitioner simply reiterates its unpersuasive anticipation argument. Prelim. Resp. 27–29. Patent Owner also contends that Petitioner provides no reasoning to explain

[8] Although Patent Owner does not dispute Petitioner's statement that "there is no requirement that once the clip legs are locked into position and the control wire is uncoupled from the clip, that it still be possible to open and close the clip legs," Petitioner has not explained how this statement has any pertinence to this obviousness ground. Pet. 34, 47; Ex. 1003 ¶¶ 102, 130.

> why a person of ordinary skill in the art would be motivated to modify the unidirectional 'pull-wire' to permit it to be operated in both the 'push' and 'pull' axial directions, why one would do so in light of Kortenbach I's grasper, how the pull-wire could be modified to have the dimensional stability (rigidity) to exert force in the 'push' direction, or why that would open the clip as opposed to pushing the closing tubes forward with the clip in them.

Id. at 28. Patent Owner contends that Dr. Jensen's testimony suffers from the same deficiencies. *Id.* at 27–29.

On the record before us, we determine that Petitioner has not shown a reasonable likelihood of prevailing. As discussed above, we are not persuaded that Kortenbach I discloses a reversibly operable control wire. In this obviousness ground, Petitioner has not provided any persuasive reasoning to explain why a person of ordinary skill in the art would have understood the pull wire of Kortenbach I's unmodified device to be capable of reversible operation, including in a pushing direction, to open or close the clip legs. Pet. 34–35. Nor does Petitioner provide any persuasive reasoning to explain why a person of ordinary skill in the art would have found it obvious to modify Kortenbach I's control wire to be reversibly operable. *Id.* Petitioner simply concludes that a person of ordinary skill would have found this obvious because Kortenbach I discloses that the clip legs move between open and closed positions, the coil and pull wire move relatively to open and close the clip legs, and the clip legs may be manipulated until the clip is fixed in position. *Id.* However, Petitioner does not explain how or why these disclosures would have led an ordinarily skilled artisan to reversibly operate the pull wire—a feature not discussed in the cited disclosures. Dr. Jensen's testimony is nearly verbatim, and provides no further reasoning

or explanation. Ex. 1002 ¶ 103; *see also id.* ¶¶ 101–104. These unsupported and unreasoned conclusions are insufficient. 37 C.F.R. § 42.65(a).

Further, we are unpersuaded by Petitioner's argument that "[t]he mere possibility that a minor difference in the opening and closing of the clip arms between the '245 patent and Kortenbach I may exist is not enough to defeat obviousness." Pet. 35. Without explanation or reasoning as to *why* a skilled artisan would have found this purportedly "minor difference" obvious, we disagree. Moreover, the '245 patent suggests that reversible operation is more than a "minor difference" over the prior art. Ex. 1001, 2:25–35, 2:61–66. The '245 patent describes the reversibly operable control wire as central to the device's ability to repeatedly reposition a clip, which the '245 patent describes as solving a problem in the prior art. *Id.*; *see also id.* at 14:40–44 (properties of the control wire), 15:25–30 (repositioning).

For the foregoing reasons, Petitioner has not supported adequately its contention that claims 1 or 15 would have been obvious over Kortenbach I. Accordingly, we are not persuaded that Petitioner has shown a reasonable likelihood of prevailing with respect to independent claims 1 or 15, or claims 3–5, 7, 9, 10, 12, or 13, which each depends from claim 1.

4. Obviousness over Kortenbach I and Kirsch

Petitioner contends that claim 2 would have been obvious over the combined teachings of Kortenbach I and Kirsch. Pet. 79–81.

Petitioner's contentions regarding claim 2 incorporate the same deficiencies discussed above regarding claim 1, from which claim 2 depends. For the same reasons, Petitioner has not established a reasonable likelihood of prevailing with respect to claim 2.

E. Kortenbach II

Petitioner contends that claims 1, 7, 9, 12, 13, and 15 of the '245 patent are unpatentable as anticipated or obvious over Kortenbach II. Pet. 4–5.

1. Overview of Kortenbach II (Ex. 1006)

Kortenbach II is a U.S. patent titled "Methods and Apparatus for On-Delivering a Medical Instrument Over an Endoscope While the Endoscope is in a Body Lumen." Ex. 1006, code (54). Kortenbach II discloses "delivering a medical instrument," e.g., a hemostasis clip, "over the exterior of an endoscope while the endoscope is installed in the patient's body [to] allow the use of instruments which are too large to fit through the lumen[(s)] of an endoscope." *Id.* at code (57), 5:1–2.

Figure 1 of Kortenbach II is reproduced below.

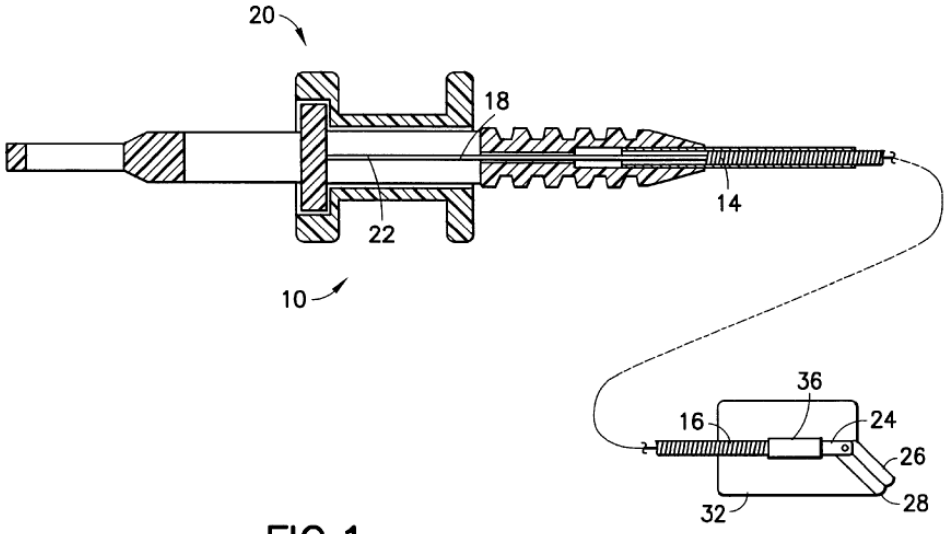

FIG. 1

Figure 1 depicts a broken side elevation view of an apparatus according to a first embodiment. *Id.* at 4:3–4. Apparatus 10 includes flexible coil 12[9] with

[9] Although reference numeral 12 is not depicted in Figure 1, reference numeral 14 (depicted) identifies the proximal end of coil 12. *Id.* at 4:45.

pull wire 18 extending though the coil, where the proximal ends of the coil and pull wire are coupled to actuation device 20. *Id.* at 4:43–50. Distal end 16 of coil 12 is coupled to clevis 24, and the clevis is rotatably coupled to jaws 26, 28. *Id.* at 4:50–52. "[J]aws 26, 28 are also coupled to the distal end (not shown) of the pull wire 18 such that movement of one of the pull wire or the coil relative to the other causes the jaws to open or close." *Id.* at 4:52–55.

In operation, Kortenbach II discloses that the endoscope is delivered toward the target tissue, and graspers are passed through the endoscope's lumen to grasp the tissue and pull it between jaws 26, 28. *Id.* at 5:2–7. "The jaws 26, 28 are then closed over the tissue," and "cam lock 35 locks the jaws in the closed position whereafter the jaws are separated from the apparatus 10 via the quick release 36." *Id.* at 5:7–15. The apparatus is then removed and another pair of jaws may be attached, for application of another clip. *Id.* at 5:15–19.

2. Anticipation by Kortenbach II

Claim 1 recites "[a] control wire reversibly operable both to open the at least two clip legs and to close the at least two clip legs when the control wire is coupled to the clip." Ex. 1001, 15:54–56. Claim 15 includes a similar limitation. *Id.* at 18:3–5. Dependent claims 7, 9, 12, and 13 incorporate this limitation of claim 1.

Petitioner contends that claims 1, 7, 9, 12, 13, and 15 of the '245 patent are unpatentable as anticipated by Kortenbach II. Pet. 38–46. Petitioner identifies Kortenbach II's hemostasis clip as the claimed clip, which includes two legs 26, 28. Pet. 39; *see, e.g.*, Ex. 1006, 4:50–52, 5:1–2.

Petitioner identifies pull wire 18 as the claimed control wire. Pet. 41, Ex. 1006, 4:52–55. Petitioner alleges,

> Kortenbach II discloses that the control wire opens the two clip legs and closes the two clip legs. For example, Kortenbach II teaches that "the jaws 26, 28 are also coupled to the distal end (not shown) of the pull wire 18 such that movement of one of the pull wire of the coil relative to the other causes the jaws to open or close." Kortenbach II further explains that the jaws may be open[ed] and closed until they are "locked shut" by the cam lock.

Pet. 41 (citing Ex. 1002 ¶¶ 110–111; Ex. 1006, 4:43–5:31; quoting Ex. 1006, 4:52–55).

Patent Owner disagrees and argues, *inter alia*, that Kortenbach II does not disclose a control wire "reversibly operable" to both open and close the clip. Prelim. Resp. 32–33. Patent Owner contends that Kortenbach II discloses "a 'pull-wire' that—in an un[-]shown and unspecified manner—supposedly opens and closes the jaws as it is pulled in a single, axial direction." *Id.* at 32. According to Patent Owner, Petitioner does not identify any disclosure suggesting that the pull wire can be pushed distally. *Id.* Patent Owner also argues that Petitioner fails to explain how relative movement between the coil and pull wire "means that the jaws can be both opened and closed by ***reversible operation*** of the pull-wire." *Id.* at 32–33. Additionally, Patent Owner argues that Petitioner lacks support for its contention that "the jaws may be open[ed] and closed until they are 'locked shut' by the cam lock." *Id.* at 32.

On the record before us, we determine that Petitioner has not shown a reasonable likelihood of prevailing with respect to this limitation. On its face, Petitioner's contentions are insufficient. Petitioner alleges that "Kortenbach II discloses that the control wire opens the two clip legs and

closes the two clip legs" and "the jaws may be open[ed] and closed until they are 'locked shut' by the cam lock." Pet. 41. However, even if accurate, this does not address the claim language requiring the control wire be "reversibly operable" to open and close the clip legs. In other words, even if the pull wire may be operated to open and close the clip legs until they are locked shut, Petitioner does not demonstrate that this involves the claimed reversible operation. For example, the legs could be opened and closed until locked shut by operating the pull wire in a single proximal direction.[10] The claims require that the control wire is "reversibly operable" to both open and close the clip legs, and Petitioner does not address the "reversibl[e]" portion of this requirement.

Moreover, Petitioner does not cite any disclosure in Kortenbach II in which the pull wire is operated reversibly. In the cited portion, the pull wire is described as moving relative to the coil. *See, e.g.*, Ex. 1006, 4:46–55 ("[M]ovement of one of the pull wire or the coil relative to the other causes the jaws to open or close."). Petitioner fails to explain how relative movement of the coil and pull wire results in the control wire itself being reversibly operable to both open and close the jaws. Prelim. Resp. 32–33; Pet. 41. For example, it is consistent with this disclosure that the pull wire is pulled only proximally toward the operator, relative to the coil, to open and close the clip legs. Petitioner does not demonstrate that this disclosure is anticipatory.

[10] Elsewhere Petitioner appears to acknowledge that the pull wire is *not* reversibly operable and is only pulled proximally toward the operator. Pet. 43 ("Pulling the actuator causes the control wire to open the two clip legs and to close the two clip legs."); *see also* Prelim. Resp. 32.

Moreover, we agree with Patent Owner that the cited portion does not disclose that the clip legs may be opened and closed repeatedly, so long as they are not locked by the cam lock. Prelim. Resp. 33; *but see supra* n.5. Kortenbach II explains only that the "jaws 26, 28 are then closed over the tissue" and "[w]hen the jaws are moved into the closed position shown in FIG. 5, the cam lock 35 locks the jaws in the closed position." Ex. 1006, 5:7–15. Kortenbach II does not discuss opening the jaws after closure has begun, or whether such an operation might be accomplished through reversible operation of the pull wire.

Finally, Petitioner relies upon Dr. Jensen's testimony to support its argument. Pet. 41 (citing Ex. 1002 ¶¶ 110–111). However, Dr. Jensen's testimony is nearly verbatim to the Petition, and lacks any further support or reasoning. Ex. 1002 ¶¶ 110–111. Accordingly, Dr. Jensen's testimony is unpersuasive. 37 C.F.R. § 42.65(a).

For the foregoing reasons, Petitioner has not supported adequately its contention that Kortenbach II discloses this limitation of claims 1 and 15. Accordingly, we are not persuaded that Petitioner has shown a reasonable likelihood of prevailing with respect to independent claims 1 or 15, or claims 7, 9, 12, or 13, which depend from claim 1.

3. Obviousness over Kortenbach II

Petitioner contends that claims 1, 7, 9, 12, 13, and 15 of the '245 patent are unpatentable as obvious over Kortenbach II. Pet. 46–48. Petitioner contends that, to the extent Kortenbach II does not disclose a reversibly operable control wire, a person of ordinary skill in the art "would find this limitation obvious over Kortenbach II." *Id.* at 46–47 (citing Ex. 1002 ¶¶ 129–133). According to Petitioner, "Kortenbach II repeatedly

discusses moving the clip between closed to open to closed positions." *Id.* at 47. Petitioner quotes Kortenbach II's disclosure that "movement of one of the pull wire or the coil relative to the other causes the jaws to open or close," and alleges that the clip legs may continue to be manipulated until the clip legs are locked shut. *Id.* (quoting Ex. 1006, 4:52–55, 5:1–31). Accordingly, Petitioner asserts that Kortenbach II "at a minimum strongly suggests[] the ability to reversibly operate the clip arms via the control wire," and a person of ordinary skill in the art would understand "that the clip may be opened and closed based on the movement of the control wire by the operator." *Id.* at 47.

Patent Owner argues, *inter alia*, that Petitioner fails to explain why a person of ordinary skill in the art would have understood Kortenbach II to disclose reversible operation, contending that Petitioner simply reiterates its unpersuasive anticipation argument. Prelim. Resp. 38–40. Patent Owner also contends that Petitioner provides no reasoning to explain

> why a person having ordinary skill in the art at that time of the invention would be motivated to modify the unidirectional "pull-wire" to permit it to be operated in both the "push" and "pull" axial directions, or how it could be modified to have the dimensional stability (rigidity) necessary to exert force in the "push" direction to open or close the clip. [Petitioner does] not address the disclosure that the Kortenbach II wire is less rigid at the distal end of the device, and thin enough to allow the wire to break. Nor [does Petitioner] provide any reasoning whatsoever why this limitation is obvious because the jaws are locked closed once they have been closed all of the way, or explain how the mechanism even opens the clip in the first place if the clip is locked shut.

Id. at 39–40. Patent Owner contends that Dr. Jensen's testimony suffers from the same deficiencies. *Id.*

On the record before us, we determine that Petitioner has not shown a reasonable likelihood of prevailing. As discussed above, we are not persuaded that Kortenbach II discloses a reversibly operable control wire, as claimed. In this obviousness ground, Petitioner has not provided any persuasive reasoning to explain why a person of ordinary skill in the art would have understood the pull wire of Kortenbach II's unmodified device to be capable of reversible operation, in a pushing direction, to open or close the clip legs. Pet. 46–48. Nor does Petitioner provide any persuasive reasoning to explain why a person of ordinary skill in the art would have found it obvious to modify Kortenbach II's control wire to be reversibly operable. *Id.* Petitioner simply concludes that a person of ordinary skill would have found this obvious because Kortenbach II discloses that the clip legs move between open and closed positions, the coil and pull wire move relatively to open and close the clip legs, and the clip legs may be manipulated until the clip is locked shut. *Id.* However, Petitioner does not explain how or why these disclosures would have led an ordinarily skilled artisan to reversibly operate the pull wire—a feature not discussed in the cited disclosures. Dr. Jensen's testimony is nearly verbatim, and provides no further reasoning or explanation. Ex. 1002 ¶¶ 131–132; *see also id.* ¶¶ 129–133. Unsupported and unreasoned conclusions are insufficient. 37 C.F.R. § 42.65(a).

For the foregoing reasons, Petitioner has not supported adequately its contention that claims 1 or 15 would have been obvious over Kortenbach II. Accordingly, we are not persuaded that Petitioner has shown a reasonable likelihood of prevailing with respect to independent claims 1 or 15, or claims 7, 9, 12, or 13, which each depends from claim 1.

F. Matsuno

Petitioner contends that claims 1, 3–7, and 9–15 of the '245 patent are unpatentable as anticipated by Matsuno; that claims 1, 3–7, and 9–15 are unpatentable as obvious over Matsuno in view of the knowledge of a person of ordinary skill in the art and/or Kirsch; and that claims 1, 3–13, and 15 are unpatentable as obvious over Matsuno in view of the knowledge of a person of ordinary skill in the art and/or Rapacki. Pet. 4–5.

1. Overview of Matsuno (Ex. 1007)

Matsuno is a U.S. patent titled "Endoscopic Treatment Tool." Ex. 1007, code (54). Matsuno discloses a treatment tool that is led into a patient's body through the channel of an endoscope, and which may be rotated inside the body. *Id.* at code (57).

Figure 1A is reproduced below.

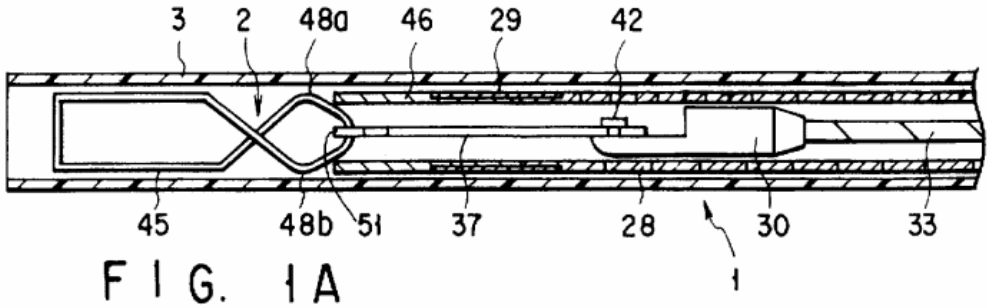

FIG. 1A

Figure 1A depicts a longitudinal sectional view of the forward end of a clip device. *Id.* at 2:19–22. The device incudes clip unit 2 mounted on clip device 1. *Id.* at 3:47–50. Lead tube 3 surrounds clip device 1, and is adapted to be passed through the channel of an endoscope. *Id.* at 3:50–55. Operating tube 28 is located within lead tube 3, and operating wire 33 is inserted in operating tube 28. *Id.* at 3:63–4:11. Operating wire 33 includes hook 30, which engages coupling plate 37 to engage a clip. *Id.* at 4:12–14.

Figure 5B is reproduced below.

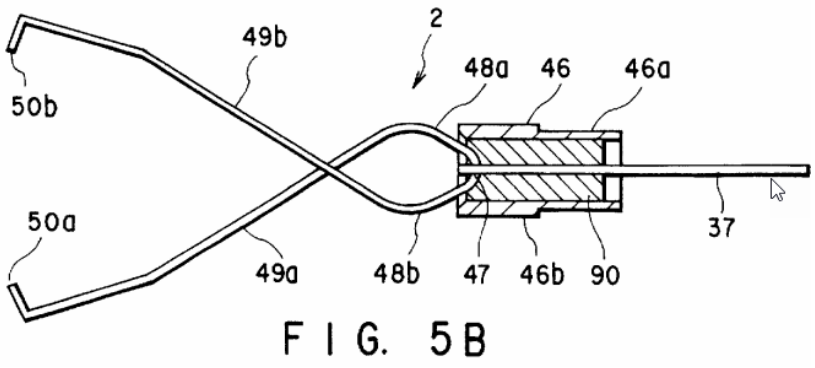

FIG. 5B

Figure 5B depicts a plan view of a clip. *Id.* at 2:29–30. As shown, clip unit 2 includes clip 45, which includes extending and intersecting arms 49a, 49b, and loosely-fitted portions 48a, 48b that are wider than the inner diameter of clip-fastening ring 46. *Id.* at 4:60–5:5. Arms 49a, 49b are biased open. *Id.* at 5:5–7. Coupling plate 37 removably engages clip 45 at base end 47, through a J-shaped hook. *Id.* at 5:8–11, Fig. 5A (hook 51).

Figure 2 is reproduced below.

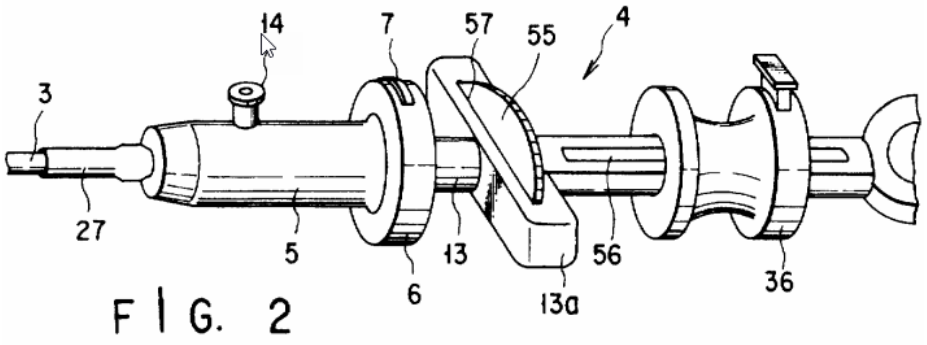

FIG. 2

Figure 2 depicts a perspective view of the operating section of a clip device, wherein the base end of lead tube 3, shown further above in Figure 1A, is coupled to the leftmost end of the operating section shown above in Figure 2. *Id.* at 2:19–24, 3:60–62. Operating unit proper 5 includes first slider 13 and second slider 36, wherein second slider 36 is rotatably coupled to operating wire 33. *Id.* at 3:56–60, 9:2–3.

Matsuno describes device operation as follows.

1. To load a clip, first slider 13 is pushed toward the forward end, projecting operating tube 28 from lead tube 3. Second slider 36 is pushed toward the forward end, projecting hook 30 of operating wire 33 from operating tube 28. A clip is loaded by engaging hole 52 of coupling plate 37 onto pin 42 of hook 30, and pulling second slider 36 toward the operator to retract the clip. *Id.* at 11:54–12:10.

2. To prepare for insertion of the device into a patient, first slider 13 is slid toward the operator to pull operating tube 28 into lead tube 3, closing clip 45, for insertion into the body cavity through an endoscope channel. *Id.* at 12:11–16.

3. To open the clip near the target location within the patient, first slider 13 is pushed forward such that operating tube 28 and clip 45 are projected out of lead tube 3, and the inherent bias of clip arms 49a, 49b causes the clip to open. *Id.* at 12:16–22.

4. To open the clip to its widest extent, hook 30 is pulled toward the operator by pulling second slider 36 and operating wire 33, such that loosely-fitted portions 48a, 48b are retracted into clip-fastening ring 46 and "crushed, with the result that the arms 49a, 49b of the clip open to the widest degree." *Id.* at 12:23–30.

5. From this position, rotative operation member 55 is rotated to orient the clip as desired. To permit smoother rotation, tension on operating wire 33 may be released by moving second slider 36 several ratchets toward the forward end. *Id.* at 12:30–42.

> 6. To engage tissue, the clip is pressed against the tissue, second slider 36 is pulled toward the operator, which pulls operating wire 33, and as a result, arms 49a, 49b are pulled into clip-fastening ring 46, which closes clip holders 50a, 50b tightly against the tissue. By continuing to pull operating wire 33, clip 45 deeply engages into the tissue and hook 51 of coupling plate 37 is extended, such that clip 45 and fastening ring 46 remain in the body. *Id.* at 12:43–61.

See generally id. at 11:61–12:67.

2. Anticipation by Matsuno – Claims 1, 3–7, 9–13, and 15

Claim 1 recites "[a] control wire reversibly operable both to open the at least two clip legs and to close the at least two clip legs when the control wire is coupled to the clip." Ex. 1001, 15:54–56. Claim 15 includes a similar limitation. *Id.* at 17:7–12; 18:3–5. Dependent claims 3–7 and 9–13 incorporate this limitation of claim 1.

Petitioner contends that claims 1, 3–7, and 9–13 of the '245 patent are unpatentable as anticipated by Matsuno. Pet. 48–71. Petitioner identifies Matsuno's clip 45 as the claimed clip, which includes two legs. Pet. 50; *see, e.g.*, Ex. 1007, 4:64–5:7. Petitioner identifies operating wire 33 as the claimed control wire. Pet. 54–55; *see, e.g.*, Ex. 1007, 4:6–11. Petitioner alleges,

> Matsuno discloses that the control wire is reversibly operable such that it both opens and closes the clip legs. Matsuno explains that the clip legs can be closed when in contact with the outer sheath (3) as shown in Fig. 1A, then opened when extending beyond the sheath as shown in Figure 14, and then can be closed again when the legs come into contact with the tube as the control wire is pulled in the proximal direction. . . . In addition, Matsuno explains that the control wire 33 is prevented from "buckling" when it is moved back and forth to control the clip legs opening

> and closing. Matsuno further explains that the control wire 33 can be "tensioned" in either direction to pull the clip legs into or out of the ring 46, which may allow for easier control of the rotation of the clip legs.

Pet. 54–55 (citing, e.g., Ex. 1002 ¶¶ 147–148).

Patent Owner disagrees and argues, *inter alia*, that Matsuno does not disclose a control wire "reversibly operable" to both open and close the clip. Prelim. Resp. 45–49. According to Patent Owner, it is insufficient that Matsuno discloses opening and closing the legs, as Petitioner contends, because this does not address reversible operation of the control wire. *Id.* at 45. Patent Owner also argues that the cited portions of Matsuno do not support Petitioner's contentions. For example, Patent Owner argues that the clip extension cited by Petitioner is caused by operation of the first slider, not by reversible operation of the control wire. *Id.* Patent Owner also contends that "[t]he only time the user operates the wire is when the second slider pulls the wire proximally. The user pulls the clip into the clip-fastening ring . . . , compressing ('crush[ing]') the proximal part of the clip." Moreover, Patent Owner alleges the "only disclosure of moving the wire distally in Matsuno" involves extending the hook out of the device to allow clip loading, which does not involve opening or closing the clip legs. *Id.* at 45–46 (also arguing Petitioner does not demonstrate that Matsuno's wire is rigid enough "to push the clip out of the clip-fastening ring"). Finally, Patent Owner argues that the cited disclosures regarding "buckling" and "tensioning" do not involve the opening or closing of clip legs. *Id.* at 47.

On the record before us, we determine that Petitioner has not shown a reasonable likelihood of prevailing with respect to this limitation. Petitioner's contention that "Matsuno explains that the clip legs can be

closed when in contact with the outer sheath . . . then opened when extending beyond the sheath . . . and then closed again . . . as the control wire is pulled in the proximal direction" fails to address the pertinent claim language, namely, whether the control wire is reversibly operable to perform these actions. Pet. 54–55. Indeed, Petitioner addresses the control wire only with respect to the second closing of the clip legs ("then closed again . . . as the control wire is pulled in the proximal direction"), but does not address whether the control wire is reversibly operable with respect to either the first closing or the opening of the clip legs. *Id.*

Moreover, Matsuno does not describe reversible operation of the operating wire to open and close the clip legs. Matsuno explains that the clip is opened to its widest extent[11] by pulling second slider 36, with coupled operating wire 33, toward the operator (i.e., proximally) to "crush[]" loosely-fitted portions 48a, 48b of the clip into clip-fastening ring 46, thereby fully opening the clip. *Id.* at 12:23–30. Then, to close the clip legs, second slider 36, with coupled operating wire 33, is again pulled toward the operator (i.e., proximally) to pull clip legs 49a, 49b into clip-fastening ring 46, thereby closing the clip. *Id.* at 12:43–61.[12] Thus, even though operating wire 33 is operable to open and close the clip legs, the wire is pulled in a single direction—proximally—to achieve these functions; it is not shown to be "reversibly operable" as claimed. *Id.*

[11] Matsuno explains that the clip legs are first opened by pushing first slider 13 forward. Ex. 1007, 12:16–22. This initial opening of the clip legs does not involve operating wire 33. *Id.*

[12] Further pulling in the proximal direction disengages the clip so that it can be left behind in the patient. *Id.* at 12:53–61.

We agree with Patent Owner that the only disclosed distal movement of second slider 36, with coupled operating wire 33, occurs when a clip is loaded onto the device. Prelim. Resp. 46; Ex. 1007, 11:54–12:10. Specifically, first slider 13 and second slider 36, with coupled operating wire 33, are pushed toward the forward end (i.e., distally) to project hook 30 from operating tube 28 such that a new clip can be loaded. Ex. 1007, 11:54–12:10. This distal movement is disclosed only in the context of loading a clip, without any discussion of opening or closing the clip legs. Moreover, neither Petitioner nor Dr. Jensen explain any pertinence of the clip loading process to the claim language. Pet. 54–55; Ex. 1002 ¶¶ 147–148.

We have considered Petitioner's contention that Matsuno's control wire "is prevented from 'buckling' when it is moved back and forth to control the clip legs opening and closing." Pet. 55 (citing Ex. 1007, 9:7–26, 11:61–12:61). However, this contention is not supported by the cited disclosures. Matsuno discloses that operating pipe 34 is fitted over operating wire 33, to prevent buckling near second slider 36. Ex. 1007, 9:7–26; *see also id.* at 11:61–12:61 (not discussing buckling at all). This disclosure, however, does not discuss moving the operating wire or opening or closing the clip legs. Likewise unsupported is Petitioner's contention that "control wire 33 can be 'tensioned' in either direction to pull the clip legs into or out of the ring 46, which may allow for easier control of the rotation of the clip legs." Pet. 55 (citing Ex. 1007, 12:23–52). Matsuno explains that tension on operating wire 33 can be released, and rotation achieved more smoothly, by "returning the second slider 36 several ratchets toward the forward end," i.e., distally. Ex. 1007, 12:30–42. Again, however, this disclosure does not address "pull[ing] the clip legs into or out of the ring

46," as Petitioner argues, nor does it address opening or closing of the clip legs. In other words, even if second slider 36 and coupled operating wire 33 are moved distally, this simply releases tension to facilitate rotation; it is not shown to open or close the clip legs. *Id.*

Finally, Petitioner relies upon Dr. Jensen's testimony to support its argument. Pet. 54–55 (citing Ex. 1002 ¶¶ 147–148). However, Dr. Jensen's testimony is nearly verbatim to the Petition, and lacks any further support or reasoning. Ex. 1002 ¶¶ 147–148. Accordingly, Dr. Jensen's testimony is unpersuasive. 37 C.F.R. § 42.65(a).

For the foregoing reasons, Petitioner has not supported adequately its contention that Matsuno discloses this limitation of claims 1 and 15. Accordingly, we are not persuaded that Petitioner has shown a reasonable likelihood of prevailing with respect to independent claims 1 or 15, or claims 3–7 or 9–13, which each depends from claim 1.

3. Anticipation by Matsuno – Claim 14

Claim 14 recites "an outer sleeve reversibly movable with respect to the clip both to open the at least two clip legs and to close the at least two clip legs; [and] a control wire coupled to the outer sleeve for moving the outer sleeve relative to the clip." Ex. 1001, 17:3–18:26. Thus, claim 14 differs from claims 1 and 15 in that it recites that the outer sleeve is "reversibly movable" to open and close the clip legs, and that this reversible movement is controlled by a control wire. *Id.*

Petitioner contends that claim 14 of the '245 patent is unpatentable as anticipated by Matsuno. Pet. 66–71. Petitioner contends that Matsuno's lead tube 3 is the claimed outer sleeve, and alleges it is "reversibly movable with respect to the clip" because, "when the outer sleeve (3) is distally

extended, the clip legs are caused to close," and "[w]hen the outer sleeve is retracted and the clip is extended, the clip legs are caused to open because they are no longer held closed by the outer sleeve." *Id.* at 66–67 (citing Ex. 1002 ¶¶ 172–174; Ex. 1007, Figs. 1A, 14). According to Petitioner, Matsuno's operating wire 33 is the claimed control wire, which "causes the outer sleeve to move relative to the clip." *Id.* at 67–68 (citing Ex. 1002 ¶ 175; Ex. 1007, 12:11–52).[13]

Patent Owner disputes Petitioner's contentions. Prelim. Resp. 52. According to Patent Owner, "wire 33 is not coupled to the outer sleeve," but instead "is coupled to hook 30, which is coupled to coupling plate 37, which is in turn coupled to the clip unit 2." *Id.* (citing Ex. 1007, 4:12–14). Moreover, Patent Owner contends that "[p]ulling the operating wire 33 pulls clip unit 2 proximally" and, "[e]ven if that motion could be considered the 'relative motion' between the clip and the outer sleeve recited in claim element 14[b], lead tube 3 does not itself move, and it is not coupled to wire 33." *Id.* (citing Ex. 1007, 12:23–34). Patent Owner contends that Petitioner's conclusory contention "is frivolous." *Id.*

On the record before us, we determine that Petitioner has not shown a reasonable likelihood of prevailing with respect to this limitation. Even if we accept Petitioner's contention that outer sleeve 3 and clip 45 exhibit relative movement, Petitioner has not shown that the control wire "mov[es] the outer sleeve" at all, let alone "mov[es] the outer sleeve relative to the

[13] Petitioner incorporates its analysis of "claim element 1[b]," but this appears to be a typographical error. Pet. 68. The analysis of element 1[b] does not address movement of the outer sleeve, *see id.* at 52–54. It appears Petitioner intended to refer to claim element 14[b]. *See id.* at 66–67.

clip," as claimed. As discussed above, pulling second slider 36, with coupled operating wire 33, toward the operator (i.e., proximally) serves to open the clip to its widest extent. Ex. 1007, 12:23–30. Further proximal pulling of second slider 36, with coupled operating wire 33, closes the clip. *Id.* at 12:43–61. And even further pulling in the proximal direction disengages the clip so that it can be left behind in the patient. *Id.* at 12:53–61. Additionally, as also discussed above, when second slider 36, with coupled operating wire 33, is pushed toward the forward end (i.e., distally), hook 30 is projected from operating tube 28 such that a new clip can be loaded. Ex. 1007, 11:54–12:10 (also disclosing that hook is retracted by proximal movement of second slider 36 and wire 33). Petitioner does not show that either the disclosed proximal movement or the disclosed distal movement of wire 33 moves outer sleeve 3 relative to clip 45, let alone in the manner shown in cited Figures 1A and 14. Pet. 66–68. Accordingly, Petitioner's statement that "[t]he control wire causes the outer sleeve to move relative to the clip" (*see* Pet. 67–68) is insufficiently supported.

Finally, Petitioner relies upon Dr. Jensen's testimony to support its argument. Pet. 66–68 (citing Ex. 1002 ¶¶ 172–175). However, Dr. Jensen's testimony is nearly verbatim to the Petition, and lacks any further support or reasoning. Ex. 1002 ¶¶ 172–175. Accordingly, Dr. Jensen's testimony is unpersuasive. 37 C.F.R. § 42.65(a).

For the foregoing reasons, Petitioner has not supported adequately its contention that Matsuno discloses this limitation of claim 14. Accordingly, we are not persuaded that Petitioner has shown a reasonable likelihood of prevailing with respect to independent claim 14.

4. Obviousness over Matsuno and Kirsch and/or Knowledge of a POSITA

Petitioner contends that claims 1, 3–7, and 9–15 would have been obvious over Matsuno in view of the knowledge of a person of ordinary skill in the art and/or Kirsch. Pet. 72–76. Petitioner incorporates its anticipation arguments and also contends that, to the extent Matsuno does not disclose the "breakable link" limitation, it would have been obvious in view of the "well-known knowledge" of a person of ordinary skill in the art, as evidenced by Kirsch. *Id.* at 72.

Petitioner's contentions incorporate the same deficiencies related to the reversibly operable control wire discussed above in the anticipation ground. Petitioner does not rely upon Kirsch to cure this deficiency. Pet. 72–76. Accordingly, for the same reasons, Petitioner has not established a reasonable likelihood of prevailing with respect to claims 1, 3–7, and 9–15.

5. Overview of Rapacki (Ex. 1008)

Rapacki is a U.S. patent titled "Endoscopic Vascular Clamping System and Method." Ex. 1008, code (54). Rapacki discloses clamp 2, with movable jaws 66, 68, which occludes a blood vessel. *Id.* at code (57). Rapacki also describes that after the clamp is applied to a vessel, "the clamp can be easily reopened and repositioned." *Id.* at 3:50–55, 9:20–24; *see also id.* at 2:60–65 (describing problems with prior art devices that could not be repositioned).

Rapacki explains that the jaws of the clamp are opened by moving shaft 3 distally toward the clamp, and the jaws of the clamp are closed by

moving shaft 3 proximally. *Id.* at 9:11–19. Further proximal movement of shaft 3 disengages the clamp from the introducer. *Id.* at 9:24–26.

6. Obviousness over Matsuno and Rapacki and/or Knowledge of a POSITA

Petitioner contends that claims 1, 3–13, and 15 would have been obvious over Matsuno in view of the knowledge of a person of ordinary skill in the art and/or Rapacki. Pet. 76–79. Petitioner incorporates its anticipation argument and also contends that, to the extent Matsuno does not disclose a reversibly operable control wire, this would have been obvious in view of the "well-known knowledge" of a person of ordinary skill in the art, as evidenced by Rapacki. *Id.* at 76 (citing Ex. 1002 ¶¶ 193–198). Petitioner contends that "no modification to Matsuno is needed to render the claims obvious." *Id.* at 77. According to Petitioner, a person of ordinary skill in the art would have understood that "it is possible to move the clip open and closed based on retracting or protracting the control wire," so long as Matsuno's j-hook is intact and the clip is not fully engaged in the lock tube. *Id.* Petitioner asserts that the ordinarily skilled artisan would have been aware of Rapacki's teaching of opening and closing the clip to reposition it before deployment and would have been motivated to combine these teachings to allow Matsuno's clip to be repositioned. *Id.* According to Petitioner, a person of ordinary skill in the art "needed to merely take what was already present in the prior art and operate the Matsuno device in that particular manner." *Id.*

Patent Owner argues, *inter alia*, that Petitioner fails to explain why a person of ordinary skill in the art would have understood that Matsuno's device could be operated as claimed given Petitioner's position that "no

modification to Matsuno is needed," and in view of Matsuno's "express disclosure . . . that the clip cannot be pushed forward and reopened" because loosely-fitted portions 48a, 48b are "crushed by the clip-fastening ring." Prelim. Resp. 54 (citing Ex. 1007, 12:25–30). Patent Owner also alleges that Petitioner "has not explained how—even if the wire were rigid enough to push the clip forward—distal movement of the wire would possibly reopen the clip instead of just pushing the clip-fastening ring (with the clip in it) off of the coupling ring at the end of the operating tube." *Id.* Moreover, Patent Owner argues that Petitioner does not show that "any teaching from Rapacki would function in an unmodified Matsuno device." *Id.* According to Patent Owner, Petitioner fails to present any "rationale for how these references would be combined, or why there would be a reasonable expectation of success for doing so." *Id.* at 55.

On the record before us, we determine that Petitioner has not shown a reasonable likelihood of prevailing. As discussed above, we are not persuaded that Matsuno discloses a reversibly operable control wire, as claimed. In this obviousness ground, Petitioner has not provided any persuasive reasoning to explain why a person of ordinary skill in the art would have found it obvious, nonetheless, to operate Matsuno's *un-modified* device in a manner that would have rendered obvious the challenged claims. Patent Owner is correct that neither Petitioner nor Dr. Jensen explain how or why an ordinarily skilled artisan would have understood to push Matsuno's operating wire 33 in the distal direction, or why this would have been expected to move the clip legs, instead of either buckling the wire (if the wire was insufficiently rigid) or pushing the clip and clip-fastening ring off the end of the device (if the wire was sufficiently rigid). Prelim. Resp. 54.

Petitioner does not discuss any structure or material properties of the Matsuno device that would have made such operation reasonably likely to succeed. Pet. 76–77. Again, Dr. Jansen's declaration is nearly verbatim to the Petition and offers no persuasive reasoning. Ex. 1002 ¶¶ 193–198.

We also agree with Patent Owner that Petitioner offers no persuasive explanation as to how or why the teachings of Matsuno and Rapacki would have been combined to render obvious the challenged claims. *See* Prelim. Resp. 54–55. According to Dr. Jensen, a person of ordinary skill in the art "need only operate Matsuno's device according to Rapacki's express teachings in order to achieve the improvement in clip repositioning." Ex. 1002 ¶ 198; Pet. 77 (similar). As discussed above, we are not persuaded that Matsuno's un-modified device could have been operated as claimed. Moreover, Rapacki discloses moving outer shaft 3 to open and close the clip legs. Ex. 1008, 7:38–45. Specifically, "[w]hen shaft is moved distally towards claim 2, inner wall 31 of axial passage 9 engages camming surfaces 66, 68 and forces the proximal portions of claim 2 together, thereby opening jaws 65, 67." *Id.* at 9:14–17. By contrast, to close jaws 65, 67, "shaft 3 is moved in the proximal direction." *Id.* at 9:17–18. Thus, Petitioner does not identify any teaching of Rapacki that would have led a skilled artisan to reversibly operate a *control wire* to open and close clip legs, as claimed. *See id.* at 9:14–18; *see also id.* at 7:12–20 (disclosing wire 23 passing through shaft 3).

We recognize that Rapacki teaches a clip that "can be easily reopened and repositioned." *Id.* at 3:53–55. However, neither Petitioner nor Dr. Jensen explain sufficiently how that teaching would have led a skilled artisan to reversibly operate Matsuno's un-modified control wire to open and

close the clip legs to allow repositioning. If anything, we discern that Rapacki's teachings would have more readily suggested modifying Matsuno such that operating tube 28 or lead tube 3—structures more akin to Rapacki's sheath 3—could have been reversibly operable to open and close the clip legs to allow repositioning. As such, Petitioner fails to provide a sufficient rationale to explain how the combined teachings of Matsuno and Rapacki would have rendered obvious claims 1 and 15.

Finally, Petitioner relies upon Dr. Jensen's testimony to support its argument. Pet. 76–79 (citing Ex. 1002 ¶¶ 193–198). However, Dr. Jensen's testimony is nearly verbatim to the Petition, and lacks any further support or reasoning. Ex. 1002 ¶¶ 193–198. Accordingly, Dr. Jensen's testimony is unpersuasive. 37 C.F.R. § 42.65(a).

For the foregoing reasons, Petitioner has not supported adequately its contention that claims 1 or 15 would have been obvious over Matsuno and Rapacki. Accordingly, we are not persuaded that Petitioner has shown a reasonable likelihood of prevailing with respect to independent claims 1 or 15, or claims 3–13, which each depends from claim 1.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has not demonstrated a reasonable likelihood it would prevail in establishing the unpatentability of any challenged claim of the '245 patent. Accordingly, we deny institution of an *inter partes* review.

IV. ORDER

Upon consideration of the record before us, it is:

ORDERED that the Petition is *denied* as to all challenged claims, and no trial is instituted.

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