

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 IPR2017-00135
Patent 8,974,371 B2

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

KINDER, *Administrative Patent Judge*.

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

Cook Group Incorporated and Cook Medical LLC (“Petitioner”) filed a Petition (Paper 1, “Pet.”) to institute an *inter partes* review of claims 1, 3–15, and 17 of U.S. Patent No. 8,974,371 B2 (Ex. 1027, “the ’371 patent”). Boston Scientific Scimed, Incorporated (“Patent Owner”) filed a Preliminary Response (Paper 6, “Prelim. Resp.”).

Applying the standard set forth in 35 U.S.C. § 314(a), which requires demonstration of a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim, we institute an *inter partes* review of claims 1, 3–5, 7, 10, 11, 13–15, and 17 based on the grounds identified in the Order section of this Decision.

I. BACKGROUND

A. *The ’371 Patent (Ex. 1027)*

The ’371 patent is titled “Through the Scope Tension Member Release Clip,” and claims “[a]n apparatus for applying clips to tissue[.]” Ex. 1027, [54], 16:59. The claimed invention relates to devices for causing hemostasis of a blood vessel through an endoscope. *Id.* at 1:17–28. As explained by the ’371 patent, “[h]emostatic clipping tools have been inserted through endoscopes to deploy hemostatic clips which stop internal bleeding by clamping together the edges of a wound.” *Id.* at 1:21–23. The Specification describes an assembly designed to provide multiple stages of “feedback” to the physician during such a procedure. *Id.* at 1:44–62, 9:43–64. This feedback allows the user, *inter alia*, to be “certain of the status of” the clip assembly during the deployment operation, reducing the likelihood of deployment of a clip at an incorrect location. *Id.* at 1:33–35, 9:37–39. For example, a control element is described as “frangible” such that it may

“detach the yoke from the delivery device” in order “to provide a second user feedback.” *Id.* at 1:59–61.

The '371 patent discloses a hemostatic clip apparatus having two main components: “a hemostatic clip assembly” designed “for mounting on a delivery device” and the delivery device. *Id.* at 1:44–62. As depicted in Figure 10, clip assembly 106 includes capsule 200, clip arms 208, tension member 206, and yoke 204:

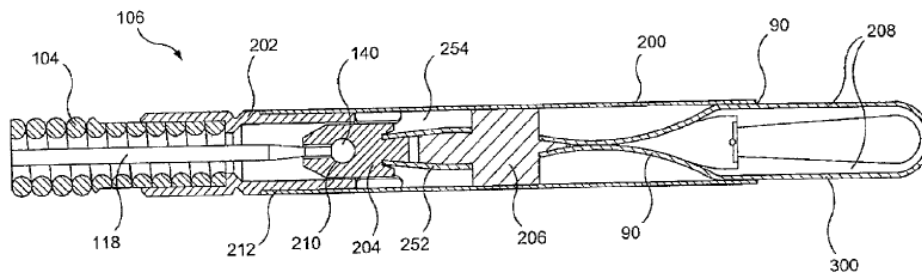


FIG. 10

Figure 10 depicts a cross-sectional top view of a distal end of a clipping device of one embodiment.

The delivery device includes shaft section 104 and control wire 118 that can be moved to open and close the clip arms 208. *Id.* at 4:27–46. Shaft section 104 “is securely connected” to capsule 200 of clip assembly 106 via bushing 202. *Id.* at 7:4–10, 8:60–62. The proximal end of capsule 200 may slide over the distal end of bushing 202 and “[a] locking arrangement” is formed between the two components by capsule tabs 212. *Id.*

The Specification describes moving control wire 118 back and forth with respect to shaft section 104 in order to open and close clip arms 208. *Id.* at 4:42–43, 6:64–7:12. In one embodiment, once clip arms 208 have been closed around a target tissue, the delivery device may be removed from the patient’s body while clip assembly 106 remains in place. *Id.* at 10:16–18. For example, when control wire 118 is moved proximally (to the left in

Fig. 10 above), the first separation occurs between yoke 204 and tension member 206. *Id.* at 9:43–10:15. Second, as control wire 118 is further moved proximally, control wire 118 fractures and bushing 202 separates from capsule 200. *Id.*

B. Illustrative Claim

Claims 1 and 11 are the only independent claims and claim 1 is illustrative of the claims at issue:

1. An apparatus for applying clips to tissue, comprising:
 - a flexible sheath extending from a proximal end which, in an operative configuration, extends into a living body to a target portion of tissue to be clipped;
 - a capsule extending from a proximal to a distal end and having an opening formed in a proximal end thereof;
 - a clip assembly provided in the capsule and configured to be operably movable between a closed configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration in which the first and second arms are separated from one another to receive target tissue therebetween;
 - a bushing extending between a proximal end coupled to the sheath and a distal end releasably coupled to the capsule via a tab on the distal end of the bushing engaging the opening of the capsule; and
 - a control member a distal end of which is releasably coupled to the clip assembly to transmit to the clip assembly forces applied thereto to move the clip assembly between the insertion and expanded configurations.

Ex. 1027, 16:58–17:11.

C. Related Proceedings

The '371 patent is the subject of *Boston Scientific Corp. et al. v. Cook Group Inc. et al*, Civil Action No. 1:15-cv-00980-LPS-CJB (D. Del). Pet. 1; Paper 3, 2. Patent Owner identifies the following petitions challenging the patentability of related patents:

1. IPR2017-00131 (U.S. Patent No. 8,685,048);
2. IPR2017-00132 (U.S. Patent No. 8,685,048);
3. IPR2017-00133 (U.S. Patent No. 8,709,027);
4. IPR2017-00134 (U.S. Patent No. 8,709,027);
5. IPR2017-00435 (U.S. Patent No. 9,271,731); and,
6. IPR2017-00440 (U.S. Patent No. 9,271,731).

Paper 3, 2–3. *See also Cook Group Inc. and Cook Medical LLC v. Boston Scientific Scimed, Inc.*, IPR2017-00440, Paper 3, 2–3.

D. References Relied Upon

Petitioner relies upon the following prior art references:

U.S. Patent No. 5,749,881 issued on May 12, 1998 (“Sackier”) (Ex. 1008);

U.S. Patent Publication No. 2002/0045909 A1, published on Apr. 12, 2002 (“Kimura”) (Ex. 1007); and,

U.S. Patent No. 8,685,048 B2, filed on Apr. 16, 2013, and issued Apr. 1, 2014 (“Adams”)¹ (Ex. 1023).

¹ Petitioner asserts that Adams “qualifies as prior art under 35 U.S.C. §102(e), issuing on April 1, 2014 from a U.S. patent application filed April 16, 2013 that claims priority to U.S. Patent Application No. 09/971,488 filed on October 5, 2001.” Pet. 11.

E. The Asserted Grounds

Petitioner contends that the challenged claims are unpatentable based on the following specific grounds (Pet. 4)²:

Reference(s)	Basis	Claim(s) Challenged
Adams	§ 102(b) ³	1, 3, 8, 9, 11, and 15
Adams	§ 103	4, 5, 7, 13, and 14
Adams	§ 103	1, 3–5, and 7–9
Adams and Sackier	§ 103	10 and 17
Sackier	§ 103	1, 3, and 10
Sackier	§ 102(b)	11, 15, and 17
Sackier and Adams	§ 103	4, 5, 7, 13, and 14
Sackier and Adams	§ 103	1, 3–5, 7, 10, and 15
Kimura	§ 102(b)	11–13
Kimura	§ 103	1, 3–6, and 15
Kimura and Sackier	§ 103	10 and 17

² Petitioner also relies on the Declaration of Mark A. Nicosia, Ph.D. (Ex. 1029).

³ The relevant sections of the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (Sept. 16, 2011), took effect on March 16, 2013. Because the application from which the ’371 patent issued was filed before that date, our citations to Title 35 are to its pre-AIA version.

II. CLAIM CONSTRUCTION

Petitioner identifies several terms for construction. Pet. 8–10. As an initial matter, Petitioner’s support for its proposed interpretation of each term is deficient. For nearly every claim limitation, Petitioner’s only cited evidence is Patent Owner’s claim construction position from the related district court litigation. Although such an approach may be acceptable if Patent Owner does not challenge an interpretation, we will not simply adopt contested interpretations because an opposing party asserts that construction in a related proceeding. Claim construction is a legal determination based on a hierarchy of evidence – intrinsic evidence, including the claim language, the specification, and the prosecution history will direct our analysis. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005).

In this case, the extrinsic evidence cited by Petitioner (Patent Owner’s litigation position) does not shed useful light on the legally operative meaning of the claim language, we therefore afford it little weight. *See id.* at 1317. We have considered each party’s litigation position, as well as the district court’s findings (Ex. 2003) for each contested term. Our decision, however, is controlled by the record and arguments before us. *See* 37 C.F.R. § 42.6(a)(3) (“Arguments must not be incorporated by reference from one document into another document.”).

Claims in an *inter partes* review are given the “broadest reasonable construction in light of the specification of the patent in which [they] appear[.]” 37 C.F.R. § 42.100(b) (2015); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2136 (2016). Below we construe two terms that are necessary to resolve the controversy before us.

A. Bushing “Coupled to the Sheath”

Relying on only Patent Owner’s litigation position, Petitioner contends that “coupled to the sheath” means “slideable inside the sheath” and “the sheath confines the bushing.” Pet. 9. Although not binding on us, the district court has tentatively rejected this broad interpretation. *See* Ex. 2003, 27–28 (“[T]he Court recommends that ‘coupled to the sheath’ be construed as ‘linked together, connected, or joined, but not slidable inside the sheath.’”).

Patent Owner contends that Petitioner’s proposed construction of “coupled to the sheath” is “unreasonably broad,” but provides little citation to the intrinsic record before us. Prelim. Resp. 13–14. Instead, Patent Owner notes that the plain and ordinary meaning of coupled is “linked together, connected, or joined” citing to an unrelated Federal Circuit decision as well as the related district court determination. *Id.* at 14.

Claim construction is not an issue of fact that can be conceded, it is a legal determination, and we are not bound by litigation positions taken by parties. In our proceeding, Petitioner has not provided persuasive evidence or argument to support its claim interpretation. Based on the limited record before us, a bushing “coupled to the sheath” means “linked together, connected, or joined” to the sheath. Our decision is guided by the common understanding of the term “coupled” in the mechanical arts to require more than simply abutting or contacting. *See generally Ex Parte Paul Robert Homrich*, Appeal 2014-005786, 2016 WL 3541285, at *3 (PTAB, June 27, 2016) (“When used in mechanical systems, the plain and ordinary meaning of ‘coupled’ means to link together or connect,” and coupled requires more than contact or abut.).

B. “Frangible Link”

Petitioner contends “that the term ‘frangible link’ means ‘a link between at least two components that become unlinked when a tensile load is applied.’” Pet. 10. Petitioner’s only supporting evidence is citation to Patent Owner’s litigation position. Patent Owner has not challenged Petitioner’s proposed construction, and Patent Owner has seemingly adopted it for purposes of its analysis. *See* Prelim. Resp. 42.

For purposes of this Decision, we agree that “frangible link” means “a link between at least two components that become unlinked when a tensile load is applied.”

III. ANALYSIS

A petition must show how the construed claims are unpatentable under the statutory ground it identifies. 37 C.F.R. § 42.104(b)(4). Petitioner bears the burden of demonstrating a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim for a petition to be granted. 35 U.S.C. § 314(a).

A. Discretion Pursuant to § 325(d)

Patent Owner argues that the grounds in the Petition based on Adams and Kimura should be denied because both references asserted in this Petition as primary references were also specifically cited, considered, and relied upon by the Examiner as primary references in rejecting the claims

under 35 U.S.C. § 102 during prosecution.⁴ Prelim. Resp. 1, 12, 13, 48, 49. Patent Owner contends that Petitioner’s arguments and prior art in support of unpatentability, here in this proceeding, are substantially the same as the rationale and prior art in the Examiner’s anticipation rejections, that were overcome by Applicant during prosecution of the application that became the ’371 patent. *Id.*

Institution of *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a); 37 C.F.R. § 42.108. In circumstances such as these, our discretion on whether to institute is guided by 35 U.S.C. § 325(d), which provides, in relevant part:

MULTIPLE PROCEEDINGS -- . . . In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

We, therefore, examine whether certain grounds asserted in the instant Petition present “the same or substantially the same prior art or arguments” as those previously presented to the Office. Then, we determine whether it is appropriate to exercise our discretion to deny institution based on those grounds.

⁴ During prosecution the Examiner relied on “U.S. Patent Application Publication No. 2003/0069592 to Adams.” Ex. 2004; Prelim. Resp. 1. Patent Owner classifies this publication as “a substantively identical Adams specification.” Prelim. Resp. 12. The Adams patent relied on by Petitioner in this proceeding references the Adams application as a divisional application. Ex. 1023, 1:13–14. After examining both publications, we agree with Patent Owner that the specifications are substantially identical.

1. The Examiner's Rejections and Patent Owner's Responses

a. Adams

In an office action mailed May 27, 2014, the Examiner rejected application claims 41, 43, 44, and 47 as unpatentable based on U.S. Patent Pub. No. 2003/0069592 (“Adams Application”). Ex. 2004, 6 (citations to Patent Owner’s added page numbering). Adams Application claims 41, 43, 44, and 47 correspond to issued patent claims 11, 13, 14, and 17, respectively. The Examiner stated that:

Adams et al. disclose an apparatus for applying clips to tissue within a living body, wherein the clip assembly includes a yoke slidably received in the capsule and removably coupled to the control element and wherein the yoke is connected to the control element via a ball and socket joint (See Figs. 12a-b and paragraph 0084).

Id.

To overcome the rejection based on the Adams Application, Patent Owner amended application claim 41 to require not just “a control element” as previously claimed, but now a “control element including a connector element . . . wherein the control element detaches from the connector element via a frangible link.” Ex. 2005, 3. Patent Owner relied on the added “connector element” limitations set forth above as the main point of distinction over the Adams Application. *Id.* at 6. After considering the amendments and Patent Owner’s contentions, the Examiner thereafter withdrew the rejection based on Adams in a subsequent final office action mailed September 16, 2014. Ex. 1028, 189–95.

b. Kimura

The Examiner issued two distinct rejections based on Kimura. The first was in the May 27, 2014, office action, in which the Examiner rejected

application claims 31–47 (corresponding to patent claims 1–17) pursuant to Section 102 based on Kimura. Ex. 2004, 7. On September 16, 2014, The Examiner issued a final rejection of claim 41–47 based on Kimura. Ex. 1028, 191–93.

To overcome the final rejection based on Kimura, Patent Owner successfully argued to the Examiner that “Kimura does not teach or suggest ‘a control element including a connector element . . . removably connected to the clip assembly via the connector element, wherein the control element detaches from the connector element via a frangible link,’ as recited in claim 41.” Ex. 1028, 197. *See also* Pet. 69–73 (discussing Patent Owner’s response). Following Patent Owner’s response, the Examiner issued a Notice of Allowability indicating allowance of claims 31–47. *Id.*

2. *Similarity of the Prior Art*

Adams and Kimura, the two primary references relied upon by the Examiner, are also two of the primary references relied upon in this proceeding by Petitioner for grounds 1–4 and 9–11. *See* Pet. 4.

a. Adams

Petitioner alleges that a different embodiment of Adams was relied upon in the rejection of claim 11. Pet. 26, n.6 (“The Examiner rejected an earlier version of [claim 11] based on a different Adams embodiment.”). We find this contention unpersuasive considering Petitioner relies on the Adams’ Figure 12A embodiment (*id.* at 32, addressing claims 13 and 14) just as the Examiner relied on the Figure 12A embodiment for the rejection of claims 11, 13, and 14 (application claims 41, 43, and 44). Ex. 2004, 6–7. Regardless, § 325(d) addresses the same “prior art,” not specific embodiments as argued by Petitioner.

b. Kimura

Kimura was before the Examiner and twice used as a basis for rejection as discussed above. *See also* Pet. 69.

3. Similarity of the Arguments

a. Adams

Regarding Adams, and independent claim 11, we see little if any difference between the arguments made in this proceeding, and those made during prosecution. For example, claim 11 was allowed over Adams in light of an amendment and argument related to the “control element including a connector element . . . wherein the control element detaches from the connector element via a frangible link.” Ex. 2005, 3. Similarly, Patent Owner presents substantially the same arguments in this proceeding. *See* Prelim. Resp. 15–18. Patent Owner contends that the issues presented here were before the Examiner, and Petitioner’s position would “read out the amendment” made to overcome Adams. *Id.* at 18 (“Cook advances no difference for present purposes between the socket on the proximal end of clip 1201 identified by the examiner as the ‘connector element’ and cut-out 106 referred to by Cook as the ‘connector element.’”).

Petitioner contends that its invalidity grounds and Patent Owner’s claim construction positions taken during related litigation raise new issues not previously considered by the Office. Pet. 11. Petitioner does not identify any specific new issue or otherwise explain why the art and arguments presented in its Petition are not substantially the same as those before the Office with respect to Adams.

Although not addressed by Petitioner, we have also considered whether the testimony of Petitioner’s expert presents new arguments not

considered by the office. *See* Ex. 1029 ¶¶ 47–53. Dr. Nicosia relies on Patent Owner’s litigation claim construction position. *See id.* ¶ 51. As discussed above, we give little weight to this extrinsic evidence when it stands alone without intrinsic evidence support. Dr. Nicosia’s declaration support for claim 11 based on Adams does not provide any new arguments, or persuasive facts, data, or analysis to support the opinions stated. *See* 37 C.F.R. § 42.65(a). We see little if any practical difference between the arguments in the Petition relying on Dr. Nicosia’s testimony and the Examiner’s assertion of Adams.

The arguments presented in the Petition and in response to the Petition related to Adams are substantially the same as those considered during prosecution for claim 11. For claim 1, however, Adams was not relied on during prosecution as a basis for rejection. Thus, although the same prior art was before the office (Adams), substantially the same arguments were not presented to the Office for claim 1.

b. Kimura

Although the arguments presented during prosecution and those before us are also similar for Kimura, Petitioner has presented sufficient evidence on this record to convince us that the arguments previously presented to the Office do not sufficiently weigh against institution in this proceeding. *See* Pet. 69–73. Specifically, Petitioner establishes by at least a reasonable likelihood that arguments made by Patent Owner and considered by the Examiner related to whether the fracture section 3d of Kimura disconnects the hook section 12 from the entire link member 3 may have been erroneous. *Id.* at 72.

4. Discretion to Deny Institution of Trial

Having found that the instant Petition raises the same or substantially the same prior art and arguments as those previously presented to the Office, § 325(d) states that we may take these facts into consideration when determining whether to reject a request. The question, therefore, is whether we should exercise our discretion to deny certain grounds based primarily on Adams and Kimura after weighing the particular circumstances of this proceeding and the interests of the parties.

a. Adams

With respect to Adams and claim 11, Petitioner effectively has asked us to reconsider the Office's decision to issue a patent, including revisiting the Examiner's analysis and findings that are supported, upon our review, by sound reasoning and related evidentiary underpinnings. We recognize that certain limitations within claim 11 were the basis for allowance, and Petitioner essentially asks us to undue the Examiner's findings with respect to the amendment and argument related to those limitations. Under these facts, we are not persuaded that adjudicating such a dispute for claim 11 and its dependent claims on an already-considered issue is an efficient use of Board resources. We therefore decline to institute trial for claim 11 and its dependent claims for the grounds in the Petition for which Adams is the sole or primary reference – Petitioner's Ground 1 (claims 11, 15), 2 (claims 13 and 14), and 4 (claim 17). *See* Pet. 4.

Considering that claim 1 has distinct limitations that were not addressed by the Examiner for the rejection based on Adams, we exercise our discretion to review the grounds presented based on Adams for claim 1 and its dependent claims. We are mindful, however, that § 325(d) affords us

discretion to not institute on grounds based on the same prior art previously before the Office, regardless of arguments.

b. Kimura

Although the same prior art and substantially the same arguments were before the Office with respect to Kimura, we exercise our discretion to review the merits of the grounds for which Kimura is the sole or primary reference. We are persuaded by Petitioner’s analysis alleging that the Office and Patent Owner misunderstood the scope and content of Kimura’s teachings. Pet. 69–73.

B. Principles of Law

1. Anticipation

To establish anticipation, each and every element in a claim, arranged as recited in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). “To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently.” *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

2. Obviousness

A claim is unpatentable under § 103(a) 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. *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) where in evidence, so-called secondary considerations. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

C. Person of Ordinary Skill in the Art

Petitioner proposes that a person of ordinary skill in the art as of the time of the filing of the application that became the '371 patent would have possessed the knowledge and skill of an engineer or similar professional with at least an undergraduate degree in engineering, or a physician having experience with designing medical devices. Pet. 8 (citing Ex. 1029 ¶ 11). Patent Owner does not dispute Petitioner's proposal, and we adopt it for purposes of this Decision.

D. Claims 1, 3, 8, 9, 11, and 15 as Anticipated by Adams

Petitioner contends claims 1, 3, 8, 9, 11, and 15 are unpatentable, under 35 U.S.C. § 102, as anticipated by Adams. Pet. 17–31.

1. Overview of Adams (Ex. 1023)

Adams is directed to a “[m]edical device used to cause hemostasis of blood vessels using a clip arrangement delivered to a target region through an endoscope.” Ex. 1023, Abstract. Petitioner relies on two embodiments disclosed in Adams. Pet. 11. In the first embodiment, as depicted in Figure 1 below, medical device 100 includes clip 101 having first clip leg 102 and second clip leg 103. *Id.* at 5:21–23.

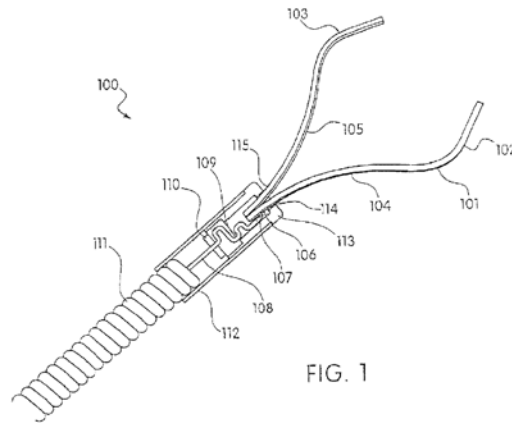


Figure 1 is an enlarged partial view of one embodiment referred to as the “J-hook” embodiment. *Id.* at 5:21–41.

As shown in Figure 1 above, “[t]he clip 101 is a deformable, multi-legged, grasping device attached to the distal portion of a flexible shaft (the sheath 111) via a frangible link (the j-hook 107).” *Id.* at 5:42–44.

The second embodiment of Adams relied on by Petitioner is referred to as the “ball-and-socket” embodiment, and it is depicted in Figure 12A below. *See* Pet. 13.

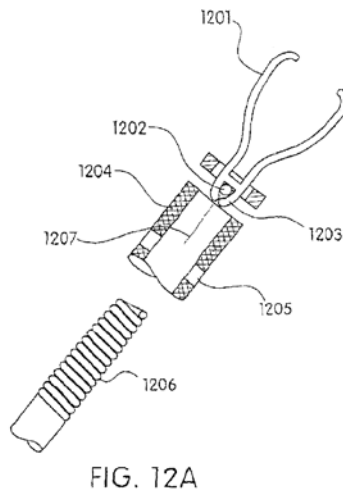


Figure 12A is an enlarged partial view of the “ball-and-socket” embodiment showing 15 the clip in an open position. Ex. 1023, 4:12–14, 9:46–64.

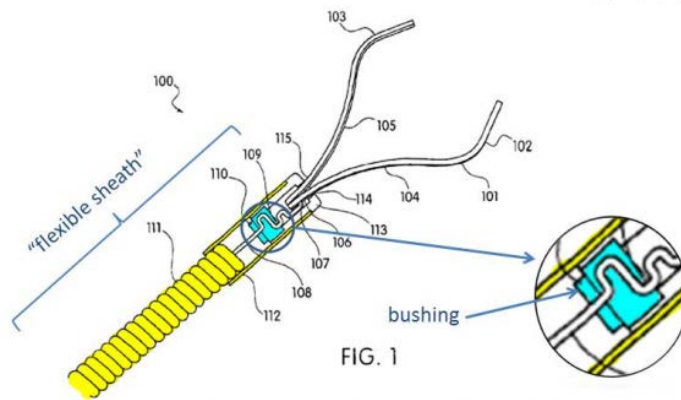
As described in Adams, “[a]nother alternative to the j-hook type frangible link is shown in FIGS. 12A and 12B.” Ex. 1023, 9:46–64. According to the

specification, “[t]his embodiment uses a ball 1202 fitting into a socket, where the socket is defined by socket tabs 1203, to attach the control wire 1207 to the clip 1201.” *Id.*

2. Discussion of Claim 1

We begin our analysis with independent claim 1. Petitioner asserts that Adams, alone, discloses all elements of claim 1. Pet. 17–22.

Claim 1 is directed to an apparatus for applying clips to tissue, which comprises a flexible sheath, a capsule, a clip assembly, a bushing, and a control member. Ex. 1027, 16:59–17:11. Pertinent for our analysis, claim 1 requires “a bushing extending between a proximal end coupled to the sheath.” *Id.* at 17:4–5. Petitioner contends that “retainer 110 [bushing] is slidable inside the sheath when a sufficient tensile force is applied to the control wire to cause disengagement.” Pet. 20. Petitioner relies on annotated Figure 1, reproduced below, for support. *Id.* at 21.



Petitioner’s annotated Figure 1 with a call out enlargement of retainer 110.

Petitioner alleges that during the “entire process, both before and after disengagement, the retainer is confined (i.e., to hold within a location, to keep within limits) by the sheath at its proximal end, center portion and

distal end.” *Id.* at 20. Petitioner acknowledges, however, that “retainer 110 (“bushing”) . . . is not touching the sheath.” *Id.* at 39. This separation is depicted above in the call out enlargement showing the gap between retainer (110 in blue) and flexible sheath (111 in yellow).

Patent Owner contends that Adams does not disclose a “bushing,” the proximal end of which is “coupled to the sheath.” Prelim. Resp. 13. Patent Owner alleges that Petitioner’s “analysis is based on an unreasonably broad construction of ‘coupled to the sheath’ as ‘slideable inside the sheath’ or alternatively, ‘the sheath confines the bushing.’” *Id.* (citing Pet. 9, 20). Patent Owner relies on the plain and ordinary meaning of “coupled to the sheath” as requiring the bushing to be “‘linked together, connected, or joined’ to the sheath.” *Id.* at 14. Patent Owner contends that “the proximal end of the retainer 110 (the alleged ‘bushing’) clearly cannot be considered ‘coupled to the sheath’ (i.e., linked together, connected, or joined to the sheath) because it fails to even touch the tubular outer sleeve 112 (the alleged ‘sheath’).” *Id.* at 15.

We are not persuaded that Petitioner has demonstrated sufficiently that Adams discloses “a bushing extending between a proximal end coupled to the sheath,” (Ex. 1027, 17:4–5) as required by claim 1 of the ’371 patent. Based on the record before us, Petitioner’s contention that retainer 110 [bushing] is slidable inside the sheath, or confined by the sheath, does not establish persuasively that the proximal end of the bushing is coupled to the sheath as required by claim 1. For the bushing and the sheath to be coupled requires them to be “linked together, connected, or joined” in some manner. Petitioner has failed to establish persuasively any reason why retainer 110 and sheath 112 would even need to be linked or connected – indeed, doing

so would negatively impact the ability of retainer 110 to freely slide out of sheath 112. *See* Prelim. Resp. 27.

Based on the record before us, Petitioner has not established persuasively that Adams discloses “a bushing extending between a proximal end coupled to the sheath.” For this reason, Petitioner has failed to show a reasonable likelihood that it would prevail in showing that Adams anticipates claim 1. Accordingly, we decline to institute a review of claim 1 under 35 U.S.C. § 102(b) as anticipated by Adams.

3. Claims 3, 8, 9, 11, and 15

Petitioner asserts that Adams discloses all elements of these claims. Pet. 4, 23–31.

Claims 3, 8, and 9 depend from claim 1. For the reasons set forth above for claim 1, Petitioner has failed to show a reasonable likelihood that it would prevail in showing that Adams anticipates claims 3, 8, and 9. Accordingly, we decline to institute a review of these claims under 35 U.S.C. § 102(b) as anticipated by Adams.

As discussed above, we exercise our discretion to decline review of claim 11, and claim 15 which depends from claim 11, pursuant to 35 U.S.C. § 325(d).

E. Obviousness of Claims 4, 5, 7, 13, and 14 over Adams

Petitioner contends that claims 4, 5, 7, 13, and 14 are obvious based on Adams. Pet. 32–37. For the reasons that follow, Petitioner has not established a reasonable likelihood that it would prevail on this ground.

Claims 4 and 5 depend from claim 3, and claim 7 depends from claim 5. These claims all depend indirectly from claim 1. Petitioner relies on the anticipation analysis of claims 1 and 3 based on Adams as the basis for its

obviousness challenge of these claims. *See, e.g.*, Pet. 32 (“Claim 4 depends from claim 3, which is anticipated by Adams.”). Because we are not convinced that Petitioner has sufficiently shown that Adams discloses the limitation of “a bushing extending between a proximal end coupled to the sheath” as required by claim 1, and because Petitioner does not contend any other embodiment of Adams teaches this same limitation, we determine that the Petition does not establish a reasonable likelihood that Petitioner would prevail in showing that claims 4, 5, and 7 would have been obvious over Adams.

As discussed above, we exercise our discretion to decline review of claim 11, and claims 13 and 14 which depend directly or indirectly from claim 11, pursuant to 35 U.S.C. § 325(d).

F. Obviousness of Claims 1, 3–5, and 7–9 over Adams

Petitioner contends that claims 1, 3–5, and 7–9 are obvious based on Adams. Pet. 38–40. For the reasons that follow, Petitioner has not established a reasonable likelihood that it would prevail on this ground.

Although this ground is partially duplicative of the last ground considered, Petitioner presents an alternative position as to how Adams could be modified to teach the claim 1 requirement of “a bushing extending between a proximal end coupled to the sheath.” *Id.* at 39. Petitioner contends that it would have been obvious for a person of ordinary skill in the art “to have modified retainer 110 (‘bushing’) such that the proximal end physically contacts, and thus is coupled to (i.e., ‘confined’), outer sleeve 112 (component of the ‘sheath’).” *Id.* Petitioner contends that “Adams is not limited to any specific type of retainer.” *Id.* Petitioner argues that because “a stable and smooth release mechanism to decouple retainer 110 from lock

sleeve 113 (“capsule”) is desirable,” a person of ordinary skill in the art would “simply increase[e] the diameter of the proximal end of retainer 110 such that it physically contacts the walls of outer sleeve 112.” *Id.*

Patent Owner disagrees with the proposed modification to Adams and again contends that Petitioner’s analysis is based on an unduly broad construction of ‘coupled to the sheath.’” Prelim. Resp. 25–26. Patent Owner contends that Petitioner’s “analysis does not provide a sufficient motivation to modify Adams’s retainer 110.” *Id.* at 26. Patent Owner argues the analysis is deficient because it simply points out “that retainer 110 ‘may be modified’ and that he/she could ‘simply increas[e] the diameter of the proximal end of the retainer 110 such that it physically contacts the walls of outer sleeve 112.’” *Id.* (quoting Pet. 39). Patent Owner contends that simply recognizing that a person of ordinary skill in the art “‘may’ modify the retainer in a way that it would contact the sheath,” is insufficient because Petitioner fails to “sufficiently explain why a person of ordinary skill would be so motivated.” *Id.* at 27.

Patent Owner also contends that Adams teaches away from proposed modification and the modification would render the Adams device nonfunctional. *Id.* at 27–28. Patent Owner reasons that “the retainer 110 is supposed to freely slide out of the tubular outer sleeve 112 (the alleged “sheath”), and Cook provides no explanation for why a PHOSITA would be motivated to modify the retainer 110 to make it touch or contact the sheath at its proximal end, which would seem to render the Adams device nonfunctional.” *Id.*

Based on the record before us, Petitioner has not established persuasively a rationale to make the proposed modifications to Adams.

Expanding the diameter of Adams' retainer 110 to create an interference fit would have a negative impact on the ability of the retainer to be "slidable inside the sheath" (Pet. 20) so the retainer could be pulled back. *See* Ex. 1023, 7:26–44 ("the retainer release 109 pulls the retainer 110 back, disengaging the retainer tabs 118, 119 from the two retainer holes 116"). Regardless, although Petitioner suggests that the retainer "may be modified," Petitioner has not provided a persuasive rationale on the record before us as to why a person of ordinary skill in the art would make such a modification. Petitioner's rationale ("help stabilize retainer 110 and allow for a smooth sliding action" (Pet. 39)) is conclusory and lacks a rationale underpinning. Petitioner does not explain persuasively why retainer 110 would need help being stabilized or why the retainer's current sliding action is not sufficient. On this record, Petitioner has not persuasively established that expanding the diameter of the retainer to touch or contact the sheath would produce any of the alleged benefits.

Further, even if the diameter of retainer 110 is expanded to "physically contact[]" (Pet. 39) the sheath, Petitioner has not established persuasively that such ancillary contact would teach or suggest the components being "coupled" as required by claim 1. As noted above, coupled requires more than just abutting or physical contact, and Petitioner has not established persuasively that the proposed modification would result in a bushing "linked together, connected, or joined" to the sheath.

Accordingly, we determine that the Petition does not establish a reasonable likelihood that Petitioner would prevail in showing that claims 1, 3–5, and 7–9 would have been obvious over Adams.

G. Obviousness of Claims 10 and 17 over Adams and Sackier

Petitioner contends that claims 10 and 17 are obvious based on Adams and Sackier. Pet. 41–44.

Claim 10 depends from claim 1. Petitioner relies on the anticipation or obviousness analysis of claim 1 based on Adams as the basis for its obviousness challenge of claim 10. *See* Pet. 41. Because we are not convinced that Adams discloses, or teaches, the limitation of “a bushing extending between a proximal end coupled to the sheath” as required by claim 1, and because Petitioner does not contend Sackier teaches this same limitation for this particular ground, we likewise determine that Petitioner’s obviousness challenge as to claim 10 is unpersuasive. Accordingly, we determine that the Petition does not establish a reasonable likelihood that Petitioner would prevail in showing that claim 10 would have been obvious over Adams and Sackier.

As discussed above, we exercise our discretion to decline review of claim 11, and claim 17 which depends from claim 11, pursuant to 35 U.S.C. § 325(d).

H. Obviousness of Claims 1, 3, and 10 over Sackier

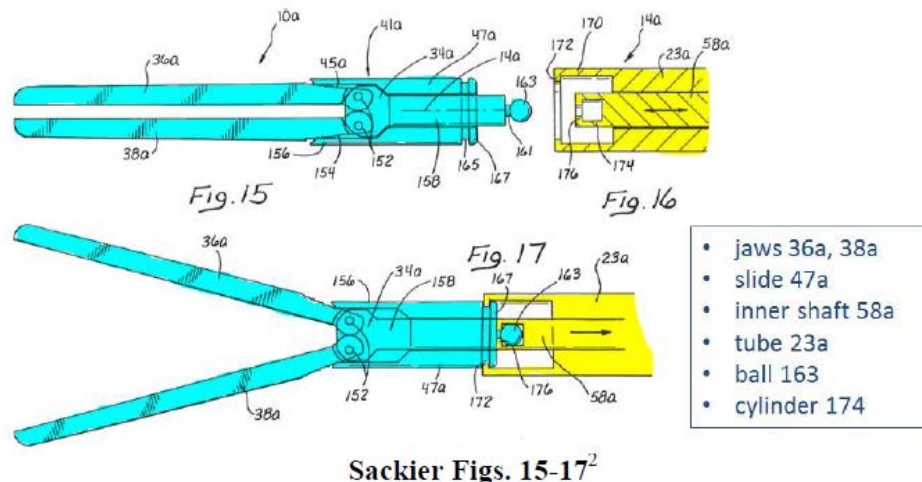
Petitioner challenges the patentability of claims 1, 3, and 10 of the ’371 patent under 35 U.S.C. § 103 as obvious based on Sackier. Pet. 45–51. In support thereof, Petitioner identifies the disclosures in Sackier alleged to describe the subject matter in the challenged claims. *Id.* Additionally, Petitioner cites the Declaration of Dr. Nicosia in support of the analysis advocated in the Petition. Ex. 1029 ¶¶ 105–113.

We have reviewed Petitioner’s contentions and supporting evidence. Given the evidence of record, we are persuaded that Petitioner has

demonstrated a reasonable likelihood of prevailing on its assertion that claims 1, 3, and 10 are obvious based on Sackier. We begin our analysis with a brief summary of Sackier, and then address Petitioner’s and Patent Owner’s contentions in turn.

1. Overview of Sackier (Ex. 1008)

Sackier is directed to a laparoscopic surgical clamp which includes a clamp. Ex. 1008, Abstract. Petitioner’s annotated Figures 15–17⁵ of Sackier are reproduced below.



Sackier Figs. 15-17²

Petitioner’s Annotated Figs. 15–17 depict an axial cross-section views of a clamp. Pet. 14; Ex. 1008, 3:60–62.

The surgical clamp includes a pair of jaws with a spring to bias the jaws to the open position: “the shaft 58a can be moved relative to the tube 23a to engage the slide 47a and move it relative to . . . the jaws 36a, 38a. As noted, this axial movement of the slide 47a relative to the jaws 36a and 38a is

⁵ We include Petitioner’s annotated Figures 15–17 because “Figures 15-26 of Sackier published without reference numbers, even though Figures 15-26 with reference numbers were submitted during prosecution.” Pet. 14, n.2.

accompanied by relative movement of the jaws 36a, 38a between the open and closed positions.” *Id.* at 10:28–34.

2. Discussion

Claim 1

We have reviewed the information provided by Petitioner, including the relevant portions of the supporting declaration of Dr. Nicosia, and are persuaded, based on the current record, that Petitioner has demonstrated a reasonable likelihood of prevailing on its obviousness challenge to claim 1 based on Sackier. *See* Pet. 41–51.

Petitioner asserts that Sackier teaches the limitations of claim 1. For example, Petitioner relies on Sackier’s teachings of “tube 23a” and “slide 47a” as teaching the claimed “sheath,” and “capsule,” respectively. *Id.* at 45–46. Below, we discuss the disputed limitations of claim 1.

Claim 1 recites, in pertinent part, “a bushing extending between a proximal end coupled to the sheath and a distal end releasably coupled to the capsule via a tab on the distal end of the bushing engaging the opening of the capsule.” Ex. 1027, 17:4–7. Claim 1 also requires “a control member a distal end of which is releasably coupled to the clip assembly.” *Id.* at 17:8–9. Patent Owner alleges that “Sackier’s device does not disclose either of these ‘releasably coupled’ limitations.” Prelim. Resp. 37.

Petitioner argues “[t]he distal end of cylinder 170 (‘bushing’) is releasably coupled to slide 47a (‘capsule’) via an inwardly facing flange 172 (‘tab’) on the distal end of cylinder 170 (‘bushing’), which engages annular recess 165 (‘opening’) of slide 47a (‘capsule’).” Pet. 48 (citing Ex. 1008, 9:64–10:6, 10:13–15, 10:25–27 (“[T]he cylinder[] 170 can be configured to

open laterally in order to permit the [] flange[] 172 to engage the recess[] 165.”)).

Patent Owner contends that although Sackier’s cylinder 170 can be opened laterally to permit flanges 172 to engage the recess 165, the design is not releasably coupled because “Sackier does not disclose that applying proximal tensile force to the inner shaft 58a will separate the connection between the ball 163 and flange 176.” Prelim. Resp. 34–35. Patent Owner cites to the Background section of Sackier, which details that maintaining a secure attachment of the clamp to the clamp applier was an important feature of the claimed invention. *Id.* at 36. Specifically, Sackier explains that it was undesirable for a surgeon to “reach into the cavity and retrieve a loose clamp” (Ex. 1008, 1:51–54) and laparoscopic surgery involved “relatively closed surgical environment [and] cannot tolerate this possibility of undesirable separation of the clamp from the applier” (*id.* at 1:54–57). Prelim. Resp. 36.

Based on the record before us, Petitioner has shown that Sackier teaches both of the “releasably coupled” limitations of claim 1. Petitioner argues persuasively that Sackier’s disclosure of cylinders 171 and 174 opening laterally in order to permit the associated flanges 172 and 176 to engage the recesses 165 and 161, teaches that the distal end of cylinder 170 (bushing) is releasably coupled to slide 47a (capsule). *See* Ex. 1008, 10:24–26. Claim 1 is an apparatus claim that requires a bushing be releasably coupled to a capsule and a control member be releasably coupled to a clip assembly. Ex. 1027, 17:4–9. There is no limitation as to when, or under

what conditions, the decoupling must occur.⁶ Although we recognize that Sackier's disclosure at column 10 concerns the initial configuration for engagement, it is just as likely that slide 47a would be decoupled from the cylinder 170 in the same manner. Further, a tensile force applied would likewise result in the elements decoupling. Sackier's disclosure in the Background of the Invention does not help Patent Owner because it states "undesirable separation," which to us, suggests that certain separation is desirable and contemplated by Sackier's invention. Ex. 1008, 1:56. For example, certain other embodiments disclosed in Sackier (Figs. 11, 12) depict disengagement of a clamp inside the body. *See id.* at 8:31–38.

Claim 1 also requires "a capsule extending from a proximal end to a distal end and having an opening formed in a proximal end thereof." Ex. 1028, 16:63–64. Petitioner contends that Sackier's annular recess 165 is the claimed "opening." Pet. 46. Petitioner relies on the testimony of Dr. Nicosia in support of this position. *Id.* (citing Ex. 1029 ¶ 106).

Patent Owner disagrees that Sackier's annular recess 165 is an opening. Patent Owner contends that "[t]here is no opening in slide 47a—just a recess." Prelim. Resp. 40. Patent Owner offers no explanation for this position as to why a recess cannot be an opening.

Based on the record before us, Petitioner has established persuasively that Sackier's annular recess 165 teaches the claimed opening. We find Dr. Nicosia's testimony particularly persuasive as to this limitation. *See* Ex. 1029 ¶ 106. Based on this testimony, and the record before us,

⁶ Neither party has presented evidence or argument as to the meaning of "releasably coupled" or whether the preamble language "for applying clips to tissue" should impact our analysis as to the conditions for decoupling.

Petitioner establishes persuasively that Sackier’s annular recess 165 teaches the claimed “opening.”

Dependent Claims 3 and 10

Each of dependent claims 3 and 10 depend directly from claim 1 and recite additional limitations. Patent Owner does not separately address claims 3 and 10. *See* Prelim. Resp. 38–39. We determine at this juncture of the proceeding that the explanations and supporting evidence presented by Petitioner demonstrates sufficiently how Sackier renders these dependent claims obvious. *See* Pet. 50–51.

I. Claims 11, 15, and 17 as Anticipated by Sackier

Petitioner challenges the patentability of claims 11, 15, and 17 of the ’371 patent under 35 U.S.C. § 102 as anticipated by Sackier. Pet. 52–55. In support thereof, Petitioner identifies the disclosures in Sackier alleged to disclose the subject matter in the challenged claims. *Id.* Additionally, Petitioner cites the Declaration of Dr. Nicosia in support of the analysis advocated in the Petition. Ex. 1029 ¶¶ 114–123.

We have reviewed Petitioner’s contentions and supporting evidence. Given the evidence of record, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that claims 1, 3, and 10 are anticipated based on Sackier. *See* Pet. 52–55. Below, we address the limitations contested by Patent Owner.

Independent claim 11 requires, in pertinent part, a “control element including connector element” which is “removably connected to the clip assembly via the connector element.” Ex. 1027, 18:10–15. Claim 11 also requires a “control element” that “detaches from the connector element via a frangible link.” *Id.*

Petitioner contends that these limitations are met by “inner shaft 58a including at its distal end a cylinder 174 that engages a ball 163,” wherein ball 163 is the “connector element.” Pet. 53–54. Further, Petitioner argues that “[c]ylinder 174 and inner shaft 58a (both parts of the ‘control element’) form a link with ball 163 (‘connector element’) that is unlinked when a tensile load is applied.” *Id.*

Patent Owner contends:

This argument should fail for the same reasons that Sackier does not disclose the “releasably coupled” limitations discussed above in Section X— Sackier does not disclose that the inner shaft 58a, cylinder 174, and ball 163 (the alleged “control element including a connector element”) is “removably connected” to the clamp 150 (the alleged “clip assembly”).

Prelim. Resp. 41. Patent Owner also alleges that “Sackier does not disclose a frangible link” because “Sackier’s clamp 150 is never deployed and left in the body of the patient.” *Id.* at 42.

For the reasons set forth above with respect to the “releasably coupled” limitations of claim 1, Petitioner has sufficiently shown on this record that Sackier discloses the “removably connected” and “frangible link” limitations of claim 11, including that the link between cylinder 174 and inner shaft 58a with ball 163 would become unlinked when a tensile load is applied. *See* Ex. 1008, 10:24–26.

J. Obviousness of Claims 4, 5, 7, 13, and 14 over Sackier and Adams

Petitioner challenges the patentability of claims 4, 5, 7, 13, and 14 of the ’371 patent under 35 U.S.C. § 103 as obvious based on Sackier and Adams. Pet. 56–60. In support thereof, Petitioner identifies the disclosures in Sackier and Adams alleged to describe the subject matter in the challenged claims. *Id.* Additionally, Petitioner cites the Declaration of

Dr. Nicosia in support of the analysis advocated in the Petition. Ex. 1029 ¶¶ 125–132.

We have reviewed Petitioner’s contentions and supporting evidence. Given the evidence of record, we are persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing on its assertion that claims 4, 5, 7, 13, and 14 are obvious based on Sackier and Adams.

These dependent claims are directed to a ball-and-socket arrangement. For example, claim 4 requires “wherein the clip assembly further comprises a yoke slidably received in the capsule and releasably coupled to the control member.” Ex. 1027, 17:18–20. Petitioner contends that the “ball-and-socket arrangement in Sackier is identical to the arrangement recited in claim 4, except that in Sackier the ball-and-socket merely is reversed.” Pet. 56. Petitioner relies on the teachings of Adams to demonstrate that the socket (“yoke”) may be part of the “clip assembly” as required by claim 4. *Id.* at 57. Petitioner contends “Adams teaches a PHOSITA that a ball-and socket connection can be reversed such that the socket, or ‘yoke,’ is part of the ‘clip assembly’ as an alternative way of connecting the ‘clip assembly’ to the ‘control member.’” *Id.* at 57–58.

Petitioner also provides a persuasive rationale, based on the current record, for combining Sackier with Adams’ teaching of reversing the yoke. *Id.* at 58 (citing Ex. 1029 ¶ 127). Specifically, reversing known components is simply rearranging old elements with each performing the same function it had been known to perform to yield predictable results. *Id.* (citing *KSR Int’l Co.*, 550 U.S. at 417).

We have considered Patent Owner’s contentions with respect to this ground, but find them unpersuasive on the record before us. *See* Prelim.

Resp. 45–48. Patent Owner first contends that Petitioner’s “obviousness analysis fails to identify precisely what it believes is missing from Sackier that requires combination with Adams.” *Id.* at 45. We find this contention unpersuasive because Petitioner explains that the ball-and-socket of Sackier is merely reversed and Adams teaches using the proper orientation through its ball-and-socket embodiment. *See* Pet. 56.

Patent Owner next contends that Petitioner relies on conflicting embodiments from Adams for claims 4, 5, and 7. Prelim. Resp. 47. We find this contention unpersuasive. For this particular ground, Petitioner relies only on the ball-and-socket embodiment of Adams, and not the J-hook embodiment, combined with Sackier. *See* Pet. 56–57.

K. Obviousness of Claims 1, 3–5, 7, 10, and 15 over Sackier and Adams

Petitioner challenges the patentability of claims 1, 3–5, 7, 10, and 15 of the ’371 patent under 35 U.S.C. § 103 as obvious based on Sackier and Adams. Pet. 61–68.

As noted above, we institute trial on each of the claims challenged in this ground as being obvious over Sackier (claims 1, 3, 10) anticipated by Sackier (claim 15), or obvious over Sackier and Adams (claims 4, 5, 7).

Each of these challenged claims require an “opening” and Petitioner contends “[t]o the extent that BSSI argues that annular recess 165 in Sackier is not an ‘opening,’ this limitation is disclosed by Sackier in combination with Adams.” *Id.* at 62. Petitioner also relies on Adams and Sackier for teaching alternative ways of releasably coupling together two components. *Id.* at 64–65.

Patent Owner contests this combination alleging Petitioner has not provided sufficient motivation to combine two distinct embodiments – Adams J-hook embodiment with Sackier’s ball-and-socket design. Prelim. Resp. 45–46.

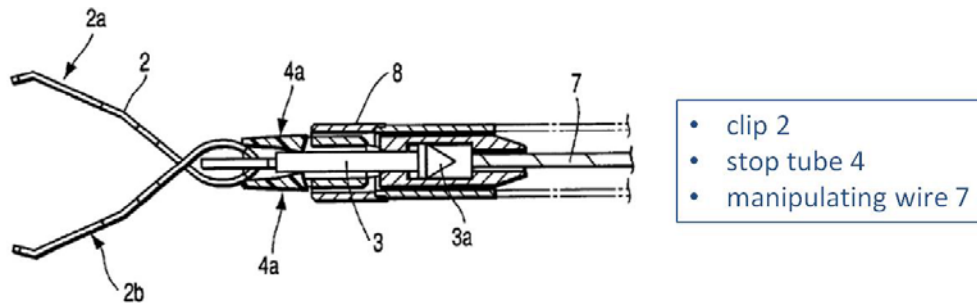
We are not persuaded by Petitioner’s contentions that it would be a simple substitution to replace Sackier’s substitute flange 172 and recess 165 with Adams’ retainer tabs 118, 119, and retainer holes 116. *See Pet.* 65. Likewise, we are not convinced that Petitioner has established a persuasive rationale for making such a significant design change to Sackier. Petitioner simply recites three generic reasons, such as simple substitution, known technique, and obvious to try, without providing sufficient analysis to support any of the given reasons for the design change. *See id.* 65–66.

L. Claims 11–13 as Anticipated by Kimura

Petitioner contends claims 11–13 are unpatentable, under 35 U.S.C. § 102, as anticipated by Kimura. *Pet.* 69–80.

1. Overview of Kimura (Ex. 1007)

Kimura is directed to a clipping apparatus with “a clip capable of being arbitrarily opened/closed.” *Ex. 1007* ¶ 33. The clip may be secured onto tissue via a clip applicator and then detached from the clip applicator. *Id.* at ¶ 31.



Petitioner’s annotated Figure 3B of Kimura depicts the clip unit connected to the clip manipulating device. *Id.* at ¶ 82.

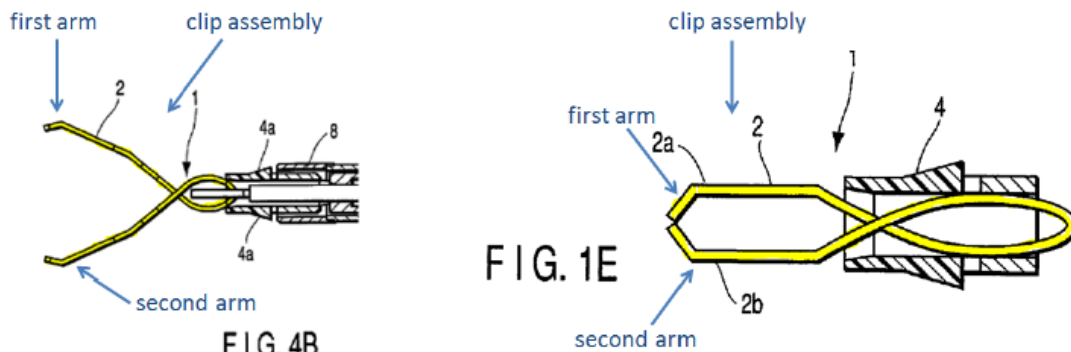
As shown in annotated Figure 3B above, “[t]he clip unit 1 has a clip 2, a link member 3 as a link member, and a stop tube 4 as a clip tightening ring.” *Id.* at ¶ 132. Clips 2 are controlled by manipulating wire 7. *Id.* at ¶ 152.

2. Discussion of Claim 11

We begin our analysis with independent claim 11. Petitioner asserts that Kimura, alone, discloses all elements of claim 11. Pet. 73–77.

Pertinent for our analysis, claim 11 requires “a clip assembly housed within the capsule for movement between an insertion configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration.” Ex. 1027, 18:4–9.

Petitioner contends that “Kimura discloses clip 2 (‘clip assembly’) having arm sections 2a and 2b (‘first and second arms of the clip assembly’) housed within stop tube 4 (‘capsule’).” Pet. 74. Petitioner relies on annotated Figures 4B and 1E, reproduced below, for support. *Id.*



Kimura Figures 4B and 1E

Petitioner's annotated Figures 4B and 1E of Kimura.

Petitioner alleges “[a]rm sections 2a and 2b move between an ‘insertion configuration’ where arm sections 2a and 2b are drawn towards one another (Fig. 1E [above]) and an ‘expanded configuration’ where the arm sections 2a and 2b are separated from one another to receive tissue therebetween (Fig. 4B [above]).” *Id.* (citing Ex. 1007 ¶¶ 133, 151, 152).

Patent Owner relies on a portion of the limitation discussed above that Petitioner allegedly overlooks. Specifically, Patent Owner points out that the “first and second arms of the clip assembly are drawn toward one another” in an “insertion configuration.” Prelim. Resp. 49–50. Thus, when in the “insertion configuration,” the clip assembly must be housed within the capsule. *Id.* Patent Owner contends that Petitioner’s “analysis overlooks that Kimura’s clip 2 (the alleged ‘clip assembly’) is never ‘housed within’ the stop tube 4 (the alleged ‘capsule’) for movement between an ‘insertion configuration’ and an ‘expanded configuration.’” *Id.* According to Patent Owner:

Kimura’s clip 2 is not “housed within” the stop tube 4 until after the clip 2 has been inserted, and at that point, it is not movable between an “insertion configuration” and an “expanded configuration.” (Kimura at ¶¶ 0146 - 0152.) In fact, Kimura’s Figure 1E that Cook cites for the “insertion configuration,”

actually shows the post-insertion, tissue-pinching configuration.

Id. at 50.

We are not persuaded that Petitioner has demonstrated sufficiently that Kimura discloses “a clip assembly housed within the capsule for movement between an insertion configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration,” as required by claim 11. Petitioner relies on Figure 1E and paragraph 152 of Kimura as teaching the insertion configuration. *See* Pet. 74. Figure 1E, however, depicts the post-insertion, tissue-pinching configuration. As Kimura explains, “[i]n this state, the clip 2 is guided so as to pinch a target physiological tissue,” and then when “retracting the manipulating wire 7, the arm sections 2a and 2b of the clip 2 are pulled into the stop tube 4, and the arm sections 2a and 2b of the clip 2 are closed as shown in FIG. 1E.” Ex. 1007 ¶ 152. Thus, Figure 1E of Kimura does not depict an “insertion configuration” as required by claim 11. Petitioner does not discuss this discrepancy or explain why or how the retraction configuration of Figure 1E would disclose the claim limitations directed to the insertion configuration.

Based on the record before us, Petitioner has not established persuasively that Kimura discloses “a clip assembly housed within the capsule for movement between an insertion configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration,” as required by claim 11. For this reason, Petitioner has failed to show a reasonable likelihood that it would prevail in showing that Kimura anticipates claim 1. Accordingly, we decline to institute a review of claim 11 under 35 U.S.C. § 102(b) as anticipated by

Kimura.

3. Discussion of Claims 12 and 13

Petitioner asserts that Kimura discloses all elements of these claims. Pet. 78–80. Claims 12 and 13 depend from claim 11. For the reasons set forth above for claim 11, Petitioner has failed to show a reasonable likelihood that it would prevail in showing that Kimura anticipates claims 12 and 13. Accordingly, we decline to institute a review of these claims under 35 U.S.C. § 102(b) as anticipated by Kimura.

M. Obviousness of Claims 1, 3–6, and 15 over Kimura

Petitioner contends that claims 1, 3–6, and 15 are obvious based on Kimura. Pet. 81–92. For the reasons that follow, Petitioner has not established a reasonable likelihood that it would prevail on this ground.

Claim 1 requires, in pertinent part, “a bushing” with a “distal end releasably coupled to the capsule via a tab on the distal end of the bushing engaging the opening of the capsule.” Ex. 1027, 17:4–7.

Petitioner contends that Kimura’s “coil pipe 8 (‘bushing’) has a distal end releasably coupled to the stop tube 4 (‘capsule’).” Pet. 83. Petitioner admits, however, that “Kimura does not explicitly disclose that coil pipe 8 (‘bushing’) is releasably coupled to stop tube 4 (‘capsule’) “via a tab on the distal end of the bushing engaging the opening of the capsule.” *Id.* at 84. According to Petitioner, “the connection in Kimura is reversed” whereas “the claimed ‘tab’ is on stop tube 4 (‘capsule’) and the ‘opening’ is on coil pipe 8 (‘bushing’).” *Id.* Although Kimura discloses that “the proximal end (‘tab’) of stop tube 4 (‘capsule’) slides into the hollow portion (‘opening’) of coil pipe 8 (‘bushing’),” under Petitioner’s modified arrangement, coil pipe

8 (bushing) could slide into the lumen of stop tube 4 (capsule) as required by claim 1. *Id.* at 84–85.

Petitioner proposes reversing Kimura’s connections because “it would have been obvious to try reversing the connection between Kimura’s stop tube 4 and coil pipe 8.” *Id.* at 85. Petitioner also contends Kimura suggests the modification because of a general statement in its specification that “the invention in its broader aspects is not limited to the specific details and representative embodiments shown and described herein.” *Id.* at 86 (quoting Ex. 1007 ¶ 316).

Patent Owner first contends that Petitioner fails to “provide a legally sufficient motivation to modify Kimura.” Prelim. Resp. 51. Patent Owner next argues that “the alleged combination does not disclose the claimed ‘tab’ on the distal end of the coil pipe 8 (the alleged ‘bushing’),” and “[c]oil pipe 8 does not include a tab on its distal end and stop tube 4 does not include a tab on its proximal end.” *Id.* Patent Owner notes that Petitioner “does not propose any modification to Kimura beyond merely reversing the connection such that the coil pipe 8 slides inside the stop tube 4,” and, as such, “that alleged combination still would not include the required tab on the distal end of the coil pipe 8 (the alleged ‘bushing’).” *Id.*

Based on the record before us, Petitioner has not established persuasively a rationale to make the proposed modifications to Kimura and Petitioner has also not established persuasively how the modified Kimura design would have a tab on the distal end of the bushing for releasably coupling with the capsule. Even if Petitioner’s proposed design modification were supported, Petitioner has not explained persuasively what structure on the bushing would serve as the claimed tab. Further, Petitioner

has not provided a persuasive rationale on the record before us as to why a person of ordinary skill in the art would make the proposed reversal modifications and add a tab that is not disclosed. Petitioner's rationales (Pet. 85–86) are conclusory and lack a rationale underpinning. For example, the generic statement in Kimura – that the invention is not limited to the specific details and embodiments disclosed – does not provide a persuasive reason for making the specific design changes proposed.

Accordingly, we determine that the Petition does not establish a reasonable likelihood that Petitioner would prevail in showing that claim 1, and claims 3–6, which depend directly or indirectly therefrom, would have been obvious over Kimura.

Claim 15 depends from claim 11. For the reasons set forth above for the anticipation analysis of claim 11 based on Kimura, we determine that the Petition does not establish a reasonable likelihood that Petitioner would prevail in showing that claim 15 would have been obvious over Kimura. Specifically, Petitioner does not propose any additional modification to Kimura for claim 15 that would address the shortcomings for claim 11. *See* Pet. 92.

N. Obviousness of Claims 10 and 17 over Kimura and Sackier

Petitioner contends that claims 10 and 17 are obvious based on Kimura and Sackier. Pet. 93–95. For the reasons set forth above for the analysis of independent claims 1 and 11 based on Kimura, Petitioner has not established a reasonable likelihood that it would prevail on this ground.

Petitioner relies on its obvious analysis of claim 1 over Kimura (*id.* at 93) and its anticipation of claim 11 based on Kimura (*id.* at 95) as the basis for this ground. Sackier is added to teach a “tension member” required by

claims 10 and 17. Because the addition of Sackier does not address the deficiencies for claims 1 and 11 examined above, the Petition does not establish a reasonable likelihood that Petitioner would prevail in showing that claim 10 and 17 would have been obvious over Kimura and Sackier.

IV. CONCLUSION

For the foregoing reasons, we determine that the information presented establishes a reasonable likelihood that Petitioner would prevail in showing that claims 1, 3–5, 7, 10, 11, 13–15, and 17 of the '371 patent are unpatentable. We, however, determine that Petitioner has not made a sufficient showing with respect to claims 6, 8, 9, and 12. At this preliminary stage, we have not made a final determination with respect to the patentability of the challenged claims or any underlying factual and legal issues.

V. ORDER

Accordingly, it is:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1, 3–5, 7, 10, 11, 13–15, and 17 of the '371 patent on the following ground of unpatentability:

Reference	Basis	Challenged Claim(s)
Sackier	§ 103	1, 3, and 10
Sackier	§ 102	11, 15, and 17
Sackier and Adams	§ 103	4, 5, 7, 13, and 14

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and

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37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, which commences on the entry date of this decision; and

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

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