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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*.

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

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 instituted an *inter partes* review. Paper 7 ("Dec.").

Patent Owner subsequently filed a Patent Owner Response (Paper 16; Paper 15 (publicly available redacted version), "PO Resp.") and Petitioner filed a Reply (Paper 24; Paper 23 (publicly available redacted version), "Pet. Reply").

Patent Owner filed a Motion to Exclude (Paper 35) certain evidence submitted by Petitioner, to which Petitioner filed an Opposition (Paper 49) and Patent Owner filed a Reply (Paper 51).

Petitioner also filed a Motion to Exclude (Paper 37; Paper 39 (publicly available redacted version) portions of "The Smith Declaration," to which Patent Owner filed an Opposition (Paper 47; Paper 48 (publicly available redacted version)) and Patent Owner filed a Reply (Paper 52; Paper 53 (publicly available redacted version)).

Patent Owner filed a Motion for Observations on Cross-Examination of Dr. Mark Nicosia (Paper 40), to which Petitioner filed a Response (Paper 50).

A combined oral hearing with Case IPR2017-00132, IPR2017 00133, and IPR2017-00134, was held on February 8, 2018, and a transcript of the hearing is included in the record (Paper 59, "Tr.").

On April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on less than all claims challenged in the petition. *SAS Inst. Inc. v. Iancu*, 138 S.Ct. 1348, 1359–60 (2018). On April 26, 2018, the Office issued Guidance on the Impact of *SAS* on AIA Trial Proceedings, which states that "if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial. Subsequently, on May 11, 2018, we issued an Order modifying the Decision on Institution "to institute on all of the claims and all of the grounds presented in the Petition." Paper 61, 3.

Pursuant to our authorization (Paper 63), the parties thereafter filed a "Joint Motion to Limit the Proceeding" (Paper 64), requesting that we limit the proceeding "to a subset of the instituted grounds and claims in the Petition," as identified in the motion. Paper 64, 1. On June 29, 2018, we issued a Decision (Paper 65), accepting the Parties' joint proposal to limit the proceeding "to those claims and grounds as set forth in Paper 64, 1–3." Paper 65, 2. The "Asserted Grounds" section below reflects the claims and grounds agreed upon by the parties and addressed in our Decision to Limit the Proceeding.

Based on the addition of claims and grounds to the proceeding, we authorized additional briefing. Paper 63, 5–8. On June 29, 2018, Patent Owner filed a Supplemental Response. Paper 66 ("Supp. Resp."). Petitioner filed a Supplemental Reply. Paper 68 ("Supp. Reply"). Patent Owner also

filed an additional Motion to Exclude Evidence. Paper 71. Supplemental oral argument was held before the Board on September 17, 2018. Paper 80 ("Sep. Tr.").

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1, 3–5, and 10 are unpatentable. Petitioner has not shown by a preponderance of the evidence that claims 7, 11–15 and 17 are unpatentable. Additionally, we address the Parties' Motions to Exclude as set forth below.

I. BACKGROUND

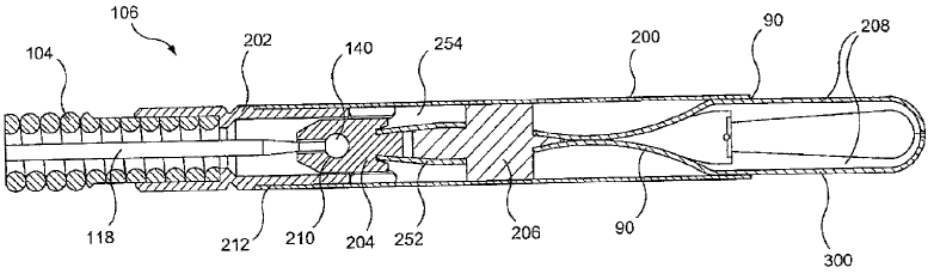
A. The '371 Patent (Ex. 1027)

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:



F I G. 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.*

Another embodiment of the '371 patent, as set forth in figures 27–29, provides additional details of a yoke and how it may function to receive a control wire and ball. In these embodiments, "[w]hen the control wire 118 is seated in the yoke 204, it is desirable to ensure that it cannot inadvertently be removed from the control wire slot 600." Ex. 1027, 13:64–67. As depicted below, it appears this embodiment has a lateral cut, or opening, into wire cavity 604.

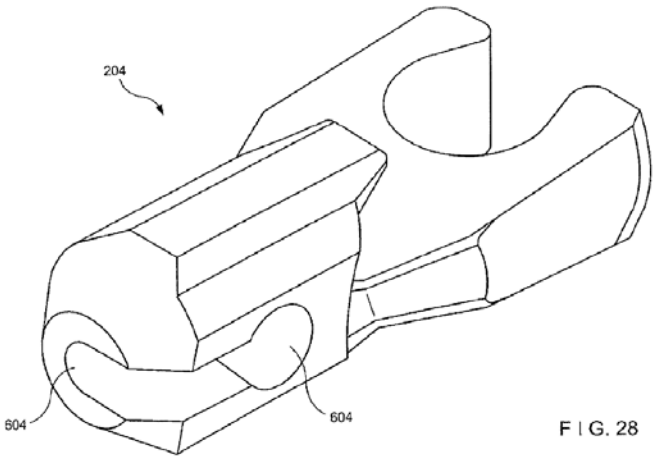


FIG. 28

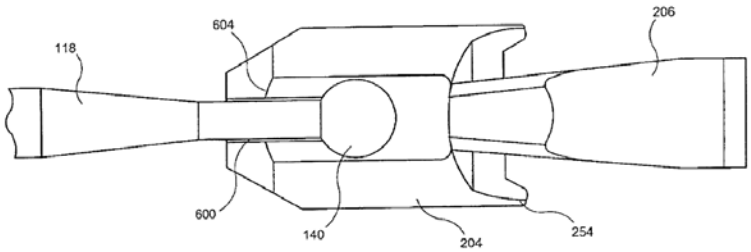


FIG. 29

Figures 28 and 29 of the '371 patent depicting an alternative embodiment with a lateral opening into wire cavity 604.

This embodiment functions by allowing ball 140 to pass into ball cavity 602 (fig. 27), which has a diameter sufficiently large to allow the ball to pass. Wire cavity 604 is large enough to allow the control wire 118 to pass into, but not large enough to allow ball 140 to pass therethrough. *Id.* at 14:1–10. In this embodiment, yoke 204 may be made of stainless steel or high strength polymer. *Id.* at 14:10–13.

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 ("litigation"). Patent Owner identifies the following proceedings in which petitions were filed 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. 18, 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).

Petitioner relies on the Declaration of Mark A. Nicosia, Ph.D. (Ex. 1029), as well as his Declaration (Ex. 1046) in support of its Reply, his

[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.

Declaration (Ex. 1108) in support of Petitioner's Supplemental Reply, and another Dr. Nicosia Declaration (Ex. 1100) for a related proceeding.

Patent Owner relies on the Declaration of Jeffrey Vaitekunas, Ph. D. (Ex. 2029) in support of its Response as well as the Declaration of Dr. Vaitekunas (Ex. 2102) in support of its Supplemental Response.

E. The Asserted Grounds

Pursuant to our Institution Decision (Paper 7) and our Decision (Paper 65) on the parties' Joint Motion to Limit Proceeding (Paper 64), the following challenges to the patentability of the '371 patent are before us for consideration:

Reference(s)	Basis	Claim(s) Challenged
Adams	§ 102(b)[2]	1, 3, 11, and 15
Adams	§ 103	4, 5, and 13
Adams	§ 103	1 and 3–5
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, 10, and 15
Kimura	§ 102(b)	11–13
Kimura	§ 103	1, 3–5, and 15
Kimura and Sackier	§ 103	10 and 17

See Paper 64, 2–3.

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

A. Bushing "Coupled to the Sheath"

Relying only on Patent Owner's litigation position from the related district court proceeding, Petitioner contends that "coupled to the sheath" means "slideable inside the sheath" and "the sheath confines the bushing." Pet. 9. Petitioner provides no additional support. The district court 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; Ex. 2003, 28.

In our proceeding, Petitioner has not provided persuasive evidence or argument to support its claim interpretation by merely pointing to what Patent Owner purportedly argued in district court. Based on the final record before us, "coupled to the sheath" means "linked together, connected, or joined" to the sheath. Our construction is consistent with the district court's analysis and reflects 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. "Releasably Coupled" and "Removably Connected"

Patent Owner contends that "the BRI of 'releasably coupled' and 'removably connected' is "coupled and capable of being released/removed within the body.'" PO Resp. 7 (citing Ex. 2029 ¶¶ 40–46). According to Patent Owner, "each of claims 1 and 11, by their express terms, require the capability to release or remove the 'bushing' and 'control member' (claim 1), or a 'control element' and a 'sheath' (claim 11), *within the body*." *Id.*

Patent Owner notes that "[c]laim 1 is directed to '[a]n apparatus for applying clips to tissue' and includes a 'flexible sheath' that, 'in an *operative configuration*,' must 'extend[ ] *into a living body* to a target portion of tissue to be clipped' (emphasis added)." *Id.* Patent Owner points to two reasons why "the claims describe that, in the operative configuration, the bushing is within a living body." *Id.* First, the claim "further includes a 'bushing extending between a proximal end coupled to the sheath and a distal end releasably coupled to the capsule." *Id.* Secondly, "[b]ecause the distal end

of the flexible sheath extends into a living body, and the proximal end of the bushing is coupled to the sheath," then the claims require the bushing to also be within a living body. *Id.*

Likewise, Patent Owner contends that "the 'control member' must be 'releasably coupled' to the clip assembly while the 'control member' and the 'clip assembly' are within a living body in an operative configuration." *Id.* at 8.

After examining the relevant language of claim 11, Patent Owner similarly argues that "claim 11 requires: (1) a releasable connection between the distal end of the sheath and the capsule; and (2) a removable connection between the control element and the clip assembly, housed within the capsule, when both are within a living body for applying clips to tissue." *Id.* Patent Owner argues that the express language of claims 1 and 11 "requires the capability to release the capsule from the sheath and remove the connector element from the clip assembly *within the body*." *Id.*

Patent Owner points out that its interpretation is supported by "the specification, which uses the word 'release' consistently to refer to decoupling after the clip has been deployed while inside the body." *Id.* at 8–10 (citing Ex. 1027, 1:35–40, 3:46–50, 3:56–59, 5:3–7, 6:55–59, 9:28–31). Patent Owner also points out that the Specification warns of the importance of ensuring that the capsule and clip are released within the patient's body. *Id.* at 10 (citing Ex. 1027, 10:5–8 ("If this condition is not satisfied, a situation may occur where the clip assembly 106 is locked in place on the patient's tissue, but cannot be released from the clipping device 100. It will be apparent that this situation should be avoided."). Thus, Patent Owner concludes that "the broadest reasonable interpretation of 'releasably

coupled' and 'removably connected' is 'coupled and capable of being released/removed within the body.'" *Id.* at 10.

Petitioner responds that "claim 1 does not require the 'control member' (or 'bushing') to be releasably coupled *while the sheath is in the 'operative configuration.'*" Pet. Reply 3–4. Instead, Petitioner argues that "[c]laim 1 is silent as to when, and under what conditions, these components decouple." *Id.* at 4. According to Petitioner, "claim 11 does not require that the 'control element' decouple from the 'connector element' (or the 'sheath' from the 'capsule') within the body." *Id.*

Reading both independent claims as a whole, we agree with Patent Owner that each of claims 1 and 11, by their express terms, require the capability to release or remove the 'bushing' and 'control member' (claim 1), or a 'control element' and a 'sheath' (claim 11), within the body. Claim 1 is directed to an "apparatus for applying clips to tissue" that further requires "in an operative configuration," must "extend[ ] into a living body to a target portion of tissue to be clipped."

The claim further includes a "bushing extending between a proximal end coupled to the sheath and a distal end releasably coupled to the capsule." We determine that because the distal end of the flexible sheath extends into a living body, and the proximal end of the bushing is coupled to the sheath, the most logical interpretation is that the claims require, in the operative configuration, the bushing to be within a living body. Further, the specification consistently uses the word "release" to refer to decoupling after the clip has been deployed while inside the body, as set forth by Patent Owner above.

Although we find Patent Owner's position more persuasive on the

final record, as explained below, our ultimate decision related to Sackier would not be materially impacted if we were to adopt Petitioner's interpretations.

C. "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 in district court. Patent Owner agrees with Petitioner's proposed construction. *See* PO Resp. 12.

Based on the final trial record, 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. 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).

B. 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.

C. Objective Evidence of Nonobviousness

At the outset, we find it helpful to discuss Patent Owner's evidence of secondary considerations and the impact of this evidence on the obviousness challenges set forth below.

Patent Owner makes and sells hemostatic clips called the Resolution™ Clip and Resolution 360™ Clip (together, the "Resolution

Clips"). PO Resp. 41. Patent Owner contends that the Resolution Clips embody claims 1, 3, 4, 5, 7, 10, 13, and 14 of the challenged patent. *Id.* at 55–61. Further, Patent Owner argues that the Resolution Clips have enjoyed considerable commercial success and industry praise, which serve as objective indicia of non-obviousness. *Id.*

Patent Owner alleges that the primary driver of the commercial success in the Resolution Clips is the superior repositionability of the Resolution Clips which is provided by the reversible open/close feature and the tactile feel feature, which Patent Owner contends are now demanded by most physicians. *Id.* at 42.

The issue we have with Patent Owner's contentions, as pointed out by Petitioner, is that Patent Owner does not establish persuasively how its claims require the "reversible open/close" feature and the "tactile feel features." *See* Pet. Reply 27–29. Even presuming that these features did indeed drive tremendous commercial success and industry praise for the commercial products, Patent Owner does not adequately explain in its analysis how the claims of the challenged patent require these particular features that drive commercial success.

Patent Owner seems to suggest that a break section in the control wire will fracture and that this feature in the commercial product relates to the tactile feel. PO Resp. 57 (citing Ex. 2029 ¶¶ 91–93) ("After the yoke has disengaged, if the handle spool is moved further proximally, a break section in the control wire will fracture, leaving the ball within the yoke and uncoupling the control wire from the distal components of the device."). This "break section in the control wire" is not, however, claimed or covered in claim 1, the claim that purportedly embodies the commercial product.

The claims alleged to cover the product do not specifically require any "tactile feel feature."[3]

Likewise, while the claims may allow for an opening and closing of the clip assembly, there is no requirement in these claims that the clip assembly, as "demanded" by physicians, repeatedly open and close. Thus, both of the drivers of commercial success and industry praise are not commensurate in scope with the claims of the patented invention. *See* Ex. 1046 ¶¶ 23–29 (explaining how features are not claimed).

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

For the reasons set forth above, we determine that Patent Owner has not sufficiently shown that its objective evidence of secondary

[3] Notably, during prosecution of the '371 patent, Patent Owner presented claims explicitly directed to the "user feedback" described in the '371 patent, including "tactile feedback." *See* Ex. 1046 ¶ 28; Ex. 1027, 7:54; Ex. 1028, 3 (original claim 1). These claims were later cancelled and replaced with the instituted claims, which do not require any user feedback.

considerations weighs in favor of the nonobviousness of any claim.

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

Petitioner contends claims 1, 3, 11, and 15 are unpatentable, under 35 U.S.C. § 102, as anticipated by Adams. Pet. 17–31. Patent Owner opposed Petitioner's contentions for the reasons explained below. *See* Prelim. Resp. 12–18.

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. There are two primary embodiments disclosed in Adams that are at issue. 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.

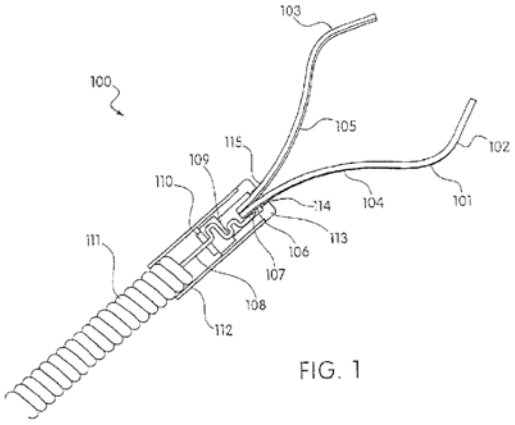


Figure 1 is an enlarged partial view of one embodiment referred to as the "J-hook" embodiment. *Id.* at 5:21–41.

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.

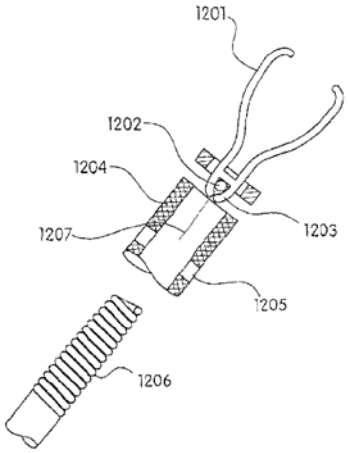


FIG. 12A

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.*

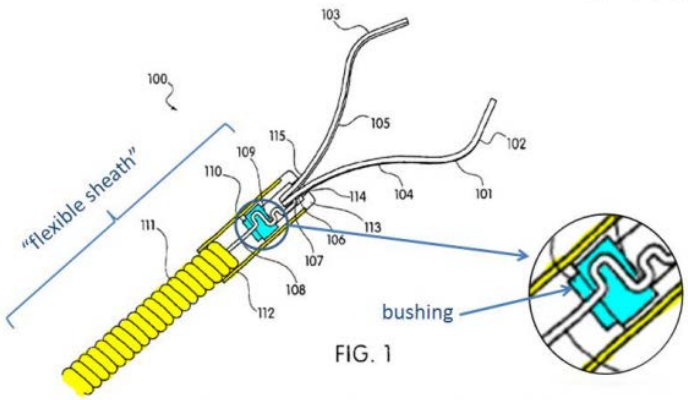
Notably, an earlier publication of a substantively identical Adams specification was considered and overcome during prosecution of the '371 patent. *See* Pet. 11.

2. Discussion of Claim 1

Petitioner asserts that Adams, alone, discloses all elements of claim 1. Pet. 17–22. More specifically, Petitioner relies on Adams's J-hook embodiment. *Id.*

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.



Adams Fig. 1

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.

In reply, Petitioner argues that retainer tabs 118, 119 link, or couple together retainer and sheath, preventing retainer from sliding with respect to the sheath. Pet. Supp. Reply 6 (citing Ex.1029 ¶ 38), Pet. 20). Thus, according to Petitioner, Adams satisfies the "coupled" limitation. *Id.* (citing Ex. 1108 ¶ 15). Relying on a new theory, Petitioner contends that Adams separately satisfies the "coupled" limitation after retainer tabs disengage from sheath, when retainer 110 is "slidable inside the sheath." *Id.* Petitioner argues that two components do not need to be touching in order to be "linked together, connected, or joined." *Id.* at 8 (citing Ex. 1108 ¶ 18). Regardless, Petitioner contends that at least a portion of the proximal end of retainer 110 does touch the "sheath." *Id.*

Patent Owner, in its Surreply, notes that "[c]laim 1 requires a 'bushing' with *two* different couplings: 1) 'a proximal end coupled to the sheath' (the 'proximal coupling'); and 2) 'a distal end releasably coupled to the capsule' (the 'distal coupling')." PO Surreply 2. Patent Owner argues that Petitioner is attempting to change its theory as to how Adams discloses this limitation by equating a single distal end coupling as also disclosing the proximal coupling. Petitioner originally argued that the distal coupling was met by the "distal end retainer tabs 118 or 119" and the proximal coupling

was met because the retainer is confined by the sheath at its proximal end. *Id.* (citing Pet. 20). Patent Owner offers that "Petitioners now argue that the proximal coupling is met via the *distal* tabs 118 and 119," but "this theory fails because the claim requires two separate couplings." *Id.* at 2, 3. Further, Patent Owner contends "that the distal tabs do not couple the proximal end of retainer 110 to sheath 111, outer sleeve 112, or lock sleeve 113" as would be required by the claim language. *Id.* at 3.

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 final record, 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. The claimed coupling must be "proximal coupling" and Petitioner can only point to distal coupling via distal tabs 118, 119 (Pet. Supp. Reply 6) – this is not "proximal" coupling. Further, for the bushing and the sheath to be coupled requires them to be "linked together, connected, or joined" in some manner and Petitioner has not established any such connection for proximal coupling.

Petitioner also has failed to establish a persuasive reason for linking or connecting retainer 110 and sheath 112 – indeed, doing so would negatively impact the ability of retainer 110 to freely slide out of sheath 112. *See* Prelim. Resp. 27. Adams suggest that when control wire 108 is actuated and the clip is locked into the lock sleeve, retainer release 109 pulls retainer 110 back, disengaging retainer tabs 118, 119 from the two retainer holes as depicted in Figure 4." Ex. 1023, 7:26–44

Finally, we note that our decision would not change if we adopted the district court's claim interpretation. The district court adopted a claim construction of "a bushing extending between a proximal end coupled to the sheath" as "linked together, connected, or joined, *but not slidable inside the sheath*." Ex. 2003, 28 (emphasis added). Should the district court's interpretation be the correct one, Patent Owner's position is much stronger whereas Petitioner's theory is based on slidable movement. *See* Pet. 9 (arguing for "slideable inside the sheath" and "the sheath confines the bushing"); Pet. Supp. Reply 6.

Having now considered the evidence in the complete record established during trial, we are not persuaded that Petitioner has demonstrated by a preponderance of the evidence that claim 1 would have been anticipated by Adams. 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 prove by a preponderance of the evidence that Adams anticipates claim 1.

3. Claim 3

Petitioner asserts that Adams discloses all elements of claim 3. Pet. 4, 23–31. Claim 3 depends from claim 1. For the reasons set forth above for claim 1, Petitioner has failed to prove by a preponderance of the evidence that Adams anticipates claim 3.

4. Claims 11 and 15

In our Institution Decision, we exercised our discretion pursuant to 35 U.S.C. § 325(d) to decline review of claim 11, as well as claim 15 which depends from claim 11. We did so because the Office had specifically considered Adams and determined that claim 11 was patentable in light of

Adams after Patent Owner made certain amendments. *See* Dec. 9–16. As noted above, we later instituted review of this ground and these claims after the Supreme Court's decision in *SAS*.

The plain language of § 325(d) limits its application to "determining whether to institute or order a proceeding under this chapter." Once a trial is instituted, we have no basis to apply § 325(d) to exercise our discretion. In effect, the Supreme Court's decision in *SAS* precludes the application of § 325(d) in situations, as here, where we would have otherwise exercised discretion to deny institution on one ground but instituted on others. We must now fully consider Petitioner's contentions on the final trial record.

Pertinent for our analysis, Claim 11 requires in part:

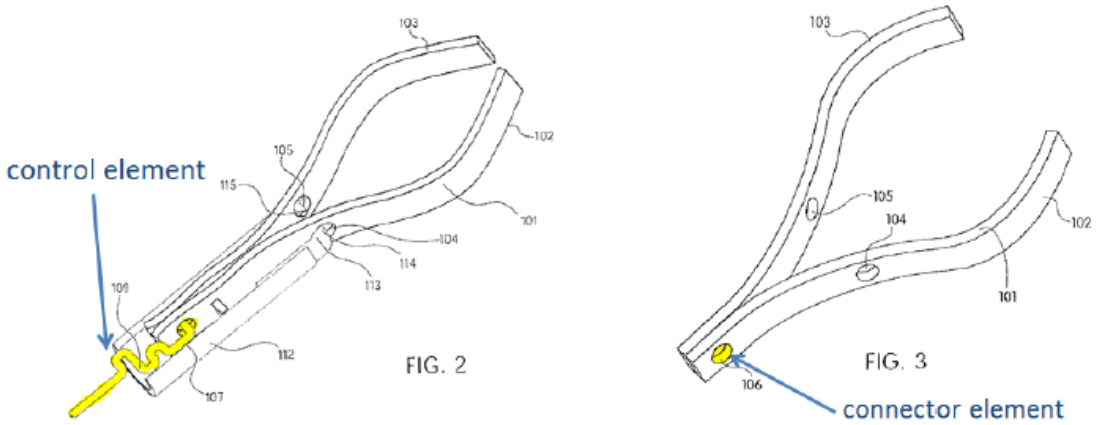
> a control element including a connector element, extending between a proximal end which, during use, remains outside the body accessible to a user and a distal end removably connected to the clip assembly via the connector element wherein the control element detaches from the connector element via a frangible link.

Ex. 1027, 18:10–15. The "control element including a connector element" was added to the claim during prosecution to overcome a rejection by Adams. Ex. 2005, 3[4] (application claim 41 became issued claim 11). Specifically, the language "including a connector element," and "the connector element, wherein the control element detaches from the connector element via a frangible link" requirements were added to the pending claim to overcome Adams. The district court's "Report and Recommendation" on claim construction also details that court's views of the file history as well as the interpretation of "a control element including a connector element." *See*

[4] We refer to the page numbering added to the exhibit.

Ex. 2003, 7–14. Interestingly, the parties appear to take opposite positions between the district court case and this proceeding.

Petitioner argues that Adams discloses these limitations. Pet. 26–28. Petitioner identifies the claimed "control element including a connector element" of claim 11 as being taught by Adam's control wire 108 having j-hook 107 on the distal end that is removably connected to clip 101 via cut-out 106 as depicted below:



Adams Figs. 2 and 3

Petitioner's annotated Figures 2 and 3 of Adams depicts the elements Petitioner contends are the control element and the connector element. Pet. 27. According to Petitioner, "[c]ontrol wire 108, j-hook 107, and cut-out 106 are multiple, distinct structures that collectively makeup the claimed 'control element including a connector element,' with cut-out 106 as the claimed 'connector element.'" *Id.* Further, "[d]uring use, the proximal end of control wire 108 (part of the 'control element') remains outside the body accessible to a user." *Id.* Petitioner also notes that Patent Owner's litigation position in district court was that "a control element including a connector element" may be "made up of multiple, distinct structures." Ex. 1013, 16. Petitioner argues that Adams's hole can be a structure. Pet. Supp. Reply 9.

Petitioner also relies on testimony of Patent Owner's expert related to Komiya (U.S. 3,958,576 (Ex.1014)), a different patent. *Id.* at 9–10. Petitioner seems to suggest that based on this testimony "'clip' is limited to portions that compress tissue, whereas remaining portions . . . are 'clip *assembly*.'" *Id.* at 11.

Patent Owner contends that Adams does not disclose a "control element including a connector element," as required by claim 11. Prelim. Resp. 15–19. Patent Owner contends that Petitioner's position is unreasonably broad and that the claimed "connector element" cannot read on Adams's cut-out 106. *Id.* at 16.

Patent Owner advances three reasons for this position. *Id.* First, Patent Owner contends that "cut-out 106 is merely a hole in the clip 101 through which the control wire is connected to the clip 101 —not a structure included in the 'control element.'" *Id.* "Second, the cut-out 106 is formed in the clip 101 —not the 'control element.'" *Id.* at 16–17. Finally, Patent Owner argues that "cut-out 106 does not satisfy other limitations of the 'connector element,' *e.g.*, that the 'control element detaches from the connector element via a frangible link.'" *Id.* at 17. Patent Owner also emphasizes that although the "clip assembly" may include the clip arms, a bushing and a yoke, the '371 patent does not equate the "clip assembly" with a mere "clip." *Id.*, n.4 (citing Ex. 1027, 6:64–7:3). Patent Owner argues that the Adams's clip does not include a "connector element." *Id.*

Patent Owner also relies on the prosecution history of the '371 patent, during which the claims were amended to overcome an argument made by the examiner similar to the one Petitioner now advances. *Id.* Specifically, the examiner asserted that Adams Figures 12A and 12B disclosed a "control

element 1207 extending between a proximal end . . . and a distal end removably connected to the clip assembly via a frangible link." *Id.* (quoting Ex. 2004, 6).

As noted above, the claims were amended to require "a control element including a connector element" wherein "the control element detaches from the connector element via a frangible link." *Id.* at 18. Patent Owner differentiated Adams by arguing that in Adams "[t]he ball at the distal end of the control wire 1207 is directly coupled to the clip 1201 and the entire control wire 1207 is then separated from the clip 1201." Ex. 2005, 7. As further argued to the Office, because both the ball and the entire control wire are separated from the clip, "the control wire 1207 includes no [control] element having a connecting element connected thereto by a frangible link as claimed." *Id.* Because the socket on the proximal end of the clip in Adams figure 12 was stated not to be a "connector element," interpreting "cut-out 106" of Adams, which is also located on the proximal end of the clip, to read on the "connector element" would effectively read out the amendment made to overcome Adams. *Id.*

Based on the totality of the record before us, we find Patent Owner's contentions more persuasive as to this issue. We are faced with a situation where both parties present opposite theories from their litigation position in district court as to the meaning of the "control element including a connector element." For example, Petitioner's litigation position was that "the control element and connector element are elements of a single, unitary structure." Ex. 2003, 7. Because neither party seemed willing to contradict their own litigation position effectively, the arguments before us are not well developed and more often than not simply point to and criticize what the

other party argued without taking a firm position. *See, e.g.*, Pet. 9 (the only evidence for construing "a control element including a connector element" was BSSI's litigation position).

Based on the final record, we do not believe that cut-out 106, which is located on the proximal end of the clip in Adams, teaches the claimed "control element including a connector element." The connector element need not be a single unitary structure with the control element, but the statements in the prosecution history distinguish the claimed invention from the prior art on the basis of the location of the frangible link in relation to the control element and connector element. This differentiation, that the connector element is not part of the clip arms, carries over to Adams cut-out 106, which is a structure located at the proximal end of the clip arms and not part of the control element.

We have considered Dr. Vaitekunas's testimony related to Komiya (Pet. Supp. Reply 11) and the meaning of clip arms. This testimony does not specifically discuss Adams and, as such, we find it less persuasive. The questions asked appear to us to be an attempt by counsel to confuse the witness by talking about a different reference at issue in a different proceeding. Patent Owner also notes that the structure of a clip may sometimes be referred to in the aggregate as the overall clip assembly, but other times in more specific context to refer to the clip arms. PO Supp. Resp. 5.

Claim 11 also requires that "a distal end [of the control element] removably connected to the clip assembly via the connector element." If the connector element is physically part of the clip arms, as it is for Adams cut-out 106, the mention of connector element in this limitation would

seemingly be superfluous. Regardless, the claim language (added to overcome Adams) also requires that "the control element detaches from the connector element via frangible link." To us, this infers that the control element and connector element must first be attached in order to detach. We do not believe that Adams's cut-out 106 teaches the claim limitations set forth above.

For these reasons, Petitioner has failed to prove by a preponderance of the evidence that Adams anticipates claims 11 and 15.

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

Petitioner contends that claims 4, 5, and 13 are obvious based on Adams. Pet. 32–37. For the reasons that follow, Petitioner has not established by a preponderance of the evidence that these claims would have been obvious over Adams.

1. Whether Adams Qualifies as Prior Art

Patent Owner challenges whether Adams may be used in an obviousness combination pursuant to 35 U.S.C. § 103(c). *See* PO Supp. Resp. 34; PO Resp. 48–49. Pre-AIA §103(c) excludes certain prior art only "where the [prior art] and the claimed invention were, *at the time the claimed invention was made*, owned by the same person or subject to an obligation of assignment to the same person." Thus, when the claimed subject matter "was made" is essential under the statute to establish the date by which Patent Owner's arguments must be judged.

Patent Owner first notes that the Petition only asserts that Adams "qualifies as prior art under 35 U.S.C. § 102(e)." PO Resp. 49 (quoting Pet. 11). Patent Owner contends that the inventions claimed in the '371 patent were conceived and actually reduced to practice on or about May 25, 2003,

and constructively reduced to practice by September 30, 2003. At that time in May, Patent Owner alleges the claimed inventions were owned by Scimed Life Systems, Inc. *Id.* (citing Ex. 2033 ¶¶ 4–7). Patent Owner notes that at the same time, Adams was owned and/or subject to an assignment to Scimed Life Systems, Inc. *Id.* (citing Ex. 2033 ¶¶ 4–7). Thus, according to Patent Owner, "Adams is not available as prior art under § 103, and [Petitioner's] arguments based on a combination of Sackier and Adams should be rejected." *Id.*

Petitioner responds that Adams is prior art. Pet. Reply 18–19. Petitioner claims it has made out a prima facie case that Adams qualifies as prior art and that Patent Owner has failed to produce sufficient evidence to demonstrate that Adams is not available as prior art under pre-AIA 35 U.S.C. §103(c). *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378–80 (Fed. Cir. 2015) (explaining burdens). We determine, for the reasons noted below, that Petitioner has shown that Adams qualifies as prior art under §103(c) / § 102(e) and Patent Owner has not produced sufficient evidence to rebut this showing.

Principally, we find that Patent Owner has not established persuasively when the claimed invention of the '371 patent was made. Patent Owner's submission regarding this crucial date is focused on a statement by Craig Smith:

> I understand that BSC's outside counsel have determined that the inventions claimed by the '371 patent were made on or about May 25, 2003, and constructively reduced to practice by September 30, 2003, the filing date of [a parent application to the '371 patent].

Ex. 2033 ¶ 5. BSC's unidentified "outside counsel" did not offer any testimony, nor did Patent Owner offer any additional supporting evidence as to the date of invention. We agree with Petitioner that Mr. Smith's testimony as to what he was told by outside counsel is hearsay and thus unreliable. Further, even if not hearsay, the testimony lacks persuasive corroborating support as to how the determination of the critical date was made, and thus is not sufficient evidence to establish the time the claimed invention was made. *See Arista Networks, Inc. v. Cisco Sys., Inc.*, IPR2016-00309, Paper 52, 42 (P.T.A.B. June 1, 2017) (holding that "Patent Owner has not met its burden of production" regarding §103(c), because "Patent Owner does not identify a 'time the claimed invention was made.'").

We also agree with Petitioner that Patent Owner failed to provide persuasive evidence to establish common ownership at the critical date. *See* Pet. Reply 19–20. This is so because Patent Owner failed to establish that any of the inventors named on the '371 patent assigned, or had an obligation to assign, their rights in the subject matter as of May 25, 2003. Patent Owner's allegations that the "named inventors . . . include individuals *affiliated* with MedVenture . . . and individuals *affiliated* with BSC," (Ex. 2033 ¶ 9) is insufficient without some persuasive evidence of assignment obligations of these "affiliated" individuals. Further, based on Petitioner's arguments, it is unclear to us whether BSC and not Scimed was meant to be the owner of patent rights. Pet. Reply 20–21. Patent Owner has therefore not rebutted Petitioner's initial showing that Adams qualifies as prior art in this proceeding.

2. Discussion of Claims 4, 5, and 13

Claims 4 and 5 depend from claim 3, which depends from claim 1. Petitioner contends that claims 4, 5, and 13 would have been obvious over Adams based on its anticipation challenge of Adams set forth above. *See, e.g.*, Pet. 32. Because Petitioner has not established by a preponderance of the evidence that Adams anticipates claim 1 for the reasons provided above, and Petitioner does not otherwise show that claim 1 would have been obvious over Adams, Petitioner has not established by a preponderance of the evidence that claims 4 and 5 would have been obvious over Adams.

Claim 13 depends from claim 11. Petitioner has not shown that Adams anticipates claim 11 for the reasons provided above, and because Petitioner relies on its anticipation analysis, Petitioner has not shown that the limitations of claim 11 would otherwise have been obvious over Adams. Accordingly, Petitioner has not established by a preponderance of the evidence that claim 13, which depends from claim 11, would have been obvious over Adams.

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

Petitioner contends that claims 1 and 3–5 are obvious over Adams. Pet. 38–40.

Under this ground, Petitioner contends 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.* In the aggregate, and as explained below, we find

Patent Owner's contentions more persuasive.

Petitioner responds that Dr. Nicosia testifies the proposed modification would not create an interference fit. Pet. Supp. Reply 18–21. Petitioner argues that a person of ordinary skill would have modified the shape of retainer 110 by "increasing the diameter of the proximal end of retainer 100 such that it physically contacts the walls of outer sleeve 122," while permitting sliding. *Id.* at 19. According to Petitioner, such a modification is a simple and obvious design choice. *Id.*

Based on the final record, Petitioner has not established persuasively a sufficient rationale to make the proposed modifications to Adams apart from hindsight reconstruction to reach the patented claims. Expanding the diameter of Adams's 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"). Once the distal tabs of retainer 110 have been deformed and released, "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 . . . can be removed." Ex. 1023, 5:59–63. In other words, the retainer 110 is supposed to freely slide out of tubular outer sleeve 112 (the alleged "sheath"), and Petitioner provides no explanation for why a person of ordinary skill in the art would be motivated to modify retainer 110 to make it touch or contact the sheath at its proximal end, which would arguably render the Adams device nonfunctional. *See* Prelim. Resp. 27–28.

Regardless, although Petitioner suggests that the retainer "may be modified," Petitioner has not provided a persuasive rationale on the record before us for making such a modification. Petitioner's rationale for modifying retainer 110 to physically contact the outer sleeve is that this would "help stabilize retainer 110 and allow for a smooth sliding action." Pet. 39; Ex. 1029 ¶ 79. 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 the alleged benefit for the modification.

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 Petitioner has not established by a preponderance of the evidence that claims 1 and 3–5 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 and claim 17 depends from claim 11. Petitioner relies on the anticipation or obviousness analysis of claims 1 and 11 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.

Moreover, because Sackier is not relied on in this ground to cure the deficiencies above noted for claim 11, (Pet. 44), we determine that Petitioner's obviousness challenge as to claim 17 is unpersuasive. Accordingly, we determine that the Petition does not establish a reasonable likelihood that Petitioner would prevail in showing that claims 10 and 17 would have been obvious over Adams and Sackier.

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

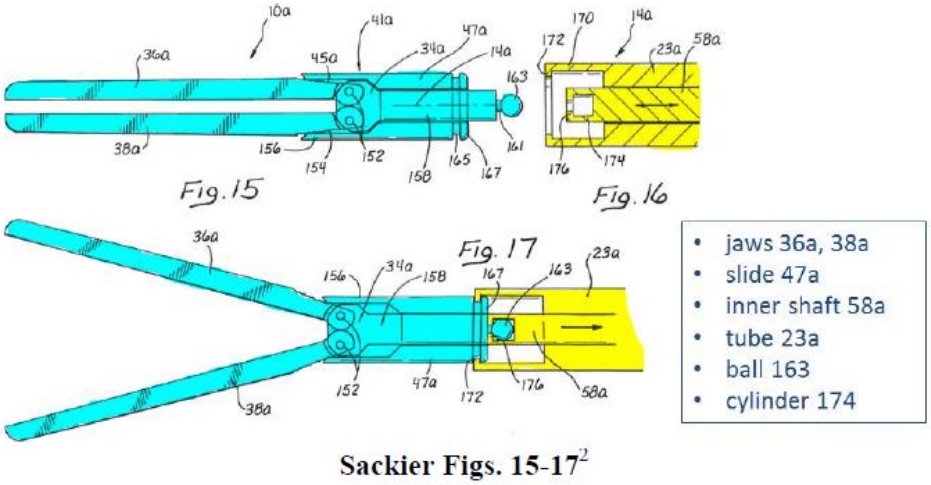
Petitioner challenges the patentability of claims 1, 3, and 10 of the '371 patent under 35 U.S.C. § 103 as obvious based on Sackier. Pet. 45–51. Patent Owner opposed Petitioner's contentions for the reasons explained below. *See* PO Resp. 29–37.

We have reviewed the parties' contentions and supporting evidence. Given the final record, we are not persuaded that Petitioner has demonstrated by a preponderance of the evidence that claims 1, 3, and 10 of the '371 patent would have been obvious based on Sackier. We begin our analysis with a brief summary of Sackier, and then address Petitioner's and Patent Owner's dispositive contentions in turn.

1. Overview of Sackier (Ex. 1008)

Sackier is directed to a laparoscopic surgical clamp which includes a clamp. Ex. 1008, Abstract. For purposes of the analysis before us,

Petitioner relies on Sackier's embodiment depicted in Figures 15–17. *See* Pet. 45–49, 52–54. Petitioner's annotated Figures 15–17[5] of Sackier are reproduced below.



Sackier Figs. 15-17[2]

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 58*a* can be moved relative to the tube 23*a* to engage the slide 47*a* and move it relative to . . . the jaws 36*a*, 38*a*. As noted, this axial movement of the slide 47*a* relative to the jaws 36*a* and 38*a* is accompanied by relative movement of the jaws 36*a*, 38*a* between the open and closed positions." *Id.* at 10:28–34.

Notably, and as discussed in more detail below, Sackier discloses several distinct embodiments and we determine that not every feature or capability in each distinct embodiment carries over to all other embodiments. *Compare* Figs. 15–17, *with* Figs. 11–14.

[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.

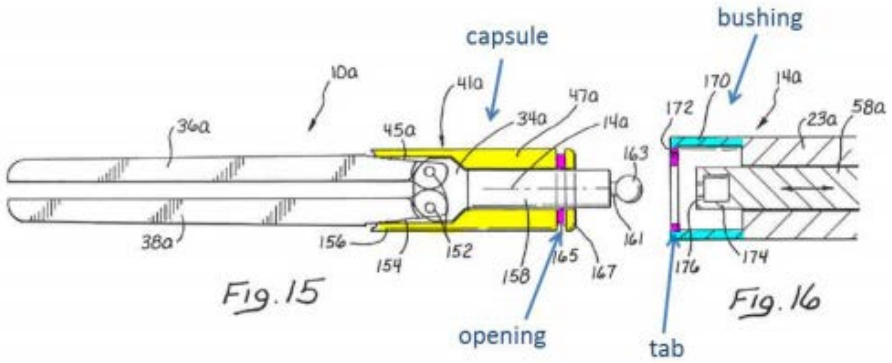
2. Discussion – Obviousness of Claims 1, 3, and 10 over Sackier

Our analysis below focuses primarily on two sets of limitations, "releasably coupled," and "bushing coupled to the sheath," as set forth under each respective header.

Releasably Coupled

Claims 1 requires a "releasably coupled" limitation. Claim 1 requires that the "bushing" must be "releasably coupled to the capsule," and the claimed "control member" must have a distal end "releasably coupled to the clip assembly." Ex 1027, 17:4–11. Claim 1 is addressed below, but the analysis for claim 1 is equally applicable to claim 11, as discussed later in this Decision. Independent Claim 11 similarly requires a "control element" with a distal end "removably connected to the clip assembly," and a "sheath" with a distal end "releasably coupled to the capsule." *Id.* at 18:10–19. Patent Owner alleges that Sackier's device does not disclose either of these "releasably coupled" limitations. PO Resp. 29, 44.

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.")). Petitioner relies on annotated Figures 15 and 16 of Sackier to show what it contends are annular snap fit connections that engage and disengage axially:



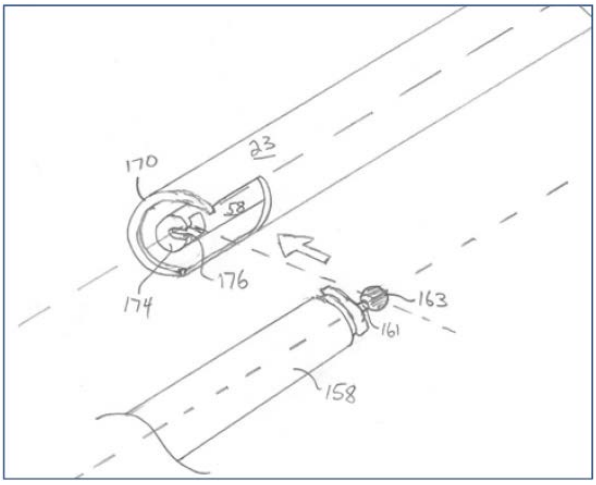
Sackier Figs. 15, 16

Petitioner's annotated Figures 15 and 16 of Sackier. Pet. 48.

Patent Owner contends that Sackier does not teach the releasably coupled limitations as claimed. PO Resp. 29–37. Patent Owner first notes that Sackier is silent as to the disengagement mechanism and a person of ordinary skill in the art would recognize that the clamp of Figures 15–17 was not designed to be released within the body. Further, Sackier does not disclose any such capability. *Id.* at 30–31.

Patent Owner relies on two portions of Sackier's disclosure. First, Patent Owner alleges that Sackier discloses an engagement mechanism comprising permanent, machined openings at the distal end of tube 23a and shaft 58a, i.e., lateral cut-outs of cylinders 170 and 174, as depicted below. Second, Patent Owner notes that because these are permanent, machined openings, Sackier impliedly discloses a mechanism for maintaining a secure fit between the clamp applier and the clamp, and that mechanism can only be a type of secure, snap fit. *Id.* at 32. Thus, because of the lateral cut-out type opening, a person of ordinary skill in the art would understand that Sackier does not disclose the "releasably coupled" limitations because a physician could not apply the requisite forces to disengage the snap fit while the clamp applier is within the body. *Id.*

Relying on Sackier's disclosure, including the statement that "[b]oth of the cylinders 170 and 174 can be configured to open laterally," (*id.* at 31), Patent Owner argues that "Sackier discloses permanent, machined openings at the distal end of tube 23a and shaft 58a," (*id.* at 32) as depicted in the figure below created by Dr. Vaitekunas:



The above Figure is a Perspective View of a Coupling.

Dr. Vaitekunas's figure shows permanent, machined lateral openings in cylinders 170 and 174. Ex. 2029 ¶¶ 120, 121. Patent Owner argues that Sackier does not disclose that flanges 172 and 176 are capable of opening laterally by temporarily increasing the diameters of the flanges. PO Resp. 33. Instead, Sackier only discloses that "cylinders 170 and 174 can be configured to open laterally in order to permit the associated flanges 172 and 176 to engage recesses 165 and 161." *Id.* (quoting Ex. 1008, at 10:25–27). According to Dr. Vaitekunas, Sackier's disclosure would be interpreted by a person of ordinary skill in the art as the outer tube 23a and inner shaft 58a terminate distally in cylinders which each have permanent, machined cutouts that open laterally to permit engagement. *See* Ex. 2029 ¶¶ 120–121; PO Resp. 33.

To support this theory, Patent Owner notes that annular flanges 172 and 176 would be designed to form a secure snap fit with recesses 165 and 161, respectively. PO Resp. 33 (citing Ex. 2029 ¶¶ 122–123). This is so because Sackier expressly teaches away from loose engagement mechanisms or those that could be inadvertently disengaged. *Id.* (citing Ex. 1008, 1:49–57, 6:22–29). Patent Owner contends that the connection would have to be more secure than Petitioner's proposed axial release because otherwise inadvertent engagement would occur when an axial tensile force is applied, such as when causing Sackier's jaws to close. *Id.* at 34.

Patent Owner contends that with its proposed lateral opening snap fit, Sackier's clamp found in figures 15–17 can be securely and reversibly coupled, but cannot be "releasably coupled" as required by the claims. *Id.* A physician could not apply the laterally opposing forces necessary to disengage the flanges and their respective recesses and release the clamp while the clamp is in the body. *Id.*

Patent Owner contends that Sackier fails to teach that the embodiment of Figures 15–17 can be released within the body, as taught by other embodiments of Sackier. Patent Owner contends that it would be impossible for the embodiment of Sackier Figures 15–17 to both release the clamp within the body and retrieve it post-operation. *Id.* The problem, as noticed by Patent Owner, is that shaft 58a and tube 23a move relative to each other and attach to the clamp at two distinct, fixed points. *Id.* Thus, a person of ordinary skill in the art would understand it to be nearly impossible for a practitioner to insert tube 23a through a trocar and manipulate shaft 58a and tube 23a laterally to obtain the precise spacing required to re-engage recess 165 and recess 161 post-operation. *Id.* at 34–35. We find this contention to

be persuasive based on Dr. Vaitekunas's supporting testimony. *See* Ex. 2029 ¶ 127.

Patent Owner also contends other embodiments of Sackier that allow release within the body, do not establish that the engagement mechanism used in the Sackier embodiment illustrated by figures 15–17 is "releasably coupled" as claimed. PO Resp. 35. Patent Owner notes that the embodiment of figures 11–14 may be useful in the method illustrated in figures 15–17, but just because clamp applier 12 can be operated to release hook 110 in the figure 11 embodiment, does not equate to it must be releasable in each embodiment. *Id.*

Patent Owner notes that although one embodiment of figures 11–14 discloses hook 110 that engages annulus 54 of the clamp, Sackier also states: "It will be apparent that the clamp 10 can be otherwise engaged by the shaft 58 of the applier 12 *in a locking but operative* position. In general, the screw 47 needs to be positively engaged by the shaft 58 *so that the clamp 10 cannot be accidentally dropped into the abdominal cavity*." *Id.* at 36 (quoting Ex. 1008, 6:22–29 (emphasis added). Although Patent Owner recognizes that certain embodiments of figures 11–14 may allow for a releasable connection, Sackier also expressly includes clamps that are "otherwise engaged by the shaft 58" to be "in a locking but operative position." *Id.*

Thus, Sackier's description of the embodiment illustrated by Figures 1–10 and the disclosure that the embodiments of Figures 15–17 "are also useful in the method illustrated in FIGS. 11-14" do not disclose that the clamp of Figures 15–17 is necessarily releasably coupled to inner shaft 58a and outer tube 23a. *Id.*; *see also id.* at 37 ("it should be noted that the only

claims in Sackier that require a releasable engagement with the clamp also require a rotatable shaft" and "the alternative embodiment illustrated in Figures 15-17 does not disclose a rotatable shaft").

Petitioner responds that "Sackier does not disclose *lateral openings* (noun form of 'opening'), but instead cylinders that '*open laterally*' (verb form of 'open'). Pet. Reply 6–7. Petitioner argues that Sackier discloses that cylinders 170, 174 (and flanges 172, 176) open, or expand laterally outward to permit axial engagement between the clamp and clamp applier. *Id.* at 7. Petitioner relies on Dr. Nicosia's testimony that hypothesizes that Sackier is referring to annular snap connections that engage and disengage axially – not laterally. *Id.* (citing Ex.1046 ¶¶ 7–13). Thus, according to Petitioner, a person of ordinary skill in the art would have appreciated that Sackier's clamp and clamp applier would be "snapped" together and "popped" apart via compressive and tensile forces (e.g., by pushing/pulling inner shaft 58a and tube 23a to engage/disengage Sackier's clamp). *Id.* at 9.

Petitioner also argues that because the method in figures 11–14 requires clamps that detach within the body, the embodiment of figures 15–17 must also permit detachment within the body. *Id.* at 9–10. Further, Petitioner argues that a person of ordinary skill in the art would recognize that if the clamps could not detach from their clamp appliers, the physician would need to use four separate clamp appliers and trocars to place the clamps, rather than the single clamp applier 12 and trocar 25 illustrated by Sackier. *Id.* at 11.

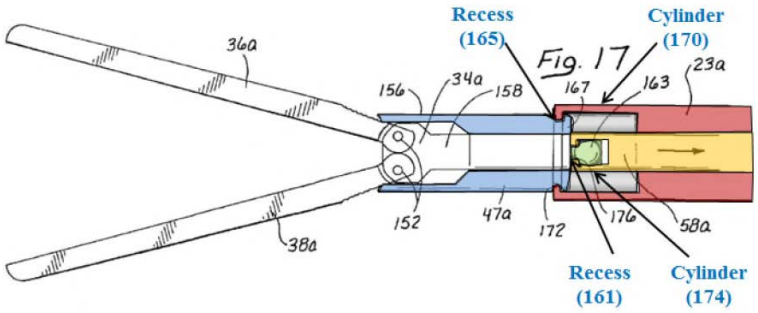
Both Petitioner and Patent Owner present theories as to how Sackier's figure 15–17 embodiment[6] may work, but Sackier itself is largely silent as to how it *would* actually work. The theories as to how Sackier may function are divergent – Petitioner's axial snap fit theory and Patent Owner's lateral side opening theory – but they are mutually exclusive. Sackier lacks conclusive support for either theory. Below we weigh these competing expert theories that attempt to fill gaps in Sackier's disclosure. In the end, our final decision is strongly influenced by who bears the ultimate burden of persuasion and not whether either party has persuasively established how Sackier would function.

The key description in Sackier relied on by both parties states: "Both of the cylinders 170 and 174 can be configured to open laterally in order to permit the associated flanges 172 and 176 to engage the recesses 165 and 161." Ex. 1008, 10:24–26. This statement raises the issue of what does it mean for the cylinders 170 and 174 to "open laterally" so that the flanges engage the recesses. This is not explained or depicted in Sackier and the parties submit two divergent theories as to how this is possible.

Petitioner's theory of an axial snap fit connection of ball 163 into the recess of cylinder 174 is theoretically possible. This theory, however, is not supported adequately by the evidence before us. Sackier makes clear that "flange 176 has an inside diameter greater than the recess 161, but less than the diameter of the ball 163." Ex. 1008, 10:22–24. For Petitioner's theory

[6] Significant errors exist in the figure 15–17 embodiment of Sackier. First, the figures (15–17) were published with no reference numbers – the reference numbers have been added to annotated figures. Next, the use of cross-hatching is inconsistent across the figures, which brings to question the accuracy of the figures themselves.

to work, ball 163 would have to be axially removable from cylinder recess 174 while in use despite the fact that flange 176 has a smaller diameter. Ex. 2029 ¶ 68. Such a separation, if even possible during use, would result in extreme bending or flexing of flange 176.



Sackier Annotated Figure 17

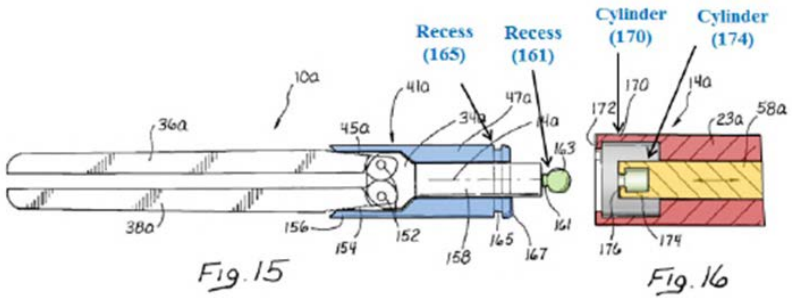
Patent Owner's annotated figure 17 of Sackier. PO Resp. 23–24. Indeed, we find somewhat persuasive Dr. Vaitekunas's testimony that axial separation would not be possible because "the diameters of the respective portions of cylinders 170 and 174 interact such that, once coupled, proximal movement would not separate slide 47a from tube 23a or ball 163 from shaft 158." Ex. 2029 ¶ 69.

Patent Owner's expert also raises a valid concern that if tube 23a inner shaft 58a and flange 176 were made of flexible material necessary to operate as Petitioner contends, the thin sections of the flange would be so soft and flexible that they could not support the clamping of the jaws in the Sackier device. PO Supp. Resp. 22 (quoting Ex. 2102 ¶ 101; *see also* Ex. 2039, 491:4–496:5). Further, Patent Owner argues persuasively that applying proximal tensile force to outer tube 23a would move slide 47a proximally before any potential disengagement, thus, proximal tensile forces could not be applied sequentially to inner shaft 58a and tube 23a to separate the second

connection between flange 172 and flange 167. *Id.* at 24 (citing Ex. 2102, ¶107; Ex. 2039, 593:11–594:3, 534:11–17; Ex. 1008, 9:43–49, 10:30–33).

Considering this testimony and the evidence of record as discussed below, we are not persuaded by Petitioner that proximal movement would separate slide 47a from tube 23a or ball 163 from recess 174, such that the structures would be "releasably coupled" as claimed.

Another valid reason we are not convinced that the clamp (within the embodiment of figures 15–17) is releasably coupled is because it would seem nearly impossible to retrieve the clamp once left in the body. *See* PO Resp. 34–35. As depicted below, shaft 58a and tube 23a move relative to each other and attach to the clamp at two distinct, fixed points (recess 165, and recess 161).

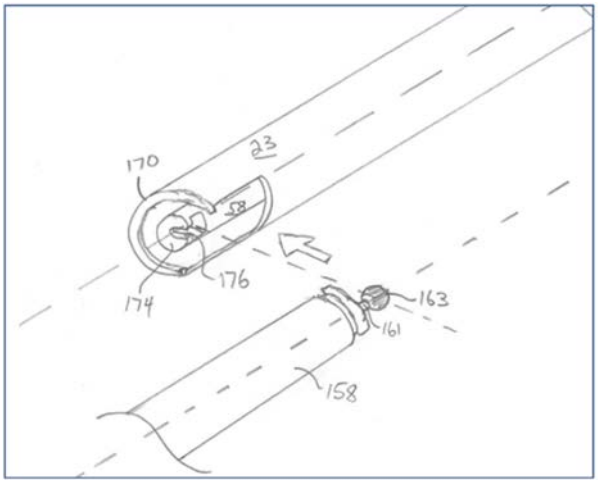


Sackier Annotated Figures 15, 16

Patent Owner's annotated figures 15 and 16 of Sackier. PO Resp. 22. Petitioner has not persuasively explained how a practitioner could reliably insert tube 23a through a trocar and manipulate shaft 58a and tube 23a laterally to obtain the precise spacing required to re-engage recess 165 and recess 161 post-operation to retrieve the clamp. This becomes even more difficult when tube 23a must be a "flexible sheath" as required in claim 1. *See* Ex. 2029 ¶ 132.

Patent Owner counters Petitioner's snap fit theory with the testimony of Dr. Vaitekunas who suggests that "[a]pplying an axially opposing force to the distal end of the clamp at this point is likely to damage the bowel and present an unacceptably high risk of injury to the patient," and that "too much force can lead to tissue damage." Ex. 2102 ¶¶ 105–106, ("

Based on the combined evidence above, Patent Owner's theory of a lateral side opening is just as likely as Petitioner's proposed interpretation of Sackier.



Dr. Vaitekunas's figure shows permanent, machined lateral openings in cylinders 170 and 174. Ex. 2029 ¶¶ 120, 121.

As Dr. Vaitekunas testifies "with the permanent, machined openings in cylinders 170, 174, the only way to securely engage the clamp is to have a type of snap fit that securely engages the recesses 161 and 165." Ex. 2029 ¶ 121. We find persuasive Dr. Vaitekunas's testimony that Sackier emphasizes the need for a secure and reliable engagement between the clamp applier and the clamp, thus, it is reasonable to conclude that the engagement between flanges 172 and 176 would have to be secure and not loose. *Id.* Thus, we find Dr. Vaitekunas's proposed theory of permanent,

machined lateral openings in cylinders 170 and 174, just as likely as Petitioner's proposed theory.

Notably, neither party has produced extrinsic evidence showing how their respective theory of operation could be implemented in release clips (as claimed) or surgical clamps (as found in Sackier).[7] Seemingly, if either Petitioner's snap fit or Patent Owner's lateral side opening theories were plausible, the connections would be employed in similar medical devices. As discussed above in the Background Section, one such example adopting Patent Owner's theory is found in the '371 patent.

The embodiment depicted in figures 27–29 of the '371 patent appears to support Patent Owner's machined lateral opening theory. Specifically, these figures provide additional details of yoke 204 in certain embodiments showing a side lateral opening to receive the ball. In the embodiment of figures 27–29, "[w]hen the control wire 118 is seated in the yoke 204, it is desirable to ensure that it cannot inadvertently be removed from the control wire slot 600." Ex. 1027, 13:64–67. As depicted below, yoke 204 has a lateral cut into wire cavity 604.

[7] Petitioner provides several examples of mechanical snap fit connections being used in every-day applications, but none being used in similar medical devices. *See* Pet. Reply 7–8; Ex. 1046 ¶¶ 10–11; *see also* Tr. 72:3–73:3 (counsel for Patent Owner explaining Dr. Vaitekunas also does not provide examples of how a lateral side opening would work in medical devices).

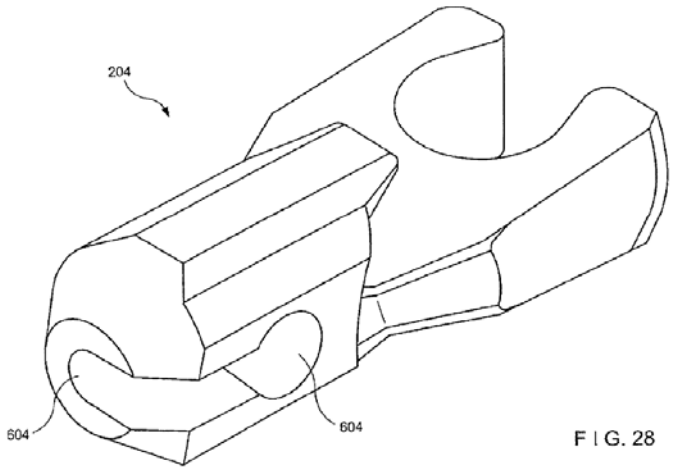


Figure 28 of the '371 patent depicting an alternative embodiment with a lateral cut out wire cavity 604.

As described above in the Background Section, wire cavity 604 is large enough to allow the control wire 118 to pass, but not large enough to allow ball 140 to pass therethrough. *Id.* at 14:1–10. Although this embodiment is distinct from Sackier's embodiment at issue, for example control wire 118 may have a frangible link with ball 140, it does tend to support Patent Owner's theory as to Sackier's lateral side opening.

We have considered Petitioner's argument that Patent Owner changed its position from the Preliminary Response. Pet. Reply 6–7 ("BSSI stated in its Preliminary Response that 'Sackier teaches that the clamp applier . . . is *opened laterally (i.e., widened),*' thereby acknowledging that 'open laterally' means *expand and widen* (verb form of 'open')."). *See also* Tr. 44:12–45:9. In the same manner we generally do not allow Patent Owner to carry over arguments from the Preliminary Response,[8] we also will not bind Patent Owner to attorney arguments made in its Preliminary Response. In this

[8] This proceeding allowed for limited incorporation due to the addition of numerous grounds after *SAS* that were originally denied institution.

instance, Patent Owner obtained the guidance of Dr. Vaitekunas as to the meaning of open laterally. *See* Ex. 2029 ¶¶ 119, 120, 121. Regardless, our decision is based on the final trial record, and not preliminary positions.

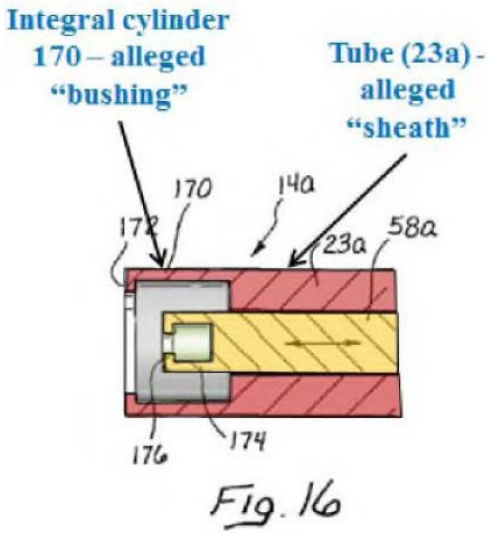
For the reasons set forth above, and based on the final trial record, Petitioner has not established that Sackier teaches the "releasably coupled" limitation.

Bushing Coupled to the Sheath

Another reason we do not believe that claim 1 is obvious over Sackier is because we agree with Patent Owner that Sackier does not teach "a bushing" with "a proximal end coupled to the sheath." Ex. 1001, 17:4–5.

The issue before us is simple. Petitioner contends that a bushing coupled to the sheath can "include[] a one-piece bushing/sheath." Pet. Reply 1–2. We disagree. In the context of the claims before us, we do not believe "a bushing" with "a proximal end coupled to the sheath" could be reasonably taught by Sackier's single unitary structure. Petitioner argues that the claimed "bushing" is met by cylinder 170 and that the "sheath" is tube 23a. Pet. 48. In the context of the '371 patent's claim requirements, we do not find persuasive Petitioner's contention that two ends of Sackier's unitary structure are "coupled to" each other.

Patent Owner contends that a person of ordinary skill in the art would know that cylinder 170 cannot be the claimed "bushing" because it is not "coupled to the sheath." PO Resp. 28 (citing Ex. 2029 ¶ 116). Sackier's specification states that, "[t]he tube 23*a* terminates distally in a cylinder 170." Ex. 1008, 10:14–15. Patent Owner relies on Sackier's figure 16, which shows that cylinder 170 and tube 23a are integral with each other as depicted below. PO Resp. 28–29 (citing Ex. 2029 ¶ 116).



Patent Owner's annotated figure 16 depicting a bushing and a sheath as a single unitary structure. PO Resp. 29.

Based on Sackier's disclosure, Patent Owner contends that a person of ordinary skill in the art would understand that a unitary structure cannot be "linked together, connected, or joined" to itself. PO Resp. 29 (citing Ex. 2029 ¶ 116).

Petitioner contends that "coupled" may include a single integral piece because the Specification uses the term "detachably coupled" when referring to distinct parts of a unitary structure as depicted in figure 5 of the '371 patent. Pet. Reply 2. As to this argument, we do not find it persuasive because "reversibly coupled" is meant to achieve an end result with two distinct structures after detachment via fracturing of the unitary structure. After detachment, there would be two structures. Further, and as noted above, the control member (ball for example) need not be a single integral piece in each embodiment. *See* Tr. 68:15–69:10.

We find Patent Owner's contentions and evidence more persuasive on the final record. Claim 1 of the '371 patent requires not just a sheath and

bushing, but also that the proximal end of the bushing is "coupled to the sheath" and the distal end is "releasably coupled to the capsule." Sackier discloses a single inseparable unitary structure, outer tube 23(a), with an integral cylinder 170. Sackier does not disclose or teach a bushing coupled to outer tube 23(a).

During cross-examination, Petitioner's expert also testifies that it does not make sense to say that the ends of a single unitary structure are coupled. *See* Ex. 2011, 148:2–7 ("Q: If you have a unitary structure, you don't say that that structure—the proximal end of the structure is coupled to the distal end of the structure, do you? A: I probably wouldn't say that, that's right."). Based on the final trial record, Petitioner has not established that Sackier teaches a "bushing" element "coupled to the sheath," as required by claim 1.

As noted above, Patent Owner presents evidence related to the objective indicia of nonobviousness. Based on our analysis above, the evidence of secondary considerations does not help Patent Owner. Regardless, because Petitioner fails to establish that Sackier teaches the "releasably coupled" and "a bushing" with "a proximal end coupled to the sheath" limitations of claim 1, the weight of the secondary considerations does not impact our analysis of claim 1.

Based on the final record before us, Petitioner has not shown persuasively that Sackier teaches the "releasably coupled" and "a bushing" with "a proximal end coupled to the sheath" limitations of claim 1. Accordingly, and because each of claims 3 and 10 depend from claim 1, Petitioner has not established by a preponderance of the evidence that claims 1, 3, and 10 are unpatentable as obvious over Sackier.

I. Anticipation of Claims 11, 15, and 17 based on 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.

Independent claim 11 requires, in pertinent part, a "control element including a 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 has not established persuasively that Sackier discloses these limitations of claim 11.

Similar to the analysis above for claim 1, Petitioner contends that the "removably connected" limitations are met by "inner shaft 58a including at its distal end a cylinder174 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.*

Again, these arguments fail for the same reasons above – Petitioner does not establish persuasively that Sackier discloses the "releasably coupled" limitations. 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").

Likewise, Petitioner has failed to establish persuasively that Sackier discloses that "the control element detaches from the connector element via a frangible link." On this matter, we find the evidence evenly divided. Petitioner relies on the embodiment of figures 15–17, as well as the

statement in Sackier that certain features of other embodiments may be used. Sackier does not disclose that flange 176 breaks or that ball 163 disengages from cylinder 174 when a tensile load is applied.

Patent Owner's theory that Sackier's clamp applier and clamp engage via a lateral opening is just as persuasive given the goal of Sackier of preventing undesirable separation of the clamp from the applier. *See* Ex. 1008, 1:49–56 ("cannot tolerate this possibility of undesired separation of the clamp from the applier"); Ex. 2029 ¶¶ 140, 141. While it appears Sackier's link may be capable of being frangible, Patent Owner has put forth sufficient evidence to make it equally plausible that the link is either not frangible, or not breakable by a tensile force, once attached in Sackier, whether or not in the body. *See* Ex. 2029 ¶¶ 140, 141.

Petitioner has failed to establish by a preponderance of the evidence on the final 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.

Based on the final record before us, Petitioner has not shown persuasively that Sackier discloses all the limitations of claim 11. Accordingly, and because each of claims 15 and 17 depend from claim 11, Petitioner has not established by a preponderance of the evidence that claims 11, 15, and 17 are anticipated by Sackier.

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. Claims 4, 5, and 7 depend indirectly from claim 1 and

claims 13 and 14 depend from claim 11. For the reasons set forth above as to why Sackier does not teach, or disclose, the limitations of claims 1 and 11, we likewise find the combination of Sackier and Adams deficient. This is so because Petitioner does not rely on Adams to cure the deficiencies noted above with respect to Sackier.

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. Adams is relied on to show the reverse orientation. Adams is not, however, relied on to remedy the deficiencies for claims 1 and 11 that are discussed above.

Likewise, claim 7 depends indirectly from claim 1 and adds the limitation: "wherein the distal end of the control member comprises a ball received in a socket in the yoke." Petitioner relies on its analysis of claims 4 and 5. Pet. 59. Petitioner does not, however, otherwise explain how the combination of Sackier and Adams would cure the deficiencies noted above in Petitioner's analysis of claim 1 as obvious over Sackier alone.

We have considered Petitioner's contentions with respect to this ground, but find them unpersuasive on the record before us for the reasons set forth above. Based on the final record before us, Petitioner has not established by a preponderance of the evidence that claims 4, 5, 7, 13, and 14 would have been obvious over Sackier and Adams.

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

Petitioner challenges the patentability of claims 1, 3–5, 10, and 15 of the '371 patent under 35 U.S.C. § 103 as obvious based on Sackier and Adams. Pet. 61–68. Patent Owner opposed Petitioner's contentions for the reasons discussed below. PO Supp. Resp. 12, 31–33.

In our Institution Decision, we originally denied institution of this ground because:

> 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.

Dec. 34. Patent Owner maintains that this position remains correct. PO Supp. Resp. 12, 31–33. Petitioner challenges our initial determination, which is not binding. Pet. Supp. Reply 27, 33–39.

Based on the final trial record before us, we determine Petitioner has not established by a preponderance of the evidence that claims 1, 3–5, 10, and 15 are obvious over Sackier and Adams. Our decision rests on two distinct reasons, each of which lead to the same determination. First, based

upon our analysis above of the limitations of claims 1 and 11,[9] Petitioner has not established that each limitation of claims 1 and 11 is taught by the combination of Sackier and Adams. Second, Petitioner has not persuasively shown a rational basis to combine two distinct, and unrelated, designs– Adams J-hook embodiment with Sackier's ball-and-socket design. We address each of these reasons in turn.

First, Petitioner has not persuasively shown that either Sackier or Adams teaches a "bushing" element "coupled to the sheath," as required by claims 1 and 15. As noted above, for claim 1, Sackier does not disclose the claimed "bushing" which is "coupled to the sheath." As we determined above, a person of ordinary skill in the art would understand that Sackier's unitary structure cannot be "linked together, connected, or joined" to itself. *See* PO Supp. Resp. 15–16 (citing Ex. 2102 ¶ 91; Ex. 2011, 148:2–7). Likewise, the requirement of claim 15 that "the sheath is coupled to the capsule via a bushing" also relies on Sackier and is likewise deficient for the reasons set forth above. Pet. 68. Accordingly, Sackier lacks a "bushing" element "coupled to the sheath," as required by both claims 1 and 15. Petitioner does not persuasively rely on Adams to cure this deficiency in this ground. *See* Pet. 63 (relying on Sackier's cylinder 170 as the bushing coupled to tube 23a). To the extent that Petitioner relies on Adams's retainer 110 as the claimed "bushing," this bushing is not "coupled to the sheath" at its proximal end. *See* PO Suppl. Resp. 30, Ex. 2102 ¶ 112. As we previously determined, Adams does not disclose a "bushing," the proximal end of which is "coupled to the sheath." For these reasons alone, we find

[9] Claim 11 was not challenged in this ground, but claim 15 was challenged and it depends from claim 11.

Petitioner has not persuasively shown that claims 1, 3–5, 10, and 15 would have been obvious over Sackier and Adams.

Further, Petitioner has not established persuasively how Sackier teaches the "releasably coupled" limitations of claim 1 in this combination. Our analysis of this issue is set forth above. Likewise, as also set forth above, Petitioner has not established persuasively that Sackier discloses the "frangible link" limitation of claim 11, from which claim 15 depends. *See* PO Resp. 37–38 ("A POSA would understand that Sackier does not disclose that any link between cylinder 174 and ball 163 unlinks via a tensile load.") (citing Ex. 2102 ¶¶ 122–123).

Second, based on the final record, Petitioner also has not provided a persuasive rationale for combining Sackier and Adams.

Petitioner contends that it would have been obvious to a person of ordinary skill in the art to "substitute flange 172 and recess 165 connection described in Sackier with retainer tabs 118, 119 and retainer holes 116 connection as disclosed in Adams as an alternative way of releasably coupling the 'bushing' to the 'capsule.'" Pet. 65; Ex. 1029 ¶ 145. Petitioner basis its rationale to combine these features on simple substation of known elements, application of a known technique, and finally obvious to try. Pet. 65–66.

Patent Owner contends Petitioner has not provided sufficient motivation to combine two distinct, and unrelated, designs – Adams J-hook embodiment with Sackier's ball-and-socket design. PO Supp. Resp. 33–34 (citing Ex. 2102 ¶¶ 116–18). Patent Owner alleges that "Petitioners oversimplify the proposed combination and provide no explanation for how the proposed combination would work." *Id.* at 33. Patent Owner also

contends that Sackier actually teaches away from the claimed "releasably coupled" connection, because in the context of laparoscopic surgery of which Sackier is a part, prior art clamps were deficient because they allowed for the "separation of the clamp from the applier." *Id.* at 34 (quoting Ex. 1008, 1:49–57).

Petitioner, in reply, contends that the modifications are not a significant design change. Pet. Supp. Reply. 27. To prove this point, Petitioner presents new testimony from Dr. Nicsosia. *Compare* Ex.1029 ¶¶ 142–49, *with* Ex. 1108 ¶ 32. Dr. Nicosia's reply testimony as to the design modifications appears guided by hindsight reconstruction to reach the claimed invention.

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's retainer tabs 118, 119, and retainer holes 116. We find Patent Owner's contentions that the proposed substitution would be a substantial structural change to Sackier more persuasive as to this issue. *See* Ex. 2102 ¶¶ 116–18. For example, as to this issue we find Dr. Vaitekunas's testimony that use of Adams's deformable retainer tabs 118, 119 in Sackier would hinder a physician from retrieving Sackier's clamp. *Id.* ¶ 118. He explains that: "The proposed substitution would be a substantial structural change to Sackier, requiring modifications to several aspects of Sackier's design . . . . If [Adams] tabs were substituted into Sackier's clamp applier, the physician would be unable to retrieve Sackier's clamp from the body." *Id.*

Petitioner has shown through Dr. Nicosia's testimony (Ex. 1108 ¶ 32) that the design modification is theoretically possible, but we are not convinced that Petitioner has provided a sufficient rationale as to why a

person of ordinary skill in the art would have made such changes. 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* Pet. 65–66. Thus, Petitioner also has not established a persuasive rationale for making the significant design changes to Sackier.

Based on the final record before us, Petitioner has not established by a preponderance of the evidence that any of claims 1, 3–5, 10, or 15 would have been obvious over Sackier and Adams.

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.* ¶ 31.

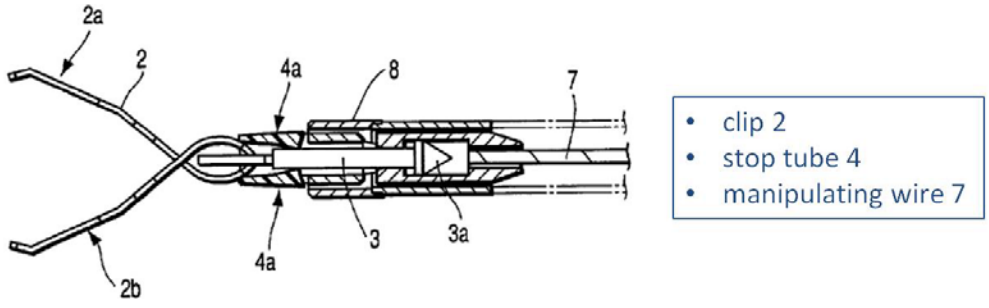


FIG. 3B

Petitioner's annotated Figure 3B of Kimura depicts the clip unit connected to the clip manipulating device. *Id.* ¶ 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.* ¶ 132. Clip 2 is controlled by manipulating wire 7. *Id.* ¶ 152.

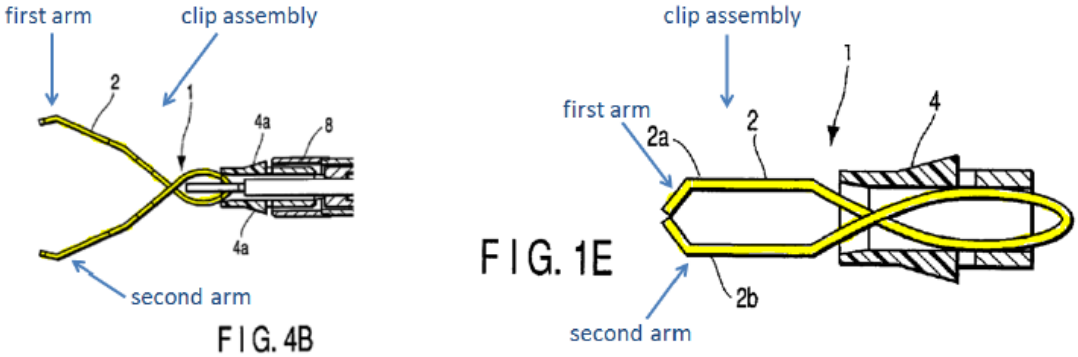
Similar to Adams, Kimura was considered and overcome during prosecution of the application leading to the '371 patent. *See* Pet. 15, 69–73.

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 relies on Figure 1E and paragraph 152 of Kimura as teaching the insertion configuration. *See* Pet. 74. 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).

In opposition, 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 [Petitioner] cites for the "insertion configuration," actually shows the post-insertion, tissue-pinching configuration.

Id. at 50.

In reply, Petitioner argues "that 'insertion configuration' refers to a configuration where the clip assembly *is inserted* (*i.e.*, closed) within the capsule, as depicted above in Figure 1E." Pet. Supp. Reply 41 (citing Ex. 1108 ¶ 42, Ex. 1029 ¶ 72). Petitioner contends that based on the language of claims 1 and 11, the "'insertion' and 'expanded' are opposing configurations." *Id.* at 42 ("In other words, 'insertion' is the opposite of 'expanded' – *i.e., closed within the capsule*."). *See also* Sep. Tr. 34:18–36:8

> Patent Owner responds as follows.
>
> Petitioners ignore that claim 11 requires "a clip assembly housed within the capsule *for movement* between an insertion configuration . . . and an expanded configuration." Kimura does not disclose, nor do Petitioners contend, that the post-insertion, tissue-pinching configuration of Figure 1E can be moved to an expanded configuration. Thus, Kimura cannot anticipate the claims, even under Petitioners' new (incorrect) proposed construction of "insertion configuration."

PO Surreply 14. We find this contention persuasive.

Based on the final trial record before us, we are not persuaded that Petitioner has proven by a preponderance of the evidence 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. We agree with Patent Owner that Figure 1E 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 2*a* and 2*b* of the clip 2 are pulled into the stop tube 4, and the arm sections 2*a* and 2*b* of the clip 2 are closed as shown in FIG. 1E." Ex. 1007 ¶ 152.

Kimura's clip 2 is not "housed within" 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." Despite Petitioner's contentions to the contrary (Sep. Tr. 39:1–16) we believe the surrounding context of the claim language makes clear there is a directionality component to the language "for movement between." Thus, Figure 1E of Kimura does not depict an "insertion configuration" such that the "clip

assembly housed within the capsule" is movable "between an insertion configuration . . . and an expanded configuration" as required by claim 11. We have considered Petitioner's additional evidence submitted in reply, but find it unpersuasive.

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 prove by a preponderance of the evidence that claim 11 is unpatentable 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 claims 12 and 13. Pet. 78–80. Claims 12 and 13 depend from claim 11. For the reasons set forth above for claim 11, Petitioner has also failed to prove that Kimura anticipates claims 12 and 13.

M. Obviousness of Claim 15 over Kimura

Claim 15 depends from claim 11. Petitioner relies on its anticipation analysis of claim 11 for its contention that claim 15 would have been obvious over Kimura. Pet. 92. For the reasons set forth above for the anticipation analysis of claim 11 based on Kimura, we determine that the Petition also does not establish that claim 15 would have been obvious over Kimura. Specifically, Petitioner does not propose an additional modification to Kimura for claim 15 that would address the shortcomings for claim 11. *See* Pet. 92. We also find Petitioner fails to provide any persuasive

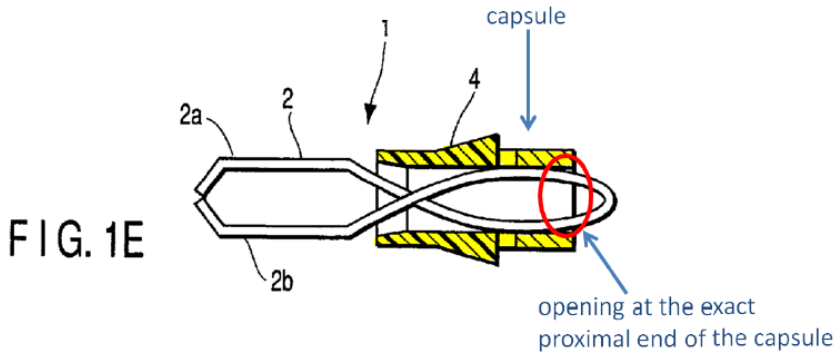
motivation or rationale for modifying Kimura for purposes of its obviousness contentions with respect to claim 15. *See id.*

N. Obviousness of Claims 1 and 3–5 over Kimura

Petitioner contends that claims 1 and 3–5 would have been obvious based on Kimura. Pet. 81–92. For the reasons that follow, Petitioner has established that claims 1 and 3–5 would have been unpatentable as obvious over Kimura.

Claim 1 first requires "[a]n apparatus for applying clips to tissue," and Petitioner identifies Kimura as teaching this limitation, specifically, Kimura's disclosure of "a physiological tissue clip apparatus . . . for . . . clipping a physiological tissue." Pet. 73 (quoting Ex. 1007 ¶ 2). Petitioner sufficiently shows on the final record that Kimura's disclosure of coil sheath 9 extending from a proximal end which extends into a living body in an operative configuration to a target portion of tissue to be clipped, teaches "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," requirement of claim 1. *Id.* at 81.

Claim 1 next requires "a capsule extending from a proximal to a distal end and having an opening formed in a proximal end thereof." Petitioner relies persuasively on Kimura's stop tube 4 ("capsule") extending from a proximal to a distal end that is hollow with an opening at its proximal end, as depicted below in annotated figure 1E. Pet. 82.



Kimura Fig. 1E

Petitioner's annotated figure 1E of Kimura depicts the capsule as stop tube 4 with an opening at the proximal end. Pet. 82.

Claim 1 next requires "a clip assembly provided in the capsule and configured to be operably movable between a closed configuration . . . and an expanded configuration . . . ." Petitioner contends that Kimura teaches these configurations and corresponding arm movement, and Patent Owner does not challenge this assertion. *See id.*; *id.* at 74. Petitioner relies on Kimura's manipulating wire 7 ("control member") with a distal end releasably coupled to clip 2 ("clip assembly"), which causes clip 2 to move "between the insertion and expanded configurations," as teaching the "control member a distal end of which is releasably coupled to the clip assembly" limitations of claim 1. *Id.* at 87. Patent Owner has not challenged Petitioner's contentions with respect to any of the above limitations for claim 1. Based on the final record, we find Petitioner's analysis persuasive as to the limitations above.

The parties' dispute is focused on claim 1's requirement of "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. As further explained by Dr. Nicosia, the only proposed change is to reverse the connection between Kimura's bushing and capsule. Ex. 1029 ¶ 184. Put more simply, Kimura discloses a capsule engaging within an opening in a bushing, whereas modified Kimura discloses the reverse – the bushing engaging within an opening in the capsule. Pet. Supp. Reply 44. Notably, Dr. Nicosia testified that the reversed connection was only one of two possible options and that the modification would have no impact on Kimura's function – the same function would be performed without any unexpected results. *Id.* (quoting Ex. 1029 ¶¶ 184–87). Thus, according to Petitioner, the proposed modification would have been obvious because it simply arranges old

elements with each performing the same function it had been known to perform while yielding expected results. *Id.*

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.* Notably, Patent Owner does not offer any expert testimony to rebut Dr. Nicosia's opinions for this ground. Sep. Tr. 40:24–25.

Patent Owner also alleges that Kimura teaches away from the proposed modification because the "unmodified engagement between coil pipe 8 and stop tube 4 is critical to its operation as intended," whereas, "Kimura teaches that the protrusions 4a of the stop tube 4 are specifically designed "'for the purpose of engagement with coil pipe 8.'" *Id.* at 52. According to Patent Owner, "the protrusions 4a abut the distal end of coil pipe 8 so as to allow proximal movement of the manipulating wire 7 to pull the clip into the stop tube 4." *Id.* If this arrangement were reversed, "this mechanism would not work as intended —the protrusions 4a would keep sliding proximally and the clip would not be drawn into the stop tube and could not pinch tissue." *Id.* At the institution phase, we found this argument somewhat persuasive. Based on a review of the final trial record before us,

we do not believe the perceived problems with the tab and protrusions 4a would exist in Petitioner's proposed modified design.

As Petitioner explains, Dr. Nicosia's proposed modification of reversing the capsule and bushing would not destroy the ability of the clip to pinch tissue. Pet. Surreply 46. This is so because Kimura uses protrusions 4a to create a "stop" between capsule (4) and bushing (8) to prevent the capsule from being pulled into the bushing. *Id.* at 46–47 (citing Ex. 1007, Figs. 3B, 4B). We find persuasive Petitioner's contention that a person of ordinary skill in the art "would have recognized that this 'stop' function would be retained in the proposed modification, and that this functionality would be retained simply by *reversing* the location of the stop," along with the reversing of the bushing and capsule. *Id.* at 47.

A person of ordinary skill in the art would understand that the modification proposed in the Petition would logically require placement of stop 4a "either on the inner surface of the modified capsule (4) or the outer surface of the modified bushing (8), to prevent the capsule from being pulled into the bushing." *Id.* We agree with Petitioner that "[t]his would have been an obvious, common sense modification, involving no more than routine skill in the art." *Id.* Patent Owner has not offered any expert testimony on the final record before us to contradict Dr. Nicosia's factual assertions as to the proposed reversal modification.

In this analysis we find it helpful to compare the '371 patent bushing/capsule engagement of one embodiment described in the Specification with the Kimura bushing/capsule bushing/capsule engagement.

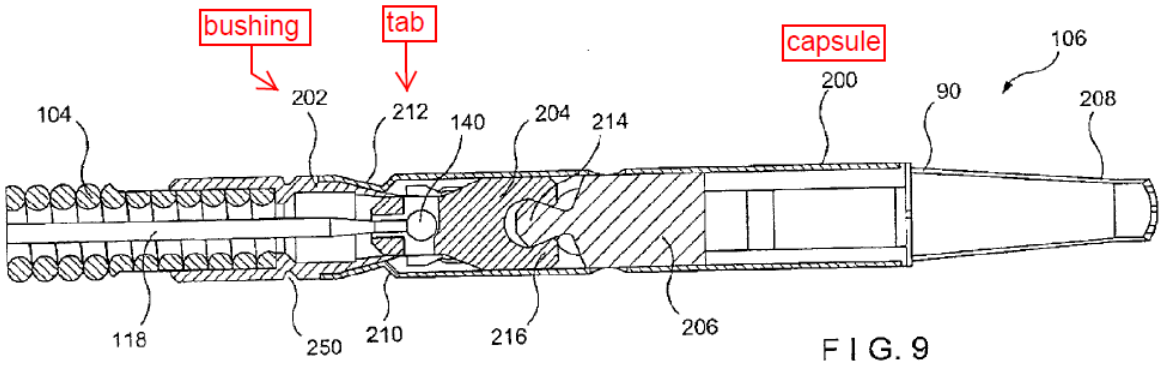


FIG. 9

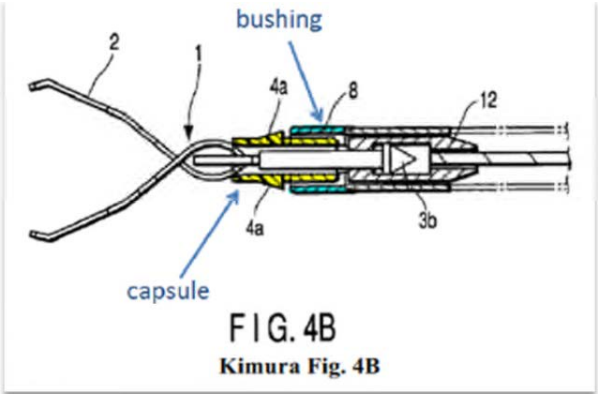


FIG. 4B
Kimura Fig. 4B

Above, figure 9 of the '371 with simple annotations added by the Board, and below, Kimura's annotated figure 4B. Prelim. Resp. 51.

As described in the '371 patent for this embodiment, "the proximal end of the capsule 200 slides over the distal end of the bushing 202," and "[a] locking arrangement between these two exemplary components is provided by *capsule tabs 212*, which are designed to lock into the bushing 202 so that mechanical integrity is temporarily maintained between the capsule 200 and the bushing 202." Ex. 1027, 7:4–11 (emphasis added). *Compare id.*, claim 1 ("a tab on the distal end of the bushing"), *with* Fig. 9 above. The discussion of the exemplary embodiment above as compared to the claim language is simply meant to highlight that the interchangeability of the tab from the capsule to the bushing seems contemplated.

Apart from the components being reversed in claim 1, we see no significant distinction between Kimura's bushing and capsule arrangement. Modifying Kimura's design to have "a tab on the distal end of the bushing," which releasably couples to the capsule as claimed would seemingly be a minor design change as recognized in the '371 patent. Petitioner persuades us that reversing Kimura's bushing/capsule connection is simply a matter of routine knowledge to a person of ordinary skill in the art.

As examined above, we determine that Patent Owner's evidence of secondary considerations does not weigh in favor of the nonobviousness of any claim.

Having now considered the evidence in the complete record established during trial, we are persuaded that, based on this record, Petitioner has demonstrated by a preponderance of the evidence that claim1 would have been obvious over Kimura as modified.

As for claims 3–5, Petitioner persuasively establishes where each respective claim limitation is taught by the modified Kimura structure. *See* Pet. 88–92. We have considered Petitioner's evidence and supporting testimony of Dr. Nicosia as to these claims and find it persuasive on the final record. Further, Patent Owner does not challenge any of these assertions for claims 3–5. *See* Prelim. Resp. 52. Accordingly, Petitioner has demonstrated by a preponderance of the evidence that claims 3–5 would have been obvious over Kimura as modified.

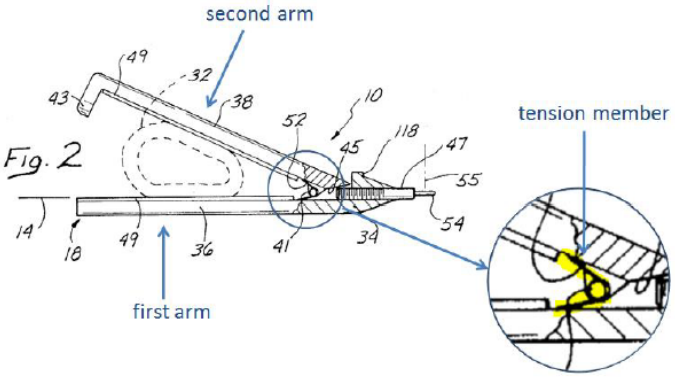
O. Obviousness of Claims 10 and 17 over Kimura and Sackier

Petitioner contends that claims 10 and 17 are obvious based on Kimura and Sackier. Pet. 93–95.

We begin with claim 17, which depends from claim 11. Petitioner relies on its anticipation analysis of claim 11 for its contention that claim 17 would have been obvious over Kimura and Sackier. Pet. 95. For the reasons set forth above for the anticipation analysis of independent 11 based on Kimura, Petitioner has not established that claim 17 would have been obvious over Kimura and Sackier.

Turning to claim 10, Petitioner relies on its obviousness analysis of claim 1 over Kimura (*id.* at 93) as the basis for this ground for claim 10. Sackier is added to teach a "tension member" required by claim 10. Specifically, claim 10 requires "further comprising a tension member slidably received in the capsule and configured to bias the first and second arms to the expanded configuration."

Petitioner proposes adding Sackier's spring 52 ("tension member") configured to bias jaws 36 and 38 ("first and second arms") to the expanded configuration, as depicted below. Pet. 93–94.



Sackier Fig. 2

Petitioner's annotated figure 2 of Sackier (Ex. 1008) showing an enlargement of a tension member (unnumbered) biasing arms 36 and 38.

Petitioner also relies on Sackier's statement that a spring can be provided in a hinge in order to bias the jaws to the open position. *Id.* at 94 (quoting Ex. 1008, 5:4–5).

Petitioner notes that it would have been obvious "to include in Kimura's clip applying apparatus a spring ('tension member') as disclosed in Sackier that is slidably received in Kimura's stop tube 4 ('capsule') and biases Kimura's arm sections 2a, 2b ('first and second arms of the clip assembly') to the expanded configuration." *Id.* As for reasoning why, Petitioner relies on a previous analysis for adding Sackier's spring into Adams. *Id.* That analysis, at pages 41–44 of the Petition, provides five reasons why a person of ordinary skill in the art would have added Sackier's spring member into Adams. These reasons are, in summary: (1) known methods to yield predictable results, (2) simple substitution, (3) use of a known technique to improve similar devices, (4) known technique to a known device, and (5) obvious to try because there are only a finite number of ways to open clip legs. *Id.* at 43–44.

Patent Owner contends that Petitioner "does not provide a legally sufficient motivation to combine the references." Prelim. Resp. 53. Patent Owner argues that it would make no sense to add a tensioning member to Kimura because Kimura is already naturally biased to an open position. *Id.*

Patent Owner's argument makes sense because Kimura is already biased, but Petitioner's strongest theory is that a biasing mechanism and spring are simply interchangeable, as would be known to a person of ordinary skill in the art. *See* Ex. 1029 ¶ 97, 202 ("the proposed combination is the simple substitution of one known element for another to obtain predictable results"). This theory recognizes that Kimura already has an

acceptable biasing mechanism to open the clip arms, but substituting a known alternative that would work equally as well is within the skill set of an ordinary artisan.

We find persuasive Dr. Nicosia's testimony that substituting Sackier's spring for Kimura's natural mechanical bias would be predictable because "Sackier's spring 52 is a simple mechanical device (a torsion spring), with well-known and predictable spring properties." Ex. 1108 ¶ 49. Further, "Sackier's torsion spring 52 is relatively compact, and can easily be designed to open over a wide range of distances," which would allow a wider potential range of opening widths within Kimura. *Id.* ¶¶ 49, 50.

Based on the above, we find persuasive Petitioner's contention that a person of ordinary skill in the art would be motivated to make the proposed modification of Sackier's spring into Kimura. Accordingly, Petitioner has demonstrated by a preponderance of the evidence that claim 10 would have been obvious over Kimura and Sackier.

IV. MOTIONS

The parties filed the following motions that we address in turn below. We dismiss as moot the request to exclude exhibits that are not relied on in our Final Decision.

1. Patent Owner's Motion to Exclude Petitioners' Evidence (Paper 35)

Patent Owner filed a Motion to Exclude Petitioners' Evidence (Paper 35) requesting that we exclude Exhibits 1007 (Kimura), 1020 (Adams publication), 1046 (¶ 30), 1051, 1052, 1054, 1055, 1056, 1066, and 1081. Paper 35, ii. Petitioner filed an opposition. Paper 41.

The request to exclude Exhibits 1007 (Kimura) and 1020 (Adams

publication) as irrelevant is denied because the grounds of unpatentability based on these reference were added back into the proceeding pursuant to our Orders based on SAS. *See* Paper 61, 4.

As regards Exhibits 1046 (¶ 30), 1051, 1052, 1054, 1055, 1056, 1066, and 1081 we dismiss this motion as moot because the decision does not rely upon those exhibits. Because we have not relied upon these exhibits, their presence or absence in the record would not affect the outcome of this proceeding, rendering moot the question of whether it should be excluded from the record.

2. Petitioners Motion to Exclude, in Part, the Smith Declaration, Exhibit 2033 (Paper 37, Paper 39 (redacted))

Petitioner filed a Motion to Exclude portions of the Smith Declaration because the Smith declaration is allegedly based on inadmissible hearsay and provides characterizations and opinions regarding various agreements that are beyond Smith's personal knowledge. Paper 37, 1. The testimony at issue is provided in paragraphs 4, 5, 9, 13, 18, and 19 of Smith's declaration. Patent Owner filed an Opposition (Paper 47 and Paper 48 (redacted).

As noted earlier in this Decision, we agree with Petitioner that Mr. Smith's testimony in paragraph 5 concerning what he was told by outside counsel as to the date of invention is hearsay and thus unreliable. *See* Paper 37, 1–2 ("Smith did not identify 'BSC's outside counsel,' how counsel 'determined' when the '371 claimed subject matter was made, or why BSC counsel's opinion is relevant when BSC is not a party to this IPR.").

Patent Owner argues that it does not offer Mr. Smith's testimony to establish the date of '371 patent's invention and does not cite to Mr. Smith's declaration for this point. Paper 47 or 48, 1–2. We disagree. In order for

Mr. Smith's testimony in paragraph 5, and in later paragraphs, to be relevant it necessarily must be predicated on the date of invention that was told to him as an out of court statement. Thus, because Patent Owner relies on Mr. Smith's testimony, it is also relying on the embedded hearsay in that testimony on which he relies. As such, we agree with Petitioner that the portion of Mr. Smith's testimony conveying what was told to him by another unidentified party, not a witness to these proceedings, is inadmissible hearsay. Although we treat this particular testimony as inadmissible hearsay for the issue of invention date, we do not "exclude" this evidence from the proceeding in whole. Likewise, although Petitioner moves to exclude all of Smith's later testimony that references the conveyed date of invention, we allow this testimony and weigh it appropriately as to the lack of admissible foundation for establishing the time of invention, as we did in the analysis above. *See* Paper 37, 3. Thus, we deny Petitioner's motion to exclude, but treat the evidence as containing inadmissible hearsay as explained herein.

Petitioner also argues that portions of ¶¶ 4, 9, 13, 18, and 19 of Mr. Smith's declaration (Ex. 2033) should be excluded as they allegedly contain opinions "beyond his personal knowledge." Paper 37, 3–6. Petitioner's arguments have some degree of merit, but we determine that Mr. Smith's role as Senior Managing Counsel for BSC, and his statement that, "I have knowledge of the general substance and intent of the agreements identified as Exhibits 2034-2037," provides sufficient foundation for his personal familiarity with how BSC generally structures inter-company agreements, and agreements with contract manufacturers, such as the Subject Agreements. Ex. 2003 ¶ 2. Accordingly, Petitioner's motion as to these portions of Mr. Smith's testimony is denied.

3. Patent Owner's Motion to Exclude Evidence (Paper 71)

Patent Owner filed a second Motion to Exclude Petitioner's Exhibit 1108 Paragraphs 16–17, 20, 21, 24, and 46, Exhibit 1112, Exhibit 1113, Exhibit 1114, and Exhibit 1115. Petitioner filed an Opposition (Paper 74). Patent Owner filed a Reply (Paper 76).

Patent Owner argues that portions of Exhibit 1108 (Declaration of Mark A. Nicosia, Ph.D. in Support of Petitioners' Supplemental Reply in Support of their Petition) should be excluded because paragraphs 16–17, 20, 21, 24, and 46 include opinions that are irrelevant or whose probative value is substantially outweighed by the risk of undue prejudice. Paper 71, 1–2. Patent Owner makes similar arguments with respect to Exhibits1112–15. *See id.* at 3–6 (arguments as to the weight that should be given to evidence related to claim construction). Patent Owner's arguments generally concern claim construction positions, our initial non-binding claim construction, as well as infringement positions. *Id.* Patent Owner's contentions go to the weight of these exhibits and not the admissibility and we therefore deny the motion. Our Institution Decision did not preclude the Parties from submitting additional evidence as to the meaning of claims. *See* Dec. 8–9 (noting that our initial determinations were "[b]ased on the limited record before us," and "[f]or purposes of this [Initial] Decision"). As to the risk of the probative value being substantially outweighed by the risk of unfair prejudice (FRE 403), this risk is reduced when three administrative patent judges weigh each exhibit. Accordingly, Patent Owner's motion as to these exhibits and testimony is denied.

V. CONCLUSION

We determine that Petitioner has shown by a preponderance of the evidence that the subject matter of claims 1 and 3–5 would have been obvious over Kimura. Petitioner also has shown by a preponderance of the evidence that the subject matter of claim 10 would have been obvious over Kimura and Sackier. Petitioner has not shown by a preponderance of the evidence that claims 7, 11–15, and 17 are unpatentable.

Patent Owner's Motion to Exclude Petitioners' Evidence (Paper 35) is denied. Petitioners Motion to Exclude, in Part, the Smith Declaration, Exhibit 2033 (Paper 37, Paper 39 (redacted)) is denied as set forth above. Patent Owner's Motion to Exclude Evidence (Paper 71) is denied.

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED Patent Owner's Motion to Exclude Petitioners' Evidence (Paper 35) is denied;

ORDERED Petitioner's Motion to Exclude, in Part, the Smith Declaration, Exhibit 2033 (Paper 37, Paper 39 (redacted)) is denied.

ORDERED Patent Owner's Motion to Exclude Evidence (Paper 71) is denied;

ORDERED that claims 1, 3–5, and 10 of U.S. Patent No. 8,974,371 B2 have been shown to be unpatentable; and

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

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