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Paper 92
Entered: December 28, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COOK GROUP INCORPORATED
and
COOK MEDICAL LLC,
Petitioner,

v.

BOSTON SCIENTIFIC SCIMED, INC.,
Patent Owner.

Case IPR2017-00440
Patent 9,271,731 B2

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

KINDER, *Administrative Patent Judge*.

FINAL WRITTEN DECISION AND ORDER ON MOTION TO AMEND

Inter Partes Review
35 U.S.C. §§ 316(d), 318(a) and 37 C.F.R. §§ 42.73, 42.121

Cook Group Incorporated and Cook Medical LLC ("Petitioner") filed a Petition (Paper 1, "Pet.") to institute an *inter partes* review of claims 1–20 of U.S. Patent No. 9,271,731 B2 (Ex. 1033, "the '731 patent"). Boston Scientific Scimed, Incorporated ("Patent Owner" or "BSSI") 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 issued a Decision to Institute an *inter partes* review of claims 1–3, 10–16, and 18 of the '731 patent, but not under all challenged claims or grounds. Paper 7, 27–28 ("Dec.").

Patent Owner subsequently filed a Patent Owner Response (Paper 18, "PO Resp.") and Petitioner filed a Reply (Paper 31, "Pet. Reply").

Patent Owner also filed a Contingent Motion to Amend (Paper 17, "Amend Mot."), subsequently followed by a Supplemental Brief in Support of Patent Owner's Contingent Motion to Amend (Paper 21). Petitioner filed an opposition (Paper 32, "Amend. Opp."), to which Patent Owner replied (Paper 41, "Reply to Opp."). Petitioner then filed a Sur-Reply in Support of their Opposition to Patent Owner's Motion to Amend (Paper 48 "Amend. Sur-Reply").

Patent Owner filed a Motion to Exclude (Paper 45) certain evidence submitted by Petitioner, to which Petitioner filed an Opposition (Paper 52), and Patent Owner filed a Reply (Paper 66).

Petitioner also filed a Motion to Exclude (Paper 60) certain evidence submitted by Patent Owner, to which Patent Owner filed an Opposition (Paper 65).

A combined oral hearing with Case IPR2017-00435 was held April 19, 2018, and a transcript of the hearing is included in the record (Paper 69, "Tr."). A second oral hearing was conducted on September 17, 2018 (Paper 91, Tr. 2").

On April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on fewer 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 3, 2018, we issued an Order modifying the Decision on Institution "to institute on all of the challenged claims and all of the grounds presented in the Petition." Paper 68, 1.

Pursuant to our authorization, the Parties thereafter filed a "Joint Motion to Limit the Proceeding" (Paper 74), requesting that we limit the proceeding to a subset of the instituted grounds and claims in the Petition, as identified in the motion. Paper 74, 1–2. On June 15, 2018, we issued a Decision (Paper 75), accepting the Parties' joint proposal to limit the proceeding "to those claims and grounds as set forth in Paper 74, 1–2." Paper 75, 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 grounds and claims to the proceeding, we authorized additional briefing. Paper 73 (also recognizing six month extension under 37 C.F.R. § 42.100(c)). On June 29, 2018, Patent Owner

filed a Supplemental Response. Paper 77 ("Supp. Resp."). Petitioner filed a Supplemental Reply. Paper 79 ("Supp. Reply"). Patent Owner then filed a Sur-Reply. Paper 88 ("Supp. Sur-Reply").

Patent Owner filed a second Motion to Exclude (Paper 81), which sought to exclude certain evidence submitted by Petitioner, to which Petitioner filed an Opposition (Paper 85), and Patent Owner thereafter filed a Reply (Paper 86).

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 1–4, 6, 7, 10–16, 18, and 20 are unpatentable. Petitioner has not shown by a preponderance of the evidence that claims 5 and 8 are unpatentable

We address the Parties' motions to exclude as set forth below. Additionally, we deny Patent Owner's Contingent Motion to Amend as the proposed amended claims are unpatentable.

I. BACKGROUND

A. The '731 Patent (Ex. 1033)

The '731 patent is titled "Device and Method for Through the Scope Endoscopic Hemostatic Clipping," and claims an apparatus and method for capturing tissue. Ex. 1033, [54], 15:36–17:15. The claimed "invention relates to compression clips, and more specifically, to compression clips used to cause hemostasis of blood vessels located along the gastrointestinal tract delivered to a target site through an endoscope." *Id.* at 1:24–27. As explained by the '731 patent, the clips stop internal bleeding by applying

sufficient constrictive forces to blood vessels so as to limit or interrupt blood flow to achieve "hemostasis." *Id.* at 2:32–38, 2:62–66. Embodiments of the invention include "a clip" with "clip arms," and a "control wire" for moving the clip between open and closed configurations. *Id.* at 16:24–42. In addition, the medical device claims describe an "opening element" for urging the clip arms into the open configuration, and the method claim describes use of the control wire to "move the first and second clip arms away from one another to the open tissue receiving configuration." *Id.* at 15:37–17:15.

The '731 patent describes "an arrangement for closing the clip and for reversing the closing process to reopen the clip after closure has begun." *Id.* at 2:64–66. As described, certain

> [e]mbodiments of the invention may include a lock arrangement for locking the clip closed; a control wire connected to the clip and able to be disconnected from the clip; an axially rigid sheath enclosing the control wire and communicating a compressive force opposing a tensile force of the control wire.

Id. at 2:66–3:7. Other elements help "close and lock the clip and to uncouple the control wire from the clip." *Id.* One advantage mentioned in the Specification is "[t]he devices ability to repeatedly open and close the clip until the desired tissue pinching is accomplished will lead to a quicker procedure, requiring less clips to be deployed, with a higher success rate." *Id.* at 3:9–13.

B. Illustrative Claims

Claims 1 and 20 are illustrative of the claims at issue:

1. A medical device, comprising:

a clip including first and second clip arms, the clip being movable between an open tissue receiving configuration in which the first

> and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween; and
>
> an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration, wherein the opening element is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration.

Ex. 1033, 15:37–52.

> 20. A method for capturing tissue, comprising:
>
> inserting a medical device comprising a clip having first and second clip arms to a target tissue site, the clip including an opening element engaging inner walls of the first and second clip arms and urging the clip to an open tissue receiving configuration;
>
> moving a control wire coupled to a proximal end of the clip distally to move the first and second clip arms away from one another to the open tissue receiving configuration;
>
> moving the control wire proximally to move the first and second clip arms toward one another to a closed tissue capturing configuration; and
>
> applying a proximal tensile force exceeding a threshold level to the control wire to separate the control wire from the clip.

Id. at 17:1–15. Independent claim 12 is similar in scope to claim 1, but further requires "a control wire coupled to a proximal end of the clip and operable to move the clip between the open and closed configurations." *Id.* at 16:40–42.

C. Related Proceedings

The '731 patent is the subject of *Boston Scientific Corp. v. Cook Group Inc.*, Civil Action No. 1:15-cv-00980-LPS-CJB (D. Del). Pet. 1; Paper 3, 2. Patent Owner identifies the following petitions challenging the patentability of related patents:

1. IPR2017-00131 (U.S. Patent No. 8,685,048);
2. IPR2017-00132 (U.S. Patent No. 8,685,048);
3. IPR2017-00133 (U.S. Patent No. 8,709,027);
4. IPR2017-00134 (U.S. Patent No. 8,709,027);
5. IPR2017-00135 (U.S. Patent No. 8,974,371); and
6. IPR2017-00435 (U.S. Patent No. 9,271,731).

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 No. 5,843,000 issued on Dec. 1, 1998 ("Nishioka") (Ex. 1005); and

Japanese Unexamined Patent Application Publication No. 60-103946, published on June 8, 1995 ("Shinozuka") (Ex. 1009; certified translation at Ex. 1042).

Petitioner also relies on

1. the Declaration of Mark A. Nicosia, Ph.D. (Ex. 1041),

2. Dr. Nicosia's Declaration in support of Petitioner's Reply (Ex. 1096),

3. Dr. Nicosia's Declaration in support of its Opposition to Patent Owner's Motion to Amend (Ex. 1097),

4. Dr. Nicosia's Declaration in Support of Petitioner's Sur-Reply to Their Opposition to Motion to Amend (Ex. 1101), and

5. Dr. Nicosia's Declaration in Support of Petitioner's Supplemental Reply (Ex. 1110).

Patent Owner relies on:

1. the Declaration of Jeffrey Vaitekunas, Ph. D. (Ex. 2017) in support of its Response,

2. Dr. Vaitekunas's Declaration in support of Reply to Patent Owner's Motion to Amend (Ex. 2095), and

3. Dr. Vaitekunas's Declaration in support of Patent Owner's Supplemental Response (Ex. 2103).

E. The Asserted Grounds

Pursuant to our Institution Decision (Paper 7) and our Decision on the Parties' Joint Motion to Limit Proceeding (Paper 78), the following challenges to the patentability of the '731 patent are before us for consideration:

Reference(s)	Basis	Claim(s) Challenged
Sackier	§ 102[1]	1, 2, 4, 6–9, 12, 13, and 20
Sackier	§ 103	3, 5, 10, 11, and 14–19
Nishioka	§ 102	1–3, 10–16, and 18
Nishioka or Nishioka and Sackier	§ 103	1–3, 10–16, and 18
Shinozuka and (Sackier or Nishioka)	§ 103	1–4, 6–10, 12–14, and 20

[1] 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 '731 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. 11–17. These terms include: "opening element," "engaging inner walls of the first and second clip arms," "movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip," and "link arms are axially aligned with one another." *Id.* Patent Owner identifies the following terms for construction: "clip," "inner walls of the . . . clip arms," and "coupled to." PO Resp. 20–25.

Claims in an *inter partes* review are given the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b) (2016); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2136 (2016). Below, we construe only two terms that are necessary to address for purposes of this Final Decision.

A. "engaging inner walls of the first and second clip arms"

Claim 1 requires, in relevant part, "an opening element engaging inner walls of the first and second clip arms." Ex. 1033, 15:45–46. Claim 12 has the same limitation. *Id.*, 16:32–33. Method claim 20 similarly requires "the clip including an opening element engaging inner walls of the first and second clip arms." *Id.*, at 17:3–5.

The Parties generally agree that the term "engaging" as used in "engaging inner walls" means contacting, but without requiring a physical connection. *See, e.g.*, Pet. 15 (interpreting engaging as contacting, but without a physical connection), PO Resp. 21 (offering no rebuttal to "engaging" as contacting). Petitioner contends that "'engaging inner walls' simply requires that the opening element 'contact[]' the inner walls, without

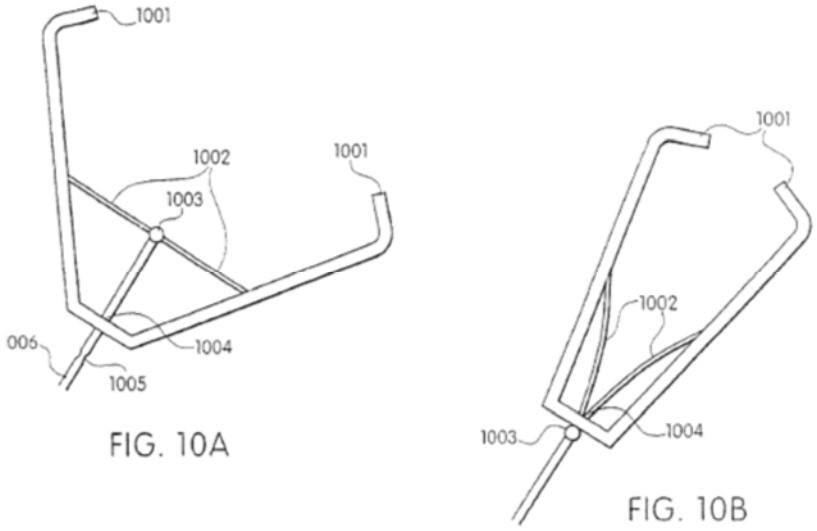
requiring a 'physical connection.'" Pet. 15 (quoting Ex. 1039, 3[2] (Patent Owner's claim construction position from district court)). Petitioner also notes "that 'engaging inner walls of the first and second clip arms' requires that the 'opening element' is 'positioned between the clip arms and of sufficient size to be able to engage the clip arms.'" *Id.* (quoting Ex. 1035, 3).

The Parties' dispute focuses on what is meant by the term "inner walls." *See* PO Resp. 21–22 (construing "inner walls"); Pet. Reply 5 ("'inner walls' refers both to interior surfaces, as well as exterior surfaces"). Below, we discuss each Parties' position related to the "inner walls" limitation and provide our determination for the proper meaning of this limitation.

"Patent Owner proposes that the Board construe 'inner walls of the first and second clip arms' to mean 'the exterior surfaces of the first and second clip arms that are radially inward-facing relative to the longitudinal axis of the clip.'" PO Resp. 22. Patent Owner, relying on the testimony of Dr. Vaitekunas, contends its interpretation is consistent with both the intrinsic evidence and how a person of ordinary skill in the art would have interpreted the phrase in view of the '731 patent. *Id.* (citing Ex. 2017 ¶ 35).

Patent Owner relies on Figures 10A and 10B, depicted below, which "show flexible linkage 1002 contacting the radially inward-facing surfaces of clip legs 1001." *Id.*

[2] We adopt the page numbering added by Petitioner at the bottom right hand corner of Exhibits 1039 and 1035.



Figures 10A and 10B of the '731 patent show enlarged partial views of one embodiment of the compression clip with flexible linkage 1002 and pill 1003 used to lock clip legs 1001. Ex. 1033, 8:61–64.

Patent Owner also relies on Figures 8A, 8B and 15A–C of the '731 patent, which purportedly "show an opening element contacting the radially inward-facing walls of the clip arms." PO Resp. 23.

Patent Owner also alleges that its proposed construction is "consistent with Petitioners' proposed construction of 'opening element,'" which requires a structure that "'engages the inner walls of the clip arms and urges them away from one another.'" *Id.* (quoting Pet. 14). According to Patent Owner, the opening element described and shown in the Specification engages the radially inward-facing walls of the clip arms. *Id.*

Patent Owner relies on other portions of the '731 patent in support of its interpretation of the "inner walls" limitation. For example, Patent Owner cites Figures 20A–C, and notes that the structure designated as 2004 is an "inner sleeve," which is radially inward of sheath 2003. PO Resp. 24 (quoting Ex. 1033, 13:30–33). Patent Owner notes that this structure "is described as having 'female threads (not shown) on its inside diameter,'

which would be the diameter facing radially inwards towards the longitudinal axis of the clip, as shown in Figures 20B and 20C." *Id.* (quoting Ex. 1033, 13:30–48). Patent Owner points out that "[b]y contrast, the specification describes that clip 2001 'is characterized by male threads 2002 on its outer surface,'" which "[a]s seen in Figures 20B and 20C, the 'outer surface' is a surface that faces radially outward with respect to the longitudinal axis of the clip." *Id.* (quoting Ex. 1033, 13:27–28). Finally, Dr. Vaitekunas testifies that a person of ordinary skill in the art would not understand "inner walls" to refer to any walls other than the radially inward-facing walls of the clip arms. PO Resp. 24 (citing Ex. 2017 ¶ 35).

In its Reply, Petitioner contends that a person of ordinary skill "would understand that 'inner walls' refers both to interior surfaces, as well as exterior surfaces." Pet. Reply 5 (citing Ex. 1096 ¶¶ 12–13). Petitioner similarly argues that a person of ordinary skill "also would understand that 'inner walls' refers to surfaces that are radially-inward facing, as well as surfaces that are not radially-inward facing, relative to a longitudinal axis of the clip." *Id.* Petitioner relies on Figures 10A and 10B of the '731 patent to support the proposition that it is "unclear what shape clip legs 1001 have in cross-section (round, rectangular, etc.) and, if not round, precisely what surface(s) linkage 1002 engages." Pet. Reply 4.

Based on the final record before us, we find Patent Owner's proposed construction more persuasive because it is grounded in, and most consistent with, the Specification of the '731 patent. Contrastingly, Petitioner does not offer a specific interpretation of "inner walls" and its arguments are generally based on extrinsic evidence, including claim charts from the related district court litigation (Pet. 15), arguments from related proceedings

(Pet. Reply 3), and the prior art reference (Nishioka) relied on to challenge the claims (*id.* at 3–4).

Petitioner criticizes the Patent Owner's position but provides no express interpretation of "inner walls of the first and second clip arms"; instead, Petitioner argues why Patent Owner's proposed construction is wrong. Pet. Reply 4–5. Dr. Nicosia does not expressly define or otherwise persuasively explain the definition of "inner walls" in his declarations either.

The Parties each address whether Figures 20A–C of the '731 patent, and the corresponding descriptions, support Patent Owner's proposed interpretation of "inner walls." *See* PO Resp. 24; Pet. Reply 2–4. Examining this intrinsic evidence, the term "outer surface" is used in the '731 patent to characterize the male threads 2002 on the outer surface of the clip found in Figure 20B. Figure 20B is reproduced below:

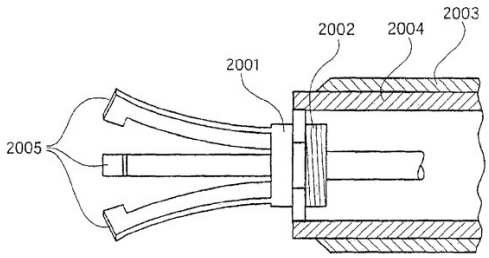


FIG. 20B

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

It is apparent that "outside surface" means what it says, the surface that faces radially outwardly from the centerline of the clip. Ex. 1001, Ex. 1033, 13:27–48. The Specification goes on to describe that the "inner sleeve 2004 has female threads (not shown) on its inside diameter." *Id.* 13:30–36. Although the term "inner surface" does not appear in the Specification, by logical extension, an inner surface would be consistent with the inner

diameter that faces radially inwardly from a centerline of the clip to engage the threads.

Petitioner's interpretation of "inner walls" to refer both to interior surfaces, as well as exterior surfaces (Pet. Reply 5), would essentially read the term out of the claim because any wall surface, regardless of position, could therefore be an "inner wall." Instead, we find Dr. Vaitekunas's testimony more persuasive as to what is meant by an "inner wall:"

> [A] POSITA would not understand the term "inner walls of the . . . clip arms" to have a broader meaning encompassing an interior portion of the clip via an aperture in the side wall of the clip arms, as Petitioners and Dr. Nicosia suggest. In addition, a POSITA would not identify the surface on which pin 142 is located in Nishioka Embodiment 2 to be an "inner wall," as suggested by the Board in the Institution Decision, as this would be inconsistent with the ordinary meaning of "inner walls of the . . . clip arms" within the context of the '731 Patent and its specification.

Ex. 2017 ¶ 35. We find this testimony to be credible and consistent with the intrinsic evidence of record.

Based on the final record before us, "inner walls" are exterior walls that face inwardly from a radial centerline of the clip. We therefore interpret "inner walls of the first and second clip arms" to mean "the exterior surfaces of the first and second clip arms that are inward-facing relative to the longitudinal axis of the clip."

B. "clip"

The Parties now agree that "clip," as the term is generally understood, and as used in the Specification, means *a device having compression legs and capable of applying a pinching pressure*. "Patent Owner does not oppose the Board's construction." PO Resp. 21.

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 proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must establish the facts supporting its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

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,[3] so-called secondary considerations. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

"To satisfy its burden of proving obviousness, a petitioner cannot employ mere conclusory statements. The petitioner must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Furthermore, in assessing the prior art, the Board must consider whether a person of ordinary skill would have been motivated to combine the prior art to achieve the claimed invention. *In re Nuvasive, Inc.*, 842 F.3d 1376, 1381 (Fed. Cir. 2016).

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 '731 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. 10 (citing Ex. 1041 ¶ 11). Patent Owner does not dispute Petitioner's proposal, and we adopt it based on the final record, as it is consistent with the level of skill evidenced by the references.

C. Claims 1, 2, 4, 6–9, 12, 13, and 20 as Anticipated by Sackier

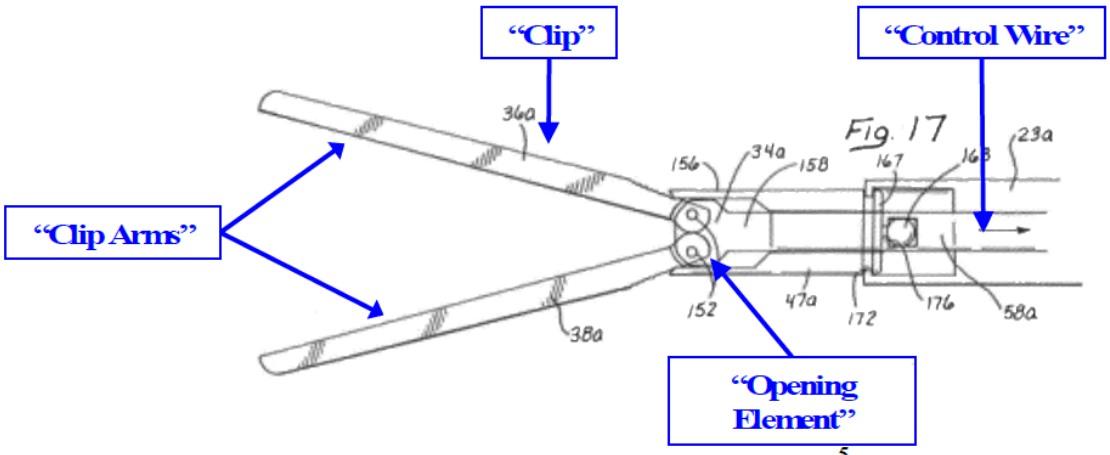
Petitioner contends claims 1, 2, 4, 6–9, 12, 13, and 20 are unpatentable under 35 U.S.C. § 102, as anticipated by Sackier. Pet. 23–38.

1. Overview of Sackier (Ex. 1008)

Sackier is directed to a laparoscopic surgical device that includes a

[3] The Parties have not introduced evidence of secondary considerations.

clamp. Ex. 1008, Abstract. Petitioner relies on the embodiment of Figure 17 of Sackier, which is reproduced below.



Sackier, Figure 17 (Annotated)[5]

Petitioner's Annotated Fig. 17[4] depicts an axial cross-section views of a clamp (Pet. 18); Ex. 1008, 3:60–62.

The surgical clamp includes a pair of jaws, or clip arms identified above, with a spring 152 to bias the jaws to the open position:

> the shaft 58a can be moved relative to the tube 23a to engage the slide 47a and move it relative to . . . the jaws 36a, 38a. As noted, this axial movement of the slide 47a relative to the jaws 36a and 38a is accompanied by relative movement of the jaws 36a, 38a between the open and closed positions.

Ex. 1008, 10:28–34.

2. Claims 1, 12, and 20

Petitioner asserts that Sackier discloses all elements of claims 1, 12,

[4] We include Petitioner's annotated figures from Sackier because "Figures 15–26 of Sackier published without reference numbers, even though Figures 15–26 with reference numbers were submitted during prosecution." Pet. 18–19, n.5.

and 20. Pet. 23–27, 35–38. Each of claims 1 and 12 requires "an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another," and method claim 20 requires a similar limitation. *See* Ex. 1033, 15:45–47, 16:32–34, 17:3–6.

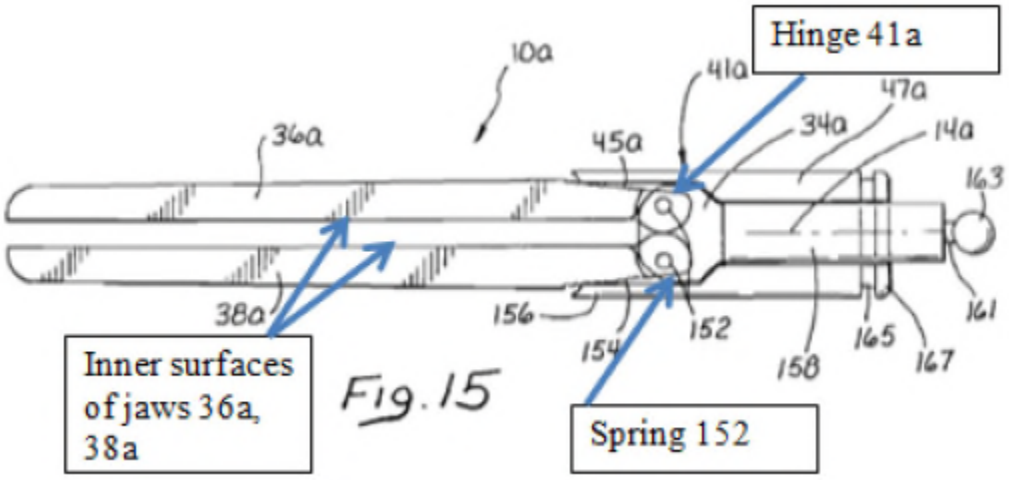
Petitioner relies on Figures 15–17 as disclosing these limitations, and more specifically, "Sackier discloses an opening element (spring 152) urging the first and second clip arms away from one another into the open tissue-receiving configuration (Figure 17)." Pet. 25. Petitioner acknowledges, however, that the disclosed spring 152 in Figures 15–17 of Sackier (the claimed opening element) does not engage, or contact, the inner walls. *See* Pet. 26. To address this shortcoming, Petitioner proposes a series of modifications to Figures 15–17 based on other distinct embodiments disclosed in Sackier. *Id.*

> First, Petitioner proposes
>
> > that instead of having two pivotal clip arms (jaws 36a, 38a) as shown in Figures 15–17, the embodiment depicted in Figures 15–17 "can . . . be formed with the jaw 38a in a fixed relationship to the supporting structure 34a and the jaw 36a pivotal relative to the supporting structure 34a on a hinge 41a in the manner previously discussed."

Id. (quoting Ex. 1008, 9:25–30). Petitioner next proposes using a fixed jaw embodiment (Figure 2), "which includes an opening element (spring 52) engaging the inner walls of the first and second clip arms and urging the clip arms away from one another into an open tissue-receiving configuration." *Id.* The modified embodiment would then adopt spring 52 from Figure 2. *Id.* Petitioner contends that spring 152 is just "one 'example' of what could

be used to bias the jaws 36a and 38a to the open position, confirming that the embodiment shown in Figures 15–17 includes spring 52 as an alternative to spring 152." *Id.* at 27.

Patent Owner contends that Sackier does not disclose a medical device with "an opening element engaging inner walls of the first and second clip arms" as required by each independent claim. Supp. Resp. 21. Patent Owner argues that the alleged "opening element" identified as springs 152 do not engage the inner walls as depicted in Patent Owner's annotated Figure 15 below.



Patent Owner's annotated Figure 15 of Sackier (Supp. Resp. 21) showing location of spring 152 and inner surfaces of jaws 36a, 38a.

Patent Owner takes issue with Petitioner's selective picking and choosing features from distinct embodiments, such as spring 52 from another embodiment, in the anticipation analysis of claims 1, 12, and 20. Supp. Resp. 22–23. Petitioner alleges that such a mixing of embodiments is improper for anticipation. *Id.*

We agree that spring 152 does not contact the inner surface of jaws 36a and 36b in Figure 15. However, Petitioner asserts that Dr. Nicosia

explained how Sackier's "labeling convention" (using successive lower-case letters to identify successive embodiments) teaches substituting the Embodiment 2 clamp/clamp applier for the clamp applier illustrated in Figures 11–14. Supp. Reply 18; Ex. 1008 9:5–15. We have carefully considered Dr. Nicosia's testimony and Petitioner's supplemental briefing.

We observe that spring 52 in the second Sackier embodiment does appear to contact the inner surface of the jaws and act to drive them apart. Ex. 1008, Figure 2. And we are now persuaded that there is an unillustrated embodiment in Sackier of Figure 2 where both legs are pivotable. Ex. 1008, 5:9–12. ("In an unillustrated embodiment (not shown), both of the jaws 36 and 36 are pivotable along the supporting structure 34 and include bevel surfaces, such as surface 45, which are engagable by the screw 47 to open and close the jaws 36, 38.").

We are not persuaded that the two different embodiments are necessarily described as (or one of ordinary skill in the art would regard them as) having interchangeable components, principally because they operate on different principles to open and close the legs. Sackier Figure 2 utilizes a spring between the legs that drives the legs out as a screw and beveled surface exert inward force.

The Sackier Figure 15–17 embodiment works on a different principle, with a spring at the pivot point 152 biasing the legs outwardly, an external sleeve holding the legs inwardly and releasing as the clip slides relative to the sleeve. This is not the same mechanism as a stationary screw and bevel.

Patent owner argues persuasively that:

> Regardless of whether the embodiment of Figure 2 has one fixed jaw or two pivotal jaws, the flaw in Petitioners' argument is the assumption that spring 52 from Figure 2 is disclosed as an

> alternative to spring 152 in the embodiment of Figures 15-17. It is not disclosed as such, and the allegedly "parallel descriptions of illustrated and alternative embodiments" (Paper 79 at 9) does not change the analysis. Numerous elements identified with the same numeral differ between the two embodiments, including for example, screw 47 in embodiment of Figure 2 and slide 47a in the embodiment of Figures 15-17. That the embodiment of Figures 15-17 designates its spring 152 differently from the numeric designation of the spring in Figure 2 drives home the point that Sackier disclosed different structures in different embodiments.

PO Sur-Reply, 1–2.

We conclude that Patent Owner has the better side of this argument. Even though Dr. Nicosia testifies that the embodiments can be interchanged (Ex. 1110 ¶¶ 9–11) we understand that the basis for that interchangeability, as stated by Sackier, is in the context *of each embodiment in the surgical procedure*, not of the *components of those embodiments*.

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). We conclude that Petitioner has not met its burden of showing this element to be present in Sackier because Petitioner combines features from distinct embodiments in Sackier without establishing persuasively that those embodiments are so directly related to each other such that one of ordinary skill in the art, looking at the reference as a whole, would recognize a disclosure of the invention as claimed. Accordingly, although a very close call, we conclude that Petitioner has failed to demonstrate anticipation of claims 1, 12, and 20 by Sackier for this reason.

3. Claims 2, 4, 6–9, and 13

Claims 2, 4, and 6–9 depend from claim 1. Claim 13 depends from claim 12. Because Petitioner has not established by a preponderance of the evidence that Sackier anticipates claim 1 or that Sackier anticipates claim 12, and for the reasons provided above, Petitioner has not established by a preponderance of the evidence that claims 2, 4, 6–9, and 13 are anticipated by Sackier.

D. Claims 3, 5, 10, 11, and 14–19 as Obvious in view of Sackier

Petitioner asserts that Sackier teaches all elements of these claims. Pet. 39–48. Claims 3, 5, 10, 11, and 14–19 depend directly, or indirectly, from claims 1 and 12. As discussed above, we determine that Petitioner has not demonstrated by a preponderance of the evidence that Sackier anticipates claims 1 and 12.

In its obvious analysis of claims 3, 5, 10, 11, and 14–19, Petitioner does not provide any argument contending that claim 1 or claim 12 would have been obvious over Sackier. Instead, Petitioner implicitly relies on its anticipation analysis of claims 1 and 12. *See* Pet. 39–48. Because Petitioner has failed to establish by a preponderance of the evidence that claims 1 and 12 are anticipated by Sackier, Petitioner has thus failed to show by a preponderance of the evidence that claims 3, 5, 10, 11, and 14–19 would have been obvious over Sackier.

Petitioner has not asserted a ground in its Petition that claims 1 and 12 would have been obvious over Sackier. As a result, Petitioner failed to provide notice to Patent Owner that claims 1 and 12 would be challenged under § 103 based on Sackier. We will not read into the Petition an allegation that claims 1 and 12 would have been obvious over Sackier

because Petitioner has not adequately alleged or presented such a challenge. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018) ("Much as in the civil litigation system it mimics, in an inter partes review the petitioner is master of its complaint and normally entitled to judgment on all of the claims it raises, not just those the decisionmaker might wish to address.)"

Accordingly, Petitioner has failed to establish that claims 3, 5, 10, 11, and 14–19 would have been obvious under 35 U.S.C. § 103 over Sackier.

E. Claims 1–3, 10–16, and 18 as Anticipated by Nishioka

Petitioner contends claims 1–3, 10–16, and 18 are unpatentable, under 35 U.S.C. § 102, as anticipated by Nishioka. Pet. 49–64. Petitioner relies on two distinct embodiments of Nishioka – Figure 2 and Figure 8. Petitioner presents a separate anticipation analysis for each embodiment. *See id.*

1. Overview of Nishioka (Ex. 1005)

Nishioka is directed to a biopsy forceps. Ex. 1005, Abstract. Nishioka's "device includes an elongated catheter body for introduction into the body." *Id.* "The distal end of the device has a pair of cutting jaws pivotally mounted at the distal end of the catheter body and controlled by control wires extending through the catheter body to a control handle at the proximal end, or by the optical fiber." *Id.*

We examine two distinct embodiments of Nishioka – Figure 2 and Figure 8. Below, we first highlight the features of Figure 2 then address Figure 8.

The Figure 2 Embodiment of Nishioka is depicted below.

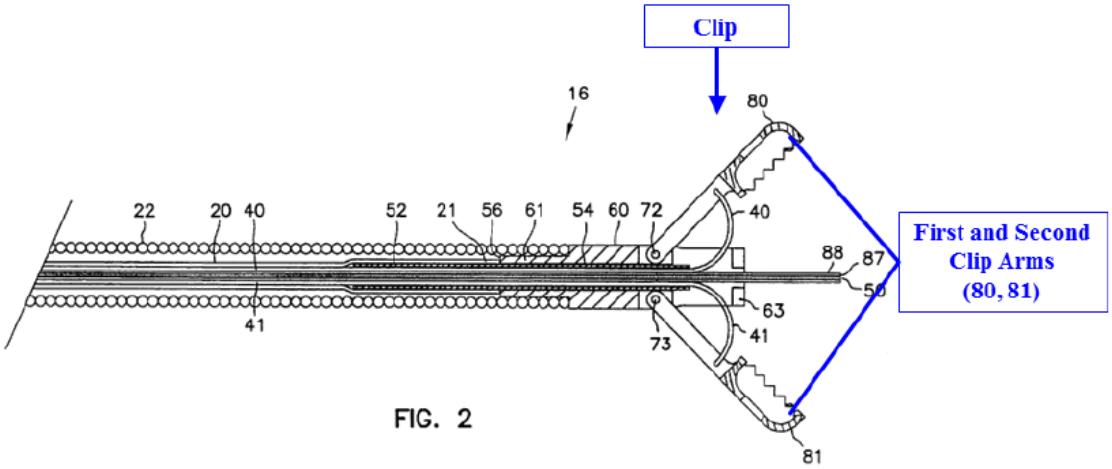


FIG. 2

Petitioner's annotated Figure 2 (Pet. 50) of Nishioka showing a cross-sectional view at an enlarged scale of the distal end of the forceps of Figure 1 with first and second clip arms, 80, 81. Ex. 1005, 3:12–14.

Positioned within inner tube 20 are a pair of control wires 40, 41, and the distal end 16 of the optical forceps includes yoke 60, which serves as a mounting member for the cutting jaws. *Id.* 3:64–4:36.

Figure 8 of Nishioka is reproduced below, which depicts forceps 100 including cutting jaws 180, 181. Ex. 1005, 7:58.

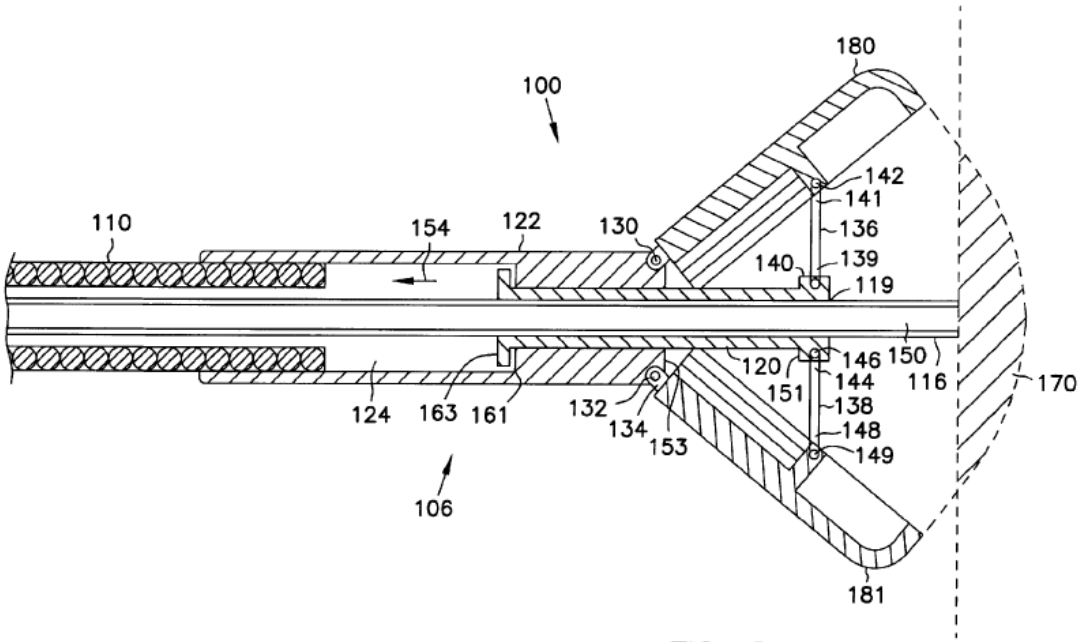


FIG. 8

Figure 8 of Nishioka is a cross-sectional view of the distal end of an optical biopsy forceps. *Id.* at 3:34–36.

As depicted in Figure 8, the cutting jaws are hingedly connected to support block 122. *Id.* at 7:65–66. Control links 136 and 138 operate to open and close the jaws when an optical fiber is displaced. *Id.* at 8:8–43.

2. Claims 1 and 12

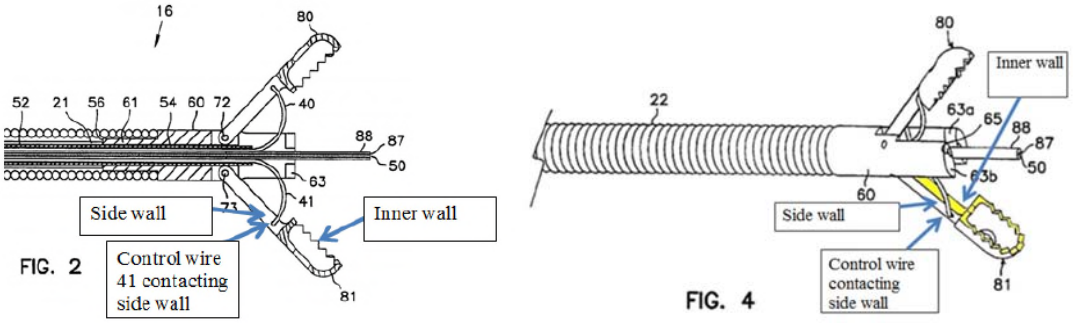
We begin our analysis with independent claims 1 and 12. Petitioner asserts that Nishioka discloses all elements of these claims. Pet. 49–55, 58–60. Petitioner relies on two embodiments of Nishioka – Figure 2 and Figure 8. Petitioner does not, however, combine features of these embodiments to arrive at the claim limitations. Instead, Petitioner provides a distinct analysis as to why each embodiment would disclose each claim limitation for claims 1 and 12. *Id.* Petitioner also relies on the supporting declaration of Dr. Nicosia. *Id.* (citing Ex. 1041 ¶¶ 69–72, 76–79). For the reasons set forth below, and based on the record before us, Petitioner has not shown by a

preponderance of the evidence that the Figure 2 Embodiment anticipates either claim 1 or 12. We determine, however, that Petitioner has proven by a preponderance of the evidence that the Figure 8 Embodiment anticipates claims 1 and 12. We first highlight the reasons why the Figure 2 Embodiment does not anticipate. Second, we provide a detailed analysis of the elements of each claim compared to the Figure 8 Embodiment.

Figure 2 Embodiment

The Figure 2 Embodiment of Nishioka does not disclose "an opening element engaging inner walls of the first and second clip arms," required by both claims 1 and 12.

Patent Owner argues, and we agree, that Figures 2 and 4, both depicted below with Patent Owner annotations, show that the control wire engaging a side wall, not an inner wall of Nishioka Figure 2 Embodiment.



Patent Owner's annotated Figures 2 and 4 of Nishioka showing highlighted inner wall. PO Resp. 35.

Patent Owner argues that "the control wire 41 contacts the side wall only and does not have any contact with the highlighted inner wall of the cutting jaws." PO Resp. 35.

We are persuaded by Figure 6A of Nishioka, which provides a side view of the cutting jaw component for the embodiment depicted in Figure 2.

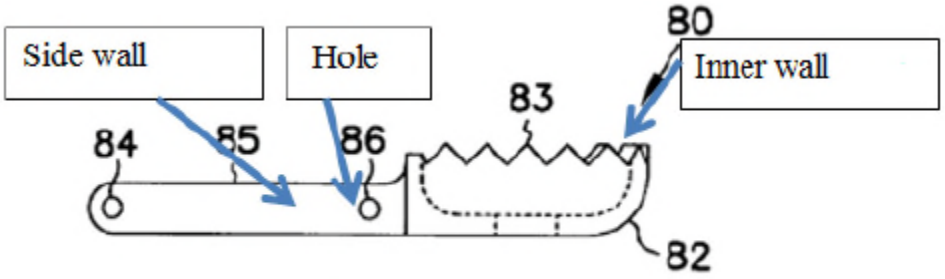


FIG. 6A

Patent Owner's annotated Figure 6A of Nishioka showing hole 86 along the side wall. PO Resp. 36.

As depicted above, the rearward lever or mounting portion 85 of the cutting jaw has hole 86 that is located approximately in the center of the side wall. *See* Ex. 2012, 376:21–24. Important for our analysis, the hole 86 is located below the edge of the side wall, such that there is no contact between the hole 86 and the inner wall. The Specification explains that the hole 86 "receive[s] the end of control wire 40 (or 41) which is crimped or bent at a right angle at its tip to be effectively captured." Ex. 1005 at 5:9–12. We agree with Patent Owner that the control wire goes through the side wall of the cutting jaw and does not engage the inner wall.

Petitioner urges in reply that the method of attachment of the control wires results in contact with an inner surface. Pet. Reply 29–31. We have considered Petitioner's arguments that the engagement "between the opening element and the inner bearing surface of the pin channels" may constitute engagement of the inner walls. *See* Pet. Reply 29–31; Ex. 1096 ¶¶ 51–52. We are unpersuaded by these arguments. The method of attachment of the wire is by passing it through a hole in the neck of the clip leg. Although the attachment mechanism — the hole itself — may have an inwardly facing hole surface, we do not find that this inwardly facing hole

surface is the required inner walls. We do not find these, and other, contentions persuasive in light of the clear descriptions and depictions of the Figure 2 Embodiment set forth above.

For these reasons, the Figure 2 Embodiment of Nishioka does not anticipate either claim 1 or 12, and thus also does not anticipate any claims dependent therefrom.

Figure 8 Embodiment

i. clip limitation

Claim 1 first requires "A medical device, comprising: a clip including first and second clip arms, the clip being movable between an open tissue receiving configuration in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween."

Consistent with Petitioner's contentions, Nishioka's Figure 8 Embodiment discloses a medical device in the form of a "forceps device." Pet. 49 (citing Ex. 1005, 1:6–9, 1:64–66, 2:58–65; Ex. 1041 ¶ 69). Petitioner contends that Nishioka discloses "a clip including first and second clip arms, the clip being movable between an open tissue receiving configuration . . . and a closed configuration" based on Nishioka's forceps having jaws 180, 181 (Figure 8). The jaws (180, 181), or clip arms, are moveable between an open tissue receiving configuration in which the first and second clip arms are separated from one another by a distance selected to receive tissue (Fig. 8 below), and a closed configuration in which the first and second clip arms are moved inward to capture the tissue received therebetween.

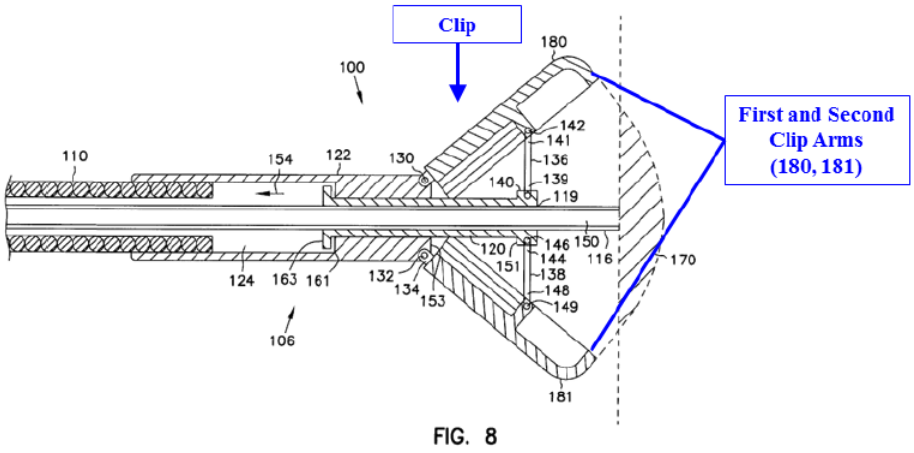


FIG. 8

Petitioner's annotated Figure 8 (Pet. 51).

Petitioner contends that "[a] person of ordinary skill in the art would have considered a forceps cutting device to be a type of clip (i.e., a device that clips tissue)." Pet. 49, n.8. We agree with Petitioner that Nishioka Figure 8 Embodiment discloses a device having compression legs and capable of applying a pinching pressure, as we interpret the claim term clip.

Patent Owner contends the Nishioka Figure 8 Embodiment is not a clip "because the cutting jaws are used to cut tissue by applying a shearing force," but "[t]he Nishioka cutting jaws are not used to pinch tissue with a compressive force." PO Resp. 43. Patent Owner's witness, Dr. Vaitekunas, testifies that Nishioka describes cutting a tissue sample using a shear force, not pinching tissue using a compressive force. Ex. 2017 ¶¶ 51–53, 73. The staggered serrations of Nishioka's cutting jaws are said to slide past one another in operation, much as the blades of a pair of scissors or shears. *Id.* ¶ 53. As a result, Patent Owner contends that Nishioka's jaws cut tissue by exerting forces that push the tissue in opposing directions to effect the cut. PO Resp. 43, 29.

On the other hand, Dr. Nicosia testifies that a person of ordinary skill in the art would understand that all biopsy forceps, including the Nishioka

forceps, apply a combination of forces when applied to tissue, including both pinching (compression) *and* shear forces. Pet. Reply 6 (citing Ex. 1096 ¶¶ 14–15). In short, it depends upon the use to which the forceps are put. Ex. 1096 ¶¶ 15–16

Dr. Nicosia analogizes this to using pruning shears to pick up and move tree clippings without cutting the clippings, or to using cutting pliers to hold, bend, and loop wire, without cutting the wire. *Id.* ¶ 16. According to Dr. Nicosia, pruning shears and cutting pliers are designed to shear and cut, but they also are capable of being used to pinch and compress without cutting. *Id.*

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

On balance, we find Dr. Nicosia's testimony more persuasive, and consistent with the description in the Specification of the '731 patent that a pinching pressure can be applied for whatever purpose the operator desires. More specifically, as the claimed clips can be used on any tissue "the operator wishes to apply a pinching pressure for whatever reason" we find Patent Owner's shear versus pinch argument unpersuasive. *See* Ex. 1001, 15:7–12. Given that we have interpreted "clip" consistent with the Specification as an element capable of applying pinching pressure, *supra*, ('731 patent 15:7–12), the biopsy forceps jaws are capable of applying sufficient pinching pressure to remove a tissue sample. Moreover, the control wires extend to the clip. Accordingly, Patent Owner's contentions related to Nishioka lacking a clip as required by claims 1 and 12 are unpersuasive on the final record.

ii. opening element engaging inner walls limitation

Petitioner identifies the claimed "an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration . . ." limitations as being taught by Nishioka's "opening element (control links 136, 138 (highlighted in yellow)) engaging inner walls of the first and second clip arms (180, 181) and urging the first and second clip arms away from one another into the open-tissue receiving configuration," (Pet. 53) as depicted below.

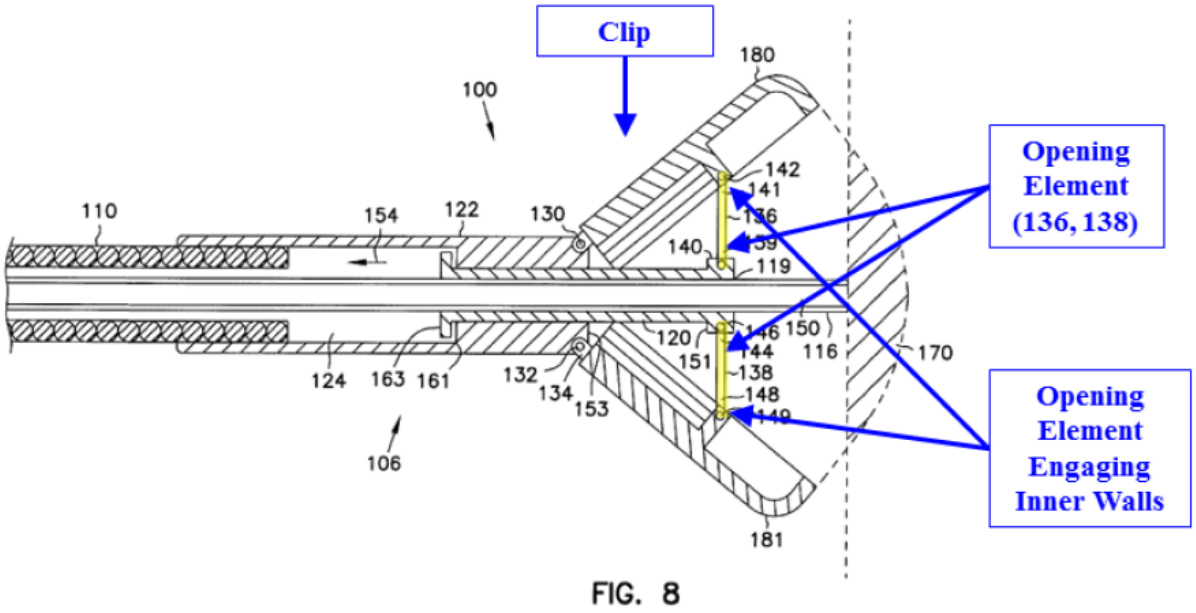


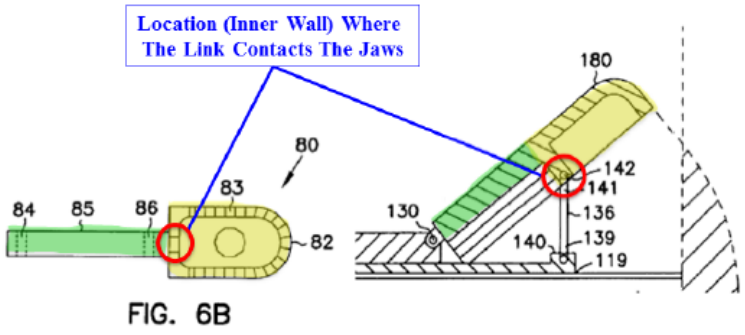
FIG. 8

Petitioner's annotated Nishioka Figure 8 (Pet. 53) with opening element 136, 138 highlighted in yellow.

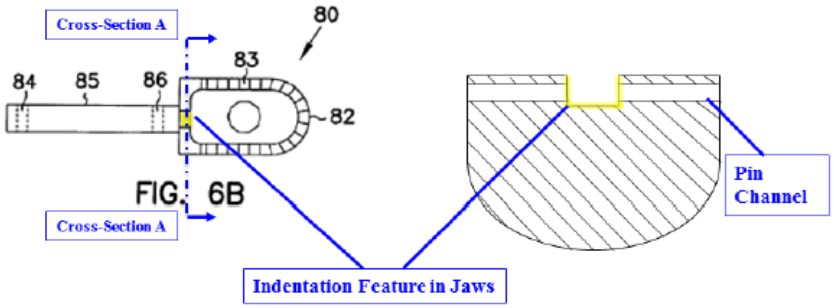
Petitioner explains how the opening element (136, 138) is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration (Figure 8) and the closed configuration. Pet. 53–55 (quoting Ex. 1005, 8:10–26, 8:63–9:2).

Patent Owner contends that Nishioka does not disclose a medical device with an "opening element engaging inner walls of the first and second clip arms" as required by claims 1 and 12. PO Resp. 44. According to Patent Owner, Figure 8 provides a cross-sectional view of the distal end of Nishioka Embodiment 2. *Id.* at 44–45. Also according to Patent Owner, because Figure 8 is a two-dimensional representation of the biopsy forceps, the figure shows only a cut-away portion of the *side* surface of the cutting jaws. *Id.* Patent Owner then interprets the figure as illustrating the linkage as being on the *side* of the jaws, and not the inner walls. *Id.* Patent Owner asserts the links would interfere with the closing of the jaws otherwise and the links fit into a recessed portion on the side of the jaws. *Id.* at 46–47.

Petitioner characterizes this position as incorrect. Pet. Reply 11. Specifically, Petitioner is of the viewpoint that the control links contact the jaws on the inner walls, not the side of the jaws. *Id.* at 11–12. We reproduce Petitioner's annotated Figures 6B and 8 as provided in the Reply on page 11 to show this point that the axial view of Figure 8 is central, not off to one side. Petitioner argues that "Figure 8 illustrates that links 136, 138 contact jaws 180, 181 at the proximal end of the 'distal cup' portion." *Id.* at 11.



Nishioka '000, Figures 6B and 8 (Excerpt)



Nishioka, Figure 6B Cross-Section A

Annotated Figures 6B and 8 (Pet. Reply 12) are partial cross sectional views depicting Nishioka Embodiment 2 and bottom right is a cross section created by Petitioner showing indentation feature in the jaws.

Petitioner contends that as shown above "in annotated Figures 6B and 8, and in the annotated partial cross-sectional view of Figure 6B prepared by Dr. Nicosia, this contact corresponds with an indentation/slot feature disposed on the *inner wall* of jaws 180, 181, which receives the distal ends of links 136, 138 (as well as pins 142, 149). (Ex. 1096, ¶26)." *Id.* at 11–12. We find particularly persuasive Petitioner's contentions, supported by Dr. Nicosia's testimony, that the control links do not interfere with closure as alleged by Patent Owner, "because the indentation/slot features in jaws 180, 181 accommodate links 136, 138 during closure, and prevent any such interference. (Ex. 1096, ¶27)." *Id.* at 12.

We do find this comparison of Figure 6B with the portion of Figure 8

helpful and it, along with Dr. Nicosia's testimony, to carry significant weight. It provides evidence that the cross sectional view of Figure 8 is a *central* cross section. We think the characterization of the view by Patent Owner as including a cross-section of the side wall is incorrect because the side wall is not centrally located.[5] Thus, we are not persuaded by Patent Owner's argument that the linkage is on the side of the clip.

Based on our review of Nishioka Figure 8, we disagree with Patent Owner's contentions. We interpreted "inner walls of the first and second clip arms" to mean "the exterior surfaces of the first and second clip arms that are inward-facing relative to the longitudinal axis of the clip." Applying this interpretation, Petitioner has persuasively established that Nishioka discloses an engagement with such a surface. As depicted in Figure 8, opening element 136 contacts the inner portion of inner wall of the clip arm 180 at pivot 142, which is located on the inner wall of clip arm 180. Opening element 138 also contacts clip arm 181 in the same manner.

Petitioner has sufficiently shown based on the final record that the opening element contacts the clip arms at the pivot point and the inner wall portion located adjacent to the pivot point during rotational movement.

With the complete trial record before us, we note that we have reviewed arguments and evidence advanced by Petitioner to support its unpatentability contentions where Patent Owner chose not to address certain limitations in its Patent Owner Responses. In this regard, the record now contains persuasive arguments and evidence presented by Petitioner, many

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

of which are unrebutted, regarding the manner in which Nishioka discloses corresponding limitations of the claims against which it is asserted. Based on the preponderance of the evidence before us, we conclude that the prior art identified by Petitioner teaches all uncontested limitations of claims 1 and 12. Below, we further discuss a contested limitation found only in claim 12.

iii. control wire coupled to a proximal end of the clip limitation

Claim 12 separately requires "a control wire coupled to a proximal end of the clip and operable to move the clip between the open and closed configurations." Ex. 1033, 16:40–42.

Petitioner relies on fiber 150, as depicted in Figure 8, which is "coupled to a proximal end of the clip and operable to move the clip between the open and closed configurations," according to Petitioner. Pet. 59–60. Petitioner cites portions of Nishioka that explain optical fiber 150 is connected to and movable with tubular slide member 120, which, in turn, is coupled to jaws 180 and 181 for actuating jaws 180 and 181 as the optical fiber is moved. *Id.* at 60 (citing Ex. 1005, 6:60–64, 7:3–32).

Patent Owner argues, with respect to claim 12, that Nishioka Figure 8 Embodiment does not disclose "a control wire coupled to a proximal end of the clip." PO Resp. 49. Patent Owner contends that the alleged "control wires" are not coupled to, or linked to, the proximal end of the cutting jaws. *Id.* Patent Owner relies on the cross examination of Petitioners' expert, and contends that Dr. Nicosia "conceded this point at his deposition." *Id.* (citing "Ex. 2012 at 369:8-11 (admitting that optical fiber 150 'is not physically touching the jaws'); 370:2-3 ('It doesn't directly contact the jaws.'); 370:17-18; 371:6-11 (agreeing that there is no disclosure of jaws 180 and 181

touching optical fiber 150)"). Patent Owner contends that "[o]ptical fiber 150 is not linked to the cutting jaws because optical fiber 150 is surrounded by the reinforcement cover 116," and also because "optical fiber 150 is separated from jaws 180 and 181 by . . . tubular slide member 120, and control links 136 and 138." PO Resp. 49–50.

The Parties agree that "'coupled to' means 'linked together, connected, or joined.'" PO Resp. 27; Pet. Reply 24. Based on this meaning, Petitioner argues that a person of ordinary skill in the art "would understand that 'coupled to' does not require direct contact between components, but merely requires that the components are linked together, connected, or joined, either directly or indirectly." Pet. Reply 24–25 (citing Ex. 1096 ¶ 44). Petitioner acknowledges there are intervening structures, but Petitioner argues that "the control wire (optical fiber 150 (yellow)) is coupled to support block 122 (green and located at the proximal end of Nishioka's 'clip') via . . . slide member 120 (orange), control links 136, 138 (orange), and jaws 180, 181 (orange)." *Id.* at 25 (citing Ex. 1096 ¶ 45). "Thus," according to Petitioner, "the control wire (150 (yellow)) and proximal end of the clip (block 122 (green)) are 'linked together, connected, or joined' via this intervening structure (orange)." *Id.* Petitioner provides the following highlighted Figure 8 of Nishioka:

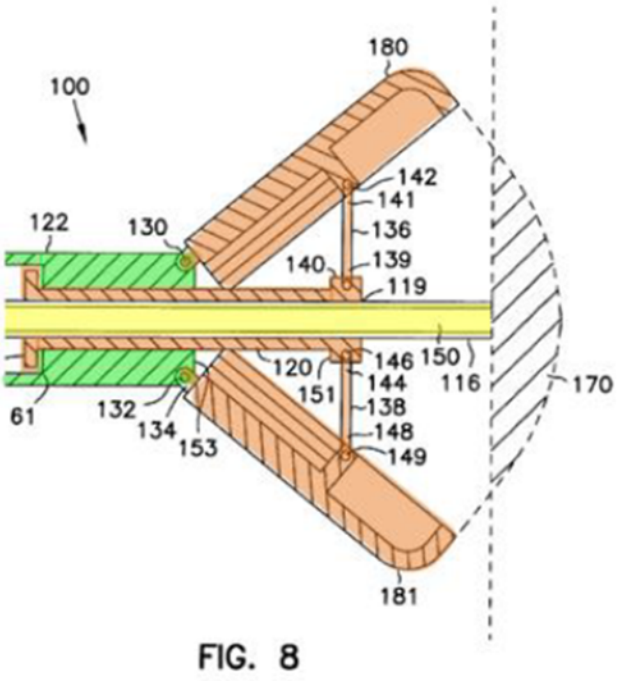


FIG. 8

Petitioner's highlighted Figure 8 of Nishioka showing control wire in yellow allegedly coupled to support block 122 in green.

Petitioner's arguments are persuasive because the control wire (optical fiber 150) directly controls the actuation of jaws 180 and 181. We find especially persuasive the description of the Figure 8 Embodiment of Nishioka that "[t]he optical biopsy forceps further includes a tubular slide member 120 *connected to the optical fiber and movable therewith*, and *coupled to the jaws 180 and 181 for actuating the jaws 180 and 181 as the optical fiber is moved* within the outer sheath 110." Ex. 1005, 7:3–7 (emphases added). The argument that the intermediate structures do not allow for coupling (linking or joining) between the optical fiber 150 and the jaws and block 122 is not persuasive because Nishioka describes each of these intermediate structures as "connected to" or "coupled to" the next, such that optical fiber 150 actuates jaws 180 and 181.

Patent Owner did not use claim language such as "directly coupled to"

or similar language to preclude intervening structures. *But cf. Immersion Corp. v. Samsung Elecs. Am., Inc.*, No. 2:17-CV-572-JRG, 2018 WL 5005791, at *8 (E.D. Tex. Oct. 16, 2018) ("Defendants have submitted persuasive evidence that 'directly' refers to the absence of intervening structures."). Further, Patent Owner has cited no authority for the proposition that "coupled to" requires two structures be "directly coupled to" one another without intervening structure, and we will not read in this additional requirement.

In summary, we find Petitioner's contentions persuasive as to this claim 12 limitation because optical fiber 150 (control wire) is connected to and movable with tubular slide member 120, which, in turn, is coupled to jaws 180 and 181 for actuating jaws 180 and 181 as the optical fiber is moved. Ex. 1005, 6:60–64, 7:3–32. As such, Petitioner has sufficiently shown on this record that Nishioka discloses the control member limitation of claim 12 as well as all remaining limitations of claim 12. *See* Pet. 59–60.

3. Claim 15

Claim 15 depends from claim 12 and further requires "wherein a proximal end of the clip includes an opening formed to receive a control wire." Ex. 1033, 16:49–51. Petitioner contends, that "[a]s shown below in annotated Figures 2 and 8, Nishioka discloses in two embodiments the control wire (. . . 150 (Figure 8)) is received through an opening formed in a proximal end of the clip (opening indicated in red).

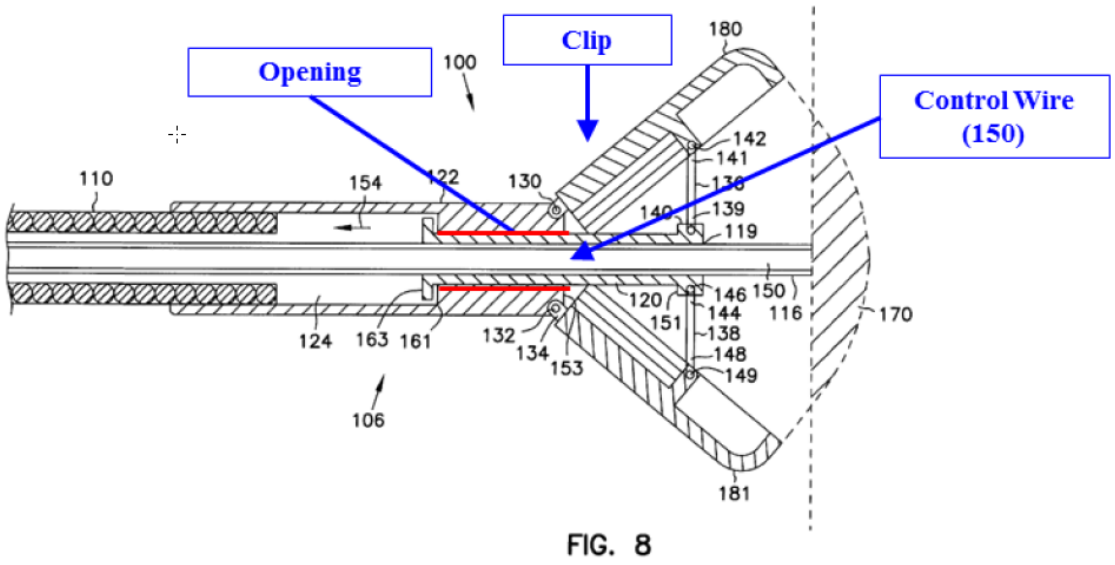


FIG. 8

Petitioner's annotated Nishioka Figure 8 (Pet. 61) depicting a purported opening in the clip as marked with red lines.

Patent Owner takes issue with this assessment because "the highlighted portion is not an opening formed in the cutting jaws themselves because the cutting jaws are not connected to one another." PO Resp. 53. According to Patent Owner, "the cutting jaws do not have an integral proximal end through which the claimed 'opening' could be formed," and, as such, "the portion of Figure 8 highlighted in red is actually an opening formed in the jaw support block 122." *Id.* Patent Owner contends that because "the cutting jaws are not directly connected to one another," that they "do not have an integral proximal end through which the claimed 'opening' could be formed." *Id.* at 53. Notably, the term "integral" does not appear in claim 12 or claim 15.

Petitioner responds in its Reply that "claim 15 does not require a 'single, integral structure,'" but instead, "claim 15 merely requires an 'opening' in the 'proximal end of the clip.'" Pet. Reply 27. According to Petitioner, additional structures besides jaws 180, 181 comprise the clip in

Nishioka because additional structures help the jaws apply the pinching pressure. *Id.* Petitioner contends that "the clip arms, by themselves, are not 'capable of applying a pinching pressure,'" but instead, "Nishioka's 'clip' includes *additional* structures that allow the clip arms to apply a pinching pressure, including at least support block 122." Id. at 27–28 (citing Ex. 1041 ¶ 82; Ex. 1096 ¶ 49). Further, it is apparent that Nishioka's support block 122 (located at the proximal end of the structures that make up the "clip") has an opening and control wire (150) is received through this opening. *Id.* at 28.

As to these arguments, Petitioner has the more persuasive position. Patent Owner attempts to frame the issue as to whether Nishioka discloses "an integral proximal end," but such a claim limitation is not required. Petitioner has presented a sufficiently persuasive analysis showing that support block 122 is coupled to and thus operationally part of the "clip" along with jaws 180, 181. Nishioka's support block 122 is located at the proximal end of the structures that make up the "clip" and it has an opening such that the control wire (150) is received through this opening.

4. Claims 2, 3, 10, 11, 13, 14, 16, and 18

Petitioner contends that each of the limitations of remaining claims 2, 3, 10, 11, 13, 14, 16, and 18 are disclosed by elements of Nishioka. *See* Pet. 55 ("Nishioka discloses the opening element comprises first and second link arms (40, 41 (Figure 2), 136, 138 (Figure 8)) engaging the inner surfaces of the first and second clip arms (. . . 180, 181 (Figure 8)"), Pet. 56 (showing axial alignment of link arms), Pet. 57, 60, 62–64.

We have considered Petitioner's evidence and arguments for each of these claims and find them persuasive. *See* Pet. 55–64. Further, Patent

Owner has not offered any persuasive argument to rebut Petitioner's contentions. We therefore determine that Petitioner has established by a preponderance of the evidence that claims 2, 3, 10, 11, 13, 14, 16, and 18 would have been anticipated by Nishioka.

F. Claims 1–3, 10–16, and 18 as Obvious in view of Nishioka alone, or in combination with Sackier

Petitioner asserts that Nishioka teaches all elements of these claims, or, in the alternative, that Nishioka and Sackier in combination teach each limitation. Pet. 65–69. Petitioner contends "[t]o the extent the forceps and jaws disclosed in Nishioka are not considered a 'clip' and 'clip arms' because they are designed to cut, rather than clamp tissue, claim 1 still would have been obvious to a person of ordinary skill in the art." *Id.* at 67. "Alternatively," Petitioner contends "it would have been obvious to substitute the Nishioka jaws with any one of the various clip arms known in the art," such as "the Nishioka cutting jaws with the Sackier clip arms (36a, 38a)." *Id.* Petitioner argues that "[a] person of ordinary skill in the art would have been motivated to make this modification, for example, so that the Nishioka devices were able to clamp, rather than cut, tissue." *Id.* at 68 (citing Ex. 1041 ¶ 89).

Because we determined above that Nishioka anticipates claims 1–3, 10–16, and 18, we likewise determine based on the record before us that Nishioka teaches each limitation of claims 1–3, 10–16, and 18 for purposes of obviousness. More specifically, the Parties have not presented any additional evidence as to the *Graham* factors, such as secondary considerations, that would impact our decision as to obviousness. Likewise, because Petitioner has framed this ground as an alternative ground (Pet. 67),

and because we are confident in our broadest reasonable interpretation of the term "clip" (*see* Ex. 1033, 15:9–12), we determine it unnecessary to reach the Parties contentions as to the combinability of Nishioka and Sackier.

Petitioner has established by a preponderance of the evidence that claims 1–3, 10–16, and 18 would have been obvious over Nishioka.

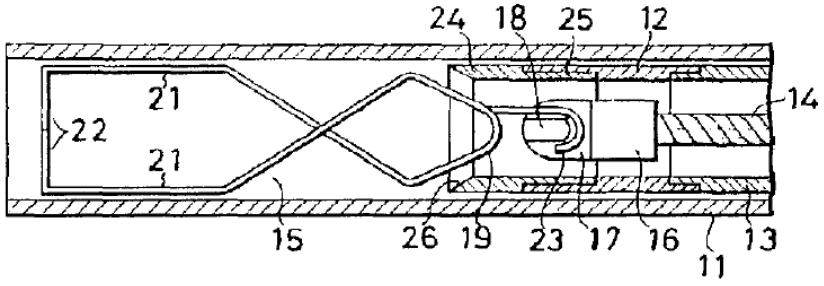
G. Claims 1–4, 6–10, 12–14, and 20 as Obvious in view of Shinozuka in Combination with Sackier or Nishioka

Petitioner contends claims 1–4, 6–10, 12–14, and 20 are unpatentable, under 35 U.S.C. § 103 as obvious over Shinozuka in combination with Sackier or Nishioka. Pet. 70–94.

1. Overview of Shinozuka (Ex. 1009, 1042)

Shinozuka is directed to a "Biotissue Clip Device." Ex. 1042, 10.[6] The clip is said to be detachably coupled to a control cord. *Id.* at 11. Nishioka is relied upon for the description discussed above. Figure 2 of Shinozuka is reproduced below:

第 2 図



Shinozuka Figure 2 is a sectional side view of a distal end. Ex. 1042, 12.

[6] We cite to the translation provided as an exhibit to the Declaration of the translator. Ex. 1042 (also removing "000" preceding each page number). The original reference, Ex. 1009, includes the Figures.

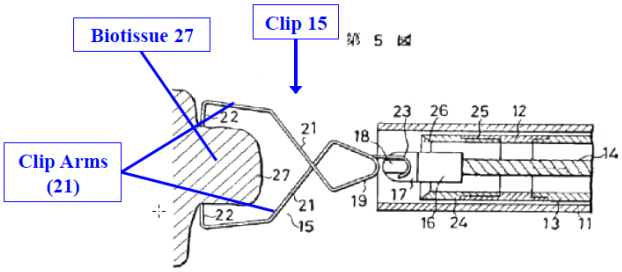
Figure 2 illustrates the clip device of Shinozuka, including insertion tube 11, control tube 13, control wire 14, and hook 16 for detachably engaging with clip 15. *Id.* at 11.

2. Claims 1, 4, 6, 7, 9, 10, 12, 20

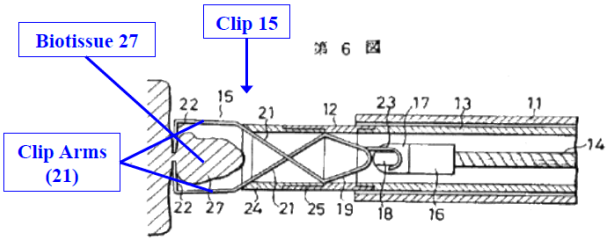
Petitioner persuasively shows how each limitation of these challenged claims is taught by the combination of Shinozuka and Sackier.[7] Pet. 70–94; Supp. Reply 27–34.

Petitioner demonstrates that Shinozuka discloses a medical device known as a "biotissue clip device." Ex. 1009 (1042), title, 261–63. Petitioner relies on Figures 5 and 6 (annotated) of Shinozuka "having first and second clip arms (arm parts 21), moveable between an open tissue receiving configuration (Figure 5) . . . and a closed configuration (Figure 6) in which the first and second arms are moved inward to capture the tissue." Pet. 70.

[7] Because Petitioner presents this ground in the alternative – Sackier or Nishioka – we exercise our discretion to address only Shinozuka and Sackier, which we believe to be Petitioner's strongest position.



Shinozuka, Figure 5 (Annotated)



Shinozuka, Figure 6 (Annotated)

Annotated Figures 5 and 6 of Shinozuka with clip 15 engaging biotissue 27.

Below, we focus our analysis on those limitations and issues contested by Patent Owner. For each limitation not contested by Patent Owner, we have examined Petitioner's evidence and argument and find it persuasive based on the final record.

Opening Element

Independent claims 1, 12, and 20 each require an "opening element" as discussed in the claim construction analysis above. Petitioner notes that Shinozuka discloses that clip 15 has an opening bias so that it tends to open, but "[a]part from this opening bias, Shinozuka does not explicitly disclose a separate structure in the form of an opening element[8] for urging the clip arms away from one another." Pet. 72. Petitioner relies on either Sackier or Nishioka to teach clips with opening elements to combine with Shinozuka.

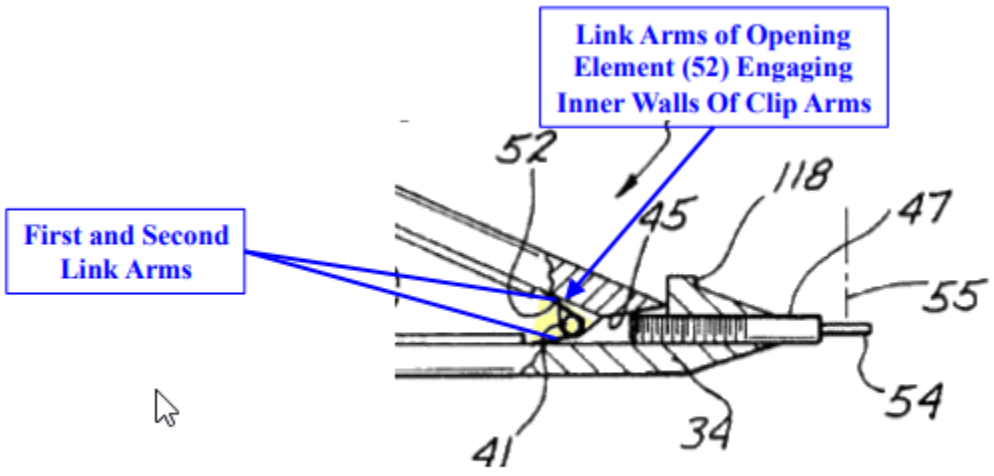
[8] Each independent claim requires an "opening element." Ex. 1033, 15:45, 16:32, 17:4.

Id. at 72–73. Petitioner addresses the motivation to combine Nishioka with Sackier or Nishioka at pages 74–77 of the Petition. Petitioner contends "[i]t would have been obvious to modify clip 15 of Shinozuka to include an opening element, as described in either Sackier or Nishioka, to assist in urging open the Shinozuka clip arms (21)." *Id.* at 74. Petitioner, with the support of Dr. Nicosia, argues "[a] person of ordinary skill in the art would have considered this modification to be a matter of routine skill in the art, using simple mechanical elements disclosed in Shinozuka, Sackier, and Nishioka to achieve predictable results." *Id.* at 74–75 (citing Ex. 1041 ¶ 98).

Patent Owner first argues that Shinozuka, Sackier, and Nishioka do not disclose, teach, or suggest "an opening element engaging inner walls of the first and second clip arms." Supp. Resp. 48. The Parties agree that Shinozuka does not teach this opening element, but Petitioner relies on Sackier or Nishioka to teach an opening element added to Shinozuka. Patent Owner then alleges that Sackier and Nishioka do not teach an opening element for reasons previously argued. *See id.*

In our prior analysis in this Decision, we determined that spring 52 in the second Sackier embodiment does appear to contact the inner walls of the jaws and act to drive them apart. *See* Ex. 1008, Figure 2. For purposes of this analysis, we adopt our prior reasoning and focus on this second Sackier embodiment (Figure 2) with spring 52 combined into Shinozuka. As to the "opening element" limitation being taught by the combination of Shinozuka and Sackier, we find persuasive Dr. Nicosia's testimony that that "it would have been obvious to modify Shinozuka to include a spring (e.g., spring 52), and to engage the link arms of the spring (i.e., the linear arms of the spring) with the inner walls of the Shinozuka clip arms (21), as disclosed in Sackier

(see annotated Figure 2, below)." Ex. 1041 ¶ 98; Supp. Reply 27–28.



Excerpt of Sackier Figure 2

Petitioner's annotated Figure 2 of Sackier depicting spring 52 highlighted in yellow. Supp. Reply 27; Pet. 73.

Accordingly, we find Patent Owner's argument that the combination of Shinozuka and Sackier fails to teach the "opening element" limitation unpersuasive.

Patent Owner challenges the rationale for combining the references. Supp. Resp. 54–58. Patent Owner asserts that a person of ordinary skill would not have combined Shinozuka with Sackier or Nishioka because Petitioner's proposed modifications would be redundant and unnecessary. *Id.* Patent Owner elaborates:

> The purpose of the opening element, per Petitioners' proposed construction, is to "urge[] [the inner walls of the clip arms] away from one another." *Id.*, 14. Shinozuka's clip has an "opening bias so that [it] tend[s] to open the pinching parts 22." Ex. 1009, 1009-00006. In Sackier, spring 52 is used to "bias the jaws 36 and 38 to the open position." Ex. 1008, 5:4-5. Thus, spring 52 is entirely redundant of the bias already in the Shinozuka clip. Likewise, using the control links 136, 138 of Nishioka as an opening element to "move the jaws apart" (Ex. 1005, 8:34-35) is

> redundant of the opening bias of the Shinozuka clip. Ex. 2103 ¶129.

Id. at 54. As explained by Dr. Vaitekunas, "[t]he purported opening elements from Sackier and Nishioka would accomplish the same function that is already provided through Shinozuka's opening bias." Ex. 2103 ¶ 131. Because Petitioner's primary rationale for the combination is to assist in urging open the Shinozuka clip arms, Patent Owner reasons that the combination is "hindsight driven, illogical motivation." Supp. Resp. 54.

Addressing Petitioner's contentions, Patent Owner asserts that Petitioner's rationale of allowing the clip arms to open wider is not supported because Petitioner fails to explain why a person of ordinary skill in the art would want to open Shinozuka's clip arms wider and why the clip of Shinozuka does not open wide enough as disclosed. *Id.* at 54–55. As further support, Patent Owner points out that "the Shinozuka clip and its bias are created by bending the wire comprising the clip," so "[e]ven if a POSA wanted the Shinozuka clip to open wider, Petitioners fail to explain why a POSA would not simply change the bended configuration of the clip to create wider pinching parts." *Id.* at 55 (citing Ex. 1009, 1009-00006; Ex. 2103 ¶ 132[9] ("a POSITA would not add Sackier's spring 52 and Nishioka's control links, which would require additional components and therefore increase the cost of the device, when the bended configuration of the Shinozuka clip could be widened to create wider pinching parts")).

In its Supplemental Reply, Petitioner further contends a person of ordinary skill in the art "would have been motivated to make the proposed

[9] Patent Owner actually cites to ¶ 130, but apparently its citations are off by two.

modifications to increase the functionality of Shinozuka's clip," and improve the clip "'to provide more force to urge open [Shinozuka's] clip arms . . . permitting the clip arms to open wider than without an opening element,' and 'to provide a wider range of open tissue receiving configurations.'" Supp. Reply 29 (quoting Ex. 1041 ¶ 100). Petitioner contends that the proposed combination "would enable a wider range of clip opening widths, without having to modify the size or geometry of the clip." Supp. Reply 30. A wider opening, according to Petitioner, would "accommodate a larger variation in tissue size and thickness." *Id.*

Patent Owner's argument is persuasive because Shinozuka's clip arms are already biased. Petitioner's stronger theory is that a biasing mechanism and spring are simply interchangeable, as would be known to a person of ordinary skill in the art. For example, Dr. Nicosia also explains that "[a] person of ordinary skill in the art would have considered this modification to be a matter of routine skill in the art, using simple mechanical elements . . . to achieve predictable results." Ex. 1041 ¶ 98. Although Petitioner presents plausible reasons why Shinozuka's performance could be improved ("would increase the functionality of Shinozuka's clip," Ex. 1110 ¶ 26), we believe it more persuasive to recognize that Shinozuka already has an acceptable biasing mechanism to open the clip arms, but Petitioner has shown that substituting a known alternative that would work equally as well is within the skill set of an ordinary artisan. As Dr. Nicosia testifies, a person of ordinary skill in the art, "would have recognized that Sackier's spring is a simple mechanical device (a torsion spring), with well-known and predictable spring properties, (characterized by standard mechanical design formulas taught in undergraduate-level engineering courses)." Ex. 1110

¶ 28. Thus, although Dr. Nicosia provides some support for the theory that Sackier's "opening elements also would enable a wider range of clip opening widths, without having to modify the size or geometry of the clip," we are more persuaded by the testimony that a torsion spring would have predictable spring properties that could be substituted for the natural bias spring action of Shinozuka's clip arms.

We have also considered Patent Owner's contentions that the proposed combination would change how Shinozuka's clip detaches. *See* Supp. Resp. 55–60, 55 ("[A] POSA would not modify Shinozuka using Sackier or Nishioka because they are contrary to the express purpose of Shinozuka, which was to create a clip that detached from the control wire in two directions."). Patent Owner notes that Sackier Figures 15–17 do not disclose a separable link. Supp. Resp. 55. We do not find that point persuasive because Petitioner is relying on the use of spring 52 from Sackier Figure 2, and Patent Owner does not explain how this spring would hinder detachment. Further, the remaining Patent Owner arguments as to this issue relate to Nishioka, and not Sackier. *See* Supp. Resp. 56–58.

Based on the final record, we are persuaded by Petitioner's showing that a person of ordinary skill would have looked to opening elements of Sackier to assist in urging open the Shinozuka clip arms. Thus, 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 Shinozuka. Accordingly, Petitioner has demonstrated by a preponderance of the evidence that claims 1, 12, and 20 would have been obvious over Shinozuka and Sackier.

Petitioner's analysis further demonstrates where each limitation of

dependent claims 4, 6, 7, 9, and 10 is found in the Shinozuka and Sackier combination. Pet. 70–94; Supp. Reply 27–34. As to each of these claims and limitations, we have considered Petitioner's evidence and find it persuasive. Patent Owner has not presented any argument contesting Petitioner's showing for these claims. *See* Supp. Resp. 58. In this regard, the record now contains persuasive arguments and evidence presented by Petitioner, which are unrebutted. We determine that 4, 6, 7, 9, 10, and 13 would have been obvious over Shinozuka and Sackier. Below, we examine the remaining dependent claims specifically challenged by the Patent Owner.

3. Claim 2 and Claim 13

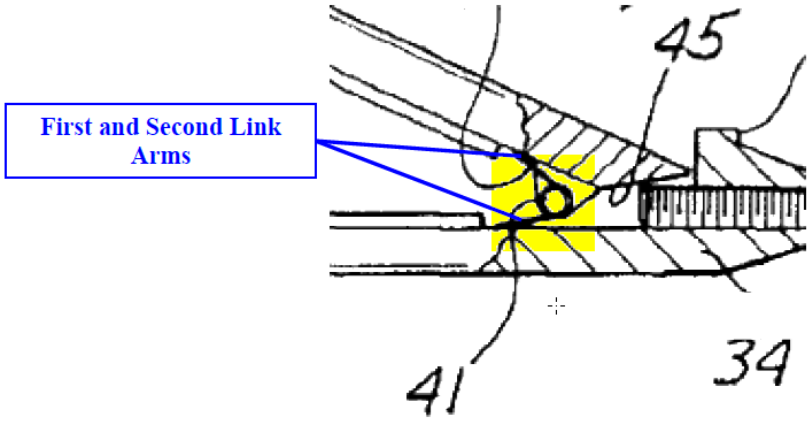
Claim 2 requires "the opening element comprises first and second link arms engaging the inner surfaces of the first and second clip arms." Ex. 1033, 15:53–55. Claim 13 has a similar requirement. Petitioner again relies on Sackier's spring with link arms that engage the inner walls of the clip arms as depicted in Figure 2 of Sackier. Pet. 75. Patent Owner addresses claim 2 separately, but Patent Owner relies on its arguments that were previously made with respect to claim 1. *See* Supp. Resp. 59, 63. For the reasons set forth above, we find Patent Owner's contentions unpersuasive. Petitioner has demonstrated by a preponderance of the evidence that claims 2 and 13 would have been obvious over Shinozuka and Sackier.

4. Claims 3 and 14

Claim 3 depends from claim 1 and requires "wherein when the clip is in the open tissue receiving configuration, the first and second link arms are axially aligned with one another." Ex. 1033, 15:53–55. Claim 14,

dependent from claim 12, has the same claim requirement. *Id.* at 16:46–48.

Petitioner contends that "this claim would have been obvious in view of Sackier, for the reasons in Section V.B.1, supra at pp. 39-40 and V.E.1.c, supra at pp. 72-77. (Ex. 1041, ¶102)." Pet. 77–78. Turning to pages 39–40, Petitioner examines only why it would be obvious to make Sackier's link arms axially aligned for the clip arms of Sackier. *See* Pet. 39. This analysis does not address the impact of making these same link arms axially aligned in Shinozuko's structure, which is distinct from Sackier's clip. As depicted below, making the highlighted spring arms axially aligned even in the Sackier embodiment of Figure 2 would have significant design implications, forcing the jaws to open to nearly a 180 degree angle. *See* Ex. 2103 ¶¶ 104, 105. Petitioner chose not to address the impact of inserting axially aligned spring arms into Shinozuka.



Excerpt of Figure 2

Petitioner's annotated Figure 2 depicting a spring with first and second link arms highlighted in yellow. Pet. 39.

Notably, Sackier does not teach or suggest axial alignment of the link arms of spring 52. As stated by Patent Owner, "Petitioners do not argue the arms of spring 52 are axially aligned and point to no disclosure in Sackier of any

axially aligned arms." Supp. Resp. at 40; Ex. 2103 ¶ 105. Because Petitioner does not address how or why axially aligned link arms would be incorporated specifically into Shinuzuko, Petitioner has not shown by a preponderance of the evidence that a person of ordinary skill in the art would have been able to make the design modifications necessary to incorporate such a structure into Shinozuka, or that a person of ordinary skill in the art would have been motivated to do so in the first instance.

When given a chance in reply to address how axially aligned link arms, which are not even disclosed in Sackier, could be integrated into Shinozuka, Petitioner again incorporates its prior analysis involving Sackier alone. Supp. Reply 32. Thus, even if Petitioner had established that axial alignment of the link arms was possible for Sackier's link arms within Sackier's clip, this showing alone is not persuasive as to how Sackier's axially aligned link arms would integrate into Shinozuka.

Petitioner's analysis of Nishioka integrated into Shinozuka suffers the same shortcoming of failing to provide any analysis as to how or why a person of ordinary skill in the art would integrate Nishioka's control links 136 and 138 (which are "rigid members" Ex. 1005, 8:14) into Shinozuka's clip arms. *See* Supp. Resp. 59, 57. Petitioner does not provide any analysis as to how or why Nishioka's axially aligned link arms could be separately integrated into Shinozuka. *See* Pet. 77, 88.

Petitioner has not demonstrated by a preponderance of the evidence that claims 3 and 14 would have been obvious over Shinozuka and Sackier, or over Shinozuka and Nishioka.

5. Claim 8

Claim 8 requires "wherein application of a proximal tensile force

greater than the predetermined threshold value causes the control wire to disengage from the clip." Ex. 1033, 16:4–6.

Petitioners propose Shinozuka meets the limitations of Claim 8 because the control wire can disengage from the clip by "jiggling" the wire so that hook 16 comes off claw 23. Pet. 82.

Patent Owner contends that Shinozuka's "jiggling" does not meet the limitations of Claim 8 because:

> The "application of proximal tensile force" requires pulling the control wire. *See, e.g.*, Pet., 33. Thus, "jiggling" does not constitute an "application of proximal tensile force." *See, e.g.*, Ex. 2006, 4 (defining "jiggle" as "to jerk lightly up and down"); Ex. 2103 ¶139.

Supp. Resp. 60. Petitioner offers no persuasive rebuttal in reply as to why "jiggling" could be considered application of a proximal tensile force. *See* Supp. Reply 33 (citing only to arguments related to Sackier for claim 8).

We are not convinced that Petitioner has proven by a preponderance of the evidence that Shinozuka teaches "application of a proximal tensile force greater than the predetermined threshold value causes the control wire to disengage from the clip" as required by claim 8. Shinozuka discloses:

> Here, when the control wire 14 is pushed well out and then the control wire 14 is jiggled, the hook 16 on it comes off the claw 23 of the clip 15. At this time, as explained above, the hook 16 comes off the claw 23 not just in one direction but in either of the two directions a and b. And of course, it will also come off in any direction between the two directions a and b. Consequently, it comes off easily.

Ex. 1042, 12, col. 1. Figure 3 of Shinozuka refers to axis "a" and "b" as depicted below.

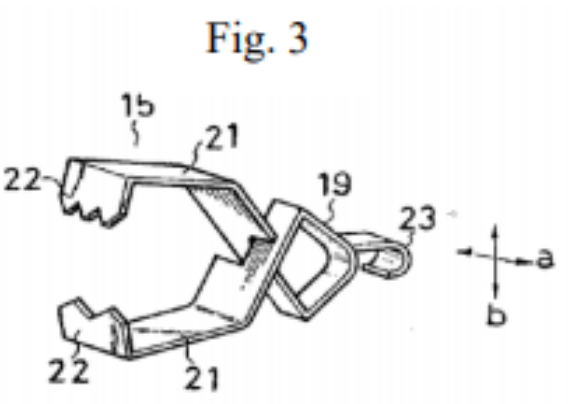


Figure 3 of Shinozuka showing a clip and including an "a-b" reference axis. Ex. 1042, 13, Fig. 3.

As seen in Figure 3, the application of the jiggling force will move claw 23 in either the "a" or "b" direction, but movement in these directions would not apply a proximal tensile force. The movement in the "a" or "b" direction or a combination of these directions allows for the claw to essentially be "jiggled" or shaken off, but not pulled by a tensile load. Accordingly, Petitioner has not shown that Shinozuka teaches an "application of a proximal tensile force greater than the predetermined threshold value causes the control wire to disengage from the clip," as recited in claim 8.

Petitioner separately argues that Shinozuka could be modified to include the ball and socket connection from Sackier Figures 15–17. Pet. 83–84 ("Sackier discloses engaging a control wire (58a) and clip (10a) via a ball (ball 163) and socket (cylinder 174 (with flange 176)) connection, such that application of a proximal tensile force greater than the predetermined threshold value (i.e., pulling on the control wire) causes control wire to disengage from the clip.").

Patent Owner responds that Petitioner's proposed modification to include the ball and socket connection from Sackier into Shinozuka would not work because Sackier's clamp is not detachable through the application

of a proximal tensile force. *Id.* "Thus, Petitioners' proposed modification would not allow Shinozuka's clip to disengage through the use of a proximal tensile force. Ex. 2103 ¶ 140." *Id.*

We also agree with Patent Owner's contentions as they relate to Sackier. As we have previously decided, Sackier's existing ball and socket clamp is not detachable through the application of a proximal tensile force. *See* IPR2017-00135, Paper 82, 46 (Nov. 15, 2018) ("[W]e 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."). Our detailed reasoning is set forth in the Final Decision in IPR2017-00135. Specifically, Petitioner does not persuasively establish that the structure disclosed in Sackier Figures 15–17 would allow for a separable ball and socket through application of a tensile force. Further, Petitioner has not persuasively shown how Sackier's ball and socket connection would be compatible with a J-hook arrangement. For these reasons, we determine that Petitioner has not proven by a preponderance of the evidence that Sackier teaches "application of a proximal tensile force greater than the predetermined threshold value causes the control wire to disengage from the clip" as required by claim 8. *See id.* 36–50.

Petitioner has thus not shown by a preponderance of the evidence that claim 8 would have been obvious over the combination of Shinozuka and Sackier or Shinozuka and Nishioka.

IV. MOTIONS TO EXCLUDE

Petitioner filed a Motion to Exclude (Paper 60) certain evidence submitted by Petitioner, to which Patent Owner filed an Opposition (Paper 65).

Patent Owner filed a Motion to Exclude (Paper 45) certain evidence submitted by Petitioner, to which Petitioner filed an Opposition (Paper 52), and Patent Owner filed a Reply (Paper 66).

Patent Owner filed a second Motion to Exclude (Paper 81), which sought to exclude certain evidence submitted by Petitioner, to which Petitioner filed an Opposition (Paper 85), and Patent Owner thereafter filed a Reply (Paper 86).

a. Petitioner's Motion to Exclude

Petitioner filed a Motion to Exclude Exhibit 2100 (Paper 60), to which Patent Owner filed an Opposition (Paper 65). Exhibit 2100 is a journal article, titled "Effect of Laparoscopic Grasper Force Transmission Ratio on Grasp Control." Ex. 2100. Petitioner contends that "Exh[ibit] 2100 was not cited in the Petition, Response, or Reply (or Motion to Amend briefing), or by any of the Parties' experts." Paper 60, 1.

Patent Owner responds that it "introduced Exhibit 2100 in response to new opinions offered in the sur-reply declaration of Petitioners' expert that supporting structure 34a must contact slide 47a before inner shaft 58a can be disconnected," thus, "Sackier jaws will always completely close." Paper 65, 1 (citing Ex. 1101 ¶ 70).

We have not considered Exhibit 2100 in our Final Decision. Exhibit 2100 is cited in Patent Owner's Contingent Motion to Amend. Because Exhibit 2100, and corresponding testimony it purportedly responds to, all

relate to Petitioner's Opposition to Patent Owner's Contingent Motion to Amend, and because we do not rely on Exhibit 2100, we deny Petitioner's Motion to Exclude (Paper 60) as moot.

b. Patent Owner's Motions to Exclude

First Motion

Patent Owner filed a first Motion to Exclude (Paper 45) certain evidence submitted by Petitioner, to which Petitioner filed an Opposition (Paper 52), and Patent Owner filed a Reply (Paper 66). Patent Owner seeks to exclude Exhibits 1009, 1010, 1017, 1035, 1036, 1038, 1039, 1041, 1070, 1071, 1072, 1073, 1074, 1075, and 1084. *See* Paper 45, 1–2.

We discuss the exhibits challenged in Patent Owner's motions, below. We first note that we do not rely on Ex. 1017 and therefore deny Patent Owner's motion as moot as it relates to this exhibit.

Exhibits 1009 and 1010

Patent Owner's request to exclude these exhibits is denied because grounds originally denied were later instituted.

Exhibits 1035, 1036, 1038, and 1039

Exhibits 1035, 1036, 1038, and 1039 relate to claim construction positions in the district court proceeding of *Boston Scientific Corp. v. Cook Group Inc.*, No. 15-980-LPS-CJB (D. Del.). Patent Owner argues these exhibits should be excluded as irrelevant under FRE 402.

We deny Patent Owner's request to exclude these exhibits. Notably, Patent Owner does not convey persuasive reasons why these exhibits would not be relevant and we are persuaded that claim construction positions taken by a party concerning the same patent and same claims being challenged are relevant to this proceeding. Paper 45, 3–4.

Exhibit 1041

Patent Owner's motion to exclude portions of Exhibit 1041 is denied because the grounds based on Shinozuka that were originally denied are now part of this proceeding.

Exhibits 1070, 1071, 1072, 1073, 1075, and 1084

As regards to Exhibits 1070, 1071, 1072, 1073, 1075, and 1084, Patent Owner asserts that these exhibits should be excluded as irrelevant under FRE 402, and even if relevant, subject to exclusion under FRE 403. Objections were timely made on January 19, 2018 in Paper 35 at II(B). Paper 45, 6.

Patent Owner observes that Exhibit 1070 is an article by DeBeer, entitled "Colonic lipomas, An endoscopic analysis," Gastrointestinal Endoscopy, Volume 22, No. 2 (1975). Patent Owner asserts that Petitioners cite Exhibit 1070 on page 7 of the Reply Brief (Paper 31) and in paragraph 17 of Nicosia's Reply Declaration (Ex. 1096), seeking to rely on DeBeer's description of biopsy forceps allegedly being used to "grasp and 'pull[] up' mucosa in the body, causing the mucosa to 'tent[] away' from underlying tissue mass." Paper 45, 6 (quoting Pet. Reply 7). Patent Owner urges that Exhibit 1070 is irrelevant because the article describes biopsy forceps other than the Nishioka biopsy forceps. *Id.* at 7.

The remaining exhibits are a similar article (Ex. 1071), patent (Ex. 1072), medical label (Ex. 1073), and product brochures (Exs. 1075, 1084). Petitioner contends that each exhibits is "relevant to BSSI's assertion that biopsy forceps (and, in particular, the biopsy forceps described in U.S. Patent No. 5,843,000 (Ex.1005 ('Nishioka')) are not 'clips.'" Paper 52, 9.

Petitioner observes that Patent Owner made the argument through Dr. Vaitekunas "that 'cutting and pinching tissue are mutually exclusive,' (*id*. at 31), and that the mere fact that Nishioka's biopsy forceps are sharp, serrated, and meshing "makes [Nishioka's] jaws unsuited for pinching tissue using a compression force." *Id.* at 10. These exhibits, along with the others, were presented to establish that "contrary to BSSI's and Dr. Vaitekunas' assertions, biopsy forceps with sharp, meshing, and serrated jaws are capable of pinching and compressing tissue (including causing hemostasis). *Id.*

Patent Owner replies that these exhibits relate to a different forceps, and are therefore irrelevant. Paper 66, 3.

We do not find that these exhibits, especially Exhibits 1070 and 1071 cited in our analysis, are irrelevant. Each was introduced to support the Petitioner's argument raised to counter the general statement made by Patent Owner that cutting and pinching are mutually exclusive. As Patent Owner placed the end use of the forceps into play in the first instance, in our view it is only fair that Petitioner could raise evidence to counter that proposition. Accordingly, this motion is denied as to Exhibits 1070, 1071, 1072, 1073, 1074, 1075, and 1084.

Exhibit 1074

Patent Owner argues that "Exhibit 1074, the Decision Instituting IPR in IPR2017-00134, should be excluded as irrelevant under FRE 402." Paper 45, 9. We will not necessarily exclude our own initial determination in a related IPR proceeding. We are well aware that initial decisions are preliminary in nature, and we are capable of weighing these decisions as appropriate. Further, IPR2017-00134 has now gone to final decision (Nov.

3, 2018, Paper 92), and, as such, the final decision supersedes any preliminary determinations. Patent Owner's request to exclude is denied.

Patent Owner's Motion to Exclude (Paper 45) is denied.

Second Motion

Patent Owner filed a second Motion to Exclude (Paper 81), which sought to exclude certain evidence submitted by Petitioner, to which Petitioner filed an Opposition (Paper 85), and Patent Owner thereafter filed a Reply (Paper 86). Patent Owner requests that the Board exclude Petitioners' Exhibits 1111 and 1118. Paper 81, 1.

Exhibit 1111

Exhibit 1111 is a June 21, 2018, Amendment from the prosecution records of U.S. Application No. 15/009,358 ("Adams Application"), submitted to the Patent Office by Patent Owner. The Adams Application and the '731 patent each claim priority to the same parent application (U.S. Application Serial No. 09/971,488), and share the same drawings and written description. Ex. 1111, 2. In addition, the Adams Application claims similar subject matter claimed as that claimed in the '731 patent and uses many of the same claim terms. See *id.* at 7 ("Claims 46–65 stand rejected on the ground of nonstatutory obviousness-type Double Patenting as being unpatentable over claims 1–20 of U.S. Patent No. 9,271,731.")). Petitioner relies on Exhibit 1111 for Patent Owner's purported admission that "Nishioka discloses control wires with 'distal end[s] being coupled to inner surfaces' of the jaws." Supp. Reply 28.

Patent Owner contends that "Exhibit 1111 is not relevant, however, for the purposes of determining whether Nishioka discloses an 'opening element engaging inner walls of the first and second clip arms' as required

by the '731 Patent in this proceeding." Paper 81, 2. Patent Owner contends Exhibit 1111 "is irrelevant because it is not the file history for the '731 Patent that is at issue in this proceeding," and because "Patent Owner's remarks were directed towards an amended claim that does not recite that the opening element engages 'inner walls.'" *Id.*

We determine that Exhibit 1111 is relevant to a key recurring issue raised by Patent Owner in this proceeding, and in related IPR2017-00133 and IPR2017-00134: whether Nishioka's opening element (or linkage) engages (or contacts) "inner walls" (or "inner surfaces") of Nishioka's jaws. *See* Paper 85, 2. Although we did not specifically discuss Exhibit 1111 in our analysis, we did consider it in the totality of the evidence before us, and these statements by patent counsel related to Nishioka before the Office are relevant and probative. For Patent Owner to take inconsistent positions (on June 21, 2018, during the heart of this proceeding) regarding Nishioka in a related patent prosecution is evidence we consider. We do not treat these patent counsel arguments as admissions of fact, especially considering that the claim language is not identical. We are also mindful of the nature of prosecution and that patent counsel was arguing different claim limitations to differentiate Nishioka in that related proceeding. Regardless, counsel made such arguments as to evidence being considered in this proceeding and therefore Exhibit 1111 is admissible.

Although Patent Owner seeks to exclude Exhibit 111, we considered Exhibit 1111 and still decided in Patent Owner's favor that the Figure 2 embodiment of Nishioka did not disclose "an opening element engaging inner walls of the first and second clip arms" as required by the independent claims.

Exhibit 1118

Exhibit 1118 is the Preliminary Response in IPR2017-00135. Patent Owner contends that Exhibit 1118 should be excluded under FRE 403. Paper 81, 3. We will not exclude our own initial determination in a related IPR proceeding. We are well aware that initial decisions are preliminary in nature, and we are capable of weighing these decisions as appropriate. Further, IPR2017-00135 has now gone to final decision (Nov. 15, 2018, Paper 82), and, as such, the final decision supersedes any preliminary determinations. Patent Owner's request to exclude is denied.

Patent Owner's Motion to Exclude (Paper 81) is denied.

V. PATENT OWNER'S CONTINGENT MOTION TO AMEND

As discussed above, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1, 12, and 20 are unpatentable. As we find claims 1, 12, and 20 to be unpatentable, we address Patent Owner's Contingent Motion to Amend. Paper 17, "Amend Mot." The Motion seeks to replace unpatentable claims 1, 12, and 20 with substitute claims 21, 30, and 38 and thereafter change the dependency of other claims to depend from the new substitute claims. *Id.* at 1. As discussed below, we deny the Motion to Amend.

a. Analysis of the 37 C.F.R. § 42.121 Requirements

In an *inter partes* review, amended claims are not added to a patent as of right, but rather must be proposed as a part of a motion to amend. 35 U.S.C. § 316(d). The Board must assess the patentability of proposed substitute claims "without placing the burden of persuasion on the patent owner." *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1328 (Fed. Cir. 2017)

(en banc). However, Patent Owner's proposed substitute claims must meet the statutory requirements of 35 U.S.C. § 316(d) and the procedural requirements of 37 C.F.R. § 42.121. *See* "Guidance on Motions to Amend in view of *Aqua Products*" (Nov. 21, 2017) (https://www.uspto.gov/sites/default/files/documents/guidance_on_motions_to_amend_11_2017.pdf) (last accessed Dec. 5, 2018) ("Guidance"). Accordingly, Patent Owner must demonstrate: (1) the amendment responds to a ground of unpatentability involved in the trial; (2) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter; (3) the amendment proposes a reasonable number of substitute claims; and (4) the proposed claims are supported in the original disclosure. *See* 35 U.S.C. § 316(d); 37 C.F.R. § 42.121.

For reasons set forth below, we determine Patent Owner has met these above-discussed threshold requirements of 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121. Patent Owner seeks to add substitute claims (one-for-one) to replace challenged claims 1, 12, and 20, found unpatentable, and each substitute claim adds limitations that narrow the scope of the original claim it replaces. Amend Mot. 2–12. As explained more below, Patent Owner also identifies disclosures in the originally-filed priority application that support the proposed substitute claims. *Id.* Based on the citations provided in the motion and for the additional reasons discussed below, we find sufficient written description support for Patent Owner's proposed substitute claims.

Moreover, Patent Owner proposes narrowing limitations in proposed substitute claims 21, 30 and 38 in direct response to the grounds of unpatentability involved in this trial, or in related proceedings. Therefore,

Patent Owner has satisfied the threshold requirements of 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121. Accordingly, we now focus on the patentability of proposed substitute claims 21, 30, and 38.

b. Analysis of the Patentability of Proposed Claims 21, 30, and 38

As discussed above, Patent Owner does not have the burden of persuasion with respect to the patentability of the substitute claims presented in its Motion to Amend. *See Aqua Prods.*, 872 F.3d at 1327; Guidance 2. For the reasons explained below, considering the record before us, we determine that Petitioner has shown by a preponderance of the evidence that proposed substitute claims 21, 30, and 38 are unpatentable.

As a replacement for independent claim 1, Patent Owner proposes claim 21. Amend Mot. 1. Proposed substitute claim 21, with added amendments indicated by underlining and deletions in brackets [ ], is shown below:

> 21. A catheter insertion device comprising:
>
> a <u>hemostatic</u> clip including first and second clip arms, the clip being movable between an open tissue receiving configuration in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween; and
>
> an opening element engaging [inner] <u>radially inward facing</u> walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration, wherein the opening element is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration

> wherein a proximal end of the clip is coupled to a control wire via a separable, non-restorable link.

Id. at Claim App., 1. Relevant to the analysis of patentability over the prior art, proposed substitute claims 21, 30, and 38 affirmatively require that the clip is a "hemostatic clip." Also, the opening element must now engage "radially inward facing" walls, not just "inner walls." Further, a limitation has been added to require the clip coupled to the control wire via a separable, non-restorable link.

i. Analysis of the Patentability of Proposed Substitute Claims 21, 30, and 38 Over the Cited Prior Art

Patent Owner makes argument that the substitute claims are patentable over the references cited in the '435 and '440 petitions, as well as over other prior art of record. Amend Mot. 13–24. In response, Petitioner contends that the substitute claims would be unpatentable over various combinations of prior art. *See generally* Amend. Opp. As detailed below, we determine that proposed substitute claims 21, 30, and 38 would have been unpatentable as obvious in light of Sackier and Kirsch.

ii. Analysis of the Patentability of Proposed Substitute Claims 21, 30, and 38 Sackier and Kirsch

Petitioner provides detailed analysis, supported by the testimony of Dr. Nicosia (Exs. 1097, 1101), as to why the combination of Sackier and Kirsch would have rendered claims 21, 30, and 38 obvious. Amend. Opp. 17–24; Amend. Sur-Reply 7–8.

In our analysis above we determined that claim 1 was not anticipated by Sackier alone because the reference did not disclose the "engaging inner walls" limitation in one embodiment as required for anticipation. Specifically, we determined that spring 52 found in Figure 2, was a distinct

embodiment from spring 152 used in the Figure 17 embodiment. We also observed that the spring 52 in the second Sackier embodiment (Figure 2) does appear to contact the inner walls of the jaws and act to drive them apart. Ex. 1008, Figure 2. We were also persuaded that there is an unillustrated embodiment in Sackier of Figure 2 where both legs are pivotable. Ex. 1008, 5:9–12. ("In an unillustrated embodiment (not shown), both of the jaws 36 and 36 are pivotable along the supporting structure 34 and include bevel surfaces, such as surface 45, which are engagable by the screw 47 to open and close the jaws 36, 38.").

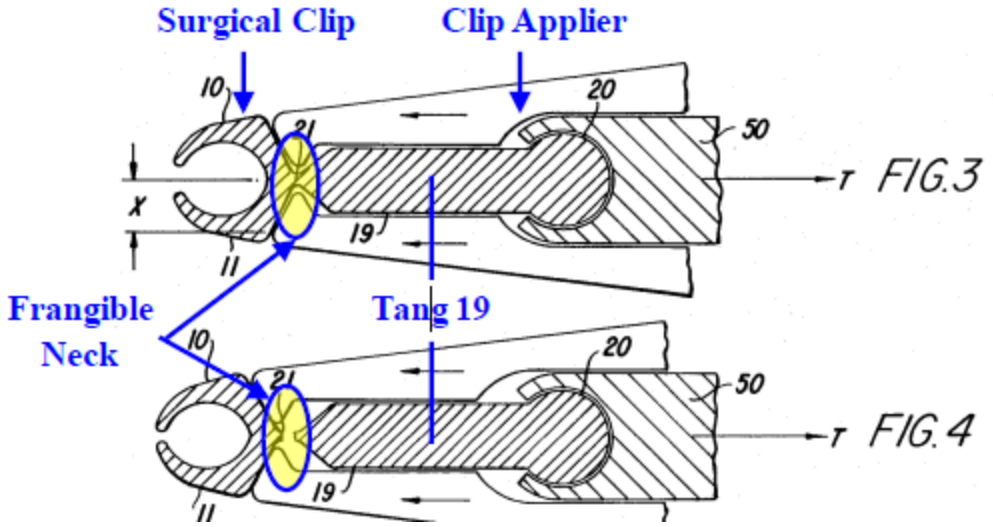
Petitioner address the issue we had with the "engaging inner walls" limitation by asserting that it would have been obvious to substitute spring 52 for spring assembly 152 in the Figure 17 embodiment. Amend. Opp. 18–19. We now consider whether Sackier's two embodiments teach the new limitation of "engaging radially inward facing walls." As detailed more below, we conclude that this limitation is taught and a person of ordinary skill in the art would have had several reasons to adopt spring 52 into the embodiment of Figure 17.

Patent Owner disputes Petitioner's contention, arguing that a person of ordinary skill in the art would not have looked to combine Sackier's two embodiments, and further that the combination with Kirsch fails to teach several limitations. Reply to Opp. 10–12.

Below we provide an overview of Kirsch (Sackier is discussed in detail above), examine the Parties' arguments, and then provide our reasoning why we agree with Petitioner's contentions that claims 21, 30, and 38 would have been obvious over Sackier and Kirsch.

a) Kirsch (Ex. 2053)[10]

Kirsch is titled "Surgical Clip, Applier, and Method." Ex. 2053, [54]. Kirsch discloses a surgical clip having a pair of spaced apart arms joined by a bridge that is deformed by pulling on a tang, which is connected to the bridge by a frangible neck. *Id.*, [57]. As depicted below in annotated Figures 3 and 4, Kirsch discloses connecting a surgical clip and clip applier via a "frangible neck." Id., [57], 1:9–11, 1:30–36, 4:5–44, Figs. 2–4, 6–7.



Annotated Figures 3 and 4 of Kirsch depicting a frangible neck area highlighted in yellow. Amend. Opp. 14; Ex. 2053, Figs. 3, 4.

According to Kirsch, the neck is "designed to break upon application of a predetermined tensile force" (from Figure 3 to Figure 4) to a control wire, which includes tang 19. Ex.2053, Figs. 2–4, 2:35–53, 3:6–9, 3:17–20, 3:27–33). The neck is sized and shaped to have a predetermined breaking strength (predetermined tensile force) sufficient to permit actuation of the clip prior to separating the clip in the body. *Id.*, 3:27–4:4). Kirsch explains that "one of skill in the art will appreciate how simple changes in jaw face geometry

[10] U.S. Patent 4,733,664, issued March 29, 1988 ("Kirsch," Ex. 2053).

or clip shoulder shape could be made to produce desired changes in the degree of clip deformation." *Id.*, 4:1–4.

b) Petitioner's Argument

Petitioner relies on Sackier as teaching most limitations of amended claims 21, 30, and 38. *See* Amend. Opp. 21–27. Petitioner's original analysis set forth in its Petition explains where each limitation of original claims 1, 12, and 20 was disclosed in Sackier. *See* Pet. 23–38. We have discussed those limitations at length above.

As discussed in more detail below, Petitioner contends that the combination of Sackier and Kirsch teach "a proximal end of the clip is coupled to a control wire via a separable, non-restorable link," or the non-restorable link limitation. Amend. Opp. 25–26. Petitioner contends that "[i]t would have been obvious to design Sackier with a fracturing link, like Kirsch's frangible neck," and a person of ordinary skill in the art "would have expected that including a fracturing link would improve the Sackier device, for example by reducing the risk of 'undesirable separation,' as described in Sackier." *Id.* at 25. Below, we examine in detail the Parties' arguments with respect to the amended claim language found in claims 21, 30, and 38.

1) hemostatic clip limitation

Petitioner argues that Sackier discloses a "hemostatic clip" under the BRI of this term," and "[i]f not, it would have been obvious to use Sackier's clip to cause hemostasis (satisfying BSSI's proposed construction)." Amend. Opp. 24. Petitioner notes that Patent Owner alleges that Sackier does not teach a "hemostatic" clip because "Sackier's clamps are not 'used' to cause hemostasis." *Id.* at 17. Petitioner argues that "Sackier's disclosed

use for its clamps is irrelevant," "[a]s shown in annotated Figure 15, Sackier discloses a device in the form of clamp 10a having compression legs (36a, 38a), and it is capable of applying a pinching pressure." *Id.* at 17–18 (citing Ex. 1097 ¶ 122; Ex. 1008, 9:16–25, 9:60–67, 10:31–34, Figs. 15–17). Dr. Nicosia testifies that Sackier's clamp 10a is also capable of causing hemostasis. Ex. 1097 ¶¶ 122–123. Petitioner contends that "using the clamp to cause hemostasis . . . is not a patentable distinction since clamp 10a is capable of causing hemostasis." Amend. Opp. 18. This contention is supported by the testimony of Dr. Nicosia, who opines "[o]ne of the most obvious uses of a medical device with compression legs capable of applying a pinching pressure (such as Sackier) would have been hemostasis." Ex. 1097 ¶ 123. Likewise, Dr. Nicosia testifies that "Sackier explains that while preferred devices and methods have been described, '[m]any modifications of these embodiments will now be apparent,' and that clamp 10a can be used 'to facilitate a wide variation in laparoscopic procedures.'" *Id.* (quoting Ex. 1008, 11:46–55).

2) opening element engaging radially inward facing walls limitation

Petitioner argues that Sackier discloses an opening element (spring 152) that urges the compression legs (36a, 38a) away from one another. Amend. Opp. 18 (citing Ex. 1097 ¶ 124; Ex. 1008, 9:30–32). Petitioner notes that "Sackier explains that there are a "wide variation in the possibilities" for designing clamp 10a." *Id.* (citing Ex. 1097 ¶ 125; Ex. 1008, 11:65–12:2). Petitioner relies on Sackier's Figure 2 embodiment that discloses opening element (spring 52) contacting the radially inward facing walls of compression legs (36, 38) in clamp 10. *Id.* at 19 (citing Ex. 1097 ¶

125). Petitioner contends that "[i]t would have been obvious to substitute opening element (52) for opening element (152) in Figures 15-17, and to configure opening element (52) so that it contacts the radially inward facing surfaces of compression legs (36a, 38a), as illustrated in Figure 2." *Id.* (citing Ex. 1097 ¶ 197).

According to Petitioner, and as supported by Dr. Nicosia, "[t]his modification would have been a simple substitution, and a matter of routine skill in the art, using simple mechanical elements disclosed in Sackier to achieve predictable results." *Id.* Also, a person of ordinary skill in the art "would have expected the resulting device to perform in at least the same manner as the original device," such that "[t]he resulting device would satisfy the 'radially inward facing walls' requirement." *Id.*

3) "non-restorabl[e]" limitations

Petitioner contends that "Sackier's clamp 10a and clamp applier 12a are connected via a simple mechanical ball and socket connection." Amend. Opp. 25. Petitioner argues that a person of ordinary skill in the art "would have been familiar with other simple mechanical connections suitable for connecting Sackier's clamp and clamp applier, including the 'frangible neck' disclosed in Kirsch." *Id.* Petitioner contends that "[i]t would have been obvious to design Sackier with a fracturing link, like Kirsch's frangible neck," and a person of ordinary skill in the art "would have expected that including a fracturing link would improve the Sackier device, for example by reducing the risk of 'undesirable separation,' as described in Sackier." Amend. Opp. 25. As Dr. Nicosia testifies, a person of ordinary skill in the art "would have understood that a fracturing link, as described in Kirsch,

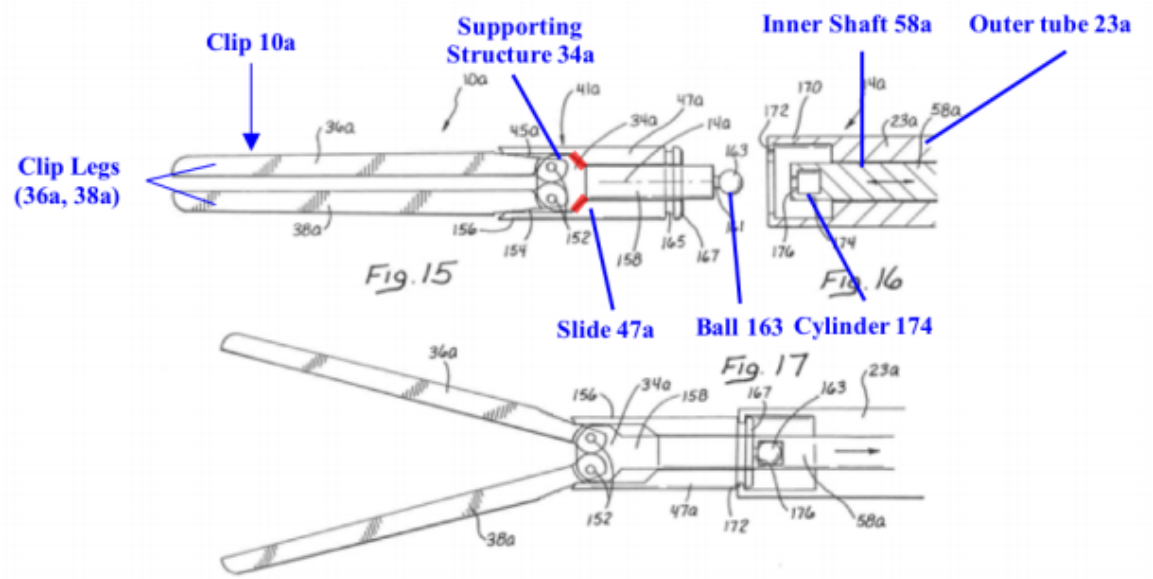
would be a more stable link than the ball/socket link described in Sackier." Ex. 1097 ¶ 179.

Petitioner also points out that a person of ordinary skill in the art would understand that Kirsch's predetermined tensile force could be modified by making simple changes to the size and shape of the "frangible neck." Amend. Opp. 15–16 (citing Ex. 1097 ¶ 105). Kirsch explains that advantages of this design include "predictability of results" and "more uniform results." *Id.* (citing Ex. 2053, 5:19–22). Dr. Nicosia likewise testifies that a person of ordinary skill in the art "would have expected that substituting a fracturing link for Sackier's ball/socket link would improve the "predictability of results," and provide "more uniform results," as described in Kirsch. Ex. 1097 ¶ 178.

In its Sur-Reply, Petitioner notes Sackier could be combined with Kirsch and that Sackier teaches that the contemplated embodiment in the combination of the two would be releasable within the body. Amend. Sur-Reply 8; Ex. 1101 ¶¶ 50–53 (discussing embodiments that detach within the body). Importantly, Dr. Nicosia testifies that Kirsch provides incentive for Sackier to adopt an axial engagement because "if Sackier's clamp and clamp applier engage and disengage axially, Kirsch's link would provide advantages over Sackier's ball and socket connection, including, 'predictability of results' and 'more uniform results.'" Ex. 1101 ¶ 69.

Petitioner, and Dr. Nicosia, also respond to Dr. Vaitekunas's assertion that "Kirsch requires a tool that can hold the jaws in place while the control wire is pulled proximally to break the frangible neck," and that "Sackier lacks this tool to apply tension to the frangible neck." Ex. 2095 ¶ 69.

Dr. Nicosia responds by opining that "Sackier's jaws 36a, 38a are closed by holding outer tube 23a stationary while pulling proximally on inner shaft 58a." Ex. 1101 ¶ 70 (citing Ex. 2092, 588:3–590:14). Dr. Nicosia testifies that "[j]aws 36a, 38a are completely closed when 'shoulders' of supporting structure 34a contact 'shoulders' of slide 47a (shoulders highlighted in red), as shown below." *Id.*



Annotated Figures 15–17 created by Dr. Nicosia showing supporting structure 34a in red highlight. Ex. 1101 ¶ 70.

Dr. Nicosia points out that "[w]hen jaws 36a, 38a are closed, contact between these "shoulders" (highlighted above in red) prevents jaws 36a, 38a from moving proximally relative to slide 47a." *Id.* Thus, according to Dr. Nicosia, "[t]his contact provides an opposing force when the inner shaft 58a is pulled further proximally while holding tube 23a stationary." *Id.* When Kirsch's frangible link is substituted for the existing ball and socket, Dr. Nicosia explains that "in the Sackier/Kirsch device this same opposing force would create tension in Kirsch's frangible link, allowing the link to break

when outer tube 23a is held stationary and inner shaft 58a is pulled proximally." *Id.* We find Dr. Nicosia's testimony on this point persuasive.

Dr. Nicosia also testifies that "Sackier's link likewise should be considered non-restorable to the extent it is not possible to reassemble the clamp and clamp applier in the body." Ex. 1101 ¶ 62.

c) Patent Owner's Argument

Patent Owner generally argues that "[e]ach embodiment disclosed in Sackier, other than Figures 15–17, has one fixed jaw and therefore, fails to meet the limitation of each substitute claim requiring that both clip arms are moveable." Amend. Mot. 15 (citing Ex. 2017 ¶ 135).

At the outset we find this position unpersuasive because there is an unillustrated embodiment in Sackier of Figure 2 where both legs are pivotable, demonstrating that spring 52 could move both jaws equally. Ex. 1008, 5:9–12 ("In an unillustrated embodiment (not shown), both of the jaws 36 and 38 are pivotable along the supporting structure 34 and include bevel surfaces, such as surface 45, which are engagable by the screw 47 to open and close the jaws 36, 38.").

1) hemostatic clip limitation

Patent Owner argues that a "hemostatic clip" means "a clip which causes hemostasis." Amend. Mot. 11 (citing Ex. 2017 ¶ 121). According to Patent Owner, "a 'hemostatic clip' is used to close the blood vessel." *Id*. Patent Owner argues that "Sackier does not disclose a 'hemostatic clip' used to cause hemostasis of a blood vessel, but rather a clamp to occlude a body conduit. *Id.* at 16 (citing Ex. 1008, Abstract; Ex. 2017 ¶ 134).

2) opening element engaging radially inward facing walls limitation

Patent Owner does not present any viable argument to counter that the combination of Sackier and Kirsch would teach this limitation. *See* Reply to Opp. 10 (arguing spring 52 cannot be used in an embodiment where both jaws move). This is so because Sackier teaches an unillustrated embodiment for Figure 2 where both legs are pivotable, which establishes that spring 52 could move both jaws equally. Ex. 1008, 5:9–12.

3) "non-restorabl[e]" limitations

Patent Owner contends that "Petitioners also have not demonstrated that Sackier's clamp is separable," and "Sackier does not disclose, teach or suggest using a separate clamp retriever to retrieve the clamp." Reply to Opp. 10–11 (citing Ex. 2095 ¶ 59).

As for the combination of Sackier and Kirsch, Patent Owner contends that a person of ordinary skill in the art would "not modify Sackier in view of Kirsch." *Id.* at 11. Patent Owner argues such a person "would not be motivated to further modify Sackier to prevent 'undesirable separation' because Sackier's clamp was already designed to avoid this problem." *Id.* According to Patent Owner, "removing only Sackier's shaft 58a would not detach the clamp and would not serve any purpose." *Id.* at 12.

d) Discussion

1) hemostatic clip limitation

Patent Owner does not identify any structural differences between a "clip" and a "hemostatic" clip as the amended claims would now require. As we previously noted in the Decision to Institute, "[h]emostatic is a statement of intended use and certainly clips can be used for that purpose."

Dec. 7–8 (citing Ex. 1033, 2:62–63 (summary of the invention)). Accordingly, "hemostatic" does not add a structural limitation to the claims. "It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (citations omitted). *In re Sinex*, 309 F.2d 488, 492 (CCPA 1962) ("[S]tatement[s] of intended use…do[] not qualify or distinguish the structural apparatus claimed over the [prior art].").

Further, to the extent that the claimed clip was limited to just hemostatic uses, Petitioner has shown by a preponderance of the evidence that Sackier and Kirsch teach a clip that could be used for hemostatic applications. We are most persuaded by the testimony of Dr. Nicosia. Ex. 1097 ¶¶ 122–123. Dr. Nicosia persuasively explains that a person of ordinary skill in the art "would have understood from the fact that clamp 10a has compression legs capable of applying a pinching pressure (via clip arms (36a, 38a) and other associated structure) that clamp 10a can be used to cause hemostasis, among other things." *Id.* As Dr. Nicosia notes that Sackier is usable in a wide variation of laparoscopic procedures and he further testifies, "[o]ne of the most obvious uses of a medical device with compression legs capable of applying a pinching pressure (such as Sackier) would have been hemostasis." Ex. 1097 ¶ 123 (quoting Ex. 1008, 11:46–55).

2) opening element engaging radially inward facing walls limitation

As noted above, Patent Owner does not present a plausible argument to counter Petitioner's position that this limitation is taught by the combination of Sackier and Kirsch. More specifically, Petitioner has

persuasively shown that the combination of the Figure 2 embodiment of Sackier (using spring 52, with both jaws pivotal) with the Figure 17 embodiment of Sackier teaches the opening element engaging radially inward facing walls limitation. *See* Ex. 1008, 5:4–16, Figs. 2, 17. Further, Dr. Nicosia testifies persuasively that spring 52 would bias both jaws evenly away from one another. Ex. 1101 ¶ 41.

3) non-restorabl[e] limitations

This limitation is somewhat of a closer call and comes down to the viability of combining Sackier and Kirsch. We determine Petitioner, through the testimony of Dr. Nicosia, has presented a persuasive explanation as to how Kirsch's frangible neck could be combined into Sackier to achieve a fracturing, non-restorable, link. Petitioner demonstrates that combining Kirsch's frangible neck into Sackier would achieve several advantages for the Sackier device, including reducing the risk of undesirable separation, as described in Sackier. *See* Ex. 1097 ¶ 179. We agree with Dr. Nicosia that a person of ordinary skill in the art would have recognized that substituting a fracturing link for Sackier's ball/socket link would provide advantages known for frangible links and also improve the "predictability of results," and provide "more uniform results," as described in Kirsch. *Id.*

In a related proceeding, we examined Sackier in detail to determine whether the reference taught a "releasably coupled"[11] limitation. IPR2017-00135, Paper 82, 38–50. In that proceeding, we stated that it was possible that Sackier taught that ball 163 and cylinder 174 form an annular snap

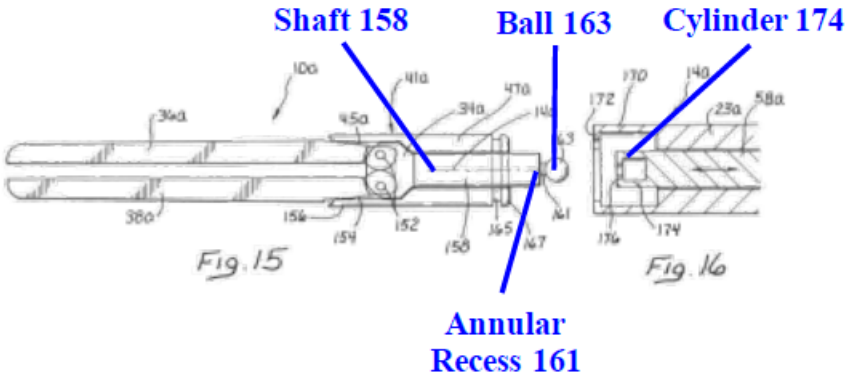
[11] At issue in IPR2017-00135 was related U.S. Patent No. 8,974,371 B2, and the limitation requiring a claimed "control member" that must have a distal end "releasably coupled to the clip assembly."

connection, which separates during use, when a sufficient proximal tensile force is applied to the control wire (58a). *Id.* at 44 ("Petitioner's theory of an axial snap fit connection of ball 163 into the recess of cylinder 174 is theoretically possible."). In our prior analysis, we noted however that although this snap-fit theory was possible, we were just as convinced that Patent Owner's lateral side fit theory was possible. *Id.* at 47 ("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."). In offering to combine Kirsch into Sackier, Petitioner presents a persuasive theory that substituting Kirsch's fracturing link for Sackier's ball/socket link would provide distinct advantages.

Most important for our analysis, the combination of Kirsch and Sackier overcomes those deficiencies detailed in our analysis of the related IPR2017-00135, which was based on Sackier alone. Further, Petitioner's modified obviousness analysis also relies on combining two embodiments of Sackier (spring 52 for spring 152), which overcomes the deficiencies noted above when addressing anticipation by Sackier. We are also persuaded by Sackier's disclosure of embodiments that are meant to disengage inside the body. *See* Ex. 1008, Figs. 11–14; 8:30–37. Allowing a frangible link connection for Sackier's Figures 15–17 embodiment further accomplishes the purpose of Sackier's embodiments that require disengagement inside the body.

Petitioner provides persuasive reasoning as to how Kirsch's frangible neck could be incorporated into Sackier, including detailing the precise location of the fit. Petitioner persuasively explains, that "[t]his modification would have been a matter of routine skill in the art, using simple mechanical

elements such as those disclosed in Kirsch and Sackier, to achieve predictable results." Amend. Opp. 26 (citing Ex. 1097 ¶¶ 180–181). Petitioner relies on annotated Figures 15 and 16, depicted below, and argues that Sackier already "discloses a neck in the form of annular recess 161 (disposed between ball 163 and cylindrical shaft 158)." *Id.*



Petitioner's annotated Figures 15 and 16 of Sackier depicting annular recess 161 where Kirsch's frangible neck connection could be substituted. Amend. Opp. 26.

We find Petitioner's analysis persuasive as to the proposed substitution. As Petitioner explains, a person of ordinary skill in the art "would have understood that Sackier's neck (161) has a breaking strength (predetermined tensile force) that is greater than the predetermined tensile force required to separate ball 163 and cylinder 174," and, as such, "application of any proximal tensile force greater than [a certain amount] will cause the ball/cylinder link to separate, while the neck link remains intact." *Id.*

Petitioner provides persuasive rationales for the combination, including improved performance as discussed above. *See, e.g.*, Ex. 1097 ¶ 178. But, we also find persuasive Petitioner's rationale, based on mechanical optimization, that "[i]t would have been obvious to optimize the size and/or shape of these components so that the neck link breaks, while the

ball/cylinder link remains intact," such as "by decreasing the thickness of neck (161)." *Amend. Opp. 26.* We agree with Petitioner that "[t]he resulting device would satisfy the "non-restorabl[e]" limitations of the substitute claims." *Id.*

Accordingly, we find Petitioner has established that a preponderance of the evidence of record supports a conclusion that the combination of Sackier with Kirsch renders the subject matter of claims 21, 30, and 38 obvious.

c. Analysis of the Patentability of Proposed Claims 21, 30, and 38 over Other Combinations Asserted

Petitioner presented several alternative proposed embodiments that we either believe deficient, or chose not to address for the reasons set forth below.

i. Sackier Grounds

Because we do not believe it necessary to add Nishioka into the combination of Sackier and Kirsch, we elect not to address the combination of Sackier, Nishioka, and Kirsch. *See* Amend. Opp. 24. Similarly for the reasons outlined above, we deem it necessary to include Kirsch in any combination with Sackier to address the non-restorable link limitation. *See id.* Petitioner presented the Matsuno reference as an alternative to Kirsch, but because this was presented as an alternative, and because we believe Kirsch is the stronger option, we decide not to address Matsuno. *See* Amend. Opp. 24 ("Obvious In View Of Sackier And (Kirsch Or Matsuno)").

ii. Malecki Grounds

Petitioner presented four distinct grounds based on Malecki. *See* Amend. Opp. ii (table of contents), 10–17. Nearly identical grounds based

on Malecki were presented in IPR2017-00435, also involving the '731 patent. In the '435 proceeding, we examined two embodiments within the overall disclosure of Malecki referred to as Embodiment #1 (Fig. 28) and Embodiment #2 (Figs. 25–27). In the '435 final decision (issued currently with this decision) we determined that Petitioner had failed to prove by a preponderance of the evidence that claims 1, 12, and 20 were unpatentable based on the Malecki embodiments. The same deficiencies that we detailed in that decision (such as "engaging inner walls" and clips to "move . . . toward one another") are present in Petitioner's grounds in opposition to the motion to amend in this proceeding. We incorporate our analysis from the concurrently decided '435 proceeding as explanation as to why Petitioner has not established unpatentability of any amended claim based on Malecki in this proceeding. Importantly, the amended claim limitations proposed by Patent Owner only further distance the Malecki embodiments from the claim scope.

d. Analysis of Proposed Claims 21, 30, and 38 for Compliance with 35 U.S.C. § 112, ¶¶ 1, 2

Petitioner asserts that proposed substitute claims 21, 30, and 38 do not satisfy the written description and definiteness requirements of 35 U.S.C. § 112, ¶¶ 1, 2. Amend Opp. 3–7. According to Petitioner, none of Patent Owner's specific citations to the Specification of the '731 patent provide adequate written description support for the claim requirements of "opening element" and the added "non-restorabl[e]" limitation. *Id.* at 4, 5. More specifically, Petitioner argues that the figures identified provide no support for an "opening element," and that term is not recited in the Specification.

Id. at 4–6. Petitioner also alleges there is no support for claim 30's two control wire embodiment. *Id.*

Petitioner also asserts that the identified figures and citations to the Specification fail to provide support for the newly added "non-restorabl[e]" claim limitations. Amend. Opp. 5. Also, Petitioner contends that this limitation is not responsive to a ground of unpatentability.

Patent Owner responds that Figures 8A–B disclose an opening element for urging the clip legs open, as highlighted in red in Dr. Vaitekunas's declaration. Reply to Opp. 2 (citing Ex. 2095 ¶ 11).

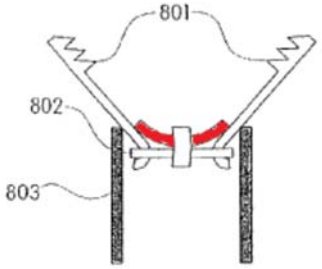


FIG. 8A

Dr. Vaitekunas's annotated Figure 8A of the '731 patent showing unnumbered opening element highlighted in red. Ex. 2095 ¶ 11.

Dr. Vaitekunas testifies that although not identified by number, a person of ordinary skill in the art would understand the component highlighted in red to be an "opening element" for "urging" the clip legs open and that this element engages radially inward facing clip arm walls.

Patent Owner also responds to Petitioner's arguments for the "non-restorable" limitation by arguing "[t]he specification explains that '[t]his embodiment [Figs. 8A, 8B] could be actuated and released in the same way the previous embodiment is activated and released.'" Reply to Opp. 2 (citing Ex. 1033, 8:17–22). According to Patent Owner, "[t]he specification explains that 'the previous embodiment' releases the clip by deforming the j-

hook 107, which is at the 'distal terminal end of the control wire 108.'" Id. (citing Ex. 1033, 7:28–65, 5:30–31; Ex. 2095 ¶ 12). Thus, a person of ordinary skill in the art "would understand this link to be non-restorable because deforming j-hook 107 is required for separation and prevents reconnection to the clip." Reply to Opp. 2. Patent Owner also contends that the Figure 10A–B embodiments teach these limitations. *Id.* at 2–3. Patent Owner contends that claim 30 does not require two control wires, but only one. *Id.* at 3.

Patent Owner also explained how the "separable, non-restorable" link limitations responded to unpatentability arguments in view of Malecki, Nishioka and Sackier. Amend. Mot., 13 (Malecki), 14 (Nishioka), 15 (Sackier). Patent Owner also contends "control wire" and "non-restorabl[e]" are definite because "non-restorable links" refer to separable links that are unable to be reconnected, and the claims only require one control wire. Reply to Opp. 4.

For the reasons set forth below we find Patent Owner's contentions persuasive.

To satisfy the written description requirement, the disclosure must reasonably convey to ordinarily skilled artisans that the inventors possessed the claimed invention as of the filing date. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The description must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Id.* (alteration in original) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)).

> [T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.

Id. "[T]he hallmark of written description is disclosure." *Id.* "This inquiry . . . is a question of fact," which "var[ies] depending on the context" and "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.* (citations omitted). Demonstrating adequate written description "requires a precise definition" of the invention. *Id.* at 1350. However, the claimed invention need not be recited *in haec verba* in the original specification in order to satisfy the written description requirement. *Id*. at 1352.

Examining Figures 8A–B, and Figures 10A–B we agree that the unnumbered element contacting the radially inward face of the clip arms adequately shows an "opening element" as recited in the claims. Ex. 1033, Figs. 8A–B, 10A–B. Specifically, the component highlighted in red in annotated Figure 8A above depicts an "opening element" for "urging" the clip legs open.

We also determine that the original Specification supports the "non-restorable" limitations. Because the Specification describes an embodiment of Figures 8A–B that could be actuated and released in the same way the previous embodiment is activated and released (Ex. 1033, 8:17–22), we agree with Patent Owner that the Specification explains that "the previous embodiment" releases the clip by deforming the j-hook 107, which is at the "distal terminal end of the control wire 108. Ex. 1033, 7:28–65, 5:30–31; Ex. 2095 ¶ 12. Thus, a person of ordinary skill in the art would understand

this link to be non-restorable because deforming j-hook 107 is required for separation and prevents reconnection to the clip. For the reasons set forth above, we also determine that each of these limitations are not indefinite.

The addition of each newly added limitation also is responsive to one or more grounds of unpatentability set forth in either this proceeding, or a related proceeding involving the same or similar claim scope. These related proceedings are discussed above.

Therefore, we determine, based on the final record before us, that Petitioner has not shown, by a preponderance of the evidence, that proposed substitute claims 21, 30, and 38 are unpatentable for failing to comply with the requirements of 35 U.S.C. § 112, ¶¶ 1, 2.[12]

e. Conclusion on Motion Amend

Amended claims 21, 30, and 38 are responsive to a ground of unpatentability in the trial, the amendments do not constitute new matter, and there is written description support for the definite claim language. Petitioner has, however, shown by a preponderance of the evidence that the subject matter of claims 21, 30, and 38 is unpatentable as obvious over Sackier and Kirsch. Accordingly, we deny Patent Owner's Motion to Amend.

[12] Our determination is the same regardless of whether Patent Owner has the burden to establish that the proposed amendment does not "introduce new matter." *See* 35 U.S.C. § 316(d)(3). Proposed substitute claims 21, 30, and 38 have sufficient written description support in the original parent application of the '731 patent, and do not introduce new matter.

VI. SUMMARY

For the foregoing reasons, we determine that Petitioner has not proven by a preponderance of the evidence that claims 1–2, 4, 6–9, 12, 13, and 20 are anticipated by Sackier. Petitioner has not shown that claims 3, 5, 10, 11, and 14–19 would have been obvious over Sackier.

Petitioner has established that claims 1–3, 10–16, and 18 are anticipated by Nishioka. Similarly, Petitioner establishes that claims 1–3, 10–16, and 18 would have been obvious over Nishioka.

Petitioner has proven that claims 1, 2, 4, 6, 7, 9, 10, 12, 13, and 20 would have been obvious over Shinozuka and Sackier. Petitioner has not shown that claims 3, 8, and 14 would have been obvious over Shinozuka and Sackier or obvious over Shinozuka and Nishioka.

Claims 1–4, 6, 7, 10–16, 18, and 20 are unpatentable.

Claims 5 and 8 have not been shown to be unpatentable.

Petitioner's Motion to Exclude (Paper 60) is denied.

Patent Owner's first Motion to Exclude (Paper 45) and second Motion to Exclude (Paper 81) are both denied.

Patent Owner's Contingent Motion to Amend is denied because proposed amended claims 21, 30, and 30 are unpatentable as obvious over Sackier and Kirsch.

VII. ORDER

Accordingly, it is:

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has shown by a preponderance of the evidence that claims 1–4, 6, 7, 10–16, 18, and 20 are unpatentable;

FURTHER ORDERED that Petitioner has *not* shown by a preponderance of the evidence that claims 5 and 8 are unpatentable

FURTHER ORDERED that both of Patent Owner's Motions to Exclude are *DENIED*.

FURTHER ORDERED that Petitioner's Motion to Exclude is *DENIED*.

FURTHER ORDERED that Patent Owner's Motion to Amend is *DENIED*; 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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