

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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COOK GROUP INCORPORATED  
and  
COOK MEDICAL LLC,  
Petitioner,

v.

BOSTON SCIENTIFIC SCIMED, INC.,  
Patent Owner.

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Case IPR2017-00435  
Patent 9,271,731 B2

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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 7, “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 1–4, 6–18, and 20 of the ’731 patent, but not under all challenged claims or grounds. Paper 8, 20 (“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 45, “Reply to Opp.”). Petitioner then filed a Sur-Reply in Support of the Opposition to Patent Owner’s Motion to Amend (Paper 52, “Amend. Sur-Reply”).

Patent Owner filed a Motion to Exclude (Paper 48) certain evidence submitted by Petitioner, to which Petitioner filed an Opposition (Paper 56), and Patent Owner filed a Reply (Paper 61).

Petitioner also filed a Motion to Exclude (Paper 64) certain evidence submitted by Patent Owner, to which Patent Owner filed an Opposition (Paper 69).

A combined oral hearing with Case IPR2017-00440 was held April 19, 2018, and a transcript of the hearing is included in the record (Paper 72, “Tr.”). A second oral hearing was conducted on September 17, 2018 (Paper 93, 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.”<sup>1</sup> Subsequently, on May 7, 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 71, 1.

Pursuant to our authorization, the parties thereafter filed a “Joint Motion to Limit the Proceeding” (Paper 77), requesting that we limit the proceeding to a subset of the instituted grounds and claims in the Petition, as identified in the motion. Paper 77, 1–2. On June 15, 2018, we issued a Decision (Paper 78), accepting the Parties’ joint proposal to limit the proceeding “to those claims and grounds as set forth in Paper 77, 1–2.” Paper 78, 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 76 (also recognizing six month

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<sup>1</sup> Available at: <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial>.

extension under 37 C.F.R. § 42.100(c)). On June 29, 2018, Patent Owner filed a Supplemental Response. Paper 80 (“Supp. Resp.”). Petitioner filed a Supplemental Reply. Paper 81 (“Supp. Reply”). Patent Owner then filed a Sur-Reply. Paper 90 (“Supp. Sur-Reply”).

Patent Owner also filed a second Motion to Exclude (Paper 83), which sought to exclude certain evidence submitted by Petitioner, to which Petitioner filed an Opposition (Paper 87), and Patent Owner thereafter filed a Reply (Paper 88).

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 not shown by a preponderance of the evidence that claims 1–4, 6–18, and 20 are unpatentable in this proceeding.

We address the Parties’ motions to exclude as set forth below. Additionally, we deny Patent Owner’s Contingent Motion to Amend as moot.

## 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 clamping

together the edge of a wound to achieve “hemostasis.” *Id.* at 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,” as well as other elements to help “close and lock the clip and to uncouple the control wire from the clip.

*Id.* at 2:66–3:7. One advantage mentioned in the Specification is that “[t]he device’s 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 Claim*

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;

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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. IPR2017-00440 (U.S. Patent No. 9,271,731).

Paper 3, 2–3.

*D. References Relied Upon*

Petitioner relies upon the following prior art reference: U.S. Patent No. 5,626,607 issued on May 6, 1997 (“Malecki”) (Ex. 1003).

Petitioner also relies on:

1. the Declaration of Mark A. Nicosia, Ph.D. (Ex. 1037),
2. Dr. Nicosia’s Declaration in Support of Petitioner’s Reply (Ex. 1095),
3. Dr. Nicosia’s Declaration in Support of Petitioner’s Opposition to Patent Owner’s Motion to Amend (Ex. 1097), and
4. Dr. Nicosia’s Declaration in Support of Petitioner’s Sur-Reply to Patent Owner’s Motion to Amend (Ex. 1101).

Patent Owner relies on:

1. the Declaration of Jeffrey Vaitekunas, Ph. D. in support of its Response (Ex. 2010), and on
2. Dr. Vaitekunas’s Declaration in support of its Motion to Amend (Ex. 2094).

*E. The Instituted Grounds*

Pursuant to our Institution Decision (Paper 8), our Decision Modifying the Institution Decision (Paper 71), and our Decision granting 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
Malecki (Embodiment #1) <sup>2</sup>	§ 102 <sup>3</sup>	1–4, 6, 9–18, and 20
Malecki (Embodiment #1)	§ 103	1–4, 6–18, and 20
Malecki (Embodiment #2)	§ 102	1, 2, 4, 10, 12, and 13
Malecki (Embodiment #2)	§ 103	3, 6–9, 14, and 20

II. CLAIM CONSTRUCTION

Petitioner identifies several terms for construction. Pet. 11–17. As an initial matter, Petitioner’s support for its proposed interpretation of each term is lacking because Petitioner’s only cited evidence is Patent Owner’s claim construction position from the related district court litigation. Patent Owner challenges two limitations for interpretation. PO Resp. 7–8.

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<sup>2</sup> Petitioner identifies and relies upon specific embodiments within the overall disclosure of Malecki referred to as Embodiment #1 (Fig. 28) and Embodiment #2 (Figs. 25–27). Pet. 9, n.3. For purposes of our analysis, we adopt Petitioner’s identification.

<sup>3</sup> The relevant sections of the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (Sept. 16, 2011), took effect on March 16, 2013. Because the application from which the ’371 patent issued was filed before that date, our citations to Title 35 are to its pre-AIA version. *See* Pet. 8, n.2.



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 the one claim limitation that is necessary to resolve the controversy before us.

“*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 a physical connection. *See, e.g.*, Pet. 15 (interpreting engaging as contacting, but without a physical connection), PO Resp. 8–9 (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<sup>4</sup> (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. 7, 11–12 (construing “inner walls”); Pet. Reply 5

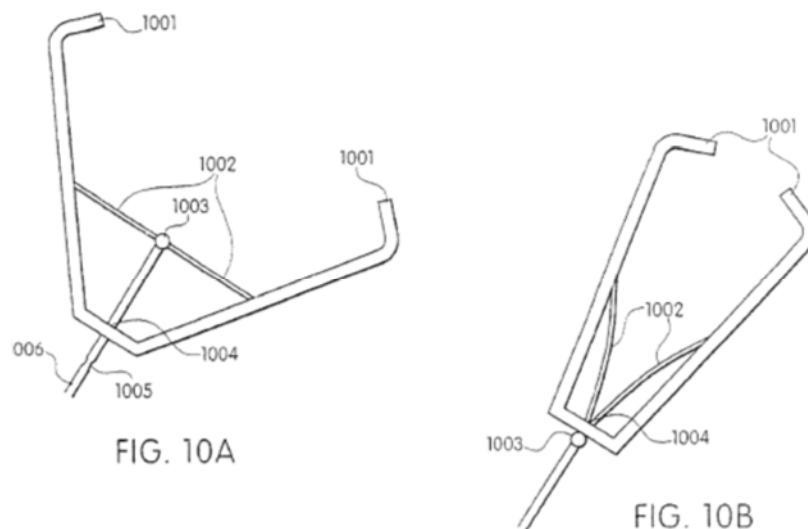
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<sup>4</sup> We adopt the page numbering added by Petitioner at the bottom right hand corner of Exhibits 1039 and 1035.

(“‘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. 11. 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.* at 12 (citing Ex. 2010 ¶¶ 42–53).

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.*



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. 12.

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.* at 13 (quoting Pet. 13). 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. 13 (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 and also would not understand a pinhole cutout to constitute a “wall” of the clip arm. PO Resp. 13 (citing Ex. 2010 ¶¶ 42–

53).

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. 1095 ¶ 15). 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.* (citing Ex. 1095 ¶¶ 14–15). 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 4–5. Petitioner then pivots away from discussing the specification of the ’731 patent and argues that “[m]ost relevant here,” a person of ordinary skill in the art would have understood that the broadest reasonable interpretation of “inner walls” at least encompasses the surfaces contacted by Malecki’s opening element and, in particular, those surfaces identified and discussed below.” *Id.*

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 (Malecki) 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. *See generally* Exs. 1037, 1095, and 1109.

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. 13; 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:

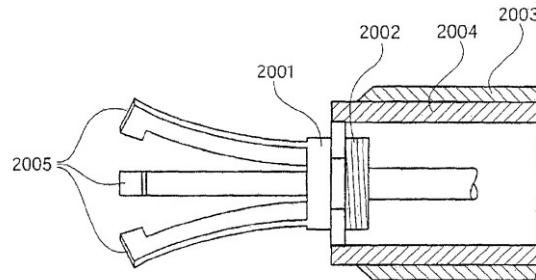


FIG. 20B

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. 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:”

Therefore, it is my opinion that a POSA reading the ’731 patent would understand “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.” Petitioners arguments fail to clearly define the term. A POSA would not understand an interior pinhole cutout to constitute a “wall” of the clip arm. A POSA would understand the “walls” of the clip arms to be the exterior surfaces of the clip arms. Moreover, a POSA would not understand portions of non-radially inward facing walls (i.e., side/lateral walls) below some imaginary line to constitute an “inner wall.” Thus, a POSA would understand the radially inward facing wall to be the “inner wall” of the clip arms.

Ex. 2010 ¶ 53. 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.”

### 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,<sup>5</sup> so-called secondary considerations. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

*B. Person of Ordinary Skill in the Art*

Petitioner proposes that a person of ordinary skill in the art as of the time of the filing of the application that became the ’731 patent would have possessed the knowledge and skill of an engineer or similar professional

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<sup>5</sup> The parties have not introduced evidence of secondary considerations in this proceeding.

with at least an undergraduate degree in engineering, or a physician having experience with designing medical devices. Pet. 10 (citing Ex. 1037 ¶ 11). Patent Owner does not dispute Petitioner’s proposal, and we adopt it based on the final record before us. It is also consistent with the level of skill evidenced by the references.

*C. Claims 1–4, 6, 9–18, and 20 as Anticipated by Malecki Embodiment #1*

Petitioner contends claims 1–4, 6, 9–18, and 20 are unpatentable, under 35 U.S.C. § 102, as anticipated by Malecki Embodiment #1. Pet. 23–41.

*1. Overview of Malecki (Ex. 1003)*

Malecki is directed to a clamp for clamping a body structure. Ex. 1003, Abstract. Petitioner relies on two distinct embodiments of Malecki – Embodiment #1 (Figure 28A) and Embodiment #2 (Figures 25–27). Pet. 9. For purposes of this ground, Petitioner relies only on Embodiment #1, represented by Figure 28A of Malecki, reproduced below.

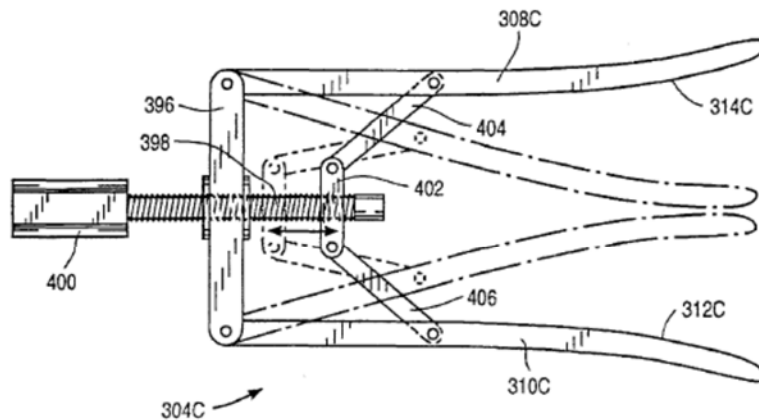


FIG. 28A

Figure 28a is a side view of a clamp depicting jaws 308C and 310C as part of the structure. Ex. 1003, 6:29–30.



Malecki describes this embodiment as “[c]lamp 304C includes first and second jaws 308C, 310C having somewhat outwardly bowed jaw surfaces 312C, 314C so that they do not touch along their entire surfaces,” and further, “[j]aws 308C, 310C are also preferably curved when viewed from the side.” Ex. 1003, 17:43–48. Malecki states that “[a]rms 308C, 310C are pivotally mounted to opposite ends of a clamp base 396.” *Id.* at 17:50–51.

Within this embodiment, “connector 402 is coupled to a distal end of the shaft 398,” and “[c]onnector 402 is [also] coupled to first and second jaws 308C, 310C by links 404, 406 so axial displacement of shaft 398 moves jaws 308C, 310C between the open, solid line position to the closed, dashed line position.” *Id.* at 17:57–62.

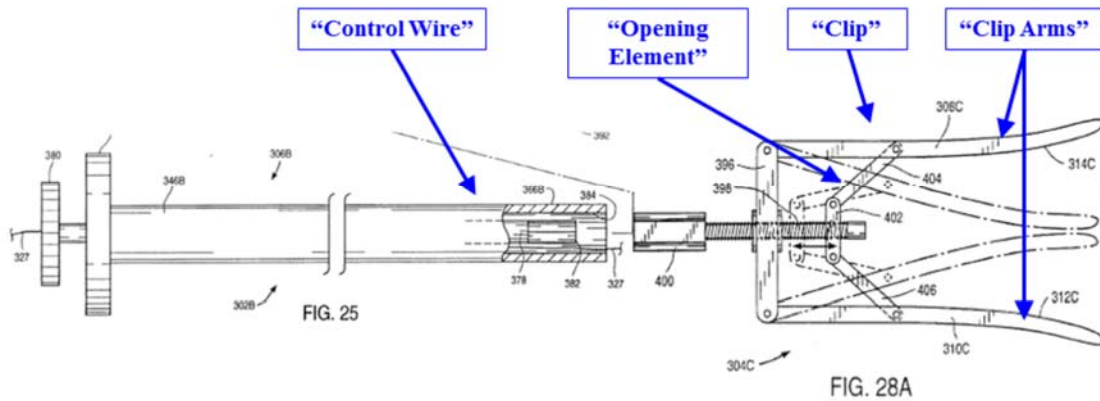
At issue, and as discussed below in detail, is how and where first and second jaws 308C, 310C are connected to links 404, 406 in this embodiment.

## *2. Discussion of Claims 1, 12, and 20*

Petitioner asserts that Malecki Embodiment #1, alone, discloses all elements of claims 1, 12, and 20. Pet. 23–27, 36–37, 40–41. Petitioner’s analysis is supported by the testimony of Dr. Nicosia. *See* Ex. 1037 ¶¶ 31–35, 44–47, 54–58. Patent Owner challenges whether Malecki discloses the “inner walls of the first and second clip arms” limitation construed above. PO Resp. 21.

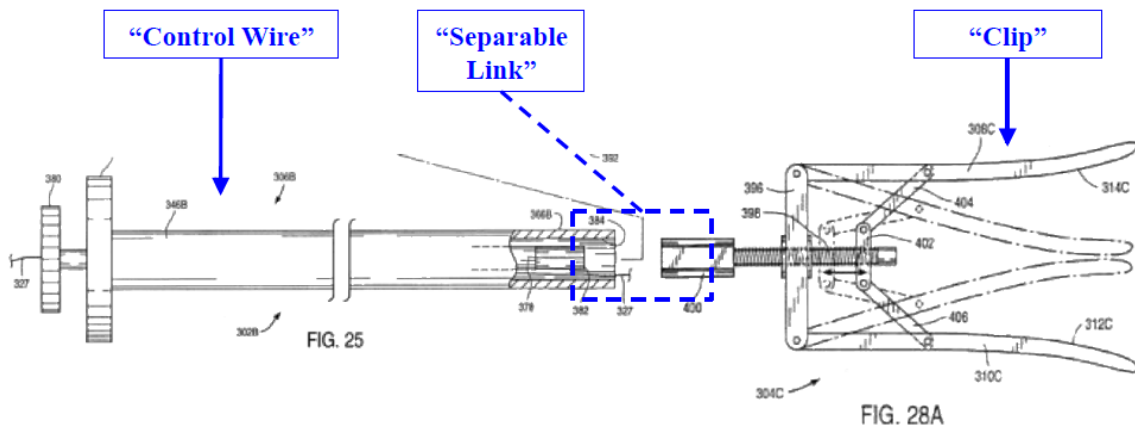
According to Petitioner, Malecki Embodiment #1 discloses a medical device including a clip with clip arms, and a control wire for opening and closing the clip. Pet. 19. Petitioner contends that an opening element urges the clip arms away from one another into an open tissue-receiving configuration as the control wire is moved distally, as depicted in annotated

Figures 25 and 28A below. *Id.*



Petitioner’s annotated Figures 25 and 28A (Pet. 19) depicting a clip with opening element 404 engaging clip arms 308C and 310C.

Petitioner alleges that Malecki discloses that the same clamp positioner (306B of Figure 25) “may be used with each of the clips shown in Malecki Embodiments #1 and # 2.” Pet. 20 (citing Ex. 1003, 17:55–57). Thus, according to Petitioner, “Malecki Embodiment[] #1 [] also disclose[s] a separable link between the control wire and clip, to allow the clip to remain in a patient’s body, as shown below.” *Id.*



Petitioner’s annotated Figures 25 and 28A (Pet. 21) depicting an alleged separable link between a control wire and a clip.

Petitioner argues that “Malecki Embodiment #1 discloses a clip (clamp 304C) including first and second clip arms (jaws 308C, 310C).” Pet.

23. Further, according to Petitioner, the clip arms are movable between an open tissue receiving configuration depicted in Figure 28A and a closed configuration (dashed line position in Figure 28A) in which the first and second arms are moved inward to capture the tissue. *Id.* For the “control wire” limitation of claims 12 and 20, Petitioner relies on rotating the drive body 346B, which results in the application of a proximal tensile force to the control wire (346B, 400, 398) to close the clip (304C), and rotating the drive body 346B in the other direction, which results in the application of a distally directed force to the control wire to open the clip of Malecki Embodiment #1. Pet. 32, 33, 37, 41.

Most relevant for our discussion below, 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,” as being taught by Malecki Embodiment #1. *Id.* at 24–25. Specifically, as depicted below, “an opening element (links 402, 404, connector 406 (highlighted in yellow)) that urges the first and second clip arms (308C, 310C) away from one another, from a closed configuration (dashed line position) into the open tissue receiving configuration (solid line position).” *Id.* at 24.

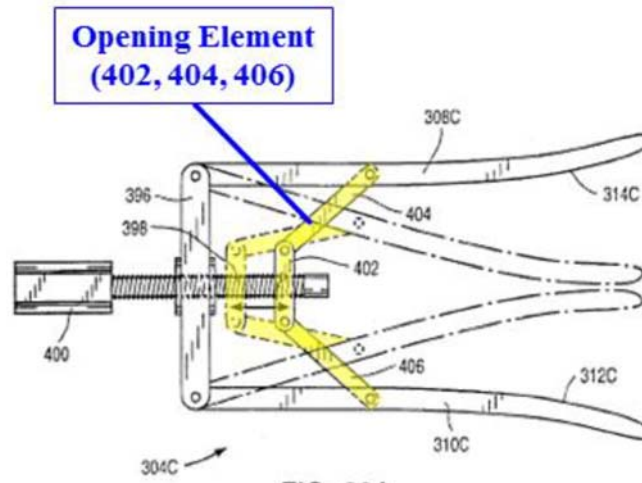
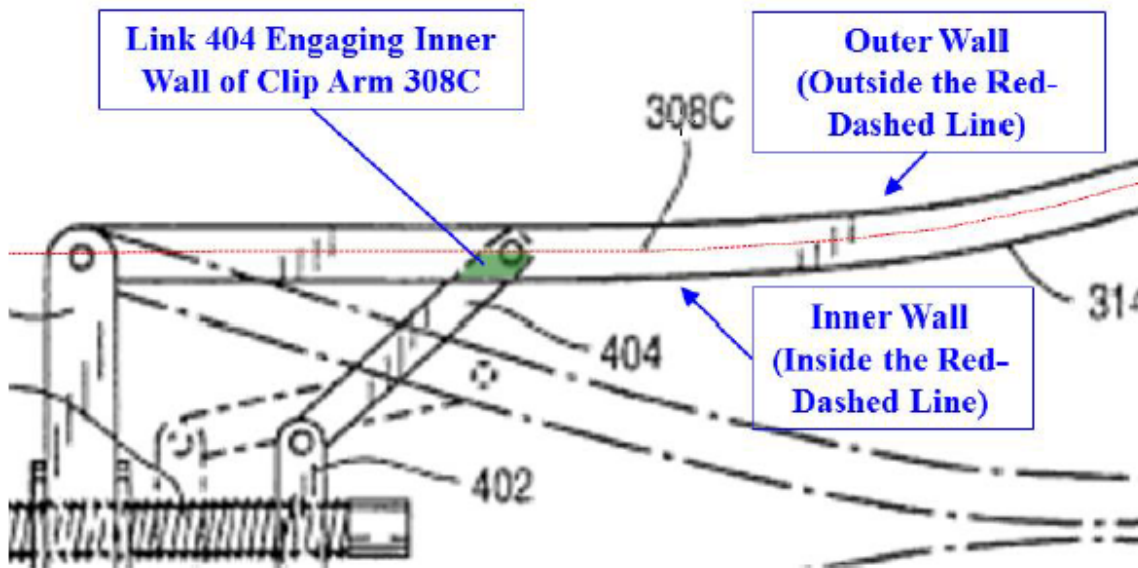


FIG. 28A

Petitioner's annotated Figure 28A (Pet. 25) showing opening element 402, 404, and 406 highlighted in yellow.

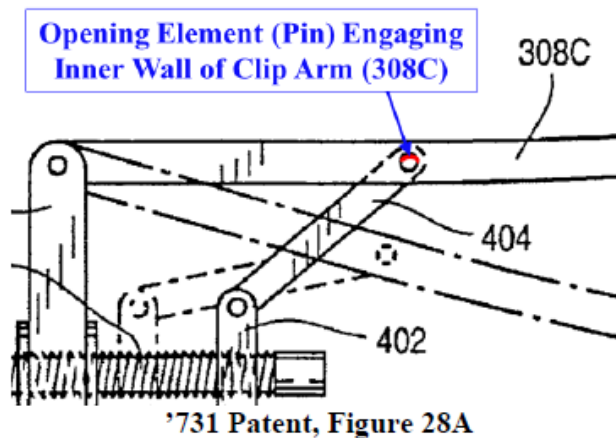
Petitioner contends that the opening element engages the inner walls of the first and second clip arms on two instances. Pet. 25–26. In the first instance, links 404, 406 of the opening element engage the inner walls of the first and second clip arms (308C, 310C). *Id.* Petitioner relies on the following annotated Figure 28A:



Petitioner's annotated partial Figure 28A (Pet. 26).

As depicted above, Petitioner contends that any surface below the red dashed line is an inner wall. More specifically, “links 404, 406 of the opening element engage the inner walls (inner wall engagement highlighted in green) of the first and second clip arms (308C, 310C).” Pet. 25.

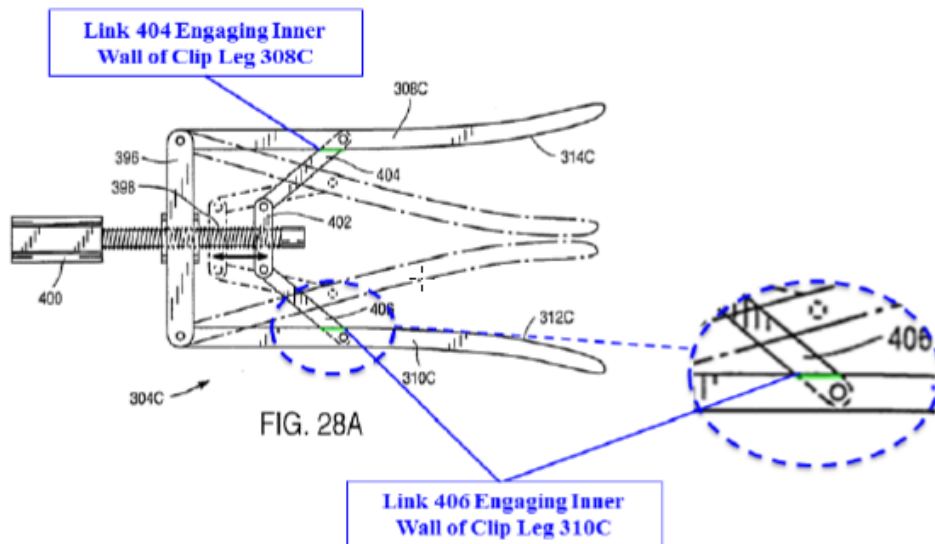
Petitioner also relies on an alternative theory. *See* Pet. 26; Pet. Reply 11. Petitioner contends “the opening element engages the inner bearing wall of pin holes in the clip arms (308C, 310C) (i.e., inner walls of the clip arms) via pins, which connect links 404, 406 to the clip arms (308C, 310C).” Pet. Reply 26. Petitioner further explains in reply that “Malecki’s links engage inner walls of the clip arms by engaging the inner bearing wall of the pinholes where the links connect to the arms via pins.” Pet. Reply 11.



Petitioner’s annotated partial Figure 28A (Pet. Reply 11) with a half circle highlighted in red on the upper portion of an alleged pin hole.

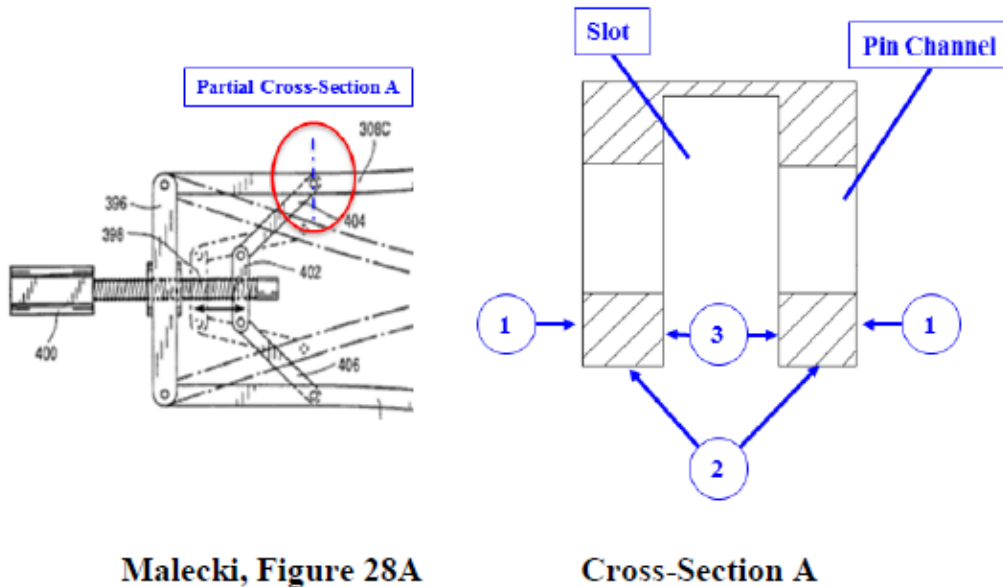
In its Reply, Petitioner modifies its theory and alleges that “Malecki’s links engage the ‘inner walls’ identified by BSSI at the edge of the walls, as highlighted in green [below]. (Ex.1095, ¶27).” Pet. Reply 14. Petitioner’s modified theory was arguably in response to Patent Owner’s claim construction position set forth in its Response. Petitioner argues that even under Patent Owner’s claim construction, which we generally adopt as noted

above, the claim limitation would still be met by contact along the green line pictured below. *See* Pet. Reply 12. As depicted below, Petitioner alleges that “links contact the ‘inner walls’ of the clip arms at the junction between these walls and the slots.” *Id.* at 14.



Petitioner’s partial annotated Figure 28A (Pet. Reply 14) with a separate call out enlargement depicting a green line.

Petitioner also argues that Malecki uses a pin channel and slot as further depicted below in a drawing created by Petitioner and Dr. Nicosia to illustrate Petitioner’s arguments:



On the left is Petitioner’s partial annotated Figure 28A (Pet. Reply 15) and on the right is a purported cross-sectional drawing created by Dr. Nicosia (Ex. 1095 ¶ 27).

Petitioner argues that “[a]nnotated Figure 28A and the partial cross-section [above] (prepared by Dr. Nicosia) illustrate the ‘inner wall’ identified by BSSI (including the surface labeled (2)), and the edges where the opening element contacts the ‘inner wall’ (including corners where surfaces (2) meet surfaces (3)).” Pet. Reply 14. Dr. Nicosia similarly states, “[i]n my opinion, this contact with the edge of the radially inward-facing wall of the clip arms satisfies the limitation ‘an opening element engaging inner walls of the . . . clip arms,’ as BSSI has applied this term.” Ex. 1095 ¶ 27.

Patent Owner argues that Malecki Embodiment #1 does not disclose “an opening element engaging inner walls of the first and second clip arms” as required by each independent claim. PO Resp. 9–12, 21–23. In its Response, Patent Owner notes that Petitioner sets forth “inconsistent constructions” of what can constitute an “inner wall.” *Id.* at 9.

Patent Owner addresses Petitioner’s first theory that an “inner wall” could be

“the portion of the jaw side wall highlighted in green below the red line in [annotated] Malecki Figure 28A” (Pet. 26 and depicted above). PO Resp. 9. Patent Owner notes that this portion of Malecki’s side wall could not be an “inner wall” “because the links 404, 406 connect to the side/lateral walls of the jaws 308C, 310C, *not* the exterior surfaces of the radially inward-facing walls.” *Id.* at 22. Thus, according to Patent Owner, “Malecki contains no disclosure that links 404, 406 engage the radially inward facing walls of jaws 308C, 310C.” *Id.*

Patent Owner’s expert, Dr. Vaitekunas, likewise, confirms that “[t]he jaws of Malecki Embodiment #1 have four walls,” and “[t]he portion of links 404, 406 that connects to the jaws are outlined with dashes.” Ex. 2010 ¶ 66. According to Dr. Vaitekunas a person of ordinary skill in the art “would understand Figure 28A to illustrate links 404, 406 connecting to the side walls of jaws 308C, 310C on the side or lateral wall opposite (or underneath) the one shown in Figure 28A.” *Id.* Thus, the portion of the jaw shaded in green is a portion of the side/lateral wall, not a radially inward-facing wall. Ex. 2010 ¶ 68.

Patent Owner next addresses Petitioner’s engagement pin theory. *See* PO Resp. 12. Patent Owner argues that the alleged pin does not engage an “inner wall” because this pin hole is first not even disclosed and is also in the direction of the outer wall. *Id.* Patent Owner argues that “[t]he assumed engagement highlighted in red is not an exterior surface but rather a cutout inside the clip arm for a pin.” *Id.* at 10. Patent Owner further argues that “the portion of the pin hole engaged by the pin would move as jaws 308C, 310C open and close,” thus, “the ‘red engagement’ is not fixed but would change based on the movement of the links and jaws.” *Id.* Patent Owner



relies on Dr. Vaitekunas testimony that “[a] POSA would not understand a pinhole cutout to constitute a ‘wall’ of the clip arm.” *Id.* at 14 (citing Ex. 2010 ¶ 53). Dr. Vaitekunas further testifies that:

Petitioners also contend that an engagement between a pin (not disclosed in Malecki) and a pin hole (not disclosed in Malecki) satisfies the “engaging the inner walls of the first and second clip arms” limitation. Petition at 27. Even if contact does occur between a pin and a pinhole, the contact occurs in the pin hole, not the exterior surface of a radially inward-facing wall.

Ex. 2010 ¶ 69.

Patent Owner also argues “that Malecki does *not* disclose that the linkages 404, 406 contact any outside portion of the inner wall.” PO Resp. 11, n.2. Patent Owner relies on the cross-examination testimony of Dr. Nicosia and argues “that Malecki does not disclose links 404, 406 contacting the radially inward-facing walls.” PO Resp. 23 (quoting Ex. 2012, 274:12–23). Specifically, when asked “Q. And there is nothing in Malecki, there is no disclosure in Malecki that says that links 404 and 406 contact the exterior surface of the radially inward facing jaws, right?” Dr. Nicosia testifies that “A. . . . Malecki doesn't specifically say the link arms contact the rad -- sorry, the exterior radially inward facing surface. Malecki does not explicitly say that, that's correct.” Ex. 2012, 274:12–23

As we explain in more detail below, we find Patent Owner's contentions more persuasive than Petitioner's three disjointed theories.

Based on the final trial record, including our interpretation of “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,” Petitioner has not persuasively established that Malecki Embodiment #1 discloses this limitation. We find persuasive the testimony

of Dr. Vaitekunas, that “[t]he jaws of Malecki Embodiment #1 have four walls,” and a person of ordinary skill in the art “would understand Figure 28A to illustrate links 404, 406 connecting to the side walls of jaws 308C, 310C on the side or lateral wall opposite (or underneath) the one shown in Figure 28A.” Ex. 2010 ¶¶ 66, 68. We agree with Dr. Vaitekunas that a person of ordinary skill in the art would not consider side or lateral walls as “inner walls” under the broadest reasonable interpretation of that term. Thus, the portion of the jaw identified by Petitioner as shaded in green (Pet. 26) is a portion of the side/lateral wall, not an inward-facing wall. *See* Ex. 2010 ¶ 68.

Petitioner has also not persuasively established that linkages 404, 406 contact any outside portion of the inner wall. As noted by Patent Owner above, Petitioner’s expert admits that Malecki does not disclose links 404, 406 contacting the radially inward-facing walls. *See* Ex. 2012 at 274:12–23.

We also do not find persuasive Petitioner’s pin engagement theory. First, neither Petitioner nor Dr. Nicosia persuasively establish that a slot and pin channel (Pet. 15) is used in Malecki Embodiment #1. *See* Ex. 1095 ¶ 27. As pointed out by Dr. Vaitekunas, Petitioner’s theory that an engagement between a pin and a pin hole satisfies the “engaging the inner walls of the first and second clip arms” limitation is based on structure that is simply not disclosed in Malecki. Ex. 2010 ¶ 69. Further, we agree with Dr. Vaitekunas that “[e]ven if contact does occur between a pin and a pinhole, the contact occurs in the pin hole, not the exterior surface of a radially inward-facing wall.” *Id.*

Finally, Petitioner seems to recognize that a modification would be necessary to meet this claim limitation because the connection between the

links and jaws occurs along the side/lateral wall, not the inner wall. *See* Pet. 45 (“It would have been obvious simply to move the pivot connections between the links (404, 406) and the clip arms (308C, 310C) in Figure 28A from lateral walls of the clip arms, to radially inward-facing walls of the clip arms.”); Ex. 1037 ¶ 64. These obviousness contentions are addressed in the next section.

Petitioner has failed to establish by a preponderance of the evidence that Malecki Embodiment #1 discloses the “engaging inner walls” limitation required by independent claims 1, 12, and 20. Thus, Petitioner has not proven that Malecki Embodiment #1 anticipates any of claims 1, 12, and 20.

*3. Discussion of Dependent Claims 2–4, 6, 9–11, and 13–18*

Having decided that Petitioner has not shown by a preponderance of the evidence that Malecki Embodiment #1 discloses the elements of each independent claim (claims 1, 12, and 20) challenged in the Petition, we determine that Petitioner has also failed to prove by a preponderance of the evidence that dependent claims 2–4, 6, 9–11, and 13–18 would have been anticipated by Malecki Embodiment #1.

*D. Claims 1–4, 6–18, and 20 as Obvious in view of Malecki Embodiment #1*

Petitioner contends claims 1–4, 6–18, and 20 are unpatentable, under 35 U.S.C. § 103, as obvious based on Malecki Embodiment #1. Pet. 42–57. Petitioner contends “[t]o the extent the walls engaged by the opening element are not considered ‘inner walls,’ this limitation is not a patentable distinction over Malecki Embodiment #1.” *Id.* at 42. Petitioner presents a modification theory that “[i]t would have been obvious to a person of ordinary skill in the art to construct the device shown in Figure 28A such

that the links 404, 406 engage any one of these walls.” *Id.* at 43–44.

As examined in detail above, we have determined that Malecki Embodiment #1 does not disclose the “inner walls” limitation. Below, we consider the parties’ arguments related to obviousness. Based on the final trial record before us, and albeit a much closer determination than anticipation, Petitioner fails to establish why it would have been obvious to make certain modifications to Malecki Embodiment #1 in order to meet the “engaging inner walls” limitation required by independent claims 1, 12, and 20.

Petitioner first points out that Malecki discloses radially outward-facing walls, side or lateral walls, and also radially inward-facing walls. Pet. 43. Petitioner contends that “[i]t would have been obvious to a person of ordinary skill in the art to construct the device shown in Figure 28A such that the links 404, 406 engage any one of these walls.” *Id.* (citing Ex. 1037 ¶ 61). Petitioner contends that the basis for this modification is that “[e]ngaging the radially inward-facing walls would have been merely one of a finite number of known and obvious options, yielding predictable results.” *Id.* (citing Ex. 1037 ¶ 61).

Petitioner also relies on other embodiments of Malecki that allegedly show opening elements that engage radially inward-facing walls of first and second clip arms. Pet. 43–44. More specifically, Petitioner relies on Figure 30B of Malecki, which purports to show a spring as an opening element engaging jaws or arms. *Id.* Petitioner contends that “[a] person of ordinary skill in the art would have recognized that the device in Figure 28A likewise could be modified so that the opening element engages radially inward-facing walls of clip arms (308C, 310C).” *Id.* at 44 (citing Ex. 1037

¶ 63).

As for the specific modifications necessary, Petitioner argues that “[i]t would have been obvious simply to move the pivot connections between the links (404, 406) and the clip arms (308C, 310C) in Figure 28A from lateral walls of the clip arms, to radially inward-facing walls of the clip arms.” Pet. 45 (citing Ex. 1037 ¶ 64). Petitioner reasons that “a bracket that contained a pivot connection could be attached to the radially inner-most wall of the clip arms to attach the links (404, 406) to the clip arms (308C, 310C).” *Id.* (citing Ex. 1037 ¶ 64); *see* Pet. Reply 29 (relying on “bracket or hook/rod connection” and arguing “a PHOSITA would have been familiar with such connections” as well as “the proposed bracket connection would satisfy the instituted claims”) (citing Malecki Fig. 19).

Petitioner further argues in its Reply, that the law does not require a design need or market pressure to make modifications. Pet. Reply 27. Petitioner also argues that a modification to engage radially inward-facing walls was a known option at the time of the invention. *Id.* at 29 (citing Malecki Figure 18). Petitioner also contends that the modification was a simple substitution that would not complicate the design because “[a] PHOSITA would have considered the modification to be, at best, a trivial, common sense variation of Figure 28A.” *Id.* at 30. Petitioner also notes “that Malecki’s clips are not limited to ‘large’ devices for use solely in ‘the arterial system,’ and that the clips could easily be adapted for endoscopic applications by optimizing their size.” *Id.* at 31 (citing Ex. 1095 ¶ 46).

Patent Owner responds, arguing that “Malecki does not disclose the claimed invention,” and “Petitioners do not provide a rationale for combining the different embodiments of Malecki or modifying Malecki

Embodiment #1.” PO Resp. 36. Patent Owner alleges that Petitioner picks and chooses structural elements of several of Malecki’s embodiments and proposes combining them to create the claimed inventions using the claimed inventions themselves as a guide, which is quintessential hindsight. *Id.* Patent Owner contends that “Petitioner[] provide[s] the conclusory assertion that it would have been obvious to modify Malecki Embodiment #1 so the link arms engage the radially inward-facing walls because it is one of a finite number of known and obvious options,” however, “Petitioners provide no motivation whatsoever explaining why a person of ordinary skill in the art would have chosen the specific permutation that Petitioners chose.” *Id.* at 38. Further, Patent Owner contends that Malecki has a plethora of different embodiments and none is the same as the claimed inventions. *Id.* Patent Owner argues that Petitioner lacks adequate support to show that a finite number of permutations exist, and, thus, the claimed permutation is obvious. *Id.*

Patent Owner argues more specifically that Petitioner has failed to demonstrate that engaging the inner walls was a known option. PO Resp. 39. Patent Owner examines Petitioner’s two proposed modifications, namely, “Petitioners assert this could be done by attaching a ‘bracket that contained a pivot connection’ to the inner wall or by modifying links 404, 406 to ‘include a hook on their distal ends that pivotally engages a rod located at the inner-most walls of the clip arms.’” *Id.* at 40 (quoting Pet. 45). Taking into consideration these options, Patent Owner argues that Petitioner fails “to cite any disclosure in Malecki or any prior art whatsoever where the inner walls of the clip arms are connected to the opening element by either a bracket with a pivot connection or a hook/rod combination.” *Id.*

Patent Owner faults Petitioner's reliance on Malecki's "embodiments that use either a spring or wedge as their opening element," because Petitioner's proposed modification does not use a spring or wedge, and Petitioner has failed to "explain how a modified Malecki Embodiment #1 using a spring or wedge would replicate the claimed inventions, let alone how it would render them obvious." *Id.* Patent Owner further argues that "Petitioners admit that Malecki does not suggest using a spring or wedge to engage the jaws of Figure 28A." PO Resp. 41 (citing Ex. 2012, 336:24–337:7). Patent Owner notes that "even if a spring or wedge could be used as an opening element in place of the disclosed arrangement involving links 404, 406, Petitioners fail to explain how the first and second jaws 308C, 310C of the modified clamp could be closed." *Id.* at 40–41, n.5.

We find this line of argument persuasive – Petitioner has not shown any prior art where the inner walls of the clip arms are connected to the opening element by either a bracket with a pivot connection or a hook/rod combination. Even though, for example, Figure 30B of Malecki shows a spring engaging what could be arguably called inner walls, this mechanism is simply not the same as that relied on by Petitioner in Figure 28. Further, Petitioner has not shown how a person of ordinary skill in the art would have integrated such embodiments, or found them compatible. Based on the record before us, we are not convinced that a person of ordinary skill in the art would have modified Malecki to adopt a spring or wedge to engage the inner walls of the jaws of Figure 28A.

Patent Owner also argues that "a modified Malecki device using Petitioners asserted hook/rod combination would still fail to meet this limitation," because "[t]he links/hooks would only contact the rods and

possibly the walls of the channel the rod is located in.” PO Resp. 40, n.4. “Thus,” according to Patent Owner, “the device still would not have an opening element contacting the radially inward-facing walls of the jaws.” *Id.* (citing Ex. 2010 ¶ 101). We do not find this argument by Patent Owner particularly persuasive because it presumes that such a hook/rod combination embedded into the inner wall would not be engaging the inner wall because of intermediate structure (the walls of the channel).

Patent Owner argues that even in the embodiments of Malecki cited by Petitioner as allegedly showing engagement of the inner walls, such as Figures 29B, 30B, and 31C, there is no actual engagement of inner walls of the first and second clip arms. PO Resp. 41. Patent Owner points to Figure 29B and the description that “a ‘[w]edge 410 is sized to engage the opposed faces 412, 414 of *extensions* 372D, 374D,’” but not the clip arms. *Id.* (quoting Ex. 1003, 18:4–6 (emphasis added)); Ex. 2012, 311:15–21 (Petitioner’s declarant admitting that “A. Again, the wedge doesn’t contact what Malecki labels jaw 308D and 310D.”). According to Patent Owner, therefore, “the wedge does not engage the jaws 308D, 310D.” PO Resp. 41. Likewise, Patent Owner argues that “[t]he spring in Figure 30B does not engage the inner walls of both jaws 308E, 310E, but rather the jaw extension 320E.” *Id.* (citing Ex. 1003, 18:10–14); *see also* Figure 30B (showing the spring 420 against jaw extension 320E); Ex. 2012, 298:11–28 (“A. The spring in 30B contacts what Malecki refers to as jaw extensions.”). Turning to the embodiment of Figure 31C, Patent Owner argues that “Malecki does not disclose or depict the spring engaging the inner walls of the jaws 308H, 310H,” because “jaw 310H does not extend the entire distance towards the spring, but rather stops near slot 441 where it connects to an extension.” PO



Resp. 42 (citing Ex. 2012, 317:14–23). Based on this analysis, Patent Owner summarizes that “Figures 29B, 30B and 31C do not disclose an opening element that contacts the inner walls of both jaws,” and “[t]hus, Petitioners fail to cite any disclosure in Malecki of an embodiment with ‘an opening element engaging inner walls of the first and second clip arms.’” *Id.*

We find somewhat persuasive Patent Owner’s arguments that these embodiments discussed above (spring/wedge) do not actually engage inner walls of the first and second clip arms. In all fairness, the extensions (e.g., extensions 372D, 374D of Fig. 29B) could arguably be considered part of the jaws, although we believe otherwise. Even if these extensions were considered part of the clamp arms, we find more persuasive Patent Owner’s related contentions that these embodiments with springs and wedges engaging inner walls of the clamp arms are simply not compatible with the structure and function of Malecki Embodiment #1’s (Figure 28’s) opening and closing mechanism as discussed more below.

Patent Owner next argues that a person of ordinary skill in the art would not be motivated to modify Malecki Embodiment #1 because it would complicate the design without any benefit. PO Resp. 42. Patent Owner contends that “adding a bracket as proposed by Petitioners would require further modifications to links 404, 406, which Petitioners do not disclose in their Petition.” *Id.* (citing Ex. 2012 at 307:20–308:9; 309:14–310:5 (“You may have to slightly modify the link arm to -- if you change that end connection assuming that’s something that we’re working with.”)). Dr. Vaitekunas opines that “[a] POSA would likely need to bend the distal end of links in some manner to have the links (and brackets) flush against

the inner walls of the clip arms (as opposed to perpendicular as shown in the original Figure 28A).” Ex. 2010 ¶ 107. Based on this reasoning, Dr. Vaitekunas testifies that a person of ordinary skill in the art would not be motivated to modify Malecki Embodiment #1 as Petitioners propose. *Id.* For reasons discussed in more detail below, we find these contentions persuasive.

Having now considered the evidence in the complete record established during trial, we are not persuaded that, based on this record, Petitioner has demonstrated by a preponderance of the evidence that claims 1–4, 6–18, and 20 would have been obvious over Malecki Embodiment #1. Petitioner argues that it would have “been obvious simply to move the pivot connections between the links (404, 406) and the clip arms (308C, 310C) in Figure 28A from lateral walls of the clip arms, to radially inward-facing walls of the clip arms,” because such a modification was simple, trivial, well-known, common-sense, or one of a limited number of options. *See, e.g.,* Pet. 30, 45. Petitioner has not established by a preponderance of the evidence that these contentions are correct.

Based on the record before us in this proceeding, Petitioner has not persuasively established that proposed changes to Malecki Embodiment #1 were well-known or simple. Petitioner does not cite one embodiment, amongst Malecki’s 51 Figures, that shows a structure similar to that of Figure 28 engaging the radially inward-facing walls. Further, even though Petitioner alleges such an arrangement of engaging inner walls was purportedly well-known or simple for Malecki Embodiment #1, Petitioner has not produced any evidence showing that such structure was well-known at the time of the invention of the ’731 patent.

Likewise, Petitioner's analysis lacks adequate support to show that a finite number of permutations exist, and, thus, the claimed permutation would have been obvious. Petitioner cites to other embodiments in Malecki as evidencing inner wall connections, but as explained by Patent Owner these embodiments do not actually engage inner walls of the first and second clip arms. *See* PO Resp. 41–42. Further, even if the cited embodiments of Malecki do engage the inner walls, such as Figure 30B's spring, these mechanisms could not be substituted in Malecki Embodiment #1 without impacting the ability of Malecki Embodiment #1 to read on certain limitations of claims 1, 12, and 20. For example, even if a spring or wedge could be used as an opening element in place of the disclosed arrangement involving links 404, 406, Petitioner fails to explain adequately how the first and second jaws 308C, 310C of the modified clamp could be closed. Thus, Petitioner's reliance on Malecki's embodiments that use either a spring or wedge as their opening element, is not convincing because Petitioner's proposed modification does not use a spring or wedge, and Petitioner has failed to explain how a modified Malecki Embodiment #1 using a spring or wedge would render the claims obvious.

Considering the design and structure of Malecki Embodiment #1 (Figure 28A) as a whole, we are not convinced that moving the pivot connections between the links (404, 406) and the clip arms (308C, 310C) from lateral walls of the clip arms to radially inward-facing walls of the clip arms would function as Petitioner contends without further modifications, which Petitioner does not adequately address. The evidence before us suggests that adding a bracket as proposed by Petitioner would require further modifications to links 404, 406, which Petitioner does not

persuasively explain in its Petition or supporting declarations.

Petitioner's expert admitted that at least a slight modification would be necessary, but offers no additional testimony as to how these changes could be integrated into the design. *See* Ex. 2012 at 307:20–308:9; 309:14–310:5 (“You may have to slightly modify the link arm to -- if you change that end connection assuming that's something that we're working with.”)). Instead, we find Dr. Vaitekunas's testimony more persuasive that a person of ordinary skill in the art would have to at least bend the distal end of links in some undisclosed manner to have the links (and brackets) flush against the inner walls of the clip arms (as opposed to perpendicular as shown in the original Figure 28A). Ex. 2010 ¶ 107.

Petitioner discounts these undisclosed, but necessary, additional modifications as minor changes, but they weigh in the totality of the evidence before us. Considering this evidence in the aggregate, we are not convinced that a person of ordinary skill in the art would be motivated to modify Malecki Embodiment #1 as Petitioner proposes, absent hindsight reconstruction using the claims of the '731 patent as a roadmap.

We agree with Petitioner that the law does not necessarily require a design need or market pressure to make modifications (Pet. Reply 27), but Petitioner does not prove its own basis for making the changes by persuasively showing that the proposed modifications were well-known or simple. Further, Petitioner does not offer a persuasive reason for why a person of ordinary skill in the art would have made the specific design modifications necessary to read on the claims. Petitioner has thus not established by a preponderance of the evidence that the subject matter of claims 1, 12, and 20 would have been obvious over Malecki Embodiment

#1. Because each challenged dependent claim depends from one of these independent claims, we likewise determine that claims 2–4, 6–11, and 13–18 would not have been obvious over Malecki Embodiment #1.

*E. Claims 1, 2, 4, 10, 12, and 13 as Anticipated by Malecki Embodiment #2*

Petitioner contends claims 1, 2, 4, 10, 12, and 13 are unpatentable, under 35 U.S.C. § 102, as anticipated by Malecki Embodiment #2. Pet. 58–69.

*1. Overview of Malecki Embodiment #2 (Ex. 1003)*

Malecki Embodiment #2 is represented by Figures 25–27. Ex. 1003. Figures 25 and 26 are depicted below.

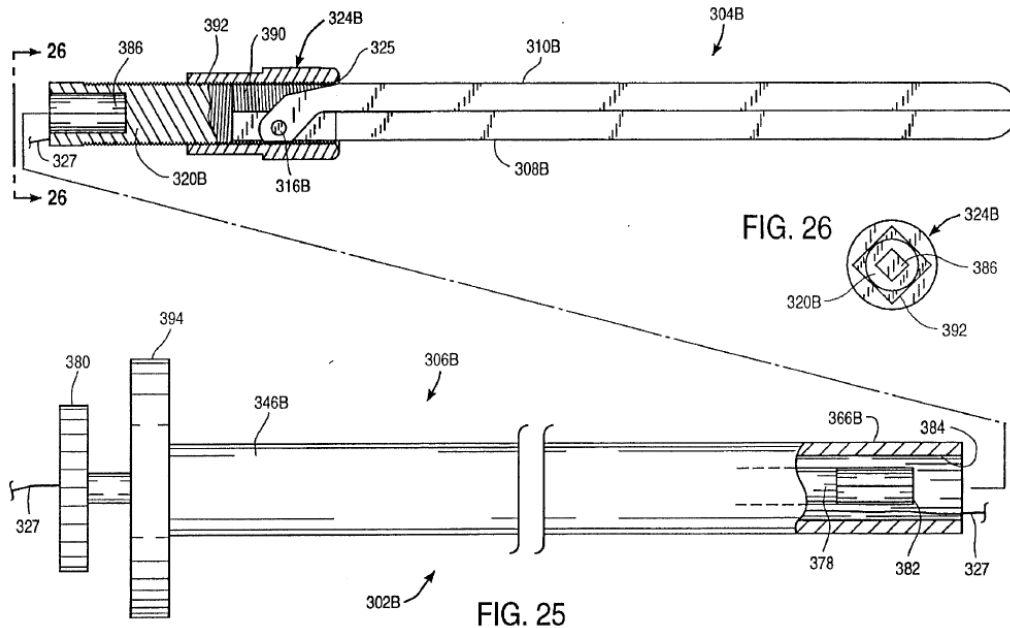


Figure 25 depicts a side view of a clamping assembly with the jaws actuated with a drive rod and Figure 26 represents an end view. Ex. 1003, 6:21–25.

Malecki describes “a clamp 304B having first and 55 second jaws 308B, 310B,” wherein “[t]he first jaw 310B is pivotally mounted to a threaded jaw extension 320B at a pivot 316B while jaw 308B is fixed.” Ex. 1003, 16:53–

59 (emphasis added). Further, “[j]aws 308B, 310B are normally biased towards the open position of FIG. 27B by a torsion spring (not shown).” *Id.*

## 2. Discussion of Claims 1 and 12

We begin our analysis with independent claims 1 and 12. Petitioner asserts that Malecki Embodiment #2, alone, discloses all elements of these claims. Pet. 58–61, 66–67. For the reasons set forth below, and based on the final record, Petitioner has not established persuasively that Malecki Embodiment #2 discloses each limitation of these claims.

Each of claims 1 and 12 require a clip movable to “a closed configuration in which *the first and second arms are moved inward* to capture the tissue received therebetween.” Ex. 1033, 15:42–44, 16:29–31 (emphasis added). Petitioner contends that

Malecki Embodiment #2 discloses a clip (clamp 304B) including first and second clip arms (jaws 308B, 310B), and moveable between an open tissue receiving configuration (Figure 27B) in which the first and second arms are separated from one another by a distance selected to receive tissue and a closed configuration (Figure 25) in which the first and second arms are moved inward to capture the tissue.

Pet. 58. Petitioner relies, in part, on annotated Figure 27B of Malecki depicted below.

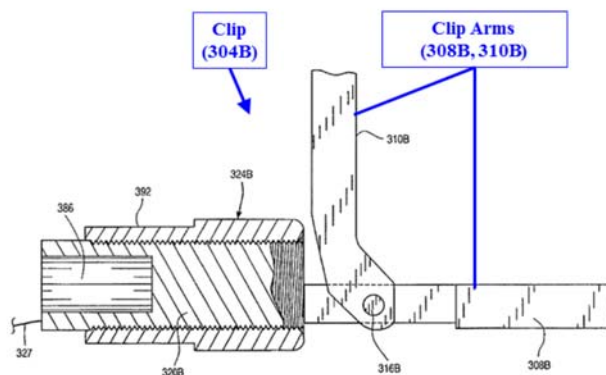


FIG. 27B

Petitioner’s annotated Figure 27B (Pet. 59) showing clip arms 308B and 310B.

Patent Owner contends that “Malecki Embodiment #2 does not disclose a medical device ‘in which the first and second arms are moved inward to capture the tissue received therebetween.’” PO Resp. 41.<sup>6</sup> Patent Owner argues that although Malecki Embodiment #2 has two jaws (308B, 310B) with the first jaw 310B being pivotally mounted, Malecki depicts and describes jaw 308B as being only fixed. *Id.* Specifically, Malecki states that “[t]he first jaw 310B is pivotally mounted to a threaded jaw extension 320B at a pivot 316B while jaw 308B is fixed.” Ex. 1003, 16:53–59 (emphasis added).

In its Supplemental Reply, Petitioner offers evidence and testimony that the claim limitation “the first and second arms are moved inward” does not require that both arms be movable inward. Supp. Reply 8–12. Petitioner argues that “[t]he phrase ‘moved inward’ does not connote an *action*, but instead a *state* of the clip legs.” *Id.* at 9. According to Petitioner, therefore, “the phrase ‘moved inward to capture the tissue received therebetween’ does not connote a requirement that each of the clip arms actually ‘move[s] inward.’” *Id.* (citing Ex. 1109 ¶ 9). Petitioner also argues that “a PHOSITA would not have understood the claims as requiring that the clip arms move ‘in relation to the clip,’” because “the clip arms cannot move in relation to the clip, itself.” Supp. Reply 9–10 (quoting Dec. 17). Petitioner argues that

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<sup>6</sup> Because we originally denied institution based on arguments set forth in Patent Owner’s Preliminary Response (Dec. 14–19), and because the intervening Supreme Court decision in *SAS* required institution of all claims, we allowed Patent Owner to file a Supplemental Response incorporating by reference its Preliminary Patent Owner Response. *See* Supp. Resp. 1.

the claims encompass any type of movement that brings the clip arms closer together to capture tissue, including where one arm is fixed. *Id.* at 10.

Based on the complete trial record, including Petitioner's Supplemental Reply brief and corresponding testimony, Petitioner has not established by a preponderance of the evidence that Malecki Embodiment #2 discloses a clip movable to "a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween." We agree with Patent Owner that the claims require a structural configuration wherein "the first and second arms are moved inward," which requires that both arms be movable inward to that closed configuration. Based on the record before us, arm 308B is fixed and thus, not able to be moved inward as required by the claim language.

Petitioner's analysis in the Petition (Pet. 58) does little more than repeat the claim language and allege that Malecki Embodiment #2 meets the claim requirement that "the first and second arms are moved inward." Pet. 58. The Petition does not adequately explain how "the first and second arms are moved inward" in relation to the clip when the embodiment relied on states that arm 308B is fixed and therefore not movable.

In its Supplemental Reply, Petitioner addresses the issue, but does not overcome the simple fact that arm 308B is fixed such that it physically cannot move inward to capture tissue. Arm 308B will never achieve the state of "a closed configuration" as required by the claim language because arm 308B cannot be "moved inward to capture the tissue." Based on the final record, Petitioner has not established persuasively that Malecki Embodiment #2 discloses "the first and second arms are moved inward" requirement of claims 1 and 12. For this reason, Petitioner has failed to



show by a preponderance of the evidence that Malecki Embodiment #2 anticipates claims 1 and 12.

*3. Claims 2, 4, 10, and 13*

Petitioner asserts that Malecki Embodiment #2 discloses all elements of these claims. Pet. 62–69.

Claims 2, 4, and 10 depend from claim 1 and claim 13 depends from claim 12. In its analysis of these claims, Petitioner does not provide any argument or evidence overcoming the deficiencies we noted above as to claims 1 and 12. For the reasons set forth above for claims 1 and 12, Petitioner has failed to prove by a preponderance of the evidence that Malecki Embodiment #2 anticipates claims 2, 4, 10, and 13.

*F. Claims 3, 6–9, 14, and 20 as Obvious in view of Malecki Embodiment #2*

Petitioner contends claims 3, 6–9, 14, and 20 are unpatentable, under 35 U.S.C. § 103, as obvious over Malecki Embodiment #2. Pet. 70–82. We note for this ground based on obviousness, Petitioner never asserts that claims 1 and 12 are obvious over Malecki Embodiment #2, but instead relies on its anticipation analysis of those claims. *See id.*

*1. Claims 3, 6–9, 14, and 20*

Petitioner asserts that Malecki Embodiment #2 teaches all elements of these claims. Pet. 70–80.

Claims 3, 6–9, and 14 depend directly, or indirectly, from either claim 1 or claim 12. As discussed above, we determine that Petitioner has not proven by a preponderance of the evidence that claims 1 and 12 are anticipated by Malecki Embodiment #2 because this embodiment fails to disclose “the first and second arms are moved inward” limitation.

In its obviousness analysis of claims 3, 6–9, and 14 Petitioner does not provide any argument or evidence overcoming the deficiencies we noted above as to claims 1 and 12. For the reasons set forth above for claims 1 and 12, Petitioner has failed to prove by a preponderance of the evidence that claims 3, 6–9, and 14 would have been obvious over Malecki Embodiment #2.

## 2. *Claim 20*

Petitioner asserts that Malecki Embodiment #2 teaches all elements of claim 20, including the requirement that the control wire is moved proximally in order “to move the first and second clip arms toward one another to a closed tissue capturing configuration.” Pet. 82. As discussed above, Petitioner does not persuasively show how Malecki Embodiment #2 discloses “moving the control wire proximally to move the first and second clip arms toward one another to a closed tissue capturing configuration,” when one such arm (308B) is fixed.

Notably, claim 20 is a method claim requiring movement to the closed configuration, specifically requiring both clips to “move . . . toward one another.” Arm 308B cannot move. In its obviousness analysis, Petitioner fails to overcome this requirement or to propose any modifications to Malecki Embodiment #2 in order to meet these limitations. We have considered Petitioner’s new arguments in its Supplemental Reply, but find them unpersuasive for the reasons set forth above. *See* Supp. Reply 30–31. Likewise, Petitioner does not offer any theory as to how any other embodiment of Malecki could be combined with Malecki Embodiment #2 to teach this limitation. Accordingly, we determine that Petitioner has failed to demonstrate that claim 20 would have been obvious over Malecki

Embodiment #2.

#### IV. MOTIONS TO EXCLUDE

##### A. *Petitioner's Motion to Exclude*

Petitioner filed a Motion to Exclude Exhibit 2100 (Paper 64), to which Patent Owner filed an Opposition (Paper 69). 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 64, 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 69, 1 (citing Ex. 1101 ¶ 70).

We have not considered this Exhibit 2100 in our Final Decision. Because Exhibit 2100, and corresponding testimony it purportedly responds to, all relate to Petitioner’s Opposition to Patent Owner’s Contingent Motion to Amend, , which we decline to reach as discussed below, and because we do not rely on Exhibit 2100, we deny Petitioner’s Motion to Exclude (Paper 64) as moot.

##### B. *Patent Owner's Motions to Exclude*

Patent Owner filed a first Motion to Exclude (Paper 48) certain evidence submitted by Petitioner, to which Petitioner filed an Opposition (Paper 56), and Patent Owner filed a Reply (Paper 61). Patent Owner also

filed a second Motion to Exclude (Paper 83), to which Petitioner filed an Opposition (Paper 87), and Patent Owner filed a Reply (Paper 88).

In its first Motion to Exclude, Patent Owner seeks to exclude Exhibits 1017, 1035, 1036, 1037 (partially), 1039, and 1074. *See* Paper 48, 1–2. Our determinations do not rely upon Exhibits 1017, 1035, or 1074, therefore, Patent Owner’s motion to exclude these exhibits is denied as moot.

We discuss the remaining exhibits challenged in Patent Owner’s motions, below.

*Exhibits 1036 and 1039*

Exhibits 1036 and 1039 (also 1035) all 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 48, 3–4.

*Exhibit 1037 (Partially)*

Exhibit 1037 is the Nicosia Declaration. In its first Motion to Exclude, Patent Owner seeks to exclude portions of this exhibit that relate to Malecki Embodiment #2 because we originally denied institution on those grounds. As noted above, we thereafter modified our institution decision to include all grounds, therefore, Patent Owner’s request to exclude is moot.

Patent Owner’s first Motion to Exclude (Paper 48) is denied.

*Exhibit 1037*

Patent Owner’s second Motion to Exclude “requests that the Board exclude Petitioners’ Exhibit 1115.” Paper 83, 1. “Exhibit 1115 is an excerpt from the Declaration of Jeffrey J. Vaitekunas, Ph.D., filed in a different inter partes review preceding, IPR2017-00440,” and Patent Owner argues that “[i]t should be excluded as irrelevant under FRE 402-403.” *Id.*

Our determinations do not rely upon Exhibit 1115, therefore, Patent Owner’s Motion to Exclude (Paper 83) this exhibit is denied as moot.

V. PATENT OWNER’S CONTINGENT MOTION TO AMEND

Patent Owner filed a Motion to Amend pursuant to 37 C.F.R. § 42.121. Paper 17 (“Amend Mot.”).

As we have previously explained:

A motion to amend claims may cancel claims and/or propose substitute claims. 35 U.S.C. § 316(d)(1); 37 C.F.R. § 42.121(a)(3). A request to cancel claims will not be regarded as contingent. However, we ordinarily treat a request to substitute claims as contingent. That means a proposed substitute claim normally will be considered only if a preponderance of the evidence establishes that the original patent claim it replaces is unpatentable. A patent owner should adopt a claim-by-claim approach to specifying the contingency of substitution, e.g., which claim for which claim and in what circumstance.

*Western Digital Corp. v. SPEX Tech., Inc.*, IPR2018-0082, -00084 3 (PTAB, Apr. 25, 2018) (Paper 13) (informative). Importantly for our consideration, a proposed substitute claim will be considered only if the original patent claim it seeks to replace is determined unpatentable or is otherwise cancelled.

As discussed above, Petitioner has not demonstrated by a preponderance of the evidence that any of the challenged claims are unpatentable. Accordingly, we do not reach the motion, and the motion is denied as moot.

## VI. SUMMARY

For the foregoing reasons, we conclude that Petitioner has not demonstrated by a preponderance of the evidence the unpatentability of any of the challenged claims of the '731 patent.

Petitioner's Motion to Exclude Exhibit 2100 (Paper 64) is denied.

Patent Owner's first Motion to Exclude (Paper 48) and second Motion to Exclude (Paper 83) are both denied.

Additionally, Patent Owner's Contingent Motion to Amend is denied as moot because we have not found any of claims 1, 12, or 20 to be unpatentable.

## VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has not shown by a preponderance of the evidence that claims 1–4, 6–18, and 20 are unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 64) is *DENIED*.

FURTHER ORDERED that Patent Owner's first Motion to Exclude (Paper 48) and second Motion to Exclude (Paper 83) are both *DENIED*.

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

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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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