

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.

IPR2017-00134
Patent 8,709,027 B2

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

MOORE, *Administrative Patent Judge*.

FINAL WRITTEN DECISION ON REMAND
35 U.S.C. §§ 144, 318(a)

I. Introduction

We address this case on remand after a decision by the United States Court of Appeals for the Federal Circuit in *Cook Group Incorporated, Cook Medical LLC v. Boston Scientific Scimed, Inc.*, 809 F. App'x 990 (Fed. Cir. 2020) (“*Cook Group I*”).¹

In our Final Written Decision of November 3, 2018, we determined that Cook Group Incorporated and Cook Medical LLC (“Petitioner”) had shown by a preponderance of the evidence that claims 1–3, 7–14, and 16–19 of U.S. Patent No. 8,709,027 B2 (“the ’027 patent”) are unpatentable, but had not shown by a preponderance of the evidence that claims 4–6, 15, and 20 of the ’027 patent are unpatentable. Paper 92, 3.

Cook Group Incorporated and Cook Medical LLC (“Petitioner”) and Boston Scientific Scimed, Inc. (“Patent Owner”) each filed notices of appeal of our Final Written Decision. Papers 93 and 94.

In *Cook Group I*, the Federal Circuit found the following:

- (1) affirmed our determination that Petitioner has not shown by a preponderance of the evidence that the ’027 patent claims 1, 3–6, 13–15, 17, and 20 are unpatentable as anticipated under § 102 by Sackier²; *Cook Group I*, 20.
- (2) affirmed our determination that Petitioner has shown by a preponderance of the evidence that the ’027 patent claims 1–3, 7–14, and 16–19 are unpatentable as obvious over Sackier and

¹ References herein are to the slip opinion, No. 19-1370 (Fed. Cir. Apr. 30, 2020).

² U.S. Patent No. 5,749,881, filed on October 20, 1994, and issued May 12, 1998 (“Sackier”) (Ex. 1008).

Nishioka³; *id.* at 20,

- (3) vacated our determination that Petitioner has not shown by a preponderance of the evidence that the '027 patent claims 4–6, 15, and 20 are unpatentable as obvious over Sackier and Nishioka, and remanded to the Board to consider, in the first instance, the weight to be afforded an admission by Patent Owner in its Preliminary Response related to the operation of Sackier; *id.* at 17,
- (4) affirmed our determination that Petitioner has not shown by a preponderance of the evidence that the '027 patent claims 1 and 3–11 are unpatentable as anticipated under § 102 by Malecki or as obvious under under § 103 over Malecki; *id.* at 20, and,
- (5) vacated our determination that Petitioner has not shown by a preponderance of the evidence that the '027 patent claim 20 is unpatentable as anticipated under § 102 by Malecki, and remanded to consider whether Embodiment #2 of Malecki anticipates claim 20 of the '027 patent.⁴ *id.* at 13.

Cook Group I, passim.

On June 30, 2020, we conducted a conference call with the parties to discuss post-remand procedures for this proceeding and a related proceeding on remand between the same parties, IPR2017-00440 (“IPR ’440”). *See* Ex. 1119 (transcript of June 30, 2020 conference call).

³ U.S. Patent No. 5,843,000, filed on May 7, 1996, and issued on December 1, 1998 (“Nishioka”) (Ex. 1005).

⁴ U.S. Patent No. 5,626,607, filed on February 1, 1996, and issued on May 6, 1997 (“Malecki”) (Ex. 1003).

We authorized each party to file in this case an opening brief on Remand and a Responsive Brief on Remand, without new evidence. Petitioner submitted an opening brief setting forth the issues for us to decide and its arguments on those issues. Paper 104 (“Pet. Remand Br.”). Patent Owner also filed an opening brief. Paper 103 (“PO Remand Br.”). Petitioner filed a responsive brief. Paper 106 (“Pet. Remand Resp.”). Petitioner also filed a responsive brief. Paper 105 (“PO Remand Resp.”).

We have jurisdiction under 35 U.S.C. § 6, and we issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons discussed below, we conclude that Petitioner has established by a preponderance of the evidence that the ’027 patent claims 4–6, 15, and 20 are unpatentable as obvious over Sackier and Nishioka and that Petitioner has not established by a preponderance of the evidence that the ’027 patent claim 20 is anticipated by Malecki.

II. Related Matters

This Decision on Remand is issued concurrently with a Decision on Remand in IPR ’440. The ’027 patent is also 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. .

III. Anticipation of Claim 20 by Malecki Embodiment #2

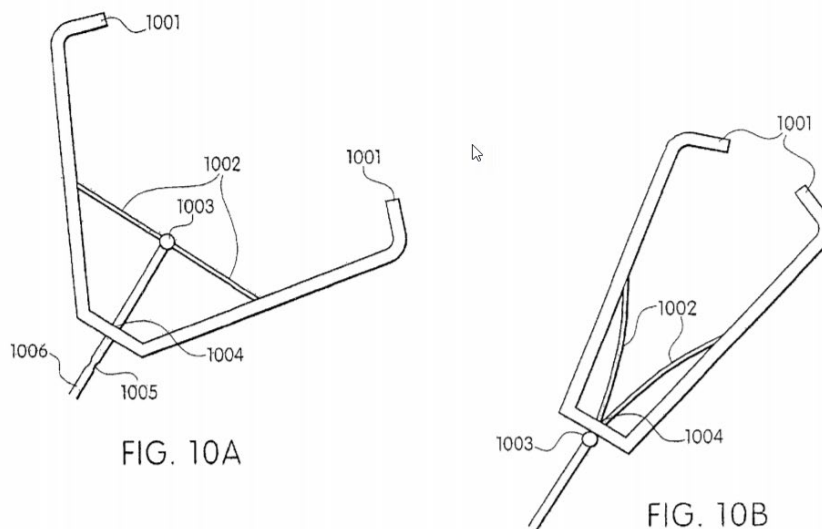
A. The ’027 Patent

The ’027 patent is titled “Device and Method for Through the Scope Endoscopic Hemostatic Clipping,” and is directed towards devices and methods of causing hemostasis of a blood vessel through an endoscope. Ex. 1001, code (52). A focus of the invention is to provide medical devices for causing the hemostasis of blood vessels along the gastrointestinal tract.

Id. at 2:51–53. The basic device and method include a compression clip used to cause hemostasis of blood vessels and a mechanism for deploying the clip. *Id.* at 2:59–61.

Various embodiments of the invention 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; a handle connected to the axially rigid sheath; and/or a trigger enclosed within the handle and engaging the control wire to close and lock the clip, and to uncouple the control wire from the clip. *Id.* at 2:63–3:5.

Figures 10A and 10B from the '027 patent are reproduced below.



Figures 10A and 10B are cross-sectional views of a compressive clip in an opened and a closed position. *Id.* at 9:4–6.

B. Claim 20

Claim 20, a method claim of the '027 patent, reads as follows:

20. A method, comprising:
inserting into a body a medical device comprising a clip
having a first clip leg having a first inner surface and a

second clip leg having a second inner surface, a control member extending from a proximal actuator to the clip and a linkage coupled to the control member;
positioning the medical device at a desired deployment location;
moving the control member distally to cause the clip to move distally relative to a sleeve housing at least a portion of the clip therein, the movement causing the linkage to contact the first and second inner surfaces to drive the first and second clip legs radially outward to a tissue receiving configuration;
adjusting a position of the clip so that target tissue is received between the first and second clip legs;
drawing the control member proximally relative to the sleeve to draw the clip into the sleeve to receive the target tissue between the first and second clip legs; and
applying a proximal tensile force of at least a threshold level to the control member to separate a link coupling the control member to the clip.

Ex. 1001, 16:52–17:6.

C. Malecki

Malecki discloses a clamp that can be used to clamp blood vessels or other body parts during medical procedures. Ex. 1003, 1:18–26. Two Malecki embodiments are relevant. Embodiment #2 is depicted in Figure 25, reproduced below:

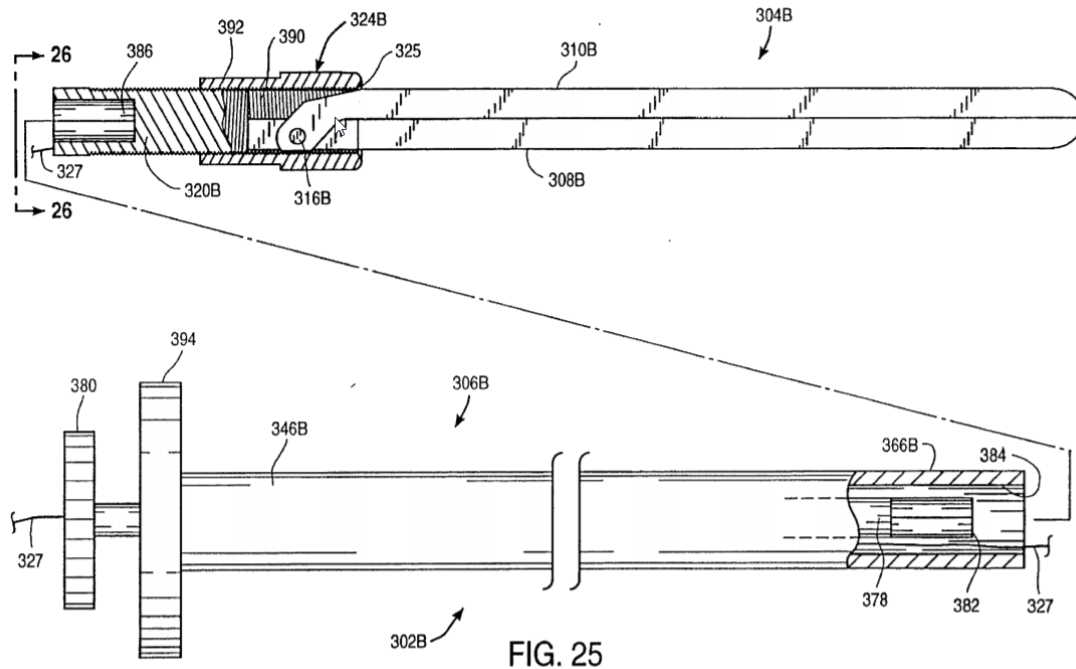


Figure 25 is a cross sectional perspective view of a clamp and a clamp positioner. *Id.* 16:53–59.

Figure 25 shows a clamp 304B and a clamp positioner 306B. The clamp 304B engages with clamp positioner 306B via engagement between square opening 384 on the clamp positioner and square outer surface 392 of jaw extension 320B. *Id.* at 16:53–17:6.

In Malecki Embodiment #2, the operator turns the hollow drive body 346B using handle 394 while stabilizing rod 378 is prevented from rotating via handle 380. *Id.* at 17:13–33. The rotation causes jaw extension 320B and actuator housing 324B to engage, further causing actuator housing 324B to move relative to jaws 308B, 310B. *See Cook Group I*, slip op. at 4–5.

D. Level of 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 '027 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. 12–13 (citing Ex. 1015 ¶ 11). Patent Owner has not disputed Petitioner's proposed level. Papers 6 and 77, *passim*.

We also consider the level of skill implied by the disclosures of the prior art references. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of skill in the art). Additionally, this person is of ordinary creativity, not an automaton. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

In view of the references, and as determined in our Final Written Decision, we find the Petitioner's suggested level of skill in the art to be appropriate as it corresponds to the technical skill level of the art disclosures. Paper 92, 15. Further, the Federal Circuit implicitly considered this determination of the level of skill in the art and did not modify our prior determination on remand.

E. Claim Construction

The Board, for purposes of this decision, interprets claims in an unexpired patent using the “broadest reasonable construction in light of the specification of the patent in which [they] appear[.]” 37 C.F.R. § 42.100(b) (2016). Under this standard, we interpret claim terms using “the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever

enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997); *see In re Smith Int'l, Inc.*, 871 F.3d 1375, 1382–83 (Fed. Cir. 2017) (“[The] broadest reasonable interpretation . . . is an interpretation that corresponds with what and how the inventor describes his invention in the specification.”). “Under a broadest reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification and prosecution history.” *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016).

We interpret only those terms necessary for deciding the issues presented in this remand. No claim terms need to be interpreted for this Decision.

F. Analysis

Petitioner contended that claim 20 is unpatentable, under 35 U.S.C. § 102, as anticipated by Malecki Embodiment #2. Pet. 84. We address each claim element below. Based on the evidence of record, we determine that claim 20 is not anticipated by Malecki. As explained below, Malecki fails to disclose the claim element of “moving the control member distally” as required by claim 20.

The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. §§ 102, 103 that became effective on March 16, 2013. Because the '027 patent has an effective filing date before March 16, 2013, we apply the pre-AIA versions of the statutory bases for unpatentability.

Claim 20 (elements in *italics*):

“A method, comprising:”

Petitioner asserts that Malecki generally describes a “[c]lamp assembly and method of use” using any of the clamp assemblies described in its specification. Pet. 84 (citing Ex. 1003 [54]; and 16:51–52). We agree that Malecki describes a method of using a clamp assembly.

“inserting into a body a medical device comprising a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface, a control member extending from a proximal actuator to the clip and a linkage coupled to the control member”

Petitioner asserts that Malecki Embodiment #2 discloses inserting into a body a medical device including a clip. Pet. 84 (citing Ex. 1003, 17:28–34 (“The clamp 304B is introduced into the thoracic cavity TC through a trocar sleeve 348 while in the closed position of FIG. 25.”)). Patent Owner does not meaningfully challenge that this limitation is disclosed in Malecki. We agree that Malecki describes inserting a clip into the body.

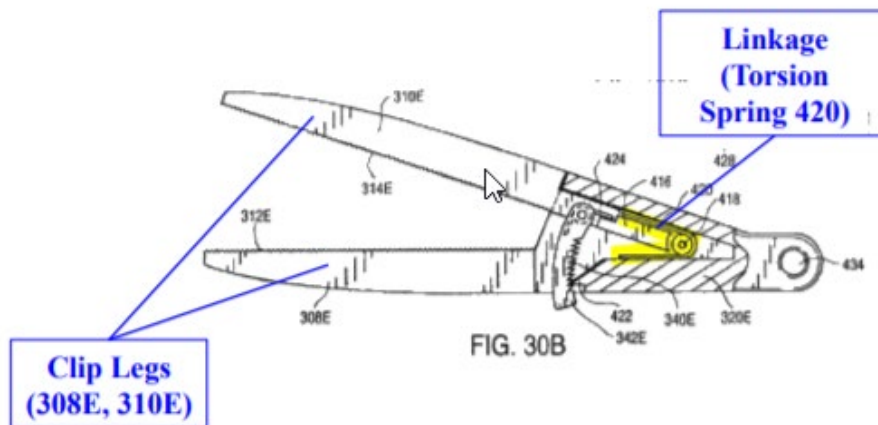
Petitioner next asserts that the clip has first and second clip legs (first and second jaws 308B, 310B, respectively), each with an inner surface, and a control member (stabilizing rod 378 and square shaft 382) extending from a proximal actuator (clamp positioner 306B) to the clip (clamp 304B) as illustrated in Figure 25. Pet. 84–85; Ex. 1003, 16:53–17:15. With specific reference to Figure 25 illustrating Malecki Embodiment #2, we agree that Malecki describes the clip legs as claimed and the control member extending from the proximal actuator to the clip.

Petitioner further asserts that Malecki’s Embodiment #2 includes a linkage (“torsion spring”), which is coupled to the control member

(stabilizing rod 378 and square shaft 382) when the actuator (clamp positioner 306B) is linked with the clip (clamp 304B), and which biases the clip legs (first and second jaws 308B, 310B, respectively) towards the open position. Pet. 85 (citing Ex. 1015 ¶ 122; Ex. 1003, 16:57–59 (“Jaws 308B, 310B are normally biased towards the open position of FIG. 27B by a torsion spring (not shown).”)).

According to Petitioner, the “torsion spring” relied upon as a linkage is shown in Figure 30B, with respect to another embodiment. *Id.* (citing Ex. 1003, 18:14–15 (“A torsion spring 420 is mounted about pivot 418 which biases jaws 308, 310 to the open position of FIG. 30B.”)).

We agree that the torsion spring illustrated in Malecki Figure 30 biases the jaws open and contacts the clip legs. *See* Ex. 1003, Figure 30B, reproduced as annotated by Petitioner, reproduced below:



Annotated Figure 30B is a side view in partial cross section of Malecki’s clamp (referred to by Petitioner as a “clip”) with yellow highlighting and a label identifying Figure 30B’s torsion spring 420 as a “linkage” and a label identifying Figure 30B’s first jaw 308E and second jaw 310E as “clip legs.” Pet. 85–86; Ex. 1003, 18:10–22.

The torsion spring (420) is a linkage coupled to the “control member” (stabilizing rod 378 and square shaft 382 (not shown in Figure 30B)), insofar as it is linked to the clip inner walls of the legs (first and second jaws 308B, 310B, respectively), which legs are then connected to the “control member” shaft and rod. We therefore agree that Malecki Embodiment 2 describes “inserting into a body a medical device comprising a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface, a control member extending from a proximal actuator to the clip and a linkage coupled to the control member.”

“positioning the medical device at a desired deployment location”

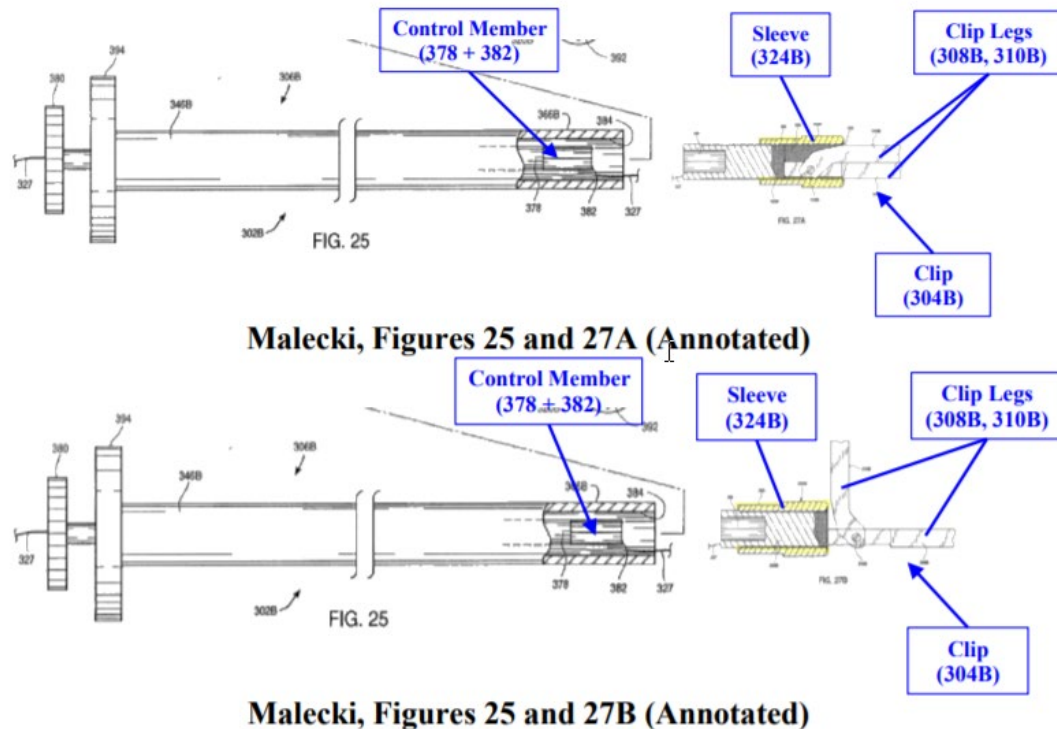
Petitioner asserts that Malecki discloses positioning the medical device of Embodiment #2 at a desired deployment location. Pet. 86. More specifically, it is urged: “The clamp 304B is introduced into the thoracic cavity TC through a trocar sleeve 348 . . . [until] clamp 304B is properly positioned . . .” *Id.* (citing Ex. 1003, 17:28–39). We agree that this describes “positioning the medical device at the desired deployment location.”

“moving the control member distally to cause the clip to move distally relative to a sleeve housing at least a portion of the clip therein, the movement causing the linkage to contact the first and second inner surfaces to drive the first and second clip legs radially outward to a tissue-receiving configuration”

Petitioner urges that annotated Figures 25, 27A, and 27B of Malecki disclose moving the control member (stabilizing rod 378 and square shaft 382) distally relative to a sleeve (actuator housing 324B) housing at least a portion of the clip therein (clamp 304B), the movement causing the clip

(clamp 304B) to move distally relative to the sleeve (actuator housing 324B) and the clip legs (jaws 308B, 310B) to move radially outward. Pet. 86.

Petitioner's Annotated Figures 25, 27A, and 27B are reproduced below:



Annotated Figures 25 and 27A–B are side partial cross sectional views of Malecki's clip and clamp positioner with labels identifying stabilizing rod 378 and square shaft 382 as a "control member" in Figures 25, and labels identifying clamp 304B as a "clip," jaws 308B and 310B as "clip legs," and yellow highlighting and a label identifying actuator housing 324B as a "sleeve" in Figures 27B." Pet. 87.

Petitioner observes that as the Malecki Embodiment #2 control member moves distally (from Figure 27A to Figure 27B), the movement causes the linkage (torsion spring 420, shown above in annotated Figure 30B of Malecki) to contact the first and second inner surfaces of the clip legs (jaws 308B, 310B) to drive the clip legs radially outward to a tissue-

receiving configuration. Pet. 87. Dr. Mark A. Nicosia,⁵ Petitioner's witness, so testifies. Ex. 1015 ¶ 124. The stabilizing rod 378 has a square shaft 382 at a distal end which matingly engages a square hole 386 formed in the jaw extension 320B.

This is a main point of contention between the parties. More specifically, the parties disagree as to the point of reference of the term “distally” in the limitation “moving the control member distally.” Patent Owner takes the position that the reference point for the term “distally” in claim 20 is “the user” of the clip, meaning that the control member must move distally from “the user.” Paper 6, 35; Paper 77, 32.

Petitioner's viewpoint is that claim 20 does not recite any use or movement of the control member relative to the user. Paper 104, 8. Instead, Petitioner contends the claim language “moving the control member distally to cause the clip to move distally relative to a sleeve” means only that the control member must also move distally in relation to the sleeve and the claim says nothing about motion in relation to the user. Paper 106, 4.

Petitioner further urges that claim 20 refers to movement of the control member relative to a sleeve in multiple locations in the claim. In particular, after reciting the disputed claim term “moving the control member distally,” it is then argued that claim 20 recites the mirror image opposite: “drawing the control member proximally relative to the sleeve.” Petitioner concludes that, given that the control member is moved “relative

⁵ Mark A. Nicosia, Ph.D. testifies via Exs. 1015, 1050, 1095, and 1100. Dr. Nicosia testifies to the substantive issues in this proceeding on behalf of Petitioner. We find him qualified to testify as to the subject matter of this proceeding. Ex. 1015 ¶¶ 4–7 and Exhibit B. Dr. Nicosia was deposed by the Patent Owner. Ex. 2011, 2039, and 2099.

to the sleeve” when moved proximally, the most reasonable and logical conclusion based on the express language of claim 20 is that the control member likewise moves relative to the sleeve when moved distally (the mirror image opposite of moving the control member proximally).

Paper 104, 8–9.

Patent Owner takes a different viewpoint – that “[t]his language ... reinforces that the patentee knew how to claim movement relative to the sleeve, and chose not to do so with respect to “moving the control member distally.” Paper 105, 4. Indeed, Patent Owner asserts that reading claim 20 without the requirement of moving the control member distally renders the claim element a nullity. Paper 105, 4.

To our view, the first term “distally” is most fairly read in the user context, i.e., moving distally is most appropriately interpreted as being from the entity that performs the claimed steps of inserting, positioning, moving, adjusting, drawing, and applying as found in claim 20. *Id.* at 16:53–17:6. Otherwise, the words are only excess verbiage. *See, e.g., In re Sabatino*, 480 F.2d 911, 913 (CCPA 1973) (“Claim limitations defining the subject matter of the invention are never disregarded.”). To the extent this differs from our previous interpretation in the Final Written Decision, as noted above, this interpretation governs.

We further observe that the ’027 patent intends for an endoscopist in particular to utilize the invention. Ex. 1001, 2:53–54 (“The goal of the invention is to give the endoscopist a technique and device which . . . 2) is easier to set up . . . and 3) is easier to deploy . . .”). Thus, we find that the most logical context of interpreting claim 20 (to the extent there is vagueness about relative motion) begins with the understanding that the

claimed method is to be performed by a user, e.g., an endoscopist inserting the device into a body. Thus, the claim language “moving the control member distally” is in relation to that user manipulating the device inside a patient. And, the second part of the limitation “to cause the clip to move distally relative to a sleeve” is a distinct distal movement of the clip in relation to sleeve as claimed.

We also find very persuasive Dr. Nicosia’s original testimony that “handle 380 is held stationary while the proximal end 394 of hollow drive body 346B is rotated thereby moving the actuator housing 324B and permitting jaws 308B, 310B to open.” Ex. 1015 ¶ 124, (quoting Ex. 1003, 17:28–39). Malecki discloses that handle 380 is coupled to stabilizing rod 378 “for preventing rotation of the stabilizing rod 378.” *Id.* at 17:13–15. If the handle 380 is held stationary as the jaws are manipulated, then the “control member,” which is physically connected to the handle, cannot move either.

We are further convinced by Malecki’s Figures 27A and 27B, reproduced below. When Figures 27A and 27B are aligned (unlike Petitioner’s Annotated Figures above), they illustrate the relative motion of the actuator housing and the clip.

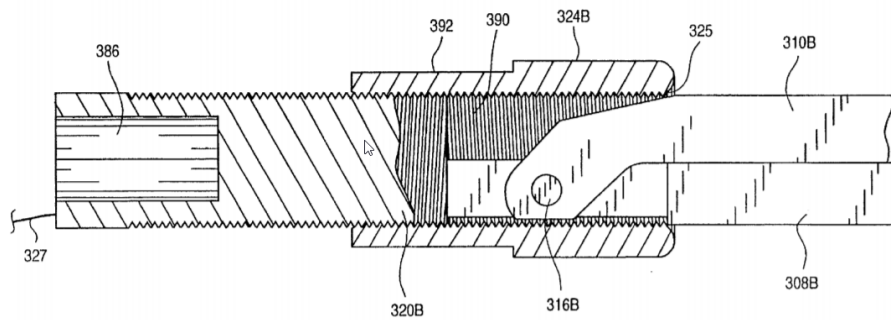


FIG. 27A

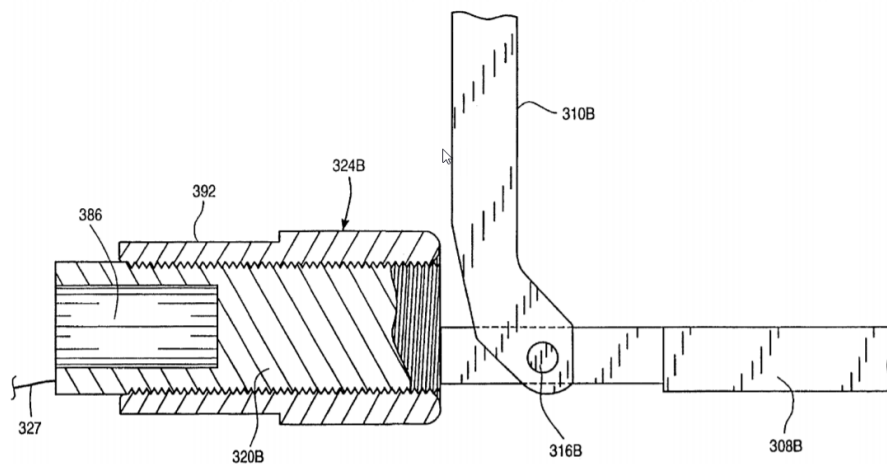


FIG. 27B

Figures 27A and 27 B are enlarged cross-sectional views of the proximal portion of the clamp of FIG. 25 in the closed and opened positions. Ex. 1003, 6:25–27.

In the above views, it becomes apparent to us that the clamp (304B in Malecki's Fig. 25 above) need not move, and the handle (380 in Malecki's Fig. 25 above) and control member (jaw extension 320B in Figs. 27A and 27B, which includes square hole 386 that matingly engages stabilizing rod 378 with square shaft 382, shown in Fig. 25 above) need not move, but the actuator housing (324B) moves proximally and distally to open and close the clip legs (jaws 308B, 310B).

Therefore, we agree with Patent Owner's assertion, backed by the Malecki Specification, that Malecki discloses that stabilizing rod 378 and square shaft 382, which Petitioner's identify as the "control member" in Malecki's Figure 25, do not move at all, let alone distally or proximally, to actuate the clip. Paper 88, 12–13.

We therefore do not find Malecki Embodiment #2 to describe distal motion of the control member, which is held steady as the housing is turned.

"adjusting a position of the clip so that target tissue is received between the first and second clip legs"

Petitioner asserts that Malecki Embodiment #2 discloses adjusting a position of the clip so that target tissue is received between the first and second clip legs: "properly position[] [the aorta] between jaws 308, 310B." Pet. 88 (citing Ex. 1003, 17:34–37). We agree that Malecki describes so receiving target tissue.

"drawing the control member proximally relative to the sleeve to draw the clip into the sleeve to receive the target tissue between the first and second clip legs"

Petitioner asserts that Malecki describes, via annotated Figures 25, 27A, and 27B, shown above, the step of drawing the control member (stabilizing rod 378, square shaft 382) proximally *relative to the sleeve* (actuator housing 324B) to draw the clip (clamp 304B) into the sleeve to receive target tissue between the clip legs (jaws 308B, 310B). Pet. 89 (citing Ex. 1003, 17:28–39).

We agree that as the "control member" of Malecki Embodiment #2 is drawn proximally *relative to the sleeve*, it draws the clip into the sleeve to perform the function of receiving the target tissue between the clip legs, even as it does not move relative to the user.

“applying a proximal tensile force of at least a threshold level to the control member to separate a link coupling the control member to the clip”

Petitioner finally asserts that Malecki discloses “applying a proximal tensile force of at least a threshold level to the control member to separate a link coupling the control member to the clip.” Pet. 90. More specifically, it is asserted that the clamp positioner 306B is preferably removed from the patient through trocar sleeve 348, while the clip (clamp 304B) remains behind in the body. *Id.* (citing Ex. 1015 ¶ 127; Ex. 1003, 17:35–39, 18:34–37). We agree that Malecki Embodiment #2 thus describes that the clip is separable from the clamp positioner after being clamped onto a hollow body structure. Ex. 1003, 18:34–37.

Considering the totality of the record before us, including instruction by our reviewing court, we determine that Petitioner has not shown by a preponderance of the evidence that Malecki Embodiment #2 anticipates claim 20 of the ’027 patent. As examined in detail above, this embodiment of Malecki fails to disclose the distal movement of the control member limitation.

IV. The Obviousness of Claims 4–6, 15, and 20 over Sackier and Nishioka

Petitioner contends that claims 1–20 were unpatentable under 35 U.S.C. § 103(a) as obvious over Sackier and Nishioka. Pet. 44–69. We previously found claim 1 unpatentable under 35 U.S.C. § 103(a) as obvious over Sackier and Nishioka. Paper 92, 41. That finding was affirmed by the court in *Cook Group I*, at 20.

A. Claims 1 and 4

Claim 1 recites as follows:

1. A medical device, comprising:
 - a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface;
 - a control member extending from a proximal actuator to the clip; and
 - a linkage operably associated with the control member to spread the first and second clip legs apart from one another into a tissue-receiving configuration as the control member is moved distally relative to the clip, the linkage contacting the inner surfaces of the first and second clip legs to drive the first and second clip legs radially outward as the control member is moved distally relative to the clip.

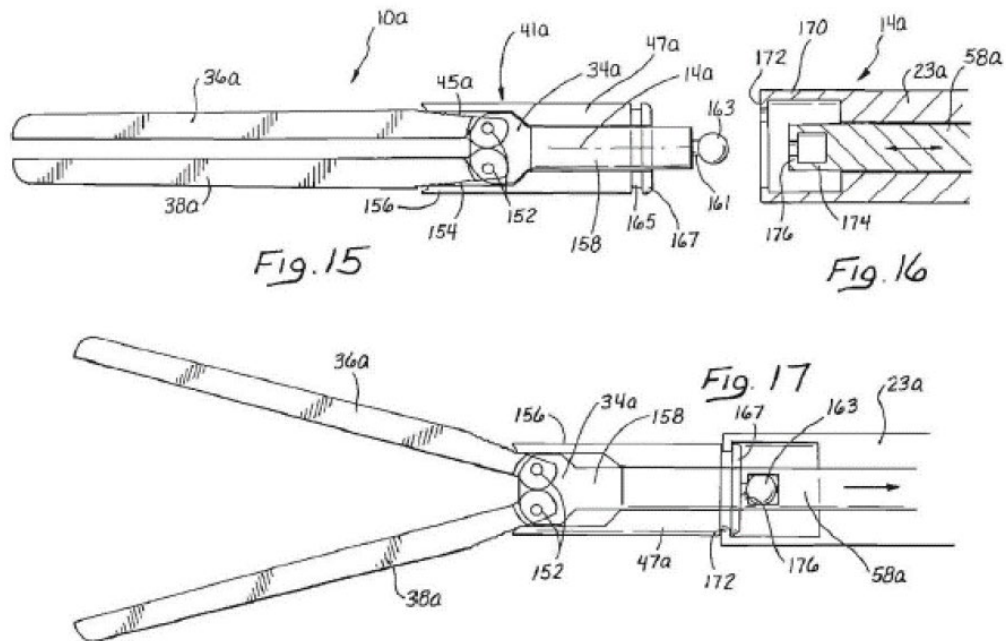
Ex. 1001, 15:33–45.

Claim 4 depends from claim 1 and recites as follows:

4. The medical device of claim 1, further comprising a frangible link coupling the clip to the control member.

B. The Cited Art

Sackier, U.S. Patent No. 5,749,881 (“Sackier”), issued on May 12, 1998, for a “Laparoscopic Surgical Clamp.” Ex. 1008. Sackier discloses a clamp that can be moved between a free (open) state and operable (closed) state for use in occluding portions of the body during laparoscopic surgery. The device is designed to fit within the trocar used to perform the surgery. Sackier also discloses a clamp applicator that contains a means to engage and disengage the clamp jaws. *Cook Group I*, slip op. at 5–6. The relevant aspects of Sackier are depicted in Figures 15–17 below:



Figures 15–17 are Petitioner’s Annotated cross sectional views of a clamp and clamp applicler.⁶

Nishioka, issued on December 1, 1998 for “Optical Biopsy Forceps and Method of Diagnosing Tissue.” Ex. 1005. Nishioka discloses an integrated optical biopsy forceps device. The device includes a pair of cutting jaws that are drawn together via control links. *Cook Group I*, slip op. at 6.

⁶ 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. 17–18, n.5.

Figure 8 of Nishioka is reproduced below:

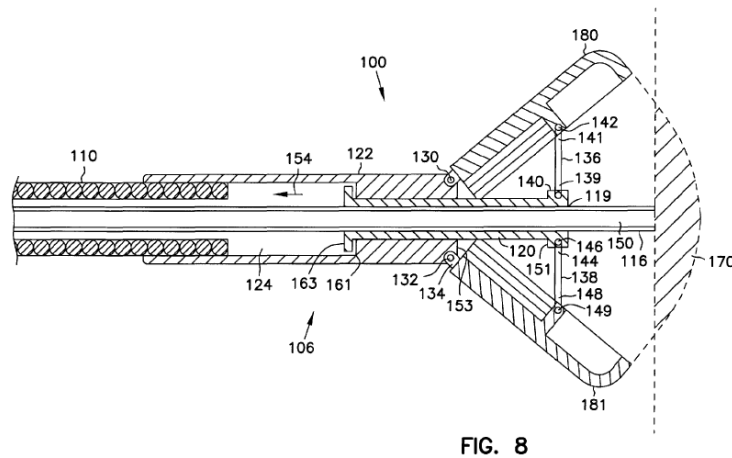


Figure 8 is a cross-sectional view of a biopsy forceps.
Ex. 1005, 3:34–36.

As shown in Figure 8 above, forceps 100 include cutting jaws 180, 181. Ex. 1005, 6:60–62. 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.

Our prior Final Written Decision finding that Petitioner had shown by a preponderance of evidence that claims 1–3, 7–14, and 16–19 are unpatentable as obvious over Sackier and Nishioka was affirmed by our reviewing court. Paper 92, 67, *Cook Group I*, 20. We therefore are limited in this remand to the court’s instruction to consider specific issues concerning only claims 4–6, 15, and 20.

C. Claim Construction

We interpret only those terms necessary for deciding the issues presented in this remand.

Frangible link

Petitioner asserts that the term “frangible link” means a “link between at least two components that become unlinked when a tensile load is applied.” Pet. 14–15. Again, this interpretation is proposed in part because Patent Owner asserted it in the related district court proceeding. Ex. 1004, 13. Patent Owner does not dispute this interpretation. PO Resp. 25. We agree this is an appropriate interpretation, principally because frangible in the Specification includes “pulled from” and “frangible” generally means “breakable.” Ex. 1001, 5:44–58.

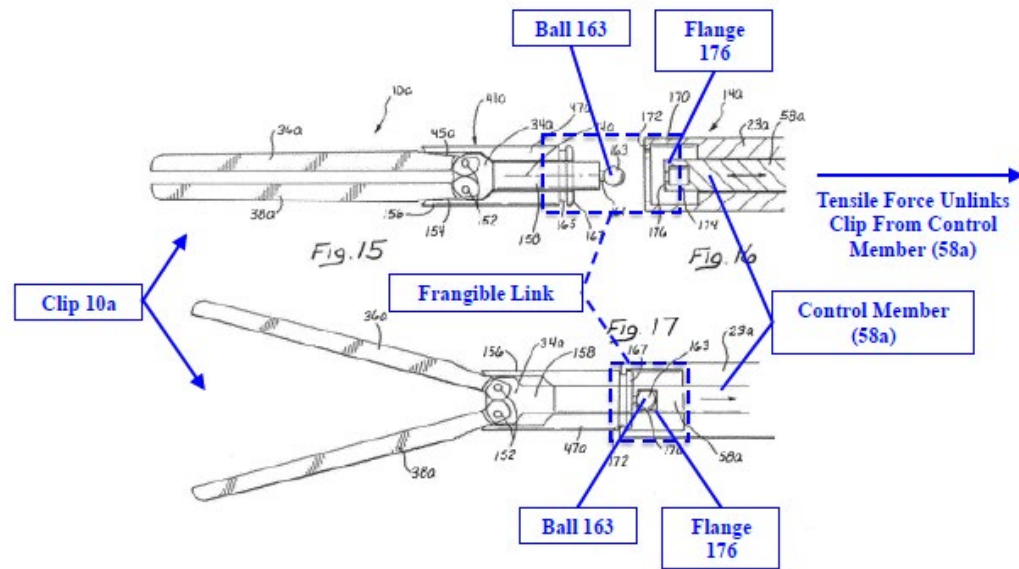
D. Analysis

Claim 4

Claim 4 depends from claim 1 and further states that there is “a frangible link coupling the clip to the control member.” Ex. 1001, 15:53–54. Petitioner asserts that Sackier’s ball 163 and flange 176 form a link coupling the clip to the control member, the link being frangible in that it becomes unlinked when a tensile load is applied. Pet. 54 (citing Ex. 1008, 10:18–30, 2:56–59).

It should be noted that claims 1 and 4 do not have a limitation that the frangibility occur within the body.

Sackier Annotated Figures 15–16, reproduced below, illustrate the ball and flange.



Figures 15–17 are Petitioner’s Annotated cross sectional views of a clamp and clamp applicator.

Patent Owner is of the position, based upon Dr. Vaitekunas’ testimony, that the link between the flange 176 and the ball 163 is not a frangible link because it does not unlink when a tensile load is applied. Ex. 2031 ¶ 95. Applying a tensile force or pulling the clamp applicator will not unlink flange 176 and ball 163, so that the jaws are no longer coupled to the control member. PO Resp. 49–50. This theory is impacted by Patent Owner’s Preliminary Response (Paper 6) as further discussed below.

Patent Owner asserts that the Sackier’s Specification states that annular flange 176 has an inside diameter greater than the recess 161, but less than the diameter of the ball 163. Paper 6, 16, citing Ex. 1008, 10:22–24. Moreover, it is asserted that this configuration does not allow the ball to be pulled axially from the flange 176 and cylinder 174, because the diameter of the ball is greater than the opening at the flange 176. Ex. 2031 ¶ 95. Sackier’s clamp is said to be explicitly designed to prevent a tensile load

from unlinking the components to prevent “undesirable separation of the clamp from the applier.” *Id.*; Ex. 1008, 1:54–57; PO Resp. 49–50.

Petitioner’s contrary position is summed this way:

The fundamental dispute here is whether Sackier’s clamp and clamp applier engage and disengage (*i.e.*, decouple) *axially*, via annular snap connections (as Petitioners contend), or laterally, via “permanent machined openings” (as BSSI contends). If Petitioners are correct, then there is no dispute that Sackier satisfies the “applying a proximal tensile force” limitation. (*See* Paper 23, at 9-10 (granting request for reconsideration based on Dr. Nicosia’s testimony that Sackier satisfies this limitation); Paper 48, at 58-59).

Paper 50, 2.

Petitioner also in response asserted that the claim does not require detachment “within the body.” Reply 26. Petitioner also contends that Patent Owner’s argument that Sackier’s clamp applier and clamp engage via a lateral opening is erroneous. *Id.*; *see also id.* at 10 (“Sackier does not disclose lateral openings (noun form of ‘opening’), but instead that the cylinders ‘open laterally’ (verb form of ‘open’).”). *See also id.* at 11–12 (providing examples of annular snap connections but none in related medical devices).

We previously found the evidence to be evenly divided as to whether one could axially detach the clips (by proximal pulling force) or whether Sackier’s clamp applier and clamp engage via a lateral opening. Given the goal of Sackier for preventing undesirable separation of the clamp from the applier, we reasoned that Patent Owner’s lateral opening theory was just as likely. Paper 92, 47. While it appeared the link may have been capable of being frangible, the Patent Owner had put forth sufficient evidence to make

it equally plausible that the link is not frangible once attached in Sackier, whether or not in the body. *Id.*

Our reviewing court determined that we should have considered a statement made by Patent Owner in its Patent Owner Preliminary Response in reaching a final decision. *Cook Group I*, slip op. at 16.

More specifically, Patent Owner argued the following in its Preliminary Response:

Sackier teaches that the clamp applier in Figure 16 is opened laterally (i.e., widened) to attach the clamp. Specifically, “[b]oth of the cylinders 170 and 174 can be configured to open laterally in order to permit the associated flanges 172 and 176 to engage the recesses 165 and 161.” By opening laterally, the cylinders are moved outwardly, thereby widening the cylinder to fit the ball into the clamp applier and permitting the flanges to engage the associated recesses. In fact, Sackier teaches that the lateral opening of the clamp applier is necessary to engage the clamp because the flange 172 “has an inside diameter . . . less than the diameter of the flange 167” and flange 176 “has an inside diameter . . . less than the diameter of the ball 163.” Thus, the ball will not fit into the clamp applier without opening the clamp applier laterally.

Paper 6, 17 (citations omitted).

Our reviewing court also determined that we erred in not considering this an admission, and that an admission in a Patent Owner preliminary response should be considered by the factfinder and assigned weight. We were instructed to consider the admission and the impact of that admission on the balance of the evidence. *Cook Group I*, slip op. at 17.

We did not consider this admission previously. Patent Owner’s initial position was that the cylinders are moved outwardly sufficiently wide enough such that the ball will fit into the clamp applier. Paper 6, 17. In

reconsidering the matter with this admission in mind, we give weight to Patent Owner's initial position. As the body of the clamp applicator has some innate ability to deform and at least open laterally to attach the clamp to the clamp applicator.

The crux of the matter before us is whether that ability to open laterally adds support to the conclusion that a proximal force can cause the ball of the clamp to detach from the clamp applicator.

Sackier Figure 17, is reproduced below:

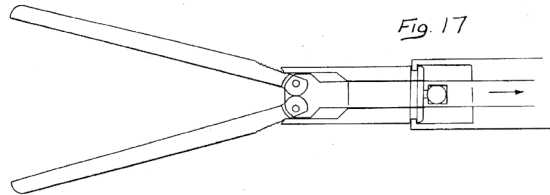


Figure 17 is an axial cross-section view of a clamp. Ex. 1008, 3:60–61.

The question, narrowly focused, is whether a force can disengage the clamp from the control member when it exceeds a certain force. Given that the court determined that Patent Owner admitted that the clamp applicator widened to admit the ball, we must analyze this change in the evidence before us.

Patent Owner asserts:

The statements upon which Petitioners rely are taken out of context and, when so read, ambiguous. The argument neither describes any radial expansion of cylinders 170 and 174, nor adopts Petitioners' theory that "axial" force can be used to engage Sackier's clamp or that a proximal tensile force can be used to disengage Sackier's clamp.

Paper 103, 2.

We understand this argument, but are constrained in that Sackier used the term “configured to open laterally” (Ex. 1008, 10:24–26), and the Patent Owner expressly used the term “widened” in describing this phrasing. IPR2017-00134, Paper 6 at 17. As such, we look at Dr. Nicosia’s testimony anew. He testified that:

The clip (10a) becomes unlinked from the control member (58a) (*i.e.*, the ball 163 separates from cylinder 174 (with flange 176)) when a tensile load is applied to the control member (58a). (*See* Ex. 1008, Figures 15 and 16, 2:56-59 (“A clamp applier is adapted to releasibly engage the clamp [(clip)]”); *see also, e.g., id.*, Abstract, 8:29-34, 8:51-53, 9:60 – 10:34).

Ex. 1015 ¶ 36.

In light of Patent Owner’s admission and Dr. Nicosia’s testimony, we determine that a preponderance of the evidence shows that the applier can radially expand. As such, we determine that this radial expansion also more likely than not allows the control member to unlink from the clip. Whether this is desirable in the body or would render the clip inoperable in the body is of little moment as the clip need not be in the body in claim 4.

As a consequence, we have reweighed the evidence, and conclude that Petitioner has established by a preponderance of the evidence that claim 4 is unpatentable over the combination of Sackier and Nishioka.

Claim 5

Claim 5 depends from claim 4 and recites that “the control member is reversibly operable to move the clip between the tissue-receiving configuration and a closed configuration.” Ex. 1001, 15:55–57. Petitioner asserts that Sackier discloses this limitation. Pet. 21–25, 28, 55.

More specifically, Petitioner asserts that Sackier describes this limitation at pages 21–25 of the Petition. We find that the cited discussion at pages 21–25 lacks any meaningful discussion of the closing configuration and is therefore unpersuasive. However, on page 28, Petitioner urged that axial movement of the Sackier 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. Pet. 28 (citing Ex. 1008, 3:14–15, 9:41–48, 14:5–24).

Consequently, we conclude that Petitioner has established by a preponderance of the evidence that claim 5 is also unpatentable over the combination of Sackier and Nishioka.

Claim 6

Claim 6 depends from claim 5, and recites that the device “further compris[es] an outer sleeve housing a proximal portion of the clip therewithin, wherein an engagement of outer walls of the first and second clip legs with inner walls of the sleeve prevents movement of the clip to the tissue-receiving configuration. Ex. 1001, 15:58–62.

Petitioner asserts that Sackier describes this limitation. Pet. 29–30, 55 (citing Figs. 15–17). We observe that Sackier describes an outer sleeve (slide 47a) housing a proximal portion of the jaws (36a, 38a). Ex. 1008, 9:64–65, Fig. 15. This sleeve engages the outer walls of the clip legs to prevent opening. *Id.* at 9:49–55.

Consequently, we conclude that Petitioner has established by a preponderance of the evidence that claim 6 is also unpatentable over the combination of Sackier and Nishioka.

Claim 15

Claim 15 depends from claim 13, and both read as follows:

13. A medical device, comprising:
a clip having a first clip leg having a first inner surface
and a second clip leg having a second inner surface;
a sleeve housing a portion of the clip therein, the clip
being axially movable relative to the sleeve by a
control member extending from a proximal actuator
to the clip; and
a linkage operably associated with the control member to
move the clip distally out of the sleeve and cause the
first and second clip legs to spread apart from one
another into a tissue-receiving configuration as the
clip is moved distally relative to the sleeve, the
linkage contacting the inner surfaces of the first and
second clip legs to drive the first and second clip
legs radially outward as the control member is
moved distally relative to the clip.

Ex. 1001, 16:12–26.

15. The medical device of claim 13, further comprising a
link positioned proximally of the clip, wherein
application of a proximal tensile force to the link via the
control member causes the clip to separate from the
control member.

Id. at 16:33–36.

Our reviewing court affirmed our decision that determined claim 13 was unpatentable as obvious over the combination of Sackier and Nishioka. *Cook Group I*, slip op. at 20. Thus, the only question remaining is whether claim 15 is also obvious when the evidence is considered in view of the Patent Owner's admission in the Patent Owner's Preliminary Response.

For the reasons noted above with regard to claim 4, we conclude that it is. Accordingly, we conclude that Petitioner has established by a preponderance of the evidence that claim 15 is also unpatentable over the combination of Sackier and Nishioka.

Claim 20

Claim 20 reads as follows:

20. A method, comprising:
inserting into a body a medical device comprising a clip
having a first clip leg having a first inner surface and a
second clip leg having a second inner surface, a
control member extending from a proximal actuator to
the clip and a linkage coupled to the control member;
positioning the medical device at a desired deployment
location;
moving the control member distally to cause the clip to
move distally relative to a sleeve housing at least a
portion of the clip therein, the movement causing the
linkage to contact the first and second inner surfaces
to drive the first and second clip legs radially outward
to a tissue receiving configuration;
adjusting a position of the clip so that target tissue is
received between the first and second clip legs;
drawing the control member proximally relative to the
sleeve to draw the clip into the sleeve to receive the
target tissue between the first and second clip legs;
and
applying a proximal tensile force of at least a threshold
level to the control member to separate a link coupling
the control member to the clip.

Ex. 1001, 16:52–17:6.

Claim 20 is an independent method claim with some different limitations than the preceding claims, including use in the body with target tissue. We address the limitations below, but note the scope of our review

on remand is principally confined to the last element, as the findings for the remaining elements have been implicitly affirmed in *Cook Group I*.

“A method, comprising . . . inserting into a body a medical device comprising a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface, a control member extending from a proximal actuator to the clip and a linkage coupled to the control member”

As previously noted, Petitioner asserts that Sackier describes inserting into a body a medical device including clamps and clamp applicators for occluding body conduits. Pet. 20–25, 37–38, 64 (citing Ex. 1008, 1:6–8, 3:1–15, 9:5–12, 11:57–64, 14:5–24). The medical device described in Sackier is asserted to include a clip having first and second clip legs, each having an inner surface, a control member extending from a proximal actuator to the clip, and a linkage coupled to the control member. *Id.* Patent Owner has not meaningfully challenged this assertion. We have reviewed Petitioner’s arguments and the underlying evidence cited in support and are persuaded Petitioner sufficiently establishes with reference to Ex. 1008 that this element is present.

“positioning the medical device at a desired deployment location”

Petitioner asserts that Sackier describes positioning the medical device at a desired deployment location. Pet. 64 (citing Ex. 1015 ¶ 96; Ex. 1008, 8:29–31). Patent Owner does not meaningfully challenge this assertion. We have reviewed Petitioner’s arguments and the underlying evidence cited in support and are persuaded Petitioner sufficiently establishes with reference to Ex. 1008 that this element is present. More specifically, we find that Sackier describes “positioning a medical device at a desired deployment

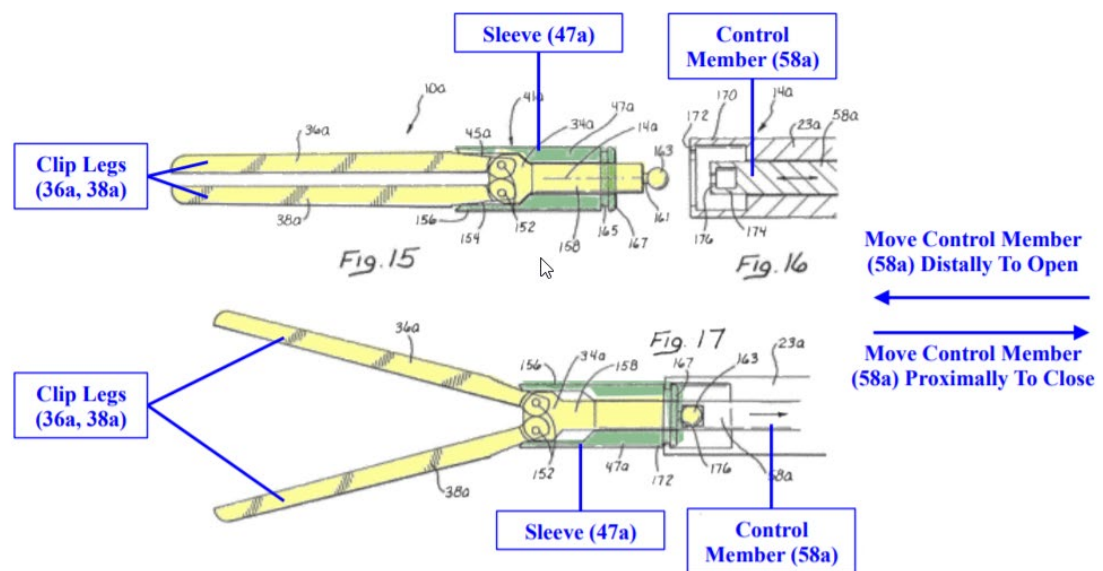
location.” *See, e.g.,* Ex. 1001, 2:59–61 (indicating that deploying includes an arrangement for opening and closing the clip).

“moving the control member distally to cause the clip to move distally relative to a sleeve housing at least a portion of the clip therein, the movement causing the linkage to contact the first and second inner surfaces to drive the first and second clip legs radially outward to a tissue receiving configuration”

Petitioner asserts that Sackier discloses moving the control member distally to cause the clip to move distally relative to a sleeve housing at least a portion of the clip therein. Pet. 65 (citing Ex. 1015 ¶ 97).

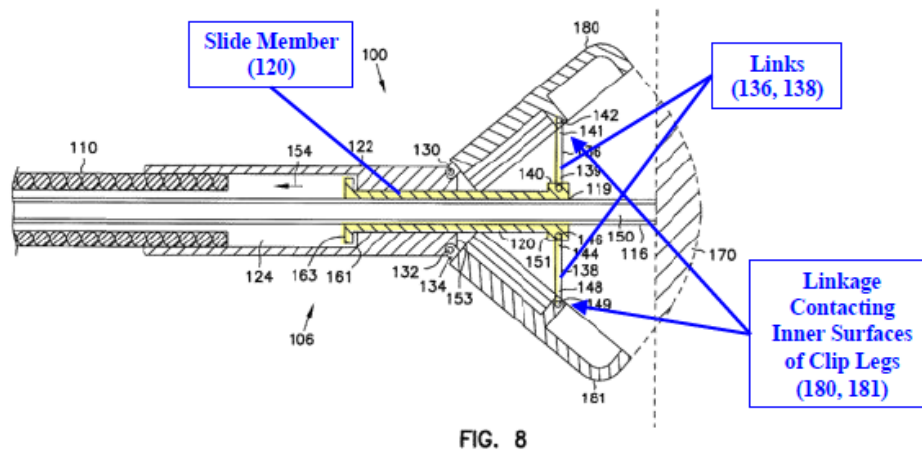
More specifically, Petitioner argues that Sackier discloses that the operable association of the linkage with the control member moves the clip legs (36a, 38a) distally out of the sleeve (47a) and causes the clip legs (36a, 38a) to spread apart into a tissue-receiving configuration as the clip legs (36a, 38a) are moved distally relative to the sleeve (47a). *Id.* at 61.

Petitioner provides annotated versions of Sackier’s Figures 15–17 depicting this motion. *Id.*



Petitioner's Annotated Figures 15–17 are cross sectional views of a clip with labels identifying jaws 36a and 38a as “clip legs” (highlighted in yellow), slide 47a as a “sleeve,” inner shaft 58a as a “control member,” and indicating that “control member” 58a moves “distally to open” and “proximally to close.”
Id.; Ex. 1008, 3:55–61.

Petitioner also asserts that Nishioka discloses a linkage (slide member 120 and control links 136, 138 (highlighted in yellow)) coupled to a control member (fiber 150), and contacting the inner surfaces of clip legs (jaws 180, 181). Pet. 47. Figure 8 of Nishioka, annotated by Petitioner, is reproduced below:



Annotated Figure 8 is Petitioner's Annotated cross sectional view of a biopsy forceps with labels identifying slide member 120, control links 136 and 138 (highlighted in yellow), and jaws 180 and 181 as “linkage contacting inner surfaces of clip legs.” Pet. 47; Ex. 1005, 3:34–36.

According to Petitioner, the linkage (slide member 120, control links 136, 138) drives the clip legs (jaws 180, 181) radially outward as the control member (optical fiber 150) moves distally relative to the clip legs (jaws 180, 181). *Id.* (citing Ex. 1015 ¶ 63; Ex. 1005, 8:21–26, 8:32–35, 8:44–52, 8:59–9:2).

Petitioner asserts that it would have been obvious to a person of ordinary skill in the art to combine the linkage disclosed in Nishioka with the clip of Sackier to assist in driving open the clip legs. Pet. 48 (citing Ex. 1015 ¶ 64). According to Petitioner, modifying the Sackier clip to include the Nishioka linkage would have been a matter of routine skill in the art, using simple mechanical elements such as those disclosed in Nishioka and Sackier to achieve predictable results. *Id.* (citing Ex. 1015 ¶ 64).

Patent Owner asserts that neither Sackier nor Nishioka describes a linkage contacting the inner surfaces of the first and second clip legs. PO Resp. 28–30. In Sackier, Petitioner states that spring 152 does not have any contact with the inner surfaces of jaws 36a or 38a.

We find Sackier’s spring 152 does not contact the inner surfaces of the jaws because spring 152 is provided within hinges 41a and thus does not contact the inner surfaces of the jaws. Petitioner’s expert conceded this point at his deposition. Ex. 2011, 210:11–23 (admitting that there is no written disclosure or explicit illustration of a spring contacting the inner surfaces). To the extent Petitioner relies upon Sackier Figure 2 as describing the spring Pet. 24–25, we observe that embodiment describes that one of the jaws 36 is fixed, and therefore cannot be driven radially outward. Ex. 1008, Fig. 2.

In Nishioka, Patent Owner states that the control links contacts the side surfaces of the cutting jaws, not their inner surfaces. PO Resp. 28. As above, we have already addressed this contention in the Final Decision, 33–36, and the determination that the Patent Owner is incorrect has been affirmed by our reviewing court, along with the propriety of making the

combination of Nishioka and Sackier. *Cook Group I*, slip op. at 20.

Accordingly, we find that Nishioka describes this element.

“adjusting a position of the clip so that target tissue is received between the first and second clip legs”

Petitioner asserts that Sackier discloses adjusting a position of the clip (clamp 10a) so that target tissue is received between the clip legs (jaws 36a, 38a): “the clamp applier can be operated to open and close the clamp 10 about a body conduit, such as a bowel 32.” Pet. 41 (citing Ex. 1015 ¶ 56; Ex. 1008, 4:35–37, 3:14–15).

Patent Owner does not meaningfully challenge this assertion. We have reviewed Petitioner’s arguments and the underlying evidence cited in support and are persuaded Petitioner sufficiently establishes with reference to Ex. 1008 that this element is present.

Accordingly, we agree and find that Sackier describes “adjusting a position of the clip so that target tissue is received between the first and second clip legs.”

“drawing the control member proximally relative to the sleeve to draw the clip into the sleeve to receive the target tissue between the first and second clip legs”

Petitioner asserts that Sackier discloses drawing (moving) the control member (inner shaft 58a) proximally relative to the sleeve (slide 47a) (i.e., the control member (inner shaft 58a) moves proximally away from the sleeve (slide 47a)) to draw the clip (clamp 10a) into the sleeve (slide 47a) to receive the target tissue between the first and second clip legs (jaws 36a, 38a) (i.e., clip (clamp 10a) moves from position in Figure 17 to position in Figure 15). Pet. 41–42 (citing Ex. 1015 ¶ 57; Ex. 1008, 3:14–15 (“[B]y

operating the shaft to close the jaws of the clamp, the body conduit can be occluded.”)).

Patent Owner does not meaningfully challenge this assertion. We have reviewed Petitioner’s arguments and the underlying evidence cited in support and are persuaded Petitioner sufficiently establishes with reference to Exhibit 1008 that this element is present.

Accordingly, we agree and find that Sackier describes “drawing the control member proximally relative to the sleeve to draw the clip into the sleeve to receive the target tissue between the first and second clip legs.”

“applying a proximal tensile force of at least a threshold level to the control member to separate a link coupling the control member to the clip.”

Petitioner asserts that Sackier describes applying a proximal tensile force of at least a threshold level to the control member to separate a link coupling the control member to the clip. Pet. 42–43, 69. More specifically, Petitioner asserts that Sackier’s link (ball 163, flange 176) separates upon application of a proximal tensile force of at least a threshold level to the control member (inner shaft 58a). Dr. Nicosia testifies that “[a] clamp applier is adapted to releasibly engage the clamp [(clip)].” Ex. 1015 ¶ 58 (citing Ex. 1008, Figs. 15 and 16, 2:56–59).

We previously found the evidence to be in equipoise. Paper 92, 60. As instructed by our reviewing court, we review that decision in light of the admission contained in the Patent Owner’s Preliminary Response.

In light of Patent Owner’s initial position and Dr. Nicosia’s testimony, we determine that Sackier’s clamp applier can radially expand. As such, we find that radial expansion makes it more likely than not that a tensile force allows the control member to unlink from the clip. Whether this is desirable

in the body or would render the clip inoperable in the body makes this question turn on a razor-thin margin. But even if the clip applicator remains attached to the clip and it is locked closed, that falls within the scope of the claim. The control member is then uncoupled to the clip, even if the entire apparatus remains attached to the tissue.

No evidence of secondary considerations has been proffered in this proceeding.

As a consequence, we have reweighed the evidence, and conclude that Petitioner has established by a preponderance of the evidence that claim 20 is unpatentable over the combination of Sackier and Nishioka.

V. Conclusion

Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
20	102	Malecki		20
4–6, 15, 20	103	Sackier, Nishioka	4–6, 15, 20	
1, 3–11 ⁷	102	Malecki	1, 3–11	
1, 3–6; 13–15, 17, 20 ⁸	102	Sackier	1, 3–6; 13–15, 17, 20	
1–3, 7– 14, 16– 19 ⁹	103	Sackier, Nishioka	1–3, 7–14, 16–19	
Overall Outcome			1–20	

VI. Order

In consideration of the foregoing, it is hereby:

ORDERED that claims 4–6, 15, and 20 of the '027 patent are held to be unpatentable and

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

⁷ Affirmed in *Cook Group I*, 20.

⁸ Affirmed in *Cook Group I*, 20.

⁹ Affirmed in *Cook Group I*, 20.

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For PETITIONER:

Jeffrey M. Nichols
Robert Mallin
Dominic P. Zanfardino
Jason W. Schigelone
James M. Oehler
Andrew S. McElligott
BRINKS GILSON & LIONE
jnichols@brinksgilson.com
rmallin@brinksgilson.com
dpz@brinksgilson.com
jschigelone@brinksgilson.com
joehler@brinksgilson.com
amcelligott@brinksgilson.com

For PATENT OWNER:

David A. Caine
Wallace Wu
Jeffrey Martin
ARNOLD & PORTER LLP
David.Caine@aporter.com
Wallace.Wu@aporter.com
jeffrey.martin@arnoldporter.com