Trials@uspto.gov
Tel: 571-272-7822

Paper 7
Entered: May 15, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COOK GROUP INCORPORATED
and
COOK MEDICAL LLC,
Petitioner,

v.

BOSTON SCIENTIFIC SCIMED, INC.,
Patent Owner.

Case IPR2017-00134
Patent 8,709,027 B2

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

MOORE, *Administrative Patent Judge*.

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

I. INTRODUCTION

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. 8,709,027 B2 (Ex. 1001, "the '027 patent"). Boston Scientific Scimed, Incorporated ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314. Based on the specific facts presented, we institute review under 35 U.S.C. § 325(d).

A. Related Matter

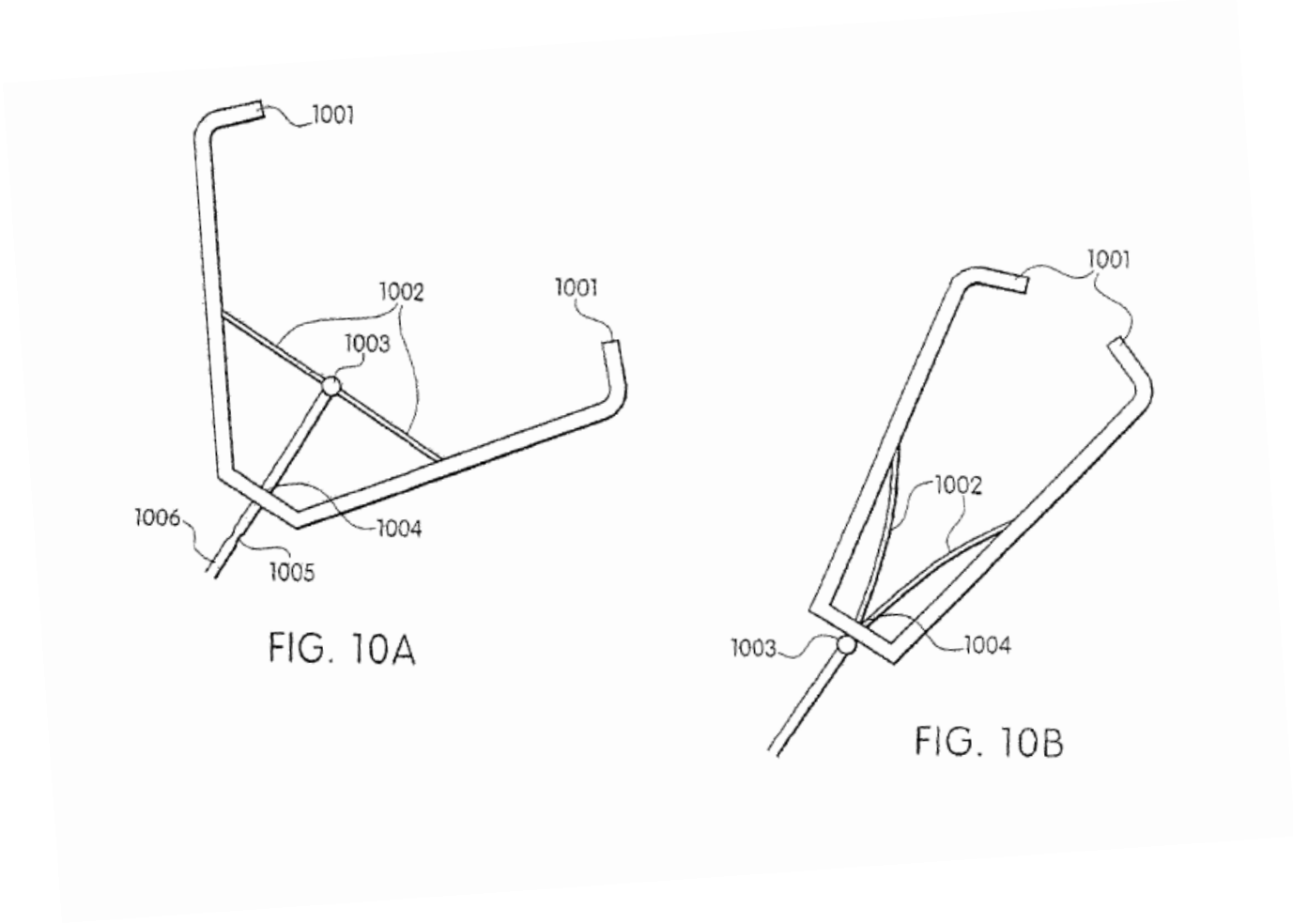
The '027 patent is the subject of *Boston Scientific Corp. v. Cook Group Inc.* , Civil Action No. 1:15-cv-00980-LPS-CJB (D. Del). Pet. 1; Paper 3, 2. Petitioner has also identified multiple additional petitions for *inter partes* review, identified more fully below, including one petition also challenging claims 1–20 of the '027 patent (IPR2017-00133), which trial has been instituted on May 3, 2017 on claims 1–3 and 7–12. IPR2017-00133, Paper 7.

B. 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, Abstract. 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.

C. Illustrative Claims

Petitioner challenges claims 1–20 of the '027 patent. Claims 1, 13, and 20 are independent, and the remaining claims depend therefrom. Claims 1, 13, and 20 are illustrative of the claimed subject matter and recite the following (formatting retained from printed patent):

> 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.

> 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.

> 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.

D. References Relied Upon

Petitioner relies upon the following prior art references:

US Patent No. 5,626,607, filed on February 1, 1996, and issued May 6, 1997. ("Malecki") (Ex. 1003);

US Patent No. 5,749,881, filed on October 20, 1994, and issued May 12, 1998. ("Sackier") (Ex. 1008);

US Patent No. 5,843,000, filed on May 7, 1996, and issued on Dec. 1, 1998. ("Nishioka") (Ex. 1005).

Petitioner also supports its Petition with the testimony of Mark A. Nicosia, Ph.D. (Ex. 1015, "Nicosia Decl.").

E. The Asserted Grounds

Petitioner contends that the challenged claims are unpatentable based on the following specific grounds (Pet. 11):

Reference(s)	Basis	Claim(s) Challenged
Sackier	§ 102	1, 3–6, 13–15, 17, and 20
Sackier and Nishioka	§ 103	1–20
Malecki	§ 102	1–12 and 20
Malecki	§ 103	1–12

II. ANALYSIS

A. Procedural Background

We are aware of two petitions filed against the '207 patent and five additional petitions against related patents. For sake of completeness of the record, we observe that those petitions have been designated as IPR2017-00131 (U.S. Patent 8,685,048); IPR2017-00132 (U.S. Patent 8,685,048); IPR2017-00133 (the '207 patent); IPR2017-00135 (U.S. Patent 8,974,371); IPR2017-00435 (U.S. Patent 9,271,731); and IPR2017-00440 (U.S. Patent 9,271,731).

B. The Standards

Institution

The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a) (Post AIA) as follows:

> THRESHOLD -- The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a

> reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Anticipation

The novelty standard is set forth in 35 U.S.C. § 102 (Pre-AIA) as follows:

> A person shall be entitled to a patent unless-
>
> (a) the invention was known or used by others in this country, or patented, or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

Obviousness

A patent claim is unpatentable 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. 35 U.S.C. § 103(a) (Pre-AIA). 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) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). In that regard, an obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

III. 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 '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 proposal.

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*, 550 U.S. at 421. In view of the references, we find the Petitioner's level of skill in the art to be appropriate as it corresponds to the technical skill level of the art disclosures.

IV. Claim Construction

Petitioner identifies several terms for construction. Pet. 13–15. Patent Owner has not challenged those specific constructions.

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). We interpret only those terms needed for this decision below.

A. 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. Again, this interpretation is proposed in part because

Patent Owner asserted it in the related district court proceeding. Ex. 1004-00013. Patent Owner does not dispute this interpretation. We agree this is an appropriate interpretation, as frangible in the specification includes "pulled from." Ex. 1001 5:44–58.

B. Moved Distally Relative to the Clip

Petitioner does not suggest a construction for this term, but some construction is in fact necessary for this decision. The phrase "moved distally relative to the clip" is not used in the specification, but appears twice in claim 1 describing motion of the control member. Ex. 1001, 15:33–45. Distal is a relative term, as one thing is said to be distal (at a distance) when compared to something that is proximal (near) to a reference point. The term proximal appears in claim 1 once, in the phrase "a control member extending from a proximal actuator to the clip." Logically, then, if the actuator is proximal to a user, then things which are more distal would be further away from the user in the direction of the clip.

Construing the claim reasonably broadly, on the present record we find that the plain language of the phrase "moved distally relative to the clip" requires motion of the control member in a distal direction and relative to the clip, which motion changes the distance between the clip and the control member distally along the line set by the proximal actuator and the more distal clip.

V. Claims 1, 3–6, 13–15, 17, and 20 as anticipated by Sackier (Ex. 1008)

Petitioner contends claims 1, 3–6, 13–15, 17, and 20 are unpatentable, under 35 U.S.C. § 102, as anticipated by Sackier. Pet. 20–43.

A. Overview of Sackier (Ex. 1008)

Sackier is directed to a laparoscopic surgical clamp which includes a clamp. Ex. 1008, Abstract. Figure 17 of Sackier is reproduced below.

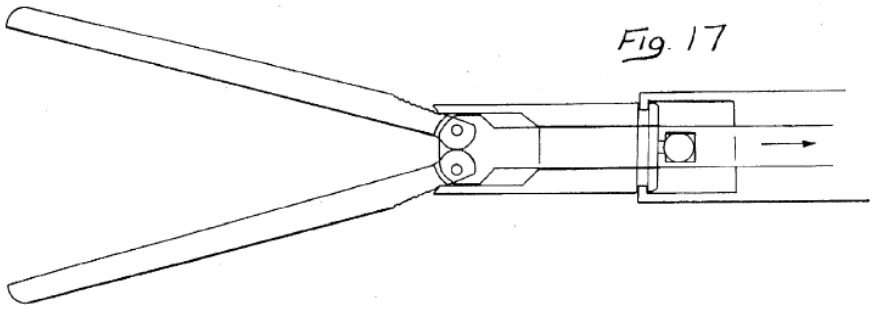


Figure 17 is an axial cross-section view of a clamp.
Ex. 1008, 3:60–62.

According to the Petitioner, Sackier describes a clip and sleeve that detach from a control member, where the clip legs are opened through a linkage. Pet. 17.

B. Discussion of Claim 1

We begin our analysis with independent claim 1. Petitioner asserts that Sackier, alone, teaches all elements of claim 1. Pet. 20–25.

Claim 1 is directed to a medical device, which comprises a clip, a control member, and a linkage. Ex. 1001, 15:33–45. Petitioner points to Figures 9, and 15–17 of Sackier and related teachings, as well as the testimony of Dr. Nicosia. Pet. 20–25 (citing *e.g.*, Ex. 1008 and Ex. 1011).

We address the claim elements below.

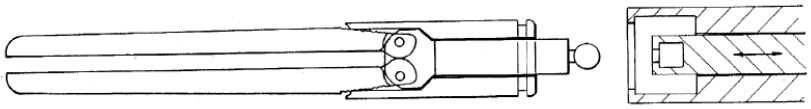
A medical device, comprising:

Consistent with Petitioner's contentions (*id.*), based on the record before us at this juncture, Sackier appears to describe a medical device – a surgical clamp. Pet. 20 (citing Ex. 1008, 1:6–8, Abstract). The medical device is a clamp and clamp applier for use in occluding body conduits. *Id.*

a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface;

Petitioner asserts that the device of Sackier describes a clip (clamp 10a and slide 47) having first and second clip legs (jaws 36a and 38a), each leg having an inner surface. Pet. 20.

Figures 15 and 16, reproduced below, illustrate the detached device.



Figures 15 and 16 are axial cross sectional views of a clamp and clamp applier. Ex. 1008, 3:56–59.

Although lacking reference numerals in the figures of the printed patent, it is evident at this juncture that a clip with jaws having inner surfaces as claimed is illustrated. Ex. 1008, 9:16–19.

a control member extending from a proximal actuator to the clip; and

Petitioner asserts that Sackier discloses a control member (inner shaft 58a) extending from a proximal actuator (clamp applier 12a) to the clip (10a). Pet. 21. Petitioner points us to Figure 9, reproduced below, and Figure 17, reproduced above. *Id.*

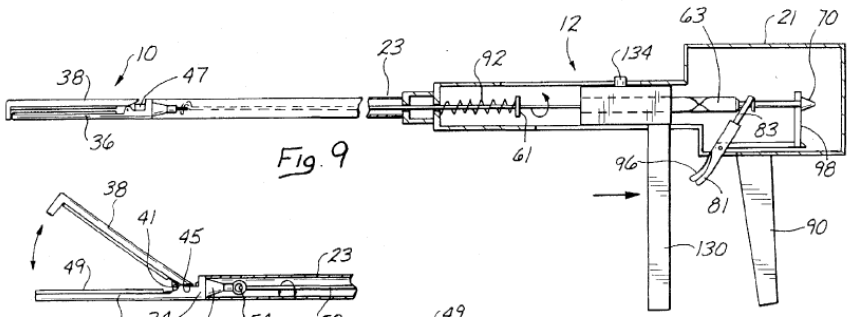


Fig. 9

Figure 9 is a side view of the clamp and clamp applier.
Ex. 1008, 3:38–40

We observe that based on the record before us at this juncture, Sackier appears to teach a "proximal" actuator, as shaft 58a must extend far enough to be controllable from outside the body.

> *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.*

Petitioner asserts, again with reference to Figures 15–17, that Sackier discloses in one embodiment a linkage (spring 152) operably associated with the control member (58a) "to spread" the first and second clip legs (36a, 38a) apart from one another into a tissue-receiving configuration as the control member is moved distally relative to the clip, and "to drive" the clip legs (36a, 38a) radially outward as the control member is moved distally relative to the outer sleeve 47a of the clip. Pet. 23.

Patent Owner, on the other hand, asserts that Sackier does not describe that the control member is moved distally relative to the clip.

Prelim. Resp. 7. Claims 1, 13, and the claims that depend therefrom require that 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, 15:42–45, 16:23–26.

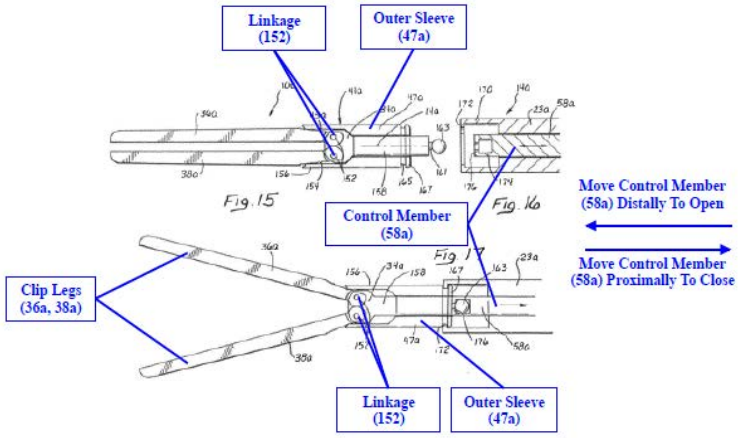
Requiring distal movement relative to the clip is consistent with the claim's scope as clarified during prosecution. We observe that the '027 patent issued from application 13/864,426. The notice of allowability indicated that it was "responsive to the persuasive arguments of 11/26/2013." Ex. 1002, 227. In the amendment filed November 26, 2013, in distinguishing over the Nash reference, applicants argued:

> In contrast, the limitations of claim 46 are directed to a control member and linkage which are shaped, sized, and oriented such that movement of the control member *relative to the clip* causes the linkage to drive the clip legs radially outward. Specifically, the control wire 1006 is advanced distally *relative to the clip*, this movement causing the clip legs 100l to extend radially outward. *Specification* ¶ [0084]; Figs. 10A, 10B. The device of Nash is not constructed to permit movement of the pusher member 112 relative to the clip 20 such that the movement causes the clip arms to move radially apart. Rather, the position of the pusher member 112 of Nash relative to the clip 20 is unchanged during the entire deployment process. *Nash*, col. 7, li. 5-col. 8, li. 57; Figs. 1–6.

Ex. 1002-00201 (Emphasis in original).

The Petition does not address this limitation in great detail, other than to assert that the control member is moved distally to open and proximally to close. Pet. 23.

We are provided with annotated Figures 15–17 from the '027 patent in support of the Petition. They are reproduced below:



Figures 15–17 are cross-sectional figures of a clamp and applicator apparatus. Pet. 23.

The annotated arrows indicate that the phrase "relative to the clip" is being omitted – as if no motion relative to the clip is required. This is contrary to both the plain language of the claim and the prosecution history of the '027 patent. We are unable to discern in either Dr. Nicosia's testimony or the Petition where this claim element was adequately considered.

As a consequence, having reviewed the Petition and Preliminary Response, and the evidence cited therein, based on the record before us at this juncture, we determine that Petitioner has not demonstrated a reasonable likelihood of showing claim 1 to be unpatentable as anticipated by Sackier alone.

C. Claims 3–6, 13–15, 17 and 20

Each of these claims also includes a claim element of "moved distally relative to the clip" either in the independent claim, or by virtue of claim dependency. For the reasons above, we find the Petition also has not

demonstrated a reasonable likelihood of showing claims 3–6, 13–15, 17, and 20 to be unpatentable in view of Sackier.

VI. Obviousness of Claims 1–20 over Sackier and Nishioka

Petitioner contends claims 1–20 are unpatentable under 35 U.S.C. § 103(a) as obvious over Sackier and Nishioka. Pet. 44–69.

A. Overview of Nishioka

Nishioka is directed to a biopsy forceps. Ex. 1005, Abstract. Figure 8 of Nishioka is reproduced below.

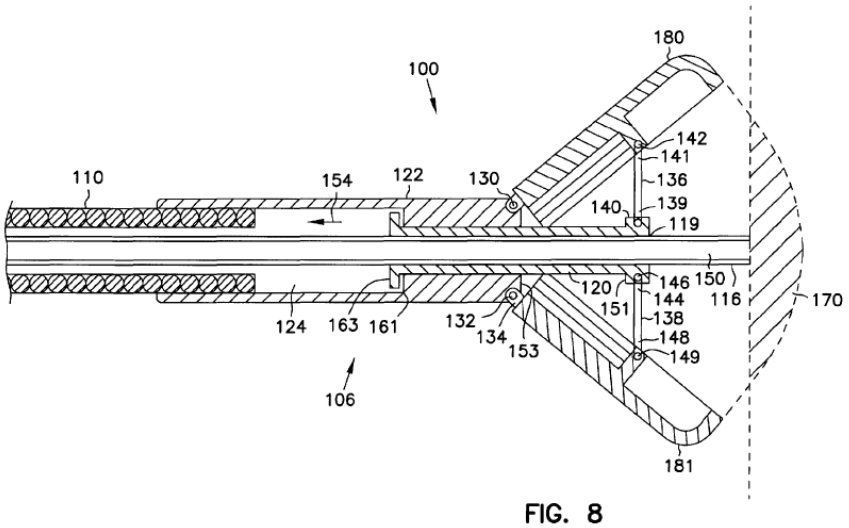


FIG. 8

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.

B. Discussion of Claim 1

We begin our analysis with independent claim 1. Petitioner asserts that the combination of Sackier and Nishioka teaches all elements of claim 1. Pet. 44–49.

Claim 1 is directed to a medical device, which comprises a clip, a control member, and a linkage. Ex. 1001, 15:33–45.

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;

Petitioner points to Sackier as describing a medical device: a "surgical clamp apparatus and more specifically . . . clamps and clamp appliers for use in occluding body conduits." Pet. 20, citing Ex. 1008, 1:6–8, Abstract.

Petitioner also asserts that Sackier Figures 15–17 describe a clip (clamp 10a and slide 47) having first and second clip legs (jaws 36a and 38a), each leg having an inner surface. Pet. 20. This assertion is consistent with the description of Sackier.

a control member extending from a proximal actuator to the clip; and

Petitioner asserts that Sackier describes a control member which is urged to be inner shaft 58a (Figure 17) extending from a proximal actuator which is clamp applier 12a (Figure 9) to the clip (10a) (Figure 17). Pet. 21. This is consistent with the evidence of record at this stage of the proceeding.

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*.

Turning to this final claim element, Petitioner again asserts that Sackier discloses in one embodiment a linkage (spring 152) operably associated with the control member (58a) "to spread" the first and second clip legs (36a, 38a) apart from one another into a tissue-receiving configuration as the control member is moved distally relative to the clip, and "to drive" the clip legs (36a, 38a) radially outward as the control member is moved distally relative to the outer sleeve 47a of the clip. Pet. 23. We have found this position to be insufficiently supported, as discussed more fully above in the anticipation grounds, as Petitioner has not shown that the control member moves relative to the clip.

Notwithstanding the deficiency with Sackier, this ground is an obviousness ground, and in bringing Nishioka into the grounds as a reference, the Petition expressly states:

> 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):

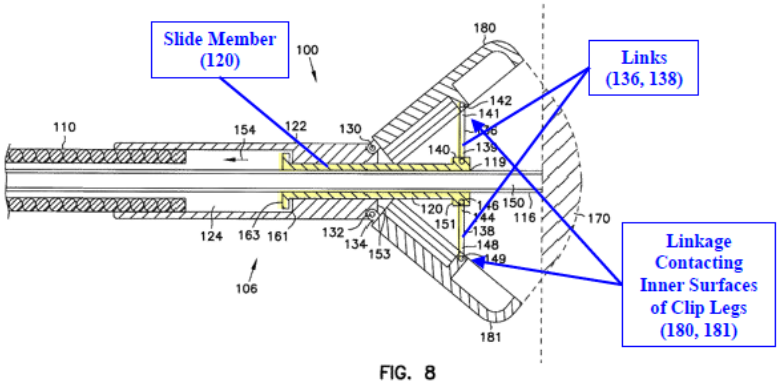


FIG. 8

> (Ex. 1015, ¶ 63; Ex. 1005, 7:3–7, 7:27–32, 8:8–10, 8:12–21). The linkage (120, 136, 138) drives the clip legs (180, 181) radially outward as the control member (150) moves distally relative to the

> clip legs (180, 181). (Ex. 1015, ¶ 63; Ex. 1005, 8:21–26, 8:32–35, 8:44–52, 8:59–9:2).

Pet. 47.

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 (21). Pet. 48, citing Ex. 1015 ¶ 64.

The Petition further asserts that 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.*

More specifically, the Petition asserts it would have been obvious to modify the Sackier clip by connecting the distal ends of Nishioka links (136, 138) to the inner surface of Sackier clip legs (36a, 38a), placing Nishioka slide member (120) slidingly within Sackier cylindrical shaft (158), and attaching Sackier ball (163) to the proximal end of Nishioka slide member (120) instead of the proximal end of the cylindrical shaft. Pet. 49 (citing Ex. 1015 ¶ 64).

Dr. Nicosia testifies that this modification would improve the performance of the clip by giving it more opening leverage and stabilizing the clip arms. Ex. 1015 ¶¶64–65.

Patent Owner asserts that the Petition fails to provide evidence that a person of ordinary skill in the art would have been motivated to combine Sackier with Nishioka. Prelim. Resp. 22–23. According to the Patent Owner, one would have no motivation to make the combination because the

clamp already functioned effectively as the spring 152 biased the jaws open. *Id.* at 24.

Patent Owner also asserts that one of ordinary skill in the art would not make the combination of a cutting biopsy forceps with a laparoscopic surgical clamp. *Id.* at 25.

At this stage of the proceedings, we are persuaded that the Petitioner has articulated a sufficient rational basis for making the combination of Sackier and Nishioka, both endoscopic instruments. The Nishioka jaw mechanism gives a mechanical advantage in that it is said to be a more robust opening mechanism than the spring in Sackier, and can help stabilize the jaws. Testimony of Dr. Nicosia supports that position. Ex. 1015 ¶¶64–65. Petitioner describes how such a modification would be made to Sackier, as well. Pet. 48. We also are persuaded that the similarity in the action of the laparoscopic instruments and their field of endeavor would lead one of ordinary skill in the art to consider the combination as proposed by the Petitioner.

Having reviewed the Petition and Preliminary Response, and the evidence cited therein, based on the record before us at this juncture, we determine that Petitioner has demonstrated a reasonable likelihood of showing claim 1 to be unpatentable based on Sackier and Nishioka.

C. Claims 2–19

Petitioner asserts that the combination of Sackier and Nishioka renders these claims obvious. Patent Owner has not discussed any of these claims with particularity separately. Prelim. Resp. *passim.*

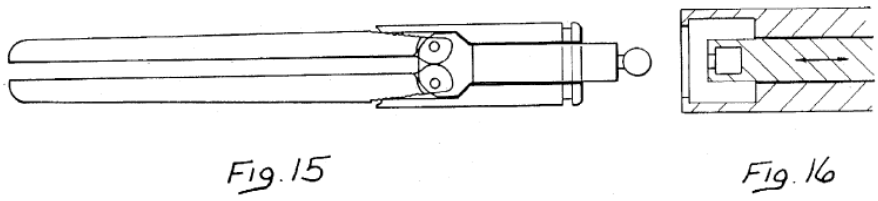
Claim 2 depends from claim 1 and further states that "the linkage is received through an opening formed in a proximal end of the clip." Ex.

1001, 15:46–48. Petitioner asserts that Nishioka Figures 2 and 8 describe that the linkage (40, 41 (Figure 2), 120 (Figure 8)) is received through an opening formed in a proximal end of the clip. Pet. 49–50.

Claim 3 depends from claim 1 and further states that "the linkage comprises first and second linkage members, proximal ends of the first and second linkage members being connected to one another." Ex. 1001, 15:49–52. Petitioner asserts that Nishioka describes that the linkage comprises first and second linkage members – the distal ends of 40, 41 in Figure 2, and links 136, 138 – in Figure 8. The proximal ends are said to be connected by the slider 120. Pet. 51–53. Figures 2 and 8 support the Petitioner's position.

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 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).

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



Figures 15 and 16 are cross-sectional views of a clamp and applier. Ex. 1008, 3:55–58.

Both figures seem to indicate the link is frangible. It follows logically that if the parts can be attached by force, it is most likely they can be detached by application of force. There is nothing in the claim prohibiting the application of a force outside the body, for example, to change the clamp being used in the applier before insertion.

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, 15:62–65. Petitioner asserts that Sackier discloses this limitation. Pet. 21–25, 28, and 55.

More specifically, Petitioner asserts that Sackier describes this limitation at pages 21–25 of the Petition. We have carefully reviewed that argument and find the cited discussion at pages 21–25 lacks any meaningful discussion of the closing configuration and is therefore unpersuasive. However, we also observe that on page 28, Petitioner urges 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, and 14:5–24. Consequently, this position appears to have sufficient merit at this stage.

Claim 6 depends from claim 5, and recites that the device "further comprises 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 Figures 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.

Claim 7 depends from claim 1 and further requires "distal ends of the first and second clip legs include curved projections which are angled with respect to a longitudinal axis of the clip." Claim 8 depends from claim 7 and further requires "the curved projections are angled radially inward." Ex. 1001, 15:63–67.

Petitioner asserts that Nishioka Figure 6A describes the distal ends of the clip legs in Figure 2 and Figure 8 include curved projections angled radially inward with respect to a longitudinal axis and that one of ordinary skill in the art could modify the jaws in Sackier to any known configuration. Pet. 56.

Nishioka Figure 6A is reproduced below:

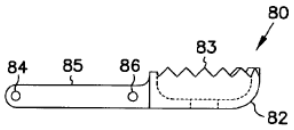


FIG. 6A

Figure 6A is a cross sectional view of a forceps jaw.
Ex. 1005, 3:28–29.

As a consequence, Nishioka appears to describe the curved projections.

Claim 9 depends from claim 1 and further requires "a distal end of the first clip leg includes an angled protrusion which interlocks with a corresponding angled recess formed in a distal end of the second clip leg." Ex. 1001, 16:1–4. Claim 10 depends from claim 9, and recites that "the protrusion is a pointed tooth and the recess is a pointed recess." *Id.* at 16:5–6. Claim 11 also depends from claim 9 and recites that "the protrusion is a plurality of pointed teeth and the recess is a plurality of correspondingly

shaped pointed recesses." *Id.* at 16:7–9. Claim 12 likewise depends from claim 9 and recites that "the protrusion is one of a multi-toothed wave and an offset L-tooth." *Id.* at 16:10–11.

Petitioner asserts that Nishioka Figures 3 and 6A describe the "angled protrusion" in the Figure 2 and Figure 8 embodiments, including one or more "pointed teeth" which "interlock" with one or more "corresponding angled recesses" as claimed in claims 9–12 and it would have been obvious to one of ordinary skill in the art to do so. Pet. 57–58.

Nishioka Figure 3 is reproduced below:

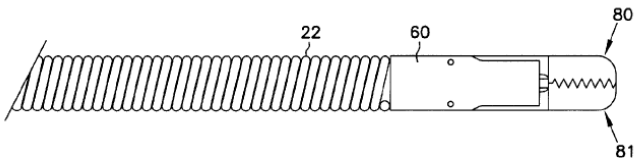


FIG. 3

Figure 3 is a side view of a forceps device. Ex. 1005, 3:16–17.

Petitioner has therefore made a sufficient showing with respect to claims 2–12 similar to its showing with respect to claim 1. Having reviewed the Petition and Preliminary Response, and the evidence cited therein, based on the record before us at this juncture, we determine that Petitioner has demonstrated a reasonable likelihood of showing claims 1–12 are unpatentable in view of Sackier and Nishioka.

Claims 13 is an independent claim, and discussed below.

A medical device, comprising:

Petitioner asserts that Sackier is a medical device. Pet. 20, 59, citing Ex. 1008, 1:6–8; Abstract.

a clip having a first clip leg having a first inner surface and a second clip leg having a second inner surface;

Petitioner asserts that Sackier describes a clip (clamp 10a and slide 47) having first and second clip legs (jaws 36a and 38a), each leg having an inner surface. Pet 20–21, 59 citing Ex. 1008 9:16–19, 9:60–67, and Figs. 15–23.

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

Petitioner asserts that Sackier describes this limitation. Pet. 21–22, 31–32, and 60, citing Sackier Figures 15–17. We have carefully reviewed pages 21–22 of the petition, and find that this discussion does not pertain to this element. However, pages 29–30 cite us to Ex. 1008, 9:64–65.

The cited portion of Sackier describes that the slide 47a is also formed with a cylindrical configuration and functions as a sleeve. *Id.* at 9:41–48, 9:60–10:6. Sackier further describes that an engagement of the outer walls of the first and second clip legs (36a, 38a) with inner walls of the outer sleeve (slide 47a) prevents movement of the clip to the open tissue-receiving configuration. Ex. 1008, 9:49–55. Although not discussed specifically in the petition in this section, it is apparent that the clip and sleeve are axially movable by the control member to effectuate opening and closing the clip legs by engagement of the legs in the recess in the slide. Ex. 1008, Figures 15–17. Sackier Figure 17 is reproduced below again:

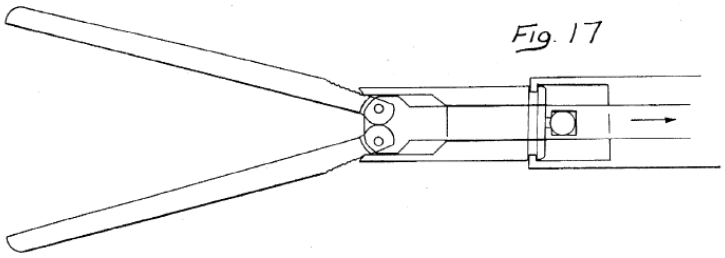


Figure 17 is a side view of an endoscopic clamp

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.

Petitioner asserts that Sackier's clip and Nishioka's linkage perform this function. Pet. 48–49, 60–61. According to the Petitioner, it would have been obvious to a person of ordinary skill in the art, and routine, to combine the linkage disclosed in Nishioka with the clip of Sackier to assist in driving open the clip legs (21). Pet. 48 (citing Ex. 1015 ¶ 64).

Petitioner asserts that the modification of Sackier would be easily effectuated by connecting the distal ends of the Nishioka links (136, 138) to the inner surface of the Sackier clip legs (36a, 38a), placing the Nishioka slide member (120) slidingly within the Sackier cylindrical shaft (158), and attaching the Sackier ball (163) to the proximal end of the Nishioka slide member (120) instead of the proximal end of the cylindrical shaft. *Id.* One would have been motivated to do so to provide more opening leverage and stabilize the clip legs. *Id.* at 49.

Nishioka Figure 8 is reproduced below:

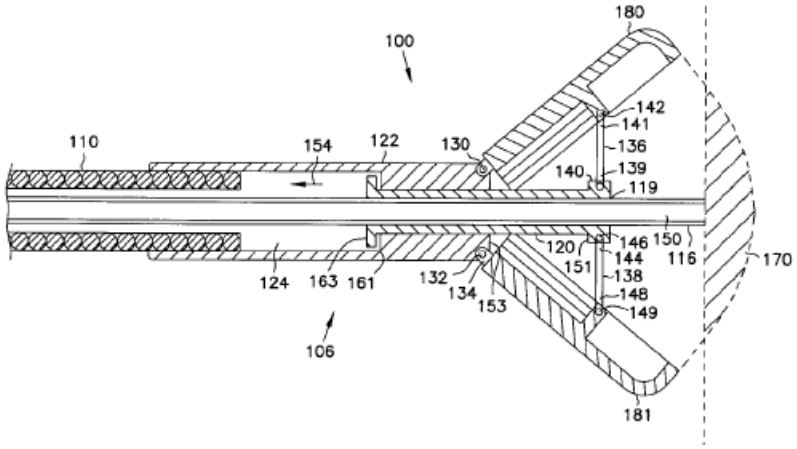


Figure 8 is a cross sectional view of a forceps device.
Ex. 1005, 3:34–35.

Patent Owner asserts that there is no motivation to combine these references. Prelim. Resp. 21–26. We disagree. Petitioner has stated a rationale for making the combination in that the clip legs would be stabilized and more opening leverage provided. Dr. Nicosia has testified in this manner. Ex. 1015, ¶ 64.

Patent Owner also asserts that Sackier is deficient in failing to describe that the control member is moved distally relative to the clip. Prelim. Resp. 26. We agree. However, the Petition does put forth a statement as to how Nishioka describes that limitation, and a sufficient reason for making the combination on the record before us. Pet. 46–49.

Accordingly, Petitioner has made a sufficient showing with respect to claim 13.

Claim 14 depends from claim 13 and further requires "movement of the control member proximally causes a corresponding proximal movement of the clip into the sleeve, moving the clip from the tissue-receiving configuration to a closed configuration in which the first and second clip legs are moved radially inward toward one another." Ex. 1001, 16:27–32.

Petitioner asserts that Sackier describes this limitation. Pet. 35, 62. More specifically, Petitioner relies on the movement of the control member (58a) proximally. Petitioner alleges this movement causes a corresponding proximal movement of the clip legs (36a, 38a) into the sleeve, moving the clip from the tissue-receiving configuration to a closed configuration in which the clip legs (36a, 38a) are moved radially inward toward one another as in Figure 15. Pet. 35, citing Ex. 1008, Figs. 15–17.

Petitioner observes that axial movement of the slide 47a relative to the jaws 36a and 38a is accompanied by relative movement of the jaws 36a, 38a between the open and closed positions. Pet. 35 (citing Ex. 1008 3:14_–15). 9:41–48, 14:5–24. Consequently, the evidence tends to support the Petitioner.

Claim 15 depends from claim 13 and further requires "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." Ex. 1001, 16:33–36.

Petitioner asserts that the clip (10a) separates from the control member (58a) (i.e., the ball 163 separates from flange 176) upon application of a proximal tensile force to the link. Pet. 36 (citing Ex. 1015 ¶ 48; Ex. 1008, Figs. 15–16, and 2:56–59). Based on the record before us, we agree that tensile force likely will release the ball and flange, as discussed above.

Claim 16 depends from claim 13 and further requires "the linkage is received through an opening formed in a proximal end of the clip." Ex. 1001, 16:37–39. Petitioner asserts that Figures 2 and 8 of Nishioka describe a linkage (40, 41 (Figure 2), 120 (Figure 8)) that is received through an opening formed in a proximal end of the clip. Pet. 49–51, 62 (citing Ex.

1008, Figs. 2, 8). We find no flaw in this position.

Claim 17 depends from claim 13 and further requires "the linkage comprises first and second linkage members, proximal ends of the first and second linkage members being connected to one another." Ex. 1001 16:40–43. Petitioner asserts that Nishioka describes that the linkage comprises first and second linkage members (distal ends of 40, 41 (Figure 2), links 136, 138 (Figure 8)). Pet. 51–53, 63 (citing Ex. 1005, Figs. 2 and 8).

Figure 2, does not appear to illustrate where the proximal ends are connected. Figure 8, however, does illustrate that the proximal ends of the first and second linkage members of Nishioka, and it is apparent they are connected via slider 163.

Claim 18 depends from claim 13 and further requires "distal ends of the first and second clip legs include curved projections which are angled radially inward with respect to a longitudinal axis of the clip." Ex. 1001, 16:44–47. Petitioner asserts that it would have been obvious that the skilled artisan would have recognized that the clip legs in Sackier could easily be modified to include any one of the common shapes and configurations known in the art, such as serrated edges to improve gripping of tissue or with inwardly curving tips to aid in containing tissue between the jaws. Dr. Nicosia testifies to this point. Ex. 1015 ¶ 75; Pet. 55–57, 63.

The Nishioka jaws appear to describe these limitations, as discussed above.

Claim 19 depends from claim 13 and further requires "a distal end of the first clip leg includes a plurality of pointed protrusions interlocking with a plurality of corresponding recesses formed in a distal end of the second clip leg." Ex. 1001, 16:48–51. Petitioner asserts that Nishioka describes the

"angled protrusion" in the Figure 2 and Figure 8 embodiments which include one or more "pointed teeth" which "interlock" with one or more "corresponding angled recesses." Pet. 57–59, 63. Those figures, reproduced above, appear to reflect the Petitioner's position.

Petitioner has therefore made a sufficient showing with respect to claims 13–19. Having reviewed the Petition and Preliminary Response, and the evidence cited therein, based on the record before us at this juncture, we determine that Petitioner has demonstrated a reasonable likelihood of showing claims 13–19 are unpatentable in view of Sackier and Nishioka.

D. Claim 20

Claim 20 is an independent method claim.

> *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;*

Petitioner asserts that Sackier describes inserting into a body a medical device including clamps and clamp appliers for occluding body conduits. Pet. 20–25, 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.*

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). Sackier has different embodiments, and the embodiment discussed at the cited 8:29–31 is that of Figures 11–14.

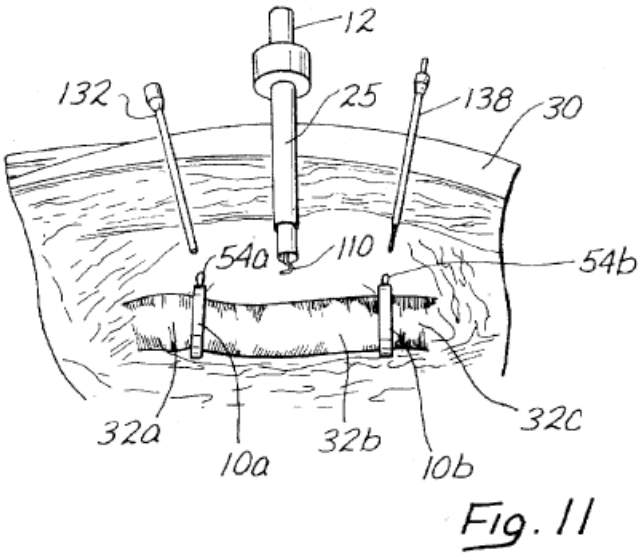


Figure 11 is a perspective view of a body with clamps and clamp appliers. Ex. 1008, 3:44–46.

These clamps (10a and 10b) can be left in the body, and are operable by an Aladdin screw which opens and closes the jaws by advancing a screw against a beveled surface. Ex. 1008, 7:3–10. This principal of operation is significantly different from the sleeve interacting with the beveled surface of the embodiments of Figure 15–17 by axial displacement of the control. Moreover, the Figure 11 embodiment allows for easy detachment and reattachment as needed in the body.

Petitioner does not explain, and we do not otherwise discern how the Figure 15–17 embodiment would controllably detach within the body. The Petition conflates these distinct embodiments and their principles of operation as if they were interchangeable. While Sakier suggests other embodiments, including those shown in Figures 15–17, "are also useful in the method illustrated in FIGS. 11–14," such a cursory statement is insufficient to conclude the principle of operation of the distinct embodiments are the same, particular in the absence of a more detailed explanation by Petitioner.

We simply do not see them in the same manner. Consequently, we are not persuaded by Petitioner's contention as to this element.

> *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, 16:60–17:6.

Petitioner also 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 the link (163, 176) separates upon application of a proximal tensile force of at least a threshold level to the control member (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).

Again, it appears the Petitioner conflates embodiments where the link can evidently be separated to leave the clamp within the body with alternative embodiments which meet the sleeve limitation, without providing adequate explanation.

We reproduce Figure 17 again below.

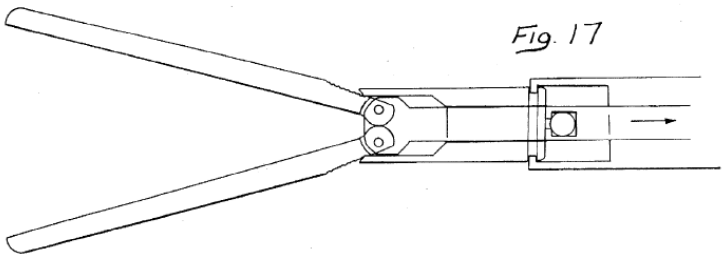


Figure 17 is a side view of an endoscopic clamp

Petitioner has not established persuasively how the Figure 17 embodiment would detach the clamp while it is within the body. Applying an axial force in the direction of the arrow will draw the jaws closed by action of the bevel against the sleeve. But unanswered are multiple engineering questions as to how the clamp could be deployed. First, we have no explanation as to how the clamp would exit the sleeve when the annular groove is physically engaged with the sleeve. What force would unseat the clip when the sleeve it is in the body? Second, we are not provided with an explanation as to how the control member element could

detach from the clip when they are locked together in the central bore of the sleeve in the closed position.

There exists a reasonable likelihood that this is the alternative embodiment as described in Ex. 1008, 3:1–18 for occluding a body conduit, but which embodiment does not specifically describe leaving a clamp in place.

Accordingly, for this additional reason we are not persuaded that Petitioner has demonstrated a reasonable likelihood of showing claim 20 is unpatentable in view of Sackier and Nishioka.

VII. Claims 1–12 and 20 as anticipated by/obvious over Malecki (Ex. 1003)

Petitioner contends claims 1–12 and 20 are unpatentable, under 35 U.S.C. § 102, as anticipated by Malecki. Pet. 70–90. Petitioner also contends claims 1–12 are rendered obvious by Malecki, alone. *Id.* at 91–99.

A. Overview of Malecki (Ex. 1003)

Malecki is directed to a clamp for clamping a body structure. Ex. 1003, Abstract. Figure 28a of Malecki is reproduced below.

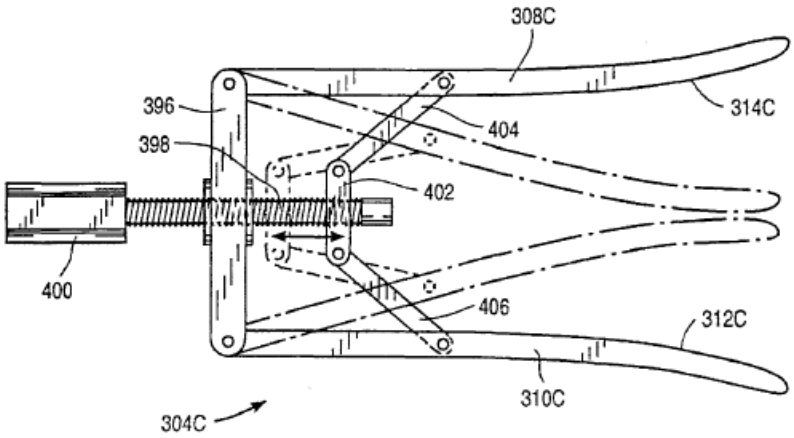


FIG. 28A

Figure 28a is a side view of a clamp. Ex. 1003, 6:29–30.

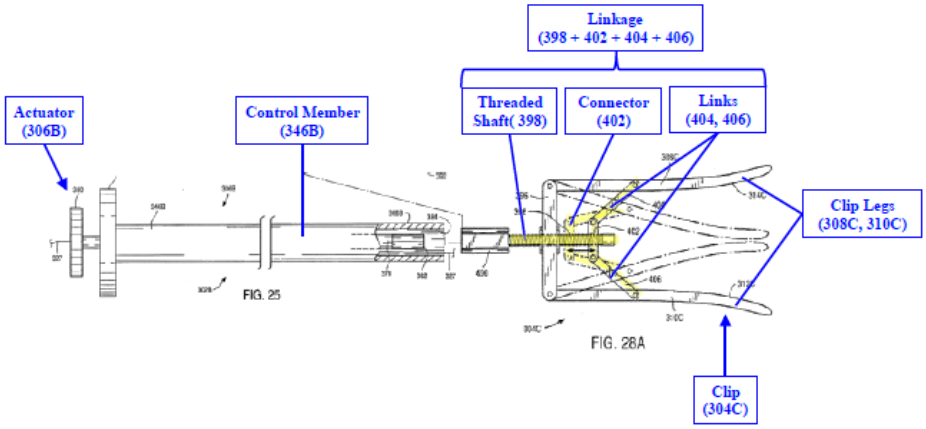
According to the Petitioner, Malecki describes medical devices and methods as claimed. Pet. 70.

2. Discussion of Independent Claims

We begin our analysis with the independent claims. Petitioner asserts that Malecki, alone, teaches all elements of the claims. Pet. 70–99.

In each of the claims of the instant patent is a limitation that a control member extends distally to a clip, and by axial displacement of the control member relative to the clip the jaws open or close. *See*, *e.g.*, independent claims 1, 13, and 30.

Petitioner points to Figures 25 and 28A as describing this control member and its axial displacement. The annotated Figures are reproduced below.



Petitioner Annotated Figures 25 and 28A are side views of a clamp and actuator. Pet. 72

Petitioner asserts that when the clip 304C is in a closed configuration (illustrated in Figure 28A as a "dashed line position"), distal movement of the hollow drive body 346B relative to the clip 304C causes the connector 402 and links 404, 406 of the linkage to spread the first and second clip legs (308C, 310C) apart from one another, and to drive the first and second clip legs radially outward into a tissue-receiving configuration (illustrated in Figure 28A as a "solid line position"). Pet. 73 (citing Ex. 1015 ¶ 108; Ex. 1003, 17:50–62).

Despite the testimony of Dr. Nicosia on this point, we find this position to be insufficiently supported. Patent Owner also observes that Petitioner's embodiment of Figures 25 and 28A uses a hollow drive body 346B that does not move, let alone distally, to open the jaws of the clamp. Prelim. Resp. 28. We agree with Patent Owner. The drive body causes a screw to rotate which causes the connector 402 to move – not distal motion relative to the clip.

As a consequence, having reviewed the Petition and Preliminary Response, and the evidence cited therein, based on the record before us at this juncture, we determine that Petitioner has not demonstrated a reasonable likelihood of showing claims 1–12 and 20 to be unpatentable in view of Malecki.

VIII. CONCLUSION

For the foregoing reasons, we determine that the information presented establishes a reasonable likelihood that Petitioner would prevail in showing that claims 1–19 of the ’027 patent are unpatentable as obvious over the combination of Sackier and Nishioka. We, however, determine that Petitioner has not made a sufficient showing with respect to claim 20. At this preliminary stage, we have not made a final determination with respect to the patentability of the challenged claims or any underlying factual and legal issues.

IX. ORDER

Accordingly, it is:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1–19 of the ’027 Patent on the following ground of unpatentability:

Reference	Basis	Challenged Claims
Sackier and Nishioka	§ 103(a)	1–19

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, which commences on the entry date of this decision; and

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

PETITIONER:

Dominic Zanfardino
Jeffry Nichols
Jason Schigelone
James Oehler
David Bernard
Robert Mallin
BRINKS GILSON & LIONE
dpz@brinksgilson.com
jnichols@brinksgilson.com
jschigelone@brinksgilson.com
joehler@brinksgilson.com
dbernard@brinksgilson.com
rmallin@brinksgilson.com

PATENT OWNER:

David Caine
Wallace Wu
ARNOLD & PORTER LLP
david.caine@aporter.com
wallace.wu@aporter.com