

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*.

FINAL WRITTEN DECISION
35 U.S.C. § 318 (a)

I. BACKGROUND

Cook Group Incorporated and Cook Medical LLC (“Petitioner”) filed a Petition to institute an *inter partes* review of claims 1–20 of U.S. Patent No. 8,709,027 B2 (Ex. 1001, “the ’027 patent”). Paper 1 (“Pet.”). Boston Scientific Scimed, Incorporated (“Patent Owner”) filed a Preliminary Response. Paper 6 (“Prelim. Resp.”). On May 3, 2017, we instituted an *inter partes* review of claims 1–19, but not on claim 20. Paper 7 (“Dec. on Inst.”). Petitioner filed a request for rehearing of our Decision on Institution as to claim 20. Paper 10. (Reh’g Req.”). The request for rehearing was granted on December 18, 2017, and trial was instituted on remaining claim 20. Paper 23.

Patent Owner in the interim had filed a Patent Owner Response (Paper 15 (“PO Resp.”) and Petitioner filed a Reply (Paper 18, “Reply”). Patent Owner subsequently filed a supplemental response as to claim 20. Paper 37 (“PO Claim 20 Supp. Resp.”). Petitioners filed a supplemental reply as to claim 20. Paper 50 (“Pet. Claim 20 Supp. Reply”).

Patent Owner also filed a Motion to Exclude (Paper 34, “Mot.”) certain evidence submitted by Patent Owner, to which Petitioner filed an Opposition (Paper 42) and Patent Owner filed a Reply (Paper 44).

A combined oral hearing with Case IPR2017-00132, IPR2017-00133, and IPR2017-00135 was held on February 8, 2018, and a transcript of the hearing is included in the record (Paper 52, “Tr. 1”). A supplemental hearing on claim 20 was scheduled for March 21, 2018, but fate and the weather intervened in the form of the only significant snowstorm of 2018. The supplemental hearing was rescheduled for April 19, 2018, and a transcript of the supplemental hearing is included in the record (Paper

72, “Tr. 2”).

Subsequent to the oral hearing, on April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on less than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018). Consequently, we instituted review on all claims and grounds, set new times, and permitted additional briefing. Paper 74. The parties filed a joint motion to limit the proceeding (Paper 75), which motion was granted. Paper 76.

The parties then briefed the newly added grounds with a Patent Owner’s Supplemental Response (“PO Supp. Resp.”) (Paper 77); a Petitioner’s Supplemental Reply (“Pet. Supp. Reply”) (Paper 79); and a Patent Owner’s Sur-Reply (“PO Sur-Reply”) (Paper 88). A third oral hearing was held September 17, 2018, and a transcript of the supplemental hearing is included in the record (“Tr. 3.”) (Paper 91).

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–3, 7–14, and 16–19 of the ’027 patent are unpatentable.

Related Matters

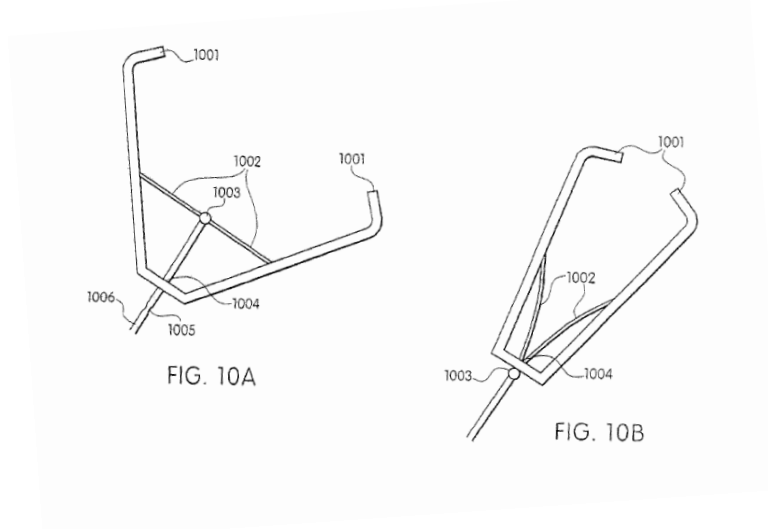
The ’027 patent is the subject of *Boston Scientific Corp. v. Cook Group Inc.*, Civil Action No. 1:15-cv-00980-LPS-CJB (D. Del). Pet. 1; Paper 3, 2. Petitioner has also identified multiple additional petitions for *inter partes* review, including one petition also challenging claims 1–20 of the ’027 patent (IPR2017-00133), which is being decided on even date herewith.

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 that cause hemostasis of blood vessels along the gastrointestinal tract. *Id.* at 2:51–53. The basic device and method is said to include a compression clip used in certain applications to cause hemostasis of blood vessels and a mechanism for deploying the clip. *Id.* at 2:59–62. The clip can also provide a pinching pressure as desired. *Id.* at 15:8–9.

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 depict cross-sectional views of a clip in an opened and a closed position, including linkages 1002 and clip legs 1001. *Id.* at 9:4–6.

Illustrative Claims

Claims 1, 13, and 20 are illustrative of the claimed subject matter and recite the following (paragraphing and line structure maintained 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.

Claim 1, an apparatus claim, is not directed to the use of the clip. By way of contrast, Claim 20, a method claim, requires separation of a link coupling the clip to the control member.

Prior Art

The pending grounds of unpatentability in the instant *inter partes* review are based on the following prior art:

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 December 1, 1998. (“Nishioka”) (Ex. 1005).

Witness Testimony

Petitioner and Patent Owner rely on the testimony of witnesses. They are the following:

- i. Mark A. Nicosia, Ph.D. 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.
- ii. Jeffrey V. Vaitekunas, Ph. D. Exs. 2031, 2040, and 2101.
Dr. Vaitekunas testifies to the substantive issues in this proceeding on behalf of Patent Owner. We find him qualified to testify as to the subject matter of

this proceeding. Ex. 2031 ¶¶ 4–9 and Appendix A. Dr. Vaitekunas was deposited by Petitioner. Ex. 1117.

We have carefully considered the testimony of the witnesses, as well as the prior art.

Pending Grounds of Unpatentability

In the instant *inter partes* review, Petitioner challenges:

(1) claims 1, 3–6, 13–15, 17, and 20 as unpatentable as anticipated under § 102 by Sackier;

(2) claims 1–20 as unpatentable as obvious under § 103 over Sackier and Nishioka;

(3) claims 1, 3–11, and 20 as unpatentable as anticipated under § 102 by Malecki;

(4) claims 1 and 3–11 as unpatentable as obvious under § 103 over Malecki § 103.^{1,2}

II. ANALYSIS

Claim Interpretation

The Board, for purposes of this decision, presently 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

¹ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the ’693 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. §§ 102 and 103.

² The parties agreed to limit the proceeding and filed a joint motion to limit the proceeding. Paper 75. The motion was granted. Paper 76.

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).

Our interpretation “‘cannot be divorced from the specification and the record evidence,’ and ‘must be consistent with the one that those skilled in the art would reach.’ A construction that is ‘unreasonably broad’ and which does not ‘reasonably reflect the plain language and disclosure’ will not pass muster.” *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (citations omitted), *overruled on other grounds by Aqua Prods., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017).

We interpret only those terms needed for this decision below.

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, 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.

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 but reasonably, 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.

Neither Patent Owner nor Petitioner challenge this interpretation. PO Resp. 20–21, Reply 2.

Inner Surfaces

Patent Owner asserts that the “inner surfaces” are “surfaces that are directly opposite one another and between the two clip legs.” PO Resp. 5. More specifically, the Patent Owner asserts that the “broadest reasonable interpretation of ‘inner surfaces of the . . . clip legs’ is ‘the exterior surface

of the clip that is radially inward-facing or inward facing relative to the longitudinal axis of the clip.” *Id.* at 22. This would tend to omit pins and slots as a method of attachment.

The term “outer surface” is used in the ’027 patent to characterize the male threads 2002 on the outer surface of the clip found in Figure 20B.

Figure 20B is reproduced below:

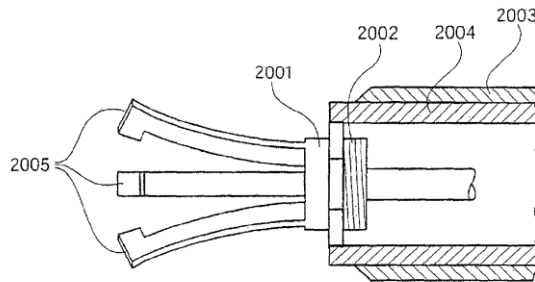


FIG. 20B

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

It is apparent to us that the “outside surface” means what it says, the surface that faces outwardly. Ex. 1001 13:24–25. The specification goes on to describe that the “inner sleeve 2004 has female threads (not shown) on its inside diameter.” *Id.* 13:30–31. Although the term “inner surface” does not appear in the specification, by logical extension an inner surface would be consistent with the inner diameter that faces inwardly to engage the threads.

Petitioner, on the other hand, criticizes the Patent Owner’s position but provides no meaningful interpretation of the claim term. Reply 2–6. Dr. Nicosia does not meaningfully discuss the definition of inner surface in his declaration either. Exs. 1011 and 1068 generally.

Dr. Vaitekunas testified at some length as to what makes up an inner surface. He testified that he understands that:

Patent Owner argues that the broadest reasonable construction of ‘inner surfaces of the . . . clip legs’ is ‘the exterior surface of the clip that is radially inward-facing or inward-facing relative to the longitudinal axis of the clip.’ Patent Owner’s proposed construction of “inner surfaces of the . . . clip legs” is consistent with what I, as a person of at least ordinary skill in the art, would understand the term to mean in the ’027 Patent. This construction is also consistent with the intrinsic evidence. Figures 10A and 10B of the ’027 Patent show flexible linkage 1002 contacting the radially inward facing surfaces of clip legs 1001. Furthermore, Patent Owner’s original claim 42 recites that ‘the handle is able to be rotated to thread a base of the clip into a female thread situated on a radially inner side of an outer sleeve, . . . and the at least two clip legs able to close when the base is threaded into the outer sleeve.’ Ex. 1002 – 00037. The ‘radially inner side of an outer sleeve’ in Patent Owner’s original claim 42 must refer to an exterior surface that is radially inward-facing, as the female thread must be located on an exterior surface so that it can be threaded with the base of the clip to close the clip.

Ex. 2031 ¶ 33.

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

We do not, however, agree that the claim requires the inner surface to specifically face “radially” inwardly, merely inwardly such that it can be engaged in some manner by the linkage. We find that the claim language is specific enough as it stands - an inner surface would appear to be a surface that faces inwardly, from the perspective of the clip.

Principles of Law

To prevail in challenging claims 1–20 of the '027 patent, Petitioner must demonstrate by a preponderance of the evidence that the claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

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...

Anticipation requires evidence “that a single prior art reference discloses each and every element of a claimed invention.” *Silicon Graphics, Inc. v. ATI Techs., Inc.*, 607 F.3d 784, 796 (Fed. Cir. 2010).

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.³ *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.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

A patent claim “is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR*, 550 U.S. at 418. An obviousness determination requires finding “both ‘that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.’” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016) (citation omitted); *see KSR*, 550 U.S. at 418 (for an obviousness analysis, “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does”).

A motivation to combine the teachings of two references can be “found explicitly or implicitly in market forces; design incentives; the ‘interrelated teachings of multiple patents’; ‘any need or problem known in the field of endeavor at the time of invention and addressed by the patent’; and the background knowledge, creativity, and common sense of the person of ordinary skill.” *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1354 (Fed. Cir. 2013) (citation omitted). Further, an assertion of obviousness “cannot

³ The parties do not present or discuss any evidence related to secondary considerations in this proceeding.

be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, 550 U.S. at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)); *In re Nuvasive, Inc.*, 842 F.3d 1376, 1383 (Fed. Cir. 2016) (a finding of a motivation to combine “must be supported by a ‘reasoned explanation’” (citation omitted)).

Level 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. Based on the record developed during trial, including our review of the ’027 patent and the types of problems and solutions described in the ’027 patent and cited prior art, 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.

*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.

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.

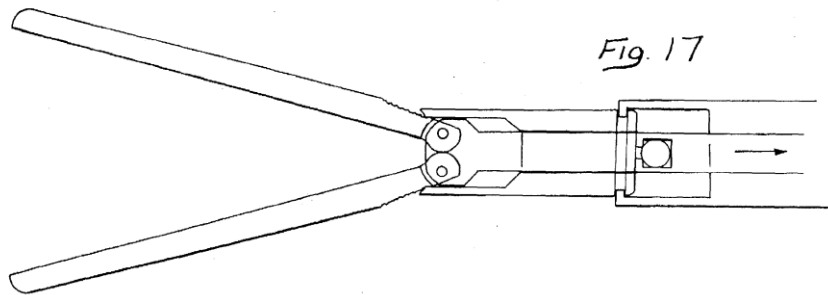


Figure 17 is an axial cross-section view of a clamp.

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.

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.

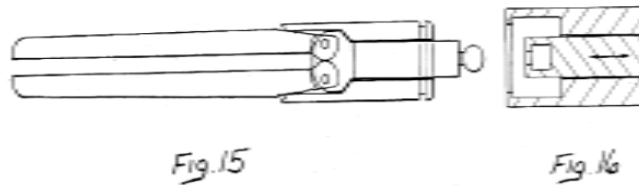
A medical device, comprising:

Consistent with Petitioner's contentions (*id.*), we find that Sackier describes a medical device – a surgical clamp. Pet. 20, cciting 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 Sackier clamp embodiment and proximal end of the clamp applicator. Ex. 1008, 3:56–59.

Although lacking reference numerals in the figures of the printed patent, we find that a clip with jaws having inner surfaces as claimed is illustrated. Ex. 1008, 9:16–19. This inner surfaces are discussed in more detail below as related to another claim limitation.

*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 applicator 12a) to the clip (10a). Pet. 21. Petitioner points us to Figure 9, reproduced below, and Figure 17, reproduced above. *Id.*

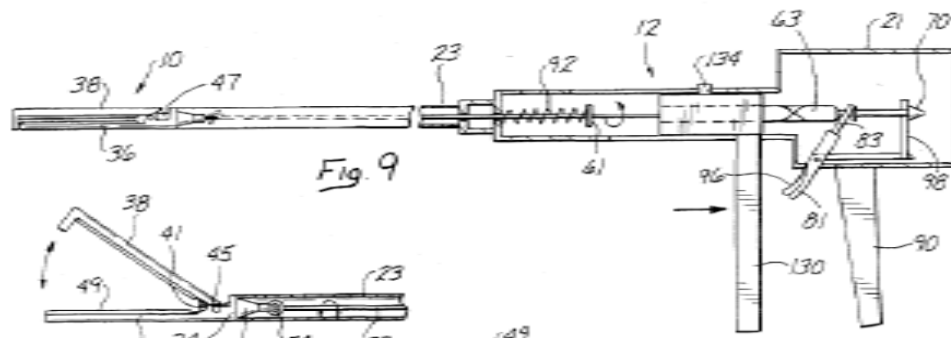


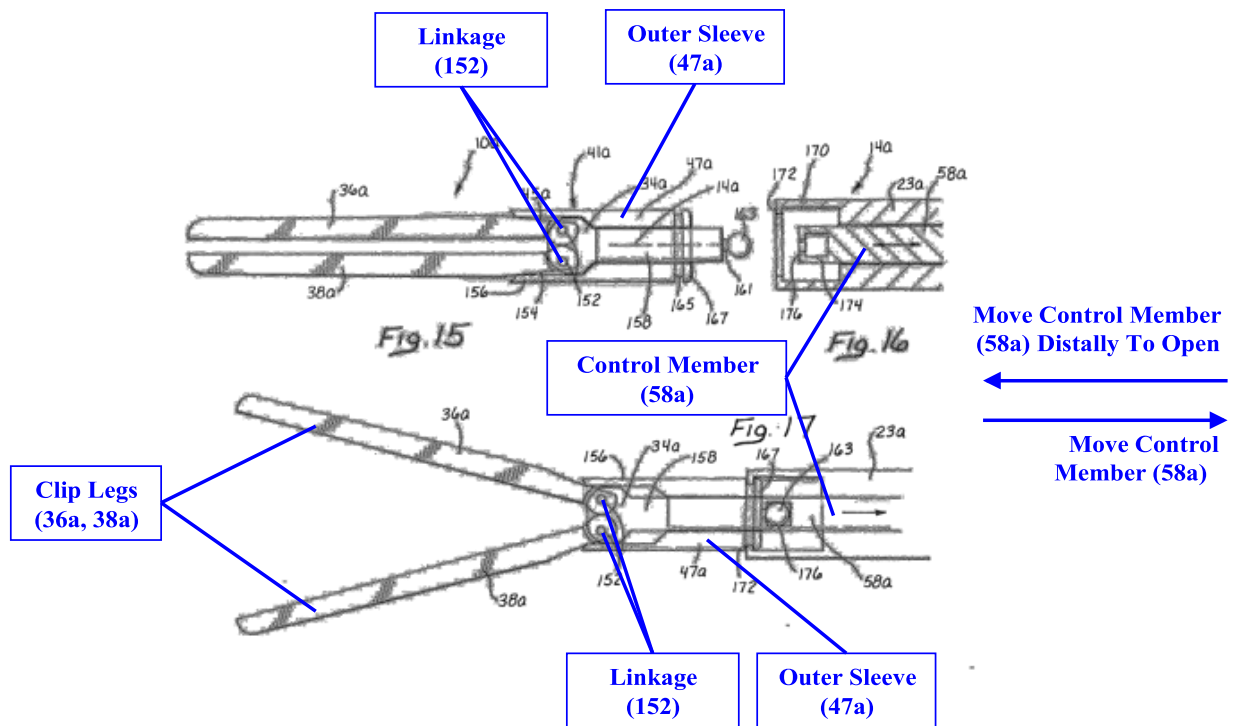
Figure 9 is a side view of an embodiment of the Sackier clamp and clamp applicator.

Ex. 1008, 3:38–40

We find that Sackier describes 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 the embodiment of 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.



Figures 15–17 are Petitioner’s Annotated Cross-sectional views of an embodiment of a clip and clip applicator

Patent Owner, on the other hand, first asserts that Sackier does not describe a control member being moved relative to a clip. PO Supp. Resp. 16. More specifically, Patent Owner asserts that Sackier’s inner shaft 58a, the purported “control member,” is not moved distally relative to the clamp. In particular, Petitioners’ annotated Figures 15 and 17 show that distal movement of inner shaft 58a maintains a fixed distance between a point on inner shaft 58a and jaws 36a and 38a, and proximal movement of inner shaft 58a maintains that same distance between a point on inner shaft 58a and jaws 36a and 38a. PO Supp. Resp. 17, citing Ex. 1012, 1012-00274; Pet., 23.

In short, Patent Owner’s position is that although inner shaft 58a can be moved distally relative to outer tube 23a to open the jaws, inner shaft 58a

is not moved distally relative to the jaws, but rather maintains the same spatial relationship with the jaws. Dr. Vaitekunas testifies persuasively that this is so. Ex. 2101 ¶58.

Petitioner responds that Sackier meets the limitation requiring distal movement of the “control member” relative to the “clip” because Sackier’s inner shaft 58a moves distally relative to slide 47a, said to be a component of the clip. Pet. Supp. Reply, 5.

We find Petitioner’s position unpersuasive. The clip is defined in instant claim 1 as having a first clip leg and a second clip leg (e.g. clip legs 36a and 36b, shown above). The clip itself is not defined as requiring a slide.

Moreover, as pointed out by the Patent Owner, the claim requires distal movement of the “control member” relative to the “clip” itself. PO Sur-Reply, 1–2.

Additionally, although not dependent from claim 1, claim 13 requires a sleeve to move relative to the clip. Ex. 1001, 16:13–26. More specifically – it further requires that “the clip is moved distally relative to the sleeve.” *Id.* at 16:19-26. We agree with Patent Owner that construing the “clip” to include a “sleeve” could read the “sleeve” out of claim 13 as a separate limitation in certain circumstances. PO Sur-Reply, 2. In any event, claim 13 clarifies that the clip must include the legs, not necessarily the sleeve, and that the control member is required to move relative to them.

Accordingly, we find that Sackier does not describe moving the control member relative to the clip.

Accordingly, Petitioner has not shown by a preponderance of the evidence that claim 1 is unpatentable as anticipated by Sackier. As claim 13

also contains this limitation, we conclude that Petitioner has not proven, by a preponderance of the evidence, that Sackier anticipates Claims 1, 3–6, 13–15, and 17.

Discussion of Claim 20

Claim 20 is an independent claim directed to a method of using a medical device, which comprises a clip, a control member, and a linkage. Ex. 1001, 15:33–45.

We address the pertinent claim elements (*italicized*) below.

20. A method, comprising:

Petitioner asserts that Sackier discloses “[a] method for operating [a] clamp.” Pet. 37, citing Ex. 1015, ¶ 50; Ex. 1008, 3:1-2. We agree with this characterization, and find that Sackier does describe such a method.

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. 37 (citing Ex. 1015 ¶ 51; 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. Pet. 37–38.

We agree and find that the evidence supports a conclusion that Sackier describes this element.

positioning the medical device at a desired deployment location;

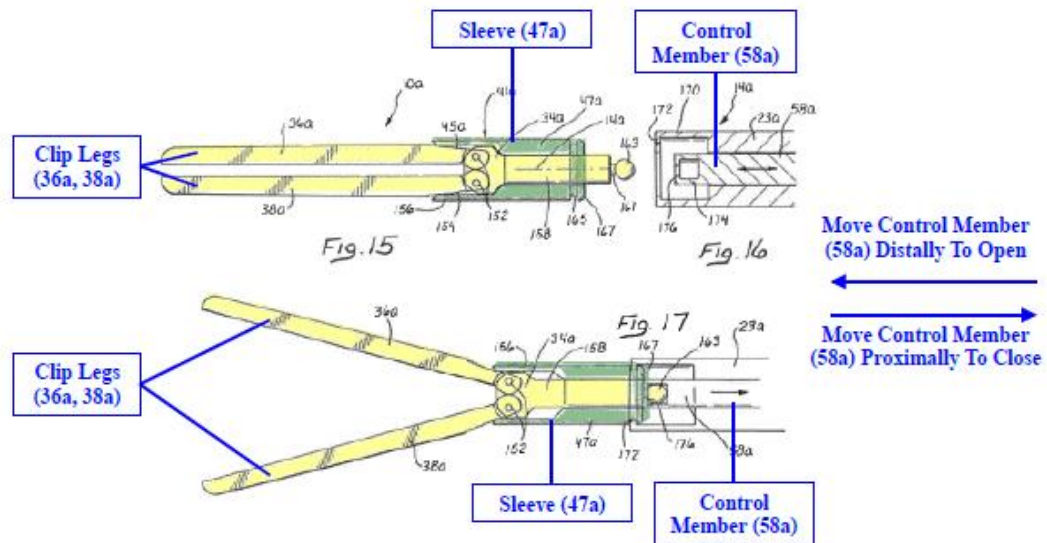
Petitioner asserts that Sackier discloses positioning the medical device at a desired deployment location. Pet. 39, citing Ex. 1015 ¶ 53; Ex. 1008, 8:29–31.

We agree that the evidence supports a finding that Sackier describes using a clip within the body, which meets the limitation of deployment. *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 (58a) distally relative to a sleeve (47a) housing the clip legs 36a, 38a), to cause the clip (10a) to move distally relative to the sleeve (47a) (*i.e.*, clip (10a) moves from position in Figure 15 to position in Figure 17). Pet 39–40.

Their contention is illustrated in the annotated figures reproduced below:



Figures 15–17 are annotated sectional views of a clip and control

Petitioner asserts that the clip moves distally relative to the sleeve (47a), as evidenced by the fact that the sleeve (47a) houses a greater portion of the clip legs (36a, 38b) in Figure 15 than in Figure 17. Pet. 40, citing Ex. 1015 ¶ 54.

Petitioner also asserts that Sackier discloses a linkage (said to be spring 52) to “contact the first and second inner surfaces to drive the first and second clip legs radially outward to a tissue-receiving configuration.” (Ex. 1015, ¶ 55). Pet 40.

Petitioner also references annotated Figure 2, asserting that Sackier discloses that the linkage in this embodiment (also said to be spring 52) contacts the inner surfaces of first and second clip legs (36, 38) to spread open and drive outward the clip legs (36, 38). Pet. 40, citing Ex. 1015 ¶ 55; Ex. 1008, 9:25–30; and 5:4-12, 9:5–12.

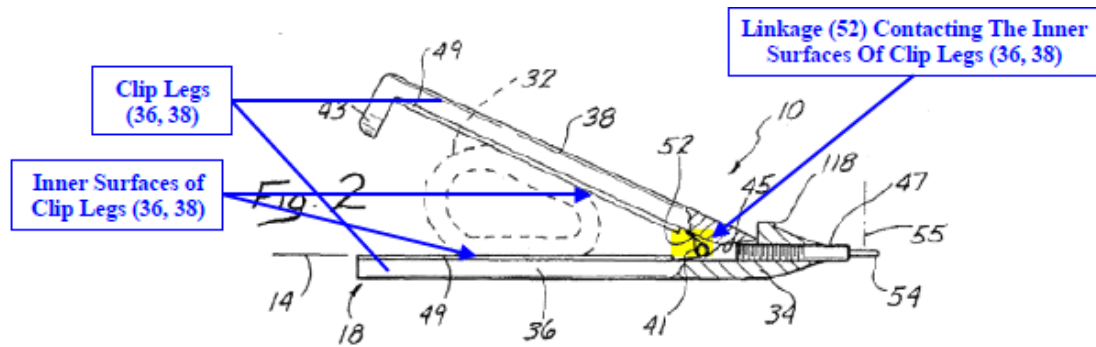


Figure 2 is a sectional view of a clip embodiment including a bowel segment

For the reasons discussed below, we do not agree with all of Petitioner's assertions in this regard. Our analysis is focused on whether anticipation is established by a preponderance of the evidence. As noted above, anticipation requires evidence that a single prior art reference discloses each and every element of a claimed invention.

The evidence of record does supports a conclusion that the Sackier control member pushes the clip out of the sleeve - as illustrated in Figures 15–17 above, causing the clip legs to open.

However, Petitioner points to the circular pivot points 152 for the legs as the claimed linkage driving the clip legs outward. Pet. 23, 40. The Petition then asserts a different embodiment of Sackier illustrated in Figure 2, where a spring 52 is located between the legs. Pet. 41. The spring 52 is said to contact the inner surfaces and drive one jaw away from a fixed jaw, thus driving the jaws as a whole apart. This combination of embodiments is said to meet the claim limitation of contacting the inner surfaces of the first clip leg and second clip leg and driving the legs radially outward. *Id.*

Patent Owner takes issue with this assertion. First, Patent Owner observes that spring 152 does not contact the inner surfaces of jaws 36a or 38a. PO Resp., 28; PO Claim 20 Supp. Resp., 10.

We agree that spring 152 does not contact the inner surface of jaws 36a and 36b in Figure 15. However, Petitioner asserts that Dr. Nicosia explained how Sackier's "labeling convention" (using successive lower-case letters to identify successive embodiments) teaches substituting the Embodiment 2 clamp/clamp applier for the clamp applier illustrated in Figures 11-14. PO Supp. Reply 17, citing Ex.1100 ¶13; Pet. Claim 20 Supp. Reply, 14–15; and Ex.1008 9:5–15. We have carefully considered Dr. Nicosia's testimony.

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

This renders the question of claim 20 much closer than we had initially apprehended it to be in the Institution Decision or the Decision on Rehearing. However, we are not persuaded that the two different embodiments are necessarily described as (or one of ordinary skill in the art would regard them as) having interchangeable components, principally because they operate on different principles to open and close the legs.

Sackier Figure 2 utilizes a spring between the legs that drives the legs out as a screw and beveled surface exert inward force.

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

Patent owner argues persuasively that:

Regardless of whether the embodiment of Figure 2 has one fixed jaw or two pivotal jaws, the flaw in Petitioners’ argument is the assumption that spring 52 from Figure 2 is disclosed as an alternative to spring 152 in the embodiment of Figures 15-17. It is not disclosed as such, and the allegedly “parallel descriptions of illustrated and alternative embodiments” (Paper 79 at 9) does not change the analysis. Numerous elements identified with the same numeral differ between the two embodiments, including for example, screw 47 in embodiment of Figure 2 and slide 47a in the embodiment of Figures 15-17. That the embodiment of Figures 15-17 designates its spring 152 differently from the numeric designation of the spring in Figure 2 drives home the point that Sackier disclosed different structures in different embodiments

PO Sur-Reply, 2–3.

We conclude that the Patent Owner has the better side of this argument. Even though Dr. Nicosia testifies that the embodiments can be interchanged (Ex. 1100 ¶ 13) we understand that the basis for that interchangeability as stated by Sackier is *of each embodiment in the surgical procedure*, not necessarily the *components of those embodiments* are interchangeable with each other.

To establish anticipation, each and every element in a claim, arranged as recited in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008).

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

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.

Overview of Nishioka (Ex. 1005)

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

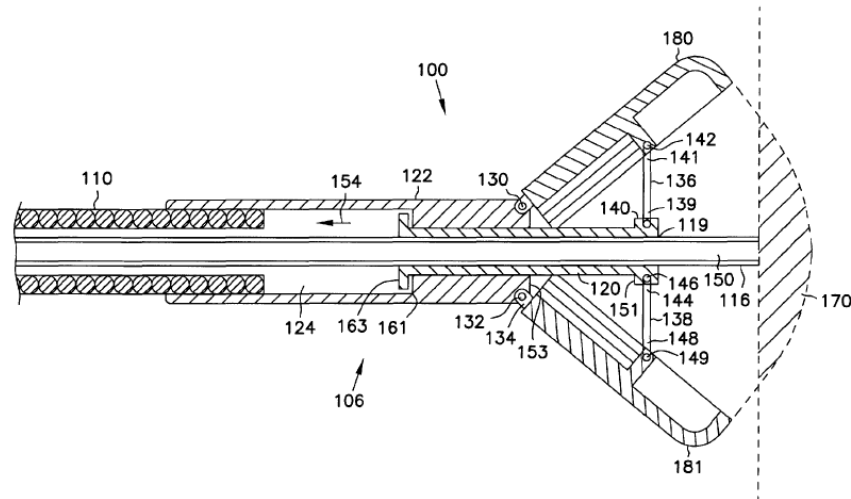


FIG. 8

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 hinged 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.

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 as discussed above.

We agree and find that Sackier describes a medical device, specifically a clip having legs with inner surfaces.

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. As discussed above, we agree and find that Sackier describes a control member extending from a proximal actuator.

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 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.

Patent Owner, on the other hand, asserts that Sackier does not describe that the control member is moved distally relative to the clip. PO Supp Resp. 16. As discussed above, Claims 1 and 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:

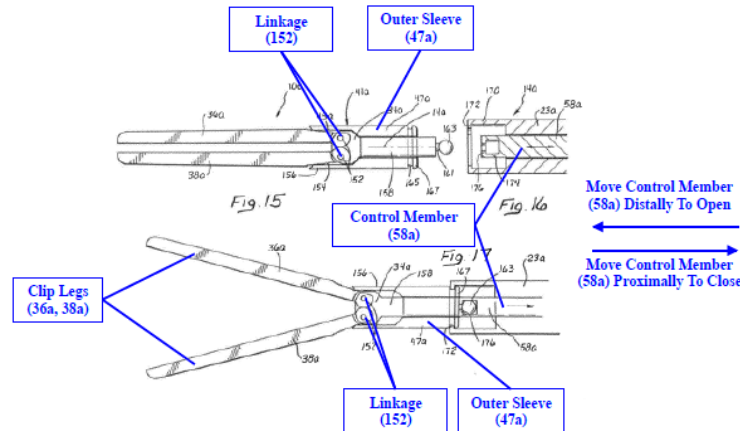
In contrast, the limitations of claim 46 are directed to a control member and linkage which are shaped, sized, and oriented such that movement of the control member *relative to the clip* causes the linkage to drive the clip legs radially outward. Specifically, the control wire 1006 is advanced distally *relative to the clip*, this movement causing the clip legs 1001 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, 201 (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 Sackier in support of the Petition. They are reproduced below:



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

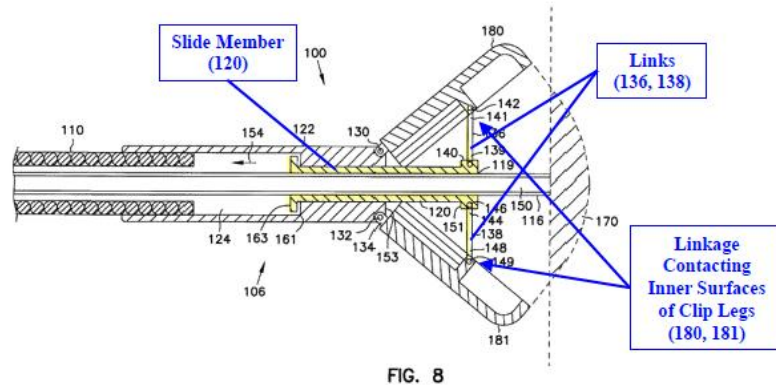
Pet. 23.

The annotated text with the arrows indicates 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 find this position to be insufficiently supported with persuasive evidence, as Petitioner has not shown that the control member moves at all relative to the clip in Sackier, notwithstanding the sleeve argument discussed above.

Notwithstanding the deficiency with Sackier as argued in the Petition, 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):



(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, on the other hand, urges several defects are present in the Petition.

First, Patent Owner urges that Nishioka's control links contact the side of the jaws, not the inner surfaces. PO Resp. 2 and 28-32.

In this regard, Patent Owner is of the view that Nishioka Embodiment 2 fails to disclose the claimed linkage contacting the inner surfaces of the first and second clip legs. *Id.* at 31. Patent Owner relies on annotated Figure 8, reproduced below.

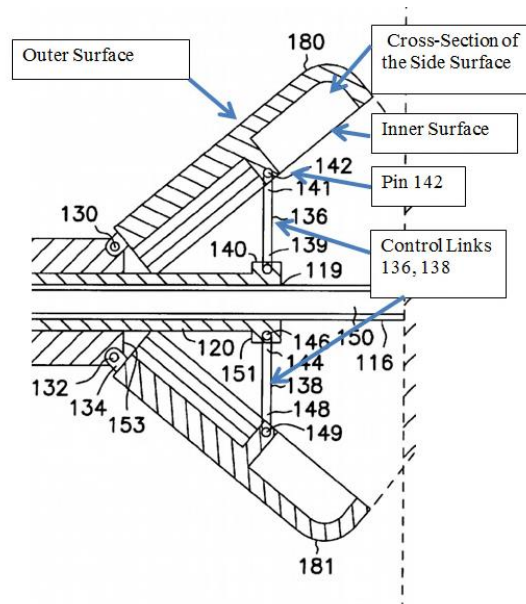


FIG. 8

Figure 8 is a partial annotated cross sectional view of a biopsy forceps

According to Patent Owner, Figure 8 provides a cross-sectional view of the distal end of Nishioka Embodiment 2. *Id.* Also according to Patent Owner, because Figure 8 is a two-dimensional representation of the biopsy forceps, the figure shows only a cut-away portion of the *side* surface of the cutting jaws. *Id.* at 33. Patent Owner then interprets the figure as illustrating the linkage as being on the *side* of the jaws, and not the inner surface. *Id.* Patent Owner asserts the links would interfere with the closing of the jaws otherwise and the links fit into a recessed portion on the side of the jaws, as shown below. *Id.* at 33–34.

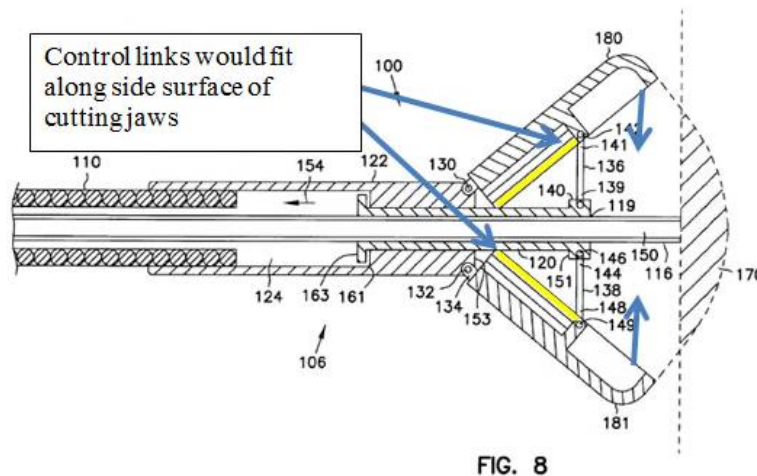
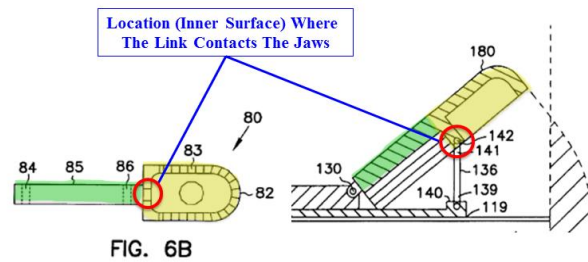


Figure 8 is a partial annotated cross sectional view of a biopsy forceps

Petitioner characterizes this position as incorrect. Reply 15. Specifically, Petitioner is of the viewpoint that the control links contact the jaws on the inner surface, not the side of the jaws. *Id.* at 16–17. We reproduce Petitioner’s annotated Figures 6B and 8 as provided in the Reply on page 17 to show this point that the axial view of Figure 8 is central, not off to one side.



Annotated Figures 6B and 8 (Reply 21) are partial cross sectional views depicting Nishioka Embodiment 2.

Petitioner asserts that mounting this link on the side does not make sense because the misalignment would cause undesirable torque, uneven jaw pressure, and potential interference with the ability of the jaws to close and grasp tissue. Reply 19, citing the testimony of Dr. Nicosia, Ex. 1068 ¶¶ 25–28.

We do find this comparison of Figure 6B with the portion of Figure 8 helpful and it, along with Dr. Nicosia’s testimony, to be persuasive. It does appear to provide evidence that the cross sectional view of Figure 8 is a *central* cross section. We find the characterization of the view by Patent Owner as including a cross-section of the side wall to be incorrect because

the side wall is not centrally located.⁴ Thus, we are not persuaded by Patent Owner's argument that the linkage is on the side of the clip.

Patent Owner also 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; that the combination would create redundancies, the combination would not work for its intended purpose, and the combination would not practice the claimed invention. PO Resp. 54–67. We address these contentions *seriatim* below.

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.

More specifically, Patent Owner asserts that this is so because no one other than the named inventors had identified the inability to reversibly open and close a medical clip prior to deployment as a problem in the art. *Id.* at 65, citing testimony of Dr. Nicosia during cross-examination, Ex. 2011 at 117:19–118:10.

Patent Owner asserts that, because a solution to an unknown problem cannot be obvious, the inventions claimed in the '027 patent cannot be obvious. PO Resp., 66.

While, as a general rule, we do not disagree that sometimes invention can lie in solving a known problem, such is not always required. *See, e.g. KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (it is “important to identify a reason that would have prompted a person of ordinary skill in the

⁴ Additionally, a cross sectional view would normally have cross hatching if the piece were solid. *See* 37 C.F.R. § 1.84(g)(3). The Patent Owner's asserted side wall does not.

relevant field to combine the elements in the way the claimed new invention does”).

Petitioner observes that Dr. Nicosia accomplished this requirement when he explained a person having ordinary skill in the art would have understood potential issues with Sackier’s clip opening mechanism and would have been motivated to improve it using Nishioka. Reply, 28–29, citing Ex.1015 ¶¶64–65.

In cross examination, it is evident that Dr. Nicosia understood precisely what motivation he was looking for in the references and when comparing them to the claims. Specifically:

Q In considering the question of obviousness, did you -- was the question you were considering whether a person of ordinary skill in the art would combine the pieces of prior art that you were looking at to achieve the claimed invention?

MR. ZANFARDINO: Objection, form.

THE WITNESS: So the goal of the obviousness analysis was to understand if a person of ordinary skill in the art would be motivated to combine to solve what may have been a limitation of one of the references by themselves and if that combination would then match a claimed -- or the claims.

So it wasn't just find out -- looking at the patents, looking at if there were deficiencies that could be solved by a person of ordinary skill by combining and then does that combination line up with the claim. And also, you know, if it would have been reasonable for them to look at those references.

Ex. 2011, 850:7–25.

The testimony of Dr. Nicosia itself was that:

The skilled artisan would have expected that modifying the clip in Sackier to include the Nishioka linkage would improve the performance of the clip. In particular, the linkage described in Nishioka would provide more leverage to drive open the clip legs because the relatively longer linkage member provides a longer moment arm than the spring arms in Sackier. Additionally, the linkage described in Nishioka would stabilize the clip legs through contact of the linkage more distally along the clip leg.

Ex. 1015 ¶ 65.

We conclude that Dr. Nicosia's testimony above provided a sufficient rational basis for making the combination of Sackier and Nishioka, both endoscopic instruments.⁵

Patent Owner also asserts that Petitioners' obviousness argument fails because the addition of Nishioka slide member 120 and control links 136 and 138 would create a redundancy that would serve no purpose (other than

⁵ Patent Owner asserted that one of ordinary skill in the art would not make the combination of a cutting biopsy forceps with a laparoscopic surgical clamp. PO Resp., 25. We recognize that our finding concerning this combination is slightly different from the finding made with the combination of Nishioka and Shinozuka presented by the Petitioner and rejected as hindsight, among other reasons, by this same panel in IPR2017-000133 (the '133 IPR). While normally we would not feel obliged to explain the conflict, recent decisions from our reviewing court indicate that inconsistency should be explained. In this instance the linkage of Nishioka is what is being substituted into Sackier to replace the spring in the proposed combination. The function of Sackier would not materially change from its intended function. In the proposed combination of the '133 IPR, the fundamental object of Nishioka forceps (identifying and retrieving samples) was eliminated and frustrated by combining it with Shinozuka (clip intended to be left behind in the body).

hindsight reconstruction of the claimed apparatus) and would increase the complexity and cost of the device. PO Resp. 59.

Patent Owner's reasoning is that Sackier already discloses use of the spring 152 to bias the jaws to an open position, and that Petitioners' expert admitted that he was not aware of any problems with opening the jaws of the clamp or with the operation of the Sackier device. *Id.*, citing Ex. 2011, 211:13-20.

Patent Owner further urges that Petitioners do not sufficiently explain why a person of ordinary skill in the art would have had a reason to include the Nishioka linkage to drive open the jaws in addition to Sackier's springs 152 that already bias the jaws open. As the springs 152 effectively opened Sackier's jaws, it would not have been obvious to add a different, superfluous structure to accomplish the same function of opening the jaws. PO Resp. 60.

While we have carefully considered Patent Owner's position, we observe that Nishioka does not add precisely the same function as the biasing spring in Sackier. Rather, as Petitioner correctly points out that Dr. Nicosia's testified that that Nishioka's linkage would provide "more leverage [than Sackier's spring 152] to drive open the clip legs" by providing "a longer moment arm than the spring arms in Sackier." Reply, 29, citing Ex.1015 ¶ 65. Accordingly, we are not persuaded by Patent Owner's argument.

Patent Owner also asserts that that the combination would render the device inoperable for its intended purpose of clamping a body conduit. PO Resp. 63–65. More specifically, it is urged that connecting the Nishioka control links 136 and 138 to the inner surfaces of the Sackier jaws would

increase the diameter of the device when Sackier teaches away from using structures that would increase the diameter of the distal end of the device. *Id.* at 64. Patent Owner urges, based upon the testimony of Dr. Vaitekunas, that a person of ordinary skill in the art would not have been motivated to connect the Nishioka control links 136 and 138 to the inner surfaces of the Sackier jaws, as this would increase the size of the combined device, interfere with the ability of the Sackier jaws to close within slide 47a, and interfere the ability of the Sackier clamp to fit within the confines of the trocars. *Id.*, citing Ex. 2031 ¶ 110. Finally, Patent Owner argues that placing the rigid member control links of Nishioka into the clip legs and clamping over a body conduit would increase the risk of perforation, and reduce the area available for clamping. *Id.* at 65, citing Ex. 2031 ¶ 110.

While these are considerations in making the combination, the Petitioner in reply notes that Nishioka itself is narrow enough to be used in laparoscopic procedures. Reply, 30. Further, Petitioner observes that the length of the jaw available for clamping is not a claim requirement. *Id.* at 31. Finally, Petitioner notes that Dr. Nicosia testified that a person of skill in the art would have incorporated the indentations in Nishioka into Sackier's jaws. *Id.*, citing Ex. 1050 ¶ 33.

Considering the above, we find that, on balance, Petitioner's evidence is greater than Patent Owner's on this point. The linkage of Nishioka appears to provide advantages that outweigh the potential disadvantages of making the combination.

Finally, Patent Owner urges that the proposed combination would not practice the invention. PO Resp. 65–68. Specifically, it is urged that for claims 1 and 13 the control member could not move distally relative to the

clip because when the inner shaft 58a is moved distally to open the jaws, the inner shaft would run into the cylindrical shaft 158 and push the cylindrical shaft 158 in unison. *Id.* at 76, citing Dr. Vaitekunas’ testimony, Ex. 2031 ¶ 114.

We do not find this argument persuasive, as Dr. Nicosia explained that the proposed modification includes “placing the Nishioka slide member 120 slidingly within the Sackier cylindrical shaft (158)” to “assist in driving open the clip legs.” Reply, 32–33, citing Dr. Nicosia, Ex.1015 ¶ 64 and Petition 48. This would enable the control member to slide within the shaft and move relative to the clip.

Accordingly, we find Petitioner has established that a preponderance of the evidence of record supports a conclusion that the combination of Sackier with Nishioka renders the subject matter of claim 1 obvious.

Claims 2–19

Petitioner asserts that the combination of Sackier and Nishioka renders these claims obvious.

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.

Patent Owner asserts that Sackier has no opening in the proximal end of the clip. PO Resp. 36–38. Patent Owner also asserts that Nishioka does not disclose the opening formed in the proximal end of the clip. *Id.* at 39.

More specifically, for Nishioka Embodiment 1, Patent Owner challenges Petitioners’ assertion that the portion highlighted in red in

annotated Figure 2 below is the claimed opening formed in a proximal end of the clip.

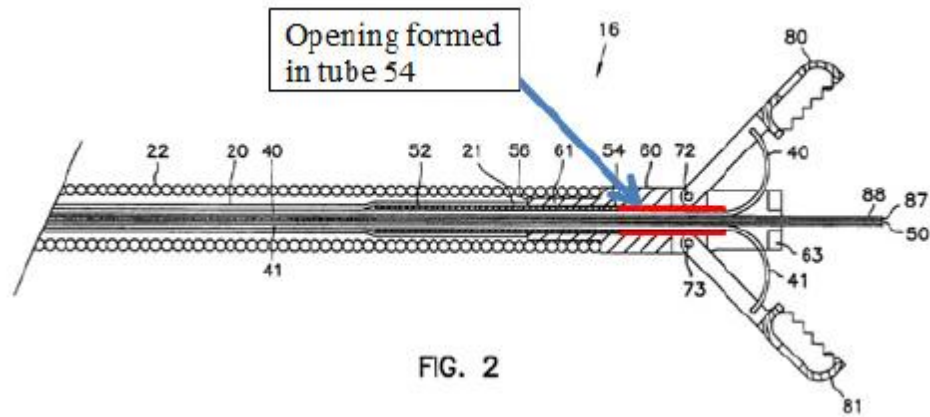


Figure 2 is Petitioner’s annotated and highlighted sectional view of a clip. Pet. 50.

Patent Owner asserts that the highlighted portion is not an opening in the cutting jaws. Rather, Dr. Vaitekunas testifies that the opening identified by Petitioners in Figure 2 above is actually an opening formed in the tube 54. Ex. 2031 ¶ 77.

This reasoning is based on the observation that clip of the ’027 Patent, is integral and consists of two clip legs and a proximal end, whereas the two cutting jaws in Nishioka are separate components that are pinned to different corners of the yoke. PO Resp. 40. Patent Owner observes that Petitioners’ expert agreed at his deposition. *Id.*, citing Ex. 2011 at 192:9–11 (agreeing that “each of the jaws 80 and 81 are separate structures”).

Patent Owner concludes that as the cutting jaws are separate structures, not a single, integral structure, Nishioka Embodiment 1 does not disclose a “linkage” that “is received through an opening formed in a proximal end of the clip.” PO Resp. 40.

We disagree with Patent Owner’s position. Claim 2 does not require

that the clip legs must be a single, integral structure. Accordingly, we conclude that Petitioner has shown by a preponderance of evidence that claim 2 is rendered obvious by the combination of Sackier and Nishioka.

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. We find that Figures 2 and 8 support the Petitioner’s position.

Patent Owner asserts that the first linkage and second linkage are not connected to each other in Nishioka, but instead the linkages are connected to separate portions of the distal end of the tubular slide member 120. PO Resp. 50.

Patent Owner points to Figure 10A, annotated, reproduced below in support of its assertion.

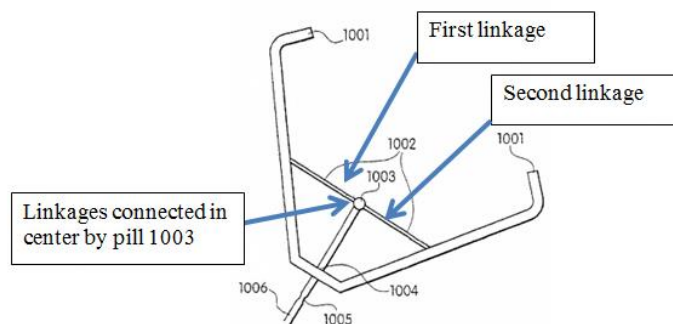


FIG. 10A

Figure 10 A is a cross sectional view of a clip

Patent Owner relies on the exemplary embodiment of Figure 10A of the '027 patent and argues that the two linkage members 1002 are connected to each other by the pill 1003. In contrast, in Nishioka it is urged that they are connected to different portions of the slider. PO Resp. 47.

Patent Owner notes that Petitioner's witness admitted that "there's not a direct physical contact between the two linkages" in Nishioka. *Id.* at 46, citing Ex. 2011 203:8–204:6. Thus, according to Patent Owner, "Nishioka Embodiment 2 does not disclose 'proximal ends of the first and second linkage members [that are] connected to one another' and does not anticipate Claim 3." *Id.*

We find this argument unpersuasive. Claim 3 requires only that the linkages are connected to each other, not directly connected with physical contact, or otherwise integral as a single unit. By claiming that the linkages are "connected to one another," Patent Owner claimed a structure that allows for intermediate linkages. *See American Piledriving Equip., Inc. v. Geoquip, Inc.*, 637 F.3d 1324, 1340 (Fed. Cir. 2011) ("claim 16 merely requires that the components be 'connected to' one another, which encompasses the use of bolts"). For example, the plain and ordinary meaning of "connected to" generally requires only that two structures are "joined together, united or linked." *See, e.g., Am. Piledriving Equip., Inc. v. Equip. Corp. of Am.*, 2009 WL 3401726, at *11 (W.D. Pa. Oct. 20, 2009) ("'connected to' be construed to mean: 'joined together, united or linked'").

The specification of the '027 patent allows for embodiments where legs have intermediate structures connecting them to form the clip. *See, e.g.*, Fig. 8E, reproduced below.

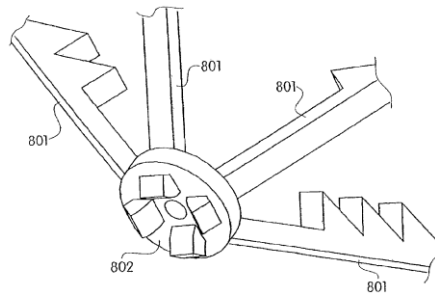


FIG. 8E

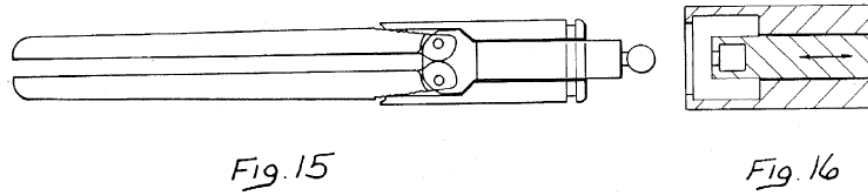
Figure 8E is a perspective view of a clip embodiment.

We find that the comparable slider 120 serves the purpose of joining, or linking the linkages as seen in Figure 8 of Nishioka, and, thus, the linkages are connected to one another.

Accordingly, we conclude that Petitioner has met its burden of establishing by a preponderance of the evidence that claim 3 is rendered obvious by Sackier and Nishioka.

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.

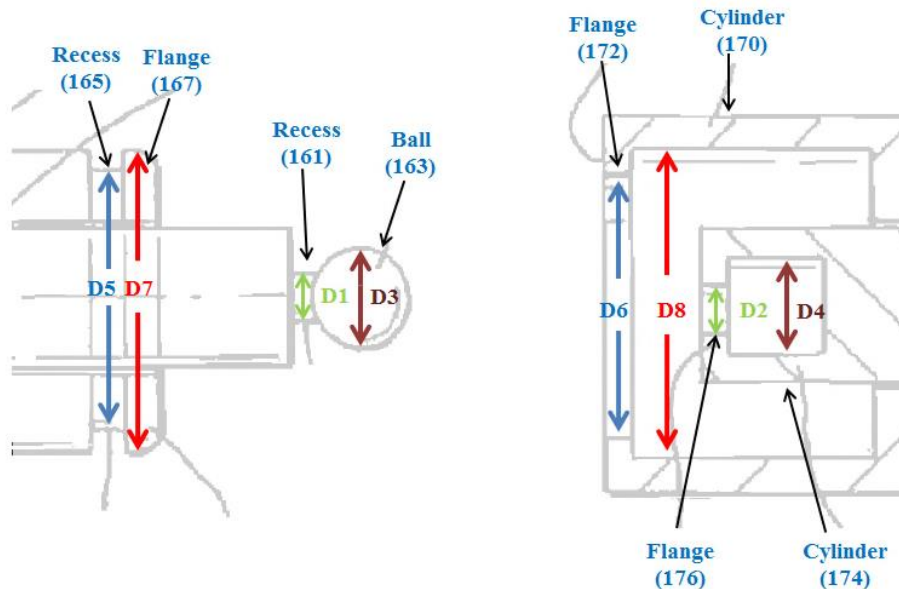


Figures 15 and 16 are cross-sectional views of a clamp and applicator.

Ex. 1008, 3:55–58.

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.

Graphically, Patent Owner represents its position as follows:



The Figure is a cross sectional drawing of a ball and flange attachment

Patent Owner asserts that the specification states that annular flange 176 has an inside diameter greater than the recess 161, but less than the diameter of the ball 163. Ex. 1008 at 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 at 1:54-57. PO Resp. 49–50. This evidence is credible.

Petitioner in response asserts 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).

On this matter, we find the evidence evenly divided. Patent Owner's theory that Sackier's clamp applier and clamp engage via a lateral opening is just as persuasive given the goal of Sackier of preventing undesirable separation of the clamp from the applier. While it appears the link may be capable of being frangible, the Patent Owner has 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.

Accordingly, we conclude Petitioner has not established by a preponderance of the evidence that claim 4 is rendered obvious by the combination of Sackier and Nishioka.

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.

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.

As both these claims depend from claim 4, we conclude that Petitioner has not established by a preponderance of the evidence that claims 5 and 6 are rendered obvious by the combination of Sackier and Nishioka

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:

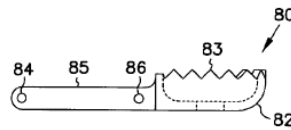


FIG. 6A

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

We find this testimony to be credible and supported by the evidence above. As a consequence, we find that Nishioka describes curved projections. Patent Owner makes no specific arguments directed to this claim.

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 Figures 3 and 6A are reproduced below:

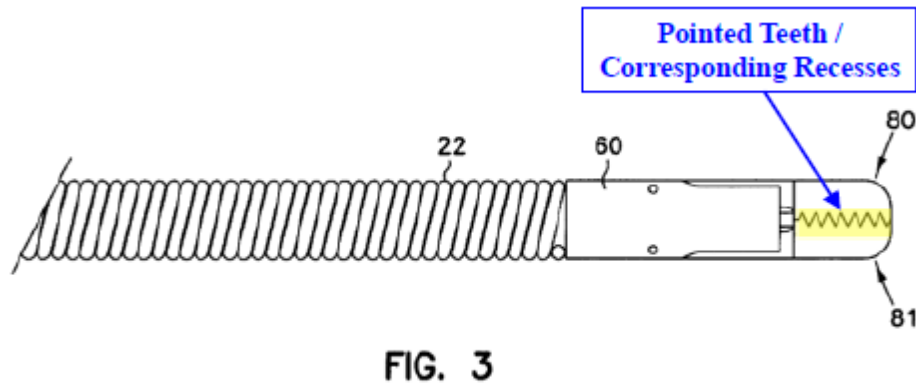


Figure 3 is an annotated side view of a forceps device.

Ex. 1005, 3:16–17.

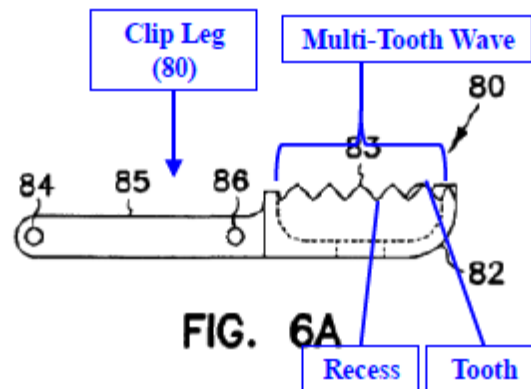


Figure 6A is an annotated cross sectional view of a biopsy forceps jaw

We observe that the Petitioner has pointed to angled protrusions, angled protrusions that interlock, a plurality of teeth and recesses, and a multi-toothed wave. The evidence of record supports a finding that Nishioka describes such. Patent Owner does not specifically challenge claims 9–11. Accordingly, we conclude that Petitioner has established by a

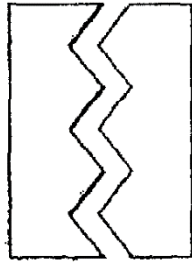
preponderance of evidence that Claims 9–11 are rendered obvious by Sackier and Nishioka.

Patent Owner, however, asserts that Claim 12 is patentable over Sackier. PO Resp. 51. More specifically, Patent Owner argues that the broadest reasonable interpretation of “multi-toothed wave” is “a repeating wave-shaped tooth pattern” and provides an illustration from Ex. 1001, Figure 8G. Resp., 51.



Patent Owner asserts that the triangular protrusions found in Nishioka are not a wave pattern. *Id.* at 52. Specifically, Patent Owner contends that the staggered serrations of Nishioka are triangularly shaped teeth, and thus not a “multi-toothed wave” or “an opposed ‘L’-shaped tooth pattern,” as required by claim 12. *Id.* at 53.

Petitioner rejoins that Dr. Nicosia testified that one of ordinary skill in the art would recognize that a multi toothed wave includes the triangular wave pattern of Nishioka. Reply 27, citing Ex. 1011 ¶ 42. Moreover, Petitioner observes that the claim should not be limited to a preferred embodiment when others are described in the specification, including the multi-tooth pointed of Fig. 8G.



Multi-Tooth Pointed

On balance, we find the Petitioner's evidence and argument more compelling. The illustration of a multi toothed waved sinusoidal jaw profile in Ex. 1001 is exemplary, absent more specific and persuasive evidence of a specific definition made by the specification restricting the wave only to the illustrated sinusoidal shape.

Accordingly, we conclude that Petitioner has established by a preponderance of evidence that Claim 12 is rendered obvious by Sackier and Nishioka.

Petitioner has therefore proven unpatentability with a preponderance of the evidence with respect to claims 2–3 and 7–12 similar to its showing with respect to claim 1. Petitioner has not met its burden as regards claims 4–6.

Claim 13

Claim 13 is an independent claim, and discussed below.

13. 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, and 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:

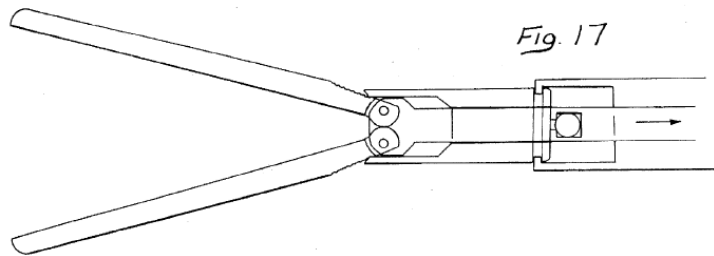


Figure 17 is a side view of an endoscopic clamp

As a consequence, we find the evidence of record above sufficient to conclude that Sackier describes this claim element.

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 and 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). *Id.* at 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.* According to Petitioner, 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:

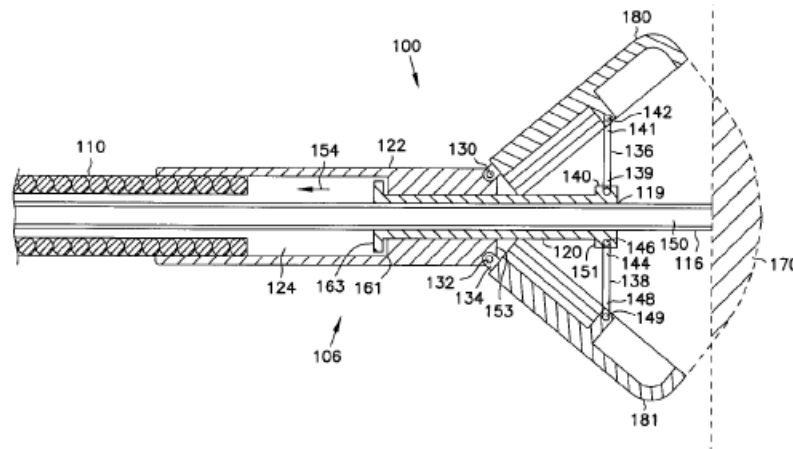


Figure 8 is a cross sectional view of a forceps device.

Ex. 1005, 3:34–35.

Patent Owner asserts that Sackier and Nishioka do not describe a linkage contacting the inner surface of the first and second clip legs, as required by claim 13. PO Resp. 28. We disagree as regards to Nishioka, for the reasons stated concerning claim 1 above.

Accordingly, we conclude that Petitioner has proven by a preponderance of the evidence that claim 13 is unpatentable as obvious over the combination of Sackier and Nishioka.

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 and 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. *Id.* at 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, and 14:5–24.

Patent Owner has made no arguments specifically concerning claim 14. Accordingly, we find that this evidence tends to support the Petitioner. We conclude that Petitioner has proven by a preponderance of the evidence that claim 13 is unpatentable as obvious over the combination of Sackier and Nishioka.

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).

However, for the reasons discussed above with respect to claim 4, we find that the Patent Owner’s evidence concerning tensile force is equally plausible to the Petitioner’s evidence. Accordingly, we conclude that Petitioner has not proven by a preponderance of the evidence that claim 15 is

unpatentable as obvious over the combination of Sackier and Nishioka.

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). As discussed above, we are persuaded by Petitioner’s petition concerning the clip structure, Patent Owner’s argument (PO Resp., 36) notwithstanding. Accordingly, we conclude that Petitioner has proven by a preponderance of the evidence that claim 16 is unpatentable as obvious over the combination of Sackier and Nishioka.

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 and 63, citing Ex. 1005, Figs. 2 and 8.

Ex. 1005, Figure 2 does not appear to illustrate where the proximal ends are connected. Ex. 1005, 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.

As discussed above, we are persuaded by Petitioner’s petition concerning the clip structure, Patent Owner’s contrary position (Resp. 43) notwithstanding. Accordingly, we conclude that Petitioner has proven by a preponderance of the evidence that claim 17 is unpatentable as obvious over the combination of Sackier and Nishioka.

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 persuasively to this point. Ex. 1015 ¶ 75; Pet. 55–57 and 63.

The Nishioka jaws describe these limitations, as discussed above. Patent Owner does not specifically challenge this claim. Accordingly, we conclude that Petitioner has proven by a preponderance of the evidence that claim 18 is unpatentable as obvious over the combination of Sackier and Nishioka.

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 and 63. Those figures, reproduced above, provide ample evidentiary support for Petitioner’s position. Patent Owner does not specifically challenge this claim. Accordingly, we conclude that Petitioner has proven by a preponderance of the evidence that claim 19 is unpatentable as obvious over the combination

of Sackier and Nishioka.

Petitioner has therefore proven with a preponderance of the evidence that claims 13–14 and 16–19 are unpatentable as obvious over Sackier and Nishioka.

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;
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, 16:60–17:6 (emphasis added).

We focus on the highlighted portion because we find it to be dispositive.

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 and 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, and 2:56–59.

As discussed above with respect to claim 4, we find the evidence to be in equipoise as to whether the tensile force in Sackier can act to detach the clip, whether or not within the body. Accordingly, we conclude Petitioner has therefore not proven with a preponderance of the evidence that claim 20 is unpatentable as obvious over Sackier and Nishioka.

Claims 1, 3–11 and 20 as anticipated by/obvious over Malecki

Petitioner contends claims 1, 3–11, and 20 are unpatentable, under 35 U.S.C. § 102, as anticipated by Malecki. Pet. 70–90. Petitioner also contends claims 1 and 3–11 are rendered obvious by Malecki, alone. *Id.* at 91–99.

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.

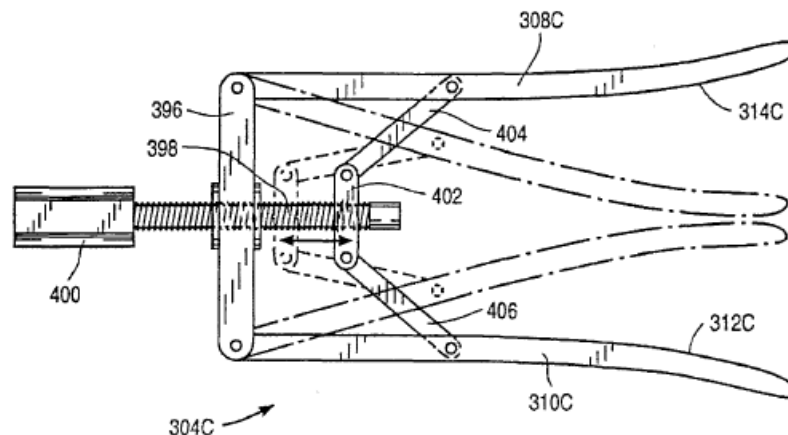


FIG. 28A

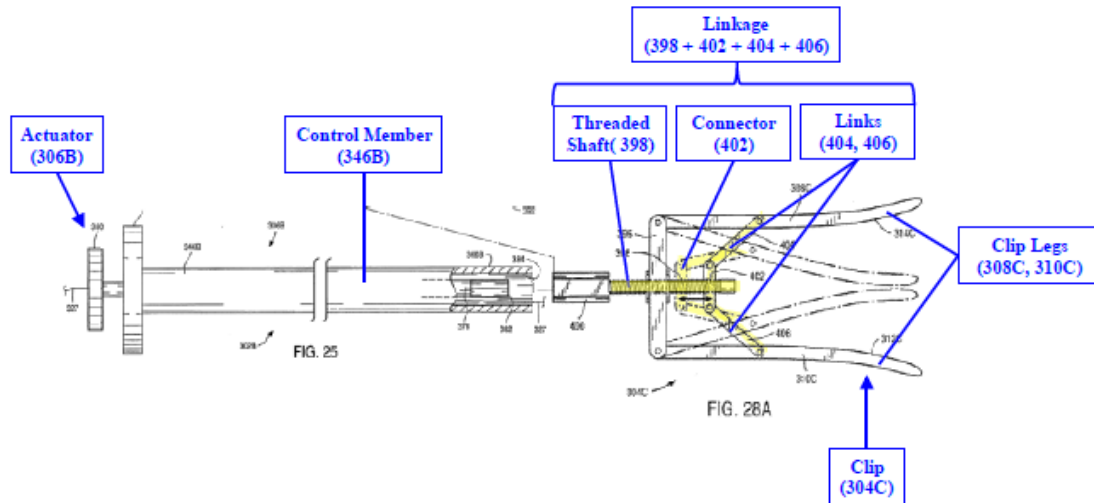
Figure 28a is a side view of a clamp. Ex. 1003, 6:29–30.

As depicted, clamp 304C uses a rotatable actuating element, including first and second jaws 308C, 310C. *Id.* at 17:42–48. The jaws have outwardly bowed jaw surfaces 312C, 314C so they do not touch along their entire surfaces. *Id.* Arms 308C, 310C are also pivotally mounted to opposite ends of a clamp base 396. *Id.* at 17:50–54. Shaft 398 rotates within the threaded hole formed in base 396 so that rotation displaces the shaft axially relative to the base.

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 '027 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 (“to drive the first and second clip legs radially outward as the control member is moved distally relative to the clip”), 13, and 20.

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



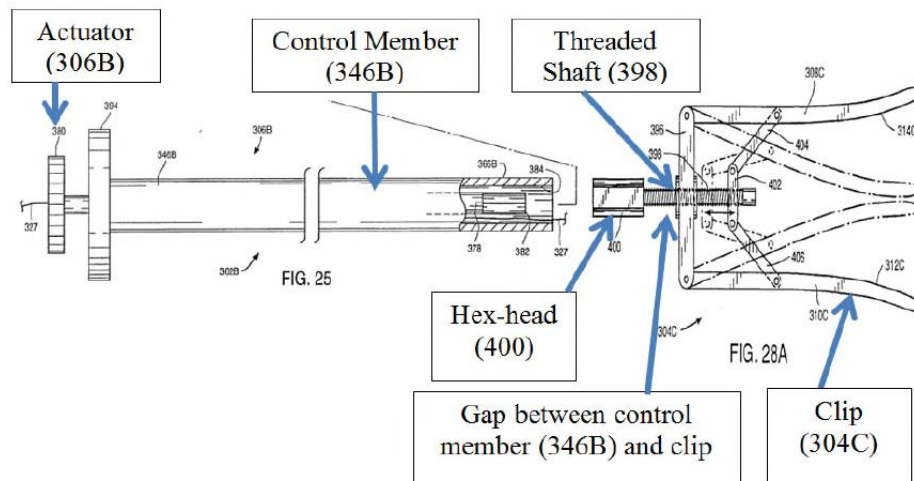
Petitioner Annotated Figures 25 and 28A are side views of a clamp and actuator.

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 and Ex. 1003, 17:50–62.

Patent Owner contends that Malecki does not disclose “the control member is moved distally” to open the clip legs. *See* Prelim. Resp. 27–40; Pet. Supp. Response 32. Patent Owner notes that “the claim specifically

requires the distal movement of the control member to open the clip legs,” and with Malecki’s hollow drive body 346B being the claimed “control member,” such movement cannot occur because the “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.



Patent Owner’s annotated Figures 25 and 28A of Malecki.

Prelim. Resp. 29.

Patent Owner contends that to operate the embodiment of Figures 25 and 28A, the user rotates wheel handle 380 (which Petitioner labels as the “Actuator 306B”) coupled to hex-head 400, which rotates to cause the threaded shaft 398 to move toward the clamp, actuating links 404, 406 to open the jaws. *Id.* at 29, citing Ex. 1003, 17:55–57. A user holds in place larger wheel handle 394, while rotating smaller wheel handle 380 to create a rotational force using hex-head 400. *Id.* Patent Owner alleges that as depicted above, “hollow drive body 346B is coupled to the large wheel handle 394,” and “[b]oth wheel handle 394 and coupled hollow drive body 346B are held in place for stability against the rotational force generated by

the smaller wheel handle 380 and hex-head 400.” *Id.* Thus, according to Patent Owner, the portions of Malecki relied on disclose that hex-head 400 rotates to cause the threaded shaft to move, not hollow drive body 346B as required by the claims. *Id.* at 30, citing Ex. 1003, 17:50-62.

Petitioner, for the first time in reply, argues that Malecki’s control member is not limited to drive body 346B. Pet. Supp. Reply 23. Petitioner argues that “Dr. Nicosia identified other components of Malecki’s control member that move distally, as claimed,” including “rod 378.” *Id.* at 24. Examining Petitioner’s original analysis for claim 1 (Pet. 72–75), and specifically the analysis as to how Malecki discloses driving the first and second clip legs radially outward as the control member is moved distally relative to the clip, Petitioner never mentions the movement of “rod 378,” nor does Dr. Nicosia. *See* Ex. 1015 ¶¶ 107, 108 (“as the control member (346B) is moved distally relative to the clip (304(C))”, 109. *See also* PO Surreply 7 (“Petitioners initially identified only the hollow drive body 346B as the control member.”).

Because this is new argument not raised in the Petition, it is improper. Reply argument and evidence may only respond to arguments raised in the corresponding opposition or patent owner response. By creating a new theory as to how Malecki discloses these particular structures, Petition has violated 37 C.F.R. § 42.23(b) by presenting a new argument and evidence for the first time in its reply brief.

Even if we were to consider rod 378, we still do not find Petitioner’s position persuasive. Petitioner’s analysis of claim 20 does mention the rod, but we do not believe the evidence establishes that stabilizing rod 378 is a component of the control member. As argued by Patent Owner, “[i]n the

'027 Patent, the 'control member' must control actuation of the clip, "[b]ut in Malecki Embodiment #1, stabilizing rod 378 does not control actuation of the clamp jaws." PO Sur-Reply, 8. Instead, Malecki discloses that "axial displacement of shaft 398 moves jaws 308C, 310C between the open, solid line position to the closed, dashed line position." Ex. 1003 at 17:59–62. Petitioner's theory is that stabilizing rod 378 and shaft 382 must be considered the "control member" because they purportedly indirectly actuate the jaws, but we agree with Patent Owner that Petitioners' logic of indirect actuation is flawed, and too attenuated. PO Sur-Reply, 8.

Finally, Patent Owner contends, and we agree, that even if stabilizing rod 378 constituted the "control member," Petitioner has not established persuasively that the stabilizing rod is moved distally relative to the clamp. *Id.* Petitioner relies on Malecki (17:7–10), for the proposition that stabilizing rod 378 moves distally relative to the clamp 304C, however, this portion of the specification does not describe any distal movement of stabilizing rod 378, but rather "rotation of the actuator housing 324B," which "moves the actuator housing 324B relative to the jaws 308B, 310B." *Id.*

Further, Malecki Embodiment #1 does not have an actuator housing 324B, but instead, rotation of hex-head 400 causes the axial displacement of shaft 398 relative to clamp base 396, not any distal movement of stabilizing rod 378. *Id.* at 8–9 (citing Ex. 1003 at 17:2–15, 17:31–34, 17:55–56). Thus, we agree with Patent Owner, that "stabilizing rod 378 does not move distally relative to the jaws." *Id.* at 9.

Based on the final trial record, we determine that Petitioner has not demonstrated by a preponderance of the evidence that claims 1, 3–11, and

20 would have unpatentable based on, or in view of, Malecki.

III. MOTIONS

Patent Owner's Motion to Exclude (Paper 34)

Patent Owner's Motion to Exclude (Paper 34) seeks exclusion of Exhibits 1003, 1015 (partially), 1017, and 1079. Paper 34, 1.

As regards to Exhibits 1003 and 1015, the grounds asserted for exclusion are that the exhibits relate to grounds that were not instituted. Paper 34, 1–3. As those grounds were later instituted in Paper 74, we deny this portion of the motion.

As regards Exhibits 1017 and 1079, and 1084, we dismiss this motion as the decision does not rely upon any of those exhibits.

Petitioner's Motion to Exclude Exhibit 2100 (Paper 63)

Petitioner moves to exclude Exhibit 2100 on the grounds of undue prejudice and hearsay. Paper 63, 2.

As regards Exhibits 2100, we dismiss this motion as the decision does not rely upon that exhibit.

Patent Owner's Motion to Exclude Exhibit 1118 (Paper 83)

Patent Owner moves to exclude Exhibit 1118 the grounds of relevancy. Paper 83, 2.

As regards Exhibits 1118 we dismiss this motion as the decision does not rely upon that exhibit.

IV. CONCLUSION

For the foregoing reasons, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1, 3–6, 13–15, 17, and 20 are unpatentable as anticipated by Sackier.

We also determine that Petitioner has shown by a preponderance of evidence that claims 1–3, 7–14, and 16–19 are unpatentable as obvious over Sackier and Nishioka. Petitioner has not shown by a preponderance of evidence that claims 4–6, 15, and 20 are unpatentable as obvious over Sackier and Nishioka.

We also determine that Petitioner has not shown by a preponderance of the evidence that claims 1, 3–11, and 20 are unpatentable as anticipated by or obvious over Malecki.

V. ORDER

Accordingly, it is:

ORDERED that claims 1–3, 7–14, and 16–19 of the '027 patent are held to be unpatentable; and

ORDERED that Patent Owner's Motion to Exclude (Paper 34) is DENIED in part and DISMISSED in part,

ORDERED that Petitioner's Motion to Exclude (Paper 63) is DISMISSED,

ORDERED that Patent Owner's Motion to Exclude (Paper 83) is DISMISSED,

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.

IPR2017-00134
Patent 8,709,027 B2

PETITIONER:

Dominic Zanfardino
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