

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COOK GROUP INCORPORATED
and
COOK MEDICAL LLC,
Petitioner,

v.

BOSTON SCIENTIFIC SCIMED, INC.,
Patent Owner.

Case IPR2017-00440
Patent 9,271,731 B2

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

KINDER, *Administrative Patent Judge*.

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

Cook Group Incorporated and Cook Medical LLC (“Petitioner”) filed a Petition (Paper 1, “Pet.”) to institute an *inter partes* review of claims 1–20 of U.S. Patent No. 9,271,731 B2 (Ex. 1033, “the ’731 patent”). Boston Scientific Scimed, Incorporated (“Patent Owner”) filed a Preliminary Response (Paper 6, “Prelim. Resp.”).

Applying the standard set forth in 35 U.S.C. § 314(a), which requires demonstration of a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim, we institute an *inter partes* review of claims 1–3, 10–16, and 18 based on the grounds identified in the Order section of this Decision. We do not institute review of claims 4–9, 17, 19, and 20.

I. BACKGROUND

A. *The ’731 Patent (Ex. 1033)*

The ’731 patent is titled “Device and Method for Through the Scope Endoscopic Hemostatic Clipping,” and claims an apparatus and method for capturing tissue. Ex. 1033, [54], 15:36–17:15. The claimed “invention relates to compression clips, and more specifically, to compression clips used to cause hemostasis of blood vessels located along the gastrointestinal tract delivered to a target site through an endoscope.” *Id.* at 1:24–27. As explained by the ’731 patent, the clips stop internal bleeding by applying sufficient constrictive forces to blood vessels so as to limit or interrupt blood flow to achieve “hemostasis.” *Id.* at 2:32–38, 2:62–66. Embodiments of the invention include “a clip” with “clip arms,” and a “control wire” for moving the clip between open and closed configurations. *Id.* at 16:24–42. In addition, the medical device claims describe an “opening element” for urging the clip arms into the open configuration, and the method claim

describes use of the control wire to “move the first and second clip arms away from one another to the open tissue receiving configuration.” *Id.* at 15:37–17:15.

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

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

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

B. Illustrative Claims

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

1. A medical device, comprising:

a clip including first and second clip arms, the clip being movable between an open tissue receiving configuration in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween; and

an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration, wherein the opening element is movable between

an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration.

Ex. 1033, 15:37–52.

20. A method for capturing tissue, comprising:

inserting a medical device comprising a clip having first and second clip arms to a target tissue site, the clip including an opening element engaging inner walls of the first and second clip arms and urging the clip to an open tissue receiving configuration;

moving a control wire coupled to a proximal end of the clip distally to move the first and second clip arms away from one another to the open tissue receiving configuration;

moving the control wire proximally to move the first and second clip arms toward one another to a closed tissue capturing configuration; and

applying a proximal tensile force exceeding a threshold level to the control wire to separate the control wire from the clip.

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

C. Related Proceedings

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

1. IPR2017-00131 (U.S. Patent No. 8,685,048);
2. IPR2017-00132 (U.S. Patent No. 8,685,048);
3. IPR2017-00133 (U.S. Patent No. 8,709,027);
4. IPR2017-00134 (U.S. Patent No. 8,709,027);

IPR2017-00440
Patent 9,271,731 B2

5. IPR2017-00135 (U.S. Patent No. 8,974,371); and,
6. IPR2017-00435 (U.S. Patent No. 9,271,731).

Paper 3, 2–3.

D. References Relied Upon

Petitioner relies upon the following prior art references:

U.S. Patent No. 5,749,881 issued on May 12, 1998 (“Sackier”)
(Ex. 1008);

U.S. Patent No. 5,843,000 issued on Dec. 1, 1998 (“Nishioka”)
(Ex. 1005); and

Japanese Unexamined Patent Application Publication No. 60-103946,
published on June 8, 1995 (“Shinozuka”) (Ex. 1009; certified translation at
Ex. 1010¹).

¹ In the related proceeding, IPR2017-00132, we issued an Order (Paper 10) allowing Petitioner to substitute a corrected Declaration of James Thornton for the declaration originally filed because the sworn statement did not explicitly conform to 37 C.F.R. § 1.68. For the same reasons set forth in that Order, we authorize the same correction in this proceeding as set forth in the Order Section of this Decision.

E. The Asserted Grounds

Petitioner contends that the challenged claims are unpatentable based on the following specific grounds (Pet. 9)²:

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

II. CLAIM CONSTRUCTION

Petitioner identifies several terms for construction. Pet. 11–17. As an initial matter, Petitioner’s support for its proposed interpretation of each term is lacking because Petitioner’s only cited evidence is Patent Owner’s claim construction position from the related district court litigation. At this stage of the proceedings, however, “Patent Owner agrees to Petitioners’ proposed constructions.” Prelim. Resp. 4 (“For purposes of this preliminary response, Patent Owner agrees to Petitioners’ proposed constructions.”).

Claims in an *inter partes* review are given the “broadest reasonable

² Petitioner also relies on the Declaration of Mark A. Nicosia, Ph.D. (Ex. 1041).

³ The relevant sections of the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (Sept. 16, 2011), took effect on March 16, 2013. Because the application from which the ’731 patent issued was filed before that date, our citations to Title 35 are to its pre-AIA version.

construction in light of the specification of the patent in which [they] appear[.]” 37 C.F.R. § 42.100(b) (2015); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2136 (2016). Below, based on the current record, we construe only two terms that are necessary to address for purposes of institution.

A. “*engaging inner walls of the first and second clip arms*”

We adopt the construction agreed upon by the parties for purposes of this Decision. Specifically, Petitioner contends that “‘engaging inner walls’ simply requires that the opening element ‘contact[.]’ the inner walls, without requiring a ‘physical connection.’” Pet. 15 (quoting Ex. 1039, 3⁴ (Patent Owner’s claim construction position from district court)). Petitioner also notes “that ‘engaging inner walls of the first and second clip arms’ requires that the ‘opening element’ is ‘positioned between the clip arms and of sufficient size to be able to engage the clip arms.’” *Id.* (quoting Ex. 1035, 3). Accordingly, the parties agree that “engaging inner walls of the first and second clip arms” means *contacting the inner walls, without requiring a physical connection, and positioned between the clip arms and of sufficient size to be able to engage the clip arms.*

The Specification of the ’731 patents suggests that the opening element can “engage” the inner walls of the clip arms, and urge those arms open simply by contacting them, rather than through a physical connection. *See* Ex. 1033, Figs. 8A, 14A, 10:66–11:24. Thus, for purposes of this Decision and based on the record before us, we adopt the parties’ agreed upon construction.

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

B. “clip”

Patent Owner asserts that the term “clip” should be interpreted as a “device component having hemostatic compression legs.” Prelim. Resp. 5–8. Patent Owner provides multiple medical dictionaries describing that clips can be used to arrest bleeding. *Id.* at 8 (citing Exs. 2001, 2002, 2003, 2004, and 2005). We partially agree. Hemostatic is a statement of intended use and certainly clips can be used for that purpose. *See* Ex. 1033, 2:62–63 (summary of the invention).

However, no such express limitation is in the claim; for example, claim 1 recites “a clip,” and the word “hemostatic” does not appear in the claim. Further, the ’731 patent Specification makes it clear that the clips of the claimed invention have more uses than hemostasis, including pinching, marking, and tagging. Ex. 1033, 15:8–12. The clips can be used on any tissue “the operator wishes to apply a pinching pressure for whatever reason.” *Id.* at 15:11–12.

“Clip,” as the term is generally understood, and as used in the Specification, is therefore broader than as presently urged by Patent Owner. We consequently interpret “clip” herein as *a device having compression legs and capable of applying a pinching pressure.*

III. ANALYSIS

A petition must show how the construed claims are unpatentable under the statutory ground it identifies. 37 C.F.R. § 42.104(b)(4). Petitioner bears the burden of demonstrating a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim for a petition to be granted. 35 U.S.C. § 314(a).

A. Principles of Law

1. Anticipation

To establish anticipation, each and every element in a claim, arranged as recited in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). “To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently.” *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

2. Obviousness

A claim is unpatentable under § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

“To satisfy its burden of proving obviousness, a petitioner cannot

employ mere conclusory statements. The petitioner must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Furthermore, in assessing the prior art, the Board must consider whether a person of ordinary skill would have been motivated to combine the prior art to achieve the claimed invention. *In re Nuvasive, Inc.*, 842 F.3d 1376, 1381 (Fed. Cir. 2016).

B. Person of Ordinary Skill in the Art

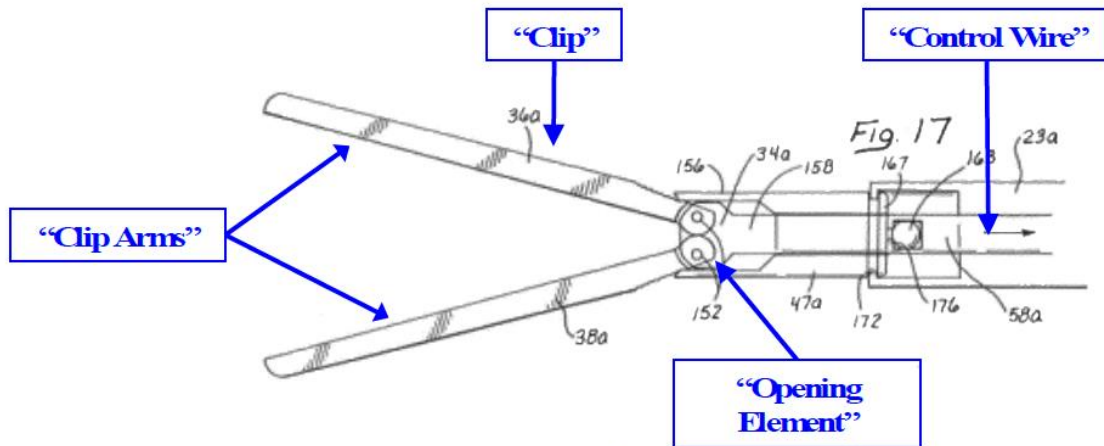
Petitioner proposes that a person of ordinary skill in the art as of the time of the filing of the application that became the ’731 patent would have possessed the knowledge and skill of an engineer or similar professional with at least an undergraduate degree in engineering, or a physician having experience with designing medical devices. Pet. 10 (citing Ex. 1041 ¶ 11). Patent Owner does not dispute Petitioner’s proposal, and we adopt it for purposes of this Decision, as it is consistent with the level of skill evidenced by the references.

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

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

1. Overview of Sackier (Ex. 1008)

Sackier is directed to a laparoscopic surgical device that includes a clamp. Ex. 1008, Abstract. Petitioner relies on the embodiment of Figure 17 of Sackier, which is reproduced below.



Sackier, Figure 17 (Annotated)⁵

Petitioner's Annotated Fig. 17⁵ depicts an axial cross-section views of a clamp (Pet. 18); Ex. 1008, 3:60–62.

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

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

Ex. 1008, 10:28–34.

2. Claims 1, 12, and 20

Petitioner asserts that Sackier discloses all elements of claims 1, 12, and 20. Pet. 23–27, 35–38. Each of claims 1 and 12 requires “an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another,” and

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

method claim 20 requires a similar limitation. *See* Ex. 1033, 15:45–47, 16:32–34, 17:3–6.

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

First, Petitioner proposes

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

Id. (quoting Ex. 1008, 9:25–30). Petitioner next proposes using a fixed jaw embodiment (Figure 2), “which includes an opening element (spring 52) engaging the inner walls of the first and second clip arms and urging the clip arms away from one another into an open tissue-receiving configuration.”

Id. The modified embodiment would then adopt spring 52 from Figure 2.

Id. Petitioner contends that spring 152 is just “one ‘example’ of what could be used to bias the jaws 36a and 38a to the open position, confirming that the embodiment shown in Figures 15–17 includes spring 52 as an alternative to spring 152.” *Id.* at 27.

Patent Owner takes issue with Petitioner's selective picking and choosing features from distinct embodiments disclosed in Sackier in the anticipation analysis of claims 1, 12, and 20. Prelim. Resp. 23–25, 29, 30, 31 (citing *In re Arkley*, 455 F.2d 586, 587 (C.C.P.A. 1972)). Patent Owner first points out that “[t]he spring 152 of Figures 15–17 does not engage the inner walls of the jaws 36a, 38a,” and that “Petitioner’s theorized embodiment [] would not satisfy Claim 1’s requirement that ‘the first and second arms are moved inward to capture the tissue received therebetween.’” *Id.* at 23–24. Specifically, Patent Owner explains that because Petitioner proposes forming the jaw 38a in a fixed relationship to the supporting structure 34a and integrating spring 52 as depicted in Figure 2, the fixed clip arm could not move inward as required by the limitation requiring “the first and second arms are moved inward.” *Id.*

Patent Owner also contends that Petitioner’s reliance on spring 52 from Figure 2 is improper because “Sackier does not suggest that spring 52 can be substituted for spring 152.” Prelim. Resp. 24. Patent Owner contends Sackier’s specification “does not suggest that spring 152 should be substituted for a different spring.” *Id.* According to Patent Owner, the portion of Sackier quoted by Petitioner (in “the manner previously discussed”) refers “to jaws 36a, 38a, which could be made pivotal or fixed, not the substitution of spring 52 for spring 152.” *Id.* at 24. Finally, Patent Owner argues that spring 52 cannot be substituted for spring 152 because “the specification states, with respect to Figures 15–17, that ‘structural elements similar to those previously discussed will be designated’ with ‘the lower case letter ‘a,’”” and “[s]pring 152 is not designated with the letter ‘a’” as are other elements in the Figures 15–17 embodiment. *Id.* at 24–25

(quoting Ex. 1008, 9:5–12).

We determine that Petitioner’s anticipation analysis is deficient on the record before us for claims 1, 12, and 20. When a prior art reference discloses multiple, distinct embodiments, combining teachings from those distinct embodiments requires an obviousness analysis, including a demonstration of why one of ordinary skill would be motivated to combine those disparate teachings. In contrast, for anticipation, “it is not enough that the prior art reference . . . includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention.” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008). In this proceeding, Petitioner seeks to merge components from the Figure 2 embodiment of Sackier into the Figures 15–17 embodiment. *See* Pet. 26–27. Petitioner’s anticipation analysis is deficient because Petitioner picks features from distinct embodiments in Sackier without establishing persuasively that those embodiments are directly related to each other such that the components could be substituted as proposed.

Petitioner’s proposed modified embodiment of Sackier also fails to satisfy other limitations of claims 1, 12, and 20 as argued by Patent Owner. *See* Prelim. Resp. 25. Petitioner contends that the embodiment depicted in Sackier Figures 15–17 can be formed with jaw 38a fixed relative to supporting structure 34a and jaw 36a pivotal relative to supporting structure 34a. Pet. 26. Such an embodiment, however, fails to meet the limitations requiring a closed configuration in which “the first and second arms are moved inward” to capture the tissue. *See Cook Group Inc. v. Boston Scientific Scimed, Inc.*, IPR2017–00435, 15–17 (PTAB June 30, 2017) (Paper 8) (examining claim requirement that “the first and second arms are

moved inward” in relation to a fixed arm clamp similar to that of Figure 2 in Sackier).

Based on the record before us, Petitioner has failed to show a reasonable likelihood that it would prevail in showing that Sackier anticipates claims 1, 12, and 20. Accordingly, we deny the Petition and decline to institute a review of claims 1, 12, and 20 under 35 U.S.C. § 102 as anticipated by Sackier.

3. Claims 2, 4, 6–9, and 13

Petitioner asserts that Sackier discloses all elements of these claims. Pet. 28–36. Claims 2, 4, 6–9, and 13 depend directly, or indirectly, from claims 1 and 12. As discussed above, we determine that Petitioner has not demonstrated a reasonable likelihood of showing that Sackier anticipates claims 1 and 12. For the reasons set forth above for claims 1 and 12, Petitioner has failed to show a reasonable likelihood that claims 2, 4, 6–9, and 13 are anticipated based on Sackier. Accordingly, we decline to institute a review of these claims under 35 U.S.C. § 102 as anticipated by Sackier.

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

Petitioner asserts that Sackier teaches all elements of these claims. Pet. 39–48.

Claims 3, 5, 10, 11, and 14–19 depend directly, or indirectly, from claims 1 and 12. As discussed above, we determine that Petitioner has not demonstrated a reasonable likelihood of showing that Sackier anticipates claims 1 and 12. In its obvious analysis of claims 3, 5, 10, 11, and 14–19, Petitioner does not provide any argument or evidence overcoming the deficiencies we noted above as to claims 1 and 12. For example, the Petition

fails to adequately explain why a person of ordinary skill in the art would have combined elements from distinct embodiments of Sackier in the way the claimed invention does. For the reasons set forth above, Petitioner has failed to show a reasonable likelihood that claims 3, 5, 10, 11, and 14–19 are obvious over Sackier. Accordingly, we decline to institute a review of these claims under 35 U.S.C. § 103 as obvious over Sackier.

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

Petitioner contends claims 1–3, 10–16, and 18 are unpatentable, under 35 U.S.C. § 102, as anticipated by Nishioka. Pet. 49–64.

1. Overview of Nishioka (Ex. 1005)

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

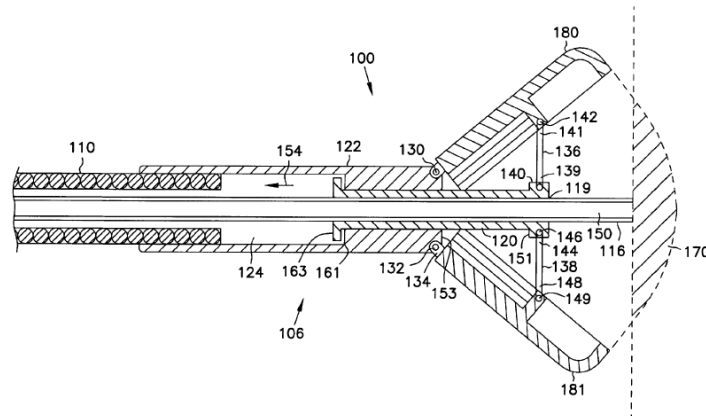


FIG. 8

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

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

2. *Claims 1 and 12*

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

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

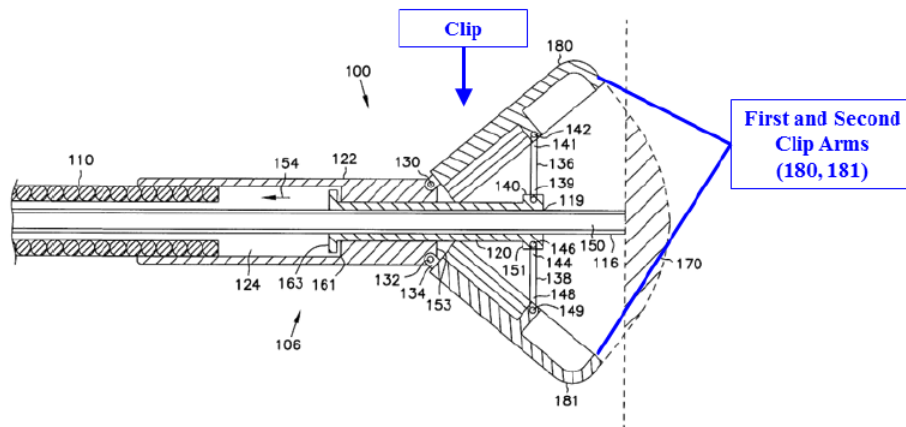


FIG. 8

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

Petitioner contends that “[a] person of ordinary skill in the art would have considered a forceps cutting device to be a type of clip (i.e., a device that clips tissue).” Pet. 49, n.8.

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

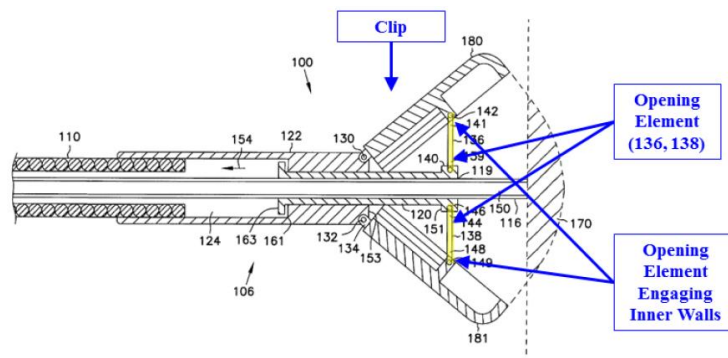


FIG. 8

Petitioner's annotated Nishioka Figure 8 (Pet. 53).

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

Claim 12 separately requires “a control wire coupled to a proximal end of the clip and operable to move the clip between the open and closed configurations.” Ex. 1033, 16:40–42. Petitioner relies on fiber 150, as depicted in Figure 8, which is “coupled to a proximal end of the clip and operable to move the clip between the open and closed configurations,” according to Petitioner. Pet. 59–60. Petitioner cites portions of Nishioka that explain optical fiber 150 is connected to and movable with tubular slide member 120, which, in turn, is coupled to jaws 180 and 181 for actuating jaws 180 and 181 as the optical fiber is moved. *Id.* at 60 (citing Ex. 1005, 6:60–64, 7:3–32).

Patent Owner contends that Nishioka is missing elements required by claims 1 and 12. Prelim. Resp. 41–44. Regarding claims 1 and 12, Patent Owner argues first that “Nishioka does not disclose a ‘clip,’” because “a ‘clip’ is ‘a device component having hemostatic compression legs.’” *Id.* at 42 (referring to the claim construction proposed at Prelim. Resp. 8). Patent Owner contends that the jaws described in Nishioka cannot be a clip because they “are ‘cutting jaws’ which ‘cut’ off ‘biopsy sample[s].’” *Id.* (citing Ex. 1005 at 1:22–26; 2:24–27)

Given that we have interpreted “clip” consistent with the Specification as an element capable of applying pinching pressure, *supra*, (’731 patent 15:8–12), it appears that the biopsy forceps jaws are capable of applying

sufficient pinching pressure to remove a tissue sample. Moreover, the control wires extend to the clip. Accordingly, Patent Owner's contentions related to Nishioka lacking a clip as required by claims 1 and 12 are unpersuasive on the record before us.

Patent Owner also contends that Nishioka does not disclose a medical device with an "opening element engaging inner walls of the first and second clip arms" as required by claims 1 and 12. Prelim. Resp. 42–43. Patent Owner contends that in the Figure 8 embodiment, "the control links 136, 138 connect on the top side of the jaws 180, 181 by pins 142, 149," and not inner walls as required. *Id.* at 43. Based on our review of Nishioka Figure 8, we disagree. We interpreted "an opening element engaging inner walls of the first and second clip arms" to mean that the opening element need only be "contacting the inner walls." Applying this interpretation, Petitioner has persuasively established on this record that Nishioka discloses this limitation. As depicted in Figure 8, opening element 136 contacts the inner portion of inner wall of the clip arm 180 at pivot 142, which is located on the inner wall of clip arm 180. Opening element 138 also contacts clip arm 181 in the same manner. Petitioner has sufficiently shown for purposes of this Decision that the opening element contacts the clip arms at the pivot point and the inner wall portion located adjacent to the pivot point during rotational movement.

Patent Owner also argues, with respect to claim 12, that "Nishioka does not disclose 'a control wire coupled to a proximal end of the clip.'" Prelim. Resp. 44. Patent Owner argues that the alleged "control wires" are not coupled to the proximal end of the jaws. *Id.* In the embodiment of Figure 8, Patent Owner contends that "the alleged 'control wire' fiber 150 is

not connected to the jaws at any point.” *Id.* We find Patent Owner’s contention unpersuasive because optical fiber 150 (control wire) is connected to and movable with tubular slide member 120, which, in turn, is coupled to jaws 180 and 181 for actuating jaws 180 and 181 as the optical fiber is moved. Ex. 1005, 6:60–64, 7:3–32. As such, Petitioner has sufficiently shown on this record that Nishioka discloses the control member limitations of claim 12. *See* Pet. 59–60.

Based on the record now before us, we determine that the information presented shows a reasonable likelihood that Petitioner would prevail in showing that Nishioka discloses all the limitations of claims 1 and 12. Although our analysis has focused on the Figure 8 embodiment of Nishioka, we have also considered the parties arguments with respect to the Figure 2 embodiment. Based on the record before us, Petitioner’s contentions regarding the embodiment of Figure 2 also demonstrate a reasonable likelihood that Petitioner would prevail in showing that Nishioka discloses all the limitations of claims 1 and 12.

3. *Claims 2, 3, 10, 11, 13–16, and 18*

Having decided that Petitioner has shown a reasonable likelihood that Nishioka discloses the elements of claims 1 and 12 as challenged in the Petition, we exercise our discretion under 37 C.F.R. § 42.108 to have the review proceed on all of the challenged claims on which Nishioka serves as the primary basis for unpatentability. *See Intex Recreation Corp. v. Bestway Inflatables & Material Corp.*, IPR2016-00180, 8–11 (PTAB June 6, 2016) (Paper 13).

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

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

Because we determined above that Nishioka anticipates claims 1 and 12, we likewise determine based on the record before us that Nishioka teaches each limitation of claims 1 and 12 for purposes of obviousness. As for the combination of Nishioka and Sackier, Patent Owner separately attacks Petitioner’s rationale for combining those references.

Patent Owner contends that Petitioner does not provide adequate motivation for why a person of ordinary skill in the art would modify Nishioka in view of Sackier. Prelim. Resp. 48. Patent Owner argues that there “would not have [been] any motivation to modify Nishioka in view of Sackier,” because “the Nishioka and Sackier devices utilize different structures (forceps vs. clamp) with different functions (cutting vs. clamping)

in different procedures (tissue biopsy vs. bowel occlusion and repositioning) to solve unrelated problems with prior art devices.” *Id.* at 48–49.

At this stage of the proceedings, we are persuaded that Petitioner has articulated a sufficient rationale for making the combination of Nishioka and Sackier, both endoscopic instruments. Based on the current record, Petitioner’s rationale that “[m]odifying Nishioka to include arms that clamp, rather than cut, would have been a matter of routine skill in the art involving simple mechanical structures, and yielding predictable results,” is adequately supported by the testimony of Dr. Nicosia. Pet. 68 (citing Ex. 1041 ¶ 89). Petitioner has sufficiently shown for purposes of this Decision that the similarity in the action of the laparoscopic instruments and their field of endeavor would lead one of ordinary skill in the art to consider the combination as proposed by the Petitioner.

Further, as set forth above, having decided that Petitioner has shown a reasonable likelihood that Nishioka discloses the elements of claims 1 and 12 as challenged in the Petition, we exercise our discretion under 37 C.F.R. § 42.108 to have the review proceed on all of the challenged claims on which Nishioka serves as the primary basis for unpatentability. *See Intex Recreation Corp. v. Bestway Inflatables & Material Corp.*, IPR2016-00180, 8–11 (PTAB June 6, 2016) (Paper 13).

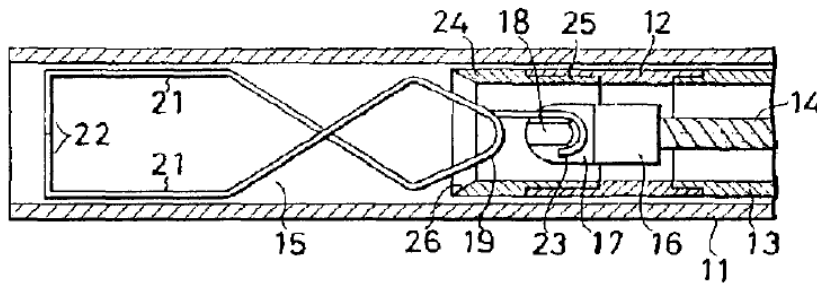
G. Claims 1–20 as Obvious in view of Shinozuka in Combination with Sackier or Nishioka

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

1. Overview of Shinozuka (Ex. 1010)

Shinozuka is directed to a “Biotissue Clip Device.” Ex. 1010-10.⁶ The clip is said to be detachably coupled to a control cord. *Id.* at 11. Nishioka is relied upon for the description discussed above. Figure 2 of Shinozuka is reproduced below:

第 2 圖



Shinozuka Figure 2 is a sectional side view of a distal end. Ex. 1010, 12. Figure 2 illustrates the clip device of Shinozuka, including insertion tube 11, control tube 13, control wire 14, and hook 16 for detachably engaging with clip 15. *Id.* at 11.

Petitioner notes that Shinozuka discloses that clip 15 has an opening bias so that it tends to open, but “[a]part from this opening bias, Shinozuka does not explicitly disclose a separate structure in the form of an opening element⁷ for urging the clip arms away from one another.” Pet. 72. Petitioner relies on either Sackier or Nishioka to teach clips with opening elements to combine with Shinozuka. *Id.* at 72–73. Petitioner addresses the

⁶ We cite to the translation provided as an exhibit to the Declaration of the translator. Ex. 1010 (also removing “000” preceding each page number). The original reference, Ex. 1009, includes the Figures.

⁷ Each independent claim requires an “opening element.” Ex. 1033, 15:45, 16:32, 17:4.

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

Patent Owner challenges this rationale for combining the references. Prelim. Resp. 52–62. Patent Owner asserts that a person of ordinary skill would not have combined Shinozuka, with Sackier or Nishioka because Petitioner’s proposed modifications would be redundant and unnecessary. *Id.* at 52. Patent Owner elaborates:

The purpose of the opening element, per Petitioners’ proposed construction, is to “urge[] [the inner walls of the clip arms] away from one another.” Petition at 14. The clip disclosed in Shinozuka has an “opening bias so that [it] tend[s] to open the pinching parts 22.” Shinozuka at 1009-00006. As explained in Sackier, the “spring 52 can be provided in the hinge 41 in order to bias the jaws 36 and 38 to the open position.” Sackier at 5:4–5. Thus, the spring is entirely redundant of the bias already in the Shinozuka clip. Likewise, using the control links 136, 138 of Nishioka as an opening element to “move the jaws apart” (Nishioka at 8:34–35) is redundant of the opening bias of the Shinozuka clip.

Id. Because Petitioner’s primary rationale for the combination is “to assist in urging open the Shinozuka clip arms” Patent Owner reasons that the combination is hindsight driven and illogical. *Id.* As an additional argument, Patent Owner asserts that Petitioner’s rationale of allowing the

clip arms to open wider is not supported because Petitioner fails to explain why a person of ordinary skill in the art would want to open Shinozuka's clip arms wider and why the clip of Shinozuka does not open wide enough as disclosed. *Id.* at 53.

We are not persuaded by Petitioner's showing that a person of ordinary skill would have looked to opening elements of Sackier and Nishioka to assist in urging open the Shinozuka clip arms. As stated by Petitioner, "Shinozuka discloses that clip 15 has an 'opening bias so that [it] tend[s] to open.'" Pet. 72. There is simply no need to urge open Shinozuka's clip arms because of the natural spring bias toward the open position. Further, Petitioner has not explained persuasively why adding clip arms to Shinozuka would allow for the system to open wider than it otherwise could. Petitioner provides other rationales for combining the references, but again these reasons lack any meaningful support or explanation. *See, e.g.*, Pet. 77 ("in order to provide a wider range of open tissue receiving configurations, as well as more accurate and precise deployment").

In sum, we are not convinced that Petitioner has presented a sufficient rationale, apart from hindsight, demonstrating that a person of ordinary skill would have combined Shinozuka with Sackier or Nishioka. Accordingly, Petitioner hasn't sufficiently shown a reasonable likelihood of prevailing as to these claims under 35 U.S.C. § 103 as obvious over Shinozuka with Sackier or Nishioka.

IV. CONCLUSION

For the foregoing reasons, we determine that the information presented establishes a reasonable likelihood that Petitioner would prevail in showing that claims 1–3, 10–16, and 18 of the '731 patent are unpatentable. We, however, determine that Petitioner has not made a sufficient showing with respect to claims 4–9, 17, and 19, and 20. At this preliminary stage, we have not made a final determination with respect to the patentability of the challenged claims or any underlying factual and legal issues.

V. ORDER

Accordingly, it is:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted as to claims 1–3, 10–16, and 18 of the '731 patent on the following grounds of unpatentability:

Reference	Basis	Challenged Claim(s)
Nishioka	§ 102	1–3, 10–16, and 18
Nishioka or Nishioka and Sackier	§ 103	1–3, 10–16, and 18

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

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

FURTHER ORDERED that Petitioner is authorized to substitute a corrected declaration of Mr. Thornton no later than seven business days from the date of this Decision for the declaration originally filed. This substitute declaration shall be titled “Corrected Declaration of Mr. Thornton,” bear the next available exhibit number, and not contain substantive changes to the original declaration beyond the addition of a statement in accordance with 37 C.F.R. § 1.68 and 37 C.F.R. § 42.63(b).

IPR2017-00440
Patent 9,271,731 B2

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