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Paper No. 13
May 15, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COOK GROUP INCORPORATED
and
COOK MEDICAL LLC,
Petitioner,

v.

BOSTON SCIENTIFIC SCIMED, INC.,
Patent Owner.

Case IPR2017-00131
Patent 8,685,048 B2

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

TARTAL, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Cook Group Incorporated and Cook Medical LLC ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting institution of *inter partes* review of claims 1–30 of U.S. Patent No. 8,685,048 B2 (Ex. 1023, "the '048 patent"). Boston Scientific Scimed, Inc. ("Patent Owner") filed a Preliminary Response (Paper 12, "Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Upon consideration of the Petition and the Preliminary Response, we conclude the information presented does not show there is a reasonable likelihood that Petitioner would prevail in showing the unpatentability of any of challenged claims 1–30. Accordingly, we do not authorize an *inter partes* review to be instituted as to the '048 patent in IPR2017-00131.

II. BACKGROUND

A. The '048 Patent

The '048 patent, titled "Device and Method for Through the Scope Endoscopic Hemostatic Clipping," issued April 1, 2014, from U.S. Application No. 13/863,494 (the '494 application), filed April 16, 2013. Ex. 1023. The '048 patent generally relates to devices and methods of causing hemostasis of blood vessels using a clip delivered through an endoscope. Ex. 1023, Abstract. A focus of the invention is to provide medical devices that cause hemostasis of blood vessels along the gastrointestinal tract. *Id*. at 2:50–52. The basic device and method include a

compression clip used to cause hemostasis of blood vessels and a mechanism for deploying the clip. *Id*. at 2:58–62.

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 2:62–3:4. The ’048 patent discloses several distinct embodiments, including an embodiment featuring a frangible link in the form of a j-hook that is used to detach a clip from a delivery device. Id. at 5:21–31, 5:52–63.

We focus on another distinct embodiment primarily relied on by Petitioner, illustrated in Figures 12A and 12B, reproduced below.

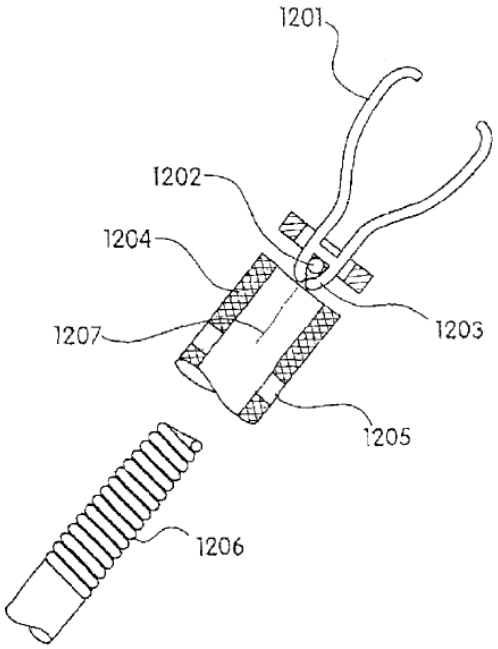

FIG. 12A

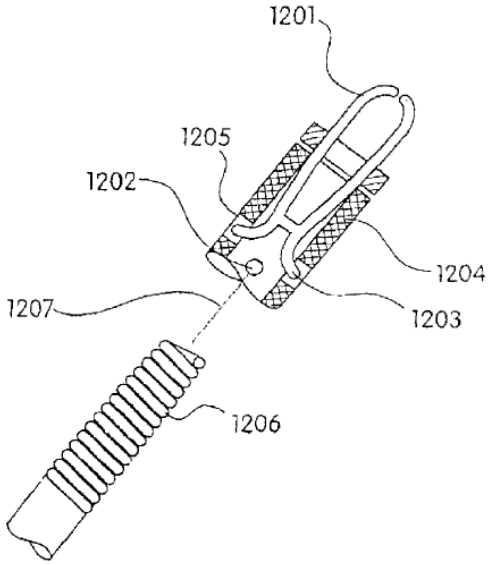

FIG. 12B

A partial view of the claimed device is illustrated showing the clip in an open position in Figure 12A and in a closed position in Figure 12B. Ex. 1023, 4:12–16. The elements shown include clip 1201, ball 1202 fitting into a socket defined by socket tabs 1203, and outer sleeve 1204 attached by way of a breakaway connection (not shown) to sheath 1206. *Id.* at 9:46–51. Rather than a j-hook type frangible link, the device illustrated in Figures 12A and 12B functions such that clip 1201 is released when socket tabs 1203 are aligned with cut-outs 1205 in outer sleeve 1204. *Id.* at 9:46–59. Outer sleeve 1204 is released with clip 1201 so that clip 1201 remains locked after deployment. *Id.* at 9:62–64.

B. Illustrative Claims

Challenged claims 1, 15, and 29 are independent. Claims 2–14 depend from claim 1, claims 16–28 depend from claim 15, and claim 30 depends from claim 29. Claims 1 and 15 are illustrative of the claimed subject matter and are reproduced below:

> 1. A medical device, comprising:
> a clip having first and second clip legs;
> a control wire being operable both to open the clip legs and to close the clip legs;
> a sheath enclosing the control wire;
> a link coupling the control wire to the clip, the link being movable from a coupled configuration in which the clip is coupled to a distal end of the control wire to a released configuration in which first and second arms of the link are configured to move radially outward at an area of the sheath to release the control wire from the clip; and
> an actuator coupled to the control wire, the control wire engageable by the actuator to move the control wire to open and close the clip legs and to move the link from the coupled configuration to the released configuration.

Ex. 1023, 15:32–46.

> 15. A medical device, comprising:
> a clip having first and second clip legs;
> a control wire coupled to the clip, the control wire being movable relative to a sheath to open and close the clip legs, a distal end of the control wire received between legs of the clip;
> the sheath enclosing a distal portion of the control wire, wherein the control wire is configured to release from the clip as the legs spread laterally away from the control wire; and
> an actuator coupled to the control wire to move the control wire relative to the sheath and to release the control wire from the clip.

Ex. 1023, 16:30–42.

C. Related Proceedings

According to the parties, the ’048 patent is a subject of a case captioned *Boston Scientific Corp. v. Cook Group Inc.*, Case No. 1:15-cv-00980-LPS-CJB (D. Del.). Pet. 1; Paper 10, 2. The parties also state that the following pending patent applications are related to the ’048 patent: U.S. Patent Application Nos. 14/988,447; 15/009,358; and 15/091,147. Pet. 2; Paper 10, 2. Petitioner concurrently filed a second petition challenging claims 1–3, 5–18, and 20–30 of the ’048 patent in IPR2017-00132. Petitioner also filed petitions challenging claims of related: U.S. Patent No. 8,709,027 in IPR2017-00133 and IPR2017-00134; U.S. Patent No. 8,974,371 in IPR2017-00135; and U.S. Patent No. 9,271,731 in IPR2017-00435 and IPR2017-00440. *See* Paper 10, 3; *Cook Group Inc. and Cook Medical LLC v. Boston Scientific Scimed, Inc.*, IPR2017-00440, Paper 3, 2–3.

D. Real Parties in Interest

Petitioner identifies Cook Group Inc., Cook Medical LLC, Cook Inc., and Cook Medical Technologies LLC as real parties in interest. Pet. 1.

Patent Owner identifies Boston Scientific Scimed, Inc. and Boston Scientific Corp. as real parties in interest. Paper 10, 2.

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–30 of the '048 patent on the following grounds:

Reference(s)	Basis	Claims challenged
Sackier[1] and Rapacki[2]	§ 103	1–28
Sackier, Rapacki, and Gourlay[3]	§ 103	14 and 28
Sackier	§ 102	29 and 30

Petitioner supports its challenge with a Declaration by Mark A. Nicosia, PhD., dated October 27, 2016 (Ex. 1025).[4]

III. ANALYSIS

A. Claim Construction

Claims in an *inter partes* review are given the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b) (2015); C*uozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2136 (2016). Claim 1 of the '048 patent recites, *inter alia*, "a sheath enclosing the control wire." Ex. 1023 15:36. Purportedly based

[1] U.S. Patent No. 5,749,881, issued May 12, 1998 (Ex. 1008, "Sackier").
[2] U.S. Patent No. 5,569,274, issued October 29, 1996 (Ex. 1021, "Rapacki").
[3] U.S. Patent No. 5,304,183, issued April 19, 1994 (Ex. 1018, "Gourlay").
[4] We have considered Patent Owner's argument that "[b]ecause Petitioners have failed to provide any comparison between the grounds or references (or their reasons for supplying multiple grounds and references) for each challenged claim limitation, trial should not be instituted," and we are not persuaded in this case that trial should be denied under the particular circumstances presented by Patent Owner's arguments. *See* Prelim. Resp. 10–14. We also are not persuaded by Patent Owner's contention that Dr. Nicosia's declaration "should be given no weight." *See id.* at 9–10.

on Patent Owner's contentions in related district court proceedings, Petitioner contends that "sheath" means "one or more components that enclose the control wire," and "may include components of the clip assembly that are left behind in the body." Pet. 12. Patent Owner does not dispute Petitioner's proposed construction. Prelim. Resp. 5. Thus, we determine no terms require express construction for purposes of this Decision. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.").

B. Asserted Obviousness Over Sackier and Rapacki

Petitioner contends that challenged claims 1–28 of the '048 patent would have been obvious over Sackier and Rapacki. Pet. 16–55.

Sackier, titled "Laparoscopic Surgical Clamp," describes a surgical clamp movable between a free state and operable state, and relates more specifically to "clamps and clamp appliers for use in occluding body conduits." Ex. 1008, Abstract, 1:6–8. In addressing the background of the invention, Sackier explains that:

> In the past, the clamp applier loosely engaged the clamp, this presented no problem to open surgery where one could merely reach into the cavity and retrieve a loose clamp. However, in laparoscopic surgery, the relatively closed surgical environment cannot tolerate this possibility of undesirable separation of the clamp from the applier.

Id. at 1:51–57.

Figures 15–17 of Sackier are reproduced below, as depicted with reference numerals provided in the ’048 patent prosecution history (Ex. 1012, 274).

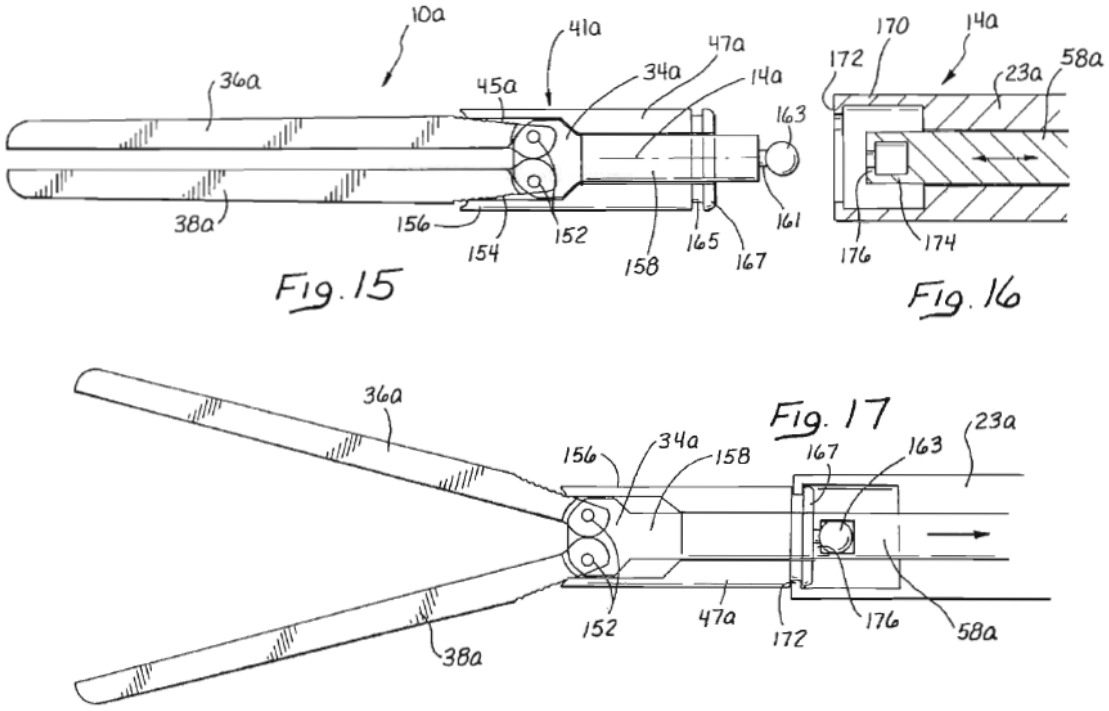

Figure 15 illustrates clamp 10a, Figure 16 illustrates a clamp applier, and Figure 17 illustrates the clamp attached to the clamp applier. Ex. 1008, 3:55–61. The clamp includes clamp jaws 36a and 38a pivotal on supporting structure 34a. *Id.* at 9:16–25. Slide 47a is movable relative to supporting structure 34a to actuate jaws 36a and 38a between open and closed positions. *Id.* at 9:42–49. “[C]lamp applier 12a includes an outer tube 23a and an inner shaft 58a which is axially movable relative to the tube 23a.” *Id.* at 10:10–13. “[T]he shaft 58a can be moved relative to the tube 23a to engage the slide 47a and move it relative to the supporting structure 34a and the jaws 36a, 38a.” *Id.* at 10:28–31.

Rapacki, titled "Endoscopic Vascular Clamping System and Method," describes a system comprised of a clamp with movable jaws and an introducer, particularly in a thoracoscopic coronary artery bypass grafting procedure. Ex. 1021, Abstract, 1:13–17. Figures 5B and 6A of Rapacki are reproduced below.

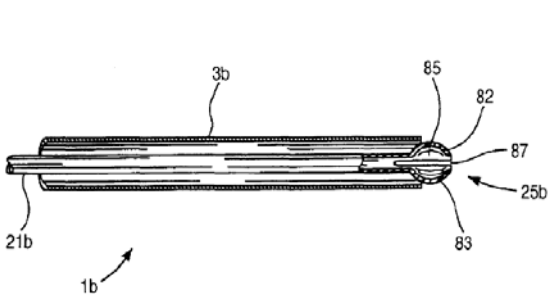

FIG. 5B

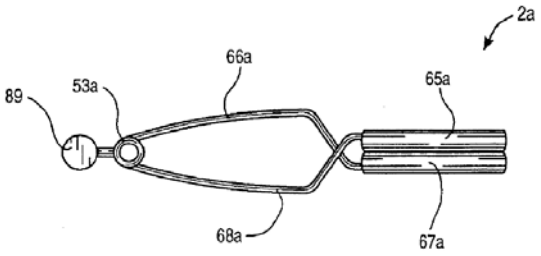

FIG. 6A

Figure 5B illustrates a distal portion of a clamp introducer used with a clamp illustrated in Figure 6A. *Id.* at 6:8–13. As shown in Figure 5B, "[i]ntroducer 1b has a clamp engaging means 25b comprising a pair of jaws 82, 83 defining a socket 85." *Id.* at 9:53–55. "Aperture 85 is configured to grasp a ball-shaped handle on the clamp," and "[j]aws 82, 83 are separated by a slot 87 in the distal end of rod 21b and are biased radially outward so that axial movement of shaft 3b with respect to jaws 82, 83 opens and closes the jaws." *Id.* at 9:55–60. As shown in Figure 6A, a ball-shaped handle 89 attached to clamp 2A at spool 53a "serves to releasably connect clamp 2a to jaws 82, 83 . . . of introducer 1b." *Id.* at 9:62–66. Rapacki explains the operation of the clamp and introducer, noting that it is "releasably connected to the introducer," and that after being guided and positioned to the appropriate position, "the introducer may be withdrawn from the patient" after the clamp has been released. *Id.* at 5:12–23.

Pertinent to our consideration of Petitioner's contentions with respect to the challenged claims, Petitioner asserts that "Sackier discloses a clip that separates from a control wire via a link (i.e., a ball and socket link), so that the clip can stay behind in the patient's body." Pet. 13–14 (citing Sackier Figures 15–17; Ex. 1025 ¶ 26). Petitioner, however, provides no explanation to support this contention, and it is not readily apparent how the structure shown in Sackier Figures 15–17 operates to disengage clamp 10a from the clamp applier "in the patient's body." To be clear, Sackier suggests some embodiments may include "a retracted position wherein the clamp is releasibly held in the operable state," and describes a procedure that utilizes clamps that are released within the body from the clamp applier. *See* Ex. 1008 2:62–67; 8:49–53. Counter to Petitioner's argument, Patent Owner asserts that "Sackier discloses two separate detent features (flange 172/recess 165 and flange 176/recess 161) that fixedly connect" outer tube 23a to slide 47a, and inner shaft 58a to cylindrical shaft. Prelim. Resp. 15. Based on the evidence provided, Petitioner has not shown that the structure it relies upon that is illustrated in Sackier Figures 15–17, which is distinct from other illustrated embodiments, operates in a manner that allows the clamp to be disengaged in the patient's body.

More particularly with regard to claim 1 of the '048 patent, Petitioner contends Sackier discloses a medical device, including "a clip" (clamp 10a), "a control wire" (inner shaft 58a), "a sheath" (outer tube 23a and slide 47a), and "an actuator" (clamp applier 12a). Pet. 14–18, 25. Claim 1 further requires a link "in which first and second arms of the link are configured to move radially outward at an area of the sheath to release the control wire from the clip." Petitioner contends that Sackier discloses a link in the form

of ball 163 which couples to cylinder 174, but does not explicitly disclose that cylinder 174 is comprised of first and second arms. Pet. 19–21. Instead, Petitioner relies on Rapacki's jaws 82, 83 as corresponding to the claimed link with first and second arms configured to move radially outward to release a clip (clamp 2a) from a control wire (rod 21b).

In support of the asserted combination of Sackier and Rapacki, Petitioner contends that:

> It would have been obvious to one of ordinary skill in the art to modify the Sackier cylinder 174 (with flange 176) to include a longitudinal slot, as disclosed in Rapacki, to provide distinct hemi-cylindrical (or similar to hemi-cylindrical) first and second link arms. Modifying the cylinder 174 to include a longitudinal slot would allow the cylinder 174 to "open laterally," as taught by Sackier. (Ex. 1008, 10:24–27). The skilled artisan would have expected that adding a slot to the cylinder 174 would decrease the force required to separate the link between the clip (10a) and control wire (58a), making the cylinder 174 easier to open. A person of ordinary skill would have recognized the importance of making the cylinder 174 easier to open, as the clip (10a) is used to secure delicate internal organs within a body. Using excessive force to release ball 163 could potentially damage the organs. This would have motivated a person of ordinary skill in the art to include a slot, as disclosed in Rapacki, or at least to try it. (Ex. 1025, ¶ 39).

Pet. 22–23 (further asserting such modification was a matter of routine skill using known methods to yield predictable results). The portion of Dr. Nicosia's Declaration cited by Petitioner appears virtually identical to the Petition and cites no additional support or basis for the opinions expressed. *See* Ex. 1025, ¶ 39.

Patent Owner argues that "[d]uring operation" Sackier inner shaft 58a is not released from clamp 10a, and that modifying Sackier based on Rapacki as proposed by Petitioner fails to permit release because Sackier

recess 165 and flange 172 remain engaged, holding outer tube 23a on to slide 47a. Prelim. Resp. 20–22.

Patent Owner further asserts that Petitioner fails to provide a "legally sufficient rationale for why Sackier and Rapacki would be combined." Prelim. Resp. 33–39. In particular, Patent Owner argues:

> Petitioners point to no disclosure that would motivate a person of ordinary skill to make the cylinder [174 of Sackier] easier to open inside the body. . . . [C]lamp 10a [of Sackier] is not intended to be separated from shaft 58a at all during operation inside the body. [Ex. 1008] at 9:30–32. Sackier never requires cylinder 174 to open inside the body. On the contrary, in its operable state while inside the body, the Sackier device is already fully assembled, with flange 176 of cylinder 174 of shaft 58a already engaging recess 161 to hold clamp 10a. [*Id.*] at 10:27–34. In fact, one of Sackier's stated benefits compared to the prior art is the tight engagement between the clamp and its applier to avoid the "possibility of undesirable separation of the clamp from the applier" in "the relatively closed surgical environment" of laparoscopic surgery. [*Id.*] at 1:51–52. Therefore, there is no reason why a person of ordinary skill in the art would attempt to separate clamp 10a and shaft 58a inside the body.

Prelim. Resp. 37–38.

Based on the record before us, Petitioner has not established that the asserted combination discloses a link "in which first and second arms of the link are configured to move radially outward at an area of the sheath to release the control wire from the clip," because Petitioner has not sufficiently shown that the structure relied on from Sackier would function to release the control wire from the clip even if modified by the teachings of Matsuno, as Petitioner proposes. Moreover, Petitioner contention that a person of ordinary skill would have been led to modify Sackier's clamp and clamp applier, based on Matsuno, to make the link between the clamp and

clamp applier easier to open because "excessive force . . . could potentially damage the organs" is supported only by conclusory assertions. *See* Pet. 22–23. Petitioner's proposed rationale of making the device easier to open runs counter to Sackier's stated objective of ensuring that "undesirable separation" does not occur between the clamp and applier when used in a body. Ex. 1008, 1:51–57. Petitioner has not provided sufficiently the "articulated reasoning with some rational underpinning" required to support the legal conclusion of obviousness. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 418 (2007); s*ee also, e.g.*, *In re Caldwell*, 319 F.2d 254, 256 (CCPA 1963) (reference teaches away if it leaves the impression that the product would not have the property sought by the applicant). Petitioner makes the same deficient arguments for each of claims 1–28 based on Sackier and Rapacki. Pet. 16–55. Accordingly, the information provided by Petitioner does not show a reasonable likelihood of prevailing in showing that any of claims 1–28 of the '048 patent would have been obvious over Sackier and Rapacki.

C. Asserted Obviousness Over Sackier, Rapacki, and Gourlay

Petitioner contends that challenged claims 14 and 28 of the '048 patent would have been obvious over Sackier, Rapacki, and Gourlay. Pet. 61–64. Gourlay, titled "Tethered Clamp Retractor," describes a tissue manipulation system, including a tethered clamp and a clamp applicator. Ex. 1018, Abstract. In the asserted combination of these three references, Petitioner addresses reasons why it would have been obvious to modify Sackier in light of Gourlay, but offers no additional reasoning to support the combination of Sackier and Rapacki beyond the assertions addressed above with respect to the combination of only Sackier and Rapacki, which we

found insufficient. *Id.* at 63–64. Accordingly, the information provided by Petitioner does not show a reasonable likelihood of prevailing in showing that either claim 14 or claim 28 of the '048 patent would have been obvious over Sackier, Rapacki, and Gourlay.

D. Asserted Anticipation By Sackier

Petitioner contends that challenged claims 29 and 30 of the '048 patent are anticipated by Sackier. Pet. 56–60. Claim 29 requires, *inter alia*, "applying a tensile force of at least a threshold level to the control wire to separate a separable link coupling the control wire to the clip." Ex. 1023, 18:17–19. Petitioner's entire analysis of how Sackier anticipates this limitation consists of the following:

> Sackier discloses applying a tensile force of at least a threshold level to the control wire (58a) to separate a separable link (ball 163 separates from flange 176 (located at the opening of cylinder 174)), coupling the control wire (58a) to the clip (10a), for the reasons in Section V.A.1, 6, and 11, *supra* at pp. 16–25, 34–36, and 42–45. (*See also* Ex. 1008, Figures 15 and 16, Abstract, 2:56–59, 8:29–34, 8:51–53, 9:60–10:34; Ex. 1001, ¶ 93).

Pet. 58. The portions of the Petition referred to by Petitioner (Section V.A.1, 6, and 11) neither address claim 29 nor claim language identical to the limitation at issue. Moreover, the portions of Sackier cited by Petitioner appear to span various distinct embodiments with no accompanying explanation of how they collectively demonstrate anticipation, and our review of the cited evidence does not reveal how the various embodiments of Sackier can all be considered detachable.

Patent Owner and the Board are not required to speculate as to what Petitioner's contentions are, or as to how a reference is to be applied to the challenged claims. Claim 29 is a distinct method claim requiring the

performance of six steps, and citation to an obviousness analysis for the medical device limitations in this case does not establish persuasively that Sackier discloses these six steps. A petition must identify how the construed claim is unpatentable, as well as the relevance of the evidence to the challenge raised. 37 C.F.R. § 42.104 (b). A string citation purporting to incorporate arguments and evidence by reference is not a sufficient substitute for an explanation of the relevance of the asserted evidence. Accordingly, the information provided by Petitioner does not show a reasonable likelihood of prevailing in showing that either claim 29 or claim 30, which depends from claim 29, is anticipated by Sackier.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition in IPR2017-00131 to institute *inter partes* review of the ’048 patent is DENIED, and no trial is instituted.

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