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 IPR2017-00132 Patent 8,685,048 B2

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

TARTAL, Administrative Patent Judge.

DECISION 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 1–3, 5–18, and 20–30 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 6, "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 shows there is a reasonable likelihood that Petitioner would prevail in showing the unpatentability of challenged claims 1-3, 5-14, 29, and 30, but not claims 15-18 and 20-28. Accordingly, we authorize an *inter partes* review to be instituted as to claims 1-3, 5-14, 29, and 30 of the '048 patent. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far (prior to Patent Owner's Response). This is not a final decision as to patentability of claims for which *inter partes* review is instituted. Any final decision will be based on the record, as fully developed during trial.

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.

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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.



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. Challenged claims

2, 3, and 5–14 depend from claim 1, challenged claims 16–18 and 20–28

depend from claim 15, and challenged 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 4, 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 4, 2. Petitioner concurrently filed a second petition challenging claims 1–30 of the '048 patent in IPR2017-00131. 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 4, 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 4, 2.

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1-3, 5-18, and 20-30 of the '048 patent on the following grounds:

Reference(s)	Basis	Claims challenged
Komiya ¹	§ 102	1–3, 5–18, and 20–28
Komiya	§ 103	2 and 17
Komiya and Crockard ²	§ 103	1, 3, 5–14, 21, 24, 25, 27, and 28
Shinozuka ³ and Matsuno ⁴	§ 103	29 and 30

Petitioner supports its challenge with a Declaration by Mark A. Nicosia, PhD., dated October 27, 2016 (Ex. 1026).⁵

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); *Cuozzo Speed Techs., LLC v. Lee*,

¹U.S. Patent No. 3,958,576, issued May 25, 1976 (Ex. 1014, "Komiya").

² U.S. Patent No. 5,174,276, issued December 29, 1992 (Ex. 1019, "Crockard").

³ Japanese Unexamined Patent Application Publication No. 60-103946, published June 8, 1985 (Ex. 1009, "Shinozuka").

⁴ U.S. Patent No. 5,766,189, issued June 16, 1998 (Ex. 1016, "Matsuno").

⁵ 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.

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 on Patent Owner's contentions in related district court proceedings, Petitioner contends that the term "sheath" means "one or more components that enclose the control wire," and that it "may include components of the clip assembly that are left behind in the body." Pet. 13. Patent Owner does not dispute Petitioner's proposed construction. Prelim. Resp. 5. Thus, we determine no term requires 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 Anticipation by Komiya

Petitioner contends that claims 1–3, 5–18, and 20–28 of the '048 patent are anticipated by Komiya. Pet. 18–45. Komiya, titled "Surgical Instrument for Clipping Any Affected Portion of a Body," describes a clip member detachably attached to an instrument body. Ex. 1014, Abstract.

Figures 6 and 7 of Komiya are reproduced below.



FIG. 7



Figures 6 and 7 illustrate the manner in which a portion of a body cavity is captured and clipped, respectively. Ex. 1014, 2:34–39. The elements shown include clip member 11, surgical instrument body 10 with outer flexible tube 12, tubular actuating member 15, metal wire 19 connected to hook member 20, and cylindrical holder 21 constituting an engaging means. *Id.* at 2:43–49, 3:7–9, 3:28–37, 3:44–45.

Claims 1–3 and 5–14

Petitioner contends that Komiya discloses clip 11 corresponding to the claimed "clip having first and second clip legs," metal wire 19 and hook

member 20 corresponding to the claimed "control wire," and tubular actuating member 15 and holder 21 corresponding to the claimed "sheath." Pet. 19–25. Petitioner further contends the claimed "actuator" is disclosed by Komiya as an instrument body (shown in Komiya Figure 2) coupled to a control wire. *Id.* at 26.

At this stage, the primary dispute of the parties, with respect to challenged claim 1, is whether Petitioner has sufficiently shown that Komiya discloses:

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.

Ex. 1023, 15:37–42. Petitioner contends hook member 20 and the proximal end of clip 11 of Komiya correspond to a "link," as claimed. Pet. 23. Petitioner further contends with respect to Komiya that "the arms of the link (offset portions 11(b)) are configured to move radially outward at a relief area of the sheath ([](hole 16))." *Id.* at 24. Claim 1, however, also requires that arms of the link are configured to move radially outward "to release the control wire from the clip." Petitioner fails to adequately address this requirement, arguing that:

In the released configuration reflected in Figure 7, the hook member 20 is able to detach from the proximal end of the clip (11), and thereby release the control wire (19, 20) from the clip (11). The radially outward movement of link arms (11b) in the released configuration also allows holder 21 to detach from guide member 16 and stay with clip (11). (Ex. 1014, 5:14–29; Ex. 1026, \P 41).

Pet. 25. Petitioner fails to explain how radial movement of the link arms of Komiya corresponds to the release of the control wire from the clip. Komiya instead states that it is "by manipulating the endoscope, the rear end portion 11a of the clip member 11 is disengaged from the cutout 21a of the hook member 20." Ex. 1014, 5:24–27; *see also* Prelim. Resp. 19–20 (arguing that in Komiya it is the sideways movement of the forward end portion of the surgical instrument that causes the clip member to become disengaged).

Petitioner has not shown sufficiently that Komiya discloses a link with arms "configured to move radially outward at an area of the sheath to release the control wire from the clip," as recited by claim 1. Accordingly, the information provided by Petitioner does not show a reasonable likelihood of prevailing in showing that claim 1 of the '048 patent, or any of claims 2, 3, or 5–14 which depend from claim 1, is anticipated by Komiya.

Claims 15–18 and 20–28

Petitioner suggests various features of claim 15 correspond to features of claim 1, and contends Komiya discloses the features of claim 15 for substantially the same reasons Petitioner asserts with respect to claim 1. *See* Pet. 40–41. At this stage the primary dispute of the parties, with respect to challenged claim 15, is whether Petitioner has sufficiently shown that Komiya discloses that "the control wire is configured to release from the clip as the legs spread laterally away from the control wire." Ex. 1023, 16:37– 39. Petitioner argues that Komiya discloses "the control wire (19, 20) is configured to release from the clip as the legs (11b) spread laterally away from the control wire, for the reasons in Section V.A.1.d and e, [Petition] at

pp. 22–25." Pet. 41. The claim language at issue in claim 15 is not the same as the claim language of claim 1. Accordingly, Petitioner's conclusory assertion that Komiya discloses a feature of claim 15 not recited in claim 1 for the "reasons" provided with respect to claim 1 in the Petition is not persuasive. Moreover, the reasons provided by Petitioner in regard to claim 1 do not persuasively show that "the control wire is configured to release from the clip as the legs spread laterally away from the control wire." As discussed above, Komiya relies on manipulating the endoscope to disengage the hook. Ex. 1014, 5:24–27. Petitioner offers no showing that this manipulation coincides with "the legs spread laterally away," as recited by claim 15.

Petitioner has not shown sufficiently that Komiya discloses "the control wire is configured to release from the clip as the legs spread laterally away from the control wire," as recited by claim 15. Accordingly, the information provided by Petitioner does not show a reasonable likelihood of prevailing in showing that claim 15 of the '048 patent, or any of claims 16–18 and 20–28 which depend from claim 15, is anticipated by Komiya.

C. Asserted Obviousness over Komiya

Petitioner contends claims 2 and 17 of the '048 patent would have been obvious over Komiya. Pet. 46–47.⁶ Claim 2 depends from claim 1 and claim 17 depends from claim 15. For the reasons provided above, Petitioner failed to show that claims 1 and 15 are anticipated by Komiya. Petitioner does not resolve this deficiency by arguing that additional features of claims 2 and 17 would have been obvious over Komiya. Accordingly, the

⁶ We understand references in the Petition to "Kimura" are typographical errors and that Petitioner intended to refer to "Komiya."

information provided by Petitioner does not show a reasonable likelihood of prevailing in showing that either claim 2 or claim 17 of the '048 patent would have been obvious over Komiya.

D. Asserted Obviousness over Komiya and Crockard

Petitioner contends claims 1, 3, 5–14, 21, 24, 25, 27, and 28 of the '048 patent would have been obvious over the combination of Komiya and Crockard. Pet. 48–60.

Crockard, titled "Endoscope Device for Applying an Aneurysm Clip," describes a device that includes an applicator for a clip comprising a remote actuator in the form of a flexible shaft inside a flexible conduit. Ex. 1019, Abstract. Figures 9A and 9B of Crockard are reproduced below.



Figures 9a and 9b illustrate a section through an aneurysm clip applicator as described by Crockard, including steerable endoscope tube 12, flexible conduit 42, and shaft 44. Ex. 1019, 3:50–57. The applicator includes jaws 92, resiliently biased in the open position, pivotally mounted on stem 94

which is attached to the distal end of shaft 44. *Id.* at 7:46–51. "When the applicator is withdrawn inside the conduit 42 of the surgical device [] the jaws are closed, since they are restrained against opening by the internal wall of the conduit 42." *Id.* at 7:52–55. Aneurysm clip 90, comprised of two legs 96 and handle 98, is held in jaws 92. *Id.* at 7:55–64. When handle 98 is released, the resilience of the clip causes legs 96 to move together. *Id.* at 7:64–68.

Claim 1

With regard to claim 1, Petitioner contends that Komiya discloses the elements of a clip, a control wire, a sheath, and an actuator, as set forth in Petitioner's ground based on anticipation by Komiya. Pet. 48, 53. Petitioner further argues that "[t]o the extent" Patent Owner argues Komiya fails to disclose "radial outward movement of the link arms 'to release the control wire from the clip," Crockard discloses this feature. *Id.* at 49. In particular, according to Petitioner, Crockard's handle 98 and jaws 92 correspond to a link between clip 90 and shaft 44, and shaft 44 corresponds to a control wire. *Id.* The jaws 92 correspond to arms of the link, and are configured to move radially outward to release control wire 44 from clip 90. *Id.* at 50.

Petitioner argues it would have been obvious to replace hook member 20 of Komiya with jaws 92 of Crockard "to simplify the operation of using Komiya's clip (11) by limiting the deployment steps." *Id.* at 51. Under such a configuration Petitioner asserts "the clip would be released immediately upon radial outward movement of the link arms (92), as opposed to the embodiment of Komiya, which requires that the hook member 20 move distally and sideways to completely separate the clip (11) from the control wire (19, 20). *Id.* at 51–52. In support of the asserted combination,

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Petitioner also contends that "simplifying the operation would potentially reduce the risk of error, and potentially decrease the time required to perform the medical procedure," would "limit the possibility of problems associated with attempting to uncouple the hook member 20," and would be a routine substitution "according to known methods to yield predictable results." Pet. 52–53.

Patent Owner argues that Crockard's jaws 92 "do not move radially outward 'at an area of the sheath to release the control wire from the clip," because "jaws 92 can only open to release clip 90 when they are outside of conduit 42." Prelim. Resp. 32–33. Patent Owner's unsupported argument fails to persuade us on the present record. Petitioner has sufficiently shown that the claimed "at an area of the sheath" encompasses a position at or near the end of a sheath, as depicted by Crockard. Patent Owner further argues that Petitioner fails to provide a "legally sufficient rationale for why Komiya and Crockard would be combined." Id. at 41–47. Patent Owner argues, for example, that Petitioner fails to show a person of ordinary skill would have had a reasonable expectation of success; fails to explain how Crockard's jaws 92 would engage Komiya's clip member 11 or how a specifically shaped loop should be added to Komiya; fails to explain why a person would expand the width of the Komiya device to accommodate Crockard's jaws 92 potentially making the device unusable in an endoscope; proposes a combined device that is not reversibly operable and could never be opened to capture tissue; and combines references intended for different purposes. Id.

We have considered Patent Owner's unsupported arguments and are persuaded on the present record that Petitioner has provided a sufficient

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rationale for the asserted combination to support institution. Accordingly, the information provided by Petitioner shows a reasonable likelihood of prevailing in showing that claim 1 of the '048 patent would have been obvious over Komiya and Crockard.

Claims 3 and 5–14

Petitioner contends claims 3 and 5–14, which depend from claim 1, would have been obvious over Komiya and Crockard. Pet. 54–58. Patent Owner disputes Petitioner's contentions with regard to claims 3, 5, 7, 10, 11, 12, and 14 for a variety of reasons in addition to the arguments asserted with respect to claim 1. Prelim. Resp. 33–38. For the reasons set forth above, Petitioner has demonstrated a reasonable likelihood that claim 1 of the '048 patent would have been obvious over Komiya and Crockard. Having decided that the asserted combination of Komiya and Crockard supports a reasonable likelihood that at least one of the challenged claims is unpatentable, we exercise our discretion under 37 C.F.R. § 42.108 to proceed with review of the challenged claims that depend from claim 1 for which the combination of Komiya and Crockard is the basis for obviousness. *See Intex Recreation Corp. v. Bestway Inflatables & Material Corp.*, IPR2016-00180, Paper 13, at 8–11 (PTAB Jun. 6, 2016).

Claims 21, 24, 25, 27, and 28

Each of claims 21, 24, 25, 27, and 28 depend from claim 15. Petitioner does not contend that claim 15 would have been obvious over Komiya and Crockard, and, for the reasons provided above, has not provided sufficient information to show a reasonable likelihood of prevailing in showing that claim 15 of the '048 patent is anticipated by Komiya. Moreover, Petitioner provides virtually no analysis of its contentions with

regard to claims 21, 24, 25, 27, and 28, and instead merely recites the claim language and ambiguously refers back to multiple other portions of the Petition concerning other asserted grounds as allegedly providing the necessary reasoning. Pet. 59–60. Accordingly, the information provided by Petitioner does not show a reasonable likelihood of prevailing in showing that claims 21, 24, 25, 27, and 28 would have been obvious over Komiya and Crockard.

E. Asserted Obviousness over Shinozuka and Matsuno

Petitioner contends claims 29 and 30 would have been obvious over the combination of Shinozuka and Matsuno. Pet. 61–73.

Shinozuka is directed to a "Biotissue Clip Device." Ex. 1009, 261. The device includes a clip detachably coupled to a control cord. *Id.* at 262. Figure 2 of Shinozuka is reproduced below:





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*.

Petitioner identifies how it contends each of the elements of claims 29 and 30 is disclosed by Shinozuka, other than "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." Pet. 61–73. Petitioner explains that

Shinozuka discloses unlinking hook 16 on clip 15 from claw 23 on control wire 14 by "jiggl[ing]" control wire 14, but Petitioner provides no sufficient explanation to support the proposition that such "jiggling" corresponds to "applying a tensile force." *See* Pet. 66–67. Instead, Petitioner argues that "to the extent [Patent Owner] argues that separating the separable link in Shinozuka does not involve applying a tensile force of at least a threshold level to the control wire, claim 29 nevertheless would have been obvious," based on Matsuno. *Id.* at 68.

Matsuno, titled "Clip Device," is directed to a device used for hemostasis, marking, and ligation of a living tissue in a body cavity. Ex. 1016, 1:6–7. Figures 5 and 6 of Matsuno are reproduced below.



FIG. 5

FIG. 6

Figures 5 and 6 illustrate a clip within a tube sheath and the clip open after being exposed from the tube sheath, respectively. Ex. 1016, 2:41–44. Petitioner contends that in Matsuno, clip 2 may be disengaged from control wire 13 by applying a sufficient tensile force to cause a hook portion of coupling plate 3 to straighten. Pet. 68–70 (*citing, inter alia*, Ex. 1016, 5:58– 65).

Petitioner argues that it would have been obvious to a person of ordinary skill to substitute Shinozuka's hook 16 with the hook of Matsuno's coupling plate 3 to "simplify and improve the procedure for separating the separable link," to avoid potential problems with "jiggling," and to reduce the risk of damage to the patient. Pet. 70. Petitioner also argues such a substitution would have been a matter of routine skill to yield predictable results. *Id.* at 71.

Patent Owner argues that one of ordinary skill would not have been motivated to combine Shinozuka and Matsuno. Prelim. Resp. 47–52. Patent Owner argues that Shinozuka was directed to a clip that could be released from the device in either of two axes, but "[r]eplacing Shinozuka's engaging projection18 with Matsuno's coupling plate 3 would not actually solve the problem with the prior art, the inability to detach a clip in more than [one] direction." Prelim. Resp. 49–50. Patent Owner further argues for a variety of reasons that Petitioner fails "to explain how or why one of ordinary skill would make the necessary changes to render the combination of Shinozuka and Matsuno a functional device." *Id.* at 50.

We have considered Patent Owner's unsupported arguments and are persuaded on the present record that Petitioner has provided a sufficient rationale for the asserted combination to support institution. Accordingly, the information provided by Petitioner shows a reasonable likelihood of prevailing in showing that claims 29 and 30 of the '048 patent would have been obvious over Shinozuka and Matsuno.

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IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that *inter partes* review is *instituted* in IPR2017-00132 with respect to the following grounds of unpatentability:

claims 1, 3, and 5–14 as obvious over Komiya and Crockard under 35 U.S.C. § 103(a),

claims 29 and 30 as obvious over Shinozuka and Matsuno under 35 U.S.C. § 103(a);

FURTHER ORDERED that no ground other than those specifically instituted above is authorized for the *inter partes* review;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '048 patent is hereby instituted in IPR2017-0132 commencing on the entry date of this Order, and 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.

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