Paper No. 9 Entered: June 29, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION, Petitioner,

v.

BOSTON SCIENTIFIC SCIMED, INC., Patent Owner.

Case IPR2017-00444 Patent 6,915,560 B2

Before NEIL T. POWELL, JAMES A. TARTAL, and STACY B. MARGOLIES, *Administrative Patent Judges*.

TARTAL, Administrative Patent Judge.

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

I. INTRODUCTION

Edwards Lifesciences Corporation ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting institution of *inter partes* review of claims 1, 2, 6, 8–11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40 of U.S. Patent No. 6,915,560 B2 (Ex. 1101, "the '560 patent"). Boston Scientific Scimed, Inc. ("Patent Owner") filed a Preliminary Response (Paper 7, "Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314, 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." *See also* 37 C.F.R. § 42.4(a).

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, 2, 6, 8–11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40. Accordingly, we authorize an *inter partes* review to be instituted as to claims 1, 2, 6, 8–11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40 of the '560 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 '560 Patent

The '560 patent, titled "Apparatus for Contracting, Loading or Crimping Self-Expanding and Balloon Expandable Stent Devices," issued

July 12, 2005, from U.S. Application No. 10/444,807 (the '807 application), filed May 23, 2003. Ex. 1101. The '807 application was a division of U.S. Application No. 09/966,686, filed on October 1, 2001 (issued as U.S. Patent No. 6,823,576), which was a continuation of U.S. Application No. 09/401,218 (the '218 application), filed on September 22, 1999 (issued as U.S. Patent No. 6,360,577). *Id.* The '560 patent generally relates to a device "capable of crimping a stent uniformly while minimizing the distortion of and scoring and marking of the stent due to crimping." Ex. 1101, 2:26–29. Petitioner contends that the alleged "AAPA [Applicant Admitted Prior Art] depicted in Figure 1 and described at 1:62–2:21 of the '560 patent is prior art." Pet. 36.

Figure 1 of the '560 patent is reproduced below.

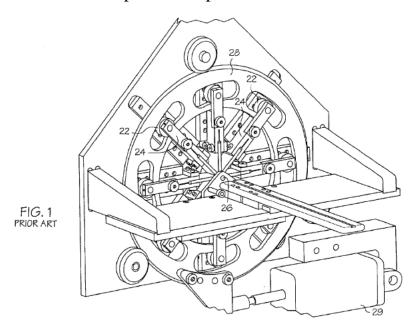


Figure 1 illustrates a perspective view of a stent crimper, with the words "PRIOR ART" appearing under the label "FIG. 1." Ex. 1101, 3:58. The description in the specification of Figure 1 does not state that the stent crimper illustrated in Figure 1 was known in the art. *See id.* at 1:62–2:21.

According to Patent Owner, Figure 1 of the '560 patent was not labeled "PRIOR ART" when filed in the parent '218 application on September 22, 1999, but rather, the label was added during prosecution of the '218 application in a May 23, 2000, filing by the applicant in response to an Examiner request dated February 23, 2000. Prelim. Resp. 9 n.1 (citing Ex. 2010, 61, 81). Patent Owner also contends that, prior to the date the Petition was filed, Patent Owner informed Petitioner, as part of district court proceedings concerning the '560 patent, that the stent crimper illustrated in Figure 1 of the '560 patent was developed by Boston Scientific and was not commercialized. *Id.* at 10 (citing Ex. 2011, 23; Ex. 2012, 3).

According to Patent Owner, "[i]mproving upon the prior art crimping methods and devices, the '560 Patent discloses and claims an innovative crimper that includes both coupled and movable blades forming a variable-sized aperture that applies even forces while minimizing distortion of the stent." Prelim. Resp. 5 (citing Ex. 1101, 2:26–29, 2:56–65).

Figure 4A of the '560 patent is reproduced below.

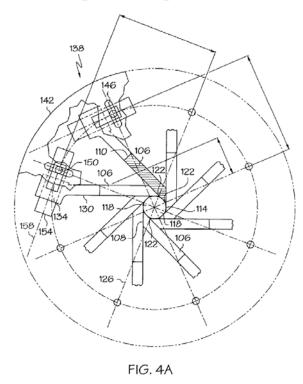


Figure 4A illustrates "a partial front view of an embodiment of the inventive apparatus." Ex. 1101, 4:1–2. Actuation device 138 includes rotatable actuation plate 142 and eight coupled blades 106 disposed about reference circle 114 to form aperture 118. *See id.* at 4:46–49. "Each blade 106 is engaged to actuation plate 142 via a cam follower bearing 150 disposed in radial slot 146 and attached to mounting means in slotted end 134." *Id.* at 5:19–21. "Each bearing 150 extends from a linear slide 154." *Id.* at 5:22. Patent Owner further explains:

In use, as an actuation plate 142 is rotated in a clockwise direction, the clockwise motion of the actuation plate is translated into linear motion of each linear slide 154 and blade 106 via bearing 150. ([Ex. 1101] at 5:46–62.) Each blade 106 moves outward in a direction parallel to the radial line 126, resulting in the opening of aperture 118. Conversely, as the actuation plate 142 is rotated in a counterclockwise direction,

IPR2017-00444 Patent 6,915,560 B2

each blade 106 moves inward in a direction parallel to the radial line 126, resulting in the closing of aperture 118.

Prelim. Resp. 6–7.

B. Illustrative Claim

Challenged claims 1, 10, 18, 27, 37, 39, and 40 are independent.

Claim 1 is illustrative of the claimed subject matter and is reproduced below:

- 1. A stent crimper comprising:
- a plurality of movable dies arranged to form an iris having a longitudinal axis, the iris defining an aperture, the dies disposed about the aperture and between stationary end-walls which are disposed about the longitudinal axis, at least one of the stationary end-walls operatively engaged to the dies at distinct connection locations such that the number of distinct connection locations and the number of dies are the same;
- each die having a first straight side and a second straight side, the first straight side and the second straight side conver[g]ing to form a tip; wherein a portion of the first straight side of each die faces the aperture, each first straight side parallel to the second side of an adjacent die.

Ex. 1101, 10:8-22.

C. Related Proceedings

The parties indicate that the '560 patent is asserted in the United States District Court for the Central District of California, in a case captioned *Boston Scientific Corp. and Boston Scientific Scimed, Inc. v. Edwards Lifesciences Corp.*, Civil Action No. 8:16-cv-0730 (C.D. Cal.). Pet. 14; Paper 4, 2. Petitioner also filed petitions challenging claims of the '560 patent on other grounds in IPR2017-00072 and IPR2017-01301.

D. Real Parties in Interest

Petitioner identifies only itself as a real party in interest. Pet. 14. Patent Owner identifies itself and Boston Scientific Corp. as real parties in interest. Paper 3, 2.

E. The Asserted Grounds of Unpatentability

Petitioner identifies the following as the two grounds on which it challenges claims 1, 2, 6, 8–11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40 of the '560 patent:

References	Basis	Claims challenged
Yasumi ¹ and "Applicant	§ 103	1, 2, 6, 8–10, 14, 15, 18, 23,
Admitted Prior Art"		25, 27, 28, 31, 33, 37, and 40
Yasumi, "Applicant Admitted	§ 103	11, 17, 19, 26, 34, 35, and 39
Prior Art," and Morales ²		

Pet. 30. Petitioner's identification of the grounds it asserts, however, fails to properly summarize the full range of arguments and grounds asserted by Petitioner in the Petition. In particular, Petitioner relies on Yasumi as disclosing all of the elements of the challenged claims, and refers to alleged Applicant Admitted Prior Art and Morales in the alternative. See, e.g., Pet. 31 (arguing that the preamble of each challenged claim is not limiting), 82 (stating that the press tool of Yasumi is a stent crimper and "to the extent necessary, it would have been obvious to a [skilled artisan] to modify Yasumi for use as a stent crimper in view of the AAPA"), 85–86 (stating that the limitations of claim 39 "are disclosed in or obvious over Yasumi alone or in view of the [alleged Applicant Admitted Prior Art]," and that "[t]o the extent these limitations are not viewed as disclosed in or obvious in view of Yasumi or the [alleged Applicant Admitted Prior Art], Morales also discloses the limitations"), 92 (stating that the limitation added by claims 11, 19, and 35 is "disclosed in or obvious over Yasumi either alone or in view of the AAPA" and that "[t]o the extent this limitation is viewed as not disclosed

¹ U.S. Patent No. 4,454,657, issued June 19, 1984 (Ex. 1103, "Yasumi").

² U.S. Patent No. 5,893,852, issued April 13, 1999 (Ex. 1104, "Morales").

in or obvious in view of Yasumi or the AAPA, Morales" discloses the limitation), 94 (same with respect to the limitation added by claims 17, 26, and 34). Further, Petitioner relies on two embodiments of the invention disclosed by Yasumi, the first shown in Figure 8 of Yasumi and the second in Figure 9(a) of Yasumi, but fails to provide any explanation of their relationship, if any, to one another.

Based on our review of the Petition, we understand Petitioner to have asserted the following grounds:

References	Basis	Claims challenged
Yasumi (Figure 8 embodiment)	§ 103	1, 2, 6, 8–11, 14, 15, 17–19,
		23, 25–28, 31, 33–35, 37,
		39, and 40
Yasumi (Figure 8 embodiment)	§ 103	11, 17, 19, 26, 34, 35, and 39
and Morales		
Yasumi (Figure 8 embodiment)	§ 103	1, 2, 6, 8–11, 14, 15, 17–19,
and alleged "Applicant Admitted		23, 25–28, 31, 33–35, 37,
Prior Art"		39, and 40
Yasumi (Figure 8 embodiment)	§ 103	1, 2, 6, 8–11, 14, 15, 17–19,
and Yasumi (Figure 9(a)		23, 25–28, 31, 33–35, 37,
embodiment)		39, and 40
Yasumi (Figure 8 embodiment),	§ 103	1, 2, 6, 8–11, 14, 15, 17–19,
Yasumi (Figure 9(a) embodiment),		23, 25–28, 31, 33–35, 37,
and alleged "Applicant Admitted		39, and 40
Prior Art"		
Yasumi (Figure 8 embodiment),	§ 103	11, 17, 19, 26, 34, 35, and 39
Yasumi (Figure 9(a) embodiment),		
and Morales		

Petitioner supports its challenge with a Declaration of Neil Sheehan, dated December 5, 2016 (Ex. 1105).

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*, 136 S. Ct. 2131, 2136 (2016).

1. "A stent crimper comprising"

Each of the challenged claims recites "[a] stent crimper comprising" in the preamble. Petitioner contends this preamble language is not limiting because the body of each challenged claim describes a structurally complete invention, and the preamble does not recite additional structure or provide antecedent basis for a claim limitation. Pet. 31–32 (citing *Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808–09 (Fed. Cir. 2002)). Petitioner further argues that during examination the preamble was not treated as limiting and that the specification acknowledges additional uses of the invention beyond stent crimping. *Id.* at 32 (citing Ex. 1101, 2:52–55, 8:65–66; Ex. 1102, 19, 45–47, 49, 72).

Patent Owner argues that the preamble is limiting because "stent" appears in the title of the patent and throughout the specification, including all of the claims, and, therefore, "stent crimper" is "an important characteristic" of the patent and should be limiting. Prelim. Resp. 27–28 (citing, *inter alia*, *Poly-America*, *L.P. v. GSE Lining Tech.*, *Inc.*, 383 F.3d 1303, 1310 (Fed. Cir. 2004); *Catalina Mktg.*, 289 F.3d at 808; *Rotatable Techs. LLC v. Motorola Mobility LLC*, 567 Fed. App'x 941, 943 (Fed. Cir. 2014)). Patent Owner also argues that in unchallenged claim 36 of the '560 patent, the body of the claim recites "the stent crimper" and refers back to

"stent crimper" in the preamble for antecedent basis, such that the preamble "stent crimper" is limiting. Further, Patent Owner argues that if the preamble is limiting in unchallenged claim 36, "it should be construed the same in other claims" of the '560 patent. Prelim. Resp. 29. We agree with Patent Owner that, as a general matter, claim terms should be construed consistently across claims in a patent. However, that principle does not dictate, on the current record, that the preambles of other claims are limiting in the same manner that the preamble of claim 36 may be.

For purposes of this decision, we are not persuaded that the preamble recitation of "[a] stent crimper comprising" is limiting as to any of the challenged claims. The preamble language merely provides a name to the claimed invention that describes a use for the invention, whereas the body of each claim describes a structurally complete invention. *See Catalina Mktg.*, 289 F.3d at 809. Accordingly, for purposes of this decision, "[a] stent crimper comprising" recited in the preamble of the challenged claims does not limit the claims beyond the complete structure set forth in the body of the claims.

2. "dies" and "blades"

Petitioner contends the term "dies" (appearing in claims 1, 10, 18, 37, 39, and 40) and the term "blades" (appearing in claim 27 and throughout the specification) mean the same thing and are interchangeable. Pet. 33 (noting that during examination "dies" were treated and corresponding to "blades). Patent Owner has not disputed Petitioner's contention. Prelim. Resp. 27 n.5. For purposes of this decision, we agree that the terms "dies" and "blades" are used interchangeably in the '560 patent, and determine no further express construction is required for purposes of this decision.

3. "stationary end-walls" and "stationary plates"

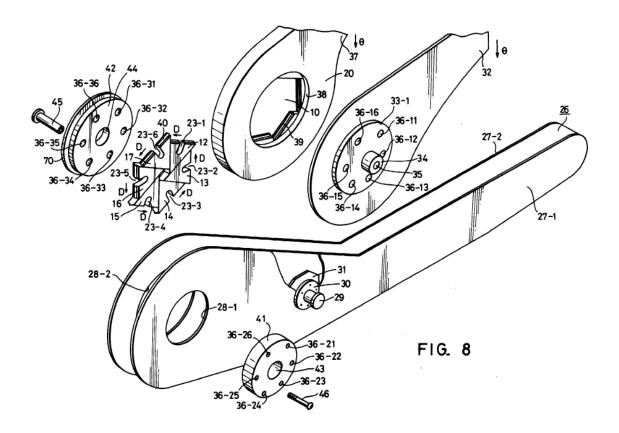
Petitioner contends the term "stationary end-walls" (appearing in claims 1, 10, 18, 27, and 37) and the term "stationary plates" (appearing in claim 40) both describe "stationary elements disposed about the longitudinal axis of an aperture formed by a plurality of movable dies or blades." Pet. 34. Petitioner further contends that, outside of the claims, the specification does not use either term or distinguish between them. *Id.* Patent Owner has not disputed that the terms are interchangeable. Prelim. Resp. 30 n.6. Patent Owner does, however, argue that Petitioner fails to provide any basis for equating claim terms "end-walls" and "plates" with the nonce word "elements." *Id.* at 29–30. We agree with Patent Owner that Petitioner fails to provide a sufficient explanation in support of its proposed construction and further determine that the term "stationary end-walls" and the term "stationary plates" are used interchangeably in the '560 patent but require no further express construction for purposes of this decision.

B. Asserted Obviousness Over Yasumi (Figure 8 Embodiment)
We understand Petitioner to contend that challenged claims 1, 2, 6, 8–
11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40 of the '560 patent would have been obvious over Yasumi, as taught in the embodiment of Figure 8. Pet. 44–100. Under this ground we do not view Petitioner's arguments as limited to the discussion of Figure 8 in Yasumi, but rather to encompass all that Yasumi discloses other than any disclosure pertaining only to another embodiment. Accordingly, we consider Petitioner's contentions based on Yasumi's explanation of features shown in Figures 3 and 10 as they relate to the Figure 8 embodiment, but we do not consider arguments asserted by Petitioner based on the embodiment of Figure 9(a).

1. Summary of Yasumi (Figure 8 Embodiment)

Yasumi, titled "Aperture Setting Device," issued June 19, 1984, generally describes a device "in which the size of a predetermined polygonal aperture can be changed, retaining the polygonal configuration," and is "made of a plurality of movable pieces each of which has a triangular section in a plane which includes an aperture and perpendicular to the axis thereof." Ex. 1103, 1:10–13, 1:46–49. According to Yasumi, the device described "would be of great utility when employed in such devices as a chuck, a press tool, an electric wire guide device, a drawing die, a control valve, and so forth." *Id.* at 1:35–39.

Figure 8 of Yasumi is reproduced below.



Yasumi Figure 8 illustrates an exploded perspective view of a manual forming and pressing tool embodying the invention described. *Id.* at 2:30–32. Fixed handle 26 is composed of parallel side plates 27-1 and 27-2 with circular holes 28-1 and 28-2. *Id.* at 7:39–46. Movable handle 37 includes frame 20 with mounted movable pieces 12 to 17. *Id.* at 7:46–52.

Frame 20 is illustrated in additional detail in Figures 3 and 10, reproduced below.

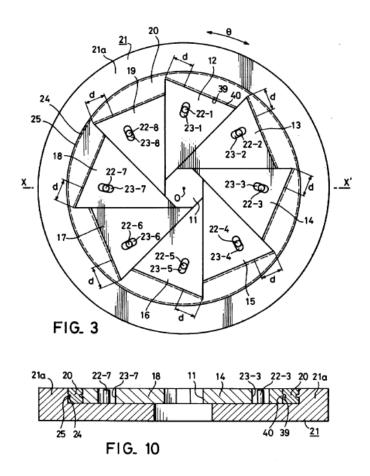


Figure 3 is a plan view illustrating the aperture setting device and Figure 10 is a sectional view of the same. Ex. 1103, 2:1–3, 2:39–40. As shown in Figures 3 and 10, guide groove 39 is cut in the inner peripheral surface of

frame 20, and each movable piece 12 to 19³ has elongated projection 40 which moves along guide groove 39 and prevents the movable pieces from getting out of frame 20. *Id.* at 5:39–57. Drive pins 22-1 to 22-8 are inserted in elongated holes 23-1 to 23-8 such that the drive pins drive the movable pieces 12 to 19 along frame 20 a distance "d" when frame 20 rotates relative to guide base 21, thereby varying the size of the regular polygon that forms aperture 11. *Id.* at 5:59–6:19.

With regard again to Figure 8, "movable handle 37 and the fixed handle 26 are designed so that they can turn about the axis of frame 20 relative to each other, and the movable pieces 12 to 17 are moved by the relative rotational movement of the handles 37 and 26." *Id.* at 7:63–68. Setting piece 32 for setting the opening of the apertures is interposed between frame 20 and side plate 27-1. *Id.* at 8:10–12. Support disks 41 and 42 are placed outside of side plates 27-2 and 27-1, respectively. *Id.* at 8:1–5. Screw 46 is screwed into the threaded hole of each pin 45 such that "the fixed handle 26, the movable handle 37 and the setting pi[e]ce 32 are coupled together, but the movable handle 37 is rotatable relative to the fixed handle 26." *Id.* at 8:38–45. In operation:

Bringing the grips of the fixed handle 26 and the movable handle 27 close to each other, the setting piece 32 also turns but butts against the fixed handle 26 when a set angle is reached, and further rotational movement of the setting piece 32 is limited, and consequently the pins 45 are fixed. Bringing the grips of the handles 26 and 37 closer to each other, the pins 45 move in the elongated holes 23-1 to 23-6 to move the movable pieces 12 to

_

³ In Figure 8, frame 20 includes only 6 movable pieces, 12 to 17, but the operation of the device appears to be substantially the same as that depicted in Figures 3 and 10, which illustrate 8 movable pieces.

IPR2017-00444 Patent 6,915,560 B2

17 in the frame 20, reducing the aperture defined by the movable pieces 12 to 17.

Id. at 8:45–54.

2. *Claim 1*

Petitioner provides a claim chart identifying how it contends Yasumi teaches each limitation of claim 1 based on the embodiment shown in Figure 8 of Yasumi. Pet. 51–58. With regard to the preamble of claim 1, Petitioner states that it is not limiting, as discussed above, but also contends that Yasumi discloses "a manual forming and pressing tool" which is capable of crimping a stent illustrated in Figure 8 of Yasumi. *Id.* at 51; Ex. 1103 2:30–32. According to Petitioner, Yasumi movable pieces 12-19 correspond to the claimed "plurality of movable dies" disposed about an aperture, and side plates 27-1 and 27-2 correspond to the claimed "stationary end-walls." *Id.* at 51–53. Petitioner asserts that the movable pieces of Yasumi also correspond to the claimed converging first and second straight sides. *Id.* 57–58.

Having reviewed the record, we determine that the information presented establishes a reasonable likelihood that Petitioner would prevail in showing that the subject matter of claim 1 of the '560 patent would have been obvious over Yasumi based on the embodiment shown in Figure 8 of Yasumi. At this stage of the proceeding, the primary issue over whether Petitioner has sufficiently shown how Yasumi discloses each feature of claim 1 focuses on the limitation: "at least one of the stationary end-walls operatively engaged to the dies at distinct connection locations such that the number of distinct connection locations and the number of dies are the same." According to Petitioner:

In Figure 8, each movable piece has one elongated hole that engages the piece to the wide-end portions of the fixed handle

IPR2017-00444 Patent 6,915,560 B2

side plates 27-1 and 27-2 via support disks 42 & 43, drive pins 45, screws 46, and setting piece 32. The six elongated holes are the six distinct connection locations that operatively engage the six dies to the stationary end-walls.

Pet. 55–56 (citing Ex. 1103, 8:1–54). Petitioner's contentions are supported by Mr. Sheehan, though with little additional elaboration beyond what is provided in the Petition. *See* Ex. 1105 ¶¶ 122, 125.

Patent Owner argues that:

Petitioner has not demonstrated that the alleged stationary end-walls are "operatively engaged" to the dies as the claims require. For example, contrary to Petitioner's assertion, there is no evidence that, in Figure 8, the side plates 27-1 and 27-2 are operatively engaged to the moving pieces 12 to 17 (or operatively engaged to these moving pieces through the frame 20, the support discs 41 and 42, or the setting piece 32). (Ex. 1103 at 7:52–57, 8:28–54.)

Prelim. Resp. 32–33. Patent Owner's argument is not persuasive on the present record because Petitioner does provide evidence supporting its contentions, including citations to Yasumi and Mr. Sheehan's declaration. Moreover, as noted above, Yasumi states that "the movable pieces 12 to 17 are moved by the relative rotational movement of the handles 37 and 26," and handle 26 is comprised of side plates 27-1 and 27-2. Ex. 1103, 7:66–68. From this, Yasumi appears to support Petitioner's contention that the side plates are "operatively engaged" to the movable pieces as required by claim 1. On the present record we are persuaded that Petitioner has sufficiently shown how it contends Yasumi teaches the "operatively engaged" limitation of claim 1 to support institution.

In support of its assertion that Yasumi renders claim 1 obvious, Petitioner contends, *inter alia*, that the aperture setting device it discloses, if not specifically directed to "a stent crimper," was not limited to certain applications and was expressly directed to a manual forming and pressing tool. Pet. 82. According to Petitioner, as supported by Mr. Sheehan, a person of ordinary skill would recognize that a manual forming and pressing tool is another term for a crimper, and that such a device could be applied to suitable crimping applications, including to stents. *Id.* at 82–83; Ex. 1105 ¶¶ 109, 126. Petitioner further contends that benefits associated with the device of Yasumi, such as uniformity of crimping, would have motivated its use in applications including stent crimping. *Id.* at 83–84.

Patent Owner advances arguments challenging the obviousness ground over Yasumi based both on a lack of motivation to combine and the absence of a reasonable expectation of success. Prelim. Resp. 34–44. For example, according to Patent Owner, Petitioner: (1) fails to provide evidence that a manual forming and pressing tool is another term for a crimper; (2) fails to explain why a skilled artisan would have been "motivated to look to Yasumi in the first place"; (3) fails to explain why a skilled artisan "attempting to improve crimping an expandable stent" would be interested in how to crimp other materials such as an electrical connector onto a wire or the end of a tube; (4) fails to explain why a skilled artisan "would be interested in the forming and pressing tool [of Yasumi] where a solid electric wire is pressed and reshaped with no regard to distortion or marking"; and (5) fails to demonstrate that a skilled artisan would have had a reasonable expectation of success since Yasumi is designed to operate on an electric wire involving large pressures, not a tubular stent. *Id*.

We have considered Patent Owner's arguments but are persuaded that Petitioner has provided a sufficient basis for obviousness of claim 1 over Yasumi based on the current record.⁴ We understand Petitioner's contention to be that Yasumi discloses all of the features of claim 1, and that, although the preamble recitation of a "stent crimper" is not limiting, it would have been obvious to use the device of Yasumi as a stent crimper based on the reasons provided by Petitioner, including the identified benefits of Yasumi. Accordingly, the information provided by Petitioner shows a reasonable likelihood of prevailing in showing that claim 1 of the '560 patent would have been obvious over Yasumi based on the embodiment shown in Figure 8 of Yasumi.

3. Claims 2, 6, 8–11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40

Petitioner provides claims charts and argument identifying how it contends claims 2, 6, 8–11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40 of the '560 patent would have been obvious over Yasumi, as taught in the embodiment of Figure 8. Pet. 58–100. Patent Owner disputes Petitioner's contentions with regard to these additional claims for the same reasons

⁴ Patent Owner also contends that institution should be declined under 35 U.S.C. § 325(d) because the same or substantially the same prior art or arguments were presented both during prosecution and in a previous petition for *inter partes* review. Prelim. Resp. 13–25. Although alleged Applicant Admitted Prior Art would have been before the Office previously, as discussed above, in this case not every ground asserted by Petitioner rests on alleged Applicant Admitted Prior Art. Petitioner contends that Yasumi was not considered during prosecution. Pet. 38. Petitioner also contends that Morales was not considered during examination, but Patent Owner argues that Morales was submitted on an Information Disclosure Statement and initialed by the Examiner. Pet. 47; Prelim. Resp. 25. We have considered Patent Owner's arguments and decline to exercise our discretion under 35 U.S.C. § 325(d) to deny the Petition under the specific circumstances presented.

asserted with respect to claim 1. Prelim. Resp. 31–44. For the reasons set forth above, Petitioner has demonstrated a reasonable likelihood that claim 1 of the '560 patent would have been obvious over Yasumi, as taught in the embodiment of Figure 8. Having decided that the asserted obviousness over Yasumi 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 all challenged claims 2, 6, 8–11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40 as obvious over Yasumi, as taught in the embodiment of Figure 8. *See Intex Recreation Corp. v. Bestway Inflatables & Material Corp.*, IPR2016-00180, Paper 13, at 8–11 (PTAB June 6, 2016).

C. Asserted Obviousness Over Yasumi (Figure 8 Embodiment) and Morales

Petitioner contends claims 11, 17, 19, 26, 34, 35, and 39 would have been obvious over Yasumi, as taught in the embodiment of Figure 8, and Morales. Pet. 85–95. Patent Owner has not separately disputed Petitioner's contentions based on Morales, but instead argues that because Petitioner's contentions based on Yasumi are insufficient, Petitioner's asserted combination with Morales fails for the same reasons. Prelim. Resp. 44.

1. Summary of Morales

Morales, titled "Stent Crimping Tool and Method of Use," issued April 13, 1999, and describes a "stent crimping tool for firmly and uniformly crimping a conventional or radioactive stent onto a balloon catheter." Ex. 1104, Abstract.

Figure 1 of Morales is reproduced below.

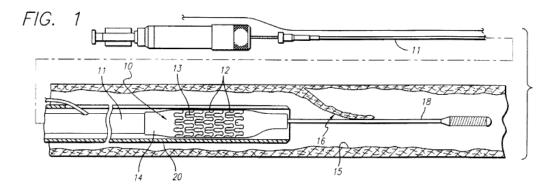
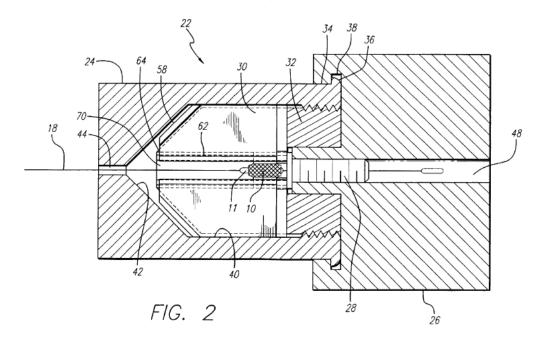


Figure 1 illustrates intravascular stent 10, comprised of radially expandable cylindrical elements 12 interconnected by members 13, mounted onto deliver catheter 11 with balloon 14 for expanding stent 10 within coronary artery 15. Ex. 1104, 5:60–67. "Stent 10 is crimped down onto balloon 14 to ensure a low profile," and the invention of Morales "addresses this crimping procedure." *Id.* at 6:24–25.

Figure 2 of Morales is reproduced below.



IPR2017-00444 Patent 6,915,560 B2

Figure 2 illustrates a sectional view of stent crimping tool 22 comprised of proximal section 24, teeth 30, collar 32, screw feed 28, and distal section 26. *Id.* at 6:67–7:3. Morales further explains that:

As screw feed 28 advances toward proximal section 24, it carries forward teeth 30 so that angular proximal edges 58 of each tooth 30 encounters tapered end 42, which in turn forces teeth 30 to converge radially inward. As this convergence occurs, radius edges 62 of teeth 30 engage and crimp the underlying stent 10 onto balloon catheter 11. Teeth 30 thus act as jaws closing down on stent 10. The mandrel optionally loaded into delivery catheter 11 prevents the crimping process from overly compressing stent 10 onto catheter 11.

Ex. 1104, 8:58–67.

2. Claims 11, 19, and 35

Claims 11, 19, and 35 each recite "wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter." Ex. 1101 10:58–60, 11:27–29, 12:7–9. Petitioner contends that Morales discloses stent 10 disposed about balloon 14, the balloon disposed about a delivery catheter 11. Pet. 92–93 (citing Ex. 1104 Fig. 1).

3. Claims 17, 26, and 34

Claims 17, 26,⁵ and 34 each recite "wherein an entire stent is disposed in the aperture." Ex. 1101 11:5–6, 11:42–43, 12:5–6. Petitioner contends that Morales discloses an entire stent 10 disposed within an aperture formed by dies 30. Pet. 94.

4. Claim 39

Petitioner contends that "[c]laim 39 recites limitations substantially similar to those previously recited in [c]laim 1, but adds limitations directed

⁵ We understand the recitation in claim 26 of an "entire stout" is intended to instead recite an "entire stent."

to an aperture 'having a center and a first opening and a second opening,' and 'the dies constructed and arranged to have a length exceeding the length of a stent with a longitudinal axis passing through both the first opening and the second opening.'" Pet. 85. Petitioner further contends that Morales "discloses an aperture (between teeth 30) having a center and a first opening and a second opening," as well as "dies (teeth 30) constructed and arranged to have a length exceeding the length of a stent," as required by claim 39. *Id.* at 88–90.

Petitioner further argues that the combination of Morales with Yasumi would have been obvious because the device of Yasumi was capable of crimping a stent, and a person of skill in the art "would have known that crimping a stent over a balloon catheter is the intended purpose for a stent crimper" and "would have known the desirability of crimping the stent evenly, and, thus, it would have been obvious to make the length of the dies exceed the length of the stent to ensure that the entire stent fit easily within the aperture, provide a margin of error so that no portion of the stent would be missed during the crimping procedure, and to account for manufacturing tolerances." Pet 86, 92–94 (citing, *inter alia*, Ex. 1105 ¶¶ 163, 168, 172–175). The information provided by Petitioner shows a reasonable likelihood of prevailing in showing that claims 11, 17, 19, 26, 34, 35, and 39 of the '560 patent would have been obvious over Yasumi based on the embodiment shown in Figure 8 of Yasumi in combination with Morales.

D. Additional Asserted Grounds of Unpatentability

The patent rules promulgated for AIA post-grant proceedings, including those pertaining to institution, are "construed to secure the just, speedy, and inexpensive resolution of every proceeding." 37 C.F.R.

§ 42.1(b); *see also* 35 U.S.C. § 316(b) (regulations for AIA post-grant proceedings take into account "the efficient administration of the Office" and "the ability of the Office to timely complete [instituted] proceedings"). Therefore, we exercise our discretion and do not institute a review of claims 1, 2, 6, 8–11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40 as obvious over the following combinations: (1) Yasumi (Figure 8 embodiment) and alleged "Applicant Admitted Prior Art"; (2) Yasumi (Figure 8 embodiment) and Yasumi (Figure 9(a) embodiment); or (3) Yasumi (Figure 8 embodiment), Yasumi (Figure 9(a) embodiment), and alleged "Applicant Admitted Prior Art." For the same reason we also do not institute a review of claims 11, 17, 19, 26, 34, 35, and 39 as obvious over the combination of Yasumi (Figure 8 embodiment), Yasumi (Figure 9(a) embodiment), and Morales. *See* 37 C.F.R. § 42.108(a).

Our decision to decline institution on these additional grounds is further supported by additional considerations. With regard to any ground based on the Figure 9a embodiment of Yasumi, Petitioner's arguments are duplicative to its arguments based on the Figure 8 embodiment of Yasumi. Additionally, unlike the ground based on the Figure 8 embodiment of Yasumi, Petitioner fails to show how the Figure 9a embodiment of Yasumi, alone, make obvious every element of any challenged claim. Petitioner also fails to address whether any rationale supports the combination of the two embodiments. *See, e.g.*, Pet. 54–57 (asserting that the embodiment shown in Figure 9(a) of Yasumi also teaches the claimed "movable dies" and "stationary end-walls" taught by the embodiment shown in Figure 8 of Yasumi).

With regard to the alleged "Applicant Admitted Prior Art," Petitioner primarily contends that it "also discloses the preamble 'stent crimper'" or features of a "stent crimper." Pet. 50–51, 85–94. Patent Owner argues that "Petitioner has not established that any aspect of the alleged AAPA constitutes a prior art patent or printed publication." Prelim. Resp. 8. The alleged Applicant Admitted Prior Art is duplicative and unnecessary to many of Petitioner's grounds. As discussed above, to the extent the preamble is not limiting, alleged "Applicant Admitted Prior Art" is not needed to explicitly show a 'stent crimper' recited in the preamble. Even if the preamble were limiting, Petitioner contends that Yasumi discloses a "stent crimper" even if it is not called a "stent crimper" in Yasumi, and that Yasumi and Morales disclose the recited features of a "stent crimper." *Id.* Thus, Petitioner's contentions are sufficiently based on prior art consisting of Yasumi, alone or with Morales. Accordingly, only those grounds identified in the Order below are instituted in this proceeding.

IV. CONCLUSION

For the foregoing reasons, we determine that Petitioner has established a reasonable likelihood of prevailing on its assertion that the challenged claims of the '560 patent are unpatentable based on the asserted grounds identified in the order below. The Board has not made a final determination on the patentability of any challenged claim.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that *inter partes* review is *instituted* in IPR2017-00444 with respect to the following grounds of unpatentability:

claims 1, 2, 6, 8–11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40 as obvious over Yasumi, as taught in the embodiment of Figure 8, under 35 U.S.C. § 103(a),

claims 11, 17, 19, 26, 34, 35, and 39 as obvious over Yasumi, as taught in the embodiment of Figure 8, and Morales 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; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter* partes review of the '560 patent is hereby instituted in IPR2017-00444 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.

IPR2017-00444 Patent 6,915,560 B2

PETITIONER:

Craig S. Summers

2css@knobbe.com

Brenton R. Babcock

2brb@knobbe.com

Christy G. Lea

2cgl@knobbe.com

Cheryl T. Burgess

2ctb@knobbe.com

PATENT OWNER:

Wallace Wu
Wallace.Wu@aporter.com
Jennifer A. Sklenar
Jennifer.Sklenar@aporter.com
Nicholas Nyemah
Nicholas.nyemah.aporter.com