Trials@uspto.gov
571.272.7822

Paper No. 42
June 28, 2018

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*.

FINAL WRITTEN DECISION
Inter Partes Review
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

We have jurisdiction to hear this *inter partes* review under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Having considered the record before us and for the reasons discussed below, we determine Petitioner has shown by a preponderance of the evidence that claims 10, 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") are unpatentable. *See* 35 U.S.C. § 316(e). We also deny Patent Owner's Motion to Exclude.

A. PROCEDURAL HISTORY

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 the '560 patent (the "challenged claims"). Boston Scientific Scimed, Inc. ("Patent Owner") filed a Preliminary Response (Paper 7, "Prelim. Resp.").

Pursuant to 35 U.S.C. § 314(a), we determined the Petition showed a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of the challenged claims and instituted *inter partes* review of the '560 patent on all of the challenged claims. Paper 9 ("Inst. Dec."). After institution, Patent Owner filed a Patent Owner Response. Paper 15 ("PO Resp."). Petitioner filed a Reply to Patent Owner's Response. Paper 17; Paper 18 (publicly available redacted version of the Petitioner Reply) ("Pet. Reply").

Patent Owner also filed a Motion to Exclude expert testimony and reply arguments (Paper 25, "PO Mot."), to which Petitioner provided a

Response in opposition (Paper 31, "Pet. Resp."), further to which Patent Owner provided a reply in support (Paper 32, "PO Reply").

Oral argument was held before the Board on March 15, 2018. Paper 37 ("Tr.").[1] On April 24, 2018, the Supreme Court held in *SAS Inst., Inc. v. Iancu* that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. 138 S. Ct. 1348 (2018). As noted above, prior to *SAS* we had instituted review on all of the challenged claims. Inst. Dec. at 31. Further, after *SAS*, we issued an order directing the parties to meet and confer to determine whether any additional briefing and modification of the schedule was desired in light of *SAS*. Paper 38. We also stated that "[t]he parties should discuss whether they seek to include the institution of additional grounds from the Petition into this proceeding." *Id.* at 3. In response, the parties informed the Board that "[n]either party seeks to include the institution of additional grounds from the Petition" and that "the parties agree that no further briefing or changes to the schedule are necessary." Paper 39; Ex. 3001.

We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

[1] Prior to the oral argument, Patent Owner filed Objections (Paper 34) to the demonstrative exhibit filed by Petitioner. The objections of Patent Owner generally relate to allegations that certain demonstrative exhibits improperly contain new evidence and argument. *See id.* Demonstrative exhibits are not evidence. In this Final Written Decision, we rely directly on the arguments presented properly in the briefs of the parties and the evidence of record, not on demonstrative exhibits; therefore, the objections of Patent Owner are overruled.

B. RELATED MATTERS

According to the parties 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.

C. REAL PARTIES IN INTEREST

Petitioner Edwards Lifesciences Corporation is identified as a real party in interest in this case. Pet. 14. Patent Owner Boston Scientific Scimed, Inc. and Boston Scientific Corp. are also identified as real parties in interest. Paper 4, 2.

II. BACKGROUND

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. As background information, below we provide a summary of the '560 patent, along with an illustrative claim from the '560 patent, and we identify the instituted grounds of unpatentability and the proffered expert testimony. We also address our reasons for denying the Motion to Exclude.

A. SUMMARY OF THE '560 PATENT

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 the crimping." Ex. 1101, 2:26–29.

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

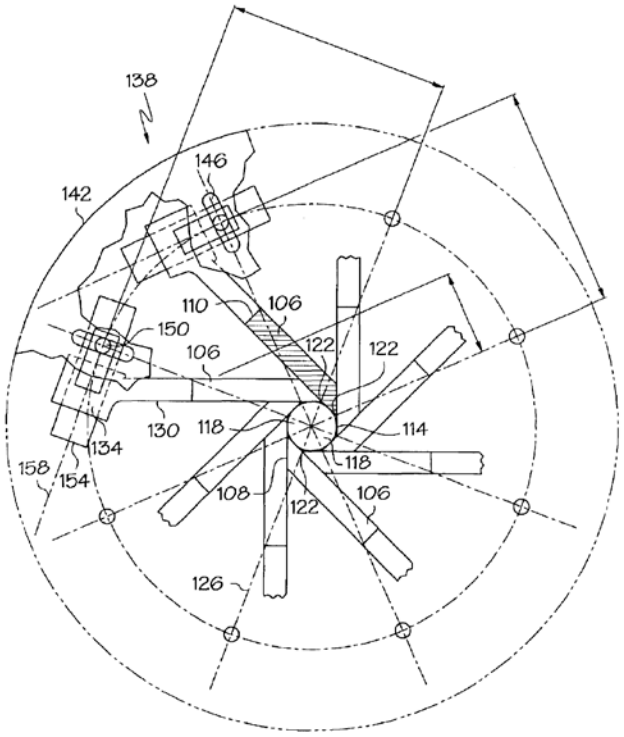


FIG. 4A

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. “In use, as actuation plate 142 is rotated in a clockwise direction, the clockwise motion of the actuation plate is translated into linear motion of each of linear slide 154 and blade 106 via bearing 150.” *Id.* at 5:46–49. “Each blade 106 moves outward in a direction parallel to the radius 126 on which the radial point 122 of the blade 106 lies, resulting in the opening of

aperture 118." *Id.* at 5:49–52. Conversely, as actuation plate 142 is rotated in a counterclockwise direction, each blade 106 moves inward, resulting in the closing of aperture 118." *Id.* at 5:52–56. "As aperture 118 closes, a radially inward force is applied to a medical device disposed in the aperture." *Id.* at 5:56–57.

Figures 8a and 8b are reproduced below.

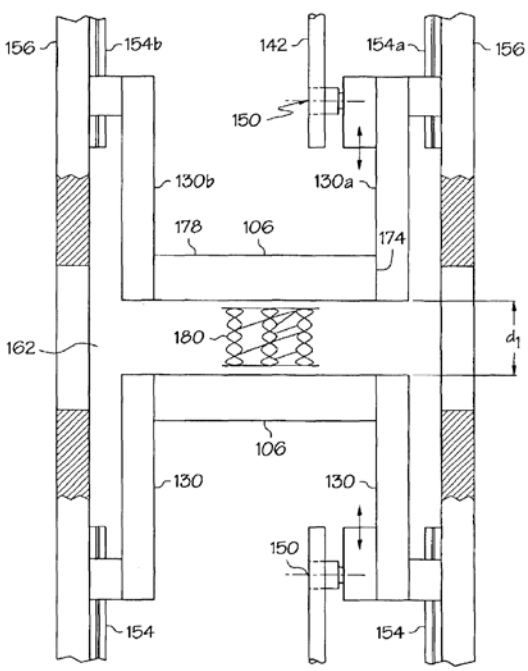


FIG. 8a

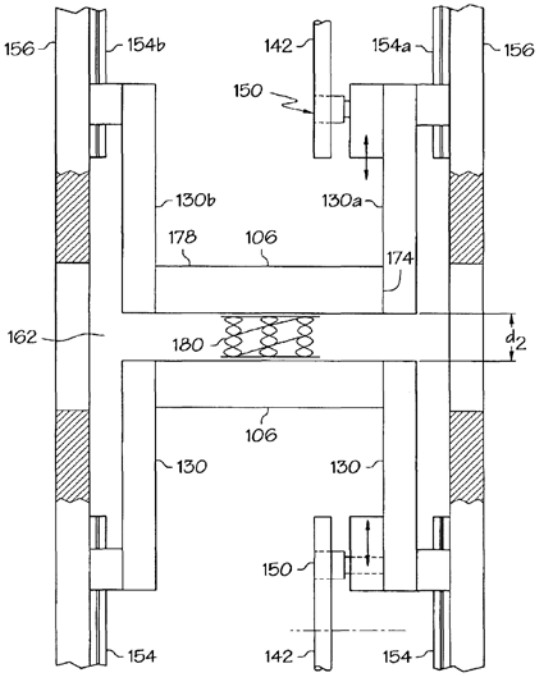


FIG. 8b

Figures 8a and 8b "are partial side elevational views of an embodiment of the inventive apparatus taken along a radial plane during the size reduction process." *Id.* at 4:14–16. In this embodiment, non-rotating plates 156 are at each end. *Id.* at 7:10–12. First end 174 of each blade 106 is connected to linear slide 154a via connecting link 130a and second end 178 is connected to linear slide 154b via connecting link 130b. *Id.* at 7:12–14. "Linear slide 154*a* is mounted on non-rotating plate 156*a* and linear slide 154*b* is mounted on non-rotating plate 156*b*." *Id.* at 7:15–16. Figure 8a illustrates stent 180

in tubular aperture 162. *Id.* at 7:23–24. Figure 8b illustrates blades 106 having moved inward by rotating actuation plate 142, thereby reducing the diameter of aperture 162 and, accordingly, the diameter of stent 180. *Id.* at 7:25–31.

According to the ’560 patent, the invention is “particularly concerned with the crimping and otherwise reducing in size of inflation expandable stents, self-expanding stents and other expandable medical devices.” *Id.* at 2:31–34; *see also id.* at 2:50–55 (“[T]he inventive apparatus may also be employed with any other suitable, generally tubular medical device which must be reduced in size.”). Moreover, according to the ’560 patent, “[t]he inventive apparatus may also be incorporated into a blow molding tool to provide a variable size balloon mold” and “[t]he invention is also directed to a method for molding a medical balloon.” *Id.* at 8:65–67, 9:10–12.

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. INSTITUTED GROUNDS OF UNPATENTABILITY

We instituted *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 the '560 patent on the following grounds of unpatentability asserted in the Petition:

References	Basis	Claims challenged
Yasumi[2] (Fig. 8 embodiment)	§ 103	1, 2, 6, 8–11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40
Yasumi (Fig. 8 embodiment) and Morales[3]	§ 103	11, 17, 19, 26, 34, 35, and 39

Inst. Dec. 25.

D. PROFFERED EXPERT DECLARATIONS

Petitioner supports its challenge with the Declaration of Neil Sheehan, dated December 5, 2016 (Ex. 1105), and the Supplemental Declaration of Neil Sheehan, dated December 14, 2017 (Ex. 1127). Mr. Sheehan is a "consulting engineer in the field of medical products" and states that he has "worked extensively in the areas of catheters, balloons, plastic and metallic materials (including nitinol), inferior vena cava filters, vascular access, syringes, pumps, tubing, bonding methods and the like." Ex. 1105 ¶¶ 1–3. Mr. Sheehan also states that he has "over 40 years of experience in medical device design and development." *Id.* at ¶ 5.

Patent Owner's opposition relies on the Declaration of Ronald J. Solar, Ph.D., dated September 22, 2017 (Ex. 2016). Dr. Solar is the President of Renaissance Biomedical, Inc., which he states "performs research and consultation in technical, marketing, commercialization, patent, clinical, and regulatory issues related to the medical device industry," and he

[2] U.S. Patent No. 4,454,657, issued June 19, 1984 (Ex. 1103, "Yasumi").
[3] U.S. Patent No. 5,893,852, issued April 13, 1999 (Ex. 1104, "Morales").

is also the President and CEO of ThermopeutiX, Inc., which he states is "a company which designs, develops, manufactures, and sells vascular catheter technology and devices, including coronary, peripheral and neuro-vascular catheters and related medical devices." *Id.* at ¶ 1. Dr. Solar states that he has over thirty years of experience working in "researching and developing coronary and peripheral vascular medical devices including balloon catheters and stents." *Id.* at ¶ 3.

In our consideration of the expert testimony, Patent Owner argues that Mr. Sheehan's declaration is "entitled to little or no weight because he lacks experience in the relevant technologies." PO Resp. 13–16. Patent Owner states that Mr. Sheehan "has never developed a stent," "has no relevant publications," and no "relevant experience in stent crimping." *Id.* at 13–14. In comparison, Patent Owner asserts that its expert has at least twenty "patents, publications, and presentations specifically relate[d] to stents or stent crimpers." *Id.* at 15. Patent Owner argues that "to the extent that there is any disagreement between Mr. Sheehan and [Patent Owner's expert], the Board should give less or no weight to Mr. Sheehan's opinions." *Id.*

Patent Owner fails to provide a persuasive justification for why the fact that Mr. Sheehan has never developed a stent or personally crimped a stent requires that Mr. Sheehan's testimony be given "little or no weight." Patent Owner also has not shown that Mr. Sheehan lacks credibility or that his opinions are not based on relevant evidence. We, therefore, determine that Patent Owner has not shown that Mr. Sheehan's opinions are entitled to little or no weight relative to the opinions of Dr. Solar.

Patent Owner also argues that Mr. Sheehan's declaration is entitled to little or no weight because he "repeatedly relies on unsupported, conclusory

assertions—rather than credible evidence." PO Resp. 16. We have considered the opinions expressed by both of the experts in this case and accord the appropriate weight to each of their opinions based on whether the opinion is credible and whether it is supported by credible evidence.

E. MOTION TO EXCLUDE

Patent Owner filed a Motion to Exclude the Supplemental Declaration of Neil Sheehan (Ex. 1127) and Petitioner's Reply (Papers 17 and 18) "for including new claim construction issues and arguments raised for the first time in Petitioner's [R]eply." Paper 25, 2. According to Patent Owner, the Supplemental Declaration of Neil Sheehan includes the construction of the claim terms "operatively engaged" and "distinct connection locations," both raised for the first time in Petitioner's Reply. *Id.* at 4. Patent Owner asserts that the Declaration and Reply "make new arguments on how the elements of the instituted claims of the '560 patent are found in the prior art reference." *Id.* at 4–5. Patent Owner also contends that by waiting to raise the new claim constructions and arguments in its Reply for the first time, Petitioner denied "Patent Owner the opportunity to respond." *Id.* at 5–6. Patent Owner, however, did not request an opportunity to either file a Surreply to Petitioner's Reply or to provide additional briefing concerning the alleged new claim constructions. Tr. 23:21–24:1.

In opposition to the Motion, Petitioner argues that a motion to exclude is an improper mechanism to argue that a reply brief contains new arguments and evidence, that the arguments in the reply are directly responsive to issues first presented in the Patent Owner Response, and that Petitioner did not apply "new" claim constructions. Paper 31, 1.

In reply to the opposition, Patent Owner argues that in one non-precedential case a panel of the Board found a motion to exclude moot, and in another non-precedential case a panel of the Board granted a motion to exclude an expert declaration for exceeding the scope of a reply. Paper 32, 1–2. Patent Owner further argues that it did not propose constructions for "operatively engaged" or "distinct connection locations" in its Patent Owner Response, but instead argued the asserted art does not disclose the claimed features. *Id.* at 2–3. Patent Owner further argues that Mr. Sheehan stated in his first declaration that claim terms were given their plain and ordinary meaning, but did not provide the constructions for "operatively engaged" or "distinct connection locations" given in his Supplemental Declaration. *Id.* at 3–4. Patent Owner also argues *for the first time* in its Reply that the brief and declaration it seeks to exclude amounts to a "new invalidity theory." *Id.* at 4–5.

Patent Owner fails to demonstrate that it is entitled to the relief it seeks. *See* 37 C.F.R. 42.20(c) ("The moving party has the burden of proof to establish that it is entitled to the requested relief."). First, a motion to exclude deals with the admissibility of evidence under the Federal Rules of Evidence. *See* 37 C.F.R. §§ 42.62 (applying the Federal Rules of Evidence to *inter partes* reviews), 42.64; Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,758 (August 14, 2012) ("Admissibility of evidence is generally governed by the Federal Rules of Evidence."). As stated in the Office Patent Trial Practice Guide, the parties may submit motions to exclude regarding evidence "believed to be inadmissible." Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,758. Further, a motion to exclude "must explain why the evidence is not admissible (*e.g.*, relevance or

hearsay)." *Id.* at 48,767. Patent Owner has made no showing that the Supplemental Declaration or Petitioner's Reply are inadmissible. We further agree with prior panels of the Board, which have determined under similar circumstances that a "motion to exclude evidence filed for the purpose of striking or excluding an opponent's brief and/or evidence that a party believes goes beyond what is permitted under 37 CFR § 42.23 is improper." *Palo Alto Networks, Inc. v. Finjan Inc.*, Case IPR2015-01979, Paper 62, 66 (PTAB Mar. 15, 2017) (stating that an "allegation that evidence does not comply with 37 CFR § 42.23 is not a sufficient reason under the Federal Rules of Evidence for making an objection and requesting exclusion of such evidence"); *see also Blackberry Corp. v. Zipit Wireless, Inc.*, Case IPR2014-01508, Paper 49, 40 (PTAB Mar. 29, 2016) ("a motion to exclude is not a proper vehicle for a party to raise the issue of arguments exceeding the permissible scope of a reply").

Second, even if the motion were proper, under Patent Owner's line of reasoning Petitioner should be precluded from providing a reply or supplemental declaration that addressed the meaning of the claim terms at issue even though Patent Owner argued the corresponding element is not disclosed in the prior art, because (1) Patent Owner declined to expressly construe the term at issue in the Patent Owner Response, and (2) Petitioner did not expressly construe the term in the Petition, but instead relied on its "plain and ordinary meaning." Thus, Patent Owner could select any claim term not expressly construed in the Petition, provide no meaning for the term, assert it is not disclosed in the asserted reference, and, thereafter, exclude virtually any reply from Petitioner addressing the meaning of the term. We find such an approach untenable as there is no requirement that

every claim term be defined expressly in the Petition. Nor are we persuaded that Petitioner's further explanation of the plain and ordinary meaning of a claim term through a reply amounts to a new invalidity theory. Even if the Patent Owner declined to provide an express definition of a claim term in the Patent Owner Response, by arguing the feature was missing from the prior art, Patent Owner was necessarily applying an implicit meaning to the claim term in this case, and Petitioner was entitled to reply to this implicit construction in its Reply, with the support of a supplemental declaration. Thus, we find the Supplemental Declaration of Mr. Sheehan and Petitioner's Reply do not exceed the proper scope provided by our rules. *See* 37 CFR § 42.23. Patent Owner's Motion to Exclude is denied.

III. ANALYSIS

In our analysis of whether Petitioner has sufficiently shown that the subject matter of the challenged claims of the '560 patent would have been obvious over the asserted prior art, we next address the applicable principles of law; the construction of certain claim terms; the scope and content of the asserted prior art of Yasumi and Morales; the differences between the claimed subject matter and the asserted prior art; the level of ordinary skill in the art; the objective evidence of nonobviousness; and, finally, the reasons supporting obviousness.

A. PRINCIPLES OF LAW

To prevail in its challenge to the patentability of claims 1, 2, 6, 8–11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40 of the '560 patent, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). In an *inter partes* review, "[a] claim in an unexpired patent . . . shall be given its broadest reasonable

construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (upholding the use of the broadest reasonable interpretation standard). In determining the broadest reasonable construction, we presume that claim terms carry their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). A patentee may define a claim term in a manner that differs from its ordinary meaning; however, any special definitions must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

A patent claim is unpatentable as obvious under 35 U.S.C. § 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." 35 U.S.C. § 103(a). An invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Rather, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.*

An obviousness determination "cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)); *see In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir.

2016). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

B. CLAIM CONSTRUCTION

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 Mktg. Int'l, 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 "the inventor of the '560 patent was working on the particular problem of crimping a stent," the word "stent" appears in the title of the patent, the invention is directed to "a device capable of crimping a stent," and the specification states that "'crimping' refers to a reduction in size or profile of a stent." PO Resp. 17–23 (citing, e.g., Ex. 1101, 1:48–56, 2:26–29, 2:6–38). Thus, according to Patent Owner, the preamble breathes "life and meaning" into the claimed invention and is, therefore, limiting. PO Resp. 20 (citing *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257

(Fed. Cir. 1989); *Gen. Elec. Co. v. Nintendo Co., Ltd.*, 179 F.3d 1350, 1361 (Fed. Cir. 1999)).

We agree with Petitioner that the preamble recitation of "[a] stent crimper comprising" is not 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. Because "the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states . . . the purpose or intended use of the invention, . . . the preamble is of no significance to claim construction." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999), citing *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997); *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989); *Kropa v. Robie*, 187 F.2d 150, 152 (CCPA 1951).

Moreover, contrary to Patent Owner's arguments, the '560 patent makes clear that the claimed invention is not intended to be limited to a stent crimper. As Petitioner notes, "the specification provides broad disclosure of multiple alternative applications for the invention," including manipulating other medical devices and as a balloon mold. Pet. Reply. 7–8 (citing Ex. 1101, 2:48–55, 3:14–22, 3:36–37, 8:65–9:62, Figs. 12, 13); Ex. 1101, 2:48–55, 3:16–21, 3:36–37, 8:65–9:62, Figs. 12, 13.

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. PO Resp. 21 n.3. Further, Patent Owner argues that if the preamble is limiting in unchallenged claim 36, "it should be the

same for all claims of the ’560 patent.” *Id.* Petitioner contends in reply that Patent Owner’s argument is contrary to *Catalina Marketing* because in that case preamble language was limiting where it appeared in both the preamble and body of the claim, but not limiting for other claims where it appeared only in the preamble. Pet. Reply 8–9 (citing *Catalina Mktg.*, 289 F.3d at 808–11).

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 that the preambles of all other claims are limiting in the same manner that the preamble of claim 36 may be. We, therefore, need not resolve whether the preamble of claim 36 is limiting, and reject Patent Owner’s contention that the same preamble of all claims of the ’560 patent are limiting based on the preamble of claim 36. Accordingly, “[a] stent crimper comprising,” as 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 agrees the terms are used interchangeably and do not require express construction. PO Resp. 24n.5. We agree that the terms “dies” and “blades” are used interchangeably in the ’560 patent and determine no further express construction is required.

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 agrees the terms are used interchangeably and contends they do not require express construction. PO Resp. 24 n.5.

We agree that the terms are used interchangeably in the '560 patent. We further find Petitioner's proposed construction duplicative to the claim language and, therefore, unhelpful. *See, e.g.*, Ex. 1101, 10:9–13 (claim 1 reciting "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").

4. "operatively engaged"

Claim 1 recites "at least one of the stationary end-walls operatively engaged to the dies." Claims 18, 37, and 40 contain similar recitations. "Operatively engaged" does not appear in the specification of the '560 patent outside of the claims.

In the Petition, Petitioner identifies how it contends Yasumi discloses the "operatively engaged" limitation, but does not offer an express definition of the term. Pet. 56, 57, 69, 76, and 79. Patent Owner argues in its response that Yasumi does not disclose the "operatively engaged" limitations. PO Resp. 25–27. Patent Owner does not provide an express construction for

"operatively engaged," but instead argues: "there is no evidence that the movable pieces, the support discs, or the setting piece is affixed to any side plate." *Id.* at 27. During oral argument, Patent Owner similarly explained that it had not proposed a definition for "operatively engaged," but that "[a]ffixing is one example of operatively engaged," but "not the only example," as "[y]ou could have an indirect connection." Tr. 24:18–25:12.

In its Reply, Petitioner contends the claims do not require dies "directly engaged or affixed to a stationary end-wall." Pet. Reply 2. Petitioner does not propose an express definition of "operatively engaged" in its Reply, but suggests that if certain elements relied on from Yasumi "were not operatively engaged," then the device would not work. Pet. Reply 14. In support of Petitioner's contentions, Mr. Sheehan explains in his supplemental declaration that applying "the ordinary and customary meaning," "[o]peratively engaged simply means engaged in a way that furthers the operation, or that the engagement produces the intended effect." Ex. 1127 ¶ 32. Patent Owner asserted at oral argument that the construction provided by Petitioner was "way too broad" because it would lead to everything in Figure 8 of Yasumi being "operatively engaged with each other." Tr. 24:2–14.

To the extent Petitioner's proposal divorces the recited "engaged" from the "operation" of the apparatus, we agree the meaning would be too broad. However, we discern little substantive difference in the arguments made by both parties with regard to what "operatively engaged" encompasses, even if they dispute the full scope of the meaning of the term. There is no reasonable dispute that an element is "operatively engaged" if it is engaged, directly or indirectly, in the operation of the device. *See, e.g.*,

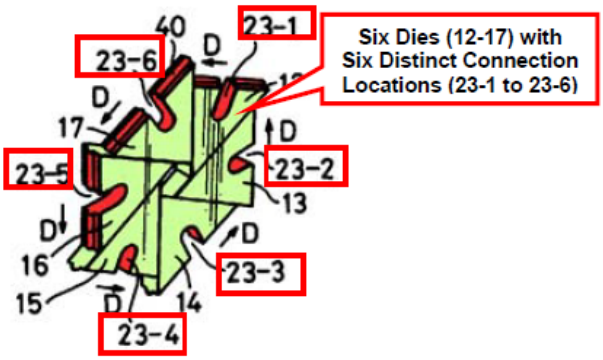
Tr. 24:13–25:12; *see also* Ex. 1126, 60:18–25 (Dr. Solar equating operative engagement to "whether it's fixed or connected in some manner that explains how that part works"). No further express construction is necessary.

5. "distinct connection locations"

Claim 1 recites "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." "Distinct connection locations" does not appear in the specification of the '560 patent outside of the claims. The feature, however, is shown above in Figures 8a and 8b of the '560 patent, which illustrate each blade 106 is engaged to non-rotating plates 156 through linear slides (154a and 154b) mounted to non-rotating plates 156 and connecting links (130a and 130b). Ex. 1101, 7:10–16. Thus, a stationary end wall (non-rotating plates 156) is operatively engaged to each die (each blade 106) at a distinct connection location (where each linear slide 154 is mounted to non-rotating plates 156).

In the Petition, Petitioner did not offer an express definition of the "distinct connection locations" and did not explain what features of the embodiments of the '560 patent correspond to this limitation. *See, e.g.*, Pet. 21–22 (reproducing and discussing Figure 8a of the '560 patent without addressing "distinct connection locations"). Petitioner's interpretation of the term is apparent only from its contentions with respect to how Yasumi allegedly teaches this feature. *See* Pet. 55–57.

Reproduced below is an illustration from the Petition depicting an annotated portion of Figure 8 of Yasumi:



Pet. 56, annotating a portion of Fig. 8 of Yasumi. The illustration identifies elongated holes 23-1 to 23-6 on movable pieces 12 to 17 as "Six Distinct Connection Locations." *See id.*, *see also* Ex. 1103, 7:46–52, Fig. 8. Petitioner reproduces in the Petition Figure 8 of Yasumi and labels "Six Dies (12–17) with Six Distinct Connection Locations (23-1 to 23-6)." *Id.* at 56. In support of the Petition, Mr. Sheehan further states that "each die has an elongated hole, which is a distinct connection location," but does not offer any additional support for such an interpretation of the claim language. Ex. 1105 ¶ 122.

Patent Owner argues that "there is no evidence that the movable pieces, the support discs, or the setting piece is affixed to any side plate *at distinct locations*." PO Resp. 27. Thus, a dispute Patent Owner raises is whether the "distinct connection locations" encompasses a location on the die (or blade).[4]

[4] During oral argument, Petitioner noted that Patent Owner's arguments concerning "distinct connection locations" are inconsistent because Patent Owner also argues in its Response that Petitioner's crimpers practice the challenged claims of the '560 patent and expressly identifies locations on the dies of Petitioner's device as corresponding to the claimed "distinct

In Reply, Petitioner asserts that "the 'distinct connection locations' recited in the claims are locations on the dies, not the stationary end-walls." Pet. Reply. 14–15. Petitioner, however, does not address the plain meaning of the claim language or the specification of the '560 patent to support its construction of the claim, and instead directs us to the deposition testimony of Dr. Solar. Pet. Reply 14; *see also* Ex. 1127 ¶¶ 44–45 (Mr. Sheehan citing Dr. Solar's testimony in support of the construction). Dr. Solar's testimony is not determinative of the meaning of a claim, but, more importantly, in proper context, his testimony does not support Petitioner's argument. Specifically, Petitioner directs us to a statement by Dr. Solar agreeing that "the distinct connection locations are on each blade." Ex. 1126, 46:6–47:7. Petitioner neglects to address the remainder of Dr. Solar's testimony:

> Q. Please turn to figure 8a of the '560 patent. Are you there?
> A. Yes.
> Q. Do you see the blades 106 in figure 8a?
> A. Yes.
> Q. Where are the distinct connection locations on the blades as shown in figure 8a?
> A. It helps if you look back to figure 4a because there are -- you have a different perspective so you can see everything and -- 156. Go back to my description. 154. So the blade 106 has a connecting rod 130.
> Q. Can you tell me where you're --
> A. I'm in figure 8a.
> Q. Thank you.
> A. Okay. I'm sorry.

---

connection locations." Tr. 40:13–18; *see also* PO Resp. 35 (citing Ex. 2016, App'x C, 6–7 (providing an illustration of a crimper and identifying the die as the claimed distinct connection location)). We agree with Petitioner that Patent Owner's arguments are difficult to reconcile; however, we do not consider Patent Owner's apparent infringement allegations (used in this case as support for secondary considerations of nonobviousness) to be persuasive evidence of the meaning of the claim term "distinct connection locations."

Q. Please continue.

A. Okay. Then 130, as you can see, connects up to this linear slide 154b, and 156 is the nonrotating station of the blade. So in this particular figure, this would be the connecting point for this particular blade 106.

Q. What would be the connecting point for the blade on 106?

A. In figure 8a where the -- you see the structure that's connected to the linear slide. 130b is the connector.

Q. So where the connector --

A. Same thing on the other side in this particular figure.

Q. So where the connecting link 130b meets the blade 106, that's the distinct connection location?

A. No, no, no. It's connecting to the stationary wall 156. So look above that.

Q. Okay.

A. 130b connected to this linear slide.

Q. The linear slide is 154b?

A. Yes.

Ex. 1126, 47:8–48:23 (emphasis added).

Fundamentally, Petitioner has not shown that the broadest reasonable interpretation of the claimed "distinct connection locations" encompasses locations on the dies. Petitioner has not shown how its construction is supported by the specification of the '560 patent or the plain language of the claim. Nor has Petitioner explained how such a construction would avoid rendering other claim language superfluous. In particular, if the "distinct connection locations" are on the dies, Petitioner neglects to address to what effect the claim limitation "such that the number of distinct connection locations and the number of dies are the same" serves. Petitioner does not suggest, and there does not appear to be any suggestion in the specification, that the limitation is directed to precluding multiple connection locations on each die. Thus, as Petitioner contends, if the distinct connection location is on each die, and each die is necessarily connected to the device for the device to operate, then the number of distinct connection locations and the

number of dies would seem to necessarily be the same. *See also* Tr. 45:17–21 (Patent Owner arguing the following: "So there must be a meaning to distinct connection location. Plus, if you look at, if you think about it, the dies themselves are distinct to begin with. If this term only modifies the dies, there would be no meaning because each die is distinct by its nature. So it has to modify the side plate as well.").

Based on the disclosure of the '560 patent and the claim language, we determine that Petitioner has not shown that the broadest reasonable interpretation of the claimed "distinct connection locations" encompasses locations on the dies (or blades). No further express construction is required for purposes of this Decision.

C. SCOPE AND CONTENT OF THE PRIOR ART

Petitioner relies on Yasumi and Morales with respect to its contentions that 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 under the instituted grounds. Patent Owner does not dispute the prior art status of either of the asserted references.

1. Yasumi (Figure 8 Embodiment) (Ex. 1103)[5]

Yasumi, titled "Aperture Setting Device," generally describes an aperture setting device "in which the size of a predetermined polygonal aperture can be changed, retaining the polygonal configuration." Ex. 1103, 1:10–13. The device of Yasumi 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." 1:46–49. According to Yasumi, the

[5] References to Yasumi in this Decision are to the teachings of the Figure 8 embodiment of Yasumi unless otherwise noted.

device described "would be of great ability 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.

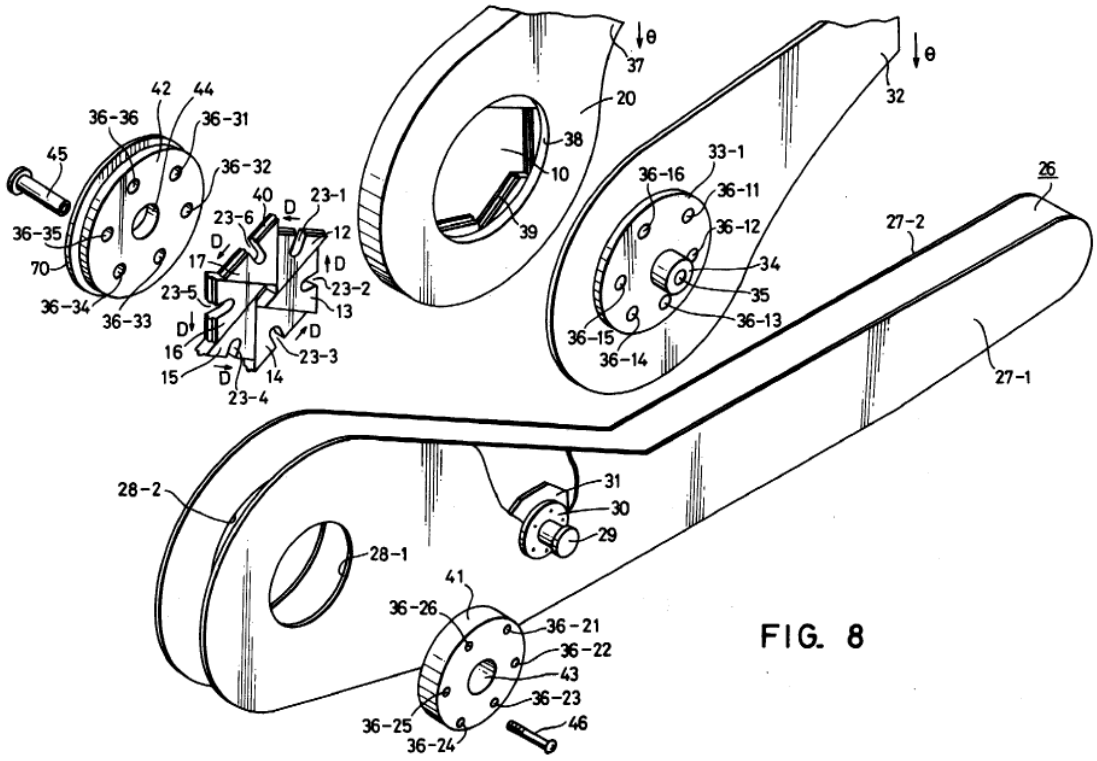


FIG. 8

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.

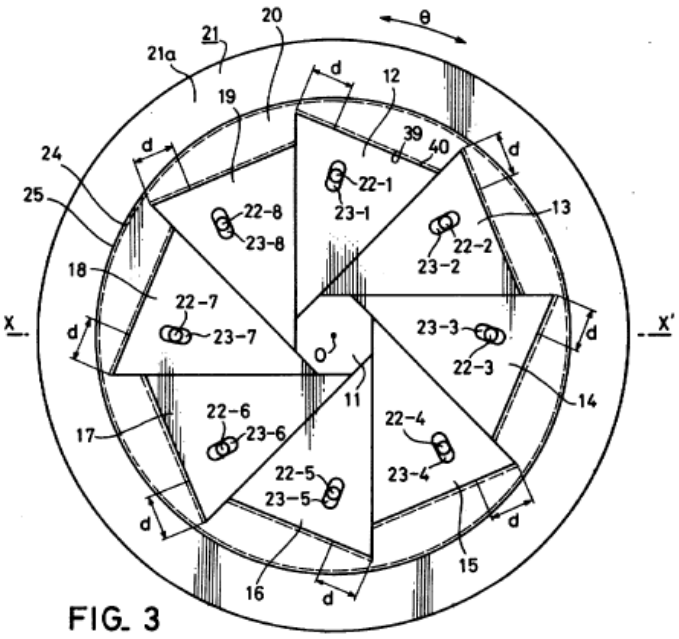


FIG. 3

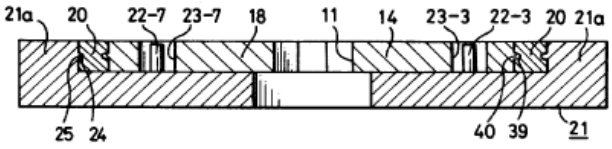


FIG. 10

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 19has elongated projection 40 which moves along guide groove 39 and prevents the movable pieces from getting out of frame 20. [6] *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

[6] In Figure 8, frame 20 includes only six 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 eight movable pieces.

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

Id. at 8:45–54.

2. Morales (Ex. 1104)

Morales, titled "Stent Crimping Tool and Method of Use," 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.

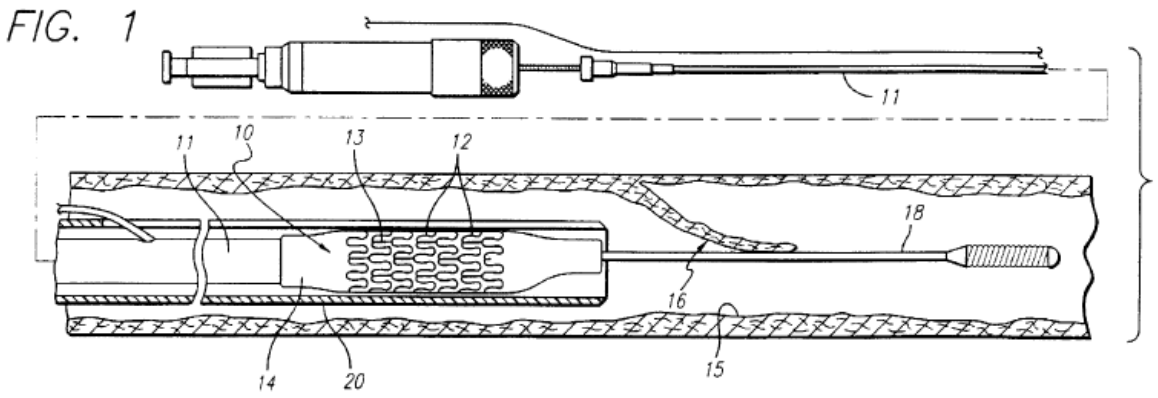


Figure 1 illustrates intravascular stent 10, comprised of radially expandable cylindrical elements 12 interconnected by members 13, mounted onto deliver catheter 11 with balloon 14 for expanding stent 10 within coronary artery 15. Ex. 1104, 5:60–67. "Stent 10 is crimped down onto balloon 14 to ensure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

Figure 2 of Morales is reproduced below.

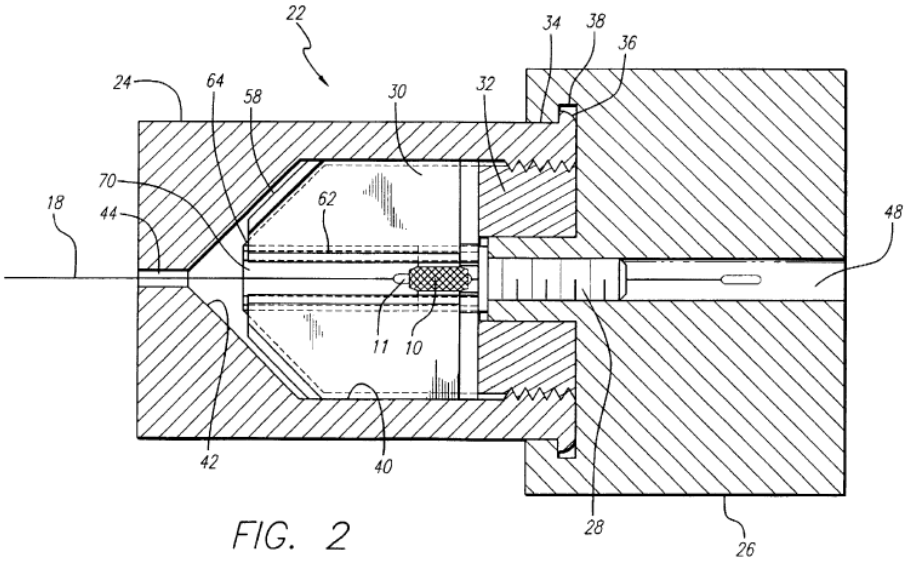


Figure 2 illustrates a sectional view of stent crimping tool 22 comprised of proximal section 24, teeth 30, collar 32, screw feed 28, and distal section 26. *Id.* at 6:67–7:3. Morales further explains:

> 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.

D. DIFFERENCES BETWEEN CLAIMED SUBJECT MATTER AND PRIOR ART

Petitioner contends the features of each of challenged claims 1, 2, 6, 8–11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40 would have been obvious over Yasumi. Pet. 50–81. For challenged claims 11, 17, 19, 26, 34, 35, and 39, Petitioner alternatively relies on Morales in combination with Yasumi. *Id.* at 85–94. Patent Owner contends that Yasumi does not disclose "(1) a stent crimper, (2) limitations relating to the dies being 'operatively engaged' with a stationary end-wall, and (3) limitations relating to the 'inward' or 'outward' movement of the dies." PO Resp. 24. Patent Owner further argues that Morales does not disclose the "operatively engaged" or the "inward" or "outward movement" limitations. *Id.* at 34.

Below, we address whether the asserted art teaches each of the limitations. We determine that Petitioner has demonstrated by a preponderance of the evidence that Yasumi teaches every limitation of claims 10, 14, 15, 18, 23, 25, 27, 28, 31, 33, 37, and 40, and that the combination of Yasumi and Morales teaches every limitation of claims 11,

17, 19, 26, 34, 35, and 39. Thus, we begin our discussion below by first addressing independent claim 10. We further determine that Petitioner has not demonstrated by a preponderance of the evidence that Yasumi teaches every limitation of claims 1, 2, 6, 8, and 9. Later, in Section III.F, we discuss the reasons supporting obviousness over the prior art, including whether Petitioner has shown that an ordinarily skilled artisan would have had reason to combine the teachings of Yasumi and Morales in the manner asserted by Petitioner.

1. Claim 10

Petitioner provides a claim chart identifying how it contends Yasumi teaches each limitation of claim 10 based on the embodiment shown in Figure 8 of Yasumi. Pet. 51–66. With regard to the preamble of claim 10, "a stent crimper comprising," Petitioner contends, and we agree, that the preamble is not limiting for the reasons explained above. *See supra* Section III.B.1. Further supporting our determination that the preamble is not limiting, Patent Owner was asked during oral argument what structural characteristic is required by the term "stent crimper" that is not shown in Yasumi. Patent Owner answered that "Yasumi only discloses the application to electrical wires," and that "Yasumi doesn't really talk about dimensions of Fig. 8." Tr. 27:22–28:13. Thus, Patent Owner identified from Yasumi an application of the tool and the absence of dimensions, but was unable to identify any structure required by the preamble of the '560 patent that is missing from Yasumi.

Additionally, we agree with Petitioner that Yasumi teaches "a manual forming and pressing tool," as illustrated in Figure 8, capable of crimping a stent and, thus, a "stent crimper," as recited in the preamble. *See* Pet. 50

(citing *In re Casey*, 370 F.2d 576, 580 (C.C.P.A. 1967)); *see also* Ex. 1105 ¶ 47 (quoting Ex. 1102, 72) (prior art applied during examination of the '560 patent considered to be a stent crimper because it was "capable of performing crimping of a stent").

Patent Owner argues that Yasumi does not disclose a "stent crimper" because "the Figure 8 embodiment of Yasumi is a 'manual forming and pressing tool' for an 'electric wire,'" and that "Yasumi does not teach or suggest a medical device application." PO Resp. 25 (citing Ex. 1103 at 7:35, 9:23; Ex. 2016 at ¶ 45.) We also have considered Dr. Solar's testimony that a person of ordinary skill in the art would not have considered Yasumi to have disclosed a device "suitable" for crimping a stent because Yasumi (1) was assigned to an aviation electronics company, (2) is directed to an aperture-setting device for use on a chuck or pressing tool, (3) does not disclose a medical device application; (4) has a purpose of forming electrical wire to a particular shape, and (5) uses a mechanism of action that could cause damage to a stent. Ex. 2016 ¶¶ 62–67. Dr. Solar also states that it is not clear how Yasumi achieves its intended purpose, that he "never considered the Figure 8 embodiment of Yasumi as a stent crimper," and that Yasumi was not mentioned in Morales's review of prior art stent crimping tools. *Id.* at ¶¶ 68–70.

We have considered Patent Owner's evidence and arguments and are not persuaded that Yasumi fails to teach a "stent crimper." In particular, whether Yasumi was applied to electric wire, was assigned to an aviation electronics company, or neglected to expressly state an application in the medical device field does not support the notion that the tool could not crimp a stent. Nor does the speculative suggestion that the tool of Yasumi could

cause damage to a stent persuade us that it was not a "stent crimper." Indeed, pliers and fingers were used to crimp stents and it stands to reason that any attempt to crimp a stent could damage the stent. *See* Ex. 1101 ("In the past, this crimping or size reduction has been done by hand often resulting in the application of undesired uneven forces to the stent."). That does not lead to the conclusion that the tool used to crimp the stent is not a "stent crimper."

Consistent with the teachings of Yasumi, Petitioner has shown that the device of Yasumi would have been capable of crimping a stent, and, thus, is a "stent crimper." Ex. 1103, 2:30–32, 7:33–38, 11:25–27; ¶ 109 (opining that a person of ordinary skill in the art "would have readily understood that a press tool is a crimper, and therefore Yasumi is directed to a crimper," and "would also have understood that the invention discussed in Yasumi could be used to crimp any object, including a stent"), ¶ 118 (stating that "Yasumi does not address crimping a stent, but the structure disclosed in Yasumi is capable of crimping a stent").

Continuing to the body of claim 10, Petitioner has shown, and Patent Owner does not dispute, that Yasumi teaches movable pieces 12–19 corresponding to the claimed "plurality of movable dies . . . disposed about an aperture," side plates 27-1 and 27-2 corresponding to the claimed "stationary end-walls," and circular frame 20 corresponding to the claimed "rotatable actuation device." Pet. 51–65 (citing, e.g., Ex. 1103 Abstract, 1:47–50, 2:45–47, 7:39–8:9, Figs 3, 8). Petitioner has also shown that each of the movable pieces of Yasumi further correspond to the claimed "each of the dies having an inward facing straight side which faces the longitudinal axis of the aperture, both when the dies move to maximize the aperture and

when the dies move to minimize the aperture." *Id.* at 57–58, 60–62 (citing, e.g., Ex. 1103, Abstract, 1:11–13, 1:40–43, 2:48–59, 4:42–44, Figs. 3, 8).

Claim 10 further requires the following: "rotation of the actuation device causing the inward facing straight sides of the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture." Petitioner contends the following:

> Yasumi discloses rotation of the actuation device (circular frame 20) causing the inward facing straight sides of the dies (movable pieces 12-17 or 12-19) to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture: "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 17 in the frame 20, reducing the aperture defined by the movable pieces 12 to 17." (Ex. 1103 at 8:42–54; *see id.* at 5:39–6:8, 7:57–68.)

Pet. 66 (emphasis omitted).

In opposition, Patent Owner argues that the dies of the '560 patent "move radially and in a linear inward and outward motion," and that Petitioner has not explained "how the movable pieces [of Yasumi] actually move to change the size of the aperture." PO Resp. 28. According to Patent Owner, Figure 8 of Yasumi illustrates the movable pieces as moving in the direction of arrows labeled "D," which "suggest an essentially circumferential movement of the movable pieces—not the inward and outward motion of the dies required by the '560 patent." *Id.* (citing Ex. 1103, 5:46–47; Ex. 2016 ¶¶ 54–56). In further support of Patent Owner's argument, Dr. Solar states that "Yasumi teaches that the movable pieces are configured in a 'windmill like' fashion, again suggesting a rotational movement of the movable pieces." Ex. 2016 ¶ 56 (citing Ex. 1103, 5:46–47).

We discern no merit to Patent Owner's argument. First, as Petitioner notes, to the extent Patent Owner is arguing that claim 10 requires "linear" movement, no such limitation appears in the claim. Thus, Patent Owner's argument is beyond the scope of claim 10 because, even if the dies of Yasumi move in a "an essentially circumferential movement," as Patent Owner suggests, there is no credible dispute that "the inward facing straight sides of the dies" of Yasumi "move inward and reduce the size of the aperture or outward so as to increase the size of the aperture," as claimed. In this regard, we agree with Petitioner:

> Generally, Yasumi discloses an aperture setting device that can change the size of a polygonal aperture. Ex. 1103 at 1:8–13, Abstract, 1:40–43. To do so, the movable pieces are moved either closer to or farther from the center of the aperture. *Id.* at 6:7–8, 7:46–57, 8:50–54. Nothing more is required by the plain words of the claims. *See* Ex. 1126 at 65:8–66:13.

Pet. Reply 15–16.

Second, if "linear" motion were required, Petitioner has persuasively explained that the dies taught in Yasumi move in the same manner as the dies claimed in the '560 patent. Ex. 1105 ¶¶ 95–104, 127–129, 136; Ex. 1127 ¶¶ 50–53. We credit the testimony of Mr. Sheehan over Dr. Solar on this point because we find Mr. Sheehan's testimony to be most consistent with the teachings of Yasumi. Indeed, Patent Owner does not dispute that Yasumi teaches "a rotatable actuation device coupled to the dies," as claimed, or that rotation of the actuation device causes the aperture to increase or decrease in size. *See generally* PO Resp. Patent Owner offers no plausible theory in rebuttal, much less any evidence, to suggest that the aperture of Yasumi formed by the inward facing straight sides of the dies increases and decreases with the rotation of the actuation device, but that the

faces do not "move inward and reduce the size of the aperture or outward so as to increase the size of the aperture," as claimed. To the extent Patent Owner is merely arguing that Petitioner has not made the necessary showing, we find such argument in this case unpersuasive as Petitioner has shown by a preponderance of the evidence that Yasumi teaches every limitation of claim 10. *See, e.g.*, Pet. 66 (citing Ex. 1103, 8:42–54).

2. Claim 18

Petitioner provides a claim chart identifying how it contends Yasumi teaches each limitation of claim 18 based on the embodiment shown in Figure 8 of Yasumi. Pet. 67–70. Many of the elements of claim 18 are substantially similar to elements of claim 10 discussed above, including, for example, "movable dies arranged to form an iris," "stationary end-walls," and "a rotatable actuation device." Petitioner has shown that these features are taught by Yasumi. Petitioner has also shown that Yasumi teaches "eight or more movable dies arranged to form the iris," "each die having an inward facing flat portion, and "the iris comprising at least eight of the inward facing flat portions." *See* Ex. 1103, 5:39–6:19 (describing eight movable pieces 12 to 19 forming adjustable aperture 11). We, therefore, focus our discussion on the elements Patent Owner contests.

Claim 18 further recites the following: "the dies between stationary end walls and operatively engaged to at least one of the stationary end-walls." Petitioner contends movable pieces 12 to 19 of Yasumi correspond to the recited dies, and that they are between stationary endwalls 27-1 and 27-2 of fixed handle 26. Pet. 53, 69. Petitioner further explains that "[i]n Figure 8, each movable piece has one elongated hole that engages the piece to the wide-end portions of the fixed handle side plates 27-1 and 27-2 via

support disks 42 & 43, drive pins 45, screws 46, and setting piece 32." *Id.* at 55, 69. Thus, Petitioner reasons that the movable pieces of Yasumi are "operatively engaged" to the side plates, as claimed.

Patent Owner argues that "[t]here is no evidence . . . that either of the side plates 27-1 and 27-2 is 'operatively engaged' with the movable pieces." PO Resp. 25–26. We disagree. For the reasons provided above, an element is "operatively engaged" if it is engaged, directly or indirectly, in the operation of the device. *See supra* Section III.B.4. Yasumi explicitly states with regard to Figure 8 that "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." Ex. 1003, 7:63–68. Fixed handle 26 is comprised of side plates 27-1 and 27-2, which correspond to the claimed "stationary end-walls." It is the movement of the movable handle 37 relative to side plates 27-1 and 27-2 of fixed handle 26 that operates the device of Yasumi by engaging the movable pieces (the "dies," as claimed) to open and close the aperture. *See* Ex. 1105 ¶ 103.

Patent Owner provides no credible evidence to the contrary to refute the express disclosure of the '560 patent. Dr. Solar states that Figure 8 of Yasumi fails to provide "sufficient detail or clarity" to indicate how it "could actually operate to achieve its intended purpose." Ex. 2016 ¶ 38; *see also id.* at ¶ 40 (stating that it is not clear how the aperture is reduced "since the setting piece in the moveable handle is already butting against the fixed handle and the pins are just fixed"). Dr. Solar concedes that support discs 41 and 42 of Yasumi are "operatively engaged" with the movable pieces, but further states that there is no disclosure of "any operative engagement

between the movable pieces and a side plate." *Id.* at ¶¶ 49–50; *see also* PO Resp. 27; Ex. 1126, 56:13–57:2 (Dr. Solar stating that from the disclosure of Yasumi he doesn't know whether or not support disk 42 is engaged with a side plate). As noted above, Yasumi, however, expressly states that the fixed handle 26 (with side plates 27-1 and 27-2) operate the device in conjunction with movable handle 37. That Figure 8 fails to illustrate "holes on any side plate that correspond to the holes 23-1 to 23-6 of the movable pieces," as Patent Owner contends, does not persuade us that side plates 27-1 and 27-2 are not "operatively engaged" to the dies. *See* Po Resp. 27.

We further find Patent Owner's arguments that the preamble is limiting, that Yasumi is not a "stent crimper," and that Yasumi does not disclose dies that move "inward" or "outward" not persuasive for the same reasons discussed above with respect to claim 10. *See* PO Resp. 25–32. Petitioner has shown by a preponderance of the evidence that Yasumi teaches every limitation of claim 18.

3. Claims 27 and 28

The only notable distinction of independent claim 27 from the limitations of claims 10 and 18 discussed above is the limitation that "the blades coupled to one another so as to be movable inward or outward simultaneously." Petitioner provides a claim chart identifying how it contends Yasumi teaches each limitation of claim 27 based on the embodiment shown in Figure 8 of Yasumi. Pet. 71–74.

Patent Owner argues that Yasumi fails to disclose all of the limitations of claim 27 for the same reasons Patent Owner raises with respect to claims 10 and 18 discussed above. PO Resp. 24–29. For the same reasons provided above, we find Patent Owner's arguments not persuasive.

We also determine that Petitioner has shown that Yasumi teaches that the blades are coupled to one another so as to be movable inward or outward simultaneously. *See* Pet. 72; *see also* Ex. 1103, 11:35–12:4 (claiming center aligning device comprising a first drive member having first drive pins inserted in elongated holes of the first movable pieces "for simultaneously moving said first movable pieces . . . to set the size of [the] first polygonal aperture"). Petitioner thus has shown by a preponderance of the evidence that Yasumi teaches every limitation of claim 27.

Claim 28, which depends from claim 27, further recites "a rotatable actuation device coupled to the blades, rotation of the actuation device causing the blades to move inward or outward." Petitioner has shown, and Patent Owner does not dispute, that Yasumi discloses this additional limitation for the same reasons the substantially similar limitation of claim 10 is taught by Yasumi. Pet. 79–80. We determine that Petitioner has shown by a preponderance of the evidence that Yasumi teaches every limitation of claim 28.

4. Claims 14, 23, and 31

Claim 14, which depends from claim 10, claim 23, which depends from claim 18, and claim 31, which depends from claims 27 and 28, each further require "wherein the dies are wedge-shaped." Petitioner has shown, and Patent Owner does not dispute, that Yasumi teaches movable pieces corresponding to the claimed wedge-shaped dies. Pet. 81 (citing Ex. 1103, Abstract ("substantially triangular movable pieces"), 1:48–49, 6:31–37, Fig. 8; Ex. 1105 ¶¶ 152–154); *see generally* PO Resp. We determine that Petitioner has shown by a preponderance of the evidence that Yasumi teaches every limitation of claims 14, 23, and 31.

5. Claim 15

Claim 15, which depends from claim 10, further recites "wherein at least eight dies are provided." There is no dispute that Yasumi teaches a device with eight movable pieces corresponding to the claimed "eight dies." *See* Pet. 67–70, 80; *see also* Ex. 1103, Fig 3. (illustrating an iris formed by the inward facing flat portions of eight dies); *id.* at 5:39–6:19 (describing eight movable pieces 12 to 19 forming adjustable aperture 11). Petitioner has shown by a preponderance of the evidence that Yasumi teaches every limitation of claim 15.

6. Claims 25 and 33

Claim 25, which depends from claim 18, and claim 33, which depends from claim 28, both further recite "wherein the dies are moved cooperatively inward during the moving step." We agree with Petitioner that "[t]he dies in Yasumi (movable pieces 12-17 or 12-19) are all configured to move cooperatively inward during the moving step because each one is linked to the same rotatable actuation device and the stationary end-walls such that the dies all move simultaneously." Pet. 80 (citing Ex. 1103, claim 1, Abstract, 2:47–59, 5:48–51, 4:12–17, 7:48–57, 8:50–54; Ex. 1105 ¶¶ 148–151). Patent Owner does not dispute Petitioner's contentions in regard to claims 25 and 33. *See generally* PO Resp. Although claims 25 and 33 suggest a method is being recited, there is no "moving step" in claims 18 and 28, which are apparatus claims, not method claims. Thus, we are persuaded that Yasumi teaches a rotatable actuation device coupled to the dies (or blades), and that rotation of the actuation device causes the dies (or blades) to move inward cooperatively, as we understand is required by claims 25 and 33. We

determine that Petitioner has shown by a preponderance of the evidence that Yasumi teaches every limitation of claims 25 and 33.

7. Claim 37

The only notable distinction of independent claim 37 from claims 10 and 18 discussed above is the limitation that the movable dies are "overlapping." Petitioner provides a claim chart identifying how it contends Yasumi teaches each limitation of claim 37 based on the embodiment shown in Figure 8 of Yasumi. Pet. 74–77; *see also* Ex. 1103, 2:44–59, Fig. 3 (describing and illustrating overlapping dies). There is no dispute that Yasumi teaches a device with "overlapping" movable dies, as claimed. *See* Pet. 75; *see also* Ex. 1101 2:44–59; Figs 1, 3. Petitioner has shown by a preponderance of the evidence that Yasumi teaches every limitation of claim 37.

8. Claims 11, 19, and 35

Claim 11, which depends from claim 10, claim 19, which depends from claim 18, and claim 35, which depends from claim 27, 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. Yasumi does not disclose a stent, a medical balloon, or a catheter. Petitioner has shown, and Patent Owner does not dispute, that Morales discloses stent 10 disposed about balloon 14, the balloon disposed about a delivery catheter 11. Pet. 92–93, citing Ex. 1104 5:60–66, 6:22–25, Fig. 1; Ex. 1105 ¶¶ 169–170; *see also* PO Resp. 34. Thus, Petitioner has shown by a preponderance of the evidence that the combination of Yasumi and Morales teaches every limitation of claims 11, 19, and 35.

9. Claims 17, 26, and 34

Claim 17, which depends from claim 10, claim 26, [7] which depends from claim 18, and claim 34, which depends from claims 27 and 28, each recite "wherein an entire stent is disposed in the aperture." Ex. 1101 11:5–6, 11:42–43, 12:5–6. Yasumi does not disclose a stent. Petitioner has shown, and Patent Owner does not dispute, that Morales discloses an entire stent 10 disposed within an aperture formed by dies 30. Pet. 94 (citing Ex. 1104, 5:5–9; Ex. 1105 ¶¶ 173–174); *see also* PO Resp. 34. Thus, Petitioner has shown by a preponderance of the evidence that the combination of Yasumi and Morales teaches every limitation of claims 17, 26, and 34.

10. Claim 39

The limitations of independent claim 39 are substantively similar to the other challenged claims discussed above with the following additional limitation: "the aperture having a center and a first opening and a second opening, 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." Ex. 1101, 12:57–61. Notably, the '560 patent does not define "the length of a stent." *See*, *e.g.*, Ex. 1101 8:5–8 ("Where lengthy stents or other medical devices are to be reduced in size, the invention contemplates using one of the above described apparatuses with long blades to accommodate the stent.").

Petitioner provides a claim chart identifying how it contends Yasumi teaches each limitation of claim 39, other than "a length exceeding the length of a stent," based on the embodiment shown in Figure 8 of Yasumi.

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

Pet. 86–91. In particular, Petitioner has shown, and Patent Owner does not dispute, that Figure 8 of Yasumi illustrates dies arranged to form an aperture with a center, a first opening, a second opening, and a horizontal axis, as claimed. Pet. 87; Ex. 1101, Fig. 8. Yasumi does not state the length of the aperture formed by the dies and does not expressly address the length of a stent. Petitioner has also shown that Morales teaches an aperture having a center and a first opening and a second open, and further teaches the length of the aperture exceeds the length of a stent. Pet. 88–90; *see also* Ex. 1104, 5:5–9 (stating that the "present invention tool is intended to be used on a variety of stent lengths" and the "total length of a preferred embodiment tooth/plate is over thirty-five millimeters long, thereby accommodating the lengths of the stents currently on the market"). Patent Owner does not dispute that Morales teaches these features. *See* PO Resp. 34. We determine that Petitioner has shown by a preponderance of the evidence that the combination of Yasumi and Morales teaches every limitation of claim 39.

11. Claim 40

The limitations of claim 40 are not significantly distinguishable from the other challenged claims discussed above. For example, claim 40 recites "stationary plates" whereas claim 10 recites "stationary end-walls." There is no dispute that the two terms are interchangeable. *See supra* Section III.B.3. Similarly, claim 40 recites "each die in communication with an actuation device," whereas claim 10 recites "a rotatable actuation device coupled to the dies." Neither party suggests a distinction between these two terms. Petitioner provides a claim chart identifying how it contends Yasumi teaches each limitation of claim 40 based on the embodiment shown in Figure 8 of

Yasumi. Pet. 77–79. Patent Owner argues that Yasumi fails to disclose all of the limitations of claim 40 for the same reasons Patent Owner raises with respect to claims 10 and 18 discussed above. PO Resp. 24–29. For the same reasons provided above, we find Patent Owner's arguments not persuasive and determine that Petitioner has shown by a preponderance of the evidence that Yasumi teaches every limitation of claim 40.

12. Claims 1, 2, 6, 8, and 9

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. Claims 2, 6, 8, and 9 depend from claim 1. Whether Petitioner has sufficiently shown how Yasumi teaches each feature in the body of claim 1 turns 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."

Petitioner contends the following:

> In [Yasumi] Figure 8, each movable piece has one elongated hole that engages the piece to the wide-end portions of the fixed handle 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). Thus, Petitioner relies exclusively on elongated holes 23-1 to 23-6 on the movable pieces of Yasumi as corresponding to the claimed "distinct connection locations." *See id.* For the reasons provided above, however, Petitioner has not shown that the broadest reasonable interpretation of the claimed "distinct connection locations" encompasses locations on the dies (or "blades" or "movable

pieces"). *See supra* Section III.A.5. Thus, Petitioner has not shown by a preponderance of the evidence that the claimed "distinct connection locations" of claim 1 are taught by the elongated holes 23-1 to 23-6 on the movable pieces of Yasumi. For the same reason, Petitioner has not shown that Yasumi discloses each of the limitations of claims 2, 6, 8, and 9, which depend from claim 1.

E. LEVEL OF ORDINARY SKILL

The Supreme Court explained in *KSR* that

> Section 103(a) forbids issuance of a patent when 'the differences between the subject matter sought to be patented 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.

550 U.S. at 405. Petitioner contends that a "person of ordinary skill in the art as at the time of the claimed invention would have had a Bachelor of Science degree in mechanical engineering, industrial design, biomedical engineering, or equivalent work experience, as well as five to ten years of experience in the design or development of medical devices." Pet. 30–31 (citing Ex. 1105 ¶¶ 65–67). Dr. Solar states that he is in general agreement with this definition of a person of ordinary skill in the art. Ex. 2016 ¶ 22.

Based on the evidence provided, including the prior art of record, we agree with Petitioner's proposed level of ordinary skill and further find that the prior art of record further reflects the level of ordinary skill in the art. *See also Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (noting that the prior art of record may reflect the level of ordinary skill in the art).

F. REASONS SUPPORTING OBVIOUSNESS OVER THE PRIOR ART

The Supreme Court instructs an expansive and flexible approach in determining whether a patented invention was obvious at the time it was

made. *See KSR*, 550 U.S. at 415. The existence of a reason for a person of ordinary skill in the art to modify a prior art reference is a question of fact. *See In re Constr. Equip. Co.*, 665 F.3d 1254, 1255 (Fed. Cir. 2011). In an obviousness analysis, some kind of reason must be shown as to why a person of ordinary skill would have thought of combining or modifying the prior art to achieve the patented invention. *See Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008). A reason to combine or modify the prior art may be found explicitly or implicitly in market forces; design incentives; the "interrelated teachings of multiple patents"; "any need or problem known in the field of endeavor at the time of invention and addressed by the patent"; and the background knowledge, creativity, and common sense of the person of ordinary skill. *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1328–29 (Fed. Cir. 2009) (quoting *KSR*, 550 U.S. at 418–21).

1. Reasons Supporting Obviousness of Claims 10, 14, 15, 18, 23, 25, 27, 28, 31, 33, 37, and 40 over Yasumi

Petitioner has shown that a single reference, Yasumi, teaches every limitation of claims 10, 14, 15, 18, 23, 25, 27, 28, 31, 33, 37, and 40 of the '560 patent. *See supra* Section III.D.1–11. Having determined that the preamble recitation of a "stent crimper" is not limiting, we find that Petitioner need not show a rationale to modify Yasumi to establish that the claims would have been obvious over Yasumi. *See In re Pearson*, 494 F.2d 1399, 1402 (CCPA 1974) (A disclosure that anticipates under 35 U.S.C. § 102 also renders the claim unpatentable under 35 U.S.C. § 103, for anticipation is the epitome of obviousness.)

Were more needed to establish the claims as obvious over Yasumi merely because Yasumi is not expressly directed to a "stent crimper,"

Petitioner has also shown that the embodiment illustrated in Figure 8 of Yasumi is capable of crimping a stent. *Id.* Indeed, Yasumi expressly discloses a broad range of applications for its tool:

> In the past, there has not been put to practical use a device which is capable of changing with a simple arrangement, a polygonal aperture into various sizes continuously or stepwise, retaining it on the same axis. Such a device, if realized, would be of great ability 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.

Ex. 1101, 1:32–39, *quoted in* Pet. 82. Petitioner further shows that "a manual forming and pressing tool is just another term used to refer to a crimper" and that "stent crimping is one field of crimping applications." Pet. 82–83 (citing Ex. 1105 ¶¶ 158–159). Petitioner reasons, and we agree, that a person of ordinary skill in the art would have been aware of the problems associated with uneven crimping and would have been motivated to apply Yasumi to obtain the benefit, known in the art, of features such as a straight–sided die and polygonal aperture, to "balance compressive forces toward the center of the work." Pet. 82–85 (citing, e.g., Ex. 1115 1:13–20; Ex. 1105 ¶¶ 155–160).

Patent Owner argues that, according to Dr. Solar, "the Figure 8 embodiment of Yasumi would not be suitable for stent crimping and that a skilled artisan would not have been motivated to use it to crimp a stent." PO Resp. 30 (citing Ex. 2016 ¶¶ 62–73). Patent Owner reasons that "Yasumi never suggests that its manual forming and pressing tool in Figure 8 could be used for any medical device application, much less crimping a stent," but is instead "used to shape and align an electrical wire, which is quite different than crimping a stent—*i.e.*, reducing the diameter of a mesh-

like tubular structure." PO Resp. 30. Patent Owner also contends that "there is no disclosure of a longitudinal dimension of the Figure 8 embodiment of Yasumi that would indicate its appropriateness for stent crimping purposes." *Id.*

We are not persuaded that the absence of an express disclosure of the use of the tool of Yasumi in a medical device application or of the dimensions of the tool renders the teachings of Yasumi inapplicable to stent crimping. As Petitioner explains, it was well known to use ordinary pliers and other plier-like tools to crimp stents and a person of ordinary skill "would appreciate the applicability of tools intended for other types of applications to stent crimping." Pet. Reply 19–21 (citing, e.g., Ex. 1105 ¶¶ 81–88; Ex. 1127 ¶ 79). Patent Owner also argues that, if used as a stent crimper, the device of Yasumi would potentially damage the stent because "Yasumi describes an apparently non-radial motion of the moveable dies." PO Resp. 31 (citing, e.g., Ex. 2016 ¶¶ 64–67). As explained above, we find not persuasive Dr. Solar's testimony that Yasumi teaches movable pieces that "move in a circumferential direction" that would "exert shear forces on the stent." *See* Ex. 2016 ¶ 64. While we agree that shear forces would be undesirable if exerted on a stent by the tool, we credit Mr. Sheehan's explanation that the movable pieces of Yasumi function in the same manner as the dies and blades of the '560 patent—moving in a linear manner, not a circumferential manner. *See* Ex. 1127 ¶¶ 50–53, 60.

Patent Owner also argues that the Figure 8 embodiment of Yasumi "would not have been suitable for crimping a stent" because "there is insufficient disclosure in Yasumi to allow a skilled artisan to discern how the Figure 8 embodiment actually works for its intended purpose, if it works

at all." PO Resp. 31 (citing Ex. 2016 ¶¶ 38–40, 68). First, Patent Owner's argument is insufficient because it seeks to incorporate by reference arguments from its expert report in place of setting forth the merits of the argument in Patent Owner's response. 37 C.F.R. § 42.4(c)(3) ("Arguments must not be incorporated by reference from one document into another document."). Second, Patent Owner appears to be arguing that Yasumi is not enabled, but has not addressed the factors necessary to support such an argument, much less shown that a person of ordinary skill could not make and use the tool of Yasumi without undue experimentation. *See, e.g.*, *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (discussing factors considered in determining whether a patent disclosure is enabled). We also are not persuaded by Dr. Solar's testimony that, in his opinion, it is unclear how Yasumi operates because "there is no sufficient description in the Figure 8 embodiment to show how the moveable pieces in the frame move to reduce (or open) the aperture." Ex. 2016 ¶ 40. We credit the testimony of Mr. Sheehan explaining how the tool of Yasumi operates as more consistent with the disclosure of Yasumi over the testimony of Dr. Solar. *See* Ex. 2205 ¶¶ 95–104; Ex. 1127 ¶¶ 30–43; Ex. 1004 7:33–9:34.

Patent Owner further argues the following:

> [E]ven if a skilled artisan tried to modify the Figure 8 embodiment of Yasumi, they would not have had a reasonable expectation of success. As an initial matter, Petitioner makes no attempt to establish a reasonable expectation of success. (Pet. at 83.) Moreover, as Dr. Solar points out, the disclosure of Yasumi lacks sufficient detail to show that it would actually function for its intended purpose and, in fact, a device according to the Figure 8 embodiment could damage a stent. (Ex. 2016 at ¶¶ 38-40, 74.)

PO Resp. 33.[8] We find Patent Owner's argument not persuasive because, as explained above, Petitioner has shown that the teachings of Yasumi are sufficient to explain how it would function and Patent Owner has not shown that the tool of Yasumi could damage a stent such that a person or ordinary skill would have no expectation of success. Moreover, we find Petitioner persuasively explained why a person of ordinary skill in the art would have had an expectation of success in using the tool of Yasumi to crimp a stent because it was known that the use of a crimping device with "radially opposed jaws that direct and balance compressive forces toward the center of the work" would be beneficial in reducing problems associated with the application of uneven crimping forces. *See* Pet. 83–85.

2. *Reasons Supporting Obviousness of Claims 11, 17, 19, 26, 34, 35, and 39*

Claims 11, 19, and 35 recite "wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter," claims 17, 26, and 34 recite "wherein an entire stent is disposed in the aperture," and claim 39 recites an aperture having "a first opening and a second opening, the dies constructed and arranged to have a length exceeding the length of a stent." There is no dispute that Morales, directed to a "Stent Crimping Tool and Method of Use," teaches these limitations. *See* Ex. 1104. Petitioner's

[8] Patent Owner also suggests in a footnote that it disputes Petitioner's contention that "Yasumi is in the same field of endeavor as the '560 patent." PO Resp. 32 n.7 (quoting Pet. 46). We are satisfied that Yasumi and the '560 patent are in the same field of endeavor in light of the purpose and structure of each, as discussed above. Petitioner further notes that Yasumi has been identified as prior art in patent applications for stent crimpers multiple times, including in applications affiliated with Patent Owner. *See* Pet. Reply 23 (citing Ex. 1127 ¶ 76).

rationale for combining Yasumi's teaching of a tool capable of crimping a stent and Morales teaching of a stent that must be crimped around a balloon and catheter, with which we agree, is not complicated: a person of ordinary skill in the art "would have known that crimping a stent over a balloon catheter is the intended purpose for a stent crimper." Pet. 92 (citing Ex. 1105 ¶ 168); *see also id.* at 94 ("[i]t would have been obvious as a matter of common sense to modify Yasumi . . . to form a stent crimper with a stent disposed about a balloon and the balloon disposed about a catheter . . . because crimping a stent to a catheter is the intended purpose for a stent crimper"). Petitioner has also shown that having the entire stent be disposed in the crimper, or for the length of the crimper to exceed the length of the stent was also known in the art and would have been desirable to avoiding uneven crimping. *See* Ex. 1105 ¶¶ 172–173; Ex. 1104, Fig. 2; *see also id.* at ¶ 177 (stating a person of ordinary skill in the art "would have had a reason, basis or motivation to ensure that the entire length of the stent resided within the aperture while crimping to impart the most even crimping forces possible," that "[i]t is a matter of common sense that the aperture must have an opening on both sides, as depicted in Morales, in order to permit the balloon catheter to pass through the opening until the stent and balloon portion is centered within the crimping aperture," and that "[i]t is also a matter of common sense (and good practice) that the aperture should exceed the length of the stent to ensure that the entire stent fit 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.

Patent Owner does not persuasively rebut Petitioner's contentions supporting the asserted combination of Yasumi and Morales, but instead

argues there would have been no motivation to combine Yasumi with Morales because "the Figure 8 embodiment of Yasumi would not have been considered a stent crimper and a person of ordinary skill in the art would not have looked to Yasumi for stent crimping applications." PO Resp. 34 (citing Ex. 2016 ¶¶ 62–73). We addressed these same arguments above in regard to the teachings of Yasumi and find them not persuasive for the same reasons. Petitioner has persuasively shown that an ordinarily skilled artisan would have had reason to combine the teachings of Yasumi and Morales in the manner asserted by Petitioner.

3. Reasons Supporting Obviousness of Claims 1, 2, 6, 8, and 9

Petitioner has not shown that Yasumi or Morales teaches the "discrete connection locations" limitation of claims 1, 2, 6, 8, and 9. Moreover, Petitioner identifies no evidence or argument to suggest that, in the absence of an express teaching of this limitation, it nevertheless would have been obvious. Accordingly, we find Petitioner has provided no persuasive reason supporting the obviousness of claims 1, 2, 6, 8, and 9.

G. *Objective Evidence of Nonobviousness*

Evidence of objective indicia of nonobviousness, when present, must always be considered en route to a determination of obviousness. *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075–76 (Fed. Cir. 2012). Patent Owner argues that "[t]he objective indicia—including commercial success, long-felt need, and failure of others—all point to the nonobviousness of the '560 patent." PO Resp. 35. To show nexus Patent Owner must show "a legally and factually sufficient connection between the [objective evidence] and the patented invention."

Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392 (Fed. Cir. 1988).

Patent Owner offers in support of its objective evidence of nonobviousness Dr. Solar's opinion that "Petitioner's crimpers embody the challenged claims of the '560 patent" and that "there is a nexus between the success of Petitioner's crimpers and the claimed features of the '560 patent." Ex. 2016 ¶¶ 76–77; *see* PO Resp. 35. Patent Owner also relies on a claim chart provided by Dr. Solar which purports to show how each element of the challenged claims is present in a patent (Ex. 2033) that Patent Owner contends is representative of Petitioner's crimpers. PO Resp. 35; Ex. 2016, App'x C. Patent Owner also contends that Petitioner admits that there was a long-felt and unresolved need for uniformly crimping a stent and a failure of others to solve that need. PO Resp. 36–37. Petitioner argues there is no evidence of commercial success or long-felt need. Pet. Reply 23–26. For the reasons that follow we determine, even assuming the requisite nexus has been shown, that objective evidence Patent Owner identifies provides little support for the nonobviousness of the challenged claims of the '560 patent.

1. Commercial Success

Patent Owner offers virtually no substantive evidence of commercial success pertaining to the '560 patent. Patent Owner merely states "Petitioner's crimpers have been commercially successful," and cites Dr. Solar's declaration (Ex. 2016) at paragraph 76 and Appendix C. PO Resp. 35. Appendix C is a claim chart, not evidence of commercial success. Dr. Solar's testimony is no more than his statement: "I understand that Petitioner's crimpers, sold with Petitioner's Sapien valves, have enjoyed substantial sales and have been commercially successful." Ex. 2016 ¶ 76

(citing Ex. 2031). The cited Exhibit 2031 appears to be a press release from Edwards Lifesciences Corporation announcing financial results of the company for the quarter ended June 30, 2017. Absent any explanation from Patent Owner of the significance of the financial results, we find no support for either Patent Owner's assertion that Petitioner's crimpers were "commercially successful" or Dr. Solar's testimony that he "understands" crimpers sold with a valve "have enjoyed substantial sales."

Petitioner notes that Patent Owner has not presented any evidence that Patent Owner's own activities have resulted in commercial success tied to the '560 patent. Pet. Reply 23. Petitioner also argues that its crimpers do not infringe the '560 patent and that there is no evidence the crimpers it sells as part of "a kit containing a transcatheter heart valve, a balloon expandable catheter delivery system, and other ancillary parts, drive the demand for all of Edwards' transcatheter heart valve sales." *Id.* at 24. We agree with Petitioner that Patent Owner has not shown a nexus between sales of its transcatheter heart valve kit, including a crimper, and the challenged claims of the '560 patent. Moreover, even is such nexus had been shown, we find that Patent Owner's arguments of commercial success are conclusory and its unexplained evidence, consisting of Dr. Solar's declaration citing a press release, provides virtually no credible support in showing the nonobviousness of the challenged claims of the '560 patent. *See* PO Resp. 35.

2. Long-Felt Need and Failure of Others

According to Patent Owner, Petitioner concedes that (1) "the problem of uneven crimping forces was well known prior to the claimed inventions of the '560 patent," and (2) "many had failed to achieve uniform stent

crimping in the past." PO Resp. 36 (citing Pet. 83, Ex. 1105 ¶¶ 159–160). Patent Owner also asserts that Dr. Solar "surveyed U.S. patents filed prior to September 1999 and found 30 unique patents filed before September 1999 discussing the long-standing problem of uneven stent crimping." *Id.* (citing Ex. 2016 ¶ 81, App'x D). Patent Owner reasons that because these patents were filed by "more than ten different entities," and that "[a]ll of them attempted to address the need for uniform stent crimping," then "the need would not have persisted had the solution been obvious." *Id.* (quoting *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1056 (Fed. Cir. 2016)). Patent Owner also asserts that the industry was trying "dramatically different methods and apparatuses in an attempt to solve the problem of uneven stent crimping" and that none of the 30 patents surveyed by Dr. Solar "even came close to proposing an Iris-like structure with the unique blade structure, connectivity, and movement in the claimed inventions of the '560 patent." PO Resp. 36–37.

In response, Petitioner argues that "it is likely that many of the 30 patents surveyed by Dr. Solar are evidence of prior art alternatives to the '560 patent that also provide uniform stent crimping." Pet. Reply 25. Indeed, Petitioner correctly contends that Patent Owner has provided no analysis to show the prior art alternatives failed to solve the problem. Thus, we are not persuaded that Patent Owners identification of other patents in the field constitutes substantial evidence of a long felt but unmet need or the failure of others. Accordingly, in consideration of all of the arguments and evidence, we find Patent Owner's evidence of long-felt need and failure of others provides very little credible support for nonobviousness of the challenged claims of the '560 patent.

H. COLLECTIVE CONSIDERATION OF THE GRAHAM FACTORS

Having considered each of the *Graham* factors individually, we now consider them collectively.

With regard to challenged claims 1, 2, 6, 8, and 9 of the '560 patent, Petitioner has not shown by a preponderance of the evidence that Yasumi teaches "distinct connection locations," as required by each claim. Nor has Petitioner provided any rationale or reason the missing limitation would have otherwise been obvious over the asserted prior art. Accordingly, in the absence of a teaching of each limitation, consideration of no other *Graham* factor persuades us that Petitioner has shown by a preponderance of the evidence that the subject matter of claims 1, 2, 6, 8, and 9 would have been obvious over Yasumi.

With regard to challenged claims 10, 14, 15, 18, 23, 25, 27, 28, 31, 33, 37, and 40 of the '560 patent, Petitioner has shown that all of the limitations are taught by Yasumi such that the scope and content of the prior art, as well as the differences between the prior art and the challenged claims, heavily favor Petitioner's contention that the subject matter would have been obvious over Yasumi. Petitioner has also shown with regard to claims 11, 17, 19, 26, 34, 35, and 39 that all of the limitations are taught by the combination of Yasumi and Morales such that the scope and content of the prior art, as well as the differences between the prior art and the challenged claims, heavily favor Petitioner's contention that the subject matter would have been obvious over Yasumi and Morales. The level of ordinary skill in the art also heavily favors obviousness because the problem of uneven crimping of stents was well known, and the use of a tool to prevent such uneven crimping would have been desirable. Even if we assume Patent

Owner has shown the requisite nexus between the alleged objective indicia of nonobviousness and the challenged claims of the ’560 patent, Patent Owner provides little credible evidence of commercial success, long-felt need, or failure of others. Finally, Petitioner has persuasively shown that an ordinarily skilled artisan would have had reason to combine the teachings of Yasumi and Morales in the manner asserted by Petitioner.

On the whole, we find that the information provided by Petitioner and Patent Owner in consideration of the *Graham* factors collectively demonstrates by a preponderance of the evidence that claims 10, 14, 15, 18, 23, 25, 27, 28, 31, 33, 37, and 40 of the ’560 patent are unpatentable as obvious over Yasumi and that claims 11, 17, 19, 26, 34, 35, and 39 are unpatentable as obvious over the combination of Yasumi and Morales.[9]

IV. CONCLUSION

Based on the evidence and arguments, Petitioner has demonstrated by a preponderance of the evidence that the subject matter of claims 10, 14, 15, 18, 23, 25, 27, 28, 31, 33, 37, and 40 of the ’560 patent would have been obvious over Yasumi and that the subject matter of claims 11, 17, 19, 26, 34, 35, and 39 would have been obvious over the combination of Yasumi and Morales. Petitioner has not shown by a preponderance of the evidence that the subject matter of claims 1, 2, 6, 8, and 9 would have been obvious over Yasumi.

[9] Having determined that Petitioner has shown by a preponderance of the evidence that the subject matter of claims 11, 17, 19, 26, 34, 35, and 39 would have been obvious over the combination of Morales and Yasumi, Petitioner's contention that the same claims would have been obvious over Yasumi, alone, is moot.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Patent Owner's Motion to Exclude is *denied*;

ORDERED that claims 10, 11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40 of U.S. Patent No. 6,915,560 B2 have been shown to be unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

PETITIONER:

Craig Summers
Brenton Babcock
Christy Lea
Cheryl Burgess
KNOBBE, MARTENS, OLSON & BEAR, LLP
2css@knobbe.com
2brb@knobbe.com
2cgl@knobbe.com
2ctb@knobbe.com

PATENT OWNER:

Wallace Wu
Jennifer Sklenar
Nicholas Nyemah
ARNOLD & PORTER KAYE SCHOLER LLP
wallace.wu@apks.com
jennifer.sklenar@apks.com
nicholas.nyemah@aporter.com