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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 No. IPR2017-01301

Patent 6,915,560

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,915,560

TABLE OF CONTENTS

	Page No.
I. SUMMARY OF THE ISSUE PRESENTED	1
II. INTRODUCTION TO THE STATE OF THE ART	6
III. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1).....	11
A. Real Party-in-Interest (37 C.F.R. § 42.8(b)(1)).....	11
B. Related Matters (37 C.F.R. § 42.8(b)(2)).....	11
C. Lead and Back-up Counsel Under 37 C.F.R. § 42.8(b)(3)	11
D. Service Information Under 37 C.F.R. § 42.8(b)(4).....	12
IV. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a).....	12
V. U.S. PATENT NO. 6,915,560	12
A. Specification and Claims.....	12
B. Prosecution History	19
1. October 22, 2003 Office Action and Response	19
2. April 22, 2004 Office Action and Response.....	23
3. October 19, 2004 Office Action and Response	25
VI. IDENTIFICATION OF CHALLENGE PURSUANT TO 37 C.F.R. § 42.104(b)	26
VII. PERSON HAVING ORDINARY SKILL IN THE ART	27
VIII. CLAIM CONSTRUCTION AND RELATED ISSUES	27
A. “A stent crimper comprising”	28
B. “Dies” and “blades”.....	29

TABLE OF CONTENTS
(cont'd)

	Page No.
C. “Stationary end-walls” and “stationary plates”	30
IX. THE PRIOR ART.....	31
A. Analogous Art	31
1. Field Of Endeavor.....	32
2. Pertinent To The Particular Problem	32
B. Yasumi.....	34
C. Williams	43
D. Morales	44
X. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS FOR CANCELLATION (37 C.F.R. § 42.22(a) AND 42.104(b)).....	46
A. Claims 1, 2, 6, 8-10, 14, 15, 18, 23, 25, 27, 28, 31, 33, 37, and 40 Are Invalid As Obvious Over Yasumi In View Of Williams	46
1. Claim 1	46
2. Claim 10.....	56
3. Claim 18.....	65
4. Claim 27	69
5. Claim 37	72
6. Claim 40.....	75
7. Claims 2 and 28.....	77

TABLE OF CONTENTS
(cont'd)

	Page No.
8. Claims 6 and 15.....	78
9. Claims 8, 25, and 33	78
10. Claims 9, 14, 23, and 31	79
11. Reason, Basis, or Motivation to Combine	79
B. Ground 2: Claims 11, 17, 19, 26, 34, 35, and 39 Are Obvious Over Yasumi In View Of Williams and Morales 2.....	82
1. Claim 39	82
2. Claims 11, 19, and 35	89
3. Claims 17, 26, and 34	91
4. Reason, Basis, or Motivation to Combine	92
XI. THIS PETITION IS NOT REDUNDANT UNDER 35 U.S.C. § 325(d).....	93
XII. SECONDARY CONSIDERATIONS CANNOT OVERCOME THE STRONG EVIDENCE OF OBVIOUSNESS.....	94
XIII. CONCLUSION.....	95

TABLE OF AUTHORITIES

Page No(s).

<i>Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC</i> , 825 F.3d 1373 (Fed. Cir. 2016)	79
<i>Ariosa Diagnostics v. Verinata Health, Inc.</i> , 805 F.3d 1359 (Fed. Cir. 2015)	4
<i>Boston Scientific Corp. and Boston Scientific Scimed, Inc. v. Edwards Lifesciences Corp.</i> , Civil Action No. 8:16-cv-0730 (C.D. Cal.)	11
<i>In re Casey</i> , 370 F.2d 576 (C.C.P.A. 1967)	47
<i>Catalina Marketing International, Inc. v. Coolsavings.com, Inc.</i> , 289 F.3d 801 (Fed. Cir. 2002)	28
<i>In re Clay</i> , 966 F.2d 656 (Fed. Cir. 1992)	31
<i>In re Cuozzo Speed Techs., LLC</i> , 793 F.3d 1268 (Fed. Cir. 2015), <i>aff'd</i> , 136 S. Ct. 2131 (2016)	27
<i>Innovention Toys, LLC v. MGA Entm't, Inc.</i> , 637 F.3d 1314 (Fed. Cir. 2011)	31
<i>Leapfrog Enters., Inc. v. Fisher-Price, Inc.</i> , 485 F.3d 1157 (Fed. Cir. 2007)	94
<i>Newell Cos., Inc. v. Kenney Mfg. Co.</i> , 864 F.2d 757 (Fed. Cir. 1988)	94

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35 U.S.C. § 102	<i>passim</i>
35 U.S.C. § 103	1, 27, 79

TABLE OF AUTHORITIES
(cont'd)

	Page No(s).
35 U.S.C. §§ 311–319	1
35 U.S.C. § 325	93
37 C.F.R. § 42.8	11, 12
37 C.F.R. § 42.10	11
37 C.F.R. § 42.100	1, 27
37 C.F.R. § 42.100	1
37 C.F.R. § 42.104	12, 26, 46
37 C.F.R. § 42.22	46

EXHIBIT LIST

Exhibit No.	Description
1201	U.S. Patent No. 6,915,560 (“the ’560 patent”)
1202	U.S. Patent No. 6,915,560 File History Excerpts
1203	U.S. Patent No. 4,454,657 (“Yasumi”)
1204	U.S. Patent No. 5,893,852 (“Morales”)
1205	Declaration of Neil Sheehan in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 6,915,560
1206	Curriculum Vitae of Neil Sheehan
1207	Materials Considered by Neil Sheehan
1208	German Patent No. DE9034 (“Nix”)
1209	Certified Translation of Nix
1210	U.S. Patent No. 2,664,996 (“Andrews”)
1211	U.S. Patent No. 4,308,744 (“Baker”)
1212	International Patent Publication No. WO1994014573 A1 (“Hartley”)
1213	U.S. Patent No. 5,918,511 (“Sabbaghian”)
1214	U.S. Patent No. 6,364,870 (“Pinchasik”)
1215	U.S. Patent No. 5,261,263 (“Whitesell”)
1216	U.S. Patent No. 3,695,087 (“Tuberman”)
1217	U.S. Patent No. 6,176,116 (“Wilhelm”)

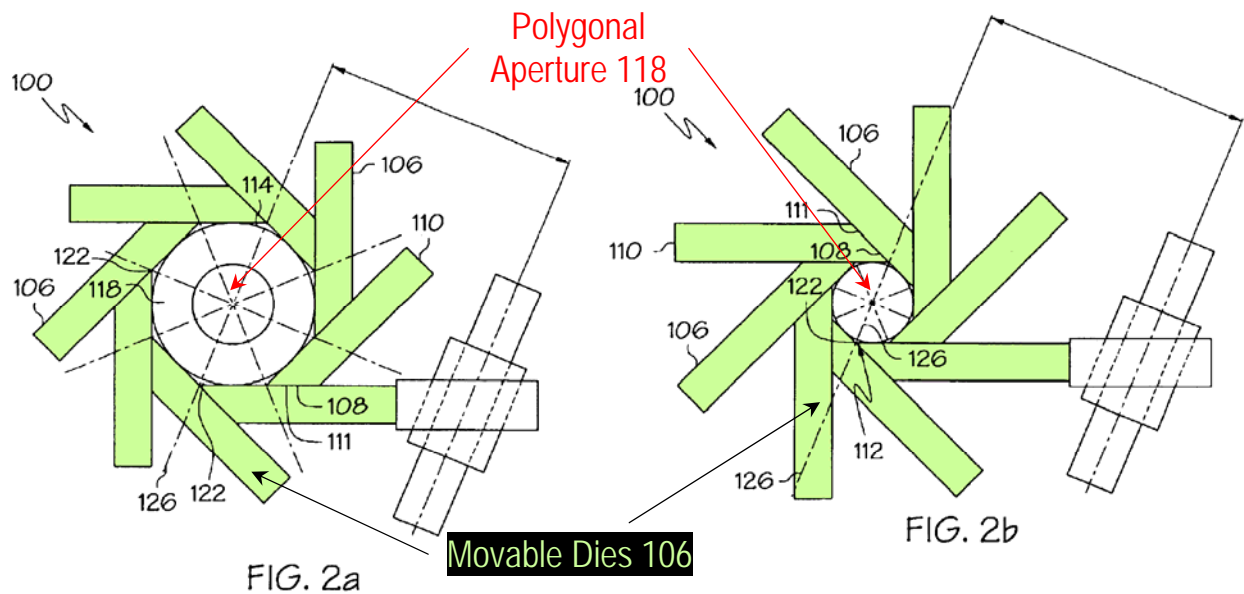
Edwards Lifesciences Corporation
IPR of U.S. Pat. 6,915,560

Exhibit No.	Description
1218	U.S. Patent No. 6,051,002 (“Morales 2”)
1219	U.S. Patent No. 5,951,540 (“Verbeek”)
1220	U.S. Patent No. 7,892,201 (“Laguna”)
1221	U.S. Patent No. 6,125,523 (“Brown”)
1222	U.S. Patent No. 3,370,451 (“Schuetz”)
1223	U.S. Patent No. 3,154,978 (“Baker 2”)
1224	U.S. Patent No. 3,417,598 (“Valente”)
1225	U.S. Patent No. 6,074,381 (“Dinh”)
1226	U.S. Patent No. 6,007,543 (“Ellis et al.”)
1227	U.S. Patent No. 5,437,083 (“Williams”)

Edwards Lifesciences Corporation (“Petitioner”) requests *inter partes* review pursuant to 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.100 *et seq.* of Claims 1, 2, 6, 8-11, 14, 15, 17-19, 23, 25-27, 28, 31, 33-35, 37, 39 and 40 of U.S. Patent No. 6,915,560 (“the ’560 patent”), owned by Boston Scientific Scimed, Inc. (“Patent Owner”).

I. SUMMARY OF THE ISSUE PRESENTED

The claims of the ’560 patent recite a device for crimping a stent onto a balloon catheter. The claimed device has three basic features: (a) movable blades or dies arranged to form a variable-sized ***polygonal*** aperture, (b) a rotatable actuation device coupled to the blades or dies, and (c) stationary end-walls on either sides of the blades or dies. By moving the dies, the size of the aperture can be increased (Fig. 2a) or decreased (Fig. 2b) while maintaining the same polygonal shape throughout.



Ex. 1201¹. Figure 4a is a partial front view that shows the dies, portions of the rotatable actuation device, and one end-wall. As the dies move, the sides of the dies push or squeeze the stent into a smaller size.

¹ For clarity, the Figures in this Petition have been colored and annotated.

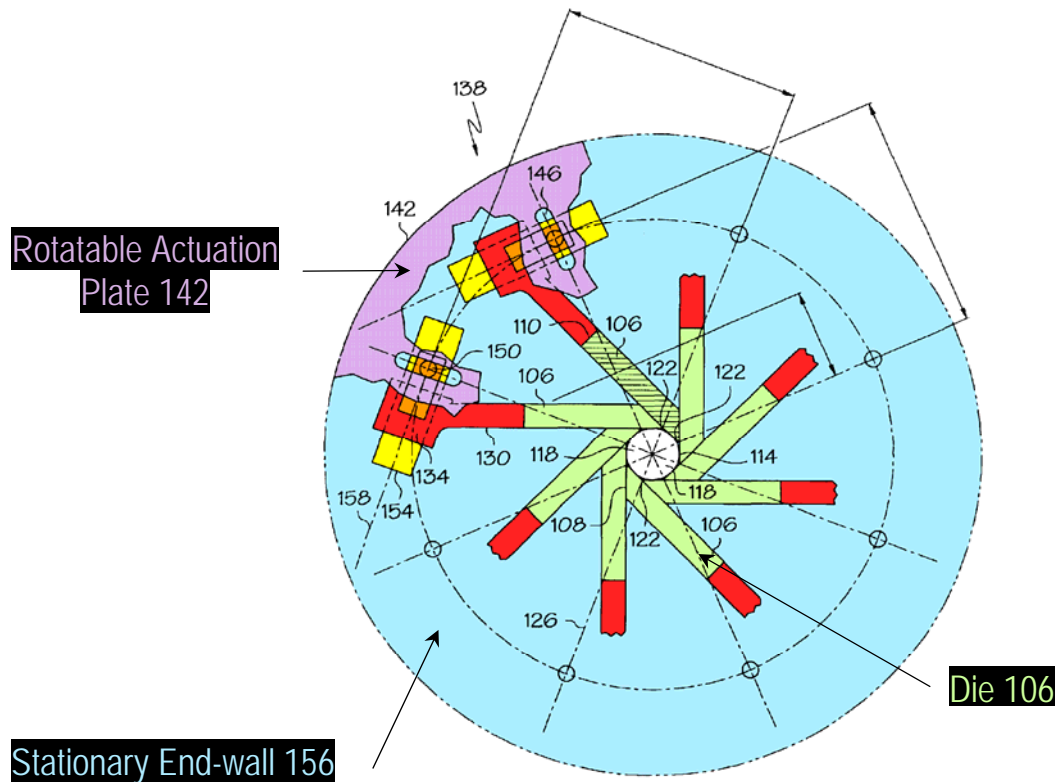
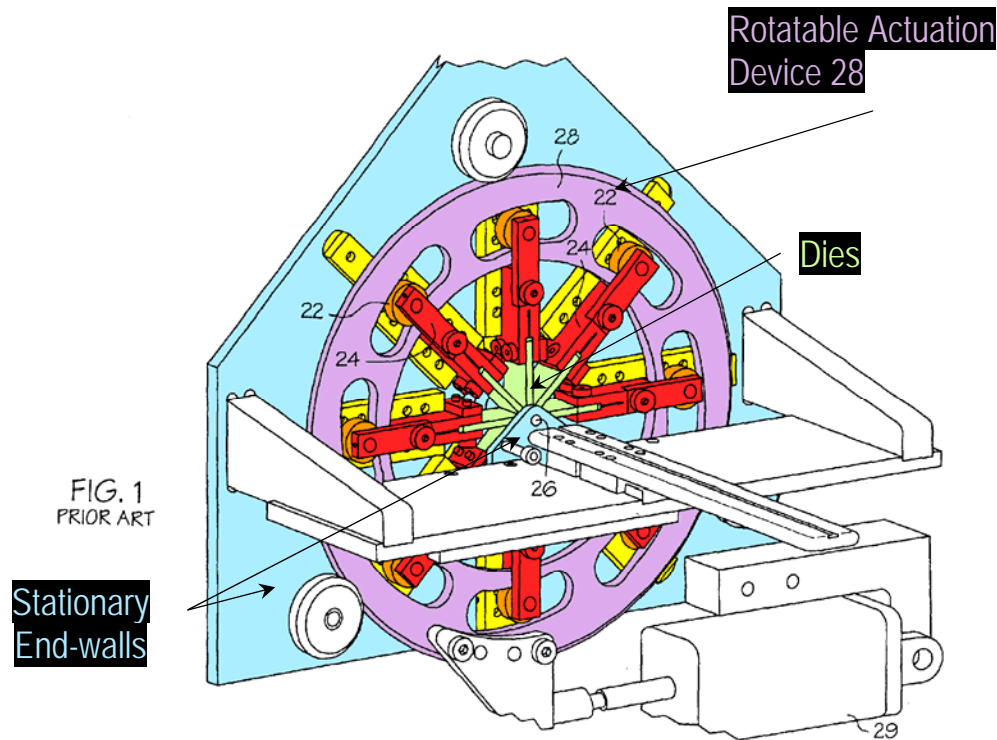


FIG. 4A

There was nothing inventive about such a device at the time of the '560 patent's earliest possible priority date of September 22, 1999. As the '560 patent admits, a stent crimper with dies coupled to a rotatable actuation device 28 and between stationary end-walls was already well known in the art. Ex. 1201 at 1:62-2:21 (describing "prior art" Figure 1). The '560 patent illustrates and describes the following admitted prior art stent crimper that embodies each of these well-known features:



Id., Fig. 1.

The only feature missing from the admitted prior art is the dies arranged to form a variable-sized ***polygonal*** aperture. But the arrangement of dies to form a polygonal-shaped aperture is nothing new.² For more than a century, skilled artisans have used such a configuration with tools that require increasing and decreasing the size of an aperture:

² Although not all the references discussed in this Petition are cited in the specific invalidity grounds below, these background references serve “to document the knowledge that skilled artisans would bring to bear in reading the prior art identified as producing obviousness.” *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015).

- Exs. 1208 and 1209 to Nix (wrench with trapezoidal jaws forming a polygonal opening that varies in size with movement of the jaws);
- Ex. 1210 to Andrews (tool with polygonal die hole for drawing, forming, or extruding bars);
- Ex. 1211 to Baker (tube pointer for compressing metal tubes with jaws forming a polygonal aperture that varies in size);
- Ex. 1203 to Yasumi (aperture setting tool with a variable size polygonal aperture for use in many applications, including as a press tool);
- Ex. 1212 to Hartley (tool with adjustable diameter polygonal opening that varies in size); and
- Ex. 1213 to Sabbaghian (wrench having gripping members forming a variable size polygonal aperture).

Dedicated stent crimpers, like the admitted prior art stent crimper, were not the only means available for crimping stents. Those of ordinary skill in the art were well aware that stents could be crimped manually by using ordinary tools, such as pliers or the like. Indeed, Patent Owner's own prior art patents explicitly teach the use of ordinary pliers to crimp a stent: "The stent is positioned over the balloon portion of the dilatation catheter and gently crimped onto the balloon either by hand or with a tool such as pliers or the like" Ex. 1226 at 3:20-23.

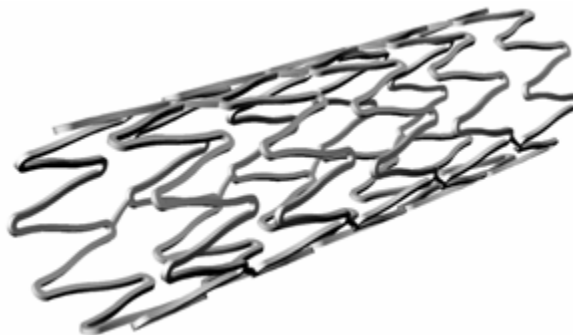
Patent Owner was not the only one to teach using ordinary pliers to crimp a stent. Prior art patents issued to Patent Owner's competitors, such as Advanced Cardiovascular Systems, Inc., Medtronic, Inc., Medinol Ltd. and IsoStent, Inc., also disclosed the use of ordinary pliers to crimp stents:

- Ex. 1218 at 2:6-9 (use of "tools, such as ordinary pliers");
- Ex. 1227 at 1:67-2:1 (same);
- Ex. 1219 at 2:1-3 (manual crimping using "pliers");
- Ex. 1214 at 1:33-35 (use of "plier-like device"); and
- Ex. 1225 at 1:43-46 (use of "modified plier-like tools").

II. INTRODUCTION TO THE STATE OF THE ART

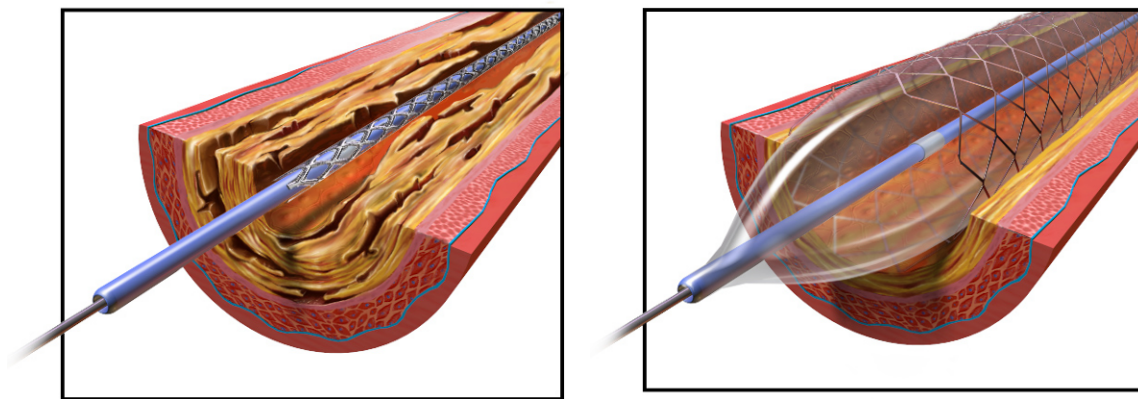
The '560 patent discloses a crimper for reducing the size of a stent. Stents are generally cylindrical wire-mesh medical devices that can be introduced via a delivery catheter into the blood vessel at a reduced diameter and then later expanded to the diameter of the vessel at the implantation site to open and reinforce an obstructed blood vessel. Ex. 1205 ¶¶ 27-30.

Stent



As part of the angioplasty procedure, a crimper is used to crimp the stent around an uninflated balloon located at the tip of a catheter. In this reduced-diameter configuration, the stent is able to travel through a patient's blood vessel in a smaller profile designed to prevent abrasion and trauma to the vessel wall. Once the stent is correctly positioned at the implantation site, the balloon is inflated and expands the stent to the proper size. Ex. 1205 ¶¶ 27-30.

Balloon Catheter & Stent Within Vessel Before & After Inflation

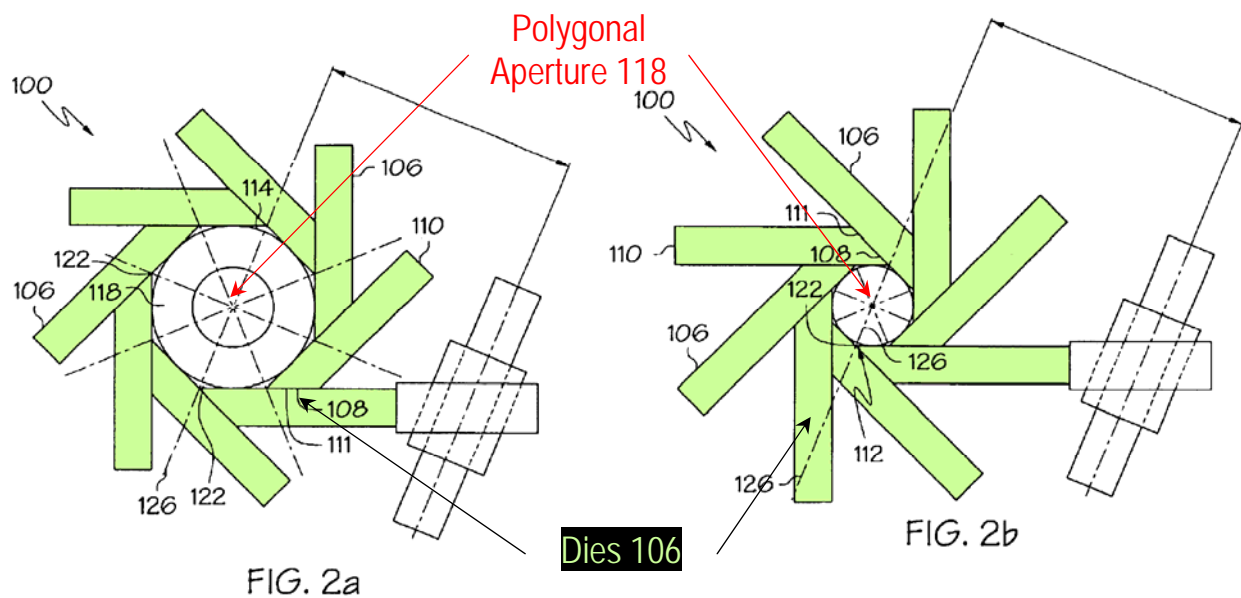


Stents must be crimped uniformly to avoid damaging the stent. Ex. 1205 ¶¶ 166-167. Many conventional stent crimping techniques in the early 1990's did not apply optimal uniform crimping forces. As explained in Pinchasik:

[C]rimping is often done utilizing the fingers or a plier-like device to pinch the stent. One shortcoming of this conventional mounting and securing means is that it often produces irregular distortion of the stent which could cause trauma to the lumen being treated. Another shortcoming is that it may weaken a portion or portions of the stent which could result in stent failure.

Ex. 1214 at 1:33-40.

The '560 patent sought to solve this problem using a plurality of movable blades or dies arranged so that the inward facing flat surfaces of the dies form a polygonal crimping aperture. By moving the dies, the size of the aperture can be increased (Fig. 2a) or decreased (Fig. 2b) while maintaining the same polygonal shape throughout.



According to the '560 patent, this die configuration improves upon the prior art because the polygonal-shaped aperture is capable of applying uniform forces to crimp a stent without distorting, scoring, or marking the stent during the crimping process. Ex. 1201 at 2:27-30.

As discussed above, this polygonal die configuration has been used for over a century in connection with tools that require increasing and decreasing the size of an aperture to grip, compress, or form an object. So, in essence, Patent Owner

merely substituted the die configuration of the admitted prior art crimper, shown in Fig. 1 of the '560 patent, with the polygonal die configuration that was prevalent in the prior art.

During prosecution of the '560 patent, the Examiner recognized that dedicated stent crimpers, like the admitted prior art, were not the only types of prior art tools for crimping stents. Notably, the Examiner relied on prior art directed to a variety of tools, including plier-like tools, to reject the claims during prosecution. For example, the Examiner cited a reference directed to radial pliers or a wrench:

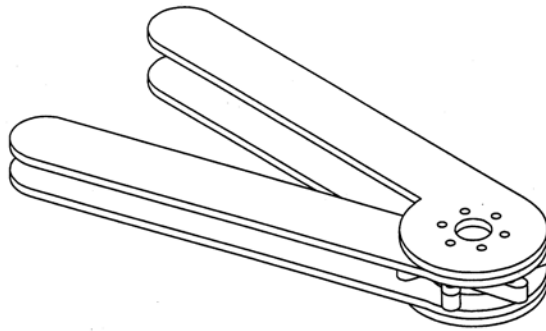
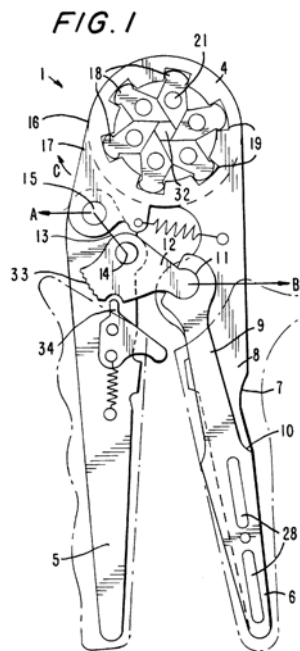


Figure 8

Ex. 1202 at 72-73, Ex. 1215, Fig. 8. The Examiner also relied upon a crimping tool for crimping lead end sleeves onto electrical conductors:



Ex. 1202 at 46, Ex. 1217, Fig. 1.

Like the Examiner, a person of ordinary skill in the art (“POSITA”) would have looked to these and other types of plier-like tools to crimp a stent. Thus, a POSITA would have viewed Yasumi as a stent crimper because it is a plier-like tool fully capable of crimping a stent. A POSITA also would have had a reason, basis, or motivation to use Yasumi, with its dies that form a polygonal aperture, as a stent crimper in order to provide uniform crimping forces and thereby avoid distorting, scoring, or marking of the stent during the crimping process.

Accordingly, as explained below, Yasumi alone is sufficient to render each of the challenged claims unpatentable as obvious. However, to the extent necessary, a POSITA would have had a reason, basis, or motivation to use Yasumi

as a stent crimper in view of Williams, which explicitly discloses the use of “a tool, such as pliers,” to crimp a stent. Ex. 1205 ¶¶ 85-92, 160-168.

III. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

A. Real Party-in-Interest (37 C.F.R. § 42.8(b)(1))

Petitioner Edwards Lifesciences Corporation is the real party-in-interest.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

Patent Owner has asserted the '560 patent against Petitioner in a lawsuit filed on April 19, 2016, captioned *Boston Scientific Corp. and Boston Scientific Scimed, Inc. v. Edwards Lifesciences Corp.*, Civil Action No. 8:16-cv-0730 (C.D. Cal.).

C. Lead and Back-up Counsel Under 37 C.F.R. § 42.8(b)(3)

Pursuant to 37 C.F.R. §§ 42.8(b)(3) and 42.10(a), Petitioner provides the following designation of counsel, all of whom are included in Customer No. 20,995:

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D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Please address all correspondence to lead counsel and back-up counsel at the address shown above. Petitioner also consents to electronic service by email to: BoxEdwards-5@knobbe.com.

IV. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a)

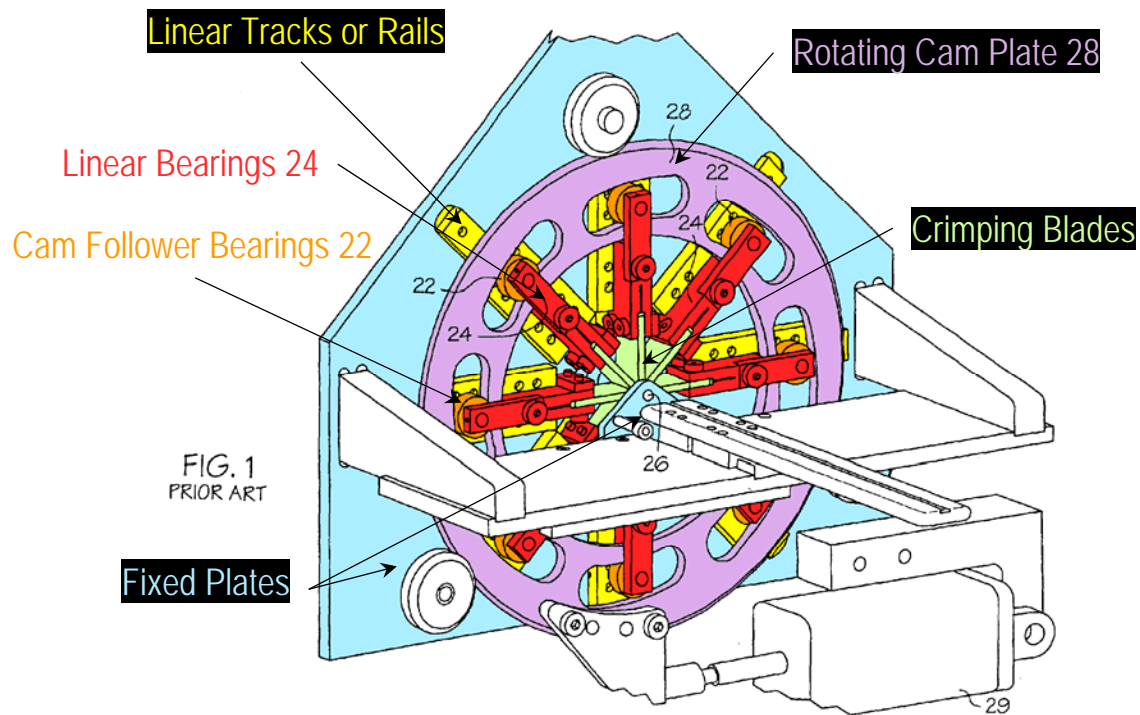
Petitioner certifies that the '560 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review challenging the patent claims on the grounds identified in this Petition.

V. U.S. PATENT NO. 6,915,560

A. Specification and Claims

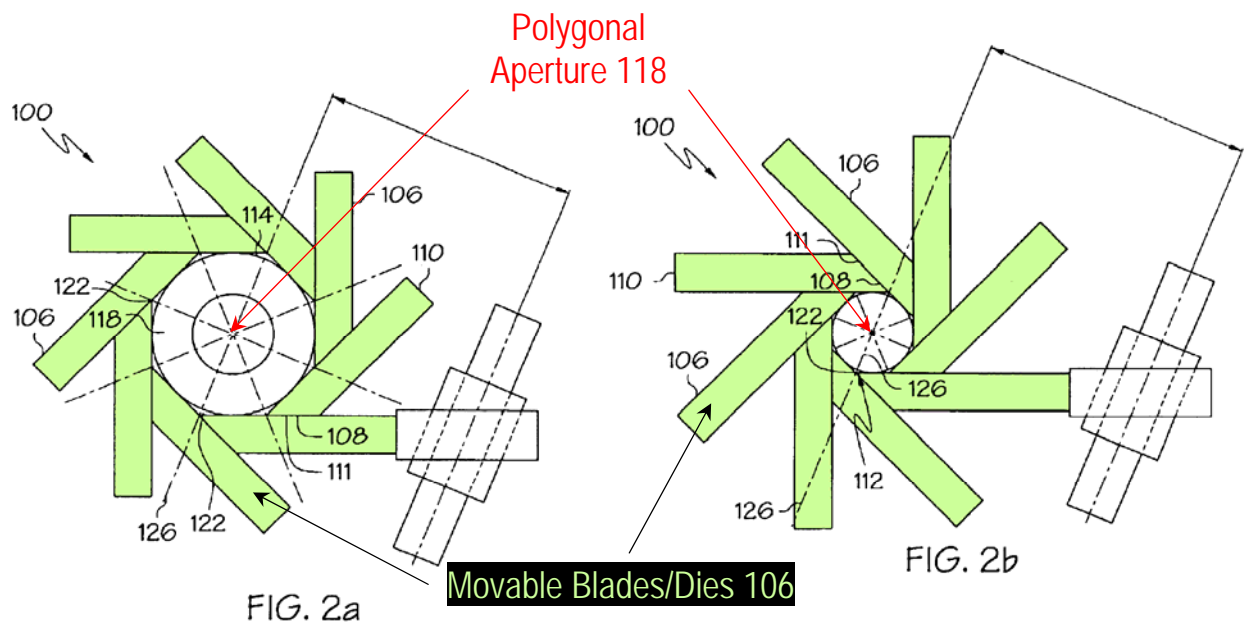
The '560 patent describes an apparatus formed of coupled movable blades that are disposed about a reference circle to form a shrinkable aperture. Ex. 1201 at Abstract, 9:20-22. The '560 patent explains that prior art crimping of stents often applied uneven crimping forces that could distort the stent and require re-crimping. However, crimping the same stent multiple times can damage the stent. Ex. 1201 at 1:42-55.

The '560 patent illustrates and describes an admitted prior art stent crimper ("Applicant Admitted Prior Art" or "AAPA"):



Ex. 1201, Fig. 1. The AAPA discloses every limitation of the challenged claims, except for the polygonal aperture.

The supposed improvement of the '560 patent over the AAPA is a crimper that uses movable blades 106 (green) to form a polygonal aperture whose size may be varied, as shown in Figures 2a and 2b below. *Id.* at 4:46-62, 4:66-5:3. According to the '560 patent, this configuration is “capable of crimping a stent uniformly while minimizing the distortion of and scoring and marking of the stent due to the crimping.” Ex. 1201 at 2:26-29.



Id., Figs. 2a, 2b.

Figures 4A and 4c of the '560 patent show one embodiment of the invention with additional structure depicted.

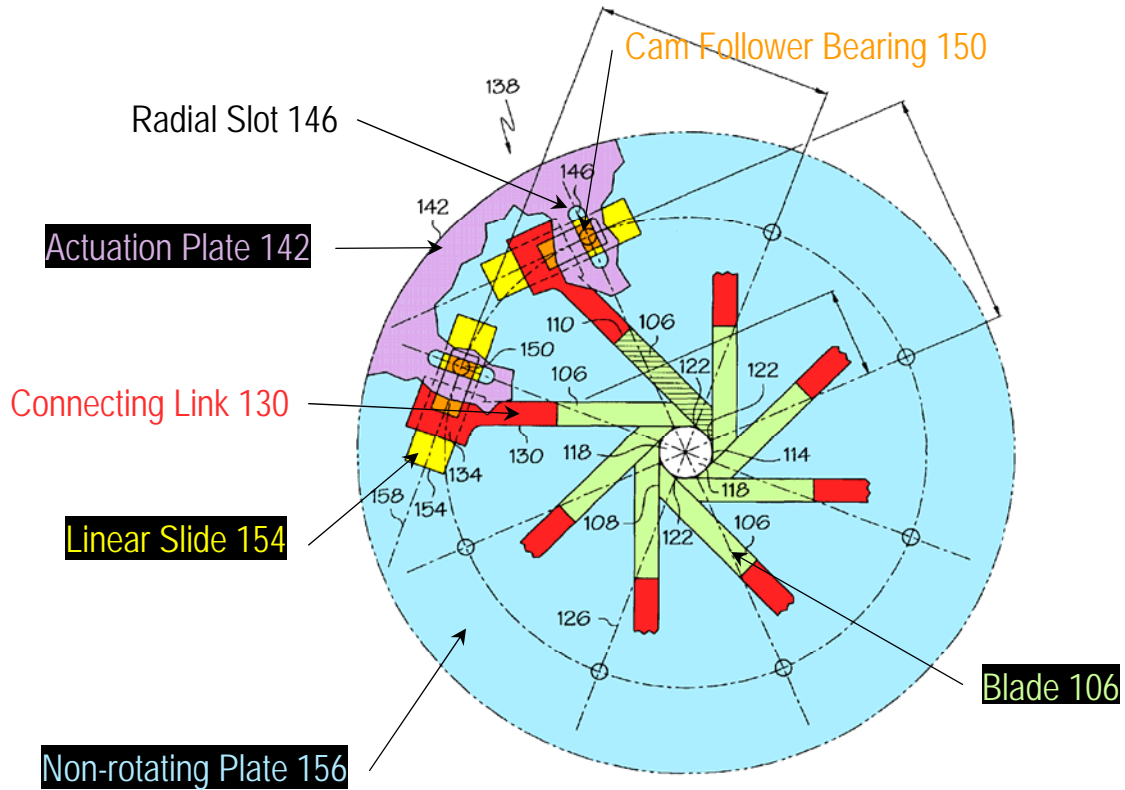


FIG. 4A

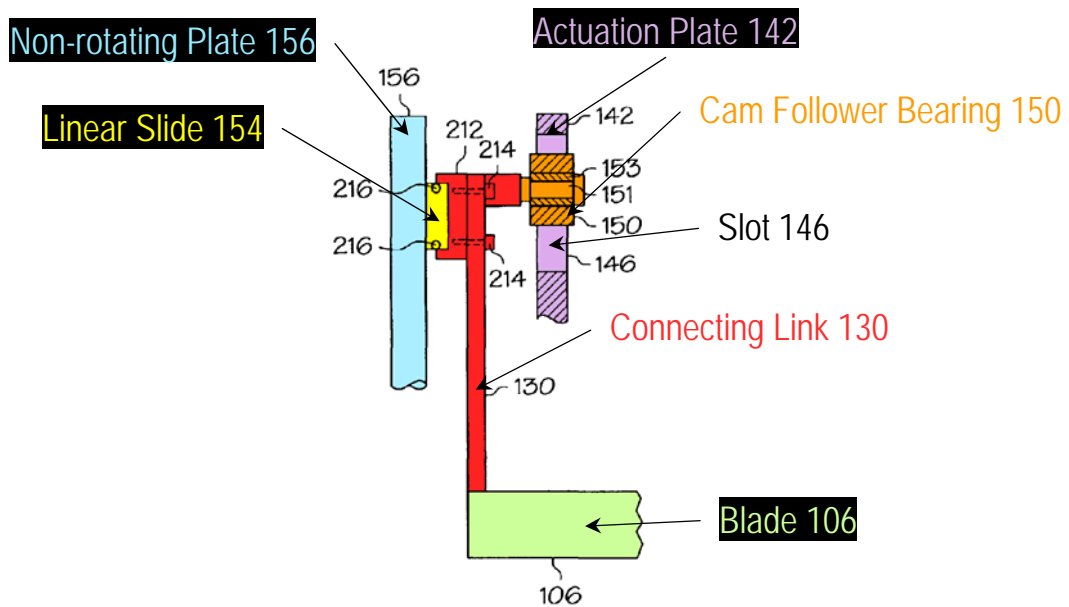
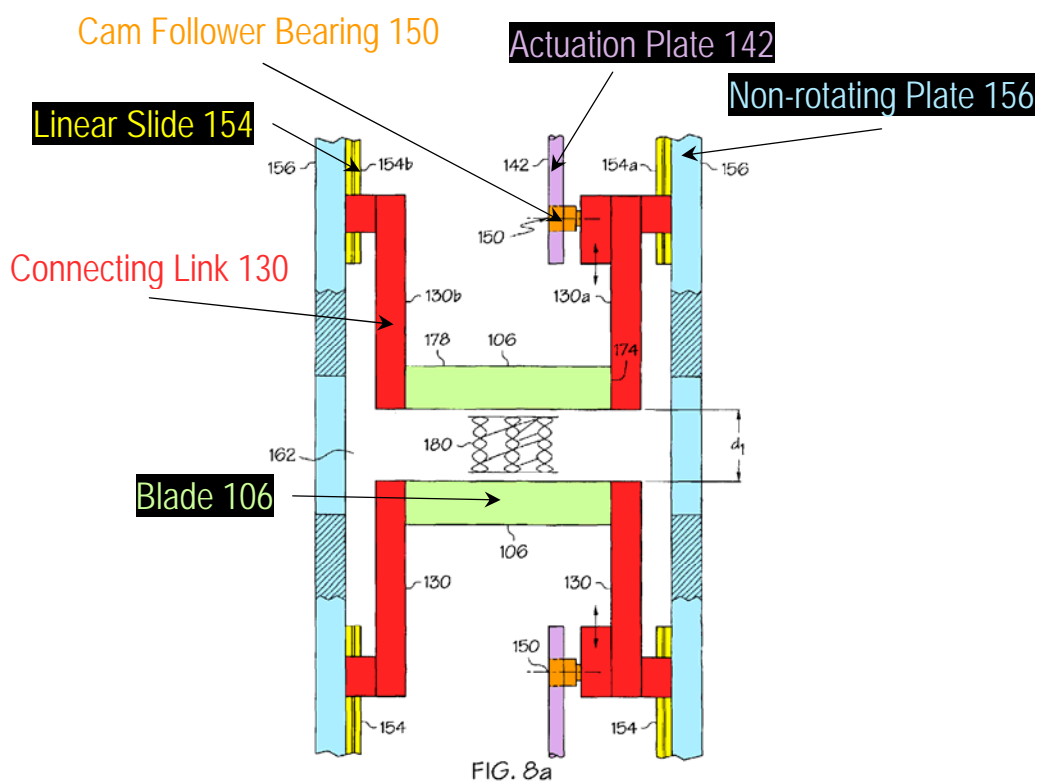
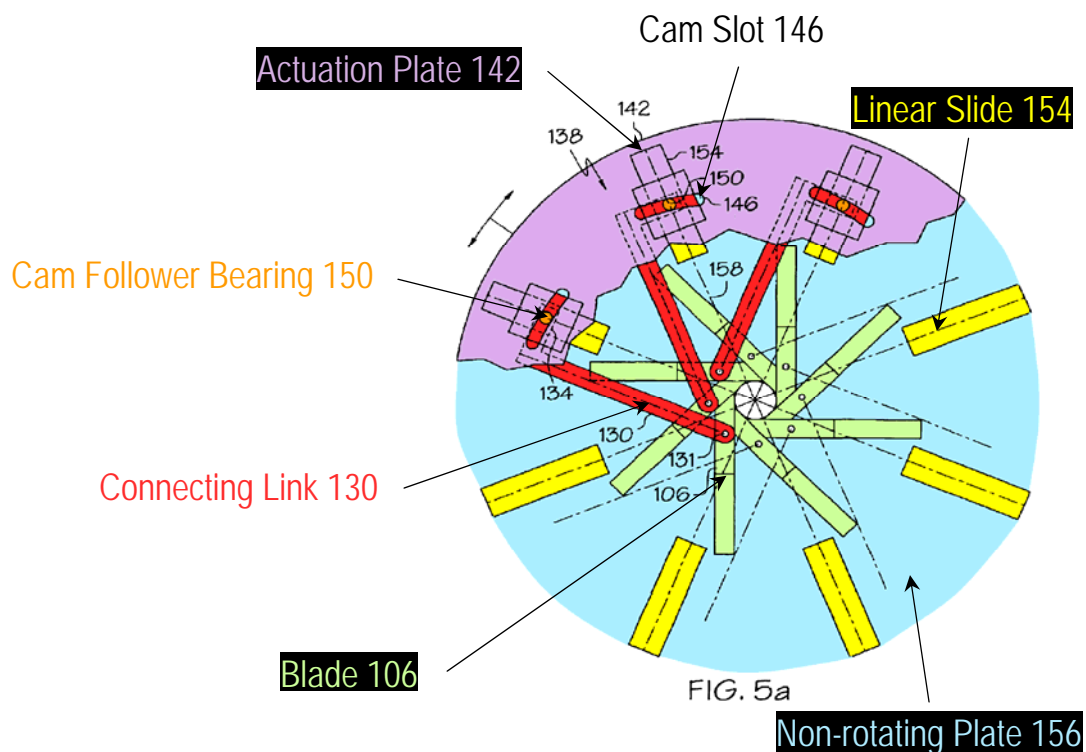


FIG. 4c

Ex. 1201 at Figs. 4A, 4c. In this embodiment, each crimping blade 106 (green) is attached to a connecting link 130 (red). *Id.* at 5:6-7. One side of each connecting link 130 (red) is adapted to slide along a linear slide 154 (yellow) mounted on a non-rotating plate 156 (blue). *Id.* at 5:17-24. The other side has a cam follower bearing 150 (orange) that extends into a slot 146 in an actuation plate 142 (purple). *Id.* When the actuation plate 142 (purple) is rotated, the connecting links 130 (red) slide along the linear slides 154 (yellow) and simultaneously move the crimping blades 106 (green) radially in and out to change the size of the aperture. *Id.* at 5:7-62.

Figures 5a and 8a disclose an alternative embodiment of the invention.



Ex. 1201 at Figs. 5a, 8a. This embodiment operates in a manner similar to the embodiment described above, but the blades 106 (green) are attached to the connecting links 130 (red) at an angle, and the linear slides 154 (yellow) are arranged to slide along a line (158) that runs along a radius of the aperture. *Id.* at 5:66-6:42.

There are 7 independent claims and 17 dependent claims challenged in this Petition. Claim 10 is a representative independent claim and reads:

A stent crimper comprising:

a plurality of movable dies arranged to form an iris, the dies disposed about an aperture, the aperture having a longitudinal axis and a substantially regular polygonal shape, 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, the dies between two stationary end-walls disposed about the longitudinal axis, the longitudinal axis passing through a point substantially centered on the end-walls,

a rotatable actuation device coupled to the dies, 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.

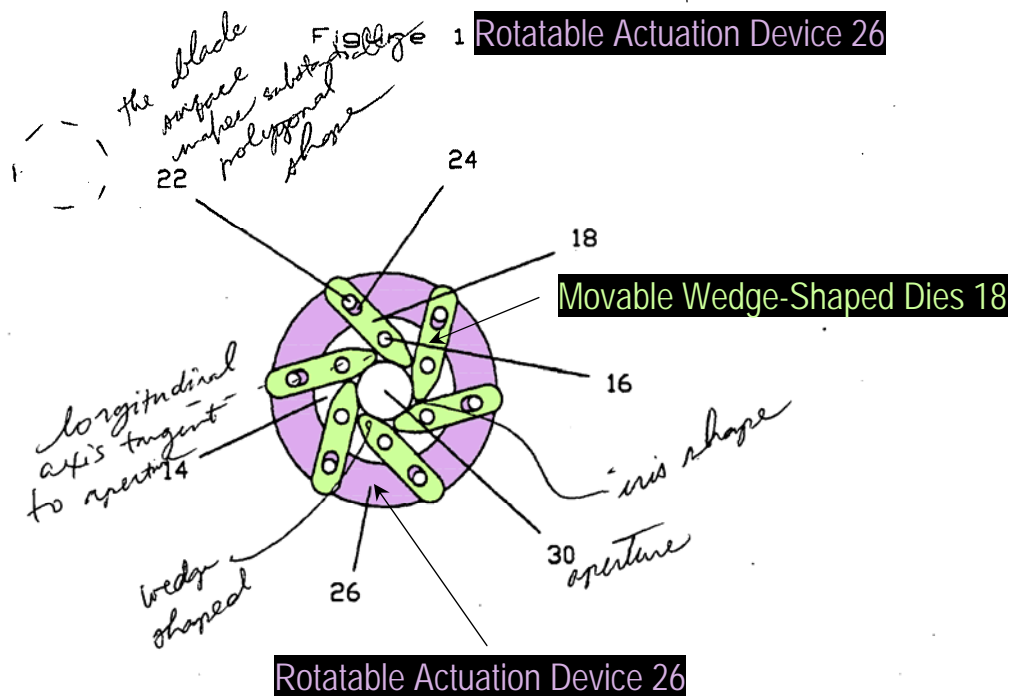
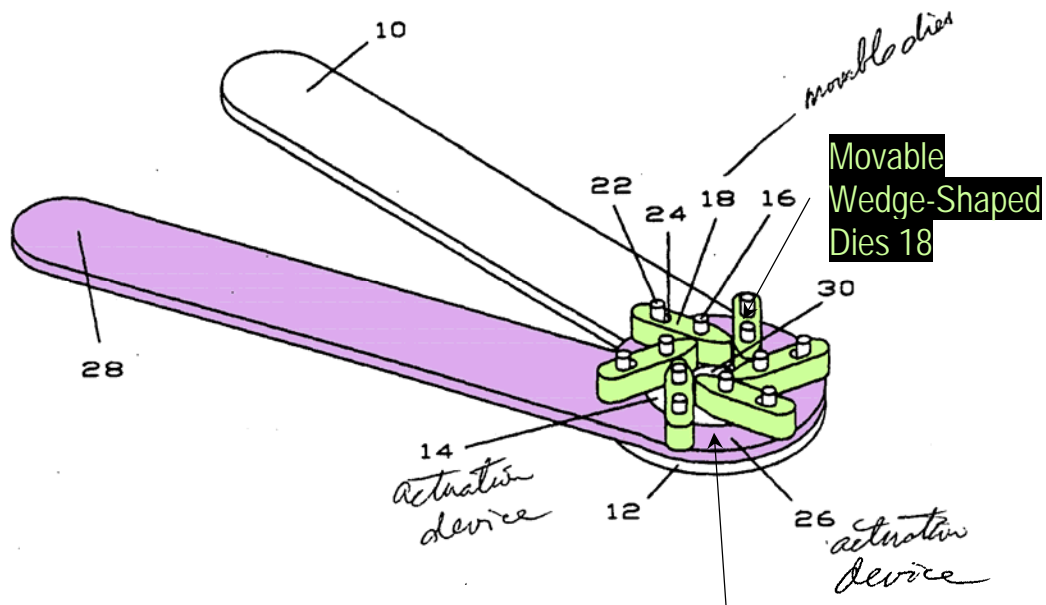
B. Prosecution History

U.S. Patent Application No. 10/444,807, which issued as the '560 patent, was filed on May 23, 2003 with 26 claims.³ Ex. 1202 at 153-157. On October 9, 2003, the Applicant responded to a restriction requirement by canceling the original claims and submitting 35 new claims. *Id.* at 93-98.

1. October 22, 2003 Office Action and Response

In an Office Action dated October 22, 2003, the Patent Examiner rejected all claims. Ex. 1202 at 69-80. Independent Claims 27, 36, 44, and 52 were rejected as anticipated by or obvious over U.S. Patent No. 5,261,263 ("Whitesell"). The Examiner found that Whitesell teaches a crimper comprising a plurality of movable dies 18 arranged to form an iris, with the dies 18 disposed about an aperture 30 with a substantially regular polygonal shape, and a rotatable actuation device 26 coupled to the dies, whereby rotation of the actuation device causes the dies to move inward to reduce the size of the aperture or outward to increase the size of the aperture. *Id.* at 72-73.

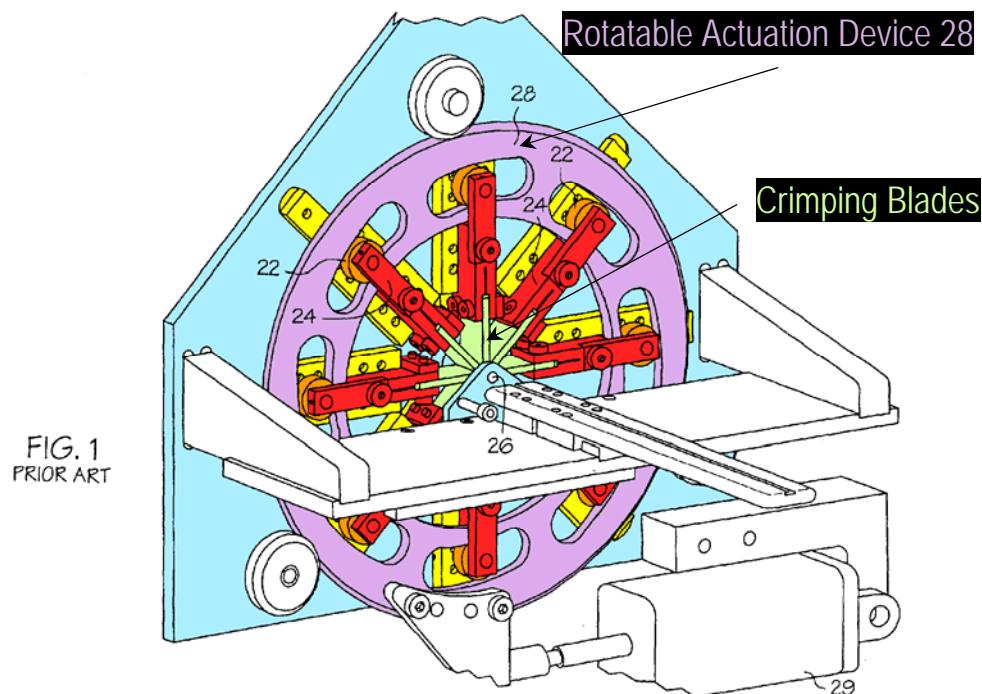
³ The application for the '560 patent is a continuation of one parent and one grandparent application. The prosecution histories of these applications are not relied upon for the purposes of this Petition.



Ex. 1202 at 84 (Whitesell, Ex. 1215, Figs. 1 and 2, handwritten notes in original; colored annotations added).

Whitesell discloses pliers for gripping and crimping cylindrical objects. Ex. 1215 at 1:28-36. The Examiner considered Whitesell a stent crimper because “Whitesell is capable of performing crimping of a stent.” Ex. 1202 at 72. The Applicant did not dispute the Examiner’s position. *Id.* at 62-67.

The Examiner also rejected Claims 27, 36, 44, and 52 as obvious over the AAPA in view of Whitesell. Ex. 1202 at 74-76. The Examiner found that the AAPA teaches a stent crimper comprising a plurality of movable dies 24 arranged to form an iris, with the dies disposed about an aperture 26, and a rotatable actuation device 28. *Id.* at 74-75.



Ex. 1201, Fig. 1. The Examiner explained that it would have been obvious “to have provided the invention of [the AAPA] with dies having a longitudinal axis

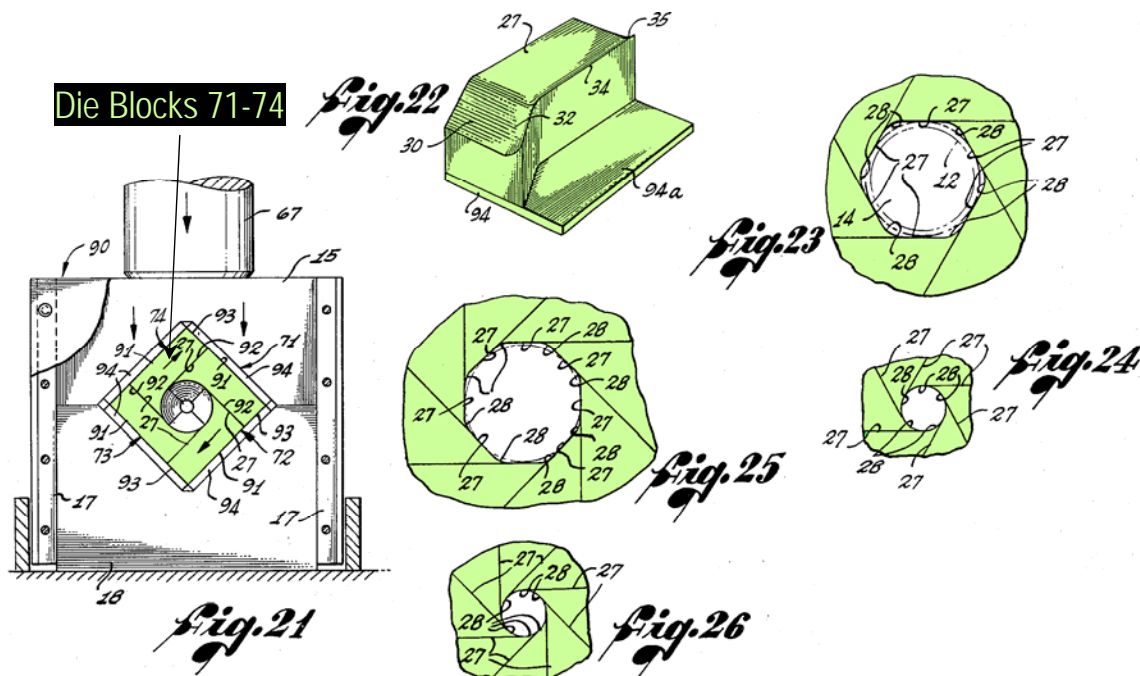
which is tangent to the aperture, in light of the teachings of Whitesell, in order to provide a symmetric crimping deformation. It is noted that Whitesell recognizes the benefits of using radial applying crimping forces over linearly applied forces like the one taught by [AAPA].” Ex. 1202 at 74-75.

In response, on January 22, 2004, the Applicant amended independent Claims 27, 36, 44, and 52 by adding limitations resulting in dies with straight or flat sides facing a substantially polygonal aperture when moved to open or close the aperture (the “straight-sided die/polygonal aperture limitation”). Ex. 1202 at 57-60. The Applicant argued that Whitesell’s dies did not have a flat side facing the aperture, and did not form a polygonal shape, when closed. *Id.* at 63-64. The Applicant further argued that the AAPA did not disclose the new limitations, noting that “an iris defining an aperture with a substantially regular polygonal shape acts about an opening or aperture such that the opening or aperture maintains a similar geometric shape while minimizing or maximizing the size of the aperture. . . . the AAPA manipulates the stent to be crimped by having elongate portions poke radially inward and press portions of the stent in order to minimize the size of the stent.” *Id.* at 65-66. The Applicant also added new independent claims, including Claim 63. *Id.* at 60-61.

2. April 22, 2004 Office Action and Response

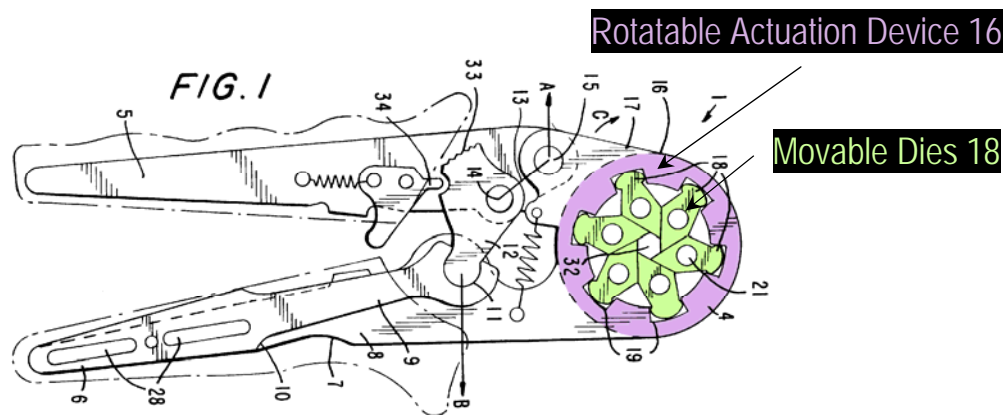
On April 22, 2004, the Examiner rejected independent Claims 27, 36, 52, and 63 as anticipated by either U.S. Patent No. 3,695,087 (“Tuberman”) or U.S. Patent No. 6,176,116 (“Wilhelm”). Ex. 1202 at 42-52. The Examiner found that both taught dies arranged to form an iris with angles that remain substantially the same when the dies move to open or close. *Id.* at 45-46.

Tuberman, depicted below, describes an apparatus for drawing or forming cylindrical points on metal tubes. Ex. 1216 at Abstract.



Id., Figs. 21-26.

Wilhelm, depicted below, describes a crimping tool for crimping lead end sleeves, contact sockets, or plugs onto electrical conductors. Ex. 1217 at Abstract.



Id., Fig. 1.

The Examiner considered Tuberman and Wilhelm stent crimpers because both are capable of crimping a stent. Ex. 1202 at 45-46. The Applicant did not dispute the Examiner's position.

On July 22, 2004, the Applicant filed a response and an amendment. Ex. 1202 at 29-39. The Applicant deleted the straight-sided die/polygonal aperture limitation from Claim 27, and added new limitations to independent Claims 27, 36, 44, 52, and 63 directed to dies disposed "between stationary end-walls substantially centered about the longitudinal axis" (the "stationary end-walls limitation".) *Id.* at 29-33. The Applicant also added independent Claim 67 that included the stationary end-walls limitation. *Id.* at 33.

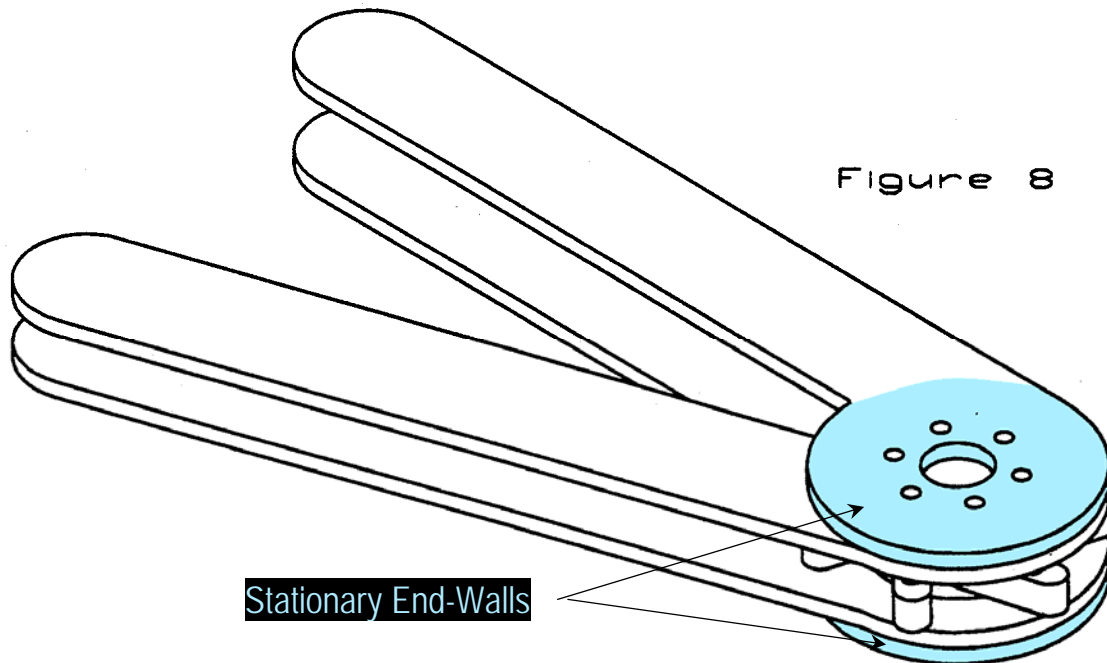
The Applicant did not dispute that Tuberman disclosed the straight-sided/polygonal aperture limitation. Instead, the Applicant focused on the stationary end-walls limitation and argued that, to the extent Tuberman teaches

end-walls, those end-walls are not centered about the longitudinal axis, *id.* at 35, and that Wilhelm teaches an open face apparatus without stationary end-walls, *id.* at 36.

On September 22, 2004, the Applicant filed a Request for Continued Examination to permit review of the July 22, 2004 amendment. Ex. 1202 at 22-23.

3. October 19, 2004 Office Action and Response

On October 19, 2004, the Examiner allowed independent Claims 36, 44, and 52, each of which contained a stationary end-walls limitation **and** a straight-sided die/polygonal aperture limitation. *See* Ex. 1202 at 20, 29-33. The Examiner rejected independent Claims 27, 63, and 67, again as anticipated by or obvious over Whitesell, finding that Whitesell teaches the stationary end-walls limitation. *Id.* at 17-18.



Ex. 1215, Fig. 8.

On January 7, 2005, the Applicant amended independent Claims 27, 63, and 67 to include a straight-sided die/polygonal aperture limitation, and argued that Whitesell does not teach this limitation. Ex. 1202 at 5, 8-12.

On February 14, 2005, the Examiner issued a Notice of Allowability. *Id.* at 1-4.

VI. IDENTIFICATION OF CHALLENGE PURSUANT TO 37 C.F.R. § 42.104(B)

Petitioner respectfully requests that the Board cancel the following claims of the '560 patent based on the following grounds:

Ground 1: Claims 1, 2, 6, 8-10, 14, 15, 18, 23, 25, 27, 28, 31, 33, 37, and 40 are unpatentable under 35 U.S.C. § 103 as obvious over Yasumi in view of Williams.

Ground 2: Claims 11, 17, 19, 26, 34, 35, and 39 are unpatentable under 35 U.S.C. § 103 as obvious over Yasumi in view of Williams, and further in view of Morales.

A detailed explanation of how the claims are unpatentable is set forth below in Part X. Additional explanation and support for each ground is included in the Declaration of Neil Sheehan. Ex. 1205.

VII. PERSON HAVING ORDINARY SKILL IN THE ART

A person of ordinary skill in the art 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. Ex. 1205 ¶¶ 69-71.

VIII. CLAIM CONSTRUCTION AND RELATED ISSUES

Pursuant to 37 C.F.R. § 42.100(b), and solely for the purpose of this review, Petitioner construes the claim language such that the claims are given their broadest reasonable interpretation in light of the '560 patent specification. *See In*

re Cuozzo Speed Techs., LLC, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015), *aff’d*, 136 S. Ct. 2131 (2016).⁴

A. “A stent crimper comprising”

Each of the challenged claims recites “[a] stent crimper comprising” in the preamble. This preamble is not limiting.

In *Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808–09 (Fed. Cir. 2002), the Federal Circuit identified several guideposts to determine whether a preamble limits claim scope. For example, “when reciting additional structure . . . underscored as important by the specification, the preamble may operate as a claim limitation.” *Id.* at 808. Additionally, a preamble that provides antecedent basis for a claim limitation generally limits the scope of the claim. *Id.* at 808. By contrast, if the body of the claim describes a structurally complete invention, a preamble is not limiting where it “merely gives a name” to the invention, extols its features or benefits, or describes a use for the invention. *Id.* at 809.

The ’560 patent claims never refer back to the preamble for antecedent basis. Moreover, “stent crimper” is not a recitation of additional structure underscored as important by the specification. While the specification acknowledges that stent

⁴ Petitioner’s position regarding the scope of the claims should not be taken as an assertion regarding the appropriate claim scope in other adjudicative forums where a different standard of claim construction and/or claim interpretation may apply.

crimping is one use for the invention, it recognizes additional uses. Ex. 1201 at 2:52-55 (“[T]he inventive apparatus may also be employed with any other suitable, generally tubular medical device which must be reduced in size”); 8:65-66 (“The inventive apparatus may be incorporated into a blow molding tool to provide a variable size balloon mold.”).

The Examiner also found that the preamble was not limiting. Ex. 1202 at 19, 45-47, 49, and 72. The Applicant did not dispute the Examiner’s position.

Accordingly, a POSITA would have understood that the preamble “merely gives a name” to the invention, or is merely a statement of purpose or intended use, *i.e.*, crimping a stent. Ex. 1205 ¶¶ 73-75. Therefore, the preamble is not limiting.

B. “Dies” and “blades”

Independent Claims 1, 10, 18, 37, 39, and 40 use the term “dies.” In these claims, the dies are “arranged to form an iris” and in all but Claim 18 are further “disposed about [an/the] aperture.” The dies are also located between stationary end-walls or between stationary plates in Claims 1, 10, 18, 37, and 40. The remaining independent claim, Claim 27, uses the term “blades” instead of “dies,” similarly claiming “an aperture with a plurality of blades disposed thereabout . . . the blades between stationary end-walls.” The claims thus use the terms dies and blades to describe similar structural components.

The specification does not further distinguish between dies or blades because it never uses the terms “die” or “dies.” The specification only discusses blades, describing, for example, “movable blades which are disposed about a reference circle to form an aperture whose size may be varied.” Ex. 1201 at Abstract.

During prosecution, the Applicant used the terms dies and blades interchangeably. For example, during prosecution the Examiner rejected Claims 28 and 36 as indefinite because the term “blades” lacked antecedent basis. Ex. 1202 at 44, 71. In response, the Applicant amended the claims to recite “dies” and deleted the term “blades,” without argument. *Id.* at 29-30, 34, 57, 63. The Examiner also commented in the Office Action dated October 22, 2003, that “dies” correspond to “blades.” *Id.* at 77.

Accordingly, a POSITA would have understood that the terms dies and blades describe similar structural components of the claimed apparatus. Ex. 1205 ¶¶ 76-80.

C. “Stationary end-walls” and “stationary plates”

Independent Claims 1, 10, 18, 27, and 37 use the phrase “stationary end-walls.” In these claims, the stationary end-walls are “disposed about the longitudinal axis” of an iris or aperture formed by a plurality of movable dies. Independent Claim 40 similarly uses the term “stationary plates disposed about the

longitudinal axis” of an aperture formed by a plurality of movable dies. The claims thus use the terms “stationary end-walls” and “stationary plates” to describe similar structural components.

The specification does not further distinguish between stationary end-walls or stationary plates because it never uses either of those terms, but, rather, refers to fixed plates or non-rotating plates. The prosecution history likewise does not distinguish between either term.

Accordingly, a POSITA would have understood that the terms “stationary end-walls” and “stationary plates” describe stationary elements disposed about the longitudinal axis of an aperture formed by a plurality of movable dies or blades. Ex. 1205 ¶¶ 81-83.

IX. THE PRIOR ART

A. Analogous Art

To be analogous art, a prior art reference must be (1) “from the same field of endeavor,” or (2) “reasonably pertinent to the particular problem with which the inventor is involved.” *Innovation Toys, LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1321 (Fed. Cir. 2011). “A reference is reasonably pertinent if . . . it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.” *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992).

1. Field Of Endeavor

The '560 patent is directed generally to an apparatus having movable blades that form a variable size aperture. Ex. 1201 at Abstract. The patent identifies multiple applications for the variable aperture apparatus, including applying a radial inward force to a medical device to reduce its size and diameter, *id.* at 8:58-61, and as a variable sized mold cavity for blow molding balloons, *id.* at 8:65-67.

Variable size aperture apparatus are not unique to the medical device field. There are countless mechanical engineering applications for such an apparatus that fall within the same field of endeavor (e.g. tube reducers, socket wrenches, surgical needle swagers, forming dies, tube pointers, extruding dies). Ex. 1205 ¶¶ 85-92. Patents directed to any apparatus that uses movable members disposed to form a variable size aperture therefore fall within the same field of endeavor as the '560 patent and constitute analogous prior art that would have been known to a POSITA. *Id.*

2. Pertinent To The Particular Problem

The '560 patent teaches that uneven forces applied to a stent while crimping necessitates either discarding or re-crimping the stent, and that re-crimping can damage the stent. Ex. 1201 at 1:48-55. The Applicant also disparaged the AAPA during prosecution as having “elongate portions poke radially inward and press portions of the stent” instead of maintaining a similar geometric shape while

maximizing and minimizing the size of the aperture. Ex. 1202 at 65. Therefore, the '560 patent allegedly solves the problem of uneven crimping forces, such as those caused by elongate members poking radially into an aperture. *See* Ex. 1201 at 2:27-30.

However, the problems associated with uneven crimping forces were recognized and solved long ago by other prior art devices by utilizing dies to form a variable size polygonal aperture without gaps between the dies. Ex. 1205 ¶¶ 93-96. Prior art directed to apparatus that can provide uniform size reduction of an aperture are reasonably pertinent to that problem and are also analogous art. *Id.*

Indeed, the Examiner took this position during prosecution, citing and relying upon numerous patents in the classes of metal working, metal deforming, and tools to reject the claims. *See* Ex. 1202 at 15-21 (relying on Whitesell), 42-49 (relying on Tuberman and Wilhelm); *see also* Exs. 1215 (Whitesell), 1216 (Tuberman), 1217 (Wilhelm) (referencing US classes 29 (metal working), 72 (metal deforming), and 81 (tools)). The Applicant did not dispute the Examiner's position. Indeed, the Applicant also disclosed prior art patents in these fields when submitting Information Disclosure Statements. Ex. 1202 at 81-82, 159-64 (disclosing patents referencing US classes 29 (metal working) and 72 (metal deforming)).

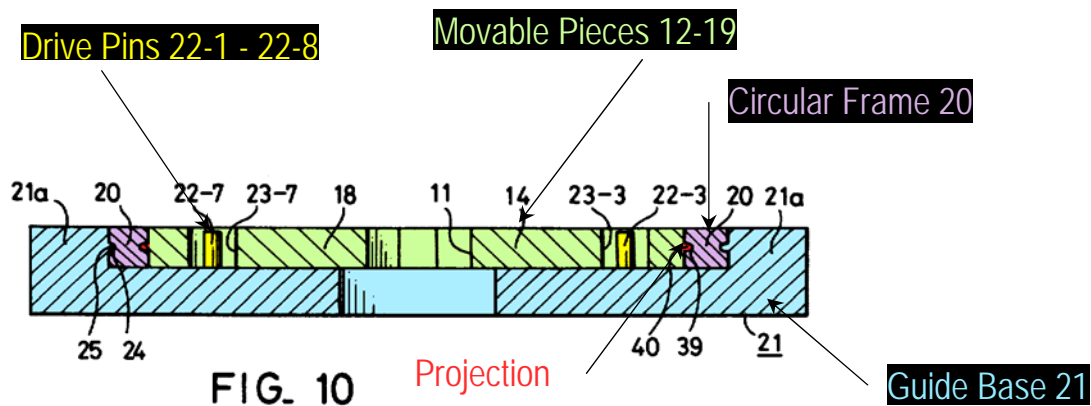
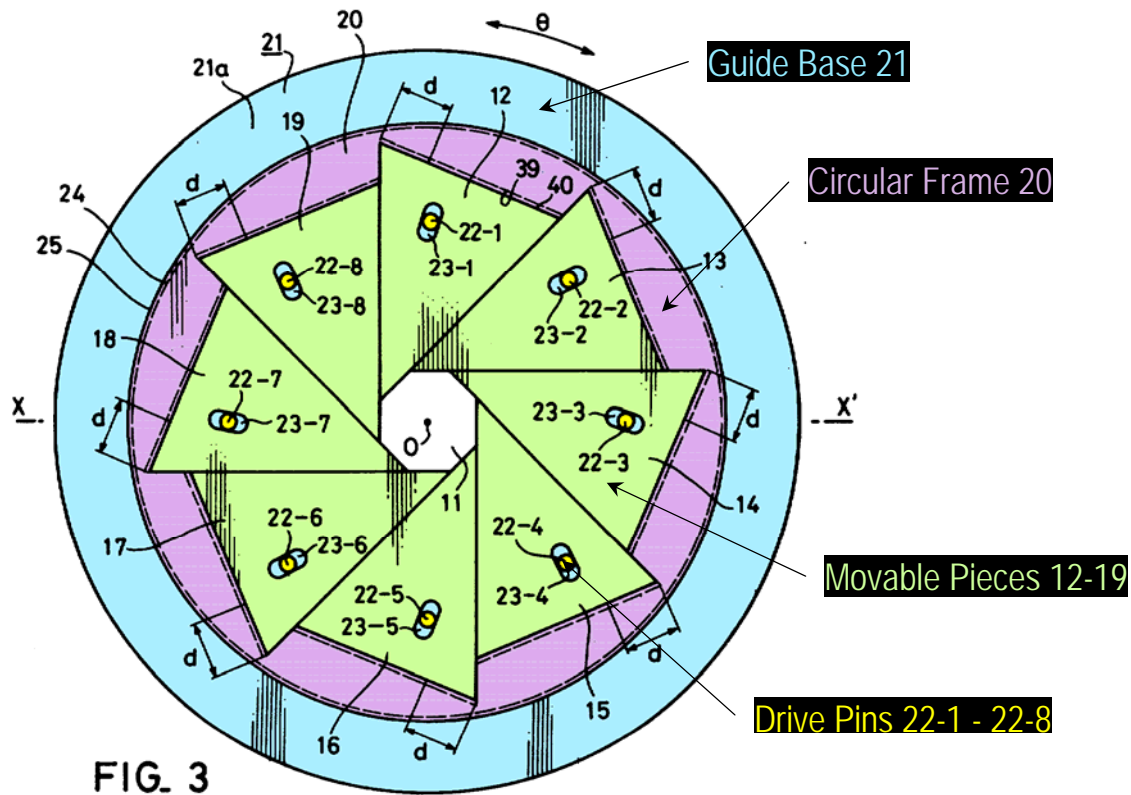
B. Yasumi

Yasumi was filed on March 25, 1982, issued on June 19, 1984, and is prior art under at least § 102(b).⁵ Yasumi was not considered by the Examiner during prosecution. Yasumi discloses a tool comprising “an aperture setting device in which the size of the predetermined polygonal aperture can be changed, retaining the polygonal configuration.” Ex. 1203 at 1:10-13.

As depicted below, triangular movable pieces (green) are arranged in a ring to define a polygonal aperture that can be opened and closed by movement of the pieces. *Id.* at Abstract, 1:45-60.

As depicted in Figure 3, one embodiment uses eight movable pieces 12-19 (green) disposed in a circular frame 20 (purple) and mounted on a guide base 21 (blue). *Id.* at 5:39-45.

⁵ All references to 35 U.S.C. §§ 102 and 103 set forth herein refer to that section in effect prior to the implementation of the America Invents Act.

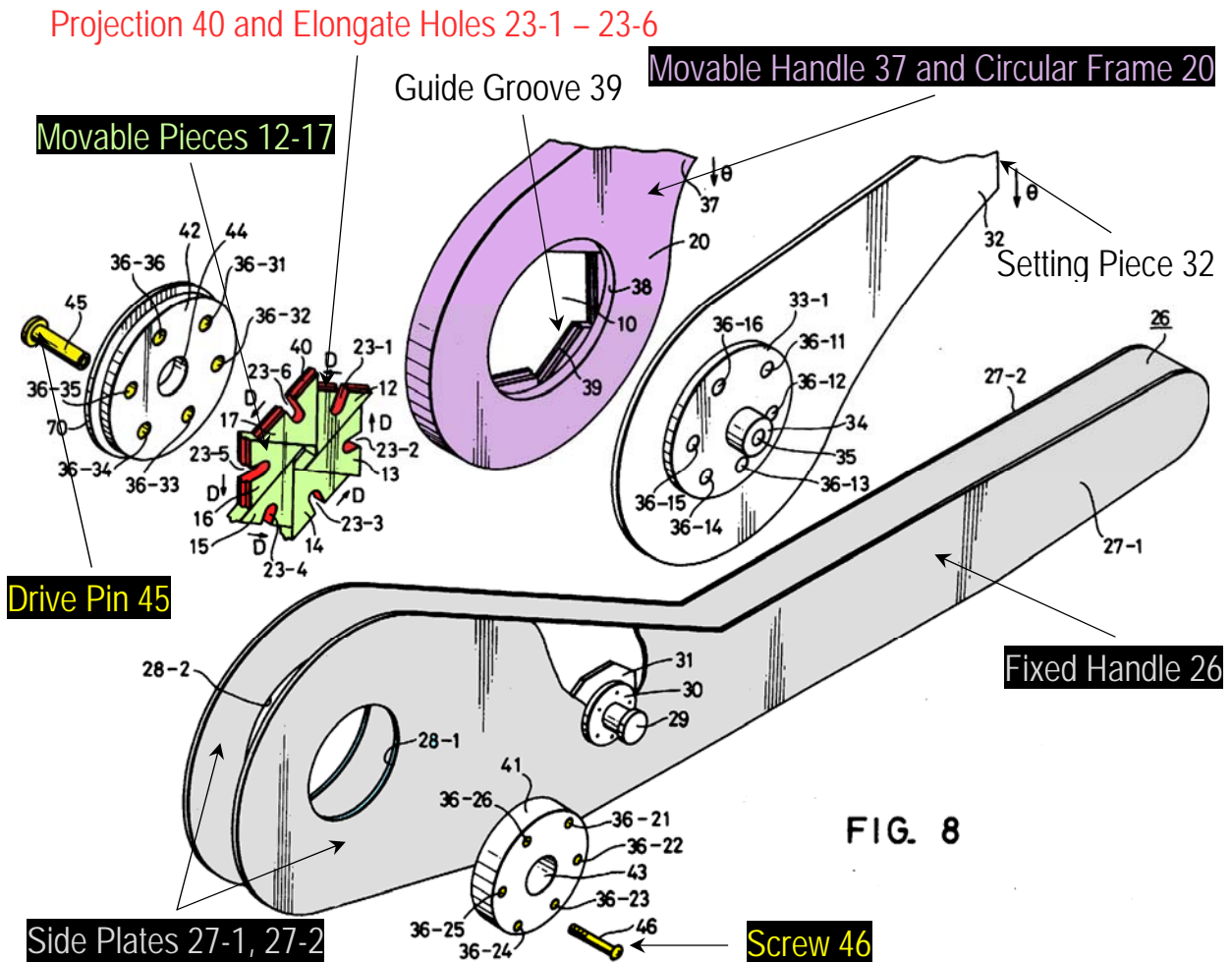


Ex. 1203, Figs. 3, 10. The base 21 (blue) has drive pins (22-1 to 22-8) (yellow) that extend through holes (23-1 to 23-8) in the movable pieces 12-19 (green). *Id.* at 5:57-6:7. The drive pins (22-1 to 22-8) (yellow) move the pieces 12-19 (green) along the frame 20 (purple) the distance “d” when the frame 20 (purple) rotates

relative to the base 21 (blue), *id.*, 6:1-8, changing the size of the aperture while maintaining the relative orientation of the movable pieces and the polygonal shape of the aperture, *id.* at Abstract, 4:54-65.

Each movable piece 12-19 has a first straight side facing the aperture, and a second straight side facing the adjacent piece and converging with the first side to form a tip. Each first straight side is parallel to the second straight side of an adjacent die. *Id.*, Fig. 3.

As depicted in Figure 8 below, another embodiment of Yasumi comprises six movable pieces 12-17 (green) disposed within a circular frame 20 (purple). *Id.* at 7:49-52.



Ex. 1203, Fig 8. The circular frame 20 (purple) and movable pieces 12-17 (green) are at the end of a movable handle 37 (not shown). *Id.* at 7:46-52. The movable pieces 12-17 (green) have projections 40 (red) that fit within guide grooves 39 in the frame 20 (purple) that guide the pieces along the frame to open and close the aperture. *Id.* at 7:52-57. The tool includes a fixed handle 26 (gray) comprising a pair of side plates 27-1 and 27-2 with wide end portions. *Id.* at 7:57-63. The frame 20 (purple) and movable pieces 12-17 (green) sit between the wide end portions of the two side plates 27-1 and 27-2 (gray). *Id.*

A support disk 42 has a larger outer flange 70 that rests against the outside of side plate 27-2 (gray), and a smaller inner portion that passes through the side plate 27-2 (gray) and fits into frame 20 (purple). Ex. 1203 at 8:1-9. Another support disc 41 rests against the outside of the other side plate, 27-1 (gray). *Id.* at 8:23-27. There is a setting piece 32, between the frame 20 (purple) and side plate 27-1 (gray). *Id.* at 8:10-12. The setting piece 32 and the support discs 41 and 42 have small holes 36-11 to 36-16, 36-21 to 36-26, and 36-31 to 36-36 (yellow) corresponding to elongated holes 23-1 to 23-6 (also red) in the movable pieces 12-16 (green). *Id.* at 8:25-32. Drive pins 45 (yellow) are individually inserted into each hole from the outside of the support disc 42. *Id.* at 8:32-34. The pins 45 (yellow) each have a threaded hole. *Id.* at 8:36-38. A screw 46 (also yellow) is screwed into the threaded hole of each pin 45 (yellow) from the outside of the support disc 41. *Id.* at 8:38-41.

The fixed handle 26 (gray), the movable handle 37 (purple) and the setting piece 32 are coupled together, and the movable handle 37 (purple) is rotatable relative to the stationary fixed handle 26 (gray). *Id.* at 8:42-45. Initially, when bringing the grip of the movable handle 27 (purple) closer to the fixed handle 26 (gray), the setting piece 32 also turns. *Id.* at 8:45-47. Once a set angle is reached, the setting piece 32 butts against the fixed handle 26 (gray), and further rotational movement of the setting piece 32 is stopped. *Id.* at 8:47-50. Consequently, the

pins 45 (yellow) are fixed by virtue of their engagement to the fixed handle via the setting piece. *Id.* Thereafter, bringing the movable handle 27 (purple) closer to the fixed handle 26 (gray) causes the pins 45 (yellow) in the elongated holes 23-1 to 23-6 to move the movable pieces 12 to 17 (green) in the frame 20 (gray), reducing the size of the aperture while maintaining the polygonal shape throughout. *Id.* at 8:50-54.

As depicted in Figure 9(a) below, yet another embodiment of Yasumi is directed to an electric wire guide device. *Id.* at 9:35-37. The device comprises two sets of movable pieces 12-1 to 15-1 and 12-2 to 15-2 (green) disposed within guide bases 21-1 and 21-2 (purple). *Id.* at 9:35-62.

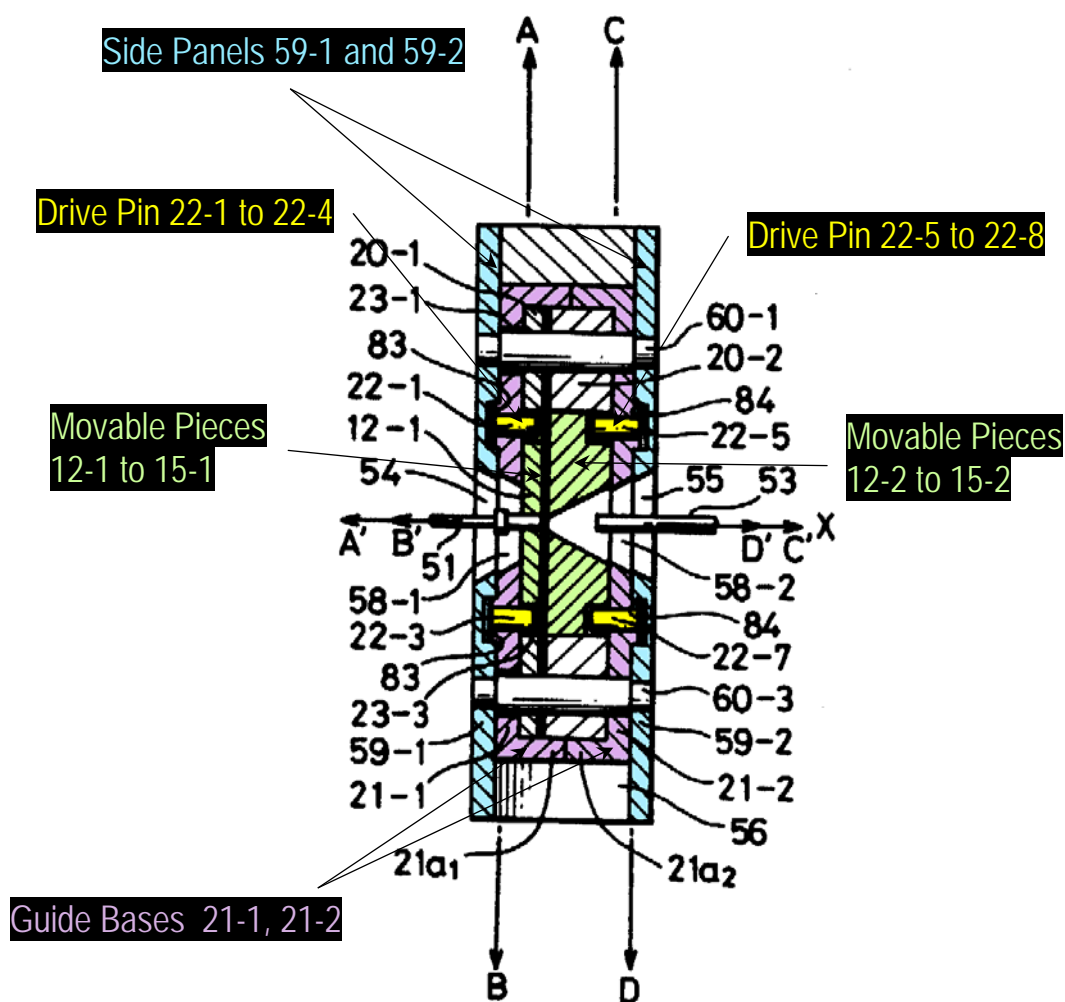


FIG. 9(a)

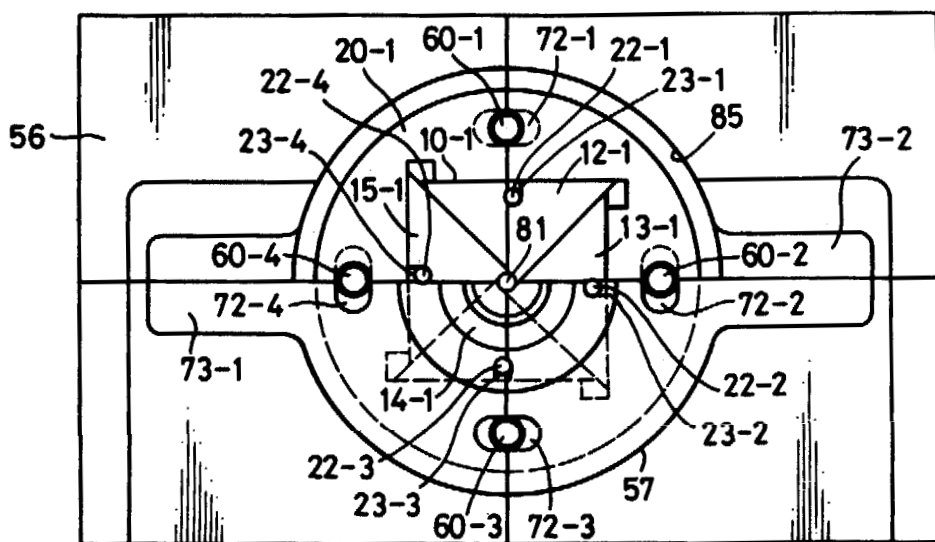


FIG. 9(b)

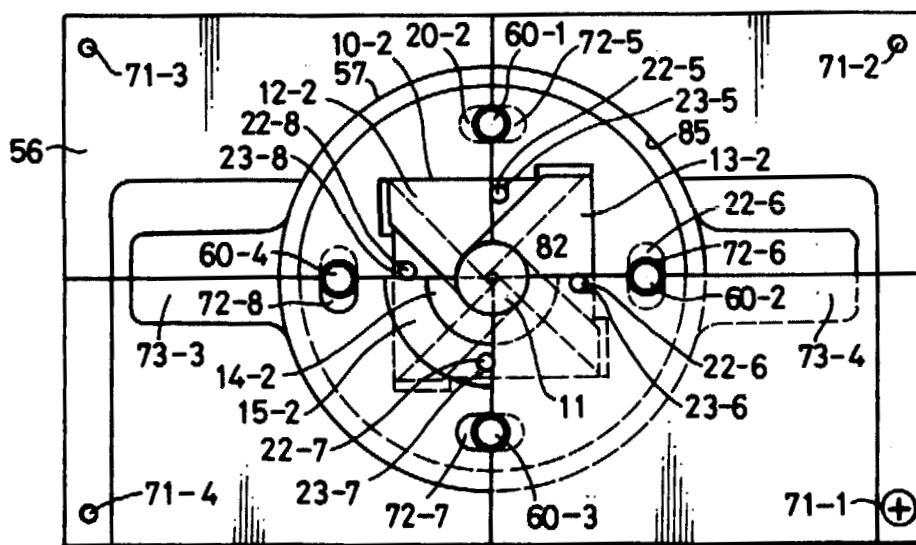


FIG. 9(c)

Ex. 1203, Figs. 9(a)-(c). The movable pieces 12-1 to 15-1 (green) fit into guide base 21-1 (purple) and movable pieces 12-2 to 15-2 (also green) fit into guide base 21-2 (also purple). *Id.* at 9:53-56. The guide bases (purple) and movable pieces (green) sit between side panels 59-1 and 59-2 (blue). Drive pins 22-1 to 22-4 fit

into a recess in the side panel 59-1, through guide base 21-1, and into movable pieces 12-1 to 15-1. *Id.* at 9:56-59, 10:68-11:4. Similarly, drive pins 22-5 to 22-8 fit into a recess in the side panel 59-2, through guide base 21-2, and into movable pieces 12-2 to 15-2. *Id.* at 9:59-62, 10:68-11:4.

The two sets of movable pieces (green) are each arranged to form an aperture. *Id.* at 9:63-67. The aperture formed by movable pieces 12-1 to 15-1 is aligned with the aperture formed by movable pieces 12-2 to 15-2. *Id.* at 67-68. These apertures are in turn aligned with the openings in guide bases 21-1 and 21-2 (purple) and in side panels 59-1 and 59-2 (blue). *Id.* at 9:39-41, 10:1-6. In operation, the guide bases (purple) are rotated to move the two sets of movable pieces (green) inward and outward to enlarge or reduce the apertures formed by the movable pieces. *Id.* at 10:7-11:9.

Yasumi is in the same field of endeavor as the '560 patent. Ex. 1205 ¶ 111. Like the '560 patent, Yasumi is generally directed to a tool that uses coupled movable members disposed about a reference circle to form a variable size aperture, Ex. 1203 at Abstract, and more specifically to a manual forming and pressing tool, *i.e.*, a crimper, *id.* at 7:33-35. A POSITA would have readily understood that Yasumi is directed to a crimper and that the tool described and illustrated in Yasumi could be used to crimp a stent. Ex. 1205 ¶ 111.

Yasumi is also reasonably pertinent to the problem to be solved by the '560 patent. Ex. 1205 ¶¶ 112-114. Yasumi recognized a problem with prior art aperture setting devices, namely that it is difficult to change the size of the aperture without introducing a gap between adjacent elements forming the aperture. Ex. 1203 at 1:17-20. Yasumi solves the problem by using an apparatus capable of changing the size of a polygonal aperture while retaining its polygonal shape. Ex. 1203 at 1:9-12, 1:32-35. A POSITA would have understood that the Yasumi device would result in uniform crimping forces to any object within the aperture and remedy the problem identified in the '560 patent. Ex. 1205 ¶¶ 112-114. Yasumi is therefore analogous prior art. *Id.*

C. Williams

U.S. Patent No. 5,437,083 (Williams) was filed on May 24, 1993, issued on August 1, 1995, and is prior art under at least §102(b). *See* Ex. 1227. Williams was cited during prosecution, but not relied upon by the Examiner.

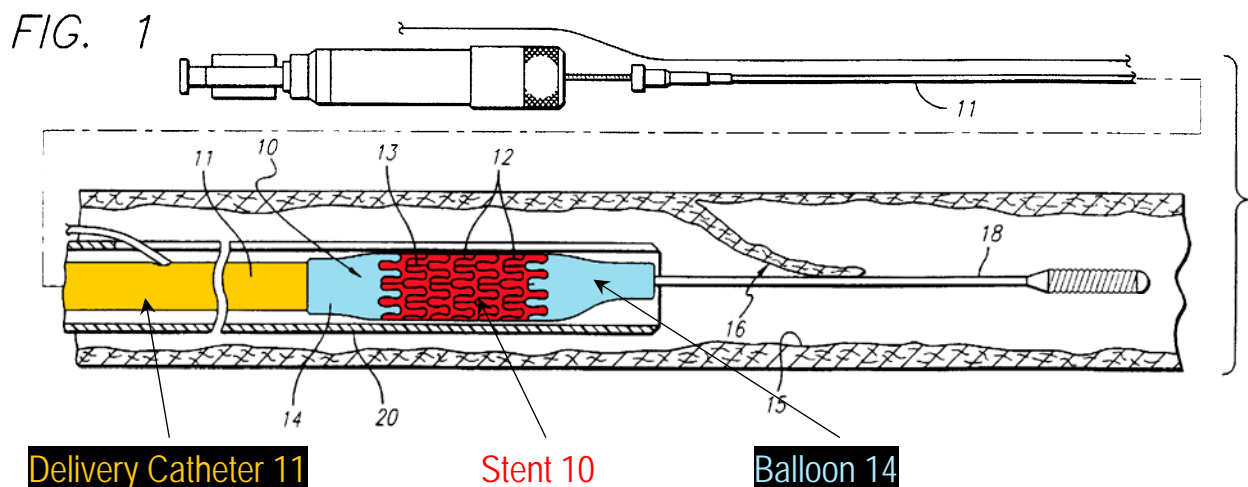
In the Summary of the Invention, Williams discloses the use of tools such as ordinary pliers to crimp a stent onto a catheter: “[S]ome tools, such as ordinary pliers, have been used to apply the stent. . .” *Id.* at 1:67-68. Williams goes on to describe various tools designed to crimp a stent. Although Williams notes that ordinary pliers were not an ideal tool for achieving a satisfactory crimp, *id.* at 1:67-2:1, there can be no doubt that the use of plier-like tools by those of ordinary skill

in the art was one of several well-known means to crimp a stent. As noted above in Part I., the prior art, including Patent Owner's patents, teach and acknowledge the use of pliers to crimp a stent.

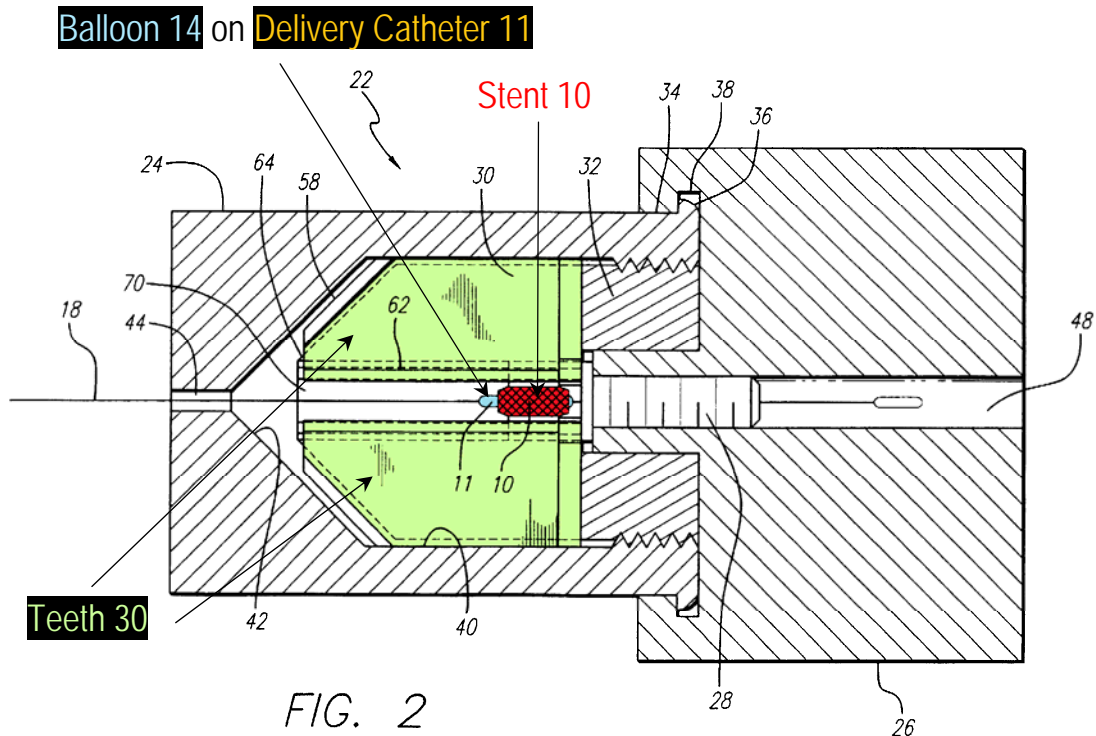
Thus, in addition to attempts to improve the design of dedicated stent crimpers, a person of ordinary skill in the art prior to September of 1999 would also be motivated and looking for improved crimping designs for pliers and other manually operated tools to crimp a stent. Ex. 1205 ¶ 164.

D. Morales

U.S. Patent No. 5,893,852 (Morales) was filed on April 28, 1998, issued on April 13, 1999, and is prior art under at least §102(a) or (e). *See* Ex. 1204. Morales was cited during prosecution, but not relied upon by the Examiner. Morales discloses “[a] stent crimping tool for firmly and uniformly crimping a . . . stent onto a balloon catheter.” *Id.* at Abstract.



Ex. 1204, Fig. 1. Figure 1 of Morales shows an exemplary stent 10 (red) that has been crimped onto a delivery catheter 11 (orange) having an expandable balloon 14 (blue) for expanding the stent 10 within an artery. *Id.* at Fig. 1, 5:60-67.



Ex. 1204, Fig. 2. Figure 2 shows the stent 10 (red) disposed about a balloon 14 (blue) and held between teeth 30. *Id.* at Fig. 2, 6:63-7:5. The teeth 30 move radially inward to crimp the stent 10 onto the delivery catheter 11 and expandable balloon 14. *Id.* at 8:58-64. The teeth 30 (green) can crimp stents of various lengths. *Id.* at 5:5-9.

X. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS FOR CANCELLATION (37 C.F.R. § 42.22(a) AND 42.104(b))

A. Claims 1, 2, 6, 8-10, 14, 15, 18, 23, 25, 27, 28, 31, 33, 37, and 40 Are Invalid As Obvious Over Yasumi In View Of Williams

1. Claim 1

Claim 1 of the '560 patent recites:

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 converging [sic] 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. 1201 at 10:8-22.

Yasumi discloses every limitation of Claim 1, with the possible exception of the preamble. The preamble recites a “stent crimper.” Yasumi is considered a stent crimper for purposes of analyzing validity of the challenged claims.

It is well established that a recitation of the intended use of a claimed invention must result in a structural difference between the claimed invention and

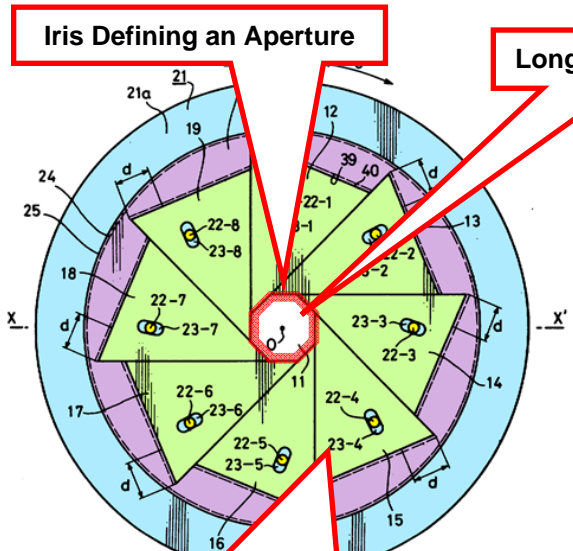
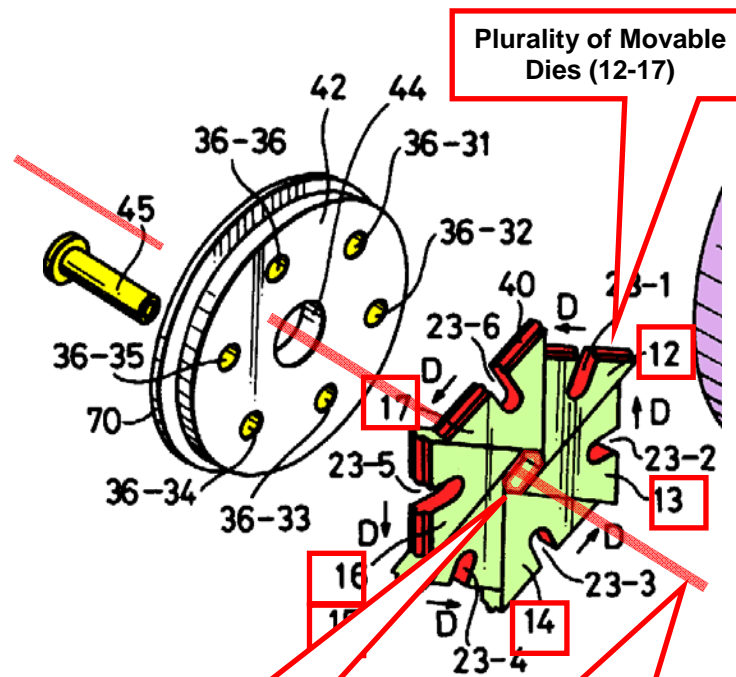
the prior art in order to patentably distinguish the claimed invention from the prior art. *In re Casey*, 370 F.2d 576, 580 (C.C.P.A. 1967). If the prior art structure is capable of performing the intended use, then it meets the claim. *Id.* The recitation in the preamble of the challenged claim to a “stent crimper” is not in the nature of a structural limitation; it merely expresses what the device is desired to do. The tools disclosed in Yasumi are capable of crimping a stent. The recitation of a “stent crimper,” therefore, does not patentably distinguish the claimed inventions from Yasumi.

Indeed, the Examiner relied on this same rationale for concluding during prosecution that Whitesell (pliers), Tuberman (tube pointer), and Wilhelm (crimping tool) were stent crimpers because each was capable of crimping a stent. Ex. 1202 at 45-46, 72. The Applicant did not dispute the Examiner’s position. *Id.* at 34-36, 62-67.

Yasumi is no different from the tools disclosed in Whitesell, Tuberman, and Wilhelm in terms of its suitability to crimp a stent. Therefore, Yasumi alone is a stent crimper for the same reasons the Examiner found Whitesell, Tuberman, and Wilhelm to be stent crimpers. Moreover, as noted above, the preamble does not limit the claims, and the Applicant did not dispute the Examiner’s position that the preamble was not limiting.

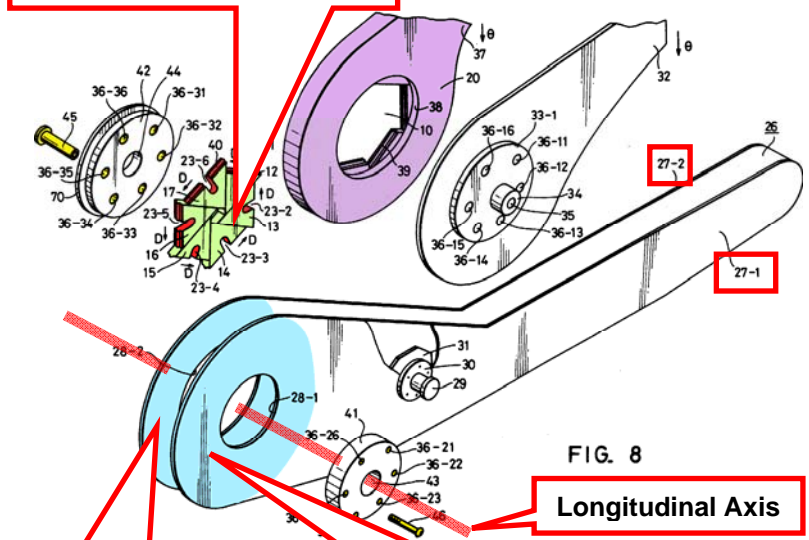
Williams discloses the use of tools such as ordinary pliers to crimp a stent. Ex. 1227 at 1:67-68. Thus, Williams expressly acknowledges and teaches the use of a tool like Yasumi to crimp a stent. Accordingly, to the extent the preamble “stent crimper” is a limitation, Yasumi in view of Williams renders Claim 1 obvious. A detailed analysis of Claim 1 is provided in the following claim chart. *See also* Ex. 1205 ¶¶ 122-131.

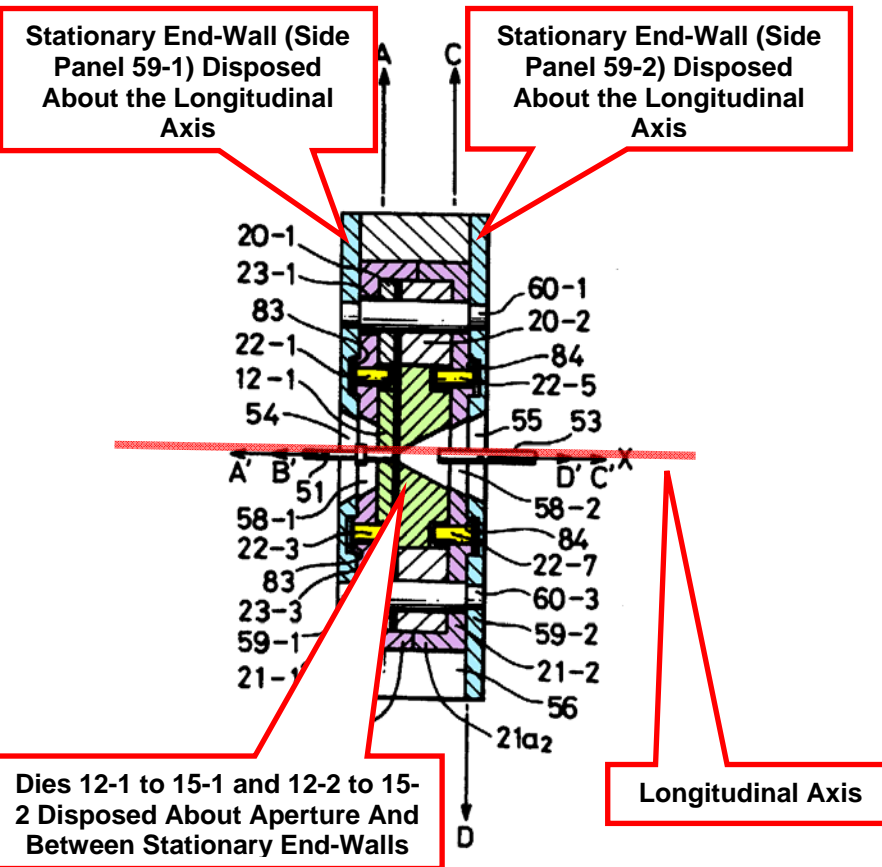
<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
[1 preamble] A stent crimper comprising:	<p><u>Yasumi discloses</u>: “a manual forming and pressing tool.” (Ex. 1203 at 7:33-38; <i>id.</i> at 1:35-39, 9:30-34, 11:25-30.) This tool is capable of crimping a stent. Therefore, Yasumi is a stent crimper. Moreover, the preamble “stent crimper” does not limit the claim. However, to the extent the preamble is found to be limiting, Williams expressly teaches the use of a tool like Yasumi to crimp a stent.</p> <p><u>Williams discloses</u>: “This invention is directed to a vascular prosthesis loading device, which automatically loads a stent onto the distal end of a catheter assembly, with a minimum of human handling, to better secure the stent onto the catheter while the stent is being delivered through the patient’s vasculature. . . . [S]ome tools, such as ordinary pliers, have been used to apply the stent” (Ex. 1227 at 1:48-68.)</p>
[1a] a plurality of movable dies arranged to form an iris having a longitudinal axis, the iris defining an aperture,	<p><u>Yasumi discloses a plurality of movable dies (movable pieces 12-17 or 12-19) arranged to form an iris having a longitudinal axis, the iris defining an aperture</u>:</p> <p>“[A]t least three or more substantially triangular movable pieces are sequentially arranged in the form of a ring, an aperture is formed by one end portion of an inner side of each movable piece.” (Ex. 1203 at Abstract; <i>id.</i> at 1:47-50, 2:45-47, 2:65-3:3, 4:42-44, 8:53-54, 9:63-67.)</p>

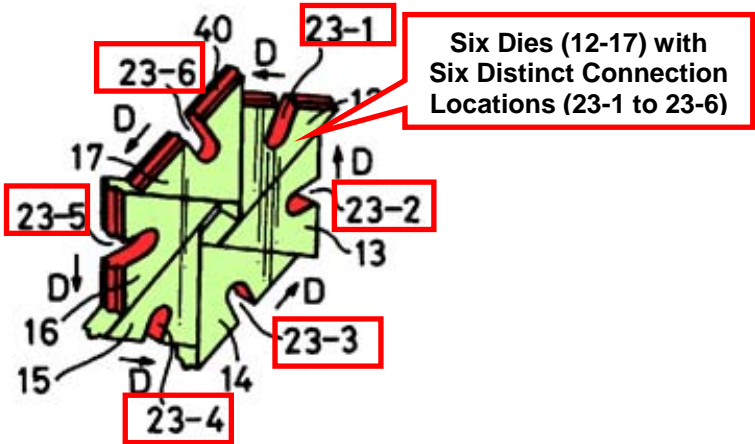
<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	 <p data-bbox="617 346 941 388">Iris Defining an Aperture</p> <p data-bbox="1071 367 1364 409">Longitudinal Axis 0</p> <p data-bbox="633 871 714 913">FIG. 3</p> <p data-bbox="730 892 1169 934">Plurality Of Movable Dies (12-19)</p>  <p data-bbox="1055 976 1331 1018">Plurality of Movable Dies (12-17)</p> <p data-bbox="649 1669 941 1711">Iris Defining Aperture</p> <p data-bbox="990 1648 1299 1690">Longitudinal Axis of Iris & Aperture</p>

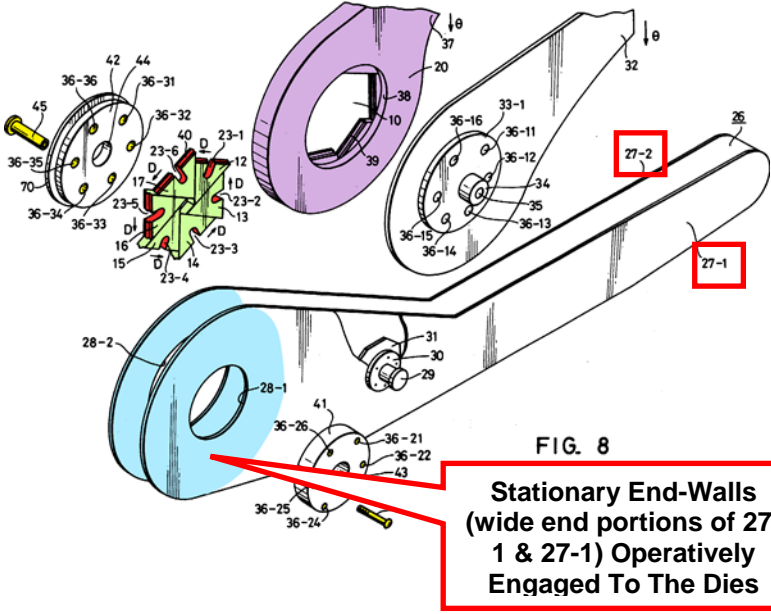
<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	(Ex. 1203, Figs. 3 & 8 (excerpt). ⁶)
<p>[1b] the dies disposed about the aperture and between stationary end-walls which are disposed about the longitudinal axis,</p>	<p><u>Yasumi discloses an embodiment with dies (movable pieces 12-17 or 12-19) disposed about the aperture and between stationary end-walls (wide end portions of the fixed handle side plates 27-1 and 27-2) which are disposed about the longitudinal axis:</u></p> <p>“A fixed handle 26 is composed of a pair of parallel spatular side plates 27-1 and 27-2 [T]he plurality of movable pieces 12 to 17 is interposed between the wide end portions of the two side plates 27-1 and 27-2 of the fixed handle 26.” (Ex. 1203 at 7:39-8:9; <i>see also id.</i> at 8:42-54, 9:3-15; 9:26-34.)</p> <p>A POSITA would have understood based on the Yasumi disclosure that the fixed handle 26 is stationary. (Ex. 1205 ¶ 131.)</p>

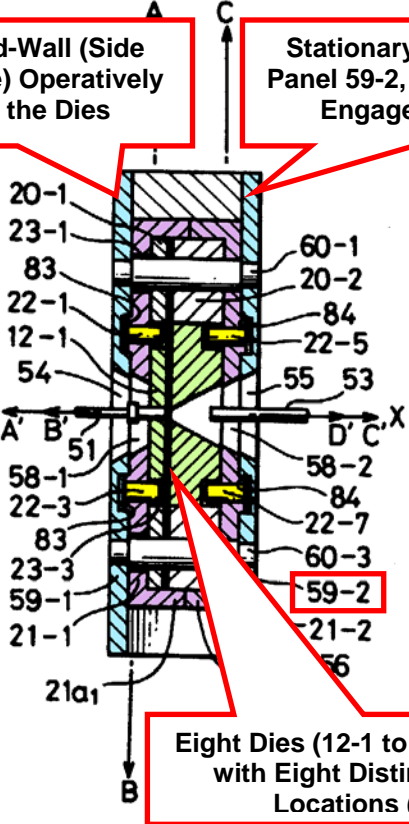
⁶ Note that figures from the prior art have been annotated in the tables throughout the Petition with red boxes to identify pertinent elements and callouts to label important features.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p data-bbox="568 346 950 451">Dies 12-17 Disposed About Aperture And Between Stationary End-Walls</p>  <p data-bbox="1104 882 1201 913">FIG. 8</p> <p data-bbox="1104 934 1339 976">Longitudinal Axis</p> <p data-bbox="625 997 852 1165">Stationary End-Wall (wide end portion of 27-2) Disposed About the Longitudinal</p> <p data-bbox="933 1050 1356 1165">Stationary End-Wall (wide end portion of 27-1) Disposed About the Longitudinal Axis</p> <p data-bbox="535 1197 812 1249">(Ex. 1203, Fig. 8.)</p> <p data-bbox="535 1260 1429 1480"><u>Yasumi includes an additional embodiment that discloses dies (movable pieces 12-1 to 15-1 and 12-2 to 12-5) disposed about the aperture and between stationary end-walls (left- and right-hand side panels 59-1 and 59-2) which are disposed about the longitudinal axis:</u></p> <p data-bbox="535 1491 1429 1659">“At this time, since the frames 20-1 and 20-2 are fixed to the side panels 59-1 and 59-2, as referred to previously, and do not move,” (Ex. 1203 at 10:42-49; <i>also id.</i> at 9:37-10:2.)</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	 <p style="text-align: center;">FIG. 9(a)</p> <p style="text-align: center;">(Ex. 1203, Fig. 9(a).)</p>
<p>[1c]</p> <p>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;</p>	<p>Yasumi discloses at least one of the stationary end-walls (wide end portions of the fixed handle side plates 27-1 and 27-2) operatively engaged to the dies (movable pieces 12-17 or 12-19) at distinct connection locations (elongated holes 23-1 to 23-6) such that the number of distinct connection locations and the number of dies are the same:</p> <p>In 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. More specifically, the pins 45 are engaged to the fixed handle via the setting piece 32. In operation, the setting piece 32</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p>abuts the fixed handle. Because the pins 45 extend through holes in the setting piece 32, once that setting piece 32 is held stationary by the fixed handle, the pins 45 are likewise held stationary. The pins 45 are also engaged to the movable pieces 12-17 or 12-19 via the elongated holes 23-1 to 23-6. In operation, the pins 45 remain stationary while the movable handle rotates. The pins 45 guide the movable pieces 12-17 or 12-19 inward to close the polygonal aperture. The six elongated holes are the six distinct connection locations on the dies that operatively engage the six dies to the stationary end-walls. (<i>See Ex. 1203 at 8:1-54.</i>)</p> 

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	 <p>(Ex. 1203, Fig. 8.)</p> <p>To the extent that it is viewed that the claim requires a more direct operative connection, it would have been obvious to a POSITA that the embodiment in Fig. 8 from Yasumi could be simplified by removing the setting piece and the support disks 42 & 43. Ex. 1205 ¶ 131. The support disks 42 & 43 would be integrated into the wide-end portions of the fixed handle side plates 27-1 and 27-2 such that the pins are connected directly to the side plates 27-1 and 27-2 on each end. <i>Id.</i> The resulting tool would have one elongated hole on each movable piece, one pin extending through each elongated hole, each pin connected to the side plates on either side of the movable pieces. <i>Id.</i></p> <p><u>Yasumi also discloses at least one of the stationary end-walls (left- and right-hand side panels 59-1 and 59-2) operatively engaged to the dies (movable pieces 12-1 to 15-1 and 12-2 and 15-2) at distinct connection locations (elongated holes 23-1 to 23-8) such that the number of distinct connection locations and the number of dies are</u></p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p><u>the same:</u></p> <p>In Figure 9(a), each movable piece has one elongated hole (23-1 to 23-8) that engages the die to the side panels 59-1 and 59-2 that are the stationary end-walls. Drive pins 22-1 to 22-8 extend through the elongated holes on each die to fit into ring-shaped grooves 83 and 84 that are formed in the side panels 59-1 and 59-2. The eight elongated holes are the eight distinct connection locations that operatively engage the eight dies to the stationary end-walls. (See Ex. 1203 at 9:56-62, 10:68-11:4.)</p>  <p>FIG. 9(a)</p> <p>(Ex. 1203, Fig. 9(a).)</p>
<p>[1d] each die having a</p>	<p><u>Yasumi discloses each die (movable pieces 12-17 or 12-19) having a first straight side (inner side) and a second</u></p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
<p>first straight side and a second straight side, the first straight side and the second straight side converging [sic] 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.</p>	<p>straight side, the first straight side and the second straight side converging 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:</p> <p>“[A]n aperture is formed by one end portion of an inner side of each movable piece and the movable piece . . .” (Ex. 1203 at Abstract; <i>see id.</i> at Claim 1, 2:48-59; 4:42-44)</p> <div data-bbox="548 667 1409 1554"> <p>Second Straight Side (Blue) Of Die 19 Converging With First Side (Red) To Form Tip</p> <p>First Straight Side (Red) of Die 19 Facing Aperture</p> <p>First Straight Side (Red) of Die 16 Parallel To Second Straight Side (Blue) of Adjacent Die 17</p> <p>FIG. 3</p> </div> <p>(Ex. 1203, Fig. 3.)</p>

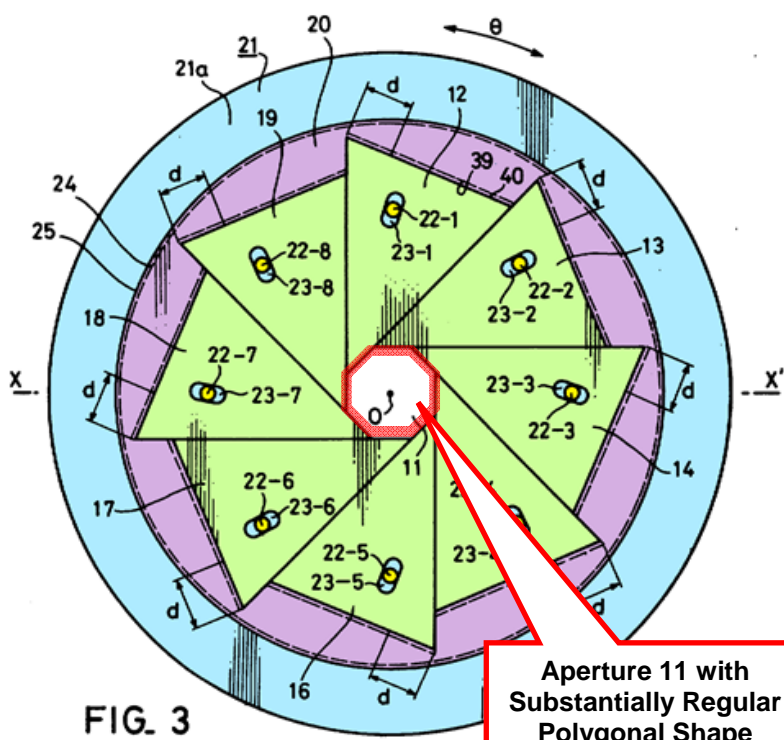
2. Claim 10

Independent Claim 10 recites limitations substantially similar to those in Claim 1, but adds limitations directed to (1) an aperture “having a substantially

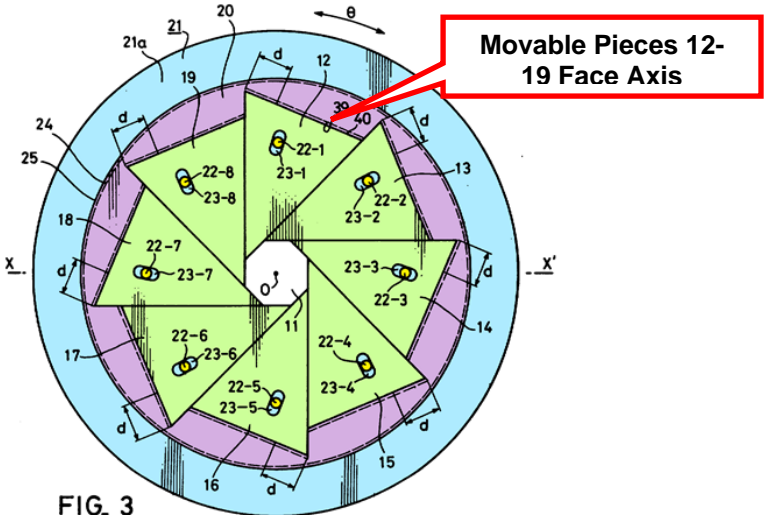
regular polygonal shape;” (2) “dies having an inward facing straight side which faces the longitudinal axis of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture;” (3) “the longitudinal axis [of the aperture] passing through a point substantially centered on the end-walls;” and (4) “a rotatable actuation device coupled to the dies, 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.”

Yasumi discloses these limitations. A detailed analysis of Claim 10 is provided in the following claim chart. *See also* Ex. 1205 ¶¶ 132-141.

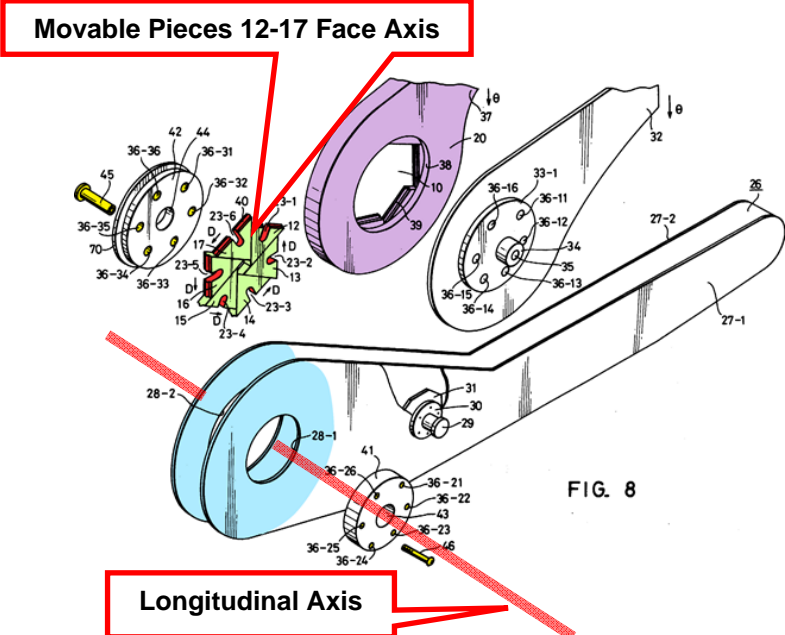
<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
[10 Preamble] A stent crimper comprising:	<i>See</i> Claim [1 Preamble].
[10a] a plurality of movable dies arranged to form an iris,	<i>See</i> Claim [1a].
[10b] the dies disposed about an aperture,	<i>See</i> Claim [1b].

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
<p>[10c] the aperture having a longitudinal axis and a substantially regular polygonal shape,</p>	<p><u>Yasumi discloses the aperture having a longitudinal axis.</u> <i>See Claim [1a].⁷</i></p> <p><u>Yasumi discloses an aperture having a substantially regular polygonal shape.</u></p> <p>“[I]t will easily be understood that the structure of this embodiment can generally be applied to regular polygonal apertures.” (Ex. 1203 at 4:62-64; <i>see id.</i> at 4:38-41, 6:14-15.)</p>  <p>FIG. 3</p>

⁷ Claim [10c] recites “the aperture having a longitudinal axis” and Claim [1a] recites “an iris having a longitudinal axis.” Because the iris defines the aperture, disclosure in Yasumi of an iris having a longitudinal axis also discloses an aperture having a longitudinal axis

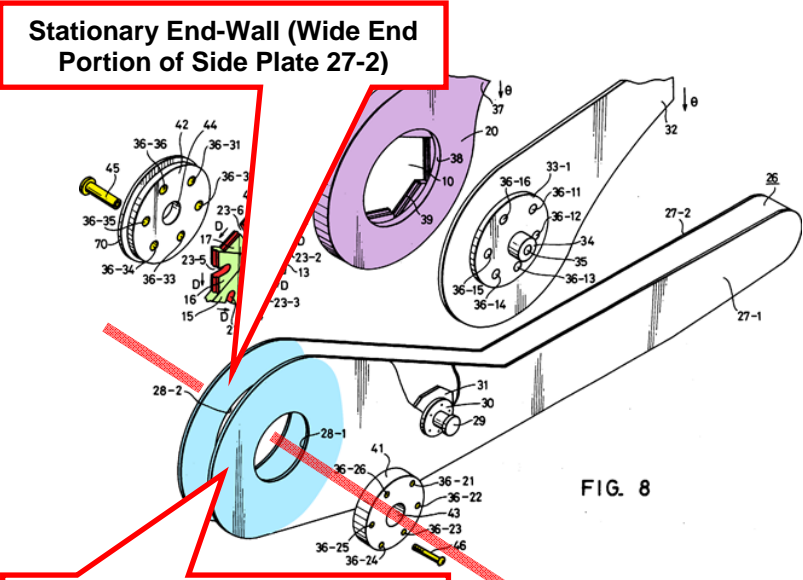
<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	(Ex. 1203, Fig. 3; <i>see id.</i> at Figs. 2, 5(a), 7(a).)
<p>[10d]</p> <p>each of the dies having an inward facing straight side which faces the longitudinal axis of the aperture,</p>	<p><i>See</i> Claim [1d].⁸</p>
<p>[10e]</p> <p>both when the dies move to maximize the aperture and when the dies move to minimize the aperture,</p>	<p><u>Yasumi discloses each of the dies (movable pieces 12-17 or 12-19) 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:</u></p>  <p>FIG. 3</p>

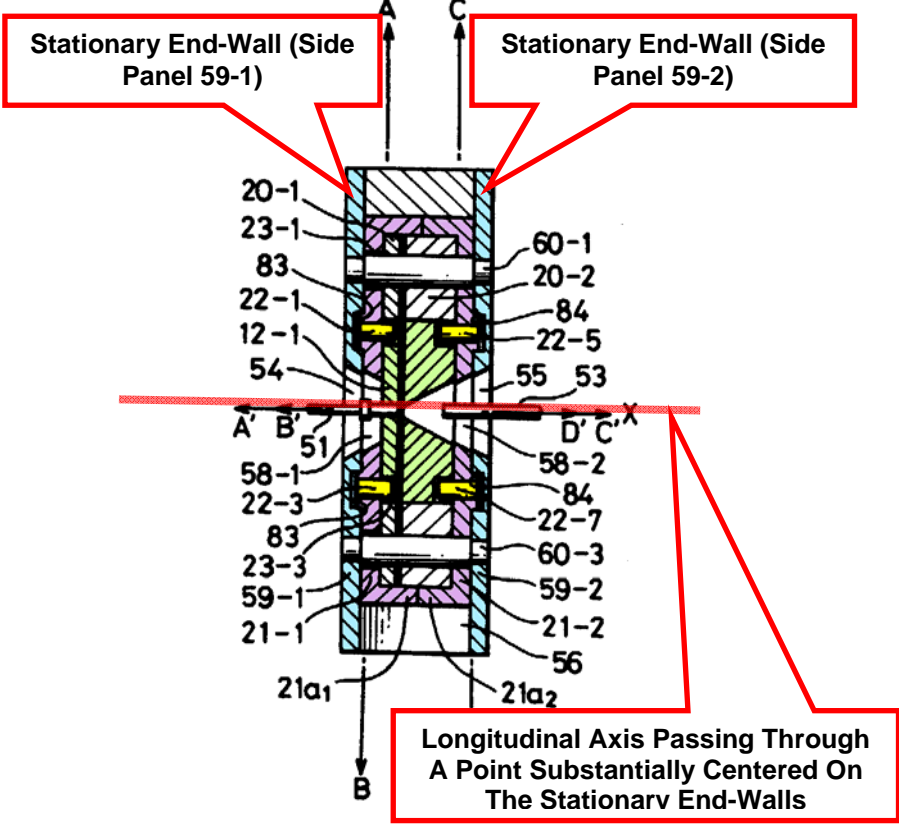
⁸ Claim [10d] recites “an inward facing straight side which faces the longitudinal axis of the aperture” and Claim [1d] recites “a portion of the first straight side of each die faces the aperture.” Because the longitudinal axis of the aperture is located central to the aperture, disclosure in Yasumi of the first straight side of each die facing the aperture also discloses an inward facing straight side which faces the longitudinal axis of the aperture.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	 <p>(Ex. 1203, Fig. 8.)</p> <p><u>Yasumi teaches that the polygonal shape of the aperture is maintained as the dies (movable pieces 12-17 or 12-19) move in or out.</u></p> <p>“[T]he size of a predetermined polygonal aperture can be changed, retaining the polygonal configuration.” (Ex. 1203 at 1:11-13; <i>see id.</i> at Abstract, 1:40-43, Claim 1.)</p> <p>Maintaining the polygonal shape results in the first straight side facing the longitudinal axis of the aperture while moving in or out.</p>
<p>[10f]</p> <p>the dies between two stationary end-</p>	<p><i>See</i> Claim [1b].⁹</p>

⁹Claim [10f] recites “two stationary end-walls” while Claim [1b] recites “stationary end-walls,” plural. Because two stationary end-walls is a subset of stationary end-walls, disclosure in Yasumi of stationary end-walls also discloses two stationary end-walls.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
walls disposed about the longitudinal axis,	
[10g] the longitudinal axis passing through a point substantially centered on the end-walls,	<p><u>Yasumi discloses the longitudinal axis passing through a point substantially centered on the end-walls (wide end portions of the fixed handle side plates 27-1 and 27-2):</u></p> <p>“The frame 20 having thus mounted therein the plurality of movable pieces 12 to 17 is interposed between the wide end portions of the two side plates 27-1 and 27-2 of the fixed handle 26, . . . The frame 20 has formed therein on the side of the side plate 27-2 a circular recess coaxial with the frame 20, . . . , and the support disc 42 is fitted into this circular recess. . . . The circular projection 33-1 is fitted into the circular hole 28-1 of the side plate 27-1.” (Ex. 1203 at 7:57-8:21.)</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	 <p>FIG. 8</p> <p>(Ex. 1203, Fig. 8.)</p> <p><u>Yasumi includes an additional embodiment that discloses the longitudinal axis passing through a point substantially centered on the end-walls (left- and right-hand side panels 59-1 and 59-2):</u></p> <p>“As shown in FIG. 9(a), a pin 51 of a connector and an electric wire 53 are inserted into the aperture setting device through openings 54 and 55 formed in left-and right-hand side panel 59-1 and 59-2 The axes of the aperture setting portions 81 and 82 lie on the same straight line, which is substantially in alignment with the centers of the openings 54 and 55 of the side panels of the casing.” (<i>Id.</i> at 9:37-10:2.)</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	 <p style="text-align: center;">FIG. 9(a)</p> <p>(Ex. 1203, Fig. 9(a); <i>see id.</i> at FIG. 9(b)-(c), 9:35-10:11.)</p>
<p>[10h] a rotatable actuation device coupled to the dies,</p>	<p><u>Yasumi discloses a rotatable actuation device (circular frame 20) coupled to the dies (movable pieces 12-17 or 12-19):</u></p> <p>“[T]he movable pieces 12 to 19 are disposed in a circular frame 20. . . . As drive means, a guide base 21 is provided, . . . Turning the guide base 21 about the axis 0 clockwise in FIG. 3 relative to the frame 20, the drive pins 22-1 to 22-8 move on the same circle about the axis 0 relative to the frame 20. The drive pins 22-1 to 22-8 drive the movable pieces 12 to 19 through the elongated holes 23-1 to 23-8, respectively, by which the movable pieces are moved along their bases to approach the axis 0.” (Ex. 1203 at 5:39-6:8.)</p> <p>“The frame 20 having thus mounted therein the plurality of</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p>movable pieces 12 to 17 is interposed between the wide end portions of the two side plates 27-1 and 27-2 of the fixed handle 26, . . . The movable handle 37 and the fixed handle 26 are designed so that they can turn about the axis of the 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.” (<i>Id.</i> at 7:57-68.)</p> <div data-bbox="574 646 1328 1255"> <p>Rotatable Actuation Device 20</p> <p>Dies 12-17 Coupled to Rotatable Actuation Device 20 by Projections 40 and Guide Grooves 39</p> <p>FIG. 8</p> </div> <p>(Ex. 1203, Fig. 8)</p>
<p>[10i] 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</p>	<p><u>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:</u></p> <p>“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. 1203 at 8:42-54; <i>see id.</i> at 5:39-6:8, 7:57-68.)</p>

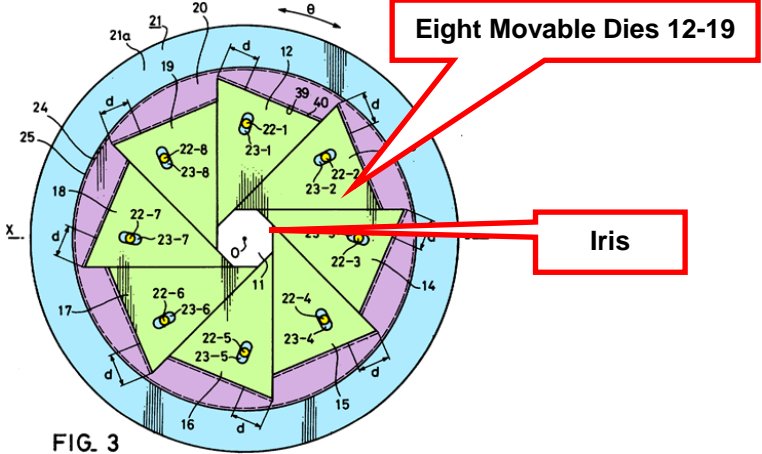
<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
the aperture.	

3. Claim 18

Independent Claim 18 recites limitations substantially similar to those previously recited in Claims 1 and 10. *See* Part X.A.1 and .2.¹⁰ Claim 18 also adds the limitation “eight or more movable dies.” Yasumi discloses this limitation. A detailed analysis of Claim 18 is provided in the following claim chart. *See also* Ex. 1205 ¶¶ 142-143.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
[18 Preamble] A stent crimper comprising:	<i>See</i> Claim [1 Preamble].
[18a] eight or more movable dies arranged to form an iris,	<u>Yasumi discloses movable dies arranged to form an iris.</u> <i>See</i> Claim [1a]. <u>Yasumi also discloses eight or more movable dies:</u>

¹⁰ Claim 18 recites an “inward facing flat portion” and Claim 1 recites a “first straight side of each die fac[ing] the aperture.” The disclosure in Yasumi of a first straight side facing the aperture equally supports disclosure of an inward facing flat portion.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	 <p>FIG. 3</p> <p>(Ex. 1203, Fig. 3; <i>see id.</i>, Fig. 2, 5:39-6:13.)</p>
<p>[18b]</p> <p>the iris defining an aperture of a substantially regular polygonal shape,</p>	<p><i>See</i> Claims [1a] (iris defining aperture), [10c] (aperture having substantially regular polygonal shape).</p>
<p>[18c]</p> <p>the aperture having a longitudinal axis,</p>	<p><i>See</i> Claim [1a], [10c].</p>
<p>[18d]</p> <p>each die having an inward facing flat portion which faces the longitudinal axis of the aperture</p>	<p><i>See</i> Claim [1d], [10d].</p>
<p>[18e]</p>	<p><i>See</i> Claim [10e].</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
both when the dies move to maximize the aperture and when the dies move to minimize the aperture,	
[18f] the dies between stationary end walls and operatively engaged to at least one of the stationary end-walls,	<i>See</i> Claims [1b] (dies between stationary end-walls) and [1c] (at least one stationary end-wall operatively engaged to the dies).
[18g] the stationary end-walls disposed about the longitudinal axis,	<i>See</i> Claim [1b].
[18h] the iris comprising at least eight of the inward facing flat portions,	<i>See</i> Claim [1a] & [1d] (movable dies arranged to form an iris and a portion of the first straight side of each die faces aperture), Claim [18a] (eight dies).
[18i]	<i>See</i> Claims [10d] (inward facing straight side which faces the

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
the aperture being reducible in size by moving the inward facing flat portions toward the longitudinal axis of the aperture,	longitudinal axis), [10i] (inward facing straight sides of the dies to move inward and reduce the size of the aperture).
[18j] a rotatable actuation device coupled to the dies,	<i>See Claim [10h].</i>
[18k] 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.	<i>See Claim [10i].</i>

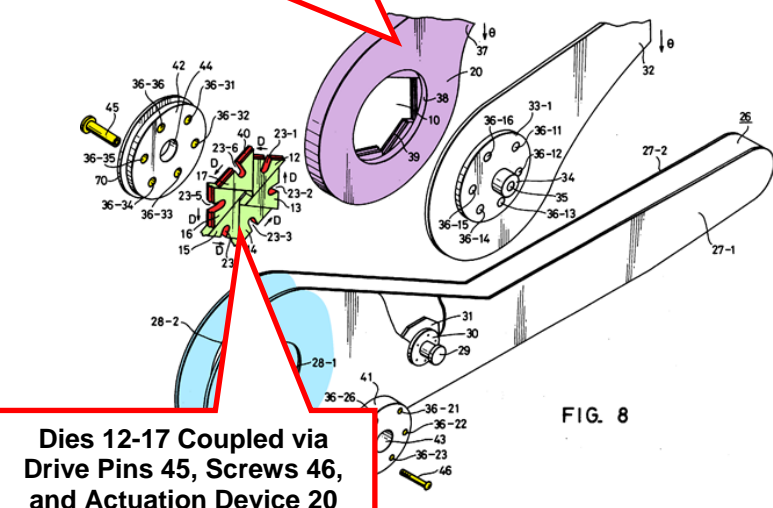
4. Claim 27

Independent Claim 27 recites limitations substantially similar to those previously recited in Claims 1 and 10. *See* Part X.A.1 and .2.¹¹ Claim 27 also adds the limitation “the blades coupled to one another so as to be movable inward or outward simultaneously.” Yasumi discloses this limitation. A detailed analysis of Claim 27 is provided in the following claim chart. *See also* Ex. 1205 ¶¶ 144-145.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
[27 Preamble] A stent crimper comprising:	<i>See</i> Claim [1 Preamble].
[27a] an aperture with a plurality of movable blades disposed thereabout,	<i>See</i> Claim [1b].
[27b] the aperture having a longitudinal axis and being substantially polygonal,	<i>See</i> Claim [10c].

¹¹ Claim 27 differs from the previous claims because it recites “blades” instead of “dies.” But those terms are used interchangeably. *See* Part VIII.B.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
<p>[27c] the blades between stationary end- walls substantially centered about the longitudinal axis,</p>	<p><i>See</i> Claims [1b] (dies between stationary end-walls), [10g] (longitudinal axis passing through a point substantially centered on the end-walls).</p>
<p>[27d] the blades coupled to one another so as to be movable inward or outward simultaneously,</p>	<p><u>Yasumi discloses the blades (movable pieces 12-17 or 12-19) coupled to one another so as to be movable inward or outward simultaneously:</u></p> <p>Each blade is connected via numerous components such that when one blade moves, they all move together simultaneously. For example, the blades are coupled via the rotatable actuation device. The blades are also coupled via the drive pins and screws.</p> <p>“A center aligning device comprising: . . . a first drive member disposed opposite one side of the faces of said first movable pieces and having first drive pins thereon, . . . for simultaneously moving said first movable pieces relative to said first frame to set the size of said first polygonal aperture.” (Ex. 1203 at Claim 1; <i>see id.</i> at 2:47-59, 4:12-17, 5:48-51, 7:48-57.)</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p data-bbox="565 338 1008 390">Rotatable Actuation Device 20</p>  <p data-bbox="565 810 938 915">Dies 12-17 Coupled via Drive Pins 45, Screws 46, and Actuation Device 20</p> <p data-bbox="1122 800 1187 821">FIG. 8</p> <p data-bbox="500 957 773 989">(Ex. 1203, Fig. 8.)</p>
<p data-bbox="191 1031 269 1062">[27e]</p> <p data-bbox="191 1094 448 1293">movement of the blades outward increasing the size of the aperture,</p>	<p data-bbox="488 1031 732 1062"><i>See Claim [10i].</i></p>
<p data-bbox="191 1335 269 1367">[27f]</p> <p data-bbox="191 1398 448 1598">movement of the blades inward decreasing the size of the aperture,</p>	<p data-bbox="488 1335 732 1367"><i>See Claim [10i].</i></p>

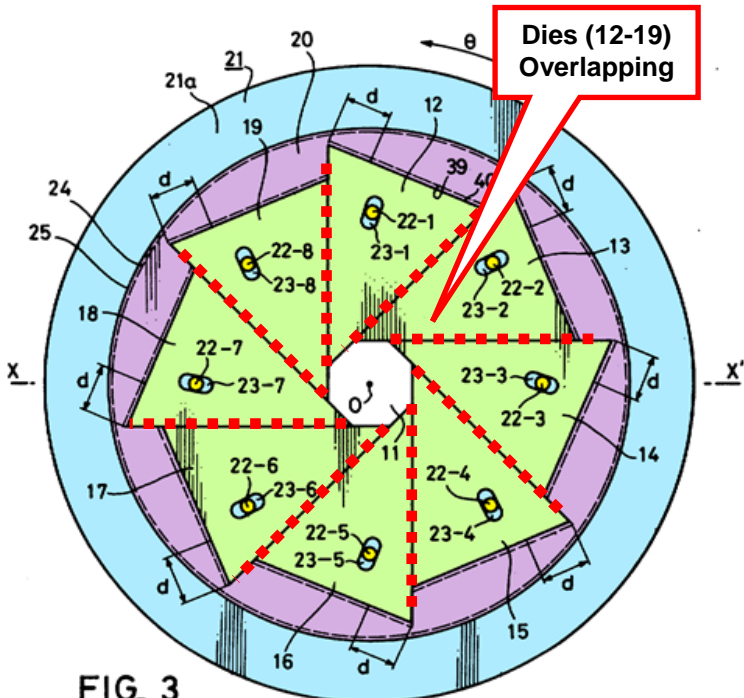
<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
[27g] the aperture remaining substantially regular polygonal when it is sized to receive a stent therein and when the blades minimize the aperture.	<i>See</i> Claims [10c] (substantially regular polygonal shape), [10e] (when the dies move to maximize the aperture and when the dies move to minimize the aperture). ¹²

5. Claim 37

Independent Claim 37 recites limitations substantially similar to those previously recited in Claims 1 and 10, *see* Part IX.A.1 and .2, but adds the limitation “overlapping movable dies.” Yasumi discloses this limitation. A detailed analysis of Claim 37 is provided in the following claim chart. *See also* Ex. 1205 ¶¶ 146-148.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
[37 Preamble] A stent crimper	<i>See</i> Claim [1 Preamble].

¹² Claim [27g] recites “when [the aperture] is sized to receive a stent therein” and Claim [10e] recites “when the dies move to maximize the aperture.” The disclosure in Yasumi supporting Claim [10e] equally supports Claim [27g] because the aperture is maximized when it is sized to receive a stent.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
comprising:	
<p>[37a] a plurality of overlapping movable dies arranged to form an iris,</p>	<p><u>Yasumi discloses a plurality of movable dies arranged to form an iris.</u> <i>See Claim [1a].</i></p> <p><u>Yasumi discloses a plurality of overlapping movable dies (movable pieces 12-17 or 12-19):</u></p> <p>“Referring first to FIG. 1, . . . the movable piece 13 is disposed with one side 13a of its triangle held partly in agreement with one side 12a of the movable piece 12 forming one side of the pentagonal aperture area 11 but with one end of the piece 13 displaced outwardly relative to the area 11. . . . The other movable pieces are also likewise disposed one after another.” (Ex. 1203 at 2:44-59.)</p>  <p>FIG. 3</p> <p>(Ex. 1203, Fig. 3; <i>id.</i> at Figs. 1-2.)</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
<p>[37b] the dies disposed about an aperture, the aperture having a longitudinal axis,</p>	<p><i>See</i> Claims [1b], [10c].</p>
<p>[37c] the dies between stationary end-walls disposed about the longitudinal axis,</p>	<p><i>See</i> Claim [1b].</p>
<p>[37d] the dies operatively engaged to at least one of the stationary end-walls;</p>	<p><i>See</i> Claim [1c] (at least one of the stationary end-walls operatively engaged to the dies).</p>
<p>[37e] each die having a first straight side and a second straight side, the first straight side and the second straight side converging to form a tip; wherein a portion of the first straight side of</p>	<p><i>See</i> Claim [1d].</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
each die faces the aperture, each first straight side parallel to the second side of an adjacent die.	

6. Claim 40

Independent Claim 40 recites limitations substantially similar to those previously recited in Claims 1 and 10. *See* Part IX.A.1 and .2.¹³ A detailed analysis of Claim 40 is provided in the following claim chart. *See also* Ex. 1205 ¶¶ 149-150.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
[40 Preamble] A stent crimper comprising:	<i>See</i> Claim [1 Preamble].
[40a] a plurality of movable dies arranged to form an iris disposed about an aperture,	<i>See</i> Claims [1a] (plurality of movable dies arranged to form an iris), [1b] (dies disposed about the aperture).

¹³ Claim 40 recites “stationary plates” while Claim 1 recites “stationary end-walls.” However, as discussed in Part VIII.C, the stationary plates of Claim 40 and the stationary end-walls of Claim 1 are interchangeable.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
[40b] the aperture having a longitudinal axis,	<i>See</i> Claim [10c].
[40c] the plurality of movable dies between stationary plates disposed about the longitudinal axis,	<i>See</i> Claim [1b].
[40d] each die in communication with an actuation device,	<i>See</i> Claim [10h]. ¹⁴
[40e] the actuation device constructed and arranged such that rotational	<i>See</i> Claim [10i]. ¹⁵

¹⁴ Claim 10 uses “coupled to” and Claim 40 uses “in communication with.” The disclosure in Yasumi for a rotatable actuation device coupled to the dies also supports each die in communication with an actuation device.

¹⁵ Claim [10i] recites “rotation of the actuation device [reducing] the size of the aperture or [increasing] the size of the aperture” and Claim [40e] recites “rotational motion of the actuation device opens or closes the aperture.” The disclosure in Yasumi showing Claim [10i] applies equally to Claim [40e].

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
motion of the actuation device opens or closes the aperture,	
[40f] the dies operatively engaged to at least one of the stationary plates;	<i>See Claim [1c].</i>
[40g] each die having a first straight side and a second straight side, the first straight side and the second straight side converging 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.	<i>See Claim [1d].</i>

7. Claims 2 and 28

Dependent Claims 2 and 28 add a limitation substantially similar to Claim [10h-i]: “a rotatable actuation device coupled to the [dies/blades], rotation of the

actuation device causing the [dies/blades] to move inward [and reduce the size of the aperture] or outward [so as to increase the size of the aperture.]”¹⁶

Accordingly, Yasumi discloses every limitation of Claims 2 and 28. *See* Part X.A.7; Ex. 1205 ¶ 151.

8. Claims 6 and 15

Dependent Claims 6 and 15 share an identical limitation substantially similar to Claim 18[a]: “wherein at least 8 dies are provided.” Accordingly, Yasumi discloses every limitation of Claims 6 and 15. *See* Part X.A.8; Ex. 1205 ¶ 152.

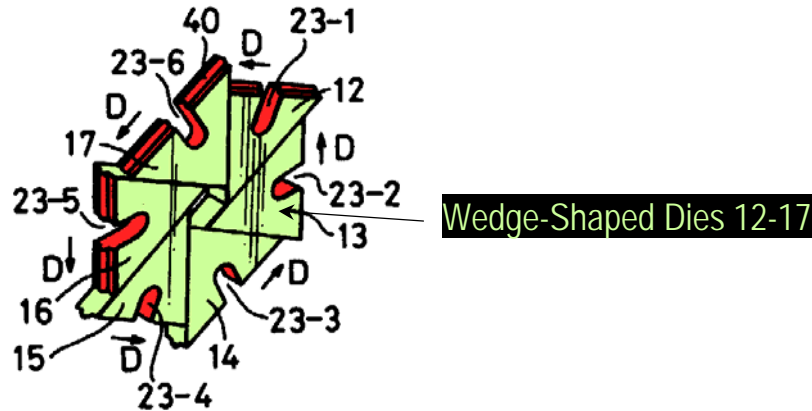
9. Claims 8, 25, and 33

Dependent Claims 8, 25, and 33 share an identical limitation of “wherein the dies are moved cooperatively inward during the moving step,” which is disclosed by Yasumi. The 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. Ex. 1203 at Claim 1; *see also id.* at Abstract, 2:47-59, 5:48-51, 4:12-17, 7:48-57, 8:50-54; Ex. 1205 ¶¶ 153-156.

¹⁶ Claim 28 differs from Claims 2 and 10 because it recites “blades” instead of “dies,” but blades and dies are used interchangeably. *See* Part VIII.B.

10. Claims 9, 14, 23, and 31

Dependent Claims 9, 14, 23, and 31 share an identical limitation of “wherein the dies are wedge-shaped,” which is disclosed by Yasumi.



Ex. 1203, Fig. 8; *id.* at Abstract (“substantially triangular movable pieces”), 1:48-49, 6:31-37; Ex. 1205 ¶¶ 157-159.

11. Reason, Basis, or Motivation to Combine

A patent claim is unpatentable if 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 to a POSITA. 35 U.S.C. § 103. It is not necessary that the prior art be physically combinable to render a claim obvious under § 103. *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016). The test is whether a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention. *Id.*

As noted previously, the press tool of Yasumi is capable of crimping a stent and, thus, it is a stent crimper. Moreover, to the extent necessary, it would have been obvious to a POSITA to use Yasumi as a stent crimper in view of Williams. Ex. 1205 ¶¶ 160-168.

Yasumi recognized that prior art aperture setting devices suffered from problems when there were gaps between adjacent dies such that the article in the aperture could end up wedged between the dies. Ex. 1203 at 1:16-28. Yasumi solved this problem by using dies arranged to form a polygonal aperture. *Id.* at 1:32-43. Yasumi did not limit the applications for the disclosed polygonal aperture setting device. As explained in Yasumi:

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.

Id. at 1:32-39. In particular, one of the embodiments disclosed in Yasumi is directed to a manual forming and pressing tool. *Id.* at 7:33-38, 9:30-34, 11:25-30. A POSITA would have understood that a manual forming and pressing tool is just another term used to refer to a crimper. Ex. 1205 ¶ 163. A POSITA would have been motivated by the disclosure in Yasumi to look for applications for the disclosed tool, and in particular would have been motivated to look for suitable crimping applications. *Id.*

It would have been well-known to a POSITA that stent crimping was one available crimping application, and that tools such as pliers were commonly used to crimp stents. Ex. 1205 ¶ 164. Numerous patents from prior to September of 1999, including Williams, recognize that tools, such as ordinary pliers, were used to crimp stents. *See* discussion in Part I. Indeed, as explicitly taught by Patent Owner in 1996, “The stent is positioned over the balloon portion of the dilatation catheter and gently crimped onto the balloon either by hand or with a tool such as a pliers or the like to be mounted for delivery as shown in FIGS. 1 and 2.” Ex. 1226 at 3:20-23. These teachings would have provided a POSITA with the knowledge and motivation to use Yasumi as a stent crimper. Ex. 1205 ¶ 164-168.

Additionally, a POSITA would have been motivated to use Yasumi as a stent crimper to apply the known technique of using a polygonal aperture to uniformly crimp an item, because uniformity was important in the stent crimping field and stent crimpers would benefit from the polygonal configuration disclosed in Yasumi. Ex. 1205 ¶¶ 165-168. It would have been well known to a POSITA prior to September 22, 1999 that stents must be crimped uniformly. For example, Williams teaches: “In procedures where the stent is placed over the balloon portion, one must crimp the stent onto the balloon portion, to prevent the stent from sliding off the catheter when the catheter is advanced in a patient’s vasculature. In the past this crimping was often done by hand, which was found to

be unsatisfactory due to uneven crimping forces being applied, resulting in non-uniform crimps. Ex. 1227 at 1:56-63; *see also* Ex. 1214 at 1:35-48; Ex. 1221 at 1:59-2:2; Ex. 1225 at 1:49-2:14; Ex. 1219 at 1:66-2:18; Ex. 1218 at 2:2-5; Ex. 1205 ¶ 166. A POSITA would have known that using the straight-sided die/polygonal aperture disclosed in Yasumi for crimping a stent would address the uneven crimping forces problem. Ex. 1205 ¶¶ 166-167. This problem existed in many crimping applications (e.g. crimpers for pointing tubes and crimping electrical connections), and was previously solved by using a straight-sided die/polygonal aperture, such as the one disclosed in Yasumi. *Id.*

A POSITA would have had a reason, basis or motivation to solve the problem in the stent crimping field in the same manner it was solved in other crimping fields. Ex. 1205 ¶¶ 160-168. This would have been nothing more than use of known technique to improve similar devices in the same way. *Id.* A POSITA therefore would have had a reason, basis or motivation to use Yasumi as a stent crimper to provide the even crimping forces necessary to safely and effectively crimp a stent. *Id.*

B. Ground 2: Claims 11, 17, 19, 26, 34, 35, and 39 Are Obvious Over Yasumi In View Of Williams and Morales 2

1. Claim 39

Independent Claim 39 recites limitations substantially similar to those previously recited in Claim 1, but adds limitations directed to an aperture “having a

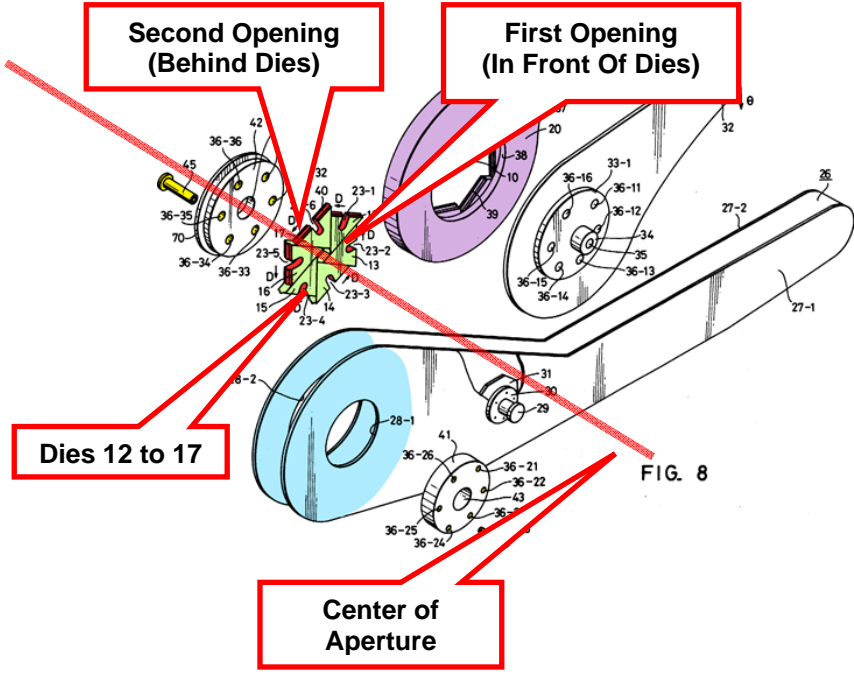
center and a first opening and a second opening,” and “the dies constructed and arranged to have a length exceeding the length of a stent with a longitudinal axis passing through both the first opening and the second opening.”

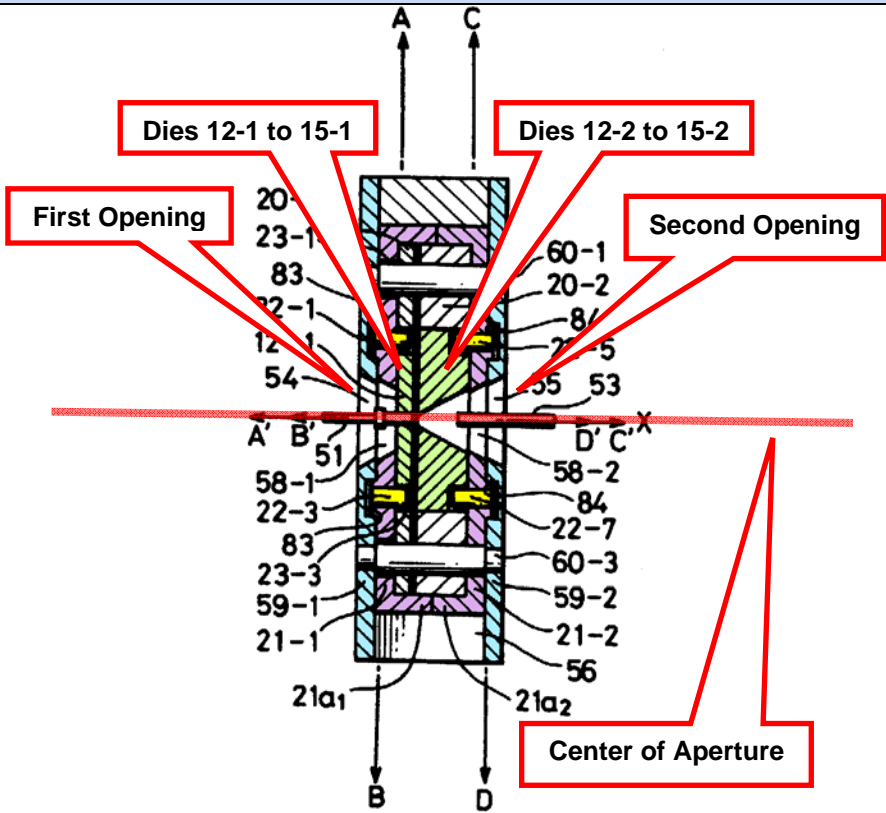
These limitations are disclosed in or obvious over Yasumi either alone or in view of Williams. Yasumi is considered a stent crimper for purposes of analyzing validity of the challenged claims. Williams teaches the use of tools such as ordinary pliers to crimp a stent. Ex. 1227 at 1:67-68. Therefore, Yasumi in view of Williams would have been constructed to accommodate a balloon catheter and stent within the crimping aperture. Ex. 1205 ¶ 170. An aperture having a center and openings on both ends, *i.e.*, a first opening and a second opening, is necessary to permit the distal and proximal portions of the balloon catheter to extend outside the crimping aperture while accommodating the stent and balloon portion of the catheter within the aperture. *Id.*

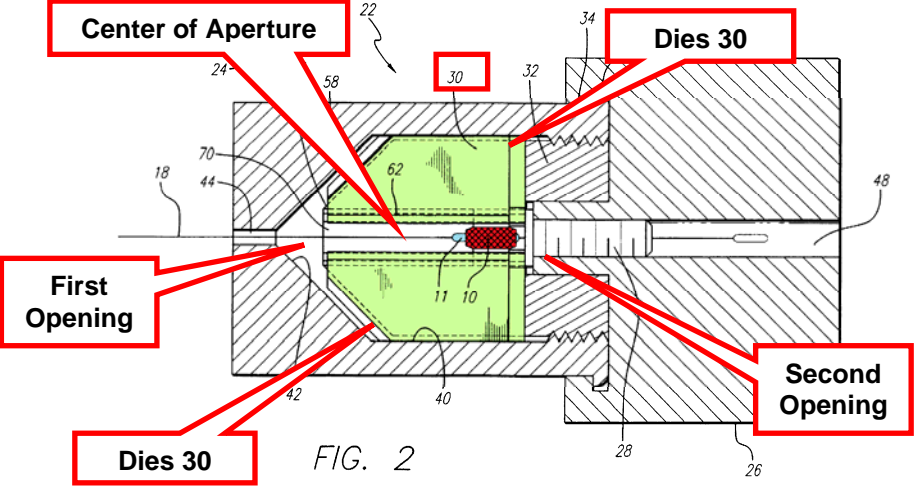
Moreover, a POSITA would have known the desirability of crimping the stent evenly and, thus, it would have been obvious to make the length of the dies exceed the length of the stent to ensure that the entire stent fit easily within the aperture, provide a margin of error so that no portion of the stent would be missed during the crimping procedure, and to account for manufacturing tolerances. Ex. 1205 ¶ 171.

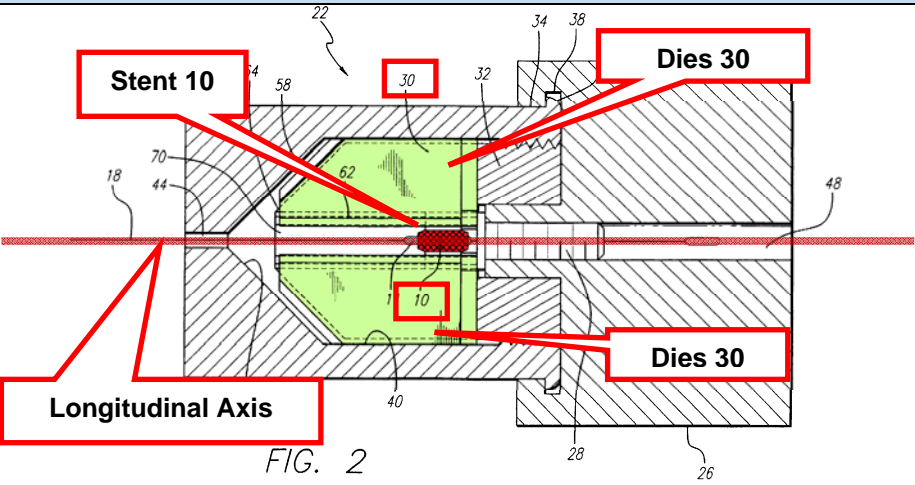
To the extent these limitations are not viewed as disclosed in or obvious in view of Yasumi alone or in view of Williams, Morales also discloses these limitations. Ex. 1205 ¶¶ 169-174. A detailed analysis of Claim 39 is provided in the following claim chart. *See also id.* ¶ 174.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
[39 Preamble] A stent crimper comprising:	<i>See</i> Claim [1 Preamble].
[39a] a plurality of movable dies arranged to form an iris disposed about an aperture,	<i>See</i> Claims [1a] (plurality of movable dies arranged to form an iris), [1b] (dies disposed about the aperture).
[39b] the aperture having a center and a first opening and a second opening,	<u>Yasumi discloses an aperture (between movable pieces 12-17 or between movable pieces 12-1 to 15-1 and 12-2 to 12-5) having a center and a first opening and a second opening.</u> “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. 1203 at 8:50-54; <i>id.</i> at 9:30-34.)

<p><u>ASSERTED CLAIMS</u></p>	<p><u>PRIOR ART</u></p>  <p>(<i>Id.</i> at Fig. 8.)</p> <p>“The movable pieces 12-1 to 15-1 are so formed as to provide a pyramidal aperture setting portion 81, The axes of the aperture setting portions 81 and 82 lie on the same straight line, which is substantially in alignment with the centers of the openings 54 and 55 of the side panels of the casing.” (Ex. 1203 at 9:63-10:6.)</p>
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<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	 <p style="text-align: center;">FIG. 9(a)</p> <p>(<i>Id.</i>, Fig. 9(a).)</p> <p><u>Morales also discloses an aperture (between teeth 30) having a center and a first opening and a second opening.</u></p> <p>“An uncrimped stent is manually loaded into the hollow core. . . .” (Ex. 1204 at 3:38-42; <i>see also id.</i> at 4:19-22.)</p> <p>“Screw feed 28 further includes hollow core 54 that extends a length of head 50 and shaft 52. Hollow core 54 serves as a chamber to hold stent 10.” (<i>Id.</i> at 7:33-35.)</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	 <p>(<i>Id.</i>, Fig. 2.)</p>
<p>[39c] 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,</p>	<p><u>Morales discloses dies (teeth 30) 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.</u></p> <p>“In unison, the radiused edges of the teeth/plates converge on the underlying stent to crimp the stent onto the balloon catheter. The radiused edges of the plates thus act as crimping jaws.” (Ex. 1204 at 4:19-22.)</p> <p>“[T]he present invention tool is intended to be used on a variety of stent lengths. 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.” (<i>Id.</i> at 5:5-9.)</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	 <p>FIG. 2</p> <p>(Ex. 1204, Fig. 2.).</p>
<p>[39d]</p> <p>each die in communication with an actuation device,</p>	<p>See Claim [40d].</p>
<p>[39e]</p> <p>the actuation device constructed and arranged such that rotational motion of the actuation device opens or closes the aperture;</p>	<p>See Claim [40e].</p>
<p>[39f]</p> <p>each die having a first straight side and a second straight side, the</p>	<p>See Claim [1d].</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
first straight side and the second straight side converging 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.	

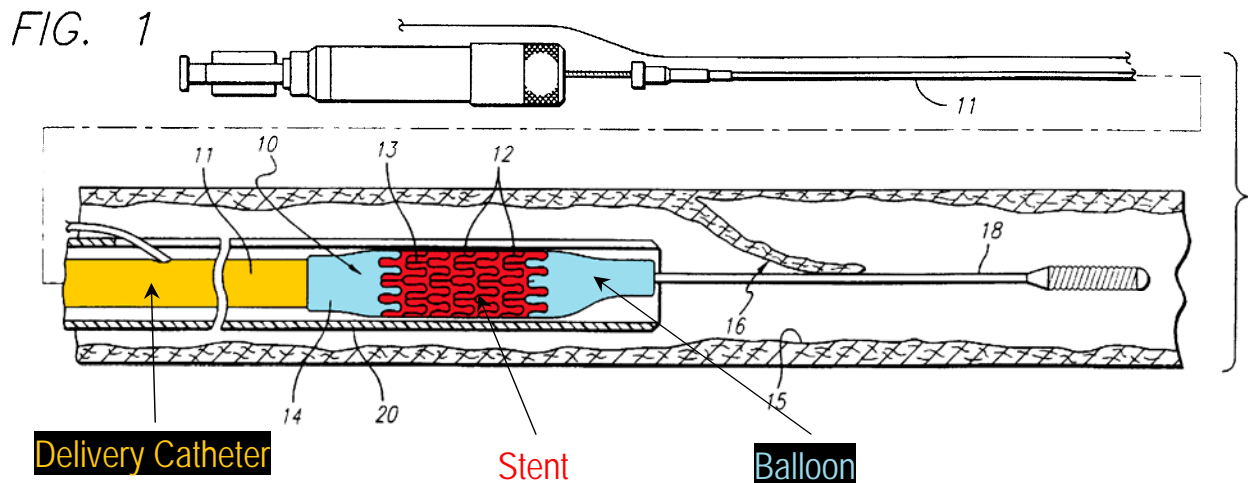
2. Claims 11, 19, and 35

Dependent Claims 11, 19, and 35 share an identical limitation of “wherein a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.”

This limitation is disclosed in or obvious over Yasumi either alone or in view of Williams. Yasumi is considered a stent crimper for purposes of analyzing validity of the challenged claims. Williams teaches a stent disposed about a medical balloon, the medical balloon disposed about a catheter. Ex. 1227 at 5:10-15. Williams also teaches the use of tools such as ordinary pliers to crimp a stent. *Id.* at 1:67-68. Therefore, Yasumi in view of Williams teaches this limitation. A POSITA at the time of the invention would have known about stents and the

balloon-based, catheter-mounted method of delivery. Ex. 1205 ¶ 176. Therefore, a POSITA would have known that crimping a stent over a balloon catheter is the intended purpose for a stent crimper. *Id.* Notably, the Examiner found this limitation inherent during prosecution. Ex. 1202 at 75.

To the extent this limitation is viewed as not disclosed in or obvious in view Yasumi or Williams, Morales discloses a stent 10 (red) disposed about a balloon 14 (blue), the balloon disposed about a delivery catheter 11 (orange):



Ex. 1204, Fig. 1; . “Stent 10 is crimped down onto balloon 14 to ensure a low profile.” *Id.* at 5:60-66, 6:22-25. *See also* Ex. 1205 ¶¶ 175-178.

3. Claims 17, 26, and 34

Dependent Claims 17, 26, and 34 share an identical limitation of “wherein an entire stent is disposed in the aperture.”¹⁷

This limitation is disclosed in or obvious over Yasumi either alone or in view of Williams. Yasumi is considered a stent crimper for purposes of analyzing validity of the challenged claims. Williams teaches the use of tools such as ordinary pliers to crimp a stent. Ex. 1227 at 1:67-68. A POSITA at the time of the invention would have been aware of the problems resulting from uneven stent crimping. Ex. 1205 ¶ 180. To avoid these problems, stent crimpers were designed and constructed to accommodate at least, and typically more than, the entire length of a stent within the die aperture to perform stent crimping. *Id.*

To the extent this limitation is viewed as not disclosed in or obvious in view of Yasumi or Williams, Morales discloses an entire stent 10 (red) disposed within an aperture formed by dies 30 (green). *See* X.B.2; *see also* Ex. 1204 at 5:5-9; Ex. 1205 ¶¶ 1179-182.

¹⁷ Claim 26 recites “a stout,” but for purposes of this *inter partes* review Petitioner construes that to be “a stent.”

4. Reason, Basis, or Motivation to Combine

It would have been obvious to a POSITA to have provided Yasumi, either alone or in view of Williams, with the additional limitations of Claims 11, 17, 19, 26, 34, 35, and 39 based on the teachings in Morales. Ex. 1205 ¶¶ 183-85.

Yasumi is considered a stent crimper for purposes of analyzing validity of the challenged claims. Williams teaches the use of tools such as ordinary pliers to crimp a stent. It would have been obvious as a matter of common sense to use Yasumi as a stent crimper, either alone or in view of Williams, with a stent disposed about a balloon and the balloon disposed about a catheter, as discussed in Williams and Morales, because crimping a stent to a balloon catheter is the intended purpose for a stent crimper. Ex. 1205 ¶ 184.

Moreover, a POSITA would have been motivated to modify Yasumi, either alone or in view of Williams, to form a stent crimper with an aperture “having a center and a first opening and a second opening with dies constructed and arranged to have a length exceeding the length of a stent,” as depicted in Morales. Ex. 1205 ¶¶ 183-85. Problems with uneven crimping forces were well known. *Id.* A POSITA would be motivated to ensure that the entire length of the stent resided within the aperture while crimping to impart the most even crimping forces possible. *Id.* It 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. It 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. *Id.*

XI. THIS PETITION IS NOT REDUNDANT UNDER 35 U.S.C. § 325(D)

This Petition follows two prior Petitions filed by Petitioner on October 13, 2016 (IPR2017-00072) and on December 7, 2016 (IPR2017-00444), respectively. The grounds in all three Petitions are materially different from each other in a number of ways.

In the present Petition, Yasumi is the primary reference that independently teaches every limitation of the challenged claims, with the possible exception of the non-limiting preamble identifying “a stent crimper” as an intended use for the claimed invention. The present petition relies on Williams for the suggestion to use Yasumi as a stent crimper. Petition IPR2017-00444 similarly relies on Yasumi, but relies on the AAPA (which Patent Owner has argued is not prior art) for the suggestion to use Yasumi as a stent crimper. Williams is prior art under 35 U.S.C. § 102(b), whereas the AAPA is prior art under longstanding legal precedent. The Patent Owner cannot overcome Williams by establishing that it is

not properly considered as patent or printed publication prior art for purposes on an *inter partes* review.

In the present Petition, Yasumi is the primary reference. In Petition IPR2017-00072, the AAPA is the primary reference and is generally directed to a stent crimper that discloses all of the limitation except for the straight-sided die/polygonal aperture limitation of the challenged claims. Sabbaghian and Baker are relied upon as secondary references for their disclosure of the straight-sided die/polygonal aperture limitation. Thus, the AAPA in view of Sabbaghian or Baker renders the challenged claims obvious in Petition IPR2017-00072. These grounds rely on a different applications of the prior art and motivations to combine references. Additionally, Yasumi qualifies as prior art under 35 U.S.C. § 102(b), whereas Sabbaghian qualifies as prior art under 35 U.S.C. § 102(e). The Patent Owner cannot overcome Yasumi by establishing an earlier invention date.

The Petitions are therefore not redundant.

XII. SECONDARY CONSIDERATIONS CANNOT OVERCOME THE STRONG EVIDENCE OF OBVIOUSNESS

Secondary considerations do not control the obviousness conclusion. *See Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Where, as here, a strong *prima facie* case of obviousness exists, even relevant secondary considerations supported by substantial evidence may not dislodge the final conclusion of obviousness. *See, e.g., Leapfrog Enters., Inc. v. Fisher-Price, Inc.*,

485 F.3d 1157, 1162 (Fed. Cir. 2007). Petitioner is not aware of any evidence of secondary considerations that would support a finding of non-obviousness, but reserves the right to respond to such evidence, if presented.

XIII. CONCLUSION

For the reasons set forth above, Petitioner has established a reasonable likelihood of prevailing in showing that the challenged claims are unpatentable as obvious and, therefore, requests that the Board institute an *inter partes* review and cancel those claims.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: April 19, 2017

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CERTIFICATE OF TYPE-VOLUME LIMITATIONS
UNDER 37 C.F.R. § 42.24

Pursuant to 37 C.F.R. § 42.24(d), Counsel for Petitioner Edwards Lifesciences Corporation hereby certifies that this document complies with the type-volume limitation of 37 C.F.R. § 42.24(a)(1)(i). According to Microsoft Office Word 2010's word count, this document contains approximately 13,857 words, including any statement of material facts to be admitted or denied in support, and excluding the table of contents, table of authorities, mandatory notices under § 42.8, exhibit list, certificate of service or word count, or appendix of exhibits or claim listing.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: April 19, 2017

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Edwards Lifesciences Corporation
IPR of U.S. Pat. 6,915,560

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,915,560** and **Exhibits 1201 – 1227** are being served on April 19, 2017, via FedEx Priority Overnight service on counsel of record for U.S. Patent 6,915,560 patent owner **BOSTON SCIENTIFIC SCIMED, INC.**, at the addresses below:

Correspondence Address of Record for U.S. Patent 6,915,560 at the U.S. Patent and Trademark Office:

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Dated: April 19, 2017

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