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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. IPR2017-00444
Patent 6,915,560

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

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EXHIBIT LIST

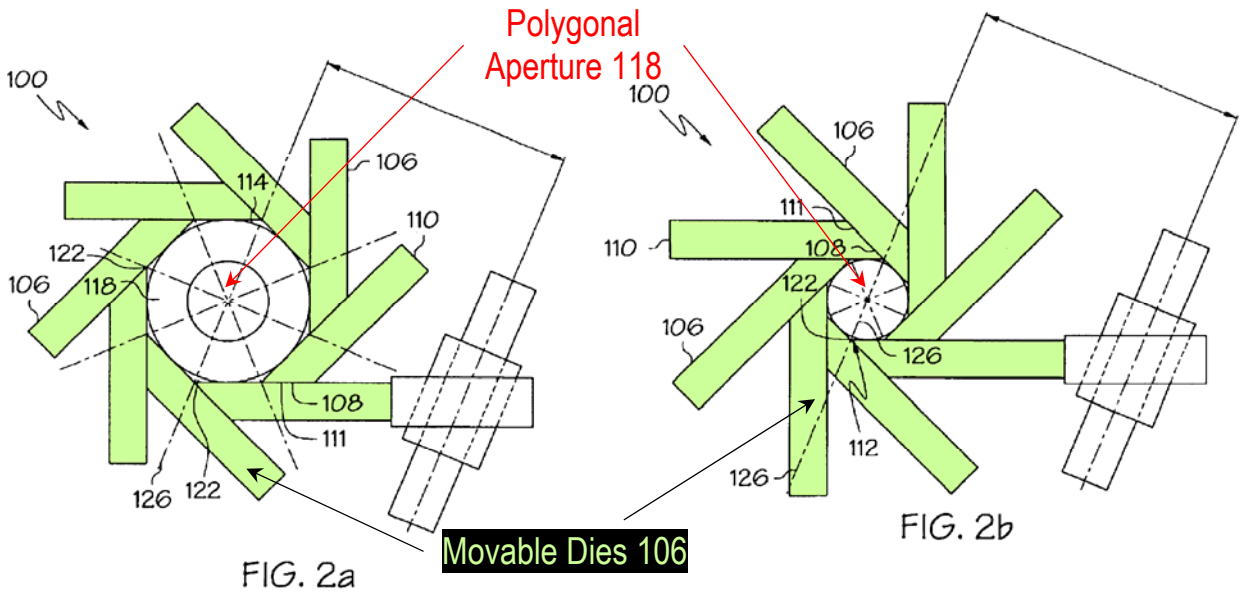
Exhibit No.	Description
1101	U.S. Patent No. 6,915,560 ("the '560 patent")
1102	U.S. Patent No. 6,915,560 File History Excerpts
1103	U.S. Patent No. 4,454,657 ("Yasumi")
1104	U.S. Patent No. 5,893,852 ("Morales")
1105	Declaration of Neil Sheehan in Support of Petition for *Inter Partes* Review of U.S. Patent No. 6,915,560
1106	Curriculum Vitae of Neil Sheehan
1107	Materials Considered by Neil Sheehan
1108	German Patent No. DE9034 ("Nix")
1109	Certified Translation of Nix
1110	U.S. Patent No. 2,664,996 ("Andrews")
1111	U.S. Patent No. 4,308,744 ("Baker")
1112	International Patent Publication No. WO1994014573 A1 ("Hartley")
1113	U.S. Patent No. 5,918,511 ("Sabbaghian")
1114	U.S. Patent No. 6,364,870 ("Pinchasik")
1115	U.S. Patent No. 5,261,263 ("Whitesell")
1116	U.S. Patent No. 3,695,087 ("Tuberman")
1117	U.S. Patent No. 6,176,116 ("Wilhelm")

Exhibit No.	Description
1118	U.S. Patent No. 6,051,002 (“Morales 2”)
1119	U.S. Patent No. 5,951,540 (“Verbeek”)
1120	U.S. Patent No. 7,892,201 (“Laguna”)
1121	U.S. Patent No. 6,125,523 (“Brown”)
1122	U.S. Patent No. 3,370,451(“Schuetz”)
1123	U.S. Patent No. 3,154,978 (“Baker 2”)
1124	U.S. Patent No. 3,417,598 (“Valente”)
1125	U.S. Patent No. 6,074,381 (“Dinh”)

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. 1101[1]. 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.

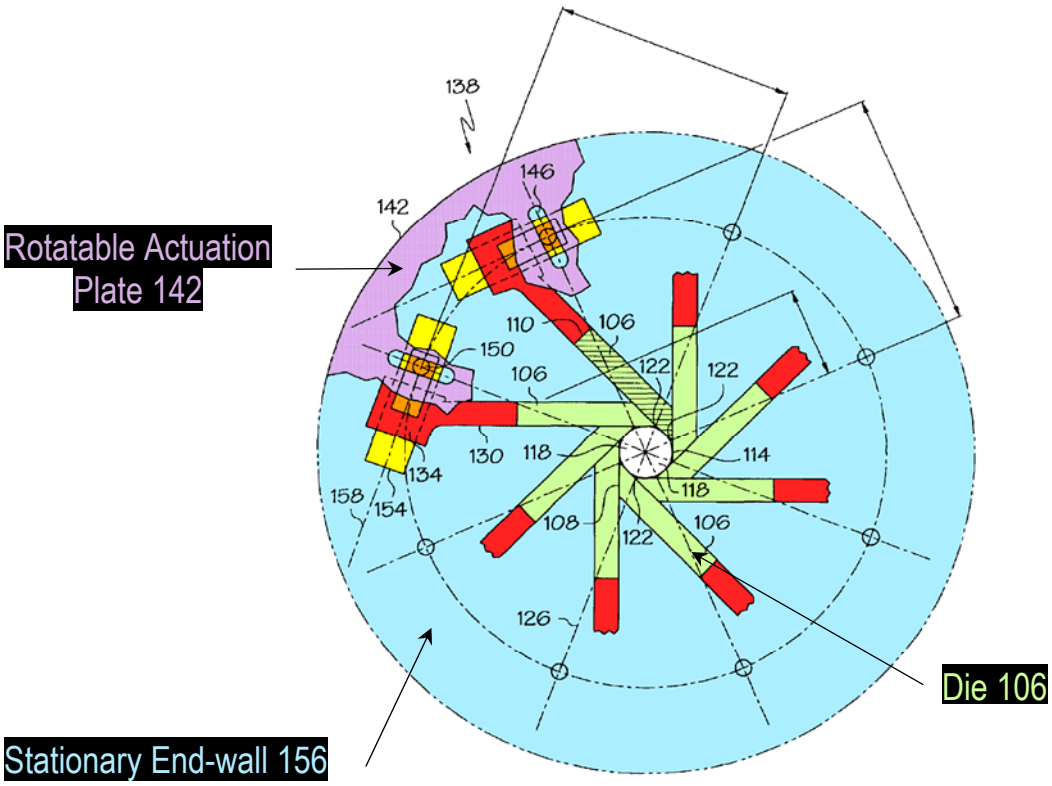
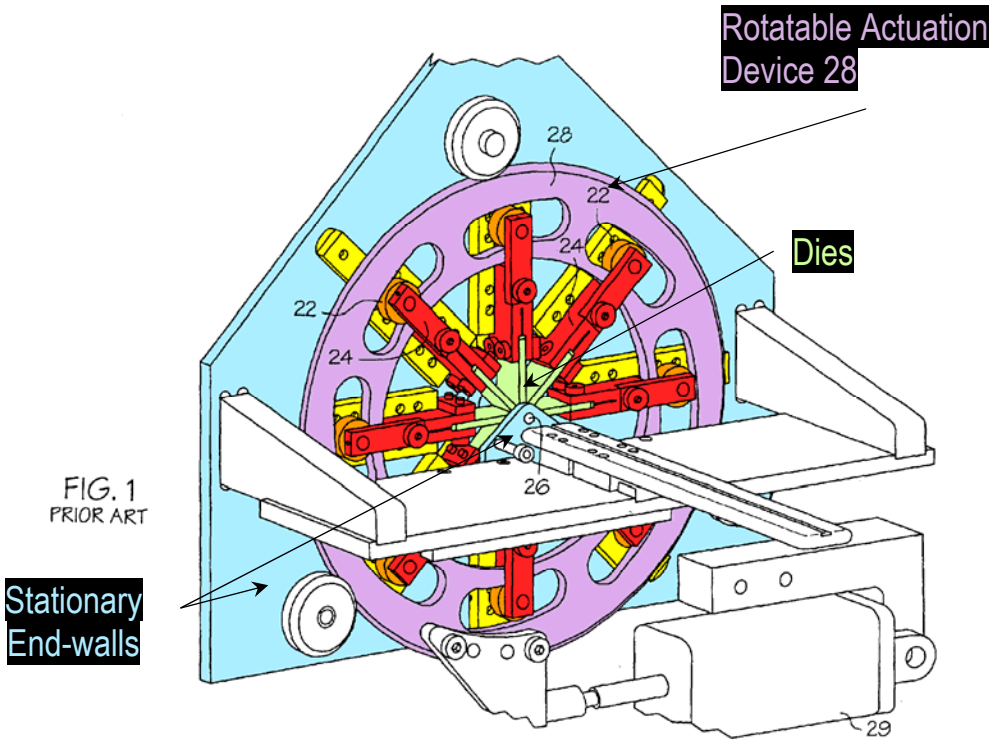


FIG. 4A

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. 1101 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.

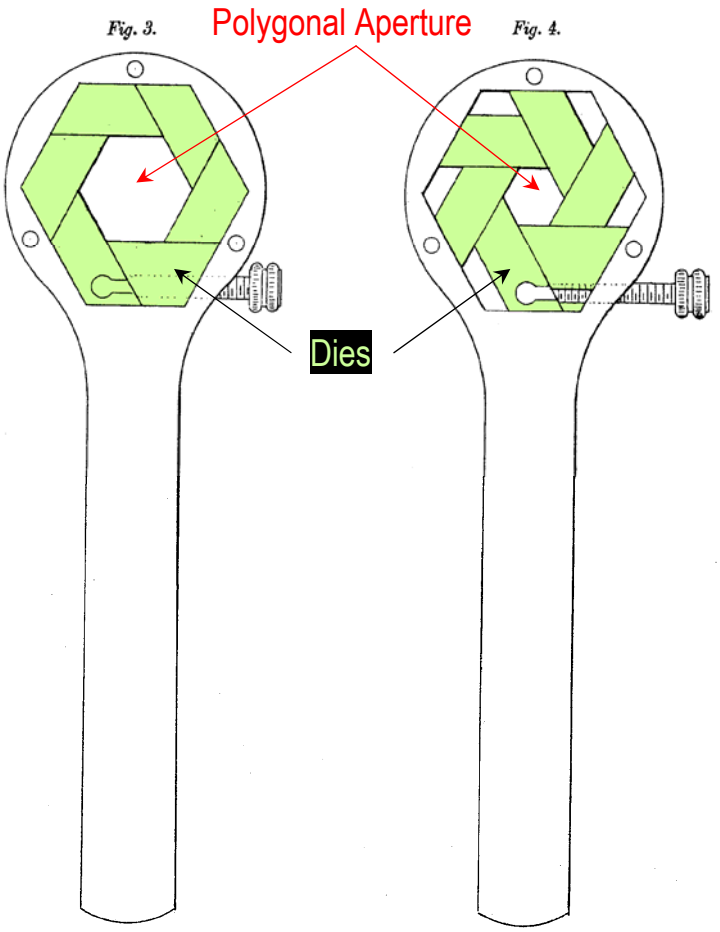
The only feature missing from the admitted prior art stent crimper is the dies arranged to form a variable-sized ***polygonal*** aperture.

During prosecution, the Examiner rejected the claims several times over the prior art, including over the admitted prior art stent crimper. To overcome the rejections, the Applicant amended the claims, ultimately focusing on the die configuration forming the polygonal-shaped aperture, illustrated in Fig. 2a and 2b above, to distinguish the prior art.

But the arrangement of dies to form a polygonal-shaped aperture is nothing new. For more than a century, skilled artisans have used such a configuration with tools that require increasing and decreasing the size of an aperture, such as

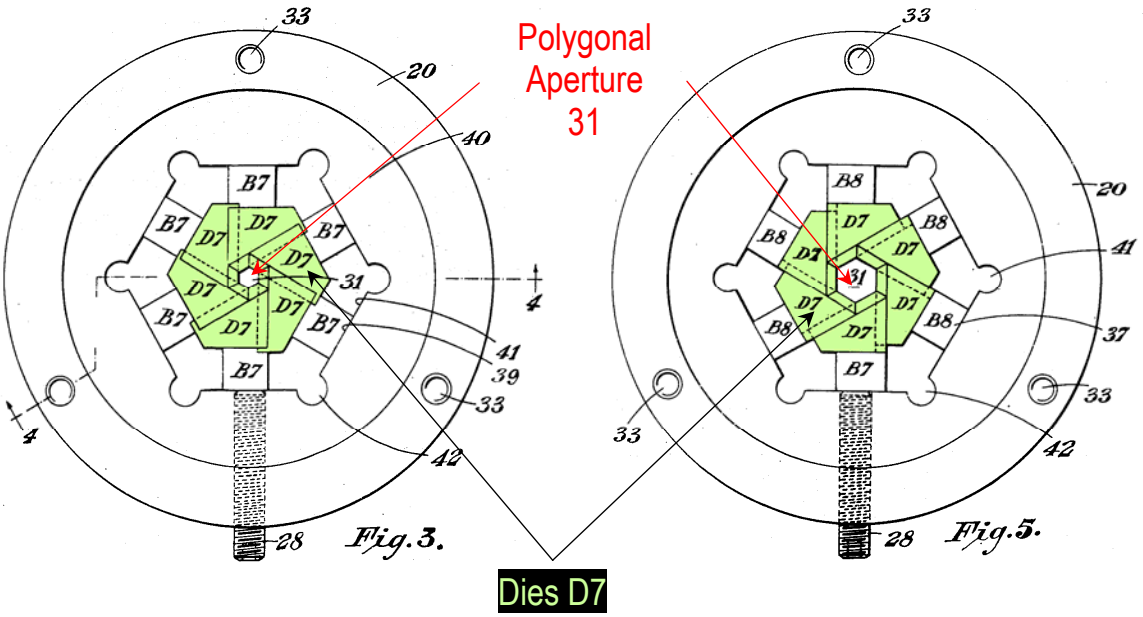
wrenches, drawing dies, tube pointers, setting devices, chucks, press tools, electric wire guide devices, and control valves.

For example, in 1880 Nix disclosed an adjustable wrench that used trapezoidal "jaws" arranged to form a "hexagonal opening" that varies in size with movement of the "jaws":



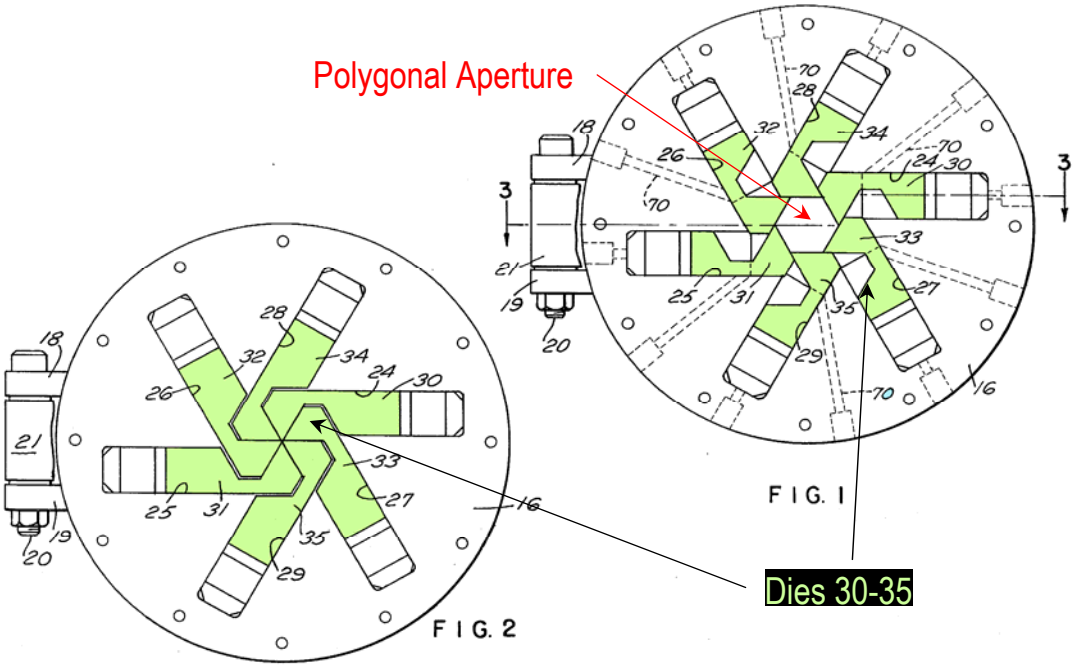
Exs. 1108 and 1109.

In 1954, Andrews disclosed an adjustable die for drawing, forming, or extruding bars of varying sections. Andrews disclosed "die blocks D7" arranged to form a polygonal "die hole 31" that varies in size with movement of the "die blocks D7":



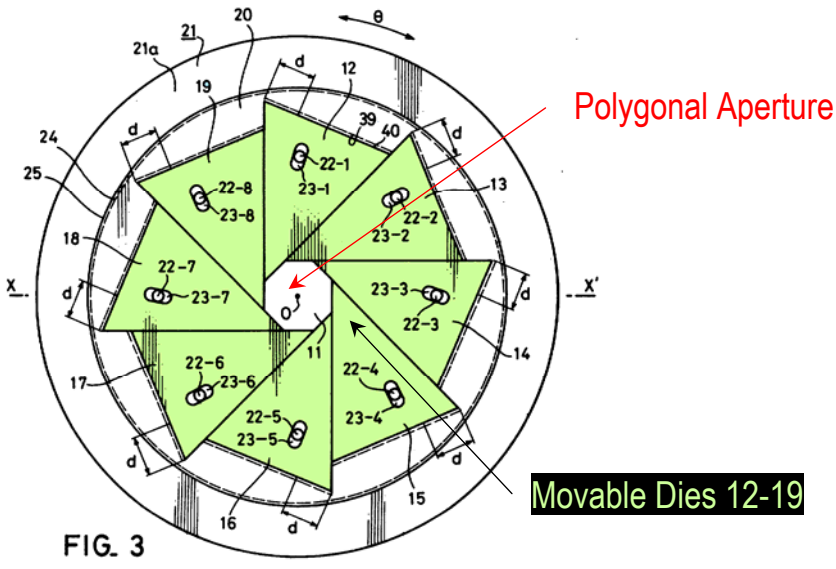
Ex. 1110.

In 1982, Baker disclosed a tube pointer for compressing metal tubes. Baker disclosed a plurality of "jaws" 30-35 arranged to form a polygonal aperture that varies in size with movement of the "jaws":



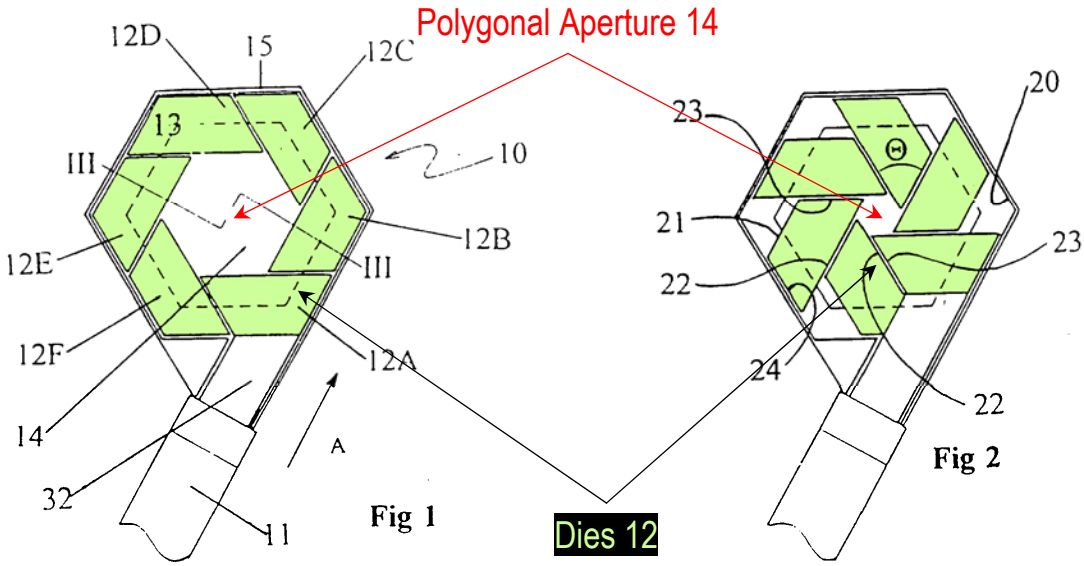
Ex. 1111.

Also in 1982, Yasumi disclosed "an aperture setting device in which the size of the predetermined polygonal aperture can be changed, retaining the polygonal configuration." Yasumi cited many uses for the disclosed device, including in a press tool.



Ex. 1103.

In 1992, Hartley disclosed an adjustable aperture apparatus having an "iris-type" arrangement providing an adjustable diameter aperture. Hartley disclosed a plurality of "jaw members 12" arranged to form a "hexagonal aperture 14" that varies in size with movement of the "jaw members 12":



Ex. 1112.

In July of 1999, Sabbaghian disclosed an adjustable socket for a wrench having a plurality of "gripping members 6" arranged to form a "gripping region 14" that varies in size with movement of the "gripping members 6":

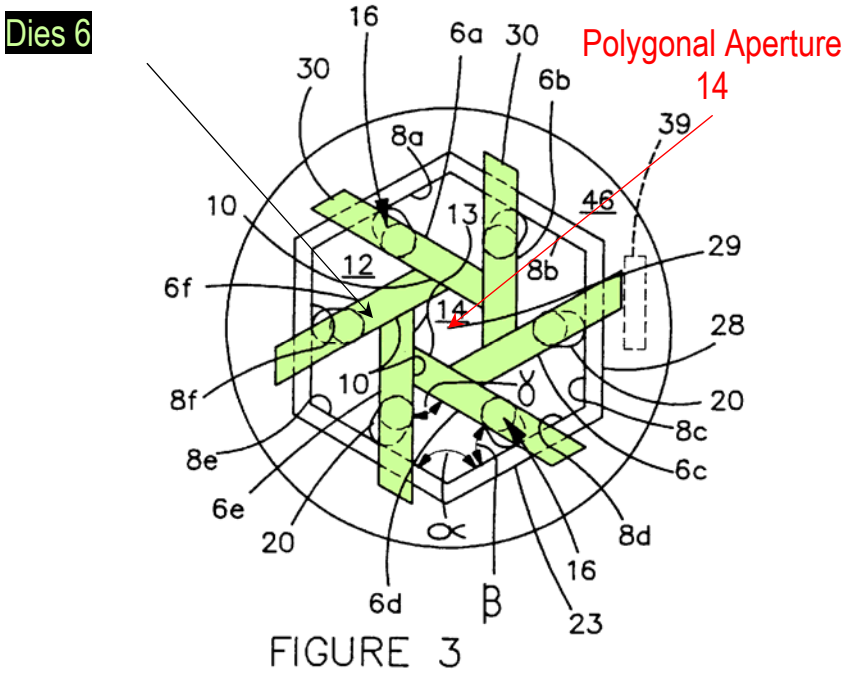


FIGURE 3

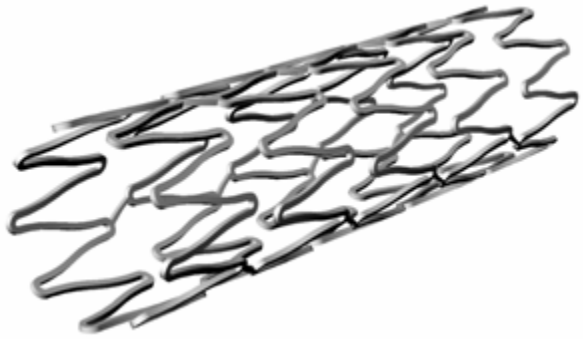
Ex. 1113.

The '560 patent's broad claims recite nothing more than a crimper with dies arranged to form a polygonal aperture, as was well known to a person of ordinary skill in the art ("POSITA") long before 1999. Thus, the claims of the '560 patent are unpatentable over the prior art and should be cancelled.

II. INTRODUCTION TO THE STATE OF THE ART

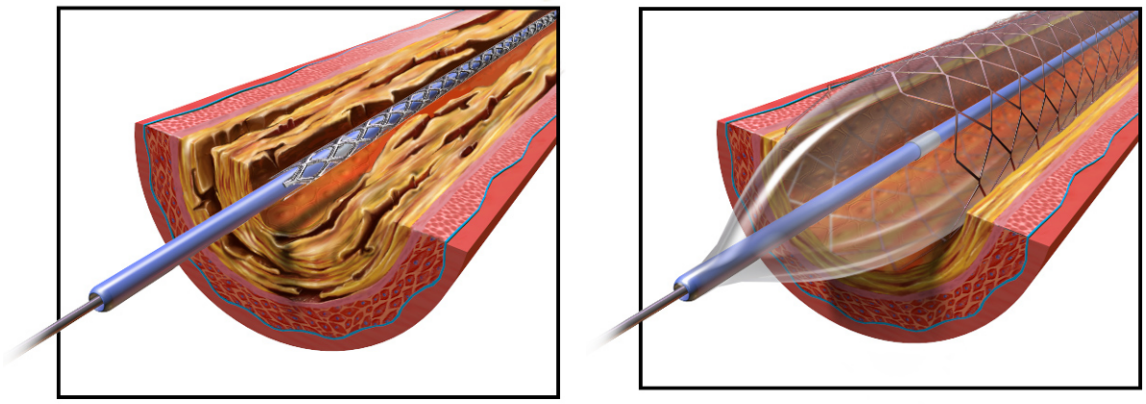
The '560 patent discloses a crimper for reducing the size of a stent. Stents are well-known medical devices used to open and reinforce an obstructed blood vessel. Stents are generally cylindrical wire-mesh devices that can be introduced via a delivery catheter into the blood vessel at a reduced diameter and then later expanded to the diameter of the vessel at the implantation site. Ex. 1105 ¶¶ 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. 1105 ¶¶ 31-33, 159-160.

Balloon Catheter & Stent Within Vessel Before & After Inflation



Stents must be crimped uniformly to avoid damaging the stent. Ex. 1105 ¶¶ 159-160. 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. 1114 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.

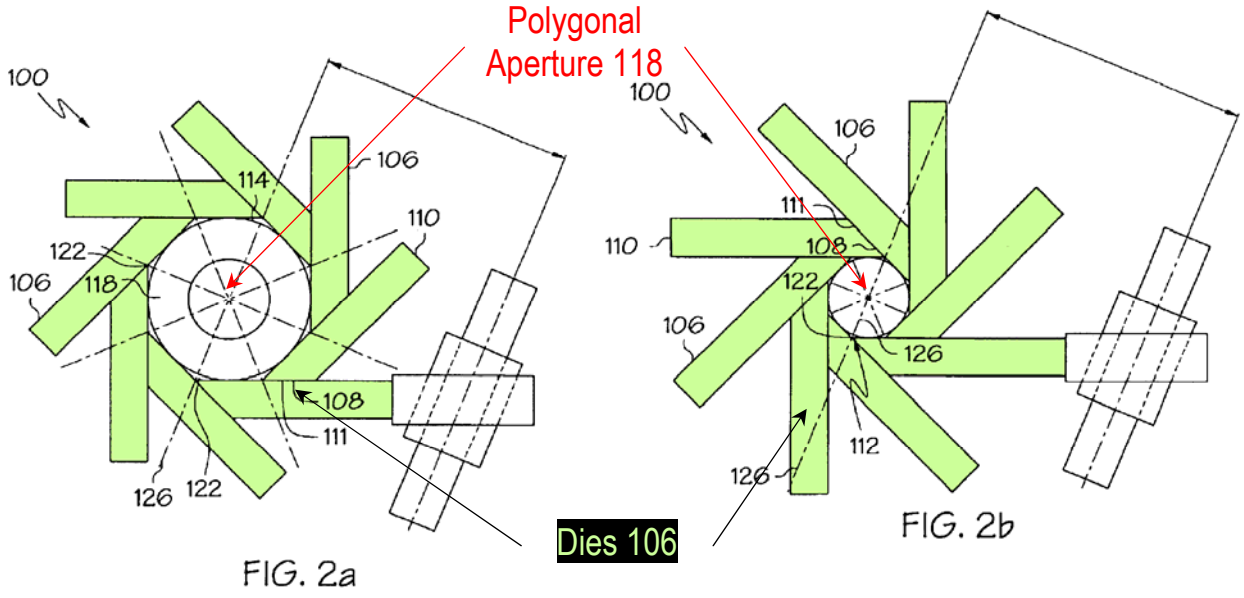


FIG. 2a FIG. 2b

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. 1101 at 2:27-30.

As discussed above, this die configuration has been used for decades in connection with tools that require increasing and decreasing the size of an aperture to grip, compress, or form an object. Notably, the Examiner relied on prior art directed to a variety of these types of tools to reject the claims during prosecution. For example, the Examiner cited a reference directed to radial pliers or a wrench.

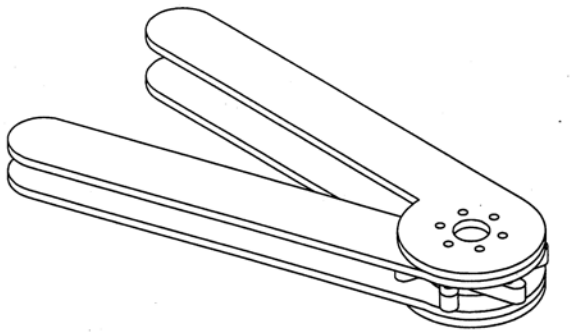
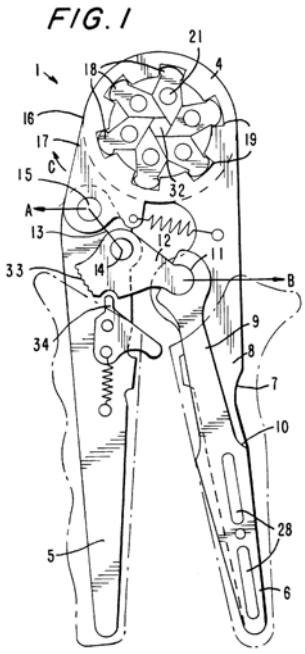
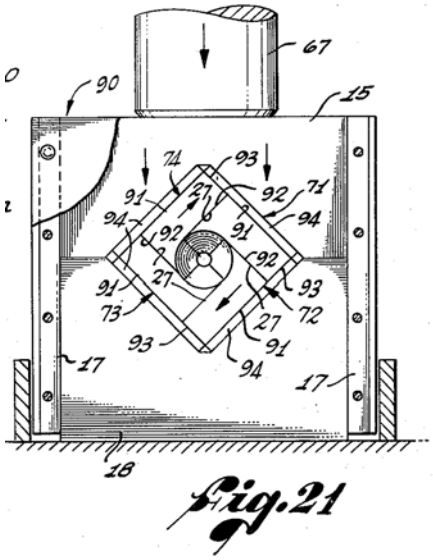


Figure 8

Ex. 1102 at 72-73, Ex. 1115, Fig. 8. The Examiner relied upon a crimping tool for crimping lead end sleeves onto electrical conductors.



Ex. 1102 at 46, Ex. 1117, Fig. 1. The Examiner also relied upon a tube pointer.



Ex. 1102 at 45-49; Ex. 1116, Fig. 21.

Like the Examiner, a POSITA would have looked to these closely related types of mechanisms to improve upon known stent crimpers. A POSITA would

have viewed Yasumi as a stent crimper because it is 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. Furthermore, to the extent necessary, a POSITA would have had a reason, basis, or motivation to use Yasumi as a stent crimper in view of the AAPA. Ex. 1105 ¶¶ 81-92, 155-160.

As further explained below, each of the challenged claims is unpatentable as obvious.

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:

Lead Counsel	Back-up Counsel
Craig S. Summers (Reg. No. 31,430) 2css@knobbe.com BoxEdwards@knobbe.com Postal and Hand-Delivery Address: Knobbe, Martens, Olson & Bear, LLP 2040 Main Street, 14th Floor Irvine, CA 92614 Telephone: 949-760-0404 Fax: 949-760-9502	Brenton R. Babcock (Reg. No. 39,592) 2brb@knobbe.com Christy G. Lea (Reg. No. 51,754) 2cgl@knobbe.com Cheryl T. Burgess (Reg. No. 55,030) 2ctb@knobbe.com Postal and Hand-Delivery Address: Knobbe, Martens, Olson & Bear, LLP 2040 Main Street, 14th Floor Irvine, CA 92614 Telephone: 949-760-0404 Fax: 949-760-9502

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@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.

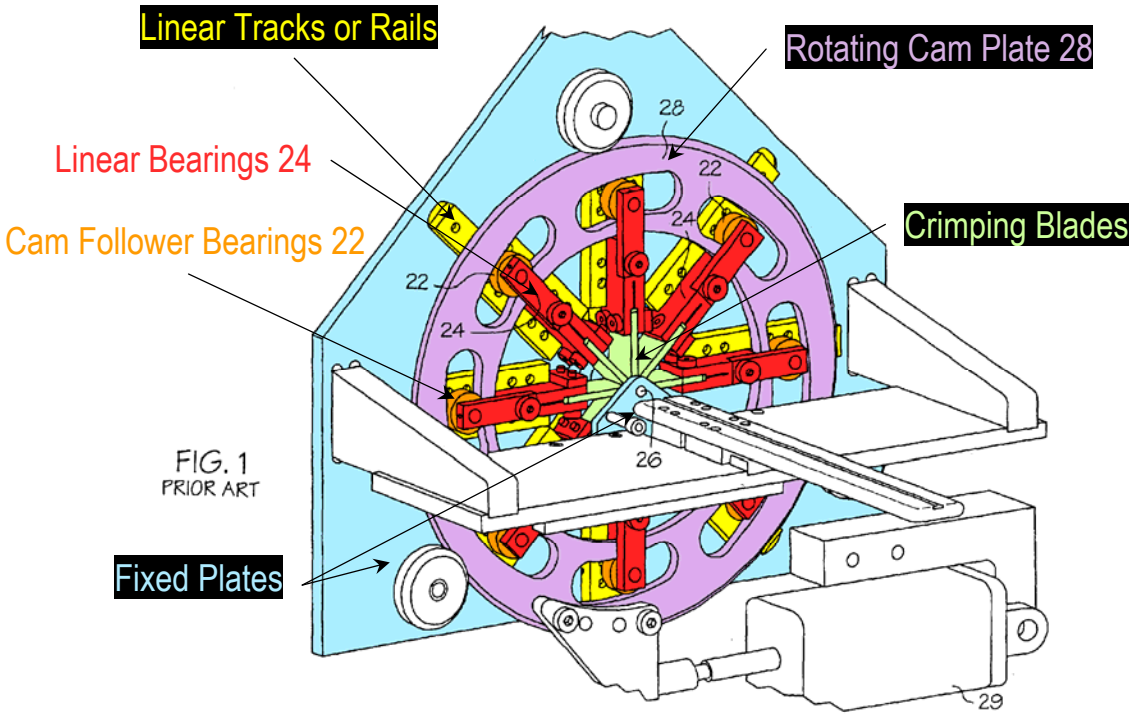
V. U.S. PATENT NO. 6,915,560

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. 1101, Abstract, 9:20-22. The apparatus may be used for multiple purposes. For example, it may be used as a crimper to reduce the size of a medical device (such as a stent), or as a mold to blow mold a medical balloon to a particular size. *Id.* at 2:48-55, 8:65-67.

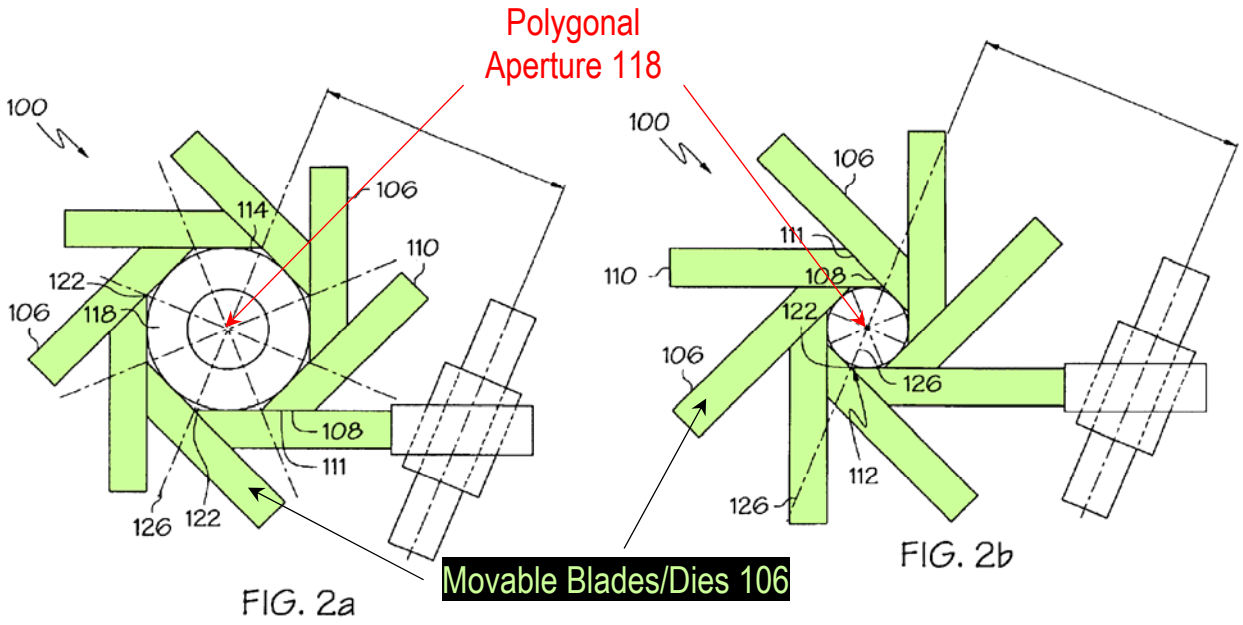
The ’560 patent notes that prior art crimping of stents often applied uneven crimping forces that could distort the stent and require re-crimping. However, crimping the same stent multiple times can damage the stent. Ex. 1101 at 1:42-55.

The ’560 patent also illustrates and discusses an admitted prior art stent crimper (“Applicant Admitted Prior Art” or “AAPA”):



Ex. 1101, Fig. 1. The AAPA is a stent crimper that uses eight movable crimping blades (green) positioned between two fixed plates (blue). The end of each crimping blade is attached to a linear bearing 24 (red), which has a corresponding linear track (yellow) mounted onto the larger of the two fixed plates. *Id*. at Fig. 1, 1:65-2:21. Each linear bearing 24 (red) is connected to its corresponding linear track (yellow) via a cam follower bearing 22 (orange) that fits within an arc-shaped slot on a rotating cam plate 28 (purple). Because the slots are not concentric with respect to the rotational axis 26, rotation of the cam plate 28 (purple) causes the linear bearings 24 (red) to slide along the linear tracks (yellow) and move the crimping blades (green) radially outward or inward to crimp a stent. *Id.*

The '560 patent proposes a crimper that is "capable of crimping a stent uniformly while minimizing the distortion of and scoring and marking of the stent due to the crimping." Ex. 1101 at 2:26-29. As shown in Figures 2a and 2b below, the crimper uses movable blades 106 (green) disposed about a reference circle 114 to form a polygonal aperture 118 whose size may be varied. *Id*. at 4:46-62, 4:66-5:3.



Id., Figs. 2a, 2b.

Each blade 106 (green) has an inner end 108 and an outer end 110. The inner end 108 is beveled 111 so that it cooperates with the adjacent blade. Ex. 1101 at Fig. 3a, 4:59-62. Each blade is connected to an actuation device 138 that simultaneously moves the blades 106 (green) to increase or decrease the size of the aperture 118 while maintaining the polygonal shape of the aperture. *Id*. at 5:5-12.

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

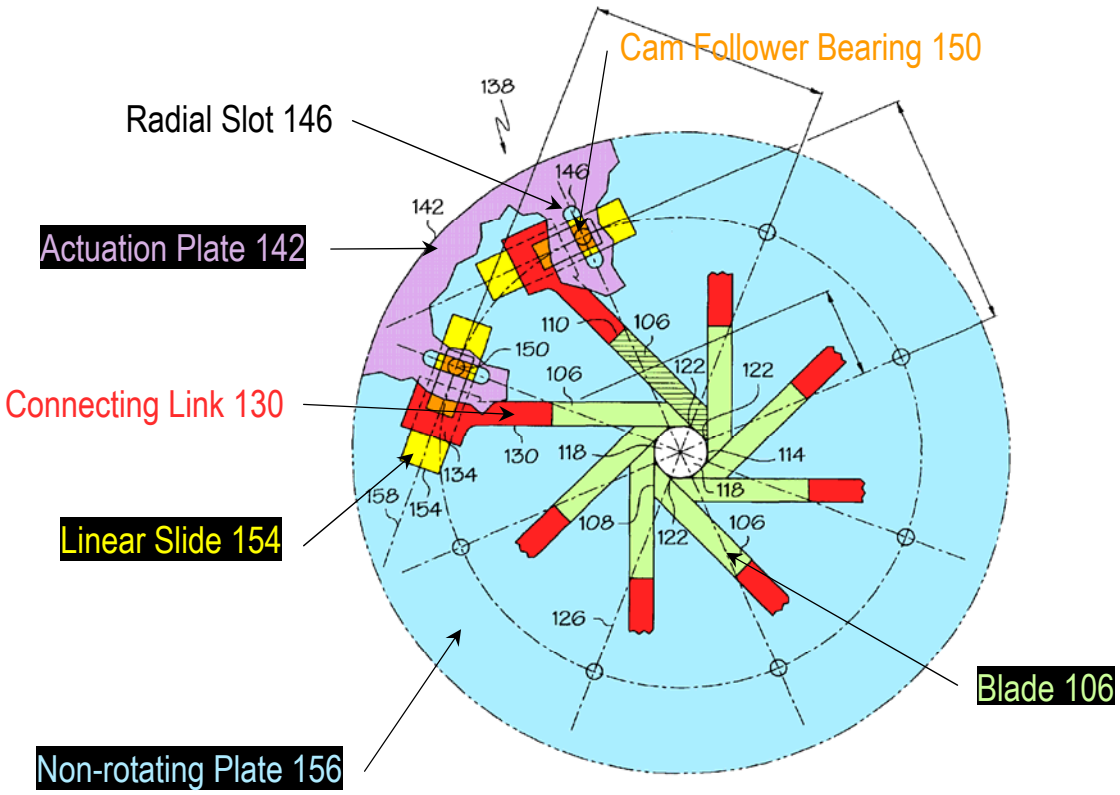


FIG. 4A

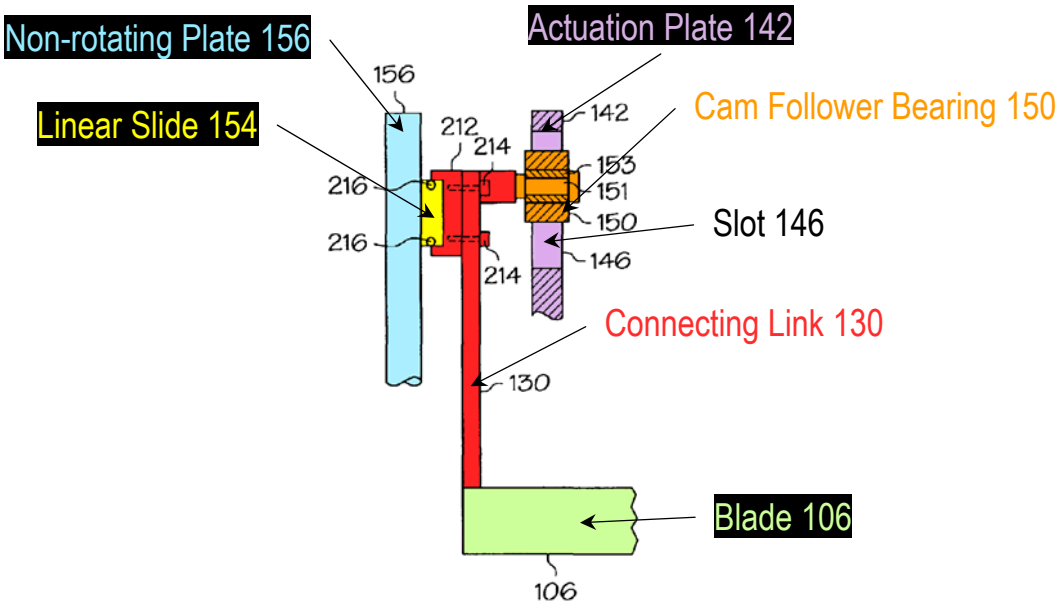


FIG. 4c

Ex. 1101 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 of the connecting link 130 (red) has a cam follower bearing 150 (orange) that extends into a slot 146 in an actuation plate 142 (purple). *Id.* at 5:17-21. 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.

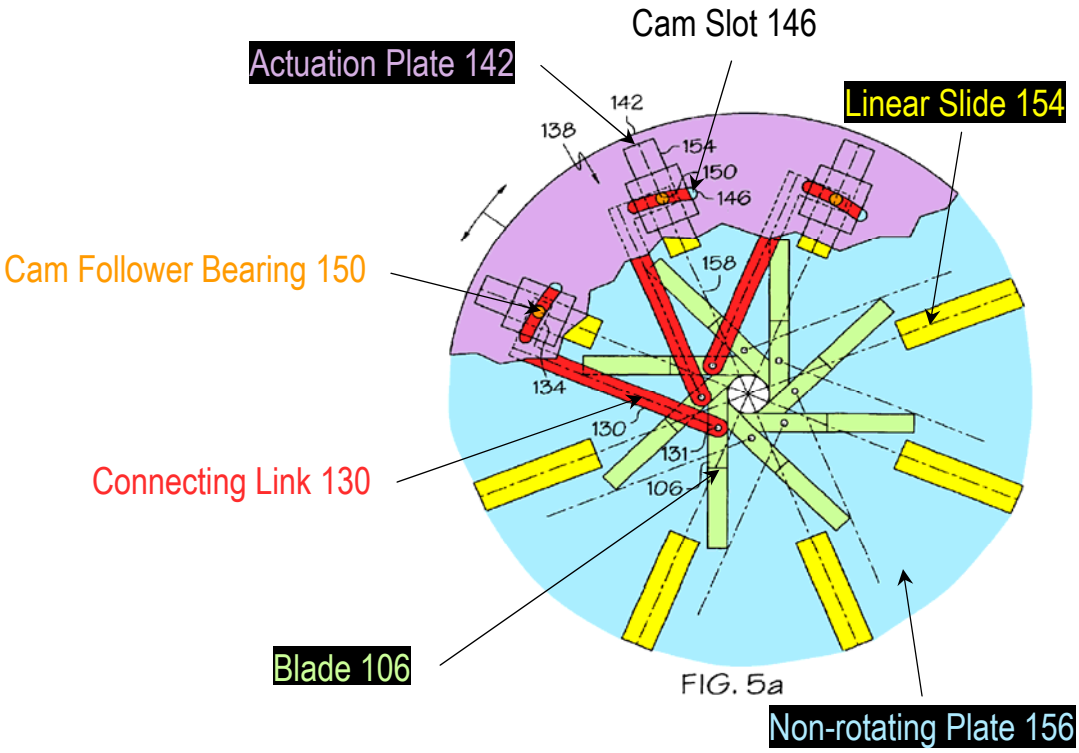

Cam Slot 146
Actuation Plate 142
Linear Slide 154
Cam Follower Bearing 150
Connecting Link 130
Blade 106
Non-rotating Plate 156
142
138
154
150
146
158
134
130
131
106

FIG. 5a

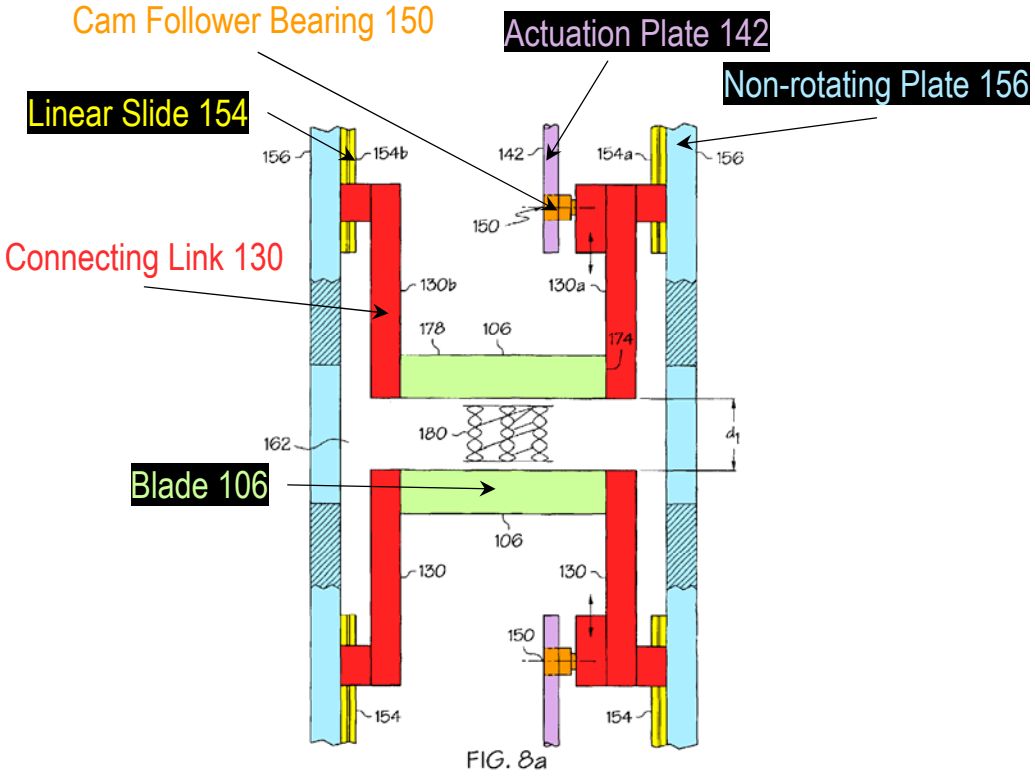

Cam Follower Bearing 150
Actuation Plate 142
Non-rotating Plate 156
Linear Slide 154
Connecting Link 130
Blade 106
156
154b
142
154a
150
130b
130a
178
106
174
180
162
d_1
130
154

FIG. 8a

Ex. 1101 at Figs. 5a, 8a. This embodiment operates in a manner similar to the embodiment described above. *Id*. at 5:66-6:42. The primary difference is that the blades 106 (green) in the alternative embodiment 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 5:67-6:2; 6:14-17.

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.[2] Ex. 1102 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. 1102 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.

[2] 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.

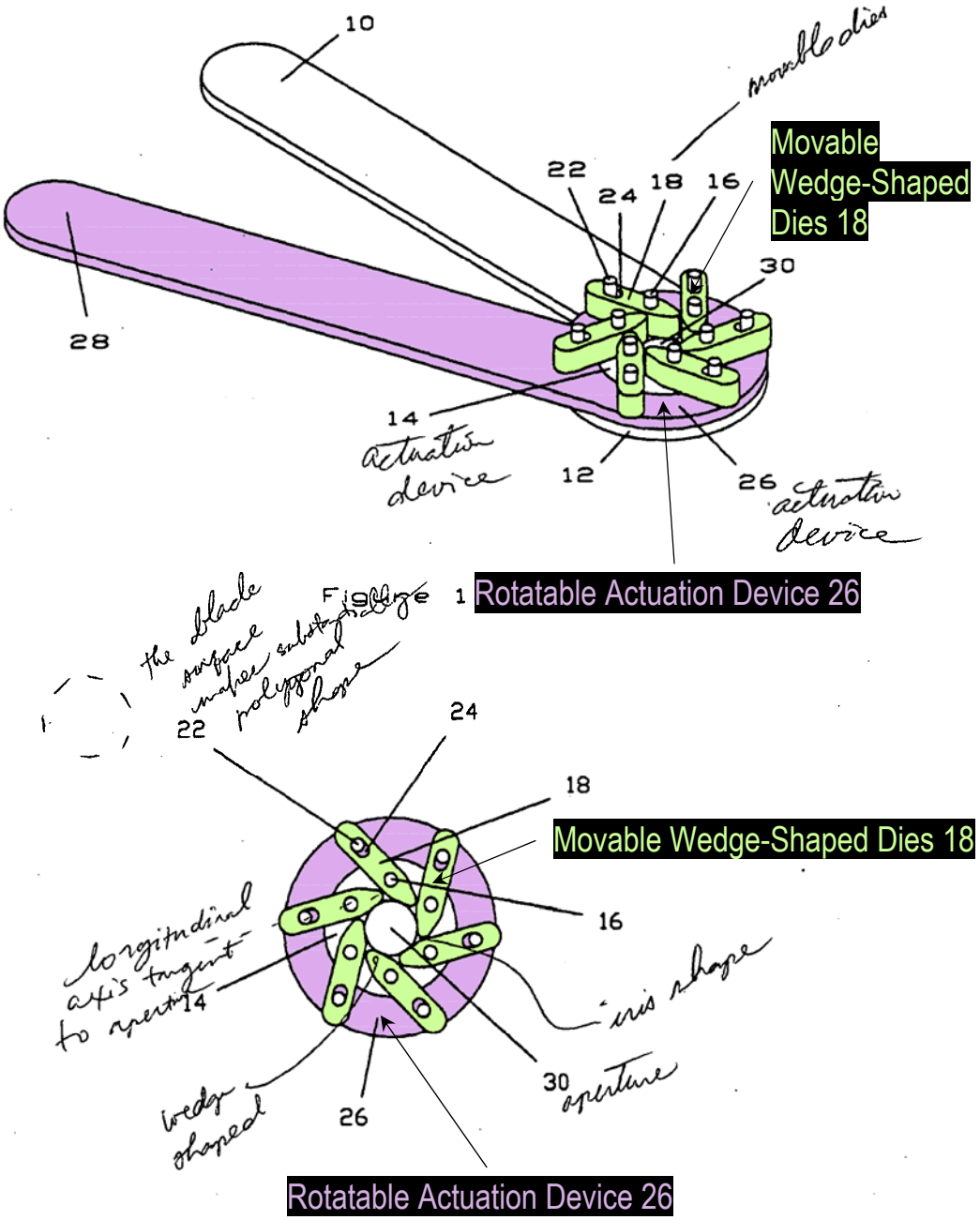
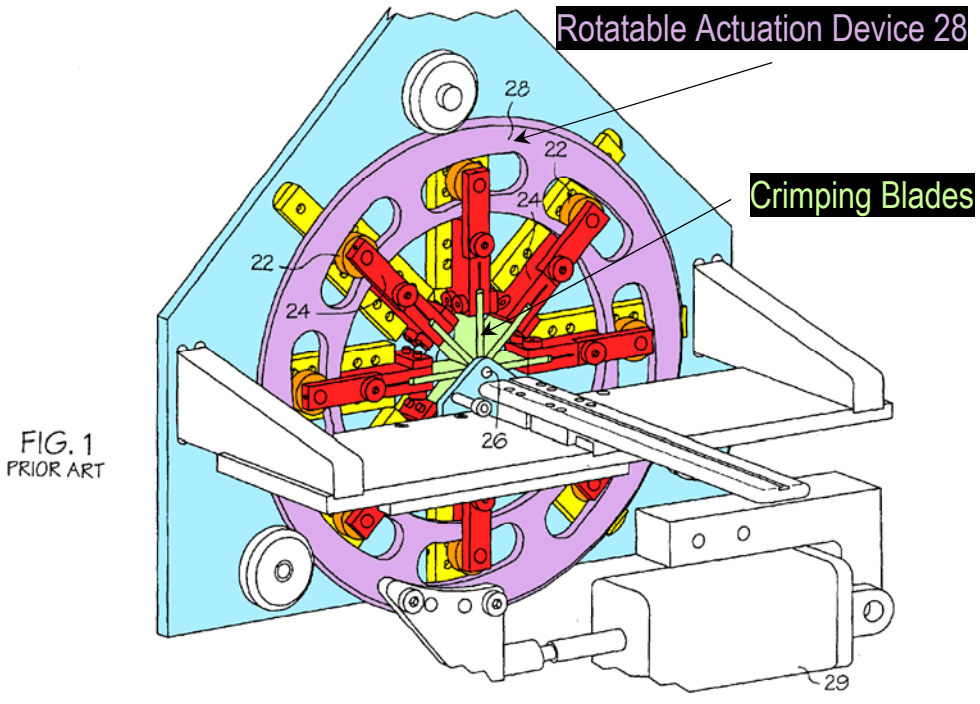


Figure 2

Ex. 1102 at 84 (Whitesell, Ex. 1115, Figs. 1 and 2, handwritten notes in original; colored annotations added).

Whitesell discloses pliers for gripping and crimping cylindrical objects. Ex. 1115 at 1:28-36. The Examiner considered Whitesell a stent crimper because "Whitesell is capable of performing crimping of a stent." Ex. 1102 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. 1102 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. 1101, 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

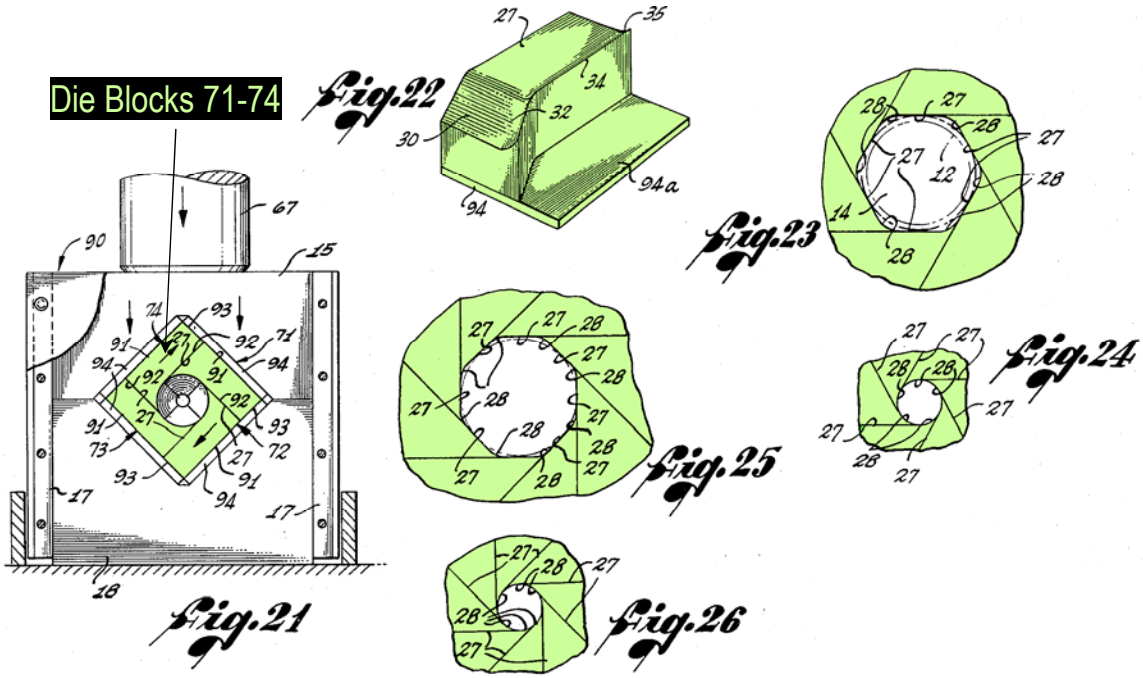
which is tangent to the aperture, in light of the teachings of Whitesell, in order to provide a symmetric crimping deformation. It is noted that Whitesell recognizes the benefits of using radial applying crimping forces over linearly applied forces like the one taught by [AAPA]." Ex. 1102 at 74-75.

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. 1102 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

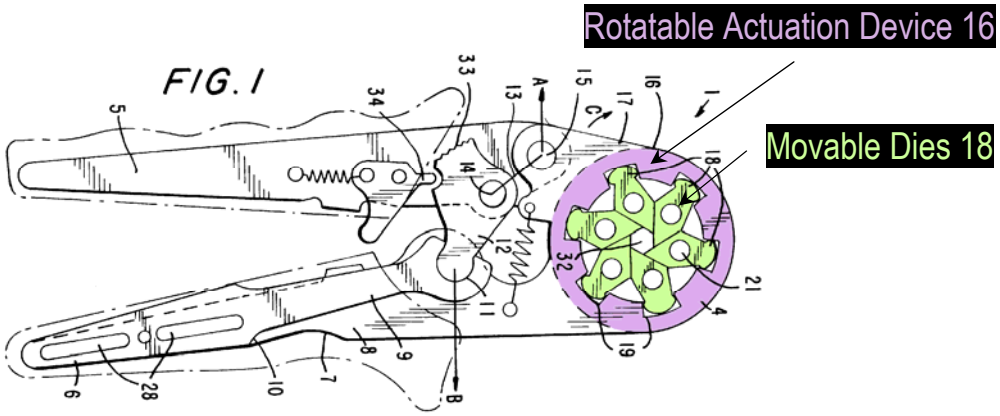
On April 22, 2004, the Examiner rejected independent Claims 27, 36, 52, and 63 as anticipated by either U.S. Patent No. 3,695,087 ("Tuberman") or U.S. Patent No. 6,176,116 ("Wilhelm"). Ex. 1102 at 42-52. The Examiner found that both taught dies arranged to form an iris with angles that remain substantially 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. 1116 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. 1117 at Abstract.



Id., Fig. 1.

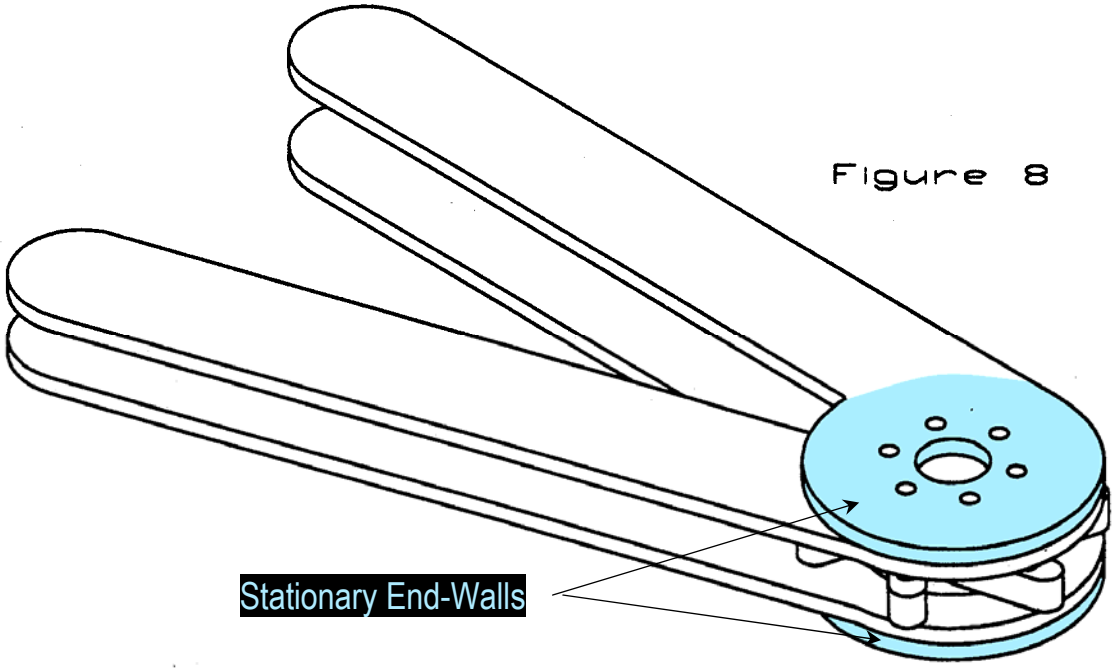
The Examiner considered Tuberman and Wilhelm stent crimpers because both are capable of crimping a stent. Ex. 1102 at 45-46. The Applicant did not dispute the Examiner's position.

On July 22, 2004, the Applicant filed a response and an amendment. Ex. 1102 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 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. 1102 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. 1102 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. 1115, 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. 1102 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 the AAPA.

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 the AAPA 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. 1105.

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. 1105 ¶¶ 65-67.

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).[3]

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

[3] 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.

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 crimping is one use for the invention, it recognizes additional uses. Ex. 1101 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. 1102 at 19, 45-47, 49, & 72.

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. 1105 ¶¶ 69-71. 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. 1101 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. 1102 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. 1105 ¶¶ 72-76.

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. 1105 ¶¶ 77-79.

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." *Innovention 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. 1101 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. Ex. 1105 ¶¶ 81-88. For example, variable aperture devices are used in tube reducers, socket wrenches, surgical needle swagers, forming dies, tube pointers, extruding dies, and more. *Id*. 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. 1101 at 1:48-55. The Applicant also disparaged the AAPA during prosecution stating: “The AAPA does not maintain a similar geometric shape while maximizing and minimizing the size of the aperture. Instead, 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.” Ex. 1102 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. 1101 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. 1105 ¶¶ 89-92. 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. 1102 at 15-21 (relying on Whitesell), 42-49 (relying on Tuberman and Wilhelm); *see also* Exs. 1115 (Whitesell), 1116 (Tuberman), 1117 (Wilhelm) (referencing US classes 29 (metal working), 72 (metal deforming), and 81 (tools)). The Applicant also disclosed prior art patents in these fields when submitting Information Disclosure Statements. Ex. 1102 at 81-82, 159-64 (disclosing patents referencing US classes 29 (metal working) and 72 (metal deforming)).

B. Applicant's Admitted Prior Art

The AAPA depicted in Figure 1 and described at 1:62-2:21 of the '560 patent is prior art. Ex. 1101. The Applicant labeled Figure 1 as "PRIOR ART" and never disputed the Examiner's application of the AAPA as prior art to reject the claims during prosecution. A patent applicant's prior art admissions are prior art for purposes of *inter partes* review. *See, e.g.*, *Intri-Plex Techs., Inc. v. Saint-Gobain Performance Plastics Rencol Ltd.*, IPR2014-00309, Paper 83 (P.T.A.B. Mar. 23, 2014).

The only distinction between the AAPA and the challenged claims is the shape and arrangement of the blades that form the claimed "polygonal aperture."

Ex. 1105 ¶ 94. This polygonal aperture arrangement is present in numerous prior art devices that would have been known to a POSITA. *Id*.

C. Yasumi

Yasumi was filed on March 25, 1982 and is prior art under at least § 102(b).[4] Yasumi was not considered by the Examiner during prosecution. Yasumi discloses "an aperture setting device in which the size of the predetermined polygonal aperture can be changed, retaining the polygonal configuration." Ex. 1103 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.

[4] 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.

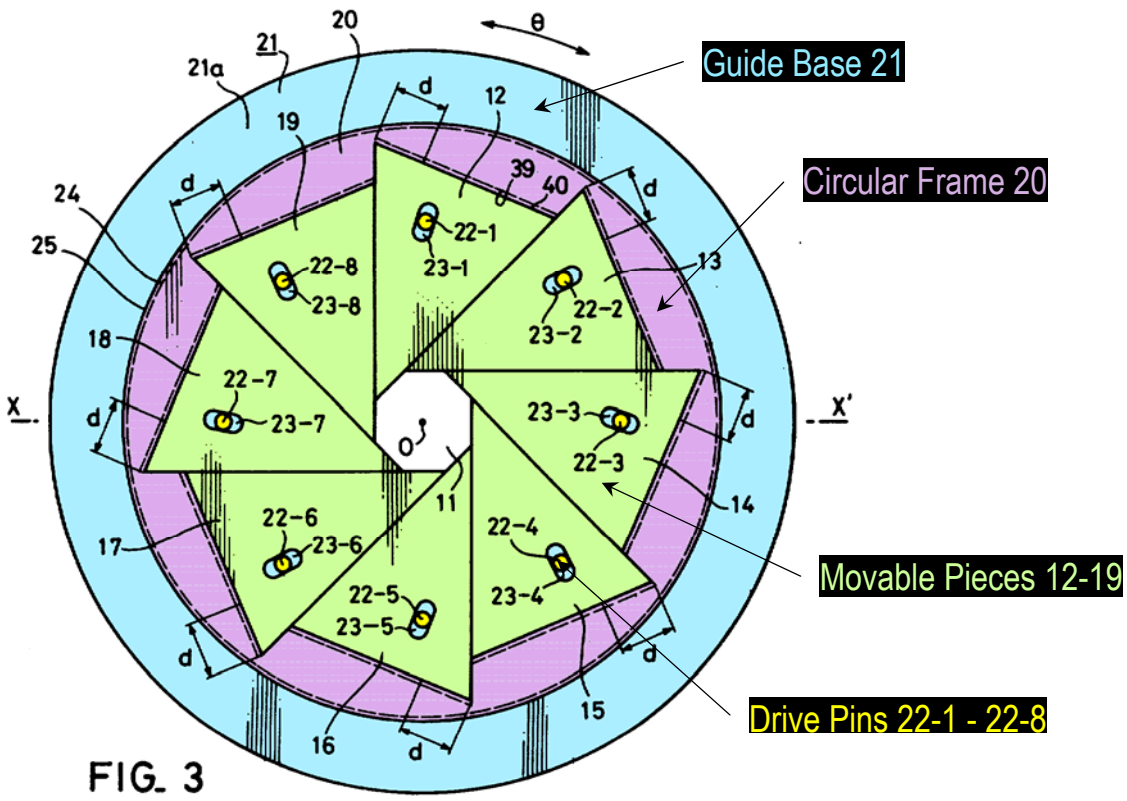


FIG. 3

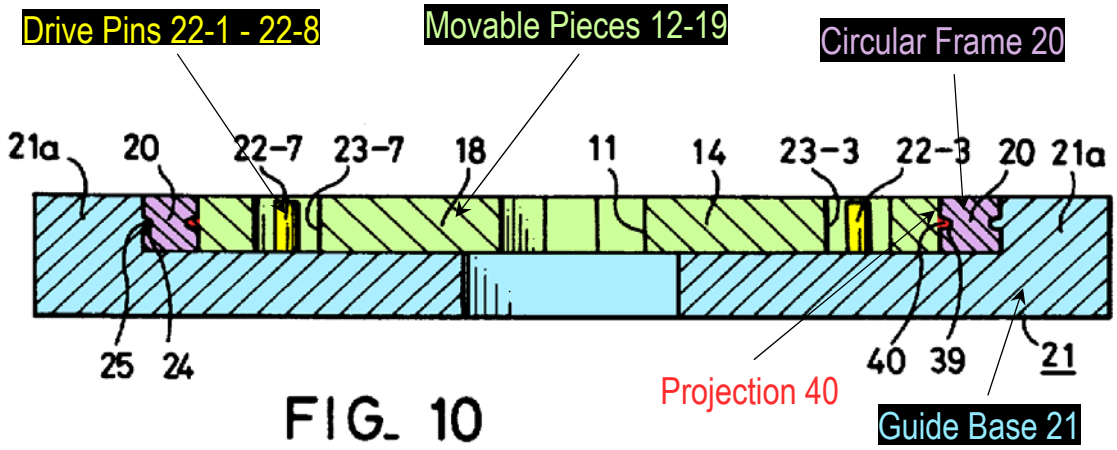


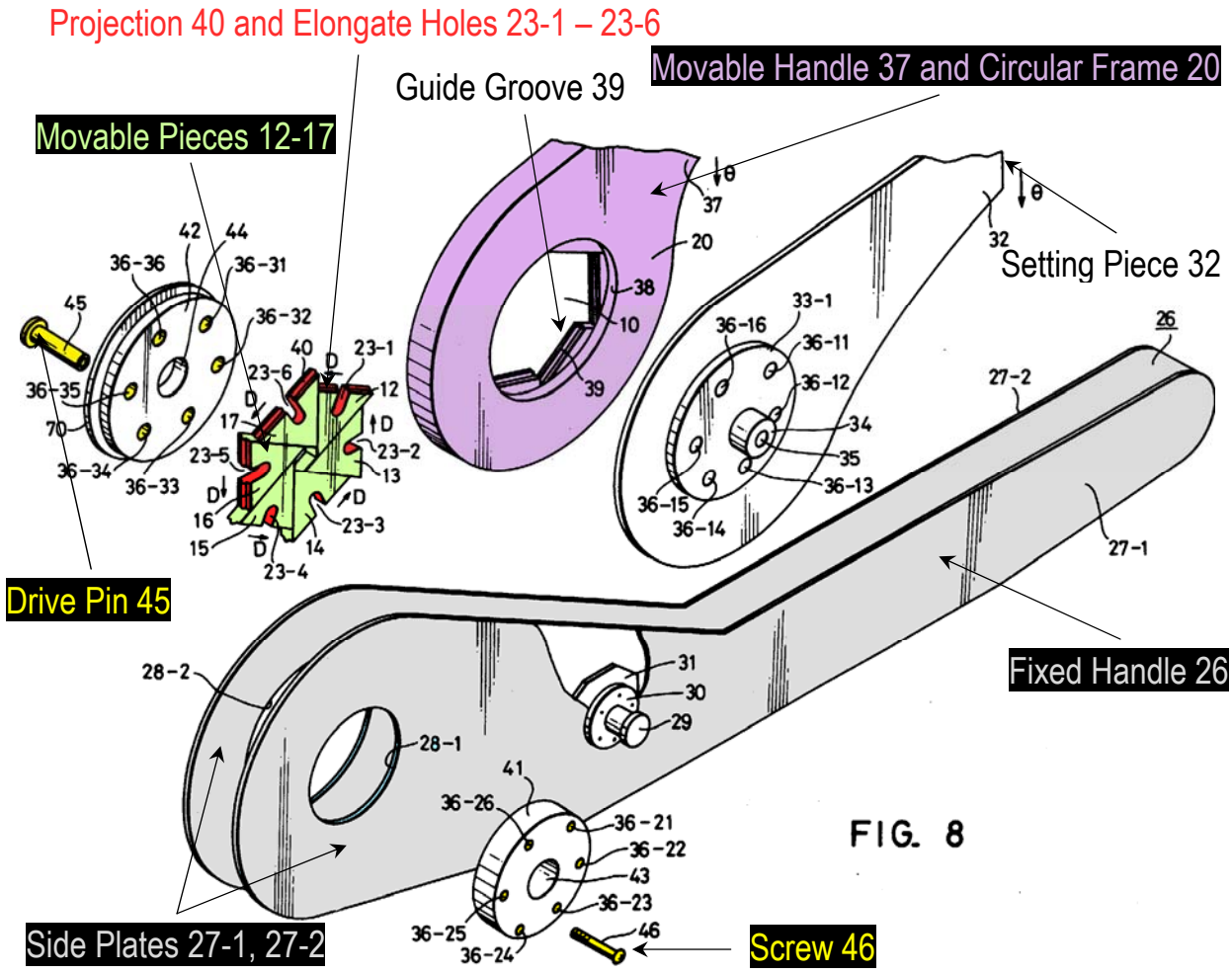
FIG. 10

Ex. 1103, 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. 1103, 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. 1103 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. *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.

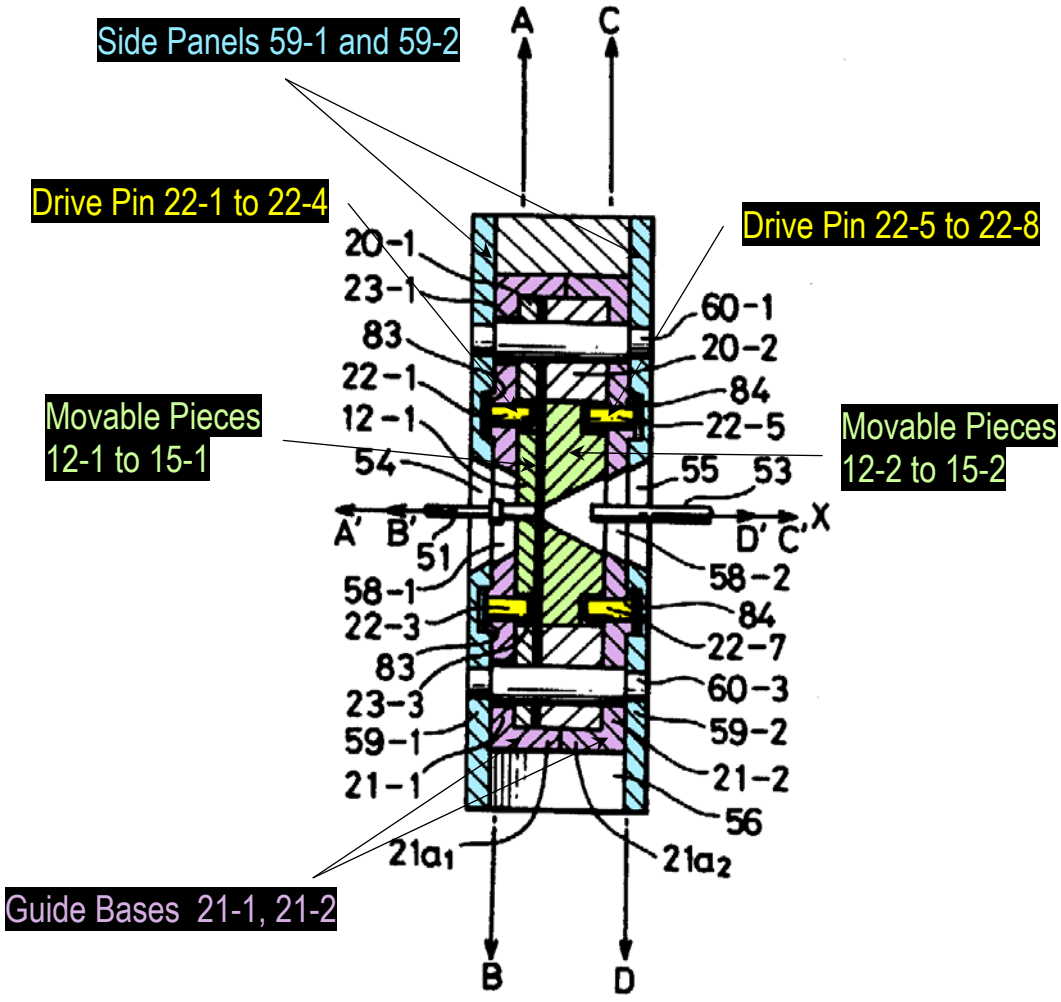

Side Panels 59-1 and 59-2
Drive Pin 22-1 to 22-4
Drive Pin 22-5 to 22-8
Movable Pieces 12-1 to 15-1
Movable Pieces 12-2 to 15-2
Guide Bases 21-1, 21-2
A
C
B
D
X
20-1
23-1
83
22-1
12-1
54
A' B'
51
58-1
22-3
83
23-3
59-1
21-1
21a1
60-1
20-2
84
22-5
55 53
D' C'
58-2
84
22-7
60-3
59-2
21-2
56
21a2

FIG. 9(a)

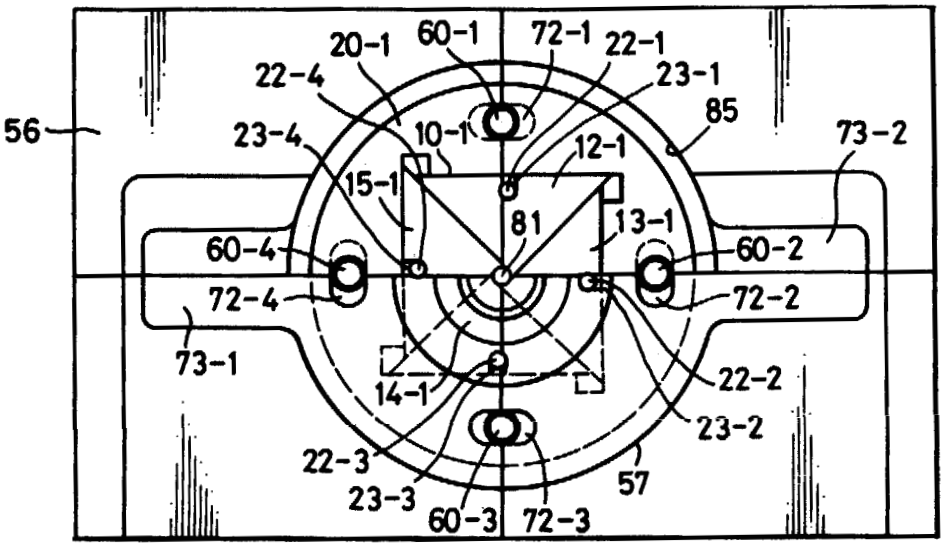


FIG. 9(b)

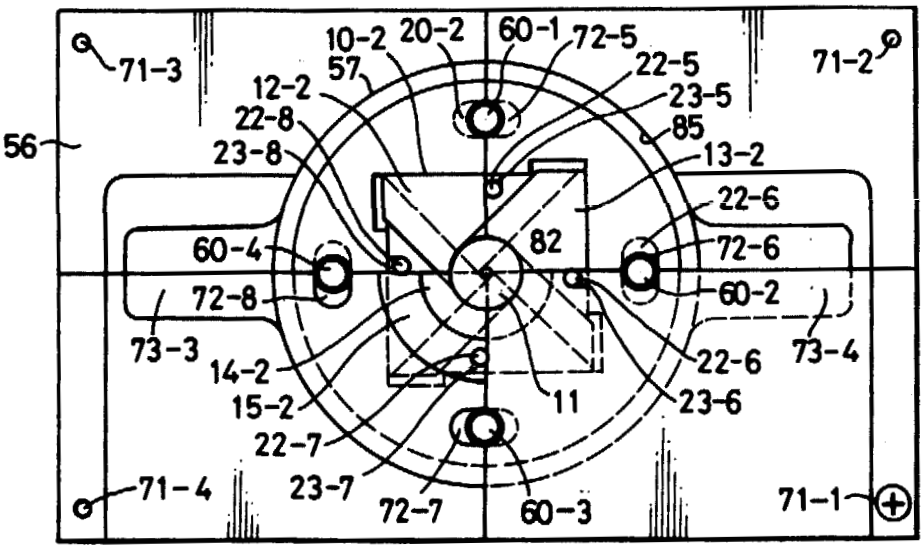


FIG. 9(c)

Ex. 1103, 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.

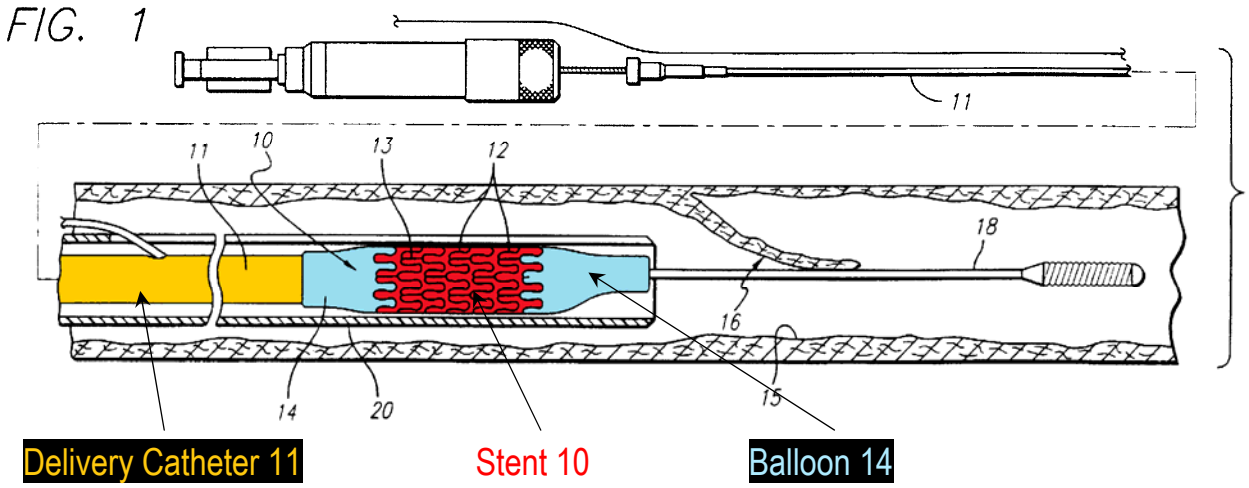
The two sets of movable pieces (green) are each arranged to form an aperture. *Id.* at 9:63-67. The aperture formed by movable pieces 12-1 to 15-1 is aligned with the aperture formed by movable pieces 12-2 to 15-2. *Id.* at 67-68. These apertures are in turn aligned with the openings in guide bases 21-1 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. 1105 ¶ 109. Like the ’560 patent, Yasumi is generally directed to an apparatus that uses coupled movable members disposed about a reference circle to form a variable size aperture, Ex. 1103 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 invention discussed in Yasumi could be used to crimp a stent. Ex. 1105 ¶ 109.

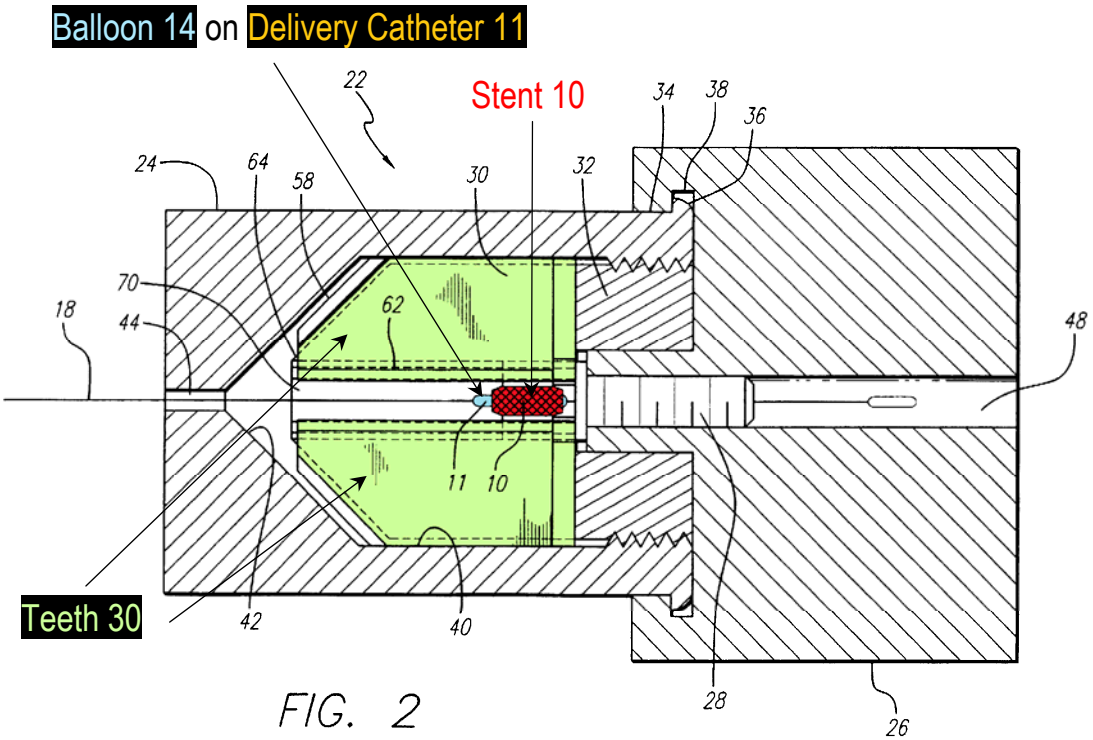
Yasumi is also reasonably pertinent to the problem to be solved by the '560 patent. Ex. 1105 ¶¶ 110-111. Yasumi recognized a problem with prior art aperture setting devices, namely that it is difficult to change the size of the aperture without introducing a gap between adjacent elements forming the aperture. Ex. 1103 at 1:17-20. This is the same problem the Applicant identified with the AAPA. Ex. 1102 at 64-66. Yasumi solves the problem by using an apparatus capable of changing the size of a polygonal aperture while retaining its polygonal shape. Ex. 1103 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. 1105 ¶¶ 110-111. Yasumi is therefore analogous prior art. *Id*.

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(b). *See* Ex. 1104. Morales was not considered by the Examiner during prosecution. Morales discloses "[a] stent crimping tool for firmly and uniformly crimping a . . . stent onto a balloon catheter." *Id.* at Abstract.



Ex. 1104, 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. 1104, 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 The AAPA

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 convering [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. 1101 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.

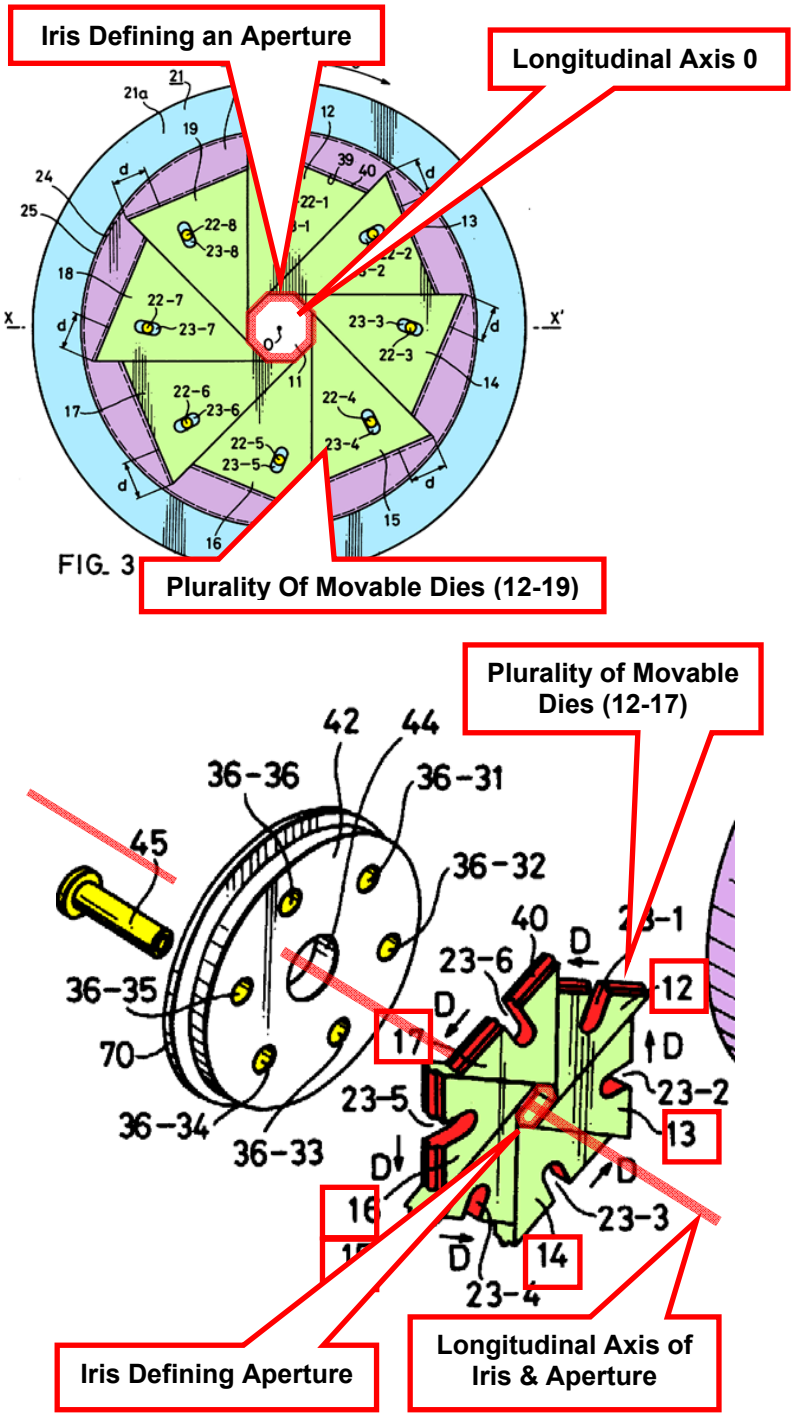
It is well established that a recitation of the intended use of a claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. *In re Casey*, 370 F.2d 576, 580 (C.C.P.A. 1967). If 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 devices 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. 1102 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.

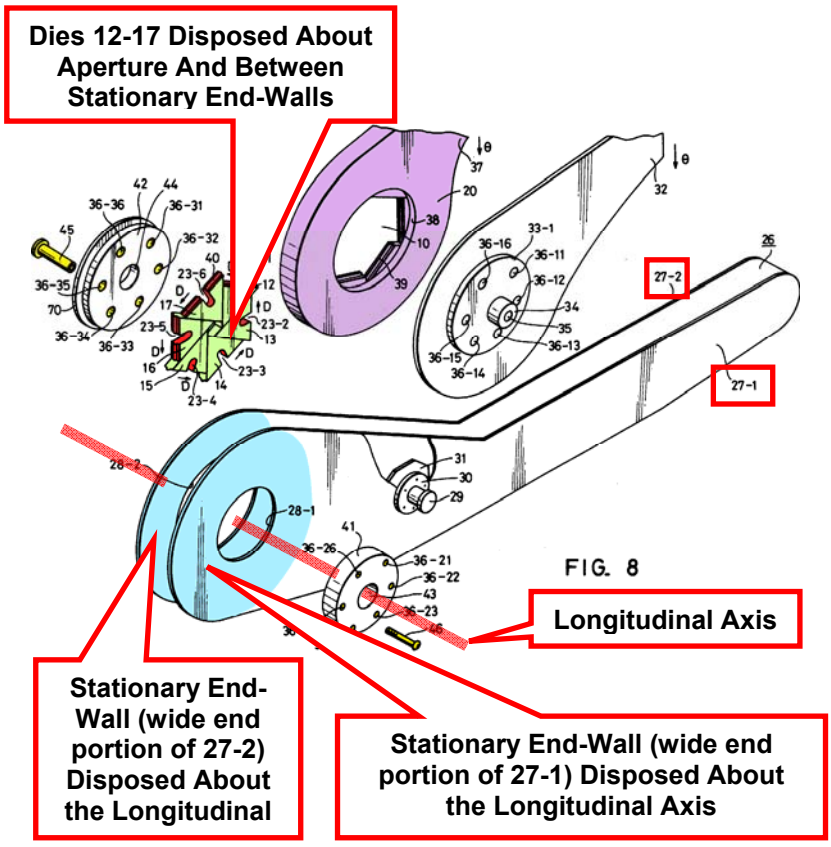
The AAPA also discloses the preamble "stent crimper." A detailed analysis of Claim 1 is provided in the following claim chart. *See also* Ex. 1105 ¶¶ 117-126.

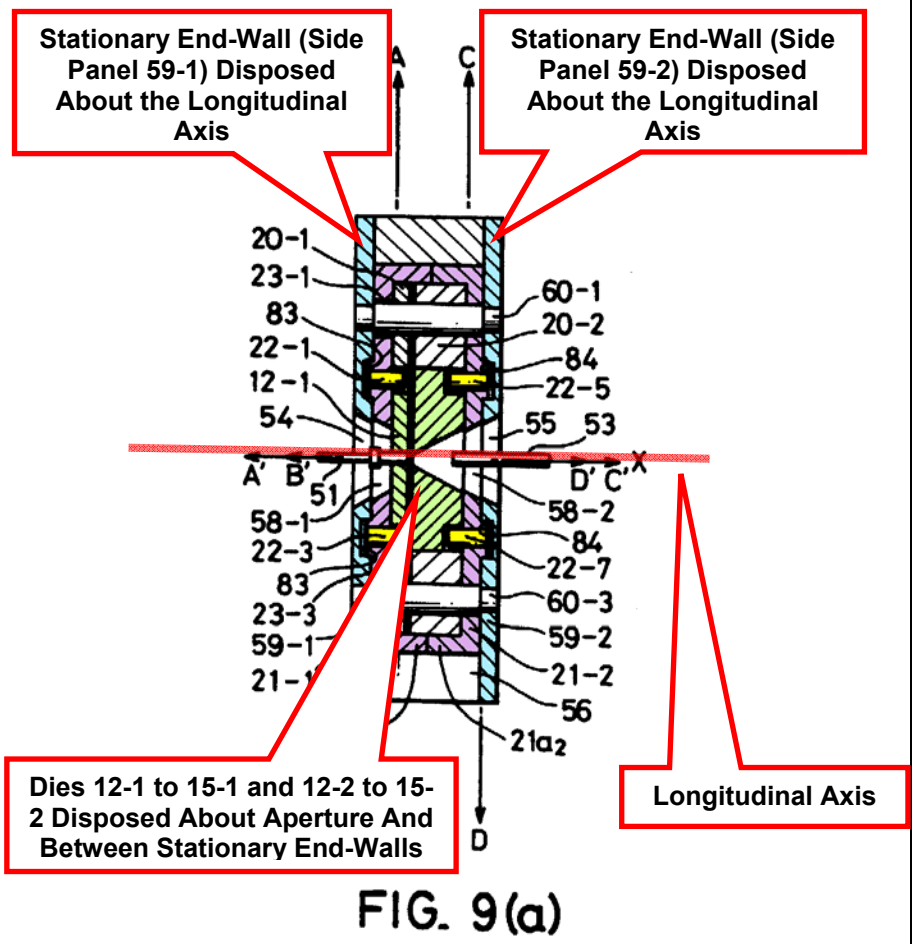
ASSERTED CLAIMS	**PRIOR ART**
[1 preamble] A stent crimper comprising:	Yasumi discloses: "a manual forming and pressing tool." (Ex. 1103 at 7:33-38; *id*. at 1:35-39, 9:30-34, 11:25-30.) This tool is capable of crimping a stent. Therefore, Yasumi is a stent crimper. Moreover, the preamble "stent crimper" does not limit the claim. The AAPA discloses: "[a] cam actuated stent crimper." (Ex. 1101 at 1:62.)
[1a] a plurality of movable dies arranged to form an iris having a longitudinal axis, the iris defining an aperture,	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: "[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. 1103 at Abstract; *id.* at 1:47-50, 2:45-47, 2:65-3:3, 4:42-44, 8:53-54, 9:63-67.)

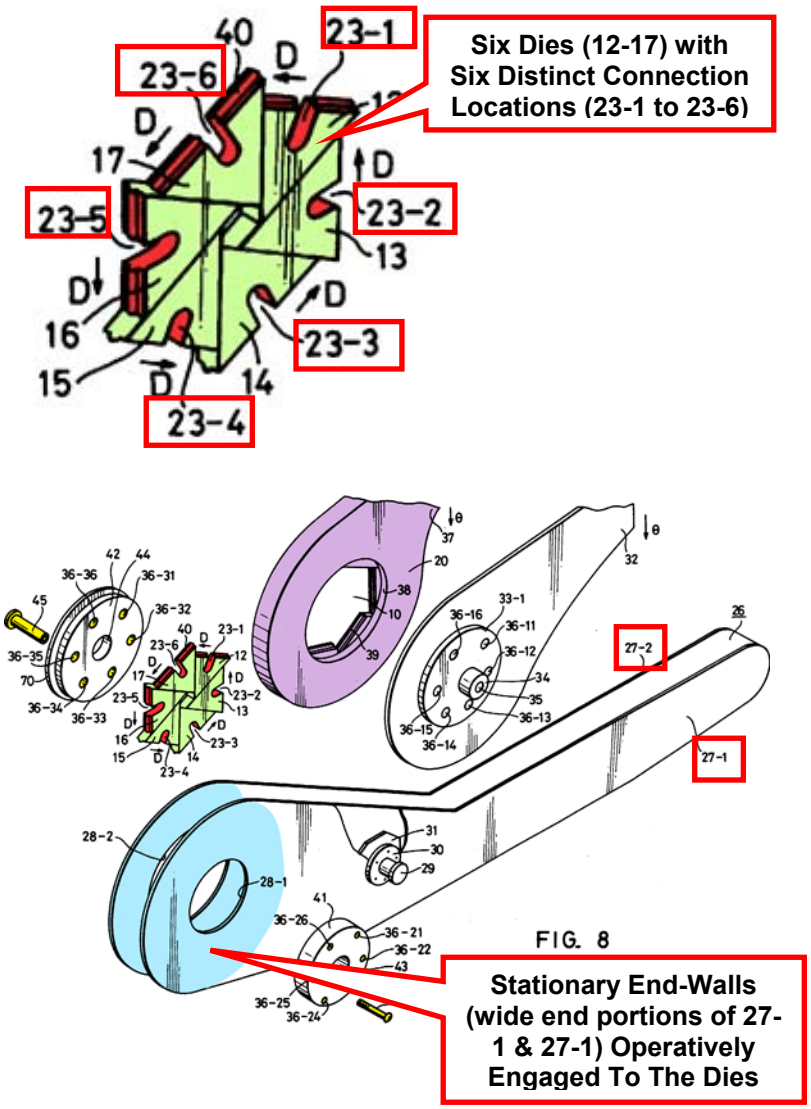
ASSERTED CLAIMS	PRIOR ART
	

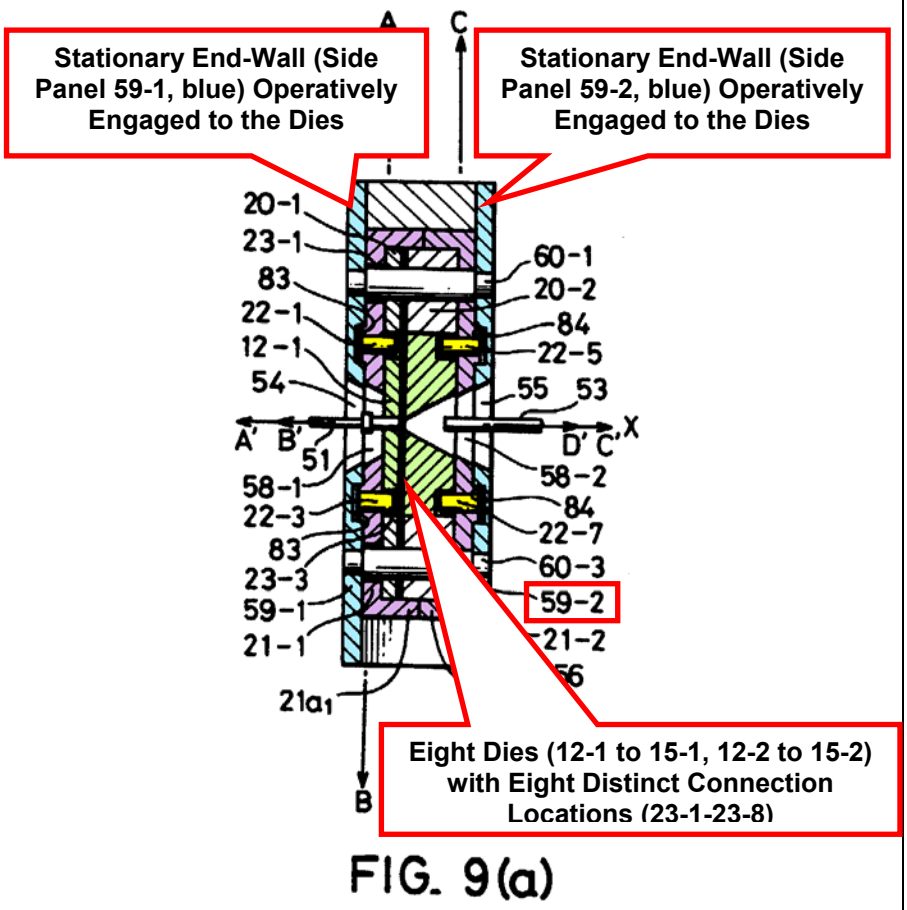
ASSERTED CLAIMS	**PRIOR ART**
	(Ex. 1103, Figs. 3 & 8 (excerpt).[5])
[1b] the dies disposed about the aperture and between stationary end-walls which are disposed about the longitudinal axis,	Yasumi discloses an embodiment with dies (movable pieces 12-17 or 12-19) disposed about the aperture and between stationary end-walls (wide end portions of the fixed handle side plates 27-1 and 27-2) which are disposed about the longitudinal axis: "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. 1103 at 7:39-8:9.) "Next, the movable handle 37 is turned to reduce the angle between it and the fixed handle 26, butting the setting piece 32 against the adjust cam 31 to stop the rotational movement of the setting piece 32. By further rotating the movable cam 37 towards the fixed handle 26, ..." (*Id.* at 9:26-34; *id.* at 8:42-54, 9:3-15. A POSITA would have understood based on the Yasumi disclosure that the fixed handle 26 is stationary. (Ex. 1105 ¶ 126.)

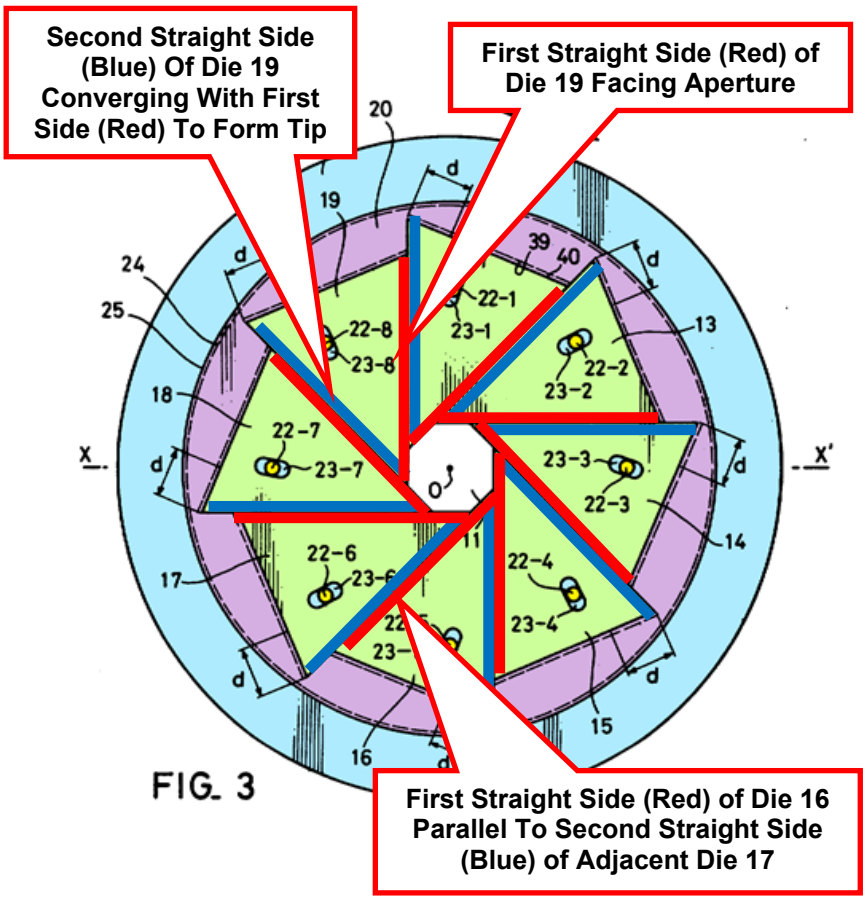
[5] Note that figures from the prior art have been annotated in the tables throughout the Petition with red boxes to identify pertinent elements and callouts to label important features.

ASSERTED CLAIMS	PRIOR ART
	 (Ex. 1103, Fig. 8.) 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: "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. 1103 at 10:42-49; *also id.* at 9:37-10:2.)

ASSERTED CLAIMS	PRIOR ART
	 FIG. 9(a) (Ex. 1103, Fig. 9(a).)
[1c] 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;	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: 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. The six elongated holes are the six distinct connection locations that operatively engage the six dies to the stationary end-

ASSERTED CLAIMS	PRIOR ART
	walls. (*See* Ex. 1103 at 8:1-54.)  (Ex. 1103, Fig. 8.) 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 the same:

ASSERTED CLAIMS	PRIOR ART
	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. 1103 at 9:56-62, 10:68-11:4.)  FIG. 9(a) (Ex. 1103, Fig. 9(a).)
[1d] each die having a first straight side and	Yasumi discloses each die (movable pieces 12-17 or 12-19) having a first straight side (inner 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

ASSERTED CLAIMS	PRIOR ART
a second straight side, the first straight side and the second straight side convering [*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.	straight side of each die faces the aperture, each first straight side parallel to the second side of an adjacent die: "[A]n aperture is formed by one end portion of an inner side of each movable piece and the movable piece . . ." (Ex. 1103 at Abstract; *see id*. at Claim 1, 2:48-59; 4:42-44)  (Ex. 1103, Fig. 3.)

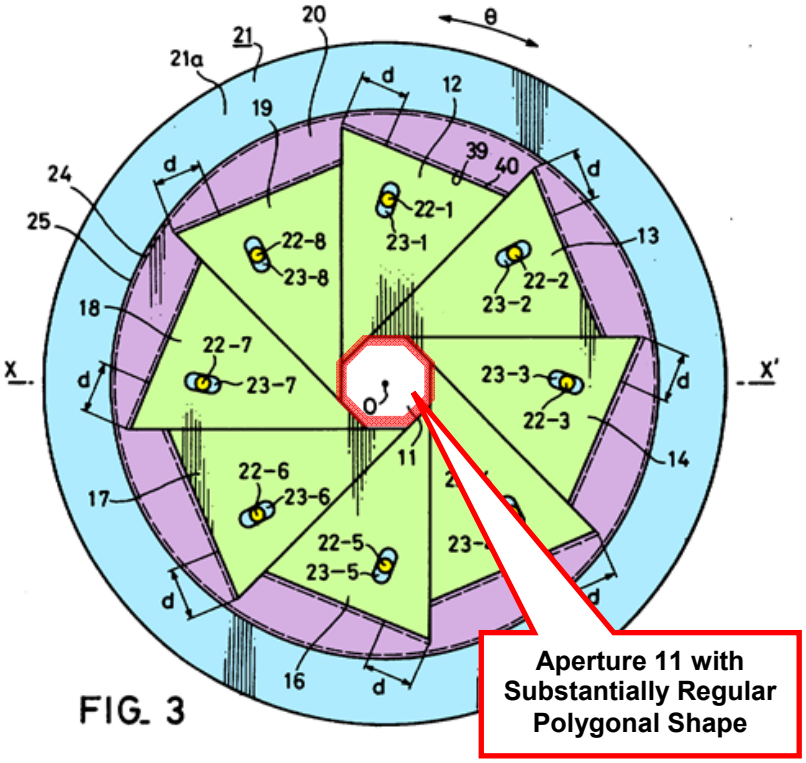
2. Claim 10

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

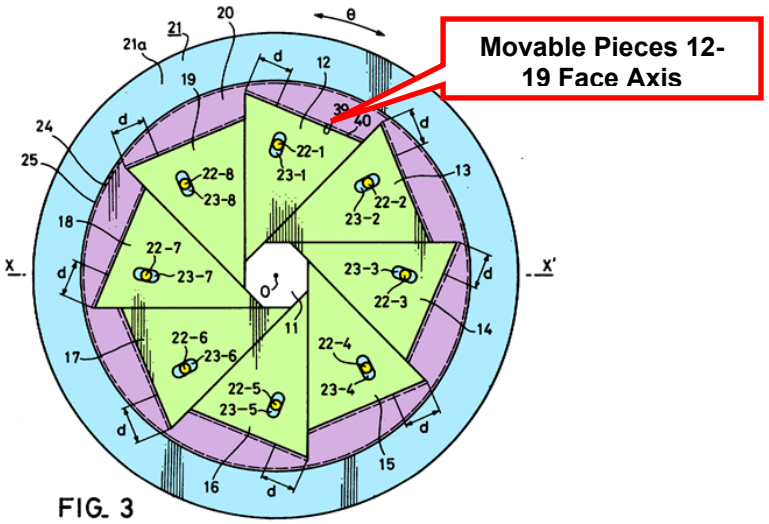
faces the longitudinal axis of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture;" (3) "the longitudinal axis [of the aperture] passing through a point substantially centered on the end-walls;" and (4) "a rotatable actuation device coupled to 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. 1105 ¶¶ 127-136.

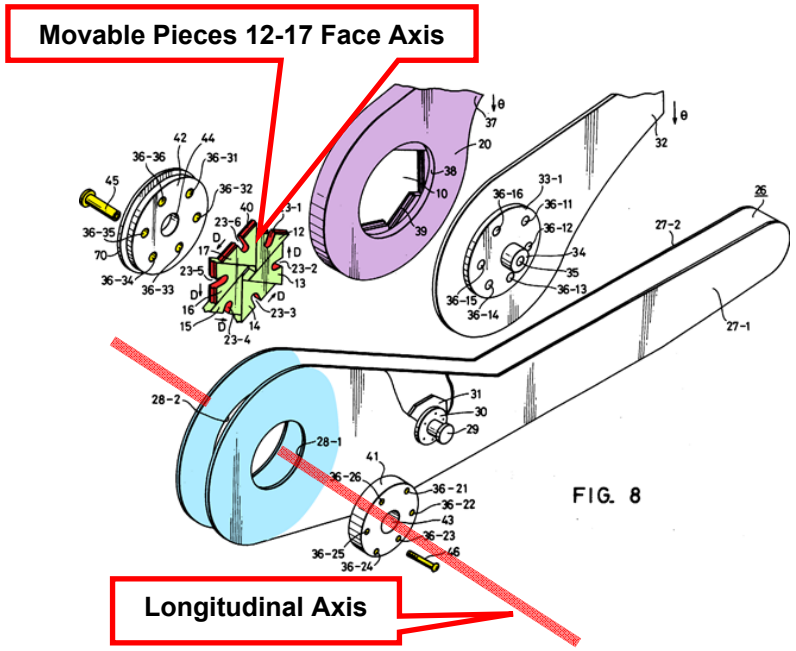
ASSERTED CLAIMS	**PRIOR ART**
[10 Preamble] A stent crimper comprising:	*See* Claim [1 Preamble].
[10a] a plurality of movable dies arranged to form an iris,	*See* Claim [1a].
[10b] the dies disposed about an aperture,	*See* Claim [1b].

ASSERTED CLAIMS	PRIOR ART
[10c] the aperture having a longitudinal axis and a substantially regular polygonal shape,	Yasumi discloses the aperture having a longitudinal axis. *See* Claim [1a].[6] Yasumi discloses an aperture having a substantially regular polygonal shape. "[I]t will easily be understood that the structure of this embodiment can generally be applied to regular polygonal apertures." (Ex. 1103 at 4:62-64; *see id.* at 4:38-41, 6:14-15.)  FIG. 3 (Ex. 1103, Fig. 3; *see id.* at Figs. 2, 5(a), 7(a).)
[10d]	*See* Claim [1d].[7]

[6] 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

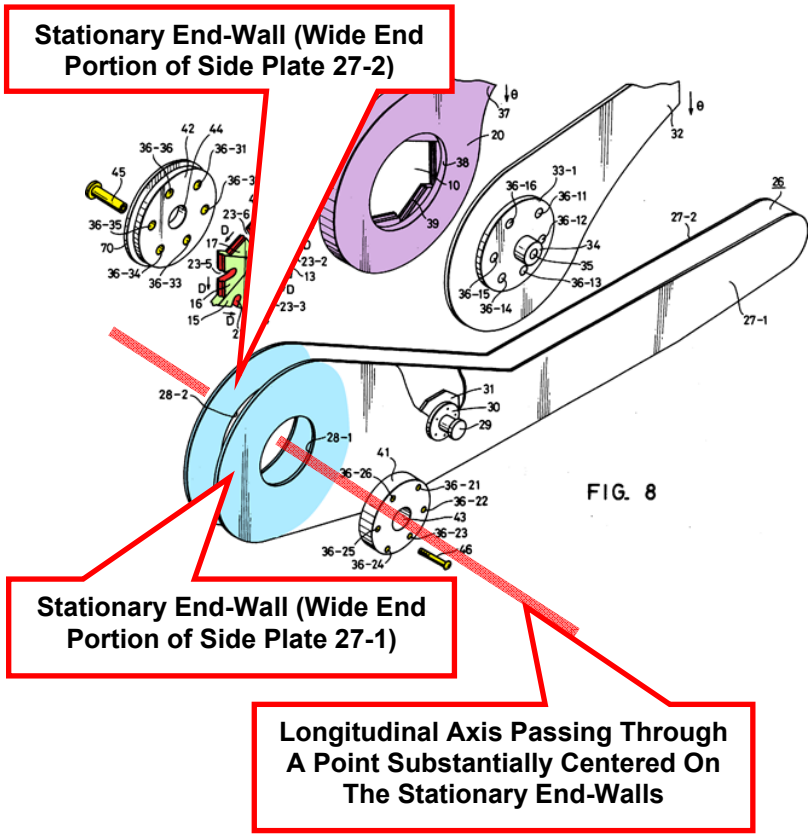
ASSERTED CLAIMS	PRIOR ART
each of the dies having an inward facing straight side which faces the longitudinal axis of the aperture,	
[10e] both when the dies move to maximize the aperture and when the dies move to minimize the aperture,	Yasumi discloses each of the dies (movable pieces 12-17 or 12-19) 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:  FIG. 3

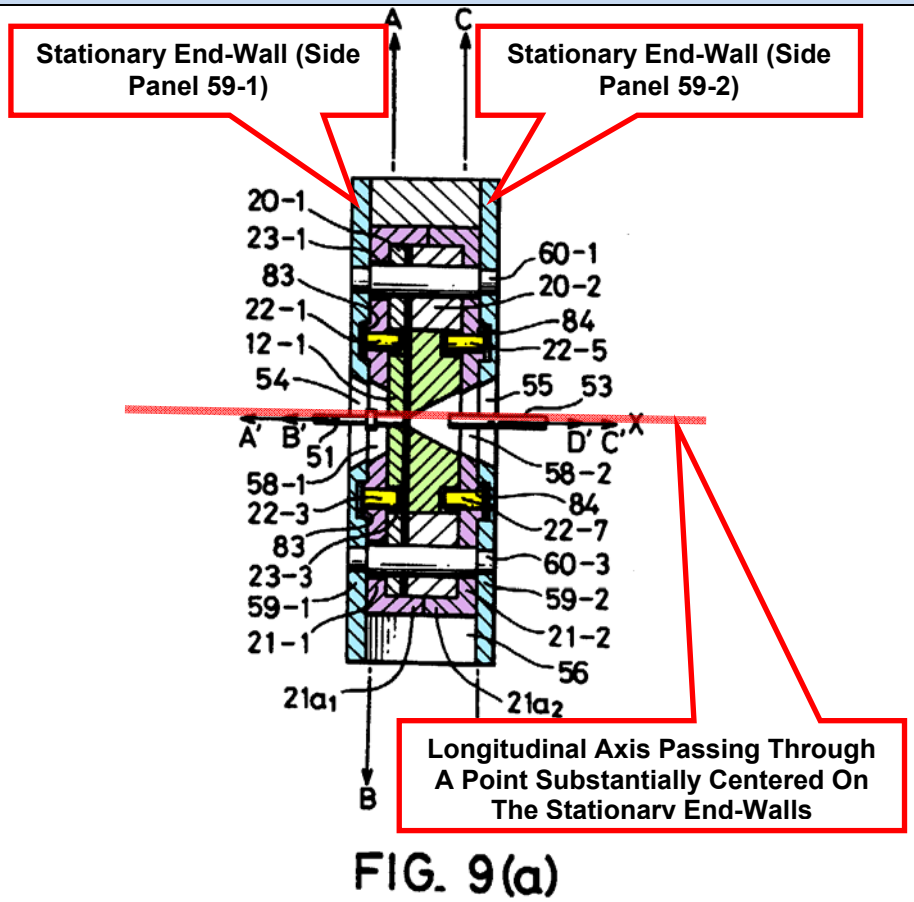
[7] Claim [10d] recites "an inward facing straight side which faces the longitudinal axis of the aperture" and Claim [1d] recites "a portion of the first straight side of each die faces the aperture." Because the longitudinal axis of the aperture is located central to the aperture, disclosure in Yasumi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

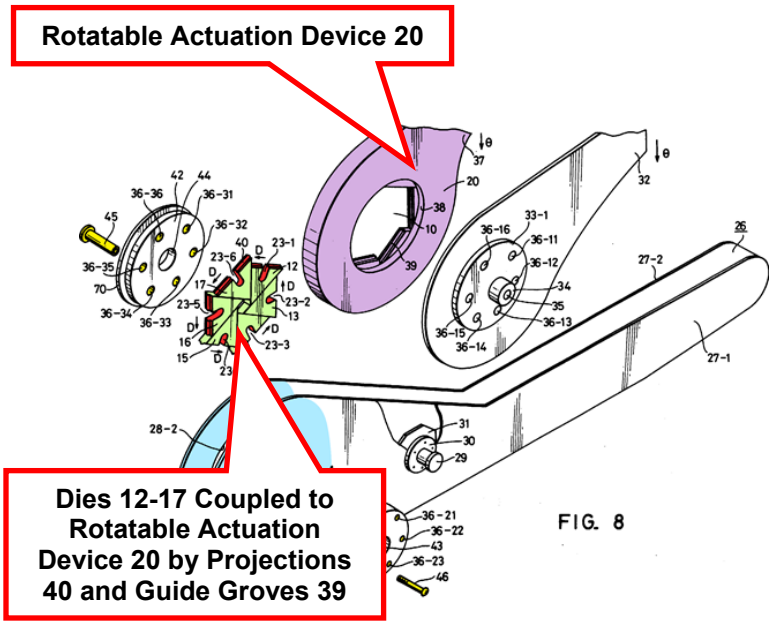
ASSERTED CLAIMS	PRIOR ART
	 (Ex. 1103, Fig. 8.) Yasumi teaches that the polygonal shape of the aperture is maintained as the dies (movable pieces 12-17 or 12-19) move in or out. "[T]he size of a predetermined polygonal aperture can be changed, retaining the polygonal configuration." (Ex. 1103 at 1:11-13; *see id.* at Abstract, 1:40-43, Claim 1.) Maintaining the polygonal shape results in the first straight side facing the longitudinal axis of the aperture while moving in or out.
[10f] the dies between two stationary end-	*See* Claim [1b].[8]

[8]Claim [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 the AAPA of stationary end-walls also discloses two stationary end-walls.

ASSERTED CLAIMS	**PRIOR ART**
walls disposed about the longitudinal axis,	
[10g] the longitudinal axis passing through a point substantially centered on the end-walls,	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): "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. 1103 at 7:57-8:21.)

ASSERTED CLAIMS	PRIOR ART
	 (Ex. 1103, Fig. 8.) 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): "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." (*Id.* at 9:37-10:2.)

ASSERTED CLAIMS	PRIOR ART
	 FIG. 9(a) (Ex. 1103, Fig. 9(a); *see id.* at FIG. 9(b)-(c), 9:35-10:11.)
[10h] a rotatable actuation device coupled to the dies,	Yasumi discloses a rotatable actuation device (circular frame 20) coupled to the dies (movable pieces 12-17 or 12-19): "[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. 1103 at 5:39-6:8.) "The frame 20 having thus mounted therein the plurality of

ASSERTED CLAIMS	PRIOR ART
	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." (*Id.* at 7:57-68.)  (Ex. 1103, Fig. 8)
[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	<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> "Bringing the grips of the handles 26 and 37 closer to each other, the pins 45 move in the elongated holes 23-1 to 23-6 to move the movable pieces 12 to 17 in the frame 20, reducing the aperture defined by the movable pieces 12 to 17." (Ex. 1103 at 8:42-54; *see id.* at 5:39-6:8, 7:57-68.)

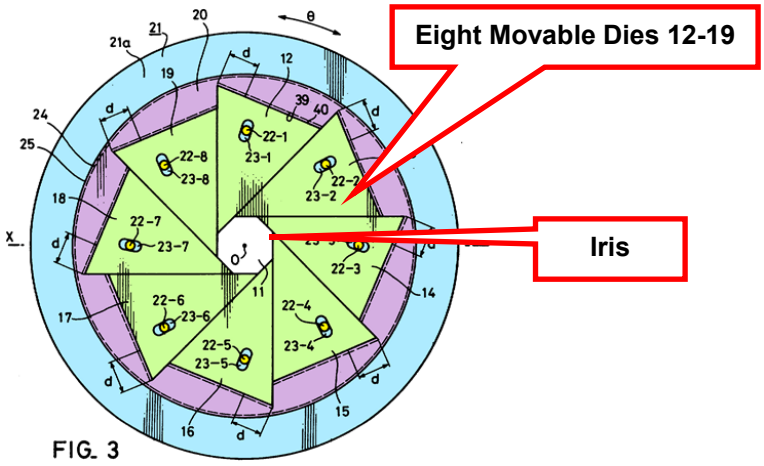
ASSERTED CLAIMS	PRIOR ART
the aperture.	

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.[9] 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. 1105 ¶¶ 137-138.

ASSERTED CLAIMS	PRIOR ART
[18 Preamble] A stent crimper comprising:	*See* Claim [1 Preamble].
[18a] eight or more movable dies arranged to form an iris,	Yasumi discloses movable dies arranged to form an iris. *See* Claim [1a]. Yasumi also discloses eight or more movable dies: "FIG. 3 and FIG. 10 embody the principles of the aperture setting device of the present invention and depict the state in which movable pieces 12, 13, 14, . . . 19 around the axis 0

[9] 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.

ASSERTED CLAIMS	PRIOR ART
	have respectively been moved along their bases by the aforesaid maximum distance d." (Ex. 1103 at 5:39-6:13.)  (Ex. 1103, Fig. 3; *see id.*, Fig. 2.)
[18b] the iris defining an aperture of a substantially regular polygonal shape,	*See* Claims [1a] (iris defining aperture), [10c] (aperture having substantially regular polygonal shape).
[18c] the aperture having a longitudinal axis,	*See* Claim [1a], [10c].
[18d] each die having an inward facing flat portion which faces the longitudinal axis of the aperture	*See* Claim [1d], [10d].

ASSERTED CLAIMS	**PRIOR ART**
[18e] both when the dies move to maximize the aperture and when the dies move to minimize the aperture,	*See* Claim [10e].
[18f] the dies between stationary end walls and operatively engaged to at least one of the stationary end-walls,	*See* 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,	*See* Claim [1b].
[18h] the iris comprising at least eight of the inward facing flat portions,	*See* 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).

ASSERTED CLAIMS	**PRIOR ART**
[18i] the aperture being reducible in size by moving the inward facing flat portions toward the longitudinal axis of the aperture,	*See* Claims [10d] (inward facing straight side which faces the 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,	*See* Claim [10h].
[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.	*See* Claim [10i].

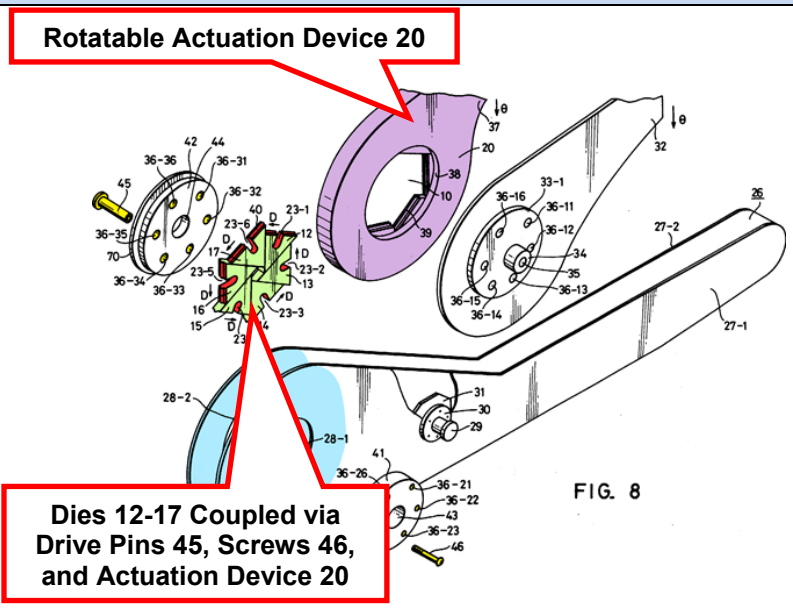
4. Claim 27

Independent Claim 27 recites limitations substantially similar to those previously recited in Claims 1 and 10. *See* Part X.A.1 and .2.[10] 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. 1105 ¶¶ 139-140.

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

[10] Claim 27 differs from the previous claims because it recites "blades" instead of "dies." But those terms are used interchangeably. *See* Part VIII.B.

ASSERTED CLAIMS	**PRIOR ART**
[27c] the blades between stationary end-walls substantially centered about the longitudinal axis,	*See* Claims [1b] (dies between stationary end-walls), [10g] (longitudinal axis passing through a point substantially centered on the end-walls).
[27d] the blades coupled to one another so as to be movable inward or outward simultaneously,	Yasumi discloses the blades (movable pieces 12-17 or 12-19) coupled to one another so as to be movable inward or outward simultaneously: 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. "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. 1103 at Claim 1; *see id.* at 2:47-59, 4:12-17, 5:48-51, 7:48-57.)

ASSERTED CLAIMS	PRIOR ART
	 (Ex. 1103, Fig. 8.)
[27e] movement of the blades outward increasing the size of the aperture,	*See* Claim [10i].
[27f] movement of the blades inward decreasing the size of the aperture,	*See* Claim [10i].

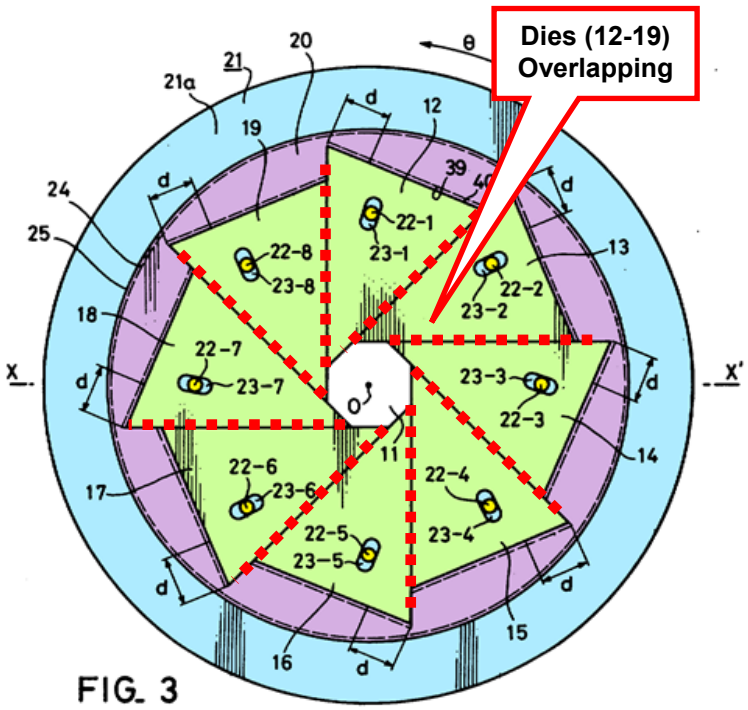
ASSERTED CLAIMS	PRIOR ART
[27g] the aperture remaining substantially regular polygonal when it is sized to receive a stent therein and when the blades minimize the aperture.	*See* Claims [10c] (substantially regular polygonal shape), [10e] (when the dies move to maximize the aperture and when the dies move to minimize the aperture).[11]

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. 1105 ¶¶ 141-143.

ASSERTED CLAIMS	PRIOR ART
[37 Preamble] A stent crimper	*See* Claim [1 Preamble].

[11] 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.

ASSERTED CLAIMS	PRIOR ART
comprising:	
[37a] a plurality of overlapping movable dies arranged to form an iris,	Yasumi discloses a plurality of movable dies arranged to form an iris. *See* Claim [1a]. Yasumi discloses a plurality of overlapping movable dies (movable pieces 12-17 or 12-19): "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. 1103 at 2:44-59.)  FIG. 3 (Ex. 1103, Fig. 3; *id.* at Figs. 1-2.)

ASSERTED CLAIMS	**PRIOR ART**
[37b] the dies disposed about an aperture, the aperture having a longitudinal axis,	*See* Claims [1b], [10c].
[37c] the dies between stationary end-walls disposed about the longitudinal axis,	*See* Claim [1b].
[37d] the dies operatively engaged to at least one of the stationary end-walls;	*See* Claim [1c] (at least one of the stationary end-walls operatively engaged to the dies).
[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	*See* Claim [1d].

ASSERTED CLAIMS	PRIOR ART
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.[12] A detailed analysis of Claim 40 is provided in the following claim chart. *See also* Ex. 1105 ¶¶ 144-145.

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

[12] Claim 40 recites "stationary plates" while Claim 1 recites "stationary end-walls." However, as discussed above in Part VIII.C, the stationary plates of Claim 40 and the stationary end-walls of Claim 1 are interchangeable.

ASSERTED CLAIMS	**PRIOR ART**
[40b] the aperture having a longitudinal axis,	*See* Claim [10c].
[40c] the plurality of movable dies between stationary plates disposed about the longitudinal axis,	*See* Claim [1b].
[40d] each die in communication with an actuation device,	*See* Claim [10h].[13]
[40e] the actuation device constructed and arranged such that rotational	*See* Claim [10i].[14]

[13] 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.

[14] 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].

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

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.]" [15] Accordingly, Yasumi discloses every limitation of Claims 2 and 28. *See* Part X.A.2; Ex. 1105 ¶ 146.

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.3; Ex. 1105 ¶ 147.

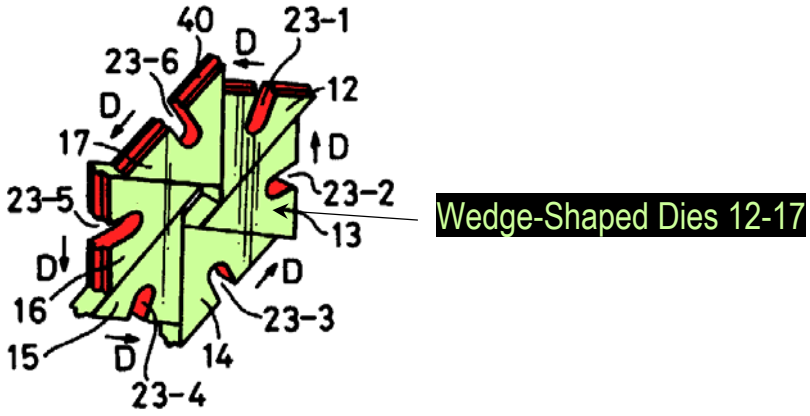
9. Claims 8, 25, and 33

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. 1103 at Claim 1; *see also id.* at Abstract, 2:47-59, 5:48-51, 4:12-17, 7:48-57, 8:50-54; Ex. 1105 ¶¶ 148-151.

[15] 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. 1103, Fig. 8; *id.* at Abstract ("substantially triangular movable pieces"), 1:48-49, 6:31-37; Ex. 1105 ¶¶ 152-154.

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 modify Yasumi for use as a stent crimper in view of the AAPA. Ex. 1105 ¶ 155.

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. 1103 at 1:16-28. Yasumi set out to solve 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. 1105 ¶ 158. 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 prior to September 22, 1999 that stent crimping is one field of crimping applications and that stents must be crimped uniformly. *See* Ex. 1105 ¶ 159 (citing Ex. 1114 at 1:35-48 ("One shortcoming of this conventional mounting and securing means is that it often produces irregular distortion of the stent . . . . Another shortcoming is that it may weaken a portion or portions of the stent . . . ."); Ex. 1121 at 1:59-2:2 ("Non-uniform stent crimping can result in sharp edges being formed along the now uneven surface of the crimped stent. Furthermore, non-uniform stent crimping may not achieve the desired minimal profile for the stent and catheter assembly."); Ex. 1125 at 1:49-2:14 ("Moreover, non-uniformity of the crimping may be experienced[.]"); Ex. 1119 at 1:66-2:18 ("[T]he stent may be non-uniformly crimped onto the delivery device which can cause problems during advancement of the stent to the desired location within a body lumen and/or during deployment of the stent."); Ex. 1118 at 2:2-5 ("In the past this crimping was often done by hand, which does not provide optimum results due to the uneven force being applied.")).

A POSITA would have recognized that many prior art stent crimpers suffered from a well-known uneven crimping problem. Ex. 1105 ¶ 160. For example, a POSITA would have known that the AAPA dies form elongate portions that poke radially inward to crimp a stent, resulting in uneven forces that can damage the stent. Ex. 1102 at 65; Ex. 1105 ¶ 160. A POSITA would have had a

reason, basis, or motivation to improve upon the AAPA, and other prior art stent crimpers, by using Yasumi as a stent crimper, thereby solving the uneven crimping forces problem. Ex. 1105 ¶ 160.

A POSITA would have known that using the straight-sided die/polygonal aperture disclosed in Yasumi for crimping a stent would address the well-known problem of uneven crimping forces. Ex. 1105 ¶ 156. The problem of uneven crimping forces exists in many crimping applications, such as crimpers for pointing tubes and crimping electrical connections. *Id*. ¶¶ 155-160. In particular, crimpers that, like the AAPA, use elongated dies equally spaced around an aperture that move radially inward to crimp a device have long been known to apply uneven crimping forces. *Id.* ¶¶ 159 (citing Exs. 1114, 1118, 1119, 1121, 1125). This problem has been solved in many instances by using a straight-sided die/polygonal aperture, such as the one disclosed in Yasumi.

For example, Whitesell recognized that asymmetric crimping detrimentally concentrated crimping force along the plane where the dies converged, compromising both electrical reliability and mechanical strength. Ex. 1115 at 1:13-20. Whitesell improved on prior art devices by providing "radially opposed jaws [or dies] that direct and balance compressive forces toward the center of the work." *Id.* at Abstract.

Baker disparaged a number of prior art tube pointing apparatus that used dies "which reciprocate radially inward" because they resulted in the metal tube extruding into openings between the dies. Ex. 1111 at 1:13-20, 1:33-37 (discussing Exs. 1122, 1123, 1124). Baker solved the problem by using dies that were arranged to form a polygonal aperture with no gaps in between. *Id.* at 1:45-48, 1:55-58.

A POSITA would have had a reason, basis or motivation to solve the problem in the stent crimping field in the same manner. Ex. 1105 ¶¶ 155-160. 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.* ¶¶ 160.

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

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."

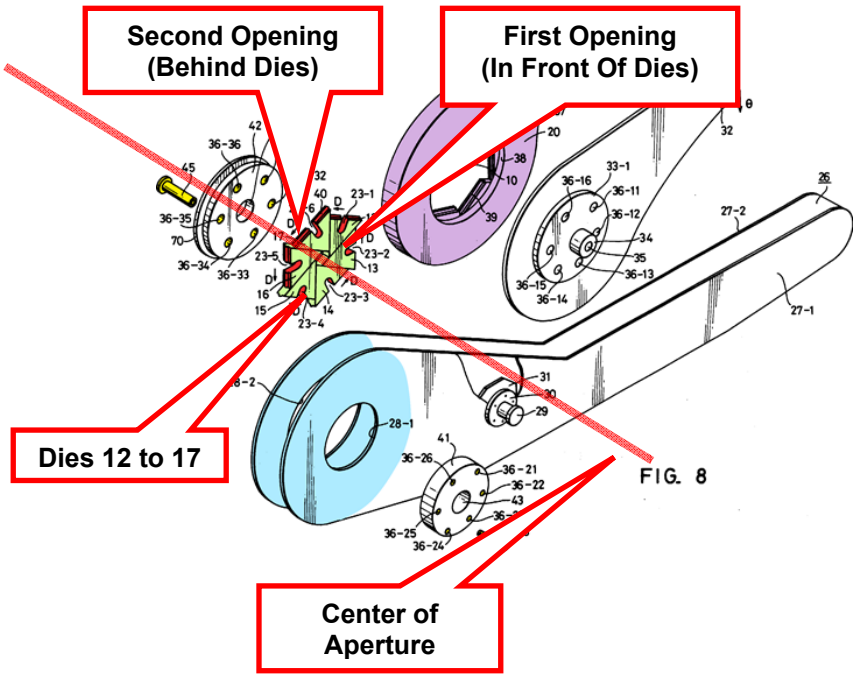
These limitations are disclosed in or obvious over Yasumi either alone or in view of the AAPA. As explained above, Yasumi is considered a stent crimper for

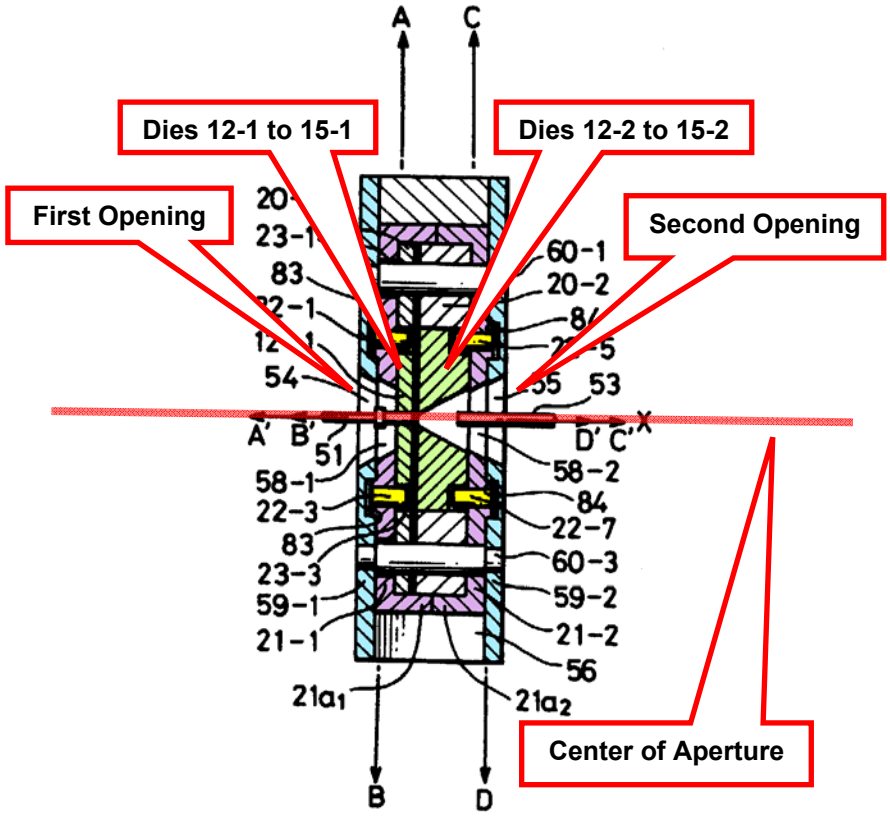
purposes of analyzing validity of the challenged claims. The AAPA is also a stent crimper. Therefore, Yasumi and the AAPA would have been constructed to accommodate a balloon catheter and stent within the crimping aperture. Ex. 1105 ¶ 162. An aperture having a center and openings on both ends, *i.e.*, 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*.

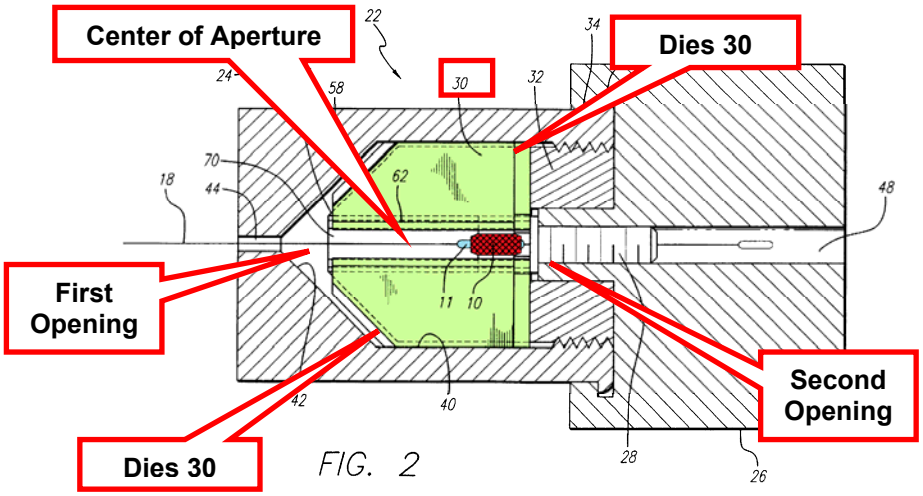
Moreover, a POSITA would have known the desirability of crimping the stent evenly and, thus, it would have been obvious to make the length of the dies exceed the length of the stent to ensure that the entire stent fit easily within the aperture, provide a margin of error so that no portion of the stent would be missed during the crimping procedure, and to account for manufacturing tolerances. Ex. 1105 ¶ 163.

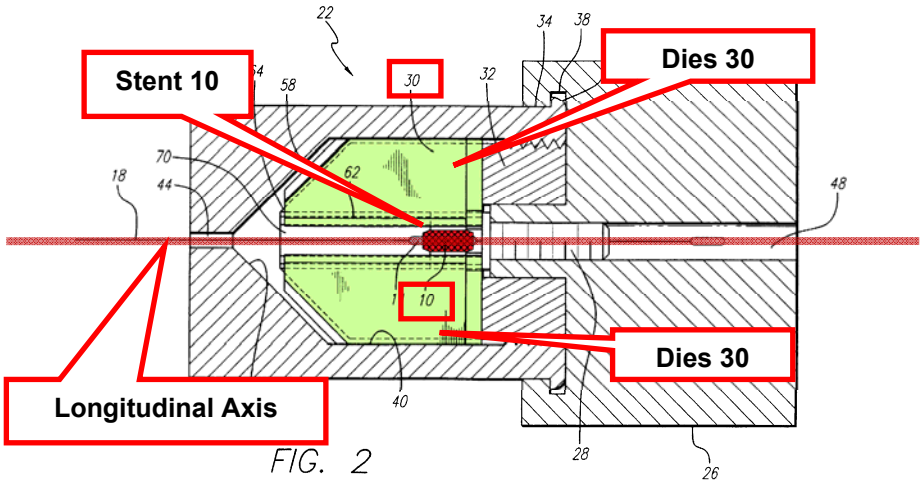
To the extent these limitations are not viewed as disclosed in or obvious in view of Yasumi or the AAPA, Morales also discloses these limitations. Ex. 1105 ¶¶ 164-165. A detailed analysis of Claim 39 is provided in the following claim chart. *See also id.* ¶¶ 166.

ASSERTED CLAIMS	**PRIOR ART**
[39 Preamble] A stent crimper	*See* Claim [1 Preamble].

ASSERTED CLAIMS	PRIOR ART
comprising:	
[39a] a plurality of movable dies arranged to form an iris disposed about an aperture,	*See* 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,	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. "Bringing the grips of the handles 26 and 37 closer to each other, the pins 45 move in the elongated holes 23-1 to 23-6 to move the movable pieces 12 to 17 in the frame 20, reducing the aperture defined by the movable pieces 12 to 17." (Ex. 1103 at 8:50-54; *id.* at 9:30-34.)  (*Id.* at Fig. 8.)

ASSERTED CLAIMS	PRIOR ART
	"The movable pieces 12-1 to 15-1 are so formed as to provide a pyramidal aperture setting portion 81, whereas the movable pieces 12-2 to 15-2 are so formed as to provide a truncated, quadrangular pyramidal aperture setting portion 82. 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. 1103 at 9:63-10:6.)  FIG. 9(a) (*Id.*, Fig. 9(a).) Morales also discloses an aperture (between teeth 30) having a center and a first opening and a second opening. "An uncrimped stent is manually loaded into the hollow core.

ASSERTED CLAIMS	PRIOR ART
	At the opposite end of the tool, the balloon catheter is inserted through the opening into the cylindrical cavity at the proximal section of the housing, which leads into the hollow core of the screw holding the uncrimped stent." (Ex. 1104 at 3:38-42.) "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." (*Id.* at 4:19-22.) "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." (*Id.* at 7:33-35.)  FIG. 2 (*Id.*, Fig. 2.)

ASSERTED CLAIMS	PRIOR ART
[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,	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. "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. 1104 at 4:19-22.) "[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." (*Id.* at 5:5-9.)  FIG. 2 (Ex. 1104, Fig. 2.).
[39d] each die in communication with an actuation device,	*See* Claim [40d].

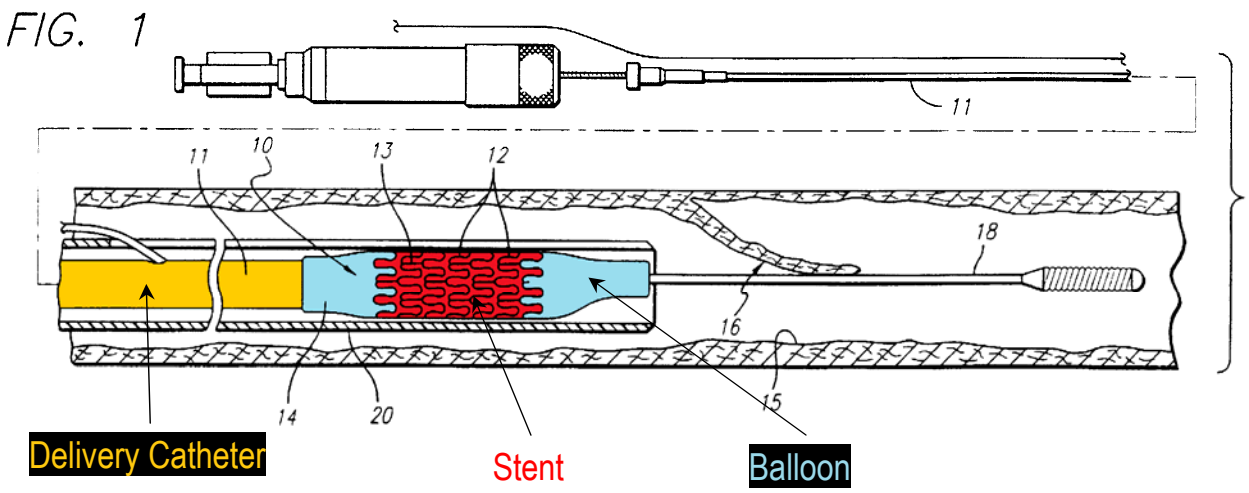
ASSERTED CLAIMS	**PRIOR ART**
[39e] the actuation device constructed and arranged such that rotational motion of the actuation device opens or closes the aperture;	*See* Claim [40e].
[39f] each die having a first straight side and a second straight side, the first straight side and the second straight 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.	*See* Claim [1d].

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 the AAPA. As explained above, Yasumi is considered a stent crimper for purposes of analyzing validity of the challenged claims. The AAPA is also a stent crimper. A POSITA at the time of the invention would have known about stents and the balloon-based, catheter-mounted method of delivery. Ex. 1105 ¶ 168. 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. 1102 at 75.

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



Ex. 1104, Fig. 1. "In order to implant stent 10, it is first mounted onto inflation balloon 14 on the distal extremity of delivery catheter 11. Stent 10 is crimped down onto balloon 14 to ensure a low profile." *Id.* at 5:60-66, 6:22-25. *See also* Ex. 1105 ¶¶ 169-170.

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."[16]

This limitation is disclosed in or obvious over Yasumi either alone or in view of the AAPA. As explained above, Yasumi is considered a stent crimper for purposes of analyzing validity of the challenged claims. The AAPA is also a stent crimper. A POSITA at the time of the invention would have been aware of the problems resulting from uneven stent crimping. Ex. 1105 ¶ 172. To avoid these

[16] Claim 26 recites "a stout," but for purposes of this *inter partes* review Petitioner construes that to be "a stent."

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*. Notably, the Examiner found that the AAPA taught this limitation during prosecution. Ex. 1102 at 75.

To the extent this limitation is viewed as not disclosed in or obvious in view of Yasumi or the AAPA, Morales (discussed above) discloses an entire stent 10 (red) disposed within an aperture formed by dies 30 (green). *See* X.B.2; *see also* Ex. 1104 at 5:5-9; Ex. 1105 ¶¶ 173-174.

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 the AAPA, with the additional limitations of Claims 11, 17, 19, 26, 34, 35, and 39 based on the teachings in Morales.

As explained above, Yasumi is considered a stent crimper for purposes of analyzing validity of the challenged claims. The AAPA is also a stent crimper. It would have been obvious as a matter of common sense to modify Yasumi, either alone or in view of the AAPA, to form a stent crimper with a stent disposed about a balloon and the balloon disposed about a catheter, as discussed in Morales, because crimping a stent to a catheter is the intended purpose for a stent crimper. Ex. 1105 ¶ 176.

Moreover, a POSITA would have been motivated to modify Yasumi, either alone or in view of the AAPA, 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. 1105 ¶ 177. 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 a prior Petition filed by Petitioner on October 13, 2016 (IPR2017-00072) seeking to cancel the challenged claims of the '560 patent. The present Petition relies on Yasumi in view of the AAPA and further in view of Morales. The prior Petition relies on the AAPA in view of U.S. Patent No.

5,918,511 ("Sabbaghian") or U.S. Patent No. 4,308,744 ("Baker"), and further in view of Morales.

While the prior art combinations in each Petition independently render obvious the challenged claims, the grounds are materially different from each other in a number of ways. For example, in the present Petition, Yasumi is the primary reference and is generally directed to an aperture setting device that can be used for a host of applications, including as a press tool or crimper. Yasumi 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. Thus, Yasumi, in view of the AAPA (and Morales) renders the challenged claims obvious in the present Petition.

In contrast, in the prior Petition, the AAPA is the primary reference and is generally directed to a stent crimper. Sabbaghian and Baker are relied upon as secondary references. Sabbaghian is generally directed to an adjustable socket for a socket wrench, and Baker is generally directed to a tube pointer for compressing metal tubes. Sabbaghian and Baker are relevant primarily for their disclosure of the straight-sided die/polygonal aperture limitation of the challenged claims. Thus, the AAPA in view of Sabbaghian or Baker (and Morales) renders the challenged claims obvious in the prior Petition.

Each reference is therefore directed at a different application and used in a different manner as part of a combination, and the rationales to combine these references are different in some respects.

Additionally, Yasumi in the present Petition qualifies as prior art under 35 U.S.C. § 102(b), whereas Sabbaghian in the prior Petition 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 Claims 1, 2, 6, 8-11, 14, 15, 17-19, 23, 25-27, 28, 31, 33-35, 37, 39 and 40 of the ’560 patent 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: December 7, 2016

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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 13,939 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: December 7, 2016

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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 1101 – 1125** are being served on December 7, 2016, 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:

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