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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. IPR2017-00072
Patent 6,915,560

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

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EXHIBIT LIST

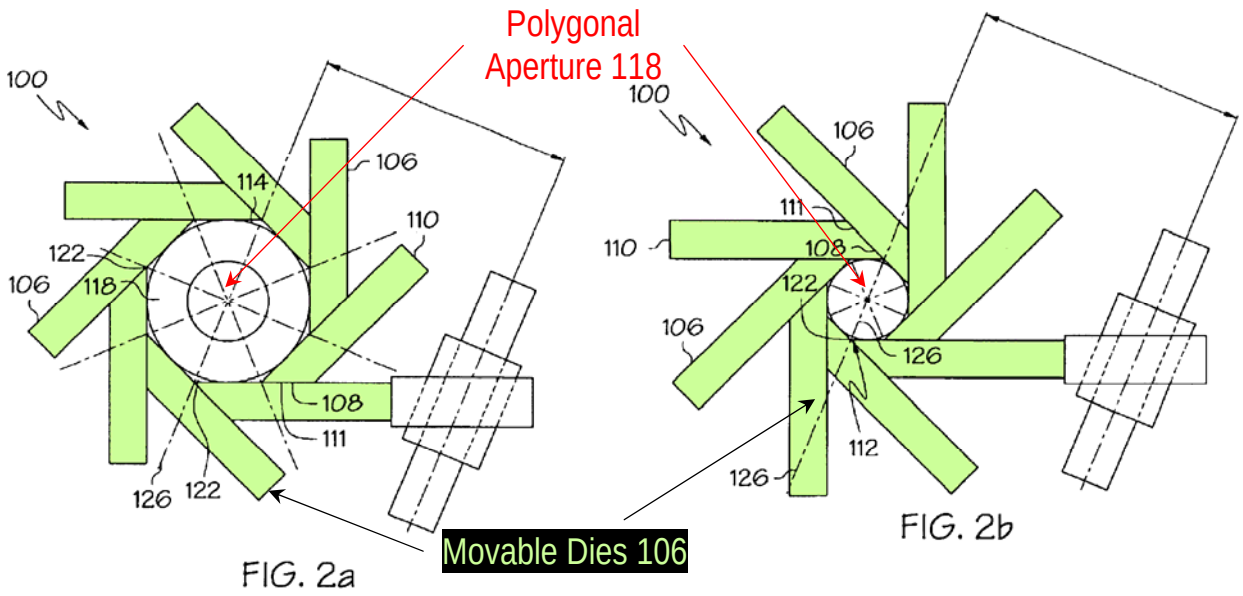
Exhibit No.	Description
1001	U.S. Patent No. 6,915,560 (“the ’560 patent”)
1002	U.S. Patent No. 6,915,560 File History Excerpts
1003	U.S. Patent No. 5,261,263 (“Whitesell”)
1004	U.S. Patent No. 3,695,087 (“Tuberman”)
1005	U.S. Patent No. 6,176,116 (“Wilhelm”)
1006	U.S. Patent No. 5,918,511 (“Sabbaghian”)
1007	U.S. Patent No. 5,893,852 (“Morales”)
1008	U.S. Patent No. 4,308,744 (“Baker”)
1009	U.S. Patent No. 2,664,996 (“Andrews”)
1010	International Patent Publication No. WO1994014573 A1 (“Hartley”)
1011	Declaration of Neil Sheehan in Support of Petition for *Inter Partes* Review of U.S. Patent No. 6,915,560
1012	Curriculum Vitae of Neil Sheehan
1013	Materials Considered by Neil Sheehan
1014	U.S. Patent No. 6,364,870 (“Pinchasik”)
1015	U.S. Patent No. 6,125,523 (“Brown”)
1016	U.S. Patent No. 6,074,381 (“Dinh”)
1017	U.S. Patent No. 5,951,540 (“Verbeek”)

Exhibit No.	Description
1018	U.S. Patent No. 6,051,002 (“Morales 2”)
1019	U.S. Patent No. 7,892,201 (“Laguna”)
1020	U.S. Patent No. 3,370,451 (“Schuetz”)
1021	U.S. Patent No. 3,154,978 (“Baker 2”)
1022	U.S. Patent No. 3,417,598 (“Valente”)
1023	German Patent No. DE9034 (“Nix”)
1024	Certified Translation of Nix
1025	U.S. Patent No. 4,454,657 (“Yasumi”)

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. 1001[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.

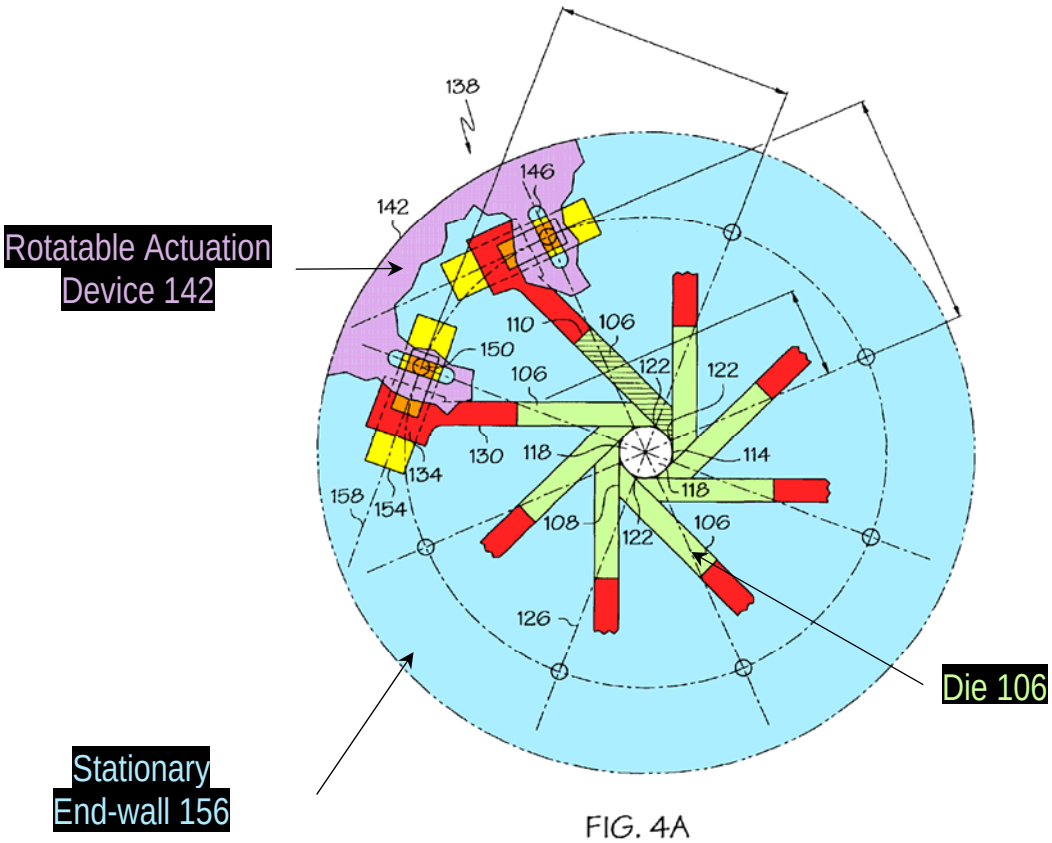
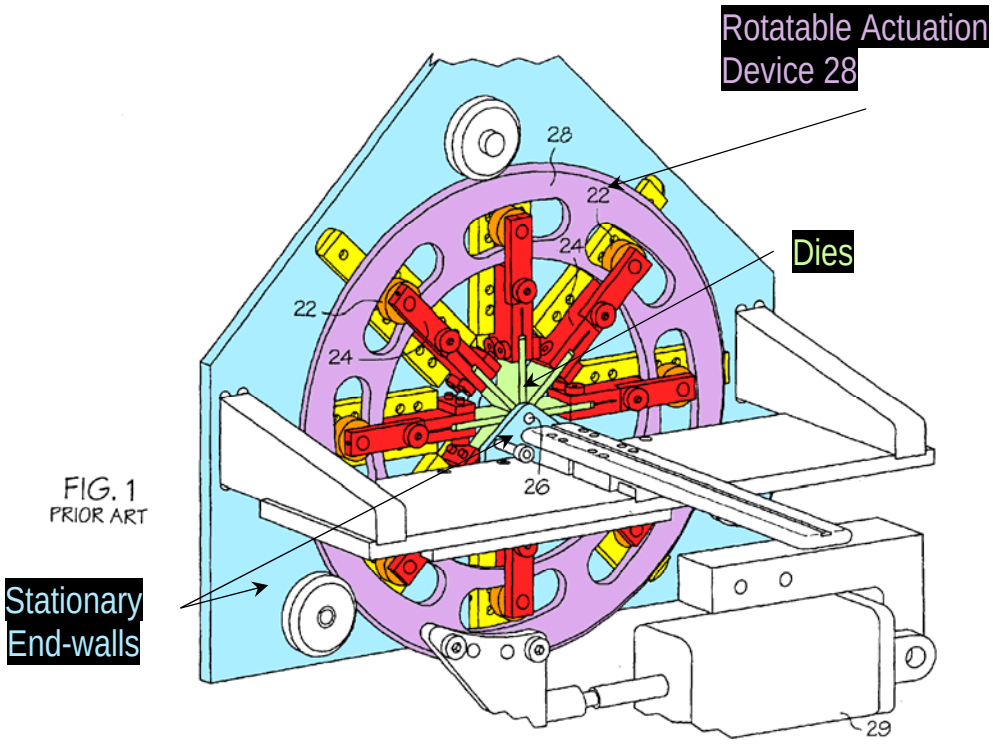


FIG. 4A

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. 1001 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.

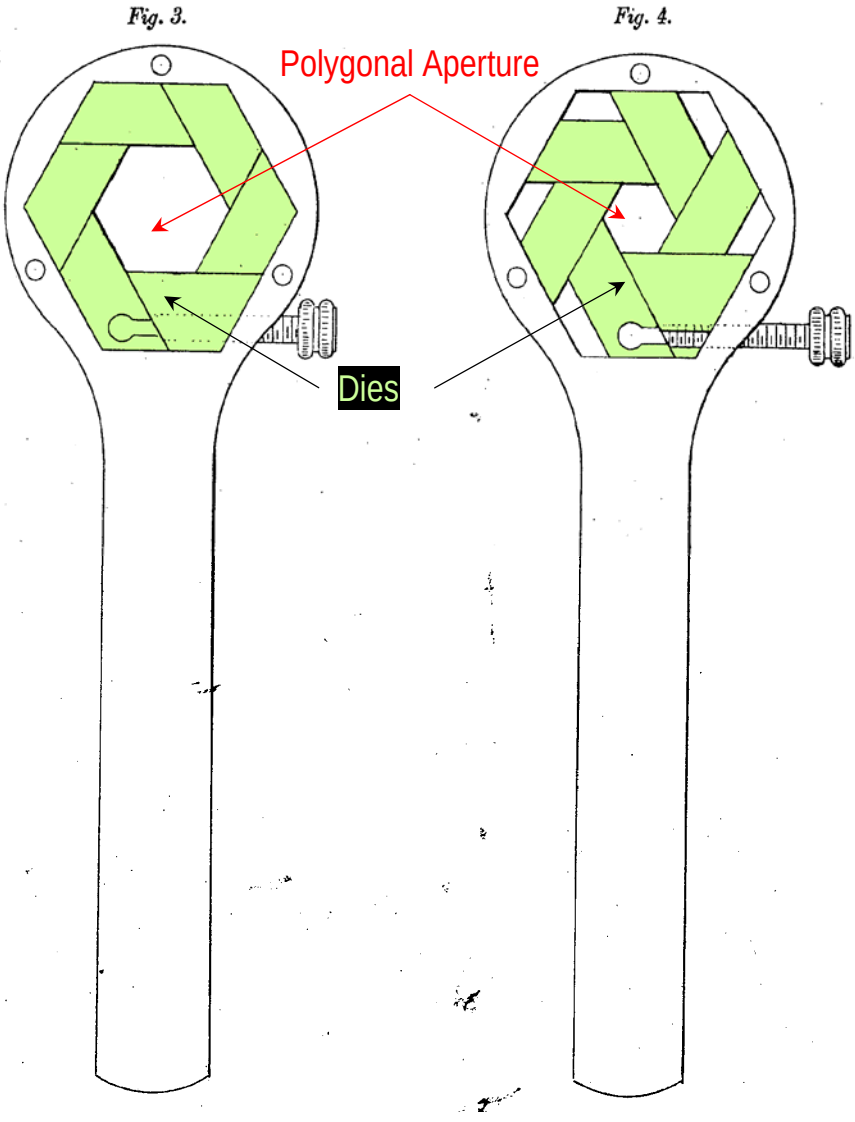
The only feature missing from the admitted prior art stent crimper is the dies arranged to form a variable-sized ***polygonal*** aperture.

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 polygonal-shaped die configuration 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,

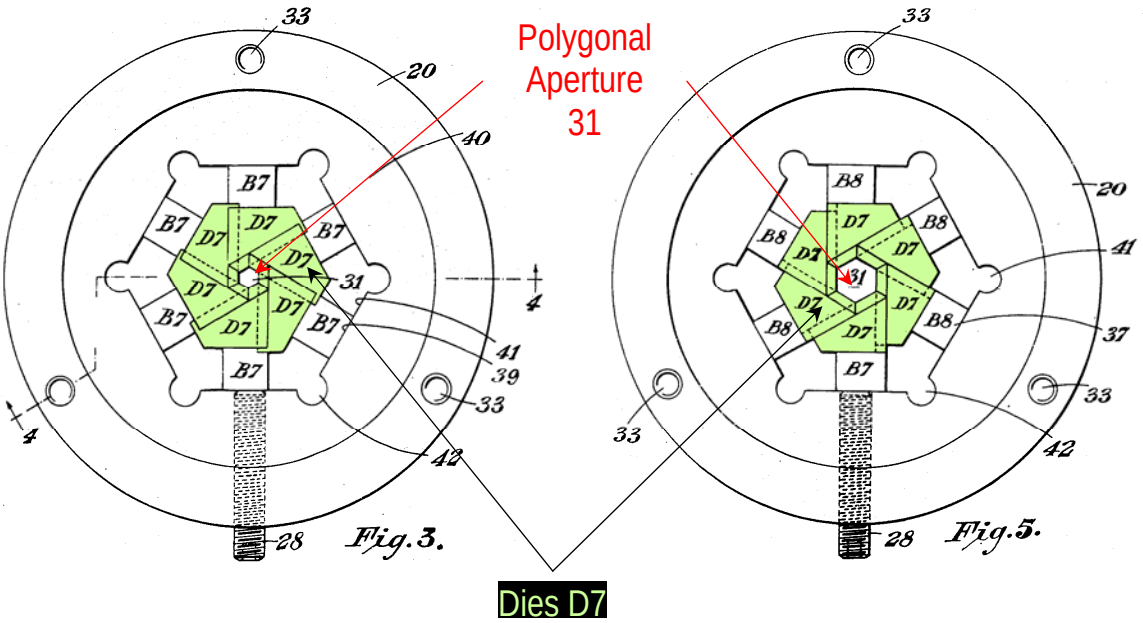
tube pointers, setting devices, chucks, press tools, electric wire guide devices, and control valves.

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



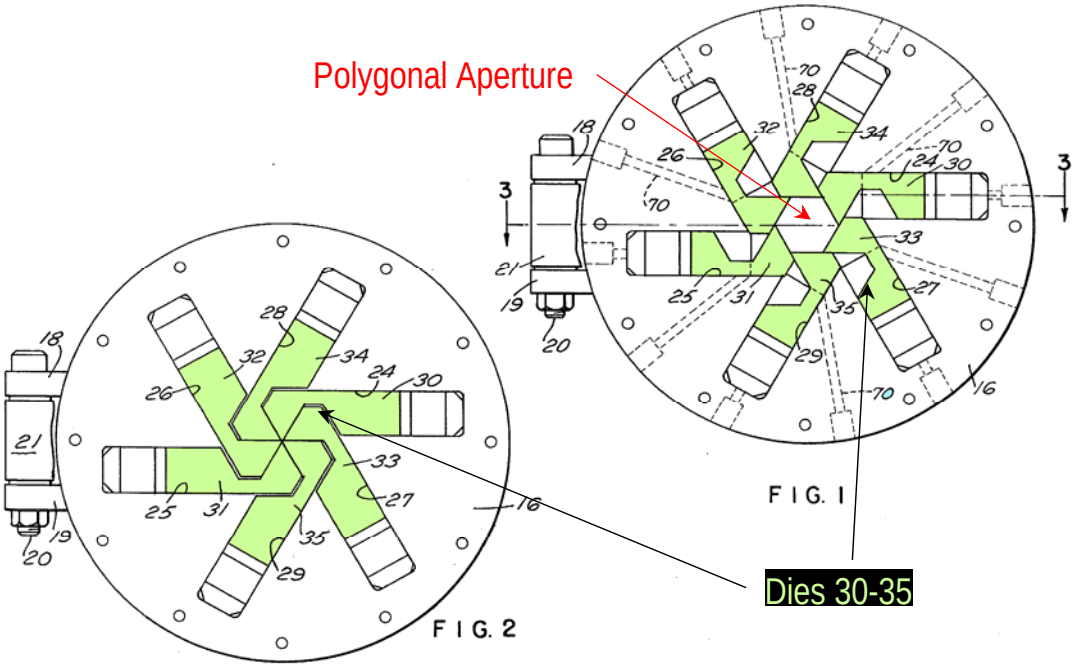
Ex. 1023 and 1024.

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":



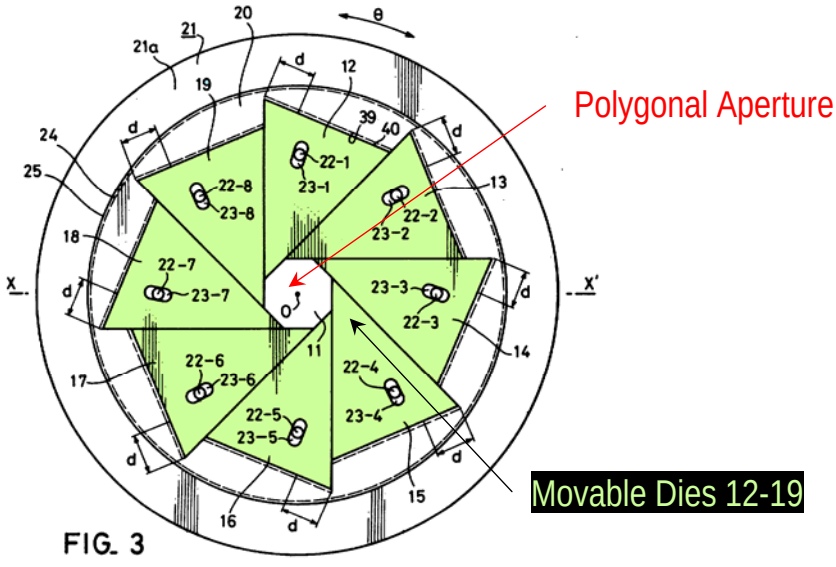
Ex. 1009.

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":



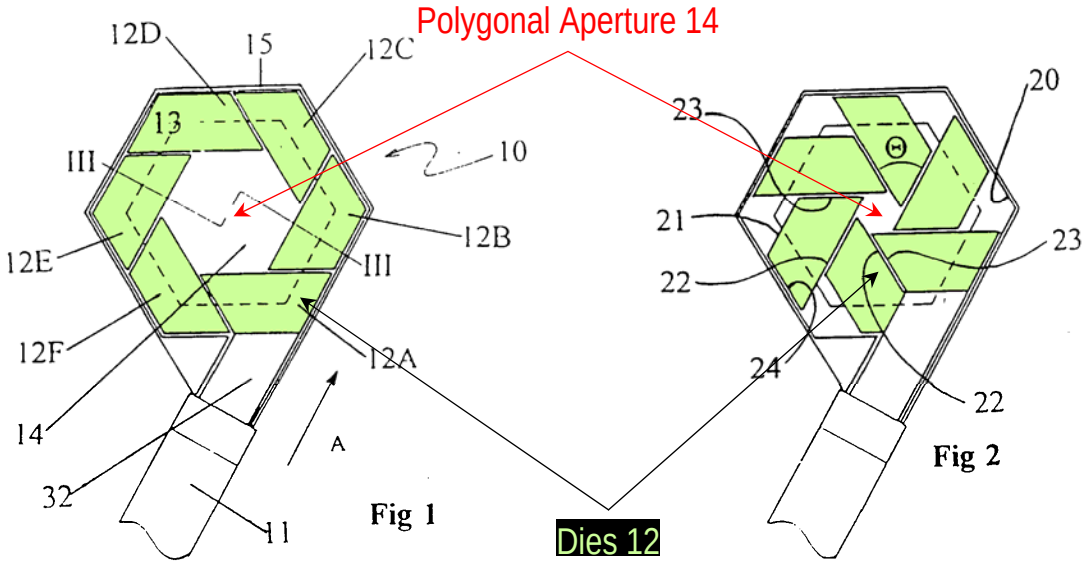
Ex. 1008.

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. 1025.

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. 1010.

On July 6, 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":

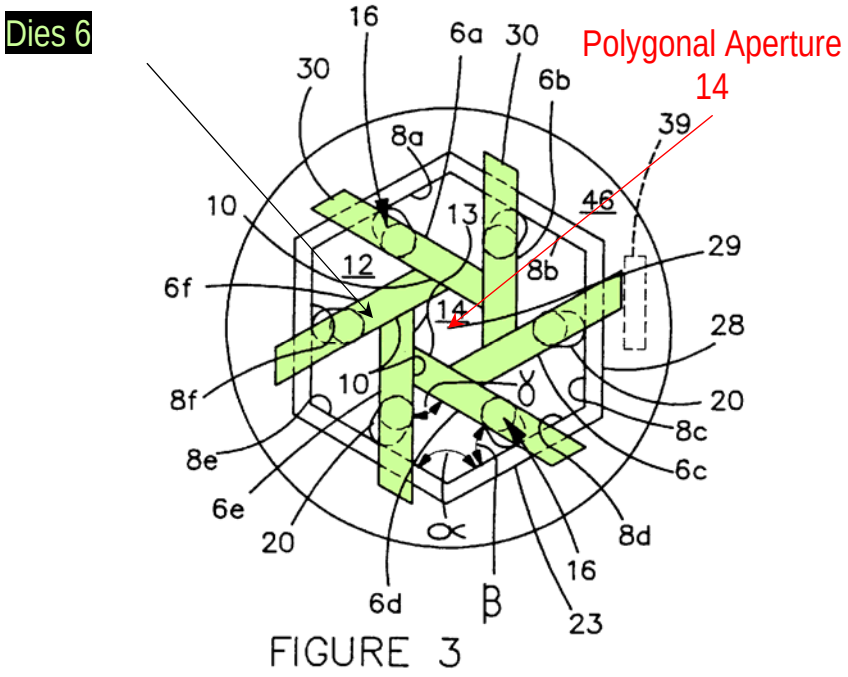


FIGURE 3

Ex. 1006.

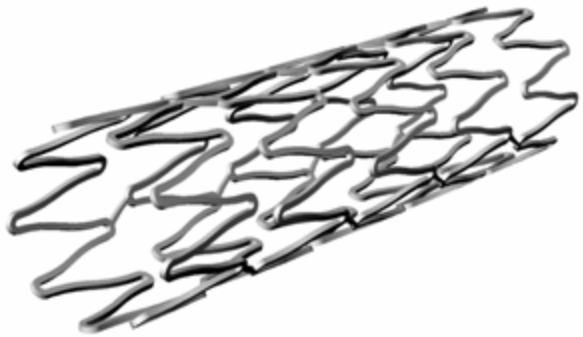
The ’560 patent’s broad claims recite nothing more than the admitted prior art stent crimper with dies arranged to form a polygonal aperture, as was well-known to a person of ordinary skill in the art (“POSITA”) long before 1999. Thus, the claims of the ’560 patent are unpatentable over the prior art 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 widen a narrowed or obstructed blood vessel. Stents are generally cylindrical wire-mesh devices that can be introduced

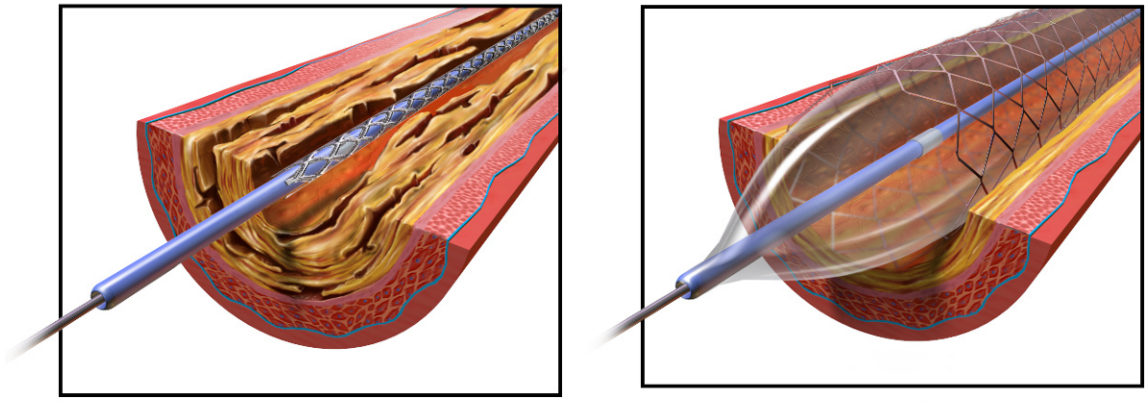
via a delivery catheter into the blood vessel at a reduced diameter and then later expanded to the diameter of the vessel at the implantation site. Ex. 1011 ¶¶ 27-30.

Stent



Prior to the implantation procedure, a crimper is used to crimp the stent around an uninflated balloon on the delivery catheter. In this reduced-diameter configuration, the stent is able to travel through a patient's blood vessel. Once the stent is correctly positioned at the implantation site, the balloon is inflated, expanding the stent to the desired size. Ex. 1011 ¶¶ 31-33.

Balloon Catheter & Stent Within Vessel Before & After Inflation

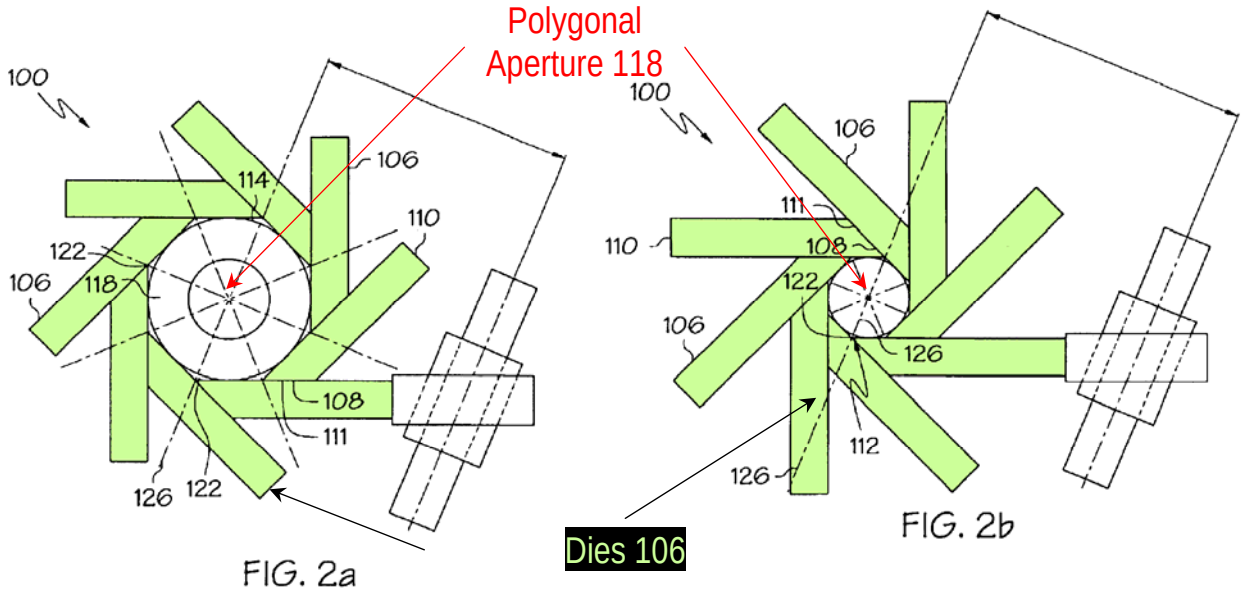


Stents must be crimped uniformly to avoid damaging the stent. Ex. 1011 ¶ 153. Many conventional stent crimping techniques in the early 1990's did not apply optimal uniform crimping forces. As explained in Pinchasik:

> [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. 1014 at 1:33-40.

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



According to the ’560 patent, this die configuration improves upon the prior art because the polygonal-shaped aperture is capable of applying uniform forces to crimp a stent without distorting, scoring, or marking the stent during the crimping process. Ex. 1001 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.

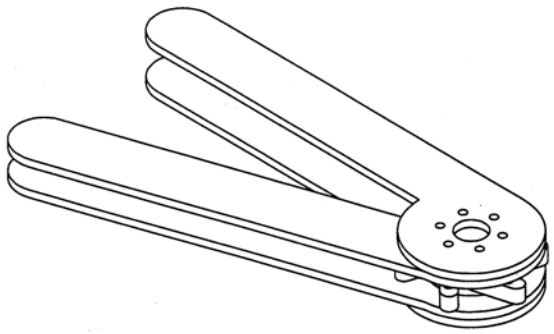
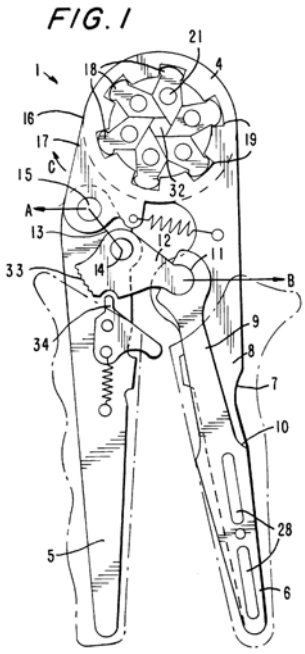
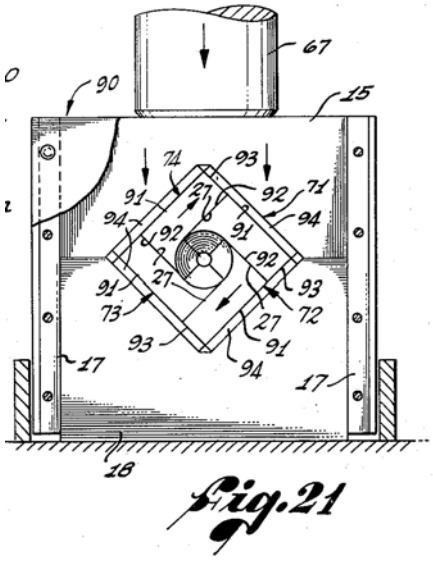


Figure 8

Ex. 1002 at 72-73, Ex. 1003, Fig. 8. The Examiner relied upon a crimping tool for crimping lead end sleeves onto electrical conductors.



Ex. 1002 at 4, Ex. 1005, Fig. 1. The Examiner also relied upon a tube pointer.



Ex. 1002 at 45-48; Ex. 1004, Fig. 21.

Like the Examiner, a POSITA would have looked to these closely related mechanical fields to improve upon known stent crimpers, and would have had a

reason, basis, or motivation to replace the dies in the admitted prior art stent crimper with dies forming a polygonal aperture, as was well-known in the prior art, to provide uniform crimping forces and thereby avoid distorting, scoring, or marking of the stent during the crimping process. Ex. 1011 ¶¶ 81-92, 153-164.

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:

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

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

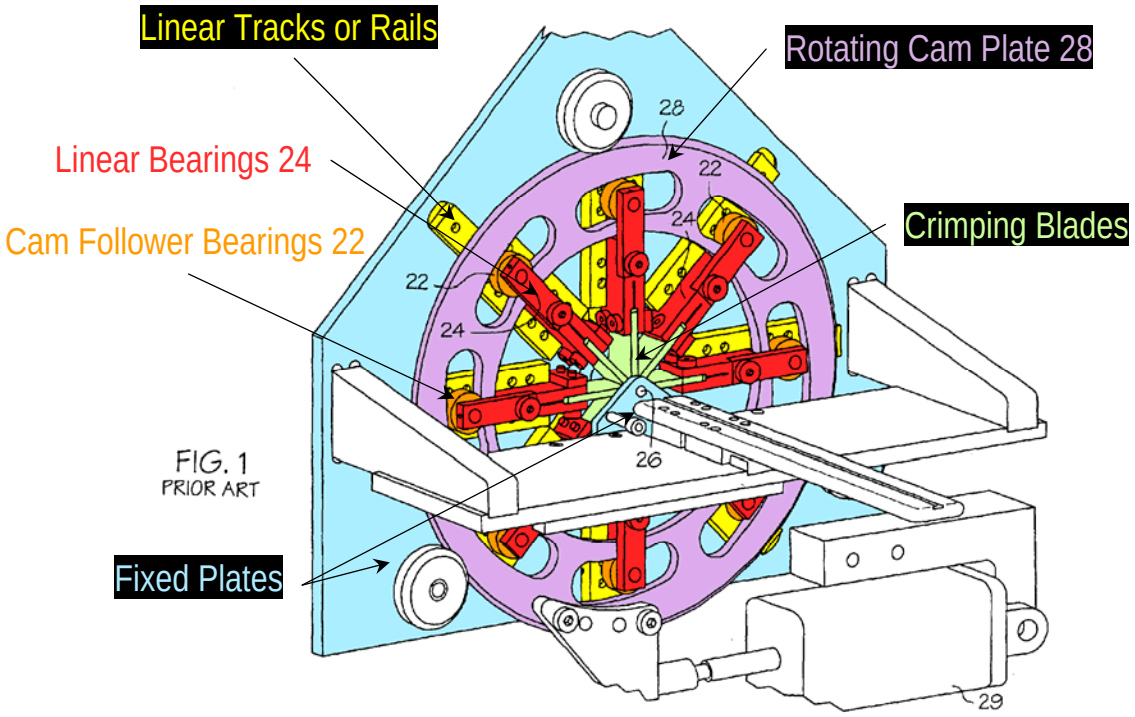
V. U.S. PATENT NO. 6,915,560

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. 1001, 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. 1001 at 1:42-55.

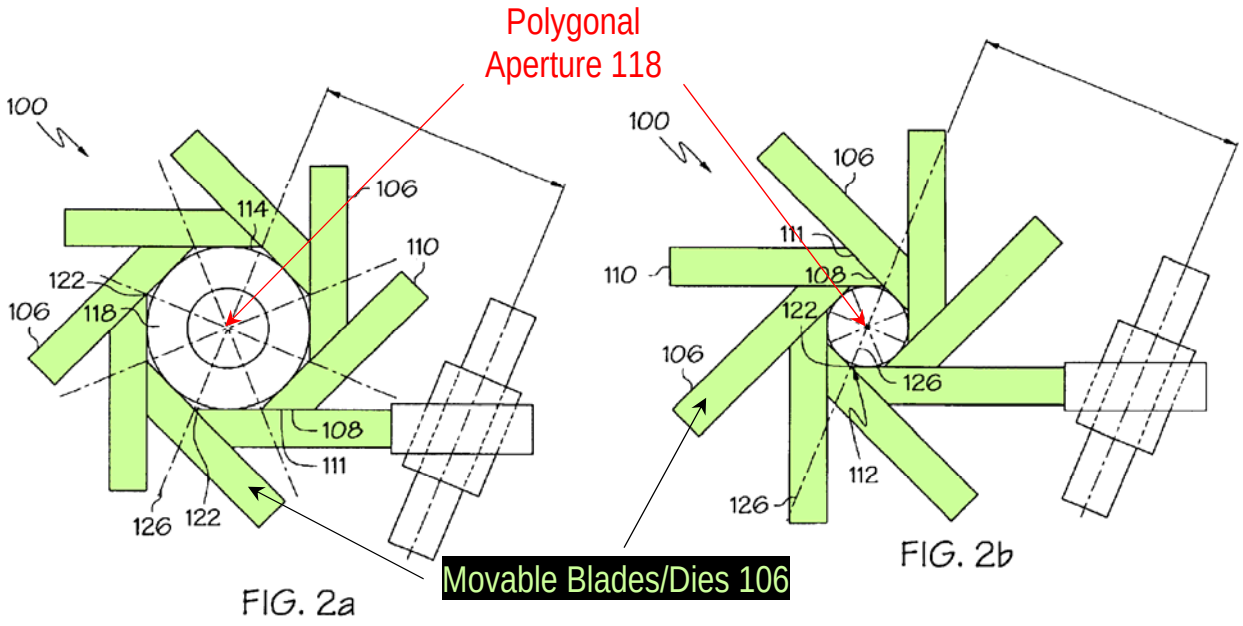
The '560 patent also illustrates and discusses an admitted prior art stent crimper ("Applicant Admitted Prior Art" or "AAPA"):



Ex. 1001, 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 purportedly improved 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. 1001 at 2:27-29. 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. 1001 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.

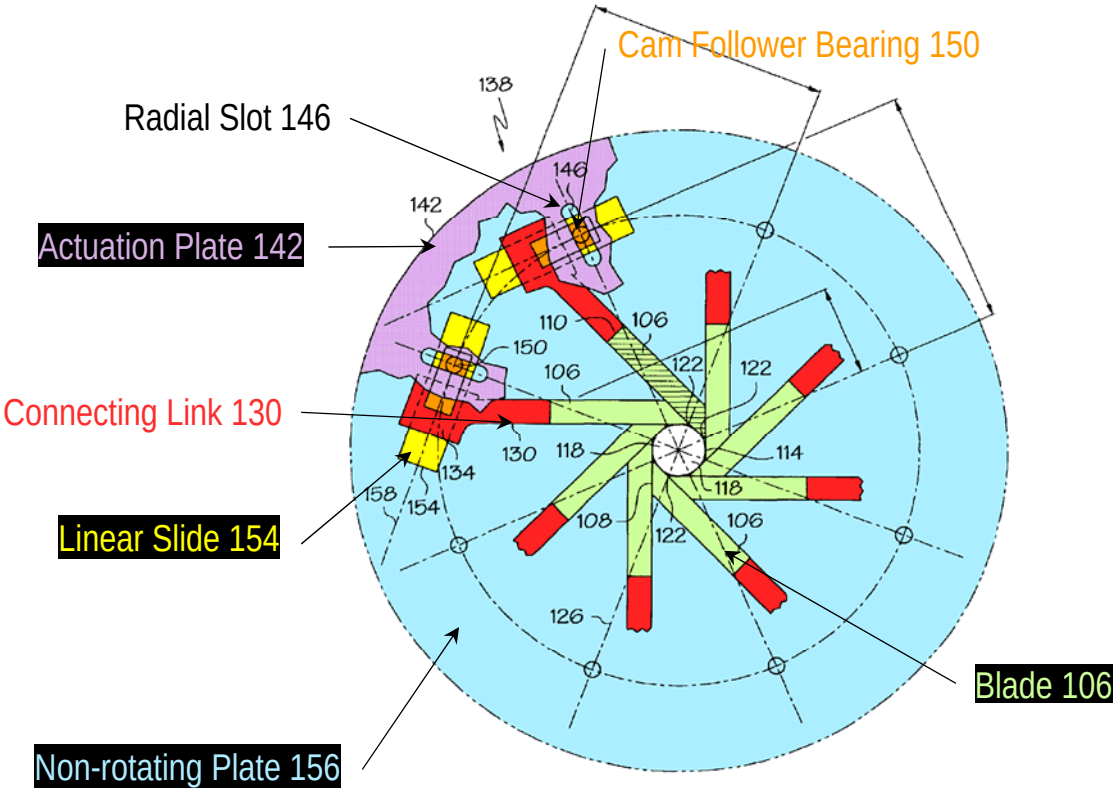


FIG. 4A

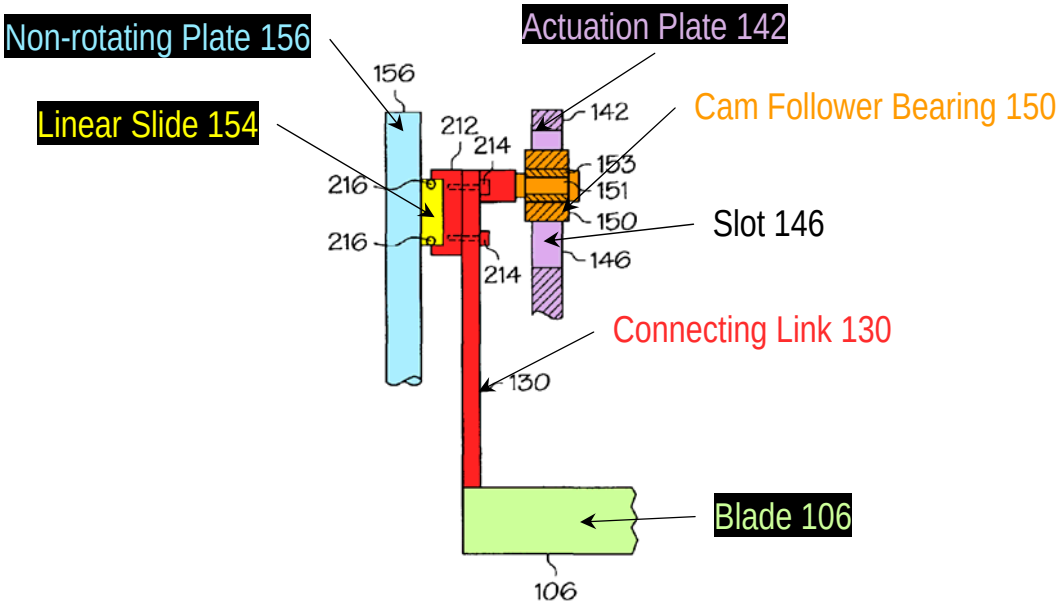


FIG. 4c

Ex. 1001 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 5:17-19. 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.

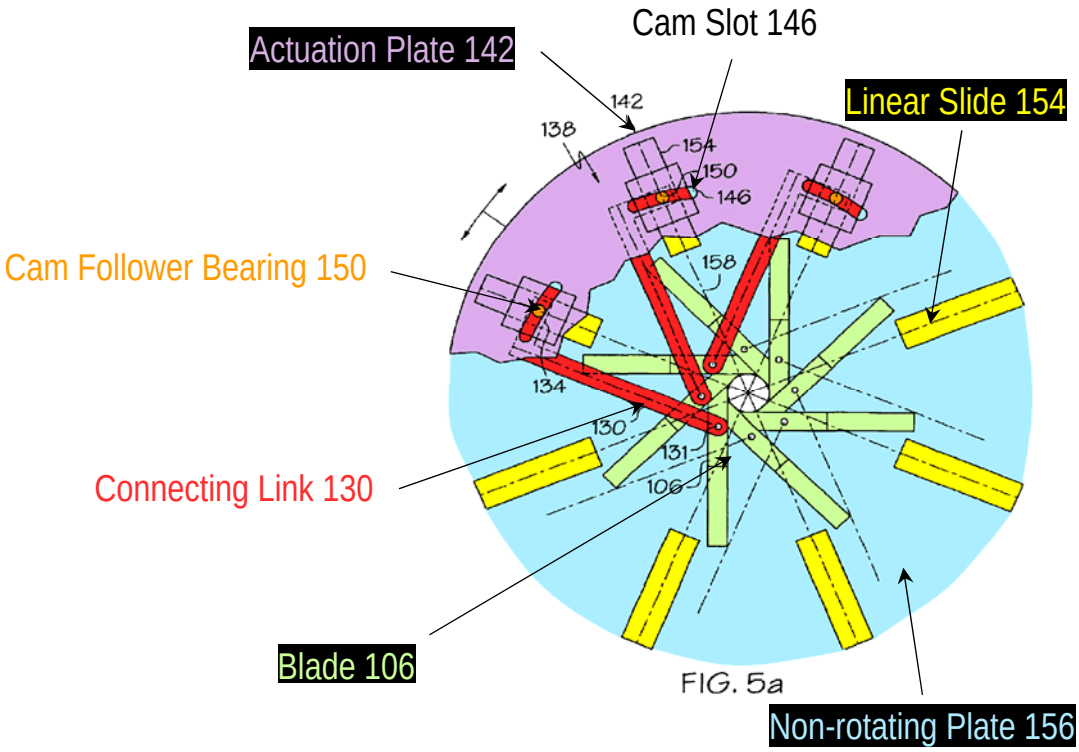
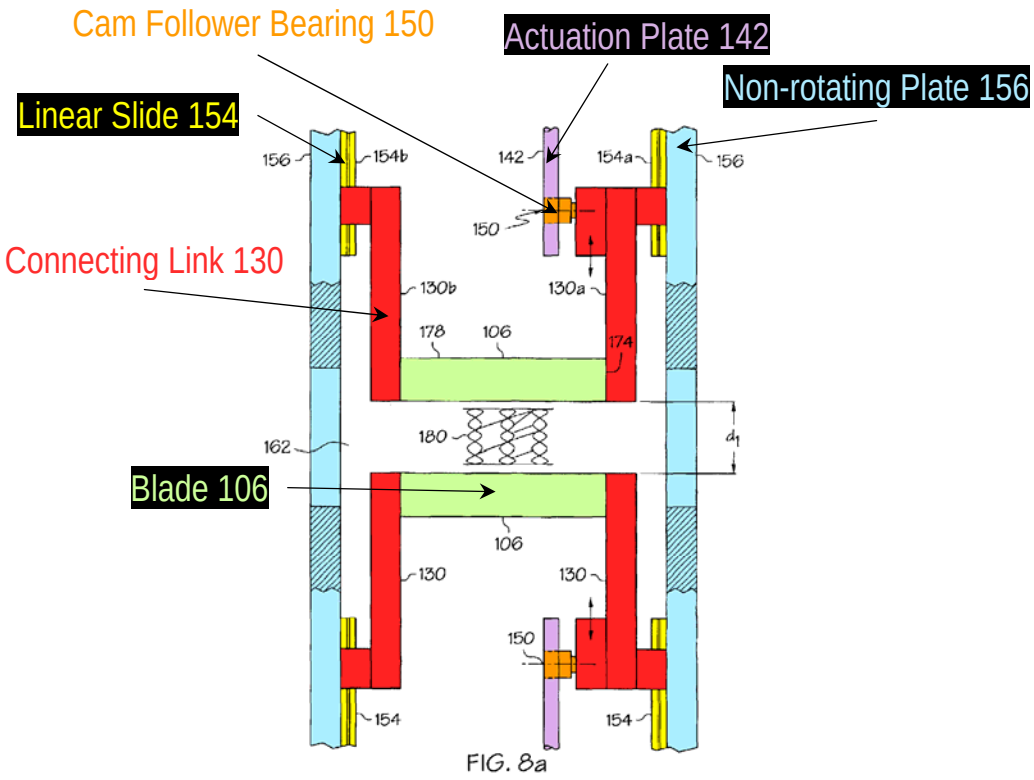


FIG. 5a



Ex. 1001 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. 1002 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 92-98.

1. October 22, 2003 Office Action and Response

In an Office Action dated October 22, 2003, the Patent Examiner rejected all claims. Ex. 1002 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

[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.

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.

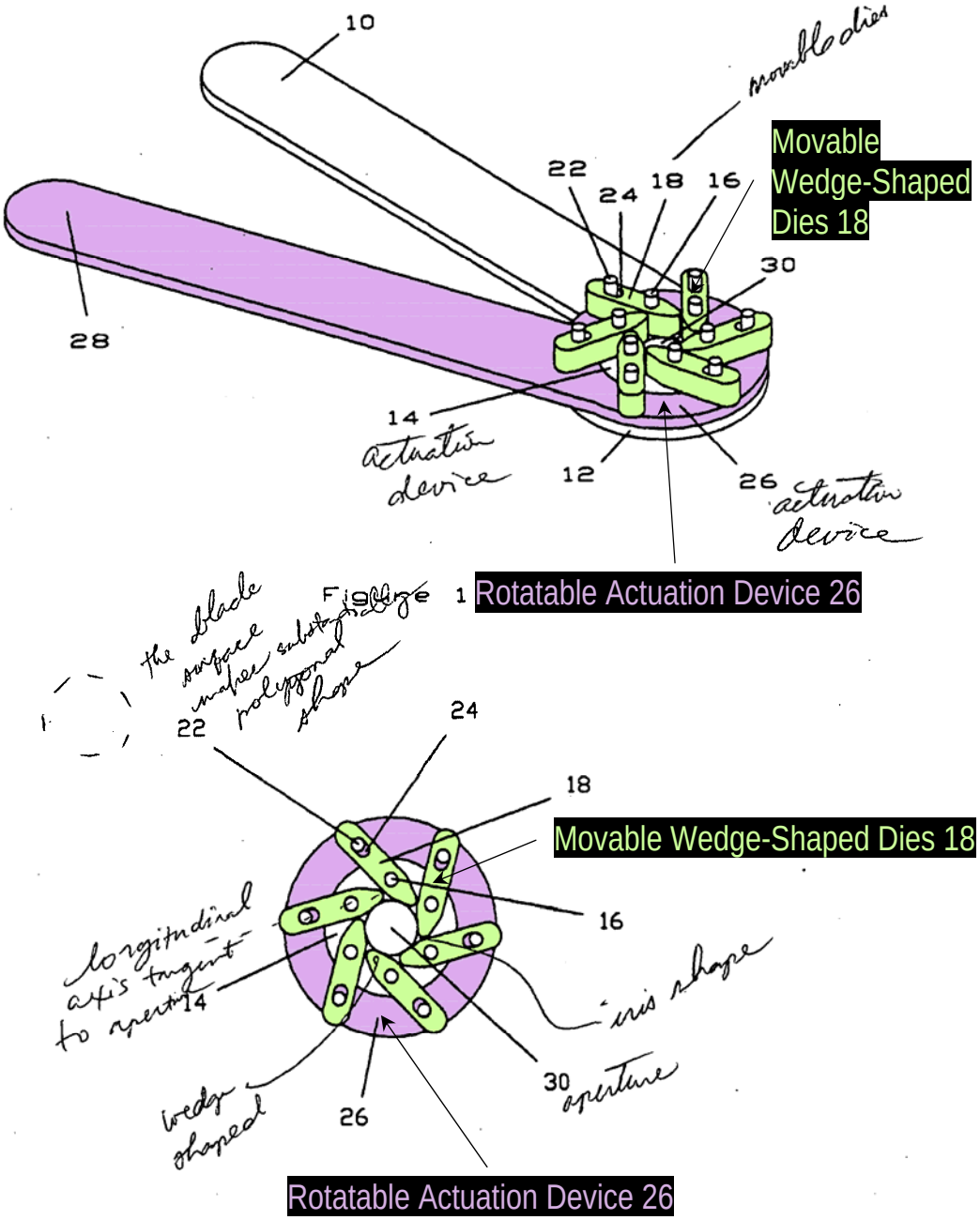


Figure 2

Ex. 1002 at 84 (Whitesell, Ex. 1003, Figs. 1 and 2, handwritten notes in original; colored annotations added).

Whitesell discloses pliers for gripping and crimping cylindrical objects. Ex. 1003 at 1:28-36. The Examiner considered Whitesell a stent crimper because "Whitesell is capable of performing crimping of a stent." *Id.* at 72. The Applicant did not dispute the Examiner's position.

The Examiner also rejected Claims 27, 36, 44, and 52 as obvious over the AAPA in view of Whitesell. Ex. 1002 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.

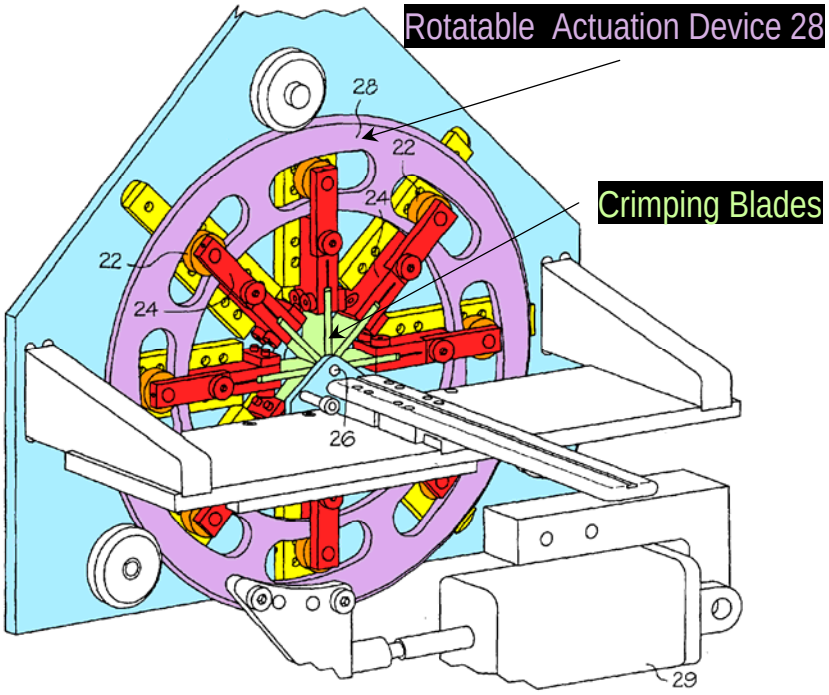


FIG. 1
PRIOR ART

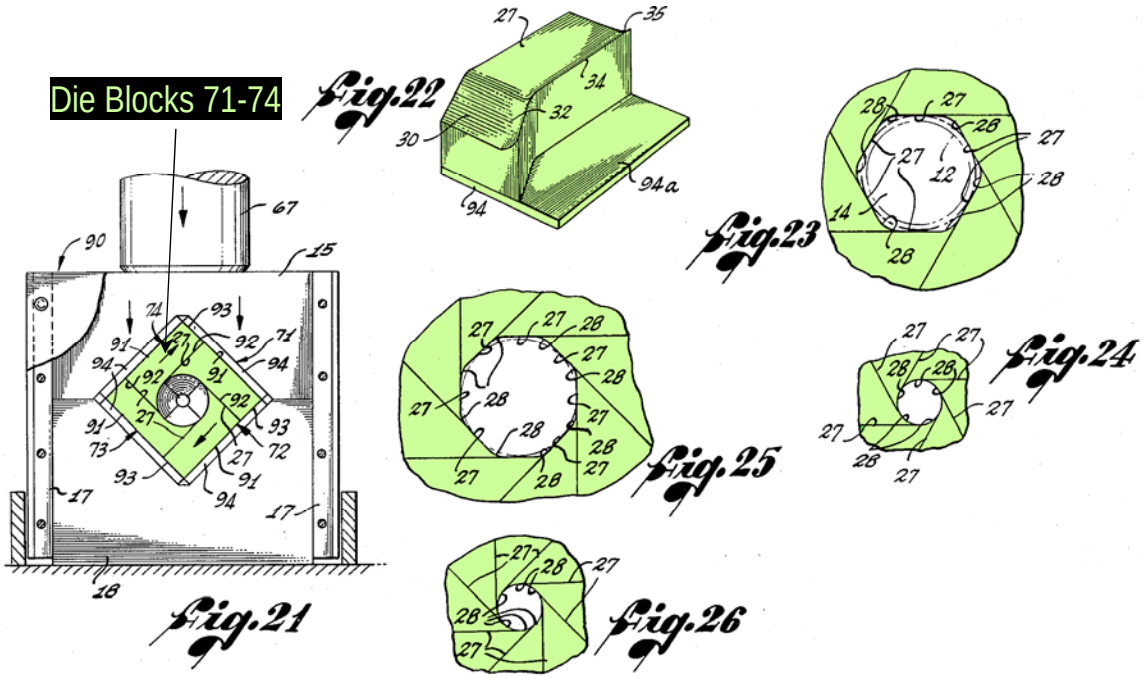
Ex. 1001, Fig. 1. The Examiner explained that it would have been obvious "to have provided the invention of [the AAPA] with dies having a longitudinal axis which is tangent to the aperture, in light of the teachings of Whitesell, in order to provide a symmetric crimping deformation. It is noted that Whitesell recognizes the benefits of using radial applying crimping forces over linearly applied forces like the one taught by [AAPA]." *Id*. 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. 1002 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

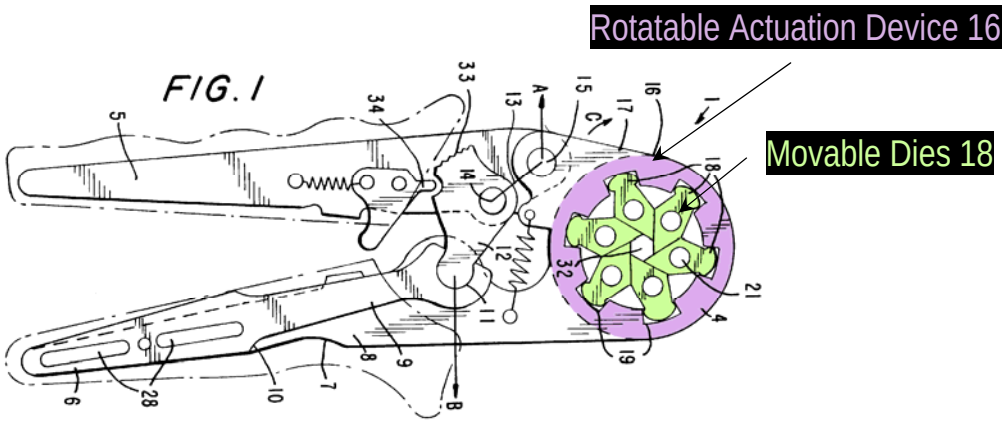
On April 22, 2004, the Examiner rejected independent Claims 27, 36, 52, and 63 as anticipated by either U.S. Patent No. 3,695,087 ("Tuberman") or U.S. Patent No. 6,176,116 ("Wilhelm"). Ex. 1002 at 42-52. The Examiner found that both taught dies arranged to form an iris with angles that remain substantially 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. 1004 at Abstract.



Ex. 1004, Figs. 21-26.

Wilhelm, depicted below, describes a crimping tool for crimping lead end sleeves, contact sockets, or plugs onto electrical conductors. Ex. 1005 at Abstract.



Ex. 1005, Fig. 1.

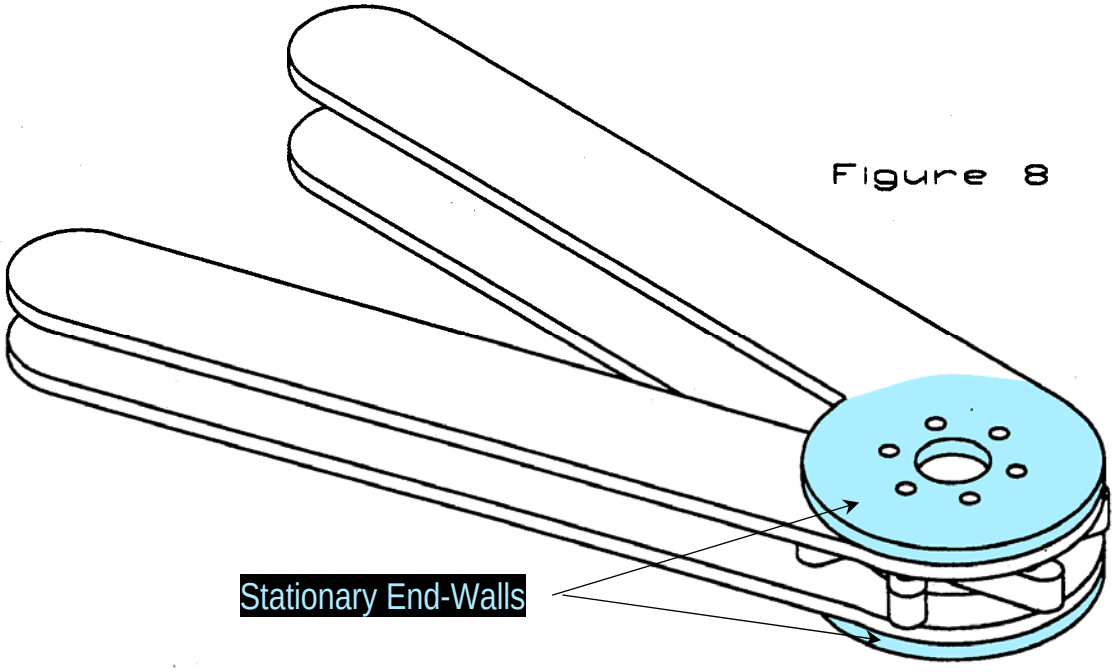
The Examiner considered Tuberman and Wilhelm stent crimpers because both are capable of crimping a stent. Ex. 1002 at 45-46. The Applicant did not dispute the Examiner's position.

On July 22, 2004, the Applicant filed a response and an amendment. Ex. 1002 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".) Ex. 1002 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. 1002 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. 1002 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. 1003, 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. 1002 at 5, 8-12.

On February 14, 2005, the Examiner issued a Notice of Allowability. Ex. 1002 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 the AAPA in view of Sabbaghian.

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

Ground 3: 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 the AAPA in view of Baker.

Ground 4: Claims 11, 17, 19, 26, 34, 35, and 39 are unpatentable under 35 U.S.C. § 103 as obvious over the AAPA in view of Baker and further in view of Morales.

A detailed explanation of how the claims are unpatentable is set forth below in Section IX. Additional explanation and support for each ground is included in the Declaration of Neil Sheehan. Ex. 1011.

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. 1011 ¶¶ 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.

[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.

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

The '560 patent claims never refer back to the preamble for antecedent basis. Moreover, "stent crimper" is not a recitation of additional structure underscored as important by the specification. While the specification acknowledges that stent crimping is one use for the invention, it recognizes additional uses. Ex. 1001 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. 1002 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. 1011 ¶¶ 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. 1001 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.

1002 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. 1011 ¶¶ 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. 1011 ¶¶ 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. 1001 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. 1011 ¶¶ 83-88. 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. 1001 at 1:42-55. 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. 1002 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. 1001 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. 1011 ¶¶ 90-92. 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. 1002 at 15-21 (relying on Whitesell), 42-49 (relying on Tuberman and Wilhelm); *see also* Exs. 1003 (Whitesell), 1004 (Tuberman), 1005 (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. *See id.* 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. 1001. 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 Tech., Inc. v. Mmi*

Holdings Saint-Gobain Performance Plastics Rencol Ltd., IPR2014-00309 (Paper 83).

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. 1011 ¶ 94. This polygonal aperture arrangement is present in numerous prior art devices that would have been known to a POSITA. *Id.*

C. Sabbaghian

Sabbaghian was filed on August 28, 1997 and is prior art under at least §102(e).[4] *See* Ex. 1006. Sabbaghian was not considered by the Examiner during prosecution. Sabbaghian discloses an adjustable socket for a socket wrench "capable of adjustably adapting to different sizes of polygonal bolt heads, nuts, or similar fastening hardware." Ex. 1006 at 1:5-9.

As depicted below, the adjustable socket includes a plurality of gripping members 6 (green) fitted inside a central opening in a collar plate 4 (blue) to form a polygonal aperture. Ex. 1006 at 1:65-2:5, 3:1-5, 3:18-20, 3:41-42.

[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.

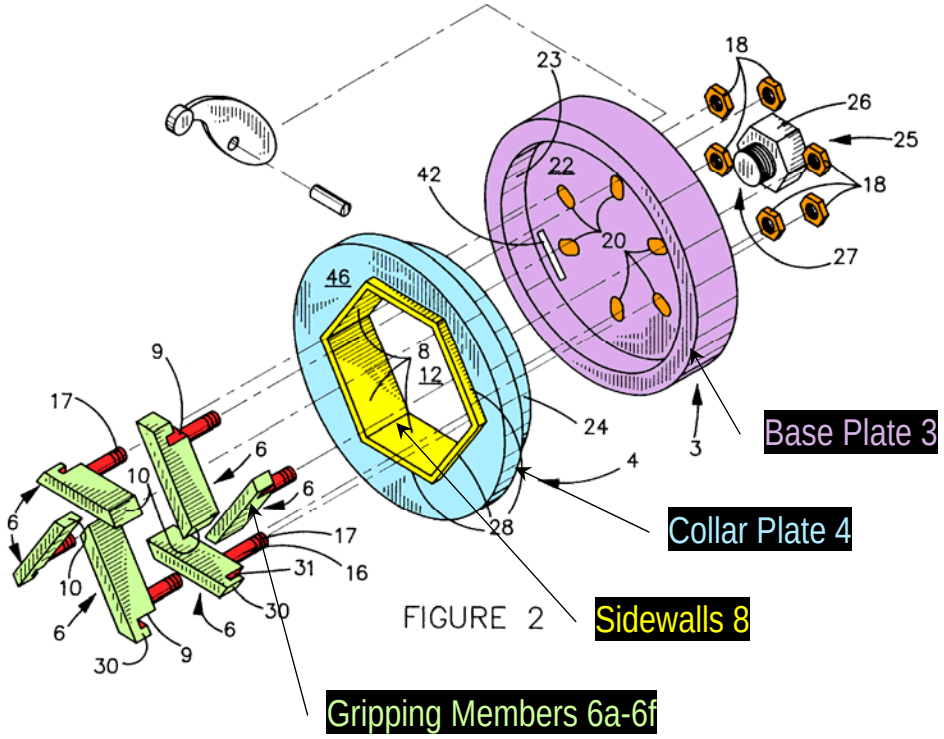


FIGURE 2

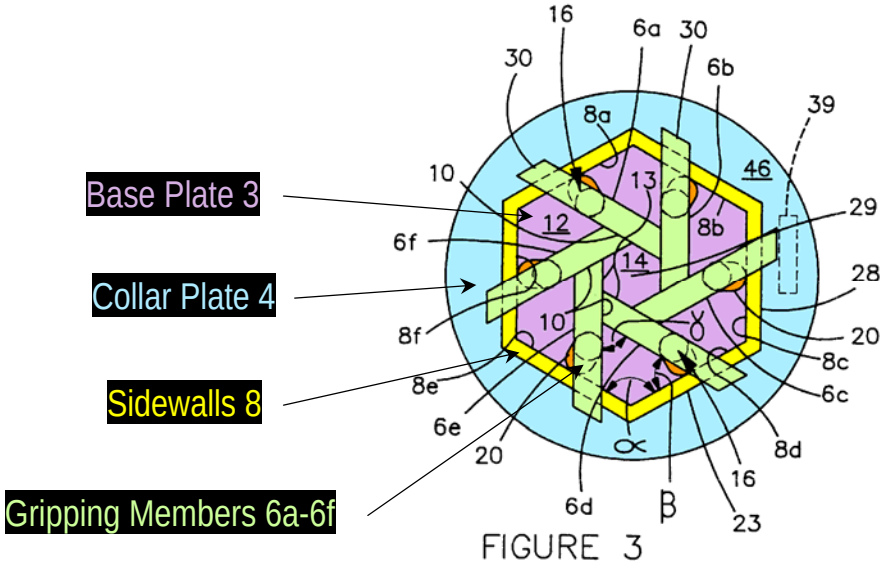


FIGURE 3

Ex. 1006, Fig. 2, 3. Each gripping member 6 (green) has a first end 9 adapted to engage one of the internal side walls 8 (yellow) of the collar plate 4 (blue). Each gripping member 6 also has a second end 10 that is adapted to slidably engage (i.e. overlap) an adjacent gripping member 6. The gripping members 6 (green) slide

along the sidewalls 8 (yellow) and adjacent gripping members to vary the size of the polygonal aperture. *See id.* at 3:30-52, 3:63-4:8.

As depicted in Figure 3, the contacting surface 13 and the second end 10 of each gripping member 6 have straight sides that converge to form a tip. The contacting surface of each gripping member is also parallel to the second end of the adjacent member. Ex. 1006, Fig. 3.

In Sabbaghian, each gripping member 6 (green) also has a first end 9 adapted to engage holes (orange) in a base plate 3 (purple). Ex. 1006 at 4:8-18. Rotation of the base plate 3 (purple) relative to the collar plate 4 (blue) will simultaneously move the gripping members 6 cooperatively inward or outward to change the size of the aperture while maintaining the relative orientation of the gripping members and the polygonal shape of the aperture. *Id.* at 4:39-5:7.

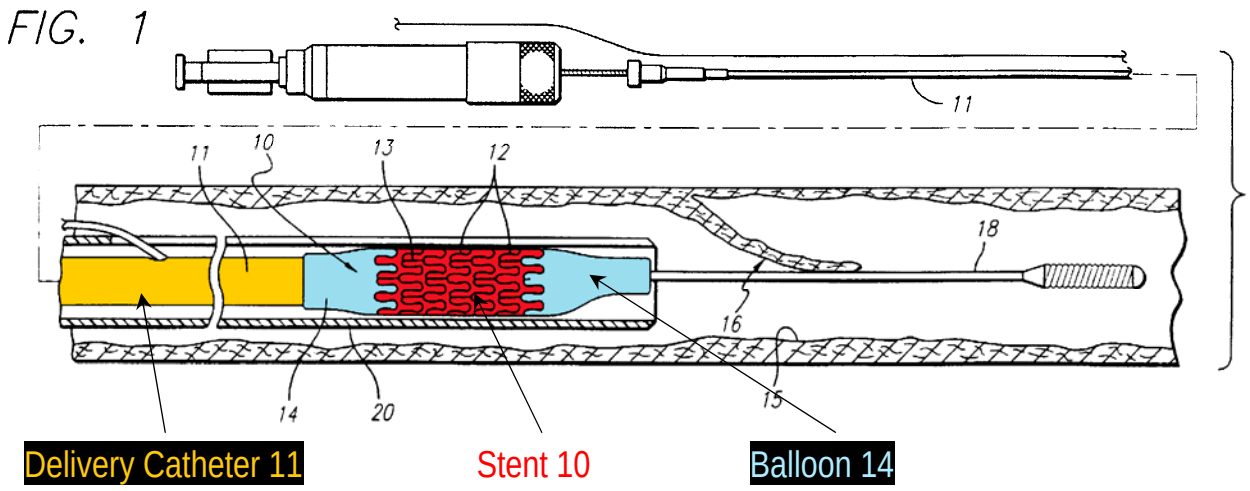
Sabbaghian is in the same field of endeavor as the ’560 patent because it is directed to an apparatus having movable members that form a variable size aperture, as in the ’560 patent. Ex. 1011 ¶ 100, *see also id.* at Ex. 1011 ¶¶ 81-88.

Sabbaghian is also reasonably pertinent to the problem to be solved by the ’560 patent. Ex. 1011 ¶ 101. The wrench in Sabbaghian has gripping members that form a gripping region that maintains the same polygonal configuration when increasing and decreasing the size of the aperture. Ex. 1006 at 3:30-35, 3:41-52, 3:58-62, 4:3-8, 4:63-65. A POSITA would have understood that the invention

disclosed in Sabbaghian would result in uniform crimping forces to any object within the aperture and remedy the problem identified in the '560 patent. Ex. 1011 ¶ 102; *see also id.* at ¶¶ 89-92. Sabbaghian 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. 1007. 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. 1007, 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.

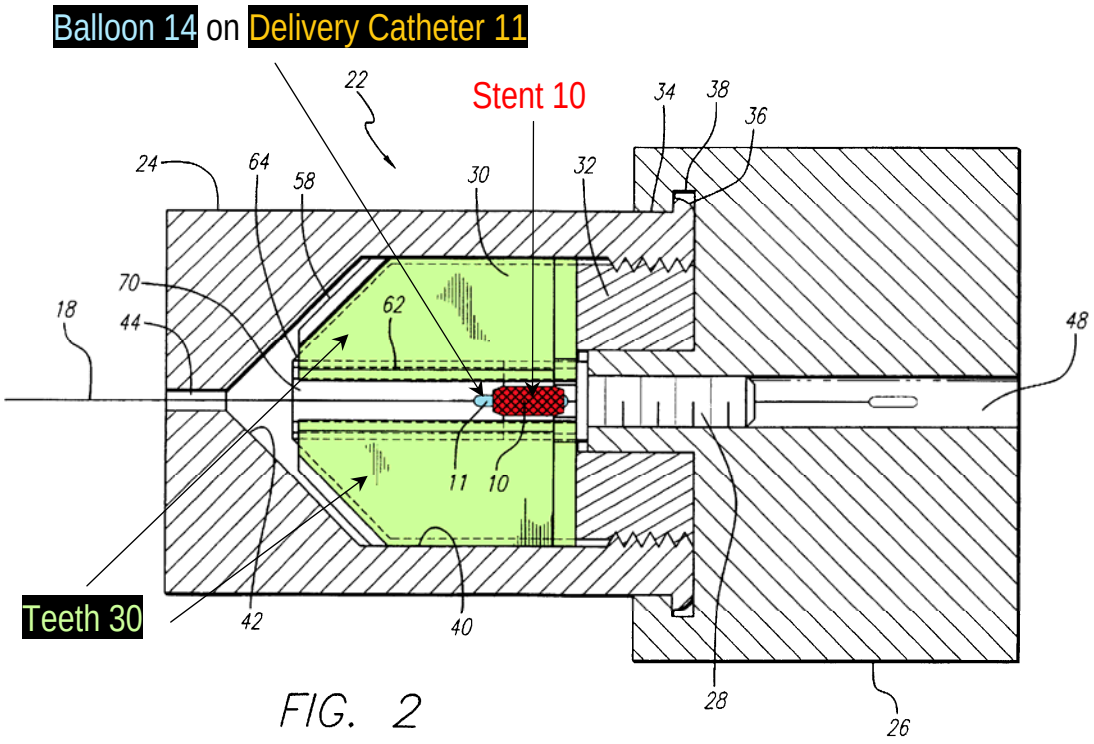


FIG. 2

Ex. 1007, 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.

E. Baker

U.S. Patent No. 4,308,744 ("Baker") was filed on February 8, 1980, issued on January 5, 1982, and is prior art under at least § 102(b). *See* Ex. 1008. Baker was not considered by the Examiner during prosecution. Baker discloses "[a] tube pointer for compressing metal tubes . . . that employs a plurality of pairs of jaws oriented about a central axis." *Id.* at Abstract.

Baker discloses jaws 30-35 (green) arranged about a central axis. *Id.* at Abstract, 2:40-43.

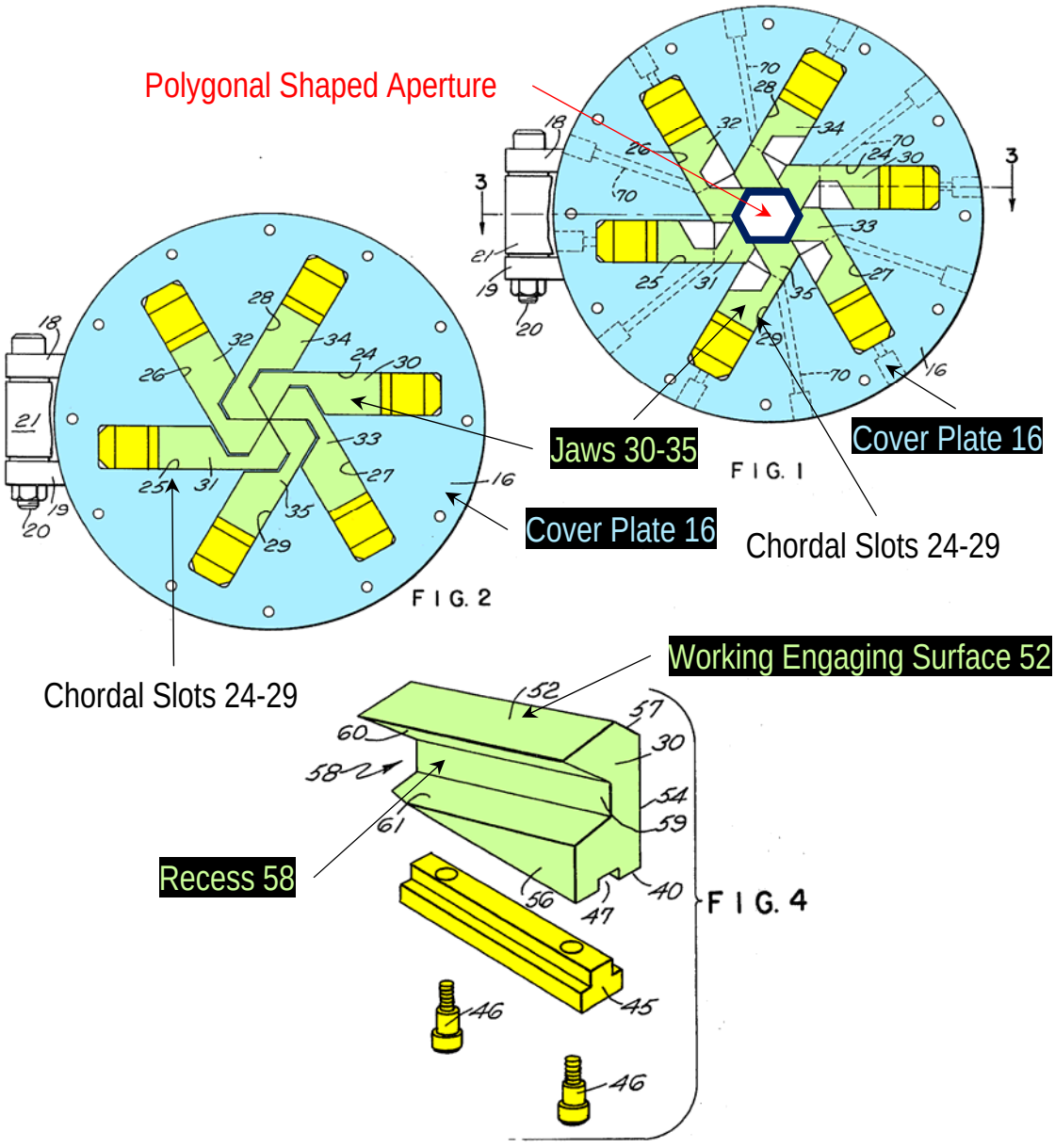


FIG. 1

FIG. 2

FIG. 4

Ex. 1008, Figs. 1, 2, 4.

As shown above, each jaw has a work-engaging surface 52, *see* Fig. 4, that faces the aperture, and together the jaws combine to form a polygonal shaped

aperture. Ex. 1008 at 1:55-58, 2:6-67. Each jaw also has a recess 58. As the jaws move radially inward, the work-engaging surface of each die will slide into the recess of the adjacent jaw, such that the aperture maintains its polygonal shape throughout. *Id.* at 1:55-60, 2:66-3:8; 4:3-7.

Baker is in the same field of endeavor as the '560 patent because it is directed to an apparatus having movable members that form a variable size aperture, like the '560 patent. Ex. 1011 ¶ 110; *see also id.* ¶¶ 81-88.

Baker is also reasonably pertinent to the problem to be solved by the '560 patent. Ex. 1011 ¶ 111. The tube pointer in Baker has jaws that cumulatively define a polygonal-shaped aperture that maintains the same polygonal configuration when increasing and decreasing the size of the aperture. Ex. 1008 at 1:55-58, 2:62-65. Further, the tube pointer disclosed in Baker aims to solve the same problem as the '560 patent. Specifically Baker's tube pointer "produces uniform points by preventing any flaring of the tube material, there being no openings in the jaws in which the flaring [of the tube] can occur." *Id.* at 1:45-48. A POSITA would have understood that the invention disclosed in Baker would result in uniform crimping forces to any object within the aperture and remedy the problem identified in the '560 patent. Ex. 1011 ¶ 111; *see also id.* ¶¶ 89-92. Baker is therefore analogous prior art. *Id.*

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

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

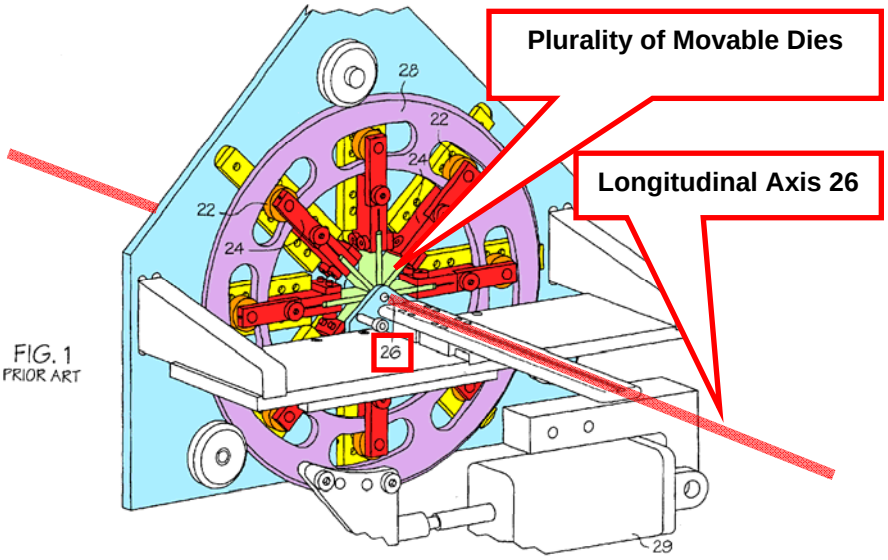
1. Claim 1

Claim 1 of the ’560 patent recites:

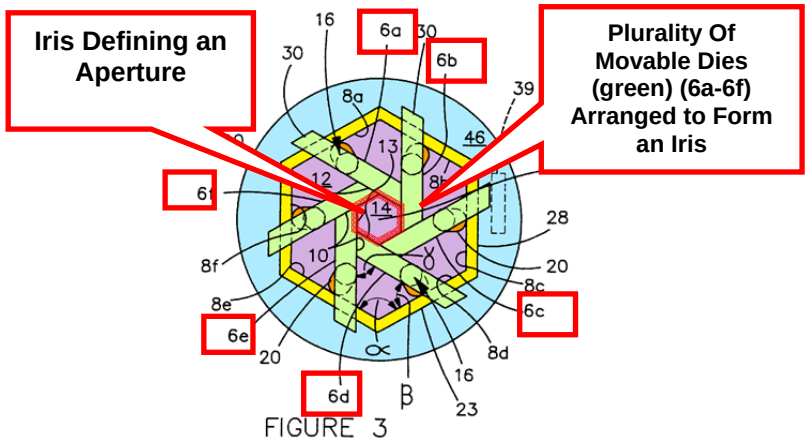
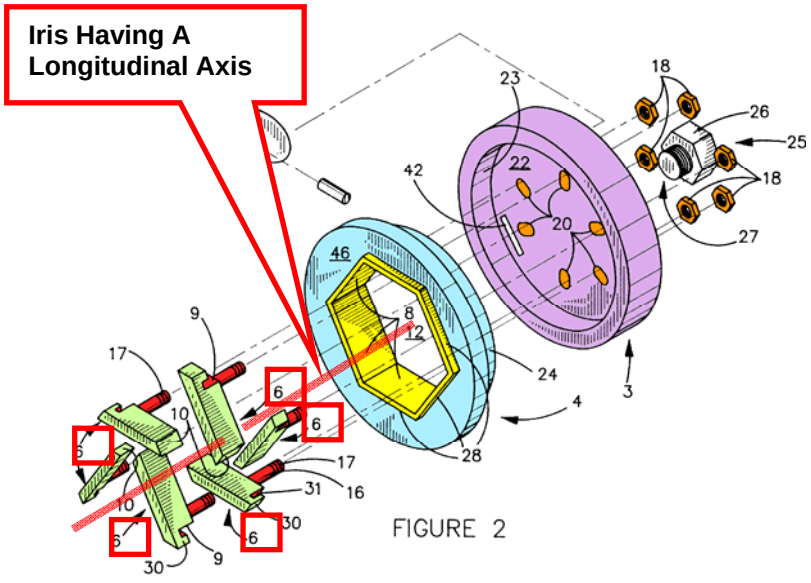
> A stent crimper comprising:
>
> a plurality of movable dies arranged to form an iris having a longitudinal axis, the iris defining an aperture, the dies disposed about the aperture and between stationary end-walls which are disposed about the longitudinal axis, at least one of the stationary end-walls 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.

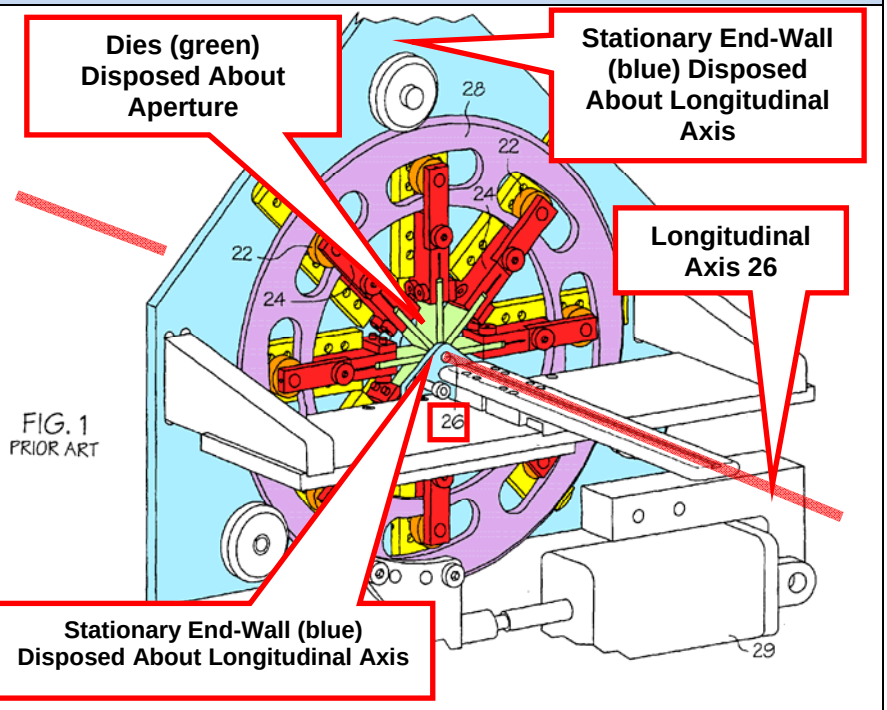
Ex. 1001 at 10:8-22.

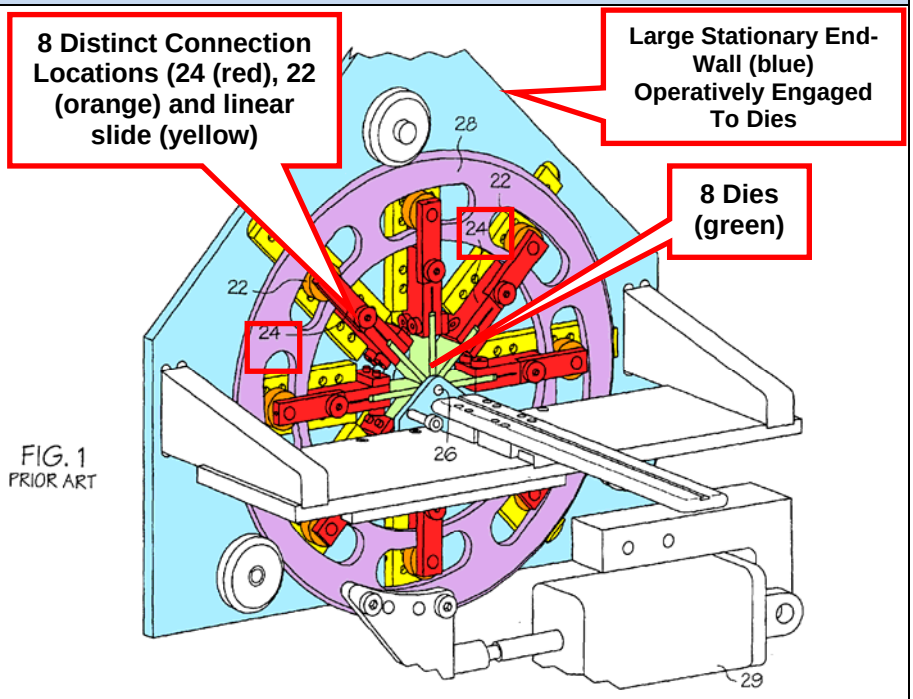
The AAPA discloses every limitation, except for the specific die configuration, which is disclosed by Sabbaghian. A detailed analysis of Claim 1 is provided in the following claim chart. *See also* Ex. 1011 ¶¶ 113-124.

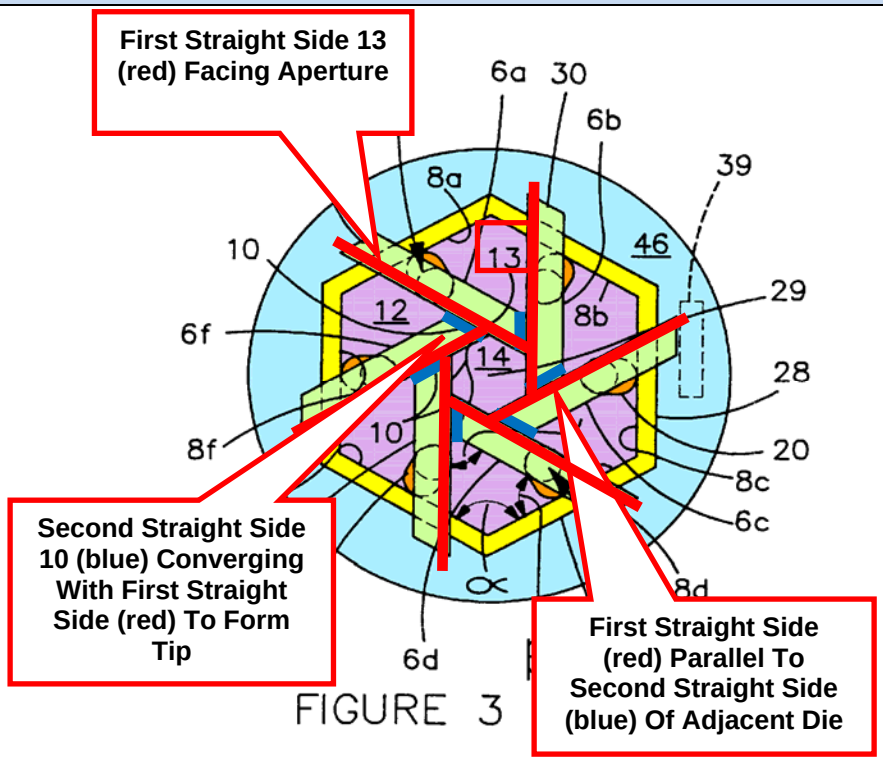
ASSERTED CLAIMS	**PRIOR ART**
[1 Preamble] A stent crimper comprising:	The AAPA discloses "[a] cam actuated stent crimper." (Ex. 1001 at 1:62.)
[1a] a plurality of movable dies arranged to form an iris having a longitudinal axis, the iris defining an aperture,	The AAPA discloses a plurality of movable dies (crimping blades) arranged about a longitudinal axis (axis of rotation) to form an aperture: "[C]rimping blade, . . . either moved inwards to apply a crimping force to the stent, or outwards to release the stent." (Ex. 1001 at 2:14-17.)  (*Id.* at Fig. 1.[5]) Sabbaghian discloses a plurality of movable dies (gripping members) arranged to form an iris having a longitudinal axis, the iris defining an aperture (gripping region): "The collar plate has . . . movably positioned inside the central opening a plurality of gripping members. Each of the gripping members has a contacting surface which

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

ASSERTED CLAIMS	PRIOR ART
	cumulatively define a gripping region." (*See* Ex. 1006 at Abstract; *see id.* at 3:56-65, 8:41-45.)  FIGURE 3  FIGURE 2 (*Id.* at Figs. 2, 3.)
[1b] the dies disposed about the aperture and between stationary end-walls which are disposed about the	The AAPA discloses dies (crimping blades) disposed about the aperture and between stationary end-walls (fixed plates) which are disposed about the longitudinal axis (axis of rotation 26):

ASSERTED CLAIMS	PRIOR ART
longitudinal axis,	 (*See* Ex. 1001. at Fig. 1; *id.* at 1:65-2:4.)
[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;	The AAPA discloses at least one of the stationary end-walls (the larger fixed plate) operatively engaged to the dies (crimping blades) at distinct connection locations (linear bearings, cam follower bearings and linear slides) such that the number of distinct connection locations and the number of dies are the same: "[R]otation of the cam plate 28 . . . simultaneously actuate[s] a like number of linear bearings 24, which have their corresponding linear tracks or rails mounted on a fixed plate. . . . Depending on the direction of rotation, the linear slides which each carry a radially disposed crimping blade, ..." (Ex. 1001 at 1:67-2:15.) As shown below, in the AAPA there are 8 dies operatively engaged to the larger stationary end wall (blue) via the 8 linear bearings 24 (red), cam follower bearings 22 (orange) and linear slides (yellow).

ASSERTED CLAIMS	**PRIOR ART**
	 (*Id.* at Fig. 1.)
[1d] 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.	Sabbaghian discloses each die (gripping member 6) having a first straight side (contacting surface 13) and a second straight side (second end 10), 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: "[E]ach gripping member 6 will further have a contacting surface 13 which provides the surface of gripping members 6 actually engaging the bold [*sic*] head." (*See* Ex. 1006 at 3:56-58.) "[G]ripping members 6 have a second end 10 which is adapted to slidingly engage adjacent gripping members 6." (*Id.* at 3:63-65; *see id.* at 7:31-40.)

ASSERTED CLAIMS	PRIOR ART
	 FIGURE 3 (*Id.* at Fig. 3.)

2. Claim 10

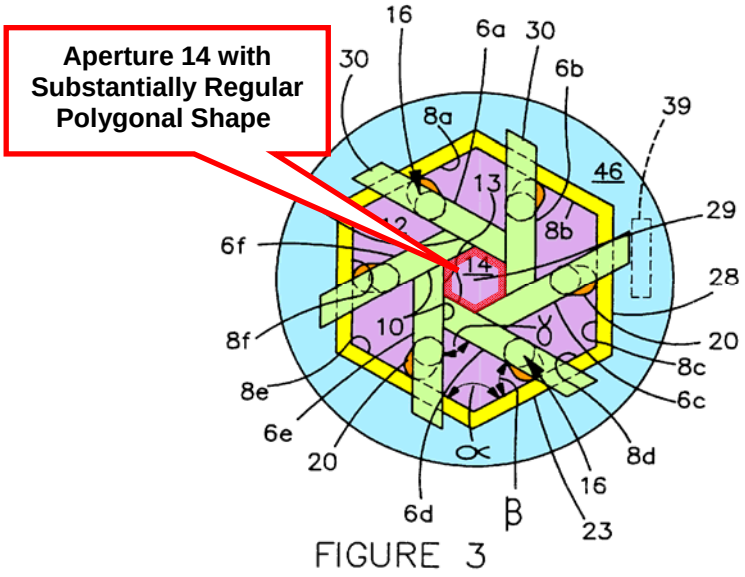
Independent Claim 10 recites limitations substantially similar to those in Claim 1, but adds limitations directed to (1) an aperture "having a substantially regular polygonal shape;" (2) "dies having an inward facing straight side which faces the longitudinal axis of the aperture both when the dies move 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."

The AAPA discloses every limitation of Claim 10 with the exception of limitations (1) and (2) above, which are disclosed by Sabbaghian. A detailed analysis of Claim 10 is provided in the following claim chart. *See also* Ex. 1011 ¶¶ 126-132.

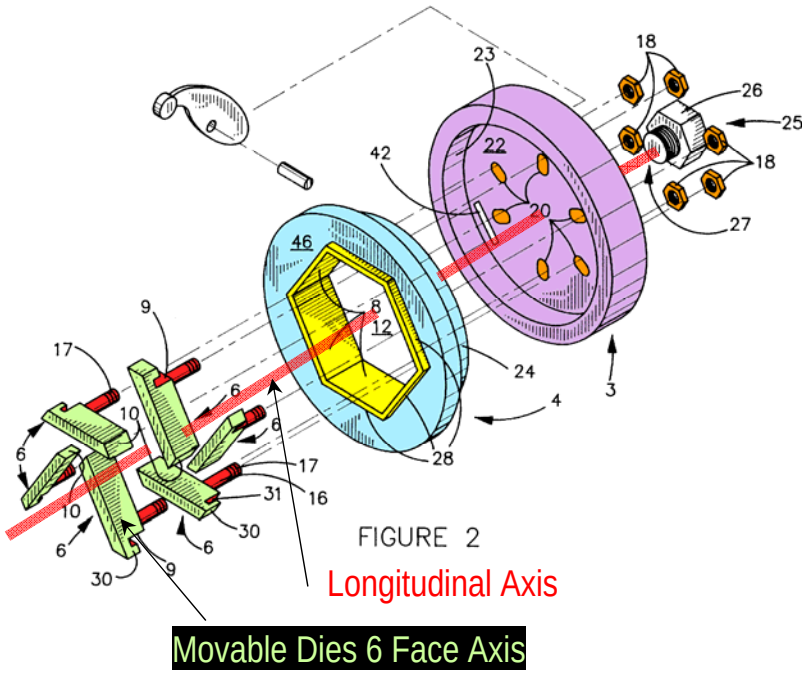
ASSERTED CLAIMS	**PRIOR ART**
[10 Preamble] A stent crimper comprising:	*See* Claim [1 Preamble].
[10a] a plurality of movable dies arranged to form an iris,	*See* Claim [1a].
[10b] the dies disposed about an aperture,	*See* Claim [1b].
[10c] the aperture having a longitudinal axis	The AAPA discloses the aperture having a longitudinal axis: *See* Claim [1a].[6]

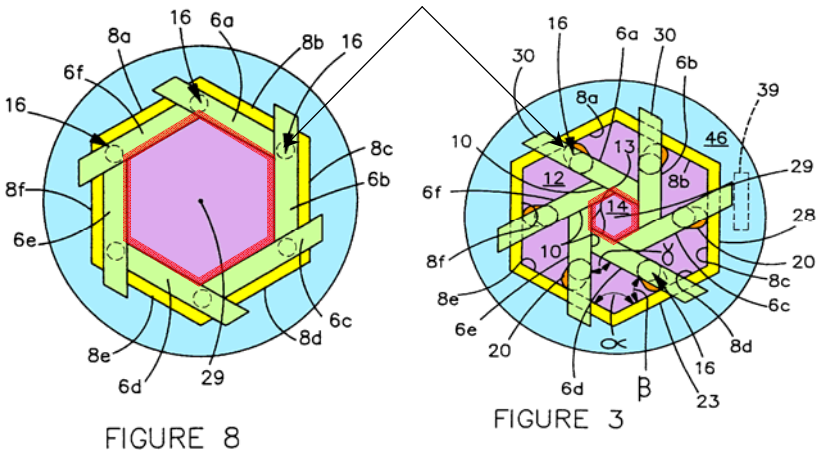
[6] Claim [10c] recites "an aperture having a longitudinal axis" and Claim [1a] recites "an iris having a longitudinal axis." Because the iris defines the aperture,

ASSERTED CLAIMS	PRIOR ART
and a substantially regular polygonal shape,	Sabbaghian discloses the aperture (gripping region) having a substantially regular polygonal shape: "[T]his will maintain the gripping members 6 in the desired polygonal configuration." (Ex. 1006 at 3:41-43; *see id.* at 1:56-58.)  FIGURE 3 (*Id.* at Fig. 3.)
[10d] each of the dies having an inward	*See* Claim [1d].[7]

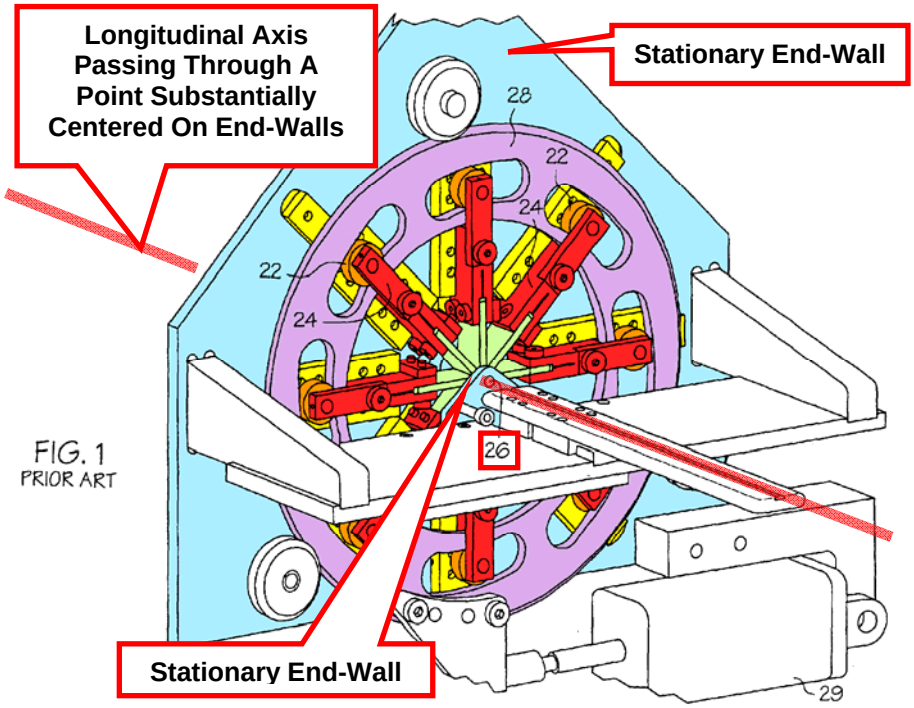
disclosure in the AAPA and Sabbaghian of an iris having a longitudinal axis also discloses an aperture having a longitudinal axis

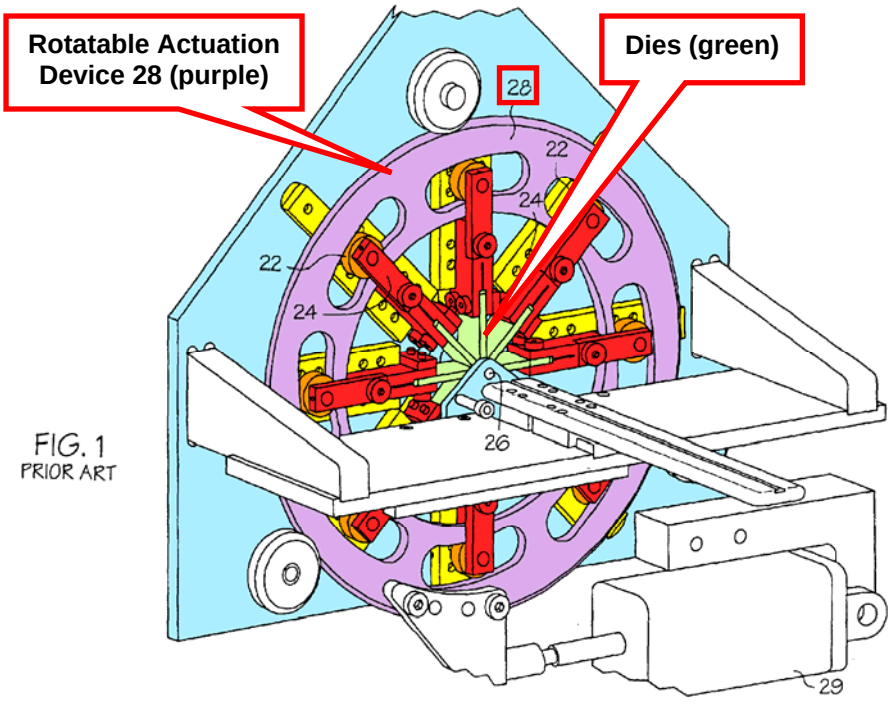
[7] Claim [10d] recites "an inward facing straight side which faces the longitudinal axis of the aperture" and Claim [1d] recites "a portion of the first straight side of each die faces the aperture." Because the longitudinal axis of the aperture is located central to the aperture, disclosure in Sabbaghian 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**
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,	Sabbaghian discloses each of the dies (gripping members) having an inward facing straight side which faces the longitudinal axis of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture:  (*Id.* at Fig. 2.) Sabbaghian teaches that the polygonal shape of the aperture is maintained as the dies move in or out. "[T]his will maintain the gripping members 6 in the desired polygonal configuration as they open and close." (*Id.* at 3:41-43; *see id.* at 1:56-58.) "The angles formed on first end 9 and second end 10 will maintain gripping members 6 in the orientation previously

ASSERTED CLAIMS	PRIOR ART
	mentioned where gripping members 6 remain parallel to an adjacent sidewall 8 and the sidewall 8 opposite the adjacent sidewall 8, as the gripping members move toward and away from the center point 29." (Ex. 1006 at 4:3-8.) "Because of the angles formed on the ends 9 and 10 of gripping members 6, gripping members 6 remain parallel to their adjacent parallel sidewalls 8 the entire time they are closing." (*Id.* at 4:63-65.) Maintaining the polygonal shape results in the first straight side facing the longitudinal axis of the aperture while moving in or out. Movable Dies 6a-6f Face Axis  FIGURE 8 FIGURE 3 **Inward Facing Straight Side Faces Aperture When Dies Move To Maximize Or Minimize Aperture** (*Id.* at Figs. 3, 8.)
[10f]	*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
the dies between two stationary end-walls disposed about the longitudinal axis,	
[10g] the longitudinal axis passing through a point substantially centered on the end-walls,	The AAPA discloses the longitudinal axis passing through a point substantially centered on the end-walls (fixed plates):  FIG. 1 PRIOR ART (*Id.* at Fig. 1.) To the extent the AAPA is viewed as not disclosing the longitudinal axis of the aperture passing through a point substantially centered on the end-walls because the walls are not symmetrical, a POSITA would have had a reason, basis, or motivation to place the aperture centered on the end walls. Ex. 1011 ¶ 129. Placing the aperture central to the walls is a general practice in the mechanical arts because it provides the apparatus with the most stable positioning of

ASSERTED CLAIMS	PRIOR ART
	the movable dies and distributes the forces equally over the supporting structures. *Id.* A POSITA would have had a reason, basis, or motivation to put the longitudinal axis of the die aperture in the center of the AAPA for added stability. *Id.* Moreover, placement of the aperture with respect to the end walls is merely a design choice. *Id.*
[10h] a rotatable actuation device coupled to the dies,	The AAPA discloses a rotatable actuation device coupled to the dies: "[R]otation of the cam plate 28 transmits equal radial displacements to the cam follower bearings 22, to simultaneously actuate a like number of linear bearings 24, which have their corresponding linear tracks or rails mounted on a fixed plate." (Ex. 1001 at 1:67-2:4.)  (*Id.* at Fig. 1.)
[10i] rotation of the actuation device	The AAPA as modified by Sabbaghian discloses rotation of the actuation device causing the inward facing straight sides of the dies to move inward and reduce the size of the

ASSERTED CLAIMS	PRIOR ART
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.	aperture or outward so as to increase the size of the aperture: "Depending on the direction of rotation, the linear slides which each carry a radially disposed crimping blade, are either moved inwards to apply a crimping force to the stent, or outwards to release the stent." (Ex. 1001 at 2:14-17.)

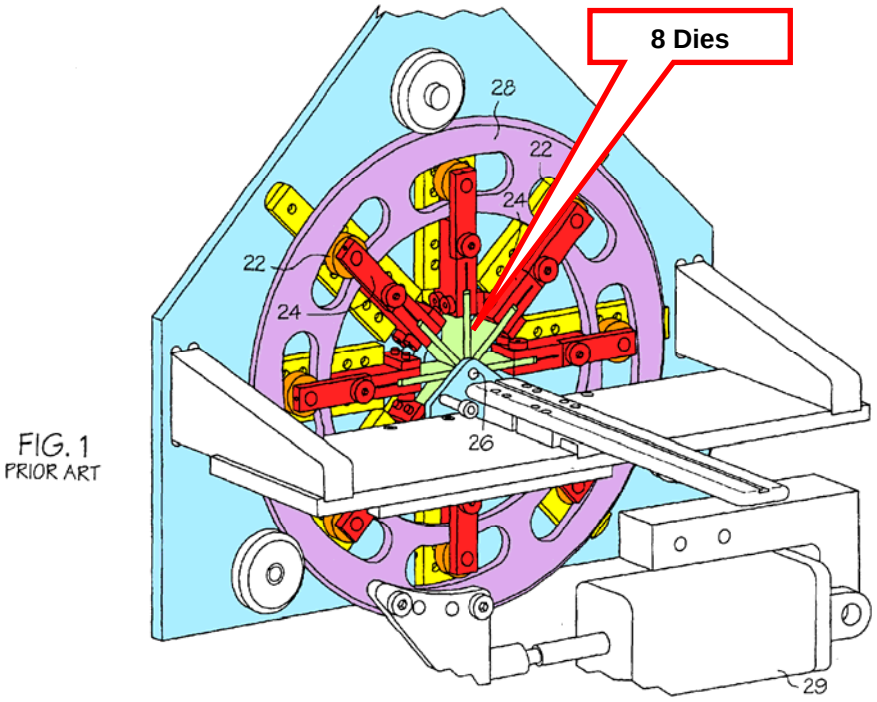
3. Claim 18

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," which is disclosed by the AAPA.

A detailed analysis of Claim 18 is provided in the following claim chart. *See also* Ex. 1011 ¶¶ 133-134.

ASSERTED CLAIMS	PRIOR ART
[18 Preamble] A stent crimper comprising:	*See* Claim [1 Preamble].
[18a]	The AAPA and Sabbaghian disclose movable dies arranged to

[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 Sabbaghian of a first straight side facing the aperture equally supports disclosure of an inward facing flat portion.

ASSERTED CLAIMS	PRIOR ART
eight or more movable dies arranged to form an iris,	form an iris: *See* Claim [1a]. The AAPA discloses eight or more movable dies: "[T]he linear slides [] each carry a radially disposed crimping blade[.]" (Ex. 1001 at 2:14-15.)  FIG. 1 PRIOR ART (*Id.* at Fig. 1.) There are eight linear slides 24 (red) depicted, so there are also eight blades (dies) (green).
[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	*See* Claim [1a], [10c].

ASSERTED CLAIMS	**PRIOR ART**
longitudinal axis,	
[18d] each die having an inward facing flat portion which faces the longitudinal axis of the aperture	*See* Claim [1d], [10d].
[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 dies).
[18g] the stationary end-walls disposed about the longitudinal	*See* Claim [1b].

ASSERTED CLAIMS	**PRIOR ART**
axis,	
[18h] the iris comprising at least eight of the inward facing flat portions,	The AAPA in view of Sabbaghian discloses at least eight of the inward facing flat portions: *See* Claim 1[a] & [d] (movable dies arranged to form an iris and a portion of the first straight side of each die faces aperture), Claim 18[a] (eight dies)
[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	*See* Claim [10i].

ASSERTED CLAIMS	PRIOR ART
increase the size of the aperture.	

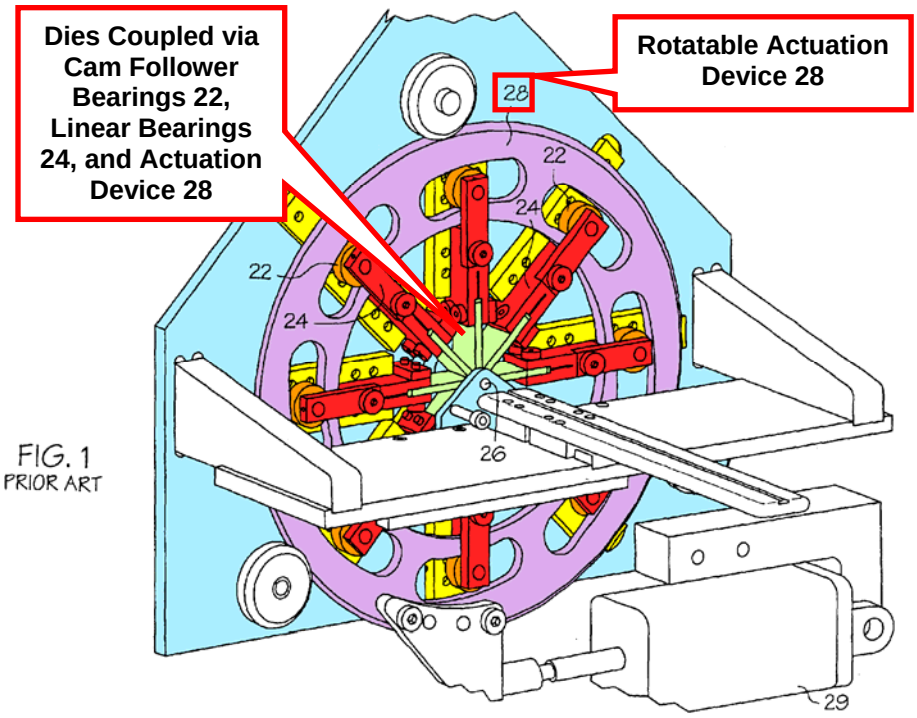
4. Claim 27

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." Both the AAPA and Sabbaghian disclose this limitation. A detailed analysis of Claim 27 is provided in the following claim chart. *See also* Ex. 1011 ¶¶ 135-136.

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].

[10] Claim 27 differs from the previous claims because it recites "blades" instead of "dies," but those terms are used interchangeably.

ASSERTED CLAIMS	**PRIOR ART**
[27b] the aperture having a longitudinal axis and being substantially polygonal,	*See* Claim [10c].
[27c] the blades between stationary end-walls substantially centered about the longitudinal axis,	*See* Claim [1b] (dies between stationary end-walls), Claim [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,	The AAPA discloses the blades (crimping blades) coupled to one another so as to be movable inward or outward simultaneously: Each die in the AAPA is connected to the same rotatable actuation device 28 such that when one die moves, they all move together simultaneously. "[R]otation of the cam plate 28 transmits equal radial displacements to the cam follower bearings 22, to simultaneously actuate a like number of linear bearings 24, which have their corresponding linear tracks or rails mounted on a fixed plate." (Ex. 1001 at 1:67-2:4.) "Depending on the direction of rotation, the linear slides which each carry a radially disposed crimping blade, are either moved inwards to apply a crimping force to the stent, or outwards to release the stent." (*Id.* at 2:14-17.)

ASSERTED CLAIMS	PRIOR ART
	 *Id.* at Fig. 1. Sabbaghian also discloses the blades (gripping members 6) coupled to one another so as to be movable inward or outward simultaneously:

ASSERTED CLAIMS	PRIOR ART

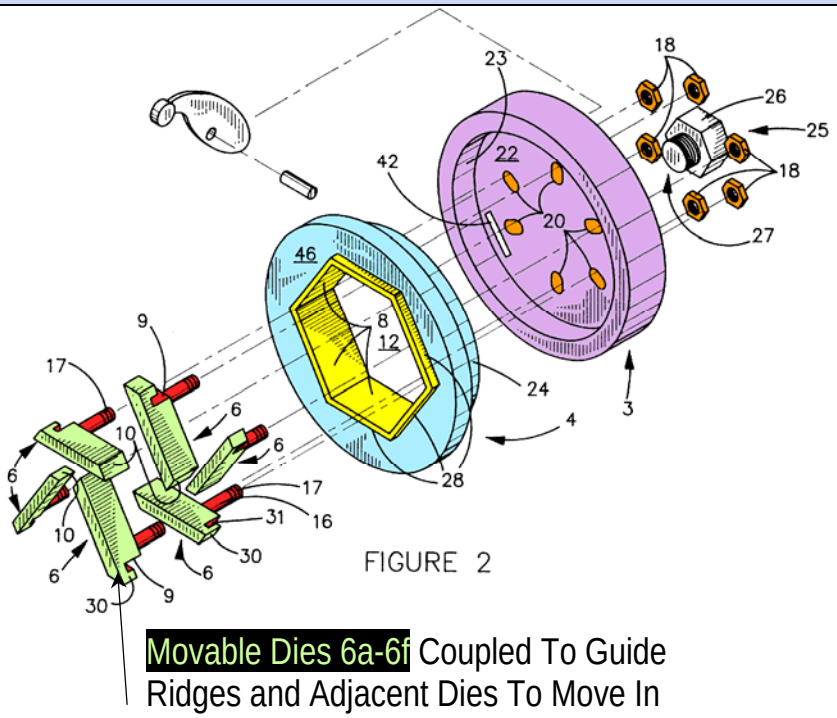


FIGURE 2

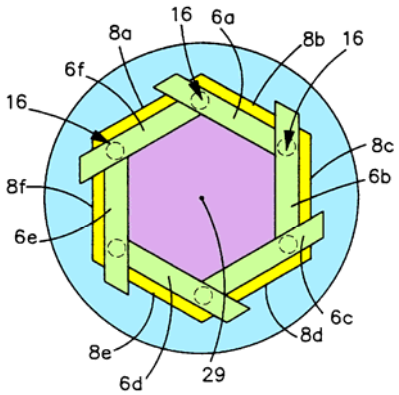
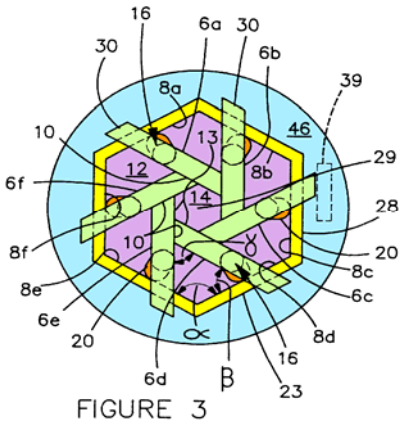
Movable Dies 6a-6f Coupled To Guide Ridges and Adjacent Dies To Move In Or Out Simultaneously

(Ex. 1006 at Fig. 2)

The Sabbaghian dies 6 (green) have an end 10 that slidingly engages an adjacent gripping member. Rotation of the base plate 3 (purple) relative to collar plate 4 (blue) will move all dies cooperatively inward or outward simultaneously.

"Returning to FIG. 2, it can be seen that gripping members 6 have a second end 10 which is adapted to slidingly engage adjacent gripping members 6 as suggested in FIG. 3." (Ex. 1006 at 3:63-65.)

"In operation, gripping members 6 will close (i.e. move toward center point 29) or open (i.e. move toward sidewalls 8) by the relative rotation between base plate 3 and collar plate 4. Viewing FIG. 3, it will be seen that movement of base plate 3 in a clockwise direction while collar plate 4 is held stationary will cause gripping members 6 to open or to move toward

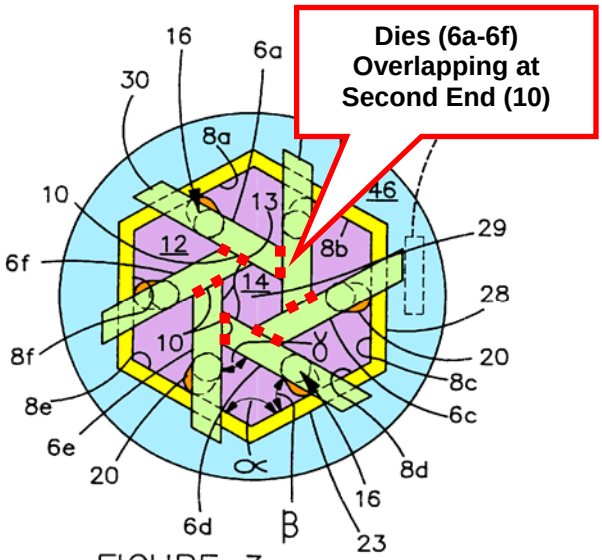
ASSERTED CLAIMS	PRIOR ART
	their respective adjacent sidewalls 8." (*Id.* at 4:39-45, 4:58-61.) "[E]ach of said gripping members being connected to said base plate and having a first end adapted to engage one of said internal sidewalls and a second end adapted to engage another one of said plurality of gripping members such that relative rotation of said base plate and said collar plate causes said first ends to slide along said internal sidewalls and said second ends to slide along another gripping member thereby adjusting an area within said gripping region." (*Id.* at 7:36-45.)  FIGURE 8  FIGURE 3 (*Id.* at Figs. 3 (gripping members in partially open position, 8 (gripping members in fully open position)).
[27e] movement of the blades outward increasing the size of the aperture,	*See* Claim [10i].
[27f] movement of the blades inward decreasing the	*See* Claim [10i].

ASSERTED CLAIMS	PRIOR ART
size of the aperture,	
[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 X.A.1 and .2, but adds the limitation "overlapping movable dies." Sabbaghian discloses this limitation. A detailed analysis of Claim 37 is provided in the following claim chart. *See also* Ex. 1011 ¶¶ 137-139.

[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 Sabbaghian supporting Claim [10e] equally supports Claim [27g] because the aperture is maximized when it is sized to receive a stent.

ASSERTED CLAIMS	**PRIOR ART**
[37 Preamble] A stent crimper comprising:	*See* Claim [1 Preamble].
[37a] a plurality of overlapping movable dies arranged to form an iris,	Sabbaghian discloses a plurality of movable dies arranged to form an iris. *See* Claim [1a] Sabbaghian discloses overlapping movable dies (gripping members 6): "Returning to FIG. 2, it can be seen that gripping members 6 have a second end 10 which is adapted to slidingly engage adjacent gripping members 6 as suggested in FIG. 3." (Ex. 1006 at 3:63-65.)  FIGURE 3 (*Id.* at Fig. 3). As depicted above, each die 6 (green) has a second side 10 that slidingly engages, and overlaps, a portion of the adjacent die that faces the aperture (red dots)

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 X.A.1 and .2.[12] A detailed analysis of Claim 40 is provided in the following claim chart. *See also* Ex. 1011 ¶¶ 140-141.

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 VII.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 the AAPA 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 the AAPA 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, the AAPA in combination with Sabbaghian discloses every limitation of Claims 2 and 28. *See* Part X.A.2; Ex. 1011 ¶ 142.

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, the AAPA in combination with Sabbaghian discloses every limitation of Claims 6 and 15. *See* Part X.A.3; Ex. 1011 ¶ 143.

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 the AAPA. The dies in the AAPA are all configured to move cooperatively inward because each one is linked to the same rotatable actuation device 28 such that when one die moves, they all move together at the same time. Ex. 1001 at 1:68-2:4; 2:14-17. *See also* Ex. 1011 ¶¶ 144-145, 147.

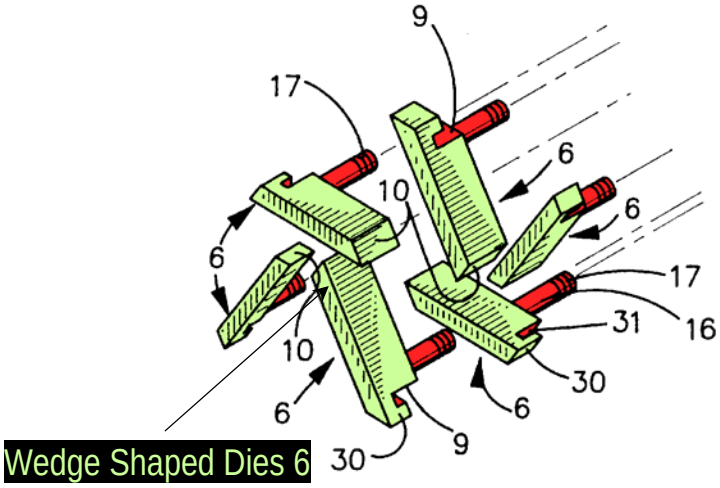
The dies in Sabbaghian are also configured to move cooperatively because each one has an end 10 that slidingly engages an adjacent die. Ex. 1006 at 3:63-65.

[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 VII.C.

Rotation of the base plate 3 (purple) relative to the collar plate 4 (blue) will simultaneously move all dies cooperatively inward together at the same time. *Id.* at 3:39-42, 3:58-5:1, 7:36-45, Figs. 2, 3. *See also* Ex. 1011 ¶¶ 146-147.

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 Sabbaghian:



Ex. 1006, Fig. 2 (excerpt). Sabbaghian explains that "gripping members 6 have a second end 10 which is adapted to slidingly engage adjacent gripping members 6 . . . this adaptation is carried out by forming an angle on second end 10." *Id.* at 3:63-67. The disclosed angle formed by the gripping members results in a wedge-shaped die. Ex. 1011 ¶¶ 148-150.

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*, No. 2015-1533, slip op. at 13-14 (Fed. Cir. June 15, 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*.

It would have been obvious to a POSITA to have provided the AAPA with dies as described in the challenged claims in light of the teachings in Sabbaghian. Ex. 1011 ¶¶ 151-164.

The '560 patent was attempting to solve the problem of uneven crimping forces that could damage a stent. Ex. 1001 at 1:42-55; 2:27-30. In particular, the Applicant identified uneven crimping forces applied by elongate portions poking radially inward as a drawback with the AAPA. Ex. 1002 at 65.

The Applicant was not the first to identify uneven crimping forces as problematic when crimping stents. This problem was well known to a POSITA prior to September 22, 1999. *See* Ex. 1011 ¶ 153 (citing Ex. 1014 at 1:27-48 ("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. 1015 at 1:59-2:63 ("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. 1016 at 1:39-2:14 ("Moreover, non-uniformity of the crimping may be experienced[.]"); Ex. 1017 at 1:65-2:18 ("[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. 1018 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 the AAPA suffered from this well-known problem, and would have had a reason, basis, or motivation to improve upon the AAPA design. Ex. 1011 ¶ 154. In doing so, a POSITA would have looked to how others solved the problem of uneven crimping forces. *Id.*

The problem of uneven crimping forces existed in other crimping applications, such as crimpers for pointing tubes and crimping electrical connections. *Id*. ¶¶ 155-160 (citing Exs. 1003, 1008, 1024). In particular, crimpers that, like the AAPA, used elongated dies equally spaced around an aperture that moved radially inward to crimp a device were known to apply uneven crimping forces. *Id.* ¶¶ 157-158 (citing Exs. 1008, 1020, 1021, 1022, 1025).

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. 1003 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. 1008 at 1:13-20, 1:33-37 (discussing Exs. 1020, 1021. 1022). 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 with the AAPA in the same manner that others, such as Baker, solved the problem with other prior art crimpers. Ex. 1011 ¶161. This would have been nothing more than applying a known technique to a known device ready for improvement to yield predictable results. *Id.* A POSITA would have had a reason, basis, or motivation to use dies that form a variable size polygonal aperture with no gaps in between, like the dies in Sabbaghian, to crimp a stent and thereby obtain the predictable result of even crimping forces. *Id.*

Indeed, polygonal die configurations were known in the medical device field, for example in balloon swagers that helped form the sleeve of the balloon

used on the delivery catheters. Ex. 1011 ¶ 162 (citing Ex. 1019, Fig. 8 (showing an iris formed by 10 wedge-shaped dies), 6:8-10 ("The iris 44 is closed around the sleeve and compressed under a compressive force for about 1 to 30 seconds.")).

Using the polygonal die configuration of Sabbaghian is a substitution of one known element (elongate dies that poke radially inward) for another (dies that form a variable sized polygonal aperture) to obtain the predictable result of even crimping forces with no potential for flaring between the dies. Ex. 1011 ¶ 163.

In addition, the AAPA and Sabbaghian operate on the same mechanical principle. The AAPA uses blades that are coupled to a rotating cam plate and slides on a stationary wall. Rotation of the cam plate causes the crimping blades to slide linearly inward or outward. Ex. 1001 at 1:65-2:17. Similarly, Sabbaghian has gripping members that are coupled to a rotating collar plate and guide ridges on a stationary base plate. Ex. 1006 at 3:30-52, 4:8-22. Rotating the collar plate causes the gripping members to slide linearly along the guide ridges to reduce or increase the size of the aperture. Ex. 1006 at 4:39-41.

A POSITA would have understood that incorporating the gripping member configuration of Sabbaghian into the stent crimper of the AAPA requires only the exercise of ordinary skill. Ex. 1011 ¶ 164. A POSITA would have realized that Sabbaghian not only provided a solution to the deficiencies in the AAPA, but could be readily combined with that art. *Id.* Further, combination of these familiar

elements would have yielded a predictable result, namely a crimper that applies a uniform crimping force to a stent. *Id*.

Indeed, during prosecution the Examiner rejected the pending claims based on the AAPA stent crimper in view of Whitesell, which disclosed radial pliers or a wrench for gripping cylindrical workpieces. Ex. 1002 at 74-76, Ex. 1003 1:28-42, 3:40-41. The Applicant never argued that combining the AAPA with prior art wrenches, pliers, or other gripping tools was improper or beyond the knowledge and skill of a POSITA.

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

1. Claim 39

Independent Claim 39 recites limitations substantially similar to those previously recited in Claim 1 and 40, 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."

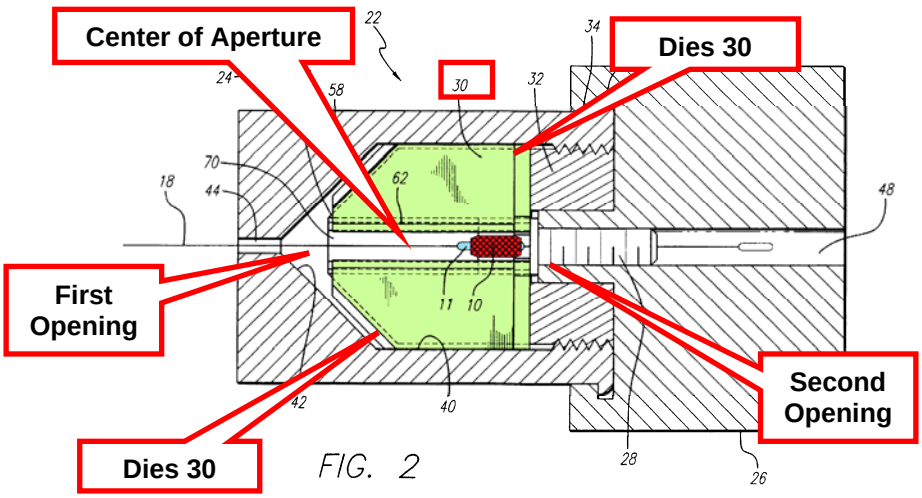
These limitations are inherent in or obvious in view of the AAPA. The AAPA is a stent crimper, and therefore would have been constructed to accommodate a balloon catheter and stent within the crimping aperture. Ex. 1011 ¶ 166. An aperture having a center and openings on both ends, *i.e.*, a first opening and a second opening, is necessary to permit the distal and proximal portions of the

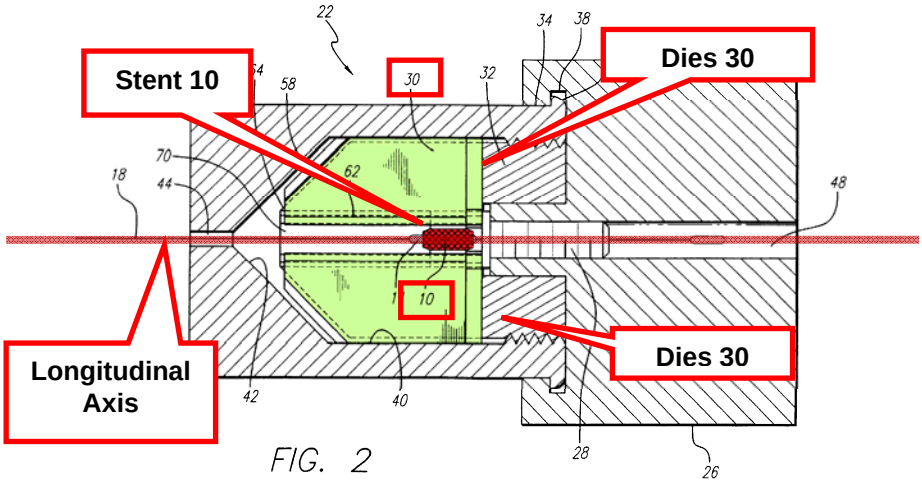
balloon catheter to extend outside the crimping aperture while accommodating the stent and balloon portion of the catheter within the aperture. *Id*.

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. 1011 ¶ 167.

To the extent these limitations are not viewed as inherent in or obvious in view of the AAPA, Morales also discloses these limitations. Ex. 1011 ¶¶ 168-69. A detailed analysis of Claim 39 is provided in the following claim chart. *See also* Ex. 1011 ¶ 170.

ASSERTED CLAIMS	**PRIOR ART**
[39 Preamble] A stent crimper comprising:	*See* Claim [1 Preamble].
[39a] a plurality of movable dies arranged to form an iris disposed about an aperture,	*See* Claim [1a] (plurality of movable dies arranged to form an iris), [1b] (dies disposed about the aperture).

ASSERTED CLAIMS	PRIOR ART
[39b] the aperture having a center and a first opening and a second opening,	Morales discloses an aperture (between teeth 30) having a center and a first opening and a 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. 1007 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." (Ex. 1007 at 7:33-35.)  FIG. 2 (*Id.* at Fig. 2.)
[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	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. 1007 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,

ASSERTED CLAIMS	PRIOR ART
opening and the second opening,	thereby accommodating the lengths of the stents currently on the market." (*Id.* at 5:5-9.)  FIG. 2 (*Id.* at Fig. 2.).
[39d] each die in communication with an actuation device,	*See* Claim [40d].
[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	*See* Claim [1d].

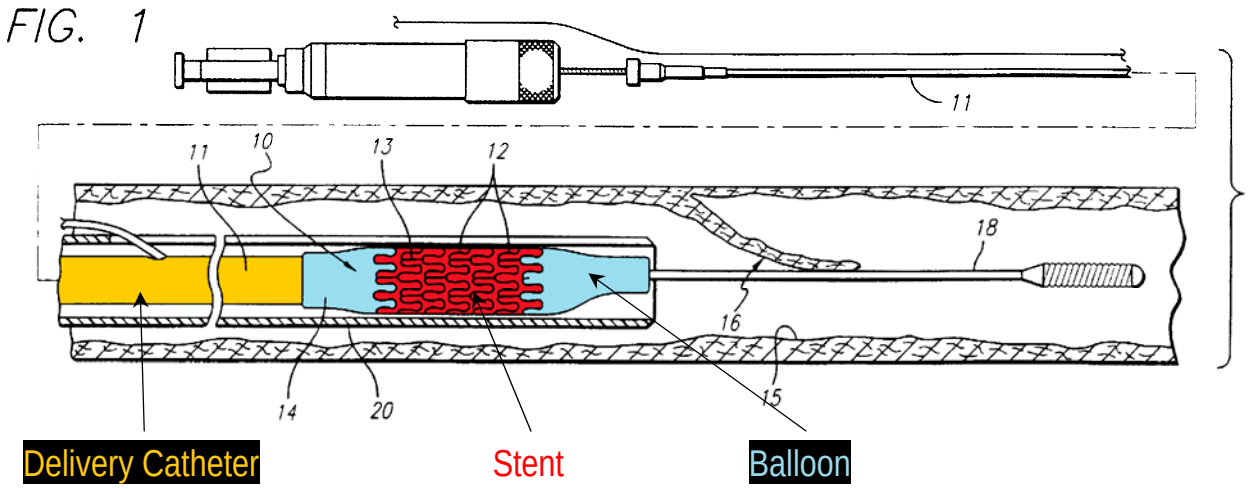
ASSERTED CLAIMS	PRIOR ART
and a second straight side, the first straight side and the second straight side converging to form a tip; wherein a portion of the first straight side of each die faces the aperture, each first straight side parallel to the second side of an adjacent die.	

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 inherent in or obvious in view of the AAPA. The AAPA is 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. 1011 ¶ 172. 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 also found this limitation inherent during prosecution. Ex. 1002 at 75.

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



Ex. 1007, 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 6:22-25, 5:64-66. *See also* Ex. 1011 ¶¶ 173-174.

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 inherent in or obvious in view of the AAPA. The AAPA is a stent crimper. A POSITA at the time of the invention would have been aware of

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

the problems resulting from uneven stent crimping. Ex. 1011 ¶ 176. To avoid these problems, stent crimpers were designed and constructed to accommodate at least, and typically more than, the entire length of a stent within the die aperture to perform stent crimping. *Id*. Notably, the Examiner found that the AAPA taught this limitation during prosecution. Ex. 1002 at 75.

To the extent this limitation is viewed as not inherent in or obvious in view of the AAPA, Morales (discussed above) discloses an entire stent 10 (red) disposed within an aperture formed by dies 30 (green). *See* X.B.II; *see also* Ex. 1011 ¶¶ 177-178.

4. Reason, basis, or motivation to combine

It would have been obvious to a POSITA to have provided the AAPA in view of Sabbaghian with the additional limitations of Claims 11, 17, 19, 26, 34, 35, and 39 based on the teachings in Morales.

The AAPA is a stent crimper and Morales is a stent crimper. It would have been obvious as a matter of common sense to use the AAPA 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 balloon catheter is the intended purpose of a stent crimper. Ex. 1011 ¶¶ 179-180.

Moreover, a POSITA would have had a reason, basis, or motivation to provide the AAPA 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 disclosed in Morales. Ex. 1011 ¶ 181. Problems with uneven crimping forces were well known. *Id.* A POSITA would have had a reason, basis, or motivation to ensure that the entire length of the stent resided within the aperture while crimping to impart the most even crimping forces possible. *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.*

C. Ground 3: Claims 1, 2, 6, 8-10, 14, 15, 18, 23, 25, 27, 28, 31, 33, 37, and 40 Are Invalid As Obvious Over the AAPA In View Of Baker

Ground 1 discussed how the AAPA discloses every limitation of Claims 1, 2, 6, 8-10, 14, 15, 18, 23, 25, 27, 28, 31, 33, 37, and 40, except for certain limitations that are disclosed by Sabbaghian. However, Sabbaghian is only one of many patents disclosing the claim limitations missing from the AAPA. As discussed below, Baker also discloses the limitations missing from the AAPA. The following sections address only the limitations missing from the AAPA;

please refer to Ground 1 for a discussion of how the AAPA discloses the remaining limitations and for the reason, basis, and motivation to combine.

1. Claim 1

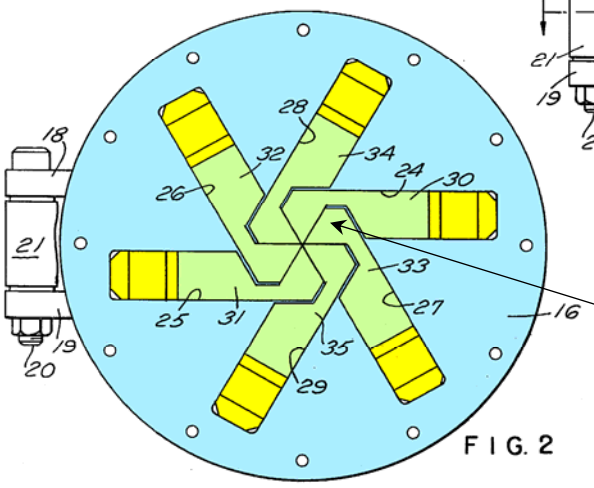
Baker discloses:

> [1a] a plurality of movable dies arranged to form an iris having a longitudinal axis, the iris defining an aperture

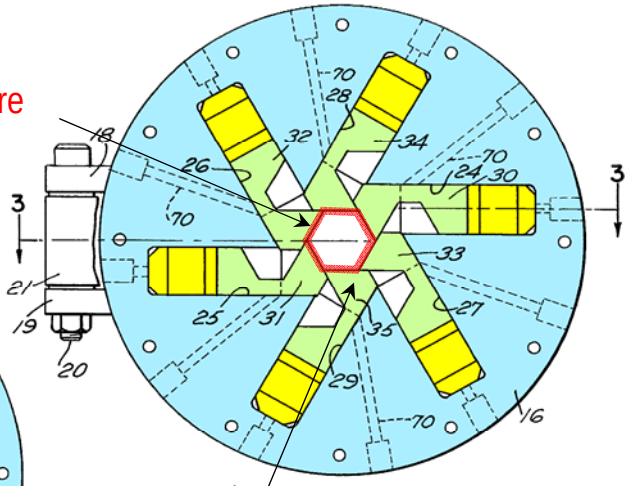
> [1d] each die having a first straight side and a second straight side, the first straight side and the second straight side convering [*sic*] to form a tip; wherein a portion of the first straight side of each die faces the aperture, each first straight side parallel to the second side of an adjacent die.

As shown below, the jaws 30-35 (dies) in Baker fit together to form an iris defining an aperture. Ex. 1008 at Abstract, 2:40-43. Each jaw has a work-engaging surface 52 (first straight side) and recess 58 with an entering wall 60 (second straight side) that converge to form a tip. *Id.* at 2:66-3:8. The work-engaging surface 52 (first straight side) of one jaw is parallel to the entering wall 60 (second straight side) of the adjacent jaw. *Id*. at Figs. 1-2. As seen in the progression from Figure 1 to Figure 2 below, the jaws are arranged so that the work-engaging surface 52 of one jaw will slide on the adjacent entering wall 60 until the jaw arrangement completely closes. *Id.* at Figs. 1, 2; *id.* 3:3-8.

Iris Defining Aperture



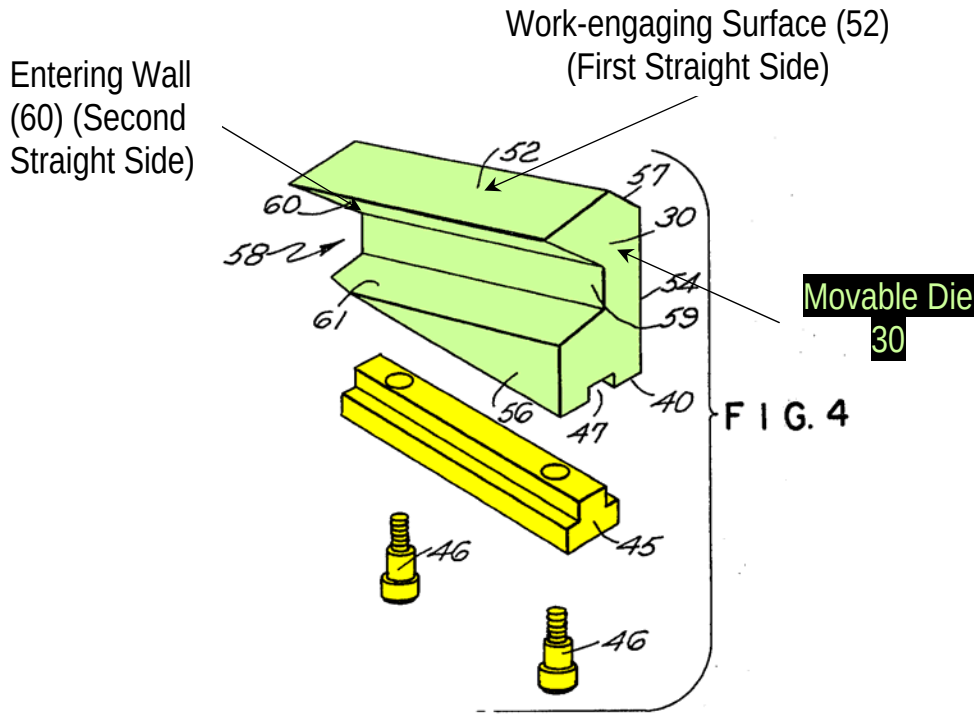
F I G. 2



F I G. 1

a) Movable Dies (30-35) Form Iris Defining Aperture
b) First Straight Side Faces Aperture
c) First And Second Straight Sides Converge To Form Tip
d) First And Second Sides Of Adjacent Dies Are Parallel

Ex. 1008 at Figs. 1-2.



Ex. 1008 at Fig. 4.

For the reasons stated in Ground 1, it would have been obvious to a POSITA to have provided the AAPA with dies as described in Claim 1 in light of the teachings in Baker in order to provide a variable size polygonal aperture that would apply uniform crimping forces to a stent. *See* Part X.A.11; *see also* Ex. 1011 ¶¶ 183-185.

2. Claim 10

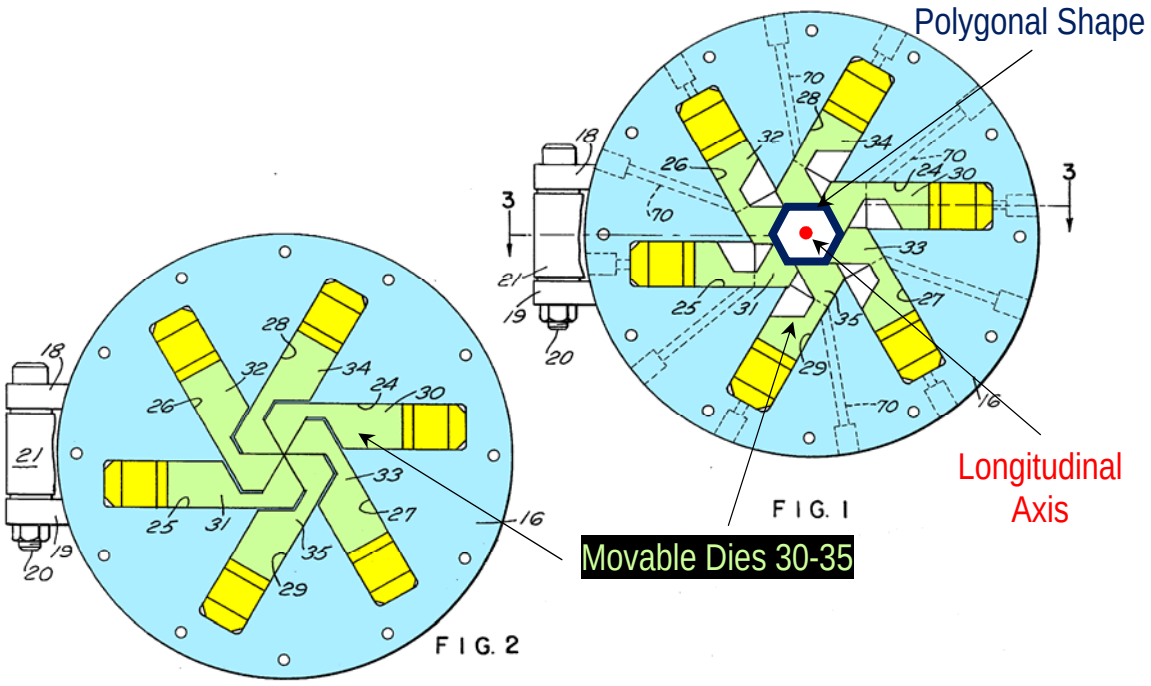
Baker discloses:

[10c] the aperture having a longitudinal axis and a substantially regular polygonal shape,

[10d-e] 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,

As shown below, the aperture in Baker has a substantially regular polygonal shape.



Ex. 1008 at Figs. 1, 2. The jaws have a work-engaging surface 52 (inward facing straight side) which faces the longitudinal axis of the aperture both when the jaws move to maximize the aperture and when the dies move to minimize the aperture. Ex. 1008 at 1:55-58 ("These jaws are interfitted to permit them to move radially inward and outward and have work-engaging surfaces which form the tube into a polygonal cross sectional shape."); *see also id.* at 2:61-67. *See also* Ex. 1011 ¶¶ 186-188.

3. Claim 27

Baker discloses:

[27d] the blades coupled to one another so as to be movable inward or outward simultaneously,

As shown below, the jaws in Baker are coupled to one another such that they are movable inward or outward simultaneously.

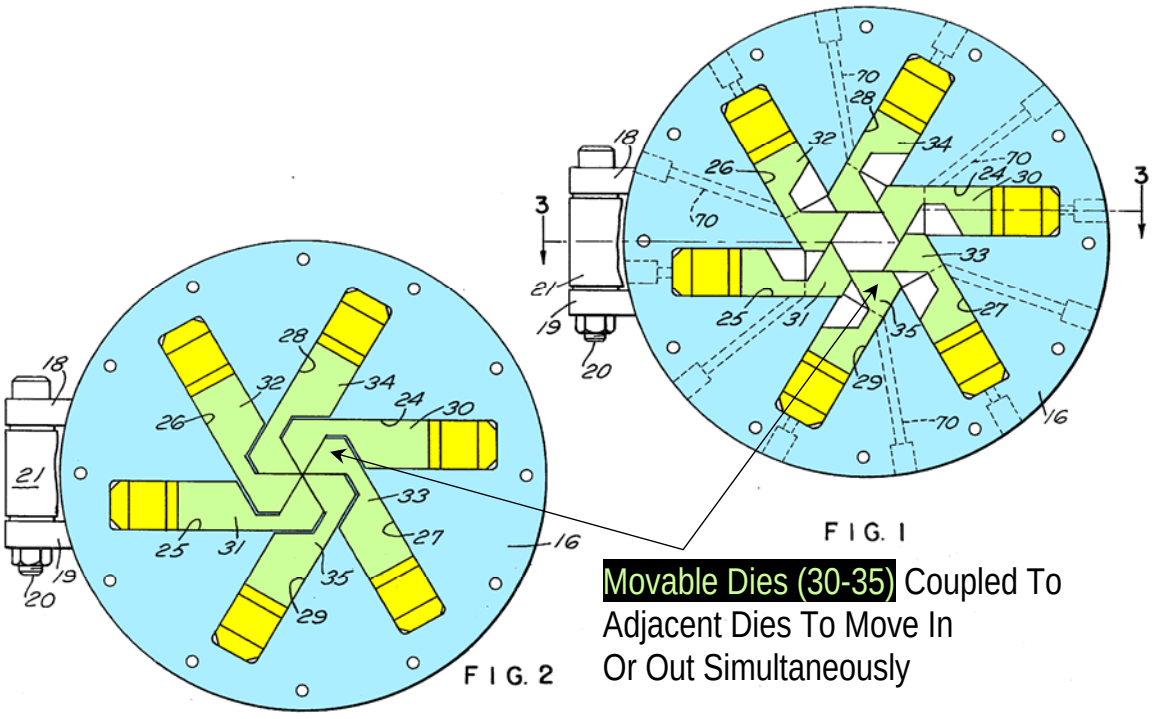


FIG. 1

FIG. 2

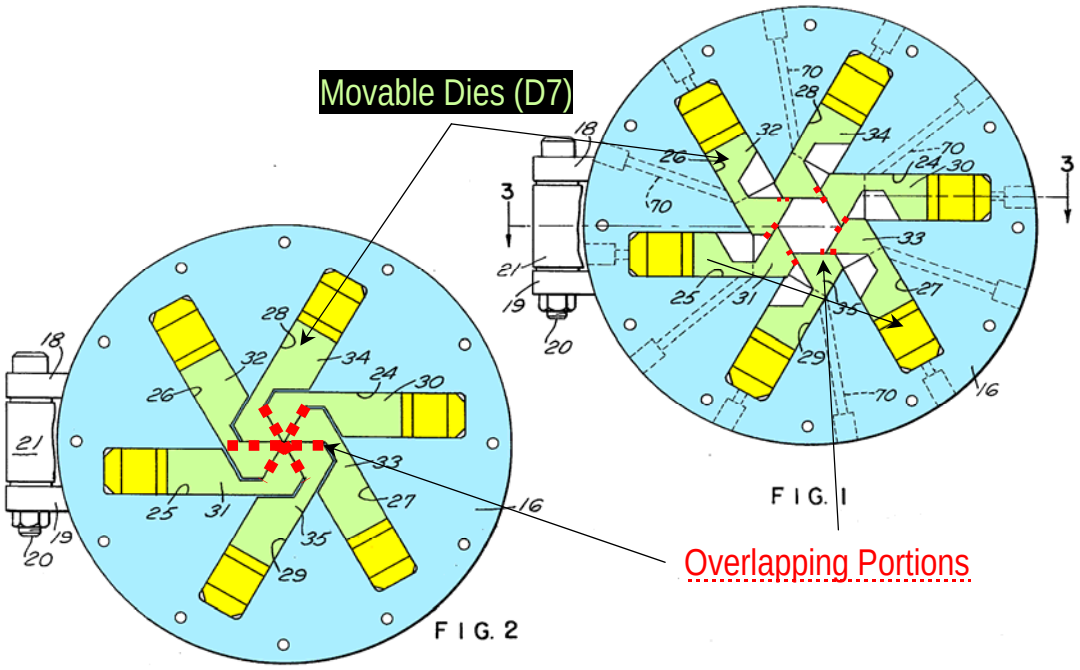
Ex. 1008 at Figs. 1, 2. In Baker, "[t]he jaws are provided with recesses and one side wall thereof receives portions of a juxtaposed jaw that allows the jaws to close fully." *Id.* at Abstract; *id.* at 2:66-3:9. "[T]he jaws will slide on the key and slot structure and can simultaneously move radially inward to compress a tube." *Id.* at 2:63-65. *See also* Ex. 1011 ¶¶ 189-190.

4. Claim 37

Baker discloses:

[37a] a plurality of overlapping movable dies arranged to form an iris,

As shown, Baker discloses overlapping movable dies.



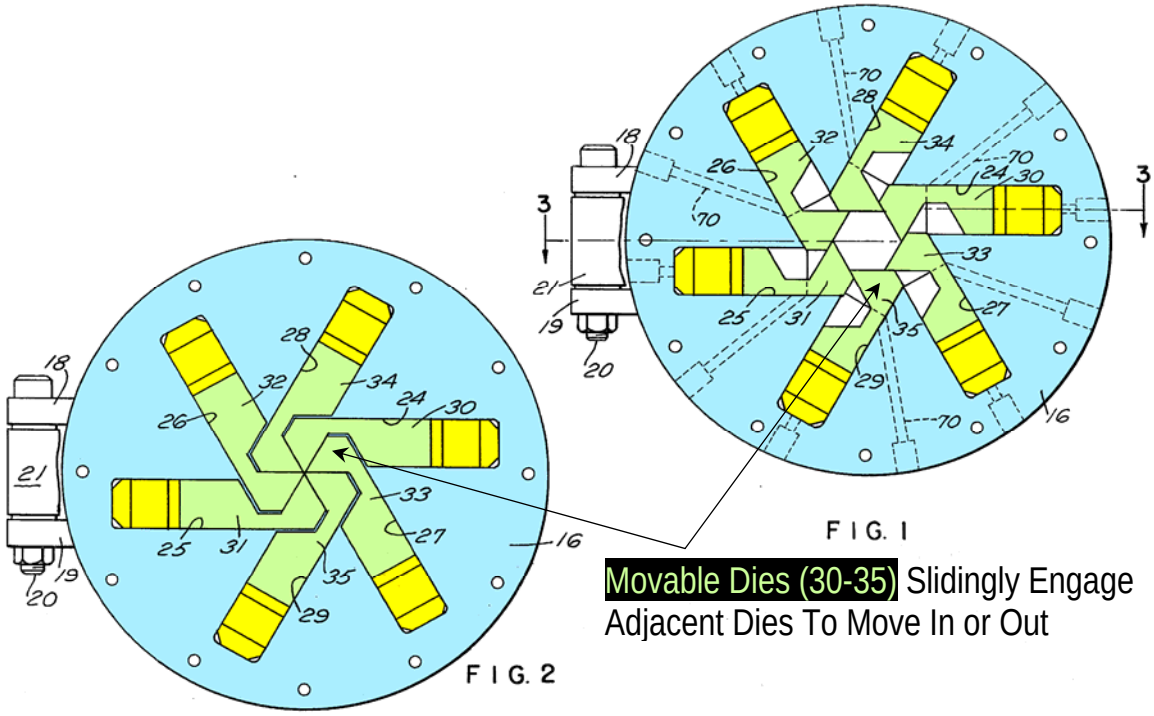
Ex. 1008 at Figs. 1, 2; *id.* at 3:5-8 ("a work-engaging surface such as 52 of a juxtaposed jaw will effectively slide on the entering wall 60 of the recess and permit the jaws to completely close[.]"). *See also* Ex. 1011 ¶¶ 191-192.

5. Claims 8, 25, and 33

Baker discloses:

[Claims 8, 25, 33] wherein the dies are moved cooperatively inward during the moving step

As shown below, the jaws in Baker move cooperatively inward during the moving step:



F I G. 1

F I G. 2

Ex. 1008 at Figs. 1, 2. In Baker, "[t]he jaws are provided with recesses and one side wall thereof receives portions of a juxtaposed jaw that allows the jaws to close fully." *Id.* at Abstract; *Id.* at 2:66-3:9. "[T]he jaws will slide on the key and slot structure and can simultaneously move radially inward to compress a tube." *Id.* at 2:63-65. *See also* Ex. 1011 ¶¶ 193-194.

6. Claims 9, 14, 23, and 31

Baker discloses:

[Claims 9, 14, 23, and 31] wherein the dies are wedge-shaped.

The dies in Baker have a wedge shape:

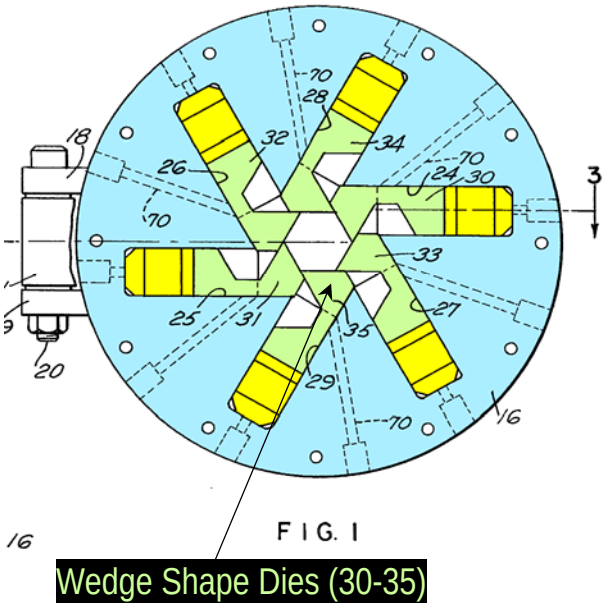


FIG. 1

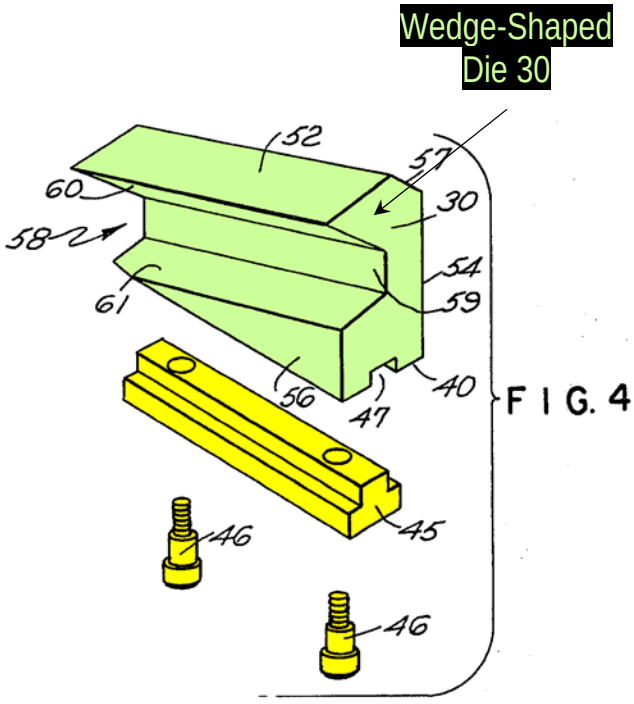


FIG. 4

Ex. 1008, Figs. 1, 4; *see also* Ex. 1011 ¶¶ 195-196

Moreover, the die shape is a design choice, and there are countless examples of wedge-shaped dies used in crimping and gripping mechanisms. Ex. 1011 ¶ 197.

Using a wedge-shaped die would be the substitution of one known element for another and would yield predictable results. *Id.*

D. Ground 4: Claims 11, 17, 19, 26, 34, 35, and 39 Are Invalid As Obvious Over the AAPA In View Of Baker And Morales

These dependent claims add limitations related to using the claimed crimper with a stent. For the reasons discussed in Part X.B (Ground 2), these limitations are inherent in or obvious over the AAPA as modified by Baker and further in view of Morales. *See also* Ex. 1011 ¶ 198.

E. The Claimed Die Configuration Was Ubiquitous In The Prior Art

The die configuration disclosed in Sabbaghian and Baker is not unique. Such a die configuration is common in the prior art.

For example, in Andrews, six die blocks D7 are arranged together to form an iris defining an aperture having a hexagonal (polygonal) cross-section. Ex. 1009 at 2:42-44.

a) Wedge-Shaped Movable Dies (D7) Form Iris Defining Aperture
b) First Straight Side Faces Aperture
c) First And Second Straight Sides Converge To Form Tip
d) First And Second Side Of Adjacent Dies Are Parallel

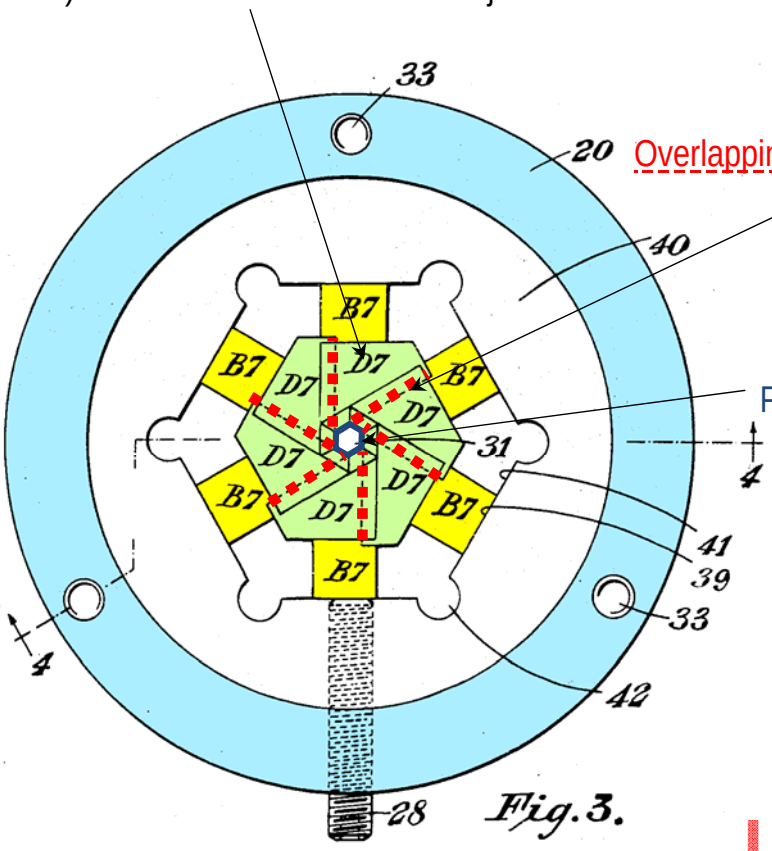


Fig. 3.

Overlapping Portions 10, 11

Aperture with Polygonal Shape

Longitudinal Axis

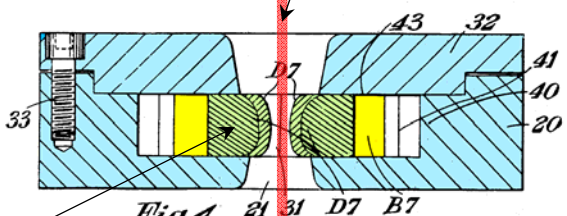


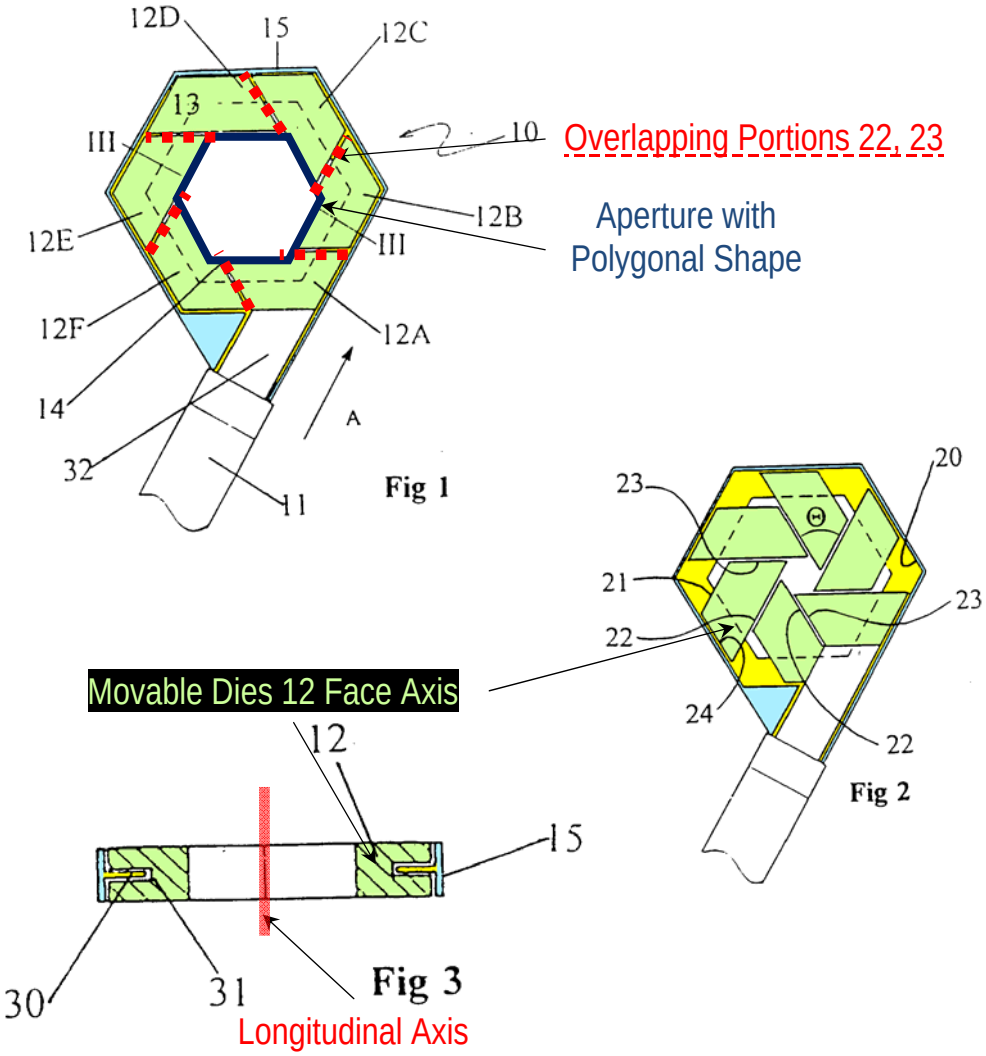
Fig. 4.

Movable Dies D7 Face Axis

Ex. 1009 (Andrews), Figs. 3-4. The dies overlap one another and move cooperatively to maintain this polygonal configuration both when the dies move to maximize and minimize the aperture. *Id.* at 1:24-31, 2:20-25.

The Hartley invention also discloses the limitations missing from the AAPA. Hartley discloses an "iris-type arrangement providing an adjustable diameter" and "a plurality of movable members defining a polygonal aperture, wherein the aperture is adjustable over a range between a minimum and a maximum aperture." Ex. 1010 at Abstract.

a) Wedge-Shaped Movable Dies 12A-12F Form Iris Defining Aperture
b) First Straight Side Faces Aperture
c) First And Second Straight Sides Converge To Form Tip
d) First And Second Side Of Adjacent Dies Are Parallel



Ex. 1010 (Hartley), Figs. 1-3.

Yasumi also discloses the limitations missing from the AAPA, as depicted below:

e) Wedge-Shaped Movable Dies (12-19) Form Iris Defining Aperture
f) First Straight Side Faces Aperture
g) First And Second Straight Sides Converge To Form Tip
h) First And Second Side Of Adjacent Dies Are Parallel

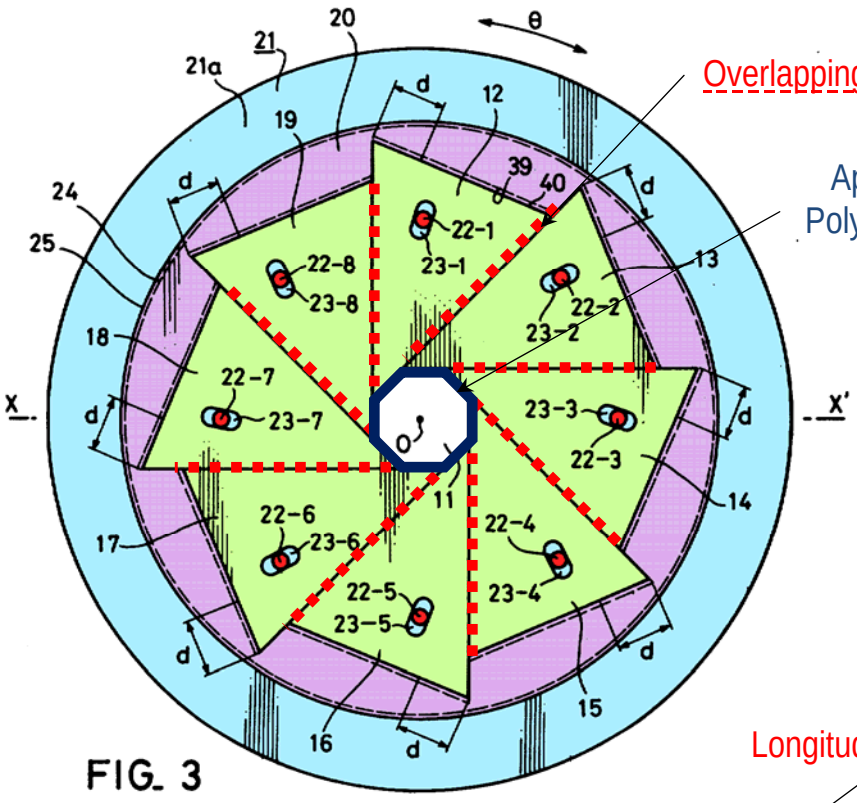
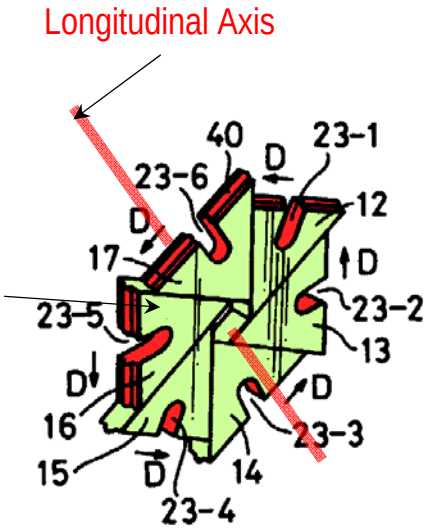


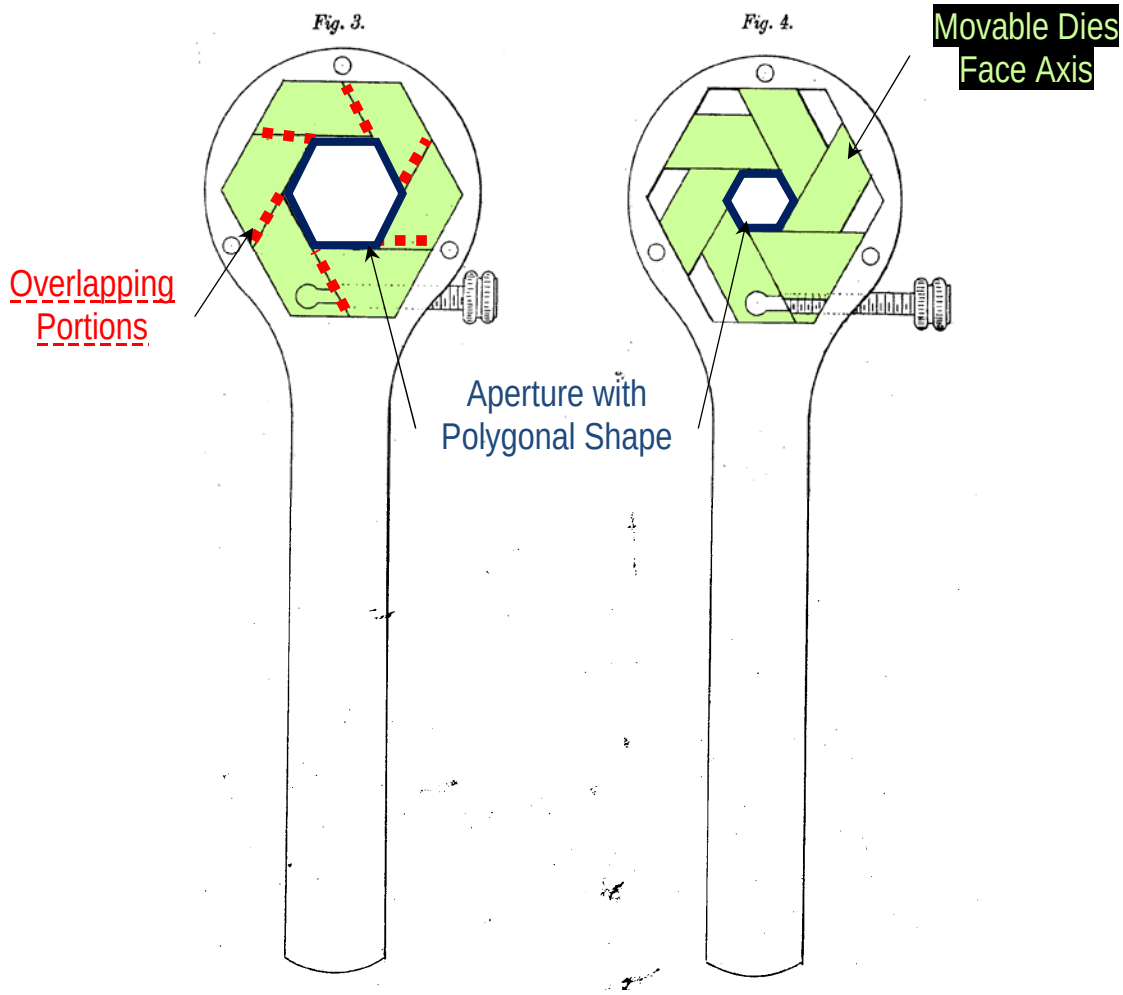
FIG. 3



Ex. 1025 (Yasumi), Figs. 3 and 8 (excerpt). In Yasumi, "the size of a predetermined polygonal aperture can be changed, retaining the polygonal configuration." *Id.* at 1:8-13; *see also id.* at Abstract, 1:40-43, Claim 1.

Nix also discloses the limitations missing from the AAPA, as depicted below:

e) Wedge-Shaped Movable Dies Form Iris Defining Aperture
f) First Straight Side Faces Aperture
g) First And Second Straight Sides Converge To Form Tip
h) First And Second Side Of Adjacent Dies Are Parallel



Ex. 1023 (Nix), Figs. 3-4; Ex. 1024 at 1.

XI. GROUNDS 3 AND 4 ARE NOT REDUNDANT UNDER 35 U.S.C. § 325(D) 2

Ground 1 relies on the AAPA in view of Sabbaghian and Ground 3 relies on the AAPA in view of Baker. These grounds are materially different from each other in a number of ways. For example, Sabbaghian is directed to a socket wrench. In contrast, Baker is directed to a tube pointer. Each reference is therefore directed at a different application. Additionally, Sabbaghian qualifies as prior art under 35 U.S.C. § 102 (e), whereas Baker qualifies under 35 U.S.C. § 102 (b). The Patent Owner cannot overcome Baker by establishing an earlier invention date. The grounds therefore are not redundant.

Grounds 2 and 4 build upon Grounds 1 and 3 respectively, and are not redundant for the same reasons.

XII. SECONDARY CONSIDERATIONS CANNOT OVERCOME THE STRONG EVIDENCE OF OBVIOUSNESS

Secondary considerations "do not control the obviousness conclusion." *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: October 13, 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 13,910 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,

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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 1001 - 1025** are being served on October 13, 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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