

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION,
Petitioners

v.

BOSTON SCIENTIFIC SCIMED, INC.,
Patent Owner

Case No. IPR2017-01301
Patent 6,915,560

**DECLARATION OF NEIL SHEEHAN IN SUPPORT OF PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 6,915,560**

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I. INTRODUCTION

A. Background and Qualifications

1. My name is Neil Sheehan. I am currently self-employed as a consulting engineer in the field of medical products. A copy of my *Curriculum Vitae*, which includes, among other things, my academic credentials and my employment history, is attached to the Petition as Exhibit 1206.

2. My field of expertise in this matter is medical products or devices (both reusable and disposable), including mechanisms, tooling, mechanical assemblies and components. This Declaration is based upon my own personal knowledge, skill, experience, training and education in my field of expertise, and upon information I have reviewed in connection with my retention in this matter.

3. I have worked extensively in the areas of catheters, balloons, plastic and metallic materials (including nitinol), inferior vena cava filters, vascular access, syringes, pumps, tubing, bonding methods and the like. Over the course of my many years in the medical device industry, I have learned much about stents and their typical balloon deployment systems. In fact, I have two stents in my right coronary artery owing to a congenital, tortuous path configuration.

4. I received my Bachelor of Science in Mechanical Engineering, *summa cum laude*, from Villanova University in 1968. I was the recipient of their 1993 Alumni Achievement Award for my work in the medical device field. I took

graduate courses in the department of Engineering and Applied Physics at Harvard University in 1968-1969. I also studied biology and organic chemistry at the University of California at Berkeley in 1974-1975.

5. I have over 40 years of experience in medical device design and development, with roles ranging from that of an individual contributor to that of a Vice President of Engineering and Manufacturing, having been directly involved in the design, development and manufacture of medical devices since 1975, both as an employee and as a consultant.

6. I am a named inventor on 41 patents (39 in the medical device field) covering a broad range of products.

7. My qualifications and testimony as an expert in the field of medical devices have been accepted in 26 different cases: 20 times by Courts, four times in arbitration proceedings, once at the International Trade Commission and once before the Board of Patent Appeals and Interferences at the United States Patent & Trademark Office.

8. I have testified as an expert witness at trial (or hearing) and in deposition in several other cases within the past four years. A list of those cases is attached as Exhibit A to my *Curriculum Vitae*, Exhibit 1206.

9. I have been retained by Petitioner Edwards Lifesciences Corporation, (“Edwards”), to assist counsel for Petitioner Edwards as a technical expert for this

Petition. I bill \$700 per hour for my services. No part of my compensation is dependent on my opinions or on the outcome of this matter. I have no financial interest in any of the parties to this case.

10. I understand that Boston Scientific Scimed, Inc. (“the Patent Owner”) has alleged that Edwards has infringed Claims 1, 2, 6, 8-11, 14, 15, 17-19, 23, 25-28, 31, 33-35, 37 and 40 of U.S. Patent No. 6,915,560 (“the ’560 patent”) in co-pending litigation captioned *Boston Scientific Corporation and Boston Scientific Scimed, Inc. v. Edwards Lifesciences Corporation*, Case No. 8:16-cv-00730-CJC-GJS (C.D. Cal) (“the Litigation”).

11. I understand that Edwards is filing a Petition for *Inter Partes* Review of Claims 1, 2, 6, 8-11, 14, 15, 17-19, 23, 25-28, 31, 33-35, 37, 39 and 40 of the ’560 patent. I have been asked by counsel for Petitioners to provide technical expert opinions for this Petition, including an opinion concerning the invalidity of Claims 1, 2, 6, 8-11, 14, 15, 17-19, 23, 25-28, 31, 33-35, 37, 39 and 40 of the ’560 patent.

12. The individuals involved in the prosecution of the ’560 patent and the inventors are referred to collectively herein as the “Applicants.”

13. In this declaration, where I have cited a reference as prior art against the ’560 patent, either the reference predates the filing date of the ’560 patent, or I

have been informed by counsel for Edwards that the reference is prior art to the '560 patent.

14. Throughout this declaration, I refer to certain exhibits that are attached to the Petition. For example, the '560 patent is attached to the Petition as Ex. 1201. Other exhibits are referred to herein as "Ex. ____."

B. Topics of Opinions

15. I offer opinions on the following general topics:

- the subject matter described and claimed in the '560 patent;
- the level of ordinary skill in the art pertaining to the '560 patent;
- Claims 1, 2, 6, 8-11, 14, 15, 17-19, 23, 25-28, 31, 33-35, 37, 39 and 40 of the '560 patent, including the meaning of certain claim terms as they would have been understood by a person of ordinary skill in the art as of the time of the invention;
- the teachings of the prior art; and
- the invalidity of Claims 1, 2, 6, 8-11, 14, 15, 17-19, 23, 25-28, 31, 33-35, 37, 39 and 40 in view of the prior art, and the bases and reasons therefore.

16. I also provide background information on medical products or devices.

C. Materials Considered

17. Exhibit 1207 to the Petition is a list of the documents and things I have considered in forming my opinions set forth herein.

18. I have also relied upon my education, training, knowledge of pertinent literature and experience in the field of the '560 patent.

II. LEGAL STANDARDS

19. I will not offer opinions of law, as I have been retained to provide opinions solely as a technical expert. Rather, I have been advised of several legal principles concerning claim construction and patent invalidity, which I used in arriving at my determinations.

A. Claim Construction

20. I am advised that in determining whether a patent claim is anticipated in view of the prior art, the Patent Office must construe the claim by giving the claim its broadest reasonable interpretation consistent with the specification. The terms also are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the specification. For the purposes of this review, I have analyzed each claim term in accordance with its plain and ordinary meaning under the required broadest reasonable interpretation.

21. I am also advised that the preamble to a claim may limit the claim scope when the preamble recites additional structure that is underscored as important by the specification, or when the preamble provides antecedent basis for a claim limitation. It is my understanding that a preamble does not limit the claim scope if the body of the claim describes a structurally complete invention, and the

preamble merely gives a name to the invention, extols its features or benefits or describes a use for the invention.

B. Obviousness

22. I am advised that a claim is invalid, and therefore unpatentable under 35 U.S.C. § 103, if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art (“POSITA”) at the time of the alleged invention. I also understand that an obviousness analysis takes into account the scope and content of the prior art, the differences between the claimed subject matter and the prior art and the level of ordinary skill in the art at the time of the alleged invention.

23. I am further advised that in determining the scope and content of the prior art, a reference is considered appropriate prior art if it falls within the field of the inventor’s endeavor. In addition, a reference is considered appropriate prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have commended itself to an inventor’s attention in considering his or her problem. If a reference relates to the same problem as the claimed invention, then that supports the use of the reference as prior art in an obviousness analysis.

24. I am further advised that to assess the differences between the prior art and the claimed subject matter, the law requires the claimed invention to be

considered as a whole. This “as a whole” assessment requires showing that one of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the elements from the prior art and combined them in the claimed manner. I understand that in considering the obviousness inquiry, it is important not to use the benefit of hindsight derived from the patent itself.

25. I am further advised that the law recognizes several rationales for combining references or modifying a reference to show obviousness of claimed subject matter. Some of these rationales include: combining prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; a predictable use of prior art elements according to their established functions; applying a known technique to a known device (method or product) ready for improvement to yield predictable results; choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and some teaching, suggestion or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

26. I am further advised that an obviousness analysis must consider whether there are additional factors that would indicate that the invention was non-

obvious. These factors include whether there was: (i) a long-felt need in the industry; (ii) any unexpected results; (iii) skepticism of the invention; (iv) teaching away from the invention; (v) commercial success; (vi) praise by others for the invention; and (vii) copying by others.

III. FACTUAL BACKGROUND AND RELEVANT CONTEXT

A. Stents and Stent Crimpers

27. Percutaneous Transluminal Angioplasty is a medical procedure for opening a constriction or narrowing of a blood vessel, such as an artery, which has been constricted by the build-up of plaque.

28. Typically, an empty collapsed balloon mounted on the distal end of a balloon catheter, is passed over a guidewire into the narrowed vessel. Once the balloon is properly positioned, the balloon is inflated to the desired size to compress the plaque against the vessel wall and force expansion of the narrowed portion within the vessel, thereby opening the blood vessel for improved flow. The balloon is then deflated and withdrawn.

29. In order to maintain the vessel in the opened state, and/or strengthen the area undergoing treatment, an intravascular prosthesis, such as a stent, may be employed. A stent is a metal (usually nitinol), mesh tubular support placed inside the passage to aid healing or relieve an obstruction.

30. Typically, a radially expandable stent is positioned on the balloon at the distal end of the balloon catheter, the stent being crimped to a small diameter around the balloon. The balloon catheter is passed over a guidewire into the narrowed vessel. Once the balloon catheter is properly positioned at the desired location, the stent is implanted by expansion of the balloon. The balloon portion of the catheter is then deflated and withdrawn from the vessel, leaving the implanted stent as a permanent scaffold to reduce the chance of re-closure (*i.e.*, restenosis).

31. Because the catheter and stent travel through the patient's vasculature, such as the coronary arteries, the stent must have a small delivery diameter and must be firmly attached to the catheter until the physician is ready to implant it. Thus, the stent must be loaded or crimped onto the catheter so that it does not interfere with delivery, and it must not come off the catheter until it is implanted.

32. To adequately mount a stent onto the balloon catheter for delivery into the patient, the stent is "crimped" or otherwise radially collapsed sufficiently to attach it to the balloon. Crimping a stent to a balloon catheter was well known at the time of the invention.

33. This crimping was performed in many different ways. One method was manual crimping. Another known method was to use a plier-like device to pinch the stent. Still other methods used dies pressed together over the stent.

B. The '560 Patent

34. I set forth herein a summary of the '560 patent. I do this not from today's perspective, but rather from the perspective of what one of ordinary skill in the art would have understood in the late 1990's.

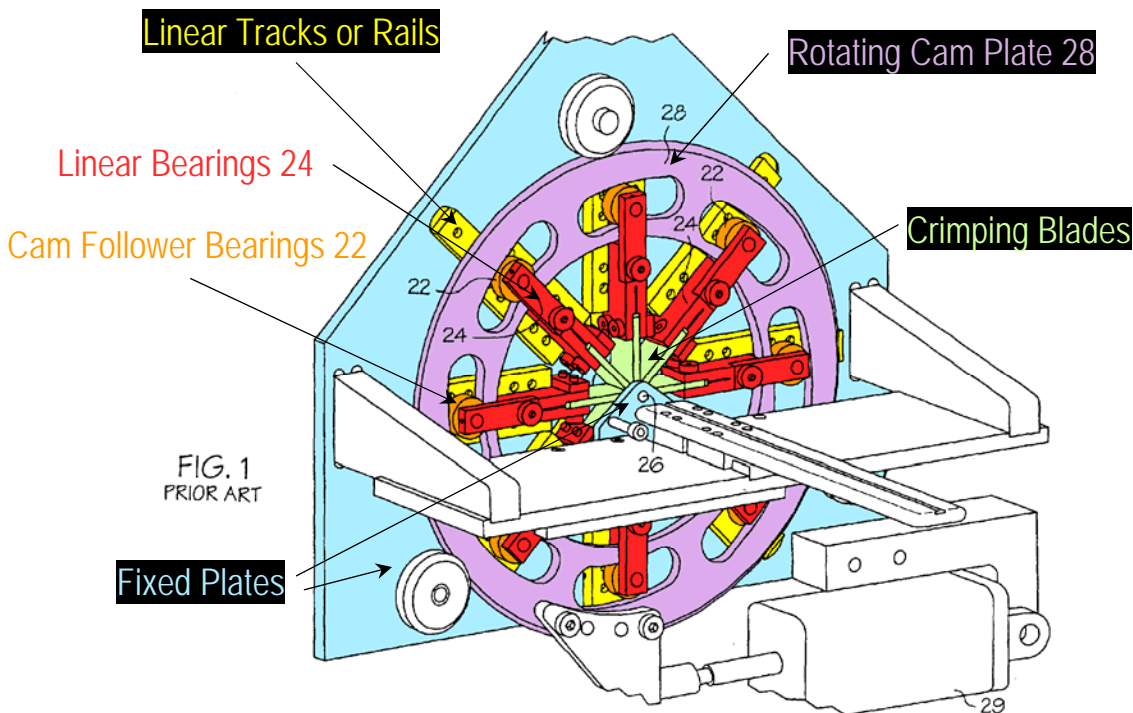
35. The expressed goal of the '560 patent is to “produce a device capable of crimping a stent uniformly while minimizing the distortion of and scoring and marking of the stent due to the crimping.” Ex. 1201 at 2:27-29. Although one object of the invention is to crimp a stent, the patent contemplates other uses for the disclosed device, such as reducing in size other tubular medical devices or as a variable size balloon mold.

- “The present invention is directed, in one embodiment, to an apparatus for reducing a medical device in size. Desirably, the medical device is a stent, a stent-graft, a graft or a vena cava filter, whether self-expandable, balloon expandable or otherwise expandable, although the inventive apparatus may also be employed with any other suitable, generally tubular medical device which must be reduced in size.” Ex. 1201 at 2:48-55.
- “Desirably, the medical device is a stent..., although the inventive apparatus may also be employed with any other suitable, generally tubular medical device which must be reduced in size.” Ex. 1201 at 2:50-55.
- “The inventive apparatus finds particular utility in crimping a medical device such as those mentioned above to a catheter or to a balloon disposed about a catheter. [¶] The inventive apparatus also finds utility in reducing the diameter of a medical device such as those mentioned above prior to crimping.” Ex. 1201 at 3:16-22.

- “The inventive apparatus may also be used as a variable size balloon mold.” Ex. 1201 at 3:36-37.
- “The inventive apparatus may also be incorporated into a blow molding tool to provide a variable size balloon mold” Ex. 1201 at 8:65-66.

36. The specification identifies a problem with prior art stent crimping, namely that prior art methods often applied uneven crimping forces that could distort the stent and require re-crimping. The specification explains that crimping the same stent multiple times can damage the stent. Ex. 1201 at 1:42-55.

37. The specification describes one such prior art stent crimper in Figure 1 of the '560 patent and further at 1:62-2:21 (“Applicant’s Admitted Prior Art” or “AAPA”).



Ex. 1201, Fig. 1 (colored annotations added).

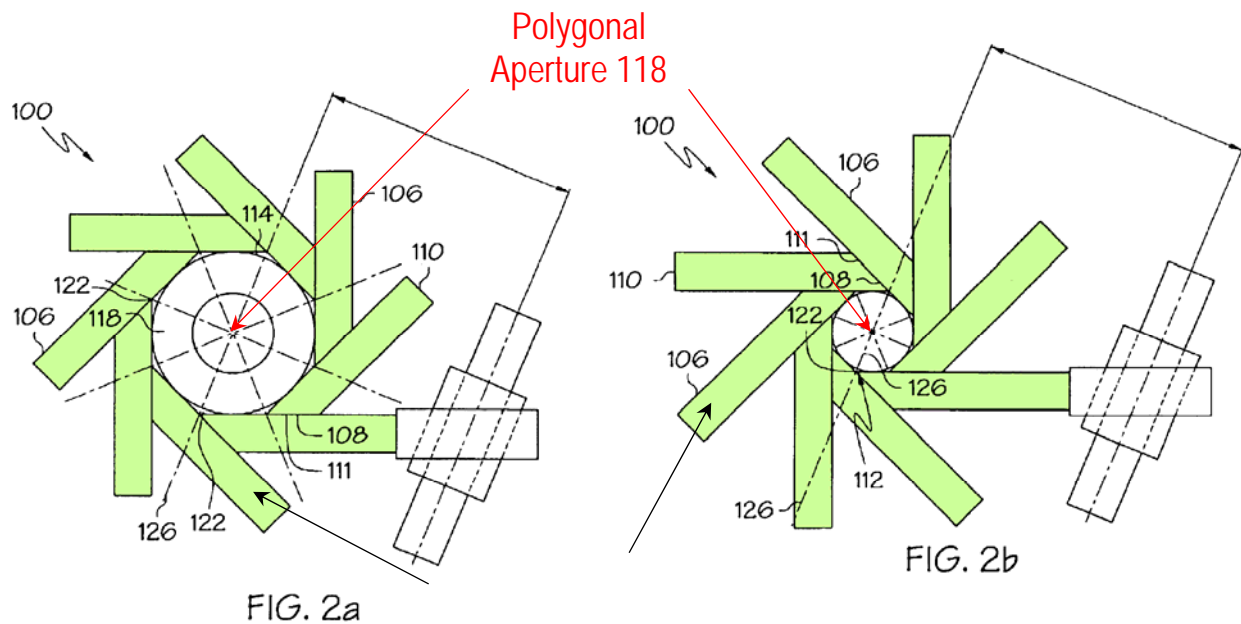
38. The AAPA, depicted at Figure 1 of the '560 patent above, employs a cam plate with a plurality of arc-shaped slots disposed such that each slot engages a cam follower bearing 22 (orange). *Id.* at 1:62-65. The follower bearing 22 (orange) is attached to a linear bearing 24 (red), which has a corresponding linear track (yellow) mounted on a fixed plate (blue). *Id.* at 2:1-4. Each linear bearing 24 (red) also has a radially disposed crimping blade (green). *Id.* at 2:14-15. The arc-shaped slots in the cam plate 28 (purple) are inclined relative to the axis of rotation 26. When the cam plate 28 (purple) rotates, it displaces the cam follower bearings 22 (orange) along with the linear bearings 24 (red) and attached crimping blades (green). *Id.* at 1:62-2:4. Depending on the direction of rotation, the linear bearings (red) and crimping blades (green) are either moved inwards to apply a crimping force to the stent, or outwards to release the stent. *Id.* at 2:14-17.

39. The specification describes a supposed improvement over the AAPA, namely a crimper that has a polygonal aperture. This configuration, according to the specification, is “capable of crimping a stent uniformly while minimizing the distortion of and scoring and marking of the stent due to the crimping.” Ex. 1201 at 2:26-29.

40. The specification describes the invention as an apparatus with “at least three coupled movable blades disposed about a reference circle to form an aperture whose size may be varied. . . . Each blade includes a single radial point on the

surface of the blade which a) lies on the circumference of the reference circle prior to movement of the blade, and b) may be moved only along a radius of the reference circle on movement of the blade.” Ex. 1201 at 2:56-65. The specification also discloses “an actuation device which is capable of moving the blade to alter the size of the aperture.” *Id.* at 2:59-60.

41. Figures 2a and 2b show one preferred embodiment of the blade configuration comprising eight coupled blades, depicted before and after reducing a stent in size. Ex. 1201 at 3:60-63.



Ex. 1201, Figs. 2a, 2b (color and annotations added).

42. Each blade has a beveled end 108 so as to mesh against an adjacent blade, and the blades cumulatively define a polygonal aperture. Ex. 1201 at 4:59-62. Element 122 identifies the single radial point (located at the tip of the blade on

the beveled end) that lies on the radial line 126 of the reference circle 114. *Id.* at 4:66-67. Element 122 moves along the radial line 126 when moving outward to increase the size of the aperture and when moving inward to reduce the size of the aperture. *Id.* at 4:66-5:4.

43. Figure 4A is a partial front view of a disclosed embodiment and Figure 4c is a partial side view.

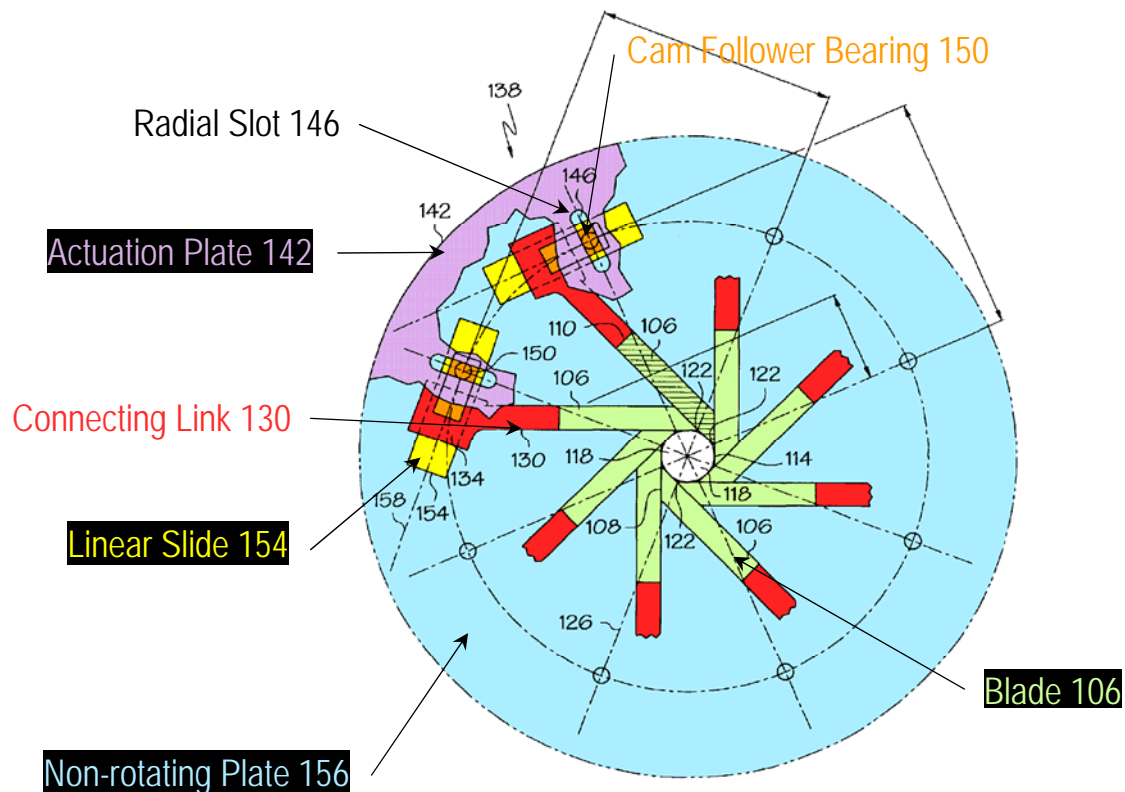


FIG. 4A

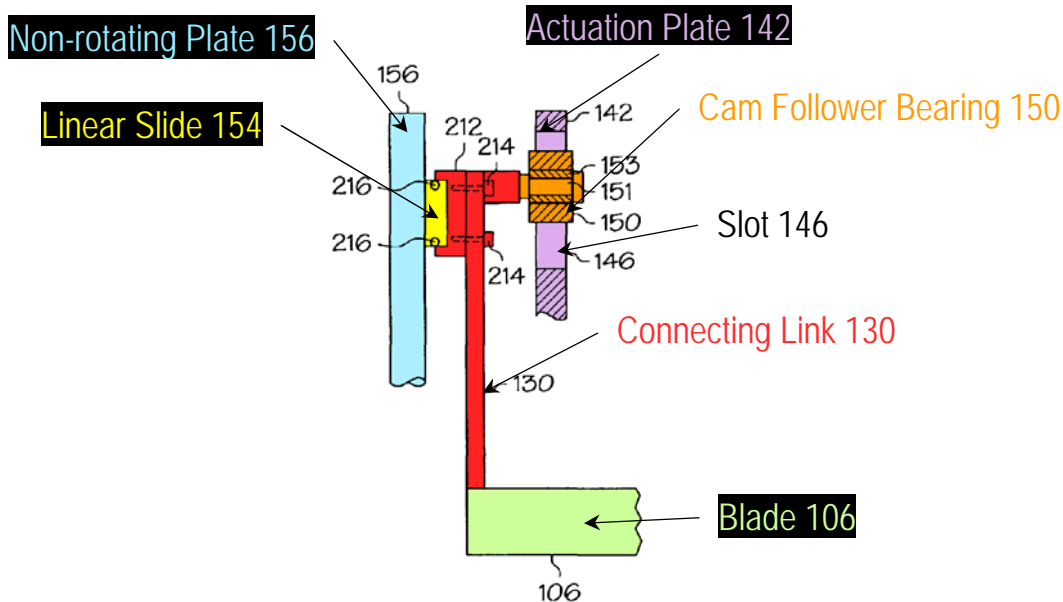
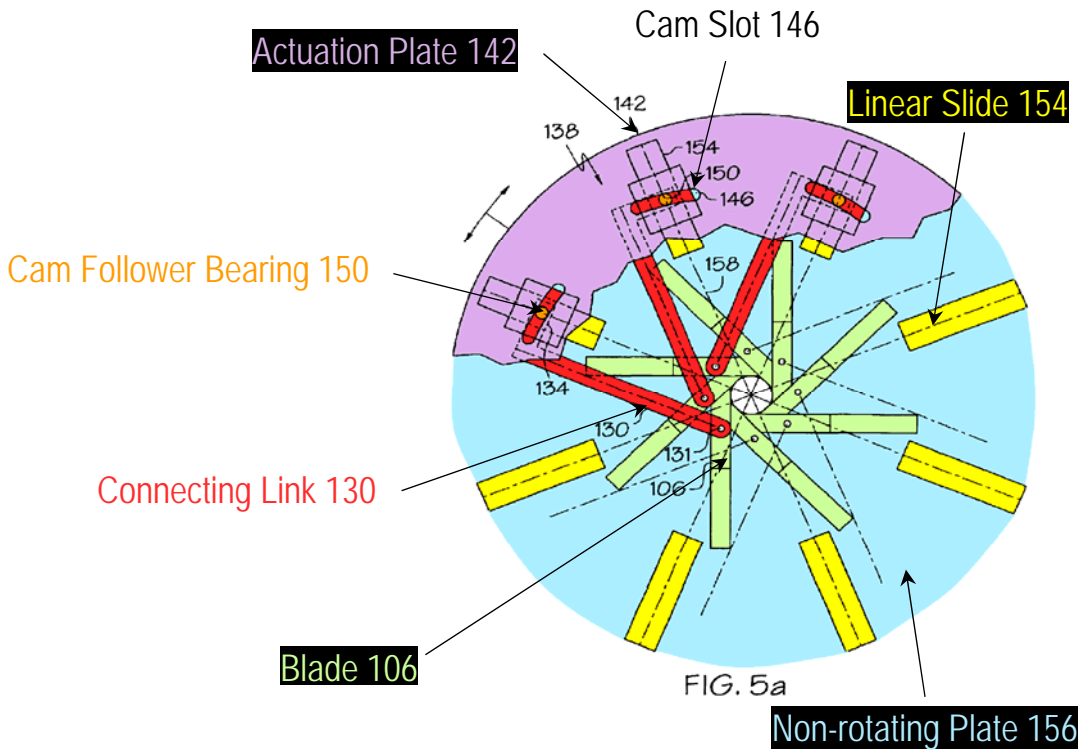


FIG. 4c

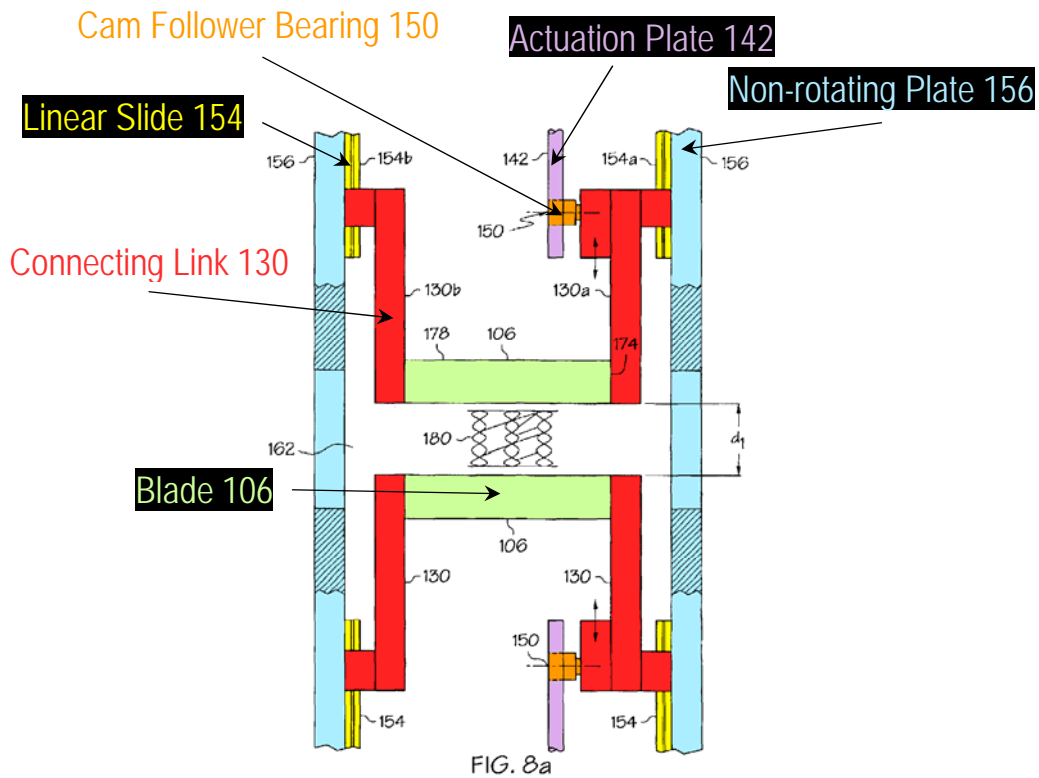
Ex. 1201, Figs. 4A, 4c (annotations and color added).

44. In the depicted embodiment each blade 106 (green) has a connecting link 130 (red) that extends from the end 110 of the blade. Ex. 1201 at 5:6-7. The connecting link 130 (red) ends in mounting means 134 that both attaches to a linear bearing block 212 on one side and interfaces with an actuation device, shown generally at 138, on the other. *Id.* at 5:7-10. The actuation device 138 has an actuation plate 142 (purple) that rotates to simultaneously move the blades to alter the size of the polygonal aperture 118. *See id.* at 5:11-14, 46-62.

45. Figure 5a is a partial front view of an alternative disclosed embodiment and Figure 8a is a partial side view:



Ex. 1201, Fig. 5a (annotations and color added).



Ex. 1201, Fig. 8a (annotations and color added).

46. The embodiment depicted in Figs. 5a (Ex. 1201 at 5:66-6:17 & 6:28-41), and 8a (*id.* at 7:9-21), operates in a manner similar to the embodiment described above with respect to Figures 4A and 4c. The primary difference is that the blades are attached to the connecting links at an angle, and the linear slides are arranged to slide along a radial line, labeled 158. *Id.* at 6:43-50.

47. I address seven independent claims and 17 dependent claims in this declaration.

C. Prosecution History

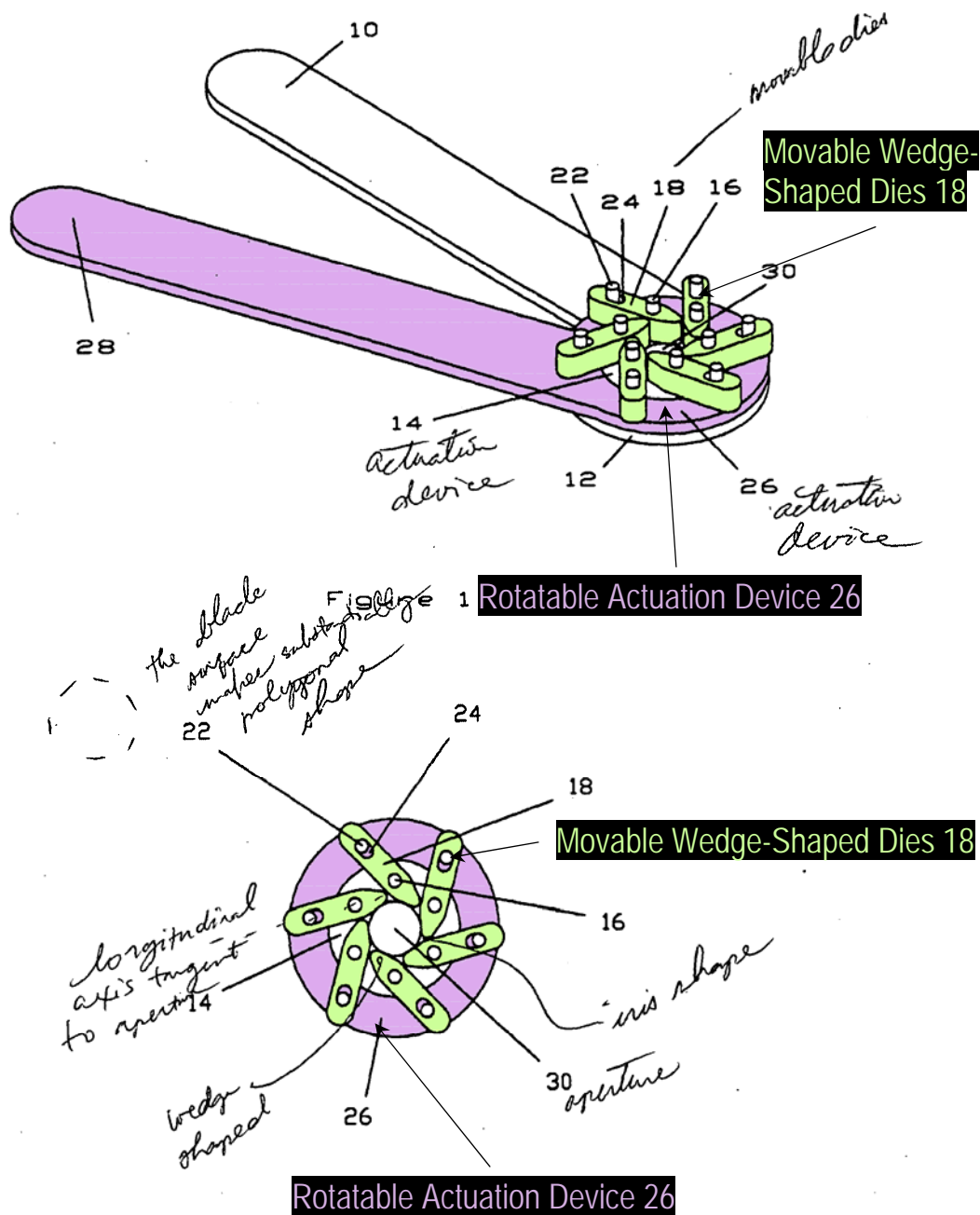
48. U.S. Patent Application No. 10/444,807, which issued as the '560 patent, is part of a family of patents deriving from an application originally filed on September 22, 1999. During prosecution, the Applicant elected to proceed only on apparatus claims, and significantly amended the claims four times in view of numerous rejections from the Examiner. Finally, on February 14, 2005, the Examiner allowed the claims. The relevant amendments are discussed below.

1. October 9, 2003 Restriction

49. U.S. Patent Application No. 10/444,807 was filed on May 23, 2003 with 26 claims. Ex. 1202 at 153-157. On October 9, 2003, the Applicant responded to a restriction requirement by selecting the apparatus claims, canceling the original apparatus claims and submitting 35 new apparatus claims. *Id.* at 92-98.

2. October 22, 2003 Office Action and Response

50. On October 22, 2003, the Patent Examiner rejected all the claims in a non-final office action. Ex. 1202 at 69-80. The Examiner rejected independent Claims 27, 36, 44 and 52 as anticipated by or obvious over U.S. Patent No. 5,261,263 (“Whitesell”). *See id.* at 72-74. The Examiner found that Whitesell teaches a crimper comprising a plurality of movable dies 18 arranged to form an iris, the dies disposed about an aperture 30 and a rotatable actuation device 26 coupled to the blades, rotation of the actuation device causing the dies to move inward and reduce the size of the aperture or outward to increase the size of the aperture. *Id.* at 72-73.



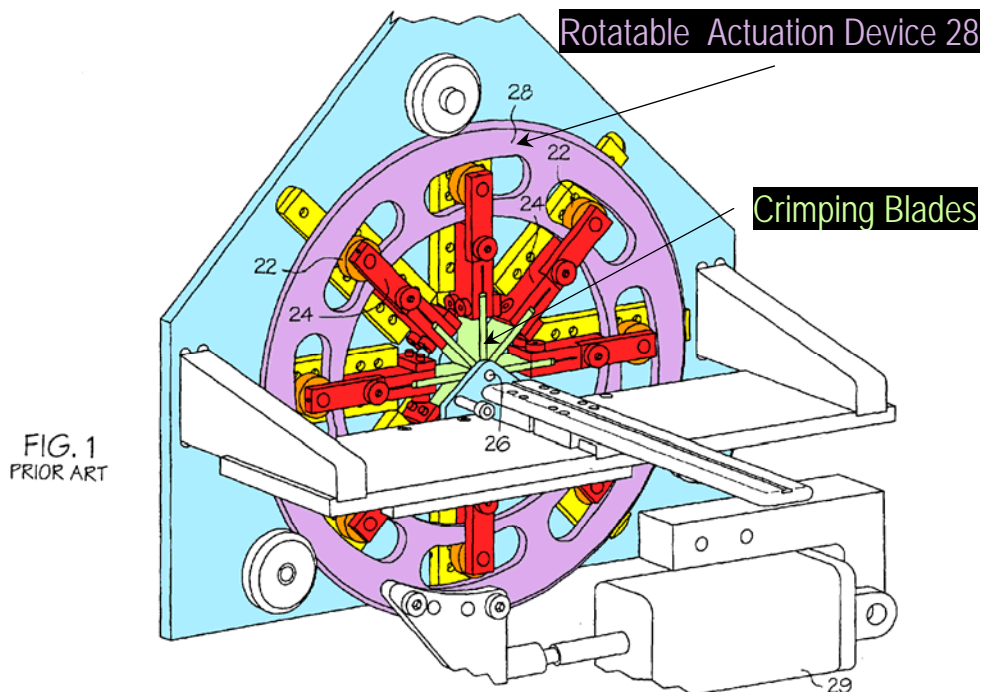
Ex. 1202 at 84 (including Whitesell Figs. 1 and 2 with Examiner's handwritten notes (colors and annotations added)).

51. Whitesell describes radial pliers or a wrench for gripping cylindrical workpieces. Ex. 1215 at 1:28-42, 3:40-41. The Examiner in particular noted:

[T]he crimper of Whitesell is considered a stent crimper because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. . . . Clearly, the crimper of Whitesell is capable of performing crimping of a stent.

Ex. 1202 at 72.

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



Ex. 1201, Fig. 1 (annotations and color added).

53. The Examiner found that the AAPA does not teach “each of the dies having a longitudinal axis which is tangent to the aperture,” but Whitesell teaches that element. Ex. 1202 at 74. The Examiner explained that it would have been obvious to a POSITA

to have provided the invention of [the AAPA] with dies having a longitudinal axis which is tangent to the aperture, in light of the teachings of Whitesell, in order to provide a symmetric crimping deformation. It is noted that Whitesell recognizes the benefits of using radial applying crimping forces over linearly applied forces like the one taught by [AAPA].

Ex. 1202 at 74-75.

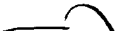
54. In response, on January 22, 2004, the Applicant amended independent Claims 27, 36, 44 and 52 to include a limitation resulting in dies with straight or flat sides facing a substantially polygonal aperture when moved to open or close the aperture (the “straight-sided die/polygonal aperture limitation”). Ex. 1202 at 57-60. Specifically, the Applicant added new limitations as shown below:

Claim 27. (Previously presented) A stent crimper comprising:

a plurality of movable dies arranged to form an iris, the iris defining an aperture of a substantially regular polygonal shape, the dies disposed about an aperture, the aperture having a center, each of the dies having a stent contacting surface, each die arranged such that the stent contacting surface extends along a line that intersects the stent contacting surface of an adjacent die and forms an angle, the angle remaining substantially the same when the dies move to open the aperture and when the dies move to close the aperture-longitudinal axis which is tangent to the aperture.

Claim 36. (Previously presented) A stent crimper comprising:

a plurality of movable dies arranged to form an iris, the dies disposed about an aperture, the aperture having a center and a substantially regular polygonal shape, each of the dies having an inward facing straight side which faces the center of the aperture, the inward facing straight side facing the center of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture.



Claim 44. (Previously presented) A stent crimper comprising:

eight or more movable dies arranged to form an iris, the iris defining an aperture of a substantially regular polygonal shape, ~~the dies disposed about an aperture~~ having a center, each die having an inward facing flat portion which faces the center of the aperture, the inward facing flat portion faces the center of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture.

Claim 52. (Previously presented) A stent crimper comprising:

an aperture with a plurality of movable blades disposed thereabout, the aperture being substantially polygonal, the blades coupled to one another so as to be movable inward or outward simultaneously, movement of the blades outward increasing the size of the aperture, movement of the blades inward decreasing the size of the aperture, the aperture remaining substantially regular polygonal when it is sized to receive a stent therein and when the blades minimize the aperture it is subsequently reduced in size.

Ex. 1202 at 57-59.

55. The Applicant argued that Whitesell does not teach the added limitations of Claim 27 because, as depicted below in Whitesell Figure 4, no angle is formed between the stent contacting surfaces of the dies in Whitesell in the closed configuration. Ex. 1202 at 63. Similarly, the Applicant argued that Whitesell does not teach straight or flat sides that face the center of the aperture in the closed position, as required by amended Claims 36 and 44, or a substantially

regular polygonal shape in the closed position, as required by amended Claim 52.

Id. at 63-64.

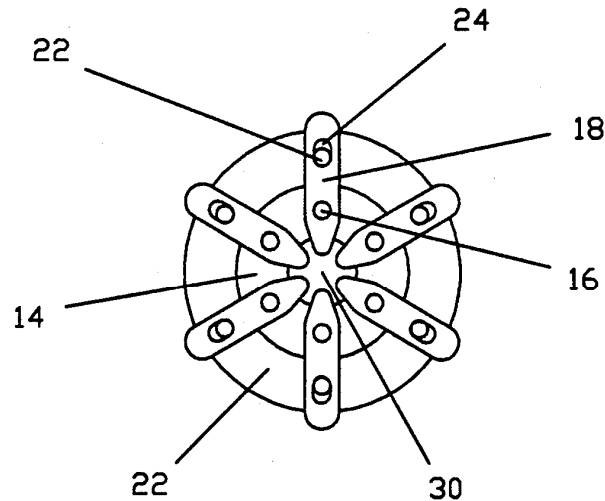


Figure 4

Ex. 1215, Fig. 4.

56. The Applicant argued that the AAPA did not disclose a plurality of dies arranged to form an iris, noting that:

[A]n 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. The aperture is not being minimized; elongate members are merely being introduced into the aperture to crimp the stent.

Ex. 1202 at 65. The Applicant also argued that the AAPA did not disclose the additional limitations added by amendment to Claims 27, 36, 44 and 52. *Id.* at 65-66.

57. The Applicant also added new independent claims, including Claim 63, as shown below:

Claim 63. (New) A stent crimper comprising:

a plurality of overlapping movable dies arranged to form an iris, the dies disposed about an aperture, the aperture having a center, each of the dies having a stent contacting surface which is curved.

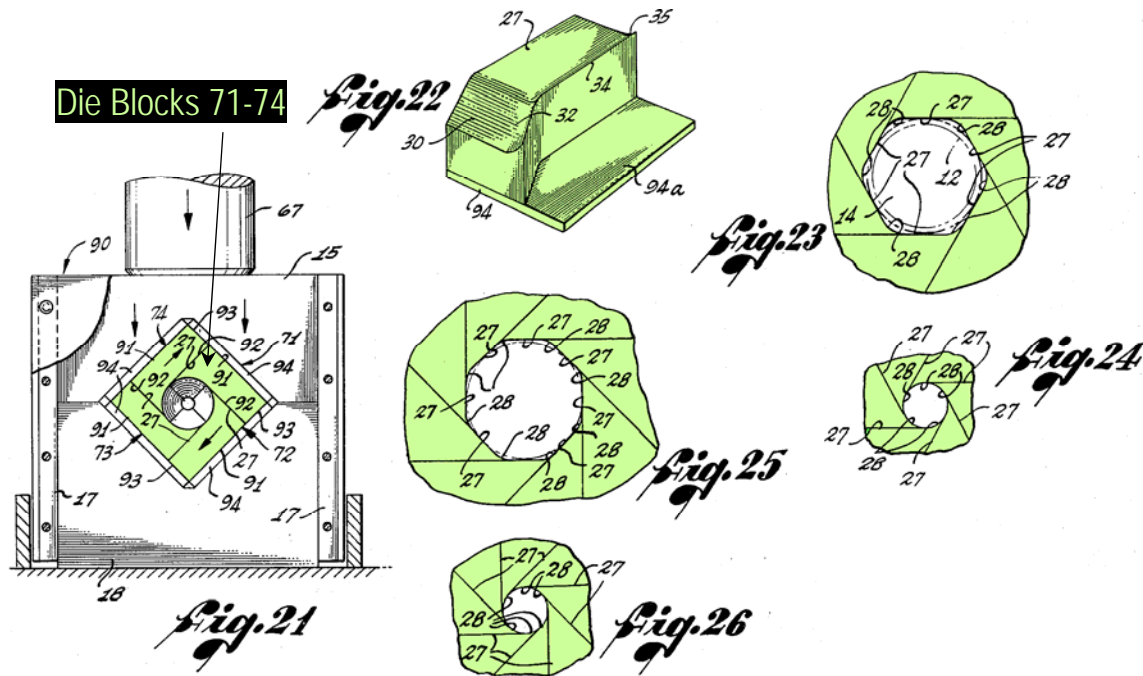
Ex. 1202 at 60-61.

3. April 22, 2004 Office Action and Response

58. On April 22, 2004, the Examiner rejected Claims 27, 36, 52 and 63 in a final office action. Ex. 1202 at 42-52.

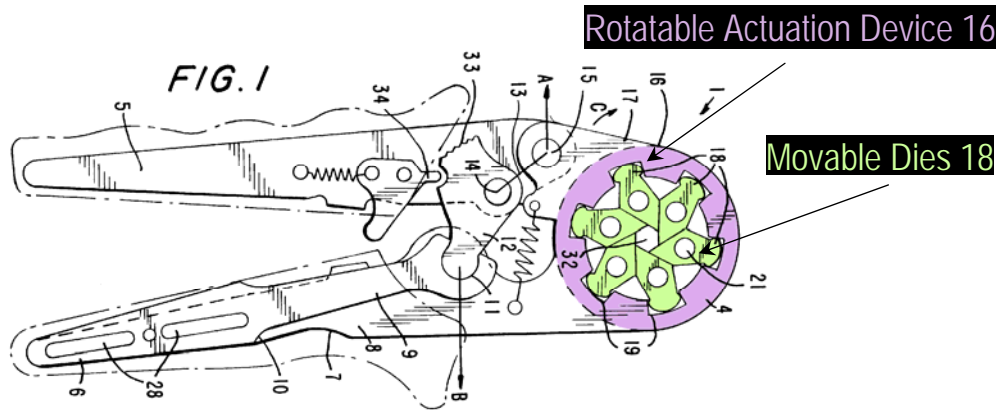
59. The Examiner rejected Claims 27 and 63 as anticipated by U.S. Patent No. 3,695,087 (“Tuberman”). Ex. 1202 at 45. Tuberman describes an apparatus for forming cylindrical points on metal tubes. Ex. 1216 at Abstract. The Examiner found that Tuberman teaches a plurality of movable dies arranged to form an iris, the iris defining an aperture of a substantially regular polygonal shape, the dies disposed about the aperture, each of the dies have a contacting surface 27, each die arranged such that the contacting surface extends along a line that intersects the contacting surface 27 of an adjacent die and forms an angle, the angle remaining substantially the same when the dies move to open the aperture and when the dies move to close the aperture. Ex. 1202 at 45. The Examiner also

found that Tuberman teaches curved dies as recited in Claim 63. *Id.* (citing Tuberman Fig. 24).



Ex. 1216, Figs. 21-26 (color and annotation added).

60. The Examiner rejected Claims 27, 36 and 52, as anticipated by U.S. Patent No. 6,176,116 (“Wilhelm”). Ex. 1202 at 46. Wilhelm describes a crimping tool for crimping lead end sleeves, contact sockets or plugs onto electrical conductors. Ex. 1217 at Abstract. The Examiner found that Wilhelm taught dies 18 arranged to form an iris 32 with angles that remain substantially the same when the dies move to open or close. Ex. 1202 at 46. The Examiner also found that Wilhelm teaches a rotatable actuation device 17 coupled to the dies 18 and wedge-shaped dies. *Id.*



Ex. 1217, Fig. 1 (color and annotation added).

61. The Examiner considered Tuberman and Wilhelm stent crimpers because both are capable of crimping a stent. Ex. 1202 at 45-46.

62. The Applicant filed a response to the office action and an amendment on July 22, 2004. Ex. 1202 at 29-39. The Applicant deleted the straight-sided die/polygonal aperture limitation from Claim 27 and added new limitations to independent Claims 27, 36, 44, 52 and 63 directed to dies disposed “between stationary end-walls substantially centered about the longitudinal axis,” (the “stationary end-walls limitation”). Ex. 1202 at 29-33. Specifically, the Applicant made the amendments shown below:

Claim 27. (Currently Amended) A stent crimper comprising:

a plurality of movable dies arranged to form an iris having a longitudinal axis, the iris defining an aperture of a substantially regular polygonal shape, the dies disposed about ~~an~~ the aperture and between stationary end-walls which are disposed about the longitudinal axis, ~~the aperture having a center, each of the dies having a stent contacting surface, each die arranged such that the stent contacting surface extends along a line that intersects the stent contacting surface of an adjacent die and forms an angle, the angle remaining substantially the same when the dies move to open the aperture and when the dies move to close the aperture, 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.~~

Claim 36. (Currently Amended) A stent crimper comprising:

a plurality of movable dies arranged to form an iris, the dies disposed about an aperture, the aperture having ~~a center~~ a longitudinal axis and a substantially regular polygonal shape, each of the dies having an inward facing straight side which faces the ~~center~~ longitudinal axis of the aperture, ~~the inward facing straight side facing the center 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 ~~blades~~ 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.

Claim 44. (Currently Amended) A stent crimper comprising:
eight or more movable dies arranged to form an iris, the iris defining an aperture of a substantially regular polygonal shape, the aperture having a center longitudinal axis, each die having an inward facing flat portion which faces the center longitudinal axis of the aperture, ~~the inward facing flat portion faces the center of the aperture~~ both when the dies move to maximize the aperture and when the dies move to minimize the aperture, the dies between stationary end-walls and operatively engaged to at least one of the stationary end-walls, the stationary end-walls disposed about the longitudinal axis.

the iris comprising at least eight of the inward facing flat portions, the aperture being reducible in size by moving the inward facing flat portions toward the center longitudinal axis of the aperture,

a rotatable actuation device coupled to the ~~blades~~ 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.

Claim 52. (Currently Amended) A stent crimper comprising:

an aperture with a plurality of movable blades disposed thereabout, the aperture having a longitudinal axis and being substantially polygonal, the blades between stationary end-walls substantially centered about the longitudinal axis, the blades coupled to one another so as to be movable inward or outward simultaneously, movement of the blades outward increasing the size of the aperture, movement of the blades inward decreasing the size of the aperture, the aperture remaining substantially regular polygonal when it is sized to receive a stent therein and when the blades minimize the aperture.

Claim 63. (Currently Amended) A stent crimper comprising:

a plurality of overlapping movable dies arranged to form an iris, the dies disposed about an aperture, the aperture having a center longitudinal axis, the dies between stationary end-walls disposed about the longitudinal axis, the dies operatively engaged to at least one of the stationary end-walls, each of the dies having a stent contacting surface which is curved.

Ex. 1202 at 29-33.

63. The Applicant also added independent Claim 67, which included the stationary end-walls limitation, as shown below.

Claim 67. (New) A stent crimper comprising:
a plurality of movable dies arranged to form an iris disposed about an aperture, the aperture
having a longitudinal axis, the plurality of movable dies between stationary plates disposed about
the longitudinal axis, each die in communication with an actuation device, the actuation device
constructed and arranged such that rotational motion of the actuation device opens or closes the
aperture, the dies operatively engaged to at least one of the stationary plates.

Ex. 1202 at 33.

64. The Applicant argued that to the extent Tuberman teaches end-walls, those end-walls (1) are there merely for support and are not operatively engaged to the dies and (2) are not centered about the longitudinal axis. Ex. 1202 at 35. The Applicant similarly argued that Wilhelm teaches an open face apparatus without stationary end-walls. *Id.* at 36.

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

4. October 19, 2004 Office Action and Response

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

arranged to form an iris 30 having a longitudinal axis, the iris 30 defining and aperture of a substantially polygonal shape, the dies 18 disposed about the aperture and between stationary end-walls that are disposed about the longitudinal axis, at least one of the stationary end-walls operatively engaged to the dies 18 at distinct connection locations such that the number of distinct connection locations and the number of dies 18 are the same. *Id.* at 17-18. With regard to Claim 63, the Examiner found that Whitesell teaches overlapping dies. *Id.* at 18. With regard to Claim 66, the Examiner found that Whitesell meets the limitation directed to dies “arranged to have a length of a stent” because stents come in different sizes. *Id.* at 18.

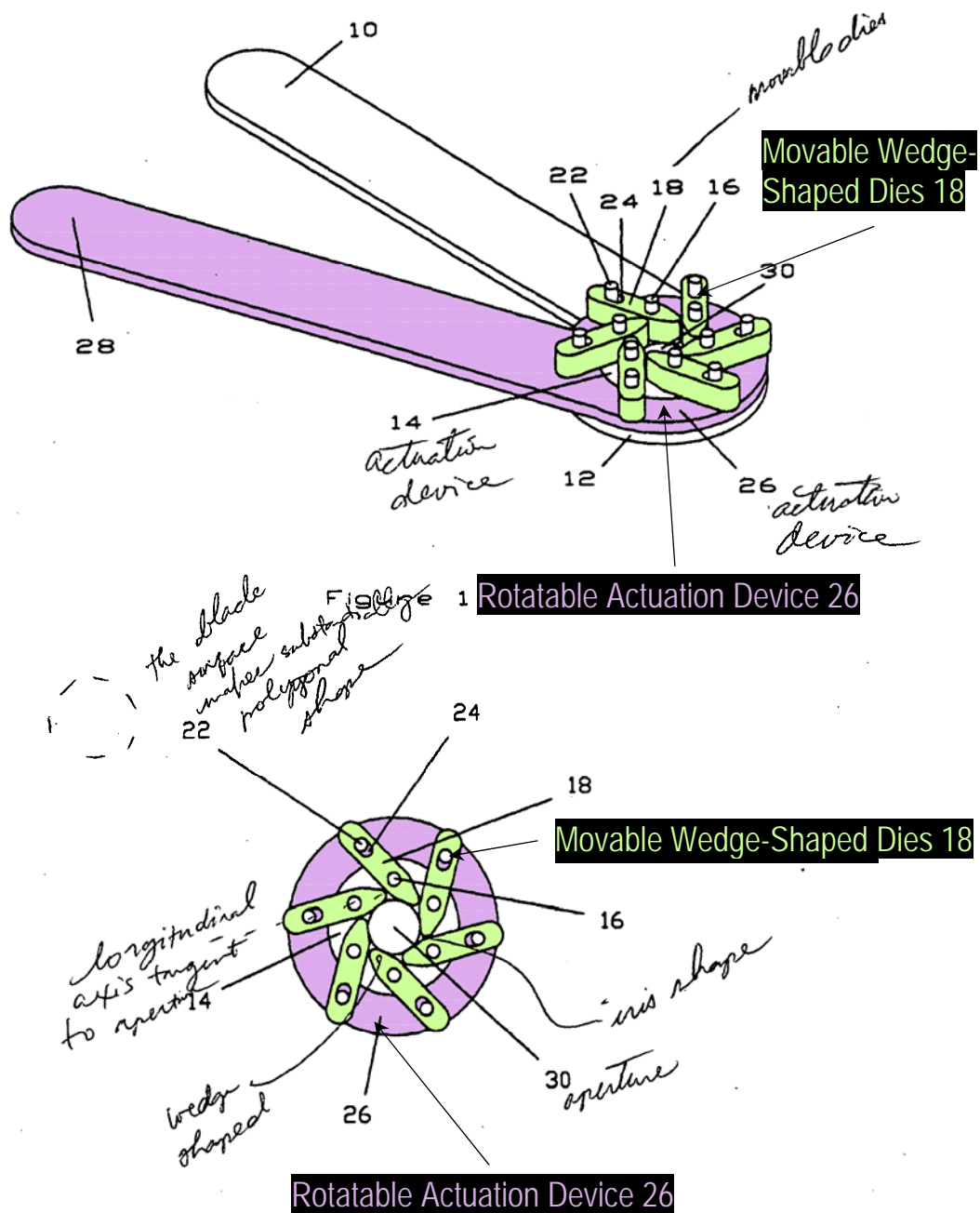
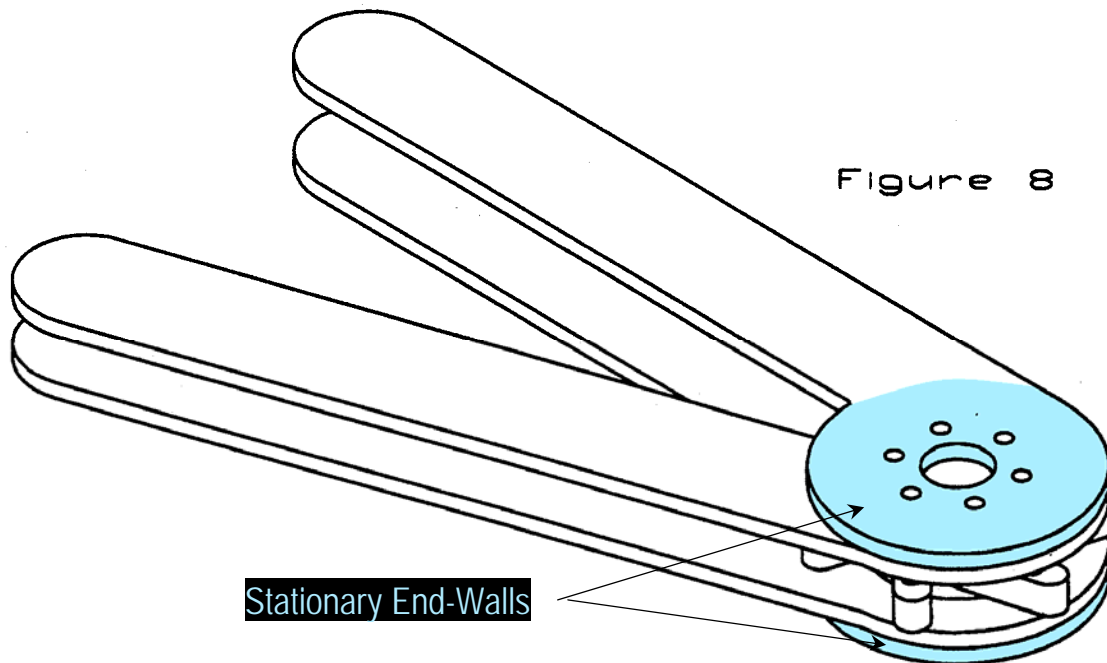


Figure 2

Ex. 1202 at 84 (including Whitesell Figs. 1 and 2 with Examiner's handwritten notes (colors and annotations added)).



See Ex. 1215. Fig. 8 (with color and annotations added).

67. On January 7, 2005, the Applicant amended claims 27, 63 and 67 to include a straight-sided die/polygonal die configuration limitation reciting:

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

See Ex. 1202 at 5-10. The Applicant argued that Whitesell does not teach this element, noting that in Whitesell two straight sides intersect a curved portion of the die and each first straight side is oblique to the second straight side of the adjacent die. *Id.* at 11-12.

68. On February 14, 2005, the Patent Examiner issued a Notice of Allowability. Ex. 1202 at 1-4. Prosecuted Independent Claims 27, 36, 44, 52, 63

and 67 issued as Claims 1, 10, 18, 27, 37 and 40 on July 12, 2005. *Compare id.* at 5-10 *with* Ex. 1201 at 10:8-14:9.

IV. LEVEL OF ORDINARY SKILL IN THE ART

69. It is my understanding that when interpreting the claims of the '560 patent, I must do so from the perspective of one of ordinary skill in the art at the relevant priority date. I am informed that the relevant priority date for the '560 patent is September 22, 1999. I have not been asked to provide an opinion as to what is the appropriate priority date.

70. Based upon my review of the specification and my experience in the field, a POSITA at the time of the claimed invention would have had at least 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.

71. I am informed that the patent law presumes that those of ordinary skill in the art have knowledge of all prior art in the field of the invention.

V. CLAIM CONSTRUCTION

72. I have reviewed the claims and specification of the '560 patent in order to determine the broadest reasonable construction of the claims in view of the patent's specification.

A. “A stent crimper comprising”

73. A POSITA would have understood that the term “stent crimper” in the preamble does not limit the claims.

74. The claims refer to a “stent crimper” in the preamble alone, and never refer back to the preamble stent crimper for antecedent basis. Moreover, the preamble stent crimper is not a recitation of additional structure underscored as important by the specification. The specification acknowledges that the disclosed apparatus can be used to crimp a stent, and also recognizes additional uses such as reducing the size of any generally tubular medical device or forming a balloon molding cavity. *See, e.g.*, Ex. 1201 at 2:50-55 (“Desirably, the medical device is a stent..., although the inventive apparatus may also be employed with any other suitable, generally tubular medical device which must be reduced in size.”); *id.* at 8:65-66 (“The inventive apparatus may also be incorporated into a blow molding tool to provide a variable size balloon mold”); *id.* at 9:20-22 (“[T]he invention may be practiced by providing at least three movable blades disposed about a reference tube to form a shrinkable tubular aperture.”).

75. Based upon the specification a POSITA would have understood that the disclosed apparatus could be used for any crimping application, or even more broadly for any application that required a variable size aperture. The intended use of the apparatus would not change the disclosed structure of the apparatus. A

POSITA would thus understand that the preamble is merely a statement of purpose or intended use for the claimed invention, *i.e.*, crimping a stent. Therefore, the preamble is not limiting.

B. “Dies” and “blades”

76. Claims 1, 10, 18, 37, 39 and 40 recite dies “arranged to form an iris.” Claims 1, 10, 37 and 39 further recite dies “disposed about [an] aperture.” Claims 1, 10, 18, 37 and 39 also recite dies located between stationary end-walls or between stationary plates. 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.” A POSITA would have understood that the claims use the terms dies and blades to describe similar structural components of the claimed apparatus.

77. The specification does not further distinguish between dies or blades because it never uses the terms “die” or “dies.” The specification only discusses “blades,” describing, for example, “movable blades which are disposed about a reference circle to form an aperture whose size may be varied.” Ex. 1201 at Abstract; *see id.* at 2:56-65.

78. The Applicant also did not distinguish between “dies” or “blades” in the prosecution history, and appears to have used the terms “dies” and “blades” interchangeably. For example, the Examiner rejected claims 2, 10 and 18 as

indefinite under 35 U.S.C. § 112, ¶ 2 because the term “blades” in the claims lacked antecedent basis. Ex. 1202 at 44, 71. The Applicant thereafter amended the claims to recite “dies” and deleted the term “blades,” without argument. *Id.* at 30-31, 34, 57, 63.

79. The Examiner also did not distinguish between “dies” or “blades” during prosecution, commenting in an office action dated October 22, 2003, that “dies” correspond to “blades.” Ex. 1202 at 77.

80. Under the broadest reasonable interpretation, a POSITA would have understood the terms “dies” and “blades” to be used interchangeably to describe similar structural components of the claimed apparatus.

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

81. Independent claims 1, 10, 18, 27 and 37 use the phrase “stationary end-walls.” The claims recite stationary end-walls “disposed about the longitudinal axis” of an iris or aperture formed by a plurality of movable dies. Claim 40 similarly uses the phrase “stationary plates disposed about the longitudinal axis” of an aperture formed by a plurality of movable dies.” A POSITA would have understood that the claims use the terms “stationary end-walls” and “stationary plates” interchangeably to describe similar structural components of the claimed apparatus.

82. The specification does not further distinguish between “stationary end-walls” and “stationary plates” because it never uses either of those terms other than in the claims. The specification instead refers to “non-rotating plate[s] 156” or “fixed plate[s] 156.” Ex. 1201 at 5:23, 5:40, 7:10-17, 9:8. The prosecution history likewise does not distinguish between either “stationary end-walls” or “stationary plates.”

83. Under the broadest reasonable interpretation, a POSITA would have understood the terms “stationary end-walls” and “stationary plates” to be used to describe similar structural components of the claimed apparatus, namely stationary elements disposed about the longitudinal axis of an aperture formed by a plurality of movable dies or blades.

VI. THE PRIOR ART

84. I summarize below several prior art references. They constitute prior art properly considered within the knowledge of a POSITA because they either fall within the same field of endeavor or they address the same problem.

A. Analogous Art

1. Field of Endeavor

85. The '560 patent is directed generally to an apparatus formed of “coupled movable blades which are disposed about a reference circle to form an

aperture whose size may be varied.” Ex. 1201 at Abstract. The specification identifies multiple applications for the variable aperture apparatus, including:

- Reducing the size of a medical device, such as a stent. *Id.* at 2:48-55 (“The present invention is directed, in one embodiment, to an apparatus for reducing a medical device in size. Desirably, the medical device is a stent, a stent-graft, a graft or a vena cava filter, whether self-expandable, balloon expandable or otherwise expandable, although the inventive apparatus may also be employed with any other suitable, generally tubular medical device which must be reduced in size.”); *see id.* at 8:41-64.
- As a variable size balloon mold. *Id.* at 3:36-37 (“The inventive apparatus may also be used as a variable size balloon mold.”); *id.* at 9:48-51 (“The use of the inventive apparatus as a mold allows for the blowing of a balloon to a predetermined size using a single adjustable size balloon mold thereby eliminating the need to have multiple molds of different sizes.”); *see also id.* at 8:65-9:9.

86. Therefore, the specification contemplates using a variable size aperture apparatus to compress objects to reduce their size, *i.e.*, crimping applications, and for use in other applications that could benefit from a variable aperture to eliminate the need for multiple apparatus, *i.e.*, non-crimping applications.

87. There are many tools used both within and without the medical device industry that would have been known to a POSITA prior to September 22, 1999 that used a variable size aperture. Other mechanical engineering applications that fall within the same field of endeavor include, for example, tube reducers, socket

wrenches, surgical needle swagers, forming dies, tube pointers, extruding dies, pipe couplers and swagers, hose crimpers, pliers, drawing dies and chucks.

88. The Applicant implicitly recognized the breadth of the analogous prior art by citing prior art apparatus used for applications that did not include crimping a stent or other medical device, including:

Document/ Patent Number	Title
565,257	Apparatus for forming couplings for pipe-sections
758,195	Machine for contracting ferrules
2,751,077	Extrusion apparatus for sheathing electric cables
2,986,192	Apparatus and method for connecting couplings to hose
3,731,518	Crimping die arrangement
4,434,645	Apparatus for the radial shaping of tubular articles
5,381,686	Dual-action pneumo-hydraulic crimping apparatus
5,509,184	Apparatus for crimping a tube in a thick panel
5,715,723	Hose crimping apparatus
5,746,644	Centerless grinder assembly and method of operating the same
5,766,057	Centerless grinding machine
5,746,644	Centerless grinder assembly and method of operating the same
5,715,723	Hose crimping apparatus
WO 90/00098	Radial Press For Essentially Cylindrical Workpieces

89. During prosecution the Examiner also identified prior art outside the medical device field. Each of the patents below was cited by the Examiner during prosecution:

Document/ Patent Number	Title
1,665,915	Pipe-swaging device
1,889,795	Method of joining pipes
2,292,421	Hose coupling-method of and means for forming same

Document/ Patent Number	Title
2,887,222	Extrusion apparatus for sheathing electric cables
3,084,389	Plastic molding process and apparatus
3,416,352	Press for deforming plastic stock
3,664,213	Wrench
3,695,087	Method and apparatus for pointing tubes
4,164,523	Method of injection-molding and cooling of shaped synthetic-resin bodies
4,578,982	Radial press for workpieces having a cylindrical exterior surface
4,942,756	Multi-jaw forming press especially suited for details of variable sections
4,854,031	Hose crimper and method of using same
5,195,350	Method for forming features on an elongated metal wire
5,261,263	Crimping pliers with radially opposed jaws
6,176,116	Crimping tool for crimping lead end sleeves and the like
6,167,605	Collet type crimping tool

90. As discussed with respect to the prosecution history, the Examiner relied on several of the above prior art references for both anticipation and obviousness rejections.

91. Indeed, a POSITA would have known that some practitioners at the time of the invention used ordinary pliers or plier-like devices to crimp stents, *see, e.g.*, Ex. 1214 at 1:33-35 (disclosing use of “plier-like device”); Ex. 1225 at 1:43-46 (disclosing use of “modified plier-like tools”); Ex. 1219 at 2:1-3 (disclosing manual crimping using “pliers”); Ex. 1218 at 2:6-9 (disclosing use of “tools, such as ordinary pliers”); Ex. 1226 at 3:20-23 (“The stent is positioned over the balloon portion of the dilatation catheter and gently crimped onto the balloon either by hand or with a tool such as pliers or the like”); Ex. 1227 at 1:67-2:1

(disclosing use of “tools, such as ordinary pliers”), and it is therefore reasonable to include these types of devices in the field of endeavor.

92. Any prior art directed to an apparatus that uses coupled movable members disposed about a reference circle to form a variable size aperture falls within the same field of endeavor as the '560 patent and constitutes analogous prior art that would have been known to a POSITA.

2. Pertinent To The Particular Problem

93. The '560 patent teaches that uneven forces applied to a stent while crimping necessitates either discarding or re-crimping the stent, and that re-crimping can damage the stent. Ex. 1201 at 1:48-55. The '560 patent set out to solve the problem of uneven crimping forces. *See* Ex. 1201 at 2:27-30.

94. Prior to September 22, 1999, the problem of uneven crimping forces was a known problem for many types of crimpers, not just stent crimpers. For example, both Whitesell (Ex. 1215 at 1:13-20), cited during prosecution, and Baker (Ex. 1211 at 1:12-24, 33-42), identify this problem. They both solve the problem by using dies that form a polygonal aperture and apply even forces around the aperture. Ex. 1215 at Abstract, 1:28-36; Ex. 1211 at 1:45-2:2. Other crimping, forming and gripping prior art therefore is relevant because it may solve similar problems as those faced by stent crimpers.

95. Indeed, the Examiner looked to crimping, forming and gripping prior art during prosecution to provide solutions to the problem identified in the '560 patent, citing and relying upon numerous patents in the classes of metal working, metal deforming and tools to reject the claims. *See* Ex. 1202 at 15-21 (relying on Whitesell), 42-49 (relying on Tuberman and Wilhelm). Whitesell (Ex. 1215), Tuberman (Ex. 1216) and Wilhelm (Ex. 1217) reference US classes 29 (metal working), 72 (metal deforming) and 81 (tools)). The Applicant also disclosed prior art patents in these fields when submitting Information Disclosure Statements. Ex. 1202 at 81-82, 159-64 (Information Disclosure Statements disclosing patents referencing US classes 29 (metal working) and 72 (metal deforming)).

96. Prior art directed to apparatus that can provide uniform size reduction around an aperture are reasonably pertinent to solving the problem of the '560 patent and are also analogous art.

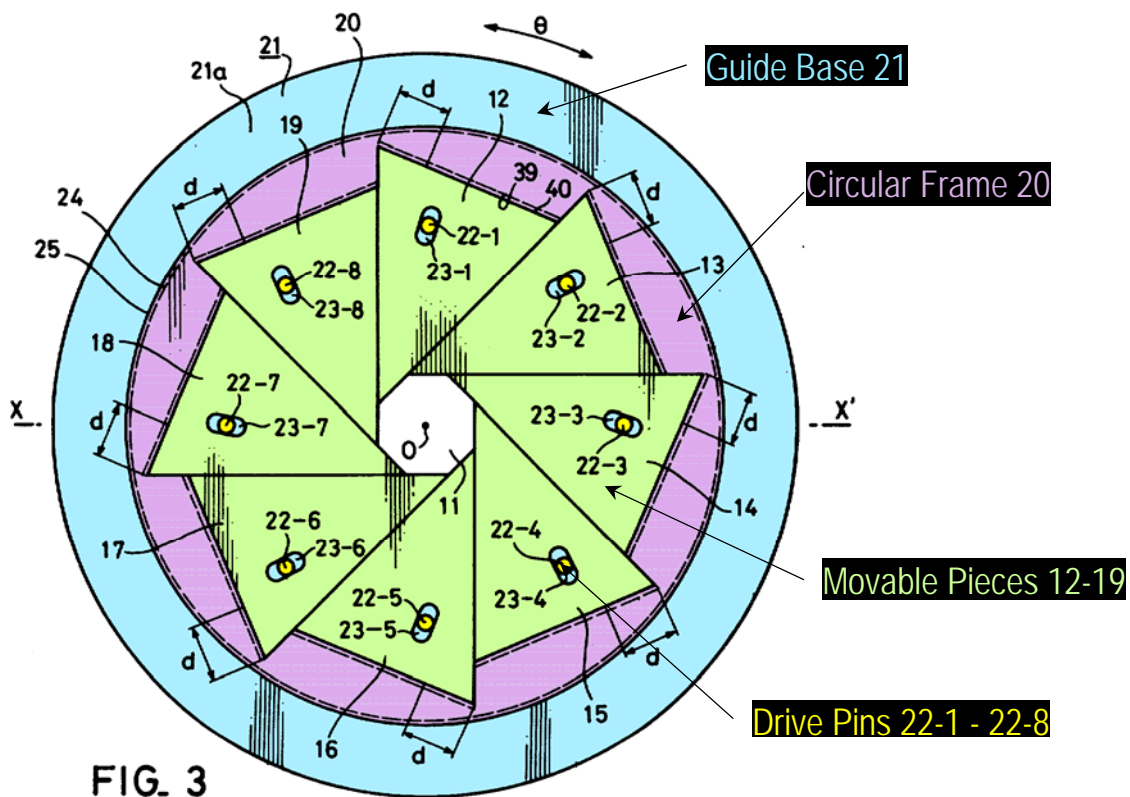
B. Yasumi

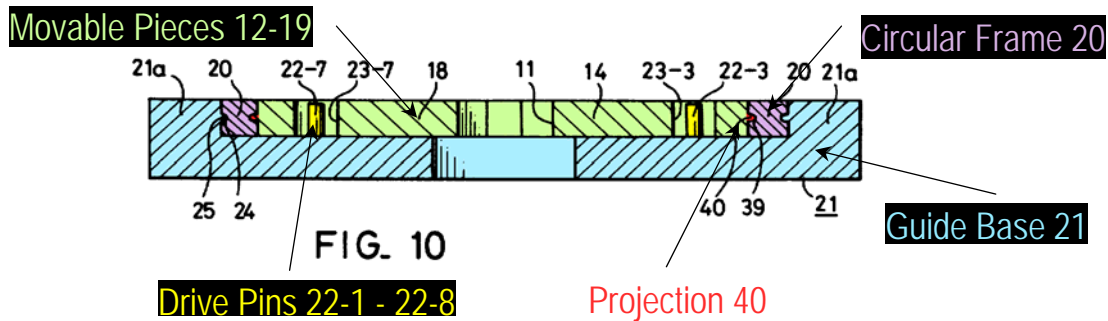
97. U.S. Patent No. 4,454,657 ("Yasumi") was filed on March 25, 1982 and issued on June 19, 1984. Yasumi was never considered by the Patent Office during prosecution of the '560 patent. I am informed that Yasumi qualifies as prior art to the '560 patent under 35 U.S.C. § 102(b).

98. Yasumi discloses "an aperture setting device in which the size of the predetermined polygonal aperture can be changed, retaining the polygonal

configuration.” Ex. 1203 at 1:10-13. As depicted below, plurality of movable pieces each of which has a triangular section (green) define a polygonal aperture that can be varied by movement of the pieces. *Id.* at Abstract, 1:45-60.

99. As depicted in Figure 3, one embodiment uses eight movable pieces 12-19 (green) disposed in a circular frame 20 (purple). The movable pieces 12-19 (green) are each arranged to be movable to the base thereof in the frame 20. A guide base 21 is provided as a drive means. The movable pieces 12-19 and the frame 20 are mounted on the guide base 21 (blue). Ex. 1203 at 5:39-59.





Ex. 1203, Figs. 3, 10. A guide groove 39 is cut in the inner peripheral surface of the frame 20 to extend in its circumferential direction. An elongated projection 40 (red), which is movable along the guide groove 39, is formed on each movable piece. This prevents the movable pieces 12-19 (green), from getting out of the frame 20 when moved. *Id.* at 5:51-57.

100. Drive pins 22-1 to 22-8 (yellow) are planted on the guide base 21 (blue) at regular intervals. Ex. 1203 at 5:63-62. The movable pieces 12 to 19 (green) have cut therein elongated holes 23-1 to 23-8 to extend substantially perpendicularly to their bases. The drive pins 22-1 to 22-8 (yellow) are respectively inserted in the elongated holes 23-1 to 23-8. *Id.* at 5:63-6:1. The area of the aperture 11 can be set to a desired value by turning the circular frame 20 (purple) and the guide base 21 (blue) about the axis 0 relative to each other. Relative rotation of the circular frame 20 (purple) and the guide base 21 (blue) moves the pieces 12-19 (green) along the circular frame 20 (purple) the distance

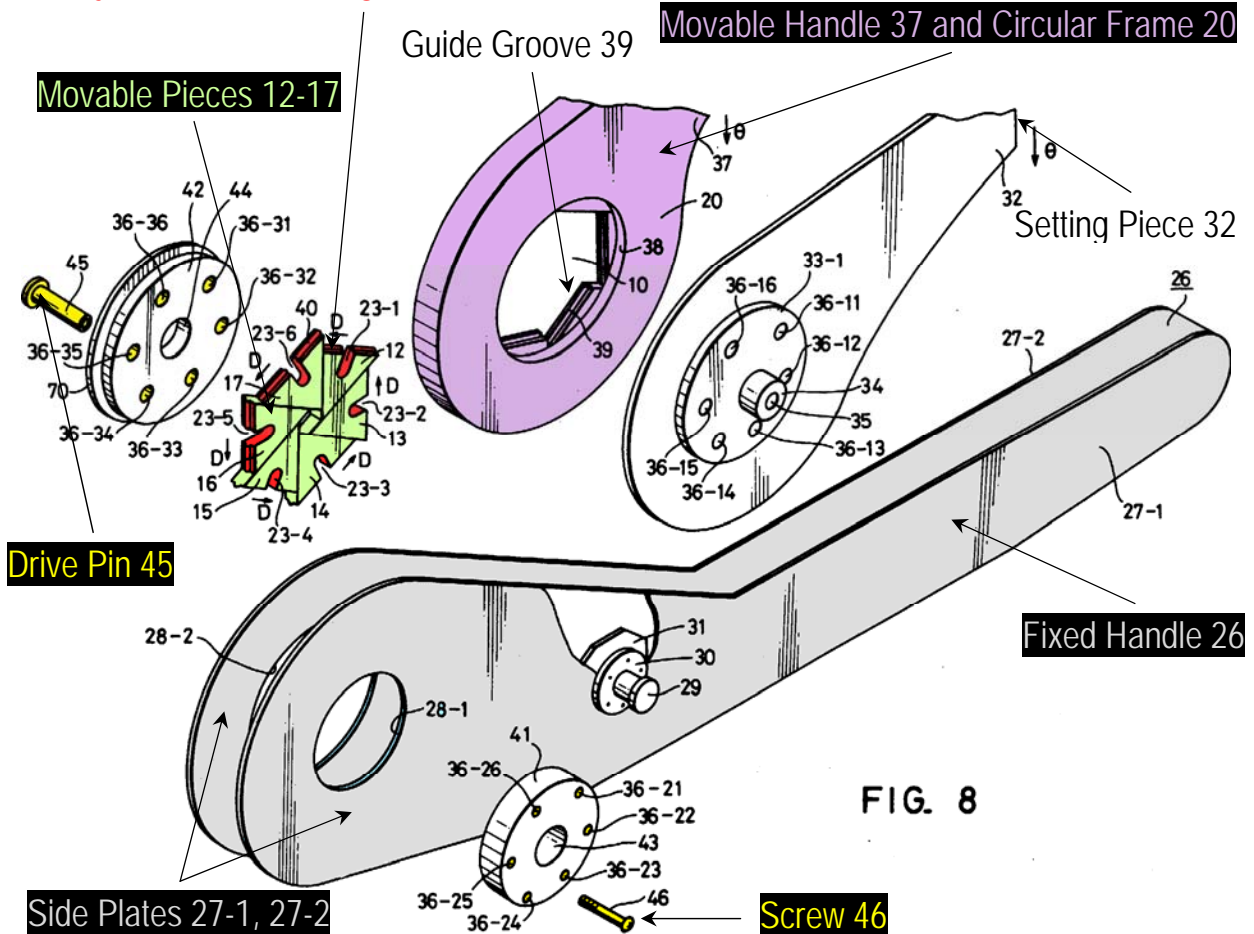
“d,” changing the size of the aperture while maintaining the relative orientation of the movable pieces and the polygonal shape of the aperture. *Id.* at 6:1-19.

101. Each movable piece 12-19 has a first straight side facing the aperture, and a second straight side facing the adjacent piece and converging with the first side to form a tip. Each first straight side is parallel to the second side of an adjacent die. Ex. 1203, Fig. 3.

102. Figure 8 is an exploded diagram illustrating an embodiment that uses a circular frame 20 (purple) and movable pieces (green) similar to those described with respect to Figure 3 in a manual forming and pressing tool. Ex. 1203 at 7:33-38.¹

¹ Please note that the circular frame and dies are depicted in different orientations in Figures 3 and 8. As depicted in Figure 3, turning the circular frame counterclockwise relative to the base will move the dies inward to close the aperture. Figure 8 depicts the obverse side (or “mirror image”), and turning the circular frame clockwise relative to the fixed handle will move the dies inward to close the aperture.

Projection 40 and Elongate Holes 23-1 – 23-6



Ex. 1203, Fig. 8.

103. The manual forming and pressing tool includes a fixed handle 26 (gray) composed of a pair of parallel spatular side plates 27-1 and 27-2. Ex. 1203 at 7:39-42. The side plates 27-1 and 27-2 are wide at one end portion and narrow at the other end portion, with circular holes 28-1 and 28-2 centrally disposed in the wide end portions. *Id.* at 7:43-46.

104. The tool also includes a movable handle 37 (purple) that has formed integrally therewith the frame 20 (also purple) described previously with respect to

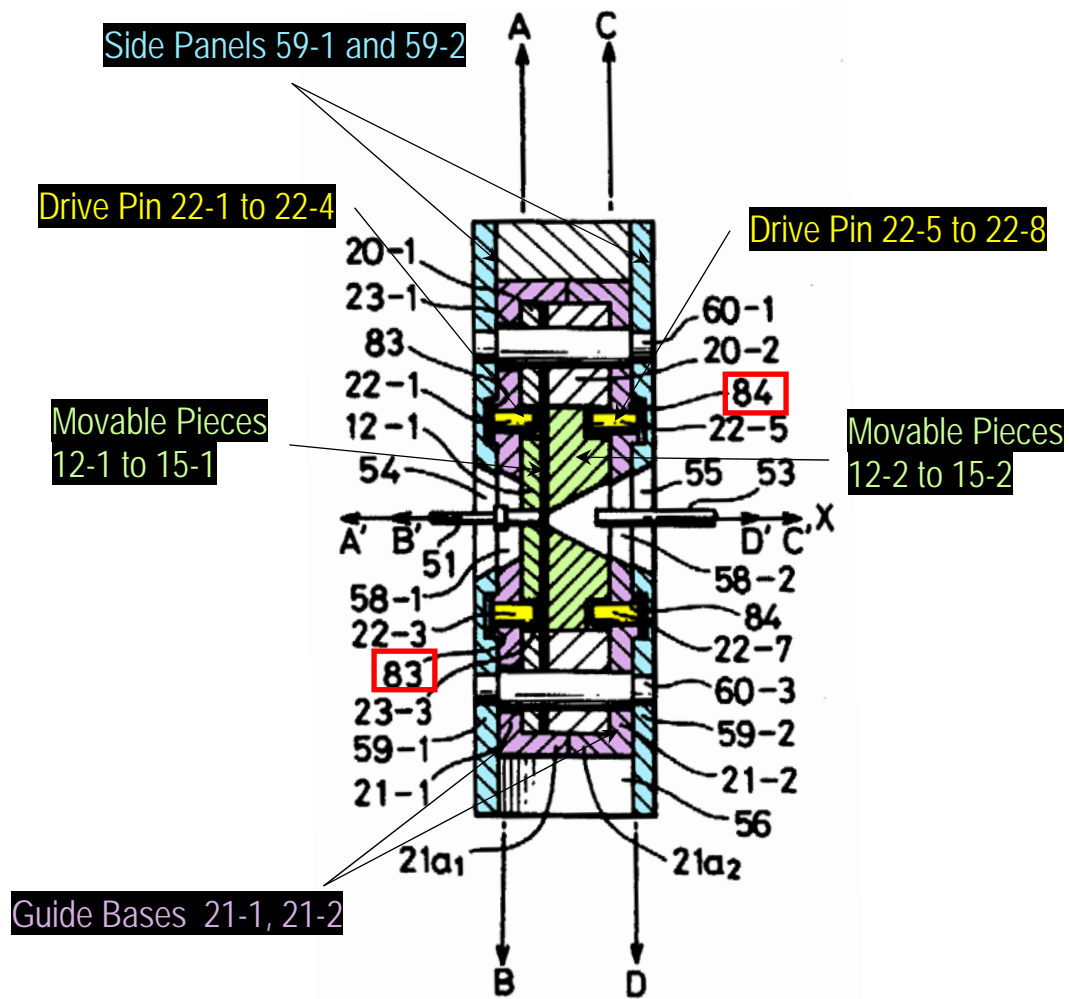
Figure 3. Ex. 1203 at 7:46-52. Movable pieces 12-17 (green) are arranged in the frame 20 in a manner to be movable along their bases by a predetermined “D.” *Id.* Guide grooves 39 are cut in the inner peripheral surface of the frame 20 (purple) and projections 40 (red) for engagement with the guide grooves 39 are formed on the surface of each movable piece on the side of its base. *Id.* at 7:52-57. The frame 20 (purple) and movable pieces 12-17 (green) are interposed between the wide end portions of the two side plates 27-1 and 27-2 of the fixed handle 26 (gray). *Id.* at 7:57-63.

105. The movable handle 37 (purple) and the fixed handle 26 (gray) are designed so that they can turn about the axis of the frame 20 (blue) relative to each other, and the movable pieces 12-17 (green) are moved by the relative rotational movement of the handles 37 and 26. Ex. 1203 at 7:63-67. To this end, a support disc 42 is fitted into the circular hole 28-2 of the side plate 27-2 (gray). *Id.* at 8:1-5. A setting piece 32 for setting the opening of the aperture is interposed between the frame 20 and the side plate 27-1 (gray). *Id.* at 8:10-14. Another support disc 41 is placed on the outside of the side plate 27-1 (gray) to cover the hole 28-1. *Id.* at 8:23-25. The setting piece 32 and the support discs 41 and 42 respectively has formed therethrough small holes 36-11 to 36-16, 36-21 to 36-26 and 36-31 to 36-36 corresponding to the elongated holes 23-1 to 23-6 of the movable pieces 12-16 (green). *Id.* at 8:27-32. Drive pins 45 (yellow) are individually inserted into

corresponding ones of the abovesaid small holes and the elongated holes from the outside of the support disc 42. *Id.* at 8:32-34. A screw 46 (also yellow) is screwed into the threaded hole of each pin 45 (yellow) from the outside of the support disc 41 through the abovesaid small holes and the elongated hole. *Id.* at 8:35-41.

106. In this way, the movable handle 37 (purple) is rotatable relative to the fixed handle 26 (gray). Ex. 1203 at 7:42-45. Bringing the grips of the fixed handle 26 (gray) and the movable handle 27 (purple) close to each other, the setting piece 32 also turns but butts against the fixed handle 26 when a set angle is reached. Further rotational movement of the setting piece 32 is limited, and consequently the pins 45 (yellow) are fixed by virtue of their engagement to the fixed handle via the setting piece. *Id.* at 8:45-50. Bringing the grips of the handles 26 (gray) and 37 (purple) closer to each other, the pins 45 (yellow) move in the elongated holes 23-1 to 23-6 to move the movable pieces 12-17 in the frame 20 (purple), reducing the aperture. *Id.* at 8:55-53.

107. Figures 9(a) – (c) illustrate another embodiment of the aperture setting device as applied to an electric wire guide device, used to mechanically connect a connector pin with an electric wire by crimping the connector pin around the electric wire. This embodiment includes *two sets* of movable pieces, 12-1 to 15-1 and 12-2-15-2 (green). Ex. 1203 at 9:35-62.



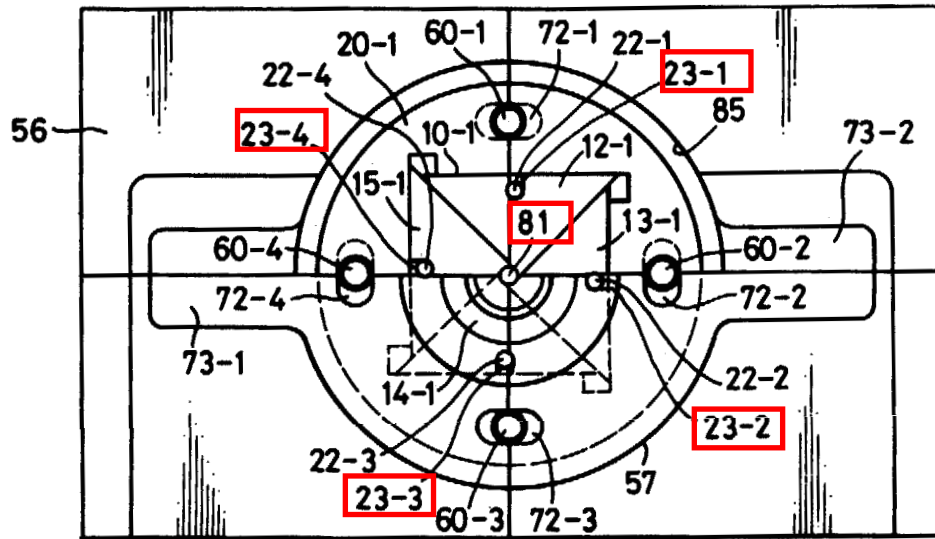


FIG. 9(b)

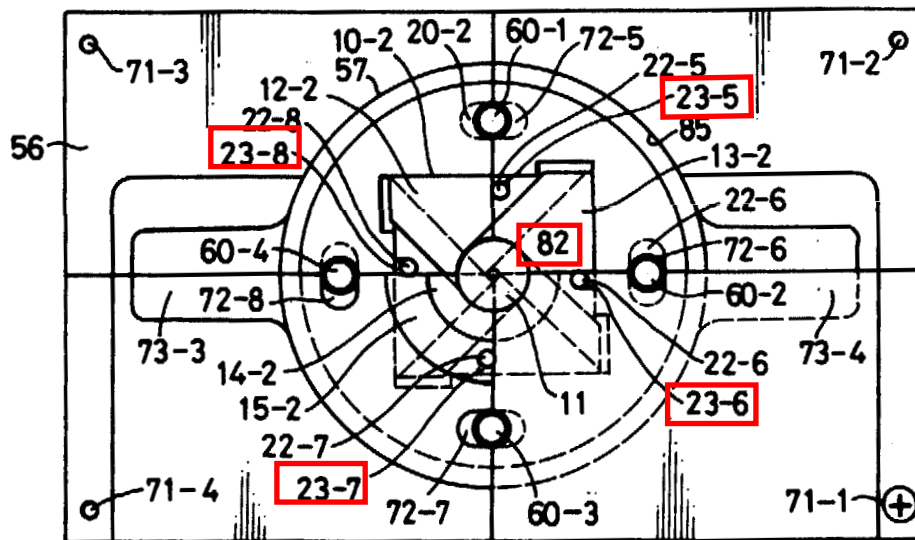


FIG. 9(c)

Ex. 1203, Figs. 9(a)-(c).

108. The two sets of movable pieces 12-1 to 15-1 and 12-2 to 15-2 (green) are fitted into two separate guide bases 21-1 and 21-2 (purple). Ex. 1203 at 9:53-56. The guide bases 21-1 and 21-2 and movable pieces 12-1 to 15-1 and 12-2 to

15-5 sit between side panels 59-1 and 59-2 (blue). *Id.* at 9:37-48. Drive pins 22-1 to 22-4 (yellow) fit into ring-shaped groove 83 in the side panel 59-1, pass through guide base 21-1 and into movable pieces 12-1 to 15-1. *Id.* at 9:56-59, 10:68-11:4. Similarly, drive pins 22-5 to 22-8 fit into a ring-shaped groove 84 in the side panel 59-2, through guide base 21-2 and into movable pieces 12-2 to 15-2. *Id.* at 9:59-62, 10:68-11:4. Each die has an elongated hole 23-1 to 23-8 through which drive pins 22-1 to 22-8 (yellow) are inserted. *Id.* at 10:68-11:4.

109. The two sets of movable pieces 12-1 to 15-1 and 12-2 to 15-2 are each arranged to form differently-shaped apertures. Ex. 1203 at 9:63-67. The aperture formed by movable pieces 12-1 to 15-1 is aligned with the aperture formed by movable pieces 12-2 to 15-2. *Id.* at 9:67-68. Dies 12-1 to 15-1 hold the connector pin 51 in position. *Id.* at 10:50-56. Dies 12-2 to 15-2 guides the wire 53 into alignment with, and into a hole in, the connector pin 51. *Id.* at 10:56-64. The apertures formed by dies 12-1 to 15-1 and 12-2 to 15-2 are in turn aligned with the openings in guide bases 21-1 and 21-2 and in side panels 59-1 and 59-2. *Id.* at 9:39-41, 10:1-6. In this way, the connector pin and the electric wire may be inserted through the disclosed electric guide wire device to align the connector pin with the electric wire and to crimp the connector pin around the electric wire. *Id.* at 9:37-39.

110. In operation, the guide bases 21-1 and 21-2 are rotated to move the two sets of movable pieces 12-1 to 15-1 and 12-2 to 15-2 inward and outward to enlarge or reduce the apertures 81 and 82, respectively, formed by the movable pieces. Ex. 1203 at 10:7-11:9.

111. Yasumi is in the same field of endeavor as the '560 patent because Yasumi is generally directed to “an aperture setting device applicable, for example, to a drawing die, a chuck and so forth, and more particularly to an aperture setting device in which the size of a predetermined polygonal aperture can be changed, retaining the polygonal configuration.” Ex. 1203 at 1:8-13. Such an apparatus “would be of great ability when employed in such devices as . . . a press tool[.]” *Id.* at 1:35-40; *see id.* at 7:33-38 (“FIG. 8 is an exploded diagram illustrating an embodiment of the aperture setting device of the present invention as used in a manual forming and pressing tool.”). A POSITA would have readily understood that a press tool is a crimper, and therefore Yasumi is directed to a crimper. A POSITA would also have understood that the invention discussed in Yasumi could be used to crimp any object, including a stent.

112. Yasumi is also reasonably pertinent to the problem to be solved by the '560 patent. The '560 patent set out to solve the problem of uneven crimping forces, such as those caused by elongate members poking radially into an aperture. *See* Ex. 1201 at 2:26-30.

113. Yasumi recognized a problem with prior art aperture setting devices, namely that it is difficult to change the size of the aperture without introducing a gap between adjacent elements forming the aperture. Ex. 1203 at 1:17-20. This is the same problem the Applicant identified with the AAPA. Ex. 1202 at 65 (“The aperture is not being minimized; elongate members are merely being introduced into the aperture to crimp the stent.”). Yasumi’s disclosure focuses on solving the problem using a tool capable of changing the size of a predetermined polygonal aperture while retaining its shape. Ex. 1203 at 1:9-12, 1:32-35.

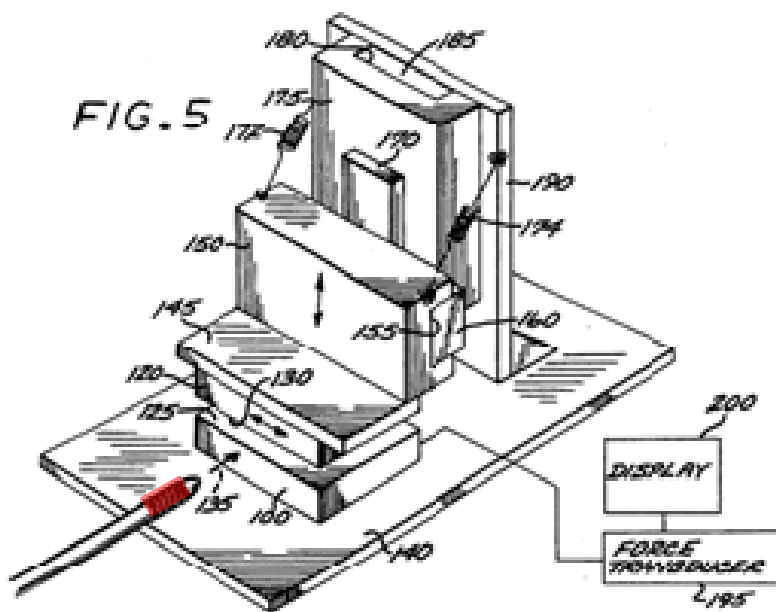
114. A POSITA would have understood that the invention disclosed in Yasumi would result in uniform crimping forces to any object within the aperture and would remedy the uneven crimping force problem identified in the ’560 patent. Yasumi is therefore analogous prior art. *Id.*

C. Williams

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

116. Williams teaches an invention “directed to a vascular prosthesis loading device, which automatically loads a stent onto the distal end of a catheter assembly, with a minimum of human handling, to better secure the stent onto the

catheter while the stent is being delivered through the patient's vasculature." Ex. 1227 at 1:48-53. Williams also notes that "some tools, such as ordinary pliers, have been used to apply the stent . . ." *Id.* at 1:67-68. Williams goes on to teach multiple different crimping tool embodiments, such as a stent-loading device using a bladder and chamber for receiving the stent, as depicted in Figures 1-4, and a stent-loading device using a series of plates that move in a rectilinear fashion with respect to each other to affix the stent onto the outside of the catheter, as depicted in Figures 5-7. For example, the stent loading mechanism depicted in Figure 5 is shown below:



Ex. 1227, Fig. 5 (colored annotation added). Williams explains that:

The device comprising [stet] a pair of plates, a lower support plate 100 and an upper support plate 120, that form flat surfaces or faces 125, 130, in between which a stent-carrying catheter may be placed, as indicated by arrow 135. Uniform pressure may be applied to crimp the stent [red] onto the catheter, by reciprocating surfaces 125, 130 relative to one another.

Id. at 4:7-16. The device is operated by:

placing a catheter that has a stent disposed about its stent-receiving portion, which in a balloon catheter would be the balloon portion of the catheter, in between the space formed between the substantially flat surfaces of faces 125, 130. The operator then gently reciprocates plate 120 to move face 130, which contacts the stent-receiving catheter, with respect to face 125, which is fixed and also contacts the catheter, to apply a slight downward force and evenly crimp the stent onto the catheter. The gentle reciprocating motion of the two substantially flat rubberized faces 125, 130, together with the downward application of force, insures an even application of force to the outside of the stent and achieves a uniform crimping of the stent onto the catheter.

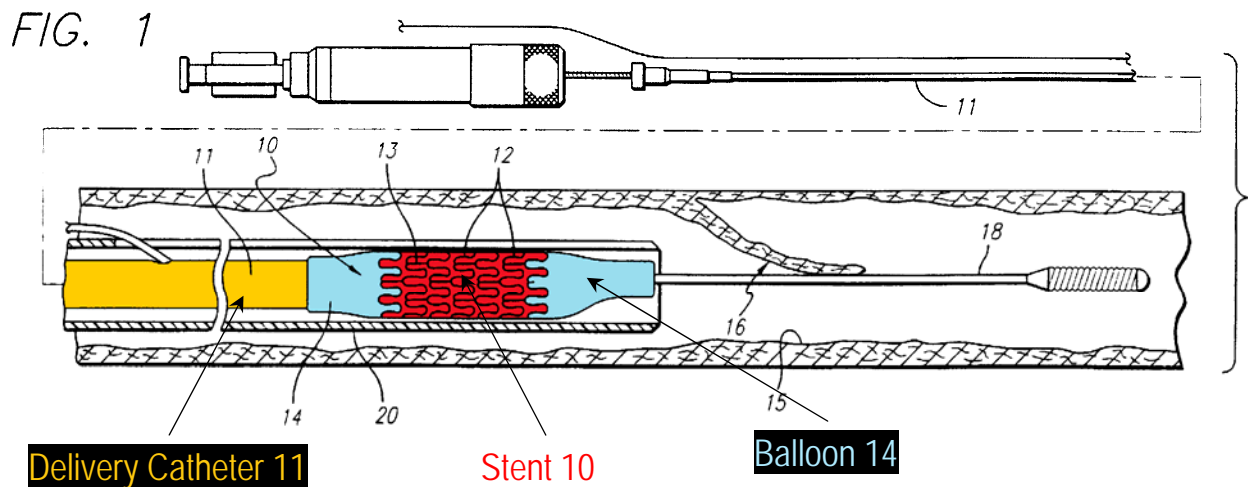
Id. at 5:11-20.

D. Morales

117. U.S. Patent No. 5,893,852 (“Morales”) was filed on April 28, 1998 and issued on April 13, 1999. *See* Ex. 1204. I am informed that Morales qualifies as prior art to the ’560 patent under 35 U.S.C. § 102 (a) or (e) and that Morales was cited during prosecution, but not relied upon by the Examiner.

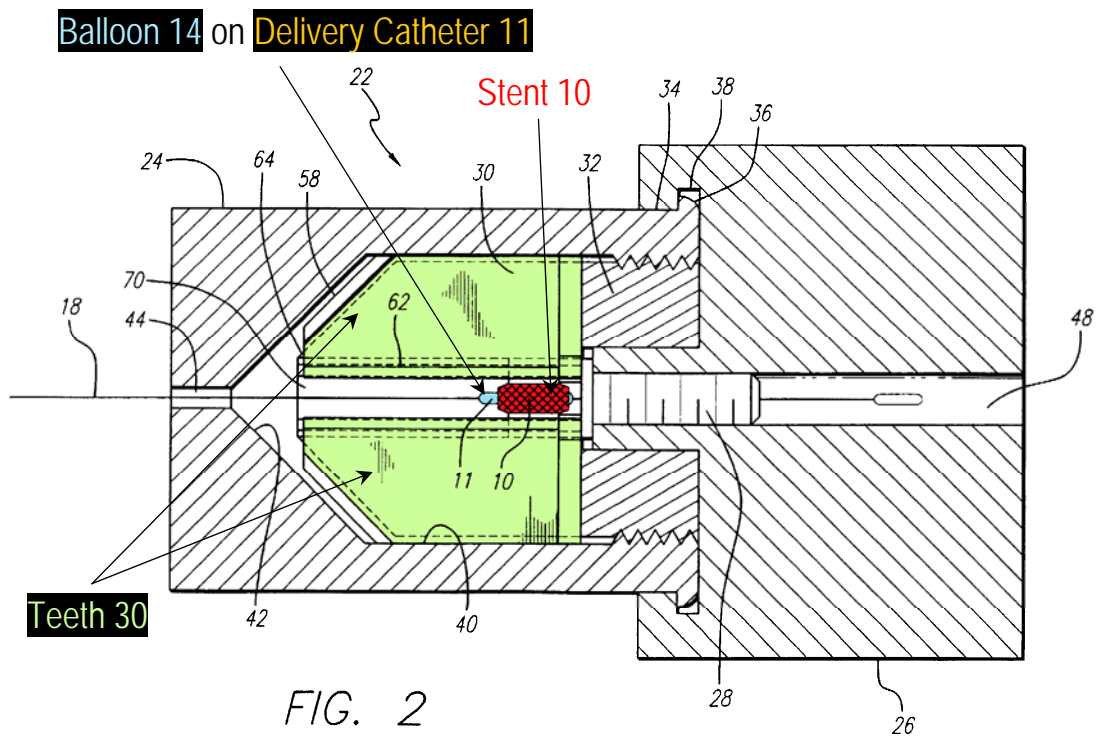
118. Morales discloses that “[i]n procedures where the stent is placed over the balloon portion of the catheter, it is necessary to crimp the stent onto the balloon portion to reduce its diameter and to prevent it from sliding off the catheter

when the catheter is advanced through the patient's vasculature.” Ex. 1204 at 1:55-59. Figure 1 of Morales shows an exemplary stent 10 (red) that has been crimped onto a delivery catheter 11 (orange) having an expandable balloon 14 (blue) for expanding the stent 10 within an artery. *Id.* at Fig. 1, 5:60-67.



Ex. 1204, Fig. 1 (annotations and color added).

119. Morales discloses “[a] stent crimping tool for firmly and uniformly crimping a . . . stent onto a balloon catheter.” Ex. 1204 at Abstract. In use, an uncrimped stent is loaded into the hollow core of the crimping tool. “At the opposite end of the tool, the balloon catheter is inserted through the opening into the cylindrical cavity at the proximal section of the housing, which leads into the hollow core of the screw holding the uncrimped stent.” *Id.* at 3:38-42. A user then crimps the stent by holding the proximal section 24 while twisting distal section 26. *Id.* at 3:66-4:3.



Ex. 1204, Fig. 2 (annotations and color added).

120. Figure 2 shows the stent 10 (red) disposed about a balloon 14 (blue) and held between teeth 30. Ex. 1204 at Fig. 2, 6:66-7:3. In operation, “[a]s screw feed 28 advances toward proximal section 24 it carries forward teeth 30 so that angular proximal edges 58 of each tooth 30 encounters tapered end 42, which in turn forces teeth 30 to converge radially inward. As this convergence occurs, radius edges 62 of teeth 30 engage and crimp the underlying stent 10 onto balloon catheter 11. Teeth 30 thus act as jaws closing down on stent 10.” *Id.* at 8:58-64. Morales also teaches that the four equally spaced teeth 30 (green) are long enough to crimp various stent lengths. *Id.* at 5:5-9.

VII. INVALIDITY ANALYSIS

121. This section contains my opinions concerning the application of specific prior art references and combinations to the elements of Claims 1, 2, 6, 8-11, 14, 15, 17-19, 23, 25-28, 31, 33-35, 37, 39 and 40. For each prior art reference, a claim chart is included below with the claim language from the '560 patent in the left column and exemplary disclosure from the corresponding prior art in the right column.

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

1. Claim 1

122. Claim 1 of the '560 patent recites:

A stent crimper comprising:

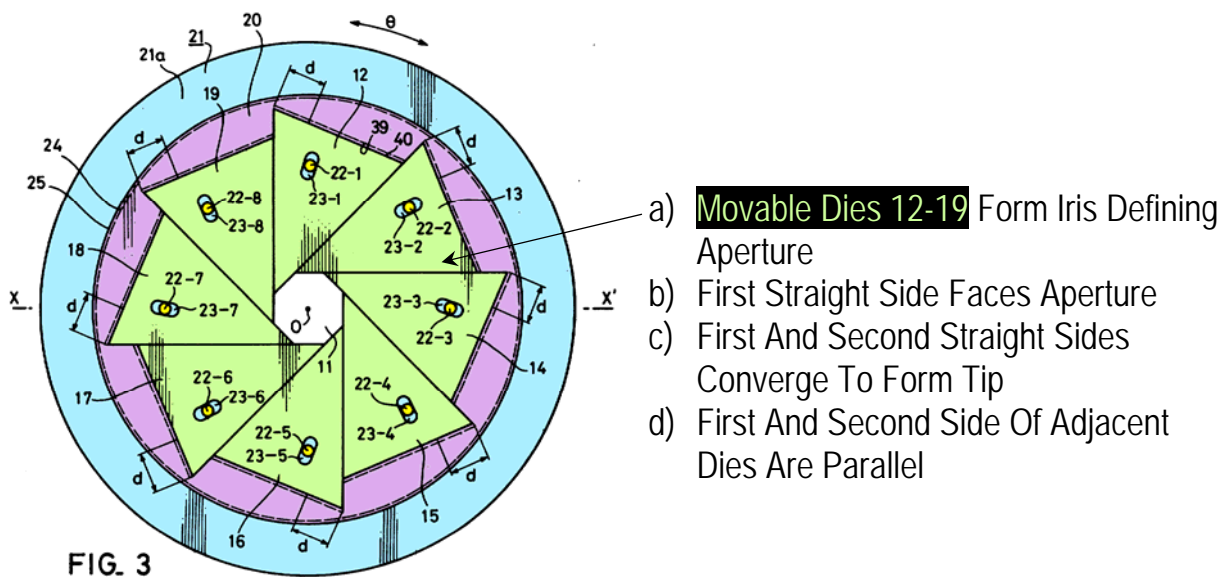
a plurality of movable dies arranged to form an iris having a longitudinal axis, the iris defining an aperture, the dies disposed about the aperture and between stationary end-walls which are disposed about the longitudinal axis, at least one of the stationary end-walls operatively engaged to the dies at distinct connection locations such that the number of distinct connection locations and the number of dies are the same;

each die having a first straight side and a second straight side, the first straight side and the second straight side converging [sic] to form a tip;

wherein a portion of the first straight side of each die faces the aperture, each first straight side parallel to the second side of an adjacent die.

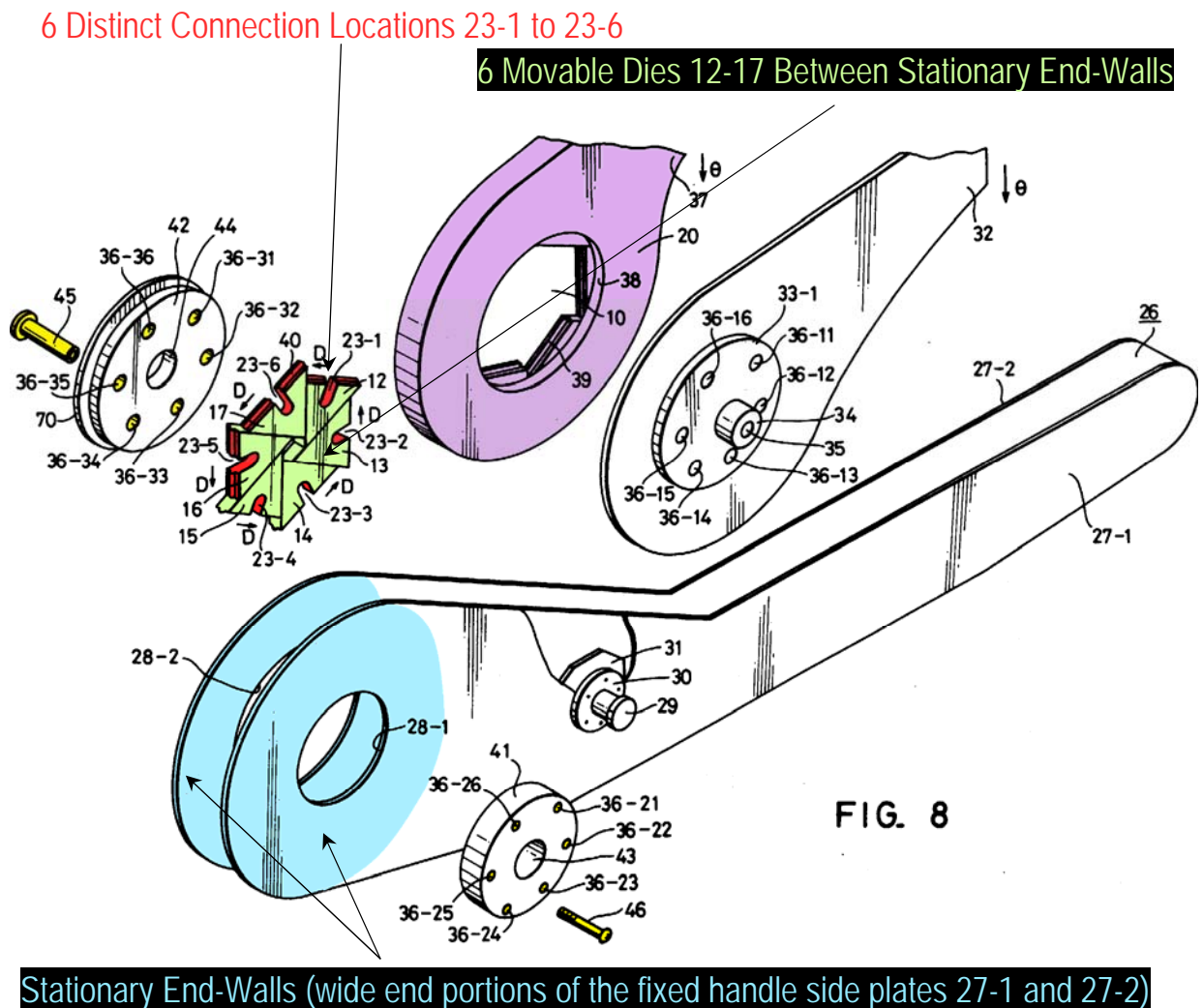
123. Yasumi discloses every limitation of Claim 1, with the possible exception of the preamble. The preamble recites a “stent crimper.” Yasumi does not address crimping a stent, but the structure disclosed in Yasumi is capable of crimping a stent. Therefore, I understand Yasumi to be a stent crimper for the purposes of my analysis. Moreover, as noted above, the preamble does not limit the claims. Williams also discloses the preamble “stent crimper.”

124. The movable pieces disclosed in Yasumi correspond to the movable dies. As depicted in Figure 3, the dies 12-19 (green) are arranged to form an iris having a longitudinal axis, the iris defining an aperture.



Ex. 1203, Fig. 3 (colored annotations added). As depicted, the dies have a first straight side facing the aperture, and a second straight side converging with the first to form a tip. Each first straight side is parallel to the second straight side of the adjacent die.

125. The embodiments depicted in Figures 8 and 9 include stationary end-walls. Yasumi's manual forming and pressing tool, depicted in Figure 8, is reproduced below with annotations and color added:



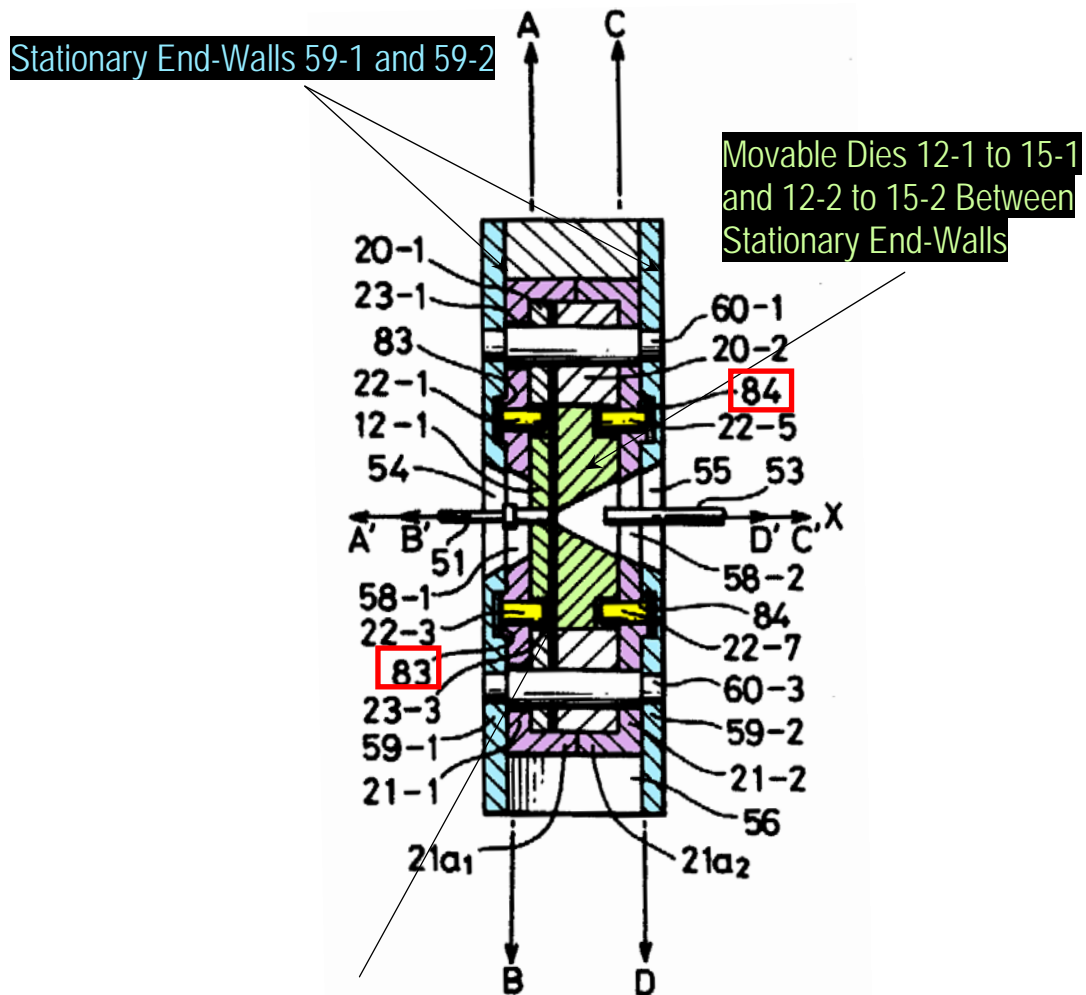
Ex. 1203, Fig. 8 (with annotation and color added).

126. The dies 12-17 (green) sit within a circular frame 20 (purple). *Id.* at 7:49-50. That entire piece is disposed between the wide end portions of side plates 27-1 and 27-2 (blue) that correspond to the stationary end-walls. *See id.* at 7:57-60.

The wide end portions of the side plates 27-1 and 27-2 are on either end of the tool and are arranged around the axis with holes therethrough to permit placement of an object into the aperture. The wide end portions of the side plates 27-1 and 27-2 remain fixed, or stationary, during the crimping process, whereas the movable handle turns closer the fixed handle to alter the size of the aperture. *Id.* at 8:42-54, 9:3-15, 9:26-34. Therefore, the dies 12-17 (green) are between stationary end-walls (blue).

127. At least one of the end-walls (blue) is operatively engaged to the dies (green) at distinct connection locations such that the number of distinct connection locations and the number of dies are the same. Each die has an elongated hole 23-1 to 23-6 (red) that ultimately engages the die to the end-walls 27-1 and 27-2 using pins 45 (yellow), screws 46 (yellow), support disks 41 and 42 and setting piece 32. *See id.* at 8:1-41. Thus, each die has an elongated hole, which is a distinct connection location, such the number of distinct connection locations and the number of dies are the same.

128. Figure 9(a) depicting an electric wire guide device, is reproduced below with annotations and color added:



8 Distinct Connection Locations 23-1 to 23-8

FIG. 9(a)

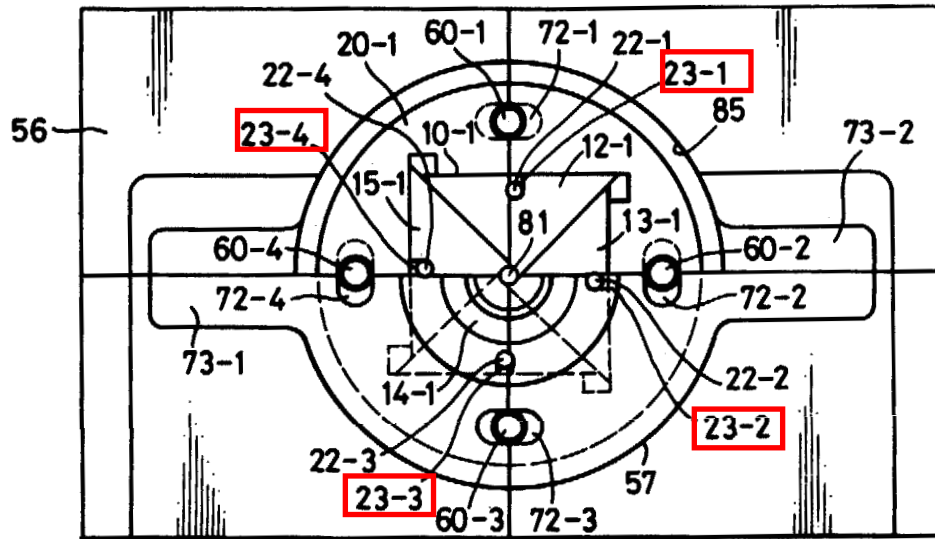


FIG. 9(b)

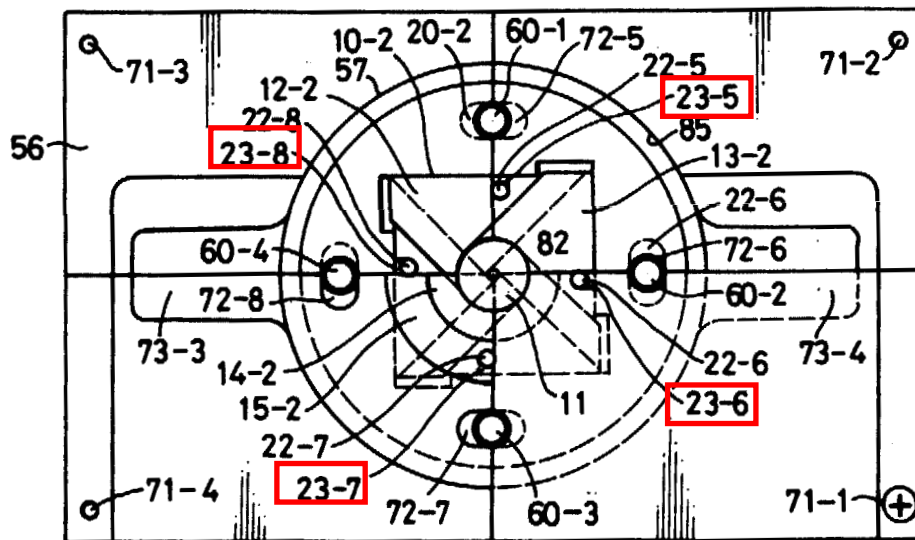


FIG. 9(c)

Ex. 1203, Fig. 9(a)-(c) (with annotation and color added).

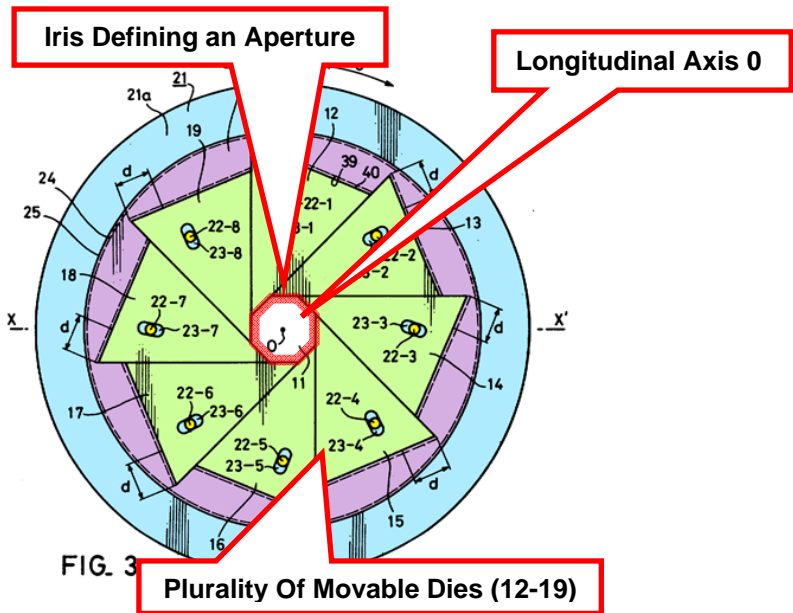
129. Two sets of movable dies, 12-1 to 15-1 and 12-2 to 15-2 (green) sit within guide bases 21-1 and 21-2 (purple), respectively. Ex. 1203 at 9:54-62. That entire piece is disposed between left- and right-hand side panels 59-1 and 59-2 (blue) that correspond to the claimed stationary end-walls. *See id.* at 9:43-47. The

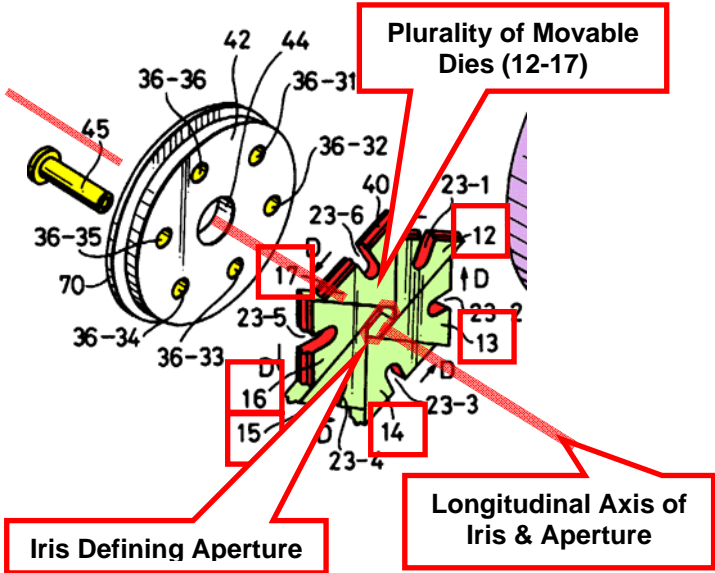
side panels are on either end of the tool and are arranged around the axis with holes therethrough to permit placement of an object into the aperture. *See id.* at 9:37-41. The side panels are fixed and do not move. Therefore, the dies 12-1 to 15-1 and 12-2 to 15-2 are between stationary end-walls (blue)

130. At least one of the end-walls (blue) is operatively engaged to the dies (green) at distinct connection locations such that the number of distinct connection locations and the number of dies are the same. Each die has an elongated hole 23-1 to 23-8 for engaging each die to the end-walls 59-1 and 59-2 using drive pins 22-1 to 22-8 (yellow) and guide grooves 83 and 84 formed into the end-walls 59-1 and 59-2 (blue). Ex. 1203 at 10:68-11:4. Each die has an elongated hole, which is a distinct connection location, such that the number of distinct connection locations and the number of dies are the same.

131. The claim chart below provides a left column with claim language from the '560 patent and provides a right column with exemplary disclosure from Yasumi and Williams.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
[1 preamble] A stent crimper comprising:	<u>Yasumi discloses</u> : “a manual forming and pressing tool.” (Ex. 1203 at 7:33-38; <i>id.</i> at 1:35-39, 9:30-34, 11:25-30.) This tool is capable of crimping a stent. Therefore, Yasumi is a stent crimper. Moreover, the preamble “stent crimper” does not limit the claim. <u>Williams discloses</u> : “This invention is directed to a

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p>vascular prosthesis loading device, which automatically loads a stent onto the distal end of a catheter assembly, with a minimum of human handling, to better secure the stent onto the catheter while the stent is being delivered through the patient's vasculature. . . . [S]ome tools, such as ordinary pliers, have been used to apply the stent . . .” (Ex. 1227 at 1:48-68.)</p>
<p>[1a] a plurality of movable dies arranged to form an iris having a longitudinal axis, the iris defining an aperture,</p>	<p><u>Yasumi discloses a plurality of movable dies (movable pieces 12-17 or 12-19) arranged to form an iris having a longitudinal axis, the iris defining an aperture:</u></p> <p>“[A]t least three or more substantially triangular movable pieces are sequentially arranged in the form of a ring, an aperture is formed by one end portion of an inner side of each movable piece...” (Ex. 1203 at Abstract; <i>id.</i> at 1:47-50, 2:45-47, 2:65-3:3, 4:42-44, 8:53-54, 9:63-67.)</p> <div data-bbox="584 1018 1372 1627">  <p>FIG. 3</p> </div>

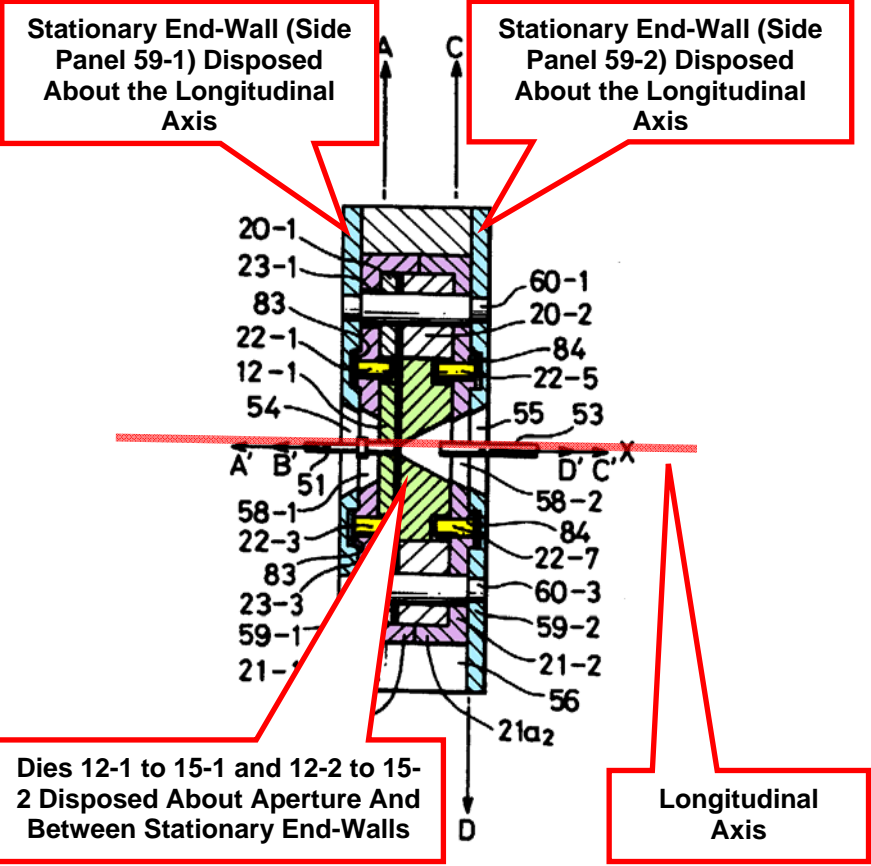
<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	 <p>The diagram is a cross-sectional view of a mechanical assembly. It features a circular component on the left with multiple small circular features, labeled with reference numerals 36-36, 42, 44, 36-31, 36-32, 40, 23-6, 23-1, 12, 23-2, 13, 23-3, 23-4, 14, 15, 16, 17, 36-35, 70, 36-34, and 36-33. A yellow cylindrical component is labeled 45. A red line indicates the longitudinal axis of the iris and aperture. Red boxes highlight specific features: 'Plurality of Movable Dies (12-17)' points to the dies 12, 13, 14, 15, 16, and 17; 'Iris Defining Aperture' points to the aperture 17; and 'Longitudinal Axis of Iris & Aperture' points to the axis line. The text '(Ex. 1203 at Figs. 3 & 8.²)' is located below the diagram.</p> <p>(Ex. 1203 at Figs. 3 & 8.²)</p>

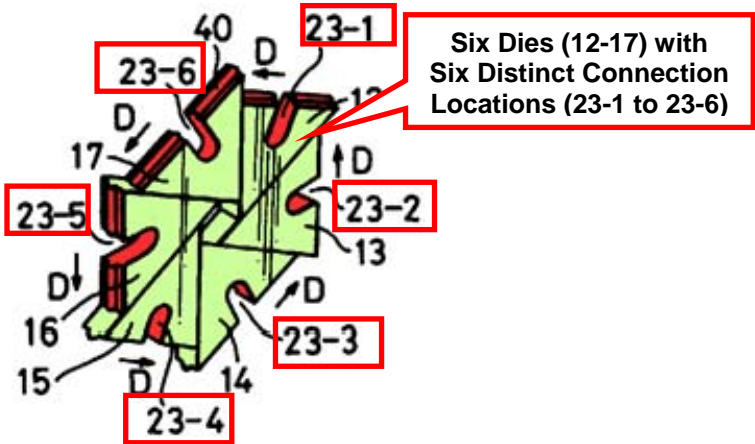
² Please note that figures from the prior art have been annotated in the tables throughout this Declaration with red boxes to identify pertinent elements and callouts to label important features.

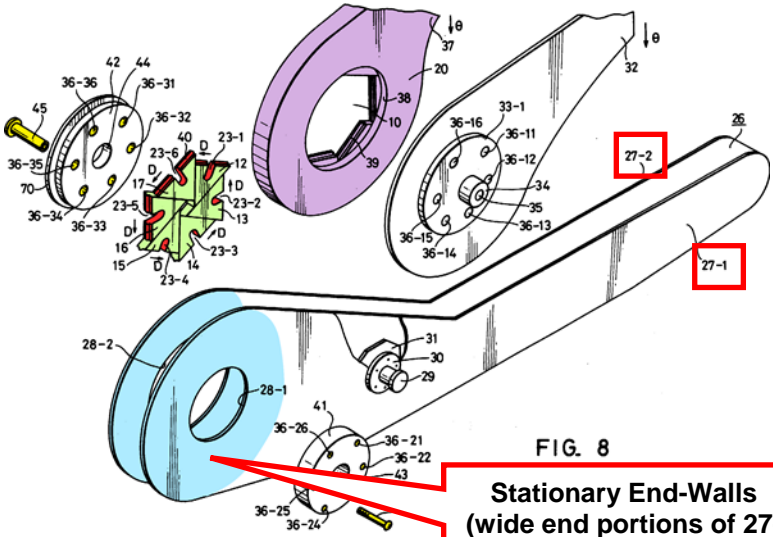
<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
<p>[1b] the dies disposed about the aperture and between stationary end-walls which are disposed about the longitudinal axis,</p>	<p><u>Yasumi discloses dies (movable pieces 12-17 or 12-19) disposed about the aperture and between stationary end-walls (wide end portions of the fixed handle side plates 27-1 and 27-2) which are disposed about the longitudinal axis:</u></p> <p>“A fixed handle 26 is composed of a pair of parallel spatular side plates 27-1 and 27-2 The frame 20 having thus mounted therein the plurality of movable pieces 12 to 17 is interposed between the wide end portions of the two side plates 27-1 and 27-2 of the fixed handle 26...” (Ex. 1203 at 7:39-8:9.)</p> <p>“In this way, the fixed handle 26, the movable handle 37 and the setting piece 32 are coupled together, but the movable handle 37 is rotatable relative to the fixed handle 26. Bringing the grips of the fixed handle 26 and the movable handle 27 close to each other, the setting piece 32 also turns but butts against the fixed handle 26 when a set angle is reached, and further rotational movement of the setting piece 32 is limited, and consequently the pins 45 are fixed. Bringing the grips of the handles 26 and 37 closer to each other, the pins 45 move in the elongated holes 23-1 to 23-6 to move the movable pieces 12 to 17 in the frame 20, reducing the aperture defined by the movable pieces 12 to 17.” (<i>Id.</i> at 8:42-54.)</p> <p>“The angle between the setting piece 32 and the fixed handle 26 does not become smaller than the angle therebetween when the setting piece 32 butts against the cam 31, and at that angle the rotational movement of the setting piece 32 is stopped. A minimum angle between the fixed handle 26 and the setting piece 32 can be altered by the set position of the adjust disc 30. Since the opening of the aperture is determined by the amount by which the movable handle 37 can be turned closer to the fixed handle 26 from the position where the setting piece 32 has been halted, as described previously, the opening of the aperture can be set by the set position of the adjust disc 30.” (<i>Id.</i> at</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p>9:3-15.)</p> <p>“Next, the movable handle 37 is turned to reduce the angle between it and the fixed handle 26, butting the setting piece 32 against the adjust cam 31 to stop the rotational movement of the setting piece 32. By further rotating the movable cam 37 towards the fixed handle 26, the member to be formed is subjected to a sufficiently large pressure by the movable pieces 12 to 17 and readily formed into a predetermined shape.” (<i>Id.</i> at 9:26-34.)</p> <div data-bbox="565 785 1360 1682"> <p>Dies 12-17 Disposed About Aperture And Between Stationary End-Walls</p> <p>FIG. 8</p> <p>Longitudinal Axis</p> <p>Stationary End-Wall (wide end portion of 27-2) Disposed About the Longitudinal Axis</p> <p>Stationary End-Wall (wide end portion of 27-1) Disposed About the Longitudinal Axis</p> </div> <p>(Ex. 1203, Fig. 8.)</p> <p>A POSITA would have understood based on the Yasumi disclosure that the fixed handle 26 is stationary.</p>

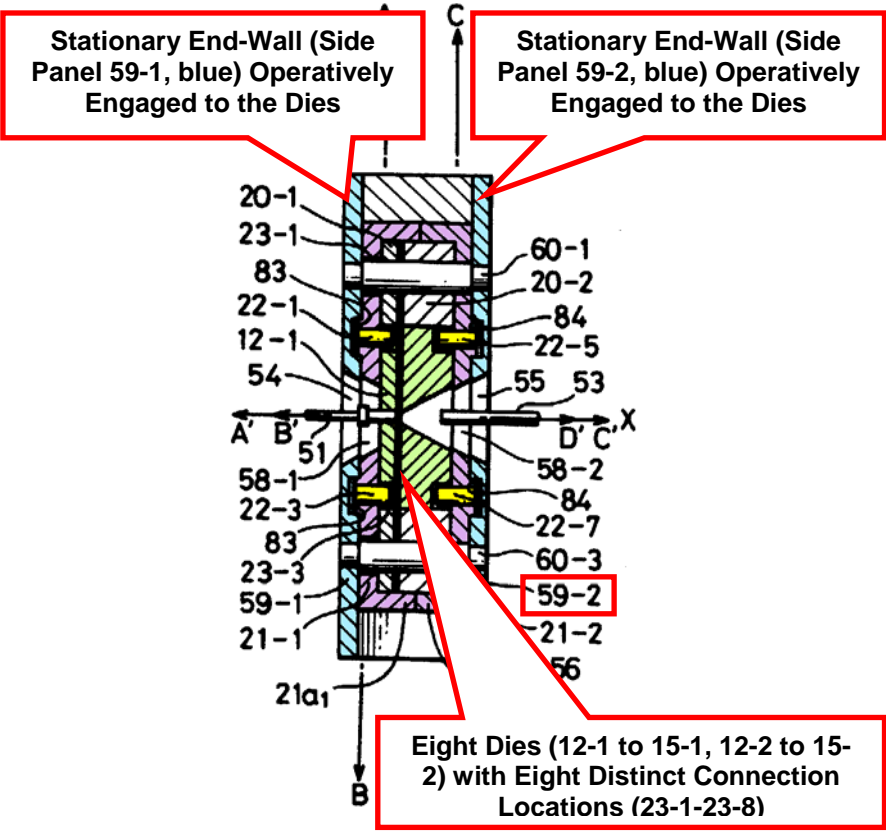
<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p><u>Yasumi includes an additional embodiment that discloses dies (movable pieces 12-1 to 15-1 and 12-2 to 12-5) disposed about the aperture and between stationary end-walls (left- and right-hand side panels 59-1 and 59-2) which are disposed about the longitudinal axis:</u></p> <p>“As shown in FIG. 9(a), a pin 51 of a connector and an electric wire 53 are inserted into the aperture setting device through openings 54 and 55 formed in left- and right-hand side panel 59-1 and 59-2 of a rectangular parallelepiped casing, and the pin 51 and the wire 53 are brought into alignment with each other. In the casing, guide bases 21-1 and 21-2 serving as drive means, which are similar to the guide base 21 described previously in connection with FIGS. 3 and 10, are respectively disposed on the insides of the left- and right-hand side panels 59-1 and 59-2 Further, as shown in FIGS. 9(a), 9(b) and 9(c), two sets of four movable pieces 12-1 to 15-1 and 12-2 to 15-2 are respectively fitted into the frames 20-1 and 20-2. The guide base 21-1 has planted thereon drive pins 22-1 to 22-4, which are respectively inserted into elongated holes 23-1 to 23-4 of the movable pieces 12-1 to 15-1. Similarly, the guide base 21-2 has planted thereon drive pins 22-5 to 22-8, which are inserted into elongated holes 23-5 to 23-8 of the movable pieces 12-2 to 15-2.” (Ex. 1203 at 9:37-62.)</p> <p>“The movable pieces 12-1 to 15-1 are so formed as to provide a pyramidal aperture setting portion 81, whereas the movable pieces 12-2 to 15-2 are so formed as to provide a truncated, quadrangular pyramidal aperture setting portion 82. The axes of the aperture setting portions 81 and 82 lie on the same straight line, which is substantially in alignment with the centers of the openings 54 and 55 of the side panels of the casing.” (<i>Id.</i> at 9:63-10:2.)</p> <p>“At this time, since the frames 20-1 and 20-2 are fixed to the side panels 59-1 and 59-2, as referred to previously, and do not move, the movable pieces 12-1 to 15-1 and 12-</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p>2 to 15-2 housed in the frames 20-1 and 20-2 respectively move along their bases, thereby enlarging both apertures 81 and 82. Conversely, by pressing the drive pieces 73-2 and 73-3, both apertures 81 and 82 are reduced.” (<i>Id.</i> at 10:42-49.)</p>  <p style="text-align: center;">FIG. 9(a)</p> <p>(Ex. 1203, Fig. 9(a).)</p>
<p>[1c] at least one of the stationary end-walls operatively engaged to the dies at distinct</p>	<p>Yasumi discloses at least one of the stationary end-walls (<u>wide end portions of the fixed handle side plates 27-1 and 27-2</u>) operatively engaged to the dies (movable pieces 12-17 or 12-19) at distinct connection locations (<u>elongated holes 23-1 to 23-6</u>) such that the number of distinct</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
<p>connection locations such that the number of distinct connection locations and the number of dies are the same;</p>	<p><u>connection locations and the number of dies are the same:</u></p> <p>In Figure 8 from Yasumi, each movable piece has one elongated hole that engages the piece to the wide-end portions of the fixed handle side plates 27-1 and 27-2 via support disks 42 & 43, drive pins 45, screws 46, and setting piece 32. More specifically, the pins 45 are engaged to the fixed handle via the setting piece 32. In operation, the setting piece 32 abuts the fixed handle. Because the pins 45 extend through holes in the setting piece 32, once that setting piece 32 is held stationary by the fixed handle, the pins 45 are likewise held stationary. The pins 45 are also engaged to the movable pieces 12-17 or 12-19 via the elongated holes 23-1 to 23-6. In operation, the pins 45 remain stationary while the movable handle rotates. The pins 45 guide the movable pieces 12-17 or 12-19 inward to close the polygonal aperture. . (See Ex. 1203 at 8:1-54.) The six elongated holes are the six distinct connection locations on the dies that operatively engage the six dies to the stationary end-walls.</p> 

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	 <p data-bbox="1110 751 1187 779">FIG. 8</p> <p data-bbox="1040 793 1382 926">Stationary End-Walls (wide end portions of 27- 1 & 27-1) Operatively Engaged To The Dies</p> <p data-bbox="537 951 813 989">(Ex. 1203, Fig. 8.)</p> <p data-bbox="537 1066 1419 1873">To the extent that it is viewed that the claim requires a more direct operative connection, it would have been obvious to a POSITA that the embodiment in Fig. 8 from Yasumi could be simplified by removing the setting piece and the support disks 42 & 43. The setting piece permits the user to customize the size of the aperture. This feature would be useful if the tool were for use with objects of varying size. In a stent crimping application, the expanded and contracted size of the stent is known in advance. Therefore, the crimping tool can be constructed in the first instance to accommodate the range of aperture sizes needed to crimp the stent, without the need to manually set the size using a setting piece. To do so, the support disks 42 & 43 would be integrated into the wide-end portions of the fixed handle side plates 27-1 and 27-2 such that the pins are connected directly to the side plates 27-1 and 27-2 on each end. <i>Id.</i> The resulting tool would have one elongated hole on each movable piece, one pin extending through each elongated hole, and each pin connected to the</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p>side plates on either side of the movable pieces.</p> <p><u>Yasumi also discloses at least one of the stationary end-walls (left- and right-hand side panels 59-1 and 59-2) operatively engaged to the dies (movable pieces 12-1 to 15-1 and 12-2 and 15-2) at distinct connection locations (elongated holes 23-1 to 23-8) such that the number of distinct connection locations and the number of dies are the same:</u></p> <p>In Figure 9(a) from Yasumi, each movable piece has an elongated hole (23-1 to 23-8) that engages the die to the side panels 59-1 and 59-2 that are the stationary end-walls. Drive pins 22-1 to 22-8 extend through the elongated holes on each die to fit into ring-shaped grooves 83 and 84 that are formed in the side panels 59-1 and 59-2. The eight elongated holes are the eight distinct connection locations that operatively engage the eight dies to the stationary end-walls. (<i>See</i> Ex. 1203 at 9:56-62, 10:68-11:4.)</p> <p>“The guide base 21-1 has planted thereon drive pins 22-1 to 22-4, which are respectively inserted into elongated holes 23-1 to 23-4 of the movable pieces 12-1 to 15-1. Similarly, the guide base 21-2 has planted thereon drive pins 22-5 to 22-8, which are inserted into elongated holes 23-5 to 23-8 of the movable pieces 12-2 to 15-2.” (<i>Id.</i> at 9:56-62.)</p> <p>“In FIG. 9(a), the pins 22-1 to 22-4 and 22-5 to 22-8 slightly jut out towards the side panels 59-1 and 59-2, respectively. In order to [<i>sic</i>] projecting ends of the pins 22-1 to 22-4 and 22-5 to 22-8, shallow, ring-shaped grooves 83 and 84 are formed in the side panels 59-1 and 59-2.” (<i>Id.</i> at 10:68-11:4.)</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	 <p style="text-align: center;">FIG. 9(a)</p> <p>(Ex. 1203, Fig. 9(a).)</p>
<p>[1d]</p> <p>each die having a first straight side and a second straight side, the first straight side, the first straight side and the second straight side converging [sic] to form a tip; wherein a portion of the first straight side of each die faces the aperture, each first</p>	<p><u>Yasumi discloses each die (movable pieces 12-17 or 12-19) having a first straight side (inner side) and a second straight side, the first straight side and the second straight side converging to form a tip; wherein a portion of the first straight side of each die faces the aperture, each first straight side parallel to the second side of an adjacent die:</u></p> <p>“[A]n aperture is formed by one end portion of an inner side of each movable piece and the movable piece . . .” (Ex. 1203 at Abstract; <i>see id.</i> at 2:48-59, 4:42-44, Claim 1.)</p>

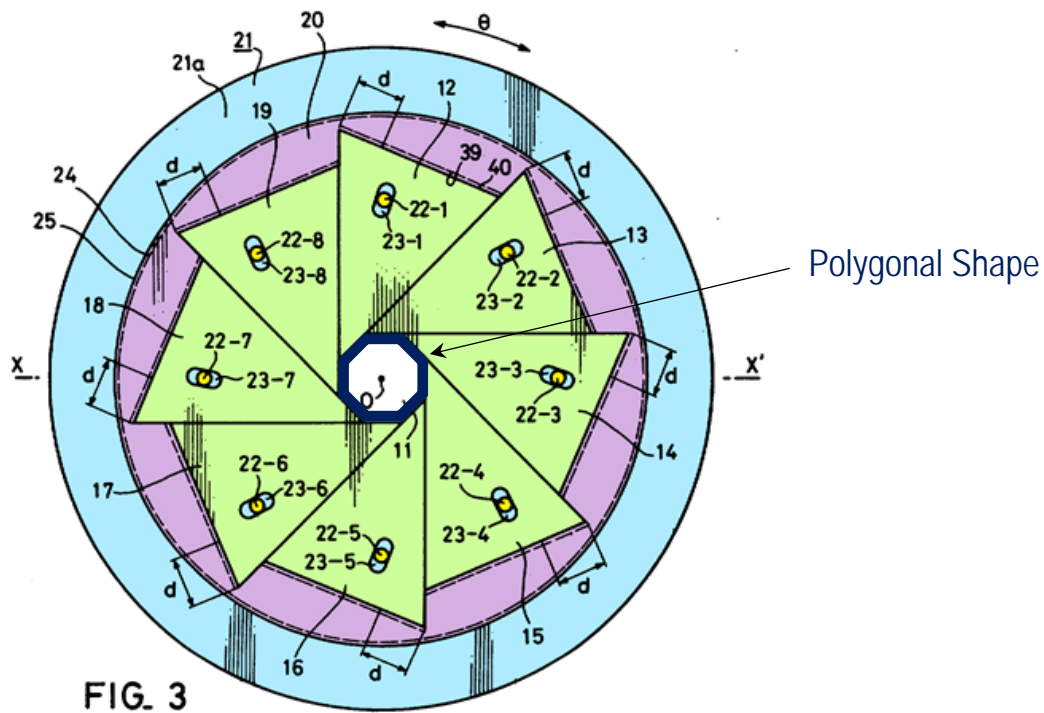
<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
<p>straight side parallel to the second side of an adjacent die.</p>	<div data-bbox="553 321 1409 1203"> <p>Second Straight Side (Blue) Of Die 19 Converging With First Side (Red) To Form Tip</p> <p>First Straight Side (Red) of Die 19 Facing Aperture</p> <p>First Straight Side (Red) of Die 16 Parallel To Second Straight Side (Blue) of Adjacent Die 17</p> <p>FIG. 3</p> </div> <p>(Ex. 1203, Fig. 3.)</p>

2. **Claim 10**

132. Independent Claim 10 recites limitations substantially similar to limitations in Claim 1, but adds limitations directed to (1) an aperture “having a substantially regular polygonal shape;” (2) “dies having an inward facing straight side which faces the longitudinal axis of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture;” (3) “the longitudinal axis [of the aperture] passing through a point substantially centered on

the end-walls;” and (4) “a rotatable actuation device coupled to the dies, rotation of the actuation device causing the inward facing straight sides of the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture.” Yasumi discloses these limitations.

133. Yasumi discloses an aperture having a substantially regular polygonal shape both when the dies move to maximize the aperture and when the dies move to minimize the aperture, as shown in Figure 3, depicting one embodiment of Yasumi:

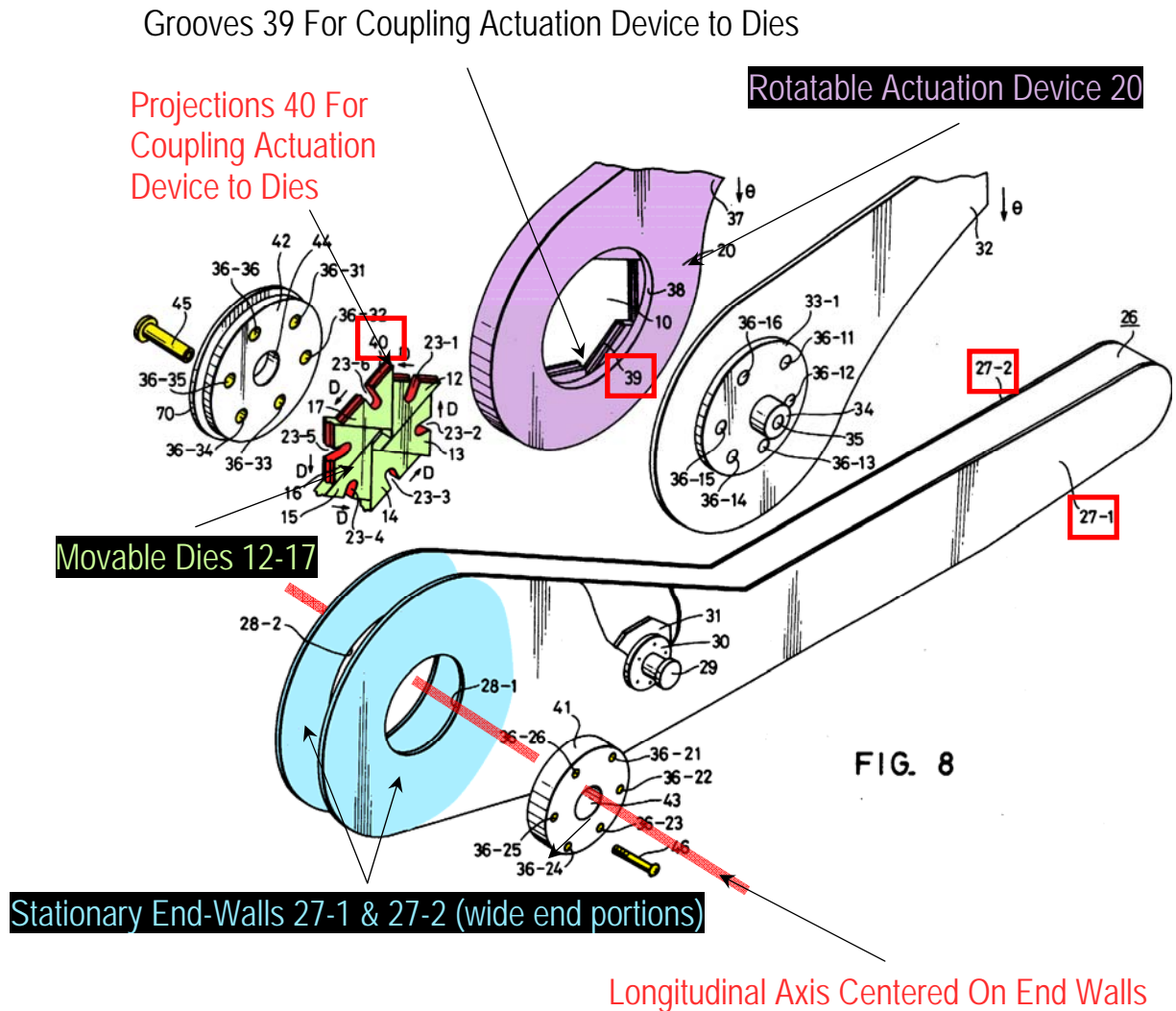


Ex. 1203 at Fig. 3.

134. In Yasumi, the dies 12-19 (green) are arranged to form a regular polygonal aperture (outlined in dark blue), and that shape is maintained when the dies move in or out. Ex. 1203 at 1:8-13; *see id.* at Abstract, Claim 1.

135. Yasumi also discloses the longitudinal axis of the aperture passing through a point substantially centered on the end-walls and 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.

136. For example, Figure 8, depicting the manual forming and pressing tool embodiment disclosed in Yasumi, is reproduced below with annotations and color added:

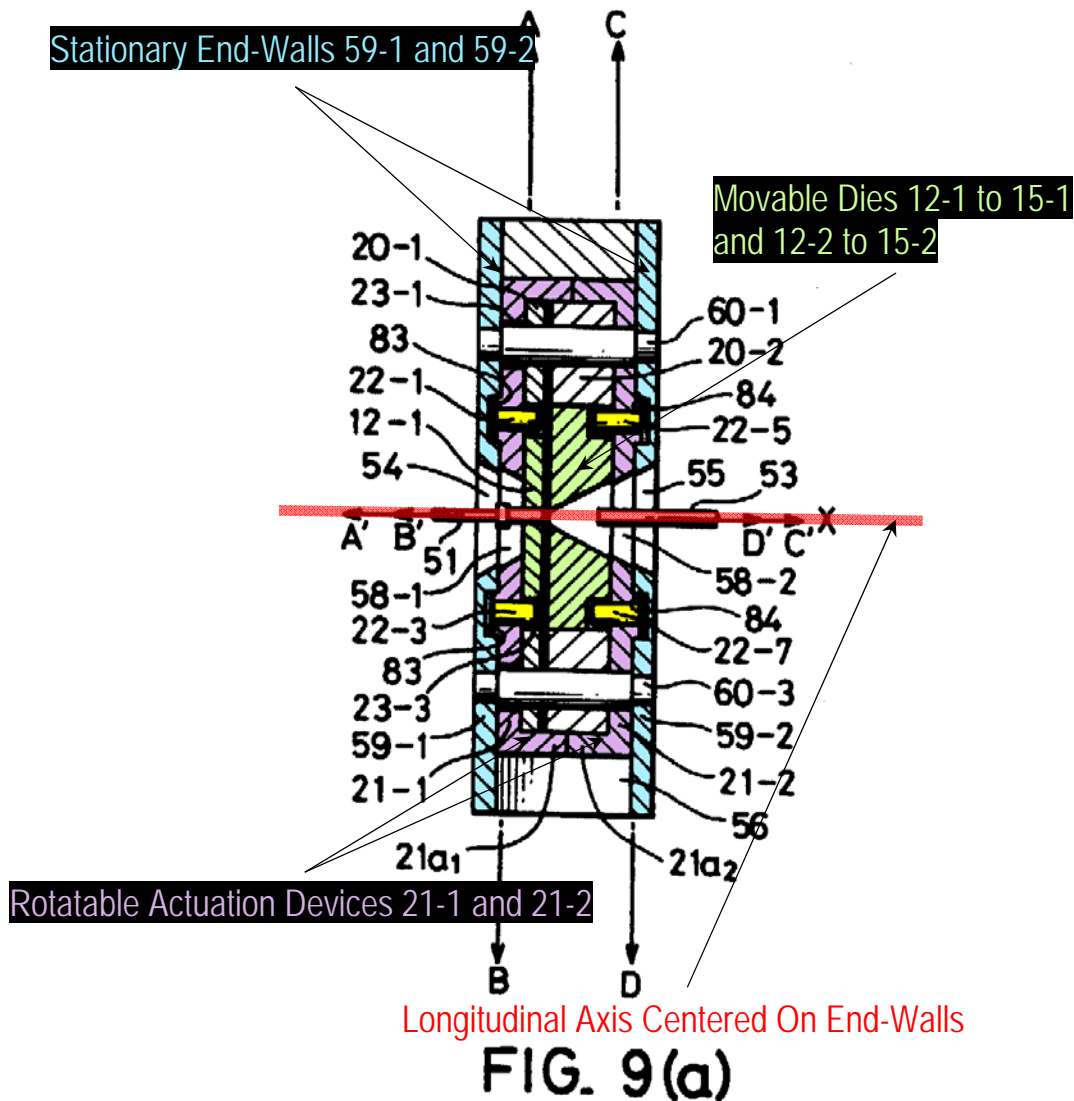


Ex. 1203, Fig. 8.

137. A POSITA would have understood that the longitudinal axis of the aperture passes through a point substantially centered on the stationary end-walls. The stationary end-walls are the wide end portions (blue) of the side plates 27-1 and 27-2. Ex. 1203 at 7:57-60, Fig. 8. As shown above, the longitudinal axis of the aperture formed by the dies passes through a point substantially centered on both of the stationary end-walls. *See id.* at Fig. 8.

138. Further, a POSITA would have understood that the movable dies 12-17 are coupled to the rotatable actuation device 20 (purple) by projection 40 (red) that fits within guide groove 39. Ex. 1203 at 7:52-57; *see id.* at 5:51-56. Moving the rotatable actuation device 20 relative to the fixed handle 26, which terminates in the wide end portions of the side plates 27-1 and 27-1, reduces or increases the aperture. *Id.* at 8:42-54 (“[T]he movable handle 37 is rotatable relative to the fixed handle 26. . . . Bringing the grips of the handles 26 and 37 closer to each other, the pins 45 move in the elongated holes 23-1 to 23-6 to move the movable pieces 12 to 17 in the frame 20, reducing the aperture defined by the movable pieces 12 to 17.”).

139. Figure 9(a) – (c), depicting an electric wire guide device disclosed in Yasumi, also discloses the longitudinal axis of the aperture passing through a point substantially centered on the end-walls, even to the casual observer:



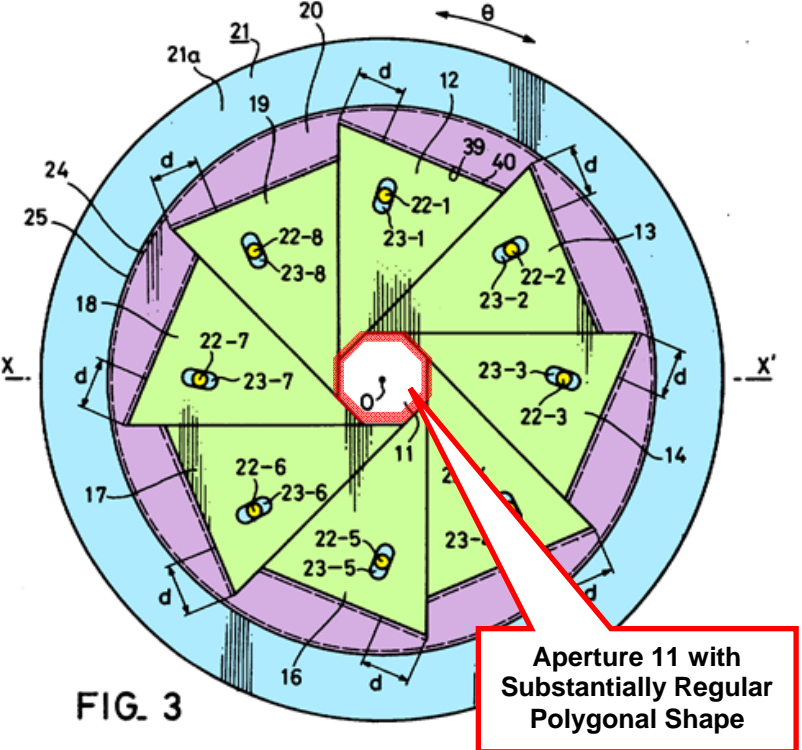
Ex. 1203, Fig. 9(a).

140. A POSITA would have understood that the longitudinal axis of the aperture passes through point substantially centered on the stationary end-walls. The stationary end-walls are side panels 59-1 and 59-2 (blue). Ex. 1203 at 9:40-41, Fig. 9(a). As shown above, the longitudinal axis of the aperture formed by the dies passes through a point substantially centered on both stationary end-walls. *See id.* at Fig. 9(a)-(c). This, of course, would also be a simple matter of design choice.

141. The claim chart below provides a left column with claim language from the '560 patent and provides a right column with exemplary disclosure from Yasumi and Williams.

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

³ 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, disclosure in Yasumi of an iris having a longitudinal axis also discloses an aperture having a longitudinal axis.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	 <p>(Ex. 1203, Fig. 3; <i>see id.</i> at Figs. 2, 5(a), 7(a).)</p>
<p>[10d]</p> <p>each of the dies having an inward facing straight side which faces the longitudinal axis of the aperture,</p>	<p><i>See</i> Claim [1d].⁴</p>
<p>[10e]</p> <p>both when the dies</p>	<p><u>Yasumi discloses each of the dies (movable pieces 12-17 or 12-19) having an inward facing straight side that faces the</u></p>

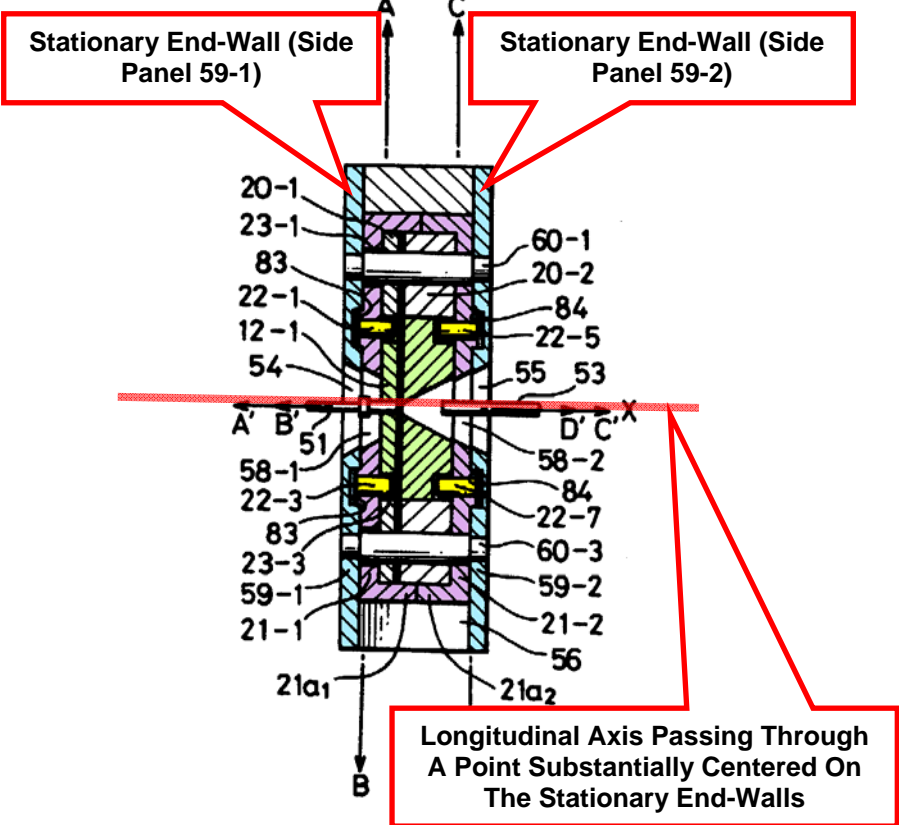
⁴ Claim [10d] recites “an inward facing straight side which faces the longitudinal axis of the aperture” and Claim [1d] recites “a portion of the first straight side of each die faces the aperture.” Because the longitudinal axis of the aperture is located central to the aperture, disclosure in Yasumi of the first straight side of each die facing the aperture also discloses an inward facing straight side that faces the longitudinal axis of the aperture.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
<p>move to maximize the aperture and when the dies move to minimize the aperture,</p>	<p><u>longitudinal axis of the aperture both when the dies move to maximize the aperture and when the dies move to minimize the aperture:</u></p> <div data-bbox="548 457 1307 976"> <p>FIG. 3</p> </div> <div data-bbox="519 1008 1307 1648"> <p>FIG. 8</p> </div> <p>(Ex. 1203, Fig. 8.)</p> <p><u>Yasumi teaches that the polygonal shape of the aperture is maintained as the dies (movable pieces 12-17 or 12-19) move in or out.</u></p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p>“[T]he size of a predetermined polygonal aperture can be changed, retaining the polygonal configuration.” (Ex. 1203 at 1:11-13; <i>see id.</i> at Abstract, 1:40-43, Claim 1.)</p> <p>Maintaining the polygonal shape results in the first straight side facing the longitudinal axis of the aperture while moving in or out.</p>
<p>[10f]</p> <p>the dies between two stationary end-walls disposed about the longitudinal axis,</p>	<p><i>See</i> Claim [1b].⁵</p>
<p>[10g]</p> <p>the longitudinal axis passing through a point substantially centered on the end-walls,</p>	<p><u>Yasumi discloses the longitudinal axis passing through a point substantially centered on the end-walls (wide end portions of the fixed handle side plates 27-1 and 27-2):</u></p> <p>“The frame 20 having thus mounted therein the plurality of movable pieces 12 to 17 is interposed between the wide end portions of the two side plates 27-1 and 27-2 of the fixed handle 26, . . . The frame 20 has formed therein on the side of the side plate 27-2 a circular recess coaxial with the frame 20, though not shown in FIG. 8, and the support disc 42 is fitted into this circular recess. . . . The circular projection 33-1 is fitted into the circular hole 28-1 of the side plate 27-1.” (Ex. 1203 at 7:57-8:21.)</p>

⁵ 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 Yasumi of stationary end-walls also discloses two stationary end-walls.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<div data-bbox="573 317 1373 1140" data-label="Image"> </div> <p>(Ex. 1203, Fig. 8.)</p> <p><u>Yasumi includes an additional embodiment that discloses the longitudinal axis passing through a point substantially centered on the end-walls (left- and right-hand side panels 59-1 and 59-2):</u></p> <p>“As shown in FIG. 9(a), a pin 51 of a connector and an electric wire 53 are inserted into the aperture setting device through openings 54 and 55 formed in left- and right-hand side panel 59-1 and 59-2 of a rectangular parallelepiped casing. . . . The axes of the aperture setting portions 81 and 82 lie on the same straight line, which is substantially in alignment with the centers of the openings 54 and 55 of the side panels of the casing.” (<i>Id.</i> at 9:37-10:2.)</p>

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

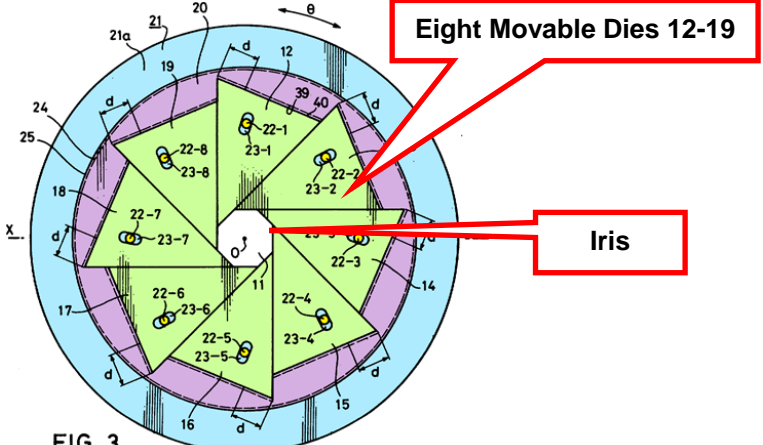
<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
the aperture.	<p>moved along their bases to approach the axis 0.” (Ex. 1203 at 5:39-6:8.)</p> <p>“The frame 20 having thus mounted therein the plurality of movable pieces 12 to 17 is interposed between the wide end portions of the two side plates 27-1 and 27-2 of the fixed handle 26, . . . The movable handle 37 and the fixed handle 26 are designed so that they can turn about the axis of the frame 20 relative to each other, and the movable pieces 12 to 17 are moved by the relative rotational movement of the handles 37 and 26.” (<i>Id.</i> at 7:57-68.)</p> <p>“Bringing the grips of the handles 26 and 37 closer to each other, the pins 45 move in the elongated holes 23-1 to 23-6 to move the movable pieces 12 to 17 in the frame 20, reducing the aperture defined by the movable pieces 12 to 17.” (<i>Id.</i> at 8:42-54.)</p>

3. **Claim 18**

142. Independent Claim 18 recites limitations substantially similar to those previously recited in Claims 1 and 10. *See* Part VII.A.1 and .2.⁶ Claim 18 also adds the limitation “eight or more movable dies.” This limitation is disclosed by Yasumi.

143. The claim chart below provides a left column with claim language from the ’560 patent and provides a right column with exemplary disclosure from Yasumi and Williams.

⁶ Claim 18 recites an “inward facing flat portion” and Claim 1 recites a “first straight side of each die fac[ing] the aperture.” The disclosure in Yasumi of a first straight side facing the aperture equally supports disclosure of an inward facing flat portion.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
<p>[18 Preamble] A stent crimper comprising:</p>	<p><i>See Claim [1 Preamble].</i></p>
<p>[18a] eight or more movable dies arranged to form an iris,</p>	<p><u>Yasumi discloses movable dies arranged to form an iris.</u> <i>See Claim [1a].</i> <u>Yasumi discloses eight or more movable dies:</u> “FIG. 3 and FIG. 10 embody the principles of the aperture setting device of the present invention and depict the state in which movable pieces 12, 13, 14, . . . 19 around the axis 0 have respectively been moved along their bases by the aforesaid maximum distance d.” (Ex. 1203 at 5:39-6:13.)</p>  <p>(Ex. 1203, Fig. 3; <i>see also</i> Fig. 2.)</p>
<p>[18b] the iris defining an aperture of a substantially regular polygonal shape,</p>	<p><i>See Claims [1a] (iris defining aperture), [10c] (aperture having substantially regular polygonal shape).</i></p>
<p>[18c] the aperture</p>	<p><i>See Claims [1a], [10c].</i></p>

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

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
axis,	
[18h] the iris comprising at least eight of the inward facing flat portions,	<i>See Claim [1a] & [1d] (movable dies arranged to form an iris and a portion of the first straight side of each die faces aperture), Claim [18a] (eight dies).</i>
[18i] the aperture being reducible in size by moving the inward facing flat portions toward the longitudinal axis of the aperture,	<i>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).</i>
[18j] a rotatable actuation device coupled to the dies,	<i>See Claim [10h].</i>
[18k] rotation of the actuation device causing the inward facing straight sides of the dies to move inward and reduce the size of the aperture or outward so as to	<i>See Claim [10i].</i>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
increase the size of the aperture.	

4. **Claim 27**

144. Independent Claim 27 recites limitations substantially similar to those previously recited in Claims 1 and 10. *See* Part VII.A.1 and .2.⁷ Claim 27 also adds the limitation “the blades coupled to one another so as to be movable inward or outward simultaneously.” Yasumi discloses this limitation.

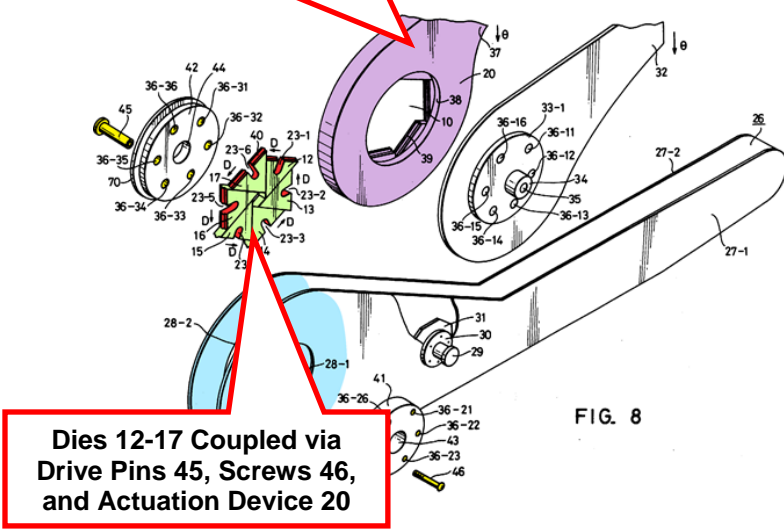
145. The claim chart below provides a left column with claim language from the ’560 patent and provides a right column with exemplary disclosure from Yasumi and Williams.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
[27 Preamble] A stent crimper comprising:	<i>See</i> Claim [1 Preamble].
[27a] an aperture with a plurality of movable blades disposed thereabout,	<i>See</i> Claim [1b].

⁷ Claim 27 differs from the previous claims because it recites “blades” instead of “dies.” But those terms are used interchangeably.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
<p>[27b]</p> <p>the aperture having a longitudinal axis and being substantially polygonal,</p>	<p><i>See</i> Claim [10c].</p>
<p>[27c]</p> <p>the blades between stationary end- walls substantially centered about the longitudinal axis,</p>	<p><i>See</i> Claims [1b] (dies between stationary end-walls), [10g] (the longitudinal axis passing through a point substantially centered on the end-walls).</p>
<p>[27d]</p> <p>the blades coupled to one another so as to be movable inward or outward simultaneously,</p>	<p><u>Yasumi discloses the blades (movable pieces 12-17 or 12-19) coupled to one another so as to be movable inward or outward simultaneously:</u></p> <p>Each blade in Yasumi is connected via numerous components such that when one blade moves, they all move together simultaneously. For example, the blades are coupled via the rotatable actuation device. The blades are also coupled via the drive pins and screws.</p> <p>“A center aligning device comprising: . . . a first drive member disposed opposite one side of the faces of said first movable pieces and having first drive pins thereon, . . . for simultaneously moving said first movable pieces relative to said first frame to set the size of said first polygonal aperture.” (Ex. 1203 at Claim 1; <i>see also id.</i> at 8:1-54.)</p> <p>“In this case, the movable piece 13 is disposed with one side 13a of its triangle held partly in agreement with one side 12a of the movable piece 12 forming one side of the pentagonal</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p>aperture area 11 but with one end of the piece 13 displaced outwardly relative to the area 11. The movable piece 14 is disposed so that its one side 14a partly lies along one side 13b forming one side of the area 11 but projects outwardly relative to the area 11. The other movable pieces are also likewise disposed one after another, and the movable piece 16 is disposed so that its one side 16a forming one side of the area 11 is in contact with one side 12b of the movable piece 12.” (<i>Id.</i> at 2:47-59; <i>see also id.</i> at 5:48-51.)</p> <p>“As is apparent from the aforesaid expressions (1) to (4), once the amount of movement of one movable piece along its base, for example, d1, is determined by setting the angles of the respective triangular movable pieces, the amounts of movement of the other movable pieces d2, d3, . . . dn are determined accordingly.” (<i>Id.</i> at 4:12-17).</p> <p>“A wide end portion of a movable handle 37 has formed integrally therewith, at the center thereof, the frame 20 described previously in respect of FIG. 3 and FIG. 10, and in the frame 20 are mounted movable pieces 12 to 16 and 17 in a manner to be movable along their bases by a predetermined distance, as indicated by the arrows D. As described previously, it is also possible to adopt an arrangement in which a guide groove 39 is cut in the inner peripheral surface of the frame and a projection 40 for engagement with the guide groove 39 is formed on the surface of each movable piece on the side of its base.” (<i>Id.</i> at 7:46-57).</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p data-bbox="560 315 1006 367">Rotatable Actuation Device 20</p>  <p data-bbox="552 787 933 903">Dies 12-17 Coupled via Drive Pins 45, Screws 46, and Actuation Device 20</p> <p data-bbox="487 934 763 976">(Ex. 1203, Fig. 8.)</p>
<p data-bbox="186 1008 462 1281">[27e] movement of the blades outward increasing the size of the aperture,</p>	<p data-bbox="487 1008 730 1050"><i>See Claim [10i].</i></p>
<p data-bbox="186 1316 462 1589">[27f] movement of the blades inward decreasing the size of the aperture,</p>	<p data-bbox="487 1316 730 1358"><i>See Claim [10i].</i></p>
<p data-bbox="186 1625 462 1749">[27g] the aperture remaining</p>	<p data-bbox="487 1625 1421 1749"><i>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).⁸</i></p>

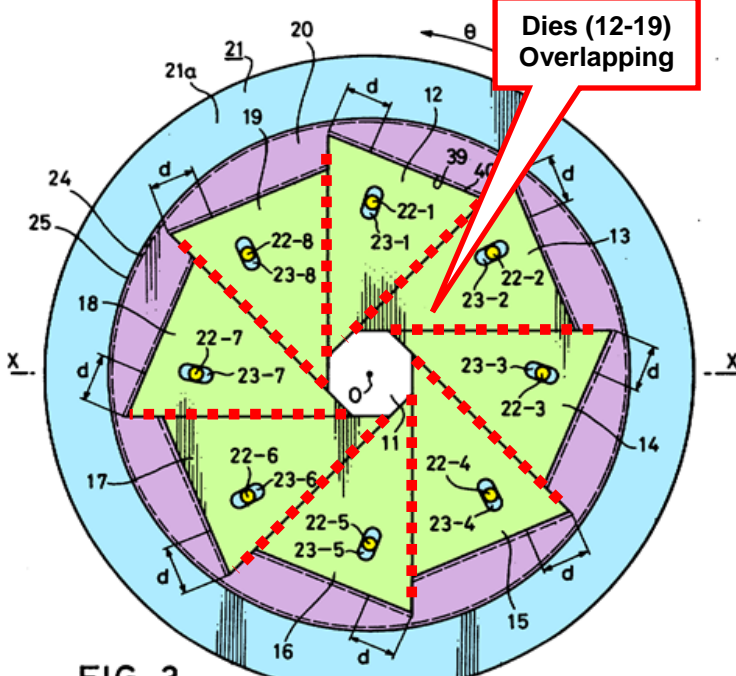
⁸ Claim [27g] recites “when [the aperture] is sized to receive a stent therein” and Claim [10e] recites “when the dies move to maximize the aperture.” The

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
substantially regular polygonal when it is sized to receive a stent therein and when the blades minimize the aperture.	

5. Claim 37

146. Independent Claim 37 recites limitations substantially similar to those previously recited in Claims 1 and 10, *see* Part VII.A.1 and .2, but adds the limitation of “overlapping movable dies.” Yasumi discloses this limitation. Figure 3, depicting the die configuration disclosed in Yasumi, is reproduced below with annotations and color added:

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

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
<p>[37a]</p> <p>a plurality of overlapping movable dies arranged to form an iris,</p>	<p><u>Yasumi discloses a plurality of movable dies arranged to form an iris.</u></p> <p><i>See Claim [1a].</i></p> <p><u>Yasumi discloses a plurality of overlapping movable dies (movable pieces 12-17 or 12-19):</u></p> <p>“Referring first to FIG. 1, . . . the movable piece 13 is disposed with one side 13a of its triangle held partly in agreement with one side 12a of the movable piece 12 forming one side of the pentagonal aperture area 11 but with one end of the piece 13 displaced outwardly relative to the area 11. . . . The other movable pieces are also likewise disposed one after another.” (Ex. 1203 at 2:44-59; <i>see</i> Figs. 1, 2, 3.)</p>  <p>FIG. 3</p> <p>(Ex. 1203, Fig. 3; <i>id.</i> at Fig. 1-2.)</p>
<p>[37b]</p> <p>the dies disposed</p>	<p><i>See Claims [1b], [10c].</i></p>

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

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
parallel to the second side of an adjacent die.	

6. **Claim 40**

149. Independent Claim 40 recites limitations substantially similar to those previously recited in Claims 1 and 10. *See* Part VII.A.1 and .2.⁹ Yasumi discloses every limitation of Claim 40.

150. The claim chart below provides a left column with claim language from the '560 patent and provides a right column with exemplary disclosure from Yasumi and Williams.

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

⁹ Claim 40 recites “stationary plates” while Claim 1 recites “stationary end-walls.” However, as discussed above in Part V.C, the stationary plates of Claim 40 and the stationary end-walls of Claim 1 are interchangeable.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
[40b] the aperture having a longitudinal axis,	<i>See</i> Claim [10c].
[40c] the plurality of movable dies between stationary plates disposed about the longitudinal axis,	<i>See</i> Claim [1b].
[40d] each die in communication with an actuation device,	<i>See</i> Claim [10h]. ¹⁰
[40e] the actuation device constructed and arranged such that rotational motion of the actuation device	<i>See</i> Claim [10i]. ¹¹

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

¹¹ Claim [10i] recites “rotation of the actuation device [reducing] the size of the aperture or [increasing] the size of the aperture” and Claim [40e] recites “rotational motion of the actuation device opens or closes the aperture.” The disclosure in Yasumi showing Claim [10i] applies equally to Claim [40e].

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
opens or closes the aperture,	
[40f] the dies operatively engaged to at least one of the stationary plates;	<i>See Claim [1c].</i>
[40g] each die having a first straight side and a second straight side, the first straight side and the second straight side converging [<i>sic</i>] to form a tip; wherein a portion of the first straight side of each die faces the aperture, each first straight side parallel to the second side of an adjacent die.	<i>See Claim [1d].</i>

7. Claims 2 and 28

151. Dependent Claims 2 and 28 add a limitation substantially similar to Claim[10h-i]. Claim 2 recites: “a rotatable actuation device coupled to the dies,

rotation of the actuation device causing the dies to move inward and reduce the size of the aperture or outward so as to increase the size of the aperture.” Claim 28 recites: “a rotatable actuation device coupled to the blades, rotation of the actuation device causing the blades to move inward or outward.”¹² *See* Part VII.A.2. Accordingly, Yasumi discloses every limitation of Claims 2 and 28.

8. Claims 6 and 15

152. Dependent Claims 6 and 15 share an identical limitation substantially similar to Claim [18a]: “wherein at least 8 dies are provided.” *See* Part VII.A.3. Accordingly, Yasumi discloses every limitation of Claims 6 and 15.

9. Claims 8, 25 and 33

153. Dependent Claims 8, 25 and 33 share an identical limitation of “wherein the dies are moved cooperatively inward during the moving step.” Yasumi discloses this limitation.

154. Figure 8, depicting the manual forming and pressing tool embodiment disclosed in Yasumi, is reproduced below with annotations and color added:

¹² Claim 28 differs from Claims 2 and 10 because it recites “blades” instead of “dies,” but blades and dies are used interchangeably. *See* Part V.B.

FIG. 8

Screw 46

155. In Yasumi, the dies 12-17 (green) are coupled to rotatable actuation device 20, which engages the dies 12-17 via projections 40 and guide grooves 39. *Id.* at 7:46-57. The dies are also coupled to the stationary end walls, which engage the dies 12-17 via elongate holes 23-1 to 23-6 (red), pins 45 (yellow) and screws 46 (also yellow). *Id.* at 8:1-42. Through this arrangement, when the actuation device 20 is rotated, the dies 12-17 are moved cooperatively inward during the moving step. *Id.* at 8:50-54.

156. The claim chart below provides a left column with claim language from the '560 patent and provides a right column with exemplary disclosure from Yasumi and Williams.

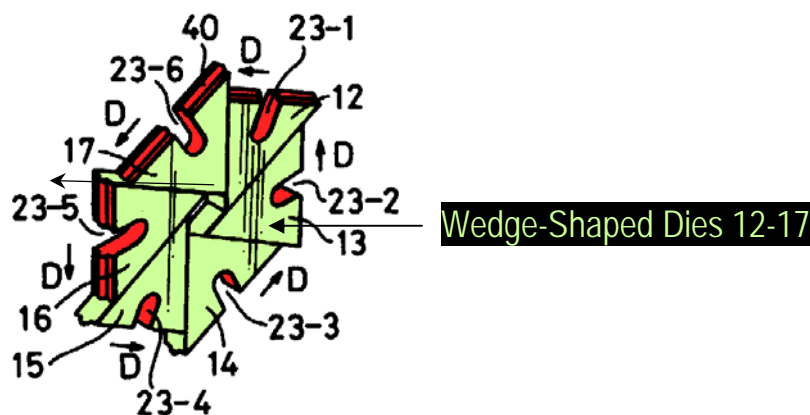
<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
<p>[8a], [25a], [33a] wherein the dies are moved cooperatively inward during the moving step.</p>	<p><u>Yasumi discloses the dies (movable pieces 12-17 or 12-19) moved cooperatively inward during the moving step.</u></p> <p>“By the movement of the movable pieces, the aperture can be varied in size without being changed in configuration.” (Ex. 1203 at Abstract.)</p> <p>“Bringing the grips of the handles 26 and 37 closer to each other, the pins 45 move in the elongated holes 23-1 to 23-6 to move the movable pieces 12 to 17 in the frame 20, reducing the aperture defined by the movable pieces 12 to 17.” (<i>Id.</i> at 8:50-54.)</p> <p>“A center aligning device comprising: . . . simultaneously moving said first movable pieces relative to said first frame to set the size of said first polygonal aperture.” (<i>Id.</i> at Claim 1.)</p> <p>“In this case, the movable piece 13 is disposed with one side 13a of its triangle held partly in agreement with one side 12a of the movable piece 12 forming one side of the pentagonal aperture area 11 but with one end of the piece 13 displaced outwardly relative to the area 11. The movable piece 14 is disposed so that its one side 14a partly lies along one side 13b forming one side of the area 11 but projects outwardly relative to the area 11. The other movable pieces are also likewise disposed one after another, and the movable piece 16 is disposed so that its one side 16a forming one side of the area 11 is in contact with one side 12b of the movable piece 12.” (<i>Id.</i> at 2:47-59; <i>see also id.</i> at 5:48-51.)</p> <p>“As is apparent from the aforesaid expressions (1) to (4), once the amount of movement of one movable piece along its base, for example, d1, is determined by setting the angles of</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p>the respective triangular movable pieces, the amounts of movement of the other movable pieces d2, d3, . . . dn are determined accordingly.” (<i>Id.</i> at 4:12-17).</p> <p>“A wide end portion of a movable handle 37 has formed integrally therewith, at the center thereof, the frame 20 described previously in respect of FIG. 3 and FIG. 10, and in the frame 20 are mounted movable pieces 12 to 16 and 17 in a manner to be movable along their bases by a predetermined distance, as indicated by the arrows D. As described previously, it is also possible to adopt an arrangement in which a guide groove 39 is cut in the inner peripheral surface of the frame and a projection 40 for engagement with the guide groove 39 is formed on the surface of each movable piece on the side of its base.” (<i>Id.</i> at 7:46-57.)</p>

10. Claims 9, 14, 23 and 31

157. Dependent Claims 9, 23 and 31 share an identical limitation of “wherein the dies are wedge-shaped.”

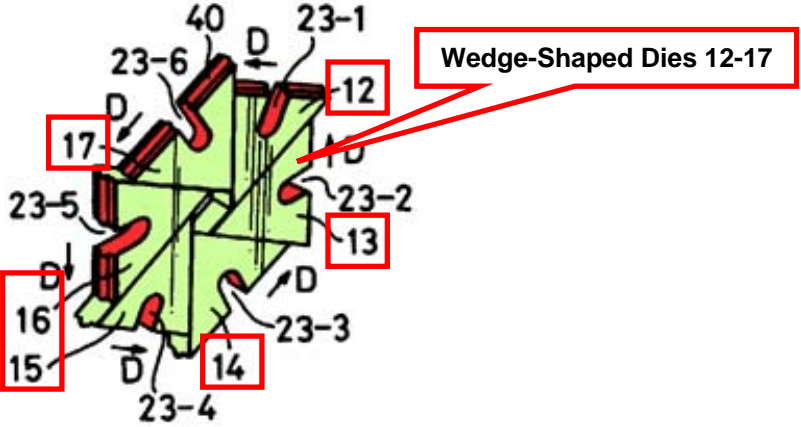
158. Yasumi discloses wedge-shaped dies. Figure 8, depicting the die configuration disclosed in Yasumi, are reproduced below with annotations and color added:



Ex. 1203, Fig. 8 (excerpt). In Yasumi, movable pieces 12-17 (green) are substantially triangular and have a thickness extending in the direction of the longitudinal axis of the aperture. *Id.* at Abstract (“substantially triangular movable pieces”), 6:31-37. This results in a wedge shape.

159. The claim chart below provides a left column with claim language from the ’560 patent and provides a right column with exemplary disclosure from Yasumi and Williams.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
<p>[9a], [14a], [23a], [31a]</p> <p>wherein the dies are wedge-shaped.</p>	<p><u>Yasumi discloses wedge-shaped dies (movable pieces 12-17 or 12-19).</u></p> <p>“An aperture setting device . . . , in which at least three or more substantially triangular movable pieces are sequentially arranged in the form of a ring . . .” (Ex. 1203 at Abstract.)</p> <p>“[A] plurality of movable pieces each of which has a triangular section in a plane . . .” (<i>Id.</i> at 1:48-49.)</p> <p>“[T]he movable pieces 12 to 19 are configurations in the plane perpendicular to the axis 0, as referred to previously.</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p>The plane in which each side of each movable piece extends along the axis 0, . . .” (<i>Id.</i> at 6:31-37.)</p>  <p>(Ex. 1203, Fig. 8.)</p>

11. Reason, Basis or Motivation to Combine

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

161. Yasumi recognized that the prior art aperture setting devices, like those used in applications such as drawing dies and a chuck, suffered from problems when the dies were not a unitary structure. This left gaps in between adjacent dies such that the article in the aperture could end up wedged between the dies. Ex. 1203 at 1:16-28. Yasumi set out to solve this problem, and did so by using dies arranged to form a polygonal aperture. *Id.* at 1:32-39 (“In the past, there

has not been put to practical use a device which is capable of changing with a simple arrangement, a polygonal aperture into various sizes continuously or stepwise, retaining it on the same axis. Such a device, if realized, would be of great ability when employed in such devices as a chuck, a press tool, an electric wire guide device, a drawing die, a control valve and so forth.”).

162. Yasumi does not limit the applications for the polygonal aperture setting device, and a POSITA would have been motivated by the disclosure in Yasumi to look for applications for the disclosed tool. As explained in Yasumi:

In the past, there has not been put to practical use a device which is capable of changing with a simple arrangement, a polygonal aperture into various sizes continuously or stepwise, retaining it on the same axis. Such a device, if realized, would be of great ability when employed in such devices as a chuck, a press tool, an electric wire guide device, a drawing die, a control valve and so forth.

Ex. 1203 at 1:32-39.

163. A POSITA would have been particularly motivated to use Yasumi as a crimper based upon the embodiment disclosing a manual forming and pressing tool, *i.e.*, a crimper. *See* Ex. 1203 at 7:33-38, 9:30-34, 11:25-30. A POSITA would have understood that a manual forming and pressing tool is just another term used to refer to the general class of tool in the crimping field. This suggestion alone would have motivated a POSITA to use Yasumi for applications in the crimping field, including as a stent crimper.

164. A POSITA would have known that stent crimping is one field of crimping applications. Moreover, it was known to a POSITA at the time of the invention that ordinary tools, such as pliers or the like, were often used to crimp stents. For example, Williams recognized that tools, such as ordinary pliers, were used to crimp stents. *See, e.g.*, Ex. 1227 at 1:67-68 (disclosing use of “tools, such as ordinary pliers,” to crimp a stent). Although Williams notes that ordinary pliers were not an “ideal” tool for achieving a satisfactory crimp, *id.* at 1:67-2:1, there can be no doubt that the use of plier-like tools by those of ordinary skill in the art was one of several well-known means to crimp a stent. This knowledge is reflected in numerous other patents filed prior to September 22, 1999:

- Ex. 1218 at 2:6-9 (disclosing use of “tools, such as ordinary pliers” to crimp a stent);
- Ex. 1227 at 1:67-2:1 (disclosing use of “tools, such as ordinary pliers” to crimp a stent);
- Ex. 1219 at 2:1-3 (disclosing manual stent crimping using “pliers”);
- Ex. 1214 at 1:33-35 (disclosing use of “plier-like device” to crimp a stent);
- Ex. 1225 at 1:43-46 (disclosing use of “modified plier-like tools” to crimp a stent); and
- Ex. 1226 at 3:20-23 (“The stent is positioned over the balloon portion of the dilatation catheter and gently crimped onto the balloon either by hand or with a tool such as a pliers or the like to be mounted for delivery as shown in FIGS. 1 and 2.”).

- *see also* U.S. Patent No. 6,077,273 at 4:41-45; U.S. Patent No. 5,968,069 at 9:25-29; U.S. Patent No. 6,203,558 at 9:30-34; U.S. Patent No. 6,663,660 at 9:35-39; U.S. Patent No. 7,670,364 at 9:20-24; U.S. Patent No. 8,709,062 at 9:22-26; U.S. Patent No. 6,371,962 at 3:27-30; U.S. Patent No. 7,749,234 at 4:45-49; U.S. Patent No. 6,712,827 at 3:27-30; U.S. Patent No. 6,203,558 at 9:30-34.

The explicit teaching in Williams to use pliers to crimp a stent, which is bolstered by the widespread knowledge that pliers and other such tools could be used for stent crimping, would have provided a POSITA with a motivation to look for improved crimping designs for pliers and other manually operated tools to crimp a stent, and thus would have motivated a POSITA to use Yasumi as a stent crimper.

165. Additionally, a POSITA would have been motivated to use Yasumi as a stent crimper to apply a known technique—using a polygonal aperture to uniformly crimp an item—to improve a similar device (stent crimpers) in the same way. This would have been nothing more than the use of a known technique to improve a similar device in the same way.

166. The problem of uneven crimping forces when crimping a stent was well known and documented prior to September 22, 1999. For example, Williams teaches: “In procedures where the stent is placed over the balloon portion, one must crimp the stent onto the balloon portion, to prevent the stent from sliding off the catheter when the catheter is advanced in a patient’s vasculature. In the past this crimping was often done by hand, which was found to be unsatisfactory due to uneven crimping forces being applied, resulting in non-uniform crimps. Ex. 1227

at 1:56-63. This knowledge is reflected in numerous other patents filed prior to September 22, 1999:

- Ex. 1214 at 1:35-48 (“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. Yet another shortcoming of conventional mounting and securing methods is that they may distort the stent in such a way as to cause the stent to expand in the target area in a non-uniform manner which could result in a portion of the lumen not being properly supported. [¶] Yet another shortcoming of conventional mounting and securing methods is irregular distortion of the stent could produce protrusions in the stent which could cause trauma to the patient.”);
- Ex. 1221 at 1:59-2:2 (“Non-uniform 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. Where the stent is not reliably crimped onto the catheter, on rare occasions it is possible that the stent may slide off the catheter and into the patient’s vasculature prematurely as a loose foreign body, possibly causing blood clots in the vasculature, including thrombosis. Therefore, it is important to ensure the proper crimping of a stent onto a catheter in a uniform and reliable manner.”);
- Ex. 1225 at 1:49-2:14 (“Problems arise when excessive crimping forces are applied to the crimp pliers which can damage the stent and/or balloon catheter. This is especially problematic given the minute size of the stents which are typically on the order of about one (1) mm to four (4) mm in diameter before crimping. Moreover, non-uniformity of the crimping may be experienced as well as the inability to determine when a reliable and uniform crimp has been achieved. [¶] In other instances, the stents may be pre-crimped or preattached onto their associated delivery balloon at the time of production by the manufacturer. While these devices more uniformly control crimping quality, a large inventory of stent-bearing angioplasty catheters must be maintained to accommodate the variety of stent types, diameters and stent lengths for each balloon catheter type. Thus, maintaining such an inventory is not only difficult to store, but can be very expensive as well. [¶] One of the most favored crimping techniques is manual crimping performed

by the physician in the catheter laboratory. This process enables the physician to ‘feel’ the crimp to determine the crimp quality. The proper crimping of a stent about a balloon catheter, however, is a technique acquired only through practice and can be affected by a variety of subjective conditions. Too much or too little pressure may be applied and the balloon and/or stent may be damaged, lost, or may not otherwise perform as desired during the procedure. In contrast, the physician may not apply sufficient crimping pressure to the stent to load it onto the balloon. During advancement through the vessel or upon deployment, an insufficiently crimped stent may slip or rotate on the catheter during, or in the worst case scenario, come off the balloon catheter entirely; the result of which is not desirable.”);

- Ex. 1219 at 1:66-2:18 (The problems facing those attempting to crimp stents onto expandable delivery devices, such as balloon catheters, are numerous. In some instances, the stents are manually crimped onto the delivery device using finger pressure or pliers. Such crimping can however, result in damage to the stent during handling prior to use as well as during the act of crimping because of the lack of control over the forces used during crimping. In either case, the damaged stents cannot be used. Furthermore, if the damage to the stent is not noticed, the stent may fail to perform as intended after deployment. In addition to damage to the stent itself before or during crimping, the crimping process can damage the delivery device if the forces applied during crimping are excessive. [¶] Even if the stent and/or the delivery device are not damaged, other potential problems remain. For example, the 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. 1218 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.”).

167. Yasumi already taught a known technique for solving the problem of uneven crimping forces, specifically by using a polygonal die configuration. Notably, Yasumi was not the only prior art device to solve the uneven crimping forces problem by using a polygonal die configuration. Whitesell also recognized

that asymmetric crimping detrimentally concentrated crimping force along the plane where the dies converged, compromising both electrical reliability and mechanical strength. Ex. 1215 at 1:13-20. Whitesell proposed a solution that used “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. 1211 at 1:13-20, 1:33-37 (discussing Exs. 1222, 1223, 1224). Baker also 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 been aware of Yasumi’s solution, as well as other mechanical tools that solved a similar problem in a similar manner.

168. Thus, a POSITA would have been motivated to use Yasumi as a stent crimper to provide the even crimping forces necessary to safely and effectively crimp a stent.

B. Obviousness of Claims 11, 17, 19, 26, 34, 35 and 39 Over Yasumi In View Of Williams And Morales

1. Claim 39

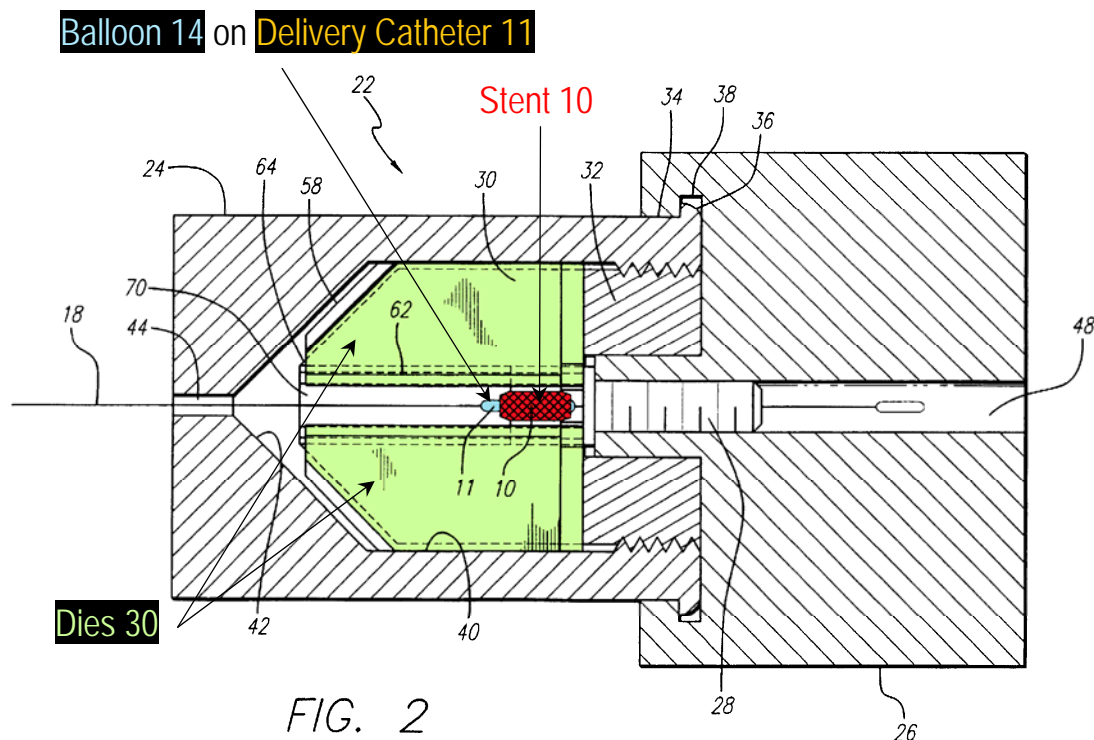
169. Independent Claim 39 recites limitations substantially similar to those previously discussed with respect to Claims 1 and 40, but adds limitations directed to an aperture “having a center and a first opening and a second opening,” and “the

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.”

170. These limitations are inherent in or obvious over Yasumi either alone or in view of Williams. I consider Yasumi a stent crimper for purposes of my analysis, and Williams for its disclosure of using pliers or tools (like Yasumi) to crimp a stent. Ex. 1227 at 1:67-68. A POSITA would have known that any stent crimper would have been constructed to accommodate the stent and the balloon portion of a balloon catheter fully within the crimping aperture. A POSITA would have understood that an aperture having a center and openings on both ends, *i.e.*, a first opening and a second opening, is helpful to permit the distal and proximal ends of the balloon catheter to extend outside the crimping aperture while accommodating the stent and balloon portion of the catheter within the aperture. Therefore, it is inherent or at least obvious over Yasumi either alone or in view of Williams to include a center and a first opening and a second opening.

171. Moreover, it was also well known that even crimping of the stent is desirable, and it would have been obvious to a POSITA to make the length of the dies exceed the length of the stent to ensure that the entire stent fit easily within the aperture, to 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.

172. These limitations are also disclosed in Morales. Figure 2 depicts a stent 10 (red) between teeth 30 (green):



Ex. 1204, Fig. 2. In Morales, an entire stent 10 (red) is disposed between teeth 30 (green) that has a center, a first opening and a second opening. *Id.* at 4:19-22. The depicted teeth have a length exceeding length of the stent with a longitudinal axis passing through both the first opening and the second opening.

173. A POSITA would have had a reason, basis or motivation to construct Yasumi either alone or in view of Williams to ensure that the length of the blades exceeded the length of the stent, as depicted in Morales, to ensure that the entire stent fit easily within the aperture, provide a margin of error so that no portion of

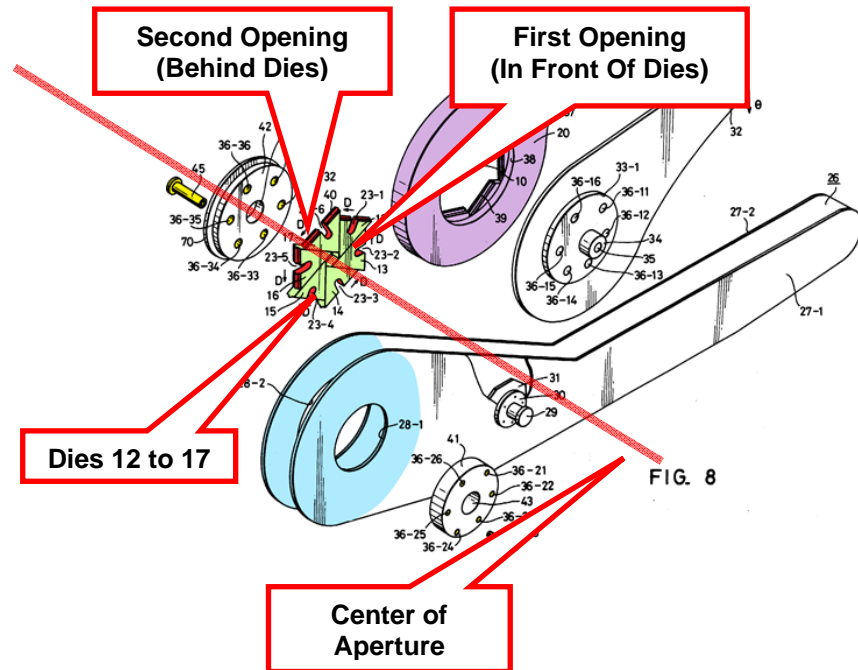
the stent would be missed during the crimping procedure and to account for manufacturing tolerances.

174. The claim chart below provides a left column with claim language from the '560 patent and provides a right column with exemplary disclosure from Yasumi, Williams and Morales.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
[39 Preamble] A stent crimper comprising:	<i>See Claim [1 Preamble].</i>
[39a] a plurality of movable dies arranged to form an iris disposed about an aperture,	<i>See Claims [1a] (plurality of movable dies arranged to form an iris), [1b] (dies disposed about the aperture).</i>
[39b] the aperture having a center and a first opening and a second opening,	<p><u>Yasumi discloses an aperture (between movable pieces 12-17 or between movable pieces 12-1 to 15-1 and 12-2 to 12-5) having a center and a first opening and a second opening.</u></p> <p>“Bringing the grips of the handles 26 and 37 closer to each other, the pins 45 move in the elongated holes 23-1 to 23-6 to move the movable pieces 12 to 17 in the frame 20, reducing the aperture defined by the movable pieces 12 to 17.” (Ex. 1203 at 8:50-54.)</p> <p>“By further rotating the movable cam 37 towards the fixed handle 26, the member to be formed is subjected to a sufficiently large pressure by the movable pieces 12 to 17 and readily formed into a predetermined shape.” (<i>Id.</i> at 9:30-34.)</p>

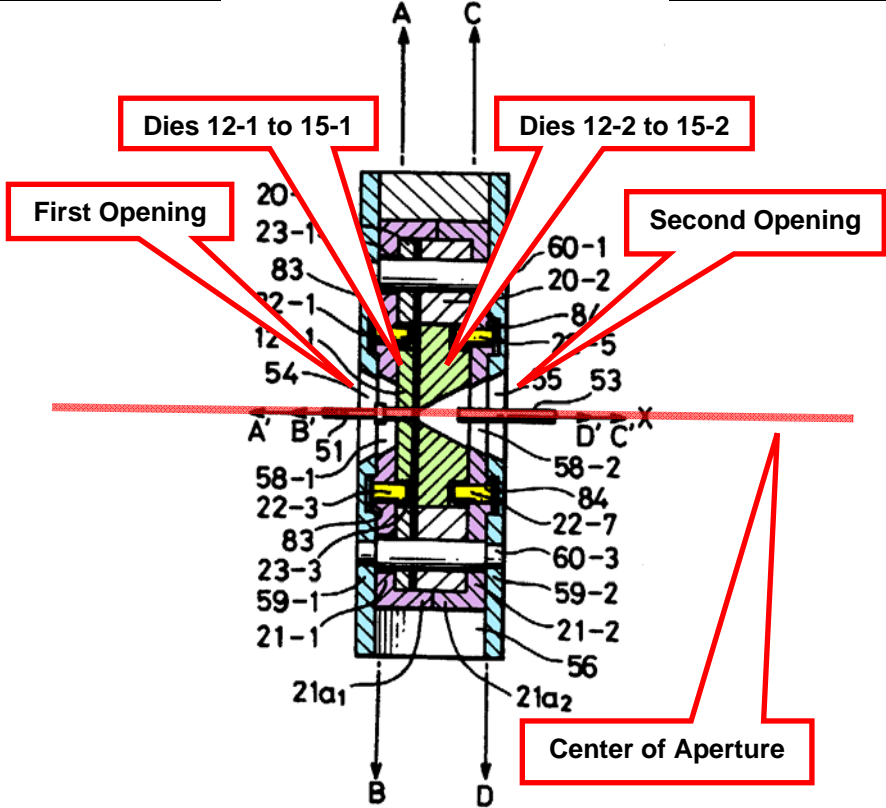
**ASSERTED
CLAIMS**

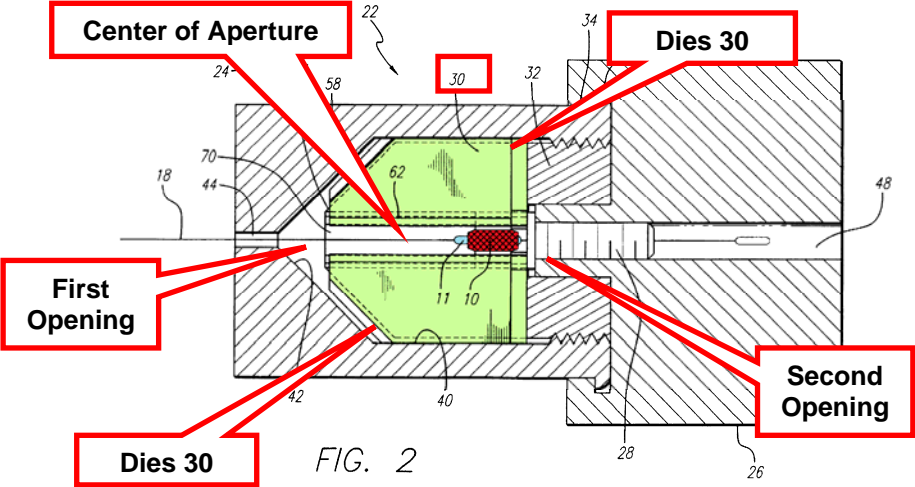
PRIOR ART

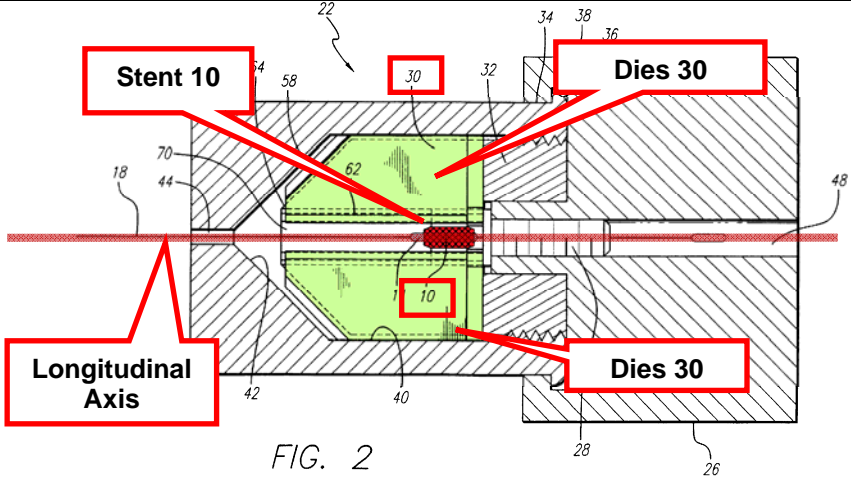


(Ex. 1203 at Fig. 8.)

“The movable pieces 12-1 to 15-1 are so formed as to provide a pyramidal aperture setting portion 81, whereas the movable pieces 12-2 to 15-2 are so formed as to provide a truncated, quadrangular pyramidal aperture setting portion 82. The axes of the aperture setting portions 81 and 82 lie on the same straight line, which is substantially in alignment with the centers of the openings 54 and 55 of the side panels of the casing. Further, the guide bases 21-1 and 21-2 respectively have centrally disposed through holes 58-1 and 58-2 which are substantially aligned with the openings 54 and 55, respectively.” (Ex. 1203 at 9:63-10:6.)

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	 <p style="text-align: center;">FIG. 9(a)</p> <p>(Ex. 1203, Fig. 9a.)</p> <p><u>Morales also discloses an aperture (between teeth 30) having a center and a first opening and a second opening.</u></p> <p>“An uncrimped stent is manually loaded into the hollow core. At the opposite end of the tool, the balloon catheter is inserted through the opening into the cylindrical cavity at the proximal section of the housing, which leads into the hollow core of the screw holding the uncrimped stent.” (Ex. 1204 at 3:38-42.)</p> <p>“In unison, the radiused edges of the teeth/plates converge on the underlying stent to crimp the stent onto the balloon catheter. The radiused edges of the plates thus act as crimping jaws.” (<i>Id.</i> at 4:19-22.)</p> <p>“Screw feed 28 further includes hollow core 54 that extends a</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p>length of head 50 and shaft 52. Hollow core 54 serves as a chamber to hold stent 10.” (Ex. 1204 at 7:33-35.)</p>  <p>(Ex. 1204, Fig. 2.)</p>
<p>[39c] the dies constructed and arranged to have a length exceeding the length of a stent with a longitudinal axis passing through both the first opening and the second opening,</p>	<p><u>Morales discloses dies (teeth 30) constructed and arranged to have a length exceeding the length of a stent with a longitudinal axis passing through both the first opening and the second opening.</u></p> <p>“In unison, the radiused edges of the teeth/plates converge on the underlying stent to crimp the stent onto the balloon catheter. The radiused edges of the plates thus act as crimping jaws.” (Ex. 1204 at 4:19-22.)</p> <p>“[T]he present invention tool is intended to be used on a variety of stent lengths. The total length of a preferred embodiment tooth/plate is over thirty-five millimeters long, thereby accommodating the lengths of the stents currently on the market.” (<i>Id.</i> at 5:5-9.)</p>

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

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

2. Claims 11, 19 and 35

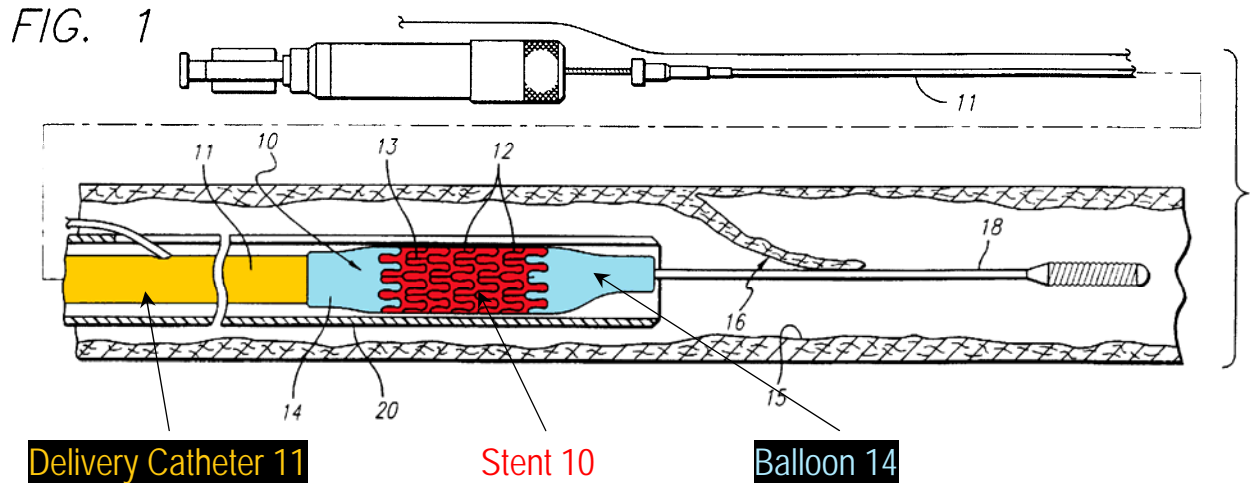
175. Dependent Claims 11, 19 and 35 share an identical limitation of “a stent is disposed about a medical balloon, the medical balloon disposed about a catheter.”

176. This limitation is inherent in or obvious over Yasumi either alone or in view of Williams. I consider Yasumi a stent crimper for purposes of my analysis, and Williams for its disclosure of using pliers or tools (like Yasumi) to crimp a stent. Ex. 1227 at 1:67-68. The first Palmaz-Schatz stent was approved for use in the U.S. as early as 1994. *See Premarket Approval (PMA) Search Result for Palmaz-Schatz (TM) Balloon Expandable Stent, PMA No. P90043*, U.S. Food & Drug Admin. (Nov. 21, 2016),

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P900043>

(indicating approval decision date of Aug. 2, 1994). By 1997, stents would have been well-known to a POSITA. A POSITA would have been familiar with the balloon catheters used to deliver stents. Thus, a POSITA would have known that balloon-expandable stents were crimped over a balloon catheter and that a balloon catheter is made of a balloon disposed about a catheter. Therefore, a POSITA would have known that anyone using a stent crimper to secure a balloon expandable stent to the catheter would necessarily provide a stent disposed about a medical balloon with the medical balloon disposed about a catheter as part of the crimping process. Indeed, Williams contemplates a stent disposed about a medical balloon with the medical balloon disposed about a catheter prior to crimping. Ex. 1227 at 5:10-15 (“Operation of the FIGS. 5–7 embodiment is achieved by placing a catheter that has a stent disposed about its stent-receiving portion, which in a balloon catheter would be the balloon portion of the catheter, in between the space formed between the substantially flat surfaces of faces 125, 130.”).

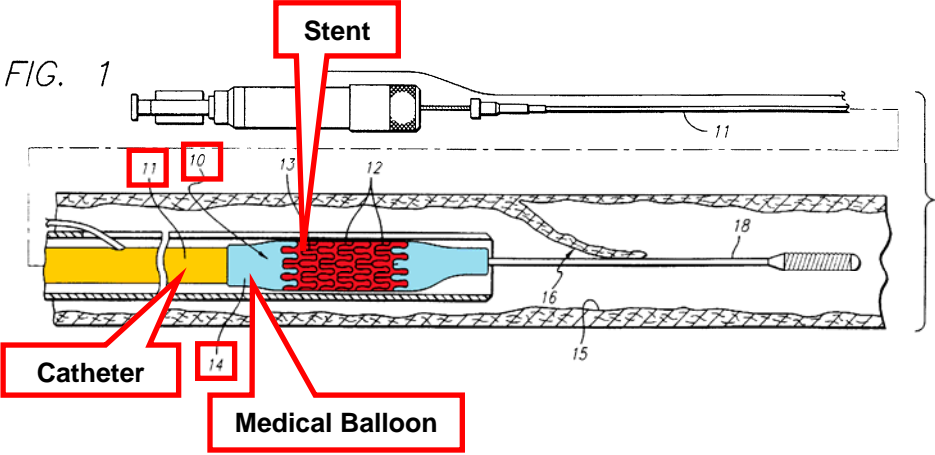
177. This limitation is also disclosed in Morales. For example, Morales discloses a stent 10 (red) disposed about a balloon 14 (blue), the balloon disposed about a delivery catheter 11 (orange):



Ex. 1204, Fig. 1. In particular, Morales discloses: “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, 5:60-67.

178. The claim chart below provides a left column with claim language from the '560 patent and provides a right column with exemplary disclosure from Yasumi, Williams and Morales.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
<p>[11a], [19a], [35a]</p> <p>wherein a stent is disposed about a medical balloon disposed about a catheter.</p>	<p><u>Morales discloses a stent (stent 10) disposed about a medical balloon (balloon 14) disposed about a catheter (catheter 11).</u></p> <p>“FIG. 1 illustrates intravascular stent 10 which is mounted onto delivery catheter 11. Stent 10 generally comprises a plurality of radially expandable cylindrical elements 12 disposed coaxially and interconnected by members 13 disposed between adjacent cylindrical elements 12. Delivery catheter 11 has an expandable portion or balloon 14 for expanding stent 10[.]” (Ex. 1204 at 5:60-66.)</p>

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
	<p>“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.” (<i>Id.</i> at 6:22-25.)</p>  <p>(Ex. 1204, Fig. 1.)</p>

3. Claims 17, 26 and 34

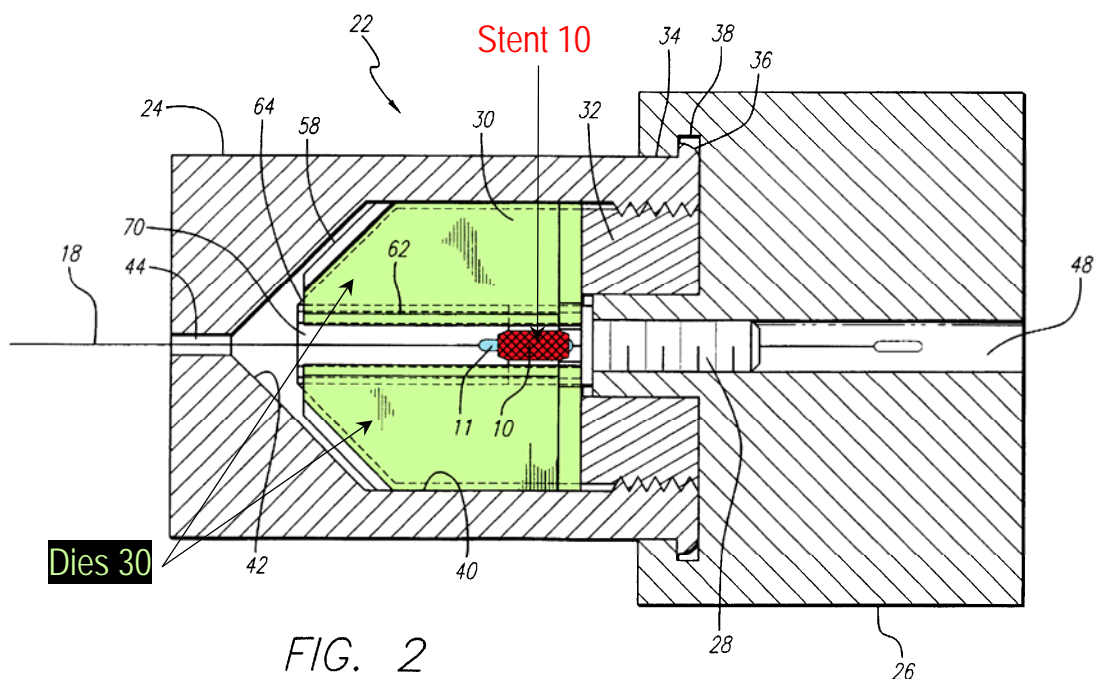
179. Dependent Claims 17, 26 and 34 share an identical limitation of “an entire stent is disposed in the aperture.”¹³

180. This limitation is inherent in or obvious over Yasumi either alone or in view of Williams. I consider Yasumi a stent crimper for purposes of my analysis, and Williams for its disclosure of using pliers or tools (like Yasumi) to crimp a stent. Ex. 1227 at 1:67-68. It was well known in the art at the time of the invention that balloon-expandable stents were crimped over a balloon catheter. The entire length of the stent had to be crimped to a smaller diameter prior to

¹³ Claim 26 recites “a stout,” but this appears to be a typographical error.

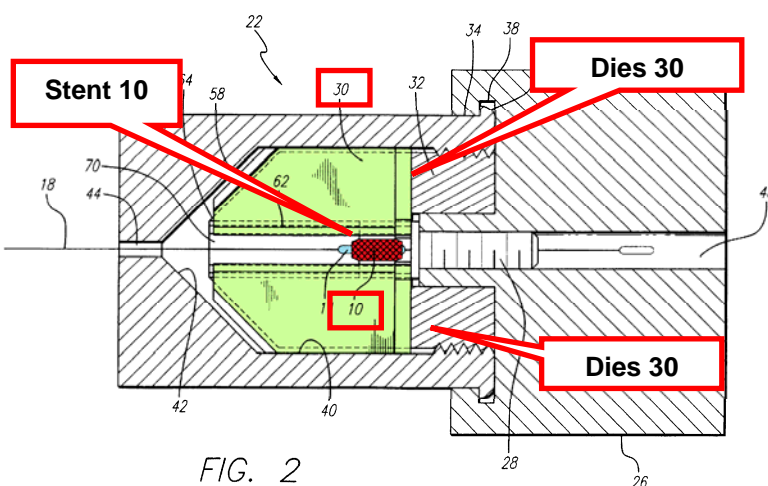
delivering the stent to the narrowed vessel in the patient. A POSITA at the time of the invention would have been aware of the problems resulting from uneven stent crimping. To avoid these problems, stent crimpers were designed and constructed to accommodate at least, and typically more than, the entire length of a stent within the die aperture to perform stent crimping. Therefore, a POSITA would have understood stent crimpers to be constructed so as to accommodate the entire stent within the crimping aperture to ensure even crimping along the length of the stent. To this end, it would have been obvious to a POSITA that the length of the crimping dies would necessarily be at least as long as the stent so as to crimp the entire stent.

181. This limitation is also disclosed in Morales. For example, Morales depicts a stent disposed within an aperture:



Ex. 1204, Fig. 2. In Morales, an entire stent 10 (red) is depicted as disposed within an aperture formed by teeth 30 (green). *See id.*

182. The claim chart below provides a left column with claim language from the '560 patent and provides a right column with exemplary disclosure from Yasumi, Williams and Morales.

<u>ASSERTED CLAIMS</u>	<u>PRIOR ART</u>
<p>[17a], [26a] and [34a]</p> <p>wherein an entire stent is disposed in the aperture.</p>	<p><u>Morales discloses an entire stent disposed in the aperture (between teeth 30).</u></p> <p>“[T]he present invention tool is intended to be used on a variety of stent lengths. The total length of a preferred embodiment tooth/plate is over thirty-five millimeters long, thereby accommodating the lengths of the stents currently on the market.” (Ex. 1204 at 5:5-9.)</p>  <p>FIG. 2</p> <p>(Ex. 1204, Fig. 2.)</p>

4. Reason, Basis or Motivation to Combine

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

184. I consider Yasumi a stent crimper for purposes of my analysis, and Williams for its disclosure of using pliers or tools (like Yasumi) to crimp a stent. Ex. 1127 at 1:67-68. It would have been obvious as a matter of common sense to use Yasumi, either alone or in view of Williams, with a stent disposed about a balloon and the balloon disposed about a catheter, as discussed in Morales, because crimping a stent to a catheter is the intended purpose of a stent crimper.

185. Moreover, a POSITA would have had a reason, basis or motivation to construct Yasumi, either alone or in view of Williams, with an aperture “having a center and a first opening and a second opening with dies constructed and arranged to have a length exceeding the length of a stent,” as depicted in Morales. Problems with uneven crimping forces were well known. *See* ¶¶ 93-95, 164-65. 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. 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.

VIII. CONCLUSION

186. For the foregoing reasons, Claims 1, 2, 6, 8-10, 14, 15, 18, 23, 25, 27, 28, 31, 33, 37 and 40 would have been obvious based upon Yasumi in view of Williams. Further, Yasumi in view of Williams in further view of Morales renders obvious claims 11, 17, 19, 26, 34, 35 and 39.

187. I reserve the right to supplement my opinions in response to any arguments or positions the Patent Owner raises or takes, as well as new information, including but not limited to any claim construction adopted by the Board, as soon as it becomes available.

188. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statement were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code

and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Executed on April 19, 2017, in Atherton, California.

A handwritten signature in black ink, appearing to read "Neil Sheehan", with a long horizontal flourish extending to the right.

Neil Sheehan