UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE UNITED STATES PATENT TRIAL AND APPEAL BOARD

ENDOLOGIX, INC.
Petitioner

v.

LIFEPORT SCIENCES LLC
Patent Owner

CASE IPR: 2015-01722

U.S. PATENT NO. 8,192,482

PETITION FOR *INTER PARTES* REVIEW

Mail Stop *Patent Board*
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box. 1450
Alexandria, VA 22313-1450

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I. INTRODUCTION

Endologix, Inc. ("Petitioner" or "Endologix") hereby petitions for *inter partes* review of claims 1-9, 12-13, 21-22, and 30 of U.S. Patent No. 8,192,482 ("'482 Patent") (Ex. 1001) under 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.

II. PAYMENT OF FEES (37 C.F.R. §§ 42.15 and 42.103)

Petitioner authorizes the USPTO to charge the required fees for *inter partes* review of 14 claims, and any additional fees, to Deposit Account No. 02–1818.

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

A. Real Parties-In-Interest (37 C.F.R. § 42.8(b)(1))

Endologix, located at 2 Musick, Irvine, California 92618, is the real party-in-interest.

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

The '482 Patent is the subject of an infringement lawsuit brought by LifePort Sciences LLC ("LifePort" or "PO") against Petitioner in the United States District Court for the District of Delaware, Case No. 1:12-cv-01791-GMS ("District Court Case"). The '482 Patent was asserted against Endologix on August 12, 2014, in the Amended Complaint (Dkt. 34) served via the CM/ECF system after the Court granted LifePort's Motion to Amend Complaint (Dkt. 33). *See* Ex. 1015.

C. Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3))

Lead Counsel	Backup Counsel
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A power of attorney designating counsel is being filed with this Petition. Petitioner hereby requests authorization to file a motion under 37 C.F.R. § 42.10(c) for Back-Up Counsel Robert J. Barz, to appear *pro hac vice*, as Mr. Barz is an experienced litigating attorney, and is counsel for Endologix in the pending District Court Case referred to in Section III.B., and as such has an established familiarity with the subject matter at issue in this proceeding. Petitioner intends to file such a motion once authorization is granted.

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

Please address all correspondence to the lead counsel at the address shown

above. Petitioner also consents to electronic service by email.

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

Petitioner certifies that (1) the '482 Patent, issued on June 5, 2012, is available for *inter partes* review; (2) under 35 U.S.C. § 315(b), Petitioner is not barred or estopped from requesting *inter partes* review of the '482 Patent on the grounds identified herein (*see Amneal Pharm., LLC v. Endor Pharm. Inc.*, IPR2014-00360, Paper 15 at 7-10 (PTAB June 27, 2014)); and (3) Petitioner has not filed a complaint relating to the '482 Patent. This Petition is filed in accordance with 37 C.F.R. § 42.106(a).

V. RELIEF REQUESTED

Petitioner asks that the Board review the accompanying prior art and analysis, institute a trial for *Inter Partes* Review of claims 1-9, 12-13, 21-22, and 30 of the '482 Patent, and cancel those claims as invalid under 35 U.S.C. § 102 or 35 U.S.C. § 103.

VI. REASONS FOR THE REQUESTED RELIEF

A. Summary of '482 Petition

Claims 1-9, 12-13, 21-22, and 30 of the '482 Patent are anticipated by the prior art, or at best, cover nothing more than obvious combinations of well known endoluminal prosthesis designs and/or very well known features of such endoluminal prostheses. Indeed, the first named inventor testified that the claimed features added to obtain allowance were merely a matter of "design choice" that

required nothing more than "routine engineering." Ex. 1016 (Goicoechea Dep.) at 144:6-20; *see also id*. at 139:14-25.

B. Overview of the Prior Art Specifically Cited Below

1. U.S. Patent No. 8,317,854 ("Ryan")

U.S. Patent No. 8,317,854 ("Ryan") (Ex. 1004) was filed on July 19, 1996, claims priority to June 19, 1994, and issued on November 27, 2012. Ryan is prior art under 35 U.S.C. § 102(e). Ryan discloses a bifurcated stent with a graft used for treating aneurysms.

2. U.S. Patent No. 5,405,377 ("Cragg")

U.S. Patent No. 5,405,377 ("Cragg") (Ex. 1005) was filed on February 21, 1992, and issued on April 11, 1995. Cragg is prior art under 35 U.S.C. § 102(e). Cragg discloses an intraluminal stent that includes hoops that are connected by adjacent apices. The stent is compressible and self-expanding.

3. U.S. Patent No. 5,064,435 ("Porter")

U.S. Patent No. 5,064,435 ("Porter") (Ex. 1006) was filed on June 28, 1990, and issued on November 12, 1991. Porter is prior art under 35 U.S.C. § 102(b). Porter discloses a non-helical stent.

4. U.S. Patent No. 4,994,071 ("MacGregor")

U.S. Patent No. 4,994,071 ("MacGregor") (Ex. 1007) was filed on May 22, 1989, and issued on February 19, 1991. MacGregor is prior art under 35 U.S.C. § 102(b). MacGregor discloses an expandable bifurcated stent that is made of a

series of interconnected wire loops.

5. U.S. Patent No. 5,135,536 ("Hillstead")

U.S. Patent No. 5,135,536 ("Hillstead") (Ex. 1008) was filed on February 5, 1991, and issued on August 4, 1992. Hillstead is prior art under 35 U.S.C. § 102(b). Hillstead discloses a non-helical stent.

6. U.S. Patent No. 4,733,665 ("Palmaz")

U.S. Patent No. 4,733,665 ("Palmaz") (Ex. 1009) was filed on November 7, 1985, and issued on March 29, 1988. Palmaz is prior art under 35 U.S.C. § 102(b). Palmaz discloses expandable intraluminal vascular graft that is non-helical in shape and can be expanded using a balloon.

7. U.S. Patent No. 5,370,683 ("Fontaine")

U.S. Patent No. 5,370,683 ("Fontaine") (Ex. 1010) was filed on February 4, 1994, claims priority to March 25, 1992, and issued on December 6, 1994. Fontaine is prior art under 35 U.S.C. § 102(e). Fontaine discloses a vascular stent for reducing hemodynamic disturbances caused by angioplasty.

8. U.S. Patent No. 5,707,386 ("Schnepp-Pesch")

U.S. Patent No. 5,707,386 ("Schnepp-Pesch") (Ex. 1011) was a PCT application filed on January 22, 1994, claims priority to February 4, 1993, and issued on January 13, 1998. Schnepp-Pesch is prior art under 35 U.S.C. § 102(e). Schnepp-Pesch discloses a stent that has high flexibility because of successively arranged hoops in the axial direction which extend over its circumference.

9. U.S. Patent No. 5,421,955 ("Lau")

U.S. Patent No. 5,421,955 ("Lau") (Ex. 1012) was filed on March 17, 1994, claims priority to October 28, 1991, and issued on June 6, 1995. Lau is prior art under 35 U.S.C. § 102(e). Lau discloses an expandable stent for implantation in the body and a method for making such a stent from a single length of wire.

10. U.S. Patent No. 5,234,457 ("Andersen")

U.S. Patent No. 5,234,457 ("Andersen") (Ex. 1013) was filed on October 9, 1991, and issued on August 10, 1993. Andersen is prior art under 35 U.S.C. § 102(b). Andersen discloses a stent assembly, delivery system and method of manufacture therefor.

C. Background of the Technology and Summary of '482 Patent

The '482 Patent describes an endoluminal prosthesis for use in a blood vessel. '482 Patent, 1:14-15; Declaration of Richard A. Hillstead, Ph.D, Ex. 1002, ¶ 22 (hereinafter, "Hillstead Decl."). For decades before the '482 Patent, doctors had used stents, grafts and prostheses for the treatment of angeological diseases. *Id*. A prosthesis is a stent (the wire portion) with a graft (the fabric portion) covering it. *Id*. at ¶ 23. A prosthesis is used to provide a prosthetic intraluminal wall because it allows the blood flow to flow within it. '482 Patent, 1:23-25; Hillstead Decl. ¶ 23. A prosthesis is used to treat an aneurysm by removing the pressure on a weakened part of an artery, thus reducing the risk of embolism, or of the natural artery wall bursting. '482 Patent, 1:27-29; Hillstead Decl. ¶ 24.

1. Well Known Prior Art Prosthesis Designs

Stents, grafts and prostheses date back to 1980's. *See, e.g.*, Palmaz; Hillstead Decl. ¶ 25. By the time of the effective filing date of the '482 Patent, a wide variety of stent designs were well known in the art. The well known stents were typically tubular and could include extensions, bifurcations, and extensions for the bifurcations. Hillstead Decl. ¶ 25. The well known tubular structures were made out of a filament (typically wire) that could take on a variety of patterns to provide various advantages such as strength, stability, and flexibility. *Id.*

One way to categorize the well known patterns was to classify a design as helical or non-helical. *Id*. at ¶ 26. Both helical and non-helical patterns often took on a well known zig-zag pattern whereby the wire forming the stent looped around an axis in a repeating zig-zag pattern to form a cylinder. *Id*. The '482 Patent explicitly recognized the existence of this well known prior art pattern. '482 Patent at 1:40-59; Hillstead Decl. ¶ 27. The '482 Patent also recognized that this prior art zig-zagging pattern was commonly utilized in prior art helical (e.g., EP-A-0556850) and non-helical (U.S. Patent No. 4,733,655) stents. *Id*.

Cragg provides a well known example of a prior art helical design.

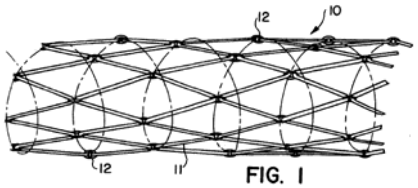
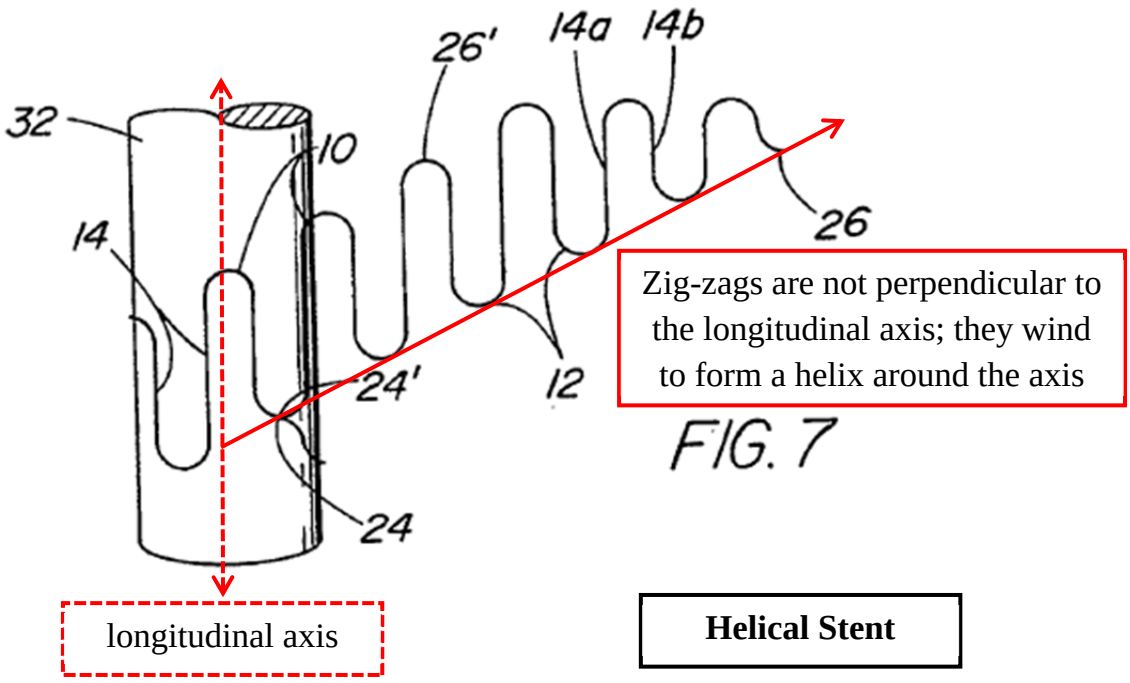


FIG. 1

Cragg at Fig. 1; Hillstead Decl. ¶ 28. The zig-zaging pattern in Cragg gradually works its way down the length of the cylinder in helical fashion. *Id*. The apices of the zigs and zags are not aligned perpendicular to the longitudinal axis of the stent. Fontaine also discloses a helical pattern. *Id*. at ¶ 29. To illustrate, Figure 7 of Fontaine depicts a partially unwound helical pattern:

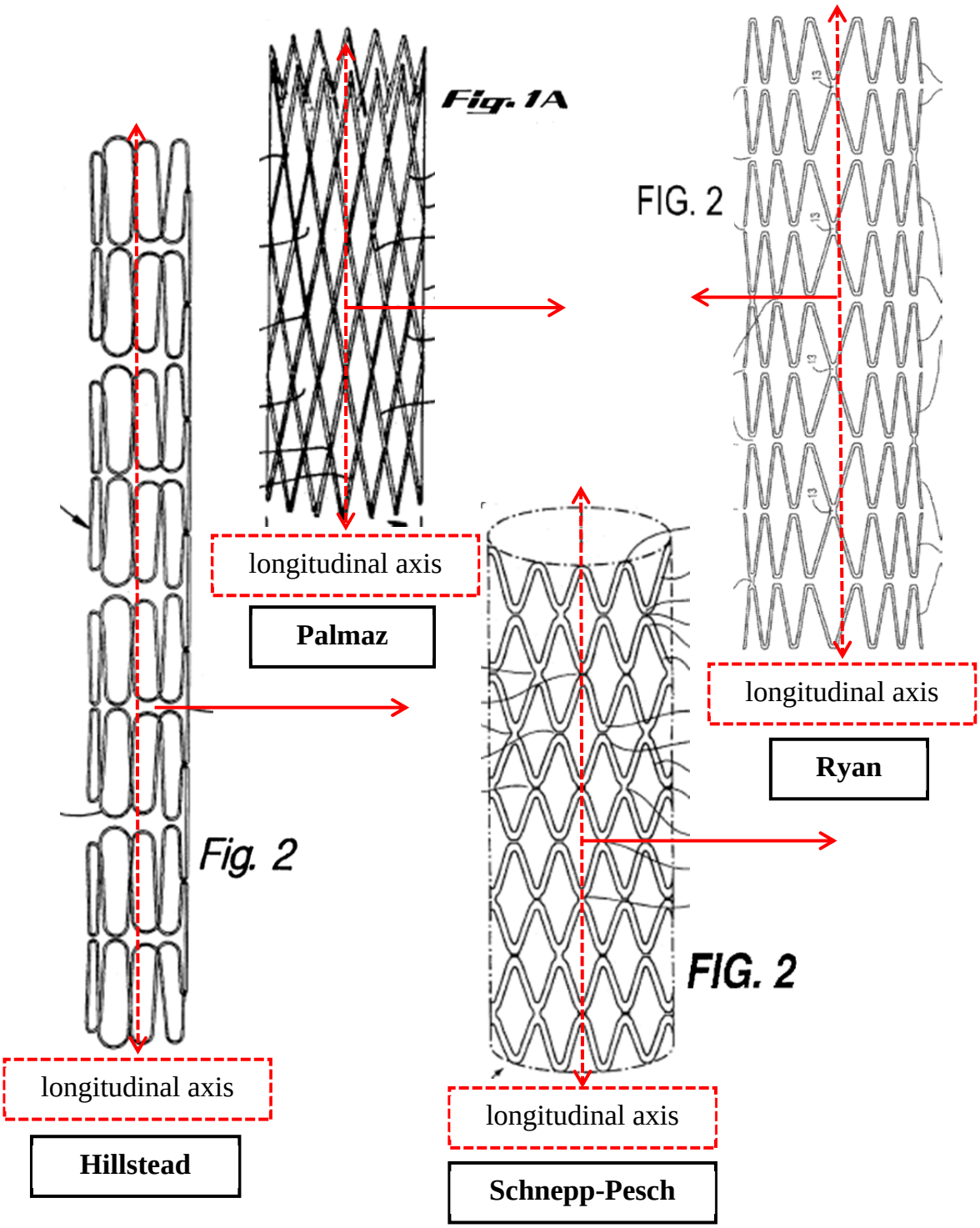


Fontaine at Fig. 7; Hillstead Decl. ¶ 29.

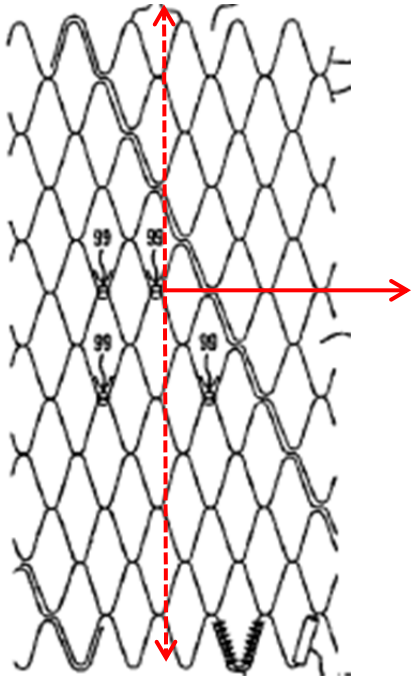
Non-helical patterns were also very well known at the time. Hillstead Decl. ¶ 30. For example, Hillstead, Palmaz, Ryan, and Schnepp-Pesch all disclose stents that include non-helical zig-zaging patterns that make a series of loops around the longitudinal axis, where each loop is in a plane perpendicular to the axis:

Well Known Prior Art Non-Helical Stent Designs

Zig-zags/Hoops are perpendicular to the longitudinal axis; they **do not form a helix** around the axis



Hillstead at Fig. 2; Palmaz at Fig. 1A; Schnepp-Pesch at Fig.2; Ryan at Fig. 2; Hillstead Decl. ¶ 30. The '482 Patent attempts to claim this well known non-helical stent design. The background of the specification of the '482 Patent acknowledges both helical and non-helical designs, but the summary of the invention only focuses on differentiating the alleged invention of the '482 Patent from the well known helical designs without giving credence to the cited non-helical designs (e.g., Palmaz). *Compare* '482 Patent at 1:48-59 with '482 Patent at 3:62-4:7; *see also* Hillstead Decl. ¶ 31. Specifically, it states: "the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent." '482 Patent at 3:63-67.



Like the four prior art examples above, the zig-zags/hoops of the '482 Patent are perpendicular to the longitudinal axis; they **do not form a helix** around the axis

'482 Patent Non-Helical Stent

This configuration, however, was not novel. As shown above, it was common and well known in the prior art. Hillstead at Fig. 2; Palmaz at Fig. 1A; Schnepp-Pesch at Fig.2; Ryan at Fig. 2; Hillstead Decl. ¶ 32. Even assuming, *arguendo*, that the design was novel, it still does not qualify as a patentable invention. The prior art was rife with examples of hoop designs for stents and the inventor himself characterized the allegedly novel feature as "design choice" and "routine engineering." Ex. 1016 ("Goicoechea Dep.") at 144:6-20.

2. The Patent Owner Only Overcame Previous Rejections By Arguing That The Disclosed Non-Helical Design Was Novel

When the application that became the '482 Patent was examined, the PO argued that the novelty of the alleged invention was its non-helical design. *See, e.g.*, Ex. 1014, File History at 1247. The PO differentiated the claims of the '482 Patent from that relied upon prior art by arguing that they are limited to non-helical stents. *See, e.g., id*. ("[claim 1] has been amended to recite, in part, 'each of said hoops being non-helical.' In Cragg and in Fontaine, each of the hoops is not non-helical."). The Patent Board recognized PO's argument that the "non-helical" configuration was an alleged "novel configuration. *Id.* at 1933.

Yet, as shown in the well known prior art examples above, and as explained in detail in the specific challenges below, there was nothing novel about the claimed "non-helical" hoop stent of the '482 Patent. Hillstead Decl. ¶ 33. Accordingly, the challenges herein establish that at least claims 1-9, 12-13, 21-22,

and 30 are unpatentable.

3. Elements from Helical and Non-Helical Stents Were Known To be Interchangeable

The '482 Patent specification describes both helical and non-helical embodiments. '482 Patent at 3:62-4:7. Importantly, the '482 Patent and the prior art make clear that well known elements disclosed as part of helical stents could be simply substituted into non-helical stents. Hillstead Decl. ¶ 33; *see also* Ex. 1016 ("Goicoechea Dep.") at 144:6-20; *see also* Ex. 1014, File History at 1693.

For example, as shown above, both helical and non-helical prior art stents could have zig-zag patterns whereby adjacent apices abut.

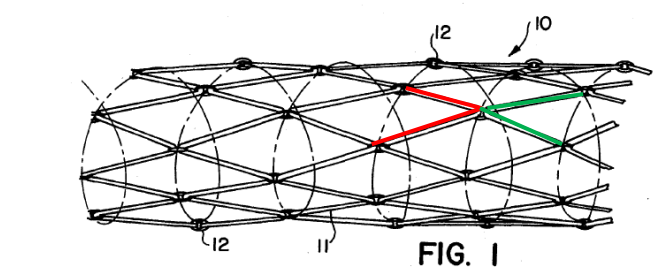


FIG. 1

Helical Prior Art (Cragg)
Apices abut and are connected/secured

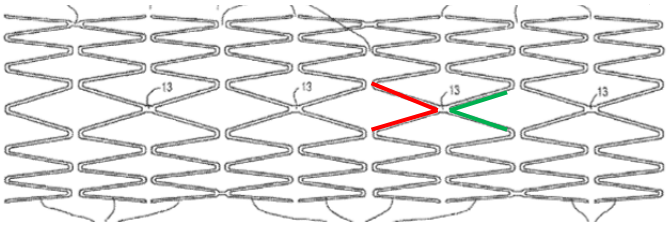


FIG. 2

Non- Helical Prior Art (Ryan)
Apices abut and are connected/secured

Cragg at Fig. 1; Ryan at Fig. 2; Hillstead Decl. ¶ 34. These patterns were well known in the prior art and, as discussed below, various means for securing abutting apices was also well known in the prior art. Hillstead Decl. ¶¶ 34, 46. Further, it was well known that those securing means were interchangeable not only with one

another, but between helical and non-helical designs. *Id*. at ¶ 35. Specifically, one of skill in the art would have been capable of implementing the securing means from the non-helical design of Cragg into the helical design of Ryan because it would have been nothing more than a simple substitution of one well known securing means for another well known securing means that would have achieved a predictable result. *Id*.

In sum, at the time of the alleged invention of the '482 Patent there was nothing novel about using a helical design, nothing novel about using a non-helical design, and nothing novel about implementing well known prior art elements into either helical or non-helical designs. *Id*. at ¶ 36.

4. Well Known, Interchangeable Prior Art Securing Means

In addition to claiming a non-helical stent design, the '482 Patent claims "means for securing an apex of one hoop to an abutting a juxtaposed apex of a neighboring hoop." This too was a well known prior art feature of both helical and non-helical stent designs. *Id*. at ¶ 37.

As briefly described above, it was well known to align the apices of one layer of zig-zags with the apices of an adjacent layer of zig-zags in both helical and non-helical designs. *Id*. at ¶ 38. It was common to align apices in order to secure the layers together at the apices where the securing means would be most effective. This practice was well known as early as the 1980s by virtue of, at least, Palmaz.

Palmaz at 6:36-52. Because this practice was so common well before the '482 Patent, a variety of well known means for securing apices had been established prior to the filing date of the '482 Patent. Hillstead Decl. ¶ 39. The various securing means all shared a common function: to secure an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop. *Id*.

The '482 Patent recognized that such means for securing were well known prior art elements at the time of the alleged invention and did not characterize them as new or novel. *Id*. at ¶ 40. Specifically, the '482 Patent states: "Typically, the stents of this invention whether of the helical or perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors." '482 Patent at 4:21-25.

The following prior art examples not only disclose several of the well known prior art structures for securing apices, they also recognize the interchangeability of such structures. Hillstead Decl. ¶ 41.

Palmaz discloses use of "welding, soldering, or gluing" or any other "conventional manner" for securing apices in order to provide "a relatively high resistance to radial collapse" and to allow the stent to retain its shape. Palmaz at 6:36-49; Hillstead Decl. ¶ 42.

Fontaine discloses using a loop or a staple-like bracket to secure apices in

addition to brazing, welding or gluing: "In practice, the connection between the loop and the filament is slidable along the filament 11, thereby allowing for radial expansion. Although this connection can be easily made using a loop as shown, it can also be made by, for example, using a bracket. The connector could also be made by brazing, welding, or gluing the end to the filament." Fontaine at 4:59-63; Hillstead Decl. ¶ 43.

Cragg discloses using "loops which connect adjacent apices of the wire." Cragg at Abstract; Hillstead Decl. ¶ 44. Cragg further discloses "loop members 12 which connect adjacent apices of adjacent helix hoops to help define the tubular stent. The loop members 12 may connect all or some of the pairs of adjacent apices." Cragg at 2:42-47; Hillstead Decl. ¶ 44. This disclosure is further depicted in the figures of Cragg.

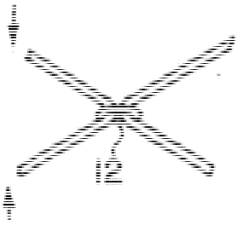


FIG. 2

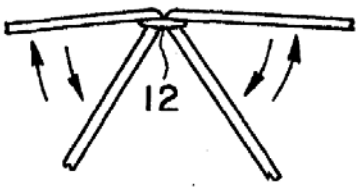


FIG. 3

FIG. 4

Cragg at Figs. 2-4; Hillstead Decl. ¶ 44.

Lau discloses that the apices may be secured integrally or by independent means: "The interconnecting elements may be formed in a unitary structure with the expandable cylindrical elements from the same intermediate product, such as a

tubular element, or they may be formed independently and connected by suitable means, such as by welding or by mechanically securing the ends of the interconnecting elements to the ends of the expandable cylindrical elements." Lau at 2:59-66; Hillstead Decl. ¶ 45.

Andersen discloses that "an improved stent structure that is formed of a self-expending filament material in loosely interlocked loops." Andersen at 3:16-18.

D. Summary of the Prosecution of the '482 Patent

The application that issued as the '482 Patent, U.S. Application No. 09/977,826, filed October 15, 2001, is a continuation of U.S. Application No. 09/313,593, now U.S. Patent No. 6,302,906 ("'906 Patent"), filed May 18, 1999, which is a continuation of U.S. Application No. 08/662,484, now U.S. Patent No. 5,916,263, filed June 13, 1995, which is a continuation of U.S. Application No. 08/317,763, now U.S. Patent No. 5,609,627, filed Oct. 4, 1994, which is a continuation of U.S. Application No. 08/312,881, now abandoned, filed Sept. 27, 1994. The examiner did not use Ryan, Hillstead or any other combinations offered herein as the basis for any rejection. *See* Ex. 1014, File History.

E. The '482 Patent Cannot Claim Priority to EP 94400284 or EP 94401306

The '482 Patent is a continuation of the '906 Patent, which is a continuation of U.S. Application No. 08/662,484, now U.S. Patent No. 5,916,263, ("'484 Application"), which is a continuation of U.S. Application No. 08/317,763, now

U.S. Patent No. 5,609,627 ("'763 Application"). Another division of the '763 Application, U.S. Application No. 08/461,402 (the "'402 Application," or "Goicoechea"), was the subject of an interference before the BPAI, No. 104,192 ("'192 Interference"). Based on this interference and subsequent district court and Federal Circuit litigation, it is conclusive that the '482 Patent cannot claim priority to EP 94400284 ("EP '284") or EP 94401306 ("EP '306").

The '192 Interference was declared on April 23, 1998, among Goicoechea and (1) U.S. Application No. 08/463,836 ("the Ryan Patent"), and (2) U.S. Patent No. 5,575,817 to Eric Martin ("the Martin Patent").[1] In the course of the '192 Interference, the BPAI found that the Goicoechea '402 Application was not entitled to claim priority to the MinTec EPO Applications under 35 U.S.C. § 119. The BPAI determined that because two of the inventors on the Goicoechea '402 Application, Michael Dake and Andrew Cragg, did not assign their rights to MinTec SARL until after the filing of the MinTec EPO Applications, the MinTec EPO Applications were not filed on Dake's or Cragg's behalf as required by 35 U.S.C. § 119, and thus the Goicoechea '402 Application could not claim priority to the MinTec EPO Applications. Ex. 1017, BPAI Decision, April 7, 2000, at 6.

[1] Because of corrections of inventorship, Goicoechea is often referred to in the '192 Interference as "Cragg," and Ryan is referred to as "Fogarty." The Ryan '836 application ultimately issued as U.S. Patent No. 8,206,427.

This determination was affirmed by the United States District Court for the District of Columbia and the Federal Circuit. Exs. 1018, 1019. Accordingly, all patents in the Goicoechea patent family that list Dake or Cragg as an inventor cannot claim priority to the EP applications.

F. Related '167 Patent IPR and Institution Decision

On August 18, 2014, W.L. Gore & Associates, Inc., filed a petition for *Inter Partes* Review of U.S. Patent No. 6,117,167 ("'167 Patent"). The '167 Patent claims priority back to the same application at the '482 Patent, U.S. Application No. 08/312,881, now abandoned, filed Sept. 27, 1994. On February 23, 2015, the Patent Trial and Appeal Board ("PTAB") instituted the *inter partes* review on claims 1-82 (i.e. all the claims). That proceeding included instituted grounds for claims similar to the claims of the '482 Patent. *Compare* claim 1 of the '482 Patent with claims 35-37 of the '167 Patent (Ex. 1020) and IPR2014-01319, Paper No. 7, Institution Decision at 16 (PTAB Feb. 23, 2015) (Ex. 1021).

VII. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art is a hypothetical person presumed to know the relevant prior art. *Gnosis S.p.A. v. South Alabama Med. Sci. Found.*, IPR2013-00116, Final Written Decision (Paper 68) at 9. Such a person is of ordinary creativity, not merely an automaton, and is capable of combining teachings of the prior art. *Id*. (citing *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398,

420-21 (2007).) Petitioner submits that a person of ordinary skill in the art of the '482 Patent as of September 27, 1994, would have had a bachelor of science degree in mechanical engineering, or the equivalent, or would have had at least five years of experience in designing stents. Hillstead Decl. ¶¶ 1-20.

VIII. CLAIM CONSTRUCTION

In the pending district court litigation, the parties agreed to constructions for some terms in the '482 Patent. Normally, a claim in *inter partes* review is given the "broadest reasonable construction in light of the specification." *See* 37 C.F.R § 42.100(b). However, the '482 Patent expired on September 27, 2014. 35 U.S.C. § 154(a). Accordingly, where a challenged patent is expired, the standard set forth in *Phillips* applies. *See Toyota Motor Corp. v. Leroy G. Hagenbuch*, Case IPR2013-00483, Paper 37 (PTAB Dec. 5, 2014).

Here, a person of ordinary skill in the art at the time of the alleged invention would have understood each term of each claim of the '482 Patent to have its plain and ordinary meaning, or alternatively, that which was agreed to in the Joint Claim Chart filed in the District Court Case (Dkt. No. 57). The agreed constructions are as follows:

Claim(s)	Claim Term	Construction
1-9, 12-13, 21-22	"non-helical"	non-spiral
1-9, 12-13,	"means for	**Function:** Securing the apex of one hoop to a juxtaposed apex of a

21-22	securing"	neighboring hoop. **Structure:** (1) loop formed of thermoplastic material; (2) a suture; (3) bead formed of a thermoplastic material; (4) loop formed of wire; (5) ring formed of wire; and (6) staple formed of wire; and equivalents. Patent Owner has further argued for a broad interpretation of equivalent structures that includes a wire structure that is integral with the apices of juxtaposed hoops. *See* Infringement Contentions at 009-010 (Ex. 1022).

A. Additional Terms for Construction

1. "segment" (Claims 2-5,8-9, and 12)

In addition to the agreed constructions, Petitioner submits that the claim term "segment" (*see* Claims 2-5, 8-9, and 12) means "portion." The '482 Patent makes clear that those terms are synonymous when used to describe a segment or portion of a stent: "straight stent **400** comprises proximal stent portion (or segment) **401**, distal stent portion **402**, and an intermediate portion **403**." '482 Patent at 16:33-35 (emphasis added).

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

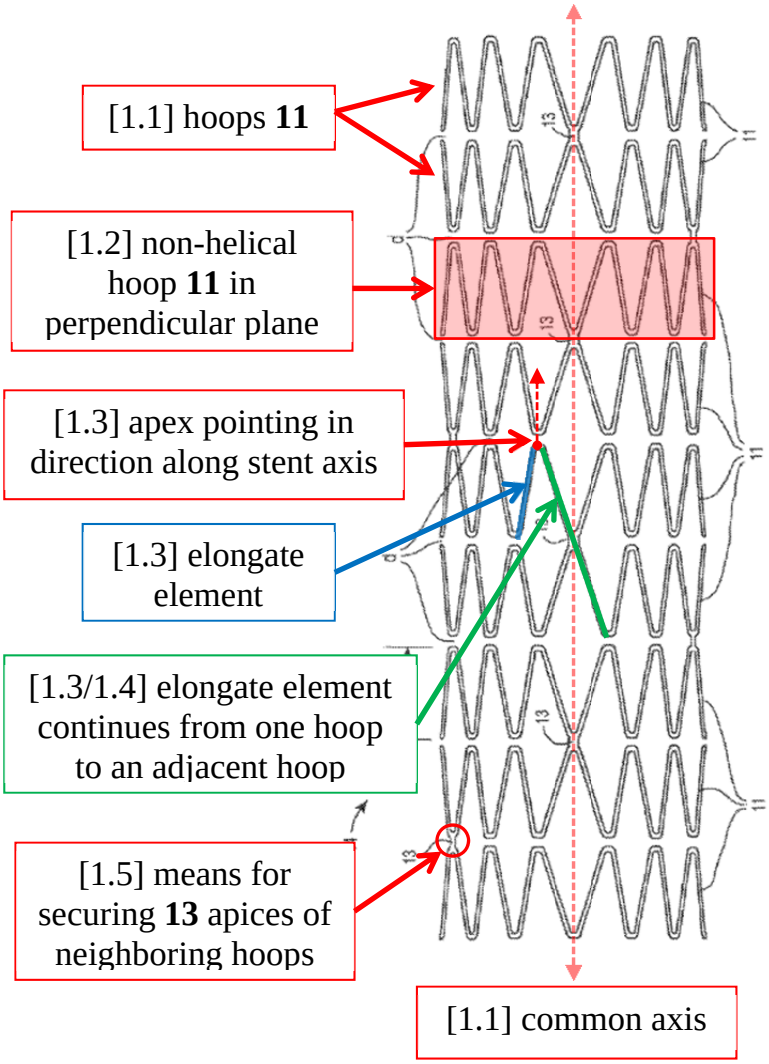
A summary of the grounds on which Petitioner requests cancellation of claims 1-9, 12-13, 21-22, and 30 is provided in the chart below. A specific explanation of the challenges follows.

Ground	Claims Challenged	Challenge
1	1-9, 12-13, 21-22, and 30	Anticipated by Ryan
2	1-9, 12-13, 21-22, and 30	Obvious over Ryan
3	1-9, 12-13, 21-22, and 30	Obvious over Ryan in view of Cragg
4	2-4, 6-7, and 12	Obvious over Ryan in view of Porter
5	2, 5, 7-9	Obvious over Ryan in view of MacGregor
6	1-3, 5-6, 12-13, 21, and 30	Anticipated by Hillstead
7	1-3, 5-6, 12-13, 21, and 30	Obvious over Hillstead in view of Palmaz
8	1-9, 12-13, 21-22, and 30	Obvious over Hillstead in view of Palmaz and Ryan

A. Ground 1: Claims 1-9, 12-13, 21-22, and 30 Are Anticipated by Ryan

All of the elements of claims 1-9, 12-13, 21-22, and 30 of the ‘482 Patent are anticipated by Ryan. Hillstead Decl. ¶¶ 51-82.

Claim 1: Ryan discloses a stent including every element of claim 1. Hillstead Decl. ¶¶ 51-59.

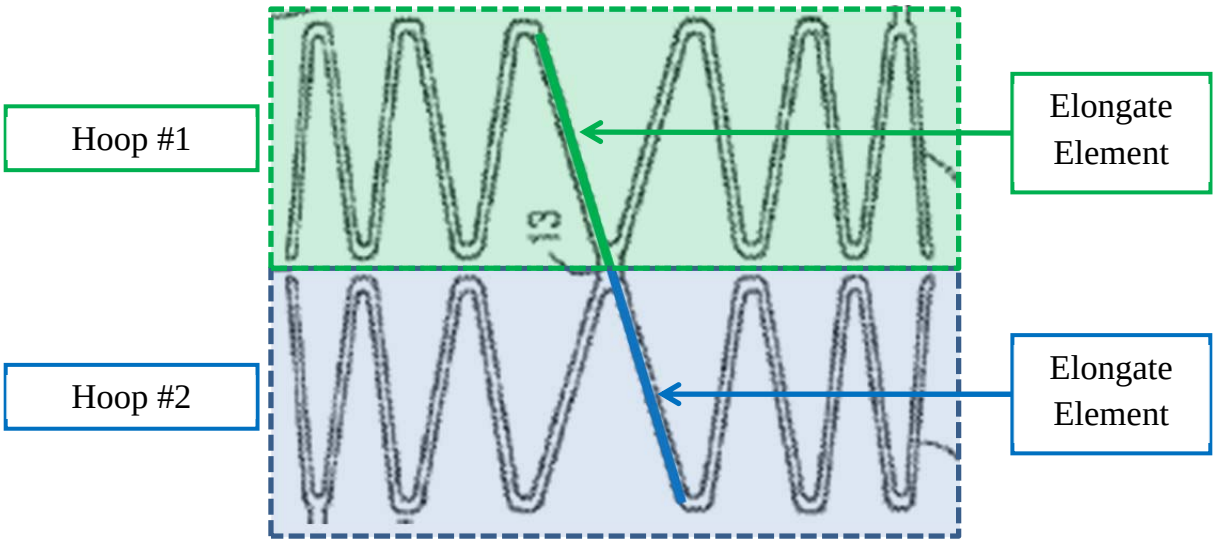
Claim 1	Ryan
[1.0] A stent comprising:	[1.0] Tubular Stent Frame (Ryan, Fig. 2) 
[1.1] a plurality of hoops aligned along a common axis,	
[1.2] each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent, and	
[1.3] each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the stent, and	
[1.4] wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop; and	
[1.5] means for securing an apex of one hoop to an abutting a juxtaposed apex of a neighboring hoop.	

Ryan describes a stent comprised of either non-helical or helical elements. Ryan at 5:24-30; Hillstead Decl. ¶ 52. Specifically, Ryan discloses that "[t]he radially compressible frame can take a variety of forms, usually comprising or

consisting of a plurality of independent or interconnected structural elements, such as rings, bands, helical elements, serpentine elements, axial struts, parallel bars, and the like." Ex. 1004 at 5:24-30; Hillstead Decl. ¶ 53. The preferred embodiments of Ryan depict and describe non-helical rings (*i.e.*, hoops). Ryan explicitly discloses that "[t]he tubular frame preferably comprises a plurality of radially compressible band or ring structures." Ryan at 3:16-17; Hillstead Decl. ¶ 53. Ryan depicts its "band or ring structures" as non-helical rings that are each oriented in a plane perpendicular to the axis of the stent. *See, eg.*, Ryan at Fig. 2; Hillstead Decl. ¶ 53. Ryan discloses that "band members **11**, each [] comprise[] a zig-zag or Z-shaped element which forms a continuous circular ring." Ryan at 7:49-52; Hillstead Decl. ¶ 53. For example, as shown above, Figure 2 of Ryan depicts nine axially aligned hoops ("band members **11"**), each oriented in a plane perpendicular to the longitudinal axis of the stent. Ryan at Fig. 2; Hillstead Decl. ¶ 54. Ryan also describes and shows that its hoops are oriented in a conventional "zig-zag" pattern constructed of elongate elements that meet at apices and shows that the apices point in a direction along the longitudinal axis of the stent. Ryan at 7:49-51, Figs. 1-5; Hillstead Decl. ¶ 54. Accordingly, Ryan discloses claim 1's limitations of [1.1] "a plurality of hoops aligned along a common axis," [1.2] "each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent," and [1.3] "each of said hoops including a

plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the stent." Ryan at 3:16-19, 7:49-61, Figs. 1-5; Hillstead Decl. ¶¶ 52-55.

Ryan further discloses limitation [1.4], "at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop." Hillstead Decl. ¶ 56. Specifically, Ryan discloses "junctions" where elongate elements of one hoop continue over into elongate elements of an adjacent hoop. Ryan at 7:54-59, 8:41-43, Figs. 1-5; Hillstead Decl. ¶ 56. The following annotated portion of Figure 2 of Ryan illustrates this disclosure:



In this illustration, the blue elongate element of "hoop #2" is explicitly shown as a continuation of the green elongate element of "hoop #1." Ryan at Fig. 2 (annotated).

Finally, Ryan discloses limitation [1.5], "means for securing an apex of one

hoop to an abutting juxtaposed apex of a neighboring hoop." Specifically Ryan is clear that "[a]djacent compressible band members . . . may be joined at one or more locations therebetween." Ryan at 3:19-21; Hillstead Decl. ¶ 57. Ryan also discloses that "the bands are preferably joined at [] diametrically opposed points," *i.e.*, apices. Ryan at 3:22-23; Hillstead Decl. ¶57. Ryan's "bridge element" preforms an identical function as claim 1's "means for securing," *i.e.*, it secures the apex of one hoop to a juxtaposed apex of a neighboring hoop. Ryan at 3:19-23, 7:49-57, Figs. 1-5; Hillstead Decl. ¶ 57. While the structure of Ryan's "bridge element **13**" may not identical to the structures disclosed in the '482 Patent, the '482 Patent does not make any statements that would foreclose on Ryan's "bridge element **13**" being an equivalent structure such that it anticipates this element. 35 U.S.C. §112(f); Hillstead Decl. ¶¶ 58-59; *see also* Ex. 1022. Indeed, as explained above, PO has argued that an integral wire connecting the apex of one hoop to a juxtaposed apex meets this limitation. Ex. 1022, Infringement Contentions at 009-010.

Claim 2: Claim 2 depends from claim 1 and requires that "at least one stent segment in combination with one or more additional stent segments." Ryan discloses several variations of a stent segment in combination with additional stent segments. Hillstead Decl. ¶¶ 60-62.

First, Ryan discloses that its "tubular frame" (stent) may be constructed of

multiple stent segments with varying properties. Ryan at 6:62-7:39; Hillstead Decl. ¶ 61. For example, Ryan discloses that "some circumferentially spaced-apart segments of the tubular frame could be malleable while the remaining circumferential segments would be elastic." Ryan at 7:19-22; Hillstead Decl. ¶ 61. This can be achieved "by forming circumferential segments of the frame from different materials having different elastic/malleable properties." Ryan at 7:32-36; Hillstead Decl. ¶ 61. By this disclosure alone, Ryan anticipates claim 2. *Id*.

Second, in Figure 12 for example, Ryan discloses a bifurcated stent structure where a base stent segment **20** is used in combination with additional leg segments **10**. Ryan at 10:23-50, Figs. 7-12. Hillstead Decl. ¶ 62. By this disclosure alone, Ryan anticipates claim 2. *Id*.

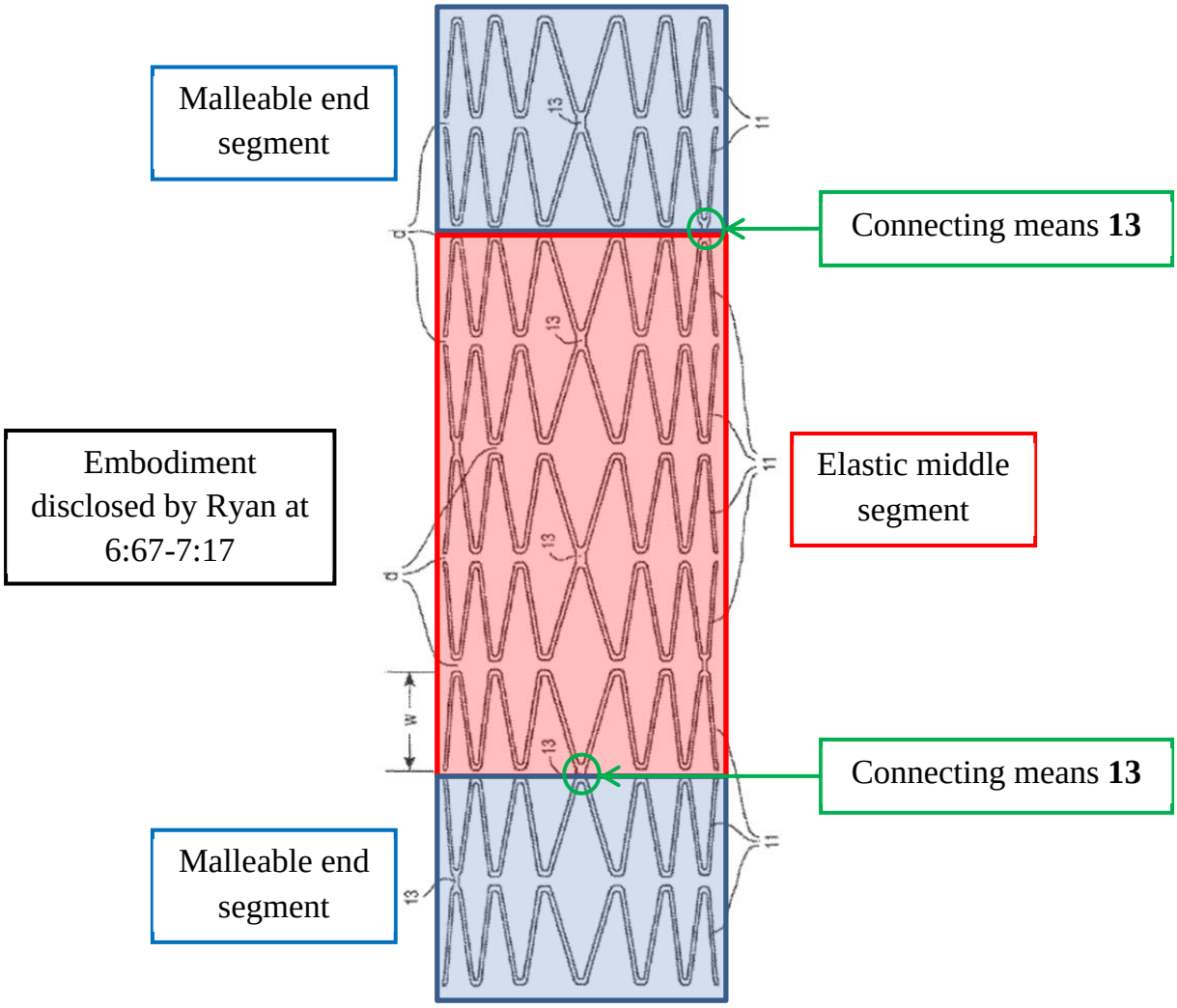
Claim 3: Claim 3 depends from claim 2 and requires that "said one or more additional segments are axially aligned with one another." Ryan's disclosure of segments of its tubular member with "different elastic or other mechanical properties at different regions along its length" anticipates claim 3. Ryan at 6:62-7:39; Hillstead Decl. ¶ 63. Ryan provides a specific example of a "malleable" end segment and an "elastic" middle segment. Ryan at 6:67-7:8; Hillstead Decl. ¶ 64. Ryan contemplates these segments would be part of the same tubular member and thus share a longitudinal axis. Ryan at 6:62-7:39; Hillstead Decl. ¶ 64. Thus Ryan discloses that "said one or more additional segments are axially aligned with one

another." Hillstead Decl. ¶¶ 63-64.

Additionally, as shown in Figure 12 of Ryan, the additional leg segments **10** of the bifurcated device are axially aligned with the body segment **20**. This disclosure of Ryan also anticipates claim 3. Hillstead Decl. ¶ 65.

Claim 4: Claim 4 depends from claim 3 and requires that "said axially aligned segments are connected to one another by a tubular fabric element." Ryan's stent segments with "different elastic or other mechanical properties," described above, are connected by a tubular fabric element(s). Hillstead Decl. ¶ 66. Ryan discloses tubular fabric elements traversing the interior and exterior of its stent. Ryan at 7:62-9:5, Figs. 1, 1A; Hillstead Decl. ¶ 66. Specifically, Ryan discloses "fabric liner **12**" depicted in Figure 1. Ryan at 7:40-48, Fig. 1. Ryan also discloses an "outer liner **110**" in conjunction with "inner liner **108**" as depicted in Figure 1A. Ryan at 8:47-9:5, Fig. 1A; Hillstead Decl. ¶ 67. In each of these embodiments, the stent segments are connected by the inner and/or outer "tubular fabric element" which are "stitched or otherwise secured to the band members 11, preferably at the junctions or nodes." Ryan at 7:64-67, Figs. 1, 1A; Hillstead Decl. ¶ 67. Ryan also discloses that the additional leg segments **10** of the bifurcated device shown in Figure 12 are connected to the body segment **20** by tubular fabric elements **26, 28**. Ryan at 10:23-50, Figs 7-12; Hillstead Decl. ¶67. Each of these disclosures anticipates claim 4. Hillstead Decl. ¶¶ 66-67.

Claim 5: Claim 5 depends from claim 2 and requires that "said one or more additional segments are secured to one another by connecting means connecting at least some of the apices of hoops at mating ends of said stent and said additional segments." Ryan's stent segments with "different elastic or other mechanical properties," described above, may be secured to one another by connecting means connecting at least some of the apices of hoops at mating ends, as depicted in Figures 1-5 of Ryan. Hillstead Decl. ¶ 68. For example, Ryan discloses that "some circumferentially spaced-apart segments of the tubular frame could be malleable while the remaining circumferential segments would be elastic." Ryan at 7:19-22; Hillstead Decl. ¶ 69. The end most hoops or bands of each segment are connected in the same manner as generally disclosed hoops or bands, *i.e.*, by connecting elements **13**. Ryan at 7:54-57, Figures 1-2; Hillstead Decl. ¶ 69.

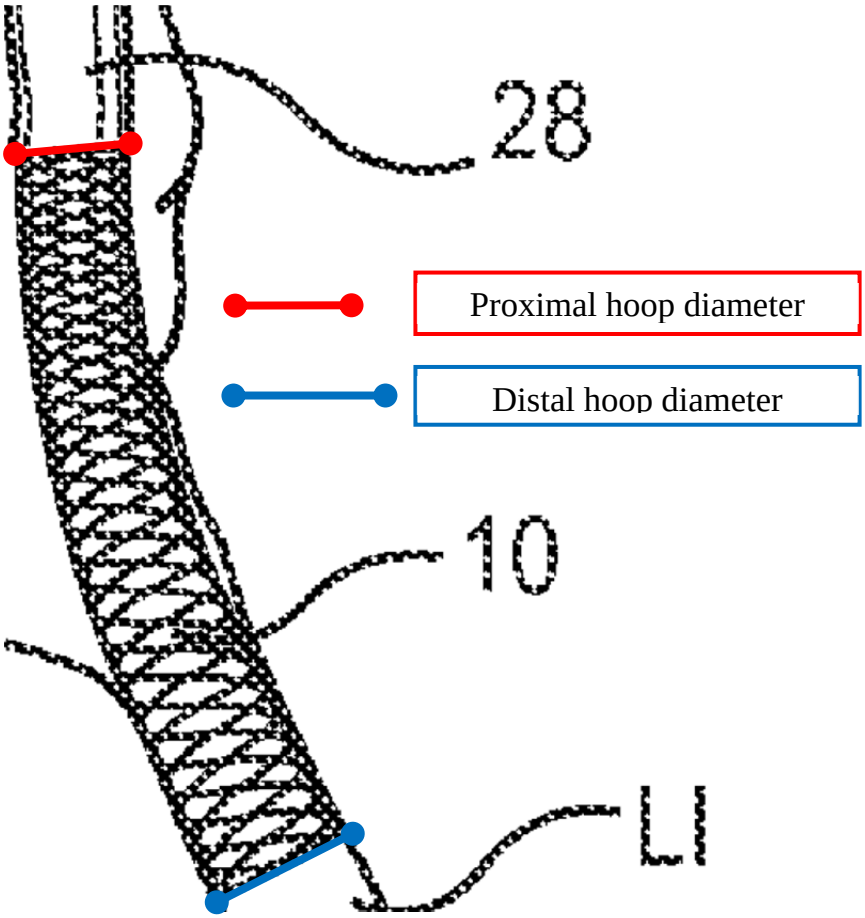


Ryan at 6:67-7:17, Figs. 1-5; Hillstead Decl. ¶ 69.

Claim 6: Claim 6 depends from claim 2 and requires that "adjacent hoops are of the same diameter." This claim does not modify the elements added by claim 2, but rather refers to the claimed "hoops" of claim 1. Hillstead Decl. ¶ 70. As shown throughout, the main tubular member of Ryan is depicted as having adjacent hoops (band members **11**) of the same diameter. Ryan at Figs. 1-5; Hillstead Decl. ¶ 70. Ryan also discloses that adjacent hoops of separate segments

are of the same diameter. *See* analysis of claim 5 above; Ryan at 6:67-7:17, Figs. 1-5; Hillstead Decl. ¶¶ 68-70.

Claim 7: Claim 7 depends from claim 2 and requires that "adjacent hoops are of a different diameter." Figure 12 of Ryan depicts integrally larger hoop diameters from the proximal end to the distal end of stent **10**. Hillstead Decl. ¶ 71.

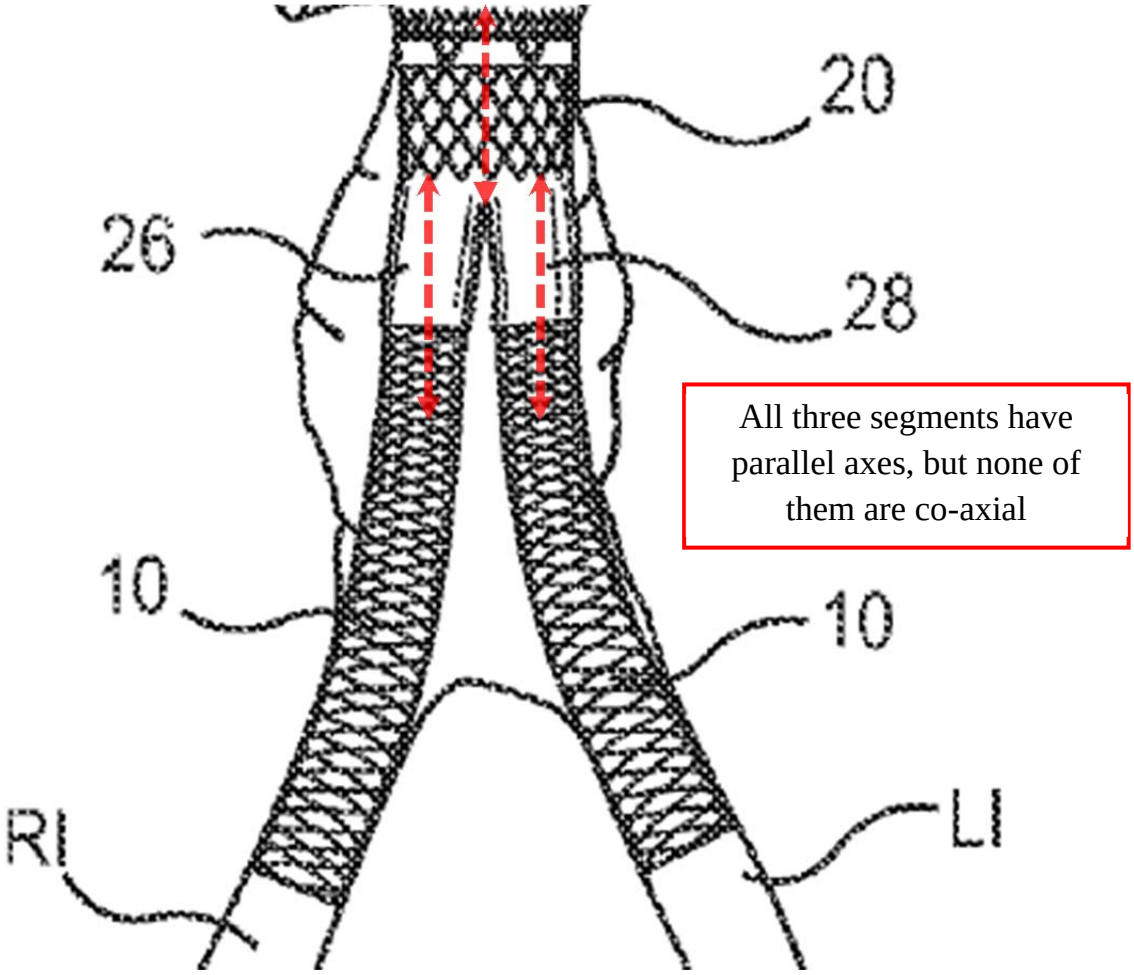


Ryan at Fig. 12. Because the diameters of the proximal-most hoop and the distal-most hoop are different, at least one set of adjacent hoops must be of a different diameter. Hillstead Decl. ¶ 71. It appears that the diameter of the hoops increases gradually, and thus, each set of adjacent hoops are of a different diameter in this

embodiment. Ryan at Fig. 12; Hillstead Decl. ¶ 71.

Claim 8: Claim 8 depends from claim 2 and requires that "a first additional segment is axially parallel to, but non-common co-axial with, said stent segment." As described above with respect to claim 3, in Figure 12 of Ryan, the additional leg segments **10** of the bifurcated device are axially aligned with the body segment **20**. Hillstead Decl. ¶ 72. Those leg segments **10** are axially parallel to, but non-common co-axial with, the body stent segment **20**. *Id*.

Claim 9: Claim 9 depends from claim 8 and requires that "a second additional segment axially parallel to said stent segment, but non-co-axial with either said stent segment or said first additional stent segment." As described above with respect to claims 3 and 8, in Figure 12 of Ryan, the additional leg segments **10** of the bifurcated device are axially parallel to the body segment **20.** Hillstead Decl. ¶ 73. Those leg segments **10** are axially parallel to, but non-common co-axial with, the body stent segment **20**. Ryan at Fig. 12; Hillstead Decl. ¶ 73. Additionally, the two leg segments **10, 10** are non-co-axial with each other. Hillstead Decl. ¶ 74. Thus if the leg segment **10** in LI of Figure 12 is the first additional stent segment and the leg segment **10** in RI of Figure 12 is the second additional stent segment, the "second additional segment axially parallel to said stent segment, but non-co-axial with either said stent segment or said first additional stent segment." Ryan at Fig. 12; Hillstead Decl. ¶ 74.



Claim 12: Claim 12 depends from claim 2 and requires that "at least one of said additional stent segments comprises:

[12.1] a plurality of hoops aligned along a common axis,

[12.2] each of said hoops oriented in a plane substantially perpendicular to the longitudinal axis of the additional stent segment,

[12.3] and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the additional stent segment; and

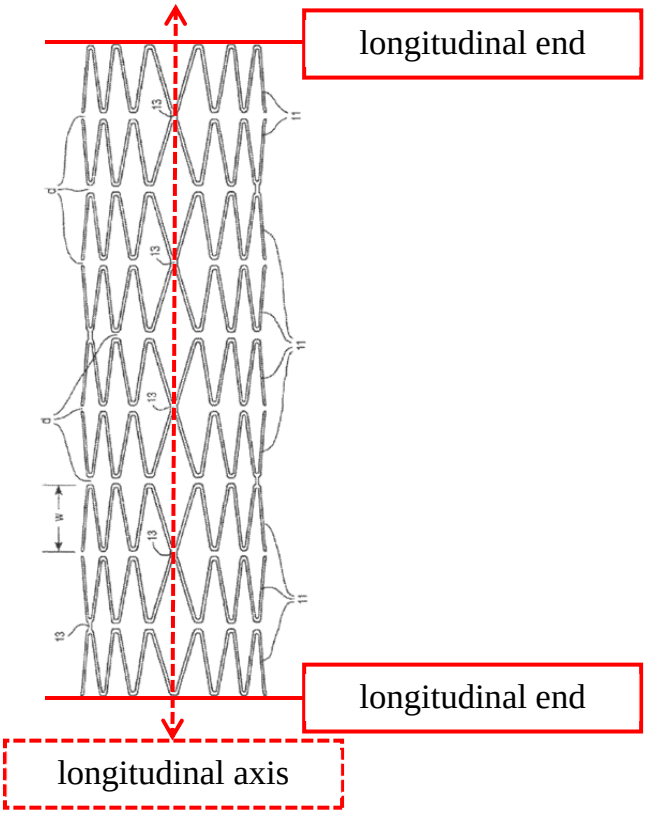
[12.4] means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop."

As discussed above with respect to claims 2-5 and as shown in the discussion of claim 5, Ryan's additional stent segments with "different elastic or other mechanical properties," may be constructed in the same way as the main stent segment such that they meet the additional limitations of claim 12 for the same reasons the stent limitations claimed in claim 1 are disclosed by Ryan. Hillstead Decl. ¶ 75. The additional limitations of claim 12, [12.1], [12.2], [12.3], [12.4], mirror limitations [1.1], [1.2], [1.3], [1.5] of claim 1. Thus, claim 12 is also anticipated by Ryan. Hillstead Decl. ¶ 75.

Claim 13: Claim 13 depends from claim 1 and requires that "said hoops are formed of a single continuous wire." Ryan depicts a stent with hoops are formed of a single continuous wire. Hillstead Decl. ¶ 76. Specifically, Ryan discloses that its hoops (band members **11**) "comprise a zig-zag or Z-shaped element which forms a continuous circular ring." Ryan at 7:49-52, Fig. 1-3; Hillstead Decl. ¶ 76. That continuous circular ring is depicted as a single zig-zaging wire in Figures 1-3.

Claim 21: Claim 21 depends from claim 1 and requires that "each longitudinal end of the stent is substantially perpendicular square to the longitudinal axis of the stent." Ryan depicts and describes that "each longitudinal end of the stent is substantially perpendicular square to the longitudinal axis of the

stent." *See, e.g.*, Ryan at Figure 2 (annotated); Hillstead Decl. ¶ 77.



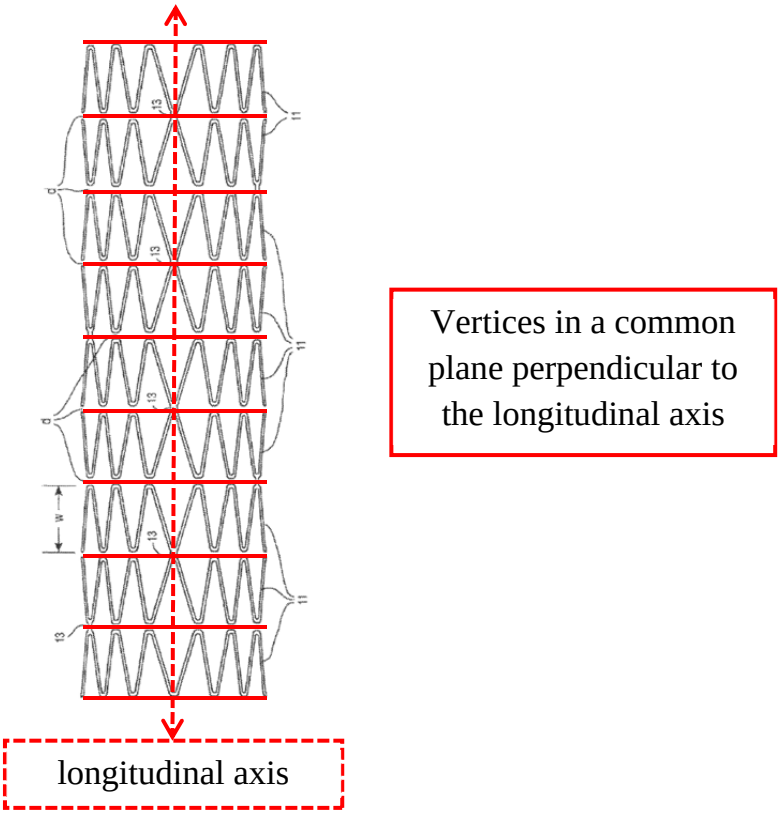
Claim 22: Claim 22 depends from claim 1 and requires that "said stent is at least partially covered in fabric." Ryan discloses that its stent is at least partially covered by outer liner **110** in Figure 1A. Ryan at 8:47-9:5, Fig. 1A; Hillstead Decl. ¶ 78. Outer liner **110** is a fabric. Ryan at 8:64-66; Hillstead Decl. ¶ 78.

Claim 30: Claim 30 is an independent claim that includes limitations from claim 1, but does not include the means plus function language of element 1.5. Rather, it merely requires "wherein at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop." Hillstead Decl. ¶ 79. Thus, there is no need to look to the '482

Patent specification's specifically disclosed and equivalent securing structures to determine anticipation. *Id.* As shown above, Ryan discloses that abutting vertices are individually connected by "junctions **13**," satisfying element [30.3] of claim 30 (listed below) for the reasons stated herein. *Id*. at ¶ 80.

Claim 1	**Claim 30**
[1.0] A stent comprising:	[30.0] A stent comprising a tubular member having
[1.1] a plurality of hoops aligned along a common axis,	[30.1] a plurality of hoops aligned adjacent one another along the longitudinal axis of the tubular member,
[1.2] each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent, and	
[1.3] each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the stent, and	[30.2] said hoops comprising a plurality of elongate elements, with pairs of said elongate elements meeting one another and forming vertices axially pointing in a direction along the longitudinal axis of the stent
[1.5] means for securing an apex of one hoop to an abutting a juxtaposed apex of a neighboring hoop.	[30.3] wherein at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop,
	[30.4] wherein the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member
[1.4] wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop; and	[30.5] and wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop.

Elements [30.1], [30.2], [30.3], and [30.5] of claim 30 correspond to elements claimed in claim 1. Hillstead Decl. ¶ 80. For the same reasons Ryan discloses the corresponding elements of claim 1, it discloses elements [30.1], [30.2], [30.3], and [30.5] of claim 30. *Id*. Claim 30 also requires element [30.4]: "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member." Ryan discloses this additional element. Ryan at 7:49-54, Fig 2; Hillstead Decl. ¶ 81.



For this reason and for those stated regarding the limitations of claim 1, Ryan anticipates claim 30. Hillstead Decl. ¶¶ 79-81.

B. Ground 2: Claims 1-9, 12-13, 21-22, and 30 Are Obvious Over Ryan

To the extent any claim is not anticipated by Ryan, it is at least rendered obvious by Ryan in view of the well known prior art. Hillstead Decl. ¶¶ 83-87. One of skill in the art would have found it obvious to implement predictable variations of Ryan that cover every claim of the '482 Patent. *See Sciele Pharma, Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012) ("The obviousness analysis entails 'an expansive and flexible approach.'. . . 'If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.'") (*quoting KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416); Hillstead Decl. ¶ 83.

Element [1.5]/[30.3] of Claims 1 and 30 - As discussed above, Ryan discloses a "means for securing an apex of one hoop to an abutting a juxtaposed apex of a neighboring hoop." Ryan at 3:19-23, 7:49-57, Figs. 1-5; Hillstead Decl. ¶ 84. To the extent Ryan does not disclose a structure equivalent to the structures disclosed in the '482 Patent "for securing an apex of one hoop to an abutting a juxtaposed apex of a neighboring hoop," one of skill in the art would have known to make the simple modification using one of the well known prior art securing structures at the junctions **13** of Ryan. Hillstead Decl. ¶ 85. As discussed above, a number of securing structures were well know to be used to "secur[e] an apex of one hoop to an abutting a juxtaposed apex of a neighboring hoop." *Id*. at ¶ 86. These well know prior art structures for securing included loops formed of

thermoplastic material or wire, sutures, wire rings, and wire staples. *Id*. Each of those well know prior art structures are disclosed by the '482 Patent as structures capable of preforming the claimed function of "securing an apex of one hoop to an abutting a juxtaposed apex of a neighboring hoop." *Id*.

C. Ground 3: Claims 1-9, 12-13, 21-22, and 30 Are Obvious Over Ryan In View Of Cragg

To the extent any claim is not anticipated by Ryan, it is at least rendered obvious by Ryan in view of Cragg. Hillstead Decl. ¶¶ 88-93.

Element [1.5]/[30.3] of Claims 1 and 30 - Cragg is a prior art stent design wherein a zig-zag pattern is wrapped around a longitudinal axis such that adjacent apices pointed in the axial direction abut one another. Cragg at 2:20-65, Figs. 1-4; Hillstead Decl. ¶ 89. Cragg discloses "means for securing an apex of one hoop to an abutting a juxtaposed apex of a neighboring hoop" for the same reasons as Ryan and to provide the same function claimed in claim 1 of the '482 Patent. Hillstead Decl. ¶ 89. Specifically, the claimed function of the "means for securing" of claim 1 of the '482 Patent is to "secur[e] the apex of one hoop to a juxtaposed apex of a neighboring hoop." *Id*.

Ryan discloses and shows that "bridge elements **13**" secure "diametrically opposed points" (i.e., abutting apices). Ryan at 5:34-37, 7:7:54-57, Figs. 1-3; Hillstead Decl. ¶ 90. While Ryan's "bridge elements **13**" are equivalents to the securing structures disclosed in the '482 Patent, Cragg discloses several of the

explicitly defined securing structures of '482 Patent. Hillstead Decl. ¶ 90. Cragg discloses: "loop members **12** which connect adjacent apices of adjacent helix hoops to help define the tubular stent." Cragg at 2:45-49; Hillstead Decl. ¶ 91. Cragg discloses several well known securing structures that are common with those defined in the '482 Patent: "[a]lthough sutures are the preferred connecting means, other connecting means such as staples and rings made of metal or plastic may provide the same function." Cragg at 3:1-4; Hillstead Decl. ¶ 91. The "function" of the securing means disclosed by Cragg is to "connect all or some of the pairs of adjacent apices." Cragg at 2:60-62, Figs. 2-4; Hillstead Decl. ¶91.

It would have been a simple substitution for one of skill in the art to use the securing means disclosed in Cragg to achieve the predictable result of "securing the apex of one hoop to a juxtaposed apex of a neighboring hoop" in place of the equivalent "bridge elements **13**" of Ryan. Hillstead Decl. ¶ 92.

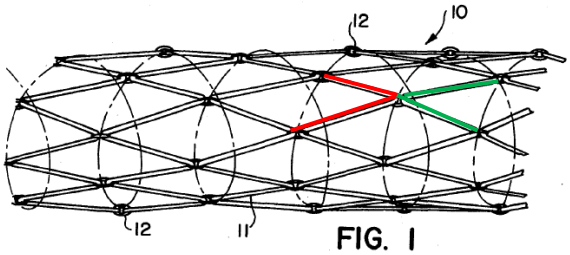
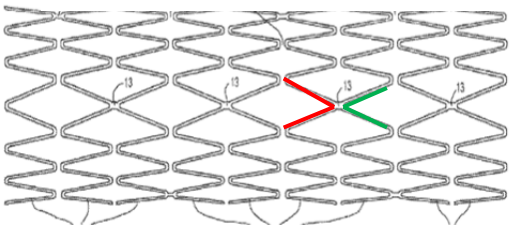


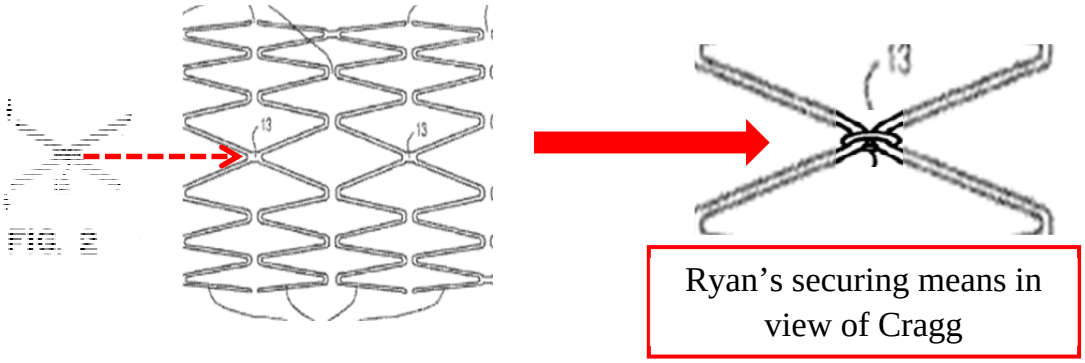
FIG. 1

Cragg's apices abut and are connected/secured by loops or sutures



Ryan's apices abut and are integrally connected/secured

It would have been obvious to substitute
Cragg's sutures/loops **12** for Ryan's junctions **13**



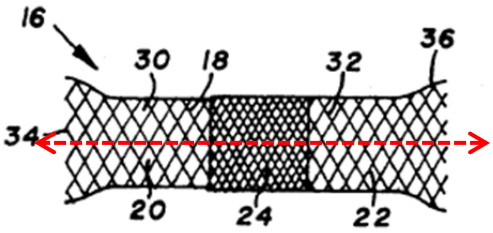
D. Ground 4: Claim 2-4, 6-7, and 12 Are Obvious Over Ryan In View Of Porter

To the extent any claim is not anticipated by Ryan alone, it is at least rendered obvious by Ryan in view of Porter. Hillstead Decl. ¶¶ 94-103. Under the construction that "segment" means "portion" as defined in the '482 Patent specification, Ryan certainly discloses multiple interacting stent segments that meet the limitations of the claims at issue, as shown above. *Id*. at ¶ 95. Yet, one of skill in the art would have also known that the stents described in Ryan could be used in the alternative segmented structures disclosed by Porter. *Id*. The teachings of Porter would not require Ryan's stents to be constructed any differently, but rather merely suggest obvious ways to utilize various stent segments, each of which could be constructed in accordance Ryan. *Id*.

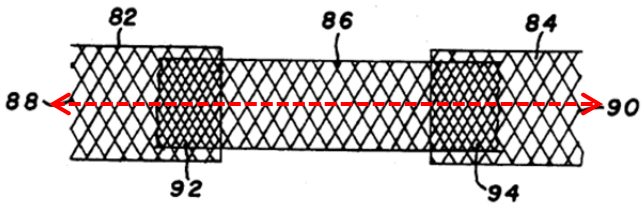
Claim 2: Porter is directed to "[a] body implantable stent consists of two or more generally tubular, coaxial and slidably connected stent segments." Porter at Abstract; Hillstead Decl. ¶ 96. As shown above, Ryan discloses that its stent(s)

may have multiple segments. Hillstead Decl. ¶ 96. Porter similarly discloses "at least one stent segment in combination with one or more additional stent segments" as claimed in claim 2. Porter at Abstract, 2:57-61, 5:13-14, 7:25-28, Figs.1, 6-11; Hillstead Decl. ¶ 96. Thus the combination of Ryan and Porter discloses all elements in claim 2. Hillstead Decl. ¶ 96.

Claim 3: Porter discloses "[a] stent as recited in claim 2 wherein said one or more additional segments are axially aligned with one another." *See* Porter at Abstract, 2:57-61, 5:13-14, 7:25-28, Figs.1, 6-11; Hillstead Decl. ¶ 97.



Two segments axially aligned (Fig. 1)



Three segments axially aligned (Fig. 9)

The combination of Ryan and Porter discloses claim 3. Hillstead Decl. ¶ 97.

Claim 4: The combination of Ryan and Porter discloses "[a] stent as recited in claim 3 wherein said axially aligned segments are connected to one another by a tubular fabric element." Hillstead Decl. ¶ 98. Specifically, Porter discloses that "[s]tent 16 is particularly well suited for use as a prosthesis or graft in a blood vessel or other body cavity." Porter at 5:63-64, Fig. 1; Hillstead Decl. ¶ 98. Ryan discloses a prosthesis that uses tubular fabric elements **26, 28** to connect axially aligned stent segments for use in a blood vessel(s). Ryan at 9:27-49, Figs. 5, 9-12;

Hillstead Decl. ¶ 98. It would have been obvious to one of skill in the art to connect the segments described in Porter using a tubular fabric element in the manner disclosed by Ryan in order to form the "prosthesis or graft in a blood vessel" suggested by Porter. Hillstead Decl. ¶ 99.

Claim 6: Claim 6 depends from claim 2 and requires that "adjacent hoops are of the same diameter." This claim does not modify the elements added by claim 2, but rather refers to the claimed "hoops" of claim 1. Hillstead Decl. ¶ 100. As discussed above, Ryan discloses this element. Porter also discloses this element. Porter at 8:25-28; Hillstead Decl. ¶ 100. Specifically Porter discloses that "all segments preferably have substantially the same radius" which would necessitate that adjacent hoops of the Ryan/Porter combination have the same diameter. Hillstead Decl. ¶ 100.

Claim 7: Claim 7 depends from claim 2 and requires that "adjacent hoops are of a different diameter." As shown above, Ryan's figures disclose this element. Hillstead Decl. ¶ 101. Porter's specification similarly discloses that "[a]t opposite ends of the stent are flared ends **34** and **36**, each having a greater radius than the nominal radius over the majority of the stent length." Porter at 5:18-25; Hillstead Decl. ¶ 101.

Claim 12: As discussed above, the Ryan/Porter combination does not require altering Ryan's stent structure. Hillstead Decl. ¶ 102. Thus, the claimed structure

for an "additional stent segment" was disclosed by the Ryan/Porter combination for the same reasons set forth with regard to Ryan alone. *Id*.

E. Ground 5: Claims 2, 5, 7-9 Are Obvious Over Ryan In View Of MacGregor

To the extent any claim is not anticipated by Ryan, it is at least rendered obvious by Ryan in view of MacGregor. Hillstead Decl. ¶¶ 104-111. MacGregor discloses a non-helical "bifurcating stent for insertion into a bifurcating vessel such as a blood vessel" similar to that of Ryan. MacGregor at Abstract, Fig 1; Hillstead Decl. ¶ 105. One of skill in the art would have known that MacGregor's bifurcated stent design was an alternative to the bifurcated stent design of Ryan and that it would have been a simple substitution to replace the fabric legs **26** and 28 of Ryan with the "cylindrical lattices **20, 22**" of MacGregor to arrive at the predictable result of a branched prosthesis for "insertion into a branching blood vessel." MacGregor at 2:50-52; Hillstead Decl. ¶ 105.

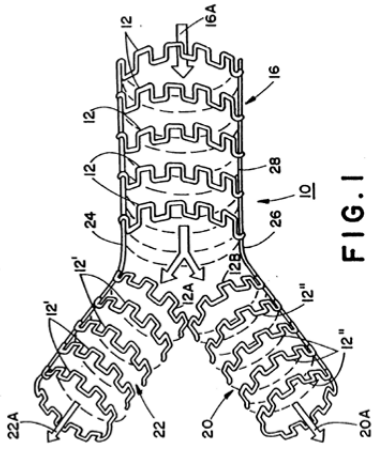
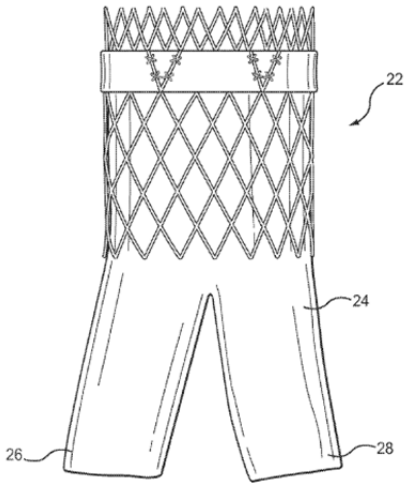


FIG. 1

MacGregor Fig. 1



Ryan Fig. 5

MacGregor discloses bifurcated stent segments constructed from non-helical hoops that are interconnected by wire at various apices of a zig-zagging pattern. MacGregor 3:54-68, Fig. 1; Hillstead Decl. ¶ 106. It would have been obvious in view of MacGregor to extend the non-helical wire stent **22** of Ryan down the legs of Ryan by connecting the main segment of Ryan to additional leg segments as taught by MacGregor. Hillstead Decl. ¶ 106. The segments would be constructed as disclosed by Ryan, but configured and connected as disclosed by MacGregor. *Id*. As MacGregor suggests, one of skill in the art would have known to connect such segments together at apices at the end of each segment. MacGregor 4:1-13, Fig. 1; Hillstead Decl. ¶ 106. This obvious alternative bifurcated structure renders at least claims 2, 5 and 7-9 of the '482 Patent obvious. Hillstead Decl. ¶ 106.

Claim 2: The Ryan/MacGregor combination discloses "a stent as recited in claim 1 comprising at least one stent segment in combination with one or more additional stent segments" because it would include at least a "main or trunk" segment and two additional leg segments. MacGregor at 3:54-4:15, Fig. 1; Ryan at 9:27-49, Fig. 5; Hillstead Decl. ¶ 107.

Claim 5: The Ryan/MacGregor combination discloses a "stent as recited in claim 2 wherein said one or more additional segments are secured to one another by connecting means connecting at least some of the apices of hoops at mating ends of said stent and said additional segments." Hillstead Decl. ¶ 108.

MacGregor discloses that the combined Ryan/MacGregor stent would be connected at apices of adjacent segments. MacGregor at 4:1-18, Fig. 1; Hillstead Decl. ¶ 108. Such a connection would be expected and simple to implement in view of Ryan's disclosure of securing hoops to one another at their apices. Ryan at 5:34-37, 7:54-57; Hillstead Decl. ¶ 108.

Claim 7: The Ryan/MacGregor combination discloses a "stent as recited in claim 2 wherein adjacent hoops are of a different diameter." Hillstead Decl. ¶ 109. MacGregor specifically states that the leg segments 20, 22 have "diameters less than the [trunk] 16." MacGregor at 3:62-68, Fig. 1; Hillstead Decl. ¶ 109.

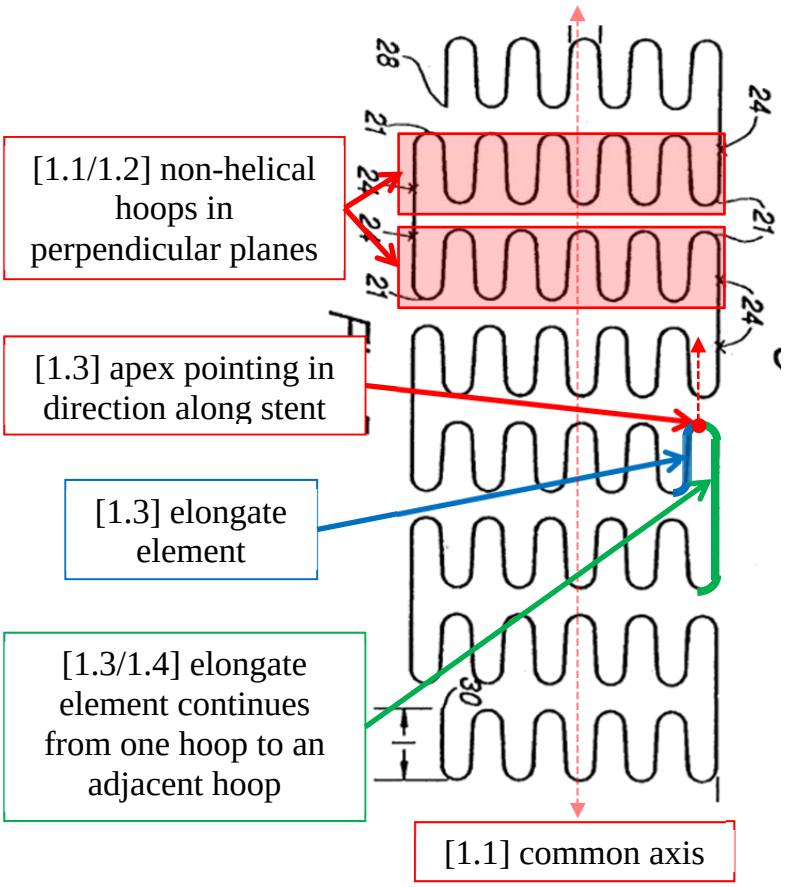
Claims 8 and 9: The Ryan/MacGregor combination discloses a "stent as recited in claim 2 wherein a first additional segment is axially parallel to, but non-common co-axial with, said stent segment" and "a stent as recited in claim 8 further comprising a second additional segment axially parallel to said stent segment, but non-co-axial with either said stent segment or said first additional stent segment." Hillstead Decl. ¶ 110. As shown above regarding the disclosure of Ryan alone, the bifurcation of a stent creates multiple longitudinal axes through the legs that are parallel to, but non-common co-axial with the longitudinal axis of the trunk. Ryan at Fig. 12; Hillstead Decl. ¶ 110.

F. Ground 6: Claims 1-3, 5-6, 12-13, 21, and 30 Are Anticipated by Hillstead

All of the elements of claims 1-3, 5-6, 12-13, 21, and 30 of the '482 Patent

are anticipated by Hillstead. Hillstead Decl. ¶¶ 112-130.

Claim 1: Hillstead discloses a stent including every element of claim 1. Hillstead Decl. ¶113-120.

Claim 1	Hillstead
[1.0] A stent comprising:	[1.0] Tubular Stent Frame (Hillstead, Fig. 5) 
[1.1] a plurality of hoops aligned along a common axis,	
[1.2] each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent, and	
[1.3] each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the stent, and	
[1.4] wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop; and	
[1.5] means for securing an apex of one hoop to an abutting a juxtaposed apex of a neighboring hoop.	[1.5] means for securing **26** apices of neighboring hoops **Filament portions at the each end 21 and location 24 are permanently adhered together to form junctions 26 to prevent the unrolling of the stent 10 upon the removal of the mandrel 22. The junctions 26 can be adhered and formed through means of welding, soldering, tying or suturing. In the situation where the junctions** (Hillstead at 3:28-33)

Hillstead discloses a non-helical cylindrical stent design. Hillstead at 3:14-27, Figs. 2, 5; Hillstead Decl. ¶ 113. Specifically, Hillstead discloses "a stent **10** built from an elongated filament **17**, typically a wire" and the wire includes "series of bends **18**." Hillstead at 3:14-15; Hillstead Decl. ¶ 113. The preferred embodiment of Hillstead depicts and describes that each series of bends **18** forms a non-helical hoop. Hillstead at 3:19-22, Figs. 2, 5, 7; Hillstead Decl. ¶ 113. Specifically, Hillstead states "[b]ending both ends **21** of each straight segment **19** forms a generally planar form defined by a series of transverse portions having a width C equal to the circumference of the stent 10 (See FIG. 5)." Hillstead at 3:19-22, Fig. 5; Hillstead Decl. ¶ 114. Each bend in Hillstead has an apex where adjacent elongate elements are joined to one another. Hillstead at Figs 5-7; Hillstead Decl. ¶ 114. Each series of bends (i.e., each hoop) in Hillstead is connected to an adjacent hoop by an elongate element **19** that continues from one hoop to the next. *Id*. Hillstead depicts its hoops (series of bends) as non-helical rings that are each oriented in a plane perpendicular to the axis of the stent. Hillstead at Figs. 2, 7; Hillstead Decl. ¶ 114. Accordingly, Hillstead discloses claim 1's limitations of [1.1] "a plurality of hoops aligned along a common axis," [1.2] "each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent," [1.3] "each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction

along the longitudinal axis of the stent," and [1.4], "at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop." Hillstead at 3:14-40, Figs. 2, 5-7; Hillstead Decl. ¶ 115.

Hillstead also discloses limitation [1.5], "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." Hillstead Decl. ¶ 116. Specifically Hillstead discloses that the filament (wire) must be attached to itself at junctions by "welding, soldering, tying or suturing" to provide stability to the stent. Hillstead at 3:28-40, 3:66-4:6, 4:20-24, 4:29-36; Hillstead Decl. ¶ 116. Hillstead describes an embodiment where the junctions are not necessarily at abutting apices, but rather that they are "regularly spaced along a length portion of said stent and are permanently adhered and aligned along said length portion of said stent to form a relatively straight backbone to said stent." Hillstead at 3:36-40, 4:20-24 (claim 6); Hillstead Decl. ¶ 117. Hillstead claimed such an embodiment as a dependent claim, leaving the independent claim limitation–*i.e.*, "closely spaced filament portions permanently adhered together to form junctions that prevent unrolling of said filament"–to include and inherently disclose junctions at the apices. Hillstead at 3:66-4:6; Hillstead Decl. ¶ 117. Hillstead also discloses and claims that the junctions may be "permanently adhered together by tying or suturing." Hillstead at 4:29-36; Hillstead Decl. ¶ 117.

To be clear, the figures of Hillstead show "means for securing . . . one hoop

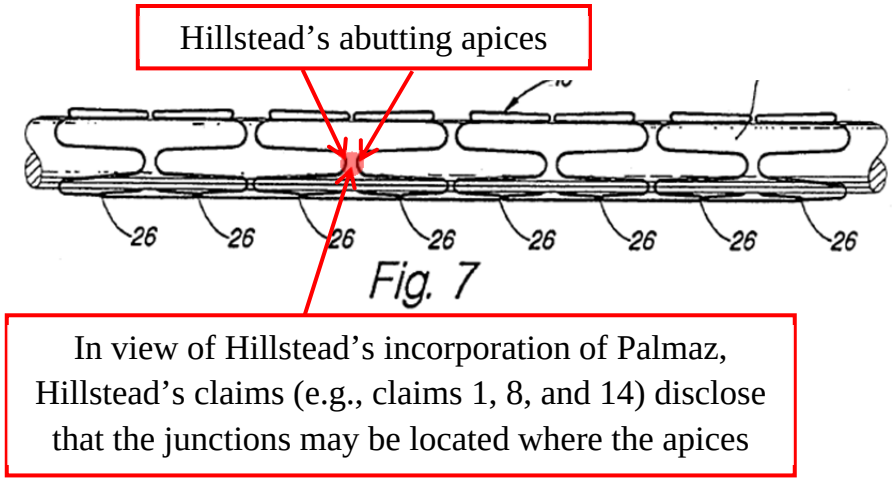
to an abutting . . . neighboring hoop," but do not explicitly show "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." Hillstead at Figs. 1-8; Hillstead Decl. ¶ 118. Yet, Hillstead's written specification and claims disclose securing one hoop to an abutting neighboring hoop at the apices by broadly claiming its junction limitation and explicitly incorporating by reference art that discloses forming the claimed junctions at the apices. Hillstead at 1:39-59, 3:66-4:6; Hillstead Decl. ¶ 118. For example, in "U.S. Patent No. 4,733,665 to Palmaz," (incorporated in Hillstead at 1:39-50) the stent configuration is similar to that of Hillstead in that it is a non-helical design having multiple hoops and the hoops are interconnected at junctions that provide stability to the stent. Palmaz at 3:20-51, Figs. 1A, 1B; Hillstead Decl. ¶ 119. Palmaz explicitly discloses that the junction claimed in Hillstead may be at an apex of one hoop and an abutting juxtaposed apex of a neighboring hoop. Palmaz at 6:36-47, Figs. 1A, 1B; Hillstead Decl. ¶ 119. Specifically Palmaz teaches:

> [I]t is preferable that the plurality of elongate members **75, 76** are fixedly secured to one another where the elongate members **75, 76** intersect with one another, such as at the [apices] intersection points **77**. Elongate members **75, 76** could be fixedly secured to one another in any conventional manner . . . [b]y fixedly securing the elongate members **75, 76**, to one another, tubular member **71** is provided with a

relatively high resistance to radial collapse.

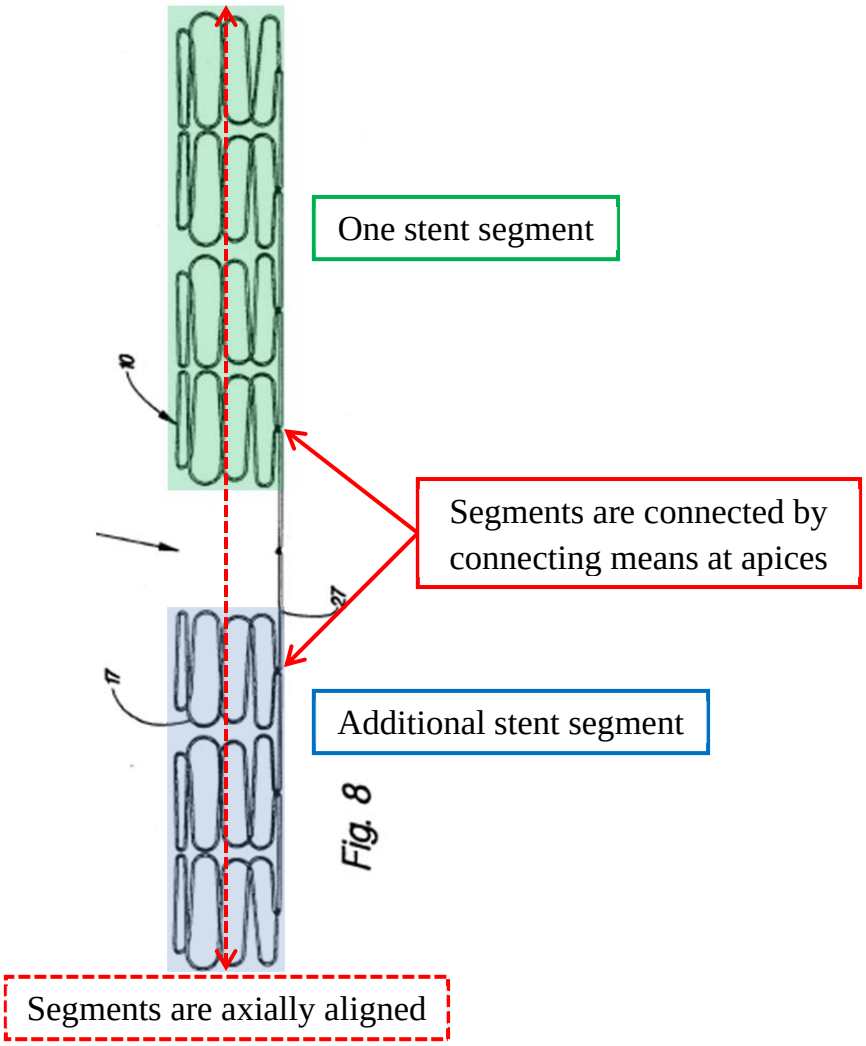
Id. Palmaz very clearly shows that where it refers to "fixedly securing" at "intersection points **77**" it refers to "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." Palmaz at Figs. 1A, 1B; Hillstead Decl. ¶ 119.

Thus, element [1.5] of the '482 Patent is anticipated, explicitly and inherently, by Hillstead in light of Hillstead's disclosure of "a cylindrical shape having closely spaced filament portions permanently adhered together to form junctions that prevent unrolling of said filament," Hillstead's disclosure and depiction of closely spaced filament hoops with apices that abut one another and Hillstead's incorporation of Palmaz's teaching to adhere the apices to prevent collapse of the filament. Hillstead Decl. ¶ 120.



Claim 2: Claim 2 depends from claim 1 and requires that "at least one stent segment in combination with one or more additional stent segments." Hillstead

discloses a stent with multiple stent segments in combination with one another. Hillstead at 3:53-60, Fig. 8; Hillstead Decl. ¶ 121. Specifically, Hillstead discloses, a multiple segment "construction [that] would accommodate, for example, the use of the stent wherein side or branch vessels are encountered and would allow unimpeded fluid flow to those side or branching vessels through judicious placement of the stent." Hillstead at 3:53-60; Hillstead Decl. ¶ 121. The multiple segment embodiment is shown in Figure 8:



Hillstead at Fig. 8; Hillstead Decl. ¶ 121. This figure also demonstrates that Hillstead anticipates claims 3 and 5 as described below. Hillstead Decl. ¶ 121.

Claim 3: Claim 3 depends from claim 2 and requires that "said one or more additional segments are axially aligned with one another." As shown above, Hillstead's stent segments are axially aligned with one another. Hillstead at Fig. 8; Hillstead Decl. ¶ 122.

Claim 5: Claim 5 depends from claim 2 and requires that "said one or more additional segments are secured to one another by connecting means connecting at least some of the apices of hoops at mating ends of said stent and said additional segments." As shown above, Hillstead's additional segments are secured to one another by connecting means connecting at least some of the apices of hoops at mating ends of said stent and said additional segments. Hillstead at Fig. 8; Hillstead Decl. ¶ 123.

Claim 6: Claim 6 depends from claim 2 and requires that "adjacent hoops are of the same diameter." This claim does not modify the elements added by claim 2, but rather refers to the claimed "hoops" of claim 1. Hillstead Decl. ¶ 124. As shown throughout, the main tubular member of Hillstead is depicted as having adjacent hoops of the same diameter and circumference. Hillstead at 3:19-24; Figs. 2, 6-8; Hillstead Decl. ¶ 124.

Claim 12: Claim 12 depends from claim 2 and requires that "at least one of

said additional stent segments comprises:

[12.1] a plurality of hoops aligned along a common axis,

[12.2] each of said hoops oriented in a plane substantially perpendicular to the longitudinal axis of the additional stent segment,

[12.3] and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the additional stent segment; and

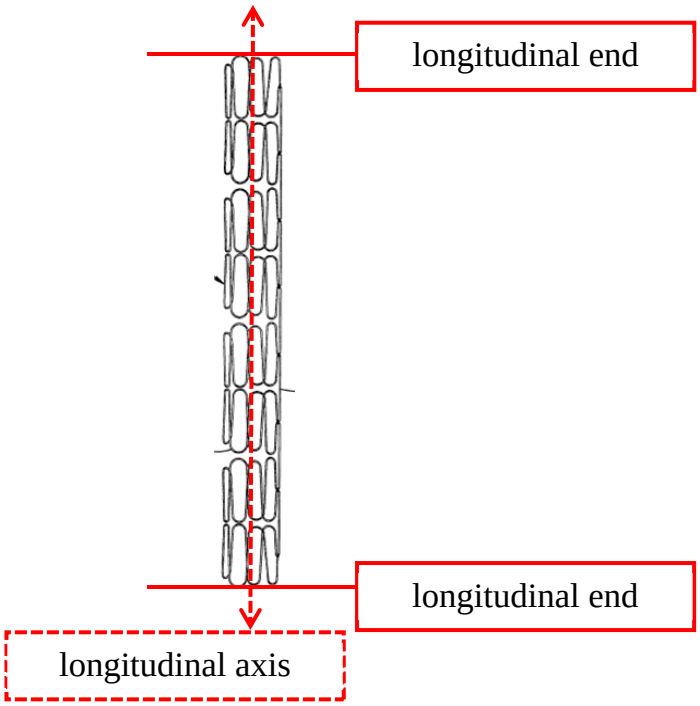
[12.4] means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop."

As discussed above with respect to claims 2-3 and 5 and as shown in the discussion of claim 2, Hillstead's additional stent segment is constructed in the same way as the main stent segment such that it meets the additional limitations of claim 12 for the same reasons the stent limitations claimed in claim 1 are disclosed by Hillstead. Hillstead Decl. ¶¶ 125-126. The additional limitations of claim 12, [12.1], [12.2], [12.3], [12.4], mirror limitations [1.1], [1.2], [1.3], [1.5] of claim 1. Hillstead Decl. ¶ 126. Thus, claim 12 is also anticipated by Hillstead. *Id*.

Claim 13: Claim 13 depends from claim 1 and requires that "said hoops are formed of a single continuous wire." Hillstead depicts a stent, in which the hoops formed of a single continuous wire. Hillstead at 2:9-11, 3:14-27; Figs. 3-7; Hillstead Decl. ¶ 127. Hillstead discloses that its stent, and thus the hoops of the

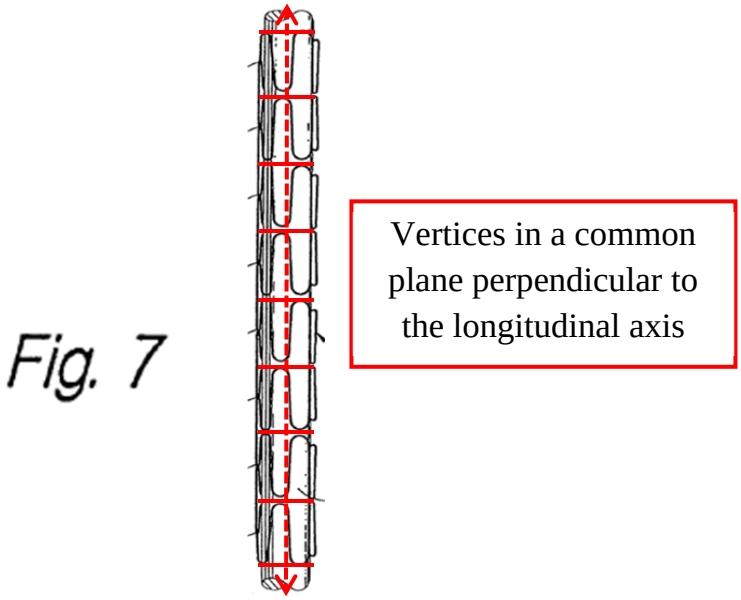
stent, are "built from an elongated filament **17**, typically a wire, in accordance with this invention." Hillstead at 3:14-16, Figs. 3-7; Hillstead Decl. ¶ 127.

Claim 21: Claim 21 depends from claim 1 and requires that "each longitudinal end of the stent is substantially perpendicular square to the longitudinal axis of the stent." Hillstead depicts and describes that "each longitudinal end of the stent is substantially perpendicular square to the longitudinal axis of the stent." *See, e.g.*, Hillstead at Figure 2 (annotated); Hillstead Decl. ¶ 128.



Claim 30: As discussed above regarding Ryan, claim 30 is an independent claim that varies slightly from claim 1. Of note, it includes the limitation of "the vertices of each hoop pointed in the axial direction lie in a common plane

perpendicular to the longitudinal axis of the tubular member." Hillstead Decl. ¶ 129. Hillstead discloses this additional element. Hillstead at 3:14-27, Figs. 2, 5-7; Hillstead Decl. ¶ 129. Hillstead discloses the remaining elements of claim 30 for the reasons provided above regarding Hillstead's anticipation of claim 1. *Id.*



G. Ground 7: Claims 1-3, 5-6, 12-13, 21 and 30 Are Obvious Over Hillstead In View Of Palmaz

As shown above, Hillstead discloses all of the limitations of claims 1, 2-3, 5-6, 12-13, 21 and 30. Hillstead Decl. ¶¶ 112-130. To the extent Hillstead does not disclose the claimed "attachment means for securing an apex of one hoop to an abutting a juxtaposed apex of a neighboring hoop" of claims 1, 12 and 30, one of skill in the art would have known to make a simple modification of Hillstead's stent to include attachment means at the intersection points **77** disclosed by Palmaz in order to provide increased stability and resistance to radial collapse. Palmaz at

6:36-52, Figs. 1A, 1B; Hillstead Decl. ¶¶ 131-137. As discussed above, Hillstead's stent discloses an apex of one hoop to an abutting a juxtaposed apex of a neighboring hoop. Hillstead at Figs. 2, 7-8; Hillstead Decl. ¶ 133.

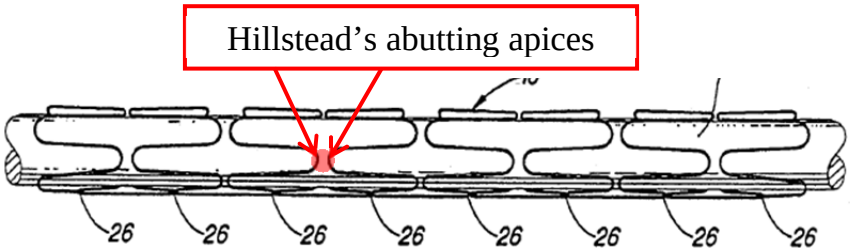


Fig. 7

One of skill in the art would have known to use a securing means at Hillstead's apices to provide strength and support to the stent the same way they are described and claimed in the '482 Patent. Hillstead Decl. ¶ 134. The '482 Patent explicitly notes that using such securing means in such a way was well known in the prior art: "EP-A-0556850 discloses an intraluminal stent which is constituted by a sinuous wire formed into a helix; juxtaposed apices of the wire are secured to one another so that each hoop of the helix is supported by its neighboring hoops to increase the overall strength of the stent and to minimize the risk of plaque herniation." *Id.*; '482 Patent at 1:52-57. The '482 Patent describes and claims that its stent uses securing means for the mere purpose described in the prior art (e.g., Palmaz): "the stents of this invention . . . also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors." '482 Patent at

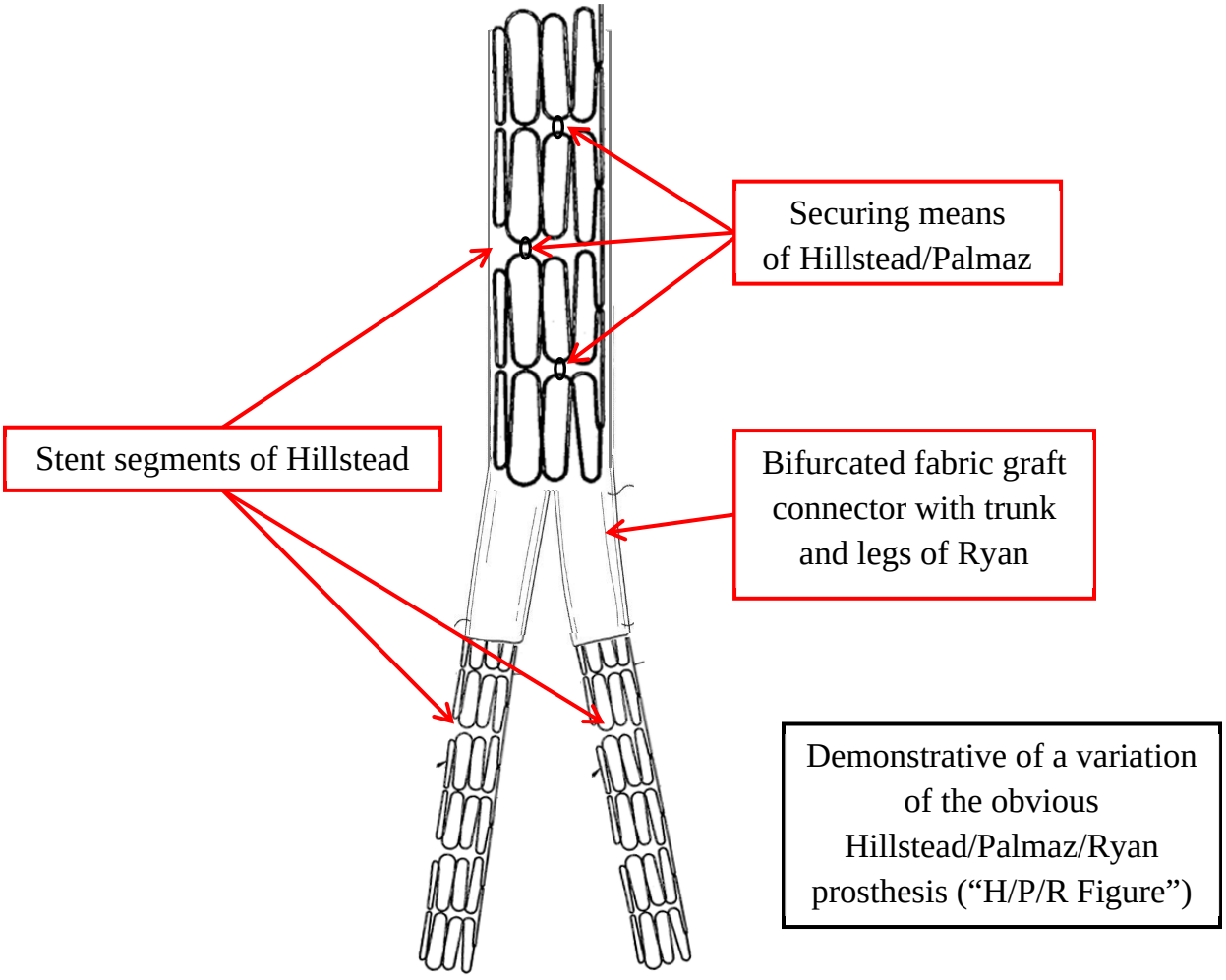
4:21-25; Hillstead Decl. ¶ 135. Further, Hillstead explicitly discloses that sutures are a suitable securing means. Hillstead at 3:31-36; Hillstead Decl. ¶ 136. Sutures are one of the securing means described and claimed in the '482 Patent. '482 Patent at 4:25-29; Hillstead Decl. ¶ 136. Accordingly, the modification of Hillstead's stent to include sutures to secure "an apex of one hoop to an abutting a juxtaposed apex of a neighboring hoop" would have been a simple modification in view of Palmaz and the well known prior art that would achieve a predictable result, *i.e.*, increased support and stability of the stent. Hillstead Decl. ¶ 136.

H. Ground 8: Claims 1-9, 12-13, 21-22, and 30 Are Obvious Over Hillstead In View Of Palmaz and Ryan

To the extent claims 1-9, 12-13, 21-22, and 30 are not anticipated by Hillstead, they are rendered obvious by Hillstead in view of Palmaz and Ryan. Hillstead Decl. ¶¶ 138-144. As discussed above, it would have been obvious to one of skill in the art to combine certain disclosures of Palmaz with Hillstead or to make simple substitutions or modifications of the Hillstead stent based on Palmaz. *Id*. at ¶ 139. It would have also been obvious for one of skill in the art at the time to make further simple modifications to the Hillstead/Palmaz stent based on the disclosures of Ryan related to the orientation of stent segments and inclusion of a fabric to connect stent segments. *Id*.

Specifically, the combined Hillstead/Palmaz/Ryan prosthesis would include the non-helical hoop structure disclosed by Hillstead where the apices of abutting

hoops would be secured as disclosed by Palmaz. *Id.* at ¶ 140. Further the prosthesis could be bifurcated with a body/trunk segment and two leg segments connected to the trunk segment by fabric as disclosed by Ryan. *Id.* One of skill in the art at the time would have recognized the Hillstead/Palmaz stent structure as a suitable design for a bifurcated prosthesis, particularly in view of Ryan's suggestion that a bifurcated structure employ a sturdy, flexible stent structure and Hillstead's goal of a "sturdy, yet flexible" stent. Hillstead at 2:24; Ryan at 5:34-37; Hillstead Decl. ¶ 140.



As shown above, Hillstead and Ryan each, individually disclose and claims 1-3, 5-6, 12-13, 21 and 30 and the combination of Hillstead and Palmaz discloses claims 1-3, 5-6, 12-13, 21 and 30. Hillstead Decl. ¶¶ 51-82, 112-137. For the reasons stated above, the Hillstead/Palmaz/Ryan combination would similarly disclose every element of claims 1-3, 5-6, 12-13, 21 and 30. *Id*. at ¶¶ 138-141. The Hillstead/Palmaz/Ryan combination additionally discloses the dependent claim limitations of claims 4, 7-9 and 22. *Id*. at ¶¶ 142-144.

Claims 4 and *22*: The Hillstead/Palmaz/Ryan combination discloses "a stent as recited in claim 3 wherein said axially aligned segments are connected to one another by a tubular fabric element" and "an endoluminal stent as claimed in claim 1 wherein said stent is at least partially covered in fabric." Hillstead Decl. ¶ 142. As shown in the H/P/R figure above, it would have been obvious to attach a Hillstead-like trunk segment to Hillstead-like leg segments using a tubular fabric element as disclosed in Ryan. *Id*.

Claim 7: The Hillstead/Palmaz/Ryan ("H/P/R") combination discloses a "stent as recited in claim 2 wherein adjacent hoops are of a different diameter." Hillstead Decl. ¶ 143. As shown in the H/P/R figure above, it would have been obvious to use a stent with hoops having a smaller diameter in the leg segments than the diameter of the trunk segment. *Id*. Additionally, as shown above, the

proximal most leg segments are adjacent to the distal most trunk segment, and thus, adjacent hoops would have different diameters. *Id*.

Claims 8 and 9: The Hillstead/Palmaz/Ryan combination discloses a "stent as recited in claim 2 wherein a first additional segment is axially parallel to, but non-common co-axial with, said stent segment" and a "stent as recited in claim 8 further comprising a second additional segment axially parallel to said stent segment, but non-co-axial with either said stent segment or said first additional stent segment." Hillstead Decl. ¶ 144. As shown above regarding the disclosure of Ryan alone, the bifurcation of a stent creates multiple longitudinal axes through the legs that are parallel to, but non-common co-axial with the longitudinal axis of the trunk. Ryan at Fig. 12; Hillstead Decl. ¶ 144.

X. CONCLUSION

Petitioner requests cancellation of claims 1-9, 12-13, 21-22, and 30 for the reasons herein.

Respectfully submitted by K&L Gates LLP,

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A copy of this Petition for *Inter Partes* Review and supporting materials have been served to counsel for the Patent Owner at the following electronic mail address, pursuant to an agreement between the parties, on this 12th day of August, 2015:

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