Filed on behalf of Stryker Corporation

By: Sandra A. Frantzen
Deborah A. Laughton
McAndrews, Held & Malloy, Ltd.
500 W. Madison St., 34th Floor
Chicago, IL 60661
Tel: 312 775-8000
Fax: 312 775-8100
E-mail: sfrantzen@mcandrews-ip.com

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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STRYKER CORPORATION,
Petitioner,

v.

ORTHOPHOENIX, LLC,
Patent Owner

_____

Case IPR2014-01519
Patent 6,623,505 B2

PETITION FOR *INTER PARTES* REVIEW

TABLE OF CONTENTS

EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 6,623,505 ("the 505 patent")
1002	Declaration of Neil Sheehan including *curriculum vitae*
1003	WO 94/24962 (published Nov. 10, 1994) ("Pathak")
1004	European Patent No. 0405831 (issued Jun. 7, 1995) ("Barbere")
1005	U.S. Patent No. 4,706,670 (issued Nov. 17, 1987) ("Andersen")
1006	WO 95/20362 (published Aug. 3, 1995) ("Reiley")
1007	U.S. Patent No. 5,766,151 (filed Jun. 7, 1995) ("Valley")
1008	U.S. Patent No. 4,024,873 (issued May 24, 1977) ("Antoshkiw")
1009	U.S. Patent No. 4,490,421 (issued Dec. 25, 1984) ("Levy")
1010	U.S. Patent No. 5,108,404 (issued Apr. 28, 1992) ("Scholten 404")
1011	U.S. Patent No. 5,547,378 (issued Aug. 20, 1996) ("Linkow")
1012	U.S. Patent No. 5,849,014 (filed Mar. 20, 1997) (issued Dec. 15, 1998) ("Mastrorio")
1013	U.S. Patent No. 281,043 (issued Jul. 10, 1883)
1014	U.S. Patent No. 397,060 (issued Jan. 29, 1889)
1015	Excerpts from the prosecution history of the 456 patent
1016	Excerpts from the prosecution history of the 505 patent

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42, Stryker Corporation ("Stryker") respectfully petitions for *inter partes* review ("IPR") of claims 1-12 of U.S. Patent No. 6,623,505 ("the 505 patent") (Ex. 1001), which issued on September 23, 2003, and is purportedly assigned to Orthophoenix, LLC ("Orthophoenix"). The earliest application to which the 505 patent claims priority is U.S. Patent No. 5,972,015 ("the 015 patent"), which was filed on August 15, 1997. Stryker has used the August 15, 1997, priority date for purposes of this Petition.

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

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

Petitioner Stryker Corporation is the real party-in-interest.

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

The 505 patent is asserted against Stryker in the following litigation pending in the District of Delaware: *Orthophoenix, LLC v. Stryker Corporation; John and/or Jane Does 1-100,* Case No. 13-1628-LPS, filed October 1, 2013. Two pending U.S. patent applications also claim priority to the 015 patent: U.S. Patent Appl. 12/869,101 (filed Aug. 26, 2010) and U.S. Patent Appl. 14/041,761 (filed Sept. 30, 2013).

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

Petitioner provides the following designation of counsel. Pursuant to 37

C.F.R. § 42.10(b), a Power of Attorney accompanies this Petition.

LEAD COUNSEL	BACK-UP COUNSEL
Sandra A. Frantzen (Reg. No. 48,799) (sfrantzen@mcandrews-ip.com) McAndrews, Held & Malloy Ltd. 500 West Madison Street, 34th Floor Chicago, IL 60661 Tel: (312) 775-8000 Fax: (312) 775-8100	Deborah A. Laughton (Reg. No. 54,253) (dlaughton@mcandrews-ip.com) McAndrews, Held & Malloy Ltd. 500 West Madison Street, 34th Floor Chicago, IL 60661 Tel: (312) 775-8000 Fax: (312) 775-8100

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

Please address all correspondence to the lead counsel at the address provided in Section I.C of this Petition. Petitioner also consents to electronic service by email at: **StrykerIPR@mcandrews-ip.com.**

II. PAYMENT OF FEES UNDER 37 C.F.R. § 42.103

Petitioner authorizes the USPTO to charge Deposit Account No. 13-0017 for the fees set forth in 37 C.F.R. § 42.15(a) for this petition and further authorizes payment for any additional fees to be charged to this Deposit Account.

III. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104

A. Grounds For Standing Under 37 C.F.R. § 42.104(a)

Petitioner certifies that the 505 patent is available for IPR and that Petitioner is not barred or estopped from requesting IPR.

B. Identification Of Challenge Under 37 C.F.R. § 42.104(b) And Relief Requested

Petitioner requests *inter partes* review of claims 1-12 of the 505 patent on

the grounds set forth below and requests that each of the claims be found unpatentable. An explanation of how the claims are unpatentable under specified statutory grounds is provided below including an identification of where each element is found in the prior art and the relevance of each reference. Additional explanation and support is set forth in the Declaration of Neil Sheehan (Ex. 1002), which is submitted in accordance with 37 C.F.R. § 1.68.

IPR of claims 1-12 is requested in view of the knowledge of one of ordinary skill in the art and the following references, which are prior art under § 102(b) unless otherwise noted:

- WO 94/24962 ("Pathak"), published Nov. 10, 1994 (Ex. 1003);
- European Patent No. 0405831 ("Barbere"), issued Jun. 7, 1995 (Ex. 1004);
- U.S. Patent No. 4,706,670 ("Andersen"), issued Nov. 17, 1987 (Ex. 1005);
- WO 95/20362 ("Reiley"), published Aug. 3, 1995 (Ex. 1006); and
- U.S. Patent No. 5,766,151 ("Valley"), filed Jun. 7, 1995 (Ex. 1007), which is prior art under § 102(e).

Additional references cited herein and in the Sheehan Declaration demonstrate the knowledge of ordinary skill in the art at the time of the invention.

Ground	Proposed Statutory Rejections for the 505 Patent
1	Pathak anticipates claims 1, 3, 5, 7, 9, and 11 under § 102.

2	Barbere anticipates claims 1, 3, 5, 7, 9, and 11 under § 102.
3	Andersen anticipates claims 1, 3-5, 7-9, 11, and 12 under § 102.
4	Reiley in combination with Andersen renders claims 1-12 obvious under § 103.
5	Valley anticipates claims 1-12 under § 102.
6	Pathak in combination with Valley renders Claims 2, 4, 6, 8, 10, and 12 obvious under § 103.

C. Claim Construction Under 37 C.F.R. § 42.104(b)(3)

A claim in an IPR is given the broadest reasonable interpretation in light of the specification to one having ordinary skill in the art. (37 C.F.R. § 42.100(b).) See Section V below.

IV. BACKGROUND OF THE ART AND THE 505 PATENT

A. Background Of The Art

As explained in the attached Sheehan Declaration (Ex. 1002), catheters carrying inflatable structures (including ones using an inner and outer tube coaxial configuration) for deployment in interior body regions have been used by physicians for many decades for a variety of applications. (Sheehan Decl. at ¶¶ 13-14.) For example, such balloon catheters have been used in urinary and vaginal applications, in the vasculature system for angioplasty and stent delivery, and in bone for compressing cancellous bone and treating fractures. (*Id*.)

With the increase in angioplasty and stent procedures in recent decades,

there was a proliferation of balloon catheter designs. (Sheehan Decl. at ¶ 15.) In these procedures, physicians would pass a balloon catheter through a guide catheter or cannula to access remote regions of the vasculature, e.g., to clear or treat blockages. (Ex. 1003 at p. 29; Ex. 1004, 1:53-2:13; Ex. 1005, 1:23-26.) Skilled artisans looking to design balloon catheters considered angioplasty and other cardiovascular catheters when contemplating balloon catheter designs. (Sheehan Decl. at ¶ 15.) As one patent explained, "[b]alloon catheters are not limited in their use to the relief of arterial stenosis but have been found useful in many medical applications involving not only insertion into blood vessels but also involving insertion into a variety of body cavities." (Ex. 1009, 1:19-23; Sheehan Decl. at ¶ 15.)

With the advent of balloon-assisted vertebroplasty (also called kyphoplasty) in the late 1980s,[1] it became well known that cardiovascular

[1] Balloon-assisted vertebroplasty is a procedure involving injecting bone cement into a vertebral body after first compressing cancellous bone and creating a cavity in the bone using a balloon catheter. (*See, e.g.*, Ex. 1010 (U.S. Patent No. 5,108,404; Sheehan Decl. at ¶ 16.) The balloon catheter is passed through a cannula into bone and the balloon is then inflated when appropriately placed to treat the bone. (Ex. 1010 at 2:8-19.)

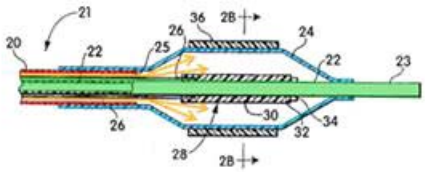
catheters could be used across applications including in bone. (Sheehan Decl. at ¶¶ 16-17, 24-25.) For example, the Pathak reference, which disclosed balloon catheters used for implanting polymeric materials such as stents, focused on cardiovascular applications but also explained how the catheter could be used "[i]n other therapeutic applications, (i.e., trachial, urinary, bronchial, bone lumens and the like) . . . ." (Ex. 1003 at p. 15;[2] *see also* Sheehan Decl. at ¶ 17; Ex. 1011 at 4:46-47 ("catheters used for balloon angioplasty [ ] are ideal for use in the present invention [in bone]"); Ex. 1012 at 3:10-13.)

Indeed, the Reiley reference (published in 1995) disclosed using a balloon catheter for compressing cancellous bone in balloon-assisted vertebroplasty and for treating bone fractures. (Ex. 1006 at Abstract, p. 6 ll. 17-21, p. 19 ll. 17-35, pp. 31-34; Sheehan Decl. at ¶ 18.) Reiley also praised the design of balloon catheters used in angioplasty including the catheter design described in Andersen (see picture below), which Reiley described as a "coaxial catheter with inner and outer tubing . . . . " (Ex. 1006 at p. 4 ll. 21-25.) After discussing a number of angioplasty balloon catheters, Reiley disclosed what was well known in the art, i.e., that "current medical balloons can compress bone . . . ." (Ex. 1006 at p. 5 l. 29.)

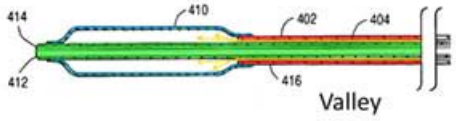
By the early 1990s, balloon catheters having a coaxial construction were

[2] Unless otherwise noted, all emphases herein have been added.

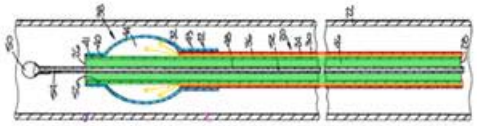
ubiquitous in the art. Specifically, as shown by the few examples below, and as explained in the Sheehan Declaration, it was well known to use a balloon catheter design with two concentric tubes where the inner tube (shown in green) extended distally beyond the outer tube (red), and where the balloon (blue) was distally attached to the inner tube and proximally attached to the outer tube (as claimed in the 505 patent). (Sheehan Decl. at ¶ 19.) It was also well known to use the passage between the outer and inner catheter tubes (orange) to convey an inflation medium to inflate the balloon. (*Id*.) As shown below and will be discussed in greater detail, the Pathak, Andersen, Valley, Barbere, Antoshkiw, and other references all disclose such catheters in various applications including bone. (*Id.*)



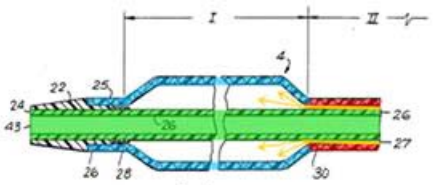
Pathak



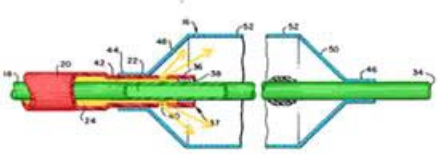
Valley



Antoshkiw



Andersen



Barbere

For example, one of the earlier references, the Antoshkiw patent, which issued on May 24, 1977, disclosed a balloon catheter assembly for use in the

vasculature with "an inner tube 24 having an open distal end 26 and an open proximal end 28." (Ex. 1008, 3:17-18; Sheehan Decl. at ¶ 20.) A concentric outer tube 30 is positioned "so that the inner tube 24 extends distally and proximally from the ends of the outer tube 30." (Ex. 1008 at 3:19-23.) "An inflatable balloon portion 38 is attached to both the inner and outer tubes" as shown above. (*Id*. at 3:28-29.) As was typical, Antoshkiw disclosed a flow passage between the inner and outer tubes and further explained that the tubes were moveable in relation to each other. (Sheehan Decl. at ¶¶ 21-23; Ex.1008 at 3:40-44; 3:53-59.)

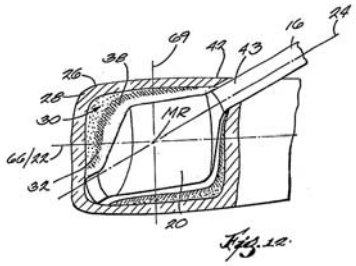
It was also known to provide balloons of different shapes and sizes so, for example, the balloons could inflate asymmetrically to conform to asymmetric cavities. (*See, e.g.*, Ex. 1007 at 31:7-10; Ex. 1006 at p. 13 ll. 17-32, p. 22 ll. 6-18, p. 24 l. 24 – p. 25 l. 13, Fig. 10-12, 15, 17A; Ex. 1010 at 2:31-32; Sheehan Decl. at ¶¶ 24-25.)

B. Brief Description Of The 505 Patent

The 505 patent was filed on July 31, 2001, and claims priority to U.S. Patent No. 5,972,015, which was filed on August 15, 1997. As is evident by its title, the 505 patent is directed to "expandable structures, which, in use, are deployed in interior body regions of humans and other animals." (Ex. 1001 at 1:12-14.) The specification of the 505 patent focuses on purportedly solving problems arising

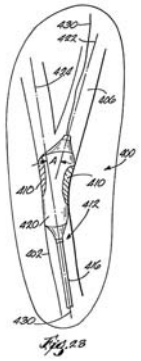
from using expandable structures such as balloons in asymmetric applications:[3]

> The deployment of expandable structures into interior body regions is well known. For example, expandable structures, generically called "balloons," are deployed during angioplasty to open occluded blood vessels. As another example, U.S. Pat. Nos. 4,969,888 and 5,108,404 disclose apparatus and methods the use of expandable structures for the fixation of fractures or other osteoporotic and non-osteoporotic conditions of human and animal bones. . . . Many interior regions of the body, such as the vasculature and interior bone, possess complex, asymmetric geometries. Even if an interior body region is somewhat more symmetric, it may still be difficult to gain access along the natural access of symmetry.



(Ex. 1001 at 1:17-30.)

As shown, e.g., by Figures 11-14, the 505 patent purported to solve this problem with asymmetrically-shaped balloons. (*Id.* at 2:64-3:16.) Figures 12 and 23 depict asymmetric balloons of the type shown in Figure 11 in a vertebra and artery, respectively. (*Id.*; *see also id.* at 3:60-65.)



While the specification focused on balloon designs to address the

[3] Indeed, the original title of the patent was "Expandable, Asymmetric Structures For Deployment In Interior Body Regions." (Ex. 1016 at p. 2.)

asymmetry issue, the specification also identified certain catheter designs for use in the claimed invention including those that were known in the prior art. For example, Figure 20 depicts a tubular balloon 110 bonded to the distal end of an outer catheter tube 118 and to the distal end of an inner catheter tube 120. (*Id.* at 10:14-29.)

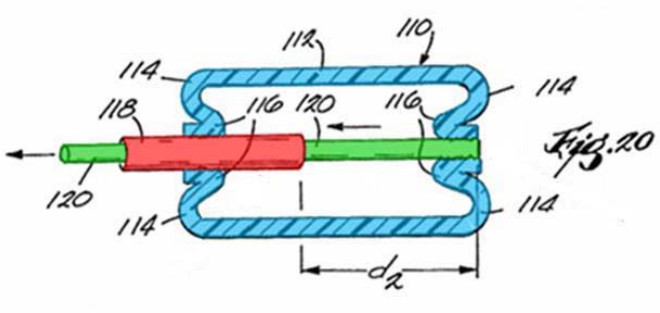


Fig. 20

Despite the fact that the specification focused on asymmetric balloon design, as discussed below, the 505 patent, which was the third patent in a series of divisionals, simply claimed the coaxial catheter design with inner and outer catheter tubes which was well known in the prior art.

C. Summary Of The Prosecution History Of The 505 Patent

The 505 patent is a divisional of U.S. Patent No. 6,280,456 ("the 456 patent"), which is a divisional of the 015 patent. (Ex. 1001.) Despite the fact that the specification focused on solving the asymmetry issue, the 505 patent claims general balloon catheter design.

Original claim 1 of the 456 patent application was directed to the asymmetric geometry of the expandable structure. (Ex. 1015 at p. 40 (claim 1).) The examiner, however, rejected Claim 1 as anticipated by Valley, which as

discussed below discloses a cardiac access system that uses a catheter with an expandable member on its distal end that allows for asymmetric applications. (*Id*. at p. 66; Ex. 1007 at Abstract.) The applicants then cancelled that claim, amended the title and specification, and added new method claims covering the use of an expandable balloon catheter – the same balloon catheter that was disclosed in the admitted prior art – "for treating bone." (Ex. 1015 at p. 68-71.) The Examiner allowed the method claims stating that, although one prior art reference (Hamlin) disclosed all of the claimed catheter elements (i.e., "a balloon catheter having an outer tube, an inner tube, and an expandable structure having a proximal end secured to the distal end of the outer tube and a distal end secured to the distal end of the inner tube"), "the Hamlin catheter is used treating in [sic] an intravascular system." (Id. at p. 73.) The applicants never advised the Examiner that the claimed catheter design was ubiquitous in the prior art and was appropriate for use in bone.

The 505 patent was filed as a divisional of the 456 patent. Original claims directed to the geometry of the expandable structure were again rejected as anticipated. (Ex. 1016 at 36, 43, 60, 62-63.) The applicants again canceled the claims, amended the title and specification, and added new claims. (*Id.* at pp. 68-78.) This time, instead of claiming methods of using the prior art catheters "for

treating bone," the new claims were directed to the prior art devices themselves. (*See id*. at pp. 76-78.) For example, new independent claim 37 is reproduced below:

> 37. (New) A device for deployment into bone comprising
>
> an outer catheter tube having a distal end,
>
> an inner catheter tube extending at least in part within the outer catheter tube and having a distal end region that extends at least in part beyond the distal end of the outer catheter tube, and
>
> an expandable structure having a proximal end secured to the outer catheter tube and a distal end secured to the inner catheter tube, the expandable structure extending outside and beyond the outer catheter tube and at least partially enclosing the inner catheter tube.

(*Id.* at p. 76.)

The Examiner (in a final office action) rejected these claims as being anticipated by references involving catheter delivery of expandable bodies (stents). (*Id*. at pp. 80-83.) The Examiner noted that:

> 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. <u>If the prior art structure is capable of performing the intended use, then it meets the claim</u>. In a claim drawn to a process of making, the intended use must result in a manipulative

> difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

(*Id*. at p. 83.)

The applicants submitted a Request for Continued Examination. (*Id*. at p. 94.) Notably, the applicants did not contest the Examiner's statement that recitation of the intended use in the claim is not limiting vis-à-vis prior art structures. Instead, the applicants amended the claims and argued that the references were "directed to expandable mesh structures [stents] that are not inflatable by the introduction of an inflation medium" and did not disclose "a flow passage between inner and outer catheter tubes to convey an inflation medium into an inflatable structure." (*See id*. at p. 98-101.) The amended claims changed "expandable" structures to "inflatable" structures and added the requirement that a "flow passage" exist "between the outer and inner catheter tubes communicating with the inflatable structure and adapted to convey an inflation medium into the inflatable structure to inflate the inflatable structure." (*See id*..) In view of these amendments, the Examiner allowed the claims. (*Id*. at pp. 102.)

V. CLAIM CONSTRUCTION UNDER 37 C.F.R. § 42.104(B)(3)

A claim subject to IPR is given its "broadest reasonable construction in light of the specification of the patent in which it appears," which is a broader construction than applied by courts during claim construction. 37 C.F.R.

§ 42.100(b); *see also In re Trans Texas Holding Corp.*, 498 F.3d 1290, 1298 (Fed. Cir. 2007) (citing *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984)). The broadest reasonable interpretation of the terms of 505 patent is their plain and ordinary meaning which is evident from the claims themselves. To the extent that the Patent Owner proposes claim constructions in the Patent Owner's Preliminary Response, Stryker clarifies the interpretation of the following claim terms.[4]

In independent claims 1, 5, and 9, the claim preambles – **"device for deployment into bone"** (claims 1 and 5) and **"system for treating bone"** (claim 9) – do not serve as claim limitations. "A preamble is not regarded as limiting, however, 'when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention.'" *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358-59 (Fed. Cir. 2010); *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 807-10 (Fed. Cir. 2002). Moreover, "preamble language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim." *Marrin v. Griffin*, 599 F.3d 1290, 1294 (Fed. Cir. 2010). Here,

[4] Because of the different claim construction standard in litigation, Petitioner reserves all of its rights with regard to constructions during litigation.

the preambles of the claims at issue simply recite the intended use for the claimed device and do not serve as claim limitations. Indeed, during prosecution, the Examiner noted, and the applicants did not disagree, that "[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." (Ex. 1016 at p. 83 (citing *In re Casey*, 152 U.S.P.Q. 235 (CCPA 1967) and *In re Otto*, 136 U.S.P.Q. 458, 459 (CCPA 1963)).) Thus, the preambles are not limiting.

In claims 3, 5, 7, 9, and 11, "***adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone***" (claims 3, 7, and 11) and "***sized and configured for passage within a [or the] cannula into bone***" (claims 5 and 9) mean the claimed inflatable structure has a structure and configuration so as to be capable of performing the recited function. *See, e.g.*, *Ex Parte Coers*, Appeal 2011-008340, 2013 WL 5402245, *3 (PTAB Sept. 12, 2013) ("the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the structural limitations of that claimed") (citing *Ex Parte Masham*, 2 U.S.P.Q.2d. 1647, 1648 (BPAI 1987)); *In re Schreiber*, 128 F.3d 1473, 1477-78 (Fed. Cir. 1997); *see also* MPEP § 2114 ("While features of an apparatus may be recited either

structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function."). Specifically, "adapted and configured to compress cancellous bone upon inflation. . ." means that the inflatable structure is of an adaptation and configuration such that it is capable of compressing cancellous bone upon inflation. Similarly, "sized and configured for passage within a cannula into bone" means that the claimed structure is of a size and configuration such that it is capable of passing within a cannula into bone (e.g., when the inflatable structure is in a collapsed condition).

This interpretation is supported by both the specification and prosecution history. The 505 patent describes balloon catheters for various applications (including for use in the vasculature and bone) but does not distinguish between an inflatable structure, "adapted and configured to compress cancellous bone" or "sized and configured for passage within a cannula into bone" and one configured and adapted for arteries. (*See, e.g.*, Ex. 1001 at 4:36-40 ("The systems and methods embodying the invention can be used virtually in any interior body region that presents an asymmetric geometry . . . ."), 4:41-11:49 (addressing deployment in bones), 11:50-12:25 (addressing deployment in the vasculature).) Moreover, during prosecution, the applicants did not dispute that the intended use of the claimed device was not limiting. (*See* Ex. 1016 at p. 83, 100.)

VI. THERE IS A REASONABLE LIKELIHOOD THAT CLAIMS 1-12 OF THE 505 PATENT ARE UNPATENTABLE

Petitioner seeks *inter partes* review of claim 1-12 of the 505 patent. Claims 1, 5, and 9 are independent claims. Claims 2-4, 6-8, and 10-12 depend on these claims.

A. Ground 1: Pathak Anticipates Claims 1, 3, 5, 7, 9, And 11

The Pathak reference, which was published on November 10, 1994, and describes the use of a balloon catheter in various applications including bone, anticipates claims 1, 3, 5, 7, 9, and 11 of the 505 patent. (Sheehan Decl. at ¶¶ 42-58.)

Pathak discloses a catheter that uses an inflatable structure (e.g., a balloon) to implant polymeric materials such as a stent. (Ex. 1003 at pp. 1, 5; Sheehan Decl. at ¶¶ 42-43.) Specifically, as shown in Figure 2A, Pathak discloses a balloon catheter with "an outer elongated flexible tube 20 [red] (i.e., a catheter) and an inner elongated flexible tube 22 [green] positioned within the lumen of the outer tube 20." (Ex. 1003 at p. 21; Sheehan Decl. at ¶ 44.) "The inner tube 22 is longer than the outer tube

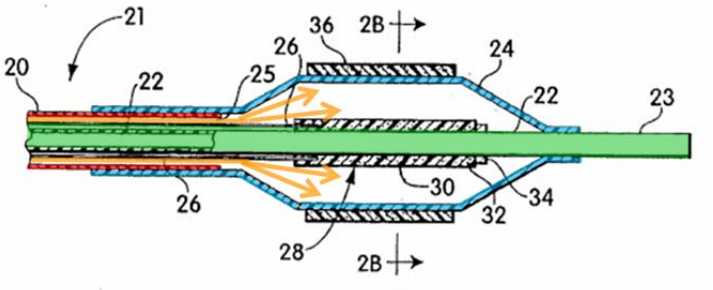


Fig. 2A

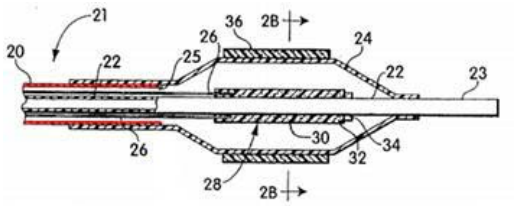
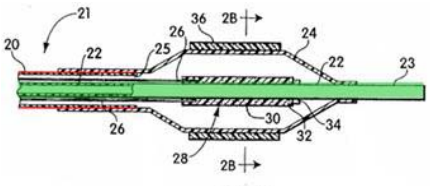
20 so as to cause its distal end 23 to extend distally beyond the distal end of the outer tube 20." (Ex. 1003 at p. 21.) An "article shaping element," such as an inflatable balloon [blue], is affixed to both the inner and outer tubes. (*Id*.) Specifically, an "inflatable balloon 24 is mounted on the distal end of the device such that the proximal end of the balloon 24 is secured near the distal end of the outer tube, and the distal end of the balloon is secured near the distal end of the inner tube." (*Id*. at p. 21; Sheehan Decl. at ¶ 44.) As shown in Figure 2A, the outer catheter tube at least partially enclosing the inner catheter tube. (Sheehan Decl. at ¶ 46, claim 1 chart.) "The annular space formed between the inner wall of the outer tube and the outer wall of the inner tube forms an inflation lumen 25 [orange] through which the balloon may be inflated and expanded." (Ex. 1003 at p. 21; Sheehan Decl. at ¶ 44.) The inflation lumen allows the balloon to be inflated by an appropriate inflation medium. (Ex. 1003 at pp. 20, 24; Sheehan Decl. at ¶ 44.)

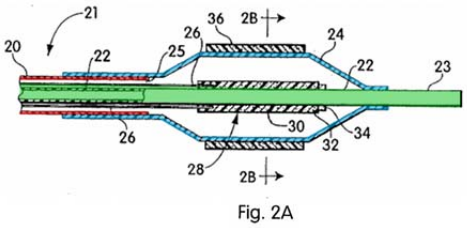
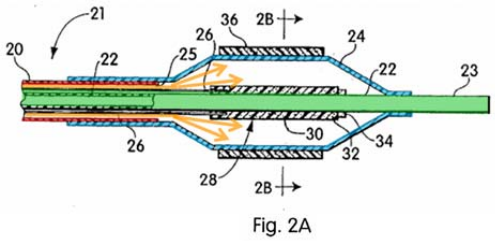
As was well known in the prior art, Pathak discloses that its balloon catheter assembly can be used in a variety of medical procedures including the treatment of bone. (Ex. 1003 at p. 15 ("In other therapeutic applications, (i.e., trachial [sic], urinary, bronchial, bone lumens and the like) shorter or longer periods may be appropriate."), p. 37 ("For example, within a bone lumen, a

coating thickness of up to 5 mm may be beneficial."), p. 9 (referring to "physiologically acceptable forces and temperature within bone tissue…"), pp., 35-36; Sheehan Decl. at ¶ 45.)

1. Pathak Anticipates Claims 1 And 3

As shown in the claim chart below (color added), Pathak discloses each of the elements of independent claim 1. (Sheehan Decl. at ¶ 46.)

505 Patent	Pathak
1. A device for deployment into bone comprising an outer catheter tube having a distal end,	See Section V regarding claim construction. Pathak discloses that the device can be deployed in various applications including bone. (Ex. 1003 at pp. 9, 15, 35, 36, 37.)  Fig. 2A "The device 21 comprises an outer elongated flexible tube 20 [red] (i.e., a catheter) and an inner elongated flexible tube 22 positioned within the lumen of the outer tube 20." (*Id.* at p. 21.) "The inner tube 22 is longer than the outer tube 20 so as to cause its distal end 23 to extend distally beyond the distal end of the outer tube 20." (*Id.*)
an inner catheter tube extending at least in part within the outer catheter tube and having a distal end region that extends at least	"The device 21 comprises an outer elongated flexible tube 20 (i.e., a catheter)  Fig. 2A

505 Patent	Pathak
in part beyond the distal end of the outer catheter tube,	and an inner elongated flexible tube 22 [green] positioned within the lumen of the outer tube 20. The inner tube 22 is longer than the outer tube 20 so as to cause its distal end 23 to extend distally beyond the distal end of the outer tube 20." (*Id.*)
an inflatable structure having a proximal end secured to the outer catheter tube and a distal end secured to the inner catheter tube, the inflatable structure extending outside and beyond the outer catheter tube and at least partially enclosing the inner catheter tube, and	See Figure 2A and Sheehan Decl. at ¶ 46, claim 1 chart. "An article shaping element, for example a radially expandable, inflatable balloon 24 [blue] is mounted on the distal end of the device such that the proximal end of the balloon 24 is secured near the distal end of the outer tube, and the distal end of the balloon is secured near the distal end of the inner tube." (*Id.*; *see also id.* at p. 20.) "The inner tube 22 is longer than the outer tube 20 so as to cause its distal end 23 to extend distally beyond the distal end of the outer tube 20." (*Id.* at p. 21.)  Fig. 2A
a flow passage between the outer and inner catheter tubes communicating with the inflatable structure and adapted to convey an inflation medium into the inflatable structure to inflate the inflatable structure.	"The annular space formed between the inner wall of the outer tube and the outer wall of the inner tube forms an inflation lumen 25 through which the balloon may be inflated and expanded." (*Id.* at p. 21.) "A preferred inflation medium comprises a mixture of equal parts of saline and  Fig. 2A

505 Patent	Pathak
	an iodinated contrast agent." (*Id.* at p. 24.)

Pathak also anticipates claim 3. ***Dependent claim 3*** requires a "*device according to claim 1 wherein the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone*." In addition to meeting the limitations of claim 1 (discussed above and incorporated herein), the balloon of Pathak is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone. As discussed above, Pathak discloses that its balloon catheter can be used in a variety of medical procedures including bone lumens, which include cancellous bone. (Sheehan Decl. at ¶¶ 45, 48-49; Ex. 1003 at pp. 9, 15, 35-37.) Like the balloon of the 505 patent that can be used for several applications including bone and is formed from materials "including vinyl, nylon, polyethylenes, ionomer, polyurethane, and polyethylene tetraphthalate (PET)," Pathak teaches that its "balloon preferably comprises a polymeric material such as polyethylene terephthalate [PET], crosslinked polyethylene or composites thereof." (*Compare* Ex. 1001 at 12:64-13:4 with Ex. 1003 at pp. 25-26; Sheehan Decl. at ¶ 50.) Thus, the balloon of Pathak is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone just like the balloon in the 505 patent. (Sheehan

Decl. at ¶¶ 49-50.) Moreover, Pathak further teaches that adaptations for applications in bone may be helpful. (*See, e.g.,* Ex. 1003 at p. 9 ("physiologically acceptable forces and temperatures within bone tissue may far exceed the amount of force and heat that is physiologically acceptable on a blood vessel or other soft tissue"), p. 37 (increasing thickness of polymer materials for use within a bone lumen); Sheehan Decl. at ¶ 50.)

2. Pathak Anticipates Claims 5 And 7

Pathak discloses each of the elements of independent claim 5 as well as claim 7, which depends on claim 5. ***Claim 5*** includes all the limitations of claim 1 plus an additional element. All of the arguments made regarding anticipation of claim 1 are incorporated by reference herein. Claim 5 further requires "*the inflatable structure being sized and configured for passage within a cannula into bone when the inflatable structure is in a collapsed condition.*" The Pathak balloon is sized and configured for passage within a cannula into bone when the balloon is in a collapsed condition. (Sheehan Decl. at ¶¶ 51-54.)

Like the 505 patent, Pathak teaches passing the balloon catheter assembly through a guide sheath, i.e., a cannula, during the procedure. (Ex. 1003 at p. 29;

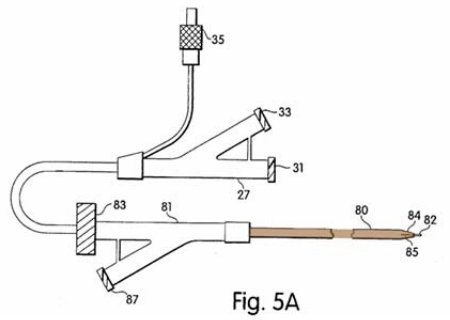


Fig. 5A

Fig. 5B

Sheehan Decl. at ¶ 53.) Specifically, Pathak states: "In each of the embodiments described above, the device may include an elongated retractable sheath as an aid to maintaining the polymeric article on the balloon . . . ." (Ex. 1003 at p. 29.) See Figures 5A and 5B. As is typical, the balloon is deflated until it is positioned at the desired treatment location. (*Id.* at p. 28.) Pathak specifically mentions use in bone as one embodiment and one of ordinary skill in the art would understand that such a cannula, like the disclosed balloon catheter, would also be used for entry into bone. As Mr. Sheehan explains, a person of ordinary skill would thus understand that the collapsed balloon of Pathak is sized and configured for passage within a cannula for use in bone. (Sheehan Decl. at ¶ 54.)

Moreover, given the small architecture of the vasculature, it would follow that anything sized for a vasculature application would not be subject to any dimensional limitations vis-à-vis bone. (*Id*.) Accordingly, a person of ordinary skill would understand that if the inflatable structure of Pathak is capable of passing within the cannula of Pathak for entry into the vascular system, the inflatable structure of Pathak is also capable of passage within a cannula into bone. (*Id*.)

It is further noted that the flow passage element of claim 5 is identical to that of claim 1 except that claim 5 states the flow passage conveys an inflation medium "to <u>expand</u> [instead of inflate] the inflatable structure." Because a

balloon is the inflatable structure, the arguments set forth in claim 1 with respect to the flow passage element and the ability to "inflate the inflatable structure" apply equally to claim 5 and the claimed ability to "expand the inflatable structure" and is hereby incorporated by reference. (Sheehan Decl. at ¶ 55.) Thus, Pathak anticipates claim 5.

Pathak also anticipates ***dependent claim 7***. (Sheehan Decl. at ¶ 56.) Claim 7 depends on claim 5 with an additional limitation that is identical to that of claim 3 (i.e., "[a] device according to claim 5 wherein the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone"). The claim is anticipated for the same reasons discussed above and the analyses of claims 5 and 3 are incorporated by reference. (*Id.*)

3. Pathak Anticipates Claims 9 And 11

Independent claim 9, a system claim, has all the limitations of the device of claim 5 plus the limitation of "a cannula." As discussed with respect to claim 5, Pathak discloses passing the catheter assembly through a sheath or a sleeve, which is a cannula. (Sheehan Decl. at ¶ 57, claim 9 chart.) The analysis of claim 5 is hereby incorporated by reference and thus claim 9 is anticipated.[5]

[5] It is noted that independent claim 9 recites "the inflatable structure being sized and configured for passage within the cannula into bone," removing the limitation

Claim 11 depends on claim 9 with an additional limitation that is identical to that of claim 3 and claim 7 (i.e., "[a] system according to claim 9 wherein the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone"). The claim is anticipated for the same reasons discussed above and the analyses of claims 3, 5, 7, and 9 are hereby incorporated by reference. (Sheehan Decl. at ¶ 57, claim 11 chart.)

B. Ground 2: Barbere Anticipates Claims 1, 3, 5, 7, 9, And 11

Barbere, which was published June 7, 1995, anticipates claims 1, 3, 5, 7, 9, and 11 of the 505 patent. (Sheehan Decl. at ¶¶ 59-73.)

Barbere discloses a percutaneous transluminal coronary angioplasty (PTCA) catheter with a balloon 16 (blue) mounted to the distal end of its shaft. (Ex. 1004 at 1:9-34, 4:23-27; Sheehan Decl. at ¶ 60.) The catheter shaft includes a pair of coaxial tubes (an inner tube 18 (green) and an outer tube 20 (red)), as shown in Figure 2. (Ex. 1004 at 4:27-30; Sheehan Decl. at ¶ 60.) As is evident from Figure

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in independent claim 5 that recites "the inflatable structure being sized and configured for passage within a cannula into bone <u>when the inflatable structure is in a collapsed condition</u>." Thus, of course, an inflatable structure (like that of Pathak) that satisfies the narrower limitation of claim 5 necessarily satisfies the broader limitation of claim 9.

2, the inner catheter tube extends within the outer tube and has a distal end region that extends beyond the distal end of the outer tube. (Sheehan Decl. at ¶ 61, claim chart.)

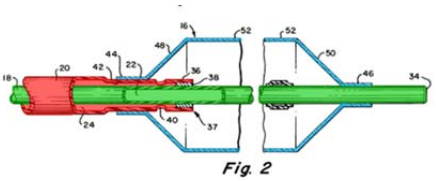


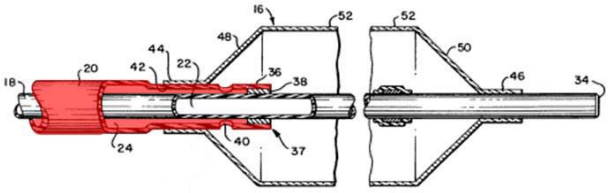
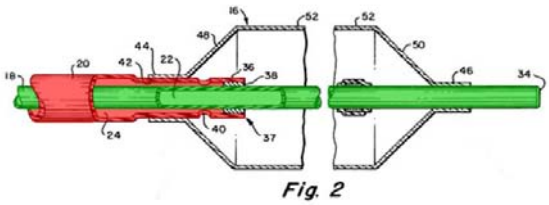
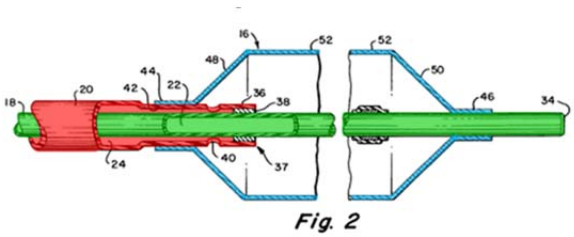
Fig. 2

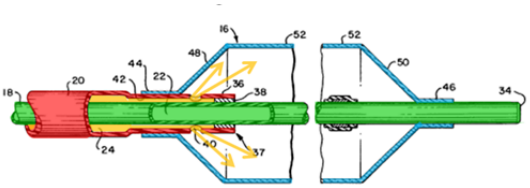
Like the claims of the 505 patent, the "balloon is mounted on the distal end of the catheter with its proximal end adhesively attached to the distal end of the outer tube and the distal end of the balloon being adhesively attached to the distal end of the inner tube." (Ex. 1004 at 3:2-6, 3:56-4:1; Sheehan Decl. at ¶ 60.) Figure 2 shows the balloon 16 (blue) extending outside and beyond the outer catheter tube 20 (red) and at least partially enclosing the inner catheter tube 18 (green). (Sheehan Decl. ¶ 61, claim chart.) There is an "inflation lumen 24 [orange] [] defined between the inner tube 18 and the outer tube 20." (Ex. 1004 at 4:50-51; Sheehan Decl. at ¶ 60.) The inflation lumen "communicates with the interior of the balloon and serves as the inflation/deflation lumen" for the balloon. (Ex. 1004 at 3:6-9; *see also id*. at 5:31-37; Sheehan Decl. at ¶ 60.)

1. Barbere Anticipates Claims 1 And 3

As shown in the claim chart below (color added), Barbere discloses each of the elements of independent claim 1. (Sheehan Decl. at ¶ 61-62.) As discussed in Section V, the preamble of each claim directed toward intended use of the device

or system in bone does not limit the claim.

505 Patent	Barbere
1. A device for deployment into bone comprising an outer catheter tube having a distal end,	See Section V regarding claim construction.  Fig. 2 *See, e.g.*, Fig. 2. "The coaxial tubes include an inner tube 18 and an outer tube 20 [red]." (Ex. 1004 at 4:30-31.) Figure 2 shows an outer catheter tube ("outer tube 20") (red) having a distal end. (Sheehan Decl. ¶ 61, claim chart.)
an inner catheter tube extending at least in part within the outer catheter tube and having a distal end region that extends at least in part beyond the distal end of the outer catheter tube,	 Fig. 2 *See, e.g.*, Fig. 2. "The coaxial tubes include an inner tube 18 [green] and an outer tube 20 [red]." (Ex. 1004 at 4:30-31.) "The outer tube 20 extends from the Y-fitting 26 to a location short of the inner tube 18 and terminates within the balloon 16." (*Id*. at 5:18-20.)
an inflatable structure having a proximal end secured to the outer catheter tube and a distal end secured to the inner catheter tube, the inflatable structure extending outside and beyond the outer catheter	 Fig. 2 See Figure 2. "The dilatation balloon is mounted on the distal end of the catheter with

505 Patent	Barbere
tube and at least partially enclosing the inner catheter tube, and	its proximal end adhesively attached to the distal end of the outer tube and the distal end of the balloon being adhesively attached to the distal end of the inner tube." (Ex. 1004 at 3:1-6; *see also id*. 5:38-44.) "The outer tube 20 extends from the Y-fitting 26 to a location short of the inner tube 18 and terminates within the balloon 16." (*Id.* at 5:18-20.)
a flow passage between the outer and inner catheter tubes communicating with the inflatable structure and adapted to convey an inflation medium into the inflatable structure to inflate the inflatable structure.	 *Fig. 2* "An annular inflation lumen 24 [orange] is defined between the inner tube 18 and the outer tube 20." (Ex. 1004 at 4:50-51.) "A pair of circumferentially spaced (e.g., 180°) apertures 40 are formed in the outer tube within the balloon to communicate the inflation lumen 24 with the interior of the balloon so as to permit inflation and deflation of the balloon with an appropriate liquid as will be familiar to those skilled in the art." (*Id.* at 5:31-37.)

Barbere also anticipates ***dependent claim 3***. Dependent claim 3 requires "*[a] device according to claim 1 wherein the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone*." (Sheehan Decl. at ¶ 63.) In addition to meeting the requirements of claim 1 (discussed above and incorporated herein), Barbere discloses this additional element of Claim 3. (*Id*.)

As discussed above in Section VI.A.1, the 505 patent describes catheters that can be used in various applications including both deployment in vasculature and bone. (Ex. 1001 at 4:41-11:49 (deployment in bone), 11:50-12:25 (deployment in vasculature).) The 505 patent does not distinguish between an inflatable structure adapted and configured to compress cancellous bone and one adapted and configured for compression of plaque in arteries. (Sheehan Decl. at ¶ 64). Instead, the specification states that the expandable structure (irrespective of intended use) "can withstand pressures of up to, for example, 250-500 psi" and can be formed from a material "selected according to the therapeutic objectives surrounding its use," "including vinyl, nylon, polyethylenes, ionomer, polyurethane, and polyethylene tetraphthalate (PET)." (*Id.* at 12:64-13:4; Sheehan Decl. at ¶ 64.)

Like the balloon of the 505 patent, Barbere indicates that its balloon "may be formed from . . . polyethylene terephthalate [PET]" and it "may be made in a manner described in U.S. Patent 4,490,421 (Levy)." (*Compare* Ex. 1001 at 12:64-13:2 (identifying PET) with Ex. 1004 at 5:47-50 (PET, Levy); *see also* Sheehan Decl. at ¶65.) Levy discloses a balloon with a burst pressure of, for example, between 200 and 500 psi, which is commensurate with the range disclosed by the 505 patent. (Sheehan Decl. at ¶ 65; Ex. 1009, 2:50-54 ("For example, the balloon of

the invention exhibits a burst pressure of at least 200 psi (1.4 MPa), preferably at least 400 psi (2.8 MPa), more preferably at least 500 psi (3.4 MPa) at ambient temperature (20ºC.)."); *id.* at 5:33-39 (claims 2-3).) Thus, just as the balloon of the 505 patent is adapted and configured to compress cancellous bone, the Barbere device is likewise adapted and configured to compress cancellous bone.

2. Barbere Anticipates Claims 5 And 7

Claim 5 includes all the limitations of claim 1 plus an additional element. All of the arguments made regarding anticipation of claim 1 are incorporated by reference herein. Claim 5 further requires "*the inflatable structure being sized and configured for passage within a cannula into bone when the inflatable structure is in a collapsed condition.*" This too is disclosed in Barbere. (Sheehan Decl. at ¶ 66.)

Barbere describes passing its balloon through a cannula in a collapsed position. Barbere states: "In a typical procedure . . . the assembly is inserted into a previously percutaneously placed guide catheter," which is a cannula. (Ex. 1004 at 1:53-56; Sheehan Decl. at ¶ 67.) Barbere discloses that "[o]nce the guidewire is in place, the balloon dilatation catheter is advanced over the guidewire, being thus guided directly to the stenosis so as to place the balloon within the stenosis. Once so placed, the balloon is inflated under substantial pressure to dilate the

stenosis." (Ex. 1004 at 2:7-13.) Specifically, a person of ordinary skill would understand that, if the collapsed balloon of Barbere is sized and configured for passage within the cannula of Barbere for entry into the vascular system, the balloon is also sized and configured for passage within a cannula into bone. (Sheehan Decl. at ¶ 68-69.) For example, Barbere discloses that the "outer tube 20 may have an outer diameter of the order of 1.14 mm . . . ." (Ex. 1004 at 4:40-41.) When collapsed, the balloon 16 would generally approximate this diameter. (Sheehan Decl. at ¶ 68.) This dimension would be understood by one of ordinary skill as being sized and configured to enable the balloon to pass through a cannula into bone. (*Id*.)

As discussed above in Section VI.A.2, it is noted that the flow passage in claim 5 is identical to the flow passage in claim 1 except that the word "expand" is used instead of "inflate." However, the invalidating disclosure in Barbere is the same and the arguments set forth in claim 1 with respect to the flow passage element is hereby incorporated by reference. (Sheehan Decl. at ¶ 70.)

Finally, Barbere also anticipates ***dependent claim 7***. Claim 7 depends on claim 5 with an additional limitation that is identical to that of claim 3 (i.e., "*[a] device according to claim 5 wherein the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure*

in bone"). The claim is anticipated for the same reasons discussed above and the analysis of claim 5 and 3 is incorporated by reference. (Sheehan Decl. at ¶ 71.)

3. Barbere Anticipates Claims 9 And 11

Independent claim 9, a system claim, has all the limitations of the device of claim 5 plus the limitation of "a cannula."[6] As discussed with respect to claim 5, Barbere discloses passing the catheter assembly through a guide catheter, which is a cannula. (Ex. 1004 at 1:53-57; Sheehan Decl. at ¶¶ 67, 72, claim 9 chart.) The analysis of claim 5 is hereby incorporated by reference.

Claim 11 depends on claim 9 with an additional limitation that is identical to that of claim 3 and claim 7 (i.e., "[a] system according to claim 9 wherein the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone"). The claim is anticipated for the same reasons discussed above and the analyses of claims 3, 5, 7, and 9 are hereby incorporated by reference. (Sheehan Decl. at ¶ 72, claim 11 chart.)

C. Ground 3: Andersen Anticipates Claims 1, 3-5, 7-9, And 11-12

Andersen, issued on November 17, 1987, anticipates Claims 1, 3-5, 7-9, and 11-12. (Sheehan Decl. at ¶¶ 105-109.) Andersen discloses the well-known balloon catheter design of a "coaxial catheter with a flexible inner tubing and an outer

[6]See footnote 5 describing how claim 9 eliminates an element from claim 5.

tubing." (Ex. 1005 at 2:17-18.) Specifically, Andersen teaches that "[a]n inflatable balloon portion [blue] is formed at the distal end of the outer tubing [red] and is anchored to the distal end of the inner tubing [green]." (*Id.* at 2:19-22; Sheehan Decl. at ¶ 105.) Figure 4a shows the inflatable structure extending outside and beyond the outer catheter tube and at least partially enclosing the inner catheter tube. (Sheehan Decl. at ¶¶ 105, 108, claim 1 chart.) "The balloon portion is capable of expansion when fluid under pressure is directed into the space [orange] between the shaft and the inner tube, while the rigid portion of the shaft is not." (Ex. 1005 at 1:36-39; Sheehan Decl. at ¶ 105.)

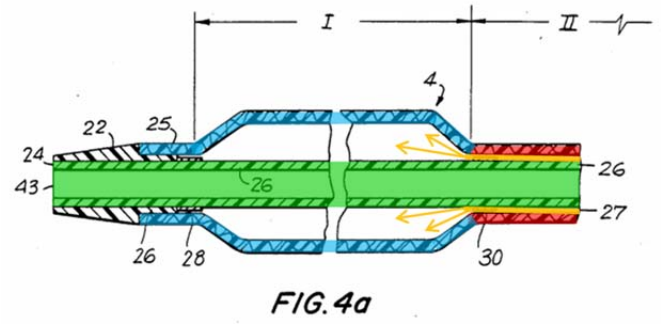


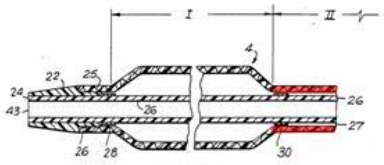
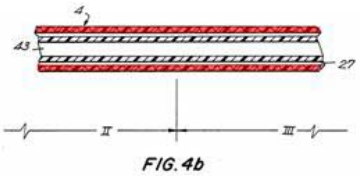
FIG. 4a

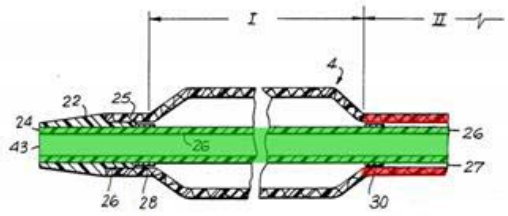
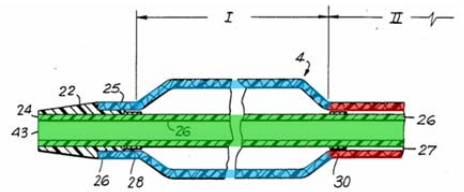
Claim 25 of Andersen is representative of the Andersen disclosure and is very similar to the claimed invention. Claim 25 claims a balloon catheter device comprising "an inner tube," "an outer tube in coaxial relation to the inner tube," with "the distal end of the inner tube extending beyond the distal end of the outer tube," and where the two tubes "are axially displaceable with respect to each other and form an annular space between the tubes." (Ex. 1005 at 10:14-48; Sheehan Decl. at ¶ 106.) In addition, Andersen notes that "[w]hile the invention has been disclosed in the setting of a catheter surgical for [sic] use, it will be clear

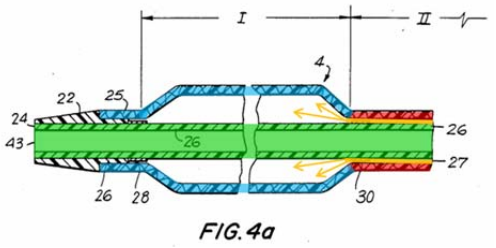
to those skilled in the art that the teachings of the invention have utility in other fields." (Ex. 1005 at 8:15-19; Sheehan Decl. at ¶ 107.)

1. Andersen Anticipates Claims 1, 3, And 4

The below chart (color added) shows how Andersen anticipates claim 1. (Sheehan Decl. at ¶ 108, claim 1 chart.) As discussed in Section V, the preamble of each claim directed toward intended use of the device or system in bone does not limit the claim. Nonetheless, as discussed in Ground 4 below, Reiley suggested that the Andersen catheter may be used in bone.

505 Patent	Andersen
1. A device for deployment into bone comprising an outer catheter tube having a distal end,	See Section V regarding claim construction.  FIG. 4a  FIG. 4b "The catheter of the present invention is a coaxial catheter with a flexible inner tubing and an outer tubing . . . ." (Ex. 1005 at 2:17-18.) Claim 25 recites "the distal end of the outer tube." (*Id.* at 10:23.)

505 Patent	Andersen
an inner catheter tube extending at least in part within the outer catheter tube and having a distal end region that extends at least in part beyond the distal end of the outer catheter tube,	 FIG. 4a "The catheter of the present invention is a coaxial catheter with a flexible inner tubing and an outer tubing . . . ." (Ex. 1005 at 2:17-18.) Claim 25 claims "an inner tube" with "the distal end of the inner tube extending beyond the distal end of the outer tube . . . ." (*Id*. at 10:16-23.)
an inflatable structure having a proximal end secured to the outer catheter tube and a distal end secured to the inner catheter tube, the inflatable structure extending outside and beyond the outer catheter tube and at least partially enclosing the inner catheter tube, and	 FIG. 4a See Figure 4A. "An inflatable balloon portion is formed at the distal end of the outer tubing and is anchored to the distal end of the inner tubing." (*Id*. at 2:19-22; *see also id*. at 4:53-56, 9:47-49.) Figure 4a shows the balloon extending outside and beyond the outer catheter tube and at least partially enclosing the inner catheter tube. (Sheehan Decl. at ¶¶ 105, 108, claim 1 chart.)

505 Patent	Andersen
a flow passage between the outer and inner catheter tubes communicating with the inflatable structure and adapted to convey an inflation medium into the inflatable structure to inflate the inflatable structure.	 FIG. 4a Claim 25 claims "the two tubes are axially displaceable with respect to each other and form an annular space between the tubes . . . . so that when fluid is introduced under pressure in to the annular space between the tubes, the balloon portions expands in diameter . . . ." (Ex. 1005 at 10:19-21, 10:34-37.) "As shown in FIG 4(*a*) the balloon has been expanded by the application of pressure to the fluid space between the inner wall of the catheter shaft 4 and the outer surface of inner tube 26." (*Id*. at 5:34-38.) "The balloon portion is capable of expansion when fluid under pressure is directed into the space between the shaft and the inner tube, while the rigid portion of the shaft is not." (*Id.* at 1:36-39; *see also id*. Fig. 4b; Sheehan Decl. at ¶ 108, claim 1 chart.)

Andersen also anticipates ***dependent claim 3***, which requires "[a] device according to claim 1 wherein the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone." (Sheehan Decl. at ¶ 108, claim 3 chart.) In addition to meeting the requirements

of claim 1 (discussed above and incorporated herein), Andersen discloses this additional element of Claim 3. (*Id*.)

As discussed above in Section VI.A.1, the 505 patent describes catheters that can be used in various applications including in vasculature and bone. (Ex. 1001 at 4:41-11:49 (deployment in bone), 11:50-12:25 (deployment in vasculature).) The 505 patent does not distinguish between a balloon adapted and configured to compress cancellous bone and one adapted and configured for compression of plaque in arteries. (Sheehan Decl. at ¶ 64.) Instead, the specification states that the expandable structure (irrespective of intended use) "is typically in the range of 2/1000ths to 25/1000ths of an inch [0.002 inch to 0.025 inch], or other thicknesses that can withstand pressures of up to, for example, 250-500 psi" and can be formed from a material "selected according to the therapeutic objectives surrounding its use," "including vinyl, nylon, polyethylenes, ionomer, polyurethane, and polyethylene tetraphthalate (PET)." (*Id.* at 12:64-13:4; Sheehan Decl. at ¶64.)

Like the inflatable structure of the 505 patent, Andersen indicates that its balloon portion may be formed from polyurethane. (*Compare* Ex. 1001 at 12:64-13:1 (identifying polyurethane) with Ex. 1005 at 5:52-54, 10:30 ("the filamentary material in the balloon portion"), 9:64-65 ("the filamentary material is embedded

in polyurethane"); Sheehan Decl. at ¶ 108, claim 3 chart.) Andersen also discloses that the balloon is capable of operation "at pressures of up to 20 atmospheres," which is approximately 294 psi, which is commensurate with the range of the 505 patent. (Ex. 1005 at 3:13-15; Sheehan Decl. at ¶ 108, claim 3 chart.) Additionally, Andersen discloses that its inflatable structure is 0.33 mm thick (1.33 mm unexpanded diameter minus 1.00 mm inside diameter) or approximately 0.013 inches thick, which is again commensurate with the range of the 505 patent. (Ex. 1005 at 5:41-45; Sheehan Decl. at ¶ 108, claim 3 chart.) Thus, just as the inflatable structure of the 505 patent is adapted and configured to compress cancellous bone, the Andersen device is likewise adapted and configured.

Andersen also anticipates ***dependent claim 4***. Dependent claim 4 requires "[a] device according to claim 1 wherein the inner catheter tube is moveable in relation to the outer catheter tube." (Sheehan Decl. at ¶ 108, claim 4 chart.) In addition to meeting the requirements of claim 1 (discussed above and incorporated herein), Andersen discloses this additional element of Claim 4. (*Id*.) For example, Claim 25 of Andersen states that the inner and outer "tubes are axially displaceable with respect to each other." (Ex. 1005 at 10:20-21; *see also id*. at 6:26-34, 4:53-56, 2:22-29; Sheehan Decl. at ¶ 108, claim 4 chart.)

2. Andersen Anticipates Claims 5, 7, And 8

Claim 5 includes all the limitations of claim 1 and further requires "*the inflatable structure being sized and configured for passage within a cannula into bone when the inflatable structure is in a collapsed condition.*" This, too, is disclosed in Andersen. (Sheehan Decl. at ¶ 108, claim 5 chart.) All of the arguments made regarding anticipation of Claim 1 are incorporated by reference. Andersen discloses that the balloon can be used in conjunction with a guide catheter, which is a cannula. (*Id*.) "The guide catheter which is also conventionally used in placing the balloon catheter in position in a blood vessel is not illustrated." (Ex. 1005 at 4:3-5.) As is typical, Andersen also discloses that the balloon is inflated once placed at the treatment site. (*Id.* at 1:1-11.) A person of ordinary skill would understand that, given the size of the vasculature, if the collapsed balloon of Andersen is sized and configured for passage within the cannula of Andersen for entry into the vascular system, the inflatable structure of Andersen is also sized and configured for passage within a cannula into bone. (Sheehan Dec. at ¶ 108, claim 5 chart.)

As discussed above in Section VI.A.2, it is noted that the flow passage in claim 5 is identical to the flow passage in claim 1 except that the word "expand" is used instead of "inflate." The invalidating disclosure in Andersen is the same and

the arguments set forth in claim 1 with respect to the flow passage element is hereby incorporated by reference. (Sheehan Dec. at ¶ 108, claim 5 chart.)

Andersen anticipates ***dependent claims 7 and 8***. Claim 7 depends on claim 5 with an additional limitation that is identical to that of claim 3 (i.e., "*[a] device according to claim 5 wherein the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone*"). Claim 8 depends on claim 5 with the additional limitation that is identical to that of claim 4 (*i.e.*, "*[a] device according to claim 5 wherein the inner catheter tube is moveable in relation to the outer catheter tube*.") These claims are anticipated for the same reasons discussed above and the analyses of claims 3, 4, and 5 are incorporated by reference. (Sheehan Dec. at ¶ 108, claims 7 and 8 charts.)

3. Andersen Anticipates Claims 9, 11, And 12

Independent claim 9, a system claim, has all the limitations of the device of claim 5 plus the limitation of "a cannula."[7] As discussed with respect to claim 5, Andersen discloses passing the catheter assembly through a guide catheter, which is a cannula. (Ex. 1005 at 6:29-33; Sheehan Dec. at ¶ 108, claims 5 and 9 charts.) The analysis of claim 5 is hereby incorporated by reference.

Claim 11 depends on claim 9 with an additional limitation that is identical

[7]See footnote 5 describing how claim 9 eliminates an element from claim 5.

to that of claim 3 and claim 7 (i.e., "*[a] system according to claim 9 wherein the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone*"). Similarly, claim 12 depends on claim 9 with an additional limitation that is identical to that of claim 4 and 8 (i.e., "*[a] system according to claim 9 wherein the inner catheter tube is moveable in relation to the outer catheter tube*.") Claims 11 and 12 are anticipated for the same reasons discussed above and the analyses of claims 3, 4, 5, 7, 8, and 9 are hereby incorporated by reference. (Sheehan Dec. at ¶ 108, claims 11 and 12 charts.)

D. Ground 4: The Combination Of Reiley And Andersen Renders Obvious Claims 1-12

As discussed above, Andersen anticipates claims 1, 3-5, 7-9, and 11-12. Further combining Andersen with Reiley renders obvious all the claims of the 505 patent. (Sheehan Decl. at ¶¶ 102-109.)

Under the Supreme Court's decision in *KSR Int'l Co. v. Teleflex Inc.*, a "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." 550 U.S. 398, 401 (2007). "Common sense teaches . . . that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle."

Id. at 420. "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill." *Id.* at 401. The reason to combine the cited prior art references is provided by the explicit and implicit teachings of the cited references themselves, the knowledge of one of ordinary skill in the art, and/or the nature of the problem(s) purportedly being solved. *See id.* at 407.

Reiley teaches using various types of balloons on balloon catheters to compress cancellous bone in vertebra (balloon-assisted vertebroplasty) and in long bones. Specifically, Reiley discloses "[a] balloon (10) for use in compressing cancellous bone and marrow (also known as medullary bone and trabecular bone) against the inner cortex of bones whether the bones are fractured or not." (Ex. 1006, Abstract; Sheehan Decl. at ¶ 102). As illustrated in Figures 2 and 8, Reiley teaches a typical balloon-assisted vertebroplasty procedure, e.g., advancing a catheter 16, with a balloon 10 (blue) at its distal end, through a cannula to compress cancellous bone (orange) upon expansion of the balloon in, for example, the vertebra (shown in

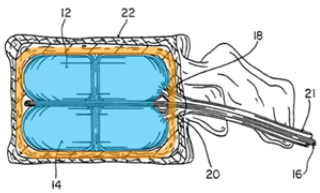


FIG. 2

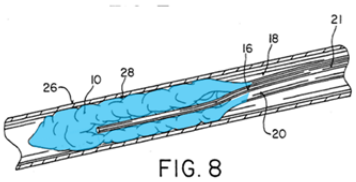


FIG. 8

Figure 2). (*Id.* at p. 19 ll. 7-12, p. 19 ll. 31-35, Figs. 2, 8; Sheehan Decl. at ¶ 102.)

Reiley recognized, however, that "[a] need has . . . arisen for improvements in the shape, construction and size of inflatable devices" to better compact the bone and prevent inadequate cavity formation, suggesting that spherically-shaped balloons may not provide adequate coverage. (Ex. 1006 at p. 3 ll. 6-7; Sheehan Decl. at ¶ 103.) Reiley solves the problem by proposing balloons of various shapes, sizes, and constructions that better approximate the shape of the bone cavity – including asymmetrical balloons. (Ex. 1006 at Figs. 1-20; Sheehan Decl. at ¶ 103.)

Focusing on the balloon design, Reiley addresses catheter design by way of background. Specifically, in the background section, Reiley praises the catheter design of intravascular catheters specifically identifying the Andersen catheter as "[a] particular improvement:"

> A particular improvement in the catheter art with respect to this patent, namely U.S. Patent 4,706,670 [Andersen], is the use of a coaxial catheter with inner and outer tubing formed and reinforced by continuous helical filaments. . . . Thus, the position of the inner and outer tubing can be adjusted as needed to keep the balloon in a desired position in the blood vessel.

(Ex. 1006 at p. 4 ll. 21-34.) Reiley also suggests that Andersen should be

consulted for balloon materials. (*Id.* at p. 10 ll. 12-14; Sheehan Decl. at ¶ 104.) Moreover, Reiley states that "[c]urrent medical balloons can compress bone," expressly teaching that current medical balloons can be used in bone.[8] (Ex. 1006 at p. 5 ll. 22-33; Sheehan Decl. at ¶ 104.)

Accordingly, as explained in the Sheehan Declaration, a person of ordinary skill in the art would have had a reason, basis, or motivation to combine Reiley with Andersen, at a minimum, based upon the explicit teaching in Reiley itself. Sheehan Decl. at ¶ 108.) Indeed, Reiley expressly teaches to use the Andersen catheter in combination with the Reiley asymmetrical balloons to compress cancellous bone. (Ex. 1006 at p. 4 ll. 21-33; Sheehan Decl. at ¶ 108.) Simply put, a person of ordinary skill in the art reading the Reiley reference would be taught to compress cancellous bone by using the Reiley asymmetrical balloons on the Andersen catheter. (Sheehan Decl. at ¶ 108.)

As discussed above in Section VI.C., Andersen teaches all the elements of ***independent claims 1, 5, and 9***; however, Andersen focuses on vascular applications, not use in bone. But Reiley, which focuses on use of balloon

[8] While Reiley notes that "generally" balloons may not provide "adequate cavity formation," this has no relevance to the elements of claims 1-12. (Ex. 1006 at p. 5 ll. 22-33.)

catheters in bone, teaches that the Andersen balloon catheter can be used in the procedure of Reiley (in bone). (Sheehan Decl. at ¶¶ 103-104, 108.) As discussed in Section V above, the preambles are not claim limitations given that the claims describe a structurally complete invention (which is why Andersen anticipates). Nonetheless, the combination of Reiley and Andersen renders claims 1, 5, and 9 obvious to the extent not anticipated.

In addition, claim 5 further requires "*the inflatable structure being sized and configured for passage within a cannula into bone when the inflatable structure is in a collapsed condition.*" Similarly, independent claim 9, a system claim, has all the limitations of the device of claim 5 plus the limitation of "a cannula."[9] In addition to the fact that Andersen discloses a cannula as addressed in the previous section, a cannula is also disclosed in Reiley. (Sheehan Decl. at ¶ 108, claim 5 chart.) "Fig. 8 shows a deflated balloon 10 being inserted through a cannula 26 into bone. The balloon in cannula 26 is deflated and is forced through the cannula by exerting manual force on the catheter 21 which extends into a passage 28 extending into the interior of the bone. The catheter is slightly flexible but is sufficiently rigid to allow the balloon to be forced into the interior of the bone where the balloon is then inflated by directing fluid into tube 88 whose

[9]See footnote 5 describing how claim 9 eliminates an element from claim 5.

outlet ends are coupled to respective parts 12 and 14." (Ex. 1006 at p. 19 ll. 7-16.) Thus, as explained in the Sheehan Declaration, the Andersen catheter could also be passed through the cannula of Reiley when used in bone. (Sheehan Decl. at ¶ 108, claim 5 chart.)

As discussed above, ***dependent claims 3, 7, and 11*** (which depend on claims 1, 5, and 9 respectively) require that "the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone." As discussed above in Section VI.C.1, the balloon of Andersen is of an appropriate adaptation and configuration to compress cancellous bone as claimed. (*See also* Sheehan Decl. at ¶ 108, claims 3, 7, and 11 charts.) Furthermore, Reiley is specifically directed toward a balloon that "has a shape and size to compress at least a portion of cancellous bone to form a cavity in the cancellous bone." (Ex. 1006 at abstract.) Likewise, with regard to ***dependent claims 4, 8, and 12***, as discussed above in Section VI.C.1, Andersen teaches that the inner and outer catheter tubes are moveable in relation to each other as claimed. (*See also* Sheehan Decl. at ¶ 108, claims 4, 8, and 12 charts.)

Dependent claims 2, 6, and 10, which depend on claims 1, 5, and 9 respectively, relate to an asymmetrically shaped balloon. Specifically, those claims each require that "the outer catheter tube has an axis, and wherein

inflation of the inflatable structure is asymmetric about the axis." As discussed above, Reiley teaches use of asymmetrically-shaped balloons in bone. (Sheehan Decl. at ¶ 103.) For example, as explained in the Sheehan Declaration (paragraph 108, claim 2 chart), Figure 12 from Reiley depicts a balloon with asymmetrical inflation about the axis of the catheter tube as claimed: "Fig. 12 shows a balloon 140 which is also kidney shaped and has a tube 142 for directing an inflatable liquid into the tube for inflating the balloon." (Ex. 1006 at p. 22 ll. 19-22; *see also id*. at Figs. 10-11, 14-15, and 17-18.) Moreover, given that Reiley praises the Andersen cathether design, a person of ordinary skill in the art would understand to use the asymmetrically-shaped balloons of Reiley with the Andersen catheter rendering claims 2, 6, and 10 obvious. (Sheehan Decl. at ¶ 108.)

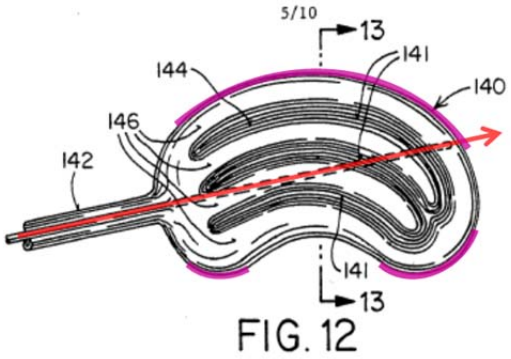


FIG. 12

Accordingly, in view of Reiley and Andersen, all of the claims of the 505 patent are obvious and should not have issued.

E. Ground 5: Valley Anticipates Claims 1-12

As shown below, Valley, which was filed June 7, 1995, and issued June 16, 1998, is prior art under 35 U.S.C. § 102(e) and anticipates every claim of the 505

patent. (Sheehan Decl. at ¶¶ 74-93.)

Valley discloses several embodiments of a cardiac access system that uses a catheter with an inflatable member on its distal end to block, for example, blood flow in an artery. (Ex. 1007 at 16:46-54; Sheehan Decl. at ¶ 74.) As shown, e.g., in Figure 8A, the catheters have a coaxial construction with "the inner tube 402 [green] and the outer tube 404 [red] [that] are axially movable with respect to one another." (Ex. 1007 at 24:29-30; Sheehan Decl. at ¶ 75.) As shown, the balloon (blue) extends outside and beyond the outer tube, at least partially enclosing the inner tube. (*Id.*) There is "an annular space between the two tubes providing a balloon inflation lumen 416 [orange]," which creates a flow passage to inflate the balloon 410 with fluid. (*Id.*; Ex. 1007 at 24:37-38.)

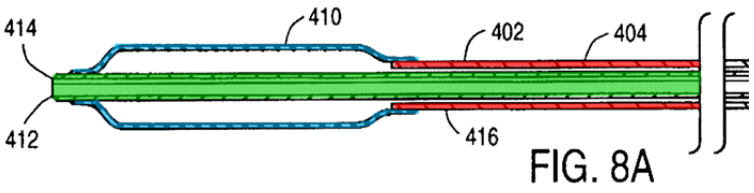


FIG. 8A

The proximal end of the balloon is secured to the outer tube and its distal end is secured to the inner tube with the inner tube extending beyond the distal end of the outer tube. (*See id.* Ex. 1007 at Fig. 8A.) The proximal balloon neck is "sealingly attached to the outer tube 504

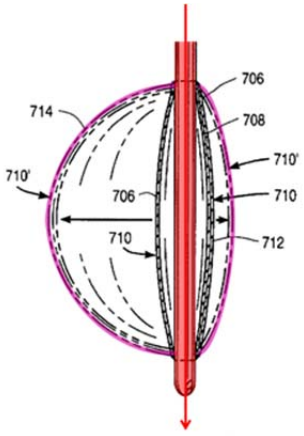


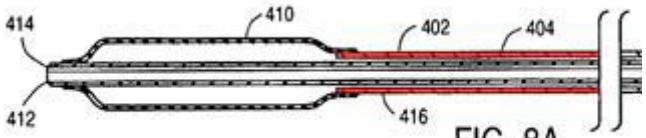
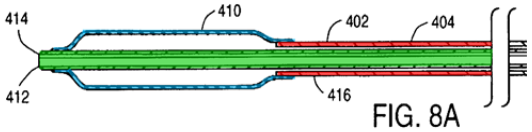
FIG. 14

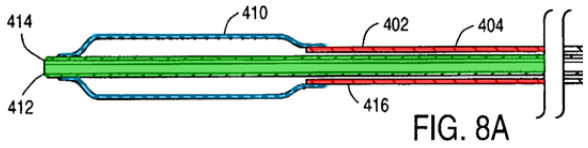
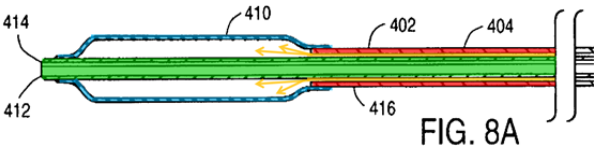
and the distal balloon neck 520 [is] sealingly attached to the inner tube 502 of the catheter 500 so that the balloon inflation lumen 516 communicates with the interior of the balloon 510." (*Id.* at 26:7-13; Sheehan Decl. at ¶ 76.)

In Figure 14, for example, the balloon inflates asymmetrically about the axis of the outer catheter to address the varying geometries of the arteries. (Ex. 1007 at 31:6-10; Sheehan Decl. at ¶ 77.)

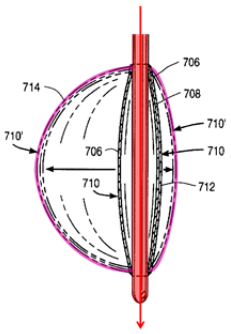
1. Valley Anticipates Claims 1-4

As shown in the claim chart below (color added), Valley anticipates claims 1 and 2. Valley also anticipates claims 3 and 4, which depend on claim 1.

505 Patent	Valley
1. A device for deployment into bone comprising an outer catheter tube having a distal end,	See Section V regarding claim construction.  FIG. 8A "The outer tube 404 fits coaxially around the inner tube 402 . . . ." (Ex. 1007 at 24:35-36; *see also id*. at 24:-25:25.) Figure 8A of Valley depicts an "outer tube 404" having a distal end. (Sheehan Decl. at ¶ 79, claim 1 chart.)
an inner catheter tube extending at least in part within the outer catheter tube and having a distal end region that extends at least in part beyond the distal end	 FIG. 8A *See* Figure 8A and Sheehan Decl. at ¶ 79. "The outer tube 404 fits coaxially around the inner tube 402 . . . ." (*Id*. at 24:35-36; *see also id*. at

505 Patent	Valley
of the outer catheter tube,	24:27-25:25.) "The catheter preferably has an inner lumen extending within the catheter to a port in the distal end of the catheter." (*Id*. at 4:46-47.)
an inflatable structure having a proximal end secured to the outer catheter tube and a distal end secured to the inner catheter tube, the inflatable structure extending outside and beyond the outer catheter tube and at least partially enclosing the inner catheter tube, and	 FIG. 8A *See* Figure 8A and Sheehan Decl. at ¶ 75. "Expandable means are disposed near the distal end of the shaft proximal to the opening at the distal end . . . ." (*Id*. at 7:13-16.) "The proximal balloon neck 118 is bonded to the distal end of the outer tube 104 in a lap joint. The bond between the proximal balloon neck 118 and the outer tube 104 and the bond between the distal balloon neck 120 and the inner tube 102 can be formed by adhesive bonding, by solvent bonding or by heat bonding on the materials chosen for each component." (*Id.* at 21:13-20.)
a flow passage between the outer and inner catheter tubes communicating with the inflatable structure and adapted to convey an inflation medium into the inflatable structure to inflate the inflatable structure.	 FIG. 8A "The outer tube 404 fits coaxially around the inner tube 402 with an annular space between the two tubes providing a balloon inflation lumen 416." (*Id*. at 24:35-38.) "[T]he endovascular device has an inflation lumen extending through the shaft from the proximal end to the interior of the balloon, and means connected to the proximal end of the inflation lumen for delivering an inflation fluid to the interior of the balloon." (*Id.* at 8:40-45; 22:24-

505 Patent	Valley
	36.)

505 Patent	Valley
2. A device according to claim 1 wherein the outer catheter tube has an axis, and wherein inflation of the inflatable structure is asymmetric about the axis.	Valley discloses a device according to claim 1 as described above. (*See id.* at Figs. 14-17, 18A, 19A.) "The occlusion balloon has a symmetrical deflated profile, shown by solid lines 710. The asymmetrical inflated profile, shown by phantom lines 710', is achieved by molding the occlusion balloon with a thicker wall 712 on one side of the balloon 710. . . . When the occlusion balloon 710' is inflated, . . . the balloon more easily expands to its full potential, resulting in the intended eccentric inflated balloon profile 710'." (*Id*. at 31:6-16; *see also* Sheehan Decl. at ¶ 79, claim 2 chart).  FIG. 14

Valley also anticipates ***dependent claim 3***, which requires "*[A] device according to claim 1 wherein the inflatable structure is adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone*." Valley discloses an inflatable structure capable of compressing cancellous bone as claimed. Similar to the disclosure in the 505 patent, Valley discloses that "an inflatable balloon made of a nondistensible balloon material, such as polyethylene, polyethylene terephthalate [PET] polyester, polyester copolymers,

polyamide or polyamide copolymers." (Compare Ex. 1007 at 8:29-33 *with* Ex. 1001 at 12:64-13:4; Sheehan Decl. at ¶ 83.) As discussed above, a person of ordinary skill in the art would understand that the disclosure of nondistensible materials, including polyethylene and PET, for the Valley balloons is consistent with balloons that can compress cancellous bone as disclosed in the 505 patent. (Sheehan Decl. at ¶ 83.) As such, the inflatable balloon of Valley is "adapted and configured to compress cancellous bone upon inflation of the inflatable structure in bone." (Sheehan Decl. at ¶¶ 81-83.)

Dependent claim 4 requires "*[A] device according to claim 1 wherein the inner catheter tube is moveable in relation to the outer catheter tube*." In addition to meeting the requirements of claim 1 (discussed above and incorporated herein), Valley discloses that "the inner tube 402 and the outer tube 404 are axially movable with respect to one another" and "the user can adjust the position of the inner tube 402 relative to the outer tube 404 to increase or decrease the length of the occlusion balloon 410 when inflated." (Ex. 1007 at 24:27-30, 25:1-4; Sheehan Decl. at ¶¶ 84-85.) Figures 8A-C show how the inner catheter tube is moveable in relation to the outer catheter tube. (Ex. 1007 at 25:8-46; Sheehan Decl. at ¶¶ 84-85.)

2. Valley Anticipates Claims 5-8

As discussed above, ***claim 5*** includes all the limitations of claim 1 plus the additional requirement that *"the inflatable structure being sized and configured for passage within a cannula into bone when the inflatable structure is in a collapsed condition."* This, too, is disclosed in Valley. (Sheehan Decl. at ¶ 86.)

Valley's "deflated balloon" is sized and configured so that it may be folded and more easily inserted through, e.g., "an introducer sheath or a dual function arterial cannula and introducer sheath." (Ex. 1007 at 22:7-10; Sheehan Decl. at ¶ 87.) Valley also describes its catheter as having an external diameter within the range of 8-23 French (Charriére scale), preferably in the range of 8-12 French including embodiments where the outer catheter tube has an external diameter of 3.4-3.5 mm or 3.2-3.3 mm. (Ex. 1007 at 20:41-48.) A person of ordinary skill would understand that if the deflated balloon of Valley is sized and configured to pass within a cannula for entry into the vascular system, it is also sized and configured to pass within a cannula into bone. (Sheehan Decl. at ¶ 88.)

As discussed previously, the only other difference between claim 1 and claim 5 is the "expand" versus "inflate" language in the flow passage claim element. The arguments set forth in claim 1 with respect to the flow passage element apply equally to claim 5 and are hereby incorporated by reference.

(Sheehan Decl. at ¶ 89.)

Valley anticipates ***dependent claims 6, 7, and 8***. Claims 6, 7, and 8 depend on claim 5 with additional limitations that are identical to those of claims 2, 3, and 4. These claims are anticipated for the same reasons discussed above and the analyses of claims 2-5 are hereby incorporated by reference. (Sheehan Decl. at ¶¶ 90-91.)

3. Valley Anticipates Claims 9-12

Independent claim 9, a system claim, has all the limitations of the device of claim 5 plus the limitation of "a cannula."[10] As discussed with respect to claim 5, Valley discloses inserting its balloon through, e.g., "an introducer sheath or a dual function arterial cannula and introducer sheath." (Ex. 1007 at 22:7-10; Sheehan Decl. at ¶¶ 87, 92.) The analysis of claim 5 is hereby incorporated by reference.

Claims 10, 11, and 12 depend from Claim 9 with additional limitations that are identical to that of claims 2, 3, and 4, respectively. Claims 10, 11, and 12 are anticipated for the same reason discussed above for Claims 2, 3, and 4 respectively, and the analyses of claim 9 and claims 2-4 are hereby incorporated by reference. (Sheehan Decl. at ¶ 92.)

Accordingly, in view of Valley, all of the claims of the 505 patent are

[10]See footnote 5 describing how claim 9 eliminates an element from claim 5.

anticipated and should not have issued.[11]

F. Ground 6: The Combination Of Pathak And Valley Renders Obvious Claims 2, 4, 6, 8, 10, And 12

For the reasons discussed in Section VI.A, Pathak anticipates independent claims 1, 5, and 9, as well as dependent claims 3, 7, and 11. The combination of Pathak and Valley renders obvious the remaining claims (dependent claims 2, 4, 6, 8, 10, and 12), which simply claim two known design options for use in such catheters (asymmetric balloon design and moveable inner and outer catheter tubes). (Sheehan Decl. at ¶¶ 94-95.)

Pathak and Valley both relate to the use of inflatable balloon catheters for similar applications. (Sheehan Decl. at ¶ 95.) Both references describe catheters that are ubiquitous in the prior art, specifically, catheters having two concentric tubes with the inner tube extending distally beyond the outer tube and an inflatable balloon distally attached to the inner tube and proximally attached to the outer tube with a flow passage between the tubes. (*Id*.; Ex. 1003 at p. 21; Ex. 1007 at 26:7-13.) Thus, a person of ordinary skill in the art would have had a

[11] Valley also renders all claims of the 505 patent obvious because it discloses all of the structural claim elements and it would be obvious to use the Valley catheter in bone. (Sheehan Decl. at ¶¶ 110-114.)

reason, basis, or motivation to combine Pathak and Valley. (Sheehan Decl. at ¶¶ 95, 97-98.) As explained below it would have been obvious to adapt the catheter in Pathak to include the additional features of Valley as claimed in the 505 patent.

1. The Combination Of Pathak And Valley Renders Obvious Claims 2, 6, And 10

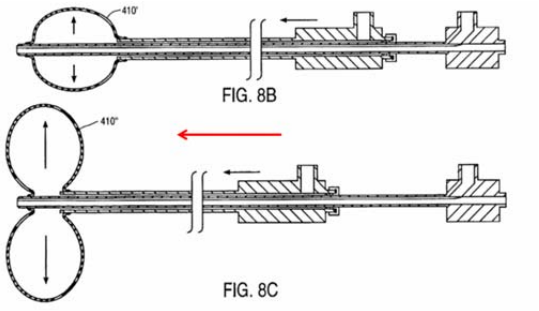
Dependent claims 2, 6, and 10 claim the device of the independent claim, which includes an inflatable structure "*wherein the outer catheter tube has an axis, and wherein inflation of the inflatable structure is asymmetric about the axis*." As discussed above in Section VI.E.1, Valley specifically discloses using asymmetric balloon configurations as well as all the elements of the independent claims. (Ex. 1007 at 31:6-10, Figs. 14, 16-17, 18A-B, 19A-D, 20A-D, 21-22, 25B, 35A-C.) Indeed, an asymmetric balloon configuration on a balloon catheter was a well-known design element in the prior art. (Sheehan Decl. at ¶ 96.) It would have been obvious to a person of ordinary skill to make use of the asymmetrical balloons of Valley in Pathak. (Sheehan Decl. at ¶ 97.)

Indeed, Pathak discloses that asymmetry is desirable. (Ex. 1003 at p. 37 (disclosing the use of polymer tubes that "may include perforations or pores to provide symmetrical or asymmetrical expansion of the polymeric material").) Thus, it would have been obvious to a person of ordinary skill in the art to make

use of the asymmetrical balloons taught in Valley for use in Pathak. (Sheehan Decl. at ¶ 97.) Accordingly, there is a reason, basis, or motivation for a person of ordinary skill in the art contemplating Pathak's already disclosed asymmetry to combine the asymmetrical balloon configurations of Valley with Pathak. (Sheehan Decl. at ¶ 98.)

2. The Combination Of Pathak And Valley Renders Obvious Claims 4, 8, And 12

Dependent claims 4, 8, and 12 claim the device of the independent claim "*wherein the inner catheter tube is moveable in relation to the outer catheter tube*." As discussed above in Section VI.E.1, Valley discloses a balloon catheter in which the inner tube and the outer tube "are axially movable with respect to one another." (Ex. 1007 at 24:27-30; Sheehan Decl. at ¶ 99.) Specifically, "the user can adjust the position of the inner tube 402 relative to the outer tube 404 to increase or decrease the length of the occlusion balloon 410 when inflated." (Ex. 1007. at 25:1-4, 24:27-30, 24:35-44.)



This was a design element disclosed in the prior art. (Sheehan Decl. at ¶ 100.) This design element allows the user to adjust the length and shape of the inflatable balloon by adjusting the position of the inner tube relative to the outer

tube. (*Id*.; Ex. 1007 at 25:1-4; *Id.*) Specifically, it "allows the user to select the inflated diameter of the balloon and the axial length of the balloon . . . ." (Ex. 1007 at 25:37-39; Sheehan Decl. at ¶ 100.) Pathak also contemplates a "'customizable' deployment geometry." (Ex. 1003 at p. 36; Sheehan Decl. at ¶ 101.) Accordingly, a person of ordinary skill would have a reason, basis, or motivation to modify the balloon catheter of Pathak to make the inner and outer catheter tubes moveable with respect to each other in order to customize the length and shape of the balloon as Pathak suggests. (Sheehan Decl. at ¶ 101.)

Accordingly, in view of Pathak and Valley, claims 2, 4, 6, 8, 10, and 12 of the 505 patent should not have issued.

VII. SECONDARY CONSIDERATIONS

Stryker is not aware of any secondary considerations that would tend to show non-obviousness (e.g., commercial success, long-felt but unresolved needs, failure of others to solve the problem that the inventor solved, unexpected results, copying of the invention by others, and industry recognition or expressions of disbelief by experts in the field of the claimed invention, etc.) (Sheehan Decl. at ¶ 115.)

VIII. CONCLUSION

For the above reasons, Petitioner respectfully requests institution of *inter partes* review of claims 1-12 of the 505 patent.

Respectfully submitted,

Dated: September 19, 2014

By: /Sandra A. Frantzen/

Sandra A. Frantzen
Registration No. 48,799
McANDREWS, HELD & MALLOY, LTD.
500 West Madison St., Suite 3400
Chicago, IL 60661
Telephone: (312) 775-8000

CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 6,623,505 and Exhibits 1001-1016 were served on September 19, 2014, via pre-paid, overnight Federal Express to the correspondence address of record for the subject patent pursuant to 37 C.F.R. § 42.105:

Ascenda Law Group, PC
84 W. Santa Clara St.
Suite 550
San Jose, CA 95113

/Sandra A. Frantzen/
Sandra A. Frantzen
Registration No. 48799