Filed on behalf of Stryker Corporation

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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 IPR2014-01535
Patent 6,280,456 B1

PETITION FOR *INTER PARTES* REVIEW

TABLE OF CONTENTS

EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 6,280,456 ("the 456 patent")
1002	Declaration of Neil J. Sheehan with *curriculum vitae* ("Sheehan Decl.")
1003	WO 94/24962 (published Nov. 10, 1994) ("Pathak")
1004	WO 95/20362 (published Aug. 3, 1995) ("Reiley")
1005	U.S. Patent No. 4,706,670 (issued Nov. 17, 1987) ("Andersen")
1006	U.S. Patent No. 5,766,151 (filed Jun. 7, 1995) (issued Jun. 16, 1998) ("Valley")
1007	U.S. Patent No. 4,024,873 (issued May 24, 1977) ("Antoshkiw")
1008	U.S. Patent No. 5,480,400 (issued Jan. 2, 1996) ("Berger")
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 (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	U.S. Patent No. 4,313,434 (issued Feb. 2, 1982)
1016	U.S. Patent No. 4,562,598 (issued Jan. 7, 1986)
1017	U.S. Patent No. 5,372,138 (issued Dec. 13, 1994)
1018	European Patent No. 0405831 (published Jun. 7, 1995) ("Barbere")
1019	Excerpts from the prosecution history of the 456 patent

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42, Stryker Corporation respectfully petitions for *inter partes* review ("IPR") of claims 1-10 of U.S. Patent No. 6,280,456 ("the 456 patent") (Ex. 1001), which issued on August 28, 2001, and is purportedly assigned to Orthophoenix, LLC ("Orthophoenix" or "Patent Owner"). The earliest application to which the 456 patent claims benefit is U.S. Patent No. 5,972,015, which was filed August 15, 1997. Stryker has used the August 15, 1997, priority date for purposes of this Petition.[1]

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 456 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 ("the litigation"). The 456 patent claims priority to U.S. Patent No. 5,972,015 ("the 015 patent"). Stryker filed a petition for IPR of U.S. Patent No. 6,623,505 which also claims priority to the 015 patent. *Stryker Corporation v. Orthophoenix, LLC*, IPR2014-01519 (PTAB Sept. 19, 2014). Two pending U.S. patent applications also claim priority to the 015 patent: U.S. Patent Appl. No. 12/869,101 (filed Aug. 26,

[1] Stryker is using this priority date only for purposes of this *inter partes* review.

2010) and U.S. Patent Appl. No. 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.

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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 456 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 1-10 of the 456 patent on the grounds set forth below and requests that each of the claims be found unpatentable. An explanation of how claims 1-10 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 1-10 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 November 10, 1994 (Ex. 1003);
- WO 95/20362 ("Reiley"), published August 3, 1995 (Ex. 1004);
- U.S. Patent No. 4,706,670 ("Andersen"), issued November 17, 1987 (Ex 1005);
- U.S. Patent No. 5,766,151 ("Valley"), which was filed June 7, 1995, and issued June 16, 1998, and is prior art under § 102(e) (Ex. 1006); and

- U.S. Patent No. 4,024,873 ("Antoshkiw"), issued May 24, 1977 (Ex. 1007).

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 456 Patent
1	Claims 1-4 are anticipated by Pathak under 35 U.S.C. § 102 (b).
2	Claims 1-7 are rendered obvious in view of Pathak and Reiley under 35 U.S.C. § 103.
3	Claims 1-7, 9, and 10 are rendered obvious in view of Reiley and Andersen under 35 U.S.C. § 103.
4	Claims 1-10 are rendered obvious in view of Reiley and Valley under 35 U.S.C. § 103.
5	Claims 1-8 are rendered obvious in view of Reiley and Antoshkiw under 35 U.S.C. § 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 456 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 configuration) for deployment in interior body regions have been used by

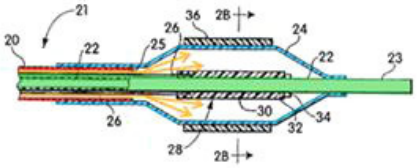
physicians for over a hundred years for a variety of applications. (Sheehan Decl. at ¶¶ 13-18.) For example, such balloon catheters have been used in the urinary tract, in the vasculature, e.g., for angioplasty and stent delivery, and in bone for compressing cancellous bone and adjusting fractures. (*Id*. at ¶¶ 13-19.)

With the increase in angioplasty and stent implantation procedures, there has been a proliferation of balloon catheter designs. (*Id*. at ¶ 15; Ex. 1003, 29; Ex. 1018,1:53-2:13; Ex. 1005, 1:23-27.) As the Sheehan Declaration explains, skilled artisans designing balloon catheters often considered angioplasty and other cardiovascular catheters when contemplating catheter designs. (Sheehan Decl. at ¶ 15.) Indeed, as one patent explained, "[b]alloon catheters are not limited to their use in 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."[2] (Ex. 1009, 1:19-23.)

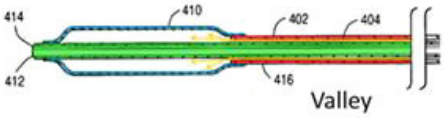
As the Sheehan Declaration explains, by the early 1990s, balloon catheters having a coaxial design were ubiquitous in the art. (Sheehan Decl. at ¶ 20.) Specifically, as shown by the few examples below, it was well known to use a balloon catheter design with two concentric tubes where the inner tube (green) extended distally beyond the outer tube (red) with an expandable structure such

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

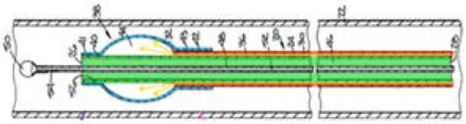
as a balloon (blue) distally attached to the inner tube and proximally attached to the outer tube (as claimed in the 456 patent) and where the distal end region of the inner catheter tube is enclosed within the expandable structure. (*Id*.) As shown in the figures, references such as Pathak, Valley, Antoshkiw, Andersen, and Barbere all disclose the use of such catheters in various applications including bone.



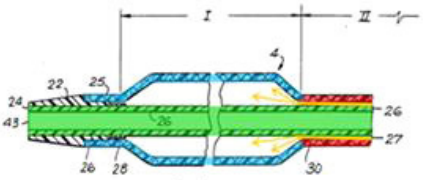
Pathak



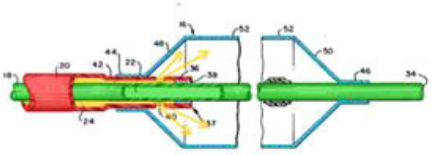
Valley



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. 1007 at 3:17-18; Sheehan Decl. at ¶ 21.) 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. 1007 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; Sheehan Decl. at ¶ 22.)

It was also known that the proximal and distal ends of the balloon could be inverted. For example, Antoshkiw teaches that "the inflated balloon 38 can be altered in configuration, as desired, by merely shifting the relative axial position between the inner tube 24 and the outer tube 30 as depicted in FIG. 3 where the inner tube has been withdrawn rearwardly toward the outer tube thereby causing the affixed balloon to deform outwardly into engagement with the walls of the vessel 22." (Ex. 1007 at 3:53-59, Figs. 2-3; *see also id.* at 1:26-29, 1:47-52; Sheehan Decl. at ¶¶ 23-24.) Likewise, Valley disclosed that it was known to use balloons of varying shapes and configurations including balloons where the proximal and distal ends of the balloon were inverted. (Ex. 1006 at 25:27-42; *see also* Ex. 1017 at Fig. 18d; Sheehan Decl. at ¶ 25.)

It was also known that balloon catheters could be used across applications including in bone. (Sheehan Decl. at ¶¶ 13-19, 27.) For example, the Pathak publication, which disclosed balloon catheters used for implanting polymeric materials such as stents, focused on vascular applications but also explained how the catheter could be used "[i]n other therapeutic applications, (i.e., trachial [sic], urinary, bronchial, bone lumens and the like)." (Ex. 1003 at 15; *see also* Sheehan Decl. at ¶ 17; Ex. 1011, Abstract, 4:46-47 ("[C]atheters used for balloon angioplasty [ ] are ideal for use in the present invention."); Ex. 1012, 3:10-14.)

Indeed, prior to the 456 patent, it was known that balloon catheters could be used to create cavities in bone and compress cancellous bone. (Sheehan Decl. at ¶ 27.) For example, U.S. Patent No. 5,108,404 (Ex. 1010) to Scholten discloses methods in which a physician can form a cavity in bone (including vertebra) using a balloon catheter as part of a vertebroplasty procedure (sometimes called balloon-assisted vertebroplasty or kyphoplasty). (*Id*.) Specifically, Scholten describes "forming an incision in the body and penetrating the bone having the fracture with instruments including a guide pin and a cannula, drilling the bone marrow of the bone . . . following which an inflatable device, such as an expandable balloon, is inserted in the cavity and inflated. The expansion of the balloon causes a compacting of the bone marrow . . . to further enlarge the cavity. (Ex. 1010, 2:9-19, Fig. 21 (reproduced above).)

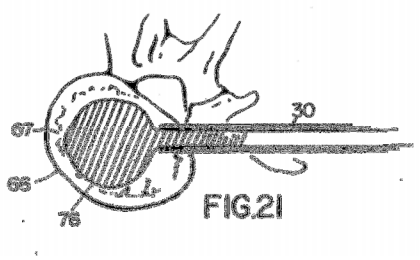


FIG.21

Likewise, the Reiley reference (published in 1995) described balloon catheters that could be used in balloon-assisted vertebroplasty and in treating fractures in long bones. (Ex. 1004 at Abstract, p. 6 ll. 17-21, p. 19 ll. 17-35, pp. 24-28; Sheehan Decl. at ¶¶ 18, 27, 30.) Reiley acknowledged that using balloons to compact cancellous bone was already known in the art (Ex. 1004 at p. 1 l. 20 – p. 3 l. 9), but Reiley sought to improve the effectiveness of the compaction by

incorporating additional engineering features into the balloons. (*See e.g., id*.) Notably, although Reiley focused on methods of using balloon catheters for treating bone, Reiley praised the design of balloon catheters used in angioplasty including the coaxial catheter design described in the Andersen patent (*see* Andersen figure on page 6), which Reiley described as a "coaxial catheter with inner and outer tubing . . . . " (*Id.* at p. 4 ll. 21-25.) After discussing the purported state of the art regarding angioplasty balloon catheters, Reiley disclosed what was well known in the art, that "[c]urrent medical balloons can compress bone . . . ." (*Id*. at p. 5 l. 29.)

Moreover, it was well known that the vascular catheters could be used in other fields for similar purposes. (*See* Sheehan Decl. at ¶¶ 15-18.) For example, Levy states, "[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 at 1:19-23.) U.S. Patent No. 5,547,378 to Linkow, a patent disclosing an inflatable balloon used to "create[] additional bone" in a sinus cavity, notes that "[t]here are catheters used for balloon angioplasty which are ideal for use in the present invention." (Ex. 1011 at 4:46-47, Abstract.) Likewise, U.S. Patent No. 5,849,014 to Mastrorio describes creating a cement plug in a bone

cavity by using an angioplasty balloon catheter that presses against the interior bone wall. (Ex. 1012 at 3:10-14 ("In an exemplary embodiment, the conduit [] and inflatable body [] are provided by a catheter of the type useful in angioplasty procedures.").)

In summary, balloon catheters of the type claimed in the 456 patent had a long history of use and their applicability to the treatment of bone was known at the time of filing. (Sheehan Decl. at ¶ 32.) Moreover, as of August 1997, a person of ordinary skill in the art designing a balloon catheter for use in bone would have known to use or consider a vascular balloon catheter. (*Id*.)

B. Brief Description Of The 456 Patent

The 456 patent, entitled "Methods For Treating Bone," is directed to "expandable structures, which, in use, are deployed in interior body regions of humans and other animals." (Ex. 1001 at 1:9-11.) Specifically, the 456 specification acknowledges that it was known to use balloon catheters for various applications including bone but identifies problems arising from using such balloons in asymmetric geometries:

> 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 [sic] 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.

(*Id*. at 1:14-26.)

The 456 patent specification purports to solve this asymmetry problem with asymmetrically-shaped balloons that are tailored to the application. Examples of such shapes are shown in a vertebra and an artery:

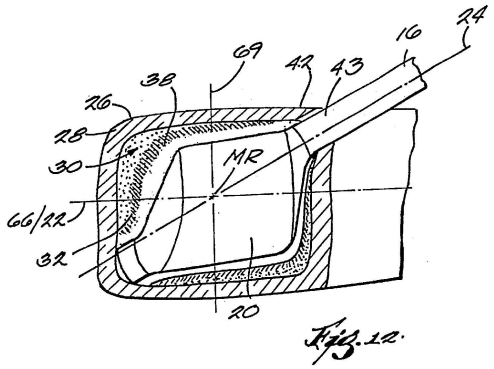


Fig. 12.

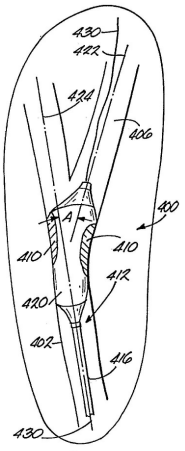
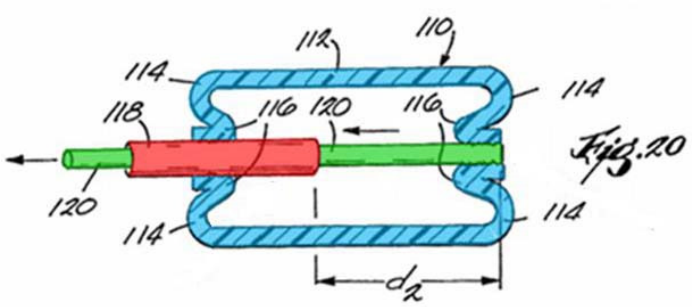


Fig. 23

(*Id*. at Figs. 12, 23.)

The specification also discusses balloons where the proximal and distal ends of the balloon are inverted so that the balloon is non-spherical. (*Id*. at 9:53-

10:61.) An example of such a balloon (with inverted ends 114) is shown in Figure 20 below.



While the specification focuses on balloon designs to address the asymmetry issue, the specification identifies certain catheter designs, including those that were known in the prior art. (Sheehan Decl. at ¶ 37.) For example, as shown above, 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 – a design that was well known in the art. (*Id*. at 10:16-31.)

C. Summary Of The Prosecution History Of The 456 Patent

The application for the 456 patent was originally filed with claims 1-36. (Ex. 1019 at pp. 40-48.) By way of preliminary amendment, claims 2-36 were cancelled. (*Id*. at p. 62.) Original claim 1 was directed toward a device with an asymmetric balloon and is reproduced below as originally presented.

> 1. A device for deployment into an interior body region comprising
>
> a catheter tube extending along a first axis, and

> a structure carried by the catheter tube comprising a body adapted to assume a collapsed geometry for deployment into the interior body region and an expanded geometry for use within the interior body region, the expanded geometry being oriented about a second axis not aligned with the first axis.

(*Id*. at p. 40.)

Original claim 1 was rejected as being anticipated by U.S. 5,766,151 to Valley et al. (Ex. 1006). (Ex. 1019 at p. 66.) The Examiner indicated that "Valley et al. disclose[s], in figs. 14, 17 and 19, a device comprising a catheter tube 700 extending along a first axis, and a structure or a balloon 710 which has a[n] expanded geometry being oriented about a second axis not aligned with the first axis." (*Id*.)

Applicants did not dispute that Valley disclosed this asymmetric design. (*Id*. at pp. 68-71.) Instead, Applicants cancelled claim 1 and presented new claims 37-46 with claim 37 in independent form. (*Id*. at pp. 69-71.) Claims 37-46 are directed toward a method and were ultimately allowed and renumbered in the 456 patent as claims 1-10. (*Id*. at pp. 72-73.) Claim 37, which ultimately issued into claim 1, is reproduced below.

> 37. (New) A method for treating bone comprising the steps of

> providing a tool comprising an outer catheter tube having a distal end, an inner catheter tube extending within the outer catheter tube and having a distal end region that extends beyond the distal end of the outer catheter tube, and an expandable structure having a proximal end secured to the distal end of the outer catheter tube and a distal end secured to the distal end region of the inner catheter tube, whereby the distal end region of the inner catheter tube is enclosed within the expandable structure,
>
> manipulating the tool to introduce the expandable structure into bone while in a generally collapsed geometry, and
>
> causing the expandable structure to assume an expanded geometry inside bone.

(*Id*. at pp. 69-70.) Notably, the "outer catheter tube," the "inner catheter tube," and the "expandable structure" catheter arrangement was not presented in original claim 1 and were first presented in claim 37. (*Id*. at pp. 40, 69-70.)

In the remarks section, Applicants stated that "[t]he claims have been amended to define a method for treating bone, which Valley et al. neither teach[es] nor suggest[s]. Furthermore, the method includes the use of a tool having an expandable structure, the proximal end of which is secured to an outer catheter tube and the distal end of which is secured to an inner catheter tube. Valley et al. neither teach[es] nor suggest[s] this structure, much less its deployment in bone." (*Id*. at p. 71.) As shown below in Ground 4, however, the

applicants' representation that Valley et al. "neither teach[es] nor suggest[s]" "a tool having an expandable structure, the proximal end of which is secured to an outer catheter tube and the distal end of which is secured to an inner catheter tube," was incorrect.

Based on applicants' statements about the prior art, the examiner allowed the claims, noting that "[c]laims 37-46 have been allowed because the prior art fails to disclose or suggest a method for treating a bone by using a catheter which has 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." (*Id*. at p. 73.)

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 the 456 patent are 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.[3]

In independent claim 1, the claim preamble - ***"A method for treating bone comprising the steps of"*** is not limiting. "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); *see also Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808-810 (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). In addition, where the preamble is not relied on for antecedent basis or to distinguish the claimed invention from the prior art, it is generally not limiting. *Catalina*, 289 F.3d at 808. Here, the preamble, which simply recites the intended use for the claimed device, i.e., treating bone, does not serve as a claim limitation.

It is also noted that dependent claims 4 and 5 require ***"A method according to claim 1 further including the step of convey [sic] material into the cavity."***

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

However, there is no antecedent basis for "the cavity" in claim 1. To the extent this claim can be understood, it means that there is an additional step of conveying material into the cavity. (Ex. 1001 at 2:13-15; Sheehan Decl. at ¶ 51.)

VI. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE 456 PATENT IS UNPATENTABLE

Petitioner seeks *inter partes* review of claims 1-10 of the 456 patent. Claim 1 is an independent claim. Claims 2-10 depend from claim 1.

A. Ground 1: Pathak Anticipates Claims 1-4

Pathak, which describes the use of the claimed catheter assembly in various applications including bone, anticipates claims 1-4 of the 456 patent. (Sheehan Decl. at ¶ 57.)

Pathak discloses a balloon catheter that uses an inflatable structure (e.g., a balloon) to implant polymeric materials such as a stent. (Ex. 1003 at 1, 5; Sheehan Decl. at ¶ 58.) Specifically, Pathak describes a procedure for implanting polymeric materials to, for example, create or preserve cavities in various applications: "[t]his invention pertains to devices for intraluminal implantation of polymeric materials . . . [a]mong the proposed uses of such materials are the alteration of tissue; the creation or preservation of lumens, channels or reservoirs for the passage or collection of fluids; the creation of matrices for the growth of tissue; the control of undesirable tissue growth; the delivery of therapeutic agents

. . . ." (Ex. 1003 at 1; Sheehan Decl. at ¶ 58.) "The resulting shaped article provides a therapeutic benefit by acting, in one embodiment, as a stent to maintain patency . . . ." (Ex. 1003 at 4.)

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." (*Id.* at 21; Sheehan Decl. at ¶ 59.) "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." (Ex. 1003 at 21.)

An "article shaping element," such as a balloon [blue], is affixed to both the inner and outer tubes. (*Id*.) As shown in Figure 2A, the "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" with the distal end region of the inner tube enclosed within the balloon. (*Id.*; Sheehan Decl. at ¶¶ 59, 61.) "The annular space formed between the inner wall of the outer tube and the outer wall of the inner tube forms an

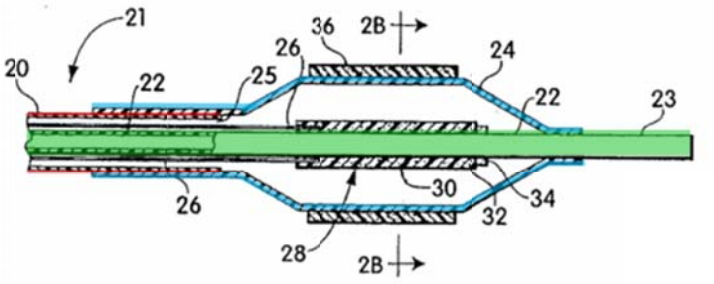


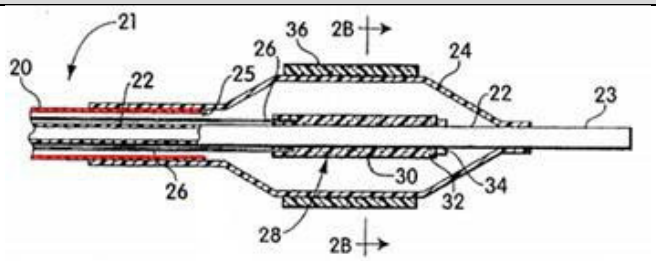
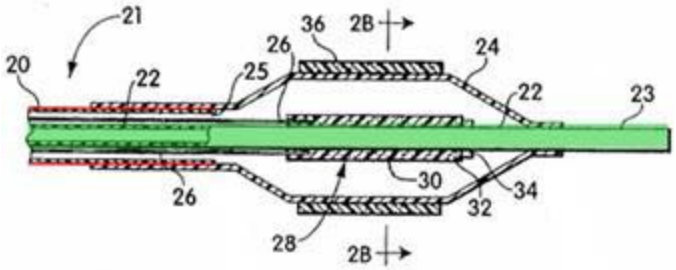
Fig. 2A

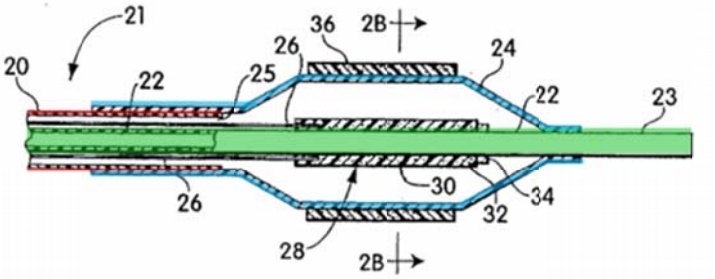
inflation lumen 25 through which the balloon may be inflated and expanded." (Ex. 1003 at 21; Sheehan Decl. at ¶ 59.) The inflation lumen allows the balloon to be inflated by an appropriate inflation medium. (Ex. 1003 at 20, 24.)

As was well known in the prior art, Pathak explicitly discloses that its balloon catheter assembly can be used in a variety of medical procedures including the treatment of bone. (*Id.* at 15 ("In other therapeutic applications, (i.e., trachial, urinary, bronchial, bone lumens and the like) shorter or longer periods may be appropriate."), 37 ("For example, within a bone lumen, a coating thickness of up to 5 mm may be beneficial."), 9 ("For example, 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 . . ."), 35-36; Sheehan Decl. at ¶ 60.)

Accordingly, in view of Pathak, claims 1-4 of the 456 patent should not have issued. Provided below is a chart (color added) showing that all elements of claim 1 are disclosed in Pathak. (*See* Sheehan Declaration at ¶¶ 61-62.)

456 Patent	**Pathak**
1. A method for treating bone comprising the steps of providing a tool	See Section V regarding claim construction. Pathak discloses that the device can be deployed in various applications including "bone lumens" and "bone tissue." (Ex. 1003 at 9, 15, 35-37.)

456 Patent	Pathak
comprising an outer catheter tube having a distal end,	 Fig. 2A *See id*. at Fig. 2A and Sheehan Decl. at ¶61. "The device 21 comprises an outer elongated flexible tube 20 (i.e., a catheter) and an inner elongated flexible tube 22 positioned within the lumen of the outer tube 20." (Ex. 1003 at 21.)
an inner catheter tube extending within the outer catheter tube and having a distal end region that extends beyond the distal end of the outer catheter tube,	 Fig. 2A "The device 21 comprises 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. 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*.)

456 Patent	Pathak
and an expandable structure having a proximal end secured to the distal end of the outer catheter tube and a distal end secured to the distal end region of the inner catheter tube, whereby the distal end region of the inner catheter tube is enclosed within the expandable structure,	 Fig. 2A See catheter configuration in Fig. 2A. and Sheehan Decl. at ¶ 61. "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." (Ex. 1003 at 21; *see also id.* at 20.)
manipulating the tool to introduce the expandable structure into bone while in a generally collapsed geometry, and	The balloon catheter includes an "annular space formed between the inner wall of the outer tube and the outer wall of the inner tube [which] forms an inflation lumen 25 through which the balloon may be inflated and expanded." (*Id.* at 21.) "The balloon is deflated and a polymeric article is positioned about its exterior. The balloon carrying the polymeric article is then advanced through a body lumen to position the polymeric article at a desired treatment location. . . . Once the molding temperature has been achieved, the balloon is inflated fully . . . ." (*Id.* at 28.) Pathak discloses that the device can be deployed in various applications including "bone tissue" and "bone lumen." (*Id.* at 9, 15, 35-37; Sheehan Decl. at ¶¶ 60-61.)
causing the expandable structure to assume an expanded geometry	"Inflation of the balloon causes the moldable polymeric material to expand outwardly, thereby pressing the polymer into contact with the tissue

456 Patent	Pathak
inside bone.	lumen." (Ex. 1003 at 5.) "[P]hysiologically acceptable forces and temperatures within bone tissue may far exceed the amount of force and heat that is physiologically acceptable on a blood vessel . . . ." (*Id*. at 9, 37 ("For example, within a bone lumen, a coating thickness of up to 5 mm may be beneficial."), 15, 35-36.)

Pathak also anticipates ***dependent claims 2 and 3,*** which depend on claim 1. (Sheehan Decl. at ¶¶ 63-67.) Dependent claim 2 requires "wherein, when assuming the expandable geometry, the expandable structure compacts cancellous bone." Dependent claim 3 requires "wherein, when assuming the expandable geometry, the expandable structure compacts cancellous bone and forms a cavity." In addition to meeting the limitations of claim 1 (discussed above and incorporated herein) and as explained in the Sheehan Declaration, the balloon of Pathak, when expanded in bone as Pathak suggests, compacts cancellous bone and forms a cavity. (Sheehan Decl. at ¶¶ 63-67.)

As discussed above, the Pathak balloon catheter is used "for the delivery of polymeric material in vivo, and more particularly to the implantation of polymeric material into tissue lumens. . . ." (Ex. 1003 at 3). Pathak suggests that its "article shaping element, for example a radially expandable, inflatable balloon" can be used "within bone tissue" and in a variety of "therapeutic applications, (i.e.,

trachial, urinary, bronchial, bone lumens and the like) . . . ." (*Id.* at 21, 15, 9, 35-37; Sheehan Decl. at ¶ 64.) The very purpose of the device is to create or maintain a cavity in the body: "[t]his invention pertains to devices for intraluminal implantation of polymeric materials . . . [a]mong the proposed uses of such materials are the alteration of tissue; the creation or preservation of lumens, channels or reservoirs for the passage or collection of fluids; . . . ." (Ex. 1003 at 1; *see also id.* at 4, Sheehan Decl. at ¶ 68, claims 2 and 3.)

Thus, as Mr. Sheehan explains, when used in bone lumens or tissue as Pathak teaches, the "article shaping element" of Pathak compacts cancellous bone upon expansion and forms a cavity. (Sheehan Decl. at ¶¶ 65 and 68, claims 2 and 3.) Indeed, Pathak and the 456 patent both describe using the same materials for the expandable balloon. (*Id.* at ¶ 66.) Specifically, Pathak discloses that "[t]he balloon preferably comprises a polymeric material such as polyethylene terephthalate [PET], crosslinked polyethylene or composites thereof" and the 456 patent also discloses using polyethylenes and PET. (Ex. 1003 at 25-26; Ex. 1001 at 12:64-13:4.) As the Sheehan Declaration further explains, one of ordinary skill in the art would understand that a consequence of compressing cancellous bone with a balloon such as that described in Pathak and the 456 patent is the formation of a cavity. (Sheehan Decl. at ¶¶ 65, 68, claim 3.)

Moreover, given that the intended purpose of the Pathak device is to create or maintain a cavity as discussed above, *see. e.g.,* Ex. 1003 at 1, 4, such a balloon would also form a cavity. In any event, Pathak also teaches that additional modifications may be useful if the device is used in bone. (Ex. 1003. at 9 (suggestion modifications where "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 . . . ."), 37 ("For example, within a bone lumen, a coating thickness of up to 5 mm may be beneficial."); Sheehan Decl. at ¶ 66.)

Dependent claim 4 requires "A method according to claim 1 further including the step of convey [sic] material into the cavity." In addition to meeting the limitations of claim 1 (discussed above and incorporated herein), Pathak discloses the additional step of claim 4. It is noted that, as described in Section V above, there is no antecedent basis in claim 1 for the term "cavity." Nonetheless, Pathak teaches conveying material into the cavity. First, Pathak teaches the delivery of polymeric material into the cavity: "The present invention pertains to apparatus and methods for the delivery of polymeric material in vivo, and more particularly to the implantation of polymeric material into tissue lumens of human or animal patients." (Ex. 1003 at 3.) "In one embodiment, the material is

intended to provide mechanical support to tissue structures." (*Id.* at 9.) Pathak also describes delivery of "a drug or other therapeutic agent" including "growth factors and growth factor antagonists, mitotic and antimitotic agents, antibiotics . . . ." (*Id.* at 18.)

Thus, Pathak anticipates claims 1 through 4 of the 456 patent.

B. Ground 2: Pathak In View Of Reiley Renders Obvious Claims 1-7

As discussed in Section VI.A., Pathak anticipates claims 1-4 as it describes a method for treating bone using the claimed balloon catheter assembly. The reasons Pathak anticipates claims 1-4 are incorporated by reference in their entirety. As discussed in the background section, the Reiley reference discloses, among other things, using a balloon catheter to compact cancellous bone, form a cavity, and convey material including bone cement into the cavity, as well as using a balloon catheter to move bone to address fractures. As discussed below, Reiley combined with Pathak further discloses all the elements of claims 1-7 and renders obvious claims 1-7 of the 456 patent.

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, 416 (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 his or her skill." *Id.* at 417. 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*.

Reiley and Pathak both relate to the use of inflatable balloon catheter assemblies for medical procedures including in bone. Pathak was discussed above. Reiley provides significant detail about various ways in which balloon catheters could be used in bone. (Sheehan Decl. at ¶¶ 69-70.) Specifically, Reiley teaches "[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. 1004 at Abstract). As illustrated in Figures 2 and 8, Reiley teaches a typical balloon-assisted vertebroplasty procedure: advancing a catheter with a balloon (blue) at its distal end (in a collapsed geometry) through a cannula into bone such as vertebra

(shown in Figure 2), expanding the balloon inside the bone and compacting cancellous bone (orange), forming a cavity, and then filling the cavity with material such as bone cement. (*Id.* at p. 19 ll. 7-12, p. 19 ll. 31-34, p. 2 ll. 25-29; Sheehan Decl. at ¶ 70.)

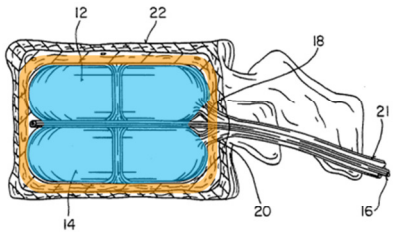


FIG. 2

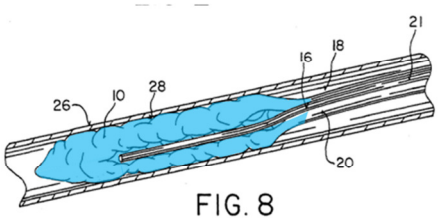


FIG. 8

Specifically, Reiley teaches that "[i]nflating [the balloon] compresses the calcium-containing soft cancellous bone into a thin shell that lines the inside of the hard cortical bone creating a large cavity." (*Id.* at p. 10 ll. 32-34.) "A flowable, biocompatible filling material, such as methylmethacrylate cement or a synthetic bone substitute, is then directed into the cavity or passage and allowed to set to a hardened condition to provide structural support for the bone." (*Id.* at p. 2 ll. 25-29.)

Reiley also discloses using the balloon to exert interior force upon cortical bone, e.g., for moving fractured cortical bone. (*Id.* at p. 6 ll. 17-26 ("[T]he present invention is directed to a balloon for use in treating a bone predisposed to fracture or to collapse. . . . The body has a predetermined shape and size when

substantially inflated sufficient to . . . restore the original position of the outer cortical bone, if fractured or collapsed.").)

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 due to spherically-shaped balloons being used in spaces that are not spherical. (*Id.* at p. 3 ll. 6-9; Sheehan Decl. at ¶ 71.) Reiley purports to solve the problem of inadequate cavity formation by proposing balloons of various shapes, sizes, and constructions that better approximate the shape of the bone cavity. (*See, e.g.*, Ex. 1004 at pp. 6-8, Figs. 1-6A, 10-14, 17A-18, 20; Sheehan Decl. at ¶ 70.)

Moreover, although Reiley is primarily directed to the design of the balloon, Reiley praises the catheter design of vascular catheters specifically identifying the Andersen catheter, which is "a coaxial catheter with inner and outer tubing," as "[a] particular improvement."[4] (Ex. 1004 at p. 4 ll. 21-25; Sheehan Decl. at ¶ 72.) Therefore, Reiley itself provides the reason, basis, or motivation to use a balloon catheter such as that disclosed in Andersen in the balloon-assisted vertebroplasty procedure described in Reiley. (Sheehan Decl. at ¶¶ 69, 71-72, 74.) As discussed by Mr. Sheehan, the Pathak catheter uses the same coaxial catheter construction

[4] The Andersen catheter is addressed in Section VI.C, Ground 3, below.

as the Andersen catheter, i.e., the design that was well known in the art as discussed above. (*Id*. at ¶¶ 72-74.) Thus, it would be obvious to one of skill in the art to use Pathak in the very way Reiley teaches. (*Id*. at ¶¶ 69-76.) Notably, Reiley also discloses that "[c]urrent medical balloons can compress bone . . . ." (Ex. 1004 at p. 5 ll. 22-33.) This passage from Reiley also teaches that current medical balloons, such as the balloon of Pathak, can be used in bone.[5] (*Id*.; Sheehan Decl. at ¶ 72.)

Other than referencing the superior "coaxial design" in the vascular art, Reiley does not focus on the details of the construction or design of the balloon catheter, but Pathak does. As discussed above in Section VI.A., and incorporated herein by reference, Pathak discloses a balloon catheter assembly as required by ***independent claim 1***. (Ex. 1003 at Figs. 2*a* and 2*b*, 20-21; Sheehan Decl. at ¶ 73; Section VI.A.) Also as discussed previously, Pathak explicitly teaches that its disclosed balloon catheter assembly can be used in a variety of medical procedures including in a method for treating bone as claimed. (*See, e.g.*, Ex.

[5] While Reiley notes that "generally" balloons may not provide "adequate cavity formation," *id.*, this has no relevance to the elements of Claims 1-7 particularly since Pathak teaches using a balloon of the type described in the 456 patent as discussed above.

1003 at 9, 15, 35-37.)

Nonetheless, Reiley also teaches "manipulating the tool to introduce the expandable structure into bone while in a generally collapsed geometry" and "causing the expandable to assume an expanded geometry inside bone" as required by claim 1. Reiley explains that: "Fig. 8 is a vertical section through a balloon after it has been deflated and as it is being inserted into the vertebral body of a human." (Ex. 1004 at p. 16 ll. 30-32.) Reiley further explains that "the deflated balloon is forced into the bone in a collapsed condition through cannula 26. . . . The balloon is then inflated to compact the bone marrow and/or cancellous bone in the cavity . . . ." (*Id.* at p. 19 ll. 19-21, p. 19 ll. 31-33.) Figure 2 of Reiley shows the balloon assuming an expanded geometry inside a vertebral body. (Sheehan Decl. at ¶¶ 70, 75, claim 1 chart.)

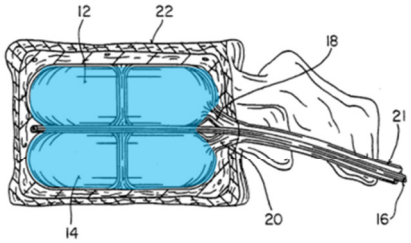


FIG. 2

Therefore, Pathak provides explicit teaching for using its balloon catheter assembly to treat bone and Reiley provides explicit teaching for using vascular balloon catheters – like the one disclosed in Pathak – to treat bone as required by claim 1. (Sheehan Decl. at ¶ 74.)

Reiley also discloses the additional elements required by claims 2 through

7, i.e., using a balloon catheter to compact cancellous bone and form a cavity, to convey material including bone cement into the cavity, and to exert interior force upon cortical bone including moving fractured cortical bone. (Sheehan Decl. at ¶ 75, claims 2-7.)

Dependent claims 2 and 3 require "A method according to claim 1 wherein, when assuming the expandable geometry, the expandable structure compacts cancellous bone [claim 3: and forms a cavity]." As discussed above, Pathak teaches such a balloon. Nonetheless, Reiley teaches using a balloon catheter for this purpose: "The [balloon] body has a shape and size to compress at least a portion of the cancellous bone to form a cavity in the cancellous bone and to restore the original position of the outer cortical bone, if fractured or collapsed." (Ex. 1004 at Abstract, p. 6 ll. 21-26.) "The balloon is then inflated to compact the bone marrow and/or cancellous bone in the cavity . . . ." (*Id.* at p. 19 ll. 31-34.) Reiley further teaches "Inflating [the balloon] compresses the calcium-containing soft cancellous bone into a thin shell that lines the inside of the hard cortical bone creating a large cavity." (*Id.* at p. 10 ll. 32-34; Sheehan Decl. at ¶ 75, claims 2 and 3.)

Dependent claim 4 requires "A method according to claim 1 further including the step of convey [sic] material into the cavity." ***Dependent claim 5***

requires "A method according to claim 4 wherein the material comprises bone cement." Reiley teaches that "[a] flowable, biocompatible filling material, such as methylmethacrylate cement or a synthetic bone substitute, is then directed into the cavity or passage and allowed to set to a hardened condition to provide structural support for the bone." (Ex. 1004 at p. 2 ll. 25-29; *see also id.* at 11:15-23 (discusses "bone cement"); Sheehan Decl. at ¶ 75, claims 4 and 5.)

Dependent claims 6 and 7 require "A method according to claim 1 wherein, when assuming the expandable geometry the expandable structure exerts interior force upon cortical bone [claim 7: to move fractured cortical bone]. Reiley teaches "[T]he present invention is directed to a balloon for use in treating a bone predisposed to fracture or to collapse. . . . The body has a predetermined shape and size when substantially inflated sufficient to . . . restore the original position of the outer cortical bone, if fractured or collapsed." (Ex. 1004 at p. 6 ll. 17-26; Sheehan Decl. at ¶ 75, claims 6 and 7.)

Accordingly, the disclosure of Reiley combined with Pathak renders obvious claims 1-7. (Sheehan Decl. at ¶¶ 69-76.)

C. Ground 3: Reiley In View Of Andersen Renders Obvious Claims 1-7, 9, And 10

Reiley combined with Andersen renders obvious claims 1-7, 9, and 10 of the 456 patent. (Sheehan Decl. at ¶¶ 77-83.) Reiley combined with Andersen,

disclose all the elements of claims 1-7, 9, and 10. As discussed in Section VI.B, 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. *KSR*, 550 U.S. at 417-419.

As discussed in Section VI.B, Reiley discloses using a balloon to compact cancellous bone and form a cavity, conveying material including bone cement into the cavity, and using a balloon to exert interior force upon cortical bone including to move fractured cortical bone. (Ex. 1004 at Abstract, p. 10 ll. 32-34, p. 11 ll. 15-26, p. 6 ll. 17-26.)

Like the claims of the 456 patent, Andersen discloses a "coaxial catheter with a flexible inner tubing and an outer tubing." (Ex. 1005 at 2:17-18.) "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.) "The distal end 25 of catheter 4 . . . has a tapered, hollow plastic tip 22 to which distal end 24 of inner catheter tube 26 is sealed." (*Id*. at 5:26-28.) "Neck 26

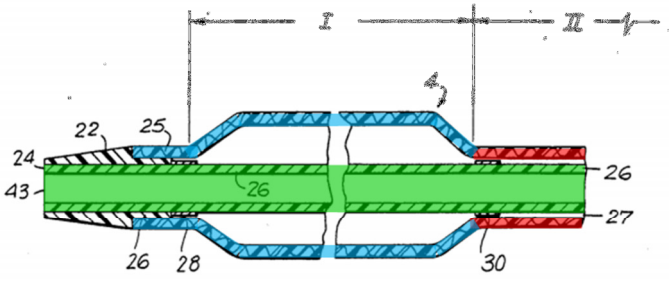


FIG. 4a

on distal tip 22 is sealed to the distal end of balloon portion I of shaft 4." (*Id.* at 5:33-34.) As shown in Figure 4a, the distal end region of the inner catheter tube extends beyond the distal end of the outer catheter tube with the distal end region of the inner tube enclosed within the balloon. (Sheehan Decl. at ¶¶ 80, 83, claim 1 chart.) Notably, claim 25 of Andersen claims an "inner tube," "an outer tube in coaxial relation to the inner tube," and "the distal end of the inner tube extending beyond the distal end of the outer tube . . . ." (Ex. 1005 at 10:14-48.) Andersen teaches that the balloon catheter is "capable of operation, at body temperature, at pressures of up to 20 atmospheres [294 psi]," which is commensurate with the range of pressures described in the 456 patent for compacting cancellous bone and forming a cavity. (*Compare id*. at 3:13-15 *with* Ex. 1001 at 13:4 (describing balloon pressures of 250-500 psi); Sheehan Decl. at ¶ 81.)

Andersen further teaches that the inner tube is more compliant than the outer tube: "[t]he catheter of the present invention is a coaxial catheter with a flexible inner tubing and an outer tubing of filament-reinforced elastomeric material." (Ex. 1005 at 2:17-19.) As explained by Mr. Sheehan, Andersen also teaches that the balloon is more compliant than the outer tube by virtue of its expansion as shown in Figures 3a, 3b, and 4a. (*Id.* at Figs. 3a, 3b, 4a; Sheehan

Decl. at ¶ 83, claim 10 chart.)

In addition, Andersen notes that "while the invention has been disclosed in the setting of a catheter surgical for 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; *see also id*. Figs. 3a, 3b, and 4a; Sheehan Decl. at ¶ 82.)

Reiley teaches that one of ordinary skill in the art would look to the balloon catheter design of Andersen for bone applications. (Sheehan Decl. at ¶¶ 77, 79.) Reiley praises the catheter design of vascular catheters specifically identifying the Andersen catheter, a balloon catheter for use in angioplasty, 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. Such filaments cross each other causing the shaft of the balloon to become shorter in length while the moving portion of the shank becomes longer in length. . . . 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.

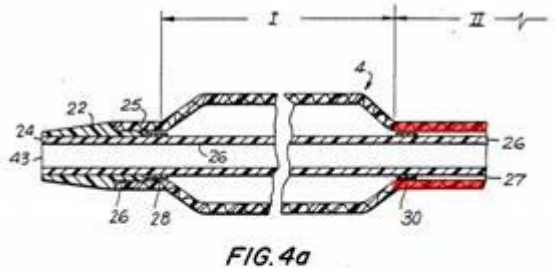
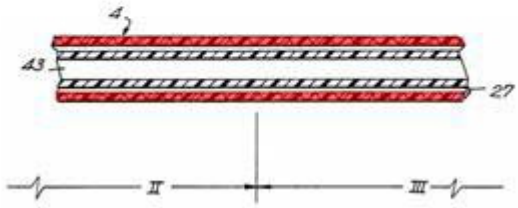
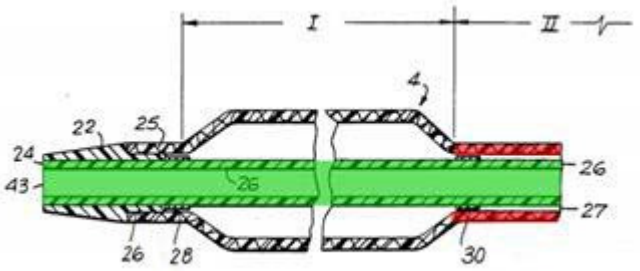
(Ex. 1004 at p. 4 ll. 21-33.) Reiley also suggests that Andersen be consulted for balloon materials. (*Id.* at p. 10 l. 14.) As discussed previously, Reiley teaches that "[c]urrent medical balloons can compress bone." (*Id*. at p. 5 ll. 22-33.) As such,

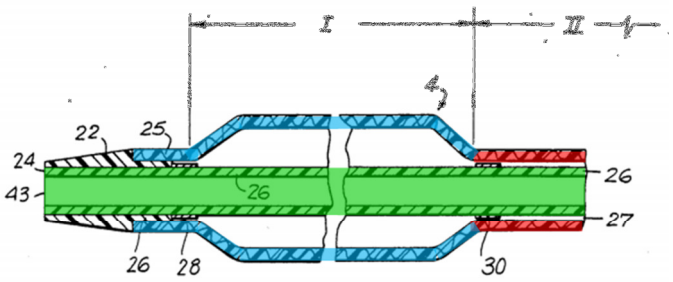
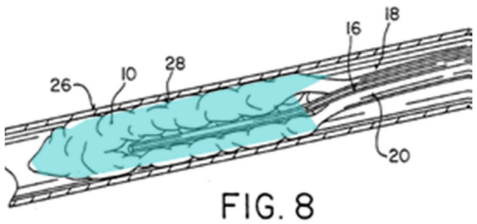
Reiley provides the specific reason, basis, or motivation to combine Reiley with Andersen. (Sheehan Decl. at ¶¶ 77-79.)

Therefore, as explained in the Sheehan declaration, Reiley provides the explicit teaching for using the claimed "tool comprising an outer catheter tube . . . an inner catheter tube . . . and an expandable structure" of Andersen in bone including "manipulating the tool to introduce the expandable structure into bone" and "causing the expandable to assume an expanded geometry inside bone." (Sheehan Decl. at ¶¶ 77-83.) Accordingly, Reiley combined with Andersen render obvious claims 1-7, 9, and 10.

Provided below is a claim chart showing how each claim limitation of claim 1 is met by Reiley combined with Andersen.

456 Patent	**Reiley / Andersen**
1. A method for treating bone comprising the steps of providing a tool comprising an outer catheter tube having a distal end,	See Section V regarding claim construction. Reiley states that it relates "to an inflatable balloon-like device for use in treating bone conditions." (Ex. 1004 at p. 1 ll. 7-13.) Reiley states that "[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…" (*Id*. at p. 4 ll. 21-2.) Claim 25 of Andersen claims "A balloon catheter assembly . . . comprising . . . an outer tube in coaxial relation to the inner tube" and makes reference to "the distal end of the outer tube."

456 Patent	Reiley / Andersen
	(Ex. 1005 at 10:14-48.) Andersen also teaches: "An inflatable balloon portion is formed at the distal end of the outer tubing . . . ." (*Id.* at 2:19-22.) See Figure 4 which depicts the balloon catheter.  FIG. 4a  FIG. 4b
an inner catheter tube extending within the outer catheter tube and having a distal end region that extends beyond the distal end of the outer catheter tube,	 FIG. 4a Reiley teaches that Andersen uses "a coaxial catheter with inner and outer tubing." (Ex. 1004 at p. 4 ll. 21-25; *see also* Ex. 1005 at Fig. 4a.) Claim 25 of Andersen specifically claims "an outer tube in coaxial relation to the inner tube" and "the distal end of the inner tube extending beyond the distal end of the outer tube . . . ." (Ex. 1005 at 10:14-48.)

456 Patent	Reiley / Andersen
and an expandable structure having a proximal end secured to the distal end of the outer catheter tube and a distal end secured to the distal end region of the inner catheter tube, whereby the distal end region of the inner catheter tube is enclosed within the expandable structure,	 FIG. 4a Andersen teaches that "[a]n 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, 9:47-49 (claim 14).) "The distal end 25 of catheter 4 of FIG. 4(a) has a tapered, hollow plastic tip 22 to which distal end 24 of inner catheter tube 26 is sealed." (*Id.* at 5:26-28.) "Neck 26 on distal tip 22 is sealed to the distal end of balloon portion I of shaft 4." (*Id.* at 5:33-34; *see also id*. at Fig. 4a showing relative placement of outer tube, inner tube, and balloon; Sheehan Decl. at ¶ 83, claim 1.)
manipulating the tool to introduce the expandable structure into bone while in a generally collapsed geometry, and	 FIG. 8 Reiley teaches that "Fig. 8 is a vertical section through a balloon after it has been deflated and as it is being inserted into the vertebral body of a human." (Ex. 1004 at p. 16 ll. 30-32.) Reiley discloses that "liquid inflates the balloon 10, particularly parts 12 and 14 thereof after the balloon has been inserted in a collapsed condition (Fig. 8) into a bone to be treated, such as a vertebral bone 22 in Fig. 2." (*Id.* at p. 18 l. 32 – p. 19 l. 1.)

456 Patent	Reiley / Andersen
causing the expandable structure to assume an expanded geometry inside bone.	Reiley teaches that "The liquid inflates the balloon 10, particularly parts 12 and 14 thereof after the balloon has been inserted in a collapsed condition (Fig. 8) into a bone to be treated, such as a vertebral bone 22 in Fig. 2. The above-mentioned patents 4,969,888 and 5,108,404 disclose the use of a guide pin and cannula for inserting the balloon into bone to be treated when the balloon is deflated and has been inserted into a tube and driven by the catheter into the cortical bone where the balloon is inflated." (*Id*. at p. 18 l. 29 – p. 19 l. 6; *see also id*. at Fig. 2.)

With regard to ***dependent claims 2 through 7***, as discussed in Section VI.B above, Reiley teaches that the balloon compacts cancellous bone and forms a cavity when expanded (claims 2 and 3), conveying material including bone cement into the cavity (claims 4 and 5), and that the balloon exerts interior force upon cortical bone including to move fractured cortical bone (claims 6 and 7). (Ex. 1004 at Abstract, p. 10 ll. 32-34, p. 11 ll. 15-26, p. 6 ll. 17-26; Sheehan Decl. at ¶¶ 69-70, 75, 79, 83, claims 2-7.) For the reasons discussed above in Section VI.B. and in the Sheehan Declaration, it would be obvious to a person of ordinary skill in the art to use the Andersen balloon catheter for the bone applications described in Reiley and as claimed in claims 2 through 7 of the 456 patent. (Sheehan Decl. at ¶¶ 77-82, 83, claims 2-7.)

It is further noted that, with regard to claims 2, 3, 6, and 7, Andersen discloses operation "at pressures of up to 20 atmospheres," which is approximately 294 psi and commensurate with the pressure ranges described in the 456 patent. (Compare Ex. 1005 at 3:13-15 with Ex. 1001 at 13:4 (describing balloon pressures of 250-500 psi); Sheehan Decl. at ¶ 81.) Thus, the Andersen balloon is capable of performing the very procedures identified in dependent claims 2, 3, 6 and 7, i.e., compacting cancellous bone and forming a cavity and exerting interior force upon cortical bone including to move fractured cortical bone, and disclosed in Reiley. (*Id.*)

Dependent claims 9 and 10 require the method according to claim 1 "wherein the inner catheter tube is [Claim 10: and expandable structure are] more compliant than the outer catheter tube." Claim 1 is discussed above. Andersen describes these additional features. Specifically, Andersen teaches that the inner tube is more flexible than the outer tube: "The catheter of the present invention is a coaxial catheter with a flexible inner tubing and an outer tubing of filament-reinforced elastomeric material." (Ex. 1005 at 2:17-19; Sheehan Decl. at ¶ 83, claims 9 and 10.) Indeed, the Reiley reference emphasizes this teaching in Andersen. (Ex. 1004 at p. 4 ll. 21-25 ("outer tubing [is] formed and reinforced by continuous helical filaments").)

Additionally, with regard to the balloon, Andersen describes "an annular space between the tubes" such that "when fluid is introduced under pressure into the annular space between the tubes, the balloon portion expands in diameter . . . ." (Ex. 1005 at 10:21, 10:34-37.) As explained in the Sheehan Declaration and as shown in Figures 3a, 3b, and 4a of Andersen, the balloon is necessarily more compliant than the outer tube given that inflation of the balloon occurs via the inflation lumen between the flexible inner tube and the reinforced outer tube (otherwise the outer tube would also expand with the balloon). (Ex. 1005 at Figs. 3a, 3b, 4a; Sheehan Decl. at ¶ 83, claim 10 chart.)

Thus, for the above reasons, Andersen combined with Reiley render obvious claims 1-7, 9 and 10. (Sheehan Decl. at ¶¶ 77-83.)

D. Ground 4: Reiley In View Of Valley Renders Obvious Claims 1-10

Reiley in view of Valley renders obvious claims 1-10 of the 456 patent. (Sheehan Decl. at ¶¶ 84-91.)

Valley discloses a cardiac access system that uses a balloon catheter with an inflatable member on its distal end to block, for example, blood flow in an artery. (Ex. 1006 at 16:46-54; Sheehan Decl. at ¶ 84.) Valley describes several possible balloons to be used in its system including asymmetric balloons. (*See, e.g.*, Ex. 1006 at Figs. 14, 17, 18A-B, 19A, 20A, 21-22, 25B.) Like other balloon

catheters in the prior art, Valley describes a coaxial construction for its balloon catheter with an inner tube (shown in green) and outer tube (shown in red). (*See, e.g., id*. at Fig. 8A; 24:27-44; *see also id*. at 19:60-61.) As shown, for example, in Figure 8A, the inner catheter tube extends within the outer catheter tube and has a distal end region that extends beyond the distal end of the outer catheter tube. (*See, e.g., id*. at Fig. 8A; Sheehan Decl. at ¶¶ 85, 90, claim 1 chart.)

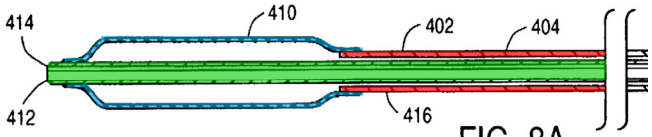


FIG. 8A

Valley teaches that "either or both of the inner tube and the outer tube may be made with varying stiffness to achieve the overall effect of a graduated stiffness catheter" and that "either or both of the inner tube and the outer tube may be reinforced with wire or filament braiding or coils for increased stiffness, torque control or kink resistance." (Ex. 1006 at 27:1-6; Sheehan Decl. at ¶ 87.)

The balloon is mounted on the distal end of the catheter with the proximal balloon neck "sealingly attached to the outer tube" and the distal balloon neck "sealingly attached to the inner tube" so that the inflation lumen communicates with the interior of the balloon. (Ex. 1006 at 26:7-13; *see also id*. at 20:48-55; Sheehan Decl. at ¶ 85.) As is shown, for example, in Figure 8A, the distal end region of the inner catheter tube is enclosed within the balloon. (*See, e.g.,* Ex. 1006 at Fig 8A.) As is typical, the balloon is manipulated into the targeted body

region while deflated and is expanded once it reaches the target area. (*Id.* at 22:1-9.) The balloon is made of "an elastomeric material that expands elastically from the uninflated to the inflated state" and may be made of materials such as "latex, silicone, and polyurethane." (*Id.* at 21:40-47; Sheehan Decl. at ¶ 87.)

Valley also teaches that the ends of the balloon may be inverted. (Sheehan Decl. at ¶¶ 86.) Specifically, as Mr. Sheehan explains, Figure 8C from Valley shows the proximal and distal ends of the balloon inverted about the distal end of the outer catheter tube and the distal end region of the inner catheter tube. (*Id*.) As Valley explains, this

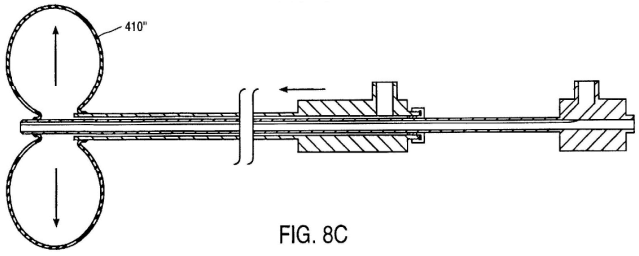


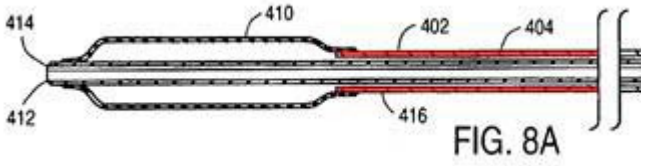
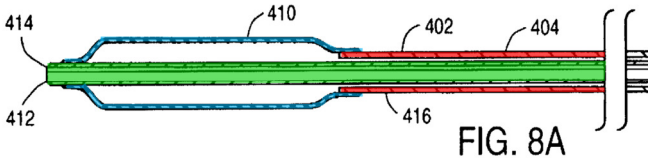
FIG. 8C

design "results in the balloon 410" having an inflated profile which achieves the full diameter of a freely inflated balloon diameter" and also "allows the user to select the inflated diameter of the balloon and the axial length of the balloon." (Ex. 1006 at 25:33-40.)

As discussed in Section VI.B, Reiley teaches methods for treating bone using a balloon catheter including using the catheter to compact cancellous bone and form a cavity, exerting interior force upon cortical bone including moving fractured cortical bone, and conveying material such as bone cement into the cavity. (Ex. 1004 at Abstract, p. 10 ll. 32-34, p. 11 ll. 15-26, p. 6 ll. 17-26.) Reiley

also teaches that it is desirable to consider vascular catheter designs (and in particular coaxial designs). (*Id*. at p. 4 ll. 21-25, p. 5 l. 22-23, p. 10 l. 14; Sheehan Decl. at ¶¶ 72, 79, 88.) As such, a person of ordinary skill in the art would be motivated to combine the Reiley and Valley references and use the Valley coaxial balloon catheter as well as teachings regarding catheter design in methods for treating bone as described in Reiley. (Sheehan Decl. at ¶¶ 88-89.) 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. *KSR*, 550 U.S. at 417-419. Therefore, Reiley provides the explicit teaching for using Valley in bone, including "manipulating the tool to introduce the expandable structure into bone . . . ." Accordingly, Reiley combined with Valley renders obvious claims 1-10.

As shown in the chart below, the combination of Reiley in view of Valley renders obvious claim 1 of the 456 patent.

456 Patent	Reiley / Valley
1. A method for treating bone comprising the steps of providing a tool comprising an outer catheter tube having a distal end,	See Section V regarding claim construction. Reiley states that it relates "to an inflatable balloon-like device for use in treating . . . bone conditions" and identifies vascular catheters as relevant catheter art. (Ex. 1004 at p. 1 ll. 9-11, p. 4 ll. 21-25.)  FIG. 8A Valley teaches a balloon catheter where "[t]he outer tube 404 fits coaxially around the inner tube 402 with an annular space between the two tubes providing a balloon inflation lumen 416." (Ex. 1006 at 24:35-38; *see also id.* at 20:37-40, Fig. 8A; Sheehan Decl. at ¶¶ 85, 90 claim 1 chart.)
an inner catheter tube extending within the outer catheter tube and having a distal end region that extends beyond the distal end of the outer catheter tube,	 FIG. 8A See Figure 8a of Valley for arrangement of inner and outer tube. Valley teaches that "[t]he 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; *see also id.* at 20:37-40, 22:24-34, 24:35-40; Sheehan Decl. at ¶¶ 85, 90, claim 1 chart.)
and an expandable structure having a proximal end secured to the distal end of the outer catheter tube and a distal end secured to the distal end region of the inner catheter tube, whereby the distal end region of the inner catheter tube is	"An aortic occlusion balloon 510 is mounted on the distal end of the catheter 500 with the proximal balloon neck 518 sealingly attached to the outer tube 504 and the distal balloon neck 520 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." (Ex. 1006 at 26:7-13; *see also id*. at 20:48-55, Fig. 8A (showing the distal end region of the inner catheter tube enclosed within the balloon,

456 Patent	Reiley / Valley
enclosed within the expandable structure,	colored blue above); Sheehan Decl. at ¶¶ 85, 90, claim 1 chart.)
manipulating the tool to introduce the expandable structure into bone while in a generally collapsed geometry, and	Valley teaches deploying the "deflated balloon." (*See, e.g.,* Ex. 1006 at 22:3-10.) Reiley teaches that "Fig. 8 is a vertical section through a balloon after it has been deflated and as it is being inserted into the vertebral body of a human." (Ex. 1004 at p. 16 ll. 30-32; *see also id.* at p. 18 l. 26 – p. 19 l. 6.)
causing the expandable structure to assume an expanded geometry inside bone.	Reiley teaches that "The liquid inflates the balloon 10, particularly parts 12 and 14 thereof after the balloon has been inserted in a collapsed condition (Fig. 8) into a bone to be treated, such as a vertebral bone 22 in Fig. 2. The above-mentioned patents 4,969,888 and 5,108,404 disclose the use of a guide pin and cannula for inserting the balloon into bone to be treated when the balloon is deflated and has been inserted into a tube and driven by the catheter into the cortical bone where the balloon is inflated." (*Id*. at p. 18 l. 31 – p. 19 l. 6; *see also id*. at Fig. 2.)

With regard to ***dependent claims 2 through 7***, as discussed in Section VI.B above and incorporated herein, Reiley teaches that the balloon compacts cancellous bone and forms a cavity when expanded (claims 2 and 3), conveying material including bone cement into the cavity (claims 4 and 5), and that the balloon exerts interior force upon cortical bone including to move fractured cortical bone (claims 6 and 7). (Ex. 1004 at Abstract, p. 10 ll. 32-34, p. 11 ll. 15-26, p. 6 ll. 17-26; Sheehan Decl. at ¶¶ 69-70, 88-89, 90, claims 2-7 charts.) For the

reasons discussed above and in the Sheehan Declaration, it would have been obvious to a person of ordinary skill in the art to use the Valley balloon catheter design to perform the bone applications described in Reiley (and claimed in claims 2 through 7 of the 456 patent). (Sheehan Decl. at ¶¶ 84-91, claims 2-7 charts.)

Dependent claim 8 requires "A method according to claim 1 wherein the proximal and distal ends of the expandable structure are inverted about the distal end of the outer catheter tube and distal end region of the inner catheter tube, respectively." It is noted that Figure 20 of the 456 patent depicts a balloon with inverted ends. The 456 patent explains that "FIG. 20 is a side section view of the tubular expandable structure shown in FIG. 19, after sliding the inner catheter tube within the outer catheter tube to invert the end regions of the structure about the distal and proximal bonds . . . ." (Ex. 1001 at 3:52-55.)

As discussed above, Valley also depicts a balloon with such inverted ends. Specifically, as Mr. Sheehan explains, Figure 8C from Valley shows the proximal and distal ends of the balloon inverted about the distal end of the outer catheter tube and the distal end region of the inner catheter tube. (Sheehan Decl. at ¶ 86.) "FIG. 8C shows the endoaortic portioning

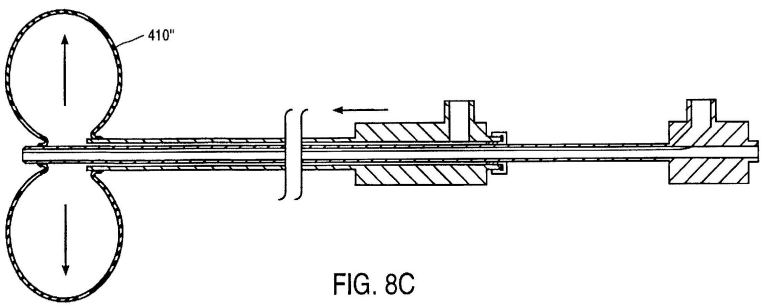


FIG. 8C

catheter 400. . . with the inner tube 402 in its farther proximal position with respect to the outer tube 404 and the occlusion balloon 410" inflated." (Ex. 1006 at 25:27-30.) This inverted design elongates "the balloon somewhat in the axial direction," "results in the balloon 410" having an inflated profile which achieves the full diameter of a freely inflated balloon diameter," and also "allows the user to select the inflated diameter of the balloon and the axial length of the balloon." (*Id*. at 25:33-40; Sheehan Decl. at ¶ 90, claim 8 chart.)

Dependent claims 9 and 10 require the method according to claim 1 "wherein the inner catheter tube is [Claim 10: and expandable structure are] more compliant than the outer catheter tube." Claim 1 is discussed above. As discussed above, Valley describes these additional features as well. With regard to claim 9, Valley discloses that "either or both of the inner tube and the outer tube may be made with varying stiffness to achieve the overall effect of a graduated stiffness catheter." (*Id.* at 27:1-6.) Valley also teaches that "either or both of the inner tube and the outer tube may be reinforced with wire or filament braiding or coils for increased stiffness, torque control or kink resistance." (*Id.*) With regard to claim 10, Valley further teaches that the balloon can be made of various "elastomeric material that expands elastically from the uninflated to the

inflated state." (*Id.* at 21:41-47; Sheehan Decl. at ¶ 87, 90, claims 9 and 10 charts.)

As Mr. Sheehan explains, a person of ordinary skill in the art would understand that selecting the disclosed option of making the inner tube and balloon more compliant than the outer tube facilitates maneuvering the inner catheter tube and balloon (in particular within bone) while maintaining the stability of the delivery system including the outer tube. (Sheehan Decl. at ¶ 91.) In any event, Mr. Sheehan explains making the inner catheter tube and balloon more flexible than the outer tube was a known and obvious design choice to ordinary skilled artisans at the time of the invention. (*Id.*)

Thus, the combination of Reiley and Valley render claims 1-10 obvious.

E. Ground 5: Reiley In View Of Antoshkiw Renders Obvious Claims 1-8

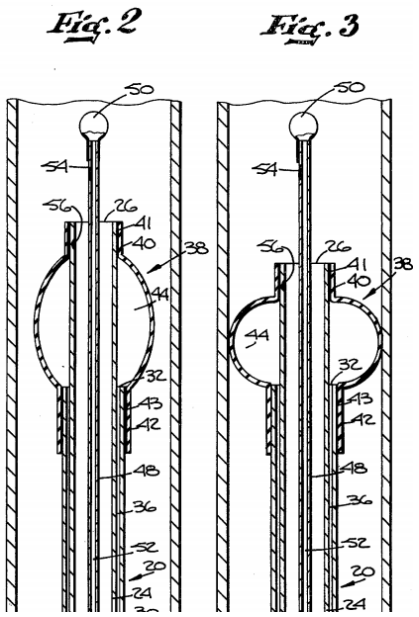
Reiley in view of Antoshkiw renders obvious claims 1-8 of the 456 patent. (Sheehan Decl. at ¶¶ 92-98.)

As discussed in Section VI.B, 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. *KSR*, 550 U.S. at 417-19.

Antoshkiw discloses a balloon catheter assembly including "concentric

tubes with the inner tube extending distally beyond the outer tube." (Ex. 1007 at Abstract; *see id.* at 3:19-23.) The inner and outer tubes are sized so that an annular space exists between the two tubes forming an annular passageway. (*Id.* at 3:24-27, 3:40-44; Sheehan Decl. at ¶ 93.)

An inflatable balloon is affixed to both the inner and outer tubes. (Ex. 1007 at 3:28-29.) "An inflatable balloon is attached distally to the outer surface of the inside tube to seal the distal portion of the balloon and is proximally attached to the outer surface of the outer tube to seal the proximal portion of the balloon." (*Id.* at Abstract, 3:29-33.) As shown, e.g., in Figures 2 and 3, the distal end region of the inner catheter tube is enclosed within the balloon. By sealing both ends of the balloon to the tubes, an inner chamber is formed in the balloon with the only access being through the annular passageway. (*Id.* at 3:40-44; Sheehan Decl. at ¶ 93.)



"The catheter system includes an arrangement which provides the capability of altering the shape of the balloon portion of the system while in vitro and/or in vivo." (Ex. 1007 at 1:26-29.) Specifically, as shown in Figures 2 and 3 and as explained by Mr. Sheehan, Antoshkiw teaches that the inner and outer

tubes are moveable with respect to each other such that the ends of the balloon may be inverted about the distal ends of the inner and outer catheter tubes. (Sheehan Decl. at ¶ 94.) As Antoshkiw explains, "the inflated balloon 38 can be altered in configuration, as desired, by merely shifting the relative axial position between inner tube 24 and outer tube 30 as depicted in FIG. 3 where the inner tube has been withdrawn rearwardly toward the outer tube thereby causing the affixed balloon to deform outwardly . . . ." (Ex. 1007 at 3:53-59.) Simply put, "[m]ovement of the inner tube with respect to the outer tube effects the distance between the distal and proximal attachments of the balloon and thereby effects the shape of the balloon." (*Id*. at Abstract.)

"All of the components of the [Antoshkiw] assembly can be of a conventional plastic and in addition the inflatable balloon can be of a more flexible material if desired such as natural or synthetic rubber." (*Id.* at 3:35-38.)

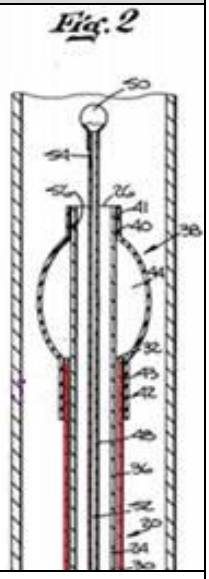
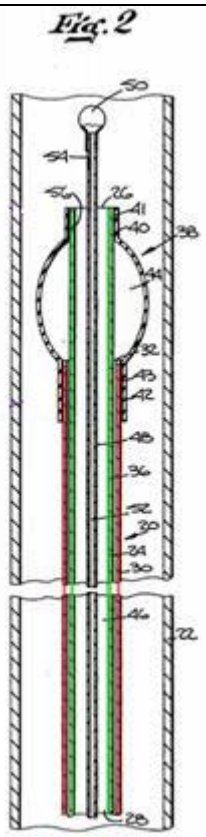
While the catheter system is directed toward the vascular system (*Id. at* 1:5-9), Antoshkiw further discloses that the catheter assembly can be utilized "in other areas of the body." (*Id.* at 2:6-14; Sheehan Decl. at ¶ 95.)

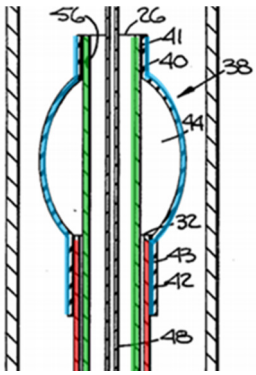
As discussed in Section VI.B and incorporated herein, Reiley teaches methods for treating bone using a balloon catheter including using the catheter to compact cancellous bone and form a cavity, exerting interior force upon cortical

bone including moving fractured cortical bone, and conveying material such as bone cement into the cavity. (Ex. 1004 at Abstract, p. 10 ll. 32-34, p. 11 ll. 15-26, p. 6 ll. 17-26; Sheehan Decl. at ¶ 93.) Reiley also teaches that it is desirable to consider vascular catheter designs, and in particular coaxial designs, such as that disclosed in Antoshkiw. (Ex. 1004 at p. 4 ll. 21-25, p. 5 l. 22-23, p. 10 l. 14; Sheehan Decl. at ¶¶ 72, 79, 88, 96.) As such, a person of ordinary skill in the art would have been motivated to combine Reiley and Antoshkiw and use the Antoshkiw coaxial balloon catheter as well as teachings regarding its flexible catheter design in methods for treating bone as described in Reiley. (Sheehan Decl. at ¶¶ 92-98.) The reason to combine the prior art references is provided by the explicit and implicit teachings of the references themselves, the knowledge of one of ordinary skill in the art, and/or the nature of the problems purportedly being solved. *KSR*, 550 U.S. at 417-419. Accordingly, Reiley combined with Antoshkiw renders obvious claims 1-10. (Sheehan Decl. at ¶¶ 92-98.)

As shown in the chart below, Reiley in view of Antoshkiw renders obvious claim 1 of the 456 patent. (Sheehan Decl. at ¶ 98, claim 1 chart.)

456 Patent	**Reiley/Antoshkiw**
1. A method for treating bone comprising the steps of providing a tool	See Section V regarding claim construction. Reiley states that it relates "to an inflatable balloon-like device for use in treating . . . bone conditions" and identifies vascular catheters as relevant catheter art.

456 Patent	Reiley/Antoshkiw
comprising an outer catheter tube having a distal end,	(Ex. 1004 at p. 1 ll. 9-11, p. 4 ll. 21-25.) Figure 2 from Antoshkiw discloses a catheter assembly with an "outer tube 30." (Ex. 1007 at 3:19-23.) "Surrounding tube 24 in concentric relationship is an outer tube 30 terminating in an open distal end 32...." (*Id.* at 3:19-23.) 
an inner catheter tube extending within the outer catheter tube and having a distal end region that extends beyond the distal end of the outer catheter tube,	 See Figs. 2-3. Antoshkiw teaches that "[t]he basic catheter assembly consists of two or more concentric tubes with the inside tube extending at least distally beyond the outside tube." (*Id.* at 1:30-32.) "[T]he catheter assembly 20 includes an inner tube 24 having an open distal end 26 and an open proximal end 28. Surrounding tube 24 in concentric relationship is an outer tube 30 terminating in an open distal end 32 and an open proximal end 34 which are positioned so that the inner tube 24 extends distally and proximally from the ends of the outer tube 30." (*Id.* at 3:16-23.)

456 Patent	Reiley/Antoshkiw
and an expandable structure having a proximal end secured to the distal end of the outer catheter tube and a distal end secured to the distal end region of the inner catheter tube, whereby the distal end region of the inner catheter tube is enclosed within the expandable structure,	 Antoshkiw teaches that "[a]n inflatable balloon portion 38 is attached to both the inner and outer tubes. The distal end 40 of the balloon portion is affixed to the outer surface of the distal end of the inner tube and the proximal end 42 of the inflatable portion 38 is attached to the outer surface of the distal end of the outer tube 30. The interengagement therebetween can be of a conventional nature such as by epoxy." (*Id*. at 3:28-35.) "By sealing both ends of the balloon portion 38 to the tubes 24 and 30, an inner chamber 44 is formed in the balloon portion with the only access to inner chamber 44 being through the annular passageway 36 between the tubes." (*Id.* at 3:40-44.) "The distal attachment of the balloon to the inside tube in effect seals the distal portion of the balloon. Proximally the balloon is attached to the outside catheter and in effect seals the proximal portion of the balloon." (*Id.* at 1:33-37.) Figures 2 and 3 depict the distal end region of the inner catheter tube enclosed within the balloon. (Sheehan Decl. at ¶ 98, claim 1 chart.)
manipulating the tool to introduce the expandable structure into bone while in a generally collapsed geometry, and	See Section VI.B-D above. Reiley teaches that "Fig. 8 is a vertical section through a balloon after it has been deflated and as it is being inserted into the vertebral body of a human." (Ex. 1004 at p. 16 ll. 30-32; *see also id.* at p. 18 l. 27 – p. 19 l. 6.)

456 Patent	Reiley/Antoshkiw
causing the expandable structure to assume an expanded geometry inside bone.	See Section VI.B-D above. Reiley teaches that "[t]he liquid inflates the balloon 10, particularly parts 12 and 14 thereof after the balloon has been inserted in a collapsed condition (Fig. 8) into a bone to be treated, such as a vertebral bone 22 in Fig. 2. The above-mentioned patents 4,969,888 and 5,108,404 disclose the use of a guide pin and cannula for inserting the balloon into bone to be treated when the balloon is deflated and has been inserted into a tube and driven by the catheter into the cortical bone where the balloon is inflated." (Ex. 1004 at p. 18 l. 32 – p. 19 l. 6; *see also id*. at Fig. 2.)

With regard to ***dependent claims 2 through 7***, as discussed in Section VI.B. and incorporated herein, Reiley teaches that the balloon compacts cancellous bone and forms a cavity when expanded (claims 2 and 3), conveying material including bone cement into the cavity (claims 4 and 5), and that the balloon exerts interior force upon cortical bone including to move fractured cortical bone (claims 6 and 7). (Ex. 1004 at Abstract, p. 10 ll. 32-34, p. 11 ll. 15-26, p. 6 ll. 17-26.) For the reasons discussed above and in the Sheehan Declaration, it would be obvious to a person of ordinary skill in the art to use the Antoshkiw balloon catheter for the bone applications claimed in claims 2 through 7 of the 456 patent, which are described in Reiley. (Sheehan Decl. at ¶¶ 92-97, 98, claims 2-7 charts.)

Dependent claim 8 requires "A method according to claim 1 wherein the proximal and distal ends of the expandable structure are inverted about the distal

end of the outer catheter tube and distal end region of the inner catheter tube, respectively." Claim 1 is discussed above. Like the 456 patent, as shown in Figures 2 and 3, Antoshkiw teaches moveable inner and outer catheter tubes that allow for the proximal and distal ends of the balloon to invert about the distal ends of the inner and outer catheter tubes. (Sheehan Decl. at ¶¶ 94, 98, claim 8 chart.) As Antoshkiw explains, "the inflated balloon 38 can be altered in configuration, as desired, by merely shifting the relative axial position between inner tube 24 and outer tube 30 as depicted in FIG. 3 where the inner tube has been withdrawn rearwardly toward the outer tube thereby causing the affixed balloon to deform outwardly . . . ." (Ex. 1007 at 3:53-58.) Simply put, "[m]ovement of the inner tube with respect to the outer tube effects the distance between the distal and proximal attachments of the balloon and thereby effects the shape of the balloon." (*Id*. at Abstract.) As Mr. Sheehan explains, given the teaching of the Antoshkiw patent regarding altering shape configuration, a person of ordinary skill in the art would understand that continuing relative movement of the tubes depicted in Figures 2 and 3 would result in inversion of the ends just as claimed in the 456 patent. (Sheehan Decl. at ¶ 94.)

Thus, the combination of Reiley and Antoshkiw render claims 1-8 obvious.

VII. SECONDARY CONSIDERATIONS

Stryker is not aware of any secondary considerations that would tend to show non-obviousness (e.g., commercial success, copying, long-felt but unresolved need, failure of others, etc.) that would have a nexus with the claimed inventions. (Sheehan Decl. at ¶ 99.)

VIII. CONCLUSION

For the above reasons, Petitioner respectfully requests institution of *inter partes* review of claims 1-10 of the 456 patent.

Respectfully submitted,

Dated: September 23, 2014

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CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 6,280,456 and Exhibits 1001-1019 were served on September 23, 2014, via pre-paid, overnight Federal Express to the correspondence address for the subject patent pursuant to 37 C.F.R. § 42.105:

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With a copy to:

Marc A. Fenster
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