IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYPHON INC., Plaintiff, v. DISC-O-TECH MEDICAL TECHNOLOGIES LTD., and DISC ORTHOPAEDIC TECHNOLOGIES, INC., Defendants.	C.A. No. 04-204-JJF **REDACTED – PUBLIC VERSION**

DEFENDANTS DISC-O-TECH MEDICAL TECHNOLOGIES, LTD.'S AND DISC ORTHOPAEDIC TECHNOLOGIES, INC.'S CLAIM CONSTRUCTION MEMORANDUM REGARDING KYPHON'S U.S. PATENT NOS. 4,969,888, 5,108,404 AND 6,235,043 B1

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April 6, 2005

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Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. (collectively, "DOT") submit this memorandum in support of DOT's interpretation of the disputed claims terms of the U.S. Patent Nos. 4,969,888, 5,108,404, and 6,235,043 B1.

I. INTRODUCTION

As demonstrated below, the critical claim interpretation issue for the three patents addressed in this brief, referred to collectively as the Inflatable Bone Tamp Patents, is that they are limited to inflatable devices (e.g., balloons), as a means of creating a cavity within a bone. That cavity is thereafter filled with a flowable bone filler material. The specification of the Inflatable Bone Tamp Patents, their file histories, the Record of Invention (which publicly disclosed the invention to the Patent Office), and the inventor testimony, all demonstrate that the sole novelty of the invention was the use of an inflatable device (particularly, a balloon) to create a void in bone. As explained in DOT's non-infringement summary judgment brief, submitted herewith, and as shown below, DOT's accused Sky Bone Expander device (the "SKy Device") does not use a balloon to create a void in bone; rather, the SKy Device uses a unique, novel and very different structure for creating a void – a plastic, polymer device that deploys into a petal-like configuration (rather than a balloon), by mechanical means (rather than by being inflated).

II. FACTUAL BACKGROUND

A. Asserted Claims and General Background

Kyphon, Inc. ("Kyphon") alleges that DOT's Sky Bone Expander Device (the "SKy Device") infringes Claims 1, 3, 7, 8, 9, 11, and 14 of the '888 Patent, entitled "Surgical Protocol for Fixation of Osteoporotic Bone Using Inflatable Device"; Claims 1, 3, 8, 9, 10, 12, and 15 of the '404 Patent, entitled "Surgical Protocol for Fixation of Bone Using Inflatable

Device" (" '404 Patent"); Claims 2, 17, 20, 23, 24, 25, 26, and 28 of the '043 Patent, entitled "Inflatable Device for Use in Surgical Protocol Relating to Fixation of Bone" (" '043 Patent"). The '888, '404 and '043 Patents are attached as Exhibits A-2, A-3 and A-4 to DOT's Appendix of Exhibits to Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. Claim Construction Memoranda and Motions for Summary Judgment of Non-Infringement and Invalidity ("DOT's Appendix of Exhibits"), submitted herewith.

Kyphon is also asserting two other patents, which the parties refer to as the "Bone Filler Patents; specifically, Kyphon is asserting claims 1, 3, 4, 5, 7, 8, 10, 11, 12, 13, 14, 15, 16, 17, 19, 20, and 21 of U.S. Patent No. 6,241,734 B1, entitled "Systems and Methods for Placing Materials into Bone" (" '734 Patent"); and Claims 26, 27, 28, 29, 36, 37, 38, 39, 41, 42, 43, 44, 46, 47, 48, and 49 of U.S. Patent No. 6,613,054 B2 entitled "Systems and Methods for Placing Materials into Bone" (" '054 Patent"). The Bone Filler Patents are attached as Exhibits B-1 and B-2 to DOT's Appendix of Exhibits. This memorandum addresses the construction of the disputed claim terms in the Inflatable Bone Tamp Patents.[1] The construction of the disputed claim terms of the Bone Filler Patents is addressed in a separate memorandum.

The application which became the '888 patent was filed on February 9, 1989; the '888 patent issued on November 13, 1990. It generally describes and claims a method of drilling a passage into a bone containing bone marrow, inflating a balloon within the bone marrow such that the bone marrow is compacted in order to increase the volume of the passage, and filling the passage created with a flowable material capable of hardening, such as bone cement.

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[1] Kyphon brought this suit against DOT alleging that the SKy Device infringes Claim 27 of the '043 Patent and certain claims of U.S. Patent No. 6,248,110 (B1) (" '110 Patent"). Kyphon is no longer asserting any claims of the '110 Patent, or Claim 27 of the '043 Patent. (See Exhibit O.) (All Exhibit references herein are to DOT's Appendix of Exhibits.)

The '404 patent is entitled "Surgical Protocol for Fixation of Bone Using Inflatable Device." The application which became the '404 patent was filed on August 15, 1990. The '404 patent is a continuation-in-part ("CIP") of the '888 patent which was filed on February 9, 1989. The '404 patent issued on April 28, 1992.

The specification and claims of the '404 and '888 patents, and more specifically the claim terms, are substantially identical, such that the claim terms can be construed together. The only substantive difference is that where the '888 patent covers only osteoporotic bone, the '404 patent covers both osteoporotic and non-osteoporotic bone.[2]

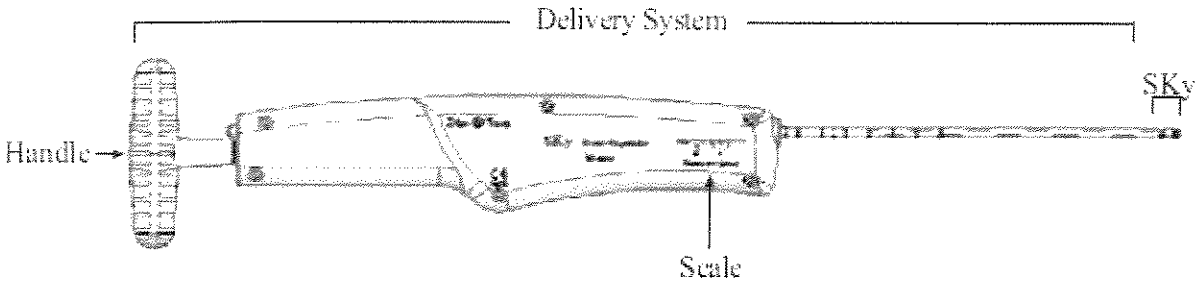
The '043 patent is entitled "Inflatable Device for Use in Surgical Protocol Relating to Fixation of Bone." The application which became the '043 patent was filed on January 23, 1997; the '043 patent issued on May 22, 2001. It generally describes an improved inflatable balloon for use in carrying out the methods claimed in the '404 and '888 patent. More specifically, the '043 patent describes balloons with additional design elements that are intended to change the shape of the balloon and constrain the expansion of the balloon when inflated.

B. The SKy Device

DOT's SKy Device is used in the reduction of vertebral compression fractures in which the spinal bone has collapsed, particularly due to weakness brought on by osteoporosis. The SKy Device consists of a hard plastic housing with a plastic crank handle protruding from one end and a metal rod protruding from the other. Surrounding the distal (or far) end of the metal rod that enters the body is a plastic polymer tube into which short, lengthwise slits have been cut. The following is a picture of the SKy Device:

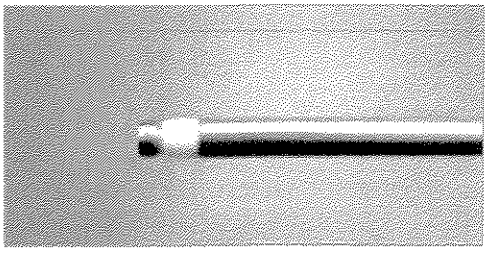
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2 In an effort to avoid a charge of double patenting, the '404 patent applicants filed a "Terminal Disclaimer," foregoing any coverage of the '404 patent beyond the life of the '888 patent. (Exhibit F).

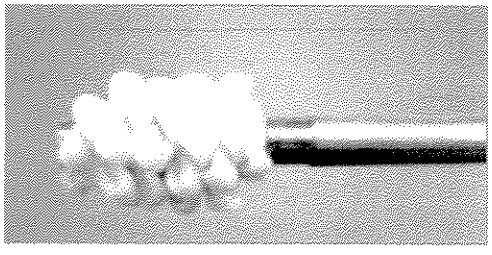


The SKy Bone Expander System

Using the SKy Device, a surgeon first makes an incision in the patient's body, and inserts a needle and then a guide wire into the injured vertebra. (See Exhibit X, Surgical Technique for SKy Device.) Through a cannula – a metal sleeve used for access to a location beneath the skin – a surgical drill is introduced into the vertebra. The distal end of the SKy Device is then placed into the vertebral space close to the point of fracture. Id. The surgeon then rotates the handle on the SKy Device clockwise causing a nut to move toward the distal end. The force of the nut against the plastic material at the end of the SKy Device causes the plastic polymer tube to bow outwards according to the pre-cut slits. As the surgeon turns the handle further, the plastic at the distal end of the SKy Device bunches up further to form plastic petals or fingers protruding out from the tube. Id. The following are pictures of the tip of the SKy Device before and after deployment:

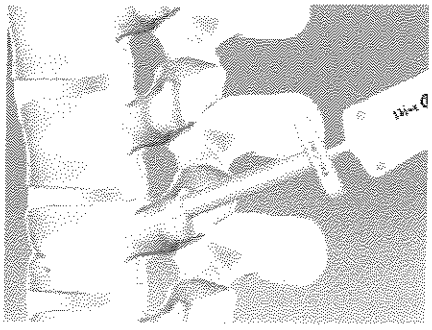


SKy before expansion



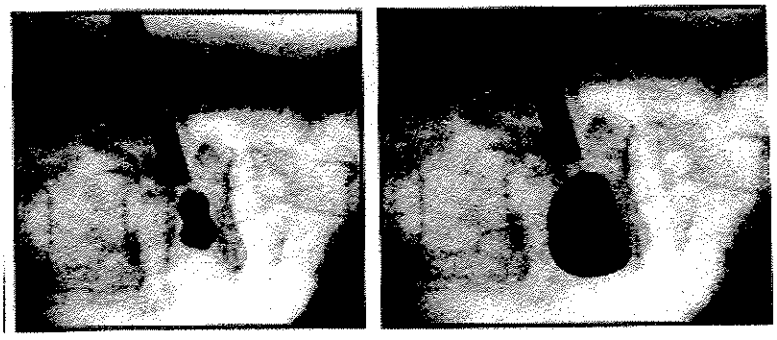
SKy after maximal expansion

In addition, the following is a depiction of the SKy Device as it would be fully deployed in a patient:



Thus, as opposed to an inflatable balloon device which has a uniform, smooth surface as it inflates, the SKy Device's petal structure opens to create an uneven surface with peaks and valleys to raise the collapsed vertebra and reduce, or repair, the fracture.

By contrast to DOT's SKy Device, Kyphon's inflatable device covered by the Inflatable Bone Tamp Patents creates a smooth, egg-shell like void. The following x-ray showing deployment of the KyphX Inflatable Bone Tamp demonstrates this:



balloon tamp inflation

(Source: I.H. Lieberman et al., "Initial Outcome and Efficacy of 'Kyphoplasty' in the Treatment of Painful Osteoporotic Vertebral Compression Fractures," Spine 2001; 26:14, pp. 1631-1638, at 1633 Fig. 2 (marked with production numbers DOTINC 050550-57).)

The contrast between DOT's accused SKy Device and Kyphon's inflatable bone tamp is further demonstrated by the figures below:

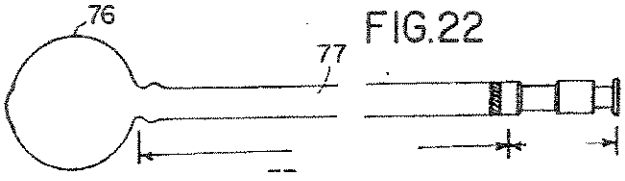
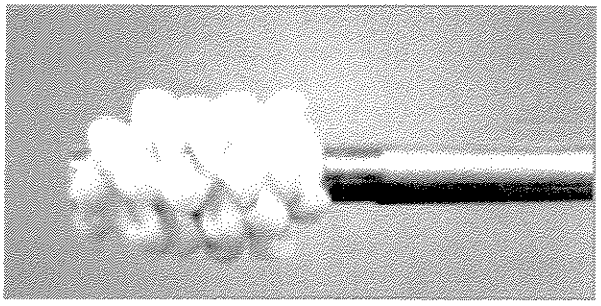


Figure 22 from U.S. Patent No. 5,108,404 (showing balloon contour)



SKy Device in deployed state (showing petal-like configuration)

The surgeon monitors the deployment of the SKy Device through the use of X-ray fluoroscopy, and a display on the hard plastic housing of the SKy Device indicates the diameter to which the SKy Device has been expanded. Id. Once the desired void is created, the surgeon then turns the handle counterclockwise to retract the petals or fingers which gradually return to their original cylindrical shape around the metal rod so that the SKy Device may be removed from the patient. The surgeon then fills the void created in the vertebra with the material of his choosing in order to stabilize the area.

C. The Relevant Anatomy

To properly construe the asserted claims, it is important to have an understanding of the anatomy of the bone structure at issue. The SKy device is used in the vertebrae in the spine. All bones consist of several different, distinct structures. The outer, hard portion of the bone that one can feel through the skin is called cortical bone. The interior volume of the bone formed by the cortical bone walls is made up of cancellous bone, a solid, porous mineral which contains a latticework of delicate bone that forms small cavities. See Stedman's Medical Dictionary ("Stedmans") (27th ed.) at p. 276. Stedman's, a standard medical text relied on routinely by surgeons, defines cancellous bone as that having "a lattice like or spongy structure,"

and Medline, the vast on-line physician search engine, defines cancellous bone as "having a porous structure made up of intersecting plates and bars that form small cavities or cells." (See Exhibit I and J.)

The cavities and pores in the cancellous bone are filled with bone marrow. (Exhibit C, ¶ 27; Exhibit L, Kyphon training manual, at KY 73082.) Bone marrow is a viscous, liquid material that, among other things, serves to generate new blood cells. (Exhibit I, Stedman's, at p. 1067.) Stedman's defines bone marrow as the "highly cellular hematopoietic [blood-cell forming] connective tissue filling the medullary cavities and spongy epiphyses of bones," and Medline defines bone marrow as "a soft highly vascular modified connective tissue that occupies the cavities and cancellous part of most bones." (See Exhibits I and J; Exhibit L, Kyphon training manual, at KY 73082.)

The relationship between the cancellous bone and the bone marrow in the interior bone cavity is analogous to a wet sponge, where the cancellous bone is the sponge structure containing crevices and pores. (Exhibit K, ¶ 32.) The bone marrow is the viscous liquid element which fills those crevices and pores. (Id.; Exhibit L, at KY 73082.)

III. THE COURT'S ROLE IN CLAIM CONSTRUCTION

A. Intrinsic Evidence Is the Most Important Evidence

Claim construction is a matter of law for the Court. Markman v. Westview Instruments, Inc., 517 U.S. 370, 384-391 (1996). To ascertain the meaning of claim terms, three sources of "intrinsic evidence" are used: the claims themselves; the patent specification; and, the prosecution history. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). These sources are referred to as intrinsic evidence because they include the public record of the patent and claims. Such intrinsic evidence is "the most

significant source of the legally operative meaning of the disputed claim language." Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

To define the scope of the invention, a court first looks to the words of the claims themselves. Id. The words of the claims are to be given their ordinary meaning unless that meaning is inconsistent with the usage of the word in the specification and prosecution history. See Desper Prods., Inc. v. QSound Labs., Inc., 157 F.3d 1325, 1336 (Fed. Cir. 1998); Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (citations omitted) (the specification may require that a term be construed more narrowly than its dictionary definition). "Throughout the construction process, it is important to bear in mind that the viewing glass through which the claims are construed is that of a person skilled in the art." Interactive Gift Express, 256 F.3d at 1332.

Significantly, the court should also review the specification to determine the meaning of the claim terms. See id.; Vitronics, 90 F.3d at 1582; Markman, 52 F.3d at 979. Claims should not be interpreted "in a vacuum," but rather, should be consistent with the specification which provides content for the proper construction of the claims because it explains the nature of the patentee's invention. See Medrad, Inc. v. MRI Devices Corp., 2005 WL 605532, No. 04-1134 (Fed. Cir. Mar. 16, 2005); Interactive Gift Express, 256 F.3d at 1331; Renishaw, 158 F.3d at 1250.

The Federal Circuit has emphasized the importance of determining the overall context and intent of the invention:

> "[U]ltimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most

> naturally aligns with the patent's description of the invention will be, in the end, the correct construction. A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent.

Renishaw, 158 F.3d at 1250. (emphasis added; citations omitted). The Federal Circuit re-affirmed these principles just weeks ago, in Medrad, quoting the emphasized language above, and further re-asserting that "[w]e cannot look at the ordinary meaning of the [claim] term . . . in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history." Medrad, 2005 WL 605532, at *6 (quoting DeMarini Sports, Inc. v. Worth, Inc., 239 F.3d 1314, 1324 (Fed. Cir. 2001); see also Interactive Gift Express, 256 F.3d at 1331-32 (citing Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186-87 (Fed. Cir. 1998)) (Because there is "a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification[,] . . . it is useful to remember that [the specification should be looked to in ascertain[ing] the meaning of the claim term as it is used by the inventor in the context of the entirety of [the] invention . . . .]") (emphasis added).

The objective and contemporaneous record provided by the intrinsic evidence is the most reliable guide to help the court determine which of the possible meanings of the terms in question was intended by the inventor to particularly point out and claim the invention. C.R. Bard, Inc. v. United States Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (citing Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1203 (Fed. Cir. 2003)). "Statements that describe the invention as a whole, rather than statements that describe only the preferred embodiments, are more likely to support a limiting definition of a claim term." Bard, 288 F.3d at 864 (citing Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1347 (Fed. Cir. 1998)). "Accordingly, other things being equal, certain sections of the specification are more likely to contain statements that support a limiting definition of a claim term than other sections, although

what import to give language from the specification must, of course, be determined on a case by case basis." Bard, 288 F.3d at 864. The Federal Circuit noted that "[i]n relying on statements in the specification to limit claim terms, while the statement's location is not determinative of claim construction, the location can signal the likelihood that the statement will support a limiting definition of a patent claim term." Bard, 288 F.3d at 864 (citation omitted).

In Bard, the Federal Circuit limited claim terms to a sole embodiment disclosed in the specification. Bard, 388 F.3d at 862-863. The Bard case involved a device used to repair hernias, known as a hernia plug. Bard, 388 F.3d at 859. At issue on appeal was whether the claim terms relating to the surface of the plug limited the plug to one having a "pleated" surface. Bard, 388 F.3d at 860. Rather, the Federal Circuit accepted the accused infringer's argument that the plug must be pleated because neither the embodiments nor the drawings in the specification described a non-pleated plug. Bard, 388 F.3d at 866. The court found that the statements in the specification sufficed by themselves to demonstrate that the plug had to be pleated. Bard, 388 F.3d at 866. The Federal Circuit evaluated the specification, and noted that in both the Summary of Invention and the Abstract, the patent effectively "defined" the inventive plug as limited to a pleated surface, by using the terms "having" or "including" a pleated surface. Bard, 388 F.3d at 864 n.3.

The prosecution history may also be of significance in determining the meaning of claim terms because. As the Federal Circuit has stated, "claims may not be construed one way [by the patentee] in order to obtain allowance and in a different way against accused infringers." Spectrum Int'l Inc. v. Sterilite Corp., 164 F.3d 1372, 1379 (Fed. Cir. 1998) (citations omitted).

Because the claimed invention must be novel and non-obvious over the prior art, the prior art cited during prosecution also gives guidance as to what the claims do not cover. See

Vitronics, 90 F.3d at 1583 (citing Autogiro Co. of America v. United States, 384 F.2d 391, 399 (Ct. Cl. 1967)).

Additionally, claims should not be construed so that they do not read on the prior art. As the Federal Circuit explained, "[w]hen claims are amenable to more than one construction, they should, when reasonably possible, be interpreted so as to preserve their validity." See Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1557 (Fed. Cir. 1996), cert. denied sub nom., Showa Aluminum Corp. v. Modine Mfg. Co., 518 U.S. 1005 (1996); Harris Corp. v. IXYS Corp., 114 F.3d 1149, 1153 (Fed. Cir. 1997) ("[C]laims should be read in a way that avoids ensnaring prior art if it is possible to do so.") (citing, inter alia, Modine, supra).

B. Extrinsic Evidence May Also Be Considered But May Not Be Used to Alter the Meaning of the Claims

Extrinsic evidence may be considered in determining the meaning of claim terms for the purpose of assisting in the Court's understanding of the underlying technology. Interactive Gift Express, 256 F.3d at 1332. Extrinsic evidence is all of the evidence outside of the patent and its prosecution history. Such evidence would include inventor and expert testimony, treatises and dictionaries. Markman, 52 F.3d at 980. Extrinsic evidence, however, must not be used to alter the meaning of claim terms as defined by the specification and prosecution history. Interactive Gift Express, 256 F.3d at 1332; Markman, 52 F.3d at 981, 986.

IV. CONSTRUCTION OF THE ASSERTED CLAIMS

A. Disputed Claims and Claim Terms in the '404 and '888 Patents

DOT's claim construction for each disputed element of claims 1, 3, 7, 8, 9, 11, and 14 of the '888 Patent, and claims 1, 3, 8, 9, 10, 12, and 15 of the '404 Patent, appears in claim charts attached hereto at Tabs A and B, respectively.

1. Claim 1 of the '404 and '888 patents

Independent claim 1 of the '404 patent (with disputed claim terms in bold) requires:

> 1. A method of fixation of a fracture or impending fracture of a bone having [a] **bone marrow** therein comprising:
> [b] **forming a passage in the bone marrow**;
> [c]**compacting the bone marrow to increase the volume of said passage**; and
> filling the passage with a **[d] flowable material capable of setting to a hardened condition.**

Claim 1 of the '404 and '888 patents are virtually identical, except as discussed above, the '888 patent relates to osteoporotic bone. For purposes of this claim construction memorandum, DOT refers to the claims of the '404 patent, as it more broadly applies to bone in general.

(a.) bone marrow

The claim term "bone marrow," should be given its ordinary meaning, which is "the viscous liquid material contained within the interstices (spaces) of the cancellous bone"

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Bone marrow is therefore separate and distinct from both cancellous bone and cortical bone. Indeed, Kyphon's expert published an article in 1987 discussing bone marrow as distinct from cancellous. (See Exhibit E-5, at p. 493.)

(b) forming a passage in the bone marrow

The parties apparently disagree regarding the "bone marrow" aspect of this claim term. DOT contends that "forming a passage in the bone marrow" means "forming a passage in the viscous liquid material contained within the interstices (spaces) of the cancellous bone." This would involve creating a passage through the cortical bone.

(c) compacting the bone marrow to increase the volume of said passage

With respect to the claim term "compacting the bone marrow to increase the volume of said passage," for the reasons set forth below, this claim term is limited to a balloon, or an inflatable device, and means "using an inflatable device to form a void in the interior of a bone, by compressing substantially all of the bone marrow away from a central portion of an interior bone volume, towards the walls of the bone, to thereby increase a volume of a passage."[3]

The '888 Patent is entirely focused on balloons or inflatable devices as a way of creating a void in a fractured bone. There is no other structure, means, or way that is disclosed for creating a void in fractured bone. There is compelling evidence to support this construction.

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[3] DOT expects that Kyphon will argue that the Court, in its preliminary injunction decision herein, determined that the invention was not limited to a balloon. A copy of the Court's decision appears at Exhibit A-30. Kyphon's argument is unavailing, for a number of reasons. First, it is well-settled that findings of fact and conclusions of law at the preliminary injunction stage are not binding. See Univ. of Texas v. Camenisch, 451 U.S. 390, 395 (1981) ("the findings of fact and conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits."); Sofamar Danek Group, Inc. v. DePuy-Motech, Inc., 74 F.3d 1216, 1221 (Fed. Cir. 1996) ("the trial court has no obligation to interpret [patent] claim[s] conclusively and finally during a preliminary injunction proceeding."); Jack Guttman, Inc. v. Kopykake Enterprises, Inc., 302 F.3d 1352, 1361 (Fed. Cir. 2002) ("District courts may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves."). Second, the evidence DOT presents at this stage in the proceedings is more comprehensive than at the preliminary injunction stage. Third, at the preliminary injunction stage, DOT made a balloon argument pursuant to invalidity principles, not claim construction principles. A copy of DOT's preliminary injunction opposition brief appears at Exhibit AA.

First, the title of the invention describes the invention as an inflatable device for fixing bone. The title of the '888 Patent is "Surgical Protocol For Fixation of Osteoporotic Bone Using Inflatable Device" and the title of the later-filed '404 Patent is "Surgical Protocol For Fixation of Bone Using Inflatable Device." Kyphon is hard-pressed to call its invention an inflatable device, and then seek to cover non-inflatable devices.

Second, the Abstract of the invention in the '888 Patent, which gives an overview of the invention (and which is identical to the '404 Patent Abstract except for the "osteoporotic" language), defines the invention as including an inflatable device to compact the bone marrow against the inner wall of the bone:

> "The method of the present invention includes a series of steps including penetrating the bone having the fracture with a guide pin, drilling the osteoporotic bone marrow of the bone to enlarge the cavity to be treated, following which a bone specific inflatable device is inserted in the cavity and inflated. The expansion of the device causes a compacting of the osteoporotic bone marrow against the inner surface of the outer wall of the bone to be treated to further enlarge the cavity. . . . In the fixation of vertebral body fractures, an elliptical inflatable device is first used to initiate the compacting of the osteoporotic bone marrow, following which a checker-shaped inflatable device is inserted into the cavity to further compact the osteoporotic bone marrow in all directions. In the fixation of Colles' fractures and proximal humerus fractures, a gourd-shaped inflatable device is used to compact the osteoporotic bone marrow." ('888 Patent, cover page)[4]

This Abstract indicates that the invention of the '888 and '404 Patent is limited to an inflatable device with respect to the step of enlarging the cavity to be treated, which corresponds to the "compacting" step of the claims. The Federal Circuit has noted that "in determining the scope of a claim, the abstract of a patent is a potentially useful source of intrinsic evidence as to the meaning of a disputed claim term." Tate Access Floors, Inc. v. Maxcess

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[4] Emphasis is added throughout this brief, unless otherwise indicated.

Technologies, Inc., 222 F.3d 958 (Fed. Cir. 2000) (citing Hill-Rom Co. v. Kinetic Concepts, Inc., 209 F.3d 1337, 1341 n.* (Fed.Cir.2000)).

Third, the "Background of the Invention" of the '888 and '404 Patents defines the technology of the invention as "percutaneous balloon technology"; more specifically, the Background of Invention states:

> "Every year in the United States there occurs approximately 1.2 million fractures due to osteoporosis. Nine hundred thousand (900,000) of those fractures occur in bones which can be treated with the percutaneous balloon technology of the present invention which includes instant fixation by methyl methacrylate cement or with liquid artificial bone substitutes." ('888 Patent, col. 1, lines 13-19.)

Fourth, the "Summary of Invention" of the '888 Patent (which is identical to the '404 Patent Summary of Invention except for the "osteoporotic" language) is a fourth place in the specification that defines the invention to include an inflatable device for compacting the bone marrow:

> "This invention relates to a method and apparatus for the fixation of fractures of osteoporotic bones. The invention is especially suitable for use in the fixation of vertebral compression fractures, Colles' fractures and fractures of the proximal humerus. The method of the present invention includes a series of steps including forming an incision in the body and penetrating the bone having the fracture with instruments including a guide pin and a cannula, drilling the osteoporotic bone marrow of the bone to enlarge the cavity or passage to be treated, 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 osteoporotic bone marrow against the inner surface of the outer cortical wall of the bone to be treated to further enlarge the cavity. ('888 Patent, col. 1, line 67- col. 2, line 14).

Fifth, the patentee's limitation of the "compacting" step of the claims of the '888 and '404 Patents to an inflatable device is consistent with, and further shown by the fact that every other time the invention of the '888 and '404 Patents is described in the specification, the description includes only a balloon or inflatable device with respect to the step of compacting

bone marrow to increase the size of the void in the bone. "Balloon" is used forty-two times to describe the invention, and "inflatable," "inflation," "inflated" and "inflating" are collectively used forty-six times to describe the invention in the '888 and '404 Patents. Moreover, no non-inflatable structure, device or method is described – or even suggested -- in the specification of the '888 and '404 Patents.

Some examples of descriptions of the 'compacting" step of the invention as including a balloon or inflatable device are the following statements in the specification of the '888 and '404 Patents, wherein the specification discloses the surgical procedure (using a balloon as the only means of increasing the size of the void in the bone) for the treatment of three types of fractures: fractures in vertebral bodies, Colles' (wrist bone) fractures, and proximal humerus (shoulder bone) fractures. As to the balloon procedure disclosed for use in treating vertebral body fractures, the specification discloses the invention of using an inflatable device:

> "The surgical procedure for treating a vertebral body is as follows: . . .
>
> As balloon 76 is inflated, it forces the osteoporotic bone marrow 67 laterally and outwardly of the wall of the vertebral body 66. This compacts the bone marrow and leaves a void in the interior of the vertebral body to be treated. The compacted bone marrow forms a dam to block any fracture of the vertebral body. Thus, when liquid synthetic bone or methyl methacrylate cement is forced into the void, the compacted bone marrow will substantially prevent flow through the fracture." ('888 Patent, col. 7, lines 17-25.)
>
> After the balloon 76 has been deflated it is removed from the cannula 30. . . . After the vertebral body has been irrigated, the artificial bone substitute, which may include a synthetic bone or methyl methacrylate cement, is injected into the void left by the inflation of balloon 76. . . . A larger volume is injected than one would predict from the size of the chamber formed with balloon 76 even in those patients injected prophylactically." ('888 Patent, col. 7, lines 26-27, 32-35, 47-49)

As to the balloon procedure disclosed for use in treating Colles' (wrist bone) fractures, the specification discloses the following:

> **"Surgical protocol for Colles' fractures are described as follows with reference to FIGS 29-32. . . . The treatment of the present invention involves the reduction of the fracture with Chinese finger traps and the subsequent use of a balloon to create a chamber followed by the injection of either methyl methacrylate cement or a flowable bone substitute into the chamber to fix the fracture.** ('888 Patent, col. 7, lines 65-66, col. 8, lines 10-15.) . . .
>
> **Expansion of the balloon 95 causes compacting of the osteoporotic bone marrow against the inner surface of the cortical wall**. The balloon is then deflated and the cavity is then injected with a mass 97 of either methyl methacrylate cement or liquid bone substitute." ('888 Patent, col. 8, lines 39-45.)

As to the balloon procedure disclosed for use in treating proximal humerus (shoulder bone) fractures, the specification discloses the same type of "balloon fixation" procedure. ('888 Patent, col. 8, line 46- col. 9, line 17.)

Sixth, the patentee's limitation of the "compacting" step of the claims of the '888 and '404 Patents to an inflatable device is further shown by the figures in the specification for those patents (which are identical in the two patents). All of the figures relating to the step of compacting the bone marrow to increase the volume of the passage in the bone marrow include a balloon or inflatable device. (See Figures 20-24, 28A-28C (Figures 1-19 relate to steps earlier in the process, such as laying the patient on the table and drilling into the bone. Figures 25-27, and Figure 28D through Figure 34 relate to other steps of the method, such as filling the void with bone filling material.)) The "Brief Description of the Drawings" in these patents describes each of these figures as "inflatable devices." ('888 Patent, col. 3, lines 27-40, 51-62.)

Seventh, the patentee's limitation of the "compacting" step of the claims of the '888 and '404 Patents to an inflatable device is further shown by the Record of Invention that the inventors on the '888 and '404 Patents, dated September 26, 1988, setting forth the invention of the '888 and '404 Patents. (Exhibit A-24.) That Record of Invention is titled "Balloon Assisted Fixation of Osteoporotic Fractures." **REDACTED**

REDACTED

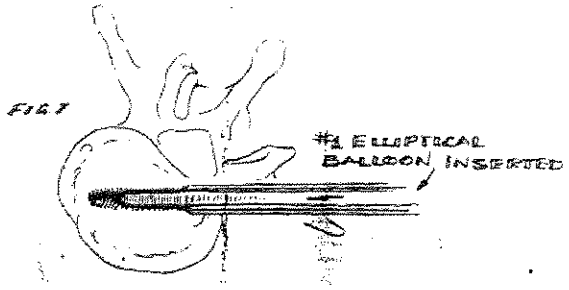
REDACTED

REDACTED

The concept described in the Record of Invention was a method of using a balloon in bone, as is described in the '888 and '404 Patents. In the description section of the invention section, the inventors on the '888 and '404 Patents titled the invention "Surgical procedure for the Osseus Balloon System Percutaneous Vertebral Body Fixation. (Exhibit A-24, at KY 116735.) After the drilling step, the invention disclosure describes solely the use of a balloon means for attempting to reduce the fracture. More specifically, "a checker shaped balloon of 4 different heights and 10 different diameters" is described. The inventors explain the step involving increasing the cavity in the fractured bone as follows: "The appropriate checker shaped balloon is then inserted into the cannula. The diameter of this balloon was determined by the pre-operative CT scan. The height of the balloon to be used is determined by the inter-operative reduction height of the vertebral body fracture." (Id., at KY 116738.)

The Record of Invention also contains the same drawings as appear in the '888 and '404 Patents. With respect to the claim element of compacting the bone marrow to increase the size of the cavity, see the comparison below:

Record of Invention **'888/'404 Figures**



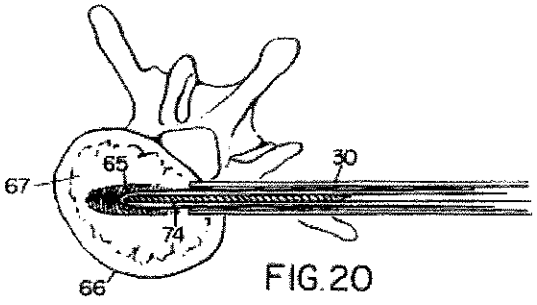
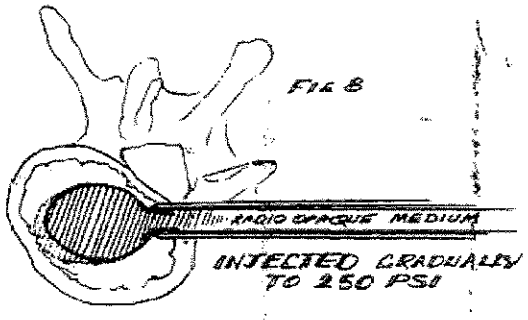


FIG.20



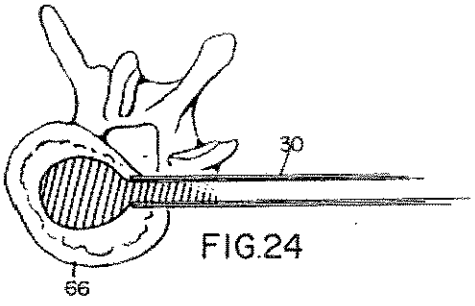
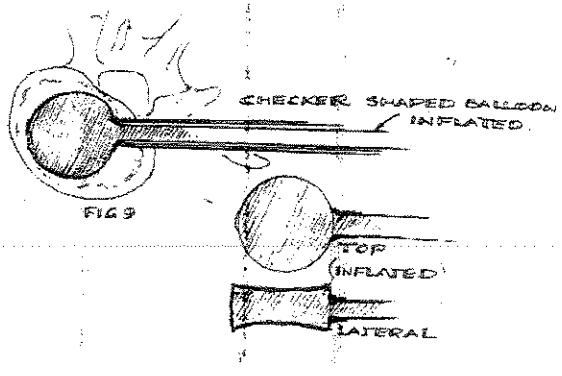


FIG.24



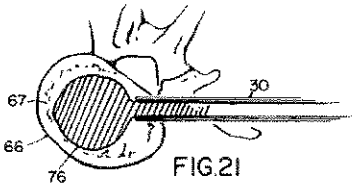


FIG.21

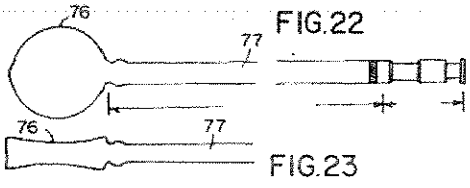


FIG.22
FIG.23

Eighth, the prosecution history describes the use of a balloon to create the cavity in bone by compacting the bone marrow to increase the size of the void. The applicants

distinguished the balloons in the prior art references, explaining that the balloons in those references were not used to create a void in the bone; rather, they were used as stops at the end of the bone, to prevent the bone filler from leaking out. With regard to the Murray reference, the applicants explained that the bone marrow had previously been reamed out of the inside of the bone, before the invention of Murray was used. The applicants stated, "the bone is previously reamed to eliminate the bone marrow therefrom; thus, there is no teaching or suggestion that the expandable devices at the end of the injector device are used for anything other than plugs or seals." (See Exhibit G, at KY 228858, Amendment dated November 28, 1989, at p. 5.)

REDACTED

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(d) flowable material capable of setting to a hardened condition

In the context of the claims and the method of filling a void in bone, "flowable material capable of setting to a hardened condition" means "bone filler material capable of flowing and setting to a hardened condition." Kyphon's patent describes using a "flowable bone substitute" or methyl methacrylate cement (PMMA). ('888 Patent, col. 8, lines 13-15.) One type of flowable bone substitute available at the time of the filing for the '888 Patent was bone graft paste. (Exhibit E, Mitchell Decl., ¶ 18; see also Ex. A-15 and Tab B to DOT's invalidity summary judgment brief, p. 689, Fig. 6.)

REDACTED

Another flowable bone substitute available at that time, and today, is a ceramic bone substitute known as tri-calcium phosphate, which was available at the time of filing in a flowable slurry or paste form. (Exhibit E, Mitchell Decl., ¶ 12; see also Tab B to DOT's invalidity summary judgment brief, p. 689, Fig. 6.) The '888 Patent also describes using "artificial bone substitute, which may include a synthetic bone or [PMMA] cement." ('888 Patent, col. 7, lines 32-25.) Even today, PMMA is used in a paste form when kyphoplasty is done. (Exhibit E, Mitchell Decl., ¶ 13.) Thus, "flowable material" should be construed to include bone filler material in paste form.

2. Claim 3 of the '404 and '888 patents

Dependent claim 3 of the '404 patent[5] (with disputed claim terms in bold) requires:

---

5 There is a corresponding claim 3 in the '888 patent. (See '888 Patent, Exhibit A-2.)

"3. A method as set forth in claim 1, wherein said compacting step includes **forcing the bone marrow outwardly of the central portion of the bone.**"

The claim language "forcing the bone marrow outwardly of the central portion of the bone" means "forcing the bone marrow outwardly of the central portion of the bone." For the reasons set forth above, this is done with an inflatable device. If the claim term were not limited to an inflatable device, it would be invalid under the prior art, as set forth in DOT's invalidity summary judgment brief.

3. Claim 8 of the '404 patent and claim 7 of the '888 patent

Dependent claim 8 of the '404 patent[6] (with disputed claim terms in bold) requires:

"8. A method as set forth in claim 1, **wherein said forming step includes drilling said bone marrow to form said passage**."

In the context of the method of this patent, which involves gaining access to the interior of the bone, the claim language "wherein said forming step includes drilling said bone marrow to form said passage" means "using a drill to break through the cortical wall of the bone."

B. Disputed Claims and Claim Terms in the '043 Patent

DOT's claim construction for each disputed element of claims 2, 17, 20, 23, 24, 25, 26, and 28 of the '043 Patent appears in a claim chart attached hereto at Tab C.

As shown below, the evidence demonstrates that the '043 invention is an improved inflatable device for use in the balloon method of the '888 and '404 Patents.

1. Claim 2 of the '043 patent

Independent claim 2 of the '043 patent (with disputed claim terms in bold) requires:

"2. A method for treating bone comprising the steps of

---

[6] Claim 8 in the '404 patent corresponds to claim 7 in the '888 patent. (See '888 Patent, Exhibit A-2.)

> inserting inside bone a device comprising [a] **a body adapted to be inserted into bone and undergo expansion** in cancellous bone to compact cancellous bone, including [b] **the body includes** material material that, during the expansion in the cancellous bone, applies a force capable of moving fractured cortical bone, and further **includes an internal restraint coupled to an interior of the body to constrain the expansion** in cancellous bone,
>
> [c] **causing constrained expansion of the body** in the cancellous bone, and [d] **compacting cancellous bone by the constrained expansion.**

(a) a body adapted to be inserted into bone and undergo expansion"

For the following reasons, the claim term "a body adapted to be inserted into bone and undergo expansion" means "an inflatable body that can be inserted into bone and expanded." The '043 Patent, like the '888 and '404 Patents is entirely directed to shaping balloons or inflatable devices for use in expanding a void in bone. The intrinsic evidence demonstrates that the patentees limited their invention to balloons or inflatable devices.

The specification is the first place the patentee limited its invention to balloons or inflatable devices. First, the title of the invention is "Inflatable Device For Use in Surgical Protocol Relating to Fixation of Bone." On that basis alone, the patentees are hard-pressed to argue that their invention covers non-inflatable devices.

Second, the Abstract of the '043 Patent defines the invention as involving a balloon for optimum compression of all the bone marrow:

> "A balloon for use in compressing cancellous bone and marrow (also known as medullary bone or trabecular bone) against the inner cortex of bones whether the bones are fractured or not. The balloon comprises an inflatable, non-expandable balloon body for insertion into said bone. The balloon is prevented from applying excessive pressure to the outer cortical bone. The wall or walls of the balloon are such that proper inflation the balloon body is achieved to provide for optimum compression of all the bone marrow. The balloon is able to be folded so that it can be inserted quickly into a bone. The balloon can be made to have a suction catheter. The main purpose of the balloon is the forming or enlarging of a cavity or passage in a bone, especially in, but not limited to, vertebral bodies."

Third, the introduction to the specification, which appears before the Background of The Invention section, also defines the invention as involving improvements to balloons used to treat bones. "This invention relates to improvements in the surgical treatment of bone conditions of the human and other animal bone systems and, more particularly, to an inflatable balloon-like device for use in treating such bone conditions." ('043 Patent, col. 1, lines 7-10.)

Fourth, the Summary of Invention section explains that the '043 Patent improves on the step of the method claimed in the '888 and '404 Patents involving using a balloon to create a cavity in bone, specifically, by improving the engineering features of the balloons:

> In U.S. Pat. Nos. 4,969,888 and 5,108,404, an apparatus and method are disclosed for the fixation of fractures or other conditions of human and other animal bone systems, both osteoporotic and non-osteoporotic. The apparatus and method are especially suitable for use in the fixation of, but not limited to, vertebral body compression fractures, Colles fractures and fractures of the proximal humerus.
>
> The method disclosed in these two patents includes a series of steps which a surgeon or health care provider can perform to form a cavity in pathological bone . . . .
>
> "**The method [of the '888 and '404 Patents] further includes drilling the bone to be treated to form a cavity or passage in the bone, following which an inflatable balloon-like device is inserted into the cavity or passage and inflated.** The inflation of the inflatable device causes a compacting of the cancellous bone and bone marrow against the inner surface of the cortical wall of the bone to further enlarge the cavity or passage. The inflatable device is then deflated and then is completely removed from the bone. A smaller inflatable device (a starter balloon) can be used initially, if needed, to initiate the compacting of the bone marrow and to commence the formation of the cavity or passage in the cancellous bone and marrow. After this has occurred, a larger, inflatable device is inserted into the cavity or passage to further compact the bone marrow in all directions.
>
> While the apparatus and method of the above patents [the '888 and '404 Patents] provide an adequate protocol for the fixation of bone, it has been found that the compacting of the bone marrow and/or the trabecular bone and/or cancellous bone against the inner surface of the cortical wall of the bone to be treated can be **significantly improved with the use of inflatable devices that incorporate additional engineering features not heretofore described and not properly controlled with prior inflatable devices in such patents. A need has therefore**

> **arisen for improvements in the shape, construction and size of inflatable devices for use with the foregoing apparatus and method, and the present invention satisfies such need.**"
> ('043 Patent, col. 1, line 19, through col. 2, line 9.)

That is the invention -- an improved inflatable device, in terms of size, construction and shape, for use in the balloon expansion method of the '888 and '404 Patents.

Fifth, the Background of the Invention section of the '043 Patent reviews and distinguishes the prior art relating to numerous patented inventions involving balloons used in medical applications. ('043 Patent, col. 2, line 10, through col. 3, line 13.) The '043 Patent then explains that the balloon invention of the '043 Patent is different from the prior art because it shows how to use shaped balloons in bone:

> "It can be concluded from the foregoing review of the prior art that there is little or no substantive information on inflatable devices used to create cavities in bone. It does not teach the shape of the balloon which creates a cavity that best supports the bone when appropriately filled. It does not teach how to prevent balloons from being spherical when inflated, when this is desired. Current medical balloons can compress bone but are too small and generally have the wrong configuration and are generally not strong enough to accomplish adequate cavity formation in either the vertebral bodies or long bones of the body.
>
> U.S. Pat. Nos. 4,969,888 and 5,108,404 disclose a checker-shaped balloon for compressing cancellous bone, but does not provide information on how this balloon remains in its shape when inflated. Thus, the need continues for an **improved inflatable device** for use with pathological bones and the treatment thereof." ('043 Patent, col. 3, lines 14-31.)

Sixth, the Summary of the Invention section of the '043 Patent further defines the invention as being an improved inflatable device for use in the balloon method of the '888 and '404 Patents:

> The present invention is directed to a balloon-like inflatable device or balloon for use in carrying out the apparatus and method of the above-mentioned U.S. Pat. Nos. 4,969,888 and 5,108,404. Such inflatable devices, hereinafter sometimes referred to as balloons, have shapes for compressing cancellous bone and marrow (also known as medullary bone or trabecular bone) against the inner cortex of bones whether the bones are fractured or not.

> In particular, the present invention is directed to a balloon for use in treating a bone predisposed to fracture or to collapse. The balloon comprises an inflatable, non-expandable balloon body for insertion into said bone. The body has a predetermined shape and size when substantially inflated sufficient to compress at least a portion of the inner cancellous bone to create a cavity in the cancellous bone and to restore the original position of the outer cortical bone, if fractured or collapsed. The balloon body is restrained to create said predetermined shape and size so that the fully inflated balloon body is prevented from applying substantial pressure to the inner surface of the outer cortical bone if said bone is unfractured or uncollapsed.
>
> In addition to the shape of the inflatable device itself, another aspect of importance is the construction of the wall or walls of the balloon such that proper inflation of the balloon body is achieved to provide for optimum compression of all the bone marrow. ('043 Patent, col. 3, lines 34-59.)

Seventh, the Background of the Invention section of the '043 Patent goes on to explain that, therefore, the invention is an improved inflatable device, involving internal and external restraints on the balloon, for use in expanding a cavity in bone:

> "The primary object of the present invention is to provide an **improved balloon-like inflatable device** for use in carrying out a surgical protocol of cavity formation in bones to enhance the efficiency of the protocol, to minimize the time prior to performing the surgery for which the protocol is designed and to improve the clinical outcome. These balloons approximate the inner shape of the bone they are inside of in order to maximally compress cancellous bone. Preferably, they are made of inelastic material and kept in their defined configurations when inflated, by various restraints, including (but not limited to) use of inelastic materials in the balloon body, seams in the balloon body created by bonding or fusing separate pieces of material together, or by fusing or bonding together opposing sides of the balloon body, woven material bonded inside or outside the balloon body, strings or bands placed at selected points in the balloon body, and stacking balloons of similar or different sizes or shapes on top of each other by gluing or by heat fusing them together. ('043 Patent, col. 4, lines 10-29.)

The Background of the Invention of the '043 Patent goes on to list embodiments of the invention, which include 9 different types of balloon embodiments, such as (1) the "doughnut (or torus) shaped balloon," (2) the spherical balloon surrounded by a ring-shapes balloon segment, (3) the "kidney bean shaped" balloon, (4) the balloon shaped like the head of the femur (thigh)

bone, (5) the "humpbacked banana" balloon, approximating the distal radius (wrist) bone, (6) the balloon approximating the shape of the proximal tibial epiphysis (leg bone just below the knee), (7) the balloon approximating the shape of the proximal humeral epiphysis (arm bone between the elbow and shoulder), (8) a balloon with a suction device, and (9) balloons with protective sheaths as puncture guards. ('043 Patent, col. 4, lines 37-65.)

The Background of the Invention confirms that these embodiments reflect that the invention is an improvement on the inflatable devices of the '888 and '404 Patents:

> "The present invention, therefore, provides **improved, inflatable devices for creating or enlarging a cavity or passage in a bone** wherein the devices are inserted into the bone." ('043 Patent, col. 4, line 66, through col. 5, line 2.)

In addition, the Summary of Invention further limits the invention to improvements in the design and construction of balloons to be used in bone by stating the goals of the invention with respect to each type of bone to be treated, and then stating that each of those goals is "satisfie[d]" by designing inflatable devices (balloons) with specific materials and construction:

> "A primary goal of percutaneous vertebral body augmentation of the present invention is to provide a balloon which can create a cavity inside the vertebral body whose configuration is optimal for supporting the bone. . . .
> The present invention satisfies these goals through the design of inflatable devices to be described. ('043 Patent, col. 5, lines 35 – 46)

* * *

> "A primary goal of percutaneous proximal humeral augmentation is to create a cavity inside the proximal humerus whose configuration is optimal for supporting the proximal humerus. . . . The present invention satisfies these goals through the design of the inflatable devices to be described. ('043 Patent, col. 6, lines 17 – 28)

* * *

> "A primary goal of percutaneous distal radius augmentation is to create a cavity inside the distal radius whose configuration is optimal for supporting the distal radius. . . . The

> present invention satisfies these goals through the design of inflatable devices either already described or to be described. ('043 Patent, col. 6, lines 50–62.)
>
> * * *
>
> "A primary goal of percutaneous femoral head (or humeral head) augmentation is to create a cavity inside the femoral head (or humeral head) whose configuration is optimal for supporting the femoral head. . . .
> The present invention satisfied these goals through the design of inflatable devices either already described or to be described. ('043 Patent, col. 7, lines 10–24.)
>
> * * *
>
> A primary goal of percutaneous proximal tibial augmentation is to create a cavity inside the proximal tibia whose configuration is optimal for supporting either the medial or lateral tibial plateaus. . . . The present invention satisfies these goals through the design of the inflatable devices to be described. ('043 Patent, col. 7, lines 50-62.)

After each of these stated goals, and statements that those goals are satisfied with balloons with particular designs, the '043 Patent goes on in each instance to explain how each of the balloons may be constructed and shaped to conform to the bone in which they are being used.

Eighth, each of the 20 figures in the '043 Patent shows a different shaped or construction of an inflatable device (e.g., a balloon).

Ninth, the inventors limited their invention to balloons in the prosecution history. For example, they stated:

> "The present invention is adapted to be used within a bone to compact or compress the inner cancellous bone to form a cavity for receiving the supporting materials which can harden to a solid and relatively rigid condition. The bone being compressed is diseased, and the balloon is designed to compact the unhealthy bone and make a cavity where the bone used to be so that it can be replaced. . . . The balloon devices and the directions for their use provided by the present invention allow a surgeon to accomplish this efficiently, yet without moving the outer cortical bone beyond its normal dimensions, preventing harm."

(Exhibit H, at KY 229160, November 27, 1995 Amendment and Response to Office Action, at p. 6.)

In addition, in the prosecution history, the inventors distinguish the '404 Patent as not specifically explaining how to shape the balloon of that invention:

> Scholten [i.e., the '888 and '404 Patents] teaches the method for compacting cancellous bone to create a cavity, but fails to teach or disclose non-elastic balloon bodies. While suggesting checker-shaped and gourd-shaped balloon, no restraint means for achieving these shapes are taught or disclosed. In addition, while suggesting shapes and sizes for these balloon bodies, there is no recognition of the [way to] provide a configuration with a predetermined shape and size.
>
> * * *
>
> Scholten discloses the concept of a checker-shaped balloon whose top and bottom are parallel, but does not provide enabling methods for maintaining the parallel sides."

(Id., at KY 229179, 229181, November 27, 1995 Amendment and Response to Office Action, at pp. 25, 27.)

REDACTED

REDACTED

(b) the body. . .includes an internal restraint couple to an interior of the body to constrain the expansion in cancellous bone

For all the reasons set forth above, the claim term "an internal restraint coupled to an interior of the body to constrain the expansion in cancellous bone" means "a structure that is connected to the interior of the inflatable body (balloon) that limits movement of the internal

walls of the inflatable body." Such a structure would include the disclosed string-like members and the disclosed glued/welded seams joining internal surfaces of walls of an inflatable body:

> "These balloons approximate the inner shape of the bone they are inside of in order to maximally compress cancellous bone. Preferably, they are made of inelastic material and kept in their defined configurations when inflated, by various restraints, including (but not limited to) use of inelastic materials in the balloon body, seams in the balloon body created by bonding or fusing separate pieces of material together, or by fusing or bonding together opposing sides of the balloon body, woven material bonded inside or outside the balloon body, strings or bands placed at selected points in the balloon body, and stacking balloons of similar or different sizes or shapes on top of each other by gluing or by heat fusing them together." ('043 Patent, col. 4, lines 15-29.)

(c) causing constrained expansion of the body

The "body" in this claim language refers to the body adapted to be inserted into bone and undergo expansion, from earlier in the claim (see above, element (a)). For all the reasons set forth above, the claim term "causing constrained expansion of the body" therefore means "constraining the expansion of the inflatable body."

(d) compacting cancellous bone by the constrained expansion

The "constrained expansion" in this claim language refers to the constrained expansion with the inflatable device, from the previous claim language. For all the reasons set forth above, "compacting cancellous bone by the constrained expansion" means "using an inflatable body to form a void in the interior of a bone, where the expansion of the inflatable body is restrained by a structure connected to the interior of the inflatable body that limits movement of the internal walls of the inflatable body."

2. Claim 17 of the '043 patent

Independent claim 17 of the '043 patent (with disputed claim terms in bold) requires:

17. A method for treating bone comprising the steps of Inserting inside bone a device comprising [a] a **body adapted to be inserted into bone and undergo expansion** in cancellous bone to compact cancellous bone, [b] **the body including at least two materials that, during the expansion** in cancellous bone, **apply a force capable of moving fractured cortical bone and constrain the expansion** in cancellous bone,

[c] causing constrained expansion of the body in cancellous bone, and

[d] compacting cancellous bone by the constrained expansion.

The claim language labeled [a] in claim 17 above is the same as in claim 2, and should be construed as in claim 2: "an inflatable body that can be inserted into bone and expanded." The claim language labeled [c] and [d] in claim 17 is the same as in claim 2, and should be interpreted the same way, as set forth above.

Consistent with the interpretation of the claim language in Claim 2, and for the reasons supporting that construction, the claim language "the body including at least two materials that, during the expansion in cancellous bone, apply a force capable of moving fractured cortical bone and constrain the expansion in cancellous bone" means "an inflatable body that can be inserted into bone and expanded, the inflatable body including at least two materials, one of which constrains its expansion by an internal or external structure connected to the inflatable body that limits movement of the walls of the inflatable body." For an example of an external restrain, see Figures 16-18 of the '043 Patent. For an example of an internal restraint, see the '043 Patent at Figures 2 and 3, and at col. 4, lines 15-29.

V. CONCLUSION

For the foregoing reasons, DOT requests that the disputed claim terms of the '888, '404 and '043 Patents be adopted by the Court and provided to the jury at trial in this matter.

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April 6, 2005

CERTIFICATE OF SERVICE

I, Maryellen Noreika, hereby certify that copies of the foregoing were caused to be served this 6h day of April, 2005 upon the following in the manner indicated:

BY HAND DELIVERY

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Maryellen Noreika (#3208)

A

U.S. PATENT NO. 4,969,888
CLAIMS AND DOT'S CONSTRUCTION

'888 Patent Claim	DOT's Construction
1. A method of fixation of a fracture or impending fracture of an osteoporotic bone having osteoporotic bone marrow therein comprising:	the viscous liquid material contained within the interstices (spaces) of the cancellous bone
forming a passage in the bone marrow;	forming a passage in the viscous liquid material contained within the interstices (spaces) of the cancellous bone
compacting the bone marrow to increase the volume of said passage and	using an inflatable device to form a void in the interior of a bone, by compressing substantially all of the bone marrow away from a central portion of an interior bone volume, towards the walls of the bone, to thereby increase a volume of a passage
filling the passage with a flowable material capable of setting to a hardened condition.	bone filler material capable of flowing and setting to a hardened condition
3. A method as set forth in claim 1, wherein said compacting step includes forcing the osteoporotic bone marrow outwardly of the central portion of the bone.	forcing the bone marrow outwardly of the central portion of the bone
7. A method as set forth in claim 1, wherein said forming step includes drilling said osteoporotic bone marrow to form said passage.	using a drill to break through the cortical wall of the bone
8. A method as set forth in claim 7, wherein said drilling step includes guiding a drill through into the proximate corticol bone marrow.	

U.S. PATENT NO. 4,969,888
CLAIMS AND DOT'S CONSTRUCTION

'888 Patent Claim	DOT's Construction
9. A method as set forth in claim 7, wherein said forming step includes drilling the osteoporotic bone marrow to a predetermined depth.	
11. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	
14. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	

B

U.S. PATENT NO. 5,108,404
CLAIMS AND DOT'S CONSTRUCTION

'404 Patent Claim	DOT's Construction
1. A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:	the viscous liquid material contained within the interstices (spaces) of the cancellous bone
forming a passage in the bone marrow;	forming a passage in the viscous liquid material contained within the interstices (spaces) of the cancellous bone
compacting the bone marrow to increase the volume of said passage; and	using an inflatable device to form a void in the interior of a bone, by compressing substantially all of the bone marrow away from a central portion of an interior bone volume, towards the walls of the bone, to thereby increase a volume of a passage
filling the passage with a flowable material capable of setting to a hardened condition.	bone filler material capable of flowing and setting to a hardened condition
3. A method as set forth in claim 1, wherein said compacting step includes forcing the bone marrow outwardly of the central portion of the bone.	forcing the bone marrow outwardly of the central portion of the bone

U.S. PATENT NO. 5,108,404
CLAIMS AND DOT'S CONSTRUCTION

'404 Patent Claim	DOT's Construction
8. A method as set forth in claim 1, wherein said forming step includes drilling said bone marrow to form said passage.	using a drill to break through the cortical wall of the bone
9. A method as set forth in claim 8, wherein said drilling step includes guiding a drill through and into the proximate cortical bone marrow.	
10. A method as set forth in claim 8, wherein said forming step includes drilling the bone marrow to a predetermined depth.	
12. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	
15. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	

C

U.S. PATENT NO. 6,235,043
CLAIMS AND DOT'S CONSTRUCTION

'043 Patent Claim	DOT's Construction
2. A method for treating bone comprising the steps of	
inserting inside bone a device comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, including the body includes [sic] material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone, and further includes an internal restraint coupled to an interior of the body to constrain the expansion in cancellous bone,	an inflatable body that can be inserted into bone and expanded a structure that is connected to the interior of the inflatable body (balloon) that limits movement of the internal walls of the inflatable body
causing constrained expansion of the body in cancellous bone, and compacting cancellous bone by the constrained expansion.	constraining the expansion of the inflatable body using an inflatable body to form a void in the interior of a bone, where the expansion of the inflatable body is restrained by a structure connected to the interior of the inflatable body that limits movement of the internal walls of the inflatable body

U.S. PATENT NO. 6,235,043
CLAIMS AND DOT'S CONSTRUCTION

'043 Patent Claim	DOT's Construction
17. A method for treating bone comprising the steps of inserting inside bone a device comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, the body including at least two materials that, during the expansion in cancellous bone, apply a force capable of moving fractured cortical bone and constrain the expansion in cancellous bone, causing constrained expansion of the body in cancellous bone, and compacting cancellous bone by the constrained expansion.	 an inflatable body that can be inserted into bone and expanded causing constrained expansion of the inflatable body using an inflatable body to form a void in the interior of a bone, where the expansion of the inflatable body is restrained by a structure connected to the interior of the inflatable body that limits movement of the internal walls of the inflatable body
20. A method according to claim 1 or 2 or 8 or 17 wherein the constrained expansion lifts vertebral end plates.	
23. A method according to claim 1 or 2 or 8 or 17 wherein the constrained expansion lifts cortical bone.	
24. A method according to claim 1 or 2 or 8 or 17 wherein the step of compacting forms a cavity.	
25. A method according to claim 24 further including the step of filling the cavity with a material.	

U.S. PATENT NO. 6,235,043
CLAIMS AND DOT'S CONSTRUCTION

'043 Patent Claim	DOT's Construction
26. A method according to claim 25 wherein the material comprises bone cement.	
27. A method according to claim 25 wherein the material comprises synthetic bone substitute.	
28. A method according to claim 25 wherein the material comprises a flowable material that sets to a hardened condition.	

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