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., Defendant.	C.A. No. 04-204-JJF **PUBLIC VERSION**

KYPHON'S OPENING BRIEF

REGARDING

CONSTRUCTION OF DISPUTED CLAIM TERMS FOR THE PATENTS-IN-SUIT

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I. INTRODUCTION

This case concerns an innovative surgical procedure to treat fractures of the spine, and particularly vertebral compression fractures. While prior treatments such as analgesics and back braces addressed some of the painful symptoms of these fractures, none dealt with the underlying cause bone that had been broken or had deteriorated due to disease like osteoporosis. Inspired largely by a desire to ease the suffering endured by elderly, osteoporotic patients with broken backs, orthopedic surgeon Mark Reiley and medical instrument specialist Arie Scholten worked together to invent a three-step method, now known as "kyphoplasty", for actually restoring the broken bone to its pre-fractured state.

First, a surgeon forms a passage through the vertebra and bone marrow in the interior of the bone and places an expandable device within that passage. The examples of an expandable device given in the patents are inflatable medical balloons. Second, the surgeon expands the device to reduce the fracture (move the fractured bone back into position) and to compact the surrounding marrow (including cancellous bone), thereby enlarging the passage and creating a void that can be safely filled. Lastly, the void created in the vertebra is filled with a flowable material that can set to a hardened condition, such as bone cement. This material forms an internal cast inside the bone and quickly fixes the fracture. This method commonly known as a "kyphoplasty," and the devices for performing the method, are the subject of the asserted patents: U.S. Patent Nos. 4,969,888 (the '888 patent) and 5,108,404 (the '404 patent), which are both directed to the fundamental kyphoplasty method; U.S. Patent No. 6,235,043 (the '043 patent), which is directed to methods for achieving constrained, controlled expansion of expandable bodies used in kyphoplasty; and US. Patent Nos. 6,241,734 (the '734 patent), and 6,613,054 (the '054 patent), which concern devices used for filling the bone with a flowable material as required in the last step of the kyphoplasty procedure.

Until DOT came to market in the United States market in early 2004 with its infringing devices, Kyphon was the pioneer and, due in large part to its patents, only company marketing devices for use in kyphoplasty. DOT does not deny that its devices are used by surgeons to perform the basic three-step kyphoplasty method; indeed, some of its own materials confirm that very fact. Instead, DOT seeks to avoid infringement by limiting the claims, via claim interpretation, so they would cover only the best ways of practicing the inventions that are specifically identified and described in the text of the patents. But this is not how patents are construed and applied. Because no basis exists for departing from the plain and ordinary meaning of the claim terms that were approved by the U.S. Patent & Trademark Office, and in particular there is no basis for limiting the scope of Kyphon's pioneering inventions to just the use of a balloon as the expandable device, DOT's arguments must be rejected.

II. BACKGROUND

A. Vertebral Compression Fractures

The spine is made up of many small bones called vertebrae. Each vertebra has a hard, outer shell of cortical bone, which surrounds and contains a softer bony matrix of cancellous bone and tissue, often referred to as bone marrow. The inner bone acts like scaffolding to provide strength and support to the outer cortical bone of each vertebra. D.I. 62, Ex. K at KY114731.

A vertebral compression fracture occurs when the cortical bone collapses because the interior of the vertebra is no longer able to support the forces placed on it. This often occurs in patients with either osteoporosis or cancer. *Id.* An estimated 100 million people worldwide are at risk of osteoporosis, including 28 million in the United States alone. Fifty percent of women and twenty five percent of men aged 50 and older will have an osteoporosis-related fracture in their lifetime. *Id.*, Ex. H at KY114403. In fact, in the United States alone, osteoporosis causes a

fracture of the spine every 45 seconds. *Id.*, Ex. J at KY114389. There are approximately 700,000 clinically diagnosed spine fractures each year due to osteoporosis in the United States. In Europe that number is approximately 550,000 patients. The direct medical costs attributed to osteoporotic fractures are estimated to be $17 billion annually. *Id.*, Ex. I at KY114715.

Vertebral compression fractures can result in significant pain, reduced physical function, decreased respiratory function, diminished quality of life, and an increased risk of death. *Id.*, Ex. H at KY114404. A single osteoporotic fracture typically changes the alignment of the spine and increases the risk of a second spine fracture 5-fold or more. Two or more fractures increase the chances of an additional fracture 12-fold. *Id.*, Ex. H at KY114404. As more fractures occur, the spine shortens and curves forward into what is commonly called the "dowager's hump." This condition – whose technical name is "kyphosis" – compresses the chest and abdomen, making normal activities such as walking, eating and sleeping, difficult and painful. Kyphosis also affects breathing and lung capacity, which puts victims at an increased risk of further disease such as pneumonia. *Id.*, Ex. J at KY114389. As a result, a single vertebral compression fracture increases the likelihood of death by 9-fold over four years. *Id.*, Ex. H at KY114404.

B. Traditional Treatments

Before Dr. Reiley and Mr. Scholten invented kyphoplasty, the painful symptoms of a vertebral compression fracture were treated without repairing the deteriorating condition of the bone. These alternatives, still used today by doctors unfamiliar with kyphoplasty, include conventional pain management such as bed rest, narcotic analgesics, and back braces. These treatments provide no long-term functional improvement, make the bone loss which led to the initial fracture worse, and, often, do not even offer pain relief. March 23, 2005 Rebuttal Expert

Witness Report of Michael Marks, M.D. [Ex. A,[1] *hereinafter* March 23, 2005 Marks Report], at 5; *see also* the '404 patent [Ex. B], at 1:27-42. In rare instances, open surgery to insert hardware in the spine has been an option. But this approach is highly invasive because the surgeon makes a long incision to access and expose the surgical site. This is an especially risky and ineffective procedure for elderly patients, and results in poor outcomes in osteoporotic bone, which often cannot even support the hardware. Indeed, such efforts are like "trying to nail a custard pie to the wall." March 23, 2005 Marks Report, at 5-6 (explaining that "[o]pen reduction procedures were rarely of any assistance, because osteoporotic fractures do not support hardware well").

Another alternative for treating vertebral compression fractures is a procedure known as vertebroplasty, in which bone cement is injected under high pressure directly into the fractured bone tissue, without first creating a cavity to receive the cement. In vertebroplasty, high-pressure bone cement injection freezes the deformity without reducing the fracture. Vertebroplasty often leads to complications from cement leakage outside the vertebra being treated, due to its high-pressure delivery and other factors. *Id.* at 3, 6.

C. Kyphoplasty

Recognizing the long-felt need for a treatment that addressed not only the painful symptoms of compression fractures, but also the deteriorating condition of weak bone, Dr. Mark Reiley and Mr. Arie Scholten invented kyphoplasty. As discussed above, kyphoplasty is a minimally invasive surgical procedure that mends vertebral compression fractures caused by conditions such as osteoporosis and cancer. In kyphoplasty, a surgeon typically makes tiny incisions in the back and forms one or more working passages through the cortical bone (the outside layer) and into the interior of the vertebra. This formation typically involves drilling into

[1] Unless otherwise specified, "Ex(s). __" refers to the exhibit(s) attached to the Declaration of Thomas L. Halkowski in Support of Kyphon's Opening Brief Regarding Construction of Disputed Claim Terms for the Patents-in-Suit.

the vertebral body. An expandable device is then inserted into the vertebra. In the case of kyphoplasty using Kyphon devices, a surgeon inserts one or more inflatable bone tamps (IBTs) into the passage and then inflates them. Expansion of the IBTs can reduce the compression fracture, and increase the volume of the passage by compacting the weakened cancellous bone (part of the bone marrow) inside the cortical bone thereby creating a void or cavity. Creation of the void in this manner allows the surgeon to safely fill the void with a flowable material that hardens, like bone cement, using low pressure. Once hardened, this filler material acts as an "internal cast" for the fractured bone, rapidly locking the pieces back into place. Once the procedure is complete, the surgeon closes the tiny surgical incisions with a few stitches and a band-aid.

Unlike prior treatments, kyphoplasty can restore vertebral height and shape, and thereby reduce spinal deformity, increase mobility, and ultimately improve the patient's quality of life. It also can reduce and stabilize the spine fracture and provide immediate pain relief. Complications due to cement leakage, common in vertebroplasty, are also significantly reduced in kyphoplasty, because the flowable filler material is delivered under low pressure into the cavity, and the cavity generally acts as a container to inhibit the flow of cement outside the vertebra. Also, because kyphoplasty is minimally invasive, it requires minimal surgical trauma, and, on average, only a one-day hospital stay. Even outpatient treatment is sometimes possible. Moreover, the patient can rapidly return to normal daily activities without requiring any type of back brace. While kyphoplasty encountered initial skepticism among doctors to whom Kyphon first introduced the revolutionary new technique, it has now become among the fastest growing approaches to remedying injuries to the spine. A recent article in Forbes reported:

> Isador (Izzy) Lieberman was dumbfounded when, in 1997, an energetic inventor named Mark Reiley showed him a new procedure for restoring the shape of broken and bent spine bones. "You're going to take

> a balloon where?" said the Cleveland Clinic orthopedist. "And do what with it?"
>
> Once Lieberman tried the procedure, known as kyphoplasty, he became a convert. Reiley's idea of using a thumb-size balloon as a bellows to prop up compressed vertebrae has become one of the fastest growing back procedures in the U.S. – 33,000 a year.

The Inflatable Spine, FORBES, June 7, 2004, at 227 [Ex. C]; *see also Kyphoplasty Employs Bone Balloon to Correct Kyphosis Due to Fractures*, ORTHOPEDICS TODAY, Nov. 1999 (KY230109-10) [Ex. D] (quoting one physician as stating, "I don't want to sound like an evangelist, but I've never done a technique that is so immediately satisfying and gratifying to the patient and the physician" and noting that the last patient treated by the physician "arrived in a wheelchair due to back pain and walked out to go home 1 1/2 hours later"). Dr. Michael Marks, an orthopaedic surgeon who has performed hundreds of kyphoplasties and who has been retained by Kyphon to address technical issues in this matter, has explained his personal experience regarding the impact of the kyphoplasty procedure:

> I have been treating patients suffering from vertebral compression fractures with kyphoplasty since June 2001. Until that time, I was extremely disappointed with the available procedures for treating these fragile patients who suffered greatly with pain. As a member of the National Osteoporosis Foundation and the only orthopaedic spine surgeon in my community, treating these patients often became my responsibility. The only real non-surgical treatment prior to 1999 was "benign neglect": give the patient narcotics and a brace, and tell them to utilize bed rest until they felt well enough to resume their activities. I literally saw these patients crumble before my eyes. The narcotics made them confused and constipated. The brace rarely fit as well as I would have liked. The bed rest often worsened their osteoporosis.
>
> As a practicing orthopaedic surgeon for more than 17 years, my most grateful patients are those on whom I have performed kyphoplasty. In relatively short order they are returned to their pre-morbid state. I have received the deepest expressions of gratitude from these patients, as well as thank you notes, plaques, and homemade gifts from the patients and their families.

March 23, 2005 Marks Report, at 5. *See also* [Ex. E] (KY375745, video news report regarding kyphoplasty procedure). Thus, the inventions at issue in this suit have been truly pioneering approaches that have literally changed the lives of thousands of patients.

II. THE FIVE PATENTS-IN-SUIT: '888, '404, '043, '734, & '054

Beginning in 1989, Kyphon applied for and received patent protection on both kyphoplasty and the devices used in the procedure.[2] The '888 patent issued on November 13, 1990 and relates to methods for the treatment of pathological conditions in osteoporotic bones. See the '888 patent [Ex. F] The '404 patent issued on April 28, 1992, as a continuation patent of the '888 patent that covers treatment of both osteoporotic and non-osteoporotic bones.[3] [Ex. B].

The '043 patent issued on May 22, 2001, and relates to constraining the expansion of devices used in kyphoplasty so that the surgeon has better control over the expandable bodies. *See* the '043 patent [Ex. G].

The '734 patent issued on June 5, 2001, and the '054 patent (a divisional of the '734 patent) issued on June 5, 2001. *See* the '734 patent [Ex. H] and the '054 patent [Ex. I]. Both of

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[2] In addition to patenting its inventions, Kyphon received FDA clearance in 1998 to market its first expandable balloon devices. D.I. 62., Ex. L [KY114452-454; DOTLTD 89-94] This clearance allowed Kyphon to begin to market its expandable devices for fracture reduction and void creation in the spine, which Kyphon almost immediately began to do. *Id.* Kyphon's products were then used by surgeons to perform kyphoplasty. However, Kyphon was still unable to promote the kyphoplasty procedure itself and the benefits it provides to patients because its bone cement lacked the necessary FDA clearance for use in kyphoplasty. That all changed in April of 2004, when the U.S. Food & Drug Administration (FDA) cleared Kyphon to promote its proprietary bone cement for use in the kyphoplasty procedure. As part of that clearance, the FDA concluded that Kyphon had demonstrated through published data gathered during the preceding five years of clinical experience that the kyphoplasty procedure is associated with significant and maintained reduction in back pain, improvement in quality of life, and increased ability to perform activities of daily living and patient mobility. [Ex. X]. Kyphon is now able to explain those advantages to doctors and patients.

[3] Certain cancers can also make vertebral bones susceptible to compression fractures.

these patents concern the use of a cannula that provides subcutaneous access to the bone, and a finger-actuated tamping instrument that slides through the interior of the cannula and moves material, such as bone cement, into the bone. This procedure is used to complete a kyphoplasty procedure by filling the void with cement.

III. SUMMARY OF ARGUMENT

1. Two claim construction issues are dispositive of DOT's entire non-infringement defense to the patents covering the basic kyphoplasty procedure ('888 and '404): (i) whether "bone marrow" should be narrowly defined as a type of "viscous liquid"; and (ii) whether the second, "compacting" step of the kyphoplasty procedure should be limited to only the particular type of compaction that would result from the use of a balloon. The Court already rejected both arguments in the context of the preliminary injunction proceedings, and neither is a close call because adopting the first would render the claims meaningless and adopting the second would require the Court to ignore a basic tenet of patent law: when interpreting claims, limitations from the specification are not to be read into the claims.

2. The remaining key terms of the '888 and '404 patents unfortunately require "interpretation" only because of DOT's effort to contort their plain meanings in an effort to invalidate Kyphon's patents with old surgical procedures that utilize decades-old standard bone tamp rods.

3. Like its approach to the '888 and '404 patents, DOT attempts to limit the '043 patent so that it covers only the inflatable devices described in the specification as the best mode of practicing the invention. Again, because the claims nowhere mention the limitation of an "inflatable device," DOT's effort to limit the plain and ordinary meaning of the claims must be rejected.

4. Lastly, with regard to the bone filler device patents, DOT asserts that the claims should be interpreted to require use of a plunger for pushing material out of a cannula tube and into a bone, such that the material and the plunger must be in *direct* contact with the cannula

tube. Again, the claims themselves do not have any such limitation. The claims instead simply require that the material and a plunger reside "in" or be advanced "into" or "through" a cannula. Thus, the claims literally cover a device, such as DOT's bone filler device, that has the claimed limitations, primarily a hollow tube inside the outer cannula, in which a plunger in turn slides to push material into a bone.

IV. LEGAL STANDARDS OF CLAIM INTERPRETATION

Claim interpretation is a question of law that must be decided before proceeding to an infringement or invalidity analysis. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71, 976 (Fed. Cir. 1995), *aff'd* 517 U.S. 370 (1996); *see also Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1362 (Fed. Cir. 1998). The construction of disputed claim terms focuses upon the intrinsic evidence, which includes the claim itself, the specification, and the prosecution history. *See Irdeto Access, Inc. v. EchoStar Satellite Corp.*, 383 F.3d 1295, 1299-1300 (Fed. Cir. 2004); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F. 3d 1576, 1582 (Fed. Cir. 1996). Among the intrinsic sources, the starting point for claim construction is always the language of the claims themselves. *Texas Digital Sys. v. Telegenix, Inc.*, 308 F.3d 1193, 1201-02 (Fed. Cir. 2002). Words of the claims are examined in their entirety and in the context of the surrounding language. *Vitronics*, 90 F.3d at 1582. There is a heavy presumption in favor of the ordinary meaning of claim language as understood by one of skill in the art. *Texas Digital*, 308 F.3d at 1202. The Federal Circuit has explained the importance of hewing close to the plain and ordinary meaning of the claims as follows:

> "In construing claims, the **analytical focus must begin and remain centered on the language of the claims themselves**, for it is that language that the patentee chose to use to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.' 35 U.S.C. § 112, ¶ 2." *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331, 59 USPQ2d 1401, 1406 (Fed. Cir. 2001). The terms used in the claims bear a "heavy presumption" that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art.

Id. at 1201-02 (emphasis added). Accordingly, "unless compelled otherwise, a court will give a claim term the full range of its ordinary meaning as understood by persons skilled in the relevant art." *Id.* at 1202. To determine the ordinary meaning of a term, courts may consider and rely on dictionary definitions. *Id.*

Once the ordinary meaning is ascertained, "the intrinsic record also must be examined in every case to determine whether the presumption of ordinary and customary meaning is rebutted." *Id.* at 1204. This presumption is overcome only if "the patentee demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term by redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002); *see also Texas Digital*, 308 F.3d at 1204 (presumption in favor of plain meaning of a claim term can be overcome where the patentee "has clearly set forth an explicit definition of the term different from its ordinary meaning").

The Federal Circuit has, clearly instructed courts to exercise due care to avoid limiting the claims solely to the embodiments disclosed in the specification, even where there may be only one such embodiment of the invention. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904 & 906 (Fed. Cir. 2004) ("[I]t is improper to read a limitation from the specification into the claims. . . . [T]his court has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment."). Indeed, the Federal Circuit has repeatedly emphasized the fundamental tenet that limitations are not imported from the specification into the claims.[4] Thus, in the absence of

[4] *See, e.g., Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 345 F.3d 1318, 1327 (Fed. Cir. 2003) (rejecting the alleged infringer's contention that the meaning of "flexing" must be limited to "cantilever flexing" because the specification "teaches only cantilever flexing," noting that there was no indication in the specification that the inventor "acted as his own lexicographer and clearly set forth a definition of the disputed claim term" or made any "express disclaimer of a particular meaning of 'flexing'"); *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1333 (Fed. Cir. 2001) (holding that the district court's "claim construction impermissibly read limitations from the specification into each of the five disputed claim limitations"); *American Permahedge, Inc. v. Barcana, Inc.*, 105 F.3d 1441, 1444 (Fed. Cir. 1997) ("Claims,

an unmistakable and clear intention by the patentee to alter the plain meaning and to limit the scope of the claims, either in the written description or the prosecution history, such a restrictive reading of the claims constitutes legal error. *Id.* at 906-908 (citing cases).

V. INTERPRETATION OF THE ASSERTED CLAIMS

A. Construction of Disputed Terms in the '888 and '404 Patents[5]

1. "Bone Marrow"

This term is included within all the asserted claims of the '404 and '888 patents. The term "bone marrow" means "a combination of the connective tissue and the cancellous bone framework inside a bone." The Court previously adopted Kyphon's interpretation in its Preliminary Injunction decision. The record amply supports that decision, and DOT has identified nothing that requires in the Court to change it's interpretation to DOT's asserted "viscous liquid" construction.

The language of the claims themselves mandate a construction of bone marrow that includes the cancellous bone framework inside the bone. In the claims of the '888 and '404 patents, the patentee "particularly pointed out and distinctly claimed" an invention that used the term "bone marrow" to reference, at least in part, the web of solid cancellous bone that forms a supportive framework for bones. *See Texas Digital Sys.*, 308 F.3d at 1201-02. Independent claim 1 of the '888 patent is directed to bone having "osteoporotic bone marrow" and requires "forming a passage in the bone marrow" and "compacting the bone marrow." Dependent claims

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not the specification embodiments, define the scope of the protection."); *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 865 (Fed. Cir. 1988) ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations.").

[5] Because the '404 patent is a continuation of the '888 patent, the common claim terms of these patents should be interpreted to have the same meaning. *Abtox, Inc. v. Exitron Corp.*, 131 F.3d 1009, 1010 (Fed. Cir. 1997) (*on rehearing*) (stating that "[a]lthough these claims have since issued in separate patents, it would be improper to construe this term differently in one patent than another, given their common ancestry").

7-9 of the '888 patent, as discussed in more detail below, require "drilling the [said] osteoporotic bone marrow" or drilling "through" and "into" the bone marrow. The claims of the '404 similarly require "forming a passage in," "compacting", and "drilling" the bone marrow. Thus, according to the ordinary meaning of the claim language itself, "bone marrow" must include a solid material such that it can be drilled, have a passage formed in it, and be compacted. One cannot drill, form a passage in, or compact a liquid.

As indicated above, the claims of the '404 patent are substantively identical to the claims of the '888 patent, except that the '888 patent claims are limited to osteoporotic bone. Osteoporosis is a disease that weakens the internal web of cancellous bone and deprives the bone of its interior support. *See* http://www.spineuniversity.com/public/spinesub.asp?id=65 (last visited November 23, 2004) [Ex. J]. The term "bone marrow" has been used in describing the effect of osteoporosis: "Normal bone marrow has small holes within it, but a bone with osteoporosis will have much larger holes." *Osteoporosis, Making the Diagnosis of Osteoporosis*, *at* http://www.endocrineweb.com/osteoporosis/diagnosis.heml (last visited November 10, 2004) [Ex. K]; *see also* Jackie Tane, *What Everyone Should Know About Osteoporosis*, THE DAILY CAMPUS, November 2, 2004, *at* http://www.dailycampus.com/global_user_elements/printpage.cfm?storyid=789865 (last visited November 10, 2004) [Ex. L]. Again, one would not describe a liquid as having holes. Moreover, because osteoporosis indisputably acts upon the supporting framework of cancellous bone – and not the soft pulpy connective tissue embedded within the framework – any reasonable interpretation of the phrase "osteoporotic bone marrow" (which is recited in the claims of the '888 patent and used repeatedly in the specification of both the '888 and the '404 patents) must logically include the cancellous framework. Thus, the plain meaning of bone

marrow, as was duly adopted by the Court, is "a combination of the connective tissue and the cancellous bone framework inside a bone." *See* D.I. 102, at 4.

The specifications of the '888 and '404 patents, which describe the best mode developed by the patentees for practicing the general method of kyphoplasty, do not depart from this ordinary meaning. In fact, the specifications of the patents are completely consistent with the interpretation of "bone marrow" previously adopted by the Court. The specifications of the '888 and '404 patents, like the claims, discuss "drilling the osteoporotic bone marrow" and "compacting of the osteoporotic bone marrow," and describe "formation of a cavity or passage" and "leaving a void" in the osteoporotic bone marrow. *See, e.g.*, the '888 patent, at 2:7; 2:9-12; 2:23-27; 2:30; 7:17-22; 8:40-42; the '404 patent, at 2:12; 2:14-17; 2:26; 2:32; 7:26-32; and 8:50-52. Thus, the specifications of the asserted patents do not provide sufficient evidence to compel the Court to interpret "bone marrow" in a manner contrary to the plain meaning of the claim language, and certainly do not require bone marrow to be defined as a viscous liquid, as DOT contends.

Turning from the intrinsic evidence to the extrinsic, a reference nearly contemporaneous with the filing of the '404 patent and not specific to the osteoporotic context defines bone marrow as including the cancellous (also called "trabecular") portion of the bone:

> The basic microstructure of ***bone marrow consists of a trabecular bone framework*** surrounding fat cells, hematopoietic cells, reticulum cells, nerves, and vascular sinusoids.

1 THE ADULT SPINE, PRINCIPLES & PRACTICE 491 (1991) (emphasis added) [Ex. M]. Other generally contemporaneous U.S. patents[6] similarly define bone marrow in a variety of contexts, as broadly referencing the material inside the bone, including cancellous bone:

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[6] *See Arthur A. Collins, Inc. v. N. Telecom, Ltd.*, 216 F.3d 1042, 1044-45 (Fed. Cir. 2000) ("Even when prior art is not cited in the written description or the prosecution history, it may assist in ascertaining the *1045 meaning of a term to a person skilled in the art.") (citing *Vitronics*, 90 F.3d at 1584).

- 5,192,282 (filed Sept. 9, 1991; issued March 9, 1993), at 1:17-20 ("However, the bone cement can only penetrate into ***the honeycombs of the bone marrow*** if they are clean and free of fat marrow and cell components.");

- 4,981,481 (filed Oct. 6, 1988; issued Jan. 1, 1991), at 5:20-24 (noting that the invention "permits driving in of the marrow nail . . . with little force while ***avoiding crushing of bone marrow*** during the driving-in process");

- 4,513,754 (filed June 19, 1984; issued Apr. 30, 1985), at 1:36-40 (describing "the subsequent ***cutting through of the trabeculae of the bone marrow***").

[Ex. N.]

Despite the straight-forward ordinary meaning of "bone marrow" compelled by the intrinsic and objective authorities,[7] DOT has advanced a contrived definition of "bone marrow" – as a "viscous liquid" that cannot be compacted - in a transparent attempt to avoid infringement liability. D.I. 83, at 9; March 23, 2005 Rebuttal Expert Report of Dr. David Mitchell Regarding Non-Infringement of U.S. Patent Nos. 5,108,404, 4,969,888, & 6,235,043 B1 [Ex. O at ¶ 27], *hereinafter* March 23, 2005 Mitchell Report. DOT's position is so extreme that even its own (now former) technical expert effectively agreed that Kyphon's view of bone marrow as including cancellous bone is the only construction that allows the patent claims and specification to make sense.[8] Indeed, under DOT's construction, the asserted claims would require drilling

[7] In addition, Dr. Reiley, an inventor of the '404 patent, and Dr. Lane, an orthopaedic surgeon who has used DOT's or Kyphon's devices in dozens of kyphoplasty procedures, have both testified that bone marrow can include cancellous bone. Transcript of November 3, 2004 Deposition of Dr. Mark Reiley [Ex. P], at 50:25-51-2; Transcript of November 4, 2004 Deposition of Dr. Joseph Lane [Ex. Q], at 51:14-52:3.

[8] Following are excerpts from the deposition transcript of the deposition of DOT's former technical expert Dr. Rosenberg:

Q. You don't understand the patent's use of the word "compaction" or "compact"?
A. That's correct.
Q. Why not?
MR. VENABLE: Objection.
Q. (By Mr. Scherkenbach) I mean, is there something about the way the patent uses those words that strikes you as, I don't know, odd or wrong?
A. Yes. I don't see how bone marrow is compacted in the way that we would use that word for other substances such as cancellous bone.

holes through a liquid to somehow form a passage in the liquid, and then, defying the laws of physics, compact the drilled liquid to increase the volume of a preexisting passage in the liquid. *See, e.g.*, DAVID HALLIDAY ET AL., FUNDAMENTALS OF PHYSICS 351 (5th ed. 1997) (stating that "gases are readily compressible but liquids are not") [Ex. R].[9] The Patent Office, however, does not issue patents that defy the laws of physics. *Blacklight Power, Inc. v. Rogan*, 295 F.3d. 1269, 1271-72 (Fed. Cir. 2002) (noting the Patent Office's rejection of an application because the inventions described "do not conform to the known laws of physics and chemistry"). Thus, this Court properly rejected DOT's "viscous liquid" construction in its Preliminary Injunction decision, noting that DOT's definition "renders the claim meaningless." D.I. 102, at 4.

DOT has not developed any new evidence that would require the Court to now change its ruling regarding the proper interpretation of "bone marrow." To the contrary, an attorney selected by DOT to study the patents-in-suit and to provide DOT with non-infringement opinions during the pendency of this lawsuit, conceded during his deposition, as follows:

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* * *

Q. I'm asking you to assume, because you're an expert, assume the definition of bone marrow does include cancellous bone. Okay? Even though you disagree, I want you to make that assumption. All right?

A. Okay.

Q. If you make that assumption, isn't it fair to say that the patent's references to compacting bone marrow, in fact, would make sense to someone of skill in the art like yourself?

MR. VENABLE [sic, Namrow]: Objection.

A. I suppose that it would make sense for that portion of whatever definition you're using that is really talking about the cancellous bone.

Q. (By Mr. Scherkenbach) All right.

A. But the other portion of this conjectured definition would not make sense.

Q. Namely, the portion of bone marrow that would include liquid, for example?

A. Well, what we in medicine call the bone marrow.

Transcript of November 22, 2004 Deposition of William S. Rosenberg, M.D. [Ex. S at 57:1-12], 59:22-60:17. DOT's expert also explained that, in his view, "[b]one marrow cannot be compacted. It's cellular and it flows." *Id.* at 58:24-25.

[9] Not only is the incompressibility of liquids something every high school student learns and every physics text teaches, but the intrinsic evidence here specifically notes this phenomenon. The Lee patent cited during prosecution (and by DOT in its preliminary injunction papers) says liquid materials such as bone cement are "virtually incompressible." [Ex. T at 1:42-43].

> In reviewing the prosecution history of these two patents, it becomes pretty clear that both the attorney who wrote these claims and the examiner at the patent office who was reviewing the patent application[] were using the claim term, bone marrow, to refer to both cancellous bone and bone marrow[.]

Transcript of March 17, 2005 Deposition of John Eisenhart [Ex. U], at 63:23-64:6.[10] Thus, DOT's "liquid bone marrow" argument not only renders the claims meaningless and contradicts the patent specifications, it also lacks support in the prosecution history.

In sum, a review of the plain language of the asserted claims, the patents' specifications, the patents' prosecution histories, objective extrinsic evidence in the form of medical definitions and contemporaneous patents, and even statements from DOT's own witnesses and attorney can lead to only one conclusion: "bone marrow" as used in the asserted claims means a combination of the connective tissue and the cancellous bone framework inside a bone.

2. "Forming a Passage in the Bone Marrow"[11]

Each of the asserted claims of the '888 and '404 patents requires the step of "forming a passage in the bone marrow." The plain and ordinary meaning of the term "passage" is: "a path, channel, or duct, through, over, or along which something may pass." THE AMERICAN HERITAGE DICTIONARY (2nd ed. 1985), at 907 [Ex. V]. Nothing in the specification or prosecution history compels a deviation from this plain and ordinary meaning. Therefore, this step should be interpreted as follows – forming a path or channel into the interior of the bone through the bone marrow.

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[10] Although Eisenhart stated that he disagreed with the above definition based upon references he found during computer research, he did not save this research or identify any such references anywhere in his written opinions. Transcript of March 17, 2005 Deposition of John Eisenhart, at 31:6-33:11.

[11] The interpretation of the kyphoplasty method claims should make clear that each of the steps is being performed by a surgeon or other qualified medical person. *See generally* the '888 patent, at 1:6-7; the '404 patent, at 1:9-10 ("This invention relates to improvements in the surgical treatment of bone conditions[.]") (emphasis added).

3. "Compacting the Bone Marrow to Increase the Volume of Said Passage"

Each of the asserted claims of the '888 and '404 patents requires the step of "compacting the bone marrow to increase the volume of said passage." In the context of the claims, particularly in combination with the last claimed step of the surgical procedure, this limitation should be interpreted to mean "compacting the bone marrow to increase the volume of the passage created by the surgeon, so that the resulting cavity can then be safely filled with a flowable material."

The claims require that the "compacting" step be separate and subsequent to the initial step of "forming" the passage, because the bone marrow is compacted to increase the volume of "said" passage. *See Mantech Env'l Corp. v. Hudson Env'l Servs., Inc.*, 152 F.3d 1368, 1375-76 (Fed. Cir. 1998) (holding that the referral in one step of a claim back to the activity in a previous step indicates that an order in steps is required). Thus, the compacting step requires the surgeon to increase the volume of the same passage that the surgeon initially created during the separate "forming" step.

The prosecution history of the '888 patent also notes the importance of compressing the cancellous bone in a manner that allows the resulting cavity to be safely filled with a flowable material. During prosecution, the Examiner rejected claim 1, as originally filed, in view of two references, U.S. Patent No. 4,488,549 ("Lee") and U.S. Patent No. 4,627,434 ("Murray"). Both Lee and Murray generally relate to reaming out a bone canal and filling the canal with bone cement. In response to the rejection, the patentee amended claim 1 (to its current form) and explained that the amended claim was allowable over Lee because the cited references fail "to even remotely suggest the compacting of the bone marrow in the bone to increase the volume of a recess so that the recess can be filled with a flowable material capable of setting to a hardened

condition." December 1, 1989 Amendment, Appl. No. 07/308,724, [D.I. 84, Ex. L at 4] (emphasis added). Similarly, the patentee argued that "[c]laim 1 as amended is allowable under 35 U.S.C. § 103 over Murray because the claim recites the step of compacting the bone marrow in the bone to increase the volume of a recess formed in the bone so that the recess can be filled with a flowable material capable of setting to a hardened condition." *Id.* at 6 (emphasis added). Thus, in light of the prosecution history of the '888 patent, Kyphon acknowledges that the compacting step, as recited in the asserted claims, requires compacting the bone marrow in a manner that allows the passage or recess to be safely filled with a flowable material. But specifically **how** that compaction is achieved is not a limitation of the claims.

DOT, however, seeks to escape liability for its infringement by attempting to limit the interpretation of the "compacting" step to a function that can ***only*** be done by "a balloon, or an inflatable device." DOT's position contradicts the fundamental nature of patents: specifications teach the best mode for practicing the invention, and claims set the metes and bounds of the invention. Neither "balloon" nor "inflatable device" appear anywhere within any of the claims of the '888 and '404 patents. Likewise, DOT cannot identified any word in the claims that has a plain and ordinary meaning that includes the terms "balloon" or "inflatable device." To alter the plain and ordinary meaning of the claims, a patentee must evidence a clear and unmistakable intent to do so in either the prosecution history or specification. The patents discuss balloons in their specifications, but DOT cannot establish that the patents' description of this best mode for practicing the invention in any way contradicts the plain and ordinary meaning of the terms chosen for the claims. In fact, the Court has already studied the specification of the '404 patent and has ruled as follows:

> The Court finds that the patent does not state that an inflatable device is an essential element of the invention or that it is the only possible embodiment for achieving the claimed invention of compacting the bone marrow.

D.I. 102, at 8-9. Thus, DOT's effort to import limitations from the specification must be rejected, and the "compacting" step should be properly interpreted to mean compacting the bone marrow to increase the volume of the passage initially created by the surgeon, so that the resulting cavity can then be safely filled with a flowable material.

4. "Filling the Passage with a Flowable Material"

Each of the asserted claims of the '888 and '404 patent requires the step of "filling the passage with a flowable material . . . ." The plain and ordinary meaning of "flow" typically references the term "fluid." *See, e.g.*, THE AMERICAN HERITAGE DICTIONARY (2nd ed. 1985), at 515 ("to move or run freeely in the manner characteristic of a fluid") [Ex. V]. Thus, in accordance with the ordinary meaning, this claim limitation should be interpreted to mean filling the passage with a material that is at some point in a fluid state (i.e., capable of flowing on its own).

5. "Drilling said Osteoporotic Bone Marrow"

Asserted claims 7 and 8 of the '888 and '404 patents, respectively, require the step of "drilling said osteoporotic bone marrow to form said passage." The verb "drill" is defined as: "to make a hole in (a hard material) with a drill." THE AMERICAN HERITAGE DICTIONARY (2nd ed. 1985), at 425 [Ex. V]. The noun "drill" is defined as follows: "an implement with cutting edges or a pointed end for boring holes in hard materials, usually by a rotating abrasion or by repeated blows." *Id.* The specifications of the '888 and '404 patents, consistent with the understanding of a drill as being a rotating shaft with cutting edges, note that the vertebral body can be drilled with a tubular drill that has cutting edges as shown in Figure 19. *See also*, the '888 patent, at 6:43-46; the '404 patent, at 6:53-56. The phrase "drilling said osteoporotic bone marrow," therefore, should be interpreted to mean rotating a shaft with one or more cutting edges to bore a hole into and through the bone marrow in the interior of the bone.

B. Construction of Disputed Terms Used in the Claims of the '043 Patent

As in the case of the '888 and '404 patents, DOT seeks to avoid infringement liability by limiting all the asserted claims of the '043 patent to an "inflatable device." However, none of the claims of the '043 ever uses the term "inflatable". Thus, DOT's argument suffers from the same flaws noted above regarding DOT's effort to limit all the claims of the '888 and '404 patent to inflatable devices, and it should be rejected for largely the same reasons.

1. "a body adapted to be inserted into bone and undergo expansion in cancellous bone"

Each of the asserted claims of the '043 patent requires "a body adapted to be inserted into bone and undergo expansion in cancellous bone." A body that undergoes expansion is not necessarily "inflatable." DOT cannot identify any word in the claims of the '043 patent that has a plain and ordinary meaning that is limited to an "inflatable device." Rather, the more general term "expansion" that is used in the claims is defined as "to increase" or "to become greater" "in size, volume, quantity or scope." THE AMERICAN HERITAGE DICTIONARY (2nd ed. 1985), at 476 [Ex. V].

To deviate from the plain and ordinary meaning of the claims, DOT must identify something in either the specification or the prosecution history that evidences a clear and unmistakable intent to redefine the plain meaning of the claims. DOT is unable to do so. Instead, DOT can only point to the various portions of the specification where many examples of the best mode of the invention, an inflatable balloon, are described and detailed. As explained above, this is not sufficient. Thus, DOT's effort to limit the claims must be rejected, and the above limitation should be interpreted as simply meaning – "a body adapted to be inserted into bone and to undergo an increase in size while in cancellous bone."

2. Additional Claim Language in the '043 Patent that DOT Contends Needs Interpreting

DOT has advised that the following additional claim language also needs interpreting:

- "the body . . . includes an internal restraint coupled to an interior of the body to constrain the expansion";
- "causing constrained expansion of the body";
- "compacting cancellous bone by the constrained expansion"; and
- "a body adapted to be inserted into bone and undergo expansion . . . the body including at least two materials that, during the expansion . . . apply a force capable of moving fractured cortical bone and constrain the expansion."

At this juncture, Kyphon sees no reason to further clarify the plain meaning of these terms, and frankly does not understand what different meanings DOT might assert. Kyphon thus reserves the right to object to or modify as appropriate any interpretations of these terms proposed by DOT in its opening brief.

C. Construction of Disputed Terms Used in the Claims of the '734 Patent

DOT seeks to avoid infringement of all the asserted claims of the '734 patent (as well as the '054 patent) by arguing that the claims require advancement of a tamping instrument into an outer cannula to push material into a bone, such that the tamp makes contact with, and acts directly on, an outer cannula. In other words, DOT wishes to read the claims as precluding, for example, a cannula consisting of two tubes (one resting within the other). According to DOT, its bone filler device pushes material into bone by advancing a tamping instrument through a nozzle tube which in turn lies within a second, outer cannula tube, and therefore does not infringe. Worthy of note is that while DOT is seeking to avoid infringement by arguing that the tamp must directly contact the walls of the outer cannula, DOT is at the same time taking the position that the prior art's purported teaching of a plunger to move material in a tube that is itself in a cannula ***does*** satisfy, and therefore invalidates, the claims. See, e.g., [Ex. W] (U.S. Patent 5,312,333 that DOT alleges anticipates various claims of the '734 patent).

The Court, however, need never decide whether DOT would escape infringement on this basis, because none of the claims has a limitation that specifically requires direct contact between the tamp and the cannula. Nor do the claims place any limit on the number of

components that may be combined to form either a tamp or cannula. Thus, DOT's effort to modify the claims via claim construction to escape infringement must be rejected.

1. "Tamping Instrument Capable of Advancement into the Subcutaneous Cannula"

This phrase should be interpreted in accordance with the plain and ordinary meaning of "into," as being "to the inside or interior of;" in other words referencing the placement of an object somewhere inside another object. *See* THE AMERICAN HERITAGE DICTIONARY (2nd ed. 1985), at 672; *see also id.* at 648 (defining "in" as being "within the limits, bounds, or area of") [Ex. V]. The specific examples given in the '734 patent show a tamp being placed directly inside a cannula. DOT again latches onto these examples and argues the claims must be narrowly construed, to require direct contact between the tamping instrument and the outer cannula. However, nothing in the specification or prosecution history evidences a clear and unmistakable intent to change the plain meaning of the claims. The plain meaning is to advance the tamping instrument "into" the cannula regardless of whether it contacts the walls of the outer cannula, or whether it is inserted into a second cannula tube which is in turn inserted into the outer cannula. All that the claims require is that the tamping instrument is inserted "into" the outermost cannula. To take just one real world example, if a person steps into an elevator which itself is in an elevator-shaft and rides the elevator up, DOT's view is that the person inside the elevator is neither "in" the elevator-shaft nor "in" the building. Kyphon's view, based on common sense, is to the contrary.

Moreover, the interpretation of this limitation should also make clear that the tamping instrument and the cannula may consist of one or more components. Nothing in the claim language says otherwise. For example, nothing in the claims requires that the "cannula," which creates a subcutaneous passage into the body, must be limited to one component, as opposed to one tube lying within another. Similarly, as the claims themselves recognize, the "tamping instrument" may also be composed of more than one component. See '734 Patent, at claim 12

(noting that the "stylet" can be combined "with the nozzle tube" "forming a tamping instrument"). Thus, this phrase should be interpreted as meaning "a tamping instrument capable of advancing through any point within the subcutaneous cannula, where the tamp and the cannula may consist of one or more components."

2. "Material Residing in the Subcutaneous Cannula"

For the same reasons noted above, this phrase, which appears in all the asserted claims except claims 12-14, should be interpreted to mean material located at any point within the subcutaneous cannula. The material, like the tamping instrument, need not be in direct contact with the outer cannula.

3. Additional Claim Language in the '734 Patent that DOT Contends Needs Interpreting

DOT has advised that the following claim language also needs interpreting:

- "a stylet . . . with the nozzle instrument, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula";
- "tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula";
- "a delivery device to convey the material into the subcutaneous cannula,"
- "a cavity forming instrument . . . to compress cancellous bone"; and
- "wherein the cavity forming instrument includes an expandable structure."[12]

At this juncture, Kyphon sees no reason to further clarify the plain meaning of these terms, but will again await DOT's interpretations while reserving the right to object to or modify as appropriate those interpretations.

[12] Any effort by DOT to interpret the last two phrases listed above as requiring the use of an inflatable device should be rejected for the same reasons as noted in the prior sections of the brief regarding the '888, '404 and '043 patents.

D. Construction of Disputed Terms Used in the Claims of the '054 Patent

1. "Tamping Instrument being Sized and Configured for Manipulation Independent of the Cannula to Enable Insertion of the Tamping Instrument into the Cannula"

and

"a Tamping Instrument for Advancement Through the Cannula"

Each of the asserted claims of the '054 patent requires a tamping instrument that is advanced or inserted into or through the cannula. As noted above, the plain and ordinary meaning of "into" references being "to the inside or interior of." THE AMERICAN HERITAGE DICTIONARY (2nd ed. 1985), at 648 [Ex. V]. Similarly, the plain and ordinary meaning of "through" references the movement of an object "in" another component. *Id.* at 1266 ("in at one end, side, or surface and out at the other; to pass through a tunnel"). Nothing in the specification or prosecution history evidences a clear and unmistakable intent to change the plain meaning of the claims. These limitations, therefore, should be interpreted in accord with their plain and ordinary meanings and consistent with similar phrases in the '734 patent. Specifically, these phrases should be interpreted as meaning: (i) a tamping instrument being sized and configured for manipulation independent of the cannula to enable insertion of the tamping instrument through any point within the cannula; and (ii) a tamping instrument for advancement through any point within the cannula. As noted above, the interpretation should also make clear that the tamping instrument and the cannula may consist of one or more components.

2. "Material Residing in the Cannula"

For the same reasons as noted above, this phrase, which appears in claims 26-29, should be interpreted to mean material located at any point within the cannula.

3. Additional Claim Language in the '054 Patent that DOT Contends Needs Interpreting

DOT has advised that the following claim language also needs interpreting:

- "advancement of the tamping terminus in the cannula to urge material residing in the cannula into bone";
- "tamping instrument for advancement through a cannula";
- "tamping instrument . . . including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula";
- "tamping instrument . . . wherein the at least one marking indicates when the distal end of the tamping instrument is aligned with the distal end of the cannula instrument";
- "tamping instrument includes a set point marking spaced from the terminus at a distance generally equal to the length of the cannula"; and
- "tamping instrument . . . comprising a body portion and a handle portion, the body portion being sized and configured to substantially fill the cannula when the tamping instrument is fully inserted into the cannula."

At this juncture, Kyphon sees no reason to further clarify the plain meaning of these terms, but will await DOT's interpretations while reserving the right to object to or modify as appropriate those interpretations.

VI. CONCLUSION

For the foregoing reasons, Kyphon respectfully requests that the Court adopt its proposed constructions of the disputed claim terms as set forth herein and collected in the addendum to this brief.

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KYPHON'S PROPOSED CLAIM CONSTRUCTIONS

'888 / '404 Patents:

CLAIM	CLAIM TERMS	CLAIM INTERPRETATIONS
1/1	"bone marrow"	a combination of the connective tissue and the cancellous bone framework inside a bone
	"forming a passage in the bone marrow"	forming a path or channel into the interior of the bone through the bone marrow
	"compacting the bone marrow to increase the volume of said passage"	compacting the bone marrow to increase the volume of the passage created by the surgeon, so that the resulting cavity can then be safely filled with a flowable material
	"filling the passage with a flowable material"	filling the passage with a material that is at some point in a fluid state (i.e., capable of flowing on its own)
7/8	"drilling said osteoporotic bone marrow"	rotating a shaft with one or more cutting edges to bore a hole into and through the bone marrow in the interior of the bone

'043 Patent:

2 and 17	"a body adapted to be inserted into bone and undergo expansion in cancellous bone"	a body adapted to be inserted into bone and to undergo an increase in size while in cancellous bone

'734 Patent:

	"tamping instrument capable of advancement into the subcutaneous cannula"	a tamping instrument capable of advancing through any point within the subcutaneous cannula, where the tamp and the cannula may consist of one or more components
	"material residing in the subcutaneous cannula"	material located at any point within the subcutaneous cannula

'054 Patent:

	"tamping instrument being sized and configured for manipulation independent of the cannula to enable insertion of the tamping instrument into the cannula"	a tamping instrument being sized and configured for manipulation independent of the cannula to enable insertion of the tamping instrument through any point within the cannula, where the tamp and the cannula may consist of one or more components
	"a tamping instrument for advancement through the cannula"	a tamping instrument for advancement through any point within the cannula, where the tamp and the cannula may consist of one or more components
26-29	"material residing in the cannula"	material located at any point within the cannula

CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of April 2005, a true and correct copy of the **DECLARATION OF THOMAS L. HALKOWSKI IN SUPPORT OF KYPHON INC.'S MOTION FOR A PRELIMINARY INJUNCTION** was caused to be served on the attorneys of record at the following addresses as indicated:

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