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.	Civil Action No. 04-0204-JJF **Redacted Version – Public Copy**

DISC-O-TECH MEDICAL TECHNOLOGIES, LTD.'S and DISC ORTHOPAEDIC TECHNOLOGIES, INC.'S RESPONSE TO KYPHON'S OPENING BRIEF REGARDING CONSTRUCTION OF DISPUTED CLAIM TERMS FOR THE PATENTS-IN-SUIT

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Originally Filed on April 14, 2005
Redacted Version Filed on April 21, 2005

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Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. (collectively "DOT") submit this memorandum in response to Kyphon's Opening Brief Regarding Construction of Disputed Claim Terms for the Patents-in-Suit ("Kyphon's Opening Claim Construction Brief").

I. SUMMARY OF ARGUMENT

The bulk of DOT's responsive arguments with respect to construction of the disputed claim terms of the patents-in-suit are set forth in DOT's claim construction memorandum regarding U.S. Patent Nos. 4,969,888 ("the '888 Patent"), 5,108,404 ("the '404 Patent") and 6,235,043 (B1) ("the '043 Patent") ("the Balloon Bone Tamp Patents Claim Construction Brief"), and DOT's memorandum regarding the claim construction of U.S. Patent Nos. 6,241,734 (B1) and 6,613,054 (B2) ("the Bone Filler Patents Claim Construction Brief"). This memorandum does not repeat those arguments, but instead refers to specific pages of those memoranda, as appropriate. DOT's main additional rebuttal points herein are the following.

1. With respect to the '888 and '404 Patents, the scope of the asserted claims must be considered in light of the prior art. The key disputed element is "compacting the bone marrow to increase the volume of said passage." This "compacting" step either requires an inflatable device, or it is unlimited as to how the compacting is performed. If "compacting" is unlimited with respect to the way in which the compacting is accomplished, as Kyphon contends, then the prior art squarely discloses conventional bone tamps that compact cancellous bone to create a void. Redacted (See DOT's brief in support of its invalidity summary judgment motion, D.I. 137, pp. 10-12, 24-24.)

In an effort to overcome invalidity, Kyphon reads in the limitation that the compacting must create a "cavity [that] can then be safely filled with a flowable material."

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(Kyphon's Opening Claim Construction Brief, D.I. 145, pp. 18-20.) But a patentee may not read limitations into a claim to avoid invalidity. Indeed, the words "safely filled" do not appear in the claim language, or in the specification to the Inflatable Bone Tamp Patents. Kyphon can't have it both ways – if Kyphon's contrived notion of "safely filled" is to be read into the claims (to try to get around the prior art), when safety is not even referred to in the prosecution history or the specification, then certainly the almost 100 references to balloons and/or inflatable devices (beginning with the title of the Record of Invention and the title of the Patent) – with not a single mention of an alternative embodiment – must be deemed to be a required element of Kyphon's invention.

Kyphon's expert's contrived notion that the prior art would not permit safe filling of voids with a flowable material, because the voids are allegedly not "compacted" (Exhibit V, pp. 9, 12), is contrary to (i) Kyphon's statements to the FDA, (ii) an article written by Kyphon's own expert showing the safe use of flowable material in non-"compacted" voids, and (iii) the fact that DOT's expert has performed the Edeland prior art procedure and has safely filled the void with flowable material.

Kyphon twists and mischaracterizes the purpose of the statements made in the prosecution history with respect to this "safety" issue. (Kyphon's Opening Claim Construction Brief, D.I. 145, pp. 18-19.) The point of the prosecution history statements was not that Kyphon's procedure was safe, and the Lee and Murray procedures were not. The point was that Kyphon invented an inflatable device that was unique in its use of an inflatable device as a substitute for reaming, with respect to the way the void was created. The notion of safely filling a void is nowhere mentioned in the prosecution history.

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2. Even if the '888 and '404 did not require use of an inflatable device, the SKy Device does not "compact" as that term is understood in the context of the '888 and '404 Patents. The SKy Device, with its petal-like configuration, does not create the egg-shell or dam-like effect in the interior of the bone that is contemplated by the '888 and '404 Patents:

> "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.)

By way of analogy, the compacting step of the '888 and '404 Patents is like the compacting that occurs with a trash compactor. (Exhibit C, ¶¶ 46-47, Inflatable Bone Tamp Non-Infringement Expert Report.)

3. With respect to the '888 and '404 Patent, to simplify the issues to be decided, DOT is no longer contesting Kyphon's interpretation of "bone marrow" as including cancellous bone.

4. With respect to Kyphon's argument that the Court should adopt its finding from the preliminary injunction stage 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," (id., pp. 19-20), for a number of reasons that finding should not, and does not, apply at this stage. (See discussion herein at pp. 10-13.)

5. With respect to the '043 Patent, which involves improvements on the inflatable devices of the '888 and '404 Patents, Kyphon fails to construe certain of the critical terms of those patents; in particular, the terms "internal restraint" (claim 2) and "two materials that . . . constrain expansion." Kyphon contends that it "does not understand what different

meanings DOT might assert." (Kyphon's Opening Claim Construction Brief, D.I. 145, p. 22.) DOT's expert proffered a claim construction for those terms, with supporting reasons, in a report dated March 23, 2005, which Kyphon received two weeks before serving its non-infringement brief (See Exhibit C, ¶ 89, 98, and generally ¶¶ 69-88.); yet, Kyphon claims it was in the dark as to what DOT might assert. Not so. Kyphon's asserted "lack of understanding" of what DOT might assert is improper.

6. With respect to the Bone Filler Patents, Kyphon's claim construction is wholly inconsistent with the patents' specification. Kyphon does not account for the nozzle instrument that is plainly part of the invention. Kyphon completely ignores the fact that the invention includes a cannula (a tube) as well as a nozzle (a separate tube). As discussed throughout DOT's Bone Filler Claim Construction Brief, the distinct purpose and operation of the nozzle instrument must be taken into account when construing the claims of the Bone Filler Patents. (See also "Mitchell Bone Filler Patent Non-Infringement Report," Exhibit D to Appendix of Exhibits (D.I. Nos. 140-144), ¶¶ 48-53.)

II. KYPHON'S DISCUSSION OF THE LEGAL STANDARDS FAILS TO ADDRESS THE REQUIREMENT THAT CLAIMS BE CONSTRUED IN LIGHT OF THE SPECIFICATION

Kyphon harps on the notion that a limitation from the specification generally should not be read into the claims. However, Kyphon ignores two important and related legal principles of Federal Circuit claim construction law. First, a claim must be interpreted in the context of the specification, to determine, and to be consistent with, what the patentee intended its invention to be. As the Federal Circuit instructed:

> "[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

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> 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 PLC v. Marposs Societa'per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (emphasis added; citations omitted); accord Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1312, 1319 (Fed. Cir. 2005) ("We 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.") (quoting DeMarini Sports, Inc. v. Worth, Inc., 239 F.3d 1314, 1324 (Fed. Cir. 2001); see also Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 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).)

Second, the specification of a patent can be the basis for limiting a claim term, particularly where the patentee has described the invention as "including" a given feature; here, a balloon. See C.R. Bard, Inc. v. U. S. Surgical Corp., 388 F.3d 858, 864 (Fed. Cir. 2004) ("Statements that describe the invention as a whole, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term.") (citing Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1347 (Fed. Cir. 1998)); id. ("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."); id. (In relying on statements in the specification to limit claim terms, "while the statement's location is

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not determinative of claim construction, the location can signal the likelihood that the statement will support a limiting definition of a patent claim term.") (citation omitted)). Bard is discussed further in DOT's Balloon Bone Tamp Patents Claim Construction Brief, D.I. 136, pp. 9-10.

III. RESPONSE TO KYPHON'S INTERPRETATION OF THE ASSERTED CLAIMS

A. Kyphon's Construction of Disputed Terms in the '888 and '404 Patents

1. "Bone Marrow"

To simplify the issues to be decided, DOT is no longer contesting Kyphon's interpretation of bone marrow as including cancellous bone.

2. "Forming a Passage in the Bone Marrow"

Kyphon's claim construction of "forming a passage in the bone marrow" is driven by its fruitless efforts to argue that the prior art reference of Edeland does not disclose this element by its disclosure of fenestration. Fenestration is defined as "[a]n opening in the surface of a structure, as in a membrane." (Exhibit BB, The American Heritage Dictionary of the English Language (4th Ed. 2000).) Kyphon's expert argues that fenestration is only done by chiseling out an opening, window, or hole in the wall of the bone, and contends that such a step would not involve "drilling the bone marrow to form a passage." (Exhibit V, p. 10.) DOT's expert noted that fenestration of a bone involves using a drill to cut through the wall of the bone. (Exhibit E, Mitchell Decl., ¶ 6.) Of course, when you drill through something, the drill goes through and into the area behind the surface you are drilling to.

DOT's initial claim construction brief defined "passage" as a "passage." (Balloon Bone Tamp Patents Claim Construction Brief, D.I. 136, p. 13.) Kyphon argues that a dictionary definition of passage should apply. DOT agrees. However, Kyphon's definition is contained in the wrong type of dictionary, and is therefore improper and inaccurate. (Hoechst Celanese Corp.

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v. BP Chem. Ltd., 78 F.3d 1575, 1580 (Fed. Cir. 1996) ("[A] general dictionary definition is secondary to the specific meaning of a technical term as it is used and understood in a particular field."), cert. denied, 519 U.S. 1115 (1996).

Kyphon improperly proposes a non-medical dictionary definition of passage. (Kyphon Br. at 17.) A medical definition of "passage" is "a channel, duct, pore, or opening." Stedman's Medical Dictionary (emphasis added). (Exhibit CC). A "pore" is defined as "[a]n opening, hole, perforation, or foramen." Id. An "opening" is defined as "[a] gap in or entrance to an organ, tube, or cavity." Id. Thus, a proper construction of "forming a passage in bone marrow" would be "forming an opening, hole or perforation in the bone marrow."

With respect to DOT's invalidity motion, the fenestration in Edeland plainly discloses creating a passage in the bone marrow. The fenestration would be by a drill, and it would create, at a minimum, an opening, hole and perforation in the bone marrow. (See DOT's brief in support of its invalidity summary judgment motion, D.I. 135, pp. 21-22 (citing to the Declaration of Dr. Mitchell, Exhibit E, ¶¶ 6, 24, and to Exhibit E-6, at KY 004591-92, KY 004594).) Fenestration would also result in the drill going through and into the bone marrow, as always happens when one drills through a surface. (See id.)

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

"**Compacting the bone marrow to increase the volume of said passage**" is the key claim term with respect to non-infringement. DOT's proposed construction of this term, and the bases therefor, are set forth in detail at pages 13-21 of the Balloon Bone Tamp Patents Claim Construction Brief. For all the reasons set forth in DOT's claim construction brief, this claim element requires an inflatable device be used to form a void in the interior of bone. Kyphon's Claim Construction Brief (p. 7) actually highlights the point that the invention includes a balloon

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or other inflatable device. In an effort to tout the novelty of the idea underlying the '888 and '404 Patents, Kyphon quotes an article stating that "Reiley's [the co-inventor on the '888 and '404 Patents] idea of using a thumb-sized 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." (Id.)

The scope of the "compacting" element should be considered in light of the prior art. This "compacting" step either requires the use of an inflatable device (as DOT contends), or if not, then it would be unlimited as to how the compacting is performed. If the "compacting" step were unlimited as to the way in which the compacting is accomplished, as Kyphon contends, then the claim element is anticipated, as the prior art squarely discloses conventional bone tamps that compact cancellous bone to create a void.

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See DOT's brief in support of its invalidity summary judgment motion, D.I. 135, pp. 10-12, 24-24.)

In an attempt to avoid invalidity, Kyphon seeks to read in the limitation that the compacting must create a "cavity [that] can then be safely filled with a flowable material." (Kyphon's Opening Claim Construction Brief, D.I. 145, pp. 18-20.) Moreover, the words "safely filled" do not appear in the claim terms, or in the specification to the Inflatable Bone Tamp Patents, yet Kyphon seeks to read in this language. Kyphon can't have it both ways – if this notion of "safely filled" is to be read into the claims, when it is not even referred to in the prosecution history or the specification, then certainly the almost 100 references to balloons and/or inflatable devices (beginning with the title of the Record of Invention and the title of the Patent) – with not a single mention of an alternative embodiment – must be deemed to be a required element of Kyphon's invention.

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Kyphon's expert erroneously argues that one could not "safely" fill a void that is compacted with the devices and procedures in Edeland and Olerud, in particular, where the void is filled with polymethylmethacrylate. In particular, Kyphon's expert concocted an argument that the Olerud and Edeland prior art references do not disclose the third element of filling the void with a flowable material. His "reason" is that it would be unsafe to fill the voids in Olerud and Edeland with a flowable material. (Exhibit V, pp. 9, 12.)

Kyphon's contrived "safety" limitation is not only absent from the claim language and the prosecution history, but it also contradicts

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Kyphon's attempt to avoid invalidity by arguing that the procedures in Olerud could not "safely" be filled with flowable material is contrary to (i)

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(ii) an article written by Kyphon's own expert showing the safe use of flowable material in non-"compacted" voids (see Exhibit E-4, at p. 487), and (iii) the fact that DOT's expert has performed the Edeland prior art procedure and has safely filled the void with flowable material. (See DOT's invalidity summary judgment brief, D.I. 135, pp. 12-16, Exhibit E, ¶¶ 8-15, and Exhibit E-1.)

The bottom line is that Edeland and Olerud disclose using a conventional bone tamps to push the inner bone from the center outwards to increase the size of the passage, and safely filling the void with a flowable material. Thus, adding a "safety" limitation to the asserted claims not only reads in a limitation that is nowhere to be found in the intrinsic or extrinsic

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evidence, but it also is unavailing with respect to Kyphon's efforts to distinguish Edeland and Olerud, in any event.

Moreover, Kyphon twists and mischaracterizes the statements made in the prosecution history with respect to this "safety" issue. The inventors stated in the prosecution history that the '888/'404 invention used a balloon to compact the bone marrow to create a void for filling, while the Murray and Lee devices were used in procedures where a reaming process previously had been implemented to create a void for filling. (Exhibit G, KY 228857-59.) In Lee and Murray, the balloons were used as stops at the ends of long bones, to keep the cement in the bone after injection. The point in the prosecution history statements was not that Kyphon's procedure was safe, and the Lee and Murray procedures were not. The point was that Kyphon invented an inflatable device that was allegedly unique in that using inflatable device substituted for reaming out the marrow, with respect to the way the void was created. The notion of "safely" filling a void after it is created is not even hinted at anywhere in the prosecution history.

A patentee may not read limitations into a claim to avoid invalidity, particularly to avoid reading on prior art that was not before the examiner. Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1384 (Fed. Cir. 2001) ("The claims can not be rewritten by the court to avoid the impact of newly discovered prior art, for the role of 'claim construction' is to describe the claim scope as it was intended when examined and obtained by the applicant, not as it might have been limited upon a different record of prosecution and prior art.")

That principle applies here. The prosecution history is silent as to the prior art relating to conventional bone tamps that create a void by compacting the inner bone -- such as those used in the prior art references of Edeland and Olerud. The inventors never put that prior art before the Examiner, and the Examiner did not indicate that he ever saw or considered

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Edeland or Olerud (or any of the other references that DOT contends invalidate the claims of the Inflatable Bone Tamp Patents). Thus, it was never considered. Kyphon's suggestion that it distinguished itself over the prior art on the grounds of safety (Kyphon's Opening Claim Construction Brief, D.I. 145, pp. 18-19) is nonsense. That "safety" limitation should not be read in to the claims now (putting aside that the prior art at issue on DOT's invalidity motion discloses safe filling with flowable material, in any event).

4. **The Court's Preliminary Injunction Decision With Respect to the Balloon Limitation Is Not Binding and Involved A Different Legal Context and Standard**

Kyphon argues that the Court's finding at the preliminary injunction stage that an inflatable device is not an "essential element" of the claims of the '888 and '404 Patents, should apply for claim construction purposes. (Kyphon's Opening Claim Construction Brief, D.I. 145, pp. 19-20.) That finding should not affect claim construction, for several 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) ("[T]he 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) ("[T]he 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 legal context and the legal standard underlying that preliminary injunction finding was different. At the preliminary injunction stage, DOT argued that the '888

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and '404 Patents are limited to a balloon, based on an invalidity principle known as the written description requirement, and relied on the Federal Circuit's Gentry Gallery decision. Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473 (Fed. Cir. 1998). (See Exhibit AA, at pp. 21-24.) Kyphon's reply brief argued that an "essential element" test should be applied, stating: "The case law cited by DOT is inapposite. In those cases, the patentee eliminated an element from the claim that the specification expressly identified as critical to the invention. . . . Contrary to the cases discussed above, the ['404] patent never states, expressly or implicitly, 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." (See Exhibit DD, pp. 14-15.) The Court applied an "essential element" test in that invalidity context, looked at whether the '404 Patent stated that an inflatable device was an essential element, or the only possible embodiment, and found that it did not.

That finding does not apply here, for two reasons. First, DOT's balloon limitation argument at this claim construction stage is based on claim construction law, not invalidity law. DOT is relying on the principles set forth in the Federal Circuit's Bard decision, which held that a specification can be the basis for limiting a claim term in the claim construction context. Bard is discussed in Section II above, and DOT's Balloon Bone Tamp Patents Claim Construction Brief, D.I. 139, at pp. 9-10. Thus, the test here is not whether the '888 and '404 Patents state that a balloon or inflatable device is an essential element or the only possible embodiment, which was the test the Court applied in the invalidity context. The test, and the analysis, here is whether the specification provides a basis for limiting the claims to an inflatable device, under claim construction principles. See Bard, 388 F.3d at 864 ("Statements that describe the invention as a

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whole, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term.")[1]

Second, and moreover, the "essential element" test that Kyphon asserted in its preliminary injunction reply brief, and which the Court applied in that invalidity context, is, DOT submits, overly rigid. In fact, the Federal Circuit has cautioned against applying the test as Kyphon proposed:

> "In Gentry, the original disclosure identified the console of a sectional sofa as the only possible location for the controls. 134 F.3d at 1479. We held that the asserted claims were invalid because the location of the recliner controls in the claims was not limited to the console. Id. at 1479-80. In reaching that conclusion, we stated: '[I]t is clear that [the inventor] considered the location of the recliner controls on the console to be an essential element of his invention. Accordingly, his original disclosure serves to limit the permissible breadth of his after-drafted claim.' Id. In so stating, we did not announce a new 'essential element' test mandating an inquiry into what an inventor considers to be essential to his invention and requiring that the claims incorporate those elements." Use of particular language explaining a decision does not necessarily create a new test. Rather, in Gentry, we applied and merely expounded upon the unremarkable proposition that a broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope. Id. ('Claims may be no broader than the supporting disclosure.'). There was no description or support whatever in the Gentry patent of the controls being other than on the console."

Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc., 291 F.3d 1317, 1323 (Fed. Cir. 2002), rehearing and rehearing en banc denied (emphasis added).

Thus, the essential element test that the Court applied at the preliminary injunction stage was not the correct standard, even in the validity context at issue at that stage.

Third, the weight of evidence marshaled by DOT at this stage of the case, with respect to the claims being limited to an inflatable device, is significantly greater.

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1 Although Bard was decided shortly before the briefing on Kyphon's preliminary injunction motion, it was not cited by any of the parties or the Court.

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In short, the preliminary injunction decision should not impact or affect the evaluation of DOT's evidence and arguments with respect to the inflatable device limitation, at this stage of the litigation.

5. "Filling the Passage with a Flowable Material"

DOT set forth a proposed construction of the term "**flowable material capable of setting to a hardened condition,**" and the bases therefor, at page 21 of the Balloon Bone Tamp Patents Claim Construction Brief. Kyphon has construed a slightly different claim term ("**Filling the Passage with a Flowable Material**") from DOT, but both DOT and Kyphon's constructions focus on the "**flowable material**" portion of the claim. Kyphon attempts to limit this claim to a fluid. That is erroneous, as flowable is not limited to a fluid or liquid. First, by the ordinary meaning of "flow," it is a relative term, and requires context. For example, lava flows and water flows. But lava may or may not be considered a fluid. "Fluid" is defined as "a nonsolid substance, such as a liquid or gas, that tends to flow or conform to the shape of the container." Stedman's Medical Dictionary. (Exhibit EE.)

However, in the context of filling voids in bone, slurries (made from calcium phosphate) and pastes (made from bone graft) have been used since prior to the filing date of the '888 and '404 Patents. (Exhibit E, at ¶¶ 11-12 and Exhibits E-2, E-3.) Slurries and pastes are flowable. (Id.) Moreover, even today, polymethylmethacrylate cement, which Kyphon concedes is flowable, is injected in kyphoplasty in a paste form – i.e., it is not flowable in the liquid sense, any more than toothpaste is. (See Exhibit E, ¶ 13.) This is consistent with the use of an "injection gun" in the '404 and '888 Patents, to inject the artificial bone or cement. (See, e.g., '404 Patent, col. 7, lines 42-65.) Thus, if the Court is inclined to define "flowable material" other than as

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"flowable material," DOT submits that it should be defined as "a nonsolid substance that tends to conform to the shape of a container."

6. "Drilling Said Osteoporotic Bone Marrow To Form Said Passage"

DOT sets forth a proposed construction of the term **"wherein said forming step includes drilling said bone marrow to form said passage"** on page 22 of the Balloon Bone Tamp Patents Claim Construction Brief. Kyphon has construed a slightly different claim term (**"Drilling Said Osteoporotic Bone Marrow"**) from DOT, but both DOT and Kyphon's constructions focus on the **"drilling to form said passage"** portion of the claim term.

Accepting Kyphon's construction of this term by reference to dictionary definitions, as set forth above with respect to "forming a passage in the bone marrow," applying a medical definition of passage, and a dictionary definition of drilling (since "drill" is not a medical term), the claim term **"wherein said forming step includes drilling said bone marrow to form said passage"** means "using a drill to form an opening, hole or perforation in the bone marrow." As Kyphon notes, drilling involves making a hole with a drill. (Kyphon's Opening Claim Construction Brief, D.I. 145, p. 20; see Exhibit FF.)

Again, with respect to DOT's invalidity motion, the fenestration in Edeland discloses creating a passage in the bone marrow. The fenestration would be by a drill, and it would create, at a minimum, an opening, hole and perforation in the bone marrow. (See DOT's brief in support of its invalidity summary judgment motion, at pp. 21-22 (citing to the Declaration of Dr. Mitchell, Exhibit E, ¶¶ 6, 24, and to Exhibit E-6, at KY 004591-92, KY 004594).) Fenestration would also result in the drill going through and into the bone marrow, as always happens when one drills through a surface. (Id.)

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Moreover, even if the fenestration in Edeland were not by drill, and instead, were by chisel, as Dr. Marks contends (contrary to reality) (see Exhibit V, p. 10), the same dictionary Kyphon relies on also notes that drilling can be by chisel: "To make (a hole) with or as if with a drill: drills holes in trees with its chisel like bill." (Exhibit FF, The American Heritage Dictionary of the English Language (4th Ed. 2000), at p. 2.) In short, either way, the "fenestration" in Edeland meets the drilling a passage element on the claims.

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

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

DOT's proposed construction of the term "**a body adapted to be inserted into a bone and undergo expansion**" is set forth on pages 23-29 of the Balloon Bone Tamp Patents Claim Construction Brief. As shown in those pages, the evidence is overwhelming that the "body" referred to is an inflatable body. In short, the '043 Patent is entirely about shaping balloons to fit various differently shaped bones, when creating a void in those various bones.

2. Additional Claim Language in the '043 Patent

Kyphon has only construed one claim term (**"a body adapted to be inserted into bone and undergo expansion in cancellous bone"**) of the '043 Patent, and has failed to propose a claim construction for the remaining terms, contending that "Kyphon sees no reason to further clarify the plain meaning of the terms, and frankly does not understand what different meanings DOT might assert." (See Kyphon's Opening Claim Construction Brief, D.I. 145, p. 22.) Again, DOT's expert proffered a claim construction for these remaining terms, with supporting reasons, in a report dated March 23, 2005, which Kyphon received two weeks before serving its non-infringement brief (See Exhibit C, ¶¶ 89, 98, and generally ¶¶ 69-88.); yet, Kyphon claims it was

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in the dark as to what DOT "might assert." Not so. Kyphon's asserted "lack of understanding" of what DOT might assert is improper.

The remaining claim terms for which DOT has proposed a construction are:

- **"the body. . .includes an internal restraint coupled to an interior of the body to constrain the expansion in cancellous bone"** (set forth on pages 29-30 of the Balloon Bone Tamp Patents Claim Construction Brief);
- **"the body including at least two materials that during expansion. . .apply a force capable of moving fractured cortical bone and constrain the expansion"** (set forth on page 31 of the Balloon Bone Tamp Patents Claim Construction Brief).
- **"causing constrained expansion of the body"** (set forth on page 30 of the Balloon Bone Tamp Patents Claim Construction Brief);
- **"compacting cancellous bone by the constrained expansion"** (set forth on page 30 of the Balloon Bone Tamp Patents Claim Construction Brief);
- **"a body adapted to be inserted into bone and undergo expansion"** (set forth on page 31 of the Balloon Bone Tamp Patents Claim Construction Brief); and

Each of the disputed claim terms of the '043 patent contains or incorporates, in part, the element of an inflatable "body" such as a balloon, and, therefore, should be interpreted with reference to the discussion at pages 23-29 of Balloon Bone Tamp Patents Claim Construction Brief, discussing the inflatable body limitation.

C. Kyphon's Claim Construction of the '734 and '054 Patents Ignores the Distinct Purpose and Operation of the Nozzle Instrument

Kyphon's claim construction of the Bone Filler Patents is utterly inconsistent with the patents' specification. Kyphon's claim construction does not account for the nozzle instrument that is plainly part of Kyphon's invention. Kyphon completely ignores the fact that the invention set forth in the Bone Filler Patents includes a cannula (a tube) as well as a nozzle (a separate tube). As discussed in DOT's Bone Filler Claim Construction Brief, the distinct purpose and operation of the nozzle instrument must be taken into account when construing the claims of

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the Bone Filler Patents. (See also Exhibit D, Mitchell Bone Filler Patent Non-Infringement Report, ¶¶ 48-53.)

There are two key factors in the claim interpretation of the Bone Filler Patents: (1) because a nozzle instrument is withdrawn into the cannula as material is expelled, material gets expelled into the bore and contacts the inner walls of the cannula; and (2) after the nozzle instrument is removed from the cannula, tamping operations are performed relative to the cannula in order to clear the residual material from the bore (and contacting the inner walls) of the cannula into the bone cavity. In complete disregard of the Bone Filler Patents' specification, Kyphon contends that the "cannula may consist of one or more components," and that a tamping instrument is advanced "into" a 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." (See Kyphon Claim Construction Brief, D.I. 145, pp. 22-23.)

Kyphon "drops" the nozzle instrument from its claim construction analysis in an effort to support its argument that the material "need not be in direct contact with the outer cannula," and in an effort to support its proffered claim construction whereby the material can be "located at any point within the subcutaneous cannula" (See Kyphon Claim Construction Brief, D.I. 145, pp. 24-25.) Yet, the specification of the '734 and '054 Patents is clear: because a nozzle instrument is withdrawn into the cannula as material is expelled, material gets expelled into the bore and contacts the inner walls of the cannula.

Likewise, Kyphon "drops" the nozzle instrument from its claim construction analysis in an effort to support its argument that the tamping instrument "need not be in direct contact with the outer cannula," and in an effort to support its proffered claim construction whereby the tamping instrument can be advanced or inserted "through any point within the

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subcutaneous cannula" Id. Yet, the specification of the '734 and '054 Patents again is clear: after the nozzle instrument is removed from the cannula, tamping operations are performed relative to the cannula in order to clear the residual material from the bore (and contacting the inner walls) of the cannula into the bone cavity.

Accordingly, DOT submits that Kyphon's claim construction is erroneous, and that the proper claim construction of the Bone Filler Patents is as set forth in DOT's Bone Filler Claim Construction Brief. (See pp. 13-27 thereto.) (See also Exhibit D, Mitchell Bone Filler Patent Non-Infringement Report, pp. 16-18.)[2]

D. DOT's Construction of the Disputed Claim Terms of the '734 Patent

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

DOT's proposed construction of the term **"tamping instrument capable of advancement into the subcutaneous cannula"** is set forth on pages 13-19 of the Bone Filler Patents Claim Construction Brief (D.I. 136). With regard to the meaning of "into," Kyphon's elevator analogy supports DOT, not Kyphon: If someone walks into an elevator, one would describe that person as having walked into the elevator, not into the elevator shaft. The elevator shaft is analogous to the cannula; the elevator is analogous to the Impactor tube, into which the Impactor rod (the person in the analogy) advances.

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[2] Contrary to Kyphon's contentions that DOT's claim construction is inconsistent with its invalidity contentions (see Kyphon Claim Construction Brief, D.I. 145, p. 22), if the Bone Filler Patents are read broadly to cover a device where material is tamped through a cannula (without a separate and additional nozzle instrument), then the Bone Filler Patents would be invalid in light of prior art. (See Exhibit B, ¶¶ 16-28, Expert Report of David Mitchell Regarding Invalidity of U.S. Patent Nos. 6,241,734 (B1) and 6,613,054 (B2), dated March 11, 2005.)

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2. "Material Residing in the Subcutaneous Cannula"

DOT sets forth a proposed construction of the term "**a tamping instrument having a tamping terminus which, during advancement of the tamping instrument in the subcutaneous cannula, urges material residing in the subcutaneous cannula into bone**" on pages 19-22 of the Bone Filler Patents Claim Construction Brief (D.I. 136). Kyphon has chosen to construe a smaller portion of that claim ("**material residing in the subcutaneous cannula**"). DOT's construction of the more detailed claim term incorporates and construes this same portion of the claim.

3. Additional Claim Language in the '734 Patent

Kyphon has only construed two terms (**"Tamping Instrument Capable of Advancement into the Subcutaneous Cannula,"** and **"Material Residing in the Subcutaneous Cannula"**) of the '734 Patent, and Kyphon has not proposed a claim construction for the remaining terms, again because "Kyphon sees no reason to further clarify the plain meaning of these terms, but will again await DOT's interpretations. . . ." (See Kyphon's Opening Claim Construction Brief, D.I. 145, pp. 25-26.) DOT's expert proffered a claim construction for these remaining terms, with supporting reasons, in a report dated March 30, 2005, which Kyphon received one week before serving its non-infringement brief (see Exhibit D, ¶¶ 30-37); yet, Kyphon again claims it was in the dark as to what DOT might assert. Here again, Kyphon's asserted "lack of understanding" of what DOT might assert is not credible.

The remaining claim terms for which DOT has proposed a construction are:

- **"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"** (set forth on pages 20-22 of the Bone Filler Patents Claim Construction Brief);

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- **"tamping instrument includes markings to visually gauge the advancement of the tamping terminus through the subcutaneous cannula"** (set forth on pages 22-25 of the Bone Filler Patents Claim Construction Brief);
- **"a cavity forming instrument. . .to compress cancellous bone"** (set forth on pages 26-27 of the Bone Filler Patents Claim Construction Brief);
- **"wherein the cavity forming instrument includes an expandable structure"** (set forth on pages 26-27 of the Bone Filler Patents Claim Construction Brief); and
- **"a delivery device to convey the material into the subcutaneous cannula"** (set forth on pages 26-27 of the Bone Filler Patents Claim Construction Brief).

E. 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"

DOT contends that "**tamping instrument being sized and configured for manipulation independent of the cannula to enable insertion of the tamping instrument into the cannula"** should be given its ordinary meaning, and should be construed to mean a "tamping instrument being sized and configured for manipulation independent of the cannula to enable insertion of the tamping instrument into the cannula."

DOT's proposed construction of the second element, a "**tamping instrument for advancement through the cannula,**" is set forth on pages 13-19 of the Bone Filler Patents Claim Construction Brief (D.I. 136).

2. **"Material Residing in the Cannula"**

DOT sets forth a proposed construction of the term "**advancement of the tamping terminus in the cannula to urge material residing in the cannula into bone"** on pages 19-22 of the Bone Filler Patents Claim Construction Brief (D.I. 136). Kyphon has chosen

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to construe a smaller portion of that claim ("**material residing in the subcutaneous cannula**"). DOT's construction of the more detailed claim term incorporates and construes this same portion of the claim.

3. Additional Claim Language in the '054 Patent

Kyphon has only construed three terms (**"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 for advancement through the cannula"** and **"material residing in the subcutaneous cannula"**) of the '054 Patent, again arguing that the plain meaning of the terms dictates their construction. (See Kyphon's Opening Claim Construction Brief, D.I. 145, p. 26.)

The remaining claim terms for which DOT has proposed a construction are:

- **"tamping instrument. . .including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula"** (set forth on pages 22-25 of the Bone Filler Patents Claim Construction Brief (D.I. 136));
- **"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"** (set forth on page 25 of the Bone Filler Patents Claim Construction Brief (D.I. 136)); and
- **"tamping instrument includes a set point marking spaced from the terminus at a distance generally equal to the length of the cannula"** (set forth on page 26 of the Bone Filler Patents Claim Construction Brief (D.I. 136)).

DOT's construction of the disputed claim terms of the '734 and '054 Patents is also summarized in the charts attached as tabs A and B to DOT's Bone Filler Patents Claim Construction Brief.

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V. CONCLUSION

For the foregoing reasons, DOT requests that its construction of the disputed claim terms of the patents-in-suit be adopted by the Court and provided to the jury at trial in this matter.

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April 14, 2005

CERTIFICATE OF SERVICE

I, Maryellen Noreika, hereby certify that copies of the foregoing were caused to be served this 14th day of April, 2005 upon the following in the manner indicated:

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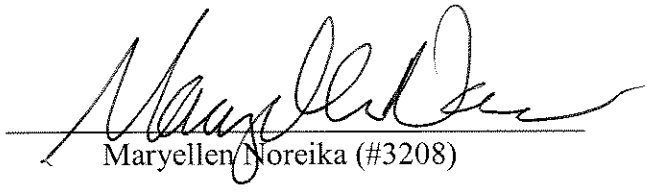
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