IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

DEFENDANTS DISC-O-TECH MEDICAL TECHNOLOGIES, LTD.'S AND DISC ORTHOPAEDIC TECHNOLOGIES, INC.'S MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF U.S. PATENT NOS. 4,969,888, 5,108,404 AND 6,235,043 B1

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Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. (collectively "DOT") submit this memorandum in support of their motion for summary judgment of non-infringement of claims 1, 3, 7, 8, 9, 11, and 14 of U.S. Patent No. 4,969,888, claims 1, 3, 8, 9, 10, 12, and 15 of U.S. Patent Nos. 5,108,404, and claims 2, 17, 20, 23, 24, 25, 26, and 28 of U.S. Patent No. 6,235,043 B1.

I. NATURE AND STAGE OF THE PROCEEDINGS

This is an action by Kyphon Inc. ("Kyphon") against Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. for infringement of U.S. Patent Nos. 4,969,888 (the "'888 patent"), 5,108,404 (the "'404 patent"), 6,235,043 B1 ("the '043 patent"), 6,248,110 B1 ("the '110 patent"), 6,241,734 B1 ("the '734 patent") and 6,613,054 B1 ("the '054 patent"). DOT has counterclaimed against Kyphon for declaratory judgments of non-infringement and invalidity of the patents-in-suit. As reflected in its letter to the Special Master herein, Kyphon no longer asserts any claims of the '110 patent against DOT. (Exhibit O.)[1] Likewise, DOT no longer asserts its related counterclaims.

Fact discovery has closed. Expert reports have been exchanged, and expert discovery is scheduled to close on April 27, 2005. A claim construction and summary judgment hearing is scheduled for April 19, 2005. Trial is scheduled to begin on June 1, 2005.

II. SUMMARY OF THE ARGUMENT

1. This motion seeks summary judgment of non-infringement of the '888, '404 and '043 patents (collectively "the Inflatable Bone Tamp Patents"). The '054 and '734

1 Exhibits cited herein are contained in to DOT's Appendix of Exhibits to Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. Claim Construction Memoranda and Motions for Summary Judgment of Non-Infringement and Invalidity ("DOT's Appendix of Exhibits"), submitted herewith.

patents (collectively "the Bone Filler Patents") relate to filling the bone with bone filler material after a void has been created by the method set forth in the Inflatable Bone Tamp Patents. DOT contests infringement and validity as to the Bone Filler patents, but is not seeking summary judgment with respect to those patents. This non-infringement motion is based on DOT's proposed claim construction, as set forth in DOT's Claim Construction Memorandum Regarding Kyphon's U.S. Patent Nos. 4,969,888, 5,108,404 and 6,235,043 B1 ("Inflatable Bone Tamp Claim Construction Brief"). DOT has focused its non-infringement arguments on the independent claims of the Inflatable Bone Tamp Patents, since that is sufficient to establish non-infringement of all of the asserted claims (i.e., if the SKy Device does not infringe the independent claims, then it does not infringe the dependent claims.)

2. The SKy Device does infringe any of the asserted claims of the '888, '404 or '043 Patents, either literally or under the doctrine of equivalents, as a matter of law, because the independent claims of those patents are limited to an inflatable device, such as a balloon, and DOT's SKy Device is not an inflatable device, or the equivalent thereof.

3. The SKy Device does infringe any of the asserted claims of the '888 or '404 Patents, either literally or under the doctrine of equivalents, because DOT's SKy Device does not "compact" (an element of independent claim 1, the only asserted independent claim of those two patents), as that term is understood in the context of the '888 and '404.

4. The SKy Device also does infringe claims 2, 20, 23-26 or 28 of the '043 Patent, either literally or under the doctrine of equivalents, because the SKy Device does not have an internal restraint element, or the equivalent thereof. Indeed, it has no restraint element.

5. The SKy Device also does infringe claims 17, 20, 23-26 or 28 of the '043 Patent, either literally or under the doctrine of equivalents, because the SKy Device is not "a

device comprising a body adapted to be inserted into bone and undergo expansion [an inflatable device] . . . the body including at least two materials that, during the expansion . . . constrain the expansion in cancellous bone." The SKy device does not have a second material that constrains its expansion. Indeed, it has no material that constrains its expansion.

III. STATEMENT OF FACTS

A. Asserted Claims and General Background

Kyphon alleges that DOT's Sky Bone Expander Device (the "SKy Device") infringes Claims 1, 3, 7, 8, 9, 11, and 14 of the '888 Patent, entitled "Surgical Protocol for Fixation of Osteoporotic Bone Using Inflatable Device"; Claims 1, 3, 8, 9, 10, 12, and 15 of the '404 Patent, entitled "Surgical Protocol for Fixation of Bone Using Inflatable Device" (" '404 Patent"); Claims 2, 17, 20, 23, 24, 25, 26, and 28 of the '043 Patent, entitled "Inflatable Device for Use in Surgical Protocol Relating to Fixation of Bone" (" '043 Patent"). The '404, '888 and '043 Patents (the "Inflatable Bone Tamp Patents") are attached as Exhibits A-2, A-3 and A-4 to DOT's Appendix of Exhibits.

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

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

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

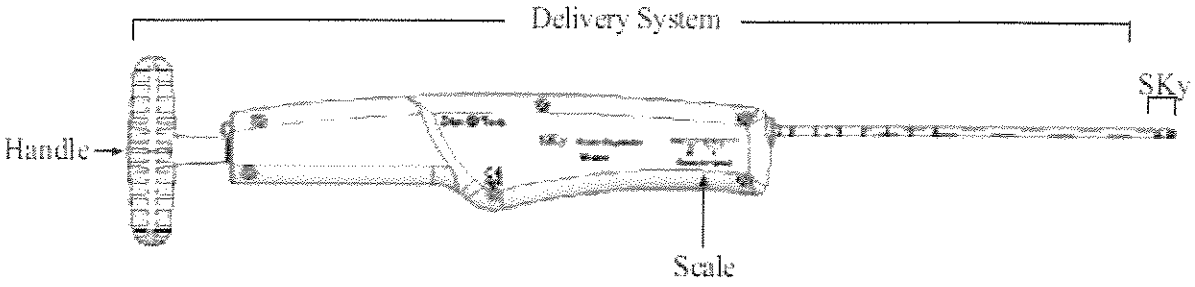
The '043 patent is entitled "Inflatable Device for Use in Surgical Protocol Relating to Fixation of Bone." The application which became the '043 patent was filed on January 23, 1997; the '043 patent issued on May 22, 2001. It generally describes an improved inflatable balloon for use in carrying out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

B. The SKy Device

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

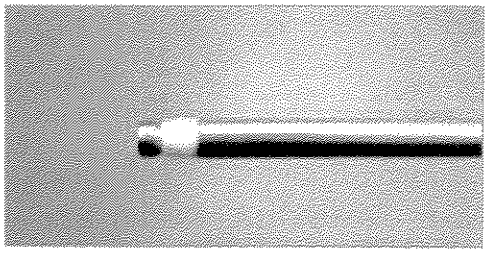
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2 In an effort to avoid a charge of double patenting, the '404 patent applicants filed a "Terminal Disclaimer," foregoing any coverage of the '404 patent beyond the life of the '888 patent.

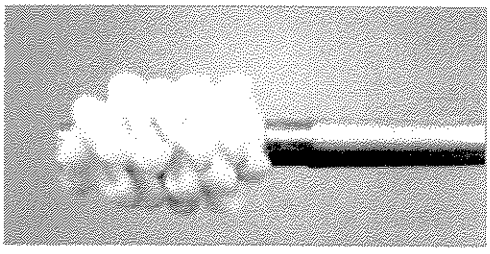


The SKy Bone Expander System

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

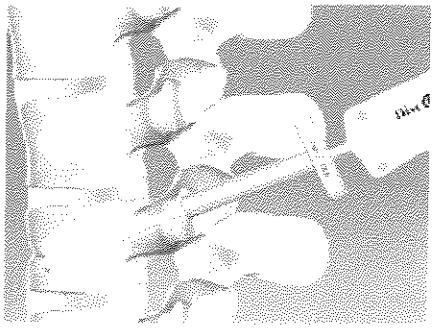


SKy before expansion



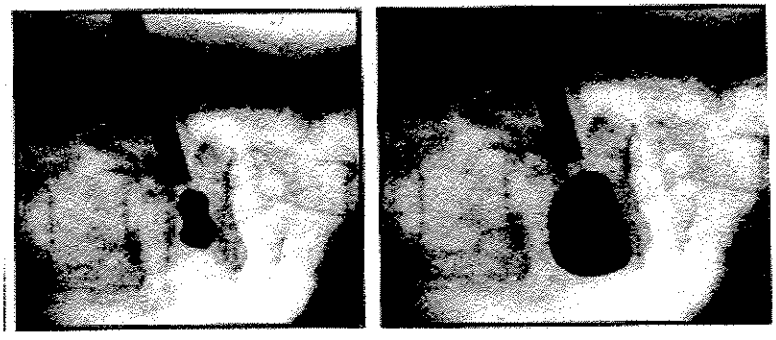
SKy after maximal expansion

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



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

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



balloon tamp inflation

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

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

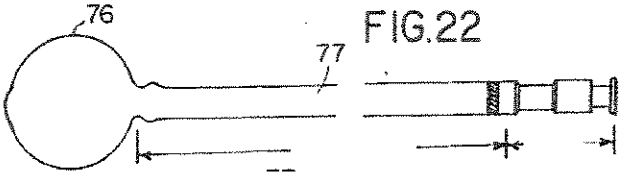
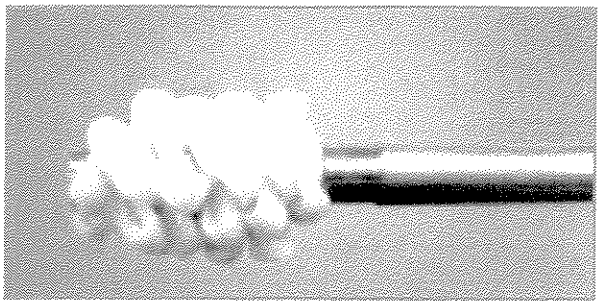


Figure 22 from U.S. Patent No. 5,108,404 (showing balloon contour)



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

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

C. The Relevant Anatomy

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

engine, defines cancellous bone as "having a porous structure made up of intersecting plates and bars that form small cavities or cells." (See Exhibits I and J.)

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

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

IV. THE LEGAL FRAMEWORK

Under Rule 56 (c) of the Federal Rules of Civil Procedure, summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admission on file, together with the affidavits, if any, show that there is no issue as to any material fact and that the moving party is entitled to judgment as a matter of law." If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with specific facts showing that there is a genuine issue for trial." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986) (emphasis in original; internal citation omitted). The mere existence of some evidence in support of the nonmoving party,

however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury to reasonably find for the nonmoving party on that issue. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986).

"Determination of patent infringement requires a two step analysis: (1) the scope of the claims must be construed; and (2) the allegedly infringing device must be compared to the construed claims." Mars, Inc. v. H.J. Heinz, Co., 377 F.3d 1369, 1373 (Fed. Cir. 2004). To establish literal infringement, the patentee has the burden to prove that every limitation in the claim(s) at issue, properly construed, is literally met by the accused products. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1466-67 (Fed. Cir. 1998).

Likewise, infringement under the doctrine of equivalents requires that the accused product literally contain each limitation of the claim or its equivalent. Leggett & Platt, Inc. v. Hickory Springs Mfg. Co., 285 F.3d 1353, 1358-59 (citing Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40 (1997)). Because each limitation is material to defining the scope of the patented invention, a doctrine of equivalents analysis must be applied to individual claim limitations, not to the invention as a whole. See Warner-Jenkinson, 520 U.S. at 40. An element in the accused product is equivalent to a claim limitation only if the differences between the two are "insubstantial" to one of ordinary skill in the art. See Leggett & Platt, 285 F.3d at 1359 (citing Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1423 (Fed.Cir.1997)). In determining whether the differences are insubstantial, "[w]hether a component in the accused subject matter performs substantially the same function as the claimed limitation in substantially the same way to achieve substantially the same result may be relevant to this determination." See id. (citing Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 149 F.3d 1309, 1315 (Fed.Cir.1998)). This is known as the function/way/result test.

V. ARGUMENT

A. DOT's SKy Device Does Not Literally Infringe the '404 or '888 Patents

Kyphon alleges that DOT's SKy Device infringes independent claim 1 and dependent claims 3, 8, 9, 10, 12, and 15 of the '404 Patent, and independent claim 1 and dependent claims 3, 7, 8, 9, 11, and 14 of the '888 Patent. Claim 1 of the '404 Patent is set forth below:

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

Claim 1 of the '888 patent is identical, except that it is further limited to osteoporotic bone and bone marrow. Thus, DOT does not infringe the narrower claim 1 of the '888 Patent, and the dependent claims of the '888 Patents, for the same reasons discussed herein. Because all of the asserted claims of the '404 and '888 Patents include the limitations addressed in this brief with respect to claim 1 of the '404 Patent, it is unnecessary to address the specific additional express limitations of the dependent claims.

The SKy Device does not infringe the asserted claims of the '888 or '404 Patents because the SKy Device does not use a balloon or other inflatable device to create a void in bone. The SKy Device therefore does not meet the step of "compacting the bone marrow to increase the volume of said passage," as that term is defined in the '888 and '404 Patents. (See DOT's Inflatable Bone Tamp Claim Construction Brief.) The SKy Device is not inflated. Rather, it uses a plastic polymer tube that folds outwards in a petal-like structure, as a result of axial compression. The petals have hollow spaces within and between them, such that the bone

marrow (the viscous liquid material contained within the interstices of the cancellous bone) flows within and between each petal. (Exhibit C, ¶ 45, Inflatable Bone Tamp Non-Infringement Expert Report.) Unlike a balloon, these petals intersperse with the bone marrow, such that the bone marrow surrounds the SKy Device at points all along, and between, each petal, including points right up against the body of the device. (Id.)

Even if the term "bone marrow" were construed to include cancellous bone, as Kyphon's expert contends it should be, the SKy Device does not "compact[] the bone marrow to increase the volume of said passage," for two reasons. First, the "compacting" step in the '888 and '404 Patents is limited to inflatable devices, such as balloons, for all the reasons set forth in DOT's Inflatable Bone Tamp Claim Construction Brief, at pp. 13-20. Second, 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.) Thus, even if "bone marrow" were interpreted to include cancellous bone, and even if the compacting step were not limited to an inflatable device, the SKy Device does not meet the "compacting" element of the claims, because it does not compress substantially all of the cancellous bone away from the central portion of the interior bone

volume, towards the wall of the bone, to increase the volume of the passage; rather, it interdigitates with the cancellous bone to create a void in the bone. (Id. ¶ 48.)

B. DOT's SKy Device Does Not Infringe the '404 or '888 Under the Doctrine of Equivalents

The SKy Device also does not infringe the claims of the '888 or '404 Patents under the doctrine of equivalents. The SKy Device does not satisfy the function/way/result test under the doctrine of equivalents. The relevant claim element for this analysis is "compacting the bone marrow to increase the volume of said passage." With respect to function, the SKy Device and the balloon mechanism for compacting bone marrow in the '888 and '404 Patents do not perform substantially the same function. As discussed above, the function of the compacting step of the method in the '888 and '404 Patents is to compress substantially all of the bone marrow away from a central portion of the interior bone volume, towards the wall of the bone, to increase the volume of the passage. The SKy Device does not perform a substantially similar function because of its petal-like structure, which interdigitates with the bone marrow to create a void in the bone. (Id. ¶ 52.)

Most importantly, with respect to the way the SKy Device operates to create a void in bone, it is not substantially the same as the balloon means of the '888 and '404 Patents; indeed, it is substantially different. The SKy Device uses a rigid, plastic polymer tube to create a void in bone. The polymer tube has sets of vertically-running slits in it. The vertically-running slits are spaced around the tube at 90 degree intervals (i.e., at the 12 o'clock, 3 o'clock, 6 o'clock and 9 o'clock positions). That tube expands as a result of axial force against the plastic polymer tube, which causes it to buckle under pressure and form into a petal-like structure. This is not substantially similar to an inflatable device; indeed, it is substantially different, for a number of reasons. (Id. ¶ 53.)

First, the inflatable device mechanism of the invention is a hydraulic mechanism of expansion, which involves injecting pressurized fluid into the interior of the balloon body. This requires a source of pressurized fluid, and some means for controlling its pressure and delivery. By contrast, the plastic polymer of the SKy Device is expanded by mechanical means, by turning a handle at the proximal end of the device. A surgeon using the SKy Device can look at the scale on the side of the handle to determine how much of the plastic polymer has been expanded at the distal end of the device. This is only possible because of the mechanical nature of how the SKy Device works, and the fact that it deploys in the same petal-like configuration each time. The size of the balloon's expansion cannot be monitored in this way, because its size will vary depending on the conditions inside the fractured bone. (Id. ¶ 54.)

REDACTED

Kyphon's expert has contended that DOT's references to "balloon" or "balloon-like" in DOT's 510(k) submission (such as Exhibit P, at DOTLTD 2014), allegedly support

REDACTED

REDACTED

REDACTED

Second, DOT's mechanical, petal-like deployment is not substantially similar to Kyphon's balloon invention because the balloon is compliant, meaning that it will change shapes and find the path of least resistance when it encounters a hard surface. By contrast, the plastic polymer of the SKy Device is rigid when it expands, such that it expands to the same pre-determined shape regardless of the resistance it encounters.

REDACTED

Because the SKy Device operates in a significantly different way than an inflatable body, the SKy Device avoids many of the problems and dangers inherent in the use of an inflatable body. There is a danger that the inflatable body can over-expand, or expand in a direction that might harm the bone being repaired. In addition, there is a danger that the walls of an inflatable body may rupture. (Exhibit D, ¶ 63.) A rupture may occur due to over-inflation, due to a material or manufacturing defect, or due to a puncture from an extrinsic source, such as a piece of sharp bone or instrumentation. This will always be a potential problem with an inflatable body. If a rupture occurs, the interior volume of a bone could become flooded with the fluid used to expand the body. This radiopaque fluid severely limits visualization of the bone contours, which hinders and threatens the safe completion of the treatment. None of these drawbacks exist with the plastic polymer tube of the SKy Device, because the SKy Device operates in a substantially different way. (Id.)

Based on Kyphon's expert report, Kyphon contends that the SKy Device is substantially similar to Kyphon's device because the two device are "interchangeable," and therefore, the two devices are equivalent for purpose of the doctrine of equivalents. (Exhibit S, ¶ 60.) While interchangeability is a relevant consideration under the doctrine of equivalents, the analysis with respect to interchangeability must be performed by determining whether a particular element of the accused device or process is interchangeable with respect to the corresponding element of the claimed device or process. See Warner Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 29-30 (1997). Whether two products may be "interchangeable" for their end use does not mean that they are equivalent for doctrine of equivalents purposes. See Wang Labs., Inc. v. America Online, Inc., 197 F.3d 1377, 1386 (Fed. Cir. 1999). The doctrine of equivalents question focuses on whether the differences between the accused device or process and the claimed device or process are insubstantial. See Warner Jenkinson, 520 U.S. at 39-40.

An analogy to illustrate this interchangeability issue can be made to devices for painting a wall. One can use a number of devices to paint a wall, such as a paint brush, a roller, or a spray gun. These devices are interchangeable in a general sense, i.e., they all work to paint the wall. However, with respect to how the devices perform that function, they are substantially different. The same goes for the SKy Bone Expander and the claimed invention of using a balloon to create a void. They perform the function of creating a void in substantially different ways. With respect to the way they perform that function, they are not interchangeable, or substitutes, or substantially the same. (See Exhibit C, ¶ 67, Inflatable Bone Tamp Non-Infringement Expert Report.)

As to whether the SKy Device and the balloon invention achieve substantially the same result (under the function/way/result test) with respect to the disputed claim element of "compacting the bone marrow to increase the volume of said passage" from the '888 and '404 Patents, the SKy Device does not achieve substantially the same result with respect to this element. The SKy Device creates a pre-configured void with petals that branch out into the surrounding area. The bone marrow flows within and around the petals. By contrast, the inflatable device of the invention creates an egg-shell-like void in the bone. The result is not substantially the same between the two. (See id. ¶ 68.)

C. DOT's SKy Device Does Not Literally Infringe the '043 Patent

The SKy Device does not infringe the claims of the '043 Patent, because it does not have "a body adapted to be inserted into bone and undergo expansion." As properly interpreted, "a body adapted to be inserted into bone and undergo expansion," which is an element of each of the independent claims that Kyphon is asserting (claims 2 and 17), means inflatable device, e.g., a balloon. (See Inflatable Bone Tamp Claim Construction Brief, at pp. 23-29; Exhibit C, Inflatable Bone Tamp Non-Infringement Expert Report, ¶¶ 70-86.) The SKy Device does not have or use an inflatable device such as a balloon, so it does not literally infringe any of the claims of the '043 Patent for that reason, including the asserted independent claims 2 and 17.

The SKy Device also does not infringe claim 2 because the SKy Device does not have "an internal restraint coupled to an interior of the body to constrain the expansion in cancellous bone." "Expansion," as properly interpreted, is limited to expansion of an inflatable device (a balloon), for the reasons set forth in DOT's Claim Construction Memorandum as to why the '043 Patent is limited to an inflatable device. (See Inflatable Bone Tamp Claim

Construction Brief, at pp. 23-29; Exhibit C, Inflatable Bone Tamp Non-Infringement Expert Report, ¶¶ 70-86.)

Additionally, the SKy Device does not infringe claim 2 because the SKy Device does not have an "internal restraint coupled to an interior of the body to constrain the expansion." The claim term "an internal restraint coupled to an interior of the body to constrain the expansion," as properly interpreted, requires a structure that is connected to the interior of the inflatable body (balloon) that limits movement of the internal walls of the inflatable body. Such a structure would include the disclosed string-like members and the disclosed glued/welded seams joining internal surfaces of walls of an inflatable body:

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

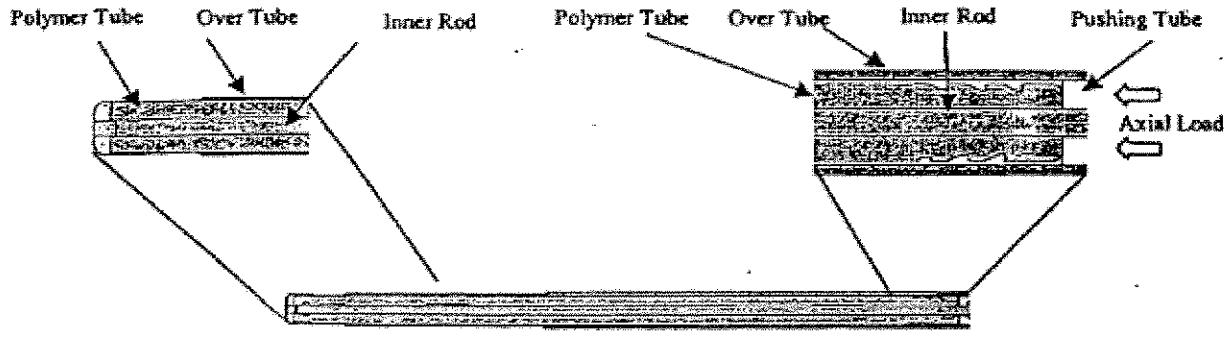
(See Exhibit C, ¶¶ 88-89.)

The SKy Device does not have any internal restraint element coupled to the plastic polymer tube that constrains its expansion (as required by claim 2 of the '043 Patent). As explained above, the expandable portion of the SKy Device is a plastic polymer tube at the distal end of the device, which has sets of vertically-running slits in it. That tube expands as a result of axial force against the plastic polymer tube, which causes it to buckle under pressure and form into the same shaped petal-like structure each time. (Id. ¶ 90.)

More importantly, the amount or degree of expansion of the SKy Device is not constrained by any internal restraint element coupled to an interior of the polymer tube. Rather,

the amount or degree of expansion of the plastic polymer tube is pre-determined, based on the length of the slits in the plastic polymer itself. If one were to make smaller slits in the tube, the expansion would be smaller, and vice versa. Thus, there is no internal restraint element on the plastic polymer. Any limitation on expansion is inherent in the polymer material itself, based on the length of the polymer slits and its physical properties (its ability to buckle outwards under pressure). (Id. ¶ 92.)

The elements of the expanding end of the SKy Device are shown below:



REDACTED

REDACTED

REDACTED

The SKy Device is inherently restrained, without the aid of a second material, or an internal restraint element coupled to the plastic tube. The plastic polymer that expands is rigid (but able to buckle under pressure), it has a fixed length, with fixed length slits in it. Thus, these properties of the plastic polymer itself limit its expansion; there is no internal restraint element. (Exhibit C, Inflatable Bone Tamp Non-Infringement Expert Report, ¶ 96.)

With respect to claim 17 of the '043 Patent, the SKy Device does not infringe for several reasons. First, it does not have "a device comprising a body adapted to be inserted into bone and undergo expansion," for the reasons set forth above as to claim 2 of the '043 Patent. That is, the SKy Device does not have or use an inflatable device. (Id. ¶ 97.)

Second, the SKy Device does not infringe claim 17 because it is not a "a device comprising a body adapted to be inserted into bone and undergo expansion . . . the body including at least two materials that, during the expansion . . . constrain the expansion in cancellous bone." That claim language, as properly interpreted, means an inflatable body having two materials, one of which constrains its expansion. First, the SKy Device does not have the inflatable body referred to by the claim. Second, the distal portion of the SKy Device that buckles outward is made of one material (a plastic polymer tube), not two. Third, there is no material that "constrain[s] the expansion" of the device, for the reasons set forth above. Fourth,

the SKy Device does not "compact[] cancellous bone by the constrained expansion," for the reasons set forth above with respect to the compacting element. (Id. ¶ 98.)

D. DOT's SKy Device Does Not Infringe the '043 Patent Under the Doctrine of Equivalents

1. Claims 2, 20, 23-28 of the '043 Patent

The SKy Device does not infringe claim 2 under the doctrine of equivalents because the differences between the SKy Device and the elements of claim 2 are not insubstantial. See Ethicon Endo-Surgery, 149 F.3d at 1315. In that regard, the SKy Device does not perform substantially the same function, in substantially the same way, to achieve substantially the same result, with respect to the steps of claim 2 of the '043 Patent. (Exhibit C, Inflatable Bone Tamp Non-Infringement Expert Report, ¶ 99.)

As to function, the function of claim 2 of the '043 Patent is to restrain expansion of an inflatable device used to create a cavity in bone. Since the SKy Device does not use an inflatable device, or the equivalent thereof (for the reasons stated above), it is not substantially similar as to function.

With respect to the way that claim 2 of the '043 Patent goes about that function, it uses an internal restraint coupled to the interior of an inflatable body. The SKy Device does not have an inflatable body, and it does not have an internal restraint element coupled to the interior of the plastic polymer tube, as explained above. The degree of expansion of the plastic polymer tube is pre-determined, based on the size of the slits in the tube. The axial force against the plastic polymer tube causes the tube to buckle and form into the same shape petals each time. If one were to make smaller slits in the tube, the expansion would be smaller, and vice versa. Thus, there is no internal restraint on the tube. The amount of expansion in the SKy Device is

determined by the length of the polymer slits. No structure or object restrains the polymer in its expansion. Thus, the SKy Device is not substantially similar as to "way," with respect to claim 2 of the '043 Patent. (Id. ¶ 101.)

With respect to result, the result is that the inflatable device can be shaped into different shapes and sizes by internal restraints coupled to the interior of the inflatable body. The SKy Device is substantially different as to result. It has no inflatable body, and it is not restrained with any restraint element, so it takes on the same pre-determined configuration each time it is used. (Id. ¶ 102.)

In addition, claim 24 is also not infringed under the doctrine of equivalents because "compacting" under the '043 Patent, like the '888 and '404 Patents, is limited to compacting with a balloon. The SKy Device does not use a balloon and does not infringe under the doctrine of equivalents for all the reasons set forth herein with respect to the '888 and '404 Patents.[3] (Id. ¶ 103.)

2. Claims 17, 20, 23-26, 28 of the '043 Patent

The SKy Device also does not infringe claim 17 under the doctrine of equivalents because the differences between the SKy Device and the elements of claim 17 are not insubstantial. In that regard, the SKy Device does not perform substantially the same function, in substantially the same way, to achieve substantially the same result, with respect to the steps of claim 17 of the '043 Patent. (Id. ¶ 104.)

As to function, the function of claim 17 of the '043 Patent is to restrain expansion of an inflatable device used to create a cavity in bone. Since the SKy Device does not use an

[3] Claims 20, 23-26 and 28 of the '043 Patent depend from claim 17, and therefore are not infringed for at least the same reasons that claim 17 is not infringed.

inflatable device, or the equivalent thereof (for the reasons stated above), it is not substantially similar as to function. (Id. ¶ 105.)

With respect to the way that claim 17 of the '043 Patent goes about that function, it uses an inflatable device having two materials, one of which constrains its expansion. The SKy Device does not have an inflatable body, and the portion that buckles outwards is made of one material, not two. For the reasons set forth above, there is no constraint on the tube from any other material. The amount of expansion in the SKy Device is determined by the length of the polymer slits. Thus, the SKy Device is not substantially similar as to "way," with respect to claim 17 of the '043 Patent. (Id. ¶ 106.)

With respect to result, the result is that the inflatable device can be shaped into different shapes and sizes by a second material that is part of the inflatable body and that restrains the inflatable body. The SKy Device is substantially different as to result. It has no inflatable body, and it is not restrained with any material, so it takes on the same pre-determined configuration each time it is used. (Id. ¶ 107.)

Claims 20, 23-36 and 28 of the '043 Patent depend from claim 17 (as well as from claim 2), and therefore are not infringed for at least the same reasons that claim 17 is not infringed.

VI. CONCLUSION

For the foregoing reasons, DOT's motion for summary judgment of non-infringement of claims 1, 3, 7, 8, 9, 11, and 14 of the '888 Patent, claims 1, 3, 8, 9, 10, 12, and 15 of the '404 Patent, and claims 2, 17, 20, 23, 24, 25, 26, and 28 of the '043 Patent, should be granted in its entirety.

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April 6, 2005

CERTIFICATE OF SERVICE

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

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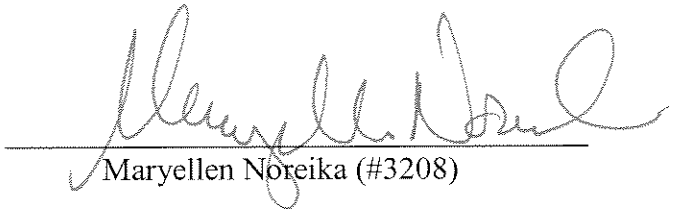
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CERTIFICATE OF SERVICE

I, Maryellen Noreika, hereby certify that copies of the foregoing were caused to be served this 13th day of April, 2005 upon the following in the manner indicated:

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