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 OPPOSITION TO DOT'S MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF U.S. PATENT NOS. 4,969,888, 5,108,404, & 6,235,043 B1

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I. NATURE AND STAGE OF PROCEEDINGS

Plaintiff Kyphon, Inc. ("Kyphon") respectfully submits this brief in opposition to arguments made in Defendants Disc-O-Tech Medical Technologies Ltd. and Disc Orthopaedic Technologies, Inc.'s (collectively, "DOT") Motion for summary judgment of non-infringement of U.S. Patent Nos. 4,969,888, 5,108,404 and 6,235,043 B1.

II. INTRODUCTION

DOT's motion for summary judgment of infringement rests largely upon two flawed premises: (1) that DOT's claim constructions will be adopted and the Court will effectively limit the claims to the best mode of practicing the inventions described in the specifications of the patents; and (2) that when DOT's claim constructions are applied and the Court conducts the fact-intensive doctrine of equivalents analysis to determine whether the method of using the SKy Bone Expander system includes steps equivalent to those portions of the asserted claims disputed by DOT, the Court will ultimately conclude that no genuine issue of material fact exists. Because neither of these premises is supportable, DOT's motion must be denied.

III. SUMMARY OF ARGUMENT

1. DOT's motion for summary judgment of non-infringement assumes that this Court will adopt DOT's claim constructions, including limiting all the asserted claims to the use of an inflatable device. DOT's claim interpretations, however, must be rejected because they deviate from the plain meaning of the terms actually chosen by the patentee and effectively define the claims as being limited to the best mode for practicing the inventions that is disclosed in the specifications. Rejection of DOT's claim constructions would, in turn, require denial of DOT's motion for summary judgment of non-infringement as a matter of law.

2. Even if DOT's claim constructions were somehow adopted, DOT's motion for summary judgment would still need to be denied because of the many factual disputes regarding whether DOT's SKy Bone Expander infringes the claims under the highly fact-based inquiry of the doctrine of equivalents. Indeed, Kyphon has put forth extensive evidence of the equivalence of the methods required by the patents and the use of DOT's SKy Bone Expander – a device that DOT, itself, has repeatedly referred to as being "balloon-like." At a minimum, such evidence establishes the existence of a genuine issue of material fact that requires denial of DOT's motion for summary judgment of non-infringement.

IV. LAW OF SUMMARY JUDGMENT

"A motion for summary judgment must be supported by a sufficient showing to establish that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law." *Scripps Clinic & Research FDN. v. Genentech, Inc.*, 927 F.2d 1565, 1571 (Fed. Cir. 1991) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986)). In determining whether there is a genuine issue of material fact, all doubts are resolved in favor of the nonmovant. *Id.* Also, the evidence submitted by the nonmovant "is to be believed, and all justifiable inferences are to be drawn in [its] favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The focus must be on whether there are genuine issues of material fact. "The purpose of the summary process is to avoid a clearly unnecessary trial, . . .; it is not designed to substitute lawyers' advocacy for evidence, or affidavits for examination before the fact-finder, when there is a genuine issue for trial." *Continental Can Co. U.S.A., Inc. v. Monsanto Co.*, 948 F.2d 1264, 1265 (Fed. Cir. 1991). Accordingly, for DOT to prevail, it must show that even drawing all factual inferences in favor of Kyphon, it has nonetheless proved non-infringement of the asserted claims, and that no reasonable jury could decide otherwise. DOT has not met this burden.

V. DOT IS NOT ENTITLED TO SUMMARY JUDGMENT OF NON-INFRINGEMENT OF THE '888 AND '404 PATENTS

Because all of the asserted claims of the '888 and '404 patents include the limitations contained within claim 1 of the '404 patent, DOT's motion addresses only that claim. DOT's SJ Motion of Non-Infringement, (hereinafter D.I. 138), at p. 10.

A. DOT's Motion for Summary Judgment Must Be Denied As a Matter of Law

DOT's motion regarding the '888 and '404 claims depends upon the Court's adoption of DOT's proposed claim constructions, including imposing three additional limitations upon the plain and ordinary terms of Claim 1: (i) requiring "bone marrow" to be a viscous liquid; (ii) requiring the "compaction" step to be performed with an "inflatable device"; and (iii) requiring the "compaction" step to also result in "compressing substantially all of the bone marrow away from a central portion of an interior bone volume." For the reasons set forth in Kyphon's opening claim construction brief and its opposition to DOT's proposed claim constructions, no credible basis supports DOT's attempts to deviate from the plain meaning of the claims – including DOT's effort to construe "bone marrow" in a manner that renders the claims "meaningless," as this Court has previously concluded. Because DOT's motion is premised upon a legally erroneous interpretation of the patent claims, DOT's motion for summary judgment of non-infringement must be denied as a matter of law on this basis alone.

B. Even If the Third Portion of DOT's Claim Construction is Adopted, The SKy Bone Expander Device *Would Literally Satisfy* that Element

With regard to at least the third limitation that DOT seeks to impose upon the claims' plain meaning, the evidence actually establishes that no reasonable juror could

side with DOT because the SKy Bone Expander ***does*** compress substantially all of the bone marrow away from the central portion of the vertebra. In fact, perhaps one of the most compelling pieces of evidence of infringement is DOT's own marketing video that it uses to explain the SKy Bone Expander product to surgeons. This presentation shows that the SKy Bone Expander compresses substantially all of the bone marrow away from the central portion of the bone. D.I. 150, Ex. N. Moreover, Dr. Lane, a surgeon who has used the SKy Bone Expander, also testified that as the device is expanded "it pushes aside the hematological bone marrow elements … and the cancellous bone, and as this is completed, as the bone is compacted in this process … the fracture is elevated up." Halkowski Opp. Decl., Ex. 1 (Lane deposition transcript at 74:17-75:2). DOT's own materials also repeatedly emphasize that the SKy Bone Expander is responsible for "creat[ing] a void" in the vertebra. *See, e.g.*, Kyphon's Motion for Partial Summary Judgment of Infringement (hereinafter D.I. 148) at p. 6 (*citing* DOT's own statements to the FDA)); *see also* Halkowski Opp. Decl., Ex. 2 (Steck deposition transcript at 32:3-40:16, 29:5-30:6, 32:3-18, 40:18-41:7) (wherein Dr. Steck confirms that the SKy Bone Expander was "designed to create a void within the vertebra"). Of course, the creation of any such void is not possible unless substantially all the tissue inside the bone has been compressed away from the central portion of the vertebra. *See* Declaration of Michael Marks, M.D., M.B.A. in Support of Kyphon's Oppositions to Defendants' Summary Judgment Motions ("Dr. Marks' 4/14/05 Declaration" filed concurrently) at ¶ 9.

The only evidence offered by DOT to the contrary are conclusory assertions by DOT's expert that the SKy Bone Expander creates an interdigitated void (i.e., a void with bumps), rather than a void without bumps. This argument, however, is irrelevant because even the claim construction chosen by DOT does not require the creation of a void without any bumps. DOT's desired claim construction merely requires that substantially all the bone marrow be compressed away from the central part of the vertebra – a function that of necessity must occur in order for the SKy Bone Expander to create a

defined void in the vertebra. Thus, even if this portion of DOT's desired claim construction were imposed upon the plain meaning of claim 1 of the '404 patent, it would not aid DOT's motion for summary judgment of literal non-infringement.

C. Even Assuming, Arguendo, No Literal Infringement Under DOT's Interpretation of the Claims, Numerous Genuine Issues of Material Fact Would Require Denial of DOT's Motion for Summary Judgment of Non-Infringement Regarding the '888 and '404 Patents

This section presumes that: (i) the Court has adopted DOT's entire proposal for construing Claim 1 of the '404 patent, including adding the three additional limitations discussed above to the plain meaning of the "compacting" step required by all the claims; and (ii) that the Court has then concluded that the SKy Bone Expander Device is not literally covered by Claim 1 of the '404 patent (as that claim is construed by DOT). Even under this scenario, DOT would still have to show that the use of the SKy Bone Expander device, in addition to not being literally within the scope of Claim 1 of the '404 patent, also does not include a step equivalent to the "compacting" step set forth in Claim 1 of the '404 patent. This equivalents analysis, otherwise known as the doctrine of equivalents, prevents the risk of injustice that may result from a limited focus on words alone. *Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 876 (Fed. Cir. 1993). Thus infringement cannot be avoided by changing mere details of a claimed invention while retaining the essential functionality. *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1424 (Fed. Cir. 1997); *Discovision Assocs. v. Disc Mfg., Inc.*, 25 F. Supp. 2d 301, 336 (D. Del. 1998).

1. The Doctrine of Equivalents is an Intensively Factual Assessment

The fundamental standard for assessing whether an accused product contains an "equivalent" of an element in an asserted patent claims is, as follows:

> An element in the accused product is equivalent to a claim limitation if the differences between the two are "insubstantial" to one of ordinary skill in the art.

Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 812-13 (Fed. Cir. 2002). Indeed, this same standard, including the requirement that the equivalence be viewed from one of ordinary skill in the art, has been repeated in numerous decisions of the Federal Circuit. *See, e.g., Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1371 (Fed. Cir. 2001); *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1359 (Fed. Cir. 2000); *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1383 (Fed. Cir. 2000); *Marquip, Inc. v. Fosber Am. Inc.*, 198 F.3d 1363, 1366 (Fed. Cir. 1999); *Overhead Door Corp. v. Chamberlain Group, Inc.*, 194 F.3d 1261, 1269 (Fed. Cir. 1999).

The issue of infringement under the doctrine of equivalents is a "highly factual inquiry." *See Jeneric/Pentron,* 205 F.3d at 1384; *Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1311 (Fed. Cir. 2003) (stating that infringement under the doctrine of equivalents frequently turns on questions of fact); *see Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1188-89 (Fed. Cir. 1998). Summary judgment of non-infringement is thus appropriate only if the evidence is such that no reasonable juror could determine two elements to be equivalent. *Abbott Labs. v. Novopharm Ltd.*, 323 F.3d 1324, 1329 (Fed. Cir. 2003) (citations omitted). That is not the situation presented here.

2. Dr. Marks' Opinions, and the Evidence He Relies Upon, Directly Dispute The Assertions of DOT (and Its Expert) Regarding the Equivalence of the use of the SKy Bone Expander vis-à-vis the "Compacting" Step Required by the Asserted Claims

There is no particular analytical framework for determining whether the differences between the claimed element and the accused product are insubstantial.

Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co., 520 U.S. 17 (1997); *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1326 (Fed. Cir. 1991) ("How equivalency to a required limitation is met necessarily varies from case to case due to many variables such as the form of the claim, the nature of the invention defined by it, the kind of limitation that is not literally met, etc."). However, the Federal Circuit has enunciated certain factors that help in this assessment of insubstantiality. Among those considerations are: (i) the pioneering nature of the invention; (ii) the "heart of the invention;" (iii) what is referred to as the function-way-result test; and (iv) the interchangeability of the relevant step in the invention with the pertinent portion of the accused method. *See, e.g., Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1351 (Fed. Cir. 2003); *Abbott Labs v. Dey, L.P.*, 287 F.3d 1097, 1102 (Fed. Cir. 2002); *Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371, 1383 (Fed. Cir. 2001); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1240 (Fed. Cir. 1989); *Perkin-Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1533 n.8 (Fed. Cir. 1987); *Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986).

a. Kyphoplasty is a Pioneering Invention

In determining the equivalence of an accused process, a court should first consider whether the patentee is asserting a "pioneering invention". In the event an invention achieves a major, or extraordinary, advance over the prior art, and is thus characterized as a pioneering invention, the claims are entitled to a broad or liberal range of equivalents. *Warner-Jenkinson,* 520 U.S. at 27, n.4; *Abbott Labs v. Dey, L.P.*, 287 F.3d 1097, 1102 (Fed. Cir. 2002); *Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n,*

805 F.2d 1558, 1563 (Fed. Cir. 1986) ("It has long been recognized that the range of permissible equivalents depends upon the extent and nature of the invention, and may be more generously interpreted for a basic invention than for a less dramatic technological advance")[1].

Kyphoplasty, as that method is detailed in the claims of the '404 and '888 patents, is without a doubt a pioneering medical advance. Dr. Marks details in his reports the remarkable change in the treatment of vertebral compression fractures that kyphoplasty has made possible. Dr. Marks' Expert Report (3/8/05) at pp. 6-8 (hereinafter D.I. 150, Ex. L), and Dr. Marks' Expert Report (3/23/05) at pp. 5-6 (hereinafter Halkowski Opp. Decl., Ex. 3. Indeed, the success of kyphoplasty, the praise that this method has received, and the positive impact the invention has had on the lives of thousands of patients are all undeniable. DOT itself highlighted the success of the procedure, and the fact that no company other than Kyphon and DOT market devices to perform the procedure, in its preliminary injunction opposition. D.I. 83, at 34-36, and 39. The invention of "kyphoplasty" is also pioneering because, *inter alia*, it is a drastic departure from the prior treatments of the spine. *See*, e.g., D.I. 150 at pp. 3-8 and Halkowski Opp. Decl., Ex. 3 at pp. 2-6. The prior art solutions to fractures of the spine merely treated the painful symptoms of vertebral compression fractures. D.I. 150, Ex. M at pp. 5-6. None attempted to put the vertebra back into its pre-fractured shape and thereby remedy the deteriorating conditions of weak bone caused by osteoporosis or cancer. *Id.* at p. 5. Kyphoplasty was the first treatment with the capability of restoring the height of the fractured bone and creating a nearly instant internal casting of the fracture (via bone cement inside the vertebra) without the use of external supports, back braces, or months of healing.

[1] This is true because a pioneer patent by definition will have little applicable prior art to limit it, whereas an improvement patent's scope is confined by the existing knowledge on which the improvement is based. *Abbot Labs.*, 287 F.3d at 1105; *Augustine Med., Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1301 (Fed. Cir. 1999). However, the fact that a patent is a mere "improvement" does not preclude application of the doctrine of equivalents. *Augustine Med.*, 181 F.3d at 1299.

Kyphoplasty's status as a pioneering invention is confirmed by the fact that Kyphon developed and introduced the kyphoplasty solution into the market of treating vertebral compression fractures on its own, until DOT came along and set out to co-opt Kyphon's business. *See generally* D.I. 55 (Kyphon's Motion for Preliminary Injunction Brief at pp. 12-13).

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Thus, in addition to generally having all facts construed in its favor, Kyphon's invention is also entitled to a liberal range of equivalents because of its pioneering nature.

b. The Heart of the Kyphoplasty Invention Is Captured by DOT's SKy Bone Expander Device

Although a specific claim limitation cannot be ignored as insignificant or immaterial in determining infringement, a court may consider the "heart of the invention" in determining whether the differences between the accused process and the claimed invention are insubstantial. *Perkin-Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1533 n.8 (Fed. Cir. 1987). Indeed, "there is no error in considering 'the principles of the claimed invention.'" *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1240 (Fed. Cir. 1989). The heart of the kyphoplasty invention is the capability of reducing a vertebral fracture by compacting bone marrow to create a void and immediately providing an internal cast by working from the inside of the vertebra via a non-invasive percutaneous opening (i.e., without the need to conduct an open operation and attach extensive metallic structures to the spine). DOT's SKy Bone Expander, when used as directed by DOT, has taken the heart of the kyphoplasty invention. This fact weighs in favor of a finding of infringement under the doctrine of equivalents.

c. Use of the SKy Bone Expander Device Performs Substantially the Same Function, in Substantially the Same Way, to attain Substantially the Same Result[2]

One of the tests adopted by the Federal Circuit in deciding whether the differences between the accused product or process and the claim limitation are "insubstantial" is the tripartite function-way-result test. *Warner-Jenkinson,* 520 U.S. at 39. Under this test, the disputed portion of an accused method is equivalent to a step in the claimed method, if the portion of the accused method performs substantially the same function, in substantially the same way, to accomplish substantially the same result as the claimed step. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.,* 339 U.S. 605, 608 (1950); *Matsushita Elec. Indus. Co. v. Cinram Int'l, Inc.,* 299 F. Supp. 2d 348, 365 (D. Del. 2004). DOT only disputes whether the method of using the SKy Bone Expander includes a corresponding equivalent to the "compacting" step of the asserted claims.[3]

However, Dr. Marks, in his report, directly applied the function-way-result test to the accused use of the SKy Bone Expander device, assuming DOT's construction of the claims that require use of a balloon, as follows:

> Even if any part of this "compacting" limitation is construed or applied so that it is not literally present in the SKy Bone Expander, in my opinion it is present under the doctrine of equivalents. As discussed in the documents and testimony referenced herein as well as in the attached claim charts, the SKy Bone Expander generally compacts the inner portion of the bone, including both the cancellous bone framework and the soft, pulpy, fibrous marrow tissue. One capable of designing or using the product, or

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[2] The Supreme Court specifically recognized that, while the tripartite test may be suitable for analyzing simple mechanical devices, it often provides a poor framework for analyzing other products or processes. *Warner-Jenkinson*, 520 U.S. at 39-40. Yet, the Court offered little additional guidance as to what might render any given difference "insubstantial."

[3] Claim 1 of the '404 patent recites the following three elements:
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.

> performing this procedure would view compaction of the inner portion of the bone and compaction of the soft, pulpy, fibrous marrow tissue that is embedded within the cancellous framework inside bone as substantially similar in the context of Kyphon's invention. The compaction of the inner portion of the bone by the SKy Bone Expander performs the same function (increasing the volume of the passage) in the same way (expanding a device inside soft, inner bone) to achieve the same result (creating a defined void inside the bone that can be filled with a flowable material) as the compaction step described in the claims of the '888 and '404 patents.

D.I. 150, Ex. M at pp. 21-22. Thus, DOT's SKy Bone Expander Device, when used as directed by DOT, performs a step substantially equivalent to the "compacting" step of the asserted claims, as construed by DOT, because it performs substantially the same function, in substantially the same way, to attain substantially the same result. DOT's various disputes with Dr. Marks' analysis, addressed in greater detail below, merely confirm the existence of numerous genuine issues of fact regarding application of the doctrine of equivalents to this matter and require the denial of DOT's motion for summary judgment.

i. The SKy Bone Expander Device Performs Substantially the Same Function Performed by the Required "Compacting" Step

DOT, echoing its approach to claim construction, disputes how to define the appropriate function being performed by the "compacting" step. DOT argues that the function of the "compacting" step 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." D.I. 138 at p. 12. According to DOT, its device does not perform an equivalent function because its SKy Bone Expander creates an interdigitated void, not a smooth void. *Id.* However, even assuming that DOT has properly defined the function performed by the "compacting" step (which Kyphon vigorously disputes), the evidence of record shows that the SKy Bone Expander does

compress substantially all of the bone marrow away from the central portion of the bone – indeed this function is necessary to the creation of a void in the vertebra. *See, supra*, part V, section B. Thus, at a minimum, even under DOT's view of the function that must be performed by the "compacting" step in the asserted claims, the record establishes a genuine factual dispute regarding whether persons of ordinary skill would view this function as being performed by the SKy Bone Expander device.

Moreover, DOT has actually adopted an incorrect definition of the function that is performed by the "compacting" step. The function performed by the "compacting" step is plain from the language of the claim – the compaction generally serves to "increase the volume of [the existing] passage" that was initially created by the surgeon.[4] DOT does not, and cannot, dispute that the SKy Bone Expander performs this basic function of enlarging the passage initially created by the surgeon. Thus, the evidence establishes that DOT's SKy Bone Expander Device satisfies this portion of the tripartite test, or, at a minimum, shows that a genuine issue of material fact exists.

ii. The SKy Bone Expander Device Performs the Required "Compacting" Step in Substantially the Same Way

The way that the "compacting" step performs the function of enlarging the passage initially created by the surgeon is via the expansion of a device inside the

[4] The specifications of the '888 and '404 patents further confirm the function of the "compacting" element, by explaining that the expansion of the device "causes a compacting of the bone marrow against the inner surface of the outer cortical wall of the bone to be treated to ***further enlarge the cavity***" (i.e., the passage that was initially created by the surgeon). '404 patent at col. 2: 15-19 (emphasis added). DOT's reliance upon the portion of the specification discussing the creation of a "dam" by the "compacting" step is misplaced and, frankly, confusing. DOT never argues in its summary judgment or claim construction briefs that the "compacting" limitation should be construed to require the creation of an "egg-shell" like or "dam-like" void. The shape of the void is therefore not part of the function that is relevant to the equivalents analysis. To the extent the shape of the void is a result of the claimed compacting function, and therefore is relevant to the equivalents analysis, there is no credible evidence of substantial differences.

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Also, DOT certainly does *not* claim that its void is unlike Kyphon's purportedly "dam-like" void, because DOT's void somehow fails to contain the cement that is injected into the vertebra.

relatively soft, inner bone. *See, e.g.*, D.I. 150, Ex. M at p. 22 (describing the way the "compacting" step is performed as "expanding a device inside soft, inner bone"). As illustrated by its very name, the SKy Bone ***Expander*** is an expandable device and DOT never claims otherwise. *See, e.g.*, D.I.151, Ex. W at 2025 (describing the SKy Bone Expander as an expandable tube and the similar expansion capabilities between the SKy Bone Expander and Kyphon's commercial embodiment of the asserted patents). Thus, the SKy Bone Expander satisfies this portion of the tripartite test.

DOT, however, defines the way the "compacting" step is performed as requiring specifically an "inflatable device." Even accepting, *arguendo*, this unduly narrow view of the way the claimed "compacting" step is performed, a genuine issue of material fact exists regarding whether one of ordinary skill in the art would view the use of the SKy Bone Expander as being equivalent to the use of an inflatable device in the performance of the "compacting" step required by the claims,

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In support of its position, DOT identifies a few differences of purported significance between the SKy Bone Expander and the use of an inflatable device. Primarily, DOT asserts that the SKy Bone Expander is mechanical and not hydraulic, that the void created is interdigitated (i.e., bumpy) as opposed to a smoother void that would purportedly be created by an inflatable device, that the inflatable device could rupture, and that it will seek the path of least resistance. D.I. 138 at pp. 12-16. To the extent DOT is asserting that the SKy Bone Expander performs additional desired functions – such as interdigitating the void, expanding to a consistent pre-determined shape, or protecting against rupture – such purported improvements are irrelevant. *See Insta-Foam Prods., Inc. v. Universal Foam Sys., Inc.*, 906 F.2d 698, 702 (Fed. Cir. 1990) (adding a function to the accused device does not avoid infringement); *Insituform Techs., Inc. v. CAT Contracting, Inc.*, 161 F.3d 688, 693 (Fed. Cir. 1998) (infringement cannot be

avoided by the fact that the accused device is more or less efficient or performs additional functions).

Moreover, when viewed from the perspective of one of ordinary skill in the art, these purported additional features do not establish that the SKy Bone Expander performs the "compacting" step in a different way from an inflatable device. Dr. Marks has considered Dr. Mitchell's assertions regarding the purportedly different way that the SKy Bone Expander device performs the "compacting" step. See Dr. Marks' 4/14/05 Declaration at ¶¶9-14. Dr. Marks, however, after reviewing extensive documentation and testimony as well as examining and using the SKy Bone Expander on human cadaver bones, explains that in his view a surgeon's turning of the handle on a SKy Bone Expander device to increase its size performs the "compacting" step in substantially the same way as turning a handle to expand an inflatable device, such as the Kyphon Inflatable Bone Tamp. *Id.*

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D.I. 151, Ex. W at DOTLTD 2027.

Whether the expansion is done via an elastic inflatable body, or via an elastic-plastic mechanical device, DOT itself has also further indicated that the basic way of carrying-out the required compaction is the same:

> The basic idea is compressing the bone material by expansion of elastic, or elastic-plastic, device, thus crating voids within the bone, and providing for fracture reduction.

D.I. 151, Ex. W at 1990. These facts, as well as those more fully set forth in Dr. Marks' report establish, at a minimum, the existence of a genuine issue of material fact regarding whether the SKy Bone Expander device operates in a substantially different way in performing the "compacting" step, even as construed by DOT.

looks to the knowledge of a skilled artisan to see whether that artisan would contemplate the interchange as a design choice." *Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371, 1383 (Fed. Cir. 2001).

Here, the use of DOT's SKy Bone Expander is plainly interchangeable with an inflatable device with regard to the required "compacting" step of the claims. DOT specifically markets the SKy Bone Expander as being interchangeable with Kyphon's commercial embodiment of the asserted claims, the KyphX® Inflatable Bone Tamp ("IBT"). It states that its device can be used instead of the IBT to perform kyphoplasty procedures. Halkowski Opp. Decl., Ex. 2 (Dr. Steck responds that a DOT representative indicated to him that the "SKy Bone Expander could be used in the same osteoporosis kyphoplasties that [he] did with the Kyphon device" and "essentially in the same manner"); *see* See D.I. 150, Ex. M (providing list of marketing documents describing operation of SKy Bone Expander); Halkowski Opp. Decl., Ex. 4 (Ex. 24 of ITC Complaint) (DOT representative explained that the SKy Bone Expander could be used "instead of Kyphon's balloons"); Halkowski Opp. Decl., Ex. 5 (Ex. 23 of ITC Complaint) (during Dr. Lieberman's meeting with a DOT representative "it was made clear to [him] that the SKy Expander device is to be used to perform a similar function as the Kyphon tool during a kyphoplasty procedure"). Thus, although the Kyphon device is generally preferred, the evidence indicates that the SKy Bone Expander is interchangeable with the IBT to perform kyphoplasty procedures. See, e.g., Halkowski Opp. Decl., Ex. 3.[5] In addition, as noted above and in Kyphon's motion for summary judgment of infringement,

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[5] "Q. Okay. Mr. Foster Indicated to you that that Disc-O-Tech SKy Bone Expander could be used in the same osteoporosis kyphoplasties that you did with the Kyphon device?

...

A. Yes.
Q. And essentially in the same manner?

...

A. Essentially the same, yes."
Id

This interchangeability, therefore, weighs strongly in favor of a finding of equivalence.

Moreover, DOT concedes that "interchangeability is a relevant consideration under the doctrine of equivalents." D.I. 138 at p.17.

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Rather than address the clear record on this point, DOT merely argues that the issue of concern is interchangeability with respect to the disputed step in the asserted claim, not interchangeability with regard to the end use. Here, however, the evidence plainly establishes both points equally. Thus, the evidence of interchangeability of the SKy Bone Expander device and an inflatable device with regard to performance of the required "compacting" step in the asserted claims at a minimum raises a genuine issue of fact regarding the doctrine of equivalents issue.

In summary, DOT's motion for summary judgment of non-infringement of the '888 and '404 patents based on the DOE must be denied because, viewing all the evidence most favorably to Kyphon, there are numerous genuine issues of material fact in dispute regarding DOT's assertions, such that a reasonable juror plainly could determine that the use of DOT's SKy Bone Expander device, as directed by DOT, performs a step equivalent to the required "compacting" step set forth in the asserted claims.

VI. DOT IS NOT ENTITLED TO SUMMARY JUDGMENT OF NON-INFRINGEMENT OF THE '043 PATENT

The '043 patent is directed toward improvement of the kyphoplasty method claimed in the '888 and '404 patents by allowing for greater control of the expansion of the expandable bodies used in the procedure. Kyphon asserts that DOT infringes claims 2,

17, 20, 23-26, and 28 of the '043 patent. DOT's motion for summary judgment of noninfringement focuses upon certain elements set forth in the two independent claims, 2 and 17, that have been asserted by Kyphon. [6]

A. DOT's Motion for Summary Judgment Must Be Denied As a Matter of Law

DOT's arguments in support of its '043 patent non-infringement position are again premised upon DOT's attempts to limit the asserted claims to the best mode, including its argument that the Court should deviate from the plain meaning of the claims to add the limitation of an inflatable device. Thus, if DOT's effort to change the plain meaning of the claims fails, then DOT's claim of literal non-infringement of the '043 patent also fails as a matter of law.

B. Even If DOT's Claim Construction is Adopted, Genuine Issues of Material Fact Would Exist Regarding The Presence of Certain Disputed Steps of the Asserted Claims

DOT asserts that the SKy Bone Expander device does not have either an "internal restraint coupled to an interior of the body to constrain the expansion in cancellous bone" (claim 2), or a "body including at least two materials that, during expansion in cancellous bone, apply a force capable of moving fractured cortical bone and constrain the

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[6] Claim 2 of the '043 patent is as follows:

A method for treating bone comprising the steps of inserting inside bone a device comprising a body adapted to be inserted into bone and undergo expansion in cancellous bone to compact cancellous bone, including the body includes material that, during the expansion in cancellous bone, applies a force capable of moving fractured cortical bone, and further includes an internal restraint coupled to an interior of the body to constrain the expansion in cancellous bone.

Claim 17 of the '043 patent is as follows:

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

expansion in cancellous bone" (claim 17). Setting aside DOT's assertion that these terms require the use of an inflatable device, the remainder of the disputed limitations are in fact present in the accused method – even under DOT's proposed claim construction.

DOT contends that "the amount or degree of expansion" of the SKy Bone Expander device is pre-determined based on the length of the slits in the plastic polymer tube that expands to create a void inside the bone. D.I. 138 at pp.19-20. DOT then concludes that there is no "internal restraint" on the tube. The existence of slits in the polymer tube of the SKy Bone Expander, however, in no way eliminates the critical role played by the internal metal rod in DOT's SKy Bone Expander device. Absent that rod (including the distal cap nut) that enables the axial compressive force to be applied to the polymer sleeve, the buckling of the polymer tube that results in the expansion of the SKy Bone Expander would be uncontrolled. The unstable polymer tube would then simply push out to one side or the other, preventing the device from attaining a controlled expansion or its repeatable, predetermined final configuration. Indeed, the necessity of the Tecoflex plastic tube and the inner metal rod working together to achieve a constrained, predetermined, configuration was confirmed by Dr. Motti Beyar, a founder of DOT and a creator of the SKy Bone Expander system:

> Q. Oh, all right. All right. So, but in any event, you need those three components together, namely, the Tecoflex tube, the metal rod and the inner tube in order to ***cause the final device to assume its predetermined configuration***, right?
>
> A. Yes

See, Halkowski Opp. Decl., Ex. 6 (Beyar deposition transcript at 53:23-54:4)(emphasis added). Though Kyphon has consistently pointed DOT to the metal rod as a portion of the structure responsible for constraining expansion of the Sky, and as one of the two materials which together constrain the expansion, DOT and its expert Dr. Mitchell have

consistently avoided engaging on this issue. DOT continues to do so in its summary judgment brief.

In addition to the Beyar testimony, Dr. Marks has also explained that, based upon his examination of the SKy Bone Expander device, the internal metal rod is coupled (slidably) to the interior of the expandable plastic polymer and assists in controlling the expansion of the plastic polymer so that the polymer can achieve its predetermined configuration. *See* D.I. 150, Ex. L at pp. 9-15. Dr. Marks has further noted that the internal metal rod (and its cap) along with the plastic polymer are two materials which, during expansion, interact to apply the required force, through the buckling of the polymer caused by the axial force, to move the cortical bone and to constrain the expansion of the SKy Bone Expander such that the device attains its predetermined configuration. *See id.*, at pp. 12-13. DOT's contentions, therefore, mistakenly ignore the critical role of the metal rod that exists inside of the expandable plastic polymer.

Thus, setting aside DOT's assertion that the claims require an inflatable device, the limitations of claim 2 and 17 are otherwise present in the SKy Bone Expander device. At a minimum, the evidence of record, including the Beyar testimony and Dr. Marks' analysis, establish the existence of genuine issues of material fact regarding these portions of the claims – even under DOT's proposed claim construction.

C. Lastly, Even Assuming, *Arguendo*, No Literal Infringement Under DOT's Interpretation of the Claims, Numerous Genuine Issues of Material Fact Would Require Denial of DOT's Motion for Summary Judgment of Non-Infringement Regarding the '043 Patent

DOT's arguments regarding application of the doctrine of equivalents to Claims 2 and 17 of the '043 patent are fundamentally flawed as a matter of law, and for that reason

must be rejected.[7] When employing the function-way-result test in aid of a doctrine of equivalents analysis, the Federal Circuit emphasizes that there should be an assessment of whether the portion of the accused method is equivalent to a particular step in the claimed method. *See, e.g., Jeneric/Pentron, Inc. v. Dillon Company, Inc.,* 205 F.3d 1377, 1383 (Fed. Cir. 2000) ("The doctrine of equivalents requires that the accused product contain each limitation of the claim or its equivalent."); *see also Graver Tank,* 339 U.S. at 608. DOT's analysis, however, generically addresses claim 2 and claim 17 without presenting an equivalency analysis directed at any particular step, or portion, of the claims. *See* D.I. 138 at pp. 22-24 (blanketly addressing the claims, as follows: "the function of claim 2," "the SKy Device is not substantially similar as to 'way', with respect to claim 2," "the function of claim 17," and "the SKy Device is not substantially similar as to 'way', with respect to claim 17"). Given DOT's flawed analysis, and the detailed discussion set forth in Dr. Marks' expert report that explains why the equivalent of each of the disputed steps in the asserted claims is present in the accused method (D.I. 150, Ex. L at pp. 22-25), DOT cannot establish that the SKy Bone Expander does not infringe under the doctrine of equivalents and DOT's motion for summary judgment of non-infringement must be denied.[8]

Moreover, to the extent DOT's analysis could conceivably be viewed as a proper assessment of the function-way-result test on an element-by-element basis, Dr. Marks' report sets forth an analysis, from the view of one of ordinary skill in the art, that contradicts DOT's positions regarding whether there are any substantial differences

[7] DOT also incorporates by reference, for the "compacting" element of Claim 24, the analysis of the '888 and '404 claim limitations regarding the "compacting" step. For the reasons set forth above in this brief regarding application of the doctrine of equivalents analysis to the "compacting" step of the asserted claims of the '888 and '404 patents, DOT is similarly not entitled to a ruling that the accused method does not infringe Claim 24 of the '043 patent.

[8] Additionally, the interchangeability of the use of the SKy Bone Expander device vis-à-vis the required claim step(s) involving an expandable body with certain constrained expansion capabilities, is detailed in Dr. Marks' report and provides another basis for concluding that genuine issues of material fact exist that preclude a grant of summary judgment of non-infringement. D.I. 150, Ex. M at pp. 22-25.

between the disputed steps of the asserted claims and the accused method of using the SKy Bone Expander device.[9] D.I. 150, Ex. M at pp. 22-25.

Thus, DOT's motion for summary judgment of non-infringement of the '043 patent based on the doctrine of equivalents must be denied because, viewing all the evidence most favorably to Kyphon, there are numerous genuine issues of material fact in dispute regarding DOT's assertions, such that a reasonable juror could determine that the use of DOT's SKy Bone Expander device, as directed by DOT, performs steps equivalent to each of the disputed steps of the '043 asserted claims.

VII. CONCLUSION

For the reasons explained above, DOT's motion for summary judgment of non-infringement of the '888, '404, and '043 patents must be denied.

[9] DOT also relies upon selected testimony from one of the inventors of the '043. However, her testimony was merely that, "*In general,* things other than balloons are inherently restrained." (emphasis added). Thus, her statement was literally "general" in nature and certainly did not either address the constrained expansion of the SKy Bone Expander, or pertain to the manner in which the SKy Bone Expander is encompassed by the claim language. DOT simply never asked her follow-up questions on these points.

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