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 **PUBLIC VERSION**

MEMORANDUM IN SUPPORT OF KYPHON'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF INFRINGEMENT

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I. NATURE AND STAGE OF PROCEEDINGS

Kyphon Inc. ("Kyphon") has sued Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. (collectively, "DOT") for infringement of five patents: U.S. Pat. Nos. 4,969,888 ("the '888 patent"); 5,108,404 ("the '404 patent"); 6,235,043 ("the '043 patent"); 6,241,734 ("the '734 patent"); and 6,613,054 ("the '054 patent"). Dispositive motions and opening claim construction briefs are due April 6, 2005. D.I. 132. Trial is set for June 1, 2005. D.I. 111.

In the present motion, Kyphon moves for summary judgment of infringement on four of the patents-in-suit: 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, claims 1, 10, 11, 13, 15, 20, and 21 of the '734 patent, and claims 26, 27, 36, 37, 41, and 48 of the '054 patent.

II. SUMMARY OF ARGUMENT

1. The '888 and '404 patents claim methods consisting principally of three interrelated steps: A surgeon (i) forms an initial passage into bone marrow; (ii) compacts cancellous bone with a device to increase the volume of the initial passage so that the resulting cavity can be safely filled with a flowable material; and (iii) fills the defined cavity with a flowable material that is capable of hardening, such as bone cement. The procedure for using DOT's SKy Bone Expander device includes those three steps. Therefore, DOT literally infringes the '888 and '404 patents.

2. DOT disputes only that its SKy Bone Expander satisfies the "compacting" element. However, DOT's own documents and marketing materials, **REDACTED** **REDACTED** an analysis by the attorney DOT hired to assess Kyphon's patents, and testimony from surgeons who have used the SKy Bone Expander, all confirm that DOT's device is used to compact cancellous bone to thereby enlarge the

initial passage created by the surgeon and create a void that can then be filled with a flowable material.

3. DOT contributes to and induces its customers to infringe the '888 and '404 patents by actively inducing surgeons to use the SKy Bone Expander to perform kyphoplasty procedures. The evidence also establishes that the SKy Bone Expander is especially made for performing the required steps of kyphoplasty procedures.

4. The '734 and '054 patents claim devices that have certain capabilities regarding the introduction of material into a bone. DOT argues that its devices are not actually used in the manner described by the '734 and '054 patents. If the asserted claims had been drafted to cover particular methods for using the bone filler devices, DOT's assertions might have some relevance. However, because the asserted claims are apparatus claims that only require devices with certain capabilities, and because DOT does not and cannot dispute that its devices have the required capabilities, DOT literally infringes the '734 and '054 patents.

III. INTRODUCTION

This case concerns kyphoplasty, Kyphon's pioneering approach for treating vertebral compression fractures caused by deteriorating bone conditions such as osteoporosis. This method is a minimally invasive surgical procedure that shores up and internally strengthens fractured bone. It principally involves three related steps performed by a surgeon:

1. Forming an initial passage into the bone marrow of a vertebral body;

2. Compacting cancellous bone in the vertebral body with an expandable device to increase the volume of the initial passage formed by the surgeon to create a cavity that can be safely filled with a flowable material; and

3. Filling the defined cavity with a flowable material that is capable of hardening, such as bone cement.

DOT's SKy Bone Expander system ("SKy system") consists of a variety of medical instruments that are used to perform kyphoplasty procedures. DOT's system includes instruments, including a drill, that permit the surgeon to create an initial passage into a vertebra, and the SKy Bone Expander device, which has, according to its very name, an expandable body used by surgeons to compress cancellous bone tissue to thereby expand the initial cavity formed by the surgeon and form an enlarged cavity within the bone. The SKy system also includes instruments (collectively "bone filler device") that are used to fill the cavity in the bone with a flowable material capable of setting to a hardened condition. Given DOT's own admissions and the ordinary meaning of the claim language, summary judgment of infringement is required. There is no genuine issue of material fact that surgeons use DOT's SKy Bone Expander device as instructed by DOT to practice each limitation in the asserted claims of the '888 and '404 patents and that DOT's bone filler device satisfies every limitation of the claims of the '734 and '054 patents.

A. Kyphon's Preliminary Injunction Motion

Kyphon moved for a Preliminary Injunction in October 2004 based on claim 1 of the '404 patent. This Court issued its decision on December 10, 2004. D.I. 102. The Court adopted Kyphon's construction of the disputed claim term, "bone marrow," as a combination of the connective tissue and the cancellous bone framework inside a bone, and further concluded that DOT's device "necessarily compacts the bone marrow to increase the volume of the passage therein." *Id.* at p. 4. The Court expressly found "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.* at pp. 8-9. Although this decision was in the context of Kyphon's Preliminary Injunction motion, nothing has occurred since that time to change the analysis underlying the Court's conclusions.

B. Kyphoplasty Background

Because Kyphon's pleadings previously filed in support of its Preliminary Injunction motion [D.I. 55 and 92] and the opening claim construction brief filed concurrently with this motion provide a detailed background regarding kyphoplasty, the procedure is addressed only briefly here.

Recognizing the long-felt need for a treatment that addressed not only the painful symptoms of compression fractures, but also the deteriorating condition of weakened bone, Kyphon invented kyphoplasty. In this procedure, a surgeon typically makes tiny incisions in the back and creates one or more passages through the cortical bone (i.e., the outer bone) of the vertebra to access the interior of the vertebra (i.e. the bone marrow). This access typically involves drilling into the vertebral body. In the case of kyphoplasty using Kyphon's devices, inflatable balloons are inserted into the central portion of the bone and then expanded. Expansion of the balloons compacts and pushes the soft cancellous bone (bone marrow) outwardly from the initial passage created by the surgeon towards the cortical bone, thereby increasing the volume of the initial passage to produce a defined cavity. Creation of the cavity in this matter allows the surgeon to safely fill it. After the expandable devices are removed from the cavity, the surgeon proceeds to fill it with a flowable material that hardens, like bone rapidly cement. Once hardened, this material acts as an "internal cast" for the fractured bone, rapidly locking the vertebra

pieces back into place. A few stitches to close the tiny incisions in the skin completes the procedure.

C. Kyphon's Patents and Products

Beginning in 1989, Kyphon applied for and received patent protection on both kyphoplasty and certain devices used in the procedure. The '888 patent, which relates to methods for the treatment of osteoporotic bones, issued on November 13, 1990. Halkowski SJ Decl., Ex. A.[1] The '404 patent, a continuation of the '888 patent that covers treatment of both osteoporotic and non-osteoporotic bones, issued on April 28, 1992. Halkowski SJ Decl., Ex. B. Both the '734 and '054 patents relate to devices used to fill a cavity in bone with material. Halkowski SJ Decl. Ex. C and D. The '734 patent issued on June 5, 2001, and the '054 patent issued on September 2, 2003. *Id.* All four of these patents are assigned to Kyphon.

In 1998, Kyphon received FDA clearance to market its kyphoplasty devices. Halkowski SJ Decl., Ex. E [KY114452-454; DOTLTD 89-94]. This clearance allowed Kyphon to market its products for the reduction of fractures and/or creation of a void in inner bone in the spine. *Id.* Kyphon began selling its devices for use in the spine in early 1999.

D. DOT's SKy System

DOT was founded in Israel and initially focused on devices used between (not in) vertebrae, and devices used for fractures of long bones (such as the leg). However, after Kyphon began to successfully develop the kyphoplasty market, DOT set out to co-opt Kyphon's kyphoplasty market as rapidly as possible. In fact, during the early

[1] All references to Halkowski SJ Decl. are to the declaration filed by Thomas L. Halkowski in support of this summary judgment motion.

development of the SKy Bone Expander, DOT's stated goal was specifically to design a "balloon" "to create bone void in cancellous bone." DOT 30(b)(6) Deposition Testimony of Oren Globerman (7/29/04) at pp.165-81 attached at Halkowski SJ Decl., Ex. F.

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In the beginning of 2004, DOT introduced the SKy Bone Expander device into Kyphon's kyphoplasty market. Halkowski SJ Decl., Ex. I. The SKy Bone Expander mimics the function of Kyphon's balloons – it is an expandable device inserted into a bone, which compacts cancellous bone by expansion to create a void inside the bone. Shortly after DOT started marketing its device, Kyphon contacted DOT to raise its concerns about DOT's patent infringement. The CEO of Kyphon, Mr. Richard Mott, and DOT's founder and Chairman of the Board, Mr. Lewis Pell, met to discuss these issues. At that meeting, Pell bluntly made the following point:

> Kyphon's done a great job of building the business, and a flawless job executing to build the company up until this point. But if you [Kyphon] don't buy us [DOT], we're going to hurt you [Kyphon] badly in the market, we're going to hurt your valuation and we're going to be the only two players in town.

D.I. 56 at ¶ 5 (Mott Decl.). DOT has followed through on Pell's threat, leaving Kyphon with no alternative but to pursue this infringement suit.

IV. LAW OF SUMMARY JUDGMENT

Summary judgment is appropriate where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that

there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). In assessing the record to determine whether there is a genuine issue of material fact, the court must resolve all ambiguities and draw all factual inferences in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986); *Vann v. City of New York*, 72 F.3d 1040, 1048-49 (2d Cir. 1995).

A dispute over the meaning of a claim term does not create a factual dispute so as to defeat summary judgment. As explained by the Federal Circuit in *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1578 (Fed. Cir. 1995):

> Claim interpretation, as a question of pure law, is amenable to summary judgment and disagreement over the meaning of a term within a claim does not necessarily create a genuine issue of material fact . . . Any other rule would be unfair to competitors who must be able to rely on the patent documents themselves, without consideration of expert opinion that then does not even exist, in ascertaining the scope of the a patentee's right to exclude.

See also, Gentex Corp. v. Donelly Corp., 69 F. 3d 527, 530 (Fed. Cir. 1995) ("Claim interpretation is a question of law amenable to summary judgment.")

Summary judgment of infringement is also appropriate where there is no dispute as to the structure and operation of an accused product. *See Johnson Worldwide Assoc. v. Zebco Corp.*, 175 F.3d 985, 988-89 (Fed. Cir. 1999) (affirming grant of summary judgment of infringement where the relevant aspects of the accused device's structure and operation were undisputed).

As Kyphon's claim construction brief filed concurrently with this motion shows, the claim language of the asserted patent claims should be interpreted in accordance with its plain and ordinary meaning. Application of this ordinary meaning compels the

conclusion that DOT infringes the asserted patents. DOT's own documents and statements conclusively demonstrate that the SKy Bone Expander system, when used by surgeons as directed by DOT, performs each element of the method claims of the '888 and '404 patents, and that the SKy system bone filler device satisfies every claim limitation of the asserted claims of the '734 and '054 patents. The issue of infringement of the four patents at issue here is therefore ripe for disposition on summary judgment.

V. DOT INFRINGES THE '888 AND '404 PATENTS

A. The Use of DOT's Device Infringes Kyphon's '888 and '404 Patents

Independent Claim 1 of the '888 patent recites:

> 1. A method of fixation of a fracture of impending fracture of an osteoporotic bone having osteoporotic 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.

'888 patent at claim 1.

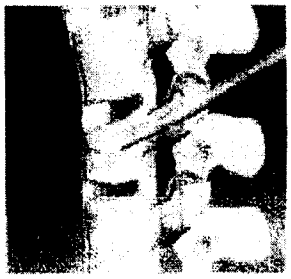
The remainder of the asserted claims of the '888 patent depend from claim 1. *See* claims 3, 7-9, 11 and 14 of the '888 patent. Independent claim 1 of the '404 patent recites claim elements identical to those of claim 1 of the '888 patent, except it is not limited to osteoporotic bone. *See* '404 patent at claim 1. The remainder of the asserted claims of the '404 patent depend from claim 1. *See* claims 3, 8-10, 12 and 15 of the '404 patent.

DOT concedes that the use of its Sky Bone Expander satisfies every element of every asserted claim of the '888 and '404 patent except for the "compacting" element. *See* D.I. 83 (DOT's Brief in Support of Opposition to Kyphon's PI Motion); *see also* Halkowski SJ Decl., Exs. J and K (DOT's Infringement Charts filed in Response to Kyphon's Interrogatories (1/24/05 Supplemental Response to Interrogatory No. 3); Dr. Mitchell's Rebuttal Expert Witness Report (3/23/05)). DOT's non-infringement position with respect to the "compacting" element, in turn, is entirely dependent upon its contrived constructions of "bone marrow" and "compacting." As Kyphon's claim construction brief explains, the term "bone marrow" means a combination of connective tissue and the cancellous bone framework inside a bone. And "compacting the bone marrow to increase the volume of said passage" means compacting the bone marrow to increase the volume of the passage created by the surgeon so that the resulting cavity can then to be safely filled with a flowable material. Neither the claim language nor the written disclosures of the '888 and '404 patents limit the specific manner of compacting.

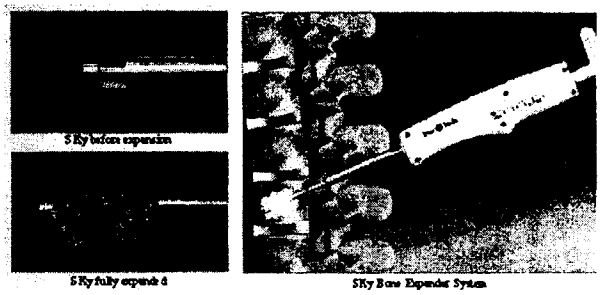
In its preliminary injunction decision, this Court concluded that, under the proper construction of the term "bone marrow," the SKy Bone Expander "necessarily compacts the bone marrow to increase the volume of the passage therein." D.I. 102 at p. 4. An overwhelming amount of evidence, including DOT's own documents and description of its device, confirms this Court's preliminary assessment.

With respect to the "compacting" step, when a surgeon introduces the SKy Bone Expander into the fractured vertebra and expands it as directed by DOT, the SKy Bone Expander compacts the cancellous bone from the central portion of the vertebra against the cortical bone and creates a defined void inside the vertebra. The pictures below from

DOT's "Surgical Techniques" brochure (first picture) and DOT's website (second picture) illustrate the use of the SKy Bone Expander device:



An expanded SKy Body Expander within a vertebral body



1. Un-expanded SKy Bone Expander; 2. and 3. Expanded SKy Bone Expander

Numerous DOT documents, including the SKy Bone Expander training materials, SKy Bone Expander Instructions For Use, and DOT's marketing materials, explain that the SKy device is inserted into the interior of bone and expanded. *See* Expert Witness Reports of Michael Marks, M.D., MBA (3/8/05) and (3/11/05) attached at Halkowski SJ Decl., Exs. L and M. The expansion of the SKy Bone Expander in the center of the vertebra compacts the cancellous framework within the vertebra to increase the volume of the initial passage. The action of the compaction—indeed, all of the steps of all of the

claims—are shown in DOT's marketing video. Ex. N (CD attached, DOTINC87552); *see also*, Ex. L (Dr. Marks' March 8, 2005 report).

DOT's "Surgical Technique" document describes the use of the DOT's SKy Bone Expander in the following manner:

> The SKy Bone Expander System is a minimally invasive procedure for fracture reduction and ***void creation*** in cancellous bone of the thoracic and lumbar spine. The SKy Bone Expander, preloaded on its Delivery System, is introduced into the vertebra in a reduced configuration. Once positioned within the vertebrae, it is ***expanded*** to its predetermined configuration. The SKy Expander is then manually contracted and removed.

Halkowski SJ Decl., Ex. O (emphasis added). Other DOT marketing materials, used outside the United States, emphasize that one of the SKy Bone Expander's "Key Selling Points" is that it allows for a safer procedure because the "SKy expansion ***compresses*** bone around void to create confined cavity." Halkowski SJ Decl., Ex. P at p. 4. (emphasis added). Also, the SKy Bone Expander training manual instructs surgeons that "the ultimate goal is to have the SKy Bone Expander expand directly under the fracture site." Halkowski SJ Decl., Ex. Q. DOT's "Instructions For Use" also explain that the SKy Bone Expander is "expanded in a controlled manner to achieve its final configuration." Halkowski SJ Decl., Ex. R.

In addition, DOT distributes an article describing the use of the SKy Bone Expander to market the device to surgeons, and also uses this article as a part of its training manual materials. Halkowski SJ Decl., Ex. S. This description of DOT's SKy Bone Expander explains that the SKy Bone Expander "***compacts***....cancellous bone." *Id.* (emphasis added). Another document, used by certain DOT's sales distributors to help them understand the SKy Bone Expander so they can explain it to doctors, states the

"[l]aser cut polymer [of the SKy Bone Expander] creates a better void environment that allows the cement to fill in the small gaps, and ***compacts*** the osteoporotic bone better." Halkowski SJ Decl., Exs. T (emphasis added). Moreover, the attorney specifically hired by DOT last year to analyze the patents-in-suit, study the DOT SKy Bone Expander device, and then compare the patents to the device, concluded that turning the handle on the SKy device causes the polymer at the end of the device to bunch up "thereby ***compressing*** the surrounding cancellous bone and forming a void in the bone." Halkowski SJ Decl., Ex. U, at DOTLTD 14362-63 (emphasis added); (also noting that, in his view, the means used by the SKy Bone Expander to "compress cancellous bone" are different than the inflatable means used by Kyphon's device). Ex. V, at DOTLTD 14144-45.

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Lastly, surgeons who have used the SKy Bone Expander verify that it is used to compact cancellous bone within human vertebrae. Dr. Joseph Lane, who has performed several kyphoplasties using the SKy Bone Expander, described the device as an "expandable device" and "controlled powerful jack" that "push[es] down within the bone vertebral body." Halkowski SJ Decl., Ex. X [Lane deposition transcript 14:9-12, 30: 4-14, 33:20 – 36:11, 43:1-4, 48:12-14]. Dr. Lane specifically noted that Kyphon's balloons and the SKy Bone Expander are "extremely similar" because a surgeon places either device "in the middle of the medullary canal of the vertebral body" and "expand[s] the device." *Id.* at 74:4 – 75:20. As the device expands, "it pushes aside the . . . cancellous bone, and as this is ***compacted***, as the bone is compacted in this process . .. the fracture is elevated up." *Id.* (emphasis added). "So, both of [the devices] do exactly the same thing." *Id.*[2]; *see also* Dr. Lane declaration attached at Halkowski SJ Decl., Ex. X.

Dr. Steck, a surgeon who has performed kyphoplasties on over 200 patients and who has used both Kyphon's devices and DOT's SKy Bone Expander made a similar

[2] Dr. Lane is a member of Kyphon's Scientific Advisory Board, but has made it clear that he does not want to "tak[e] sides in the pending dispute[]" and that he is a "neutral academic individual" *Id.*

assessment. Halkowski SJ Decl., Ex. Y [Steck deposition transcript 24:15-25, 42:17-24]. He explained that a DOT "physician educator" advised him that the SKy Bone Expander is placed into the vertebrae and expanded to create a void -- thereby ***compressing*** the cancellous bone -- that can then be filled with cement. *Id.* at 32:3 – 40:16.[3] He further acknowledged that according to DOT's own representations and in his own experience, both the SKy Bone Expander and Kyphon's IBT can be used to perform kyphoplasty procedures in essentially the same manner, and both had the same goal of creating a void within the vertebrae, and both compete for the same patients. *Id.* at 29:5 – 30:6, 32:3 – 18, 40:18 – 41:7, 46:3-9. Thus, as a factual matter, there can be no dispute that, when used as directed by DOT, the SKy Bone Expander compacts cancellous bone to form a cavity.

In summary, the structure and operation of the SKy Bone Expander as represented by DOT itself leaves no doubt that its use by surgeons meets every requirement of the asserted method claims in the '888 and '404 patents. Therefore, Kyphon is entitled to a finding of summary judgment of infringement on the asserted claims of the '888 and '404 patents.

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[3] Q. During your meeting with Mr. Foster and this ER doctor where they presented the device, did they indicate to you that the SKy Bone Expander from Disc-O-Tech went into the vertebra and expanded and created that cavity, ***compressing the cancellous bone*** that could then be filled with cement?
MS CHOW: Objection to form. Lack of foundation. Are you asking him in the context of the patent?
MR. MICLEAN: No, I'm just asking what they told him.
THE WITNESS: Yes.
Id. at 39-40 (emphasis added).

B. By Selling the SKy system, DOT Infringes the '888 and '404 Patents

Infringement includes both inducement of infringement and contributory infringement. *See Linear Technology Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1325 (Fed. Cir. 2004) (stating that a party that does not directly infringe may still be liable for inducement or contributory infringement of a method claim if it sells infringing devices to customers who use them in a way that directly infringes the method claim). There is no genuine issue of material fact as to DOT's contribution to and inducement of its customers' infringement of the asserted claims of the '888 and '404 patents, and DOT has never contended otherwise. DOT actively induces surgeons to use the SKy system to perform kyphoplasty procedures. And, since the SKy system is especially made for performing infringing procedures, the evidence establishes, as a matter of law, that DOT is a contributory infringer.

1. DOT Induces the Infringement of the '888 and '404 Patents

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b) (1994). To prove infringement by inducement under § 271(b), the patentee must establish that the alleged infringer's actions induced the infringing acts and that the alleged infringer knew or should have known his actions would induce the infringing acts. *See Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365, 1379 (Fed. Cir. 2001); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990).

DOT freely admits that it encourages surgeons to use the SKy system as directed by DOT's IFUs, and that DOT has attended surgical procedures during which it has

provided guidance to surgeons regarding the use of the SKy Bone Expander. *See* DOT's Reponses to Kyphon's First Set of Requests for Admissions (Request Nos. 24 and 25) attached at Halkowski SJ Decl., Ex. Z. Aside from DOT's own admissions, several people have confirmed that DOT encouraged surgeons to use the SKy Bone Expander to perform kyphoplasty procedures.[4] These undisputed activities establish that the surgeons' use of the SKy Bone Expander in an infringing manner was induced by DOT, and that DOT intended for such a use to occur. *See Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1311-12 (Fed. Cir. 1998) (finding that the district court properly granted summary judgment of indirect infringement when the alleged infringer's own advertisements suggested that its product be used in a way covered by the claims).

2. DOT Contributes to the Infringement of the '888 and '404 Patents

Section 271(c) of Title 35 states that:

> Whoever offers to sell or sells within the United States or imports into the United States . . . a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

[4] DOT markets and offers to sell the accused products directly to surgeons in the United States, including members of Kyphon's own Scientific Advisory Board, and encourages them to perform kyphoplasty procedures using their SKy system. *See* Mott Decl., at ¶ 15; Declaration of Dr. Joseph M. Lane, at ¶ 5; Declaration of Christian S. McCutcheon, at ¶ 4; Declaration of Andrew V.S. Doggett, at ¶¶ 4-5; Declaration of Heather A. Ramey, at ¶ 4. **D.I. 56-60**; *see also* Halkowski SJ Decl., Ex. Y, at 29-47 (excerpt from Dr. Steck's deposition). In fact, DOT tells physicians who perform kyphoplasty procedures that its SKy Bone Expander device can be used to perform kyphoplasty procedures and even that the DOT device can be "substituted for Kyphon's balloons." *See, e.g.,* Lane Decl., at ¶ 5. DOT in fact targets its marketing activities at surgeons who performed kyphoplasty surgeries with Kyphon's devices. *See* Declaration of Andrew V.S. Doggett ¶4-5; Declaration of Christian S. McCutcheon ¶4 .

35 U.S.C. § 271(c) (1994). To establish contributory infringement under § 271(c), Kyphon must show that DOT knew about the patent in question and that the product used in carrying out the patented method is not a staple article of commerce that would have substantial noninfringing use. *See C.R. Bard, Inc. v. Adv. Cardiovascular Sys., Inc.*, 911 F.2d 670, 673-74 (Fed. Cir. 1990); *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990).

DOT has known about some of the asserted patents since November 2002 (Halkowski SJ Decl., Ex. BB), and indisputably had actual notice of Kyphon's patents as of March 3, 2004. Halkowski SJ Decl., Ex. AA. Moreover, the SKy system plainly does not have any substantial non-infringing uses—it was specifically designed to be used in kyphoplasty procedures. *See* Dr. Mitchell's Rebuttal Expert Witness Report (3/23/05) at pp. 22-33, 41-48 attached at Halkowski SJ Decl., Ex. K.

3. DOT's Customers Directly Infringe the '888 and '404 Patents

A finding of infringement by inducement or contributory infringement requires underlying proof of direct infringement. *See Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1033 (Fed. Cir. 2002). A patentee may prove such direct infringement with circumstantial evidence. *See Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1272 (Fed. Cir. 1986) (finding that circumstantial evidence, including an instruction sheet teaching the patented method of using the sold product, was enough to establish someone had used the product in an infringing manner). Circumstantial evidence, similar to that found in *Moleculon*, is present in this case. Indeed, the evidence is clear that surgeons have actually used the SKy Bone Expander to perform kyphoplasty procedures to reduce vertebral compression fractures. *See*, e.g., supra, at n. 4; *see also*,

e.g. Ex. Y, at p. 42 (excerpt from Dr. Steck's deposition). DOT therefore cannot dispute that the SKy Bone Expanders have been used to perform the claimed methods in the asserted patents.

VI. DOT INFRINGES THE '734 AND '054 PATENTS

The SKy system includes a bone filler device for filling the void created within the cancellous bone by the SKy Bone Expander with a flowable material (e.g. bone cement). For this entire litigation until March of 2005, DOT did not even dispute that its original version of the bone filler device—which it refers to as its Bone Impactor—infringed these patents and all the asserted claims; DOT's only response to Kyphon's allegations on these two patents was that it had ceased selling the infringing products in June 2004. As a result of DOT's belated change of heart, the parties now dispute how the claims of the bone filler patents should be interpreted in certain respects. The dispute centers primarily upon DOT's insistence that the claims specifically require the tamping instruments to be in direct contact with the outermost subcutaneous cannula, and that the bone cement cannot be introduced through that cannula via a second cannula, or nozzle. Kyphon strongly disagrees. However, even if DOT's claim construction on this principle point is applied to DOT's bone filler device sold prior to July 2004, Kyphon is still entitled to summary judgment of infringement regarding claims 1, 10, 11, 13, 15, 20, and 21 of the '734 patent, and claims 26, 27, 36, 37, 41, and 48 of the '054 patent because that device, as sold, was capable of what DOT says the claims require.[5]

[5] At this time, Kyphon accuses only the DOT bone filler device sold before July 1, 2004 of infringement, prior to DOT's redesign of that device, and that is the only device at issue in this motion. The bone filler device includes primarily: (1) an "Impactor Rod"; (2) an "Impactor Tube"; (3) an outer cannula; and (4) a syringe delivery device. *See* Infringement Charts for the '734 and '54 patents attached as Addendum A.

The following claims from the '734 and '054 patents are exemplary. Independent claim 1 of the '734 patent reads:

> 1. Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus including:
>
> [a] a subcutaneous cannula,
>
> [b] a delivery device to convey the material at a delivery pressure of no greater than about 360 psi,
>
> [c] a nozzle instrument capable of advancement into the subcutaneous cannula and comprising a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle terminus through which the material conveyed by the delivery device enters bone at the delivery pressure, and [d] a tamping instrument ***capable*** of advancement into the subcutaneous cannula and having a tamping terminus which, during the advancement, urges material residing in the subcutaneous cannula into bone.

Claim 1 of the '734 patent (element labeling added). Independent claim 26 of the '054 patent reads:

> 26. Apparatus for delivering material into bone comprising
>
> [a] a cannula for establishing a subcutaneous path into bone, and
>
> [b] a tamping instrument having a tamping terminus and including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula,
>
> [c] the tamping instrument being sized and configured for manipulation independent of the cannula to ***enable*** insertion of the tamping instrument into the cannula, advancement of the tamping terminus in the cannula to urge material residing in the cannula into bone, and withdrawal of the tamping terminus from the cannula.

Claim 26 of the '054 patent (element labeling added). Except as noted, the summary judgment analysis is the same for all of the asserted claims. The sections below address the areas in which DOT attempts to generate a dispute. A chart is attached as an addendum to this brief and sets forth all of the claims of the '734 and '054 patents upon

which Kyphon seeks summary judgment. *See also* Ex. M (Dr. Marks' March 11, 2005, Report).

A. DOT's Bone Filler Device Infringes the '734 and '054 Patents Because the Device Is Capable of Performing the Claimed Elements

The '734 and '054 patents are device patents. A device can be described in many ways. For example, a device could be described by specifying certain absolute physical dimensions. A device also could be described by requiring that the device have certain capabilities. The asserted claims of the bone filler devices have primarily taken the latter approach. A device infringes these claims if it is capable of operating in the manner claimed ***regardless of whether it is actually operated in that manner.*** *See Lucent Techs., Inc. v. Newbridge Networks Corp.*, 168 F. Supp. 2d 181, 225-26 (D. Del. 2001) (*citing Intel Corp. v. United States Int'l Trade Comm'n,* 946 F.2d 821 (Fed. Cir. 1991) (emphasis added). In other words, since the asserted claims are drawn to the device and not the method of using it, how in fact the device is used is not material to this motion.

In *Intel,* the relevant claim required EPROM chips to have "programmable selection means for selecting alternate addressing mode." *Intel,* 946 F.2d at 831. In other words, the claims required the chips to be capable of being programmed to operate in an alternate addressing mode. *Id.* The accused chips were in fact capable of operating in an alternate addressing mode, specifically "page mode." *Id.* at 831-32. But, the accused infringer did not sell the chips to operate in page mode. In fact, no customer was ever told how to convert the chips to page mode or even that such conversion was possible. *Id.* at 832. The accused infringer further argued that its chips did not infringe because it did not intend for the chips to be used in an infringing fashion. *Id.* The Federal Circuit

rejected these arguments, noting that there is no intent element to a finding of direct infringement. *Id.* The Court found infringement because the accused chips were capable of operating in page mode and specifically stated that actual operation in page mode was not required for infringement. *Id.*

Relying on *Intel,* this Court has also recognized that "a device may infringe if it has the presently existing capability of functioning in the same manner described by the [asserted claim]." *Lucent,* 168 F. Supp.2d at 225-26. In *Lucent,* the software in the accused device did not enable the device to perform in an infringing manner. *Id.* at 227. But, the Court noted that the device was nevertheless capable of operating in an infringing manner and the software did not prevent operation in the infringing manner. *Id.* This Court therefore found infringement because the asserted claims "read on the device without alteration by the customer and thus, the accused device has the presently existing capability of performing in an infringing manner." *Id*; *cf. Stryker Corp. v. Davol, Inc.* 10 F. Supp.2d 841, 844 (W.D. Mich. 1998) (holding that device did not infringe because the probe that would be necessary to enable the device to perform in the infringing manner did not exist.[6]

With regard to claims 1, 10, 11, 13, 15, 20, and 21 of the '734 patent, and claims 26, 27, 36, 37, 41, and 48 of the '054 patent, DOT attempts to generate two basic areas of dispute: (1) whether DOT's device has a tamping instrument that acts vis-à-vis the cannula to push material from the cannula out to the bone; and (2) whether DOT's device

[6] Conversely, if a device must be altered to meet a clam limitation, the accused infringer may be able to avoid a judgment of infringement. *See High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.,* 49 F.3d 1551, 1555-56 (Fed. Cir. 1995) Here, DOT's SKy system does not need to be altered in any way to meet the limitations of the asserted claims of the '734 and '054 patents.

has a tamping instrument with markings on it to gauge advancement into the cannula, to determine whether the tamp is aligned with the cannula, or to identify a distance generally equal to the length of the cannula.

With regard to the first area, Claim 1 of the '734 patent requires "a tamping instrument ***capable*** of advancement into the subcutaneous cannula and having a tamping terminus which, during the advancement, urges material residing in the subcutaneous cannula into bone," and claim 26 of the '054 patent similarly requires that a tamping instrument be appropriately sized to ***enable*** its use as a tamp to push material out of a cannula. In DOT's bone filler device, the "Impactor Rod" instrument (a plunger-like device) can be slid into and close the opening of the Impactor Tube. These components, acting in combination, are then ***capable*** of operating as a tamping instrument and advancing into the outer cannula and pushing material out of the cannula and into bone. DOT nowhere disputes that its bone filler device in fact has this capability, including in its 25-page long expert report on the infringement of these patents. Instead, DOT argues that when its bone filler device is actually ***used,*** the Impactor Rod is purportedly not combined with the Impactor Tube to form a tamp that pushes material from the cannula into bone. DOT's assertions regarding how its bone filler device is used, or what it is best suited for, are, however, irrelevant. Because the DOT bone filler device indisputably has the requisite capability, the various elements of the '054 and '734 patents that include the requirement of a tamping instrument that is capable of pushing material out of a cannula are literally met by DOT's bone filler device. *See*, generally, Ex. M (Dr. Marks' March 11, 2005, Report).

With regard to the second area that DOT attempts to dispute, the asserted claims of the '734 and '054 patents typically require that the tamping instrument have certain markings – to visually gauge the advancement of the tamping instrument through the subcutaneous cannula, to indicate when the distal (far) end of the tamping instrument is aligned with the distal end of the cannula, or to identify a distance generally equal to the length of the cannula (so that the surgeon knows when he has advanced the tamp far enough). As indicated above, DOT cannot and does not dispute that its Impactor Rod can be slid into the nozzle tube to form a tamping instrument. Nor does DOT dispute that the markings on the outside of the nozzle tube are capable of indicating, among other things, how far the combined tamping instrument has been advanced into the outer cannula tube, when the distal end of the tamping instrument is aligned with the outer cannula, and a distance generally equal to the length of the cannula. *See id.* (detailing evidence of the required capabilities of DOT's device).

Thus, given that DOT cannot dispute that its bone filler device has the required capabilities, Kyphon is entitled to a finding of summary judgment of infringement on the claims addressed in this section (except claims 10, 11, 20, and 21, which are addressed below), even if DOT's claim construction is adopted for the '734 and '054 patents.

B. Under Kyphon's Proposed Claim Constructions, the DOT Bone Filler Device Indisputably Infringes Additional Claims of the '734 Patent

Claims 10 and 20 of the '734 patent require, inter alia, a "cavity forming instrument" "to compress cancellous bone," and claims 11 and 21 recite the additional limitation of the instrument including an "expandable body." DOT attempts to limit these claims to requiring "inflatable devices" for the same reasons it seeks to impose such

a limitation in all the asserted claims of the '888, '404, and '043 patents. Therefore, if the Court rejects DOT's effort to also limit these claims of the '734 patent to covering only inflatable devices, then DOT indisputably infringes claims 10, 11, 20 and 21 of the '734 patent—in addition to the claims of the '734 patent addressed in the prior section. *See* Ex. M (Dr. Marks' March 11, 2005, Report).

VII. CONCLUSION

For the above reasons: (i) DOT infringes claims 1, 3, 7, 8, 9, 11, and 14 of the '888 patent and claims 1, 3, 8, 9, 10, 12, and 15 of the '404 patent, because the SKy Bone Expander, when used as directed by DOT, meets every limitation of these claims; and (ii) the bone filler device instruments within the SKy system satisfy every limitation of claims 1, 10, 11, 13, 15, 20, and 21 of the '734 patent, and claims 26, 27, 36, 37, 41, and 48 of the '054 patent.

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ADDENDUM A

U.S. PATENT NO. 6,241,734 B1[1]

U.S. Patent 6,241,734	DOT's Bone Filler Device as sold before July 1, 2004
Claim 1 *Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus including*	*DOT contends that its device, as used, does not convey material directly through a cannula. However, DOT does not dispute that its bone filler device is capable of introducing material into bone through a subcutaneous cannula. [Brief in Support of Kyphon's Motion for Partial Summary Judgment of Infringement at § 6 (hereinafter "Kyphon's S.J. Brief"); DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Ex. 29 of International Trace Commission (hereinafter "ITC") Complaint; Kyphon Depo Exhs. 37, 86 and 140] DOT provides cannulae (long thin tubes) to aid delivery of the bone cement into the created void. Id.*
a subcutaneous cannula,	DOT **does not dispute** that the SKy system contains a subcutaneous cannula. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]
a delivery device to convey the material at a delivery pressure of no greater than about 360 psi,	DOT **does not dispute** that the SKy system contains a delivery device to convey the material at a delivery pressure of no greater than about 360 psi. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]
a nozzle instrument capable of advancement into the subcutaneous cannula and comprising a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle terminus through which the material conveyed by the delivery device enters bone at the delivery pressure, and	DOT **does not dispute** that the SKy system contains a nozzle instrument. Nor does DOT dispute that the nozzle instrument is capable of advancement into the subcutaneous cannula and comprises a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle terminus through which the material conveyed by the delivery device enters bone at the delivery pressure. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]

[1] The elements addressed in Kyphon's brief are italicized.

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U.S. Patent 6,241,734	DOT's Bone Filler Device as sold before July 1, 2004
a tamping instrument capable of advancement into the subcutaneous cannula and having a tamping terminus which, during the advancement, urges material residing in the subcutaneous cannula into bone.	*DOT contends that, as used, the Impactor Rod does not act as a tamp directly vis-à-vis the cannula, and that material does not reside directly in the cannula. However, DOT does not dispute that the Impactor Rod acting in combination with the Impactor Tube is capable of forming the claimed tamp that can be inserted into the cannula to urge material from the cannula into bone. [Kyphon's S.J. Brief at § 6; see also DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]*
Claim 10 Apparatus according to claim 1 *and further including a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone.*	*DOT contends that this claim should be limited to an inflatable device. However, the SKy Bone Expander is capable of advancement through the outer cannula to compress cancellous bone [Dr. Marks' March 8, 2005, Expert Report], and if the Court rejects DOT's effort to limit this claims to inflatable devices, this element is indisputably present in DOT's device. [Kyphon's S.J. Brief at § 6]*
Claim 11 Apparatus according to claim 10 *wherein the cavity forming instrument includes an expandable structure.*	*DOT contends that this claim should be limited to covering an inflatable device. However, the SKy Bone Expander device includes the claimed expandable structure [Dr. Marks' March 8, 2005, Expert Report], and this element is indisputably present in DOT's device, if the Court rejects DOT's effort to limit this claim to an inflatable device. [Kyphon's S.J. Brief at § 6]*
Claim 13 *[Included from Claim 12]* *[Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus including]*	*DOT contends that its device, as used, does not convey material directly through a cannula. However, DOT does not dispute that its bone filler device is capable of introducing material into bone through a subcutaneous cannula. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140] DOT provides cannulae (long thin tubes) to aid delivery of the bone cement into the created void. Id.*
[a subcutaneous cannula,]	DOT **does not dispute** that the SKy system contains a subcutaneous cannula. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint;

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U.S. Patent 6,241,734	DOT's Bone Filler Device as sold before July 1, 2004
	Kyphon Depo Exhs. 37, 86 and 140]
[a delivery device to convey the material at a delivery pressure of no greater than about 360 psi,]	DOT **does not dispute** that the SKy system contains a delivery device to convey the material at a delivery pressure of no greater than about 360 psi. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]
[a nozzle instrument capable of advancement into the subcutaneous cannula and comprising a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle bore through which the material conveyed by the delivery device enters bone at the delivery pressure, and]	DOT **does not dispute** that the SKy system contains a nozzle instrument. Nor does DOT dispute that the nozzle instrument is capable of advancement into the subcutaneous cannula and comprises a proximal fitting to couple the nozzle instrument to the delivery device and a nozzle bore through which the material conveyed by the delivery device enters bone at the delivery pressure. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]
[a stylet capable of advancement into the nozzle bore through the proximal fitting to close the nozzle bore and, with the nozzle instrument, forming a tamping instrument capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula.]	*DOT contends that its Impactor Rod, as used, is not combined with the Impactor Tube to form a tamp. However, DOT does not dispute that the Impactor Rod (like the claimed stylet) is capable of advancement into the Impactor Tube through the proximal fitting to close the Tube bore and, with the Tube instrument, forming a tamping instrument. Nor does DOT dispute that the stylet and nozzle instrument when combined are capable of advancement into the subcutaneous cannula to urge residual material from the subcutaneous cannula. [Kyphon's S.J. Brief at § 6; see also DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]*
Apparatus according to claim 12 wherein the nozzle instrument includes markings to visually gauge the advancement of the nozzle instrument through the cannula.	DOT **does not dispute** that the nozzle instrument includes markings to visually gauge the advancement of the terminus through the subcutaneous cannula. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]

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U.S. Patent 6,241,734	DOT's Bone Filler Device as sold before July 1, 2004
Claim 15 *Apparatus for introducing material into bone through a subcutaneous cannula, the apparatus comprising*	*DOT contends that its device, as used, does not convey material directly through a cannula. However, DOT does not dispute that its bone filler device can be used for introducing material into bone through a subcutaneous cannula. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140] DOT provides cannulae (long thin tubes) to aid delivery of the bone cement into the created void, where the cement then sets. Id.*
a subcutaneous cannula,	DOT **does not dispute** that the SKy system contains a subcutaneous cannula. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]
a delivery device to convey the material into the subcutaneous cannula at a delivery pressure of no greater than about 360 psi, and	*DOT contends that the SKy system, as used, does not convey material into the cannula at any delivery pressure. However, DOT does not dispute that the SKy system contains a delivery device that can convey material at a delivery pressure of no greater than about 360 psi. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140] Nor, does DOT dispute that its delivery device is capable of delivering material into the subcutaneous cannula at the required delivery pressure. Id.*
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.	*DOT contends that, as used, its bone filler device does not have a tamping instrument that advances directly into the cannula to urge material from the cannula into bone. However, DOT does not dispute that the Impactor Rod is capable of acting in combination with the Impactor Tube to form a tamp that can be advanced directly into the cannula and can urge any material residing in the subcutaneous cannula into bone. [Kyphon's S.J. Brief at § 6; see also DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]*

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Claim 20 Apparatus according to claim 15 and *further including a cavity forming instrument capable of advancement through the subcutaneous cannula to compress cancellous bone.*	*As discussed above in relation to claim 10, this element is indisputably present if the Court rejects DOT's effort to limit this claim to an inflatable device. [Kyphon's S.J. Brief at § 6]*
Claim 21 Apparatus according to claim 15 *wherein the cavity forming instrument includes an expandable structure.*	*As discussed above in relation to claim 11, this element is indisputably present if the Court rejects DOT's effort to limit this claim to an inflatable device. [Kyphon's S.J. Brief at § 6; see also Dr. Marks' March 8, 2005, Expert Report]*

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U.S. PATENT NO. 6,613,054

U.S. Patent 6,613,054	Disc-O-Tech's SKy Bone Expander System (SKy Bone Expander)
Claim 26 Apparatus for delivering material into bone comprising	DOT **does not dispute** that its bone filler device is used for introducing material into bone. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]
a cannula for establishing a subcutaneous path into bone, and	DOT **does not dispute** that the SKy system contains a subcutaneous cannula. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]
a tamping instrument having a tamping terminus and including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula,	*DOT contends that, as used, the Impactor Rod does not have the required markings. However, DOT does not dispute that the Impactor Rod acting in combination with the Impactor Tube is capable of forming a tamp that has the required markings. [Kyphon's S.J. Brief at § 6; see also DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]*
the tamping instrument being sized and configured for manipulation independent of the cannula to enable insertion of the tamping instrument into the cannula, advancement of the tamping terminus in the cannula to urge material residing in the cannula into bone, and withdrawal of the tamping terminus from the cannula.	*DOT contends that, as used, the Impactor Rod does not act as a tamp directly vis-à-vis the cannula, and that material does not reside directly in the cannula. However, DOT does not dispute that the Impactor Rod acting in combination with the Impactor Tube is capable of forming the claimed tamp that can be inserted into the cannula to urge material from the cannula into bone. [Kyphon's S.J. Brief at § 6; see also DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]*

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U.S. Patent 6,613,054	Disc-O-Tech's SKy Bone Expander System (SKy Bone Expander)
Claim 27 Apparatus according to claim 26 *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.*	*DOT contends that, as used, the Impactor Rod does not have the required markings. However, DOT does not dispute that the Impactor Rod acting in combination with the Impactor Tube is capable of forming a tamp that has the required markings. [Kyphon's S.J. Brief at § 6; see also DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]*
Claim 36 Apparatus for delivering material into bone comprising	DOT **does not dispute** that its bone filler device is used for introducing material into bone. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]
a cannula for establishing a subcutaneous path into bone; and	DOT **does not dispute** that the SKy system contains a subcutaneous cannula. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]
a tamping instrument for advancement through the cannula including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula and comprising a body portion and a handle portion, the handle portion having a cross-sectional area greater than the cross-sectional area of the body portion.	*DOT contends that, as used, the Impactor Rod does not act as a tamp directly vis-à-vis the cannula and that the Rod does not have the required markings. However, DOT does not dispute that the Impactor Rod acting in combination with the Impactor Tube is capable of forming a tamp that has the required markings and dimensions. [Kyphon's S.J. Brief at § 6; see also DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]*
Claim 37 Apparatus according to claim 36 *wherein the at least one marking indicates when the distal end of the tamping instrument is aligned with the distal end of the cannula*	*DOT contends that, as used, the Impactor Rod does not act as a tamp directly vis-à-vis the cannula and that the Rod does not have the required markings. However, DOT does not dispute that the Impactor Rod acting in combination with the Impactor Tube is capable of forming a tamp that has the required markings. [Kyphon's S.J. Brief at § 6; see also DOT's Infringement Charts served on March 10, 2005; Dr.*

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U.S. Patent 6,613,054	Disc-O-Tech's SKy Bone Expander System (SKy-Bone Expander)
instrument.	*Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]*
Claim 41 Apparatus for delivering material into bone comprising	DOT **does not dispute** that its bone filler device is used for introducing material into bone. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]
a cannula for establishing a subcutaneous path into bone; and	DOT **does not dispute** that the SKy system contains a subcutaneous cannula. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]
a tamping instrument for advancement through the cannula including at least one marking to visually gauge the advancement of the terminus relative to the distal end of the cannula, and comprising a body portion and a handle portion, the body portion being sized and configured to substantially fill the cannula when the tamping instrument is fully inserted into the cannula.	*DOT contends that, as used, the Impactor Rod does not act as a tamp directly vis-à-vis the cannula and that the Rod does not have the required markings. However, DOT does not dispute that the Impactor Rod acting in combination with the Impactor Tube is capable of forming a tamp that has the required markings and dimensions. [Kyphon's S.J. Brief at § 6; see also DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]*
Claim 48 Apparatus for delivering material into bone comprising	DOT **does not dispute** that its bone filler device is used for introducing material into bone. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]
a cannula for establishing a subcutaneous path into bone; and	DOT **does not dispute** that the SKy system contains a subcutaneous cannula. [DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]
a tamping instrument for advancement through the	*DOT contends that, as used, the Impactor Rod does not act as a tamp directly vis-à-vis the cannula and that the*

ADDENDUM A

U.S. Patent 6,613,054	Disc-O-Tech's SKy Bone Expander System (SKy Bone Expander)
cannula including a set point marking spaced from the terminus at a distance generally equal to the length of the cannula and comprising a body portion and a handle portion, the body portion having a substantially constant diameter along its length.	*act as a tamp directly vis-à-vis the cannula and that the Rod does not have the required markings. However, DOT does not dispute that the Impactor Rod acting in combination with the Impactor Tube is capable of forming a tamp that has the required markings and dimensions. [Kyphon's S.J. Brief at § 6; see also DOT's Infringement Charts served on March 10, 2005; Dr. Marks' March 11, 2005, Expert Report at p.8-9; Exh. 29 of ITC Complaint; Kyphon Depo Exhs. 37, 86 and 140]*

CERTIFICATE OF SERVICE

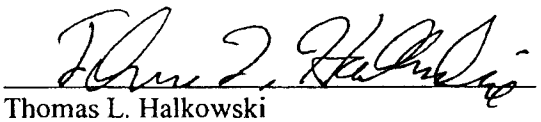
I hereby certify that on this 6th day of April a true and correct copy of the **MEMORANDUM IN SUPPORT OF KYPHON'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF INFRINGEMENT** was caused to be served on the attorneys of record at the following addresses as indicated:

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