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. 04-204-JJF

SPECIAL MASTER'S OPINION IN SUPPORT OF SUMMARY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NOS. 4,969,888 AND 5,108,404

This is an action for patent infringement brought by plaintiff Kyphon Inc. ("Kyphon") against defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. (collectively, "Disc-O-Tech"). This matter was referred to me, as Special Master, by order of the Honorable Joseph J. Farnan, Jr., on November 16, 2004 (D.I. 88). Jurisdiction is proper pursuant to 28 U.S.C. §§ 1331 and 1338.

This opinion supports the Special Master's order of May 16, 2005 granting Kyphon's motion for partial summary judgment that Disc-O-Tech infringes U.S. Patent No. 4,969,888 (the '888 patent) and U.S. Patent No. 5,108,404 (the '404 patent). D.I. 209. Concurrently therewith, the Special Master denied Disc-O-Tech's motion for summary judgment of non-infringement with respect to the same two patents. D.I. 210.

BACKGROUND

On April 2, 2004, Kyphon brought this action against Disc-O-Tech, asserting that Disc-O-Tech infringes multiple patents. The patents-in-suit collectively describe methods and/or apparatus for the internal fixation of bones weakened by disease or damaged by injury. Two of

these patents, the '888 patent and the '404 patent -- a continuation of the '888 patent – are directed to the basic method of bone fixation known as kyphoplasty. The '888 and '404 patents describe a method of internal fixation of bones that includes the surgical formation of a passage in bone marrow, the compaction of the bone marrow to increase the volume of that passage, and the filling of the passage with a flowable material that will set to a hardened condition, to create what Kyphon describes as an internal cast.

In response to the parties' respective cross-motions for summary judgment of infringement and non-infringement, the Special Master heard argument in conjunction with the *Markman* hearing held on April 19, 2005. On May 16, 2005, the Special Master issued an order construing the claims of the patents-in-suit, including the '888 and '404 patents. D.I. 212. Charts summarizing the Special Master's construction of the disputed terms of the '888 and '404 patents are attached hereto as Exhibits A and B, respectively, and are incorporated herein by reference.

DISCUSSION

I. Standard of Review

Rule 56(c) of the Federal Rules of Civil Procedure ("Fed. R. Civ. P.") provides that a party is entitled to the entry of summary judgment "forthwith":

> if the pleadings, depositions, answers to interrogatories and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. A summary judgment, interlocutory in character, may be rendered on the issue of liability alone although there is a genuine issue as to the amount of damages.

Fed. R. Civ. P. 56 (c)

On a motion for summary judgment, the moving party bears the burden of proving that no genuine issue of material fact exists. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986). "Facts that could alter the outcome are 'material,' and disputes are

'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." *Horowitz v. Fed. Kemper Life Assurance Co.*, 57 F. 3d 300, 302 n.1 (3rd Cir. 1995) (internal citations omitted).

Where the moving party demonstrates an absence of material fact, then the non-moving party "must come forward with 'specific facts showing that there is a genuine issue for trial'." *Matsushita*, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The Court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." *Pennsylvania Coal Ass'n v. Babbitt*, 63 F.3d 231, 236 (3d Cir. 1995).

The mere existence of some evidence in support of the non-moving party, however, will not be sufficient for a denial of a motion for summary judgment. There must be enough evidence to enable a jury to reasonably find for the non-moving party on that issue. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-50 (1986). In order to defeat a motion for summary judgment, Fed. R. Civ. P. 56(e) requires that the non-moving party "not rest upon the mere allegations or denial of [its] pleading, but . . . by affidavits or as otherwise provided [by the] rule, must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e).

II. Infringement Analysis

A. Literal Infringement

35 U.S.C. § 271(a) provides in relevant part:

> whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States any patented invention during the term of the patent thereof, infringes the patent.

The owner of a patent may prove literal or direct infringement – that is whether the accused product or method practices the invention of the patent – by proving that the elements of at least one claim of the patent are found in the accused product or method. *Panduit Corp. v. Dennison*

Mfg. Co., 836 F.2d 1329, 1330 n.1 (Fed. Cir. 1987) ("One is liable for patent infringement if one claim be infringed.").

A patent infringement analysis requires a two-step process: first, the Court must determine the meaning and scope of the patent claims asserted to be infringed and, second, once the meaning and scope of the claims are ascertained, the Court must determine whether the defendant's allegedly infringing device or method falls within the scope of the claims. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd* 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996).

1. Step 1 - Claim Construction

The Special Master has previously construed the disputed terms of the '888 and '404 patents, D.I. 212, as summarized in Exhibits A and B hereto. The claims and, more specifically, the claim terms of both patents are substantially identical. The parties agree that the only substantive difference is that the '888 patent covers osteoporotic bone, and the '404 patent covers all bone.

Disc-O-Tech raised two primary arguments in asserting that it does not infringe the patents-in-suit. Both arguments were based upon Disc-O-Tech's proposed claim construction. First, Disc-O-Tech initially argued that the proposed construction of the claim term *bone marrow* does not contain the cancellous bone network inside bones but, rather, is "the viscous liquid material contained within the interstices (spaces) of the cancellous bone." D.I. 139 at p.12. Disc-O-Tech further argued that, because bone marrow is a liquid, its accused device did not compact bone marrow but, instead, "intersperses" with the liquid marrow within the interstices (spaces) of the cancellous bone structure. D.I. 138 at pp. 10-12.

Disc-O-Tech subsequently abandoned this proposed construction of *bone marrow*. *See*, D.I. 163 at p.6 ("DOT is no longer contesting Kyphon's interpretation of bone marrow as

including cancellous bone.") and Transcript of April 19, 2005 *Markman* Hearing, D.I. 193 at 77:13-20 ("I'm not going to sit here and argue about bone marrow and what it means . . . We accept that whatever [our device] does, it does to bone marrow.").

The claim construction issue that forms the basis then for Disc-O-Tech's remaining non-infringement defense is that the patents-in-suit disclose only inflatable (balloon) devices and the compacting of bone marrow as performed by such devices. *See generally* D.I. 163 at pp. 1-14. However, the Special Master has already determined, as a matter of law, that the patents-in-suit are not limited to inflatable (balloon) devices or to the compaction of bone marrow by such devices. *See* D.I. 212. *See also* Exhibits A-B attached hereto (summarizing claim constructions for the '888 patent and '404 patent).

The Special Master will therefore proceed to a comparison of the operation of the accused device against the claims of the '888 and '404 patents, as construed by the Special Master, to determine if use of the SKy Bone Extender Device (the "SKy Device") falls within the scope of the asserted claims of these patents.

2. Step 2 – Comparison to Construed Claims

In its own briefing, Disc-O-Tech describes the SKy Device and the method of its use as follows:

> [Disc-O-Tech's] SKy Device is **used in the reduction of vertebral compression fractures in which the spinal bone has collapsed, particularly due to weakness brought on by osteoporosis**. The SKy Device consist of a hard plastic housing with a plastic crank handle protruding from one end and a metal rod protruding from the other. Surrounding the distal (or far) end of the metal rod that enters the body is a plastic polymer tube into which short, lengthwise slits have been cut . . . .
>
> Using the SKy Device, a **surgeon first makes an incision in the patient's body**, and **inserts a needle and then a guide wire into the injured vertebrae**. Through a cannula – a metal sleeve used for access to a location beneath the skin – **a surgical drill is**

> **introduced into the vertebra.** The **distal end of the SKy Device is then placed into the vertebral space close to the point of fracture**. The surgeon then rotates the handle on the SKy Device clockwise causing a nut to move towards the distal end. The force of the nut against the plastic material at the end of the SKy Device causes the plastic polymer tube to bow outwards of the pre-cut slits. As the surgeon turns the handle further, the plastic at the distal end of the SKy Device bunches up further to form plastic petals or fingers protruding out from the tube . . . .
>
> Thus, as opposed to an inflatable balloon device which has a uniform, smooth surface as it inflates, **the SKy Device's petal structure opens** to create an uneven surface with peaks and valleys to raise the collapsed vertebra and reduce, or repair, the fracture . . . .
>
> The surgeon monitors the deployment of the SKy Device through the use of X-ray fluoroscopy, and a display on the hard plastic housing of the SKy Device indicates the diameter to which the SKy Device has been expanded. Once **the desired void is created**, the surgeon then turns the handle counterclockwise to retract the petals or fingers which gradually return to their original cylindrical shape around the metal rod so that the SKy Device may be removed from the patient. The **surgeon then fills the void created in the vertebra with the material of his choosing in order to stabilize the area**.

D.I. 138 at pp. 4-7 (internal citations and illustrations omitted) (emphasis added).

Using Disc-O-Tech's own words, the Special Master makes the following comparison of the operation and use of the SKy Device to claim 1 of both the '888 and '404 patents:

Claim 1/'888 and '404 Patents	SKy Device
A method of fixation of a fracture or impending fracture of an [osteoporotic] bone having [osteoporotic] bone marrow therein comprising:	"[U]sed in the reduction of vertebral compression fractures in which the spinal bone has collapsed, particularly due to weakness brought on by osteoporosis." D.I. 138 at p.4.
Forming a passage in the bone marrow;	"[S]urgeon first makes an incision in the patient's body . . . . inserts a needle and then a guide wire into the injured vertebra . . . surgical drill is introduced into the vertebra. . . distal end of the SKy Device is then placed into the vertebral space close to the point of facture". D.I. 138 at p.5.
compacting the bone marrow to increase the volume of said passage and	**DISPUTED** by Disc-O-Tech. *But see* "SKy Device's petal structure opens . . . the desired void is created" D.I. 138 at pp. 6-7.
filling the passage with a flowable material capable of setting to a hardened condition.	"[S]urgeon then fills the void created in the vertebra with the material of his choosing in order to stabilize the area." D.I. 138 at p.7.

In comparing the construed claim terms of claim 1 of the '888 and '404 patents to the elements of Disc-O-Tech's own description of the SKy Device, it is clear from the very face of Disc-O-Tech's description of its own device that all elements necessary to support the literal infringement of claim 1 exist. However, Disc-O-Tech continues to dispute that the SKy Device performs the step of *compacting the bone marrow to increase the volume of said passage*. In the words of its counsel at the *Markman* hearing:

> I disagree with Mr. Scherkenbach in that we don't agree that if [the claims are] not limited to inflatable devices and balloons that we agree that we infringe, because compacting, as we say in our papers, I'm not going to spend a lot of time here, **we don't compact**.
>
> Our device, you saw the way it works. We make little holes in the cancellous bone, and we fill those bones. Their device, the balloon, it pushes everything away from the center.

> And that's -- and if we just think of what compact means, we think of compacters as things that push down uniformly and compact. Ours makes holes. This interdigitation as I call it. As the – pardon me, as the documents call it. So we don't infringe these claims, even if it isn't limited to a balloon. Although I dare say it is.

D.I. 193 (Transcript of April 19, 2005 *Markman* hearing) at 83:18-24 to 84:1-14 (emphasis added).

The Special Master must analyze whether Disc-O-Tech has adduced evidence sufficient to enable a jury to find, in its favor, that the SKy Device does not compact bone marrow. *See, e.g., Liberty Lobby*, 477 U.S. at 250 ("[T]here is no issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.") (internal citations omitted). In this regard, the Special Master has reviewed the following materials.

a. **Reports of Disc-O-Tech's Expert**. Given Disc-O-Tech's retreat from its position on bone marrow and the Special Master's construction of that claim term, the opinion of Disc-O-Tech's expert, Dr. David Mitchell – that the accused device does not compact bone marrow because the liquid bone marrow "flows within and between each petal" of the SKy Device, D.I. 150, Ex. K at ¶ 45 ("Rebuttal Expert Report of Dr. David Mitchell Regarding the Non-Infringement of U.S. Patent Nos. 5,108,404; 4,969,888 and 6,235,043 B1") – is of no value and, therefore, does not present the Special Master with any genuine issue of disputed fact.

The Special Master is mindful that Dr. Mitchell also opined that even if bone marrow were construed to include cancellous bone -- which is now conceded by Disc-O-Tech – the Sky Bone Expander does not "compact the bone marrow to increase the volume of said passage" for two reasons:

1. The compacting step is limited to inflatable devices such as balloons; and

2. The petal-like configuration does not create an egg-shell or clam-like effect in the interior of the bone.

D.I. 150, Ex. K at ¶ 46. However, Dr. Mitchell's opinion is based on an incorrect construction of the disputed claims – one that assumes the '888 and '404 patents describe only inflatable (balloon) devices and, therefore, compaction by inflation. That construction has been rejected by the Special Master as a matter of law. *See* D.I. 212.

Dr. Mitchell also opines that the SKy Device:

> does not compress substantially all of the cancellous bone away from the central portion of the interior bone, towards the wall of the bone to increase the volume of the passage. Rather, it interdigitates with the cancellous bone to create a void in the bone.

D.I. 150, Ex. K at ¶ 48. The Special Master is satisfied as a matter of law that, regardless of what meaning should be ascribed to Dr. Mitchell's opinion, it can have no meaning different from Disc-O-Tech's own descriptions of its device,[1] as described in sections b. and c. *infra*.

b. Sworn FDA Submissions. The Special Master takes particular note of statements made by Disc-O-Tech in its 510(K) Premarket Modification Application[2] filed with the United States Department of Health and Human Services, Food and Drug Administration (the "FDA"), on July 30, 2003, in which it sought approval to market the "B-Twin Bone Extender

[1] The Special Master has not been advised of any contrary description that may be attributed to Disc-O-Tech. Compare *Jean v. Dugan*, 814 F. Supp. 1401, 1405 (N.C. Ind. 1993) (striking allegation in summary judgment affidavit of president/business manager of union where president/business manager had signed earlier labor organization annual form under applicable penalties of law stating contrary facts.)

[2] Statements made during a 510(K) disclosure are subject to various provisions designed to detect, deter and punish false statements made during the FDA approval process. *See, e.g.* 21 U.S.C. § 372 (empowering the FDA to investigate suspected fraud); 21 U.S.C. § 332 (empowering the FDA to seek injunctive relief); 21 U.S.C. § 333(f)(1)(A) (empowering the FDA to seek civil penalties); and 21 U.S.C. § 333(a) (empowering the FDA to seek criminal prosecution).

(BE)" (an earlier name for the SKy Device).[3] Disc-O-Tech's representations to the FDA include the following statements:

- The system is **substantially equivalent** to similar systems previously cleared for marketing and available on the market, and **especially to the KyphX Inflatable Bone Tamp (KO10246) by Kyphon, which is a balloon-based system having similar indications for use as those of the B-Twin BE**. The main difference between the devices . . . is with regards (sic) to the method of expansion of the device, which is done for the B-Twin BE System by the exertion of mechanical force, and not by the insertion of liquid, as is done for the KyphX System.

D.I. 151, Ex. W at DOTLTD001990 (emphasis added).

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

Id. (emphasis added).

- The expansion of the B-Twin BE tube **results in creation of a void** within the vertebrae. The **void has a shape of cylinder, similar to the void created by the KyphX balloon. The dimensions of the void are also similar to these (sic) of the void created by the KyphX balloon**.

Id. at DOTLTD002014 (emphasis added).

- As the B-Twin BE tube, as the KyphX balloon, is **inserted into the vertebra in a relative small diameter, expands to cylinder shape and creates a cylinder void, and then removed in a small diameter, and as the dimensions of the insertion, expansion and extraction of both devices are similar, the outcome of jacking and void creation is similar as well**. Although the expansion mechanism differs (polymer compression for the B-Twin BE tube and fluid inflation of the KyphX balloon), **similar geometric shape and dimensions of void are created as a result of the expansion of both systems**.

Id. at DOTLTD002020 (emphasis added).

- The B-Twin BE System **intended use, design, material, technological characteristics**, and **principles of operation are substantially equivalent to those used in Kyphon's KyphX Inflatable Bone Tamp** (K 981251, K010246).

Id. at DOTLTD002024 (emphasis added).

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[3] B-Twin is "just a different name" for the SKy Device; it is "the same product, just a different name." D.I. 176, Ex. 6 (Deposition of Motti Beyar, M.D.) at 57:19-25.

c. **Representations by Disc-O-Tech Employees/Agents**. The Special Master has also reviewed numerous statements made by Disc-O-Tech employees and agents made subsequent to Disc-O-Tech's 2003 submission to the FDA. These latter representations include the following statements made in marketing and training materials, and in opinion letters:

- Disc-O-Tech's B-Twin Bone Expander System (an earlier name for the SKy Device) in its "Instructions for Use" states:

> The B-Twin Bone Expander (B-Twin BE) System is intended for use as conventional bone tamp for the reduction of factures and/or **creation of a void in cancellous bone** in the spine, hand, tibia, radius and calcaneus.
>
> ***
>
> The expandable tube is provided in its reduced diameter configuration, mounted on its delivery system. It is inserted into the bone, and once the tube is in position **it is expanded in a controlled manner to achieve its final configuration**.

D.I. 151, Ex. R ("Instructions for Use") at DOTINC000687 (emphasis added).

- Disc-O-Tech's "Surgical Technique" document states:

> 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 vertebra, it is **expanded to its predetermined configuration**. The SKy Expander is then manually contracted and removed.

D.I. 151, Ex. O ("Surgical Technique") at DOTINC000990 (emphasis added).

- Disc-O-Tech's SKy Bone Expander Training Manual states:

> Locating the pedicle and establishing a proper entry point are vital. In the transpedicular approach, an adequate distance must be kept from the peripheral cortex of the pedicle in order to prevent breaching when the drill is used . . . The ultimate goal is to have the SKy Bone Expander expand directly under the fracture site and as near and parallel to it as possible.

D.I. 151, Ex. Q ("Training Manual") at DOTLTD014788 (internal citations omitted).

- Disc-O-Tech's "Partner Sales Meeting" power point materials for June 1, 2004 Spineweek meeting in Porto, Portugal states:

> The SKy Bone Expander . . . **[c]reates a defined void**
>
> SKy expansion **compresses bone around void to create confined cavity**
>
> Defined void can contain significant amount of cement

D.I. 151, Ex. P ("Partner Sales Meeting") at p.4.

- Disc-O-Tech's reproduction of an article entitled *Preliminary Outcomes and Short Term Experience with the Sky Bone Expander System in the Treatment of Osteoporotic Fractures of the Spine*, authored by Mohammad E. Majd, M.D., describes the characteristics of the SKy Bone Expander to include:

> Directional expansion.
>
> User's **control of the extent of expansion** diameter.
>
> **Creates a defined void** due to the mechanical strength of polymer **which compacts broken cancellous bone to the cortical bone**.

D.I. 151, Ex. S (Majd Article, Reproduction) at DOTINC009409.

- Disc-O-Tech's "The Down and Dirty on the Sky Bone Expander" states:

> 1. Sky Bone should be positioned as a 'second generation' Kyphoplasty device.
>
> 2. Ours is a mechanical expansion v. hydraulic expansion. It is consistent, defined and predictable. Kyphon is a compliant balloon that will seek out the least resistive areas.
>
> 3. Concentrated inferior/superior expansion for a greater height restoration.
>
> 4. Added safety and control of our incremental expansion.
>
> 5. **Laser cut polymer creates a better void environment that allows the cement to fill in the small gaps, and compact the**

> **osteoporotic bone better**. Theirs is a smooth surface, and the cement can create a 'hockey puck' effect. Loose within the body.
>
> 6. Easier back table set up and quicker to get things set up.

D.I. 151, Ex. T ("The Down and Dirty") at TR0107 (emphasis added).

- An opinion letter obtained by Disc-O-Tech from the law firm of Fleshner & Kim, by John C. Eisenhart, Esquire, states:

> As explained in the literature provided with the SKy Bone Expander, the device is intended to be used in bone surgery. The device can be **used to form a defined void within an interior of a bone**, and to increase the height or to reconstruct vertebrae and other bone structures.
>
> During a typical surgery, the surgeon would create an access path into the interior cavity of a bone. The distal end of the SKy Bone Expander would be inserted into the interior cavity of the bone. The surgeon would then turn the handle clockwise to cause the slit sections of the TECOFLEX tube to bunch up at the distal end of the device. The bunched up portions of the TECOFLEX tube would create a void space within the interior bone volume, and would possibly also expand the bone back to its original anatomical shape.
>
> ***
>
> As explained above, the SKy Bone Expander lacks any type of inflatable body. Instead, **the SKy Bone Expander utilizes the TECOFLEX tube, which bunches up at the end of the rod to compress cancellous bone**.

D.I. 151, Ex. V (June 18, 2004 Opinion of Counsel) at DOTLTD014133, DOTLTD014135 (emphasis added).

Based on the above Disc-O-Tech references, and because Dr. Mitchell's opinions are predicated upon incorrect constructions of the claim terms of the '888 and '404 patents, the Special Master concludes that Dr. Mitchell's opinions – that the SKy Device does not perform the step of *compacting the bone marrow to increase the volume of said passage* – do not create a genuine dispute of material fact.

d. Statements of Surgeons Using SKy Device. The Special Master also concludes that the statements of record from surgeons who have used the Sky Bone Expander, and verify that it is used to compact cancellous bone, go unrebutted. For example, Dr. Joseph Lane, who has performed surgeries using the SKy Bone Expander, testified in his November 4, 2004 deposition as follows:

> Q: What's your understanding of what's going on inside the vertebrae with these devices?
>
> Dr. Lane: Well I think they're extremely similar. I mean, basically you end up with a fracture of varying age. You place a device in the middle of the medullary canal of the vertebral body, hopefully in a more – a biocathy advantageous spot and then you expand the device.
>
> Now, in the Kyphon device you use a balloon, and in the Disc-O-Tech device they use a high-strength polyethylene. And **as this expands it pushes aside the hematological bone marrow elements, the stroma cells, and the cancellous bone, and as this is compacted, as the bone is compacted in this process,** eventually you reach a point at which you come into resistance against the elements of the fracture. And then at that point the fracture is elevated up, given the flexibility of the fracture at that time, and you will continue to keep doing this until one of several events takes place: 1, In the Kyphon if the balloon is moving in the direction which you think is nonadvantageous or you reach the extent of what the balloon can expand, or you can't move it any further. And with the Disc-O-Tech device, you move it to the point at which the device can no longer be expanded . . .
>
> So, **both of them do the same thing, as best I can tell, in terms of moving the elements aside. . . The bony elements have no place to go but to be compressed**. . . And from autopsy studies you see that there's a ring of bone around the edge of these expansions in the limited studies that are available.

D.I. 176, Ex. 1 (Deposition of Joseph M. Lane, M.D.) at 74:7-22 to 75:1-20 (emphasis added). *See also* Deposition of Joseph C. Steck, M.D., D.I. 151, Ex. Y at 25:3-7 (confirming he has performed kyphoplasties with the SKy Device).

The Special Master is therefore satisfied that no genuine issue of fact exists that the SKy Device "compacts bone marrow to increase the volume of said passage," and therefore concludes, as a matter of law, that the SKy Device infringes the terms of claim 1 of both the '888 and 404 patents. The Special Master therefore turns to the remainder of the asserted claims. Asserted claims 3, 7 to 9, 11 and 14 of the '888 patent depend from claim 1. The corresponding asserted claims 3, 8 to 10, 12 and 15 of the '404 patent also depend from claim 1 of that patent. The dependent claims and claim terms of both patents are identical, with the only exception being that the '404 patent is not limited to osteoporotic bone like the '888 patent.

With respect to dependent claim 3 of both patents, the Special Master concludes that there is unrefuted evidence the operation of the SKy Device infringes the claim terms:

Claim 3 of '888 and '404 Patents	**SKy Device**
3. A method as set forth in claim 1, wherein said compacting step includes forcing the [osteoporotic] bone marrow outwardly of the central portion of the bone.	Creates similar shape and dimension of void as created by KyphX device. D.I. 151, Ex. W at DOTLTD002024. SKy Device "creates a defined void . . . compacts broken cancellous bone to the cortical bone." D.I. 151, Ex. S at DOTINC009409.

With respect to dependent claim 7 of the '888 patent and corresponding dependent claim 8 of the '404 patent, the Special Master concludes that there is unrefuted evidence the operation of the SKy Device infringes the claim terms:

Claim 7 of '888 Patent/ Claim 8 of '404 Patent	SKy Device
7./8. A method as set forth in claim 1, wherein said forming step includes drilling said [osteoporotic] bone marrow to form said passage.	"[Surgical drill is introduced into the vertebra . . . the distal end of the SKy Device is then placed into the vertebral space." D.I. 138 at p.5.

With respect to dependent claim 8 of the '888 patent and corresponding dependent claim 9 of the '404 patent, the Special Master concludes that there is unrefuted evidence the operation of the SKy Device infringes the claim terms:

Claim 8 of '888 Patent/ Claim 9 of '404 Patent	SKy Device
8./9. A method as set forth in claim 7/8, wherein said drilling step includes guiding a drill through into the proximate cortical bone marrow.	"[S]urgeon first makes an incision in the patient's body . . . inserts a needle and then a guide wire into the injured vertebra . . . surgical drill is introduced into the vertebra" D.I. 138 at p.5.

With respect to dependent claim 9 of the '888 patent and corresponding dependent claim 10 of the '404 patent, the Special Master concludes that there is unrefuted evidence the operation of the SKy Device infringes the claim terms:

Claim 9 of '888 Patent/ Claim 10 of '404 Patent	SKy Device
9./10. A method as set forth in claim 7/8, wherein said forming step includes drilling the [osteoporotic] bone marrow to a predetermined depth.	"[S]urgeon first makes an incision in the patient's body . . . inserts a guide wire into the injured vertebra . . . surgical drill is introduced into the vertebra" D.I. 138 at p.5.

With respect to dependent claim 11 of the '888 patent and corresponding dependent claim 12 of the '404 patent, the Special Master concludes that there is unrefuted evidence the operation of the SKy Device infringes the claim terms:

Claim 11 of '888 Patent/ Claim 12 of '404 Patent	**SKy Device**
11./12. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	"[U]sed in the reduction of vertebral compression fractures in which the spinal bone has collapsed." D.I. 138 at p.4. "The SKy Bone Expander Systems is a minimally invasive procedure for fracture reduction and void creation in cancellous bone of the thoracic and lumbar spine." D.I. 151, Ex. O at DOTINC000990.

With respect to dependent claim 14 of the '888 patent and corresponding dependent claim 15 of the '404 patent, the Special Master concludes that there is unrefuted evidence the operation of the SKy Device infringes the claim terms:

Claim 14 of '888 Patent/ Claim 15 of '404 Patent	**SKy Device**
14./15. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	"[S]urgeon then fills the void created in the vertebra with the material of his choosing in order to stabilize the area." D.I. 138 at p.7. "I use the Simplex cement . . . It's methyl methacrylate." D.I. 151, Ex. Y at 50:18-25 to 51:1.

In summary, the Special Master concludes that Kyphon has demonstrated there is no genuine issue as to any material fact and that the operation of the SKy Device literally infringes the '888 and '404 patents by meeting every requirement of asserted claims 1, 3, 7, 8, 9, 11 and 14 of the '888 patent, and of asserted claims 1, 3, 8, 9, 10, 12 and 15 of the '404 patent.

B. Inducement of Infringement

Pursuant to 35 U.S.C. § 271(b), "Whoever actively induces infringement of a patent shall be liable as an infringer." A party may be liable for inducement to infringe a method claim if it sells infringing devices to customers who use them in a way that directly infringes the method claim. *Linear Technology Corp. v. Impala Linear Corp.*, 379 F. 3d 1311, 1326 (Fed. Cir. 2004).

To establish infringement by inducement under § 271(b), Kyphon must establish that (i) Disc-O-Tech's actions induced acts of direct infringement and (ii) Disc-O-Tech knew or should have known that its actions would induce the infringing acts. See, e.g. *Mentor H/S Inc. v. Medical Device Alliance, Inc.*, 244 F. 3d 1365, 1379 (Fed. Cir. 2001); *Manville Sales Corp. v. Paramount Sys., Inc.*, 919 F. 2d 544, 553 (Fed. Cir. 1990). With respect to the showing required under this second prong, the Federal Circuit has opined:

> [I]n view of the very definition of "active inducement" in pre-1952 case law and the fact that § 271(b) was intended as merely a codification of pre-1952 law, we are of the opinion that **proof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement**.

Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F. 2d 1464, 1469 (Fed. Cir. 1990) (emphasis added).

Kyphon has submitted declarations and affidavits establishing that Disc-O-Tech has distributed materials to inform surgeons that the SKy Device can be used to perform kyphoplasty procedures in accordance with the asserted claims of the '888 and '404 patents; that Disc-O-Tech has trained surgeons on such use and attended surgical procedures during which it has provided guidance to surgeons regarding such use; and that surgeons have actually used the SKy Device to perform kyphoplasty procedures in accordance with the methods claimed in the '888 and '404 patents. *See generally* D.I. 149 at pp. 16-19.

However, the Special Master is mindful that Disc-O-Tech alleges that it first learned of the existence of the '888 and '404 patents on or about March 3, 2004. D.I. 151, Ex. AA and BB (Response No. 4). Kyphon's President acknowledged in his deposition that, as of March 2004, "it was clear that [Disc-O-Tech] did not believe their device infringed our patents." Deposition of Richard Mott dated January 31, 2005, D.I. 165 at 210:12-13. Shortly thereafter, on April 2, 2004, Kyphon filed suit. D.I. 1. In June 2004, Disc-O-Tech obtained opinion letters from the law firm of Fleshner & Kim opining that the SKy Device did not infringe at least two of the patents-in-suit. D.I. 151, Ex. U-V.

Viewed in a light most favorable to Disc-O-Tech, as the non-moving party, the Special Master concludes that there is a material dispute as to whether Disc-O-Tech had the requisite intent to induce infringement. *See, e.g.*, *Manville Sales*, 917 Fed. 2d. at 553-54 (reversing finding of infringement by inducement where defendants were not aware of patent until suit was filed and defendants' subsequent infringing acts continued upon "good faith belief" based on advice of counsel that its products did not infringe).

Accordingly, the Special Master is satisfied that a genuine issue of material fact exists as to whether Disc-O-Tech had the requisite intent to cause the acts of infringement and concludes, on this record, that Disc-O-Tech is not liable for inducement of infringement of the '888 and '404 patents, pursuant to 35 U.S.C. § 271(b).

C. Contributory Infringement

Pursuant to 35 U.S.C. 271(c):

> 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 non-infringing use, shall be liable as a contributory infringer.

In order to establish contributory infringement under § 271(c), Kyphon must show that Disc-O-Tech (i) offers to sell or sells the SKy Device for use in practicing kyphoplasty under the method of the '888 and/or '404 patents; (ii) knew about the '888 and '404 patents; and (iii) that the SKy Device is not a staple article of commerce suitable for substantial non-infringing use. See, e.g., *C. R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc.*, 911 F. 2d 670, 673-75 (Fed. Cir. 1990); *Hewlett-Packard,* 909 F.2d at 1469. Section 271(c) does not require proof of Disc-O-Tech's intent. *Id.* ("Section 271(c) codified the prohibition against the common type of contributory infringement . . . and made clear that only proof of a defendant's *knowledge*, not *intent*, that his activity cause infringement was necessary to establish contributory infringement.") (emphasis in original). The Special Master will address these required showings, *seriatim*.

Prong 1. Kyphon has adduced unrebutted evidence that Disc-O-Tech offers to sell and sells the SKy Device for use in practicing kyphoplasty in accordance with the method taught by the '888 and/or '404 patents. This evidence includes testimony that Disc-O-Tech solicited surgeons to use the SKy Device in kyphophasty, D.I. 151, Ex. X at 31:19-22, 32:1-7, 46:19; D.I. 151, Ex. Y at 32:3-11; and D.I. 176, Ex. 4 at p.1; Disc-O-Tech trained surgeons in the use of the SKy Device in performing kyphoplasties, D.I. 151, Ex. Y at 33:2-9, 40:1-16; and that the SKy Device has actually been used by surgeons to perform kyphoplasties on their patients, D.I. 151 Ex. X at 43:1-11, 48:6-7; and D.I. 151, Ex. Y at 25:3-7. *See also* D.I. 151, Ex. P. ("Spineweek Power Point") at 6 (presenting clinical case study information showing use by U.S. surgeons.).

Prong 2. Disc-O-Tech has admitted that it had actual notice of the '888 and '404 patents since its receipt of the March 3, 2004 letter from Kyphon's President asserting that the sale and use of the SKy Device infringe the patents-in-suit, including the '888 and '404 patents. D.I. 151,

Ex. AA and Ex. BB (Response No. 4). Thereafter, Disc-O-Tech continued to market the SKy Device at its own risk.

Prong 3. Kyphon has also adduced evidence that the SKy Device is specifically intended for use in performing kyphoplasties under the method of the '888 and /or '404 patents. *See, e.g.* D.I. 151, Ex. W at DOTLTD002024 (in seeking premarket approval for its device, Disc-O-Tech represented to the FDA that "The B-Twin BE System **intended use,** design, material, technological characteristics, and principles of operation are substantially equivalent to those used in KyphX Inflatable Bone Tamp.") (emphasis added); and D.I. 151, Ex. O at DOTINC000990 (in its "Surgical Technique" document, Disc-O-Tech states that "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."). Disc-O-Tech has not provided rebuttal evidence of any other uses for the SKy Device that would be non-infringing given the Special Master's claim construction.

Accordingly, the Special Master determines that there are no genuine issues of material fact and therefore concludes, as a matter of law, that Disc-O-Tech is liable for contributory infringement of the '888 and '404 patents.

WHEREFORE, the underlying order having been issued on May 16, 2005 granting Kyphon's Motion for Partial Summary Judgment of Infringement of U.S. Patent Nos. 4,969,888 and 5,108,404 (D.I. 209), the Special Master's opinion in support thereof is HEREBY DOCKETED.

/s Vincent J. Poppiti
Vincent J. Poppiti (DSBA No. 100614)
Special Master

Dated: May 24, 2005

EXHIBIT A

EXHIBIT A
SPECIAL MASTER'S CLAIM CONSTRUCTION FOR U.S. PATENT NO. 4,969,888

'888 Patent Claim	Special Master's Construction
1. A method of fixation of a fracture or 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**.	a combination of the connective tissue and the cancellous bone framework inside a bone forming a channel in the bone marrow compacting the bone marrow to increase the volume of the created channel filling the created channel with a material that is capable of flowing into the channel and of setting to a hardened condition
3. A method as set forth in claim 1, wherein said compacting step includes **forcing the** osteoporotic **bone marrow outwardly of the central portion of the bone.**	compacting the bone marrow so as to force it outwardly from the central portion of the bone
7. A method as set forth in claim 1, wherein said forming step includes **drilling said osteoporotic bone marrow to form said passage.**	using a drill to form a channel into and through the bone marrow
8. A method as set forth in claim 7, wherein said drilling step includes **guiding a drill through into the proximate cortical bone marrow.**	guiding a drill through the cortical bone into and through the proximate bone marrow

EXHIBIT B

EXHIBIT B
SPECIAL MASTER'S CLAIM CONSTRUCTION FOR U.S. PATENT NO. 5,108,404

'404 Patent Claim	Special Master's Construction
1. A method of fixation of a fracture or impending fracture of a bone having **bone marrow** therein comprising: **forming a passage in the bone marrow**; **compacting the bone marrow to increase the volume of said passage** and filling the passage with a **flowable material capable of setting to a hardened condition.**	a combination of the connective tissue and the cancellous bone framework inside a bone forming a channel in the bone marrow compacting the bone marrow to increase the volume of the created channel filling the created channel with a material that is capable of flowing into the channel and of setting to a hardened condition
3. A method as set forth in claim 1, wherein said compacting step includes **forcing the bone marrow outwardly of the central portion of the bone**.	compacting the bone marrow so as to force it outwardly from the central portion of the bone
8. A method as set forth in claim 1, wherein said forming step includes **drilling said bone marrow to form said passage.**	using a drill to form a passage into and through the bone marrow