IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

DEFENDANTS DISC-O-TECH MEDICAL TECHNOLOGIES, LTD.'S AND DISC ORTHOPAEDIC TECHNOLOGIES, INC.'S OBJECTIONS TO THE SPECIAL MASTER'S ORDER AND SUPPORTING OPINION GRANTING KYPHON'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF INFRINGEMENT OF THE '404 AND '888 PATENTS

MORRIS, NICHOLS, ARSHT & TUNNELL
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200

Attorneys for Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc.

OF COUNSEL:
Eric J. Lobenfeld
Jonathan M. Sobel
Arlene L. Chow
Robert J. DeMento
HOGAN & HARTSON L.L.P.
875 Third Avenue
New York, NY 10022
(212) 918-3000

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Pursuant to Rule 72(b), Fed. R. Civ. P., Defendants, Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. (collectively "DOT") submit the following Objections to the Special Master's Order and Supporting Opinion Granting Kyphon's Motion for Partial Summary Judgment of Infringement of the '404 and '888 Patents.

DOT'S OBJECTIONS TO SUMMARY JUDGMENT OF INFRINGEMENT

The Special Master's Order (D.I. 209) and Opinion ("Summary Judgment Opinion") (D.I. 229) in Support of Summary Judgment of Infringement of U.S. Patent Nos. 4,969,888 and 5,108,404 reflect a misunderstanding of DOT's non-infringement arguments. The Summary Judgment Opinion improperly lumps together the claim construction and non-infringement opinions set forth in the reports of DOT's expert, Dr. David Mitchell, and proceeds on the premise that Dr. Mitchell's non-infringement opinion depends solely upon a finding that the claims of the patents require a balloon. (See Special Master's Summary Judgment Opinion, D.I. 229 at pp. 8-9.) But that is not the case, and even if the Court were to adopt the Special Master's claim construction, DOT's SKy Bone Expander ("SKy Device") does not "compact" cancellous bone as that term is understood in the patents, as is set forth in Dr. Mitchell's Reports. At a minimum, questions of fact preclude summary judgment of infringement.

The Special Master relies on DOT's various FDA documents and representations by DOT employees and agents to support of his finding that the SKy device infringes. For several reasons, those documents do not support the Special Master's ruling and, at best, demonstrate an issue of fact that must be decided by the jury. In support of his findings, the Special Master cites to many documents that discuss the creation of a "void." But the Special Master improperly construes the step of "compacting" to equal "creating a void."

DOT does not dispute that the SKy Device creates a void as it expands; a void is necessarily created as inner bone is moved. The real issue is whether the SKy Device "compacts" as contemplated by the patents-in-suit, and simply because the documents show that the SKy Device creates a void is not probative of that issue. To the contrary, the term "compact" has a specific meaning in the context of the claims of the patents-in-suit, which are properly subject to interpretation by the experts in this case. Documents that discuss "compacting" from a marketing perspective are not entirely dispositive of the technical meaning of that term in the context of a patent.

Finally, the Special Master's Summary Judgment Opinion not only reflects a misapprehension of DOT's non-infringement arguments, but highlights the Special Master's misinterpretation of Bard,[1] and its applicability to the facts of this case. The Special Master states: "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 Special Master's Summary Judgment Opinion, D.I. 229 at 5.) To be blunt, that was not DOT's argument. Quite differently, and as fully set forth in DOT's companion Objections to the Special Master's Opinion and Order on Claim Construction, the inventors of the patents-in-suit made clear and unequivocal statements that defined their invention as requiring a balloon, and the claims should be so limited under Bard.

[1] C.R. Bard Corp. v. U.S. Surgical Corp., 388 F.3d 858 (Fed. Cir. 2004).

A. Even if the Court Adopts the Special Master's Claim Construction, Issues of Fact Prohibit Summary Judgment in Favor of Kyphon

DOT objects to the Special Master's grant of partial summary judgment of infringement, because there are issues of fact as to whether DOT's SKy Device infringes under the Special Master's claim construction. Specifically, there are issues of fact as to whether the SKy Device "compacts" bone marrow in the context of the '888 and '404 Patents.

1. The SKy Device Does Not "Compact"

As the Special Master stated in his Claim Construction Opinion, claim 1 of the '888 and '404 Patents is "ground zero" for the parties' dispute. (See Claim Construction Opinion, D.I. 212 at p. 4.) The primary claim element disputed by the parties is "compacting the bone marrow to increase the volume of said passage." (See '404 Patent, claim 1.)

DOT's Non-Infringement Brief [2] and Dr. Mitchell's reports and declaration demonstrate that, even under the Special Master's claim construction, the SKy Device does not "compact" as that term is understood in the context of the '888 and '404 Patents. DOT submits that "compacting" means to compress substantially all of the bone marrow away from the central portion of the interior bone volume, towards the walls of the bone, to increase the volume of the passage. This is confirmed by the specification, which describes the "compacting" step as causing a dam-like effect in the interior of the bone:

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[2] Defendants Disc-O-Tech Medical Technologies, Ltd.'s and Disc Orthopaedic Technologies, Inc.'s Motion for Summary Judgment of Non-Infringement of U.S. Patent Nos. 4,969,888, 5,108,404 and 6,235,043 B1 ("DOT's Non-Infringement Brief") (D.I. 134). See also Defendants Disc-O-Tech Medical Technologies, Ltd.'s and Disc Orthopaedic Technologies, Inc.'s Brief in Opposition to Kyphon's Motion for Partial Summary Judgment of Infringement ("DOT's Infringement Opposition") (D.I. 164). Kyphon's Memorandum in Support of Kyphon's Motion for Partial Summary Judgment of Infringement ("Kyphon's Infringement Motion") (D.I. 149). Kyphon's Opposition to DOT's Motion for Summary Judgment of Non-Infringement of U.S. Patent Nos. 4,969,888, 5,108,404 & 6,235,053 ("Kyphon's Non-Infringement Opposition") (D.I. 173).

> "As balloon 76 is inflated, it forces the osteoporotic bone marrow 67 laterally and outwardly of the wall of the vertebral body 66. This compacts the bone marrow and leaves a void in the interior of the vertebral body to be treated. The compacted bone marrow forms a dam to block any fracture of the vertebral body. Thus, when liquid synthetic bone or methyl methacrylate cement is forced into the void, the compacted bone marrow will substantially prevent flow through the fracture."

('888 Patent, col. 7, lines 17-25.) (emphasis added). By way of analogy, the "compacting" step of the '888 and '404 Patents is like the compacting that occurs with a trash compactor. (See DOT's Non-Infringement Brief, D.I. 134 at p. 11.) Another analogy is to think of the "compacting" step like the compacting that occurs when a person steps in new-fallen wet snow.

The SKy Device does not "compact" or cause a dam-like effect, because the SKy Device has a petal-like structure, which "interdigitates" with the bone marrow to create a void in the bone, as discussed throughout DOT's expert report on non-infringement. (See Appendix,[3] Exhibit C, 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, dated March 23, 2005 ("Inflatable Bone Tamp Non-Infringement Expert Report") at ¶ 52.) The SKy Device does not compress substantially all of the cancellous bone away from the central portion of the interior bone volume, towards the wall of the bone, to increase the volume of the passage. Rather, as the device expands, the cancellous bone intersperses with the petals (i.e., "interdigitates"). The SKy Device acts more like a mechanical jack, lifting the end plates of the vertebra, and DOT submits that merely moving cancellous bone does not equal "compacting." The interspersion of cancellous bone with the petals of the SKy Device creates a void with irregular bumps. Thus, it does not create the dam-like effect or pack down the bone marrow as contemplated by the patents-in-suit.

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[3] Appendix of Exhibits to Defendants Disc-O-Tech Medical Technologies, Ltd.'s and Disc Orthopaedic Technologies, Inc.'s Claim Construction Memoranda and Motions for Summary Judgment of Non-Infringement and Invalidity, D.I. Nos. 140-144.

The Special Master bases his finding of Summary Judgment in favor of Kyphon in-part on his opinion that "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." (See Summary Judgment Opinion, D.I. 229 at p. 9.) But as discussed above, Dr. Mitchell's report clearly discusses the "interdigitation" and "petal-like" configuration of the SKy Device. Therefore it was improper for the Special Master to group Dr. Mitchell's claim construction opinion together with his non-infringement opinion.

2. The Documents Cited By the Special Master to Support His Finding Demonstrate There are Outstanding Issues of Fact

The Special Master's finding relies heavily on numerous DOT marketing and FDA documents for the proposition that the SKy Device "compresses" or "compacts" cancellous bone. (See, e.g., Kyphon's Infringement Motion, D.I. 149 at p. 11.) Those documents do nothing more than demonstrate that there are issues of fact that must be put to the jury.

Many of the documents cited by the Special Master merely discuss the "creation of a void," "void creation" or "void." The Special Master construes "compacting" to equal "void creation" as is evident from the chart comparing claim 1 of the '888 and '404 Patents with the operation of the SKy Device:

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.

(See Summary Judgment Opinion, D.I. 229 at p. 7.) Simply put, "compact" does not equal "create a void." Kyphon did not invent "creating a void" or the idea of a cavity forming instrument. DOT does not dispute that the SKy Device creates a void when used in the manner directed. As the SKy Device is expanded and moves bone marrow, a void is necessarily created.

But as discussed above, because of the structure of SKy Device, the bone marrow intersperses with the petals of the SKy device, and does not compact the bone marrow.

Moreover, many of these "void" passages cited by the Special Master are made in the context of comparing the void created by the SKy Device to the void created by Kyphon's commercial embodiment of the patents-in-suit. (See Summary Judgment Opinion, D.I. 229 at 12 ("The void has a shape of a cylinder, similar to the void created by the KyphX balloon").) The Federal Circuit "ha[s] repeatedly said, [that] it is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent." Zenith Labs. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1423 (Fed. Cir. 1994). Thus, the Special Master's citation to these passages that compare the SKy Device to the Kyphon balloon was improper.

In addition, the term "compact" has a specific technical meaning within the context of the patents-in-suit, which the experts in this case should have an opportunity to address to the finder of fact. The differences between the two sets of expert reports, and the opinions contained therein, clearly show that there are issues of fact outstanding which should preclude summary judgment.

Therefore, even if the Court were to adopt the Special Master's claim construction, DOT respectfully submits that the Court should nevertheless reject the Special Master's grant of summary judgment of infringement in favor of Kyphon, and allow the parties to present these disputed issues of fact to the jury.

B. DOT's Device Does Not Infringe Because All Claims of the Patents-In-Suit All Require a Balloon

As set forth in DOT's Objections to the Special Master's Opinion and Order on Claim Construction, DOT submits that the invention(s) of the '404, '888 and '043 Patents each require a balloon. Therefore, because the patents-in-suit require a balloon, and the SKy Device does not have a balloon, it does not literally infringe. In addition, as discussed in great detail in DOT's summary judgment briefing on infringement issues, the SKy Device also does not infringe under the doctrine of equivalents because it does not meet the function/way/result test.

Because the SKy Device does not infringe, DOT objects to Special Master's Grant of Partial Summary Judgment of Non-Infringement of the '404 and '888 Patents. DOT further objects to the Special Master's failure to grant DOT's Motion, and respectfully requests that DOT's Motion Summary for Judgment of Non-Infringement of the '888, '404 and '043 Patents be granted.

MORRIS, NICHOLS, ARSHT & TUNNELL

/s/ Maryellen Noreika (#3208)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
Attorneys for Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies Inc.

OF COUNSEL:
Eric J. Lobenfeld
Jonathan M. Sobel
Arlene L. Chow
Robert J. DeMento
HOGAN & HARTSON L.L.P.
875 Third Avenue
New York, NY 10022
(212) 918-3000

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CERTIFICATE OF SERVICE

I, Maryellen Noreika, hereby certify that on June 6, 2005, I have caused a true and correct copy of the foregoing **DEFENDANTS DISC-O-TECH MEDICAL TECHNOLOGIES, LTD.'S AND DISC ORTHOPAEDIC TECHNOLOGIES, INC.'S OBJECTIONS TO THE SPECIAL MASTER'S ORDER AND SUPPORTING OPINION GRANTING KYPHON'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF INFRINGEMENT OF THE '404 AND '888 PATENTS** to be served upon the following in the manner indicated:

BY HAND DELIVERY
Thomas L. Halkowski
FISH & RICHARDSON P.C.
919 N. Market Street, Suite 1100
P.O. Box 1114
Wilmington, DE 19899-1114

/s/ Maryellen Noreika (#3208)
Maryellen Noreika (#3208)
mnoreika@mnat.com