IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

DEFENDANTS DISC-O-TECH MEDICAL TECHNOLOGIES, LTD.'S AND DISC ORTHOPAEDIC TECHNOLOGIES, INC.'S OBJECTIONS TO THE SPECIAL MASTER'S OPINION AND ORDER ON CLAIM CONSTRUCTION

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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 Opinion and Order on Claim Construction ("Claim Construction Opinion") (D.I. 212).

I. SUMMARY OF DOT'S OBJECTIONS TO CLAIM CONSTRUCTION

In this case, the inventors of the patents-in-suit invented a balloon for creating a void, or cavity, in bone, to be filled by bone filler material. The inventors told the Patent Office and, ultimately, the world (in their patent) that their invention is an inflatable device for creating a void. The claims of the patent should be construed to require the use of a balloon, based on the patentees' clear definition of its invention as such.

The Special Master's Claim Construction Opinion is inconsistent with the well-settled principle that claims must be construed based on what the inventors actually invented and intended to envelop with the claims of their patent. See Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (emphasis added). The Special Master's Claim Construction Opinion almost exclusively, and DOT submits improperly, relied upon Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898 (Fed. Cir. 2004), and the "clear disavowal" standard set forth therein. (See D.I. 212 at pp. 7-8.) But this case must be analyzed under C.R. Bard Corp. v. U.S. Surgical Corp., 388 F.3d 858 (Fed. Cir. 2004) ("Bard"), because Kyphon, as did the patentee in Bard, repeatedly and unequivocally defined the invention as requiring a balloon. Contrary to the Special Master's Claim Construction Opinion, Bard does not require a "clear disavowal" of other embodiments in order to limit a patent to what was actually described as the "invention."

The "clear disavowal" cases hinge on what the inventor tells the world his invention is not; Bard and this case, by contrast, hinge on what the inventor tells the world his invention is. In the Bard context (i.e., this case), the claims are deemed to require or comprise that element. Since Kyphon expressly told the world in the specification of its '888 and '404 patents that its invention involves using a balloon to make a void in bone, Kyphon may not successfully claim that its invention includes any means to make a void in bone, as it has, and as the Special Master so held.

In this case, as in Bard, the patentee made unequivocal statements throughout the entire specification describing the invention as a whole as including a balloon. Bard, therefore, mandates the conclusion that the asserted claims require a balloon. This Court recently explicitly recognized that the specification of the patent-in-suit in Bard provided a separate and independent ground for limiting the claims:

> "In C.R. Bard, the Federal Circuit held that language appearing in the Summary of Invention and Abstract sections of the patent specification narrowed the meaning of the term 'plug' to mean a plug with a pleated surface. C.R. Bard, 388 F.3d at 866. The Federal Circuit concluded that the 'pleat' language narrowed the meaning of 'plug' based in part on the fact that the language appeared in sections of the specification that describe the invention as a whole, rather than merely preferred embodiments. Further, the Federal Circuit found that the language expressly defined the plug as having or including a pleated surface. Id. at 865. The court went on to hold that the prosecution history of the patent provided an independent ground for the same conclusion. . . ."

Lucent Technologies v. Extreme Networks, Inc. et al., No. Civ.A. 03-508 JJF, 2005 WL 859255 (D. Del. Apr. 14, 2005) ("Lucent") at *2 (citing Bard, 388 F.3d at 869).

This Court first addressed whether the patents-in-suit required a balloon during the preliminary injunction stage. As this Court noted then, the Court's claim construction at that stage is like "play dough." (See P.I. Hearing Tr., D.I. 112 at 26:20-23.) Since the preliminary

injunction hearing, DOT has presented substantial evidence that demonstrates that the claims of the patents-in-suit require a balloon.[1]

The clear and unequivocal statements describing the invention as a whole as requiring a balloon begin on page 1 of the '888 Patent in the Abstract:

> "The method of the present invention includes a series of steps including penetrating the bone having the fracture with a guide pin, drilling the osteoporotic bone marrow of the bone to enlarge the cavity to be treated, following which a bone specific inflatable device is inserted in the cavity and inflated. The expansion of the device causes a compacting of the osteoporotic bone marrow against the inner surface of the outer wall of the bone to be treated to further enlarge the cavity."

('888 Patent, cover page; DOT's Presentation, D.I. 184 at slide 34.) (emphasis added). The statement "[t]he method of the present invention includes" clearly shows what the patentee deemed to be the invention as a whole, which requires a balloon.

The clearest statement describing the invention as a whole appears on the next page, in the "Background of the Invention" section, which was not even addressed by the Special Master:

> "Every year in the United States there occurs approximately 1.2 million fractures due to osteoporosis. Nine hundred thousand (900,000) of those fractures occur in bones which can be treated with the percutaneous balloon technology of the present invention which includes instant fixation by methyl methacrylate cement or with liquid artificial bone substitutes."

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[1] DOT's arguments and evidence presented at the preliminary injunction stage were in the invalidity context under Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473(Fed. Cir. 1998). Bard, on the other hand, deals with claim construction. The evidence presented at this claim construction stage, which is much more substantial, must be analyzed in the context of Bard, which was not addressed at the preliminary injunction stage. DOT certainly does not rely on Gentry Gallery for claim construction purposes, nor is it applicable. An evaluation of the patents-in-suit under Bard yields the proper result – the claims require a balloon. (See DOT's Claim Construction Response, D.I. 163 at 11-14.)

('888 Patent, col. 1, lines 13-19; DOT's Presentation, D.I. 184 at slide 38.) (emphasis added). "The percutaneous balloon technology of the present invention" could not possibly make any clearer what the patentee deemed the invention to be.

The Special Master also failed to consider the numerous clear and unequivocal statements that continue throughout the specification which summarize the invention as a whole. For example, in the "Summary of Invention":

> "This invention relates to a method and apparatus for the fixation of fractures of osteoporotic bones. The invention is especially suitable for use in the fixation of vertebral compression fractures, Colles' fractures and fractures of the proximal humerus. The method of the present invention includes a series of steps including forming an incision in the body and penetrating the bone having the fracture with instruments including a guide pin and a cannula, drilling the osteoporotic bone marrow of the bone to enlarge the cavity or passage to be treated, following which an inflatable device, such as an expandable balloon, is inserted in the cavity and inflated. The expansion of the **balloon** causes a compacting of the osteoporotic bone marrow against the inner surface of the outer cortical wall of the bone to be treated to further enlarge the cavity."

('888 Patent, col. 1, line 67- col. 2, line 14; DOT's Presentation, D.I. 184 at slide 32.) (emphasis added).

Furthermore, the Record of Invention is a telling piece of evidence,

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In short, the evidence presented above, below, in DOT's papers on claim construction and at the hearing before Special Master Poppiti, clearly supports the conclusion that the inventors of the '888 and '404 Patents invented a balloon for creating voids in bone.[3] But that is all they invented, and to provide a claim construction that rewards Kyphon with something more effectively grants Kyphon a legal monopoly on all procedures for creating voids in bone. That cannot be, because people were creating voids in bone well before the '888 and '404 Patents were filed, using conventional bone tamps. Thus, if the claims are not construed to

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[2] 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.

[3] See Defendants Disc-O-Tech Medical Technologies, Ltd.'s and Disc Orthopaedic Technologies, Inc.'s Claim Construction Memorandum Regarding Kyphon's U.S. Patent Nos. 4,969,888, 5,108,404 and 6,235,043 B1 ("DOT's Claim Construction Brief") (D.I. 139), Kyphon's Opening Brief Regarding Construction of Disputed Claim Terms For the Patents-In-Suit ("Kyphon's Claim Construction Brief") (D.I. 145), Defendants Disc-O-Tech Medical Technologies, Ltd.'s and Disc Orthopaedic Technologies, Inc.'s Response to Kyphon's Opening Brief Regarding Construction of Disputed Claim Terms for the Patents-In-Suit ("DOT's Claim Construction Response") (D.I. 163) and Kyphon's Opposition to DOT's Proposed Claim Construction of Disputed Claim Terms of U.S. Patent Nos. 4,969,888; 5,108,404; 6,235,043 B1 and U.S. Patent Nos. 6,241,734 B1 & 6,613,054 B2 ("Kyphon's Claim Construction Opposition") (D.I. 174). See also Transcript of Hearing held on 4/19/05 before Vincent Poppiti, Special Master (D.I. 193) and Presentation on Behalf of Disc-O-Tech ("DOT's Presentation") (D.I. 184).

require a balloon, they are so broad that they must be invalid, as DOT demonstrates in its companion Objections to the Special Master's ruling on DOT's motion for summary judgment of invalidity, filed herewith.

For the reasons set forth below, DOT further objects to the Special Master's claim construction based on (i) errors in the Special Master's analysis of the claims and the prosecution history of the patents-in-suit, and (ii) the Special Master's failure to address the inventor testimony in this case as well as statements from the '043 Patent specification that discuss the '888 and '404 invention. DOT also objects to the Special Master's construction of the specific claim terms of the '888, '404 and '043 Patents.

II. STANDARD OF REVIEW

The Special Master's patent claim construction and decisions on dispositive motions are subject to plenary review by the Court. See ADE Corp. v. KLA-Tencor Corp., 288 F. Supp. 2d. 590, 592-93 (D. Del. 2003) ("[P]atent claim construction and decisions on dispositive motions are subject to plenary review" under Fed. R. Civ. P. 72(b)) (citing Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir. 1995) (en banc), aff'd, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996) (patent claim construction is a question of law); Haines v. Liggett Group, Inc., 975 F.2d 81, 91 (3d Cir. 1992) (a district court exercises plenary review of a magistrate judge's rulings of law)).

III. DOT'S OBJECTIONS

A. DOT Objects to the Special Master's Legal Analysis

DOT's fundamental objection to the Special Master's construction is his improper application of a "clear disavowal" standard to the facts of this case. The Federal Circuit's decision in Bard was based on the court's conclusion that Bard had defined its invention as a

plug with a pleated surface. In this case, the intrinsic evidence demonstrates that Kyphon defined its invention as the use of a balloon to compact bone marrow. Contrary to the Special Master's decision, an analysis under Bard does not require a "clear disavowal" of other embodiments.

In fact, the evidence presented to the Special Master was even more substantial than the evidence presented in Bard. As noted above, the Summary of Invention, Abstract, Background of Invention and Record of Invention contain clear, unequivocal statements that define the invention as requiring a balloon. In addition, all of the evidence from the remainder of the specification, the prosecution history, as well as inventor testimony, support DOT's construction that the claims require a balloon. DOT submits that, for at least these reasons, this case is even stronger than Bard.

1. DOT Objects to the Special Master's Improper Application of an "Affirmative Disavowal" Standard

Bard did not create or rely on a "clear disavowal" standard for limiting the claim language based on the specification. Rather, the "clear disavowal" standard is derived from Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898 (Fed. Cir. 2004). But the facts of Liebel-Flarsheim are clearly distinguishable from Bard and from the instant case, and therefore DOT objects to the Special Master's application of the "clear disavowal" standard. In fact, in Bard itself, as discussed below, the Federal Circuit distinguished Liebel-Flarsheim in a way that clearly applies to this case.

In Liebel-Flarsheim, the defendant argued that because all the embodiments described in the specification of the patent had a particular feature, the claims of the patent must be construed as limited to devices with that feature. Liebel-Flarsheim, 358 F.3d at 905-906. In rejecting the defendant's arguments, the Federal Circuit noted that "this court has expressly

rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." Id. at 906. The court continued: "Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expression of manifest exclusion or restriction.'" Id. (citation omitted). Thus, under the Liebel-Flarsheim line of cases, the only evidence presented in support of a limiting claim interpretation was that all embodiments included a certain feature; in those circumstances, the Federal Circuit required a "disclaimer" or "clear disavowal" of claim scope.

By contrast, the Bard context – like this case -- is quite different. Bard stands for the proposition that "[s]tatements that describe the invention as a whole, rather than statements that describe only the preferred embodiments, are more likely to support a limiting definition of a claim term." Bard, 388 F.3d at 864 (emphasis added). (See DOT's Claim Construction Brief, D.I. 139 at pp. 9-10, and DOT's Claim Construction Response, D.I. 163 at pp. 4-6 and follow-up submissions to Special Master Poppiti.)[4]

In holding that the claims required pleats based on the language of the specification, Bard distinguished Liebel-Flarsheim in the following important way, which the Special Master's Claim Construction Opinion does not address:

> "[T]he holding of Liebel-Flarsheim did not depend on the number of times the term 'pressure jacket' was used or on details of preferred embodiments. Instead, the Liebel-Flarsheim court rejected the trial court's reasoning because, inter alia, the specification did not clearly define the term in question, even implicitly. In this case, however, the specification explicitly defines the inventive plug as 'having' or 'includ[ing] a pleated

[4] Subsequent to the hearing on April 19, 2005, the parties submitted several follow-up letters to Special Master Poppiti discussing Lucent and related matters, which are attached hereto as Exhibits 1, 2, 3, 4 and 5.

> surface.' See '432 patent, Abstract (first quotation); id. at col. 1, ll. 52 (second quotation). Accordingly, Liebel-Flarsheim provides no support for Bard's position."

Bard, 388 F.3d at 864-865.

A critical point that undermines the Special Master's Claim Construction Opinion is that in limiting the claim language based on the specification, the Federal Circuit in Bard did not rely on (or even discuss) a "disclaimer" or "clear disavowal" of other embodiments. Bard examined both the specification and the file history, and found that each provided a separate and independent ground for a limiting interpretation of the claims at issue. See Bard, 388 F.3d at 866 ("Although the statements in the specification suffice by themselves to demonstrate that the plug in claim 20 must be pleated, we also consider the prosecution history of the specification.") (emphasis added).

As mentioned, this Court explicitly recently recognized that the specification of the patent-in-suit in Bard provided a separate and independent ground for limiting the claims. See Lucent, 2005 WL 859255, at *2 (citing Bard, 388 F.3d at 869).

The Special Master relies on a portion of a concurring opinion in Bard by Judge Prost, which focused on the disclaimer language of the prosecution history in Bard. (See Claim Construction Opinion, D.I. 212 at p. 6.) That reliance was misplaced, because the Bard majority clearly recognized that the specification provided a separate and independent ground for limiting the claims to a certain embodiment. Bard, 388 F.3d at 866. And nothing in ***Bard*** indicates that there was any "disclaimer" or "clear disavowal" language in the ***Bard*** specification.

In Lucent, this Court discussed both Bard and Liebel-Flarsheim. Lucent, 2005 WL 859255, at **2-4. Similar to the defendant in Liebel-Flarsheim, the defendants in Lucent contended that the claims of the patent should be limited because every embodiment disclosed in

the specification incorporated the proposed limitation. Lucent, 2005 WL 859255 at *2. Also like Liebel-Flarsheim, this was the only evidence presented by the defendants in Lucent in support of their argument. Id. The limiting elements that the Court rejected were mere features of the invention, and not the invention itself. Therefore, in Lucent, the application of a "clear disavowal" standard was appropriate because of the limited evidence presented by the defendants.

Kyphon has argued that this case is dead on with Lucent. It is quite different. The patents-in-suit in both Lucent and Liebel-Flarsheim, while disclosing only embodiments with a particular feature, did not define the invention as including that feature. In this case, as in Bard, it is not a matter of the balloon being the only embodiment disclosed, or being the best mode disclosed; rather, the specifications of the '888 and '404 patents define the invention in terms of the feature, specifically the use of a balloon in the patented method. The specification repeatedly describes the claimed method as a balloon. Those statements describe the invention as a whole, as required for a limiting claim construction under Bard. Thus, a finding that the patents-in-suit in this case require a balloon is entirely consistent with the Federal Circuit precedent in both Liebel-Flarsheim and Bard, and is consistent with this Court's claim construction in Lucent.

In fact, if the claimed invention does not require a balloon, as Kyphon urges, the logical question is, "then what did Kyphon invent?" As DOT explains in its Objections to the Special Master's ruling on DOT's motion for summary judgment of invalidity, submitted herewith, if Kyphon did not invent the use of a balloon, the claims are extremely broad and encompass the prior art of conventional bone tamps, and are invalid.

2. DOT Objects to the Special Master's Analysis of the Intrinsic Evidence

In addition to DOT's general objection regarding the application of the "clear disavowal" standard, and the broad unequivocal statements in the specification and Record of Invention noted above in Section I, DOT objects more specifically to several additional points of analysis, or failure to analyze, as the case may be, by the Special Master.

a. Language of the Abstract

First, DOT objects to the Special Master's analysis of the language of the Abstract, and citation to Innova. (See Claim Construction Opinion, D.I. 212 at p. 5 ("However, like the language of a title, the language of an Abstract does not weigh heavily in claim construction.") (citing Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1121 (Fed. Cir. 2004).) Innova is inapposite, however, because in that case the defendant actually argued that the patentee had made a "clear disavowal" of certain embodiments, and that the disavowal was evident in the language of the Abstract. See Innova, 381 F.3d at 1120-21 ("Undaunted, [the defendant] contends that even if we disagree that the written description contains specific language clearly showing disavowal, the applicant's clear and unmistakable disavowal of all embodiments in which the tube is not tenaciously engaged to the cap is evident from reading the written description as a whole.")

In contrast, in Bard, the Federal Circuit noted that the patentee had made statements in the Abstract that defined the invention as a whole that supported a limiting interpretation. See Bard, 388 F.3d at 864. Likewise, in this case, the patentee made statements in the Abstract defining the invention as requiring a balloon, as noted above in Section I.

b. Background of Invention

DOT objects to the Special Master's analysis because it did not include an analysis of a clear and unequivocal statement describing the invention as a whole from the

Background of Invention, as noted above in Section I ("percutaneous balloon technology of the present invention").

c. Language of the Claims

DOT objects to the Special Master's analysis of the language of the claims. First, the Special Master's opinion distinguishes the claim at issue in Bard because it had a "structure." (See Claim Construction Opinion, D.I. 212 at p. 6 ("First, the language of claim 1 of the '888 and '404 patents does not claim or describe or limit any device or structure.") (emphasis added).) But this is a distinction without a difference. Whatever "structure" was present in Bard in the claim language, as written, still potentially encompassed a broader range than what the Federal Circuit deemed was the patentee's invention.

The Special Master's Claim Construction Opinion suggests that in Bard, the claim terms themselves had language that implicitly required that the claim terms were limited to pleats. (See Claim Construction Opinion, D.I. 212 at p. 6.) ("First, the language of claim 1 of the '888 and '404 patents does not claim or describe or limit any device or structure.") (emphasis added). This alleged structure in the claim language was not discussed in Bard, nor does Bard reflect that either party made such an argument.

In the claim at issue in Bard, the Federal Circuit found that the term "pliable" equaled "pleats." Pliable, on its face, is open-ended and broader than pleats; however, the specification was sufficiently clear that the invention "included" pleats, and that was the only embodiment disclosed. That language from the specification -- and not purportedly limiting language from the claim itself -- was the basis upon which the Federal Circuit found that the claims required that the plug be pleated.

Specifically, Bard relied on the Summary of Invention and the Abstract – describing the invention as "including" or "having" pleats: "The implant includes a pleated

surface" (Summary of Invention) and "[a]n implantable prosthesis including a conical mesh plug having a pleated surface which conforms to the contours of the defect being repaired." Bard, 388 F.3d at 865. The Federal Circuit explained that this "including" language effectively "define[d]" the invention, and noted: "[W]e use the term ["define"] merely to denote that 'the specification makes clear at various points that the claimed invention is narrower than the claim language might imply based on a reading of the specification as a whole.'" Id. at n.3 (citation omitted). Because the claims of the patents in this case are sufficiently broad, one of ordinary skill in the art must look to the specification to understand what the claims actually mean.

d. The Specification

As noted in Section I above, DOT objects to the Special Master's analysis of the Specification, and specifically that the Special Master failed to address the various broad definitions of the invention as a whole as requiring a balloon. In addition to the "Summary of Invention" section noted above, the descriptions of the method of the invention in the various portions of the specification, which the Special Master failed to address, further reflect that the invention of the patents-in-suit is the balloon itself. For example: "The surgical procedure for treating a vertebral body is as follows: . . .

> 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.('888 Patent, col. 7, lines 17-20.)
>
> After the balloon 76 has been deflated it is removed from the cannula 30. . . . After the vertebral body has been irrigated, the artificial bone substitute, which may include a synthetic bone or methyl methacrylate cement, is injected into the void left by the inflation of balloon 76. . . . A larger volume is injected than one would predict from the size of the chamber formed with balloon 76 even in those patients injected prophylactically. ('888 Patent, col. 7, lines 26-27, 32-35, 47-49.)

(See DOT's Presentation, D.I. 184 at slides 39-40.)

DOT further objects to the Special Master's statement that implies that the thrust of DOT's argument is simply based on the sheer number of times the invention is described as a requiring a balloon. (See Claim Construction Opinion, D.I. 212 at 7 ("This is true no matter how frequently an inflatable (balloon) device is mentioned in the specifications.") (citations omitted).) Indeed, during oral argument, DOT made the point that the word "balloon" is used 42 times in the specification, and the words "inflatable," "inflation," "inflated," and "inflating" are collectively used 46 times." (See DOT's Presentation, D.I. 184 at slide 47.) But this was merely further support for DOT's primary argument that the specifications of the patents-in-suit clearly describe the invention as a whole as requiring a balloon.

3. DOT Objects to the Special Master's Analysis of the Prosecution History of the Patents-In-Suit

As a preliminary matter, as noted supra, this Court recognized the principle in Bard that language from the specification provided an independent and distinct basis for the Court to conclude that the patentee's invention was limited to the sole embodiment disclosed. See Lucent, 2005 WL 859255 at *2. But the prosecution history in this case further supports DOT's contentions that the claims of the patents-in-suit require a balloon.

The Special Master's Claim Construction Opinion suggests that DOT improperly references the extrinsic record by pointing to language from the '043 file history. (See Claim Construction Opinion, D.I. 212 at 8.) But the Special Master is incorrect; the language cited in the Claim Construction is from the '888 File History. (See '888 File History, Appendix Exhibit

G at KY 228854-64.) DOT objects to and respectfully notes the Special Master's error in this regard.[5]

In addition, DOT further objects to the Special Master's substantive analysis of the '888 file history, and specifically the analysis of the statements made by the applicant regarding claims 1 and 16. During a November 28, 1989 Amendment, the applicant made statements to overcome the examiner's rejection. In doing so, the patentee made clear statements that claim 1 of the '888 Patent, requires a balloon:

> Claim 16 recites the same combination of elements as allowable Claim 1 and is distinguished over Claim 1 by reciting the step of inserting an inflatable device in the recess. Claim 16, like Claim 1, recites the step of inflating the device to force the bone marrow outwardly of the recess and against the bone marrow to form a void in the bone. Thus, the bone marrow is not removed from the bone as in the case of Murray, and Murray fails to teach or suggest the combination of steps of Claim 16. Thus, Claim 16 is allowable under 35 U.S.C. 102 (b) over Murray.

(See November 28, 1989 Amendment, Appendix Exhibit G at KY 228858-59.; DOT's Presentation, D.I. 184 at slides 49-50 and amended slide 50.) (emphasis added).

DOT objects to the Special Master's finding that the language of claim 1 should not be construed in the same manner as the different language of claim 16 because to do so "ignores the presumption under the doctrine of claim differentiation that there is a difference in meaning and scope when different words or phrases are used in separate claims." (See Claim Construction Opinion, D.I. 212 at 9.)[6] But the applicant stated that the difference between claim

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[5] At the claim construction hearing, DOT did argue that the language from the '043 Patent demonstrated that the claims of the '404 and '888 Patents were limited to a balloon. (See DOT's Presentation, D.I. 184 at slides 53-57.) However, the prosecution history that the Special Master analyzed and discussed in detail, and as discussed above, is from the '888 prosecution history.

[6] As DOT pointed out in its presentation, claim differentiation should not broaden claims beyond their correct scope. "[C]laim differentiation only creates a presumption that each claim

(Continued. . .)

16 and claim 1 was that claim 16 recited the additional step of inserting the device. The applicant unmistakably stated that claim 16 was the same as claim 1 because it "recites the step of inflating the device." Any additional language in the passage discussed above is irrelevant to the indisputable point that during prosecution, the patentee expressly told the examiner that a claim that included the phrase "inflatable device" (claim 16) as well as one that did not (claim 1) both "recite[] the step of inflating the device . . . ." (See Appendix Exhibit G at KY 228859.) (emphasis added). To the extent there is a dispute as to what these statements mean, the November 28, 1989 Amendment, when read as a whole, supports DOT's interpretation.[7]

4. DOT Objects to the Special Master's Failure to Consider Additional Intrinsic Evidence

a. Figures of the '888 and '404 Patents

DOT objects to the Special Master's analysis, because it did not include an analysis of the Figures, which support a limiting interpretation of the claims. (See DOT's Claim Construction Brief, D.I. 139 at p. 17; DOT's Presentation, D.I. 184 at slides 42 & 44-46.)

b. Record of Invention

DOT objects to the Special Master's analysis, because it did not include an analysis of the Record of Invention, which supports a limiting interpretation of the claims, as noted above in Section I. (See DOT's Claim Construction Brief, D.I. 139 at p. 17; DOT's Presentation, D.I. 184 at slides 42-43.)

(. . . continued.)
in a patent has a different scope; it is 'not a hard and fast rule of construction.'" (See DOT's Presentation, D.I. 184 at slide 59, citing Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1368 (Fed. Cir. 2000) (citations omitted).)

[7] The parties' post-hearing submissions to Special Master Poppiti specifically discussed this Amendment. See Letter from Thomas Halkowski to Special Master Poppiti, dated April 22, 2005, Exhibit 1 at p. 2 and Letter from Maryellen Noreika to Special Master Poppiti, dated April 27, 2005, Exhibit 4 at p. 3.

5. DOT Objects to the Special Master's Failure to Consider Extrinsic Evidence in the Form of Inventor Testimony

DOT objects to the Special Master's analysis, because it did not include an analysis of the inventor testimony. Both inventors' testimony clearly demonstrate that their invention was the balloon itself. (See DOT's Claim Construction Brief, D.I. 139 at p. 20-21.)

6. DOT Objects to the Special Master's Failure to Consider Extrinsic Evidence from the '043 Patent in Construing the '888 and '404 Patents

DOT objects to the Special Master's analysis, because it did not include an analysis of statements made in the '043 Patent specification. The '043 Patent specification contains explicit statements that clearly describe the invention of the '888 and '404 Patents. The '043 Patent is extremely relevant to this inquiry, because two of the three named inventors of the '043 Patent were the inventors of the '888 and '404 Patent.[8] The '043 Patent specification contains numerous clear and unequivocal statements describing the invention of the '888 and '404 Patents as a balloon. "U.S. Pat. Nos. 4,969888 and 5,108,404 disclose a checker-shaped balloon for compressing cancellous bone but does not provide information on how this balloon remains in its shape when inflated." ('043 Patent, Background of Invention; see DOT's Presentation, D.I. 184 at slide 53-57.) The statements made by the inventors of the '888 and '404 patent are entirely relevant to the claim construction inquiry, therefore DOT objects to the Special Master's failure to incorporate them into his analysis.

[8] Mark A. Reiley, Arie Scholten and Karen Talmadge are the named inventors of the '043 Patent. Arie Scholten and Mark Reiley are the inventors of the '888 and '404 Patents.

B. DOT Objects to the Claim Construction Of the Patents-In-Suit

1. DOT Objects to the Special Master's Construction of Claim Terms in Claim 1 of the '888 and '404 Patents

Claim 1 of the '404 Patent (with terms construed by the Special Master noted in bold) requires:[9]

> 1. A method of fixation of a fracture or impending fracture of a bone having bone marrow[10] 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. **"forming a passage in the marrow"**

DOT objects to the Special Master's summary construction of the term "forming a passage in the marrow" to mean "forming a channel in the bone marrow." (See Claim Construction Opinion, D.I. 212 at pp. 11-12.) For the reasons set forth in DOT's Claim Construction Response, DOT contends that "forming a passage in the bone marrow" means "forming an opening, hole or perforation in the bone marrow."[11] (See DOT's Claim Construction Response, D.I. 163 at pp. 6-7; DOT's Presentation, D.I. 184 at slide 29.)

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[9] As noted in DOT's Claim Construction Brief, Claim 1 of the '404 and '888 patents are virtually identical, except the '888 patent relates to osteoporotic bone. For the purposes of DOT's objections, DOT refers to the claims of the '404 patent, as it more broadly applies to bone in general. (See DOT's Claim Construction Brief, D.I. 139 at p. 12).

[10] The parties originally disputed the meaning of the term "bone marrow," however DOT no longer disputes Kyphon's construction of that term. In accordance with Kyphon's construction, Special Master Poppiti construed the term "bone marrow" to mean "a combination of connective tissue and the cancellous bone framework inside a bone." (See Claim Construction Opinion, D.I. 212 at p. 12.)

[11] DOT respectfully notes that the Special Master has provided no analysis for the claim construction beyond the analysis of the threshold "compacting" issue. Because there is no analysis for DOT to specifically dispute with regard to claim terms, DOT will not restate the same arguments as are contained in the parties' briefs. DOT simply directs the Court to the appropriate portions of DOT's claim construction submissions.

DOT further objects to the Special Master's construction of this term because it would appear as if the Special Master's choice of construction was completely arbitrary, and based on a definition attached to the Kyphon's presentation at the claim construction hearing. The Stedman's definition Kyphon attached for passage is: "a channel, duct, pore or opening." The Special Master gave no reasoning as to why he chose the narrow, limiting definition. Even Kyphon's proposed definition was broader. (See Kyphon's Claim Construction Presentation, D.I. 192 at p. 16 ("path or channel").

DOT objects to the Special Master's construction, because the purpose of the passage is to provide access for the device that will be compacting, nothing more. (See Exhibit 6 hereto, Dr. Marks Deposition Transcript, taken May 20, 2005 at 75:10 ("The working channel is the means by which you gain access into the vertebral body.")).

b. "compacting the bone marrow to increase the volume of said passage"

DOT objects to the Special Master's construction of the term "compacting the bone marrow to increase the volume of said passage" to mean "compacting the bone marrow to increase the volume of the created channel." (See Claim Construction Opinion, D.I. 212 at pp. 11-12.) For the reasons set forth above, as well as the reasons set forth in DOT's Claim Construction Brief and Claim Construction Response, DOT contends that "compacting the bone marrow to increase the volume of said passage" means "using an inflatable device to form a void in the interior of a bone, by compressing substantially all of the bone marrow away from a central portion of an interior bone volume, towards the walls of the bone, to thereby increase the volume of a passage." (See DOT's Claim Construction Brief, D.I. 139 at pp. 13-21 and DOT's Claim Construction Response, D.I. 163 at pp. 7-14; DOT's Presentation, D.I. 184 at slides 32-52.)

c. "flowable material capable of setting to a hardened condition"

DOT objects to the Special Master's construction of the term "flowable material capable of setting to a hardened condition" to mean "filling the created channel with a material that is capable of flowing into the channel and of setting to a hardened condition." (See Claim Construction Opinion, D.I. 212 at pp. 11-12.) For the reasons set forth in DOT's Claim Construction Brief and Claim Construction Response, DOT contends that "flowable material capable of setting to a hardened condition" means "a nonsolid substance that tends to conform to the shape of a container." (See DOT's Claim Construction Brief, D.I. 139 at p. 21 and DOT's Claim Construction Response, D.I. 163 at pp. 14-15.)

2. DOT Objects to the Special Master's Construction of Claim Terms in Claim 7 of the '888 Patent and Claim 8 of the'404 Patent

Claim 8 of the '404 Patent (with terms construed by the Special Master noted in bold) requires:

> 8. A method as set forth in claim 1, wherein said forming step includes **drilling said bone marrow to form said passage**.

DOT objects to the Special Master's construction of the term "drilling said bone marrow to form said passage" to mean "using a drill to form a channel into and through the bone marrow." (See Claim Construction Opinion, D.I. 212 at pp. 13-14.) DOT specifically objects to the Special Master's construction because "into and through" is overly restrictive; a passage is an access point. DOT further objects to "through" as vague and unduly restrictive because the point of the claim term is to provide the element of drilling an access point into the bone. (See Exhibit 6 hereto, Dr. Marks Deposition Transcript, taken May 20, 2005 at 75:10 ("The working channel is the means by which you gain access into the vertebral body."))

For the reasons set forth in DOT's Claim Construction Response, DOT contends that "drilling said bone marrow to form said passage" means "using a drill to form an opening,

hole or perforation in the bone marrow." (See DOT's Claim Construction Response, D.I. 163 at p. 15.)

3. DOT Objects to the Special Master's Construction of Claim Terms in Claim 2 of the '043 Patent

Claim 2 of the '043 Patent (with terms construed by the Special Master noted in bold) requires:

> 2. A method for treating bone comprising the steps of inserting inside bone a device comprising **a body adapted to be inserted into bone and undergo expansion** in cancellous bone to compact cancellous bone, including the body includes material that, during the expansion in the cancellous bone, applies a force capable of moving fractured cortical bone, and further **includes an internal restraint coupled to an interior of the body to constrain the expansion** in cancellous bone, **causing constrained expansion of the body** in the cancellous bone, and c**ompacting cancellous bone by the constrained expansion.**

As a preliminary matter with regards to the '043 Patent, DOT contends that the '043 Patent, like the '888 and '404 Patents, is entirely directed to shaping balloons or inflatable devices for use in expanding a void in bone, and the principles of Bard are equally applicable. (See DOT's Presentation, D.I. 184 at slides 67-95.)

Page after page of the specification of the '043 Patent describe the invention of the '043 as a restrained balloon:

> The present invention is directed to a balloon-like inflatable device or balloon for use in carrying out the apparatus and method of the above-mentioned U.S. Pat. Nos. 4,969,888 and 5,108,404. Such inflatable devices, hereinafter sometimes referred to as balloons, have shapes for compressing cancellous bone and marrow (also known as medullary bone or trabecular bone) against the inner cortex of bones whether the bones are fractured or not.
>
> In particular, the present invention is directed to a balloon for use in treating a bone predisposed to fracture or to collapse. The balloon comprises an inflatable, non-expandable balloon body for insertion into said bone. The body has a predetermined shape and size when substantially inflated sufficient to compress at least a

> portion of the inner cancellous bone to create a cavity in the cancellous bone and to restore the original position of the outer cortical bone, if fractured or collapsed. The balloon body is restrained to create said predetermined shape and size so that the fully inflated balloon body is prevented from applying substantial pressure to the inner surface of the outer cortical bone if said bone is unfractured or uncollapsed.
>
> In addition to the shape of the inflatable device itself, another aspect of importance is the construction of the wall or walls of the balloon such that proper inflation of the balloon body is achieved to provide for optimum compression of all the bone marrow.

('043 Patent, col. 3, lines 34-59.) (emphasis added). The numerous descriptions of the invention of the '043 Patent as a restrained balloon are fully set forth in DOT's Claim Construction Brief, Claim Construction Response, and Claim Construction Hearing Presentation. (See DOT's Claim Construction Brief, D.I. 139 at pp. 23-29; DOT's Claim Construction Response, D.I. 163 at pp. 16-17; DOT's Presentation, D.I. 184 at slides 61-88.) The intrinsic evidence in support of DOT's argument that the '043 Patent requires a balloon is overwhelming, therefore DOT generally objects to the Special Master's construction of claim terms of the '043 Patent, which do not limit the claims to an inflatable (balloon) device.

a. "body adapted to be inserted into a bone and undergo expansion"

DOT objects to the Special Master's construction of the term "a body adapted to be inserted into a bone and undergo expansion" to mean "a body adapted so as to be capable of insertion into bone and of expansion in cancellous bone." (See Claim Construction Opinion, D.I. 212 at pp. 15-16.) For the reasons set forth above, as well as the reasons set forth in DOT's Claim Construction Brief and Claim Construction Response, DOT contends that "a body adapted to be inserted into bone and undergo expansion" means "an inflatable body that can be inserted

into bone and expanded." (See DOT's Claim Construction Brief, D.I. 139 at pp. 23-29 and DOT's Claim Construction Response, D.I. 163 at pp. 16-17.)

b. "includes an internal restraint coupled to an interior of the body to constrain the expansion"

DOT objects to the Special Master's construction of the term "includes an internal restraint coupled to an interior of the body to constrain the expansion" to mean "includes an internal restraint coupled to the interior of the body, that constrains the expansion of the body in the cancellous bone." (See Claim Construction Opinion, D.I. 212 at pp. 15-16.) For the reasons set forth above, as well as the reasons set forth in DOT's Claim Construction Brief, DOT contends that "includes an internal restraint coupled to an interior of the body to constrain the expansion" means "a structure that is connected to the interior of the inflatable body (balloon) that limits movement of the internal walls of the inflatable body." (See DOT's Claim Construction Brief, D.I. 139 at pp. 23-30.)

c. "causing constrained expansion of the body"

DOT objects to the Special Master's construction of the term "causing constrained expansion of the body" to mean "causing constrained expansion of the body." (See Claim Construction Opinion, D.I. 212 at pp. 15-16.) For the reasons set forth above, as well as the reasons set forth in DOT's Claim Construction Brief, DOT contends that "causing constrained expansion of the body" means "constraining the expansion of the inflatable body." (See DOT's Claim Construction Brief, D.I. 139 at pp. 23-30.)

d. "compacting cancellous bone by the constrained expansion"

DOT objects to the Special Master's construction of the term "compacting cancellous bone by the constrained expansion" to mean "compacting cancellous bone by the body's constrained expansion." (See Claim Construction Opinion, D.I. 212 at pp. 15-16.) For

the reasons set forth above, as well as the reasons set forth in DOT's Claim Construction Brief, DOT contends that "compacting cancellous bone by the constrained expansion" means "using an inflatable body to form a void in the interior of a bone, where the expansion of the inflatable body is restrained by a structure connected to the interior of the inflatable body that limits the movement of the internal walls of the inflatable body." (See DOT's Claim Construction Brief, D.I. 139 at pp. 23-30.)

4. DOT Objects to the Special Master's Construction of Claim Terms in Claim 17 of the '043 Patent

Independent claim 17 of the '043 patent (with terms construed by the Special Master noted in bold) requires:

> 17. A method for treating bone comprising the steps of inserting inside bone a device comprising a **body adapted to be inserted into bone and undergo expansion** in cancellous bone to compact cancellous bone, **the body including at least two materials that, during the expansion in cancellous bone, apply a force capable of moving fractured cortical bone and constrain the expansion** in cancellous bone,
>
> causing constrained expansion of the body in cancellous bone, and
>
> compacting cancellous bone by the constrained expansion.

a. "body adapted to be inserted into bone and undergo expansion"

DOT objects to the Special Master's construction of the term "a body adapted to be inserted into a bone and undergo expansion" to mean "a body adapted so as to be capable of insertion into bone and of expansion in cancellous bone." (See Claim Construction Opinion, D.I. 212 at pp. 17-18.) For the reasons set forth above, as well as the reasons set forth in DOT's Claim Construction Brief and Claim Construction Response, DOT contends that "a body adapted to be inserted into bone and undergo expansion" means "an inflatable body that can be inserted

into bone and expanded." (See DOT's Claim Construction Brief, D.I. 139 at pp. 23-31 and DOT's Claim Construction Response, D.I. 163 at pp. 16-17.)

b. "the body including at least two materials that, during the expansion in cancellous bone, apply a force capable of moving fractured cortical bone and constrain the expansion"

DOT notes that the Special Master did not construe this term. DOT objects that the Special Master did not explicitly construe this term, given its importance to DOT's non-infringement position. Consistent with the interpretation of the claim language in Claim 2, and for the reasons supporting that construction, the claim language "the body including at least two materials that, during the expansion in cancellous bone, apply a force capable of moving fractured bone and constrain the expansion in cancellous bone," means "an inflatable body that can be inserted into bone and expanded, the inflatable body including at least two materials, one of which constrains its expansion by an internal or external structure connected to the inflatable body that limits movement of the walls of the inflatable body." (See DOT's Claim Construction Brief, D.I. 139 at pp. 30-31.)

IV. CONCLUSION

For the reasons set forth above, DOT respectfully requests that the Court adopt DOT's claim construction in all respects.

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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 OPINION AND ORDER ON CLAIM CONSTRUCTION** to be served upon the following in the manner indicated:

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