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.	Civil Action No. 04-0204-JJF **Redacted Version – Public Copy**

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

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Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. (collectively "DOT") submit this Brief in Opposition to Kyphon Inc.'s ("Kyphon") Motion for Partial Summary Judgment of Infringement of U.S. Patent Nos. 4,969,888 (the "'888 patent"), 5,108,404 (the "'404 patent"), 6,241,734 B1 ("the '734 patent") and 6,613,054 B1 ("the '054 patent").

Kyphon has not moved for summary judgment of infringement of the 6,235,043 B1 ("the '043 patent"), which, along with the '888 and '404 Patents, DOT refers to collectively as the "Inflatable Bone Tamp Patents." DOT has moved for summary judgment of non-infringement of all three Inflatable Bone Tamp Patents.

The bulk of DOT's responsive points with respect to non-infringement of the Inflatable Bone Tamp Patents are set forth in detail in DOT's previously-submitted Brief in support of its Motion for Summary Judgment of Noninfringement of U.S. Patent Nos. 4,969,888, 5,108,404 and 6,235,043 B1, dated April 6, 2005 (D.I. 138, "DOT's Non-Infringement Summary Judgment Brief"). Rather than repeat those points here at length, the Summary of the Argument section below addresses DOT's response with respect to the '888 and '404 Patents.

The foundation for DOT's non-infringement of the '734 and '054 Patents (the "Bone Filler Patents") is set forth in DOT's claim construction memorandum for those patents (D.I. 136). Additional legal analysis with respect to the non-infringement of the Bone Filler Patents is set forth herein.

I. SUMMARY OF ARGUMENT

1. Kyphon's infringement motion with respect to the '888 and '404 Patents is based entirely on the premise that Kyphon's claim construction of "compacting the bone marrow to increase the volume of the passage" will be adopted. Kyphon chose to do no analysis of

whether DOT would infringe if the compacting step requires compacting with an inflatable device. If the compacting step of the method requires an inflatable device, as DOT contends it is, then DOT would not literally infringe, as a matter of law, because the SKy Device does not use an inflatable device to create a void. That much the parties agree upon.

2. If the compacting step requires an inflatable device, as DOT contends, then the SKy Device could only infringe if it were deemed to infringe under the doctrine of equivalents. Kyphon agrees with that premise as well, as its expert witness performed his infringement analysis based on that instruction from Kyphon' counsel. (See Exhibit S, ¶¶ 50-54.) Kyphon performed no doctrine of equivalents analysis in its motion; indeed, Kyphon never mentioned the legal concept. As explained in DOT's Non-Infringement Summary Judgment Brief, one must analyze the substantiality of the differences, and perform a function/way/result analysis, to determine infringement under the doctrine of equivalents. Thus, if the "compacting" step requires an inflatable device, then the SKy device could only infringe if, with respect to the element of "compacting bone marrow to increase the volume of said passage," it performs substantially the same function, in substantially the same way, to achieve substantially the same result.

3. The "way" inquiry is dispositive of non-infringement – i.e., the SKy Device does not "compact bone marrow" to create a void in substantially the same way as the inflatable device of the '888 and '404 Patents.

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5. Even if the '888 and '404 did not require use of an inflatable device, the SKy Device does not "compact" as that term is understood in the context of the '888 and '404 Patents. The SKy Device, with its petal-like configuration, does not create the egg-shell or dam-like effect in the interior of the bone that is contemplated by the '888 and '404 Patents:

> "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.)

By way of analogy, the compacting step of the '888 and '404 Patents is like the compacting that occurs with a trash compactor. (Exhibit C, ¶¶ 46-47, Inflatable Bone Tamp Non-Infringement Expert Report.)

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6. With respect to the Bone Filler Patents, Kyphon's infringement motion rests on the argument that, whether or not DOT's bone filler device is used in an infringing way (to tamp residual material from the cannula), it is "capable" of being used in an infringing way. Kyphon mischaracterizes and misapplies that law regarding "capable," and has not shown that the pre-July 2004 Impactor (bone filler) device at issue on this motion was either designed to be used, intended to be used, or actually used, in an infringing manner.

7. With regard to Kyphon's atmospherics suggesting that DOT acted improperly (see Kyphon's summary judgment brief, D.I. 149, p. 6), the record reflects that the concept and design for the SKy device was based directly on a device that the founders of DOT had invented and sold prior to learning that Kyphon or its device even existed. (See Exhibit GG, Beyar Deposition, pp. 22-35, and Exhibit HH, Globerman Deposition, pp. 17-18, 27-31, 42-52.) DOT's founders, who designed the SKy Device, had a history of developing innovative products for the spine, and for other medical applications. (See Exhibit GG, pp. 11-31, and Exhibit HH, pp. 8-11, 14-18, 27-33.)

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II. DOT DOES NOT INFRINGE THE '888 OR '404 PATENTS

DOT does not infringe the '888 or '404 Patents, either literally or under the doctrine of equivalents, for the reasons set forth in detail in DOT's Non-Infringement Summary Judgment Brief, at pp. 9-18, and for the reasons stated in the Summary of Argument section above.

Kyphon argues that the Court's finding at the preliminary injunction stage that an inflatable device is not an "essential element" of the claims of the '888 and '404 Patents, should

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apply for claim construction and infringement purposes. (See Kyphon's summary judgment brief, D.I. 149, p. 3.) That finding should not affect claim construction or infringement, for several reasons. First, it is well-settled that findings of fact and conclusions of law at the preliminary injunction stage are not binding. See Univ. of Texas v. Camenisch, 451 U.S. 390, 395 (1981) ("[T]he findings of fact and conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits."); Sofamar Danek Group, Inc. v. DePuy-Motech, Inc., 74 F.3d 1216, 1221 (Fed. Cir. 1996) ("[T]he trial court has no obligation to interpret [patent] claim[s] conclusively and finally during a preliminary injunction proceeding."); Jack Guttman, Inc. v. Kopykake Enterprises, Inc., 302 F.3d 1352, 1361 (Fed. Cir. 2002) ("District courts may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves.").

Second, the legal context and the legal standard underlying that preliminary injunction finding was different. At the preliminary injunction stage, DOT argued that the '888 and '404 Patents are limited to a balloon, based on an invalidity principle known as the written description requirement, and relied on the Federal Circuit's Gentry Gallery decision. Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473 (Fed. Cir. 1998). (See Exhibit AA, at pp. 21-24.) Kyphon's reply brief argued that an "essential element" test should be applied, stating: "The case law cited by DOT is inapposite. In those cases, the patentee eliminated an element from the claim that the specification expressly identified as critical to the invention. . . . Contrary to the cases discussed above, the ['404] patent never states, expressly or implicitly, that an inflatable device is an essential element of the invention or that it is the only possible embodiment for achieving the claimed invention of compacting the bone marrow." (See Exhibit DD, pp. 14-15.) The Court applied an "essential element" test in that invalidity context, looked at whether the '404 Patent

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stated that an inflatable device was an essential element, or the only possible embodiment, and found that it did not.

That finding does not apply here, for two reasons. First, DOT's balloon limitation argument at this claim construction stage is based on claim construction law, not invalidity law. DOT is relying on the principles set forth in the Federal Circuit's Bard decision, which held that a specification can be the basis for limiting a claim term in the claim construction context. Bard is discussed in Section II above, and DOT's Balloon Bone Tamp Patents Claim Construction Brief, D.I. 139, at pp. 9-10. Thus, the test here is not whether the '888 and '404 Patents state that a balloon or inflatable device is an essential element or the only possible embodiment, which was the test the Court applied in the invalidity context. The test, and the analysis, here is whether the specification provides a basis for limiting the claims to an inflatable device, under claim construction principles. See Bard, 388 F.3d at 864 ("Statements that describe the invention as a whole, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term.")[1]

Second, and moreover, the "essential element" test that Kyphon asserted in its preliminary injunction reply brief, and which the Court applied in that invalidity context, is, DOT submits, overly rigid. In fact, the Federal Circuit has cautioned against applying the test as Kyphon proposed:

> "In Gentry, the original disclosure identified the console of a sectional sofa as the only possible location for the controls. 134 F.3d at 1479. We held that the asserted claims were invalid because the location of the recliner controls in the claims was not limited to the console. Id. at 1479-80. In reaching that conclusion, we stated: '[I]t is clear that [the inventor] considered the location of the recliner controls on the console to be an essential element of his invention. Accordingly, his original disclosure

[1] Although Bard was decided shortly before the briefing on Kyphon's preliminary injunction motion, it was not cited by any of the parties or the Court.

> serves to limit the permissible breadth of his after-drafted claim.' Id. In so stating, we did not announce a new 'essential element' test mandating an inquiry into what an inventor considers to be essential to his invention and requiring that the claims incorporate those elements." Use of particular language explaining a decision does not necessarily create a new test. Rather, in Gentry, we applied and merely expounded upon the unremarkable proposition that a broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope. Id. ('Claims may be no broader than the supporting disclosure.'). There was no description or support whatever in the Gentry patent of the controls being other than on the console."

Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc., 291 F.3d 1317, 1323 (Fed. Cir. 2002), rehearing and rehearing en banc denied (emphasis added).

Thus, the essential element test that the Court applied at the preliminary injunction stage was not the correct standard, even in the validity context at issue at that stage.

Third, the weight of evidence marshaled by DOT at this stage of the case, with respect to the claims requiring the use of an inflatable device to compact bone marrow, is significantly greater.

In short, the preliminary injunction decision should not impact or affect the evaluation of DOT's evidence and arguments with respect to the inflatable device limitation, at this stage of the litigation.

DOT should be granted summary judgment of non-infringement of all three of the Inflatable Bone Tamp Patents.

III. DOT DOES NOT INFRINGE THE BONE FILLER PATENTS

Kyphon argues that the accused pre-July 2004 SKy Impactor Device infringes the asserted apparatus claims of the Bone Filler Patents because the accused device has the "required capabilities" -- even though the accused device is designed to be used, intended to be used, and, indeed, is used in a manner completely different from how the Bone Filler Patents dictates the

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claimed apparatus is designed and intended to be used. (See Kyphon Infringement Brief, D.I. 136, p. 2.) Kyphon's argument fails for two reasons. First, Kyphon mischaracterizes the law. Second, pursuant to the correct legal standard, the accused SKy Impactor Device cannot infringe, either literally or under the doctrine of equivalents.

First, Kyphon mischaracterizes the Federal Circuit's Intel decision. The asserted claim in Intel required memory chips to have "programmable selection means for selecting alternate addressing mode." Intel Corp. v. United States Int'l Trade Comm'n, 946 F.2d 821, 832 (Fed. Cir. 1991). The asserted claims specifically required that the chips be "programmable" to operate in an alternate addressing mode, not that they actually be so programmed. The accused chips were, indeed, "programmable" to operate in that alternate mode. See id. Because the accused chips specifically met the limitation (i.e. "programmable" to operate in the alternate addressing mode), so they met the limitation literally, and the Federal Circuit affirmed the district court's finding of infringement. Thus, in holding that the accused device literally met the claim language, the Federal Circuit substituted "capable" for "programmable." Contrary to Kyphon's characterization of Intel, its holding is narrow: the accused device literally met the limitation, "programmable" to operate in the alternate addressing mode.

Kyphon mischaracterizes Intel as standing for the broad proposition that, even if a device is not intended to be, nor actually is, used in an infringing manner, the device infringes if it is capable of infringing use. The Federal Circuit has repeatedly held that Intel does not stand for so broad a proposition. See Zygo Corp. v. Wyko Corp., 79 F.3d 1563, 1570 (Fed. Cir. 1996) ("The patentee "argues that under [Intel] . . . a device which is capable of infringing use does not escape infringement although not actually used in an infringing manner. However, [the patentee] over reads Intel."); High Tech Med. Instrumentation v. New Image Indus., 49 F.3d 1551, 1555

(Fed. Cir. 1995) ("The question is not what [a device] might have been made to do, but what it was intended to do and did do . . . . [T]hat a device could have been made to do something else does not of itself establish infringement.") (quoting Hap Corp. v. Heyman Mfg. Co., 311 F.2d 839, 843 (1st Cir. 1962)).

In High Tech, the Federal Circuit rejected the district court's reading of Intel "to mean that if a particular device can be altered without undue difficulty to operate in an infringing manner, the device, as sold, must be deemed to infringe[, concluding that] Intel does not support so broad a holding." Id. at 1555. The asserted claim in High Tech required a "camera. . . rotatably coupled" to a "body member." High Tech, 49 F.3d at 1553. As sold, the accused device was not "rotatably coupled" to a "body member," and could be made to do so only after removal of two screws from the accused device. Id. The High Tech court stressed that the accused device was not designed to be used, not intended to be used, and, indeed, never in fact used in a manner that practiced the asserted claim:

> "As the district court found, [the alleged infringer] did not design the [accused device] to rotate within its housing during operation; nor was there any reference to the rotation of the camera in the [accused device] promotional materials that were made part of the record. In addition, it does not appear from the record that removing the set screws would serve any functional purpose not already accomplished by other means, and [the patentee] offered no evidence that any user of the [accused device] had loosened or removed the set screws prior to or during actual use."

Id (emphasis added).

Finding no infringement, the High Tech court concluded: "[A] device does not infringe simply because it is possible to alter it in a way that would satisfy all the limitations of a patent claim." Id. at 1555; see Fantasy Sports Properties, Inc. v. Sportsline.com, Inc., 287 F.3d

1108, 1118 (Fed. Cir. 2002) (rejecting patentee's characterization of Intel as requiring a finding of infringement when a device is capable of being altered in an infringing manner).

Based on a proper reading of Intel, in light of subsequent Federal Circuit decisions, such as High Tech, the controlling law is as follows: There is no infringement if a device is not designed to be used, intended to be used, or actually is used in a manner such that it meets the asserted claim. Because the accused SKy Impactor device is not designed to be used, intended to be used, or, indeed, is not used in a manner such that it practices the asserted claims of the Bone Filler Patents, it does not infringe the Bone Filler Patents, either literally or pursuant to the doctrine of equivalents.

Kyphon places undue reliance on the term "capable," in a manner inconsistent with the specification of the patent. (See "Mitchell Bone Filler Patent Non-Infringement Report," Exhibit D to Appendix of Exhibits, ¶ 47.) Proper construction of the asserted claim term, "tamping instrument capable of advancement into the subcutaneous cannula," dictates a finding that the SKy Impactor does not infringe the Bone Filler Patents. As discussed in DOT's Bone Filler Claim Construction Brief, there are two key factors in the claim interpretation of the Bone Filler Patents: (1) according to the Bone Filler Patents, by virtue of a nozzle instrument being withdrawn into the cannula as material is expelled, material gets expelled into the bore and contacts the inner walls of the cannula; and (2) after the nozzle instrument is removed from the cannula, tamping operations are performed relative to the cannula to clear the residual material from the bore (and contacting the inner walls) of the cannula into the bone cavity. (See pp. 1, __) The specification for the Bone Filler Patents compels the same construction for the following two claim terms: (a) "a tamping instrument capable of advancement into the subcutaneous cannula," and (b) a tamping instrument for advancement through the cannula." (Id. at pp. 13-19; emphasis

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added) Both claims mean: an instrument that, when it advances, clears the residual material from the inner walls of the cannula into the bone cavity." (Id.; see also Mitchell Bone Filler Patent Non-Infringement Report, ¶¶ 30, 47.)

Based on a proper claim construction, SKy Impactor does not infringe the Bone Filler Patents. As detailed in the Mitchell Bone Filler Patent Non-Infringement Report (at ¶¶ 38 - 56), the SKy System (the pre-July 2004 Impactor at issue on this motion) was designed and intended to be used so that material does not get into the bore (or contacts the inner walls) of the SKy cannula. It follows that the Impactor Rod (or the Impactor Tub nested within it) does not tamp relative to the SKy cannula – the Impactor Rod does not clear material from the bore (i.e., material contacting the inner walls) of the SKy cannula. (Id. at ¶54.)

Moreover, the SKy System was not designed or intended to be used the way the Bone Filler Patents dictate the claimed apparatus is used, and there is no evidence that anyone used the SKy system in the foregoing manner. (Id. at ¶ 44.) In short, Kyphon's motion for summary judgment should be denied.

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IV. CONCLUSION

For the foregoing reasons, and for the reasons stated in DOT's Motion for Summary Judgment of Non-Infringement, DOT requests that Kyphon's motion for summary judgment of infringement of the asserted claims of the '888 and '404 Patents be denied in its entirety, and that DOT's motion for summary judgment of non-infringement of claims 1, 3, 7, 8, 9, 11, and 14 of the '888 Patent, claims 1, 3, 8, 9, 10, 12, and 15 of the '404 Patent, and claims 2, 17, 20, 23, 24, 25, 26, and 28 of the '043 Patent, be granted in its entirety.

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CERTIFICATE OF SERVICE

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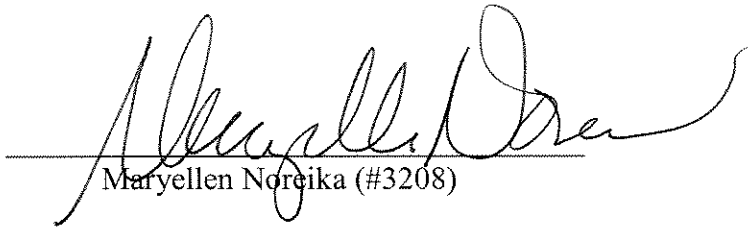

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