IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

KYPHON'S RESPONSE TO DOT'S OBJECTIONS TO THE SPECIAL MASTER'S ORDER DENYING SUMMARY JUDGMENT OF INVALIDITY RE THE '888 AND '404 PATENT

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I. INTRODUCTION

DOT's objections to the Special Master's validity rulings rest on DOT's mistaken view that the claims at issue must be interpreted in one of two extreme ways: (i) reading in a limitation, so that all the methods in the asserted claims would be limited to the use of a balloon; or (ii) ignoring the limitations actually set forth in the claims, so that they would cover every conceivable approach to compacting bone and/or creating a void in bone. Neither alternative is correct. The plain terms of the claims at issue do not limit the claimed surgical procedures to the use of only a balloon device. At the same time, the claims are not simply open-ended. They are directed toward surgical methods that include a particular series of steps – for creating a passage into a bone, creating a cavity specifically by expanding the volume of that newly-created passage, and then filling the expanded passage with a material that has the capability of being flowable and also is capable of setting to a hardened condition.

When the claims are properly interpreted – as the Special Master has construed them – DOT's summary judgment motion falls short of carrying the heavy burden of establishing with clear and convincing evidence that either of the two references relied on anticipates or renders obvious the truly pioneering surgical approach invented by Kyphon. Moreover, DOT does not come close to showing that the evidence of record is so one-sided that no juror could find that DOT's evidence fails to carry its heavy burden, particularly when all factual inferences are drawn in Kyphon's favor.

While DOT's motion and its objections to the Special Master's Order do not entitle DOT to summary judgment of invalidity, they do illustrate how a jury could be confused through misleading use of Kyphon's FDA submissions. DOT's mischaracterizations of those submissions in its motion and objections is as startling as it is repeated. For example, DOT trumpets that "Kyphon repeatedly told the FDA that the conventional bone tamps in the prior art meet the very same limitations with respect to which the Special Master … finds genuine issues of disputed fact exist." D.I. 232 at 2 (emphasis in original). DOT then devotes page after page of its

objections to detailing all the various "admissions" that Kyphon purportedly has made regarding the limitations set forth in the patent claims. But in truth, and as the Court knows from its own experience on this issue, Kyphon's FDA submissions do not even address the asserted patents (Kyphon's principal patent application had been submitted nearly a decade earlier), much less contain repeated "admissions" regarding the particular claim limitations at issue.

At most, the FDA submissions discuss the general similarity in intended use and therapeutic results between Kyphon's commercial device (the "*KyphX* IBT") and various conventional bone tamps. In doing so, the FDA submissions confirm certain basic and undisputed points – for example, that conventional tamps are capable of compacting bone and creating voids inside bone, and that bone graft can be used to fill voids in a bone. Kyphon also specifically noted in its submissions that the probe in Olerud operates "to compact the cancellous bone and push the end plates apart, to achieve the desired reduction." D.I. 141, Ex. A-27 at p. 7-4 (KY 4842). Indeed, this lone sentence is the only information of substance in Kyphon's FDA submissions that is not explicitly contained in the prior art references themselves on which DOT relies.

None of these points will be disputed by Kyphon at trial, because none is material to the distinctions that exist between the asserted claims and the prior art on which DOT relies.[1] Moreover, the central focus of all the statements made in the FDA submissions is a comparison of the use of and results achievable by Kyphon's *commercial device* and conventional bone tamps – which, with the exception of Olerud, DOT does not even rely on in its invalidity case. As such, DOT's use of these FDA submissions would inevitably shift the focus away from where it must remain: properly comparing the *actual claim language*, as construed by the Court, to the disclosures in the prior art references. DOT's use of the FDA submissions does not, therefore, advance the proper validity analysis; the FDA documents are merely a

[1] Kyphon is comfortable with the actual information that it provided to the FDA, but not with DOT's creative use of excerpts nor with the inherent confusion regarding the validity analysis that would result from such misleading use of the FDA documents.

sideshow for DOT to make accusations regarding Kyphon's purported "admissions" of facts that are not actually in dispute and that do not, in any event, specifically address the claim language at issue here. Thus, the FDA materials upon which DOT relies so heavily are at best of marginal relevance, do not support issuance of a summary judgment invalidating Kyphon's '888 and '404 patents, and should not be admitted or used at trial.

II. APPLICABLE LEGAL STANDARDS

DOT inexplicably complains in a number of places that "the Special Master placed undue reliance on Kyphon's expert submission." D.I. 232 at 4. Yet, DOT's objections ignore the difficult burden that must be carried by DOT to secure a summary judgment that all the asserted claims of the '888 and '404 patents are invalid. A review of the applicable standards shows that DOT's complaints regarding the Special Master's analysis lack any merit.

First, because DOT is seeking to avoid a trial, the evidence submitted by the non-movant, Kyphon, "is to be believed, and all justifiable inferences are to be drawn in [its] favor." *Anderson v. Liberty Lobby, Inc.* 477 U.S. 242, 248 (1986); *see also Continental Can Co. U.S.A., Inc. v. Monsanto Co.*, 948 F.2d 1264, 1265 (Fed.Cir. 1991) ("The purpose of the summary process is to avoid a clearly unnecessary trial, …; it is not designed to substitute lawyers' advocacy for evidence, or affidavits for examination before the fact-finder, when there is a genuine issue for trial.") (internal citation omitted). It is thus not only appropriate, but mandatory, that the Special Master believes the statements of Kyphon's expert, made in opposition to DOT's motion, concerning, for example, the proper understanding of the references at the heart of DOT's invalidity defenses.

Second, with Kyphon being given the benefit of any doubts regarding the evidence, DOT must nonetheless establish the absence of any genuine issues of material fact while providing clear and convincing evidence that the '888 and '404 patents are invalid. *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 222 F.3d 973, 980 (Fed.Cir. 2000) ("Thus, a moving party seeking to invalidate a patent at summary

judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise."). Accordingly, to prevail, DOT must show that even after drawing all factual inferences in favor of Kyphon, it has still proved invalidity by clear and convincing evidence, and that no reasonable jury could decide otherwise. Not surprisingly, given the sworn detailed statement and expert report presented by Dr. Michael Marks as to how one of ordinary skill in the art would understand the asserted references, the Special Master determined that genuine issues of material fact preclude the issuance of a summary judgment in DOT's favor.

III. EDELAND DOES NOT ANTICIPATE THE '888 AND '404 PATENTS[2]

Edeland is a short article published over a decade before conception of the inventions at issue here. It describes a surgical technique that Edeland concedes is "probably only suitable for the treatment of uniformly depressed central condylar fractures" (i.e., a particular type of fracture that occurs at the top of the tibia – the larger bone in the leg below the knee). D.I. 140, Ex. A-17, at p. 689. Edeland, thus, on its face does not even arguably anticipate those asserted claims directed toward the spine.[3] Edeland also fails to disclose, for example, at least the following limitations of the other asserted claims: (i) the particular series of steps that result in the formation of an enlarged passage within the bone, including the drilling step required by certain dependent claims;[4] and (ii) the use of material that has the capability of being flowable and the capability of setting to a hardened condition, including the

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[2] DOT's objections purport to describe the evidence relied upon by the Special Master for his denial of DOT's summary judgment regarding the Edeland reference. DOT, however, fails to provide a complete description of the points set forth in Dr. Marks' report and sworn declaration.

Moreover, in response to DOT's objections, Kyphon respectfully incorporates by reference the points raised in its opposition to DOT's motion for summary judgment regarding validity (D.I. 172), and at argument in this matter (D.I. 193 (transcript); and 192 (slides)). Herein, Kyphon merely focuses upon key points regarding DOT's assertion that Edeland anticipates the asserted claims.

[3] *See* Claim 12 of the '404 and claim 11 of the '888.

[4] Dependent claims 7, 8 and 9 of the '888, along with dependent claims 8, 9, and 10 of the '404 patent, require the passage to be formed by drilling the bone.

specific types of materials recited in certain dependent claims.[5] See D.I.172, at pp. 12-16.

In addition, DOT asserts that if claim 1 of the '404 patent is not limited to only covering balloons, the claim "covers any means of creating a void in the bone." D.I. 232, at p. 2. However, the claimed surgical procedure that results in the creation of a void plainly concerns two distinct, but related, steps: (1) the forming of a passage; and then (2) subsequently increasing the volume of ***that*** passage. The claims at issue, therefore, do not simply cover "any means" of compacting bone to create a void and the Special Master's claim construction makes this clear. In fact, ironically, DOT nowhere appears to contest the basic requirement that the surgeon must first form the passage and subsequently enlarge that same passage by compaction. Yet, DOT's analysis, including its analysis of Edeland, overlooks this critical aspect of the claimed surgical methods.

Turning from claim construction to the disclosure of Edeland, DOT asserts that a "passage" is created in Edeland by making a "cortical window" via fenestration (i.e., making a window in the outer cortical bone) and then this "passage" is enlarged by pushing the probe through the bone to create a void. This is wrong, or at least disputed, for two reasons: (1) the window in the cortex is not "in the marrow" and is never enlarged by any means, and (2) any passage in the marrow created by pushing the probe into the bone to access the fracture site is likewise not subsequently enlarged. See D.I. 172, at pp. 13-14.

Dr. Marks, an orthopedic surgeon engaged by Kyphon as its expert, has explained that Edeland does not teach the two distinct steps required by claim 1 to form a cavity in the cancellous bone. *See, e.g.*, D.I. 172 at 13. Based upon Dr. Marks' explanations, Kyphon has asserted that making a window in the outer *cortical* bone has nothing to do with the required formation of a passage (*i.e.*, channel) into

[5] Dependent claim 14 of the '888 and dependent claim 15 of the '404.

and through the interior of the *bone marrow*. *Id.*[6] At most, Edeland discloses the formation of a passage when the probe is pushed through the bone marrow.[7] But, as explained by Dr. Marks and as plainly shown in Figures 3, 4 and 6 of Edeland, *that* passage is never subsequently enlarged as required by the claims. Regardless of whatever work is done in the area of the fracture beneath the top of the tibia, the passage (i.e., the tunnel that is created to get from the outer cortical bone on one side of the tibia to the site of the fracture at the top of the tibia) remains constant in volume. DOT has never addressed this fundamental short-coming of Edeland nor the significant disagreement between the experts on the import of Edeland in this critical respect. With such oversights and significant disagreements, DOT is not entitled to summary judgment that Edeland anticipates the asserted claims, and a triable issue of fact exists regarding the experts' competing understandings of what Edeland would have taught to one of ordinary skill in the art at a time just prior to the inventions at issue.

Edeland also does not disclose "filling the passage with a flowable material capable of setting to a hardened condition." Edeland discloses the use of bone graft

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[6] DOT cites Kyphon's FDA submissions and asserts that Kyphon has acknowledged that a drill could both form a cortical window as well as establish a working channel into the interior of the bone. D.I. 232, at 15-16. However, Kyphon's statements that a drill *could* be used both to create a cortical window and to establish a working channel into the interior of the bone say nothing about the ***actual*** disclosure of Edeland, and do nothing to aid DOT's assertion that the cortical window in the outer shell of the bone in Edeland is the ***same thing*** as forming a channel in and through the marrow of the bone. This is one of the many examples of the mischief DOT would make with Kyphon's FDA submissions.

[7] DOT also cites to testimony by Dr. Marks that purportedly states that the fenestration, *can* be done by a drill. Again, how it might be done and how Edeland in fact teaches to do it are two different things. The fenestration of the cortical bone could just as well be done by "cutting" a window into the bone. (See D.I. 176, Ex 3 at p. 10). Edeland does not say which approach to use. Thus, drilling is not "inherently" disclosed by the article. See *Scaltech, Inc. v. Retec/Tetra, LLC.*, 178 F.3d 1378, 1384 (Fed. Cir. 1999) ("Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency.").

Moreover, regardless of how the fenestration is done, Edeland teaches that it is done in the cortex only, so fenestration does not result in the formation of a channel into and through the interior of the bone marrow as required by the claims. See D.I. 176, Ex. 3 at p. 10).

and tricalcium phosphate. Dr. Marks has explained why neither of these materials in use is flowable (see generally D.I. 176, Ex. 3 at p. 9, 11-12; and D.I. 175, at ¶ 5), and Edeland certainly never says that they are. DOT also asserts that these materials set to a hardened condition but that again is contradicted by Dr. Marks, and also by DOT's own assertions about how the hardening results from the body's own bone tissue invading the filled area over a long period of time, thus knitting new bone. See D.I. 172, at 14-16. A material that the body uses to create new bone in the manner disclosed in Edeland is not "a material capable of setting to a hardened condition" as required by the claims. In other words, neither bone graft nor a granular material like tricalcium phosphate, when used as Edeland teaches, ***themselves*** possess the required capability of setting to a hardened condition. See also D.I. 172 at 9-11, and 14-16 (further detailing the deficiencies of DOT's assertions). Left alone, these materials could sit for years without ever "setting to a hardened condition."[8] This is an important distinction from the sorts of materials (such as liquid synthetic bone and methyl methacrylate cement) disclosed and claimed in Kyphon's patents, because it is critical to the success of the claimed kyphoplasty procedure that the material flow into place and become hard. For this additional reason, Edeland fails to anticipate the asserted claims, and summary judgment is, once again, inappropriate to resolve the experts' differing understandings of Edeland's disclosure with respect to the "filling" step in the asserted claims.

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[8] DOT argues that Dr. Marks "concedes" that tri-calcium phosphate "hardens over time and becomes bone." D.I. 232. DOT is mistaken. Dr. Marks explained that tri-calcium phosphate, itself, does ***not*** in fact set to a hardened condition. See D.I. 175, at ¶ 7; D.I. 176, Ex. 3 at p. 9. Rather, the patient's natural bone heals around the tri-calcium phosphate and reinforces the area by knitting new bone. Id.

IV. OLERUD DOES NOT ANTICIPATE THE ASSERTED CLAIMS[9]

Olerud is an article describing the use of a specially designed hardware apparatus used in an open surgical procedure to attempt to reduce traumatic vertebral burst fractures. The article describes how that hardware, described as a "posterior segmental fixator" (PSF), is screwed into healthy vertebrae above and below the fractured vertebra. Using handles that protrude from the PSF hardware,[10] the surgeon exerts leverage and thereby attempts to reduce the fracture and create a "void" in the damaged vertebra. A hole is then drilled to access the void created by the PSF hardware in the damaged vertebra, and a conventional bone tamp is used to cause further reduction "if possible" by lifting up on the vertebral endplates to increase the size of the PSF-created void. The void is then filled with bone graft which the surgeon presses into place with a probe.

Olerud lacks largely the same disclosure as Edeland and thus is deficient with respect to similar claim limitations. First, to the extent any compaction of bone occurs in Olerud, and Kyphon willingly acknowledges, again, as it did to the FDA, that some might, any such compaction occurs when the probe is being used in an attempt to increase the size of the already-created, PSF-leveraged void. It does not

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[9] While DOT's objections purport to describe the evidence relied upon by the Special Master for his denial of DOT's summary judgment regarding the Olerud reference, DOT fails to provide a complete description of the points set forth in Dr. Marks' report and sworn declaration.

Moreover, in response to DOT's objections, Kyphon respectfully incorporates by reference the points raised in its opposition to DOT's motion for summary judgment regarding validity (D.I. 172), and at argument in this matter (D.I. 193 (transcript); and 192 (Kyphon PPTs).

[10] DOT faults Kyphon for explaining the role that the PSF hardware plays in the procedure as described by Olerud, and implies that Kyphon's position is somehow at odds with statements Kyphon made to the FDA. However, Kyphon's statements to the FDA, of course, focused upon the use of the bone tamp, because that was the portion of Olerud that was arguably relevant to the form and function of Kyphon's commercial *KyphX* IBT kyphoplasty product. Thus, Kyphon's statement that the PSF hardware "is not related to the bone tamping" is in no way inconsistent with Olerud's own description of the PSF as being responsible for the initial reduction of, and creation of a void in, the damaged vertebra before the bone tamp is even used. DOT's position, however, once again evidences how mischaracterization of the FDA documents may mislead the jury.

increase the volume of the passage initially formed by the surgeon when drilling into the vertebra. Thus, Olerud, like Edeland, lacks a fundamental requirement of the asserted claims because: (i) the only passage disclosed by Olerud is the hole drilled to access the PSF-created void; and (ii) that access passage is ***never*** increased in size, by compaction of bone or otherwise. See D.I. 172, at pp. 5-9.

DOT nonetheless argues that the Special Master's Order should be reversed because (among other things) Kyphon has purportedly admitted to the FDA that the conventional bone tamp in Olerud may be used to compact bone and increase a void within a vertebral bone. DOT's discussion of Kyphon's FDA materials, however, ignores the crucial point that the series of steps required by the asserted patent claims is not discussed anywhere in the FDA submissions. As noted above, Kyphon generally stated that the probe in Olerud operates "to compact the cancellous bone and push the end plates apart, to achieve the desired reduction." However, for the reasons explained above and further detailed in Kyphon's opposition to DOT's summary judgment motion, the FDA submissions in no way help DOT overcome the fundamental failure of Olerud to disclose the key steps actually required by the asserted claims, including creating a passage though the bone marrow in the interior of a bone and then expanding the volume of ***that*** passage. *Id.* DOT's assertions regarding the "repeated admissions" by Kyphon are, therefore, beside the point.

Second, Olerud's disclosed bone graft is not flowable and does not set to a hardened condition for the same reasons as discussed above with respect to Edeland's bone graft. See also D.I. 172, at pp. 9-11. DOT's argument that Kyphon has "admitted" to the FDA that bone graft can be used to fill the void created by Kyphon's commercial device has nothing to do with whether the bone graft of Olerud that must be pressed into place has the characteristics required by the asserted claims.[11] Therefore, DOT's use of the FDA-related documents, again, is merely a

[11] DOT also argues that Dr. Marks has conceded that bone paste hardens over time. D.I. 232 at 8. That is simply not true, and is unsupported by either DOT's citation of Dr. Marks' declaration or his deposition testimony. Contrary to the graft itself hardening, Dr. Marks' expert report and declaration explain that the area containing

distraction that fails to advance DOT's request for a summary determination that the '888 and '404 patents are invalid.[12]

Lastly, DOT's assertion that Olerud necessarily discloses the applicability of his surgical method for use in osteoporotic bone boils down to mere hand-waving and attorney argument that, because the Olerud method can be used in bone, it can therefore be used in osteoporotic bone. This again confuses what might be done with what is actually disclosed. And here Kyphon disputes even what DOT says might be done. Dr. Marks has explained in detail that the attachment of the large PSF hardware of Olerud to osteoporotic bone would risk "ripping the hardware out of the soft osteoporotic bone and further injuring the patient." D.I. 176, Ex. 3, at pp. 23-24; See also D.I. 172, at p. 12. DOT never even attempts to address these facts, much less establish that no genuine issue exists regarding the purportedly inherent disclosure that Olerud is applicable for use in osteoporotic bone.

For the above reasons as well as those set forth in Kyphon's opposition brief to DOT's motion for summary judgment and Kyphon's presentation at oral argument

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the bone graft hardens due to the body's own healing process whereby the living bone tissue surrounding the void knits bone into the bone graft over a long period of time. See, e.g., D.I. 175, at ¶ 6. Similarly, the portion of deposition cited by DOT concerns a question that Dr. Marks plainly addressed in the context of his previously-stated position regarding bone graft. Indeed, DOT's counsel even qualified his question regarding the hardening of bone graft material with the phrase "whether bone grows around it or not." D.I. 232, Exhibit C at 219:17.

[12] DOT also appears to argue that it would be obvious to use bone cement to fill the void created by the method disclosed in Olerud. However, DOT's reference to the fact that bone cement can be used in a semi-hardened state fails to aid DOT's cause. Bone cement certainly can be used in a semi-hardened chewing-gum consistency by a surgeon who could then wad-up the semi-hard cement and manually press it directly into a bone void during an open procedure (i.e., where the fracture was directly accessible by the surgeon). On the other hand, bone cement, because it can be used in a flowable state, can also be injected through a tube and into a remote void such as is needed to access the cavity created in a vertebral bone during a kyphoplasty procedure. However, injection of a flowable material into the extensively damaged vertebral bones caused by the type of traumatic fractures depicted in the Olerud article (see D.I. 232, at 5), would "make no sense" as Dr. Marks has explained because of the grave concern that cement could easily leak from the vertebra and cause severe neurological damage to the spinal cord. See D.I. 176, Ex. 3 at pp. 11-12. Thus, use of bone cement in the Olerud procedure would have been far from obvious to one of ordinary skill in the art at the time of the inventions.

on the motion, DOT's objection to the Special Master's Order denying summary judgment that Olerud anticipates the asserted claims are without merit and should be overruled. It is the jury's province to resolve these issues.

V. THE '888 AND '404 PATENTS ARE NOT INVALID FOR OBVIOUSNESS[13]

DOT's arguments regarding the issue of obviousness are one of the places where DOT argues that the Special Master "placed undue reliance on Kyphon's expert submissions."[14] As noted above, DOT's argument is wrong. DOT apparently overlooks the fact that the Special Master cited evidence submitted by DOT as well as evidence submitted by Kyphon. Moreover, DOT also ignores the fundamental requirement that facts properly submitted by Kyphon must be assumed to be true for purposes of assessing DOT's motion for summary judgment. For the reasons set forth in Kyphon's opposition to DOT's motion for summary judgment (D.I. 172) as well as those set forth during Kyphon's presentation during oral argument (D.I. 193 (transcript); D.I. 192 (Kyphon's PPT)) the Special Master's denial of DOT's request for summary judgment of obviousness was proper and DOT's objections should be overruled.

VI. CONCLUSION

For all the reasons referenced above, DOT's objections should be overruled and Kyphon respectfully requests that the Special Master's decision denying DOT's motion for summary judgment of invalidity of all the asserted claims of the '888 and '404 patents be adopted by the Court.

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[13] DOT has now apparently withdrawn its belated attempt to seek summary judgment that various combinations of references, including references other than Olerud and Edeland, render the asserted claims obvious. D.I. 232 at 3 n.1. Kyphon therefore sees no need to respond to DOT's assertions regarding these other references.

[14] This appears to be the only point specifically addressed by DOT concerning the obviousness issue – setting aside DOT's boilerplate complaints that the Special Master incorrectly determined that genuine issues of material fact existed. Given the law, this "objection" does not seem well-designed to provide the Court with any real basis to revisit the Special Master's balanced ruling.

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I hereby certify that on June 3, 2005, I electronically filed **KYPHON'S RESPONSE TO DOT'S OBJECTIONS TO SPECIAL MASTER'S OPINION AND ORDER DENYING SUMMARY JUDGMENT OF INVALIDITY RE THE '888 AND '404 PATENTS** with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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