IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| KYPHON INC.,<br><br>Plaintiff,<br><br>v.<br><br>DISC-O-TECH MEDICAL TECHNOLOGIES LTD., and DISC ORTHOPAEDIC TECHNOLOGIES, INC.,<br><br>Defendants. | C.A. No. 04-204-JJF<br><br>**PUBLIC VERSION** |

**KYPHON'S OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT THAT THE '404 AND '888 PATENTS ARE INVALID BASED ON ANTICIPATION AND/OR OBVIOUSNESS**

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## I. INTRODUCTION

This case illustrates the benefits of considering summary judgment in conjunction with claim construction. If Kyphon's asserted claims in the '404 and '888 patents are not artificially narrowed to the preferred embodiments given as examples in the patents, DOT effectively concedes infringement. It is therefore essential for DOT to persuade the finder of fact that every one of the asserted claims is invalid, by clear and convincing evidence. This is a very high burden, which DOT barely acknowledges. And while one might debate whether DOT ultimately can carry that burden at trial – which is all, really, that the Court previously decided in its preliminary injunction Order – DOT surely cannot carry it on summary judgment.

DOT has therefore found it necessary in its motion to: (1) rewrite the claims, from being about a procedure for compacting bone marrow in a specific way to being about a device for mere "void creation" or "fracture reduction"; (2) mischaracterize the Court's preliminary injunction Order, which merely concluded that there was a "substantial question" about anticipation of claim 1 of the '404 patent in the absence of any expert testimony from Kyphon; and (3) misuse Kyphon's statements to the FDA, which had nothing at all to do with the patents and certainly nothing to do with specific claim limitations that were not germane to the FDA approval process. Each of these flaws, and others, are detailed below and they collectively compel denial of DOT's motion.

## II. SUMMARY OF THE ARGUMENT

1. DOT's motion for summary judgment that U.S. Patent Nos. 5,108,404 ("'404 patent) and 4,969,888 ("'888 patent") are invalid under both 35 U.S.C. §§ 102 and 103, rests on incorrect and disputed factual assertions, and must be denied.

2. DOT asserts that two references, Olerud and Edeland, each anticipate various asserted claims of the '404 and '888 patents. In addition, DOT asserts that these references render the asserted claims obvious. In fact, these references relate to different surgical procedures (one in the spine and one in the leg), each of which in turn is different than the claimed procedures.

3. Neither Olerud nor Edeland (nor, for that matter, any unspecified combination of the two) discloses key elements of all of the asserted claims. For instance, neither discloses a "flowable material capable of setting to a hardened condition." Instead, the bone graft/paste of Olerud, and the tri-calcium phosphate of Edeland, both require the patient to endure long periods of recovery during which the body's own healing processes knit bone together. By themselves, bone graft and tri-calcium phosphate could sit around for years, flow no further than the Court's toothpaste, and never "set[] to a hardened condition."

4. The claims do not require merely reducing a fracture or creating a void by any means. Neither Edeland nor Olerud discloses "compacting the bone marrow to increase the volume of said passage." DOT takes the approach that some compaction of any interior bone is sufficient, but that is not what the claim requires. In addition, Edeland does not disclose drilling the bone marrow, and Olerud does not disclose osteoporotic bone.

5. Summary judgment of obviousness is also inappropriate. As demonstrated in the anticipation analysis, not every element of the asserted claims is disclosed in Olerud and Edeland. Moreover, apart from DOT's lack of sufficient evidence of a motivation or suggestion to combine, DOT did not even attempt to address the extensive

objective indicia of non-obviousness, such as commercial success, long-felt but unmet need, and initial skepticism followed by praise.

6. In sum, once the facts surrounding the prior art references are fully described, it becomes clear that DOT's invalidity arguments and the disputed material facts regarding both DOT's anticipation and obviousness arguments are not appropriately resolved on summary judgment.

## III. DOT'S HIGH BURDEN

### A. DOT must show invalidity by clear and convincing evidence

The ordinarily-demanding standard for summary judgment is especially difficult for a party seeking a declaration of a patent's invalidity. Under Fed. R. Civ. P. 56, a party must show that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." In a patent case, this standard is particularly demanding because a patent is entitled to a presumption of validity. 35 U.S.C. § 282. That presumption may only be overcome by clear and convincing evidence. *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 715-716 (Fed. Cir. 1991). "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." *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 222 F.3d 973, 980 (Fed. Cir. 2000).

### B. All factual inferences must be drawn in favor of Kyphon

In determining whether there is a genuine issue of material fact, all doubts are resolved in favor of the nonmovant. *Id.* Also, the evidence submitted by the nonmovant "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). In deciding a motion for summary

judgment of invalidity, the "clear and convincing" burden of proof must be considered. *See Anderson*, 477 U.S. at 254 (holding that heightened standard of clear and convincing evidence, which would be DOT's burden at trial, is to be considered when evaluating the sufficiency of the evidence on motion for summary judgment). The focus must be on whether there are genuine issues of material fact. "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." *Continental Can Co. U.S.A., Inc. v. Monsanto Co.*, 948 F.2d 1264, 1265 (Fed. Cir. 1991) (internal citation omitted). Accordingly, for DOT to prevail, it must show that even drawing all factual inferences in favor of Kyphon, it has nonetheless proved invalidity by clear and convincing evidence, and that no reasonable jury could decide otherwise. DOT has not met this burden. In fact, the record underscores the patent's validity over the prior art proffered.

**C. Claim construction**

Before a court can determine that claims are either valid or infringed, the court must construe the claims. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). Kyphon agrees with DOT that the same claim construction must be applied for the purposes of both infringement and validity. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1279 (Fed. Cir. 1988). Kyphon also agrees with the premise of DOT's summary judgment motion that Kyphon's patents are ***not*** limited to an "inflatable device." Under this proper construction, there are genuine issues of material fact that preclude summary judgment of invalidity.

## IV. OLERUD DOES NOT ANTICIPATE THE '404 AND '888 PATENTS

Kyphon has accused DOT of infringing claims 1, 3, 8, 9, 10, 12, and 15 of the '404 patent, and parallel claims 1, 3, 7, 8, 9, 11, and 14 of the '888 patent. The difference between the '888 and '404 patents is that the '888 patent is limited to osteoporotic bone, and the '404 patent does not have this limitation. Claim 1 is the only independent claim in both patents:

> A method of fixation of a fracture or impending fracture of a(n osteoporotic) bone having (osteoporotic) bone marrow therein comprising:
>
> forming a passage in the bone marrow;
>
> compacting the bone marrow to increase the volume of said passage; and
>
> filling the passage with a flowable material capable of setting to a hardened condition.

Because a dependent claim includes the limitations of any claims from which it depends, all of which here trace back to Claim 1, if Claim 1 is not shown to be invalid, then summary judgment of anticipation must be denied with regard to all of the dependent claims as well.

Olerud is an article that describes the use of an external hardware device in an open procedure to attempt reduction[1] of traumatic vertebral burst fractures. That is, the procedure described is for treating people who break their backs in car crashes and other traumatic accidents, and it involves surgically opening up large parts of the back to access the spine directly. Nowhere does it describe the minimally invasive percutaneous (through small incisions in the skin) kyphoplasty techniques of reducing osteoporotic and other compression fractures, and compacting bone marrow to create a cavity for insertion of a flowable material that hardens to support the reduced vertebra. [Halkowski Opp. Decl., Ex. 3 at 10-11.] Indeed, the device described in the Olerud article would be

contraindicated in a patient with osteoporosis, because the device is required to be screwed into healthy vertebra on either side of the fractured vertebra to attempt reduction. [*Id.* at 23-24.] Olerud's brief mention of possible use of a "curved punch" to attempt additional reduction of a fractured vertebra nowhere mentions "increasing the volume" of the passage inside the vertebra. Further, Olerud's use of bone graft paste "pressed" into the vertebra does not describe the filling of a compacted cavity inside a fractured vertebra with a "flowable material capable of setting to a hardened condition."

### A. Olerud does not anticipate independent claim 1 of the '888 and '404 patents.

There are two elements from Claim 1 missing from Olerud that preclude the grant of summary judgment of anticipation of the '404 and '888 patents: "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." In addition, summary judgment on the '888 patent is precluded because Olerud nowhere discloses use of the method in osteoporotic bone.

#### 1. Olerud does not disclose "compacting the bone marrow to increase the volume of said passage."

Claim 1 of the '888 and '404 patents requires three basic, and separate, steps: (1) forming an initial passage in the bone marrow; (2) compacting the bone marrow to increase the volume of that passage; and (3) filling the passage with a specified type of material. What is critical in the analysis of Olerud is that—even assuming that the movement of the curved punch through the vertebra forms a passage in the bone marrow—it ***never subsequently increases the volume of that passage.*** [Marks Rebuttal Expert Report at 11; April 14, 2005 Declaration of Michael Marks, M.D., M.B.A. in

[1] Reduction is moving fractured bone back into its pre-fractured position.

Support of Kyphon's Oppositions to Defendants' Summary Judgment Motions (hereinafter "Marks Declaration") at ¶ 3.] Instead, as explained below, the only compaction described in Olerud occurs inside the void in the vertebra that *preexisted* the formation of the passage. Olerud does not disclose or describe any compaction occurring in the passage that the surgeon drilled to access the pre-existing void.

In Olerud, the first step of the surgical intervention is the reduction of a compressed vertebra with a complex mechanical device that essentially screws into unfractured vertebra above and below the fracture, and leverages against those vertebra to pull the fractured vertebra open and reduce the fracture. [Halkowski Opp. Decl., Ex. 3 at 10-11; Marks Declaration at ¶ 3.] The Olerud article calls this mechanical device a "posterior segmental fixator" ("PSF") and explains that it is this PSF that achieves reduction.[2] [D.I. 141, Ex. A-27 at 44 (abstract).] This initial reduction creates a "defect," or void, in the vertebra. It is only at this point, after the void already exists in the bone, that the surgeon drills into the vertebra and inserts a curved punch into the vertebra, forming a passage into the void that had been created by the PSF. To the extent the curved punch causes further reduction of the fracture—as Olerud puts it, further reduction occurs "if possible"—it only increases the original void (a.k.a. defect) that had been first created by the PSF. The curved punch in no way increases the volume of the passage drilled by the surgeon to gain access to the PSF-created defect. Nowhere in Olerud is there any such disclosure and DOT cites none. Indeed, there is nothing at all disclosed in Olerud that shows an increase in the volume of the passage made by the

[2] Note that Olerud itself thus teaches that reduction is not the same thing as compaction, since the PSF reduces the fracture without compacting anything. At times, DOT's motion seems to equate the two. It is essential that the Court understand the (undisputed) fact that they are different, because the claims under attack require a specific type of compaction, not reduction per se.

curved punch. Figure 3 of Olerud shows the probe pushing on the endplates (i.e. the top and bottom) of the vertebra; there is no indication that the probe even touches the walls of the passage, let alone presses against those walls with sufficient force to compact the bone marrow there and increase the volume of the passage. [Marks Declaration at ¶ 3.]

DOT never really says otherwise. Its expert, Dr. Mitchell, explains that the curved punch in Olerud "compacts the cancellous bone *on its way to*, and in the process of, reducing the fracture." [D.I. 143, Exhibit E at ¶20.] But Dr. Mitchell never says that the curved punch (1) forms a passage, and (2) *subsequently* increases the volume of that passage. Neither does DOT's brief argue otherwise. DOT concedes that when Olerud describes "a conventional bone tamp placed through a drill channel in each pedicle," that description is the "forming a passage" element. [D.I. 137 at 11.]

Kyphon's FDA filings are not to the contrary. DOT makes much of Kyphon's submissions to the FDA where Kyphon compared reduction using conventional bone tamps with reduction using Kyphon's kyphoplasty devices. The critical point that DOT leaves out is that these FDA submissions ***are not talking about Kyphon's patents***. They never even mention the patents. They say nothing about whether Olerud or any other conventional procedure compacts bone marrow "to increase the volume of said passage" as that term is used in the patents. The explanation for the FDA submissions not being focused on the patents is simple: Kyphon's first FDA submissions came ***nine years after*** its patent applications.[3] Kyphon's patents are nowhere near as generic as the bone tamp

[3] DOT says on page 10 of its brief that Kyphon's 510(k) application was filed "[a]lmost a year before the effective filing date." DOT is off by a decade. The filing date of the '404 and '888 patents is in 1989. [D.I. 150 Exs. A and B).] Kyphon filed its first 510(k) application in 1998. [D.I. 141, Ex. A-27 at KY 004435.] Thus, aside from the fact that Kyphon made no "admissions" about its patents, the timing of the FDA submission makes the submission inapposite. The relevant time period for an invalidity analysis is the time of invention, not nine years after a patent application.

description in the FDA submissions. Instead, the patents focus specifically on enlargement of a passage created by a surgeon in accessing the bone.

The issue, then, is whether Olerud actually discloses or teaches enlarging the passage, not the preexisting void. Olerud itself says nothing of the sort. DOT's expert implies that it does. Kyphon's expert declares that it does not. Given this dispute about an unquestionably material fact, a triable issue of fact exists. A jury needs to decide, based on the Olerud reference and testimony from Drs. Marks and Mitchell regarding what the reference would have taught to someone of ordinary skill in the art at a time just prior to the invention at issue, whether the reference disclosed the formation of a passage in the bone marrow that is then increased in size by compaction. Further, the jury should be allowed to weigh the credibility of the experts in making its determination. At bottom, though, this issue precludes summary judgment of anticipation by Olerud.

**2. Olerud does not disclose "filling the passage with a flowable material capable of setting to a hardened condition."**

Here again, DOT makes much of Kyphon's submissions to the FDA, where Kyphon discussed the use of bone grafts/pastes with its kyphoplasty devices. And, again, these FDA submissions, filed nine years after the patent applications, ***are not talking about Kyphon's patents.*** They never mention the patents, nor do they say (as DOT claims), that bone grafts/pastes are "flowable material[s] capable of setting to a hardened condition." Instead, the submissions simply note that one way to complete a procedure is to fill the void created by Kyphon's device with bone graft or a variety of other materials. The submissions never say that such a procedure would be covered by Kyphon's patents. DOT's repeated argument that because a variety of materials can be used to fill the void,

***all*** such materials therefore ***must*** be deemed to satisfy the patents' limitations is logically flawed.

As explained in Kyphon's opposition to DOT's claim construction briefs (filed concurrently with this brief), there appears to be little dispute that the plain language of the "flowable" claim limitation controls. What the limitation means is a question of law for the Court, which Kyphon will not rehash here. The further question of whether Olerud's disclosure discloses this element—whether Olerud's bone paste is a "flowable material capable of setting to a hardened condition—is, however, one of fact. *Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1366 (Fed. Cir. 1998) (denying summary judgment of anticipation and noting that there was a question of fact as to whether the asserted prior art reference disclosed the claimed invention).

Bone graft/paste is not flowable. [Marks Declaration at ¶ 5.] First, as a threshold matter, DOT's argument that one can infer, as a matter of law, what a material is by how it is used or delivered is a non sequitur. One could stuff cotton in a tube and force it out the end with a plunger, but that doesn't make cotton a "flowable material capable of setting to a hardened condition." It's cotton. And low temperature physicists have been known, for fun,[4] to freeze bananas with liquid nitrogen and then hammer nails with them – but that doesn't make frozen bananas into hammers. What matters is what the "material" is to one of ordinary skill in the pertinent art, here orthopaedic surgical procedures.

On that score, even assuming DOT gets its preferred construction of the "flowable" limitation, disputed factual issues abound. Dr. Mitchell, DOT's technical

[4] Kyphon apologizes in advance if the Court knows or is related to such a person – we mean no disrespect.

expert, says "[bone] 'paste' constitutes a 'flowable material' because it can be inserted into the bone via a cylinder-and-piston type instrument . . . and this substance would harden over time." [D.I. 143, Exhibit E at ¶ 18.] On the other hand, the reference itself refers to the bone paste as being "pressed into the vertebra," which is hardly a description one would use for something that is flowable. [D.I. 140, Ex. A-20 at 47.] Further, Dr. Marks, Kyphon's technical expert, explains:

> There are important differences between using bone graft—which is simply pieces of bone that the body's own healing processes will eventually "knit" into its own bone—and bone cement. For example, one difference is that bone cement provides an immediate internal cast for the bone, which is an important part of the kyphoplasty solution to problems presented by the previous approaches to treating these fractures. Another difference is that bone cement, which is flowable, can leak, causing complications. . . .

[Marks Rebuttal Expert Report at 11-12; *see also* Marks Declaration at ¶ 5-6.] Moreover, the bone graft/paste is pressed into the cavity created by the PSF, not any enlargement of a passage created by the probe. [Marks Declaration at ¶4.]

In summary, bone graft/bone paste, is neither "flowable," because it is never a fluid, nor can it "set to a hardened condition." Nor is it used to fill the "passage," as described in the patent. Because there is, at the very least, a genuine issue of fact as to whether Olerud discloses "filling the passage with a flowable material capable of setting to a hardened condition," summary judgment of anticipation by Olerud cannot be granted.

### 3. Olerud does not disclose performing any procedure on osteoporotic bone.

DOT simply declares that Olerud "inherently" discloses osteoporotic bone because it discloses "bone." But, as Dr. Marks, Kyphon's expert, explains in his expert report:

> Only healthy (although fractured) bone is disclosed in [Olerud], and treatments of osteoporotic and non-osteoporotic bone are very different from each other because of the limited structural integrity and healing potential of osteoporotic bone. For instance, osteoporotic bone is particularly ill-suited to use rigid metallic stabilizing implements, like screws, plates, or rods. As I've noted above, trying to use such stabilizers in osteoporotic bone is like trying to nail a custard pie to a wall. Further, no surgeon would attempt to reduce an osteoporotic fracture by using screws in adjacent vertebrae and rods to lever apart the fracture as shown in Olerud, because of the risks of ripping the hardware out of the soft, osteoporotic bone and further injuring the patient.

[Marks Rebuttal Expert Report at 23-24.] Thus, Olerud does not anticipate any of the claims of the '888 patent.

## V. EDELAND DOES NOT ANTICIPATE THE '404 AND '888 PATENTS

### A. Edeland does not anticipate independent claim 1 of the '888 and '404 patents.

Edeland is a brief article describing a surgical technique that is "probably only suitable for the treatment of uniformly depressed central condylar fractures." [D.I. 140 , Ex. A-17 at 689.] Depressed central condylar fractures occur at the top of the tibia—the larger bone in the lower leg. Edeland describes the use of a curved probe to attempt reduction by "repeated careful pushes of the probe" on the fractured bone. The article passingly mentions use of bone grafts (called "bone transplants" in the article) or ceramic material to fill the "bone defect region" after reduction—but nowhere describes compaction to increase the volume of a passage, or use of a flowable material that hardens. Like Olerud, then, there are two elements from Claim 1 missing from Edeland

that preclude granting summary judgment of anticipation: "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."

**1. Edeland does not disclose "compacting the bone marrow to increase the volume of said passage."**

Like Olerud, Edeland discloses inserting a probe into a bone, and reducing a fracture with that probe by pushing the fracture bone back into place. However, again, the probe does not (1) form a passage and then (2) ***subsequently*** increase the volume of ***that*** passage. [Marks Rebuttal Expert Report at 9; Marks Declaration at ¶ 8.]

First, with respect to the "forming a passage in the bone marrow" element, though DOT points to passages from Edeland relating to a "cortical window" and "fenestration," these have nothing to do with forming a passage in **bone marrow**. DOT itself has been at pains to point out that the cortical bone is different than the marrow, [D.I. 138 at 7-8.], so by DOT's own admission the portions of Edeland on which DOT relies for what it calls the "forming the passage" step in fact have nothing to do with that step.

This is not an oversight. At most, Edeland discloses compacting bone marrow to form a passage but not to enlarge it. Figures 3, 4, and 6 plainly show a passage of constant volume throughout the procedure; whatever the probe is doing in the area underneath the condyle (i.e., the area immediately beneath the top of the tibia), doing it does nothing to increase the volume of the passage made to get there. Thus, DOT finds it necessary to identify something for the "forming" step that does not involve the probe, so that it can rely upon the probe for the separate "compacting" step.

DOT never comes to grips with this fundamental shortcoming of Edeland. It's expert, Dr. Mitchell, explains that the probe in Edeland "compacts the cancellous bone on

its way to, and in the process of, reducing the fracture." [D.I. 143, Exhibit E at ¶4.] But Dr. Mitchell never says that the probe (or anything else) performs the sequential steps required by all of the asserted claims: (1) that it initially forms a passage, and (2) that it subsequently increases the volume of that initial passage by compaction.

At a minimum, there is a triable issue of fact here. A jury needs to decide, based on the Edeland reference and Drs. Marks's and Mitchell's testimony as to what that reference would have taught to those of ordinary skill in the art at the time just before the invention, whether Edeland discloses the creation of a passage in the bone marrow that is then subsequently increased in volume by compaction of the bone marrow.

**2. Edeland does not disclose "filling the passage with a flowable material capable of setting to a hardened condition."**

In addition to bone graft like that described in Olerud, Edeland also discloses the use of tri-calcium phosphate for filling the bone defect. But, like Olerud again, there is a triable issue of fact as to whether tri-calcium phosphate is a "flowable material capable of setting to a hardened condition."

Like bone graft/paste, tri-calcium phosphate does not "set" to a hardened condition. It is the process of osteogenesis (the body's own healing processes that build bone) that heals a fracture treated with tri-calcium phosphate. [Marks Rebuttal Expert Report at 9.] Dr. Mitchell, DOT's expert, concedes this point: "Calcium phosphate compounds are ceramics which, after insertion into a bone cavity, become bone over time." [D.I. 143, Ex. E at ¶ 12.] Thus, on this record, there is strong evidence to suggest that summary judgment that Edeland does ***not*** anticipate the '404 and '888 patents would be appropriate, because it does not disclose a material that itself sets to a hardened condition.

Moreover, DOT has failed to meet its burden of showing that tri-calcium phosphate is "flowable." In response to Dr. Marks's explanation that tri-calcium phosphate ceramic "is a crystalline substance that has a consistency roughly similar to rock salt," [Marks Rebuttal Expert Report at 9], DOT, through Dr. Mitchell, responds that calcium phosphate ceramics "***can be*** made into a slurry by suspension in a liquid medium." Of course, Edeland discloses no such slurry and therefore fails to anticipate for this reason alone.

DOT apparently realizes this, as it turns to a 1985 patent to Brown and Chow [D.I. 143, Ex. E-3] to fill the gap. The Brown and Chow patent relates to an "aqueous mixture" of calcium phosphates. But Edeland was published in ***1976***. Even assuming that the Brown and Chow mixture is "flowable," Edeland could not possibly be talking about their mixture if it was not even invented until nine years later.[5] Moreover, Edeland certainly does not disclose a slurry of tri-calcium phosphate; Dr. Mitchell merely states that it could be done. Further still, to the extent that Dr. Mitchell is relying on the "Background" section of the Brown and Chow patent (Col. 1, lines 63-65), that section does not discuss tri-calcium phosphate (as used in Edeland). In fact, the Brown and Chow patent says: "Single calcium phosphate cements, are ***incapable*** of setting to a hard consistency." (Col. 3, lines 4-5) (emphasis added). It goes on to be explicit with regard to tri-calcium phosphate: "Though [a reference] discloses putty-like pastes containing α-

[5] DOT produced the Brown and Chow patent to Kyphon for the first time two days before its invalidity summary judgment motion. Its invalidity motion was the first time it articulated any argument regarding this patent. Kyphon objects to DOT's belated disclosure of this additional reference. Also, to the extent that DOT tries to assert a new obviousness combination relying on this patent, which DOT did not do even in its summary judgment motion, Kyphon objects as well to that assertion as untimely.

$Ca_3(PO_4)_2$,β-$Ca_3(PO_4)_2$ . . . it is believed that ***none of these pastes harden*** into cements." (Col. 3, lines 9-14) [*see also* Marks Declaration at ¶7.]

Thus, the tri-calcium phosphate of Edeland is not "flowable," because it is not a fluid, and, according to DOT's own reference, it cannot "set to a hardened condition." There is, therefore, at the very least, a genuine issue of fact as to whether tri-calcium phosphate is "a flowable material capable of setting to a hardened condition" and summary judgment of anticipation by Edeland cannot be granted.

**B. Edeland does not anticipate dependent claims 7, 8, and 9 of the '888 patent and 8, 9, and 10 of the '404 patent because it does not disclose drilling the bone marrow to form a passage.[6]**

Edeland does not disclose drilling the bone marrow. It describes cutting a fenestration (window) in the exterior cortical bone, and then pushing a probe through the marrow. As DOT concedes in Dr. Mitchell's expert report, fenestration is cutting a window through the cortical bone to gain access. Edeland does not disclose drilling into the interior of the bone to form a passage through the bone marrow. [Marks Rebuttal Expert Report at 10.] To the extent that Dr. Mitchell disagrees with Dr. Marks, there is a genuine issue of material fact precluding summary judgment.

## VI. THE '888 AND '404 PATENTS ARE NOT INVALID FOR OBVIOUSNESS

Obviousness under 35 U.S.C. § 103 is a legal conclusion based on underlying factual inquiries: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966). Resolution of the obviousness issue involves the difficult process of turning

[6] Dr. Mitchell's declaration that he performed a procedure like that in Edeland in the last month and he drilled into bone marrow is irrelevant to the question of what Edeland

back the clock to a time when the invention was made and asking what one of ordinary skill in the art might have thought then. The temptation to use hindsight in performing the analysis is both overwhelming and improper, and often results in appellate reversal of improvidently granted summary judgments. See *Monarch Knitting Mach. Corp. v. Sulzur Morat GmbH.*, 139 F.3d 877 (Fed. Cir. 1998) (vacating summary judgment of obviousness because material issues of fact existed and district court applied hindsight); *Rockwell Int'l Corp. v. United States*, 147 F.3d 1358 (Fed. Cir. 1998) (vacating summary judgment of obviousness because material issues of fact existed and district court made factual inferences in movant's favor).

The obviousness inquiry is "highly fact-specific by design," *In re Ochiai*, 71 F.3d 1565, 1569 (Fed. Cir. 1995), and includes examining "what a prior art reference teaches, whether a reference provides a motivation to combine its teachings with others, whether the invention experienced commercial success, and whether it satisfied a long-felt, but unmet need." *Tec Air, Inc. v. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1359 (Fed. Cir. 1999) (internal citation omitted). Because of its intensely factual nature, summary judgment of obviousness is rarely appropriate. This case is no exception. In words that could just as easily describe the case at bar, the Federal Circuit vacated the grant of summary judgment of obviousness where there were conflicting expert opinions, observing that a trial with "the refining fire of cross examination" is "a more effective means of arriving at the legal conclusion of obviousness *vel non* than perusal of *ex parte* affidavits and declarations of partisan experts lobbed at each other from opposing trenches." *Hodosh v. Block Drug Co.*, 786 F.2d 1136, 1143 (Fed. Cir. 1986).

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describes, which is the only relevant inquiry in an anticipation analysis. Kyphon objects to this testimony, and the testimony should not be considered.

Here, summary judgment is inappropriate because Kyphon has raised genuine issues regarding each of the three prongs of an obviousness analysis. Kyphon has shown above that each and every element of the claims is not found in the prior art, and will show below that (A) there is no suggestion in the prior art to make the combinations urged by DOT, and (B) the "objective factors" of commercial success, satisfaction of a long-felt, unmet need, and copying preclude a finding of obviousness.

**A. There is no suggestion in the prior art to combine the references**

DOT does not show where there is a suggestion within the references, either individually or as a whole, to combine them. To take just one example, Edeland concerns the tibia and was published in 1976, while Olerud concerns the spine and was published in 1987. Why would an orthopedic surgeon in or about 1989, when the '888 patent application was first filed, have combined them? With a small army of lawyers, DOT apologizes that it did not even find Olerud until sometime late last year, after the preliminary injunction proceedings. [D.I. 138 at fn 6.]

Apparently recognizing that there is no suggestion in the art to combine the cited references, DOT makes the bald statement that "[o]ne of ordinary skill in the art would have had the suggestion and motivation to combine the teachings of the Olerud and Edeland references, because both references teach the treatment of a fractured bone." [D.I. 143 at 3.] Using this logic, it would be appropriate to combine any reference relating to any treatment of any fractured bone anywhere in the body with another.

Edeland itself shows this is wrong: "The method described is probably only suitable for the treatment of uniformly depressed central condylar fractures." [D.I. 140, Ex. A-17 at 689.] When examining the teachings of a prior art reference, the reference "must be considered in its entirety, i.e., as a whole, including portions that would lead

away from the invention in suit." *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 (Fed. Cir. 1987) (emphasis omitted). "There is no suggestion to combine[] if a reference teaches away from its combination with another source." *Tec Air*, 192 F.3d at 1360. Edeland does just this.

DOT's approach is at odds with the case law regarding combining references. At trial, DOT has the burden of proving by clear and convincing evidence that there is a suggestion in the prior art to combine the cited references. Even if each of the limitations in each of the asserted claims could somehow be gleaned from DOT's cited references, a point Kyphon vigorously disputes, DOT has failed to demonstrate that a person having ordinary skill in the art in the late 1980s would have been motivated to combine the references to arrive at the claimed invention. *See Carella v. Starlight Archery*, 804 F.2d 135, 140 (Fed. Cir. 1986) ("Obviousness cannot be established by combining the teachings of the prior art . . . absent some teaching, suggestion or incentive supporting the combination."); *Orthopedic Equip. Co. Inc. v. United States*, 702 F.2d 1005, 1012 (Fed. Cir. 1983) ("It is wrong to use the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve [a desired result]."). And to whatever extent the Court is tempted to use the very elegance and simplicity of Kyphon's inventions against Kyphon in performing the obviousness analysis, the Federal Circuit has cautioned that "[c]lose adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one 'to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.'" *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999). (quoting *W.L. Gore*, 721 F.2d 1540 at 1553) (Fed Cir. 1983). Instead, the Court must

"consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field." *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999).

The Federal Circuit has set forth three potential sources for a motivation to combine, none of which DOT has shown. Motivation to combine may be shown from "[1] the nature of the problem to be solved, [2] the teachings of the prior art, and [3] the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). A party seeking to invalidate a patent must submit clear and convincing evidence, deriving from one of these three sources, that a person having ordinary skill in the art would have been motivated to combine elements of the prior art to arrive at the claimed invention. ("the [challenger] must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.") *Id.* DOT has not met this evidentiary hurdle. Instead, it offers the conclusory statement that Olerud and Edeland should be combined "because both references teach the treatment of a fractured bone." [D.I. 138 at 24.] DOT cites to no caselaw, though, that says this sort of "hand-waving" is sufficient, especially on summary judgment. Indeed, the law is to the contrary. The fact that the references are in the same technical field as the invention merely makes them prior art; it does not suggest that they could or should be combined. The Federal Circuit explained in *In re Dance*, 160 F.3d 1339, 1343 (Fed. Cir. 1998):

> When the references are in the same field as that of the applicant's invention, knowledge thereof is presumed. However, the test of whether it would have been obvious to select specific teachings and combine them as did the applicant must still be met by identification of some suggestion,

> teaching, or motivation in the prior art, arising from what the prior art would have taught a person of ordinary skill in the field of the invention.

In short, because DOT fails to provide any such meaningful suggestion to combine, DOT's request for a summary judgment that the asserted patent claims would have been obvious fails for this reason alone.

### B. DOT fails to address the "objective factors" of nonobviousness, which must be considered by the court

The final factors that must be considered in an obviousness analysis are the so-called "objective factors" or "secondary considerations." These objective factors, which serve "as insurance against the insidious attraction of the siren hindsight," *W.L. Gore*, 721 F.2d at 1553, include commercial success, long felt but unresolved need, initial skepticism, and praise. *Panduit*, 810 F.2d at 1569; *see also Graham*, 383 U.S. at 17-18. The reasoning is straight-forward: if an invention had been long-needed, and, when released, was commercially successful and praised, it cannot have been obvious because, if it had been, others would have invented it earlier. These objective factors ***must*** be considered in any obviousness analysis. "[T]he judicial process requires that a court withhold a conclusion of obviousness until it has fully assessed the impact of any objective evidence of nonobviousness. Only then can a court base its judgment, as it must, on all probative evidence of record." *Panduit*, 810 F.2d at 1570-71 (emphasis omitted) (citing *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573 (Fed. Cir. 1984) and *Stratoflex Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) (holding that "evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness")).

Despite the requirement that the objective factors be considered, DOT's motion is silent on them. For this reason as well, DOT's motion for summary judgment of obviousness must fail.

For instance, there is no dispute that Kyphon's kyphoplasty line is commercially successful. DOT even emphasized this success in its opposition to Kyphon's preliminary injunction:

> Plaintiff is a very large, successful medical device company that manufactures surgical devices utilizing balloon technology to repair spinal fractures. Plaintiff has hundreds of employees, over $131million in net sales last year [2003], and commands ***99.7%*** of the market for the devices at issue. Plaintiff's net sales in the first nine months of 2004 were $151million, a 65% increase over the same period in 2003. Plaintiff estimates that its revenues from sales in 2004 will be between $210 and $213 million. As of December 31, 2003, over 60,000 spine surgeries had been performed using Plaintiff's instruments.

[D.I. 83 at 3. Citations and footnote omitted. Emphasis in original.]

DOT does not dispute that Kyphon's product embodies the claimed invention. Indeed, DOT emphasizes that fact in its motion. Where the product embodies the claimed invention, courts presume that the commercial success is due to the invention. *Echolochem v. Southern California Edison*, 227 F.3d 1361, 1377 (Fed. Cir. 2000). DOT does not even attempt to rebut this nexus.

This undisputed showing of commercial success precludes the grant of summary judgment of obviousness. *Pro-Mold and Tool Co., Inc. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568 (Fed. Cir. 1996) (vacating grant of summary judgment because the patentee's evidence of commercial success raised a genuine issue of material fact).

There is also evidence of long felt, but unresolved need, initial skepticism, and praise. For instance, a recent article in Forbes reported:

> Isador (Izzy) Lieberman was dumbfounded when, in 1997, an energetic inventor named Mark Reiley showed him a new procedure for restoring the shape of broken and bent spine bones. "You're going to take a balloon where?" said the Cleveland Clinic orthopedist. "And do what with it?"
>
> Once Lieberman tried the procedure, known as kyphoplasty, he became a convert. Reiley's idea of using a thumb-size balloon as a bellows to prop up compressed vertebrae has become one of the fastest growing back procedures in the U.S. – 33,000 a year.

*The Inflatable Spine*, FORBES, June 7, 2004, at 227 [D.I. 146 Ex. C]; *see also Kyphoplasty Employs Bone Balloon to Correct Kyphosis Due to Fractures*, ORTHOPEDICS TODAY, Nov. 1999 (KY230109-10) [D.I.. 146 Ex. D] (quoting one physician as stating, "I don't want to sound like an evangelist, but I've never done a technique that is so immediately satisfying and gratifying to the patient and the physician" and noting that the last patient treated by the physician "arrived in a wheelchair due to back pain and walked out to go home 1 1/2 hours later").

These are but two bits of the wealth of evidence that goes to the nonobviousness of the '888 and '404 patents, yet DOT completely ignores this evidence and the analysis that is required in any obviousness determination. Its motion must therefore, be denied.

## VII. CONCLUSION

As Dr. Marks's expert report and the other evidence in this case demonstrates, there are numerous genuine issues of material fact connected with both the Olerud and Edeland references. Kyphon therefore respectfully requests that the Court deny DOT's motion for summary judgment relating to invalidity and let this decision be made by the fact-finder in the best position to make it: the Jury.

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