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A

KYPHON'S OPPOSITION TO DOT'S MOTION *IN LIMINE*
TO PRECLUDE KYPHON FROM PRESENTING EVIDENCE
REFLECTING PRAISE OF KYPHON'S COMMERCIAL EMBODIMENTS

Evidence showing praise of Kyphon's kyphoplasty procedure is objective evidence of non-obviousness that is relevant to DOT's obviousness claim. Not only should it be admitted, but it can be reversible error to exclude it. *See, e.g. Pro-Mold and Tool Co., Inc.*, 75 F.3d 1568, 1574 (Fed. Cir. 1996) (vacating summary judgment of obviousness, remanding for consideration of objective indicia, and noting "It is ***within the province of the fact-finder*** to resolve these factual disputes regarding whether a nexus exists between the commercial success of the product and its patented features, and to determine the probative value of [the patentee's] evidence of secondary considerations for rebutting the *prima facie* case of obviousness.") (emphasis added).

Time and again the Federal Circuit has emphasized the critical nature of objective indicia (also called "secondary considerations"):

- "Under *Graham* [383 U.S. 1 (1966)], objective evidence of nonobviousness includes commercial success, longfelt but unresolved need, failure of others, and copying. When present, such objective evidence ***must be*** considered." *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 960 (Fed. Cir. 1986) (emphasis added).

- "The commercial response to an invention is significant to determinations of obviousness, and is entitled to fair weight . . . ." *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1391 (Fed. Cir. 1988).

- "[O]bjective evidence such as commercial success, failure of others, long-felt need, and unexpected results ***must be*** considered before a conclusion on obviousness is reached. . . . Indeed, as then Chief Judge Markey said in *Stratoflex, Inc. v. Aeroquip Corp.* [713 F.2d 1530, 1538 (Fed. Cir. 1983)] . . ., 'evidence of secondary considerations may often be the most probative and cogent evidence in the record.'" *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1573 (Fed. Cir. 1992) (emphasis added).

- "[O]bjective indicia of nonobviousness, when present, are ***invariably relevant*** to the determination under section 103." *Litton Systems, Inc. v. Honeywell, Inc.*, 87 F.3d 1559, 1569 (Fed. Cir. 1996) (emphasis added).

- "The consideration of the objective evidence presented by the patentee is a ***necessary part*** of the obviousness determination." *WMS Gaming Inc. v. International Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999) (emphasis added).

DOT argues that the objective evidence here should be excluded because—according to DOT—the praise for Kyphon's procedure was actually praise for the use of the balloon embodiment in that procedure. DOT's position is not supported by the law. DOT's motion is premised on the fact that if the claims at issue are construed as Kyphon contends, they cover embodiments other than balloons. (DOT motion at 2). Kyphon agrees. But there is no dispute that, under either party's construction, use of Kyphon's balloon device for performing kyphoplasty is covered by the patents. (DOT motion at 4.) That is all that is required to make objective evidence regarding Kyphon's "balloon" commercial embodiment relevant and admissible. DOT seems to say that Kyphon has commercialized one particular embodiment, and that objective evidence related to that particular embodiment is irrelevant to the broader invention because the patent claims are broader. But it would be impossible to "generically" commercialize a broad claim—by definition broad claim covers many embodiments, while a commercialized product is merely one particular embodiment.

Unsurprisingly, DOT cites no caselaw in support of its novel position that objective evidence for a particular claimed embodiment is irrelevant. The cases that DOT does cite do not come close to bearing on its position. In *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317 (Fed. Cir. 2004), the Federal Circuit, examining unchallenged evidence, concluded that the patentee had not proven commercial success,

satisfaction of long-felt need, or copying. *Id.* at 1325. And in *J.T. Eaton & Co., Inc. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997), the Federal Circuit remanded for determination of whether the commercial embodiments were covered by the patent-in-suit—***a fact here that DOT concedes.***

Moreover, DOT's factual premise is unsupported. DOT claims that Kyphon's evidence only shows that the balloons have been praised. If DOT had actually submitted the evidence that it seeks to exclude, the Court could see that it is the patented ***procedure*** that is praised. For instance, in the Forbes article entitled "The Inflatable Spine" (KY 377458, attached as Exhibit A), the opening paragraph describes "a new procedure for restoring the shape of broken and bent spine bones." Kyphon's invention is described:

> Reiley was an orthopedic surgeon in Berkeley, Calif. In 1984 when he began working on techniques to restore shape to spines. He figured it would be possible to restore shape to a collapsed bone if he could first hollow out a space inside it before injecting bone cement.

The focus of this article is on the kyphoplasty procedure as a whole: compacting the interior of a collapsed vertebra to create a void, then filling the void with bone cement. Kyphoplasty is contrasted with vertebroplasty throughout the article. The fact that Kyphon's product happens to be a balloon is a neat little fact, but it is secondary to the praise of the procedure itself. Indeed, even the snippet quoted in DOT's motion says in the second paragraph that "[o]nce Lieberman ***tried the procedure***, known as Kyphoplasty, he became a convert." (DOT motion at 3) (emphasis added).

Likewise, the Orthopedics Today article (KY 230109-10, attached as Exhibit B) that DOT points to praises the procedure as a whole. That article, again, compares vertebroplasty—"a method of setting osteoporotic compression fractures through the injection of bone cement"—with kyphoplasty, where one "approximates the vertebra's

natural shape and height before stabilizing it." Again, while the fact that Kyphon's product is a balloon is discussed, it is the innovative kyphoplasty procedure as a whole that is praised.

At bottom, the objective evidence of nonobviousness is something that the fact finder is obligated to consider. If DOT wishes to challenge the conclusions to be reached based on that evidence, or whether nexus is established, it is free to do that on cross-examination and in closing argument. But DOT cites no law in support of its position that the Court should act as a gatekeeper here and keep the jury from even considering the evidence. Nor has it even come close to establishing that the probative value of the evidence is "substantially outweighed" by prejudice under Fed. R. Ev. 403. Indeed, it hasn't even identified any improper "prejudice."

For these reasons, Kyphon respectfully requests that the Court deny DOT's motion *in limine* to exclude evidence of praise of Kyphon's invention.

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Exhibit A

The Inflatable Spine

Doctors are realigning broken backs with an injection of a small balloon. BY MATTHEW HERPER

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.

Some 800,000 spinal fractures afflict Americans each year as a result of osteoporosis or bone cancer. If not treated by braces or surgery, fractures can leave the back painfully hunched, crushing the lungs and digestive system so that breathing and eating become difficult.

Kyphoplasty, says Lieberman, who now directs the Cleveland Clinic's center for minimally invasive surgery, is the only way to restore a fractured spine to its normal shape. In the older surgery, vertebroplasty, a doctor injects cement to solidify brittle bone mass. That alleviates pain but leaves the bone deformed, something Lieberman detests. "The premise of orthopedics is to restore alignment so you can retain function," says Lieberman. "I trained for six years as an orthopedic resident to learn to put bones back where they belong."

Kyphon, the Sunnyvale, Calif. company that Reiley founded in 1994, saw its sales rise 72% to $131 million last year, even though the Food & Drug Administration cleared Kyphon's premixed cement recipe only two months ago, allowing the company to market the full procedure, where before it could not mention cement injection or the name kyphoplasty. Kyphon's market value is up 120% in a year to $940 million, or 34 times last year's net earnings.



A weakened or injured vertebra can fracture and collapse.



To restore shape, a surgeon inserts two balloons into the fracture.



The balloons are inflated, lifting the bone mass and creating a cavity.



The balloons are deflated one at a time and the cavity is filled with cement, fixing the spine in place.

Reiley was an orthopedic surgeon in Berkeley, Calif. in 1984 when he began working on techniques to restore shape to spines. He figured it would be possible to restore shape to a collapsed bone if he could first hollow out a space inside it before injecting bone cement. He dove into spines of cadavers with tiny jacks, scrapers, expandable rotors, lasers and ultrasound when he happened upon a stack of balloons used to clear small kidney stones. He brought them into the anatomy lab and tried them, first drilling a hole in the bone for the balloon to go in, then inflating it, deflating it and injecting cement into the cavity created. The balloons were a success, strong enough to move bone. In an October 2003 study 29 patients had their painfully hunched backs unbent by 8.8 degrees. Eventually Reiley created even hardier versions. Kyphon began marketing the device in 1999, after being cleared by the FDA. A kyphoplasty kit for a single vertebra costs $3,500, six times more than some vertebroplasty kits, according to Shawn Fitz, an analyst at Stephens Inc. Eeric Truumees, an orthopedist at Detroit's William Beaumont Hospital, says that his hospital gets the same payment from insurers or Medicare of about $5,000 for each procedure.

Critics of the procedure say it's too early to call it a success. "I am certainly not going to say that it doesn't work, because it may be the greatest thing since sliced bread," says Richard Deyo, a professor of medicine at the University of Washington. "I just don't think we know that yet." Jeffrey Goldstein, an assistant professor of orthopedic surgery at New York University's Hospital for Joint Diseases, has been impressed with the results of his kyphoplasties, but he worries about performing the surgery too broadly, especially on elderly patients under general anesthesia. "I think this is an excellent procedure in the proper patient," says Goldstein. "I just wonder how many properly indicated patients there will be after all the dust has settled."

Who's the patient to believe? "Find a doctor who does both procedures," says John Mathis of the Virginia College of Osteopathic Medicine. "Then let him decide which is in your best interest."

"Sure," says Reiley, "but if it's your mother, get the balloon." He and other kyphoplasty proponents say that their procedure is safer than vertebroplasty. Using the balloon to create a space in the bone supposedly allows doctors to inject cement under less pressure, potentially preventing harmful leaks of this toxic substance. Reiley, now a consultant at Kyphon, would like to see studies comparing postoperative lung function after the two procedures to prove his theory that kyphoplasty patients will breathe better. "I think more people would use it anyway," he says. "Because it is safer." F

KY 377458

Exhibit B

ORTHOPEDICS today®

November 1999 CURRENT NEWS IN MUSCULOSKELETAL HEALTH & DISEASE Volume 19 Number 11

Kyphoplasty employs bone balloon to correct kyphosis due to fractures

Balloon restores bone height lost due to osteoporotic compression fractures before they are stabilized with PMMA

by Patrick McGee
ORTHOPEDICS TODAY staff writer

BERKELEY, Calif. – While vertebroplasty – a method of setting osteoporotic compression fractures through the injection of bone cement – has grown in popularity as a minimally invasive tool for a prevalent medical problem, spine surgeons are now analyzing the efficacy and, in some cases, advantages of kyphoplasty over vertebroplasty.

Like vertebroplasty, this technique uses polymethylmethacrylate (PMMA) bone cement to stabilize such fractures. However, it differs because it uses a balloon to approximate the vertebra's natural shape and height before stabilizing it.

Researchers say that in patients treated to date, kyphoplasty restored, on average, at least 50% of the lost vertebral body height and improved kyphosis by 50%. That is key, because the kyphosis that often accompanies vertebral compression fractures (VCF) has been linked to an increased incidence of death due to pulmonary disease.

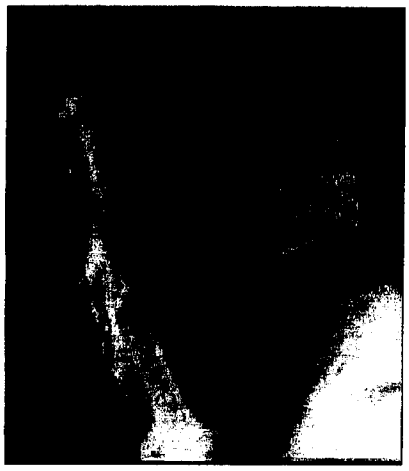
While the study has only just begun, early results have been dramatic, said **Steven R. Garfin**, MD, the study's principal investigator.

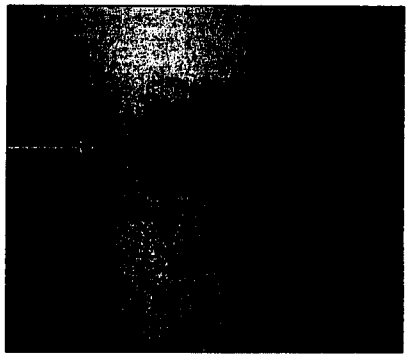
"I'm being cautious with my words until the study's done. I don't want to sound like an evangelist, but I've never done a technique that is so immediately satisfying and gratifying to the patient and the physician," said Garfin, professor and chair of the department of orthopedics at the University of California, San Diego.

Study will involve 25 centers

The study, which will be conducted at 25 centers across the United States, is set to enroll 200 patients. It will compare kyphoplasty with nonoperative treatments like bed rest, narcotic analgesics and bracing, said **Mark A. Reiley**, MD, the general orthopedic surgeon who developed the technique and the tools used to perform it.

However, if the results continue to be as impressive as they have been early on, the study may be halted after 100 patients, said Reiley, who is on staff at Alta Bates Hospital, located here. To be included in the study, the subjects must be at least 40 years old, the vertebra has to be collapsed at least 20%, and the fracture must be less than eight weeks old, Reiley said.





COURTESY OF MARK A. REILEY

The preop radiograph (top) shows a post-collapse view of the anterior cortex at T11 in an 89-year-old osteoporotic woman. The postop view (bottom) shows the anterior height raised to 22 mm. Prior to the kyphoplasty, the anterior height was 13 mm.

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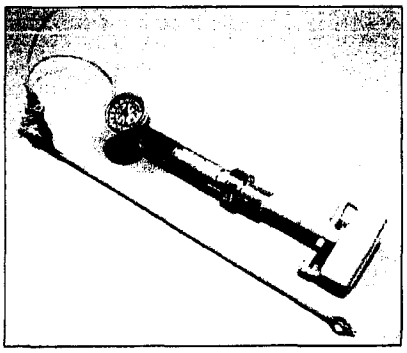
Prior to the outcomes study, 150 fractures were treated in 80 patients, 70% of whom were female. The longest follow-up was 10 months and there were no failures. In addition, 95% of patients experienced pain relief, and there was a 2% complication rate that was not device-related.

In that same group of patients, in six cases where the technique was used to treat kyphosis at T5-L1, patients with an average pretreatment kyphosis of 33° experienced a 17° reduction in kyphosis after treatment.

Reiley said he came up with the idea for the technique in 1985. It grew out of the three years he spent in the bone tumor clinic at the University of California, San Francisco, using bone cements to fill voids left by benign tumors.



COURTESY OF KYPHON

The KyphX inflatable bone tamp is used in kyphoplasty, which uses bone cement to repair osteoporotic compression fractures and restore vertebral body height.

"As far as we can tell from our own cases and from the giant-cell literature with 21 years of follow-up, there's no fatigue, there are no fractures, there's no time limit, and the cement that's inside the bone seems to last forever," he said. Reiley and an engineer spent several years developing the technique. Food and Drug Administration approval for the bone tamp was granted via a 510(k) clearance last July.

Inflatable bone tamp

Key to the technique is the Inflatable Bone Tamp system, which is produced by Kyphon Inc. of Santa Clara, Calif., the company Reiley founded with **Karen Talmadge**, PhD, the company's executive vice president. The device is called the KyphX inflatable bone tamp and is used via either a posterolateral or transpedicular approach.

The surgeon percutaneously creates a drill channel into the damaged vertebra that allows for the introduction of the bone tamp through a cannula. The bone tamp is then inflated with radiopaque contrast medium while being visualized fluoroscopically.

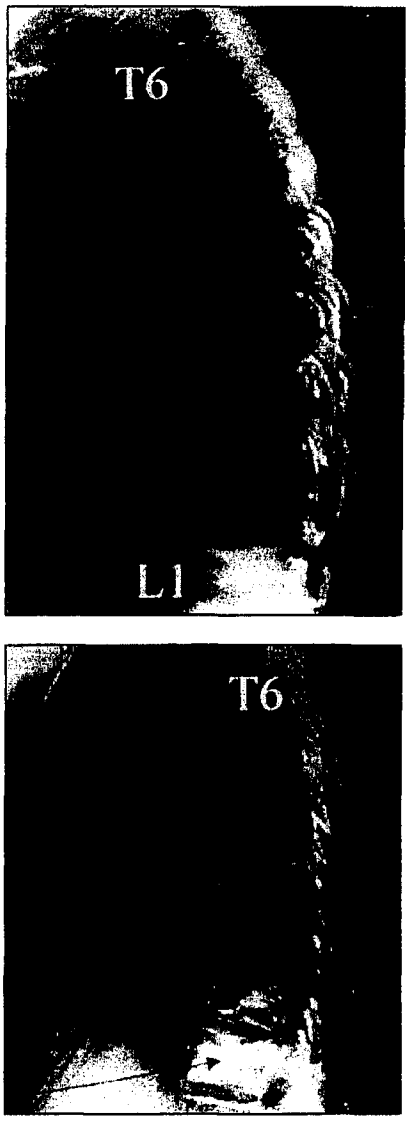
After a cavity has been created and the fracture reduced, the tamp is withdrawn to allow for injection of PMMA bone cement under low pressure. Depending on the approach used, the technique can take anywhere from 30 to 60 minutes, said Garfin, who has performed the procedure about 10 times. The last time he did it, the patient arrived in a wheelchair due to back pain and walked out to go home 1½ hours later, he said.

Kyphoplasty is similar to vertebroplasty, which originated in France in the mid-1980s. Since then, published studies involving 300 to 500 cases report "very, very good" results with vertebroplasty, Garfin stated.

Vertebroplasty, which is most often performed by interventional radiologists, uses PMMA bone cement for VCF. However, it differs from kyphoplasty because it does not restore vertebral body height before stabilizing the fractures, Reiley said. If a patient's fractures are treated early enough – preferably six to eight weeks after being sustained – kyphoplasty can restore a good deal of the vertebral body height, he said.

In addition, the PMMA is extremely wet and is injected under high pressure during vertebroplasty. That, Reiley said, can cause the cement to leak out of the vertebral body.

Because a cavity is created in the vertebral body during kyphoplasty, the PMMA can be injected under much lower pressure. In addition, because lower pressure is needed, the PMMA can be cured for about four minutes until it has a doughy consistency. Injecting the cement in that state makes it unlikely it will leak out of the vertebral body, Reiley said.



COURTESY OF MARK A. REILEY

A preoperative radiograph shows 38° kyphosis between T6 and L1 caused by a fracture at T12 (top). After the fracture was set using kyphoplasty, the kyphosis was reduced to 18° (bottom).

Perhaps the key reason orthopedic spine surgeons are drawn to the kyphoplasty technique is that it can be done relatively quickly and yields almost immediate results, Reiley pointed out. "It's a very quick fix and the patients do well, so the surgeons really like doing them," he said. ■

Dr. Garfin has a financial interest in the product discussed in this article.

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KY 230110

KYPHON'S OPPOSITION TO DOT'S MOTION *IN LIMINE*
RE BONE FILLER DEVICE PATENTS

Kyphon opposes DOT's motion *in limine* to preclude evidence regarding DOT's belated assertion of any defense for the infringement of DOT's original bone filler devices. Contrary to the thrust of DOT's motion, Kyphon has no intention of presenting discussions or draft stipulations exchanged in the context of settlement discussions regarding the bone filler device patents, and Kyphon advised DOT of this fact well prior to the filing of DOT's motion.. The real issue here is DOT's belated assertion of a defense for its original bone filler devices. DOT obscures this fact by citing settlement negotiations as an excuse for failing to present any non-infringement defense at all for the original version of DOT's bone filler devices. This Court, through Special Master Poppiti, however, has already recognized that DOT's desire to settle Kyphon's infringement claims regarding the bone filler device patents provided no excuse for DOT's failure to timely present its defenses regarding the original bone filler device. DOT made a conscious decision not to provide meaningful non-infringement and invalidity contentions when it was obligated to do so, despite this Court's Orders, and DOT only provided its final contentions long after the close of discovery. It is this fact – DOT's belated effort to assert any non-infringement defense for the original bone filler devices – that Kyphon is entitled to present to the jury.

I. FACTS DOT DOES NOT MENTION

On September 3, 2004, Kyphon served discovery seeking DOT's contentions regarding, inter alia, the bone filler patents asserted by Kyphon. But, DOT twice chose to not fulfill its discovery obligations despite the Court's Orders, and only provided the requested discovery well after all imposed deadlines had passed.

Because DOT failed to provide complete non-infringement and invalidity contentions by January 7, 2005, as required by the Court's Scheduling Order, Kyphon was forced to ask this Court for relief. The Court gave DOT another opportunity to fulfill its obligations by ordering DOT to provide the requested discovery by January 24, 2005. DOT, therefore, had ample opportunity – nearly 5 months – to set forth any defenses it had regarding the original version of the bone filler device. Yet, the second Court-Ordered date of January 24th came and went and DOT chose not to assert the existence of any non-infringement defenses related to DOT's original bone filler devices. It was not until nearly a month and a half later, in early March, when DOT finally provided any such contentions. On March 18, 2005, the parties then came before this Court on the very issue presented here – DOT's belated contentions. As it does here, DOT argued that its delay in providing its contentions was justified because the parties were in the midst of settlement negotiations that came to an *impasse* in early March[1]. This Court recognized that despite such settlement discussions between the parties, DOT did not have a valid justification for failing to meet court ordered discovery deadlines and that Kyphon was prejudiced by DOT's improper delay. As this Court stated, "[W]hy should good faith hard negotiation to settle out a portion of the case result in [a court ordered date] passing?" [March 28, 2005, hearing transcript at p. 12]; see also Order Re: Kyphon's Rule 37 Motion, at ¶ 2, dated March 22, 2005 ("DOT has not provided substantial justification for its failure to comply with these discovery obligations and Court Orders").

[1] There was no agreement between the parties or an order of the Court excusing compliance of discovery obligations in view of settlement discussions. Moreover, DOT did not take the opportunity to state that it may have further contentions and request an extension of the court ordered discovery deadline pending settlement. [See, e.g., March 28, 2005, hearing transcript at p. 21-23].

To remedy the consequences of DOT's unjustified and prejudicial delay, this Court imposed sanctions upon DOT and provided Kyphon with discovery relief.

II. RULE 408 DOES NOT PRECLUDE EVIDENCE OF DELAYED DISCOVERY RESPONSES

Federal Rules of Evidence 408 does not provide a safe haven for litigants who rely upon settlement discussions as a basis for not complying with their discovery obligations. DOT cannot, therefore, use Rule 408 to exclude from evidence its failure to timely assert any defense for the original bone filler devices. Rather, "[t]he purpose of Rule 408 is 'to encourage full and frank disclosure between parties in order to promote settlements, rather than protracted litigation.'" *Pharmastem Therapeutics, Inc. v. Viacell, Inc.,* 2003 WL 22387938 at 31 (D. Del. Oct. 7, 2003). In *Pharmastem Therapeutics,* a case cited by DOT, plaintiff moved *in limine* to exclude from evidence all discovery relating to settlement negotiations regarding a patent license agreement with non-defendants relating to the patents-in-suit that was entered into after the commencement of the litigation with defendants. *Id.* at *1. Because the license agreements arose in a context where litigation was threatened or at least probable, this Court excluded all evidence relating to negotiations of the third-party licenses, including the license agreements themselves. *Id.* at * 4. The facts of *Pharmastem* are far removed from the situation here. As noted above, Kyphon has no intention of presenting evidence relating to settlement negotiations with DOT. It is the timing of DOT's belated assertion of a defense that Kyphon is entitled to present to the jury. The jury is entitled to know of the belated nature of DOT's defense and to then draw its own conclusions regarding the merits of that defense. These facts can easily be presented without ever discussing the parties' settlement efforts. Thus, DOT's attempt to use settlement negotiations to now

shield from the jury the fact that DOT offered no defense for the original version of its bone filler device until after the close of discovery is without merit.

III. RULE 403 DOES NOT SUPPORT DOT'S ATTEMPT TO EXCLUDE RELEVANT EVIDENCE

Although DOT invokes Federal Rule of Evidence 403, it provides no support for DOT's position. The fact of DOT's belated contention responses is relevant to the willfulness of DOT's actions, which is an assessment based on the totality of the circumstances. The timing of DOT's belated decision to come up with a defense for its original bone filler devices also bears upon the merits of DOT's assertions. DOT, of course, is entitled to state its excuse – i.e., that DOT did not believe initially that it was worth DOT's time or effort to present any defense for these devices. The jury should then be free to assess the totality of the facts in reaching its assessment regarding infringement as well as the willful nature of DOT's infringing activities.

Thus, Kyphon respectfully requests that the Court deny DOT's motion in limine regarding the bone filler device patents.

Attachment

REDACTED DOCUMENT