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>**REDACTED VERSION** |

**DEFENDANTS DOT'S MEMORANDUM IN SUPPORT OF ITS MOTION *IN LIMINE* PRECLUDING KYPHON FROM PRESENTING EVIDENCE REFLECTING PRAISE OF KYPHON'S COMMERCIAL EMBODIMENTS**

Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. ("DOT") respectfully submit this motion in limine, pursuant to Rules 401 and 403 of the Federal Rules of Evidence ("FRE"), to preclude Kyphon Inc. ("Kyphon") from presenting evidence at trial, whether in the form of videotapes, CD's or otherwise, reflecting praise for Kyphon's commercial embodiments of the inventions of the patents-in-suit.

## PRELIMINARY STATEMENT

Kyphon's exhibit list contains numerous videos and other presentations and articles purportedly reflecting praise of Kyphon's commercial embodiment of the invention of

the patents-in-suit.[1] Kyphon contends that this praise evidence reflects long-felt need for its invention, which is a secondary consideration of non-obviousness. (See D.I. 172, Kyphon's Opposition to Defendants' Motion for Summary Judgment That The '404 And '888 Patents Are Invalid Based On Anticipation And/Or Obviousness ("Invalidity Opp. Br."), at pp. 21-23.) Kyphon argued that if an invention has 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. (Id.)

Kyphon's praise evidence is irrelevant to the issues in this case, because, if anything, it shows alleged non-obviousness of the balloon invention of the patents-in-suit – i.e., an inflatable bone tamp for creating a cavity in bone. As DOT's expert reports and summary judgment and claim construction briefs make clear, DOT is not asserting that a balloon (or other inflatable bone tamp) is obvious. (See also Transcript of summary judgment hearing, at pp. 142-43, attached hereto as Exhibit 1.) DOT's obviousness contention is that if Kyphon's purported invention is broader than a balloon, such that it would encompass any device for creating a void in bone, then such a broad invention is obvious. Thus, Kyphon's proposed evidence praising its balloon device is irrelevant to the obviousness inquiry. See Rule 401, Fed. R. Evid. ("Relevant evidence means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.").

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[1] See, e.g., Kyphon's Preliminary Exhibit List, dated May 6, 2005, at exhibits 700, 701, 712, 713, 759, 1380, 2151 ("CD-Channel 3 CBC Kyphoplasty Segment"), 2152 ("CD-News Channel 12 Connecticut-Dr. Michael Marks [Kyphon's expert witness]") and 1401. At this point, DOT has not been able to fully identify all exhibits that reflect praise, given that Kyphon has not provided hard copies of its exhibits and given that Kyphon's Preliminary Exhibit List lists over 2100 exhibits, and was served just two business days ago.

As the Federal Circuit has held: "Our cases make clear that a nexus must be established between the merits of the claimed invention and evidence of commercial success before that evidence may become relevant to the issue of obviousness. Ordinarily, this nexus may be inferred when the patentee shows both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent." Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1324 (Fed. Cir. 2004) (internal quotations omitted; emphasis added); accord J.T. Eaton & Co. v. Atlantic Paste & Glue Co., 106 F.3d 1563, 1571 (Fed. Cir. 1997) ("[The patentee] cannot demonstrate commercial success, for purposes of countering the challenge of obviousness, unless it can show the commercial success of the product results from the claimed invention. Furthermore, the asserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art.") (citation omitted; emphasis added).

The praise evidence at issue relates to Kyphon's use of a balloon. By way of example, Kyphon's summary judgment opposition quoted the following praise for its balloon, as evidence of non-obviousness:

> "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."

(See Exhibit 2 hereto, D.I. 172, Invalidity Opp. Br. at p. 23 (emphasis added) (citing articles that appear as Exhibits PTX 760 and 1109 (duplicates) and PTX 1119 and 1635 (duplicates) on Kyphon's Preliminary Exhibit List.)) Kyphon stated that these articles "are but two bits of the

wealth of evidence that goes to nonobviousness." (D.I. 172, at p. 23, attached as Exhibit 2 hereto.)

Again, DOT contends that the patents require a balloon, and does not contest that the use of a balloon in bone is non-obvious. It is undisputed that DOT does not use a balloon or other inflatable device as part of its product. Thus, praise for the balloon is irrelevant to the legal issue of obviousness in this case.

Kyphon's mass of self-serving praise evidence is also unduly prejudicial, and should be precluded under Rule 403, Fed. R. Evid. The crux of this case involves alleged infringement and alleged invalidity (based on anticipation) of the patents. Praise for Kyphon's balloon has no relevance to those inquiries. The issue of obviousness in this case involves detailed aspects of the prior art, such as whether using a certain type of bone filler material was obvious or not, which is not the subject of the praise evidence. Yet, Kyphon intends to use the obviousness hook to bootstrap its way into presenting one after another video and witness portraying Kyphon as having a miracle product that cures people's pain.

Kyphon's praise evidence plainly is intended to warm the cockles of the jurors' hearts; indeed, Kyphon's own expert report, and Kyphon's summary judgment briefs, speak of the letters from patients thanking Kyphon's expert for curing their pain with this amazing balloon device. Kyphon's videos about a miracle balloon device are equally sappy. But given that DOT is not challenging the novelty of the balloon element as obvious, this praise evidence is not relevant to any legal or factual issue. And, even if it had some nominal relevance, the prejudice is outweighed by the drama of the evidence. DOT would stipulate to the novelty of using a balloon to create a void in bone. DOT would also stipulate that Kyphon's device (like DOT's device and like vertebroplasty procedures, the latter of which involves injecting bone

cement into the spine to stabilize a painful vertebral compression fracture) is effective in reducing pain.

Beyond that, Kyphon's proposed evidence is designed merely to win the juror's hearts. It is misleading, and distracting from the crux of the trial – i.e., what the patents say, how the devices work and what the prior art discloses or does not disclose. It should be precluded for all those reasons, under FRE 403. See Rule 403, Fed. R. Evid. ("Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.")

## CONCLUSION

For the foregoing reasons, DOT's motion in limine to preclude Kyphon from introducing evidence reflecting praise for its commercial embodiment of the patented invention, whether in the form of videotapes, CD's or otherwise, should be granted in all respects.

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