IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYPHON INC., Plaintiff, v. DISC-O-TECH MEDICAL TECHNOLOGIES LTD., and DISC ORTHOPAEDIC TECHNOLOGIES, INC., Defendants.	C.A. 04-204-JJF

**DECLARATION OF MICHAEL MARKS, M.D., M.B.A.
IN SUPPORT OF KYPHON'S OPPOSITIONS TO
DEFENDANTS' SUMMARY JUDGMENT MOTIONS**

1. I have been retained as a technical expert in this case and have submitted several expert reports in connection with this case. My curriculum vitae, outlining my qualifications, is attached as Exhibit A.

2. I am over 18 and could and would competently testify as to the matters in this declaration if called upon to do so.

3. I have reviewed the Olerud article relied on by DOT. In that article, the primary reduction is performed by the posterior segmental fixator ("PSF"), and that initial reduction creates a void (which is also called a "defect" in the article) in the compressed vertebra. Following the initial PSF reduction, a curved punch can be introduced through a passage drilled in the bone marrow. The probe, to the extent it causes further reduction of the fracture, increases the original void that had been caused by the PSF. Olerud does not show the passage drilled by the surgeon being increased in size. Figure 3 of Olerud shows the probe pushing on the endplates (i.e. the top and bottom) of the vertebra in the void previously created before the passage was even drilled; 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.

4. Further, in Olerud, when the bone graft is pressed into the vertebra, the cavity that the bone graft fills is the cavity that was created by the PSF, not any enlarged volume of the original passage created by the surgeon.

5. In the course of my practice as an orthopedic surgeon, I have often used bone grafts and bone pastes. They are both made from small pieces of bone. They are not fluids, nor would I describe them as "flowable." With the exception of Dr. Mitchell in this case, I have never heard anyone describe these substances as "flowable," nor have I seen that description in the literature. I certainly do not see anything in Olerud to indicate that this bone chip paste is "flowable." Indeed, it is pressed into place.

6. Bone grafts and bone pastes do not set to a hardened condition. Instead, the body's own healing processes "knit" bone into the bone graft. This process is called osteogenesis. Because osteogenesis is a process that takes weeks to months, when you use bone grafts or pastes, you need to use external casting or metal stabilizers (like screws and plates), to stabilize the fracture while the bone is healing. This is in contrast to polymethylmethacrylate and other bone cements and substitutes that set to a hardened condition.

7. I have reviewed the Brown and Chow patent (U.S. Patent No. 4,518,430) cited in Dr. Mitchell's April 6, 2005 declaration. The "background" section relied on by Dr. Mitchell does not discuss tri-calcium phosphate, as used in the Edeland reference. It does, however, explain in column 3 that tri-calcium phosphate, a single calcium phosphate, does not set to a hardened condition.

8. I have reviewed the Edeland article relied upon by DOT. I have also considered the information presented in DOT's recently filed motion for summary judgment of invalidity, including the declaration submitted by Dr. Mitchell. I continue to disagree with the arguments made by DOT and the explanation of the Edeland reference presented

by Dr. Mitchell for all the reasons previously detailed in my March 23, 2005, Report. As I explained in that Report, Edeland does not disclose all the steps required by the asserted claims of the ’888 and ’404 patents; among other things, Edeland does not disclose compacting the bone marrow to increase the volume of the passage formed by the surgeon, and it does not disclose the use of a flowable material that sets to a hardened condition.

9. I understand that DOT asserts that the “compacting” step in the asserted claims of the ’888 and ’404 patents should include the requirement of “compressing substantially all of the bone marrow away from a central portion of the interior bone volume.” I disagree with this interpretation of the claims, for the reasons set forth in my March 8, 2005, Report. Nonetheless, DOT’s SKy Bone Expander device, in my opinion, satisfies this requirement. The documents and testimony that I have reviewed regarding the DOT SKy Bone Expander, which are detailed in my March 8, 2005, Report, plainly show that the SKy Bone Expander pushes aside and compresses substantially all of the bone marrow away from the central portion of the vertebra in order to create a defined void. The creation of such a void in a vertebral body, in fact, requires that substantially all the interior tissue be moved out of the way, and, given the confined space within the vertebra, compression of the bone marrow material unquestionably occurs during use of the SKy Bone Expander device. Therefore, if the claims of the ’888 and ’404 patent were interpreted to require “compressing substantially all of the bone marrow away from a central portion of the interior bone volume,” I believe that the SKy Bone Expander system, when used as directed by DOT, would satisfy this requirement.

10. Under the proper interpretation of the function, way and result of the disputed “compacting” step of claim 1 of the ’404 and ’888 patents, the use of the SKy Bone Expander is equivalent to this limitation for the reasons stated in my March 8, 2005, Report.

11. Even using DOT's definition of the function, way, and result, however, the use of the SKy Bone Expander still is a substantially similar equivalent to the "compacting" step required in all of the asserted claims of the '888 and '404 patents. First, as noted above, the SKy Bone Expander device performs the function of the "compacting" step, as defined by DOT, of "compressing substantially all of the bone marrow away from a central portion of the interior bone volume, towards the wall of the bone, to increase the volume of the passage."

12. With regard to the way the "compacting" step required by the claims of the '888 and '404 patents is performed, in my opinion the SKy Bone Expander device also performs the "compacting" step required by the claims of the '888 and '404 patents in a substantially similar way as an inflatable device, such as a balloon, performs the "compacting" step. I have considered all of Dr. Mitchell's assertions regarding this comparison, including whether an expandable device uses power from a hand to increase its size hydraulically or mechanically, whether a device creates a void that has some indentations or not, whether a device poses the risk of rupture or mechanical breakdown, and whether a device more easily conforms to the interior of the bone or expands in a predetermined shape. However, I continue to disagree with Dr. Mitchell regarding the substantial similarity in the way the SKy Bone Expander device performs the "compacting" step as compared to an inflatable device, such as a balloon. In my opinion, an inflatable device and a mechanically expanding device both perform the "compacting" step in substantially the same way – by insertion into a passage created by the surgeon, being expanded by hand to increase their size, and thereby compacting the surrounding bone material inside the vertebra to create a defined void. My opinion is based upon the many documents and substantial testimony referenced in my March 8, 2003 Report. Therefore, turning the handle on a SKy Bone Expander device to increase its size performs the "compacting" step as required by the claims of the patent, in substantially

the same way as turning a handle to expand an inflatable device, such as is done with the Kyphon Inflatable Bone Tamp.

13. I have reviewed the assertions of Dr. Mitchell that certain “petals” of the SKy Bone Expander device branch out to create a void with indentations and allow fluid to flow around them, as compared to the “egg-shell” void that would be created by an inflatable device. In my opinion, however, the defined void that is created by the SKy Bone Expander device is substantially similar in result to the void created by an inflatable device. The result of both approaches to compacting the bone marrow is a defined void in the central portion of the vertebra that can be safely filled with a flowable material capable of setting to a hardened condition. Because both of the approaches achieve precisely the result necessary to complete the procedure required by the claims of the ’888 and ’404 patents, in my opinion both approaches provide substantially the same result.

14. I have reviewed the assertions of Dr. Mitchell regarding the interchangeability of the use of the SKy Bone Expander in lieu of the "compacting" step required by the claims of the '888 and '404 patents. I continue to disagree with Dr. Mitchell regarding this issue. In light of the documents and testimony detailed in my March 8, 2005, report, including my own experience in examining and using the SKy Bone Expander device on human cadaver vertebral bones, I believe that use of the SKy Bone Expander device is interchangeable with the "compacting" step required by all of the claims of the '888 and '404 patents.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: April 14, 2005

Michael Marks, M.D., M.B.A.

CERTIFICATE OF SERVICE

I hereby certify that on April 14, 2005, I electronically filed the attached **DECLARATION OF MICHAEL MARKS, M.D., M.B.A. IN SUPPORT OF KYPHON'S OPPOSITIONS TO DEFENDANTS' SUMMARY JUDGMENT MOTIONS** with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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I hereby certify that on April 14, 2005, I have mailed by overnight mail, the document to the following non-registered participants:

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/s/ Thomas L. Halkowski
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