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

SPECIAL MASTER'S MEMORANDUM ORDER RE: D.I. 135

1. Defendants Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. (collectively, "Disc-O-Tech") have moved for Summary Judgment that U.S. Patent Nos. 5,108,404 (the '404 patent) and 4,969,888 (the '888 patent) are invalid due to anticipation and/or obviousness. (D.I. 135).

2. Disc-O-Tech asserts that:

a. claims 1, 3, 8, 9, 10 and 12 of the '404 patent are invalid based on anticipation by an article entitled "Transpedicular Fixation of Thoracolumbar Vertebral Fractures" published in February 1988 (the "Olerud Reference") that predates the effective filing date of the '404 patent;

b. claims 1,3, 8, 9 and 10 of the '404 patent are invalid based on anticipation by an article entitled "Open Reduction of Central Compression Fractures of the Tibial Plateau" published in 1976 (the "Edeland Reference"), approximately 14 years before the patent application resulting in the '404 patent was filed; and

c. the '888 patent is invalid based on anticipation by the Edeland Reference, the Olerud Reference and/or an article entitled "Fractures of the Tibial Condyles" published in

July-August 1978 (the "Kennedy Reference")[1] that, alone or in combination, render obvious all of the asserted claims of the '888 and '404 patents.

3. Pursuant to Fed.R.Civ. P 56(c), it is Disc-O-Tech's burden to ". . . show that there is no genuine issue as to any material fact and that [it] is entitled to judgment as a matter of law." 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). Accordingly, Disc-O-Tech "must submit such clear and convincing evidence of invalidity such that no reasonable jury could find otherwise." *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 222 F.3d 973, 980 (Fed. Cir. 2000).

4. In examining the record for the purpose of determining whether there is a genuine issue of material fact, all evidence of record is to be considered in a light most favorable to the non-moving party. Advisory Committee Notes, 1963 Amendment to Fed.R.Civ.P. (56(c)); *Goodman v. Mead Johnson & Co.*, 534 F.2d 566, 573 (3d Cir. 1976).

5. Disc-O-Tech has offered expert opinion evidence in support of its claim of anticipation based on the Olerud references. Expert Report of Dr. David Mitchell Regarding the Invalidity of U.S. Patent Nos. 5,108,404, 4,969,888 and 6,235,943B1 dated March 7, 2005, D.I. 140, Tab A; and Declaration of Dr. David Mitchell in Response to Dr. Marks' Report Regarding Validity Issues, executed April 6, 2005. ("Mitchell Report/Declaration"), D.I. 140, Tab E. Kyphon has offered expert opinion evidence to refute the Olerud Reference, namely that:

- Olerud does not disclose "compacting the bone marrow to increase the volume of said passage." Rebuttal Expert Witness Report of Michael Marks, M.D., M.B.A., dated March 23, 2005, D.I. 176, Tab 4 at 11 ("Marks Rebuttal Expert Report"); April 14, 2005 Declaration of Michael Marks, M.D., M.B.A. in Support of Kyphon's Opposition to Defendants' Summary Judgment Motions, D.I. 175 at ¶ 3 ("Marks Declaration").

[1] Kyphon has not had an opportunity for its experts to respond to Disc-O-Tech's argument regarding the Kennedy Reference, claiming it was first raised at the *Markman* hearing on April 19, 2005.

- Olerud does not disclose "filling the passage with a flowable material capable of setting to a hardened condition." Marks Declaration D.I. 175 at ¶4-6; Marks Rebuttal Expert Report D.I. 176, Tab 4 at pp. 11-12.

- Olerud does not disclose performing any procedure on osteoporotic bone. Marks Rebuttal Expert Report D.I. 176, Tab 4 at pp. 23-24.

6. Disc-O-Tech has offered expert opinion evidence in support of it claim of anticipation based on the Edeland Reference. Mitchell Report/Declaration, D.I. 140, Tab A, E. Kyphon has offered expert opinion evidence to refute the Edeland Reference, namely that:

- Edeland does not disclose the sequential steps of "compacting" bone marrow to increase the volume of said passage. Marks Rebuttal Expert Report D.I. 176 at p. 9; Marks Declaration at D.I. 175 ¶ 8.

- Edeland does not disclose "filling" the passage with a flowable material capable of setting to a hardened condition. Marks Rebuttal Expert Report D.I. 176 at p. 9 and Marks Declaration D.I. 175 at ¶ 7.

- Edeland does not disclose "drilling the bone marrow to form a passage." Marks Rebuttal Expert Report D.I. 176 at p. 10.

7. The Special Master concludes, therefore, that Kyphon has demonstrated through expert opinion evidence that there exists genuine issues of material fact with respect to anticipation.

8. Pursuant to 35 U.S.C. § 103, a patent is invalid for "obviousness" if the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. Obviousness is a legal conclusion based on a "highly fact specific" inquiry into: (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 non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 14 (1996); *In re: Orhiai*, 71 F.3d 1565 (Fed. Cir. 1995).

9. Having determined that Kyphon has demonstrated through expert opinion evidence that there exists genuine issues of material fact with respect to the teaching of the Olerud and Edeland References, the Special Master is satisfied that there exists genuine issues of material fact that preclude the Special Master from performing the obviousness analysis as a matter of law.

NOW, THEREFORE, IT IS HEREBY ORDERED that Disc-O-Tech's Motion for Summary Judgment that U.S. Patent Nos. 4,969,888 and 5,108,404 Are Invalid Due to Anticipation and/or Obviousness (D.I. 135) is **DENIED**.

/s Vincent J. Poppiti
Vincent J. Poppiti (DSBA No. 100614)
Special Master

Dated: May 16, 2005