IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYPHON, INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 04-204 JJF
	:	
DISC-O-TECH MEDICAL TECHNOLOGIES LTD. and DISC ORTHOPAEDIC TECHNOLOGIES, INC.,	:	
	:	
Defendants.	:	

Thomas L. Halkowski, Esquire of FISH & RICHARDSON P.C., Wilmington, Delaware.
Of Counsel: Frank E. Scherkenbach, Esquire and Michael R. Hamlin, Esquire of FISH & RICHARDSON P.C., Boston, Massachusetts; Karen I. Boyd, Esquire of FISH & RICHARDSON P.C., Redwood City, California; and Rama G. Elluru, Esquire, of FISH & RICHARDSON P.C., Washington, D.C.,
Attorneys for Plaintiff.

Maryellen Noreika, Esquire, and James W. Parrett, Jr., Esquire or MORIS, NICHLS, ARSHT & TUNNELL, Wilmington, Delaware.
Of Counsel: Julie A. Petrusselli, Esquire; Eric S. Namrow, Esquire; and Meredith A. Miles, Esquire of VENABLE LLP, Washington, D.C.,
Attorneys for Defendant.

MEMORANDUM OPINION

December 10, 2004
Wilmington, Delaware

Farnan, District Judge.

Presently before the Court is Plaintiff Kyphon Inc.'s Motion For A Preliminary Injunction (D.I. 54). For the reasons set forth, Plaintiff Kyphon Inc.'s Motion For A Preliminary Injunction (D.I. 54) will be denied.

BACKGROUND

Plaintiff Kyphon, Inc. ("Kyphon") brought this action against Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc. (Collectively, "Disc-O") alleging that Disc-O's SKy Bone Expander Device infringes U.S. Patent Nos. 5,108,404 ("the '404 patent"), 4,969,888, 6,235,043, 6,248,110, 6,241,734, and 6,613,054. Trial is scheduled for June 1, 2005.

On October 8, 2004, Kyphon brought the instant Motion for Preliminary Injunction (D.I. 54) to forestall Disc-O's marketing and sales efforts in the kyphoplasty market until this case can be resolved on the full merits. In support of its Motion, Kyphon relies only upon Claim 1 of the '404 patent. The '404 patent relates to kyphoplasty, a minimally invasive surgical procedure that mends vertebral compression fractures, such as those that result from cancer or osteoporosis. Claim 1 of the '404 patent reads as follows:

> A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:
>
> i) forming a passage in the bone marrow;
>
> ii) compacting the bone marrow to increase the volume of said passage; and

iii) filling the passage with a flowable material capable of setting to a hardened condition.

DISCUSSION

A party seeking a preliminary injunction pursuant to 35 U.S.C. § 283 must establish: "(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest." Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001). "These factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested." Hybritech, Inc. v. Abbott Labs., 849 F.2d 1446, 1451 (Fed. Cir. 1988).

I. Likelihood of Success on the Merits

If the alleged infringer raises a substantial question concerning validity by asserting an invalidity defense that the patentee is unable to prove "lacks substantial merit," then the preliminary injunction will not issue. Genentech, Inc. v. Novo Nordisk, 108 F.3d 1361, 1364 (Fed. Cir. 1997). "Thus, the patent challenger retains the burden of establishing invalidity, and the applicant for preliminary injunctive relief retains the burden of showing a reasonable likelihood that the attack on the validity of the patent would fail." Robert L. Harmon, Patents and the Federal Circuit § 13.2(b) (5th ed. 2001).

A. Infringement

Kyphon contends that Disc-O's product infringes Claim 1 of the '404 patent. Determining whether a product or process infringes a patent is a two-step process. Step one requires the Court to construe the claims of the patent-in-suit. Step two requires the Court to compare the accused products with the properly construed claims of the patent. Step one is a question of law; step two is a question of fact. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-81 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996); Organon, Inc. v. Teva Pharm., Inc., 244 F. Supp. 2d 370, 377 (D.N.J. 2002).

With regard to step one, claim construction, the parties dispute the meaning of the term "bone marrow." Disc-O contends that bone marrow is a "viscous liquid" that cannot be compacted. In support of this contention, Disc-O offers the declaration of its expert, Dr. William Rosenberg. (D.I. 86, paras. 30-32.) Kyphon contends that the language of the claim, coupled with the specification and prosecution history of the patent, leads to the conclusion that bone marrow is not a liquid, as Disc-O contends. If the term were construed to mean a liquid substance, Kyphon contends that the steps of both forming a passage in the liquid and compacting the liquid would render Claim 1 of the patent nonsensical. Thus, Kyphon proposes that "bone marrow" be construed to mean a combination of the connective tissue and the cancellous bone framework inside a bone.

For purposes of this Motion only, the Court concludes that the term "bone marrow" of Claim 1 of the '404 patent should be interpreted according to Kyphon's proposed construction. The Court agrees with Kyphon that the construction proposed by Disc-O renders the claim meaningless. See Sofamor Danek Group, Inc. v. DePuy-Motech, Inc., 74 F.3d 1216, 1221 (Fed. Cir. 1996) (noting that a trial court has no obligation to interpret claims conclusively and finally during a preliminary injunction proceeding).

With regard to step two, comparing the accused product with the claim of the patent, the parties' dispute centers on element ii, "compacting the bone marrow to increase the volume of said passage." Kyphon contends that Disc-O's SKy Bone Expander Device expands within the inner bone tissue, thereby increasing the diameter of the portion of the device inside the bone and compacting the tissue surrounding the tip as a result. Disc-O contends that its product is not capable of compacting bone marrow because bone marrow is a liquid.

In light of the definition of "bone marrow" adopted by the Court, the Court finds that Disc-O's device necessarily compacts the bone marrow to increase the volume of the passage therein. Thus, the Court finds that the accused device meets every limitation of the claims as described in the claim language of Claim 1. Accordingly, the Court concludes that Kyphon has shown a

likelihood of success on the merits as to infringement of Claim 1.[1]

B. Invalidity

Disc-O contends that the '404 patent is invalid because it was anticipated. Disc-O also contends that Claim 1 of the '404 patent is invalid for a lack of sufficient written description as required by 35 U.S.C. § 112 paragraph 1. Disc-O further contends that Kyphon's patent is invalid because of alleged public use and disclosure by Norian Corporation. The Court will discuss each of Disc-O's contentions in turn.

1. Anticipation

Disc-O contends that broadening the term "bone marrow" to include "cancellous bone" means that the claim is anticipated by two printed publications--an article by H.G. Edeland and a book entitled Campbell's Operative Orthopaedics--each of which discloses a method of remedying a compression fracture.

A determination of anticipation involves two steps. Harmon, supra, § 3.2(g). The first is to construe the claim, and the second is to compare the construed claim to the prior art. Id. The Court will focus its analysis on the second step, i.e., comparing Claim 1 of the '404 patent to the prior art. To prevail,

[1]In a letter dated December 7, 2004 (D.I. 101), Disc-O called to the Court's attention the Federal Circuit's recent decision in Centricut, LLC v. ESAB Group, Inc., No. 03-1574,-1614 (Fed. Cir., Dec. 6, 2004). The Court finds that the decision in Centricut does not change the outcome of the Court's infringement analysis in the circumstances of this case.

Disc-O has the burden of proving there is a substantial question concerning whether Claim 1 is anticipated by a single prior art reference that disclosed each and every limitation of the claimed invention. For Kyphon to prevail it must prove that Disc-O's invalidity defense of anticipation lacks substantial merit.

At the Oral Argument held on November 30, 2004, Disc-O presented two demonstrative exhibits, each purportedly showing that, when the term "bone marrow" in Claim 1 is replaced with the term "cancellous bone," a single reference anticipated Claim 1 of the '404 patent. The first demonstrative, entitled "Edeland Anticipates Every Limitation Of Claim 1 Of the '404 Patent," compares each element of Claim 1 of the '404 patent with an invention described in an article written by H.G. Edeland that appeared in Volume 47 of the Acta Orthopaedica Scandinavica at pages 686-89. The second demonstrative, entitled "Campbell Anticipates Every Limitation Of the '404 Patent," compares each element of Claim 1 with an excerpt from the seventh edition of Campbell's Operative Orthopaedics, written by A.H. Crenshaw in 1987.

With regard to the Campbell reference, the Court finds that Disc-O has modified the language from the Campbell reference in an effort to convince the Court that the Campbell device "compresse[s] cancellous bone in one large mass." In fact, the reference states that the Campbell device "elevates ... the ... compressed cancellous bone in one large mass." The Court finds that the

compressed cancellous bone referred to in the Campbell reference results from the fracture and not from the invention. Thus, the Court concludes that the Campbell reference does not disclose the element "compacting the bone marrow to increase the volume of said passage" of Claim 1 of the '404 patent. Accordingly, the Court concludes that the Campbell reference does not anticipate the '404 patent.

The Court finds that the Edeland reference presents a closer question. The Edelman reference discloses a method of fixation of a fracture of the tibia by surgically inserting a concave probe via fenestration into the fracture site, pushing the probe into the bone to reduce the fracture by compacting cancellous bone, and injecting a material into the void. Because the probe is inserted via fenestration, the Edeland method appears to form a passage in the bone. With regard to the element "compacting bone marrow to increase the volume of said passage," the probe is pushed in order to transfer and compact cancellous bone in front of the probe. The Court finds that pushing the probe to compact cancellous bone could be read to "increase the volume" of the passage. Furthermore, the Court finds that the Edelman reference could be read to disclose "filling the passage with a flowable material capable of setting to a hardened condition." For these reasons, the Court concludes that Disc-O has demonstrated that there is a substantial question concerning anticipation of Claim 1 by the Edelman reference. Kyphon has not presented any expert testimony, but rather relies on

attorney argument, to refute Disco-O's anticipation argument based upon the Edelman reference. On the record evidence before the Court at this time, the Court concludes at this juncture that Kyphon has failed to show that Disc-O's anticipation defense with regard to the Edelman reference "lacks substantial merit."

2. Written Description

Disc-O contends that Claim 1 of the '404 patent is invalid for a lack of sufficient written description as required by 35 U.S.C. § 112 paragraph 1. In support of this contention, Disc-O argues that the written description of the patent discloses only the compaction of bone marrow through the use of an inflatable device. In Disc-O's view, to the extent that Claim 1 seeks to cover any other means of compacting bone marrow, it is invalid under § 112.

Pursuant to § 112 paragraph 1, the written description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. In re Gosteli, 872 F.2d 1008 (Fed. Cir. 1989). Each and every element originally described by the inventor as being a part of his invention are the 'essential elements' of the invention. See Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1479 (Fed. Cir. 1998). These essential elements must appear in the claims ultimately issued in the patent. Id.

The Court finds that the patent does not state that an inflatable device is an essential element of the invention or that it is the only possible embodiment for achieving the claimed invention of compacting the bone marrow. Thus, the Court concludes that the '404 patent is not invalid for a lack of sufficient written description as required by 35 U.S.C. § 112 paragraph 1.

3. Public Use

Disc-O contends that the '404 patent is invalid because of

alleged public use by Norian Corporation. In support of this contention, Disco-O offers the declaration of Dr. Brent Constantz, Norian's founder, in which Dr. Constantz testified that in 1985 he conceived the procedure described and claimed in the '404 patent. Dr. Constantz further testified that the procedure disclosed in the '404 patent was described in Norian's 1986-87 business plan that was distributed publicly more than one year before the filing date of the '404 patent. Dr. Constantz also testified that the procedure had been in use at Norian since 1987.

Kyphon contends that Dr. Constantz's declaration, without corroboration, is insufficient as a matter of law to establish a case of invalidity. Kyphon cites applicable Federal Circuit case law in support of this contention. See Price v. Symsek, 988 F.2d 1187, 1194 (Fed. Cir. 1993); Finnigan Corp. V. Int'l Trade Comm'n, 180 F.3d 1354, 1367 (Fed. Cir 1999). Kyphon also points to evidence that directly contradicts Dr. Constantz's contentions. Specifically, this evidence shows that Dr. Constantz and the inventors of the device claimed in the '404 patent first met on May 1, 1988. The evidence also establishes that Dr. Constantz's 1987 business plan does disclose the procedure claimed in the patent-at-issue. For these reasons, the Court concludes that, at this juncture, Kyphon has shown that Disc-O's invalidity arguments based on Norian's public use and disclosure of the procedure claimed in the '404 patent lack substantial merit.

In sum, after reviewing the contentions and arguments of the

parties, the relevant facts, and the applicable law, the Court concludes that Kyphon has shown that Disc-O's anticipation defenses based on the Campbell reference and Dr. Constantz's declaration lack substantial merit. Further, the Court concludes that Kyphon has shown that Disc-O's argument with regard to a lack of a sufficient written description is without substantial merit. However, the Court concludes that Kyphon has not shown that Disc-O's anticipation defense based on the Edelman reference lacks substantial merit.

II. Irreparable harm

Irreparable harm is presumed when a clear showing of patent validity and infringement has been made. Amazon.com, Inc., 239 F.3d at 1350 (citing Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 708 (Fed. Cir. 1997)). Among the types of evidence that have been found sufficient to rebut a presumption of irreparable injury are: 1) the movant's undue delay in seeking an injunction; 2)the movant's large market share as compared with the minuscule market share of the respondent; and 3) lack of showing that damages would be inadequate as a remedy. See Rosemount v. U.S. Int'l Trade Comm'n, 910 F.2d 819, 821 (Fed. Cir. 1990).

Kyphon contends that it is entitled to a presumption of irreparable harm and that it is suffering irreparable harm each day that Disc-O's product is on the market. Specifically, Kyphon contends that because the kyphoplasty market is still in its

formative stage, the 2004-05 time frame constitutes a critical period in determining Kyphon's success. Kyphon argues that price erosion in the market may occur due to Disc-O's aggressive underpricing strategies. Kyphon further contends that it is suffering significant monetary damages in lost sales and licensing revenue.

In response, Disc-O contends that Kyphon has failed to demonstrate that the harm it alleges could not be compensated for by monetary damages or reversed by a permanent injunction.

The Court finds for several reasons that the record refutes Kyphon's contention that it is entitled to a presumption of irreparable harm. First, there was no showing of a likelihood of success on the validity issue with regard to the Edelman reference. Second, the Court finds that Kyphon waited six months after filing this lawsuit before seeking a preliminary injunction. Third, the Court finds that Kyphon has not shown that damages would be inadequate as a remedy. Kyphon has not demonstrated that compensation of damages would be difficult or that Disco-O would be unable to pay any damage award.

Thus, the Court concludes that Kyphon is not entitled to a presumption of irreparable harm. Further, the Court concludes that Kyphon has not made a sufficient showing of irreparable harm to find that this factor weighs in favor of granting a preliminary injunction.

III. Balance of Hardships

Important considerations in weighing the balance of hardships include, but are not limited to, whether the hardship to the alleged infringer would be merely temporary in duration, and whether the infringer had yet entered the market. Ortho Pharm. Corp. v. Smith, 15 U.S.P.Q.2d 1856 (E.D. Pa. 1990).

The Court finds that granting the Motion for Preliminary Injunction will cause Disc-O minimal hardship because such an injunction will leave Disc-O in the same position as it was in shortly before the injunction was filed. The Court also finds that allowing Disc-O to continue its sales and marketing efforts in the kyphoplasty market would cause Kyphon to lose revenue, market share, and good will in the marketplace that it may find difficult to recover should it prevail on the merits in this action. Additionally, the Court finds that the June 1, 2005, trial date mitigates any hardship to Disc-O and weighs in favor of granting the preliminary injunction.

For these reasons, the Court concludes that the balance of hardship tips in Kyphon's favor.

IV. Public interest

"The public has an interest in the enforcement of valid patents." Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 674 F.Supp. 1074 (S.D.N.Y. 1987). "Typically, in a patent infringement case, although there exists a public interest in protecting rights

secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief." Hybritech Inc. v. Abbott Labs, 849 F.2d 1446, 1458 (Fed. Cir. 1988) (footnotes omitted) (finding the public interest in enforcing valid patents outweighed the adverse impact on the market caused by the alleged infringer's absence). Kyphon contends that no public interest will be adversely affected by granting the preliminary injunction and that denying the injunction will adversely impact the public's interest in protecting intellectual property rights. Disc-O contends that granting the preliminary injunction will adversely impact the public interest in obtaining alternative and less expensive means of performing kyphoplasty.

The Court finds that the public interest in protecting valid patent rights is not outweighed by any cited competing public interests. For these reasons, the Court concludes that granting a preliminary injunction in the instant case will have a favorable impact on the public interest.

CONCLUSION

In sum, the Court concludes that while the balance of hardships and impact on the public interest support issuing an injunction, Kyphon’s failure to show a likelihood of success on the validity issue and failure to demonstrate irreparable harm weigh against issuing one. Balancing these factors against each other and considering the magnitude of the relief requested, the Court

concludes that a preliminary injunction should not issue. Accordingly, the Court will deny Plaintiff Kyphon Inc.'s Motion For A Preliminary Injunction (D.I. 54).

An appropriate Order will be entered.

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FOR THE DISTRICT OF DELAWARE

KYPHON, INC.,	:	
	:	
Plaintiff,	:	
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v.	:	Civil Action No. 04-204 JJF
	:	
DISC-O-TECH MEDICAL TECHNOLOGIES LTD. and DISC ORTHOPAEDIC TECHNOLOGIES, INC.,	:	
	:	
Defendants.	:	

O R D E R

At Wilmington, this 10th day of December 2004, for the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that Plaintiff Kyphon Inc.'s Motion For A Preliminary Injunction (D.I. 54) is **DENIED**.

JOSEPH J. FARNAN, JR.
UNITED STATES DISTRICT JUDGE